Dr. Nahed Khalaf Consultant OBGYN Al-Hada Military Hospital Tau Saudi Arabia

Cleaning, Disinfection, and Sterilization







introduction

Surgical site infections (SSIs) are the second to third most common site of health care associated infections

Deep SSIs at the site of the procedure, can carry mortality as high as 77%

Exogenous sources of SSI pathogens include surgical personnel, the operating room environment and all tools, instruments, and materials brought to the sterile field during an operation



Medical equipments and surgical instruments are usually designed for reuse

It transmit pathogens if any of the steps involved in reprocessing, cleaning, disinfection, or sterilization are inadequate or fail



Decontamination:

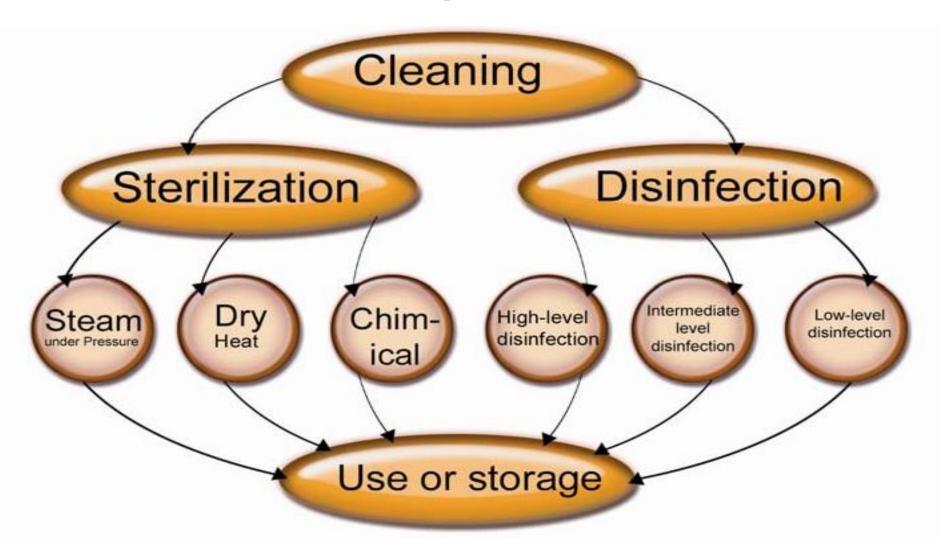
is the process by which microorganisms are removed or destroyed in order to render an object safe, Could comprise cleaning, disinfection or sterilization as appropriate

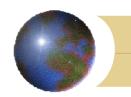
Cleaning:

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 Steps





Cleaning is the removal of all foreign material (dirt and organic matter) from the object being reprocessed

Thorough cleaning alone can provide a 10 000 fold reduction in contaminant microbes from endoscopes

Cleaning can be very effective in removing microbial contaminants from surgical devices



- An antiseptic is a substance that prevents or arrests the growth or action of microorganisms, either by inhibiting their activity or by destroying them
- Antiseptics should never be used for HLD. They are for use on the skin and mucous membranes, not on inanimate objects

2. Chlorhexidine gluconate (4%)

Antimicrobial spectrum	Effective against a broad range of microorganisms, but less so against gram-negative bacteria and fungi and minimal efficacy against <i>M. tuberculosis</i> .	
Advantages	 Has a good, persistent effect; remains effective for at least 6 hours after being applied. 	
	Effectiveness is not reduced by blood or other organic material.	
Disadvantages	 It stains fabrics brown (in the presence of chlorine-based disinfectants). 	
	 Effectiveness can be reduced by hard water, hand creams, and soaps. 	
Comments	 Recommended antiseptic for surgical hand antisepsis and skin preparation. 	
	 Preparations without cetrimide are preferable to those with cetrimide. 	
	 Caution: Savlon™ or Citiel products containing at least 4 % chlorhexidine are appropriate for use as antiseptics; Products containing less than 4 % chlorhexidine in an alcohol base are also adequate, but should not be used on mucous membranes. Chlorhexidine is relatively non-toxic. It must not be allowed to come into contact with the brain, meninges, eye or middle ear. 	

3. lodine compounds, including tincture of iodine (iodine and alcohol)

Antimicrobial spectrum	Effective against a broad range of microorganisms (same as alcohol)	
Advantages	Fast-acting (tincture preparations only)	
Disadvantages	Can cause skin irritation.	
	 Effectiveness is markedly reduced by blood or other organic material. 	
	Less persistent activity.	
	 Can cause contact dermatitis therefore has limited usefulness as an OT hand antiseptic. 	
	 Because of the potential to cause skin irritation, when iodine is used for preprocedure skin preparation, it must be allowed to dry; then is removed from the skin with alcohol. 	

