

# Cleaning, Disinfection, and Sterilization of Medical Equipment

## Introduction

Medical equipments and surgical instruments are examples of devices that are essential to the care of patients; however, because they typically are designed for reuse, they also can transmit pathogens if any of the steps involved in reprocessing, cleaning, disinfection, or sterilization are inadequate or experience failures. Because the vast majority of pathogens are present in organic matter, e.g. visible soil, the first step in reprocessing, cleaning, is the most important. Any failure to remove soil at this point creates the potential for transmission of infection as the efficacy of subsequent disinfection or sterilization will be compromised. Decontamination is the process by which microorganisms are removed or destroyed in order to render an object safe. It includes:<sup>31</sup>

- Cleaning,
- Disinfection, and
- Sterilization.

All hospitals and health care facilities should have a decontamination policy and help staff to decide what decontamination process should be used for which item of equipment.<sup>11</sup>

## Processing Instruments

### Definition of Terms

**Antimicrobial agent:** Any agent that kills or suppresses the growth of microorganisms.

**Biocide:** A chemical or physical agent that kills all living organisms, pathogenic and nonpathogenic.

**Biologic indicator (BI):** A standardized preparation of bacterial spores on or in a carrier serving to demonstrate whether sterilizing conditions have been met. The type of spore varies by type of sterilization.

**Cleaning:** Cleaning is a process, usually involving detergent or enzymatic presoak that removes foreign material (e.g. dirt or microorganisms) from an object. Cleaning is the most essential step in reprocessing instruments and equipment.

**Decontamination:** The use of physical or chemical means to remove, inactivate, or destroy pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, for use, or for disposal. Decontamination could comprise cleaning, disinfection or sterilization as appropriate.

**Disinfection:** Any process, chemical or physical, that destroys pathogens such that an item is safe to handle for its intended use.

**Disinfectant:** A disinfectant is a chemical agent that destroys most pathogens but may not kill bacterial spores. Chemical disinfection should only be used if heat treatment is impractical or if it may cause damage to the equipment. There is a broad spectrum of chemical disinfectants that have different anti-microbial activities. Most of them do not necessarily kill all microorganisms or spores that are present on an inanimate object but instead reduce the number of microorganisms to a level that is not harmful to health. Disinfectants are used on inanimate objects only and not on living tissue. Chemicals used to kill microorganisms on skin or living tissue are known as antiseptics.

The broad category of disinfection may be subdivided into high-level, intermediate-level, and low-level disinfection according to the anti-microbial activity of the disinfectant.

**Low level disinfectant (LLD):** LLD is an agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungus, but not bacterial spores.

**Intermediate-level disinfectant (ILD):** ILD is an agent that destroys all vegetative bacteria, including tubercle bacilli, lipid enveloped and some nonlipid enveloped viruses, and fungus spores, but not bacterial spores.

**High-level disinfectant (HLD):** A high-level disinfectant is a chemical or physical agent or process that is capable of killing some bacterial spores when used in sufficient concentration, temperature, and under suitable conditions. It is therefore expected to be effective against vegetative bacteria, fungi, viruses and other microorganisms. It does not kill high numbers of bacterial spores.

**Note:**

Some of the chemicals used for disinfection can also be used as chemical sterilants which can kill bacterial spores. Contact with the heat-sensitive items normally requires prolonged exposure times. For more details about chemical sterilants see the sterilization section in this chapter.

**Lipid virus:** A virus whose core is surrounded by a coat of lipoprotein whose disruption renders the virus non-infectious. Viruses included in this structural category are generally easily inactivated by many types of disinfectants, including low level disinfectants. Also referred to as enveloped viruses. Examples are HIV, herpes, HCV, HBV and myxoviruses.

**Nonlipid virus:** A virus whose nucleic acid core is not surrounded by a lipid envelope. These viruses are generally more resistant to inactivation by disinfectants. These are also referred to as hydrophilic viruses as coxsackie, enteroviruses, etc.

**Pasteurization:** A process developed by Louis Pasteur of heating milk, wine, or other liquids to 60 C to 100 C for approximately 30 minutes to reduce or to significantly kill the number of pathogenic and spoilage organisms. The higher the temperature, the shorter the time needed. Also termed as “heat disinfection”.

**Pyrogens:** Fever producing agents or substances, e.g., endotoxins from the outer membranes of gram negative bacteria.

**Spaulding classification:** A strategy developed by Dr. Earle H. Spaulding for reprocessing contaminated medical devices. The system classifies devices as critical, semicritical, or noncritical based on the risk from contamination of a device to a patient. Three different levels of disinfection are applied based on this risk scheme. For example a needle used for entry into tissue is critical and needs to be sterile. A speculum (endoscopes) has contact with mucous membranes and therefore needs to be cleaned and then undergo high-level disinfection. A blood pressure cuff has contact with intact skin and only needs cleaning.

**Sterilant.** An agent that destroys all viable forms of microbial life to achieve sterilization.

Sterilization methods remove or destroy all forms of microbial life including bacterial spores by either physical or chemical processes. It is recommended that any instrument or equipment classified as critical that comes in contact with the blood stream or with subdermal tissues be cleaned and sterilized in between each use.<sup>78</sup> Sterilization is accomplished principally by steam under pressure, by dry heat, and by chemical sterilants.

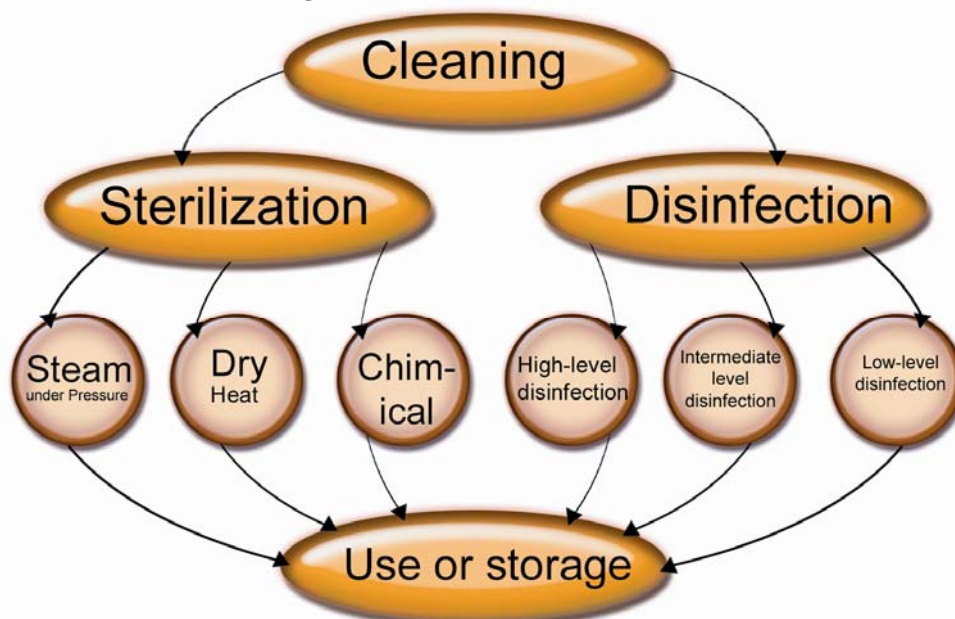
The choice of the method for sterilization depends on a number of factors including the type of material that the object to be sterilized is made of, the number and type of microorganisms involved, the classification of the item, and availability of sterilization methods.

