

## **EQUIPMENT STERILIZATION DISINFECTION**

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This section of the manual is intended to be an overview of disinfection and sterilization in the health care setting. For more specific details and recommendations go to infection control websites.

Not everything in the hospital can, or should be sterile. The intended use of the item, cost, safety and feasibility determine whether sterilization, disinfection, or simple cleaning is indicated.

**Sterilization** is the complete removal or destruction of all forms of microbial life, including bacteria, viruses, fungi and spores. Sterilization is achieved by steam, dry heat, ethylene oxide gas and liquid chemosterilizers.

Sterility is a probabilistic notion. There is no absolute assurance that an item contains zero microorganisms. The sterility assurance level (SAL) is used as a measure of sterility. It is the probability of survival of a microorganism after a sterilization process. It is expressed as the log<sub>10</sub> of the probability of survival. A SAL of '6' means that there is less than one chance in a million (10<sup>-6</sup>) that a particular item is contaminated. A SAL of 6 is acceptable for a critical item.

**Disinfection** is a process that eliminates a defined scope of pathogenic microorganisms but not necessarily all microbial forms. Disinfection does not attempt to remove all viable microorganisms. Disinfection's main difference with sterilization is the lack of sporocidal activity, although this is an oversimplification. Disinfection has been categorized into three levels: high, intermediate and low:

**High level disinfection** eliminates all pathogenic organisms but some viable spores may persist on an item disinfected to the high level. The critical distinction between high and intermediate is the elimination of ALL VIRUSES in high disinfection.

**Intermediate disinfection** eliminates all pathogenic vegetative bacteria, fungi and most viruses but some viruses (particularly small viruses without envelopes), and bacterial spores are not eliminated. The critical distinction between intermediate and low level disinfection is the elimination of the most resistant bacteria in intermediate level (*Mycobacterium tuberculosis* is used as an indicator because it is relatively resistant to disinfection).

**Low level disinfection** eliminates most pathogenic bacteria but some of the less sensitive vegetative forms (*M.tb* for example), the non-lipid viruses and bacterial spores are not eliminated.

**Cleaning** is the removal of adherent visible soil (blood, protein substance and debris), dust or other foreign material by a manual or chemical process.

**Sanitizing** is the process that reduces the microbial population on an object to a safe level.

**Decontamination** is the process that removes pathogenic microorganisms from an object to make it safe to handle.

**Antiseptics** are chemicals which prevent the growth of a microorganism or destroys it. Antiseptics are used on living tissues and are regulated in the U.S. by the Food and Drug Administration (FDA).

**Disinfectants** are chemicals used to carry out disinfection of objects and they are regulated in the U.S. by the Environmental Protection Agency. AOAC (Association of Official Analytical Chemists) tests are used on antiseptics and disinfectants.

### 1-Resistance Of Microorganisms

In descending order of resistance:

<b>Sterilization</b>	
Spores bacterial, fungal	<i>Bacillus stearothermophilus, Bacillus subtilis, Clostridium sporogenes</i>
<b>High Level Disinfection</b>	
Mycobacteria, TB Bacilli	
<b>Intermediate Level Disinfection</b>	
Hydrophilic viruses Polio, Cocksackie, Rhinoviruses	
<b>Low Level Disinfection</b>	
Vegetative fungi	Trichophyton, Cryptococcus, Candida
Vegetative bacteria	Pseudomonas, Staphylococcus, Salmonella
Lipophilic viruses	HSV, CMV, RSV, HBV, HIV

*From FDA Office of Device Evaluation 1995. Labeling reusable medical devices.*

### 2-Spaulling’s classification

The Spaulding’s classification scheme is applied to determine the level of sterilization/disinfection to be recommended according to the instrument’s purpose.

Item	Comes in contact with	Type recommended
Critical	Tissue, vascular space	Sterilization
Semi critical	Mucous membrane, Non intact skin	High level disinfection
Non critical	Intact skin only, not mucous membranes	Intermediate or low level disinfection

For example: a critical item is an item that comes in contact with tissue, so it needs sterilization.

These recommendations must be interpreted with common sense. For example, mouth pieces have to be disinfected to a high level while silverware is simply cleaned; however both come into contact with the mucosal area of the mouth.

Other considerations must also be taken into account such as the feasibility of the disinfection method, the effect of the disinfectant on the instrument (for example tonometer tips do not take well to heavy use of disinfectants), and safety to the employee.

Some of the factors that may affect the effectiveness of the disinfection are:

- Cleaning of the object: Residual particles may harbor organisms and shelter them from the disinfectant; the organic load may restrict the effectiveness of some disinfectants (alcohol, phenols, chlorine and iodines are inactivated by organic materials);

- Nature of the object, crevices, hinges, lumens are more difficult to disinfect.
- Concentration of the disinfectant - Disinfectants may become diluted during application and may lose some of their potency with time.
- Time of contact
- Physical and chemical environment: temperature, water hardness, pH.

### Wiping /Soaking /Contact time:

When using a germicide-soaked cloth it is important to consider the time needed by the germicide to kill the microorganisms. All germicides require a minimum time to kill a microorganism. If the wiped surface is dry before the required disinfection time, disinfection cannot be assured. Wiping would remove a large amount of contamination and the germicide may kill some left over microorganisms, but there is no assurance that all microorganisms were killed.

### 3-Sterilization

**Note on D and Z values:** Heat inactivation can be better described by using the D-value, which is the time needed at certain temperature to reduce the microbial contamination by one log cycle. For instance, starting with 1,000,000 *E.coli* O157:H7 per mL of fluid and heating the fluid to 57.2 °C, it takes approximately 270 minute to decrease to 100,000 cells per mL. With an additional 270 minutes the count goes down to 10,000, and so on. The D-value for *E.coli* O157:H7 at 57.2°C is 270 minutes. Plotting the log number of survivors against the time for a heat treatment at a certain temperature forms a line, which slope is exactly the D-value. D-values are therefore temperature dependent. The D-value for *E.coli* O157:H7 at e.g. 60°C will be lower than 270 minutes: it is 45 minutes. The D-values at 62.8°C and 64.3°C are 24 and 9.6 minutes respectively.

Plotting the log D-values against the temperature forms have a line, in which the slope is called z-value. The z-value is the increase in temperature needed to lower the D-value by one log. D- and z-values are species dependent, that means *Salmonella enteritidis* or *Bacillus cereus* or *Staphylococcus aureus* will show different values. Moreover, heat resistance depends on the environment, e.g. D-values in humid environments are lower than in dry ones.

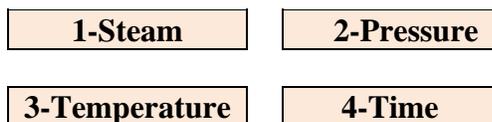
The heat treatment of choice therefore depends on the target organism (the most heat resistant, undesired species that is usually found on targeted equipment). Once there is agreement, D- and z-values are found on specific tables. By using the z-value it is possible to calculate how much to increase the temperature for a one-log reduction (= 90%) of the time

#### 3.1-Steam Sterilization

Steam sterilization is done by saturated steam under pressure.

**Indication:** It is cheap and nontoxic. It penetrates fabric. For all its advantages, it the **method of choice for all items except those which are moisture or heat sensitive.**

There are four parameters of importance in steam sterilization:



**To obtain sterilization:** Air must be removed and steam must reach the item for the required time, at the required temperature.

- Anhydrous materials (oil, greases, powders) cannot be sterilized by steam because steam will not penetrate the substance; steam condensates on the outside. The correct method for such materials is dry heat.
- Steam cannot penetrate hollow needles or instruments packed in moisture resistant materials (test tube, glass) therefore steam sterilization should not be used for those. If an instrument is placed in a glass container for protection, it should not be plugged heretically but with a loose cotton plug that will allow steam to go through. The position of the container should be such that air can easily be removed by steam (place sideways).
- Saturated steam (100% relative humidity) has a high heat content and is best to obtain sterilization. Ideally there should be no water in the form of a fine mist. Superheated steam (RH<100%) or wet steam (RH>100%) are much less effective at sterilizing. If saturated steam was used, the pack of equipment should come out of the sterilizer dry. Wet packs must be considered as non-sterile.
- Surgical dressings are the large bulk of the materials to be sterilized: hand towels, towels, lap sheets, table drapes, gowns, sponges. These materials are arranged in surgical packs. To obtain reliable sterilization, surgical packs should be no larger than 30cm\*30cm\*50cm and average weight of 5.5kg.

There are several basic types of steam sterilizers:

**High speed pre-vacuum sterilizer:** A vacuum pump removes the air from the sterilizing chamber and the load. Once the proper vacuum has been attained (15mm Hg ±1mm, steam is admitted. Steam penetration is very fast into the load. Sterilization time:

Penetration	Kill	Safety	Total time
1 minute	2 minutes	1 minute	<b>4 minutes at 133°C 272°F</b>

A sterilization cycle includes 1-warming of the chamber, 2-vacuum extraction, 3-pre-steam penetration time, 4-steam penetration time, 5-holding time, and 6-cooling time. The sterilization time is 4mn. The temperature recorder should show the sterilization time properly.

The Bowie Dick test is used to evaluate the efficacy of air removal. It should be performed daily, in the first cycle of the day for all vacuum type sterilizers. A heap of cotton surgical towels is placed in the sterilizer. In the center of the pack a steam penetrable paper is placed. The test verifies that the paper indicated steam penetration.

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to ⇨	/ / /

Pre-vacuum sterilizers can be packed to capacity. Bad packing can be overcome in this method. Rubber goods survive more cycles because of shorter exposure time and the absence of air.

**Gravity displacement autoclave:** The air is removed by displacement of cool air at the bottom by steam on top. The air is forced down by the steam. When steam enters a material, the air in the shape of a bubble is gradually pushed out. The air bubble prevents sterilization of the material. It takes time for steam to penetrate materials and expel air bubbles.

Sterilization takes for wrapped items:

Penetration	Kill	Safety	Total time
12 minutes	12 minutes	6 minutes	<b>30 minutes at 121°C 250 °F</b> <b>15 minutes at 133°C 272°F</b>
12 minutes	2 minutes	1 minute	

Flash sterilization takes for UNwrapped items:

Penetration	Kill	Safety	Total time
0 (1)	2 minutes	1 minute	<b>3 minutes at 133°C 272 °F</b> <b>10 minutes at 133°C 272°F</b>
7 minutes (2)	2 minutes	1 minute	

(1) Metal and glass only

(2) Towels, rubber

**Small table top sterilizers** found in dental and medical offices are pressure cookers, reaching a temperature of 121°C.

**Chemical indicators** are paper strips, tubes containing granules or fluids that change colour at a particular temperature. Most are not influenced by the time at which the temperature is maintained. They should not be the only means of testing sterility. They are used inside the packs or outside the packs to distinguish sterile from unsterilized items.

**Biological indicators** are standardized preparations of bacterial spores (the most resistant form of microorganisms). They are placed among the equipment. After sterilization, the spores are placed in a suitable growth medium and incubated at the proper temperature. No growth should be observed. *Bacillus stearothermophilus*, whose spores are among the most resistant to heat, are commonly used. Expiration date and proper storage of the biological indicator is important to avoid false negative tests.

