Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable (New England Journal of Medicine). A major risk of all such procedures is the introduction of pathogens that can lead to infection. Failure to properly disinfect or sterilize equipment carries not only risk associated with breach of host barriers, but also risk for person-to-person transmission (e.g. hepatitis B virus) and transmission of environmental pathogens (e.g. Pseudomonas aeruginosa).

The Central Sterile Services Department’s major function is to provide surgical instruments and medical equipment that have been thoroughly decontaminated, to render them bacteria free and safe to use during patient’s operation or medical procedure. Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items’ intended use, whether cleaning, disinfection, or sterilization is indicated. The choice of disinfectant, concentration, and exposure time is based on the risk for infection associated with use of the equipment and other factors discussed in this guideline.

Multiple studies in many countries have documented lack of compliance with established guidelines for disinfection and sterilization leading to numerous outbreaks. This guideline presents a pragmatic approach to the judicious selection of the preferred methods for cleaning, disinfection and sterilization of patient-care medical devices and for cleaning and disinfecting the healthcare environment.

I would like to congratulate all who were involved in development of these guidelines. All healthcare workers involved in preparing, processing, and distributing medical and surgical supplies and equipment required for patient diagnosis, treatment and ongoing care, are mandated to use these guidelines.
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<td>Central Sterile Services Department</td>
</tr>
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<td>HLD</td>
<td>High Level Disinfection</td>
</tr>
<tr>
<td>IAP</td>
<td>Inspection, Assembly and Packaging</td>
</tr>
<tr>
<td>IPC</td>
<td>Infection Prevention and Control</td>
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DEFINITION OF TERMS

**Sterilization** describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, ETO gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilizing agents used in health-care facilities. Sterilization is intended to convey an absolute meaning; unfortunately, however, some health professionals and the technical and commercial literature refer to “disinfection” as “sterilization” and items as “partially sterile.” When chemicals are used to destroy all forms of microbiologic life, they can be called chemical sterilants. These same germicides used for shorter exposure periods also can be part of the disinfection process (i.e., high-level disinfection).

**Disinfection** describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. In health-care settings, objects usually are disinfected by liquid chemicals or wet pasteurization. Each of the various factors that affect the efficacy of disinfection can nullify or limit the efficacy of the process. Factors that affect the efficacy of both disinfection and sterilization include prior cleaning of the object; organic and inorganic load present; type and level of microbial contamination; concentration of and exposure time to the germicide; physical nature of the object (e.g., crevices, hinges, and lumens); presence of biofilms; temperature and pH of the disinfection process; and in some cases, relative humidity of the sterilization process (e.g., ethylene oxide). Unlike sterilization, disinfection is not sporidical.

**Cleaning** is the removal of visible soil (e.g. organic and inorganic material) from objects and surfaces and normally is accomplished manually or mechanically using water with detergents or enzymatic products. Thorough cleaning is essential before high-level disinfection and sterilization because inorganic and organic materials that remain on the surfaces of instruments interfere with the effectiveness of these processes.

**Decontamination** removes pathogenic microorganisms from objects so they are safe to handle, use, or discard. Terms with the suffix ‘cide’ or ‘cidal’ for killing action also are commonly used. For example, a germicide is an agent that can kill microorganisms, particularly pathogenic organisms (“germs”). The term germicide includes both antisepsics and disinfectants. Antiseptics are germicides applied to living tissue and skin; disinfectants are antimicrobials applied only to inanimate objects. In general, antiseptics are used only on the skin and not for surface disinfection, and disinfectants are not used for skin antisepsis because they can injure skin and other tissues. Virucide, fungicide, bactericide, sporicide, and tuberculocide can kill the type of microorganism identified by the prefix. For example, a bactericide is an agent that kills bacteria.
CHAPTER 1: INTRODUCTION

The Central Sterile Services Department (CSSD) is responsible for preparing, processing, and distributing safe sterile medical and surgical supplies and equipment required for patient diagnosis, treatment and ongoing care.

Some medical equipment and surgical instruments are typically designed for reuse and therefore can transmit infections including hepatitis B, C and HIV, if any of the steps involved in reprocessing, cleaning, disinfection, or sterilization are inadequate or experience failures. It is therefore essential that all CSSD staff is trained in all aspects related to CSSD, to ensure that they have an in-depth knowledge regarding sterile medical supplies.

The effective use of disinfection and sterilization procedures is important in preventing healthcare associated infections. Therefore proper CSSD services are vital for an effective Infection Control and Prevention program.

Having this guideline in place, will guide staff to decide what decontamination process (i.e. cleaning/disinfection/sterilization), should be used for which items or equipment.

1.1 Purpose of the Guidelines

These guidelines cover a number of the key issues related to cleaning, inspection, disinfection, sterilization, storage and transportation of instruments and equipment in a variety of healthcare settings. It also covers universal precautions and the general set up of the CSSD plus linkages with other departments.

1.2 Objectives of the Guidelines

The objectives of these guidelines are to ensure:

- Reusable medical devices are processed to the level intended for their use (Spaulding Classification)
- The process of sterilization, storage and transport meets the required standards
- Only health facilities or services that meet the minimum requirements (for cleaning, disinfection and sterilization) are permitted to provide these services
- Continuous education, training and written instructions on reusable medical equipment processing are provided to CSSD staff
CHAPTER 2: OVERVIEW OF THE CENTRAL STERILE SERVICES DEPARTMENT

The Central Sterile Services Department (CSSD) is the area in the hospital where medical devices and equipment both sterile and non-sterile, are cleaned, prepared, processed, stored and issued for patient care.