**Table 22: Decreasing order of resistance of microorganisms to disinfection and sterilization and the level of disinfection or sterilization.** <sup>79</sup>

	Types of organisms	Level
<div style="display: flex; flex-direction: column; align-items: center;"> <div><b>Resistant</b></div> <div style="margin: 10px 0;">↓</div> <div><b>Susceptible</b></div> </div>	Prions (e.g., Creutzfeldt-Jakob Disease)	- Sodium Hydroxide soap for one hour - 18 min prevacuum steam sterilization (134-137C)
	Bacterial spores (e.g. Clostridium tetani, Clostridium difficile)	Sterilization
	Coccidia (Cryptosporidium)	
	Some spores generated by spore forming bacteria	High Disinfection
	Mycobacterium tuberculosis	
	Nonlipid or small viruses (polio, coxsackie)	Low Disinfection
	Fungi (e.g., Aspergillus, Candida)	
	Vegetative bacteria (S. aureus, P. aeruginosa)	
	Lipid viruses (HIV, HBV, HCV, herpes, myxoviruses)	

## The Instrument Processing (Decontamination Steps)

There are two steps to processing items that are used during clinical and surgical procedures. Cleaning is the first and the most important step. Cleaning is followed by either sterilization or disinfection and by immediate use or proper storage of the item.

**Fig. 21: Decontamination Steps**

## **Risks of Infection from Equipment**

The risks of infection from equipment may be classified into three categories. Placing instruments and equipment into one of the following categories can be helpful in choosing the proper level of disinfection or sterilization needed in order to protect the patients and the health care personnel.<sup>11</sup>

### **Low risk (noncritical items)**

Noncritical items are items that come into contact with normal and intact skin as stethoscopes or with the inanimate environment (e.g. walls, floors, ceilings, furniture, sinks, etc.). Cleaning with a detergent and drying is usually adequate. Stethoscopes are usually cleaned and in rare cases they should be disinfected if used on infectious patient or highly susceptible patient.

### **Intermediate risk (semi-critical items)**

Semi-critical items are items that do not penetrate the skin or enter sterile areas of the body but that are in close contact with mucous membranes or with non-intact skin. Cleaning followed by HLD is usually adequate. Examples include respiratory equipment, flexible endoscopes, laryngoscopes, specula, endotracheal tubes, thermometers, and other similar instruments.

### **High risk (critical items)**

High risk items are items that penetrate sterile tissues such as body cavities and the vascular system. These items are called critical items because of the high risk of infection if such an item is contaminated with any microorganism before penetrating the tissue. Cleaning followed by sterilization is required. High-level disinfection may sometimes be appropriate if sterilization is not possible, e.g., flexible endoscopes. Examples of high-risk items include surgical instruments, intra-uterine devices, vascular catheters, implants, etc.

### **Single Use Items**

These items may be used in critical, semi-critical, or noncritical areas; however, they are single use items that are prepackaged with the appropriate level of disinfection or sterilization and are disposed of after a single use. Examples include gloves, needles, syringes, and tongue depressors.

The figure below shows the relationship between types of items and the sterilization or disinfection that they must undergo.

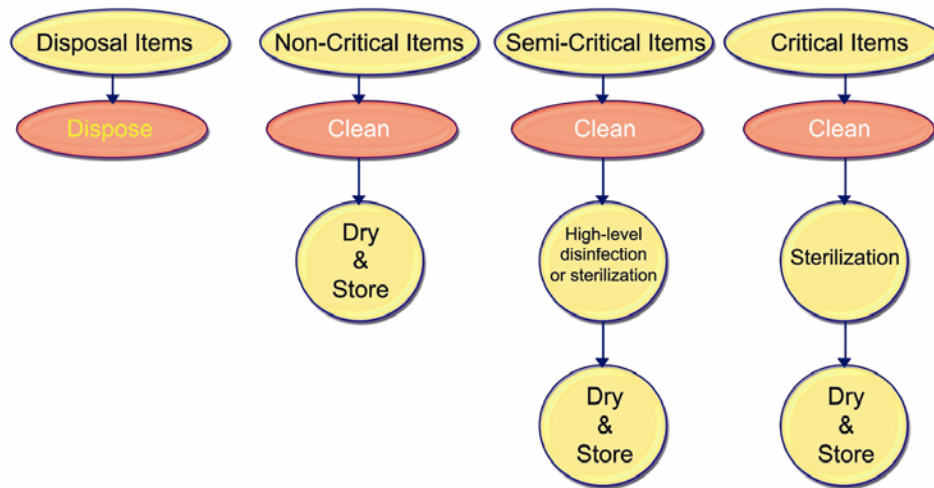


Fig. 22: Relation between type of item & its decontamination

## Cleaning

Cleaning is the removal of all foreign material (dirt and organic matter) from the object being reprocessed. Two key components of cleaning are friction to remove foreign matter and fluids to remove or rinse away contamination. Thorough cleaning will remove most organisms from a surface and should always precede disinfection and sterilization procedures. If instruments and other items have not been cleaned, sterilization and disinfection may not be effective because microorganisms trapped in organic material may survive sterilization or disinfection.<sup>80</sup>

Cleaning is normally accomplished by the use of water, detergents and mechanical actions. Detergent is essential to dissolve proteins and oil that can reside on instruments and equipment after use.

Cleaning may be manual or mechanical. Mechanical cleaning includes ultrasonic cleaners or washer/disinfectors that may facilitate cleaning and decontamination of some items and may reduce the need for handling.<sup>31</sup>

The solution used most often to clean is an enzymatic presoak (protease formula that dissolves protein). Alternatively a detergent can be used. Detergents lower surface tension and lift dirt or oil away from the device. Studies have shown that thorough cleaning alone can provide a 10 000 fold reduction in contaminant microbes from endoscopes.<sup>79, 81, 82</sup> Cleaning can be very effective in removing microbial contaminants from surgical devices.

## Mechanical Cleaning

Most modern sterilization units are automated and there is minimal handling of dirty equipment by staff. The equipment is placed in trays ready for washing:

- Washing machine. The washing machine gives a cold rinse followed by a hot wash at 71 °C for 2 minutes. This is followed by a 10-second hot water rinse at 80-90 °C and then by drying by a heater or a fan at 50-75 °C.

- Washer/disinfector. The washer/disinfector is used for anesthetic equipment. It runs a 45-minute cycle of washing and cleaning plus a 2-minutes cycle with water at 80-100 °C and with a detergent solution.
- Ultrasonicator. The ultrasonicator is a sophisticated and expensive but extremely efficient piece of equipment. It uses high-power output of 0.44 W/cm<sup>3</sup> and dislodges all organic matter.

## Manual Cleaning

All items requiring disinfection or sterilization should be dismantled before cleaning. Cold water is preferred; it will remove most of the protein materials (blood, sputum, etc.) that would be coagulated by heat and would subsequently be difficult to remove. The most simple, cost-effective method is to thoroughly brush the item while keeping the brush below the surface of the water in order to prevent the release of aerosols. The brush should be decontaminated after use and should be dried.

Finally, items should be rinsed in clean water and then should be dried. Items are then ready for use (noncritical items) or for disinfection (semi-critical items) or for sterilization (critical items).