### 3.2-Dry Heat Sterilization

**Indication:** Dry heat is used for materials that cannot be steam sterilized because of damage from steam, lack of penetration, or instruments that cannot be disassembled.

Sterilization takes:

<b>60 minutes at 170°C (340°F)</b>
<b>120 minutes at 160°C (320°F)</b>
<b>150 minutes at 150°C (300°F)</b>
<b>12 hours at 121°C (250°F)</b>

Hot air ovens use gravity convection, or mechanical convection.

*Bacillus subtilis* spores should be used as a biological indicator because of their higher resistance to dry heat.

### 3.3-Flash Steam Sterilization

Flash steam sterilization is defined as sterilization of an unwrapped object at 132°C for three minutes at 27 to 28 lb of pressure in a gravity displacement autoclave. Implants could ideally not be flash sterilized, and utilization should be restricted to emergencies. It should not be used to compensate for inadequate inventories of instruments. Flash sterilization has a smaller margin of safety because the cycle parameters are the minimal parameters for sterilization and deviation from the exposure time, temperature, pressure can produce nonsterile items. In addition the sterilized item will not be protected by packaging after sterilization, allowing for exogenous contamination.

The standard biological indicator used for monitoring full cycle steam sterilizers may not be adequate when used for monitoring flash sterilizers. Biologic indicators specifically designed for monitoring flash sterilization are now available. Rapid-readout biological indicators that detect the presence of enzymes of *B. stearothermophilus* by reading a fluorescent product produced by the enzymatic breakdown of a nonfluorescent substrate, has recently been marketed. Initial studies demonstrate that the sensitivity of a rapid readout test parallels the conventional flash-sterilization specific biologic indicators.

There is no industry standard ratio of flashes per day or per cases. The ratio of the number of flashes per day may need to be collected by the OR / IC group to determine the trends in flash sterilization in the OR. This would help for making a case to increase or decrease the use of flash autoclaving. The issues with flash autoclaving are quality control and the presentation of properly sterilized equipment into the surgical field. Generally the instrumentation that is needed in the surgical cases is cleaned and prepared in the Central Supply area by staff that are trained and competent in the cleaning and preparation of surgical instrumentation. The Central Supply area also wraps the instruments, which enables the equipment to be presented into the surgical field with greater ease and assurance of sterility ( if aseptic / sterile technique is followed). The other advantage of the Central Supply processing equipment used in surgical cases is the access to quality control records of each load being processed. The managers, IC Practitioners and QC personnel can review records to assure QC and sterility standards have been met. The issue with flash sterilization is generally the lack of assurance and records to show that the parameters have been met to assure sterilization. The literature shows that if the time, temperature and pressure parameters are met, the equipment is sterilized, regardless of flash or Central processing sterilization. The issue is in ensuring the operator is trained and is able to present the equipment into the surgical field and maintain sterility.

### 3.4-Ethylene Oxide Sterilization

Ethylene oxide (ETO) is used almost exclusively in the United States to sterilize medical products that cannot be steam sterilized. ETO is a colorless gas that is flammable and explosive; however, mixtures of ETO (10-12%) with carbon dioxide or the fluoridated hydrocarbons reduce the risk. Because of implications of the effect of the halocarbons on the ozone layer, restrictions are emerging.

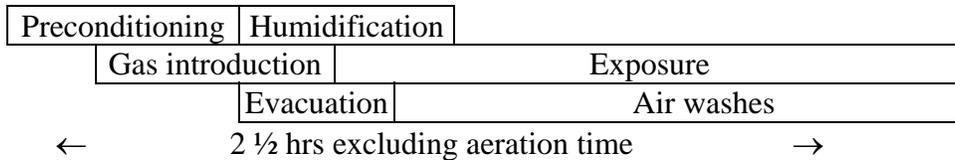
The effectiveness of ETO sterilization is influenced by four essential parameters:

- gas concentration: 450mg to 1200 mg/l,
- temperature: 29°C to 65°C,
- humidity: 45% to 85%,
- exposure time: 2 to 5 hours.

Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization. The total cycle time is three to six hours.

**Activity:** ETO inactivates all microorganisms although the bacterial spores (especially *B. subtilis*) are more resistant than other microorganisms. For this reason *B. subtilis* is the recommended biologic indicator. The microbiocidal activity of ETO is considered to be the result of the alkylation of protein, DNA and RNA. Alkylation, or the replacement of a hydrogen atom with an alkyl group, within cells prevents normal cellular metabolism and replication.

The basic ETO **sterilization cycle** consists of five stages:



- Mechanical aeration for 8 to 12 hours at 50°C to 60°C allows desorption of the toxic ETO residual contained in exposed absorbent materials.
- Ambient room aeration will also achieve desorption of the toxic ETO but requires 7 days at 20°C.

The main **disadvantages** associated with ETO are the lengthy cycle time, the cost and its potential hazards to patients and staff; whereas the advantage is that it can sterilize heat or moisture sensitive medical equipment without deleterious results

The **toxicity of ETO to employees** has raised considerable concerns. In 1984, OSHA reduced the permissible exposure limit (PEL) for ETO to a time-weighted average (TWA) of 1ppm. Determination of employee exposure shall be made from breathing zone air samples that are representative of the 8-hour TWA for an employee in each work area.

Precautions:

- Unloading the sterilizer: immediately after the cycle, the door should be opened 5-10cm and the personnel should leave the area for 15mn unless the sterilizer has a purge system that forces the gas out of the chamber.
- Exhaust directly to the outside
- Room ventilation: 10 air exchanges/hour, 50% relative humidity, temperature = 21°C
- Monitoring of ETO exposure levels may be performed by passive sampling or by direct readout instruments. For <0.5 ppm, the employer can discontinue the monitoring for affected employees. If > 1 ppm, the employer must establish a regulated area, then must make an effort to comply through work practice alterations and by engineering controls (e.g., improved ventilation, process isolation, or effective equipment repair). When these modifications are not sufficient to reduce employee exposure to 1ppm, the employer needs to supplement them by use of respiratory protection- Employees who are exposed to ETO above the action level of 0.5 ppm for at least 30 days per year are covered by a medical surveillance program.
- ETO tanks should be stored upright, securely fastened. If >10kg are stored, the area should be suitable for flammable liquids.
- Action plan for leaks and spills.

### Symptoms associated with ETO exposure:

- Irritation of eyes, upper respiratory passages,
- Peculiar “taste”
- Headache, nausea, vomiting
- Dyspnea, cyanosis, pulmonary edema, unsteadiness, EKG abnormalities
- Dermal irritation, or burns if direct contact
- Elevated lymphocytes, decreased Hgb
- High number of chromosomal aberrations

**Other Methods** which are not commonly used in hospitals but are used in the pharmaceutical industry are ionizing radiation, filtration, microwaves.

**3.5-Low Temperature Sterilization Technologies** were developed to substitute ETO sterilization altogether.

#### 3.5.1-Liquid Peracetic Acid (Steris ®)

This system uses a solution of peracetic acid which contains acetic acid and hydrogen peroxide. This solution is sporicidal at 0.02% in 2 minutes. Peracetic acid disrupts and denatures proteins. The extra oxygen rapidly inactivates many cell systems. All products are harmless to the environment and very safe for personnel. Peracetic acid remains effective with hard water and organic matter.

The Steris system had made the use of peracetic acid possible by finding an effective buffer to counteract the corrosiveness of peracetic acid. The system is fully automated with a rapid cycle time of 30 to 45 minutes. It is compatible with a wide variety of materials (plastics, rubber, endoscope glues), but not all: aluminum anodized coating (becomes dull); moist sensitive instruments (non-immersibles). The chamber is relatively small allowing sterilization of one scope and a few instruments. It can also be used for sterilization of small surgical items that require a rapid turn-around time.

#### 3.5.2-Hydrogen Peroxide Plasma Sterilization (Sterrad ®)

This system uses a completely new technology: Radio frequency emissions are applied to the hydrogen peroxide substrate. The electric field creates a gas plasma. A deep vacuum is generated to avoid using excessive heat and to facilitate maximum dispersion of the hydrogen peroxide vapor around the equipment. It does not produce any harmful substances: water and oxygen are the final products.

The Sterrad system is also fully automated with a cycle time of 75 minutes:

- 1-Vacuum stage of 5 to 20 minutes reaching 0.3 torr (for comparison atmospheric pressure=760 torr, steam sterilizer 100 torr). The more moisture, the longer the vacuum time
- 2-Injection phase of 58% solution of H<sub>2</sub>O<sub>2</sub> for six minutes
- 3-Diffusion stage of 50 minutes to allow H<sub>2</sub>O<sub>2</sub> to diffuse throughout the chamber
- 4-Plasma stage during which the radio waves are applied (the unit is shielded to comply with strict electromagnetic emissions standards)
- 5-Air flush stage (2 minutes) consists of a series of vacuum and repressurizations with air filtered (0.03 μ filter). It is compatible with a wide variety of materials, heat sensitive and moisture sensitive. Items may be wrapped but only in polypropylene. Deep metal trays cannot be used.

Cellulose (paper), linens, any material that absorbs liquids cannot be processed. Items to be sterilized must be thoroughly cleaned and dry before going into the chamber. Moisture interferes with the ability to obtain a good vacuum. It is not fully approved for long lumen scopes( ≥ 30cm long and ≤6mm Ø) . The sterilization chamber is small.

#### 4-Indications For Sterilization / Disinfection

The following is a short list of which type of sterilization/disinfection is to be used according to the instrument.

+ recommended, xxx Not recommended, ± depending on type

<b>STERILIZATION: contact with vascular space and tissue</b>	<b>Disposable</b>	<b>Steam</b>	<b>ETO- Ethylene Oxide</b>	<b>Glutaraldehyde (10 hrs.)</b>	<b>ClO<sub>2</sub> - Demand Release Chlor. (6 hrs.)</b>	<b>H<sub>2</sub>O<sub>2</sub> . Hydrogen Peroxide (6%)</b>	<b>Steris® - Peracetic acid</b>	<b>Sterrad® - Gas Plasma System</b>
Surgical metallic instruments, smooth surface		+	+	+	+	+	+	+
Instrument with electric connections		xxx	+				xxx	+
Implantable devices		+	+	+	+	+	+	
Catheters, rubber tubing	+	+	+	-	+	+	xxx	xxx
Catheters, polyethylene tubing	+	+	+	+	+	+	xxx	xxx
Needle, IV lines	+	+	+	+	+	+	xxx	xxx
Dental instruments		+	+	+	+	+	+	+
Dental handpieces		+	+				+	+
Urethral catheter		+	+	xxx	+	+	+	xxx
Internal Scopes: Lensed instrument		xxx	+	+	+	+	+	±
Arthroscope, Culoscope		xxx	+	+	+	+	+	±
Cystoscope, Peritoneoscope		xxx	+	+	+	+	+	±
Ureteroscope		xxx	+	+	+	+	+	±
All GI/UR rigid endoscopes		-	+	+	+	+	+	±
Endoscopic biopsy forceps		+	+	+	+	+	+	+
Cannulas, guidewires		+	+	+	+	+	+	+
Vaginal speculum (after rupture of membranes)		+	+	+	+	+	+	+
Material, gauze, swabs, linen	+	+		xxx	xxx	xxx	xxx	

