Disinfection and Sterilization of Patient-Care Equipment
Definition of terms

- **Cleaning** - the physical removal of organic material or soil from objects, is usually done by using water with or without detergents.

- **Sterilization** is the destruction of all forms of microbial life; it is carried out in the hospital with steam under pressure, liquid or gaseous chemicals, or dry heat.

- **Disinfection**, defined as the intermediate measures between physical cleaning and sterilization, is carried out with pasteurization or chemical germicides.
The level of disinfection achieved depends on several factors:

- contact time
- temperature
- type and concentration of the active ingredients of the chemical germicide
- the nature of the microbial contamination.
Types of disinfection

- **High-level disinfection**: can be expected to destroy all microorganisms, with the exception of large numbers of bacterial spores.

- **Intermediate disinfection**: inactivates *Mycobacterium tuberculosis*, vegetative bacteria, most viruses, and most fungi; does not necessarily kill bacterial spores.

- **Low-level disinfection**: can kill most bacteria, some viruses, and some fungi; cannot be relied on to kill resistant microorganisms such as tubercle bacilli or bacterial spores.
Medical devices, equipment, and surgical materials are divided into three general categories based on the potential risk of infection involved in their use:

- critical items
- semicritical items
- noncritical items
Critical items

- Critical items are instruments or objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.

*Examples* of critical items are surgical instruments, cardiac catheters, implants, pertinent components of the heart-lung oxygenator, and the blood compartment of a hemodialyzer.

Sterility at the time of use is required for these items; consequently, one of several accepted sterilization procedures is generally recommended.
Semicritical items

- These items come in contact with intact mucous membranes, but they do not ordinarily penetrate body surfaces.

*Examples* are noninvasive flexible and rigid fiberoptic endoscopes, endotracheal tubes, anesthesia breathing circuits, and cystoscopes.

Sterilization is not absolutely essential; at a minimum, a high-level disinfection procedure that can be expected to destroy vegetative microorganisms, most fungal spores, tubercle bacilli, and small nonlipid viruses is recommended. In most cases, meticulous physical cleaning followed by an appropriate high-level disinfection treatment gives the user a reasonable degree of assurance that the items are free of pathogens.
Noncritical items

- Noncritical items are those that either do not ordinarily touch the patient or touch only intact skin.

Such items include crutches, bedboards, blood pressure cuffs, and a variety of other medical accessories.

These items rarely, if ever, transmit disease. Consequently, washing with a detergent may be sufficient.
Items **must be thoroughly cleaned** before processing, because organic material (e.g., blood and proteins) may contain high concentrations of microorganisms. Also, such organic material may inactivate chemical germicides and protect microorganisms from the disinfection or sterilization process.
For noncritical items

cleaning can consist only of

1) washing with a detergent or a disinfectant-detergent,
2) rinsing,
3) thorough drying.
Steam sterilization

- Steam sterilization is the most inexpensive and effective method for sterilization.
- Steam sterilization is unsuitable for processing plastics with low melting points, powders, or anhydrous oils.
- Items that are to be sterilized but not used immediately need to be wrapped for storage.
- Sterility can be maintained in storage for various lengths of time, depending on the type of wrapping material, the conditions of storage, and the integrity of the package.
Monitoring of steam sterilization processes

- to check the highest temperature that is reached during sterilization and the length of time that this temperature is maintained
- heat- and steam-sensitive chemical indicators can be used on the outside of each pack
- a large pack might have a chemical indicator both on the outside and the inside to verify that steam has penetrated the pack
Microbiological monitoring

- Microbiological monitoring of steam sterilizers is recommended at least once a week with commercial preparations of spores of *Bacillus stearothermophilus* (a microorganism having spores that are particularly resistant to moist heat, thus assuring a wide margin of safety).

*One positive spore test (spores not killed) does not necessarily indicate that items processed in the sterilizer are not sterile, but it does suggest that the sterilizer should be rechecked for proper temperature, length of cycle, loading, and use and that the test be repeated.*
Sterilization of implantable items

- **Implantable items**, such as orthopedic devices, require special handling before and during sterilization; thus, packs containing implantable objects need to be clearly labeled so they will be appropriately processed. To guarantee a wide margin of safety, it is recommended that each load of such items be tested with a spore test and that the sterilized item not be released for use until the spore test is negative at 48 hours.