Manual cleaning is necessary when:

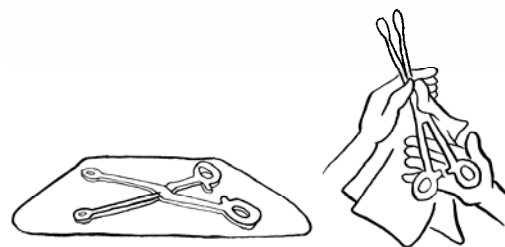
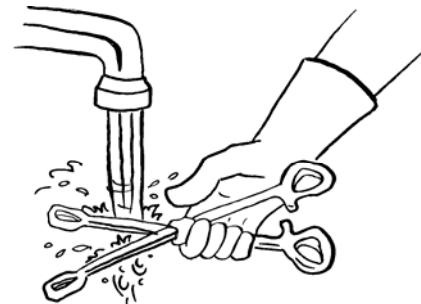
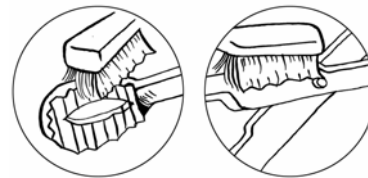
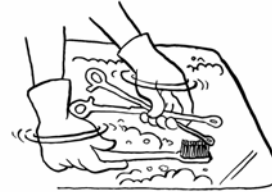
- Mechanical cleaning facilities are not available;
- Delicate instruments have to be cleaned;
- Complex instruments need to be taken apart to be cleaned;
- Items with narrow lumens need to be cleaned (endoscopes).

Manual or hand-cleaning must be done with extreme caution. The staff should follow the set procedure:

## Steps for cleaning

1. Wear heavy-duty rubber gloves, a plastic apron, eye protection, and mask during cleaning.
2. Soak the instruments in normal tap water containing a detergent.
3. Scrub instruments and other items vigorously to completely remove all foreign material using a soft brush or old toothbrush, detergent, and water. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing. Disassemble instruments and other items with multiple parts, and be sure to brush in the grooves, teeth, and joints to items where organic material can collect and stick.
4. Flush through lumens with an adapted water jet.
5. Rinse items thoroughly with clean water to remove all detergent. Any detergent left on the items can reduce the effectiveness of further processing.
6. Inspect items to confirm that they are clean.
7. Allow items to air dry or dry them with a clean towel if chemical disinfection is going to be used. This is to avoid diluting the chemical solutions used after cleaning. Items that will be high-level disinfected by boiling or steaming do not need to be dried.<sup>80</sup>

**Fig. 23: Steps for cleaning**





**Remember when cleaning:**

- Do not use hand soap to clean instruments because fatty acids in the soap react with hard water to leave a soap scum on the instruments.
- Always wear utility gloves, a mask, and eye protection when cleaning instruments.
- Do not use abrasive materials that scratch or pit instruments. Scratches, pits, or grooves can harbor microorganisms and promote corrosion. Automatic washing machines are preferable to washing by hand.

## **Soaking of Instruments Prior to Cleaning**

Sometimes the level of contamination of the instrument makes it necessary to soak items prior to cleaning (e.g. instruments in operating theatres). A deep container, e.g. a bucket, containing a wire-mesh basket can be filled with water and detergent. The instruments are placed in the wire basket, agitated for 3-5 minutes, and then lifted out. The basket is overturned onto a table or tray in order to separate the instruments prior to cleaning, packing and autoclaving.

## **Disinfection**

Disinfection can be carried out either by thermal or chemical processes. Thermal disinfection is preferred whenever possible. It is generally more reliable than chemical processes, leaves no residues, is more easily controlled, and is non-toxic. Heat sensitive items have to be reprocessed with a chemical disinfectant.

Organic matter (serum, blood, pus or fecal material) interferes with the antimicrobial efficiency of either method. The larger the number of microbes present, the longer it takes to disinfect. Thus scrupulous cleaning before disinfection is of greatest importance.

## **High Level Disinfection (HLD) - Semi-critical Items**

**There are three types of HLD:**

- Disinfection by boiling
- Moist heat at 70-100°C
- Chemical disinfection

**Note:**

When sterilization is not available, HLD is the only acceptable alternative for instruments and other items (=semi-critical items) that will come into contact with the bloodstream or tissues under the skin.

Boiling is HLD, not sterilization. Flaming is not an effective method of HLD because it doesn't effectively kill all microorganisms.

## **HLD by Boiling**

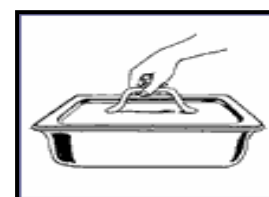
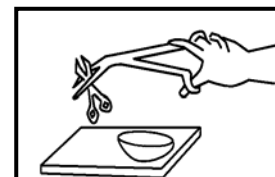
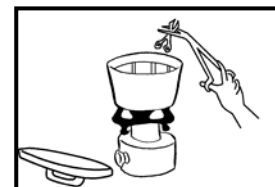
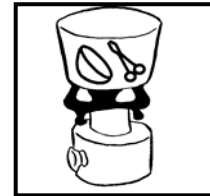
High-level disinfection is best achieved by moist heat such as boiling in water (100°C for one minute holding time), which kills all organisms except for a few

bacterial spores. It is important to note that boiling equipment items in water will not achieve sterilization.

### Steps of boiling:

1. Clean all items to be high-level disinfected.
2. Open all hinged instruments and disassemble those with sliding or multiple parts. Place bowls and containers upright so they fill with water. Make sure that all items are completely submerged because water must touch all surfaces for HLD to be achieved.
3. Cover the pot or close the lid on the boiler and bring the water to a gentle, rolling boil.
4. Once the water is in a rolling boil, start timing for at least 1 minute. Use a timer or make sure to record when the boiling begins. From this point on do not add or remove any water or items.
5. Lower the heat to keep the water at a gentle, rolling boil. Too vigorous boiling may damage items and will speed the evaporation of the water.
6. After 1 minute holding time, remove items using dry, high-level disinfected pickups. Place items to air-dry on a high-level disinfected tray or on a high-level disinfected container that is away from dust and insects and in a low-traffic area. Never leave boiled instruments and other items in water that has stopped boiling; they can become contaminated as the water cools.
7. Store the dry items in a high-level disinfected and covered container and use items immediately or keep in a covered, dry, high level disinfected container and use within one week. 92
8. The boiler should be emptied and dried daily.

Fig. 24: Steps for boiling



**Note:**

Addition of a 2% solution of sodium bicarbonate elevates the temperature and helps to prevent corrosion of the instruments and utensils.

**Tips for HLD by boiling:**

- Instruments and other items must be completely covered with water. Open all hinged instruments and other items and disassemble those with sliding or multiple parts.
- Always boil for 1 minute. Start counting the one minute when the water reaches a rolling boil. If you forget to start timing the HLD procedure, start timing at the point at which you realize that you did not begin timing.
- Do not add anything to or remove anything from the pot/boiler once boiling begins.<sup>92</sup>
- A white, scaly deposit may be left on instruments and other items that have been boiled frequently and on the pot/boiler itself. These are lime deposits caused by lime salts in the water.
- To minimize lime deposits:
- Add some vinegar to the water to remove deposits from instruments, other items, and the inside of the pot/boiler.
- Boil the water for 10 minutes at the beginning of each day that the pot/boiler is used; this will precipitate the lime (make it come out of the water and settle on the bottom or sides of the pot/boiler instead of on the instruments or other items) before the instruments or other items are added.
- Use the same water throughout the day, adding only enough to keep the instruments and other items below the surface.
- Drain and clean out the pot/boiler at the end of each day that it is used.<sup>92</sup>
- A high-level disinfected tray or container can be prepared either by:
  - Boiling it for 1 minute and drying thoroughly, or
  - Filling it with a 0.5% chlorine solution and letting it soak for 20 minutes, draining the chlorine solution, and rinsing thoroughly with boiled water.
- Stainless steel containers are preferred as containers for HLD.

## **HLD by mechanical - thermal disinfection**

Disinfection by hot water can also be performed in specially constructed washing machines (e.g., for linen, dishes and cutlery). In these machines the processes of cleaning, of hot water disinfection, and of drying are combined in a very effective procedure, providing some items ready for use (e.g., respiratory circuits) or safe to handle (e.g. surgical instruments). The thorough initial rinsing and washing removes most of the microorganisms and shorter disinfection times. If machines are used they should be regularly maintained and checked for efficacy.