<b>HIGH LEVEL DISINFECTION</b>	
Glutaraldehyde (2%)	Unstable 45minutes
Demand relchlorine dioxide	Corrode 20 minutes
Hydrogen peroxide (6%)	Corrode 20 minutes
Wet pasteurization 75°C	30 minutes
Chlorine 1000 ppm	Corrode 20 minutes

<b>INTERMEDIATE LEVEL DISINFECTION</b>	
Ethyl alcohol	10 minutes
Isopropyl alcohol	10 minutes
Chlorine 1000 ppm	10 minutes
Phenolic germicidal solution	10 minutes
Iodophor germicidal solution	10 minutes
Cl1= 500ppm CloNa	10 minutes
Cl2=5000ppm	xxx

<b>LOW LEVEL DISINFECTION</b>	Non-critical	Contact With Intact Skin	Ethyl alcohol 70-90	ClO <sub>2</sub> Na 100 ppm	Phenolic	Iodophor	Quaternary NH <sub>4</sub>
Ethyl alcohol	≤ 10mn	Thermometer (single patient)	+				
Isopropyl alcohol	≤10mn	Bathtub					
Chlorine 100 ppm	≤10mn	Hydrotherapy tank		+			
Phenolic germicidal solution	≤10mn	Blood pressure cuff	+				
Iodophor germicidal solution		Earphones	+				
Quaternary germicidal	≤10mn	Ventilation bag	+				
		<b>Furniture:</b> Bedpan, bedrail Bathtub Examination table, countertops					
		<b>Food utensils</b>					

<b>Contact With Mucous Membrane Semi-critical</b>	<b>Glutaraldehyde 2%</b>	<b>ClO<sub>2</sub> - Demand Release Chlor. (6 hrs.)</b>	<b>H<sub>2</sub>O<sub>2</sub> - Hydrogen Peroxide (6%)</b>	<b>Paste</b>	<b>ClONa 1000 ppm</b>	<b>Ethyl alcohol 70-90</b>
<b>Upper airway:</b> Bronchoscope	+	+	+	-	-	-
Endotracheal tubes	+	+	+	+	+	+
Laryngeal blades	+	+	+	+	+	+
Sinuscope	+	+	+	+	+	+
<b>GI:</b> Tract flexible endoscopes	+	+	+	-	-	-
<b>UG:</b> Prostate ultrasound probe	+	+	+	-	-	-
Tonometer					+	+
<b>Contact with intact skin non-critical</b>	<b>Ethyl alcohol 70-90</b>	<b>ClONa 1000 ppm</b>	<b>Phenolic</b>	<b>Iodophor</b>		
ENT: Ear speculum						
Ear exam instrument						
Laryngeal mirror						
Nasal speculum						
Skin: Electrodes: EEG, EKG						
UG: Vaginal speculum						
GI: Thermometer						
Ventilation bag connector						
Mouthpieces for anesthesia						
Transducer head for UltraSound	±					
Anoscope						
Rubber stoppers of mdose vials	+					
Dental hand piece (before)						
CPR manikin		Cl1				
Blood spills		Cl2				

## 5-Disinfectants

Plan followed for each chemical discussed:

Concentration/Time,Activity

Advantages

Shortcomings

Uses/Misuses

### 5.1-Alcohol: Ethyl alcohol and isopropyl alcohol.

Bacterial spores: Inactive

*M.tb*: Partially active

Hydrophilic viruses: Active ethanol only, not isopropyl

Lipophilic viruses and vegetative forms of bacteria and fungi: Active, all alcohols

Concentration/Time,Activity:

They have their best disinfectant power at concentrations between 60% and 90% dilution in water; very poor below 50%.

They require a wet contact for at least five minutes to disinfect, therefore simple wiping with alcohol cannot be considered as intermediate disinfection. Wiping with alcohol is a low level disinfection.

Ethyl alcohol is a potent bactericidal agent (10 to 20 seconds for vegetative enterobacteriaceae, 30 seconds for staph, 15 seconds for *M.tb* in water suspension, five minutes for *M.tb* in mucin loop test, one minute for all viruses).

Isopropyl alcohol is equally effective on bacteria but lacks effectiveness against enteroviruses which lack lipid envelopes.

Methyl alcohol is much weaker and not recommended.

Shortcomings:

- Wet contact for five minutes to get High Level disinfection
- No residual activity
- Volatile and flammable.
- Damages adhesives, mounting of optical instruments, glue of tonometers,
- Hardens rubber and plastic tubing
- Coagulates proteinaceous material
- Drying the skin

Uses/Misuses:

- NOT for sterilization because of
  - lack of action on spores
  - inability to penetrate proteinaceous material
- NOT for tonometers because of deterioration of the glue and cause the tonometer biprisms to become rough and possibly irritate the cornea (APIC 1995). Risk of corneal opacification.
- Disinfection of thermometers
- Used for disinfection of endoscopes BUT not practical because:
  - 1-good cleaning essential
  - 2-flammability is a major safety problem
  - 3-evaporation may lead to insufficient contact time

- Disinfection of small surfaces with wipes: sthethoscopes, blood pressure, rubber stoppers, ventilators, transducer heads
- Disinfection of CPR manikins

## 5.2-Chlorine

- Sodium hypochlorite (ClONa), Clorox, Eau de Javel, household bleach: 5% solution
- Extrait de Javel: 15% solution of ClONa
- Calcium hypochlorite (powder, granules or tablets) with 70% Cl
- Demand release chlorine dioxide
- Chloramine T powder or tablets. Diluted in water, it provides a more stable solution than regular Na hypochlorite.
- Sodium diClisocyanurate (NaDCC), 60% Cl, tablets, which dissolved in water generate Na hypochlorite, which is more stable.

The disinfectant power of all chlorine releasing compound is expressed as available chlorine in ppm (parts per million):

1mg/litre = 1 ppm = 0.0001%

Some countries express the chlorometric degree (1°=0.3%)

Bacterial spores: Inactive  
*M.tb*: Active at 100 ppm -1,000 ppm  
 Hydrophilic viruses: Active  
 Lipophilic viruses and vegetative forms of bacteria and fungi: Active

### Concentration/Time,Activity:

Bleach = 5.25% or 52,500 ppm ClONa  
 For 24 hr. 1: 10 ⇨ 5000 ppm \* 1: 50 ⇨ 1000 ppm  
           1:100 ⇨ 500 ppm \* 1:500 ⇨ 100 ppm  
 For 30 days, use twice the amount

Kills vegetative bacteria without organic load at 25 ppm in 10 seconds, with organic and heavy load at 100 ppm in 10 minutes. Kills viruses at 200 ppm in 10 minutes. Inactivates HBV at 500 ppm in 10 minutes. Inactivates HIV at 50 ppm in 10 minutes. Tuberculocidal at no less than 1000 ppm. Does not destroy spores.

It is very effective against HBV and HIV viruses, therefore its use is recommended at 1:10 dilution for disinfection of blood spills. It is also recommended for disinfection of counter tops and work surfaces, CPR manikins, hydrotherapy tanks, laundry, tonometers, diaper surface areas and dental impressions at dilutions of 1:100.

### Advantages:

- Low cost
- Low level of toxicity or irritancy

### Shortcomings:

- Difficult to combine with detergents
- Corrosive to metals
- Damages some plastic equipment
- Unstable over time: Ca hypochlorite is more stable than Na hypochlorite.
- Inactivated by organic matter

- Hazardous when coming in contact with formaldehyde (carcinogen bis chloromethyl ether) or with acid (chlorine gas).

Uses/Misuses:

- Disinfection of tonometer heads (Total immersion in 1:10 chlorox solution for 10 minutes, rinse, dry).
- Disinfection of countertops, floors, environmental surfaces
- Decontamination of blood spills
- Disinfection of CPR training manikins
- Disinfection of renal dialysis equipment

Stability: Current recommendations are that chlorine solutions be prepared daily. However this may not be necessary. Under poor conditions, the concentration at 30 days in a translucent container was 40% of the original concentration (Rutala 1998. IC&HE 19:323). A solution at 100 ppm is still able to kill common bacteria after one month.

### **5.3-Formaldehyde**

It was used as a disinfectant and sterilant in gaseous or liquid form. The commercial preparation of Formalin is a liquid formulation with 37% formaldehyde, 10% methanol and water.

Formalin kills vegetative bacteria, fungi and viruses in less than 30 minutes, spores in several hours.

Formaldehyde fumes are a strong irritant and are a potential carcinogen. For this reason it is no longer used in most hospitals.

If used, equipment should be thoroughly rinsed after disinfection.

### **5.4-Glutaraldehyde,**

Glutaral (Cidex® = 2% glutaraldehyde) is commonly used as a high level disinfectant (30 minutes contact) or even as a chemical sterilizer (10 hours contact).

Activation and shelf life:

It is sold as a 2.5% solution to be activated. Aqueous solutions are acidic and in this state are not sporocidal. Once they are made alkaline (activated) at pH 7.5 to 8.5 they become sporocidal but they have then a shelf life limited to 14 days due to polymerization that occurs at alkaline pH. The minimal concentration to be effective is 1% to 1.5%. Checking the concentration is important: Glutaraldehyde may get diluted (in an automatic washer, concentration went from 2.5% to 0.5% in 3 days).

Formulations of glutaraldehyde with phenol /phenates have a longer shelf life (up to 28 days).

Concentration/Time,Activity:

Kill vegetative bacteria in two minutes, fungi, and hydrophilic viruses in 10 minutes, spores of Bacillus and Clostridium in three hours. Loads of 100,000 *M.tb* were killed in 20 minutes, suspensions of atypical mycobacteria (*M.avium*, *M.gordonae*) are less sensitive, takes up to 30 minutes to be killed.

Advantages:

- Not corrosive to metals
- Good for lensed instruments, rubber and plastics
- Active in presence of organic matter to some extent
- No coagulation of proteinaceous material

### Shortcomings:

- Exposure to health care workers should be limited because of the irritation it may cause to workers exposed in poorly ventilated areas.
- Unstable, monitor activity
- Leaves some residue on metals and endoscopes

### Uses/Misuses:

- Cold sterilizer for heat-sensitive items which cannot be autoclaved or gas sterilized: endoscopes, spirometry tubing, transducers, anesthesia and respiratory therapy equipment, dialysate delivery systems.

## **5.5-Hydrogen peroxide**

Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) is available commercially as a 3% solution or as a 30% stabilized solution. A solution at 6% is also used for disinfection: it is prepared before use from the 30% stabilized solution (one part), and sterile water (four parts).

It takes hours to kill spores but kills all other microbial forms in less than one hour.

### Shortcomings:

- 30% concentrate is very corrosive. It should be stored in a cool place and protected from the light.
- Corrosive to metals

### Uses:

- Surface disinfectant
- Disinfection of soft contact lenses
- Disinfection of ventilators

## **5.6-Peracetic acid**

Peracetic acid solutions are stabilized solutions of hydrogen peroxide, acetic acid and peracetic acid.

Concentration/Time,Activity: Sporocidal in low concentrations (0.01% - 0.2%, 100 ppm - 2000 ppm).