4. lodophors

(Solutions such as povidone iodine (e.g., Betadine) that contains iodine in a complex form, making them relatively nonimitating and nontoxic)^{25, 26}

Antimicrobial spectrum	Effective against a broad range of microorganisms (mainly gram +ve and gram -ve bacteria. Less effective against mycobacteria).	
Advantages	Less irritating to the skin than iodine tincture.	
	Can be used on mucous membranes.	
Disadvantages	 Effectiveness is moderately reduced by blood or other organic material. 	
	 Release of active ingredient, free iodine, takes relatively long time therefore it needs to be applied to skin and left on for > 2 minutes prior to initiating procedure. 	
	 Less persistent antimicrobial activity compared to chlorhexidine. 	
Comments	 Recommended for surgical hand antisepsis and pre-operative skin preparation. 	
	Best antiseptic for use in the genital area, vagina, and cervix.	
	 Becomes effective >2 minutes after application; for optimal effectiveness, wait several minutes after application. 	
	Most preparations should be used full strength; do not dilute.	
	 Distinctly different from iodine but can be confused for iodine tincture. 	
	Note: If any antiseptic solution is received from the facility's pharmacy or central supply that is labeled simply "iodine" the pharmacist or person in charge of supplies should be asked what the solution contains. For example, if a brown liquid in a bottle is received, a small amount has to be put in hand and be rubbed. If it seems more sudsy than usual, it is an iodophor, not iodine.	



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.



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

Intermediate-level disinfectant (ILD): 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 does not kill high numbers of bacterial spores.

Note: HIV, herpes, HCV, HBV and myxoviruses are (Lipid virus) while Coxackie, enteroviruses are (Nonlipid virus).



Disinfection can be carried out either by thermal (preferred) or chemical processes

There are three types of HLD - Semi-critical Items:

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

When sterilization is not available, HLD is the only acceptable alternative



Chemical disinfection is used most commonly for heat-labile equipment (e.g. endoscopes) where single use is not cost effective

Disinfectants should always be stored in a cool, dark place; they should never be stored in direct light or excessive heat



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



There is no all purpose disinfectant

For selection of a disinfectant, the level of disinfection required should be determined according to the contamination likely to be present



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.

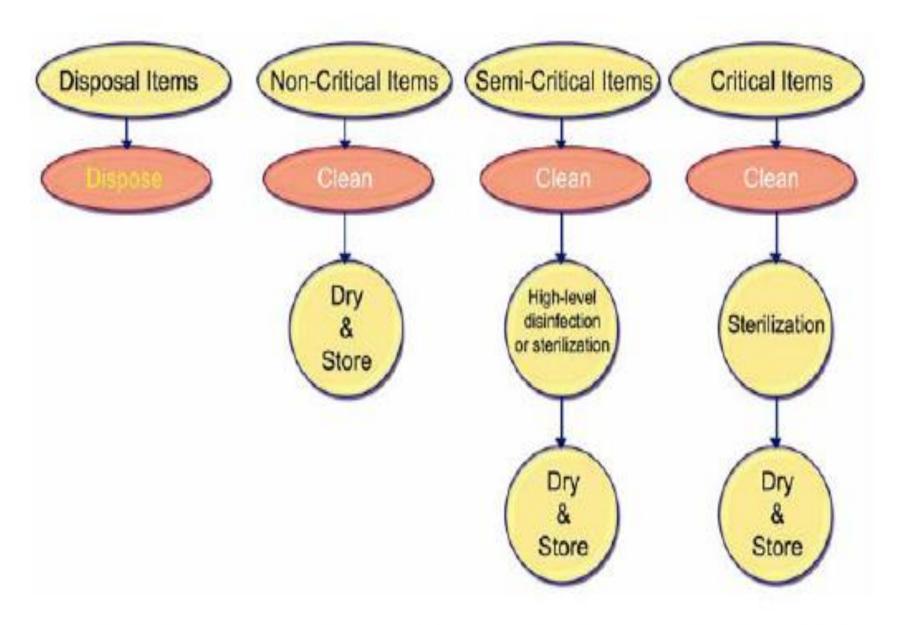


Fig. 22: Relation between type of item & its decontamination



A needle used for entry into tissue is critical and needs to be sterile

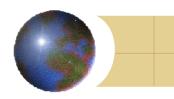
A speculum (endoscopes) has contact with mucous membranes and therefore needs to be cleaned and then undergo high-level disinfection

A blood pressure cuff has contact with intact skin and only needs cleaning



Sterilization is accomplished principally by steam under pressure, by dry heat, and by chemical sterilants

Sterilization methods remove or destroy all forms of microbial life including bacterial spores by either physical or chemical processes



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



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

Availability of sterilization methods



Sterilization is principally accomplished by:

- Steam under pressure (Autoclaving)
- Dry heat (Hot Air Oven)
- The use of chemicals such as ethylene oxide gas (which is mainly used in industry)



Pressure Steam Sterilization (Autoclaving) is the most common and most preferred method employed for sterilization of all items if they are heat stable

Steam sterilization is dependable, non toxic, inexpensive, sporicidal, and has rapid heating and good penetration of fabrics

The steam must be applied for a specified time so that the items reach a specified temperature

Advantages and disadvantages of steam sterilization

Advantages:

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

Disadvantages:

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





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

Table 25: Sterilization times 90

Type of instruments to be sterilized	Sterilization time			
Gravity sterilizer:				
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.			
High-speed vacuum sterilizer				
wrapped: 134 °C (2.026 Bar)	4 min.			