Low to high-level disinfection is achieved depending on type of machine and complexity of the items.<sup>31</sup>

## Chemical HLD

Before deciding to use a chemical disinfectant, consider whether a more appropriate method is available. Chemical disinfection is used most commonly for heat-labile equipment (e.g. endoscopes) where single use is not cost effective.

A limited number of disinfectants can be used for this purpose. e.g.:

- Glutaraldehyde 2% for 20 min.,
- Hydrogen peroxide 6% - 7.5% for 20 – 30 min.,
- Peracetic acid 0.2-0.35% for 5 min.
- Ortho-phthalaldehyde (OPA) for 5-12 min.

The object must be thoroughly rinsed with sterile water after disinfection. If sterile water is not available, freshly boiled water can be used. After rinsing, items must be kept dry and stored properly.

### Steps:

1. Clean and dry all items to be high-level disinfected. Water from wet instruments and from other items dilutes the chemical solution, thereby reducing its effectiveness.
2. When using a glutaraldehyde solution: Preparations of glutaraldehyde are non-corrosive to metals and other materials and inactivation by organic matter is very low. Alkaline solutions require activation; once activated they remain active for at least 2 weeks depending on the frequency of use. If the solution is not activated prepare it in a sterile container by following the manufacturer's instructions. Fresh solution should be made each day (or sooner, if the solution becomes cloudy).
3. If using a previously prepared solution, use an indicator strip to determine if the solution is still effective. If preparing a new solution, put it in a clean container with a lid and mark the container with the preparation date and expiration date.
4. Open all hinged instruments and other items and disassemble those with sliding or multiple parts; the solution must contact all surfaces in order for HLD to be achieved.
5. Place all items in the solution so that they are completely submerged. Place bowls and containers upright, not upside-down, so that they fill with the solution.
6. Cover the container and allow items to soak for 20 minutes. During this period, do not add or remove any items from the container. Monitor the time.

7. Remove the items from the container using, dry, high-level disinfected pickups (e.g., forceps).
8. Rinse thoroughly with boiled water to remove the chemical residue that is left on items. This residue is toxic to skin and to tissues.
9. Place items to air-dry on a high-level disinfected tray or in a high-level disinfected container before use or storage. Use instruments and other items immediately or keep them in a covered, dry, high-level disinfected container and use within one week.<sup>92</sup>

#### **Notes on Disinfectants:**

- There is no all purpose disinfectant. The best housekeeping disinfectants are not the best instrument disinfections. Example, 2% glutaraldehyde is a good instrument and equipment disinfectant but it is inappropriate for the floors and walls.
- Environmental sampling to verify the effectiveness of disinfectants is of no value.
- For selection of a disinfectant, the level of disinfection required should be determined according to the contamination likely to be present.
- Antiseptics should never be used for HLD. They are for use on the skin and mucous membranes, not on inanimate objects. Disinfectants should always be stored in a cool, dark place; they should never be stored in direct light or excessive heat.

**Table 23: Comparison of the characteristics of chemical sterilants used primarily as high-level disinfectants.**

	<b>HP(6%-7.5%)</b>	<b>PA (0.2%)</b>	<b>Glut (≥2.0%)</b>	<b>OPA (0.55%)</b>	<b>HP/PA (7.35% 0.23%)</b>
<b>HLD Claim</b>	20-30m @ 20°C	5m@40°C	20m	12m	15m
<b>Sterilization Claim (sporicidal effect)</b>	6h @20°	10 m@40°C	10 h	None	3h@20°C
<b>Activation</b>	No	No	Yes (alkaline glut)	No	No
<b>Reuse Life<sup>1</sup></b>	21 days	Single use	14-30days (acid glut-1yr)	14 d	14 d
<b>Shelf Life Stability<sup>2</sup></b>	2 y	6 mo	2 y	2 y	2 y
<b>Disposal Restrictions</b>	None	None	Local <sup>3</sup>	Local <sup>3</sup>	None
<b>Materials Compatibility</b>	Good	Fair	Excellent	Excellent	No data
<b>Monitor MEC<sup>4</sup></b>	Yes (6%)	No	Yes (1.5% or higher)	Yes (0.3% OPA)	No
<b>Safety</b>	Serious eye damage (safely glasses)	Serious eye & skin damage (conc soln) <sup>5</sup>	Respiratory	Eye irritant, stains skin	Eye damage
<b>Processing</b>	Manual or automated	Automated	Manual or automated	Manual or automated	Manual
<b>Organic material resistance</b>	Yes	Yes	Yes	Yes	Yes

Abbreviations: HLD= high-level disinfectant; HP= hydrogen peroxide; PA= peracetic acid; glut=glutaraldehyde; HP/PA= hydrogen peroxide and paracetic acid; OPA= ortho-phthalaldehyde; m=minutes; h=hours; NA=not applicable; TWA=time-weighted average for a conventional 8-hours workday.

<sup>1</sup> number of days a product can be reused as determined by re-use protocol

<sup>2</sup>time a product can remain in storage (unused)

<sup>3</sup>no U.S. EPA regulations but some states and local authorities have additional restrictions

<sup>4</sup>MEC= minimum effective concentration is the lowest concentrated of active ingredients at which the product is still effective

<sup>5</sup>Conc soln=concentrated solution.

**Note :**

Concentration of used disinfectant and contact time should be revised because different companies provide different concentrations for a single disinfectant, so manufacture's instructions should be carefully read before use of any disinfectant.

**Table 24: Disinfectant properties (High level disinfection)**

Disinfectant	Properties *				Antimicrobial activity				
	Stability	Inactivation Organic matter	Corrosive/ Damaging	Irritant/Sen- sitzizing	Spores	Myco- bacterial	Other Bacteria	Viruses	
								E	NE
<b>Glutaraldehyde 2% (20 min.)</b>	Moderately (14-28 days)	No (fixative) **	No	Yes ***	Good 3h	Good *****	Good 5-10 min.	Good 5-10 min.	Good 5-10 min.
<b>Peracetic acid 0.2-0.35% (5-10 min.)</b>	No (< 1 day)	No	Slight	Slight	Good	Good	Good	Good	Good
<b>Alcohol **** 60-90% (ethanol or isopropanol) (10 min.)</b>	Yes (in closed container)	Yes (fixative) **	Slight	No	None	Good	Good	Good	Moderate
<b>Peroxygen compounds 6-7.5% (20-30 min.)</b>	Moderately (7 days)	Yes	Slight	No	Variable	Variable	Good	Good	Variable
<b>Chlorine releasing agents 200-1000 PPM</b>	No (< 1 day)	Yes	Yes	Yes *****	Good	Good	Good	Good	Good
<b>Clear soluble phenolics *****</b>	Yes	No	Slight	Yes	None	Good to moderate	Good	Moderate	Poor
<b>Quaternary ammonia compounds *****</b>	Yes	Yes	No	No	None	Variable	Moderate	Moderate	Poor

\* Use protective clothing when handling disinfectants

\*\* Poor penetration

\*\*\* Should only be used in a well ventilated room

\*\*\*\* Flammable

\*\*\*\*\* In high concentration

\*\*\*\*\* Less active against *M. avium* intracellulare

\*\*\*\*\* Potentially toxic

\*\*\*\*\* Diluted solutions may allow the growth of Gram-negative bacilli

E = enveloped

NE = non enveloped

## Sterilization

Sterilization is a process which achieves the complete destruction or killing of all microorganisms, including bacterial spores.