Kills vegetative forms in five minutes at 100 ppm, in five minutes at 500 ppm in presence of organic matter, kills all viruses in 15 minutes at 2200 ppm, inactivates spores in 15 seconds at 10,000 ppm (1%), or in 15 minutes at 500 ppm.

### Advantages:

- Rapid action
- No harmful decomposition products
- No residue
- Effective in presence of organic matter

### Shortcomings:

- Corrodes metals
- Unstable: a 1% solution loses its strength in 6 days

### Uses/Misuses:

- Automated machines using peracetic acid to sterilize medical, surgical and dental equipment are in use.
- Reprocessing of dialysers.

Currently in the United States there are two peracetic acid solutions which have been cleared by the FDA for use as sterilants or high-level disinfectants. One is designed for single use in an automated system (Steris®). In this system, concentrated (35%) liquid peracetic acid is diluted with a buffer, surfactant and anti-corrosive dry powder to its 0.2% (2000 ppm) use dilution.

A second solution is provided pre-diluted and ready to use. This formulation contains approximately 1% hydrogen peroxide and 0.08% peracetic acid. The formulation is reusable up to 14 days. Unlike the more concentrated solutions, this ready-to-use solution is not a skin irritant and does not cause dermal sensitization. However, it is corrosive to ocular tissue.

## 5.7-Iodophors

These are compounds that were developed to palliate the shortcomings of tincture of iodine. Tincture of iodine 1% or 2% in alcohol is irritant and staining. The iodophors are a combination of iodine and a solubilizing agent (Povidone-Iodine, Clinidine, Betadine) with a concentration of 10% iodine (yielding 1% free iodine).

*Note: Iodine ( $I_2$ ) is not very soluble in water, about 300 ppm is all that can be dissolved. In Lugol's solution, KI is added, the  $I^-$  ion combines with  $I_2$  to form  $I_3^-$  which is soluble. The iodine in excess of 300 ppm (0.03%) constitutes a reservoir. Iodophor use a variety of solubilizing agents or carriers. The complexes formed are able to free small amounts of iodine. The amount of free iodine is about one ppm in a 10% povidone iodine solution. Diluted povidone iodine solution yields a higher concentration of iodine (7 to 20 ppm), and could cause skin irritation if used as skin antiseptic (Favero 1982. Infection Control (3):30.).*

### Concentration/Time,Activity

It is important to dilute according to specifications because dilution seems to weaken the bond with iodine and increase bactericidal activity. Some are formulated as disinfectants, others as antiseptics.

Good to kill bacteria. Ability to kill small hydrophilic viruses is questionable. Does not kill spores.

### Advantages:

- Povidone iodine does not stain, does not irritate
- Detergent action powerful
- Rapid action

### Shortcomings:

- Tincture of iodine is staining and irritant
- Gram negative bacteria can survive and grow in iodophors. Commercial solutions of povidone iodine containing 1% available iodine were found to harbor *Pseudomonas cepacia* on several occasions. These solutions were prepared with deionized water that contain *P.cepacia* in high concentrations ( $10^5$ - $10^7$  /ml).
- Lose effectiveness after drying
- Corrosive to metals: particularly aluminum and copper
- Damages rubber and plastics

### Uses/Misuses:

- NOT for damaged/diseased skin or tissue
- Superficial disinfection of the skin; preop preparation of the skin
- Hydrotherapy tanks disinfection

- Thermometers
- Endoscopes: practically never used because of damages
- Antiseptic iodophors should not be used as surface disinfectants.

Immersion at 15minutes in a 2.5% solution (one part 10% solution with three parts sterile water) provides High Level disinfection for clean equipment. Solution should be prepared fresh every day. This is rarely used in western hospitals.

### 5.8-Phenolics

They have been used for a long time as hospital disinfectants. Ortho-phenyl phenol (PP) and o-benzyl-p-chlorophenol (BCP) are two of the most commonly used derivatives.

Bacterial spores:	Inactive	
<i>M.tb</i> :	Partially active	
Hydrophilic viruses:	Partially active	
Lipophilic viruses and vegetative forms of bacteria and fungi:		Low activity

#### Concentration/Time,Activity:

Kills easily vegetative forms of bacteria and fungi. A 0.5% dilution of PP or BCP inactivates HIV. Some doubts exist about activity against hydrophilic viruses (>10mn to inactivate polio virus).

#### Advantages:

- Cheap - \$0.10/Gal
- Residual film

#### Shortcomings:

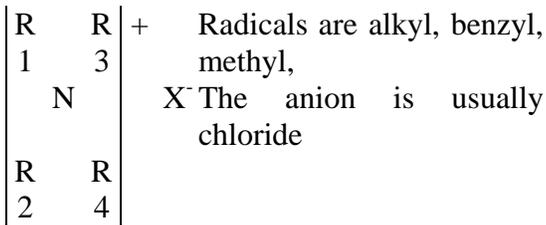
- Slow acting: wet contact for 10 minutes to get disinfection
- Absorbed by porous materials, may be released even after thorough rinsing
- Skin irritation, depigmentation
- Irritation of tissues if instruments are not thoroughly rinsed
- Gloves and goggles are to be used when applying in large quantities
- Gram negative bacteria can survive and grow in phenolic solutions
- Sometimes an accumulation of film needs to be removed

#### Uses/Misuses:

- NOT used for skin disinfection
- NOT for disinfection of semicritical item
- NOT recommended to disinfect infant bassinets after one study had identified the use of phenolic agents with hyperbilirubinemia in infants.
- NOT for anything that comes in contact with patients
- Disinfection of environmental surfaces

## 5.9-Quaternary ammonium compounds

All contain a nitrogen with four radicals:



These are cationic compounds (+), they are incompatible with soaps (anionic -).

Bacterial spores:	Inactive
<i>M.tb</i> :	Inactive
Hydrophilic viruses:	Inactive
Lipophilic viruses and vegetative forms of bacteria and fungi:	Active

### Concentration/Time,Activity:

There are wide variations according to products. Commercial claims are difficult to substantiate.

### Advantages:

- Not irritating
- Detergent action

### Shortcomings:

- Gram negative bacteria may grow in solutions.
- Lack of activity on spores, hydrophilic viruses and mycobacteria.
- Activity depressed in contact with organic matter

### Uses/Misuses:

- NOT to be used as skin antiseptic
- NOT to be used for disinfection of semicritical items
- Disinfectants for environmental sanitation (floors, furniture, walls).

### **References**

- AHA 1991. *Recommended practice for central service: Decontamination*. American Society for Health care Central Service Personnel, American Hospital Association, Chicago.
- Bennett JV & Brachman PS 1992. *Hospital infections*. Little Brown & Co, Boston.
- Wenzel RP 1993. *Prevention and control of nosocomial infections*. Williams & Wilkins, Baltimore.

## 5.10-Environmentally friendly products

A number of environmentalists groups and some agencies have advocated environmentally friendly products as alternatives for some of the acceptable disinfectants.

In this category, ammonia, baking soda, borax, and vinegar were proposed. All were evaluated for the EPA. None met the requirements to be acceptable as a disinfectant by the AOAC.

## 6-Prevention of transmission of CJD agents by instruments

### Patients are classified according to their risk status:

1-High risk patients: Patients with proven CJD; patients with clinically suspected CJD, asymptomatic carriers of pathogenic mutations of PrP occurring within the context of familial CJD /GSS /FFI; all members of a family with familial CJD /GSS /FFI in whom the genotype is undetermined or uncertain.

2-Low risk patients: Any patient with undiagnosed progressive neurological illness with or without dementia; all members of a family in which there is a strong family history of undiagnosed dementing /neurological illness; recipients of human pituitary hormones (growth hormones or gonadotrophins); recipients of dura mater grafts.

### Instruments processing:

⇒ Destroy by incineration instruments used on high risk patients

⇒ Reprocess instruments used on low risk patients as:

- Use disposable instruments as often as possible.
- Autoclave with prevacuum at 134 °C, 203 kPa (30 psi) for one hour.
- Exposure to sodium hydroxide for one hour at room temperature

### Reference:

• *National Health & Medical Research Council, 1995. Creutzfeldt-Jacob disease and other transmissible spongiform encephalopathies guidelines on patient management and infection control. Australia*

## 7-Sterilization/Disinfection of Specific Equipment

### Anesthesia mouthpieces:

IL disinfection

### Ambu bags:

These are used for resuscitation and in developing countries, relatives usually help ventilate the patient. Ambu-bags are extremely difficult to disinfect and become contaminated very quickly:

- Heat is the most reliable method of disinfection; 2% glutaraldehyde is a less acceptable alternative.
- The bags must be rinsed thoroughly in sterile water after immersing in glutaraldehyde. This will reduce the risk of chemical irritation, which can itself precipitate respiratory infection.

### Aquarium:

Aquariums are often located in family waiting rooms. The only requirement is that the person who feeds the fish and cleans the tank should NOT be a caregiver. A clinical person should understand that he/she should wash hands after contact with aquarium water.

### Bassinette, crib, domes, circumcision boards, radiant warmers:

Wash with detergent.

**Beds, air fluidized:**

The polyester filter sheet should be disinfected with sodium hypochlorite and a quaternary ammonium compound between patients, and once a week, if used with the same patient.

**Bedpans and urinals:**

- Non-sterile gloves should be worn to empty bedpans and their contents directly into the bedpan disinfector, or alternatively, put down the sluice or toilet.
- Wash thoroughly with warm water using a brush and detergent to remove all visible signs of organic contamination. Dry.

- Methods for disinfection of bedpans (in order of preference)

1. Dispose of bedpan contents and disinfection in a disinfector, which functions at no less than 80°C for one minute.

2. Wash in hot water and detergent. Dry.

3. Wash thoroughly to remove all visible contamination. Dry. Wipe over with 1% phenolic only if essential. Wipe again with wet paper towel. Dry. This is the least satisfactory method and is subject to much abuse.

Do not soak bedpans or urinals in disinfectant. It is unnecessarily expensive and increases the risk of cross-infection with Gram negative bacilli, which are usually multiply antibiotic-resistant.

**Biopsy forceps, instruments:**

- Sterilization

**Blood spill**

- Soak up the blood using an absorbent material, taking precautions to avoid exposure; dispose of the blood-soaked material in infectious waste. This step is important as it removes a lot of the protein material that would prevent the disinfectant to be fully effective.

- Apply a 10% dilution of household bleach (5,000 ppm chlorine) for one minute.

*Resnick I 1986. Stability and inactivation of HTLV 3/LAV under clinical laboratory experiment. JAMA 255: 1887-1891.*

**Blood pressure cuff:**

Wash with soap and water.

**Catheter:**

- Sterilization or use disposable.

**Clippers:**

Clipper blades are to be brushed off and cleaned between each use. If the blade is not removable, it is to be sprayed after cleaning with an EPA registered disinfectant. If the clipper blade is removable, the barber should have several blades available, placing the used one in a disinfectant solution to clean after each use. The latter situation makes it easier to assure sufficient contact time with the disinfectant.

**CPR Manikin:**

Intermittent decontamination between trainees with more thorough daily decontamination

- Trainees to use individual face shields

- Cleanse external buccal area in between each trainee use with a chemical application of 70% isopropyl alcohol for five to 10 seconds followed by a dry wipe and a 30-second drying time.