Dry heat sterilization (Hot Air Oven)

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.

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

Table 26: Dry heat sterilization temperatures & times

Holding	Sterilization Time
Temperature	(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



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.



Low Temperature Sterilization

Ethylene oxide gas

Ethylene oxide can be used to sterilize most articles that can withstand temperatures of 50-60 °C.

Used under carefully controlled conditions because it is extremely toxic and explosive

Used for heat-labile equipment, fluids, and rubber, etc.

Long period of aeration is required before the equipment can be distributed

The operating cycle ranges from 2-24 hours and it is a relatively expensive process



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.

The immersion time to achieve sterilization or sporicidal activity is specific for each type of chemical sterilan



in contrast with steam sterilization methods, a biological indicator is not available for most chemical sterilants

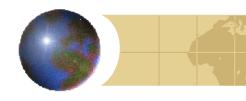
most liquid chemical sterilants are instead used for highlevel disinfection



Types of chemical sterilants

Glutaraldehyde is a commonly available solution that can be used for sterilization.

A 2% glutaraldehyde solution for at least 10 hours that can be used to sterilize heat labile items.



Other chemical sterilants may be locally available, such as peracetic acid, 7.5% hydrogen peroxide, or hydrogen peroxide (1%) plus peracetic acid (0.08%).

A 0.2 – 0.35% peracetic solution for 10 minutes can be used to sterilize heat-labile items (e.g. arthroscopes, dental instruments)



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.



Biologic indicator (BI):

A standardized preparation of bacterial spores in a carrier serving to demonstrate whether sterilizing conditions have been met. The type of spore varies by type of sterilization



Mechanical indicators

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



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.

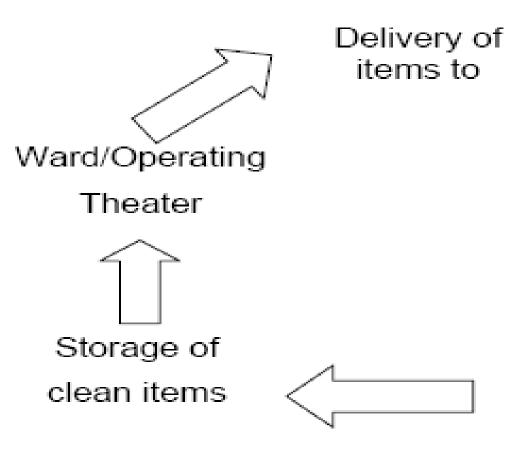


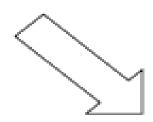
These indicators are used internally, placed where steam or temperature take longest to reach, or put on the outside of the wrapped packs to distinguish processed from non processed packages.

Sterile Services Department (SSD)

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

Fig. 27: Flow diagram of items processed in SSD





Receiving dirty instruments



Processing:

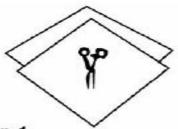
Cleaning, Disinfection, Sterilization, Packing



Wrapping instruments (use two layers of material such as paper) before steam sterilization avoid contamination before use

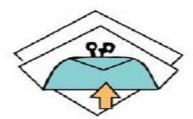
Make points while wrapping the instruments so that the packs can be easily opened without contaminating their contents

The autoclave should be checked each time it is used



Step 1

Place the instrument or other item in the center of the top wrapper should be positioned so that the points –not the flat edges- are at the top, bottom, and sides.



Step 2

Fold the bottom section of the top wrapper to the center, and fold back the point.



Step 3

Fold the left section to the center, and fold back the point.



Step 4

Fold the right section to the center, and fold back the point.



Step 5

Fold the top section to the center, and fold back the point.



Step 6

Fold the bottom section of the bottom wrapper to the center, and fold back the point.



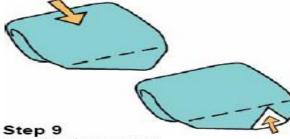
Step 7

Fold the left section to the center, and fold back the point.

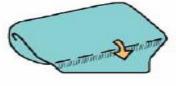


Step 8

Fold the right section to the center, and fold back the point



Fold the top section to the center, and fold back the point.



Step 10

Tuck the point under the right left sections.



Step 11

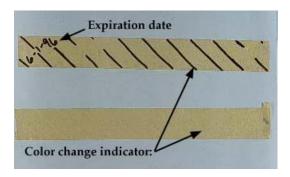
Fasten the folds securely, using autoclave tape, if available.

Sterility Check List

Before assuming a pack is sterile, always evaluate the following before opening the pack:

Expiration or sterilization date
Indicator color change
General condition of wrapper and how it had been stored
Always check for holes or moisture damage







The responsibility for efficient sterilization must remain now as always with the surgeon themselves

Inadequate sterilization is an important cause of wound sepsis in poorly maintained theatres



- Antibiotics have not reduced the essential role of asepsis and sterile precautions.
- Protocols with regards to instrument sterilization, equipment maintenance, air filtration and ventilation, and staff behaviour are essential.