Sterilization is principally accomplished by: <sup>31</sup>

- Steam under pressure (Autoclaving)
- Dry heat (Hot Air Oven)
- The use of chemicals such as ethylene oxide gas (which is mainly used in industry) or other low temperature methods (e.g. hydrogen peroxide gas plasma).

### Note:

- Boiling and flaming are not effective sterilization techniques because they do not effectively kill all microorganisms.
- Large health care facilities should have more than one type of sterilization system in case of power outage, equipment failure, or shortage of supplies. <sup>78</sup>

## Pressure Steam Sterilization (Autoclaving)

Steam sterilization is the most common and most preferred method employed for sterilization of all items that penetrate the skin and mucosa if they are heat stable. Steam sterilization is dependable, non toxic, inexpensive, sporicidal, and has rapid heating and good penetration of fabrics.

### Method

The steam must be applied for a specified time so that the items reach a specified temperature. For unwrapped items:

- 121 °C for 20 min. at 1.036 Bar (15.03 psi) above atmospheric pressure.
- 134 °C for 3-4 minutes at 2.026 Bar (29.41 psi) above atmospheric pressure.
- (See next table)

## Types of steam sterilizers

### 1. Small table-top sterilizers

- Sometimes used in physicians' and dentists' offices and clinics.
- Are essentially horizontal pressure cookers.
- Holding temperature for unwrapped items:
  - 121°C for 20 minutes or 134 °C for 3-4 minutes. <sup>87</sup>



## 2. Portable steam sterilizer

These can be adapted for processing critical devices in low resource settings.<sup>88</sup> In addition, pressure cookers can provide adequate steam sterilization in situations where conditions and resources are severely limited.<sup>89</sup>

## 3. Gravity downward-displacement sterilizers

- Larger than tabletop sterilizers with addition of more automatic controls.
- The chamber fills with steam, displacing the air downward and forcing it out of the drain valve.
- Holding temperature for unwrapped items: 121°C for 20 minutes or 134 °C for 3-4 minutes.<sup>87</sup>

## 4. Emergency (flash) sterilizers (these are a form of gravity-displacement sterilizer):

- Normally located in operating room suite.
- Quick sterilization cycle at 134°C for 3-4 minutes.
- Should be used only when there is insufficient time to sterilize an item by the preferred prepackaged method.<sup>87</sup>
- Only for unwrapped items.



## 5. High-speed prevacuum vacuum sterilizers (Porous load autoclaves)

- Similar to downward-displacement sterilizers, with the addition of a vacuum pump system.
- Vacuum pump removes the air from the chamber before the steam is admitted, reducing the penetration time and total cycle time.
- Holding temperature 134°C for 3-4 minutes for wrapped items.<sup>87</sup>
- Ideally used for wrapped items and porous loads (fabrics, swabs, instruments with lumens).

**Table 25: Sterilization times** <sup>90</sup>

Type of instruments to be sterilized	Sterilization time
<b>Gravity sterilizer:</b>	
Unwrapped 121 °C (1.036 Bar)	20 min.
Unwrapped: 134 °C (2.026 Bar) (metal and glass only)	3 min.
Unwrapped: 134 °C (2.026 Bar) (e.g., rubber)	10 min.
Wrapped 121 °C (1.036 Bar)	30 min.
Wrapped 134 °C (2.026 Bar)	15 min.
<b>High-speed vacuum sterilizer</b>	
wrapped: 134 °C (2.026 Bar)	4 min.

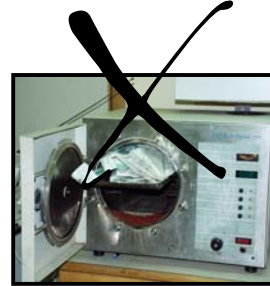
**Note:**

Sterilization time does not include the time it takes to reach the required temperature or the time for exhaust and drying; therefore, it is shorter than the total cycle time.

The temperatures required for steam sterilization are lower than those for dry-heat sterilization because moist heat under pressure allows for more efficient destruction of microorganisms. <sup>90</sup>

**Steps for pressure steam sterilization:**

1. Clean all items to be sterilized.
2. Open or unlock all hinged items and disassemble items with multiple parts. Do not arrange items close together.
3. Arrange all labeled packs, drums, or unwrapped items in the chamber of the autoclave in a way that allows the steam to circulate freely. **DO NOT STACK.**
4. Follow the manufacturer instruction for operating the autoclave. Adjust time, temperature and pressure according to the table before. It is best to use a timer, which helps ensure that the appropriate timing is achieved.
5. Do not begin timing until the autoclave reaches the desired temperature and pressure
  - If the timing process is forgotten, start the cycle again. If the autoclave is automatic, the heat will shut off and the pressure will begin to fall off once the sterilization cycle is complete.
  - If the autoclave is not automatic, turn off the autoclave after achieving the required time.
6. Wait until the pressure gauge reads "0" to open the autoclave. Open the lid or door to allow remaining steam to escape. Leave all items in the autoclave until they dry completely. It may take up to 30 minutes.
7. Remove packs, drums, or unwrapped items from the autoclave using sterile pick-ups to handle unwrapped items. The packs of equipment should come out of the autoclave dry. **Wet packs must be considered non-sterile.** Do not store packs, drums or unwrapped items until they cool to room temperature. This may take several hours.
8. Store items using the following guidelines:
  - Wrapped items – The length of time (=shelf life) that a wrapped, sterile item is considered sterile depends on whether or not a contaminating event occurs not necessarily on how long an item has been stored. Store items in a closed, dry, cabinet with moderate temperature and low humidity in an area that is not heavily trafficked. A wrapped pack can be considered sterile as long as it remains intact and dry. When in doubt about the sterility of a pack, consider it contaminated and re-sterilize the items.



- Unwrapped items – use immediately after removal from the autoclave or keep them in a covered, dry, sterile container for up to one week.<sup>87</sup>

9. Label accurately with contents, date of processing and expiration date and store wrapped materials in storage cabinet.

## Advantages and disadvantages of steam sterilization

### Advantages:

- Highly effective;
- Rapid heating and rapid penetration of instruments;
- Nontoxic;
- Inexpensive;
- Can be used to sterilize liquids.<sup>90</sup>

### Disadvantages:

- Items must be heat and moisture resistant;
- Will not sterilize powders, ointments or oils.<sup>90</sup>
- Needs good maintenance.