- Corless IB et al 1992. Decontamination of an HIV contaminated CPR manikin. Am J. Pub. Health 82:1542-1543.*

### **Dental handpieces:**

- Sterilization

There should be sufficient number of handpieces for the entire session.

### **Dental instruments:**

- Sterilization

### **Dishware, crockery and cutlery:**

Each patient should have an individual set, either provided by the hospital or brought from home.

- Wash crockery and cutlery in very hot water (@ 60°C) with detergent.

- Disposable crockery is not necessary.

In some hospitals (e.g. in Asia), banana leaves may be used.

### **Endotracheal suction catheters:**

- These are usually disposable but may be used for up to 24 hours on the same patient, provided that the catheter is stored properly, and does not become contaminated.

- The water used for flushing the catheter after each suction must be sterile and changed every time.

- The bowl must be washed (with sterile water only), and dried after each suction, before use.

Alternatively:

- Where there is a shortage of supplies the catheters may be used for more than 24 hours (and possibly until the patient leaves the unit), provided that the catheter is stored properly and rinsed thoroughly after each use.

- Nursing staff and attendants must disinfect their hands before and after each use

- Suction catheters must not be shared between patients.

### **Endotracheal tubes**

- These may be recycled after thorough cleaning and autoclaving.

- Disposable endotracheal tubes are available, but are more expensive than recyclable ones.

- Reports of allergic reactions to the red rubber used in endotracheal tubes has led manufacturers to use equally heat-resistant, but less reactive materials.

### **E.N.T. equipment:**

- IL disinfection

Ear speculum, nasal speculum, laryngeal mirror.

NOTE: laryngeal blades must have High Level disinfection

### **Furniture, exam table, scales:**

- Clean with detergent

### **Glass ampoules:**

To avoid sharps injury, hold top with cotton wool or tissue before breaking open.

**Humidifiers:**

These are a common source of Gram-negative bacilli (and viruses) associated with respiratory tract infection:

- Empty daily
  - Refill with sterile water
  - Disinfect when contaminated. Wash and leave in a solution of 1% hypochlorite for 30 minutes then wash thoroughly and dry
  - Routine heat disinfection after each patient use
  - If humidification is required for a prolonged time, the humidifier should be cleaned thoroughly, dried, filled daily with sterile water
- 
- Humidifier should be disinfected when the circuit is changed
  - Humidifiers should never be topped from the tap.

**Hydrotherapy tanks:**

- Low Level disinfection, hypochlorite at 100 ppm

**Incubators:**

- Clean thoroughly with warm soapy water to remove contamination.
- Dry and wipe over with 70% isopropyl alcohol.

**Infusion pumps:**

(An example of policy -)

1. All devices will be cleaned on the unit after being removed from the patient's room.
2. Nursing units have the responsibility of cleaning the devices they use after each patient use. Each unit may devise the best method and personnel to accomplish the process.
3. The device will be externally cleaned by wiping with the hospital-approved disinfectant and disposable rag, or disposable wipes which are available on each unit.
4. If the device is soiled with visible blood, it will be cleaned first with the tuberculocidal product approved for cleaning blood.
5. After cleaning, a clean plastic bag will be placed over the top of the device. This will serve as notice that the device was cleaned. Any device without the plastic covering will be considered contaminated and must be cleaned prior to placement in a patient room.

**Instruments:**

[www.fda.gov/medwatch/safety/1997/device.htm](http://www.fda.gov/medwatch/safety/1997/device.htm)

This document gives guidelines on the entire issue of receiving instruments from some outside party such as vendors, physicians, or other institutions.

**IV Administration sets:**

- Administration sets for IV fluids must be disposable; they carry the same risks as cannulae. Alternatively recycle but use for a completely different purpose, e.g. urinary catheters.

**Laryngeal blades, airway blades:**

- High Level disinfection

**Leather:**

Leather products should not be sterilized in ETO because of the difficulties in airing out ETO. There is no Center for Disease Control and Prevention (CDC) approved method for sterilizing or disinfecting

**leather** products. The traditional methods of disinfection (i.e. bleach, autoclaving, steam and ETO gas sterilization) cannot be used since leather is a very porous and biogenic material and will deteriorate with exposure to germicidal chemicals, or high heat/moisture. Furthermore, because of the natural porosity of leather, residual disinfectant may accumulate to pose possible risk to the caregiver or patient. Since effective disinfection of leather cannot be achieved, all leather products contaminated with blood or body fluids should be discarded.

To remove some of the gross contamination, clean with a gentle soap and then spray with a disinfectant.

### **Masks, Oxygen delivery face masks:**

These can be disposable or reusable. If reused:

- Wash thoroughly.
- Dry and wipe over with 70% isopropyl alcohol. This will remove mucus.

### **Mattresses and pillows:**

are a major source of cross-infection and contribute to bed sores.

- Soggy (wet) mattresses must be changed.
- They must be covered with an impervious layer so that they can be cleaned thoroughly between patients.
- Clean with warm water and detergent.
- Damaged and cotton-covered mattresses filled with horse-hair (or other fibers that can become contaminated) can be a source of cross-infection with spores, e.g. *Clostridium tetani*.
- Never admit new patients onto soiled, stained, or contaminated mattresses.

Rubber covers can be uncomfortable in hot countries. It may be possible to cover the mattress cover with absorbable paper, which should be changed frequently.

### **Nail brushes:**

- These are not recommended for ward use.
- Single-use disposable or autoclavable brushes should be used in specialized wards.

### **Ophthalmologic equipment:**

#### Goldmann tonometers

•Cleaning of tonometers was done by cleaning of the entire tip with an alcohol sponge, ideally immediately after use and allowed to dry for at least one or two minutes before being used again to make sure that no alcohol is transferred to the eye. This approach was efficient in preventing transmission of HSV but failed to have prevented some outbreaks of adenoviral conjunctivitis. Typical outbreaks of epidemic keratoconjunctivitis (Adenovirus) have occurred in settings in which alcohol was used as the disinfectant. (Nafzinger, 199. Inf Dis Clin North Am 11:279).

Recent CDC recommendations are more stringent:

- Remove the prism and place in a receptacle that allows the applanating surface and adjacent 2 to 3 mm of the tonometer to be immersed
  - in a 1:10 dilution of household bleach
  - or in 500 ppm sodium hypochlorite for 10 minutes
  - or immersion in 1% chloramine-T solution for 15 minutes.

One method uses a Petri dish with small holes drilled in the lid, which allows just the tonometer tip to be partially immersed in the solution. After a five-minute period of soaking, the tip should be washed under running water and dried before use. Two tonometer prisms should be available so that one can be used

while the other is being disinfected. Soaking the entire tip will eventually remove the coloring of the etched calibration marks. These disinfecting solutions should be changed at least once daily.

- As an alternative, the CDC recommends that a similar approach can be followed with 3% hydrogen peroxide. This solution needs to be changed at least twice daily.
- Cleaning with alcohol: Immersing the tip in 70% isopropyl alcohol for five minutes is also recommended by the CDC, although it may dissolve the glue of the tonometer.

Schiotz tonometer: The tonometer should be disassembled between each use, cleaning the barrel with two pipe cleaners (the first soaked in alcohol, the second dry), and the footplate with an alcohol swab. All surfaces must be dried before reassembly. Disposable covers are also available.

Digital Pneumotonometer: Tips of pneumotonometers should be cleaned with an alcohol sponge, taking care that the surface is dry before using it again.

Non-contact Tonometers: The non-contact tonometer does not make contact with the cornea or tears and therefore, is an ideal instrument for measurement of intraocular pressure in patients suspected of having any contagious viral condition. The front surface may be wiped with an alcohol-soaked sponge, since it may occasionally touch the eye.

Diagnostic Contact Lenses: The lens is inverted so that the contact lens surface is uppermost. The outer casing and inner surface of the lens is then wiped with an alcohol sponge. For added protection, the inner cup may be filled to the rim with a fresh 1:10 dilution of household bleach. After five minutes, the bleach is removed and the device is briskly irrigated with running water and dried. This method allows cleansing of the outer surface as well as the contact portion without exposing the glue (that cements the antireflective coating to the operator surface of the contact lens) to the bleach.

Other Instruments that may come into contact with patients.

Routine cleaning with alcohol of all surfaces of instruments (eg, slit lamp) after each patient is impractical and is unnecessary, since the HIV is a fragile virus and there is no evidence of casual spread from surfaces. However, it is known that other viruses, such as adenovirus, may persist for many hours on a dry surface and thus, could conceivably be transmitted to other patients. Therefore, if an instrument, such as a slit lamp, has been used for a patient who clearly has an infectious disease, it is recommended that the surfaces on the instrument be cleaned with alcohol.

Facial Fitting Contact Lenses: Contact lenses need to be disinfected between patients. Rigid gas permeable and hard contact lenses can be disinfected using hydrogen peroxide or a chlorhexidine-containing disinfectant system. Soft contact lenses can be disinfected with either hydrogen peroxide or a heat disinfection system.

### **Respiratory equipment, Spirometer:**

Mouthpieces and spirometry tubing should be submitted to High Level disinfection between each user. Cleaning and disinfection of the inside surfaces of the machine do not need to be cleaned or disinfected because they do not get contaminated (Rutala 1991)

- Rutala DR 1991. Infection risks associated with spirometry. Infect Control Hosp Epidemiol 12:89-92.*

### **Sinks:**

The main problem with porcelain sinks is that they are often constructed in two layers, a steel base coated with porcelain as a finish. If the porcelain chips or wears through, as often happens over time, the steel under layer is exposed and begins rusting. Once that occurs, it cannot be cleaned adequately. This

also happens in facilities with steel/porcelain bed pan flushers. Porcelain is easily cracked, chipped and stained. It is porous despite its appearance of being smooth and non-porous. These factors preclude its being ideal for scrub sinks, although there are many porcelain scrub sinks! Usually they are of long time vintage in the site where they are used. Stainless steel can be stained, but is cannot be chipped, pitted, or cracked. Iodine will stain it, some cleaners will be hard to remove leaving white residue requiring elbow grease, (hard to purchase sometimes) to remove. In this case, of remodeling, consider the cost of harboring organisms in porcelain if and when the insults to the porcelain surface occur, as opposed to the one-time cost of stainless steel which has a better and longer future.

**Sinuscope:**

- High Level disinfection

**Sitz bath:**

- Fill with detergent and water. Scrub thoroughly. Drain completely. Wipe dry.

**Stethoscopes:**

Wipe with alcohol after each use

**Stretcher:**

- Wash with detergent.

**Suction and drainage bottles**

- These are usually disposable, with a self-sealing inner container held in a clear plastic outer container.
- Before buying a system, ensure that the outer container can be heat-disinfected or autoclaved.

Non-disposable bottles:

- Must be changed every 24 hours, or sooner if full.
- The contents may be emptied down the sluice.
- Must be rinsed and sent to the Central Sterile Stores Department (CSSD) for autoclaving.
- If autoclaving facilities are not available, wash thoroughly and dry.
- Recyclable connector tubing should be cleaned thoroughly and sterilized. The system must be closed; risk to staff from body fluids should be minimal.
- Do not leave fluids standing in suction bottles.