If it is not possible to process an implantable object with a confirmed 48-hour spore test before use, it is recommended that the unwrapped object receive the equivalent of full-cycle steam sterilization and not flash sterilization.
Ethylene oxide gas sterilization

- It is a more complex and expensive process than steam sterilization.
- It is usually restricted to objects that might be damaged by heat or excessive moisture.
- Before sterilization, objects also need to be cleaned thoroughly and wrapped in a material that allows the gas to penetrate.
Because ethylene oxide gas is toxic, precautions (e.g., local exhaust ventilation) should be taken to protect personnel. All objects processed by gas sterilization also need special aeration according to manufacturer's recommendations before use to remove toxic residues of ethylene oxide.

Chemical indicators need to be used with each package to show that it has been exposed to the gas sterilization process.

Moreover, it is recommended that gas sterilizers be checked at least once a week with commercial preparations of spores, usually Bacillus subtilis.
- Powders and anhydrous oils can be sterilized by **dry heat**. Microbiological monitoring of dry heat sterilizers usually provides a wide margin of safety for dry heat sterilization.

- **Liquid chemicals** can be used for sterilization and disinfection when steam, gas, or dry heat sterilization is not indicated or available
The most *appropriate chemical germicide* for a particular situation can be selected by responsible personnel in each hospital based on

- the object to be disinfected,
- the level of disinfection needed,
- and the scope of services, physical facilities, and personnel available in the hospital.
- Gloves may be indicated to prevent skin reactions when some chemical disinfectants are used.

Items subjected to high-level disinfection with liquid chemicals need to be rinsed in sterile water to remove toxic or irritating residues and then thoroughly dried. Subsequently, the objects need to be handled aseptically with sterile gloves and towels and stored in protective wrappers to prevent recontamination.
Recommendations

- **Cleaning**
  All objects to be disinfected or sterilized should first be thoroughly cleaned to remove all organic matter (blood and tissue) and other residue.

- **Indications for Sterilization and High-Level Disinfection**
  - Critical medical devices or patient-care equipment that enter *normally sterile tissue* or the *vascular system* or through which blood flows should be subjected to a sterilization procedure before each use.
  - Laparoscopes, arthroscopes, and other scopes that enter normally sterile tissue should be subjected to a sterilization procedure before each use; if this is not feasible, they should receive at least high-level disinfection.
Equipment that touches *mucous membranes*, e.g., endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment, should receive high-level disinfection.

**Methods of Sterilization**

- Whenever sterilization is indicated, a *steam sterilizer* should be used unless the object to be sterilized will be damaged by heat, pressure, or moisture or is otherwise inappropriate for steam sterilization. In this case, another acceptable method of sterilization should be used.

- **Flash sterilization** [270°F (132°C) for 3 minutes in a gravity displacement steam sterilizer] is not recommended for implantable items.
**Biological Monitoring of Sterilizers**

- All sterilizers should be monitored at least once a week with commercial preparations of spores intended specifically for that type of sterilizer (i.e., Bacillus stearothermophilus for steam sterilizers and Bacillus subtilis for ethylene oxide and dry heat sterilizers).

- Every load that contains implantable objects should be monitored. These implantable objects should not be used until the spore test is found to be negative at 48 hours.

- If spores are not killed in routine spore tests, the sterilizer should immediately be checked for proper use and function and the spore test repeated. Objects, other than implantable objects, do not need to be recalled because of a single positive spore test unless the sterilizer or the sterilization procedure is defective.

- If spore tests remain positive, use of the sterilizer should be discontinued until it is serviced.
Use and Preventive Maintenance
- Manufacturers' instructions should be followed for use and maintenance of sterilizers.

Chemical Indicators
- Chemical indicators that will show a package has been through a sterilization cycle should be visible on the outside of each package sterilized.

Use of Sterile Items
- An item should not be used if its sterility is questionable, e.g., its package is punctured, torn, or wet.

Reprocessing Single-Use or Disposable Items
- Items or devices that cannot be cleaned and sterilized or disinfected without altering their physical integrity and function should not be reprocessed.
- Reprocessing procedures that result in residual toxicity or compromise the overall safety or effectiveness of the items or devices should be avoided.