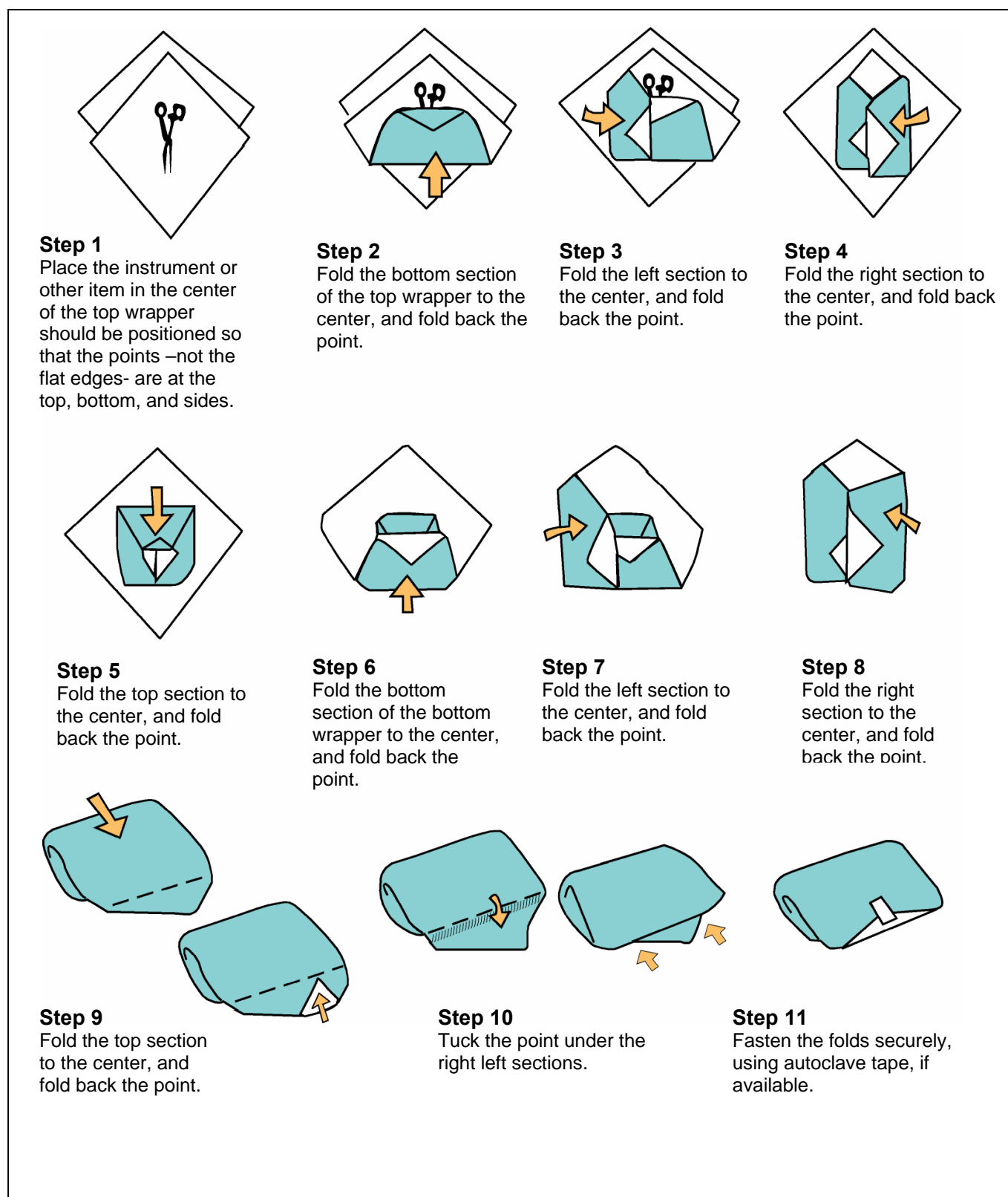
## Wrapping instruments and other items for steam sterilization

- Wrapping instruments and other items before steam sterilization helps to decrease the likelihood that, after sterilization, they will be contaminated before use.
- To wrap instruments and other items for steam sterilization, use two layers of material such as paper, newsprint, or muslin or cotton fabric. Do not use canvas because it is difficult for steam to go through canvas. Make points while wrapping the instruments and other items so that the packs can be easily opened without contaminating their contents.<sup>90</sup>



**Fig. 25: Wrapping instruments and other items for steam sterilization**

**Fig. 26: Steps for wrapping instruments and other items**



## Autoclave maintenance

The autoclave should be checked each time it is used in order to make sure that it is functioning properly. An equipment log should be used to monitor performance including temperature, timing, and cycle.

- The autoclave is not working correctly if:
  - Steam comes out of the safety valve instead of the pressure valve. In such a case, the pressure valve must be cleaned and inspected.
  - Steam comes out from under the lid or around the door. If this happens, the gasket must be cleaned and dried or replaced.<sup>87</sup>

### To ensure that the autoclave is properly maintained

- Routine maintenance should become standard procedure. Someone should be assigned to be responsible for this task.
- Follow the manufacturer's instructions whenever possible since autoclave maintenance varies depending on the type of autoclave.

## Dry-heat Sterilization

### Dry heat sterilization (Hot Air Oven):

For dry heat-sterilization to be achieved, a constant supply of electricity is necessary. Dry heat is preferred for reusable glass, metal instruments, oil, ointments and powders. Do not use this method of sterilization for other items, which may melt or burn.<sup>87</sup>

Dry heat ovens should have fans to give even temperature distribution and faster equilibrium of load to sterilization temperatures.

#### Steps of dry-heat sterilization:

1. Clean and dry all items to be sterilized.
2. Either (1) wrap with foil or (2) place unwrapped items on a tray or shelf, or (3) put them in a closed metal container.
3. Place items in the oven and heat to the holding temperature.

**Table 26: Dry heat sterilization temperatures & times**

Holding Temperature	Sterilization Time (After reaching the holding temperature)
180 °C	30 minutes
170°C	1 hour
160°C	2 hours
149°C	2.5 hours
141°C	3 hours

4. Leave items in the oven to cool to room temperature before removing. When items are cool, remove instruments and other items (using sterile pickups for unwrapped items) and use immediately or store.
5. Proper storage is as important as the sterilization process itself.

**Store items using the following guidelines:**

- Wrapped items – store in a closed, dry, cabinet with moderate temperature and low humidity in an area that is not heavily trafficked.
- Unwrapped items – use immediately after removal from the autoclave or hot oven, keep them in a covered, dry, and sterile container for up to one week.<sup>87</sup>

**Note:**

- The oven must have a thermometer or temperature gauge to make sure that the designated temperature is reached.
- Do not begin timing until the oven reaches the desired temperature.
- If the timing process is forgotten, start it when the oversight is realized.

## **Advantages and disadvantages of dry-heat sterilization**

### **Advantages**

- Can be used for powders, anhydrous oils, and glass.
- Reaches surfaces of instruments that cannot be disassembled.
- No corrosive or rusting effect on instruments.
- Low cost.

### **Disadvantages**

- Penetrates materials slowly and unevenly.
- Long exposure time's necessary.
- High temperatures damage rubber goods and some fabrics.
- Limited package materials.<sup>90</sup>

## **Maintenance of dry-heat ovens**

Dry heat ovens should be checked to make sure that they are functioning properly. Staff should:

- Keep the oven clean.
- Check that the temperature gauge is working correctly on a regular basis – every few weeks is sufficient. To check the temperature gauge,

put a thermometer in the oven and compare the temperature reading with the one on the gauge.<sup>87</sup>

## Low Temperature Sterilization

Low temperature sterilization is used for heat- and moisture- sensitive medical devices. Since the 1950s ethylene oxide has been the most common method of low temperature gas sterilization. Other methods have emerged that include hydrogen peroxide + gas plasma and immersion in a dilute liquid peracetic acid.

### Ethylene oxide gas

Uses: Ethylene oxide can be used to sterilize most articles that can withstand temperatures of 50-60 °C. However, it should be used under carefully controlled conditions because it is extremely toxic and explosive. Although it is very versatile and can be used for heat-labile equipment, fluids, and rubber, etc., a long period of aeration (to remove all traces of the gas) is required before the equipment can be distributed. The operating cycle ranges from 2-24 hours and it is a relatively expensive process.<sup>87</sup> Sterilization with ethylene oxide should be monitored by using bacterial spore tests.

### Hydrogen peroxide gas plasma

Uses: Gas plasma is generated in a chamber under deep vacuum and acted on by radiofrequency radiation wherein free radical particles which disrupt microbial cellular components. The plasma is combined with hydrogen peroxide. The cycle time is approximately 75 minutes. Diffusion of the vapor and plasma into long, narrow lumens can be enhanced with use of additional devices to assure flow of gas through the device's lumen. Diffusion into long lumens even with H<sub>2</sub>O<sub>2</sub> injection is of poor quality assurance.