**Surgical instruments:**

- Sterilization

**Syringes and needles:**

- These present a high risk of blood-borne disease
- Fine-bored needles cannot be cleaned and therefore should never be recycled.

Recycling of syringes must be well controlled. After thorough cleaning, the syringes must be autoclaved or processed in ethylene oxide.

**Thermometers:**

- Use individual thermometers for each patient.
- Wash in warm water and detergent, and dry.
- Wipe over with a swab or cotton wool ball soaked in 70% isopropyl alcohol, or soak in alcohol 10 minutes.
- Use plastic shields.

**Toiletry articles:** Towels, soap, hairbrushes, shaving brushes, razors, etc.  
These items should be for individual use only and should never be shared.

**Tonometer (see Ophthalmologic equipment):**

**Toys:**

At the end of the shift, collect dirty toys, wash them, spray them with alcohol and air dry them for the next day

**Trolley tops:**

- Wipe with warm water and detergent to remove dust.
- Dry.

**Ultrasound**

**Transducer cables, transducer head:**

Wipe with alcohol or detergent after each use.

**Prostate ultrasound probe:** High Level disinfection

**Vaginal ultrasound probe:** Low Level disinfection with condom

**Urinary catheters and drainage bags:**

These should be single-use and disposable.

**Vaginal speculums:**

- Sterilization if used after the rupture of membranes
- High Level disinfection for other uses. Many hospitals use glutaraldehyde.

**Ventilatory circuits**

- Multiple-use circuits must be heat-disinfected for at least 80°C for at least three minutes or autoclaved (check manufacturer's guidelines) between each patient. Ethylene oxide is an alternative.
- The use of undisinfected circuits between patients increases the risk of chest infection due to Gram-negative bacilli, e.g. *Pseudomonas aeruginosa*.
- Shortage of equipment may necessitate the use of the same circuit up to 72 hours for the same patient. As long as the circuit has not been contaminated this is acceptable. Install filters on the expiratory and inspiratory ends of the ventilator to prevent contamination.
- Filters may be used between patients and ventilator circuits to increase the usage time.
- If properly maintained, a ventilated patient may use the same circuit for four to five days before disinfection becomes necessary.
- Heat exchange filters (Pall filters) eliminate the need for humidifiers, but are expensive.

Pathogens that can survive in moisture and mucus are:

- Haemophilus influenzae*
- Streptococcus pneumoniae* and other streptococci
- Staphylococcus aureus*
- Gram-negative bacilli, e.g. *Pseudomonas*
- Mycobacterium tuberculosis*
- Mycoplasma pneumoniae*.

**Washing bowls:**

These must be washed thoroughly between each patient and inverted to dry. Use fresh water and towels for each patient.

**Wheelchairs:**

Wash with detergent.

**Whirlpool tub:**

Scrub the tub to remove soil. Fill with a 1/100 bleach solution and run the jets for 10 minutes. Drain and refill.

**8-Endoscope Disinfection****8.1-Are endoscopes a risk of infection ?**

Overall, the complication rate of endoscopy is 1.33% with half of them of infectious nature and a 26% case fatality rate for the infectious complications.

- Contamination of endoscopes after clinical uses does occur. Bacteria, viruses and parasite cysts can be recovered from used endoscopes. Microbial loads have never exceeded 100 million cfu /mL (mean for any single organism 1 to 10,000 cfu /mL).
- Infections transmitted by endoscopes have been reported in the medical literature: in 1995, the literatures includes reports of 281 infections transmitted by gastrointestinal endoscopy, 96 by bronchoscopy. The range of severity of the infection went from colonization to death. The main pathogens were Salmonella and Pseudomonas for GI endoscopy, and *M.tb*, atypical mycobacteria and Pseudomonas for bronchoscopy.
- Internal channels are the most difficult parts to disinfect. Their role in the transmission is not clear. A study showed that 24% of internal channels from 71 GI endoscopes grew 100,000 cfu after completion of all the disinfection processes.
- Kaczmarek RG et al 1992. Multistate investigation of the actual disinfection /sterilization of endoscopes in the health care facilities. *Am. J. Med.* 92:257-261.

**8.2-The disinfection process consists of six steps:**

- 1)Cleaning is an extremely important step in the sterilization /disinfection of endoscopes (see cleaning).
- 2)Rinsing and drainage of the channels
- 3)Disinfection
- 4)Rinsing with sterile water. If not feasible, tap water is acceptable provided it is followed by an alcohol rinse.
- 5)Drying
- 6)Storage

**Dress Code:**

- All personnel should change into scrub clothes.
- Barrier protection should be used by personnel to prevent exposure to blood and body fluids.
- Gloves should be worn for performing all vascular access procedures, for all clean-up procedures and for handling items or surfaces soiled with blood or body fluids.
- Masks and eye protection should be worn if splashing is likely.
- Water repellent gowns or aprons should be worn if soiling is likely.
- Patients should change into a hospital gown and robe prior to the endoscopy procedure.

### **8.3-Cleaning of Equipment:**

- Endoscopes are used with patients who may harbor both recognized and unrecognized infections. To prevent the spread of infection, all endoscopes should be thoroughly cleaned and disinfected after each patient use.
- The manufacturer's instructions for cleaning and disinfecting each particular endoscope should be followed.
- Mechanical cleaning of all immersible parts of the endoscope, including all channels and removable parts, is important.

Cleaning of endoscopes and accessories should be performed with non-abrasive, manufacturer-recommended enzymatic detergents for medical instruments promptly after use to prevent drying of secretions. If a powdered detergent is used, care must be taken to make sure that all product granules are completely dissolved before washing. Undissolved detergent granules could block the internal channels of the instrument. Before cleaning, all channels should be irrigated with copious amounts of detergent and tap water to soften, moisten, and dilute the organic debris. All detachable parts (e.g., hoods and suction valves) should be removed and soaked in a detergent solution. The insertion tube should be washed with detergent solution and rinsed. Accessible channel(s) should be brushed to remove particulate matter, and the detergent solution must be suctioned or pumped through all channels to remove dislodged material. Channel irrigators and some automated endoscope washer /disinfectors may be useful in this step. Meticulous attention must be given to crevices, which are likely to harbor contaminated organic material. The tip of the endoscope must be gently wiped/brushed to remove any debris or tissue lodged in, or around the air and water nozzle. When cleaning an ERCP endoscope, the distal tip must be brushed with the elevator both up and down to ensure that no matter is lodged in that movable part. Detachable parts must be thoroughly cleaned with detergent. Irregular surfaces of the detachable parts should be brushed to ensure complete removal of all organic debris. The cleaning brushes should be disposable, or thoroughly cleaned and receive high level disinfection or sterilization at least daily. After mechanical cleaning, immersible equipment should be thoroughly rinsed with water. Nonimmersible endoscopes should rarely be in service today. Newer models of endoscopes are totally immersible.

At all stages of handling, the equipment should be inspected for damage and a leak test should be performed before submerging the entire instrument. If damage is detected, the equipment should not be submerged or reused and the manufacturer should be consulted.

When total immersion of the endoscope is impossible because of potential damage to the scope, the handle should be cleaned with water and detergent and then wiped with 70% alcohol. The umbilical cord, which attaches the endoscope to the light source, should be disinfected in the same manner as the control head. Whenever possible, however, the entire endoscope should be immersed in an Environmental Protection Agency (EPA) registered sterilant/disinfectant.

#### Automated Processing

Automated machines have been developed for endoscope reprocessing. Meticulous manual cleaning as described previously must precede the use of automated machines. Currently available machines vary in

certain fundamental aspects, such as: whether or not all channels are effectively irrigated; whether fluids are passed through the channels by a suction pump, or by other means; whether fluids are reused or discarded; whether cycle lengths can be set automatically and adjusted. Although expensive, automated machines are useful, especially in clinics performing large numbers of procedures. Machines may

reduce exposure of personnel to toxic chemicals and may standardize the contact time of the disinfecting agent. These machines are designed to irrigate most channels (biopsy/suction, air/water) of the instrument. The air/water channel is the one most likely to become occluded with organic debris during use. Channel blockage is particularly difficult to clean manually; however, a blockage of one channel may be missed by a channel irrigator because the flow will continue to be maintained in the open channel. When automated machines are used to disinfect or sterilize endoscopes for ERCP, the channel for the elevator must still be cleaned and disinfected manually.

It is useful if the operator can set the timer on the pump to select appropriate cycle lengths. The machine should be equipped with a basin (holding tray) to allow immersion of the insertion tube and the umbilicus (light guide connector). A typical automated cycle begins with a washing cycle, in which tap water is fed into the machine, detergent is added, and the detergent-containing water is pumped through the endoscope channels by way of tubing and a series of connectors on the light-guide connector and the biopsy port. Detergent and water also flow into a basin where the insertion tube is submerged and soaked. Water is then drained out while air is delivered through the channels. During the disinfection cycle, glutaraldehyde (or another chemosterilant) fills the basin holding the endoscope and flows through the channels. It is left in contact with the internal and external surfaces of the scope for a predetermined period. The disinfectant then flows out and water is admitted for a second time to the channels and the holding tray to remove disinfectant residues. In the final drying cycle, the water is drained out and air is blown through the channels.

#### **8.4-Sterilization and Disinfection**

Endoscopes, which come into contact with mucous membranes, are classified as semicritical equipment. Endoscopes that enter sterile body cavities would be classified as critical in the Spaulding scheme. Some endoscopic accessories (e.g., sclerotherapy needles, cutting forceps) are classified as critical equipment.

The minimum recommended practice for endoscopes is high-level disinfection with an EPA-registered liquid sterilant/disinfectant with objective evidence of efficacy in clinical practice published in the scientific literature. To achieve adequate high-level disinfection, all internal and external surfaces and channels must be in contact with the disinfecting agent for at least 20 minutes.

##### Glutaraldehyde Preparations:

Alkaline glutaraldehyde - When aqueous solutions of glutaraldehyde are "activated" by adding bicarbonate to raise the pH from 7.5 to 8.5, their microbial (including sporicidal, fungicidal, and viricidal) activity is greatly enhanced. Several preparations of glutaraldehyde are marketed as a 2% solution to which a separately packaged "activating" preparation containing an alkaline buffer, a surface-tension depressant, an anticorrosive compound, and a water-soluble dye is added.

Glutaraldehyde is noncorrosive to metal and does not damage endoscopes. In contrast to many disinfectants, it is highly resistant to neutralization by organic soil. Although alkalization enhances the microbicidal activity of glutaraldehyde, it also promotes polymerization, with subsequent loss of free aldehyde groups. This limits the shelf life of activated solutions to about 14 days. Chemically stabilized solutions have a shelf life (i.e., a period during which they maintain adequate glutaraldehyde concentrations) of at least 14 days and of 28 days when in-use dilution does not exceed 50%.

Acid glutaraldehyde - Compared with alkaline preparations, some acid solutions are more corrosive to metal. Acid solutions of glutaraldehyde (pH 3 to 6.3) are stable for long periods, without loss of active aldehyde groups. A 2% acid glutaraldehyde acts as a chemical sterilant and is acceptable for high-level disinfection (and therefore, endoscope reprocessing).