## Chemical Sterilization

Before deciding to use a chemical sterilant, consider whether a more appropriate method is available. Chemical sterilants are primarily used for heat- labile equipment where single use is not cost effective. Instruments and other items can be sterilized by soaking in a chemical solution followed by rinsing in sterile water.<sup>87</sup> The immersion time to achieve sterilization or sporicidal activity is specific for each type of chemical sterilant. The difficulty lies in the fact that immersion for the appropriate time, rinsing with sterile water, and then transferring the device to a sterile field for use is challenging. Also, in contrast with steam sterilization methods, a biological indicator is not available for most chemical sterilants. Given these limitations most liquid chemical sterilants are instead used for high-level disinfection. If an item is sterilized chemically, it should be used immediately after sterilization, to be sure that it is sterile.



## Types of chemical sterilants:

Glutaraldehyde is a commonly available solution that can be used for sterilization. Other chemical sterilants may be locally available, such as peracetic acid, 7.5% hydrogen peroxide, or hydrogen peroxide (1%) plus peracetic acid (0.08%).<sup>87</sup> Formaldehyde is obsolete and toxic.

### Glutaraldehyde

**Uses:** A 2% glutaraldehyde solution for at least 10 hours that can be used to sterilize heat labile items. Glutaraldehyde solution is irritating to the skin, to the eyes, and to the respiratory tract. There are two types of glutaraldehyde available in Egypt. One alkaline solution that requires activation (e.g., Cidex®) and one acidic solution that is stable and does not require activation but is slower in activity than the activated alkaline buffered solution.

**Precautions:** Glutaraldehyde is an eye and nasal irritant and may cause respiratory illness (asthma) and allergic dermatitis. Glutaraldehyde should not be used in an area with little or no ventilation. Eye protection, a plastic apron, and gloves must be worn when glutaraldehyde liquid is made up, disposed of, and used for sterilization. Latex gloves may be worn and discarded after use if the duration of contact with glutaraldehyde is brief, e.g. less than 5 minutes. For longer duration, nitrile gloves must be worn. Glutaraldehyde should be stored away from heat sources and in containers with close-fitting lids. The length of time that glutaraldehyde solutions can be used varies but they are usually good for up to 14 days. Solutions should be replaced any time they become cloudy.<sup>87</sup>

### Peracetic acid

**Uses:** A 0.2 – 0.35% peracetic solution for 10 minutes can be used to sterilize heat-labile items (e.g. arthroscopes, dental instruments). A special advantage of peracetic acid is that it has harmless decomposition products and leaves little residue on sterilized items. It remains effective in the presence of organic matter and is sporicidal even at low temperatures. Peracetic acid can corrode copper, brass, bronze, plain steel, and galvanized iron, but additives and pH modification can reduce these effects. It is considered unstable, particularly when diluted. It is more effective than glutaraldehyde at penetrating organic matter, e.g. biofilms. It is known to be highly corrosive and its use as a disinfectant in its natural state is therefore limited unless there is a corrosion inhibitor in the formulation. Nu-Cidex® is stabilized peracetic acid solution with a corrosion inhibitor. The solution is activated to provide the appropriate in-use strength. Once prepared the current manufacturer's recommendations is that it should be used within 24 hours.

Sterilization using peracetic acid can be done through an automated reprocessor that dilutes the 35% peracetic acid to a use concentration of 0.2%. This system can only be used if the device being reprocessed is immersible as endoscopes. Filtered water is used to rinse the device. Connectors to assure free flow of the liquid chemical sterilant are important and the connectors are very specific to

each model of device being reprocessed. This system is used to chemically sterilize both flexible and rigid endoscopes.

#### **Steps for chemical sterilization:**

- Wear protective clothing.
- Clean, and dry all items to be sterilized.
- Prepare the chemical sterilization solution following the manufacturer's instructions.
- If using a previously prepared solution, use an indicator strip to determine if the solution is still effective.
- If preparing a new solution, put it in a sterile container with a lid and mark the container with the preparation date and expiration date.
- Open all hinged instruments and other items. Disassemble those instruments with sliding or multiple parts because the solution must contact all surfaces for sterilization to be achieved.
- Place all items in the solution so that they are completely submerged. Place bowls and containers upright so that they are filled with the solution.
- Cover the container and follow the manufacturer's instructions regarding the time necessary for sterilization. During this period, do not add or remove any items from the container.
- Remove the items from the container using large sterile pickups.
- Rinse thoroughly with sterilized water to remove the residue that chemical sterilants leave on items.
- Place items on a sterile tray or in a sterile container and allow to air dry before use or storage.
- When items are dry, use or store immediately.
- If items are to be stored, keep them in a covered, dry, sterile container for up to one week. 87

### **Monitoring the Effectiveness of Sterilization**

To ensure that sterilization has been successful the process of sterilization (and not the end product) is tested. Indicators have been developed to monitor the effectiveness of sterilization by measuring various aspects of the process through different indicators.

## **Mechanical indicators**

These indicators, which are part of the autoclave or dry-heat oven itself, record and allow you to observe time, temperature, and/or pressure readings during the sterilization cycle.<sup>87</sup>

## **Chemical indicators**

- Tape with lines that change color when the intended temperature has been reached.
- Pellets in glass tubes that melt, indicating that the intended temperature and time have been reached.
- Indicator strips that show that the intended combination of temperature, time, and pressure has been achieved.
- Indicator strips that show that the chemicals and/or gas are still effective.<sup>87</sup>
- Chemical indicators are available for testing ethylene oxide, dry heat, and steam processes. These indicators are used internally, placed where steam or temperature take longest to reach, or put on the outside of the wrapped packs to distinguish processed from nonprocessed packages.<sup>11</sup>

## **Biological indicators**

These indicators use heat-resistant bacterial endospores to demonstrate whether or not sterilization has been achieved. If the bacterial endospores have been killed after sterilization, you can assume that all microorganisms have been killed as well. After the sterilization process the strips are placed in a broth that supports aerobic growth and incubated for 7 days. The advantage of this method is that it directly measures the effectiveness of sterilization. The disadvantage is that this indicator is not immediate, as are mechanical and chemical indicators. Bacterial culture results are needed before sterilization effectiveness can be determined.<sup>87</sup>

## **Recommended ideal monitoring system**

Perform the following monitoring activities whenever possible.

### **For steam sterilization**

- If the autoclave has recording chart, review it after each load. If not, record the temperature, time and pressure information in a log book that is reviewed after each load.

- Place heat-and steam-sensitive chemical indicators, if available, on the outside of each pack.
- Perform testing with biological indicators weekly (or monthly, if testing weekly is not possible).
- Indicators should be in the middle of the item reprocessed (the most difficult part of the load).
- A thermometer could be put in the most difficult part of the load.

#### **For dry-heat sterilization**

- If the oven has a recording chart, review it after each load. If not, record the temperature and time information in a log that is reviewed after each load.
- Place heat-sensitive chemical indicators, if available, on the outside of each pack.
- Perform testing with biological indicators weekly (or monthly, if testing weekly is not possible).<sup>87</sup>
- A thermometer could be put in the most difficult part of the load.

#### **For chemical sterilization**

- Record the time information in a log that is reviewed after each load.
- Use an indicator strip, if available, to determine if the solution is still effective.<sup>87</sup>

#### **Correcting sterilization failure**

- If monitoring indicates a failure in sterilization, attempt to determine the cause of the failure and arrange for corrective steps, as follows:
  - Immediately check that the autoclave or dry-heat oven is being used correctly or replace the chemical solution.
  - If correct use of the unit has been documented and monitoring still indicates a failure in sterilization, discontinue using the unit and have it serviced.
  - Any instruments or other items that have been processed in the faulty autoclave or dry-heat oven must be considered nonsterile and must be processed again with the unit is functioning properly.