Hydrogen Peroxide ( $H_2O_2$ )- Hydrogen peroxide has been used as a germicide for more than a century. Early preparations were dilute and unstable, and decomposed rapidly in the presence of trace amounts of impurities. Since the 1950's it has been possible to produce concentrated solutions with stabilizers added to deactivate impurities. Hydrogen peroxide is a rapid oxidizer which facilitates the removal of organic debris and it is relatively free of toxic fumes. Although hydrogen peroxide is a potent anti-microbial agent, it can damage rubbers and plastics, and corrodes copper, zinc and brass. A 6% hydrogenperoxide/0.85% phosphoric acid solution, classified as a high-level disinfectant, is acceptable

for endoscope preprocessing unless incompatible with endoscopic equipment.

Peracetic Acid - Peracetic acid is a component of an equilibrium mixture of acetic acid, hydrogen peroxide, and water. A 1% peracetic acid solution has broad-spectrum activity against bacteria, fungi, spores, and enteroviruses in 10 minutes. Although this peroxyacid can also be corrosive, an automated endoscope reprocessing system has been designed that dilutes 35% peracetic acid to a final concentration of 0.2% and adds a buffer to an anticorrosive agent. The system is designed only for reprocessing totally immersible endoscopes.

### **8.5-Agents not recommended for disinfection of endoscopes:**

Specific agents are not recommended for use on endoscopes and endoscopic equipment because of incomplete microbiologic coverage (i.e., failure to meet the definition of a high-level disinfectant), toxic exposure to personnel, or physical damaging to the equipment.

Preparations of glutaraldehyde with phenol derivatives:

2.0% glutaraldehyde/7.05% phenol/1.20% sodium phenate (GPP). Attempts have been made to potentiate the activity of glutaraldehyde solutions by combining glutaraldehyde with one or more additional antimicrobial agents while decreasing the concentration of glutaraldehyde, to decrease the incidence of toxicity among endoscopy personnel. When diluted 1:16, GPP contains 0.125% glutaraldehyde with 0.44% phenol and 0.075% sodium phenate. A working party of the British Society of Gastroenterology and the "APIC Guideline for Selection and Use of Disinfectants" do not recommend its use at a 1:16 dilution for high-level disinfection. In 1991, the product was recalled by the U.S. FDA.

10% glutaraldehyde/0.5% orthophenylphol/0.1% paratertiary amyphenol (GPA). Whereas a 1:5 final dilution of GPA is appropriate for high-level disinfection, a 1:20 dilution is not acceptable for use because the 1:20 dilution contains 0.5% glutaraldehyde. It was recently shown that concentrations of less than 2% glutaraldehyde, even when combined with phenol derivatives, were unable to inactivate *C.difficile* spores at exposure times of 10, 20 and 60 minutes. At the time of this publication, the manufacturer has voluntarily removed this product from the United States market.

### Iodophors

A common problem in health care facilities is the inappropriate use of povidone-iodine antiseptics as equipment disinfectants. Povidone-iodine products, which are formulated, registered and intended as antiseptic agents, should not be used as disinfectants.

### Hypochlorite

Hypochlorites are not appropriate for disinfecting endoscopes. Their use is limited by their corrosiveness and inactivation by organic matter.

### Quaternary Ammonium Compounds

Contaminated quaternary ammonium compounds have been associated with nosocomial infections, not only when used as antiseptics, but also when used as disinfectants. They are in general not sporicidal,

tuberculocidal, or viricidal against hydrophilic viruses. They are adequate for use on noncritical surfaces, but are not appropriate for the disinfection of endoscopes.

### Phenolics

Phenolics are intermediate-level disinfectants commonly used to clean floors and laboratory work surfaces. Phenolics are absorbed through porous materials. Even after disinfected articles are thoroughly rinsed, residual phenolics have caused tissue irritation and injury to mucous membranes. Hazardous concentrations in the air have been noted in laboratories. For these reasons, and because phenolics are not sporicidal, they are not recommended for the disinfection of semicritical equipment, including endoscopes.

### New technologies for which there are insufficient data regarding sterilization /disinfection of endoscopes

- There are a number of sterilization and disinfection products emerging in the field for which there are insufficient published data with which to formulate a recommendation at this time of publication. The following technologies are under investigation and may prove useful in the reprocessing of endoscopes: (1) chlorine dioxide, (2) ozone, (3) vapor-phase hydrogen peroxide, (4) plasma technology, and (5) disposable, sterile-sheathed flexible endoscopes.

### **8.6-Endoscope brushes**

Fragments of cleaning brushes may become dislodged and stuck inside an endoscope channel to become dislodged later during an endoscopic procedure. The release of a foreign body could cause an infection or require surgery for removal.

- Examine the cleaning brush before use and after use. Check carefully for missing bristles or for a missing tip. Do not use brushes that appear to be damaged.
- If any piece is missing, flush or use another brush or any device to force this fragment out of the channel.

### **8.7-Treatment of the Endoscope after Disinfection or Sterilization**

Rinsing. To prevent toxic effects of residual chemicals after disinfection, the equipment must be adequately rinsed. Chemical colitis mimicking pseudo-membranous colitis, caused by 3% hydrogen peroxide and glutaraldehyde, has been reported. Ordinary tap water may contain microbes, including *Pseudomonas* spp. and *Mycobacterium* spp. In several reports, contaminated rinse water was the suspected source of *P.aeruginosa* transmission to patients through previously disinfected endoscopes. Certain endoscopes through which specimens for cultures are often obtained, such as bronchoscopes, may become contaminated by a tap water rinse. For these reasons, rinsing should be done with sterile water. If sterile water is not used, a tap water rinse followed by complete drying is essential. Only sterile water should be used for endoscopes that pass through sterile tissues.

Drying. To prevent growth or transmission in a moist environment, the insertion tube and channels should be thoroughly dried. Rinsing channels with 70% alcohol and directing compressed air through the damp lumens will facilitate drying. Allen and Associates described an outbreak of colonization and infection with *P.aeruginosa* associated with ERCP. Clinical manifestations ranged from asymptomatic carriage to fatal infection. The organism was able to proliferate in the channels of the endoscope until the investigators adopted a procedure of suctioning 70% alcohol through all channels, followed by compressed air to completely dry the instrument. Therefore, drying with alcohol and compressed air should be done; (1) between each patient use when tap water is used to rinse the endoscope channels, and (2) before storage, whether tap water or sterile water is used.

Storage. Endoscopes should be stored in a manner to prevent recontamination or damage. Endoscopes should be stored without control valves, distal hoods, caps, etc. in place. There should be adequate space to keep the endoscopes and other equipment from coming into contact with each other.

## Design of Facilities for Performing Endoscopic Procedures, including Support Space

There are a number of factors to be considered in the design and use of space for endoscopic procedures and the cleaning, disinfection, sterilization, and storage of endoscopes and endoscopic equipment. Patient volume, traffic flow, and types of endoscopic procedures (e.g. bronchoscopy, gastrointestinal endoscopy) performed should all be taken into account during space planning.

Space for the performance of procedures should be separate from space used for cleaning and disinfection or sterilization of equipment. There should be a designated sink for handwashing. The room should be equipped with adequate utilities to support the patient during the procedure (e.g., suction, oxygen). Procedure areas should have space available for charting, logbooks, procedure manuals, equipment manuals, and other administrative materials.

Because of the reemergence of tuberculosis, the air handling in procedure rooms, especially for bronchoscopies, should conform to the latest CDC guidelines for preventing the transmission of tuberculosis in health care facilities.

Space used for the cleaning and disinfection or sterilization should have adequate ventilation to exhaust toxic vapors and airborne pathogens. If large volumes of glutaraldehyde in basins are used, basins should be covered with snug lids and consideration should be given to the installation of an exhaust hood. There should be separate handwashing and utility sinks. The utility sink must be large enough to accommodate the cleaning and rinsing of endoscopes and accessories. If machines are used for disinfection, the area must be designed with adequate space and appropriate utilities specific to the machines being used. There must be adequate space for the storage of chemosterilants, some of which have special handling requirements as hazardous materials. The area should be designed so that the work flow can facilitate sound infection control practices (e.g., avoid the commingling of contaminated with clean equipment).

There are some important design features to consider in the storage of clean endoscopes and accessories. Closets or cabinets used for drying and storage should be constructed of materials that can be cleaned easily. Endoscopes must not be stored in foam-lined cases because the foam lining is impossible to clean should it become contaminated. Endoscopes should be stored in a manner that will protect the endoscope while minimizing the potential for residual moisture accumulation. The storage should accommodate a sufficient number of endoscopes to support the patient volume.

There are additional support issues to be addressed during the development of an endoscopic service. Patients should have private changing and bathroom facilities. Staff should have lounge space to discourage prohibited eating and drinking in the procedure rooms, or utility rooms. There should be easy access by the staff to personal protective equipment. Policies and procedures should be developed for the cleaning of procedure rooms and all support space.

### **9-Cleaning**

The purpose of cleaning is to remove organic material that is clinging to a piece of equipment. Cleaning does not provide any guaranty of sterility. However by removing the organic material, it also removes microorganisms and this, sometimes, to a large extent.

Soil protects microbes from contact with disinfectants or sterilants, and reacting with cleaning agents. Cleaning by removing the soil allows these agents to act more effectively. Residual detergent left after cleaning may inactivate the disinfectants used after cleaning, therefore rinsing is important to remove all residual chemical.

Cleaning involves:

- Mechanical energy by friction
- Thermal energy by elevated temperature
- Chemical action by detergents. A cleaning product should emulsify (suspend fat in water), then saponify fats (render fat water soluble by adding hydrophilic poles). It should reduce the surface tension (surfactant factor) to allow better penetration into the soil, break up the aggregate of soil (dispersion or deloculation), break up the protein (peptization), and soften the water (precipitate Ca and Mg by chelation or sequestration).

Cleaning can be done by hand, in a washer sterilizer or by ultrasound:

- Hand washing carries a high risk of exposure to personnel.
- Washer sterilizers avoid personnel exposure but may damage heat-sensitive instruments. Instruments must be opened and disassembled.
- Ultrasonic cleaning is achieved by generating ultrasounds in a solution. Bubbles are formed, expand and collapse. In the process they create vacuum spaces which dislodge dirt. This process removes dirt from inaccessible areas.

**Cleaning endoscopic equipment** is very effective in eliminating microorganisms. In a series of studies carried out on endoscopes contaminated with bacteria (2-8 cfu/mL), HIV and HBV viruses (4-7 pg/mL) and pneumocystis (1 cyst/mL) (Hanson 1989, 1990 & 1991), cleaning reduced the microbial load to 0 for HIV and HBV viruses, and reduced it to 1/1000 - 1/10,000 of its original level (99.9% - 99.99% reduction or 3 - 4 log reduction).

In a study examining 30 endoscopes used on persons with AIDS, cleaning alone removed all detectable microorganisms from 84 of the 86 contaminated sites. Cleaning removed HIV to such an extent that virus was undetectable by PCR which can identify one infected cell in a sea of 1,000,000 infected cells.

Thus cleaning is very important in setting the stage for fast action by the disinfectant. To reach high level disinfection with glutaraldehyde (2%) of an endoscope:

- |  |                     |
|--|---------------------|
| - well cleaned                                       | 10 minutes at 20°C  |
| - poorly cleaned (experimental- with 2% horse serum) | 45 minutes at 25 °C |

In summary cleaning removes about 99.99% of microorganisms and allows for faster and more efficient disinfection.