## **Sterile Services Department (SSD)**

The sterile services department (SSD) is vital for an effective Infection Control and Prevention program. The expertise and knowledge of SSD personnel is

important to ensure high standards of decontamination; an effective SSD always results in long-term savings.

Not all hospitals can afford to have an SSD and a separate surgical services unit to deal with the operating theatres and associated departments. At the least, they should have a single department covering all areas.

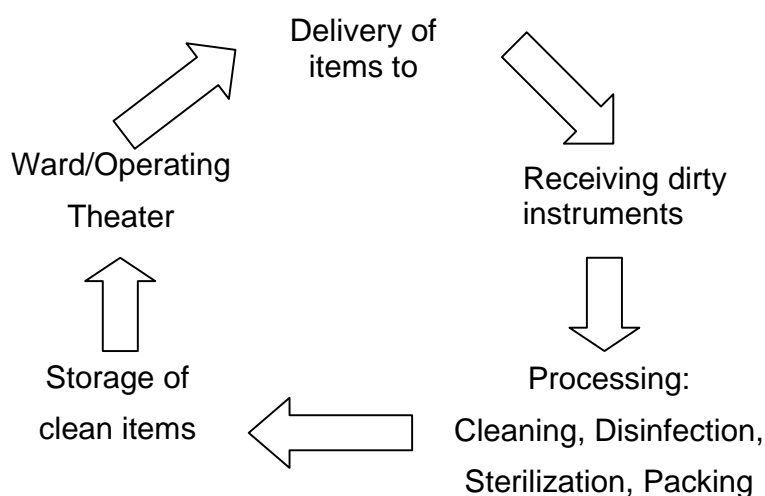
## Preparing an Area for Processing Instruments and Other Items

One goal of a comprehensive infection control program is to minimize the level of contamination in areas in which “clean” activities take place.<sup>86</sup> Examples of areas where “clean” activities take place are operating theaters, procedure rooms, and working areas for sterilizing, high-level disinfecting, and storing instruments and other items. Areas in which “dirty” activities take place include rooms where soiled instruments and other items are washed.<sup>86</sup> It is ideal to have separate rooms – one for receiving and cleaning instruments and other items and another room for final processing (sterilization or high-level disinfection) and storage. However, in many settings in Egypt this is not possible. When only one room is available, it should be arranged so that activities and objects flow in an organized way. It is necessary to have at least one sink (two are preferable), sufficient counter top space for receiving dirty items and for drying and packaging clean items, and for storage space (preferably closed cabinets).<sup>86</sup> It is key to have good spatial separation between soiled handling area and the clean, packaging area.

## Establishing an SSD

Soiled, used, and recyclable equipment should be collected from the wards and then should be transferred to the SSD where it is washed, inspected, disinfected or packaged and sterilized, and dispatched back to the wards.

**Fig. 27: Flow diagram of items processed in SSD**



**In the ward:**

- Collect instruments that are to be re-used in a clearly labeled container.
- Arrange for dirty instruments to be delivered to the SSD – DO NOT ATTEMPT TO WASH THEM ON THE WARD.
- Discard cotton wool balls and dressings into regular waste disposal containers (for more details see chapter on Waste Disposal I).

**In the SSD:**

- Receive instruments in the dirty area.
- Wash all instruments in water and detergent or enzymatic presoak either mechanically or manually using appropriate protective barriers.
- Inspect all equipment for cleanliness and damage.
- Send damaged instruments for repair after appropriate decontamination or discard them if necessary.
- Pack cleaned instruments on a tray.
- Autoclave trays at recommended temperature and/or disinfect as required.
- Ensure that the packaged trays are dry – inspect tapes.
- Sort the packaged trays for ward collection.
- Return equipment to the ward or store in the clean treatment room.

**The layout of the SSD**

Ideally, physical barriers should separate dirty and clean areas in the reprocessing room. However, if this is not possible (perhaps because of shortage of space or of funds) the same room can be used, provided that:

- The air moves from the clean area to the dirty area.
- Both areas have separate storage facilities.
- There are adequate hand disinfection facilities.
- Activity patterns are established in which soiled objects never cross paths with clean, sterilized, or high-level disinfected instruments and other items.
- The doors are kept closed in the reprocessing rooms in order to minimize dust contamination and to eliminate flies.
- There is separate equipment for each area.
- The staff work in either area– never in both.

## Storage in the SSD

After items have been reprocessed, the sterile packs should be stored in well-ventilated, clean stores ready for dispatch to the wards. Collection should be regular and there should be a written record of receipt and delivery. This helps to monitor the use and the loss of instruments.

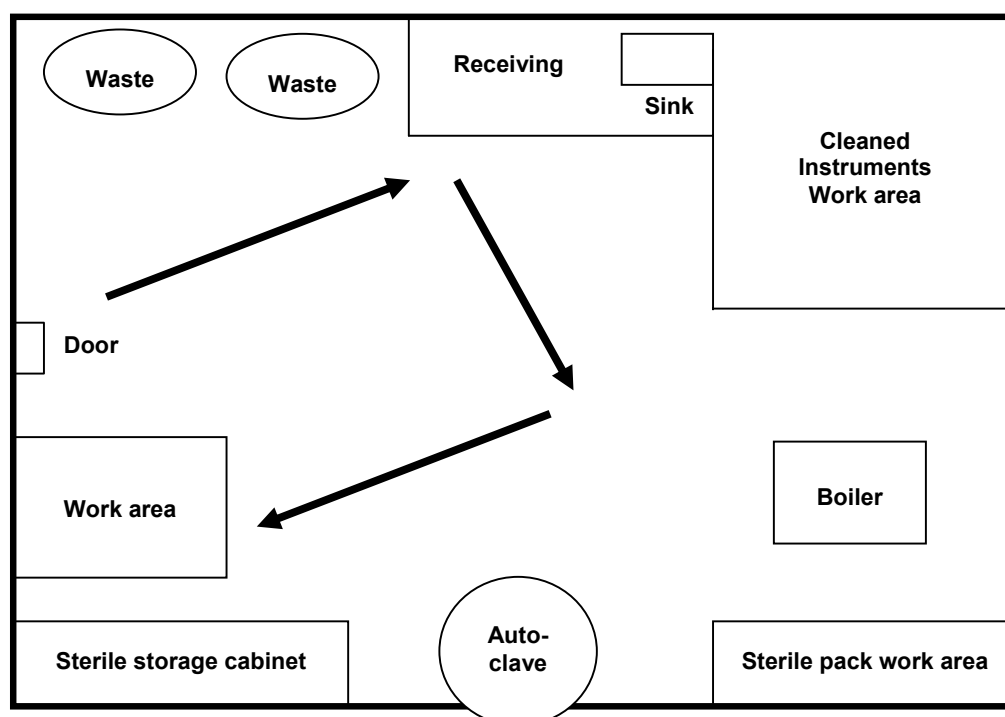
### Note!

Do not store instruments or other items such as scalpel blades and suture needles in solutions—always store them in a dry container. Microorganisms can live and multiply in both antiseptic and disinfectant solutions which can contaminate instruments and other items and which can lead to infections.

## SSD staff facilities

- All SSD staff should be provided with adequate protective clothing (e.g. heavy duty gloves, plastic aprons, and eye protection if manual cleaning is undertaken). Overshoes are not necessary.
- SSD staff should be immunized against hepatitis B. (See chapter “Occupational Safety and Employee Health”)

**Fig. 28: Single room for processing instruments and other items**



The flow of work in a single room for reprocessing of instruments should be designed to minimize the likelihood of contamination. Activity patterns should be established in which soiled objects never cross paths with clean, sterilized, or high-level disinfected instruments and other items.