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## 10-Sterilizing Practice: Central Sterilizing Service (CSS)

Monitoring of sterilization procedures is done by several groups: the American Hospital Association (AHA) Guidelines for Hospital CSS Personnel, the Association of Operating Room Nurses (AORN) Recommended Practices for in Hospital Sterilization, CDC Guidelines for Prevention of Nosocomial Infections, the AAMI Steam Sterilization and Sterility Assurances. There are minor variations in the recommendations.

Most cleaning, disinfecting and sterilizing of equipment should be performed in a central area. Some hospitals are able to promote the same level of efficiency and safety in the preparation of supplies in other areas like the operating room, anesthesia and respiratory therapy.

The central processing area(s) should ideally be divided into at least three areas:

### **Decontamination ⇨ Packaging and Sterilization ⇨ Storage**

#### **10.1-Decontamination area**

Should be separated by physical barriers from the other sections to contain contamination on used items, but ideally all three sections should be separated by physical barriers. In the decontamination area reusable supplies (and possible disposable items that are reused) are received, sorted, and decontaminated.

#### **10.2-Cleaning**

Items must be cleaned using water with detergents or enzymatic cleaners before processing. Precleaning in patient-care areas may be needed on items that are heavily soiled with feces, sputum, blood, etc. Items sent to central processing without removing gross soil may be difficult to clean because of dried secretions and excretions.

**There is no need to sterilize or disinfect before cleaning. Standard precautions should be applied at all times, and they are sufficient.**

There are several types of mechanical cleaning machines (e.g., utensil washer-sanitizer, ultrasonic cleaner, washer-sterilizer, dishwasher) that may facilitate cleaning and decontamination of most items. Delicate and intricate objects as well as heat-or moisture-sensitive articles are carefully cleaned by hand. All used items sent to the central processing area should be considered contaminated and need to be handled with gloves (forceps or tongs are sometimes needed to avoid exposure to sharps), and decontaminated by one of the aforementioned methods to render them safer to handle.

Personnel in cleaning areas should be adequately protected: thick gloves, goggles or other appropriate eyewear, aprons or gowns.

#### **10.3-Loading**

All items to be sterilized should be arranged so:

- 1-all surfaces will be directly exposed to the sterilizing agent.
- 2-Packs should rest on edge in loose contact with each other,
- 3-Packs should be stacked cross-wise not piled up neatly,
- 4-Packs should not exceed the maximal dimensions, weight, and density of:

<b>Dimensions</b>	30 x 30 x 50 cm	12 x 12 x 20 inches
<b>Weight</b>	5.4 kgs	12 lbs
<b>Density</b>	115 kg/m <sup>3</sup>	7.2 lbs/cu.ft

Unload the packs on an aerated shelf. Let them cool at ambient temperature. Avoid unnecessary handling.

#### **10.4-Packaging**

The packaging area is for assembling and packaging clean but not sterile material. The storage area should be a limited access area with a controlled temperature (65-72°F), and relative humidity (35-50%).

Personnel in the packaging area must wear scrub suits. Shoe covers are not necessary in the CSS.

Once items are cleaned, dried, and inspected, objects requiring sterilization must be wrapped or packaged.

### **The packaging material**

Must allow penetration of the sterilant and maintain the sterility of the processed item after sterilization. Commonly used packaging material includes:

- Cloth wrap, Muslin (140 thread count/inch): least effective, should be used as a double layer; must be laundered, delinted and inspected before use; for steam, heat and ETO.
- Jean cloth (160 thread count): should be used as a double layer; must be laundered, delinted and inspected before use; for steam and ETO, but not heat.
- Barrier cloth (272-288 thread count): can be used as a single layer; must be laundered, delinted and inspected before use; may retain moisture, long drying time; for steam and ETO.
- Kraft paper: two wraps preferred, better barrier than muslin; cannot be reused; for steam and ETO.
- Glassine type paper for syringes
- Plastic film pouches and polyethylene wraps for ETO; excellent barrier, impervious to moisture; cannot be reused.

### **10.4-Monitoring**

The sterilization procedure should be monitored routinely by a combination of mechanical, chemical, and biologic parameters. These process parameters evaluate the sterilizing conditions and indirectly, the microbiologic status of the processed items. The mechanical techniques for steam sterilization include the daily assessment of cycle time and temperature by examining the temperature record chart, as well as an assessment of pressure via the pressure gauge. Unfortunately, two other essential elements for ethylene oxide sterilization (i.e., the gas concentration and humidity) cannot be monitored.

**10.4.1-Chemical Indicators** are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator should also be placed on the inside of each pack to verify steam penetration. Chemical indicators are usually either heat or chemical sensitive inks that change color when one or more germicidal related parameters are present. Most recommend use indicators, either in the package, or outside the package; some in both places.

**10.4.2-Biological Indicators** are the only process indicators that directly measure sterilization. *Bacillus subtilis* spores are used to monitor ethylene oxide and dry heat, and *B. stearothermophilus* spores are used to monitor steam sterilization. *B. stearothermophilus* is incubated at 55°C, and *B. subtilis* is incubated at 35°C to 37°C. Steam and ethylene-oxides sterilizers should be monitored at least weekly (some recommendations are to monitor each load, some to monitor daily) with the appropriate commercial preparation of spores, but each load should be monitored if it contains implantable objects. When feasible, do not use implantable items until the results of spore tests are known to be negative.

The procedure to follow **in the event of positive spore tests** vary. The most common cause of false positive tests is laboratory contamination or defective biological indicators.

#### CDC recommendations:

- Check the sterilizer and recall equipment if defects found
- Do not recall if sterilizer found to be functioning properly
- Recall any implantable objects

AORN (Association of Perioperative Registered Nurses) states that a single, positive spore test does not necessarily indicate a sterilizer failure. If the test is positive, the sterilizer should immediately be rechallenged for proper use and function. Items, other than implantable ones, do not necessarily need to be recalled unless a sterilizer malfunction is found. If a sterilizer malfunction is discovered, the items must be considered nonsterile, and the items from the suspect load(s) should be recalled and reprocessed.

This, or a more conservative approach of considering any unexplainable positive-spore test as a sterilizer malfunction that requires retrieval and reprocessing of all items, are the only defensible positions. One can assume sterilizer malfunction, unless there is strong evidence for the biologic indicator being defective, or that the growth medium contained a *Bacillus* contaminant.

AAMI (Association for the Advancement of Medical Instrumentation) recommends the evaluation of the sterilizer and determining the cause of failure. Recall all equipment processed during the same batch and reprocess it.

The size and composition of the biologic indicator test pack should be standardized to obtain interpretable results. Unfortunately there is no biologic indicator test pack that has gained acceptance for either steam or gas sterilization.

The biologic-indicator test pack recommended by the AORN for both types of steam sterilizers consists of three muslin surgical gowns, 12 towels, 30 '4x4' gauze sponges, five laparotomy sponges and one muslin drape sheet, or equivalent linens. The biologic and chemical indicators are placed in the center of the pack but are separated by one towel. The pack should be placed in such a way so that the center of the pack is as close to the cold spot as possible. This means that the test pack should be placed on the bottom shelf of a steam sterilizer in the area above the chamber drain.

The biologic-indicator test pack recommended by the AORN for ethylene oxide sterilizers is a plastic (or glass) syringe of a sufficient size that the plunger diaphragm does not touch the biological indicator when the plunger is inserted into the barrel of the syringe. The needle end of the syringe must be open (tip guard removed). The syringe is placed in the folds of a clean surgical towel and placed in one peel pouch or non-oven wrapper. If only one test pack is placed in the load, it should be in the geometric center of the load.

**10.4.3-Mechanical indicators** are the recording charts for time and temperatures, pressure gauges in steam or heat sterilizers, humidity gauge and gas conditioner steam pressure gauge for the ETO sterilizer.

## **10.5-Storage**

Safe storage times for sterile packs vary with the porosity of the wrapper and storage conditions (e.g., open versus closed cabinets). Heat-sealed, plastic peel-down pouches, and wrapped packs sealed in 3 mm (3/1000 inch) polyethylene overwrap have been reported to be sterile for as long as nine months after sterilization. The 3 mm polyethylene is applied after sterilization to extend the shelf-life for infrequently used items. Supplies wrapped in double thickness muslin comprising of four layers, or equivalent remain sterile for at least 30 days. Any item that has been sterilized should not be used after the expiration date has been exceeded, or if the sterilized package has been dropped, wet, torn, or punctured.

Although many hospitals continue to date every sterilized product and use the **time-related shelf-life practice**, some hospitals have switched to an **event-related shelf-life** practice. This latter practice recognizes that the product should remain sterile until some event causes the item to become

contaminated (e.g. tear in packaging, packaging becomes wet, or dropped on a contaminated surface such as the floor). There are some data that support this policy.

There is no need to wear gowns and show covers in the storage area (Crow 1989). Items are packaged and there is no risk of contamination if the integrity of package is maintained.

## Shelf Life

### 1-Time related shelf life

In the past, hospitals used to date every sterilized product; this date printed on the package would determine how long the package could be used. This was called **time-related shelf life**. After this date, the product was sent back to CSS for reprocessing.

Some studies had suggested that safe storage ranged from two days to nine months depending on the wrapper and conditions of storage. The conclusions of these studies became a standard for most hospitals. The standard was modified as time and studies went by. In 1996, a survey of U.S. hospitals showed that for woven and non-woven material, the shelf life ranged from 28 days (20% of hospitals) to 30 days (80% of hospitals); for peel-pouched items the range was from six months (40% of hospitals) to 12 months (60% of hospitals). Only 5% of hospitals used a dust cover. Studies showed that **there was no trend toward increased probability of contamination over time for any of the packs considered**. For storage periods up to one year, there was no increase in contamination regardless of wrapping material (non barrier-woven, barrier non-woven, polypropylene pouches), regardless of dust cover use, and regardless of storage location.

### 2-Event related shelf life

Loss of sterility was clearly **event related**. Factors such as method of handling, storage area conditions, temperature and humidity, space and crowding, flooding, insects were determining in creating breaks in the packaging.

### 3-Maintaining the integrity of a sterile pack

Maintaining the sterility of a sterile pack is the responsibility of every user of a sterile pack.

#### Store pack in safe conditions

- Avoid moisture or any exposure to water.
- Do not store under a sink.
- Do not handle with sweaty hands.
- Minimize handling.
- Do not cram packs in a tight container (drawer or boxes).
- Do not fold or create creases in the packs.
- Do not drop packs.

#### Handle with tender loving care

**Inspect packs  
before opening look for:**

Cracks, holes, deep creases  
Rupture of seal  
Deterioration of package wrapper (moldy, moist)

**Rotate the inventory:  
First in first out**

Place new supplies  
    at bottom of a pile  
    at back of a row  
    left of a row

Take old supplies first.

**11-Sterilization of Disposable Items**

Sterilization of disposable items may be done in some cases. Most hospitals would do this when disposable items are opened, and not used. The safest approach is to contract with a re-sterilizer company which has the know-how.