The CSSD is vital for an effective Infection Control and Prevention program. The expertise and knowledge of CSSD personnel is important to ensure high standards of decontamination and reprocessing of medical devices. In the hospital or clinic, it is important that all equipment and materials used for treating patients are safe for use.

2.1 Scope of Work of CSSD

Though CSSD services extend beyond the hospital walls, the Operating Theatre (OT) services is a major stakeholder. To ensure continuity of service delivery, there must be direct links between sterilizing and OT services. In instances whereby both units are onsite is it preferable that they are situated close to each other but in separate complexes, to assist in communication and the transfer of dirty, clean and sterile equipment and instruments. It is however preferred to have different managers responsible for CSSD and OT.

It is essential that Sterilizing Services are included/ but not limited to being consulted in the following instances:

- OT scheduling
- Procurement of reusable instruments and equipment
- OT management meetings
- Peri-operative education and training
- Changes in models of care and processes across Peri-operative services
- Plans for the redevelopment, refurbishment and/or redesign and commissioning of new OT and sterilizing services

2.2 Establishing a CSSD

Systems should be put in place where all soiled, used, and recyclable equipment is collected from the wards and OT and transferred to the CSSD. The equipment is washed, inspected, disinfected or packaged, sterilized, and dispatched back to the wards.
Note: when dirty items are received, they should be counted and recorded in a logbook – the same applies to dispatch.

2.2.1 Essential Requirements of a CSSD Worker
The level of education for those working in Sterile Services should be at least a high school leaving certificate, the person should be able to read and write and follow simple instruction.
The supervisor should have had a minimum of two years’ experience in Sterile Services, and should have attended at least one training course where the basic principles of decontamination and sterilization are explained and practically applied to the place of work. It is best if the supervisors go towards a 6 month’s course in sterile services so that they may be able to carry out their duties diligently.

The Manager should have a higher qualification in health and should have had at least 5 years or more, experience in Sterile Services. They should have attended an Advanced Course in Sterile Services, with skills in managing the CSSD, including knowledge on financial, administrative and procurement. Further they should know how to control flows of medical devices through the CSSD, know basics of the processing equipment and how it works and most importantly, understand and apply validation.

CSSD workers should:

- Protect the patient from harm- understand Duty of Care
- Understand the setup of each section of CSSD
- Operate the machinery effectively after training
- Protect oneself and colleagues
- Undergo continuous training and attain new knowledge
- Have a basic English knowledge
- Have basic reading and writing skills
- Have basic calculating skills
- Have knowledge of the principles of infection control
- Have knowledge of the principles of disinfection and sterilization

2.3 The Design of CSSD

When designing or redevelopment sterilizing services, planning and design should include input from relevant experts including those involved in the processing of reusable medical items, engineering and infection control. The location of the CSSD and sterile supply area should be away from the main traffic pattern. The ideal location should be close to the OT with a dedicated passage or lift from OT into the decontamination area.

Ideally, the design of the CSSD must have physical barriers which separate dirty and clean areas in the reprocessing room. However, if this is not possible, the same room can be used, provided that:

- There is clear demarcation of clean and dirty areas
- The air moves from the clean area to the dirty area (positive pressure in the clean side and negative pressure in the decontamination area)
- Clean and dirty areas have separate storage facilities
- There are adequate hand hygiene facilities (disinfection and washing)
- 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 reprocessing equipment for each area
- The staff at CSSD should work in either clean or dirty areas and never in both

**Note:** In some Health Service Districts, the potential exists for centralizing the provision of sterilizing services through one facility with a properly designed and equipped sterilizing unit that is able to meet the sterilizing needs of a number of other facilities.

## 2.4 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 e.g. working areas for sterilizing (inspection, loading, packing, and off-loading and storage areas).

The following is recommended for the small reprocessing areas (CSSD):

- It is ideal to have separate rooms – one for receiving and cleaning medical devices (the Wash room) and another for Inspection, Assembly and Packaging (IAP) and for final processing (sterilization or high-level disinfection) followed by a storage and dispatch area
- When only one room is available, it should be arranged so that activities and objects flow in an organized way with physical barriers to stop dirty and clean medical devices from crossing over
- Adequate counter top space for receiving dirty items and for drying and packaging clean items
- There must be at least one sink (two or more are preferable) and should be deep enough to allow soaking of the medical devices
- It is important to have good space for separation between soiled handling area and the clean, packaging area
- The high-level disinfection area has to be separated from the sterile area, must preferably be in a separate room

### 2.4.1 Hand Washing Sinks

A proper hand basin should be located at the entry of the cleaning area. The location of a hand basin for the packaging and storage areas must take into consideration the risk of sink splash, contacting preparation areas and sterile consumables or packs (linen wrapped). If a hand basin is unable to be located in this area, it should be located outside the room in close proximity to the entry. Consideration may also be
given to the use of alcoholic hand gel in consultation with the Infection Control coordinator.

2.4.2 Jet guns
There should be one air and one water high pressure jet gun. The water pressure jet is used to clean out narrow lumen tubing such as suction tubing or similar. The air gun is used to dry the interior of the tubing before hanging it to dry further.

2.5 Storage of Sterile Items
Sterile items should be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source.

The following storage conditions are recommended:

- Sterile storage areas should be clearly indicated and controlled to prevent contamination of sterile stock
- Storage areas must be dedicated for that purpose only
- The storage area must be kept clean and free of dust, insects and pests
- Store items in an open rack shelving with moderate temperature ranging from 18°C to 22°C, with a relative humidity of 35% to 68%, in an area without heavy traffic
- Cardboard boxes should not be used as they are porous, cannot be cleaned and they may harbor organisms
- All items should be stored at least 250 mm from the floor level, and at least 440 mm from the ceiling and protected from direct sunlight
- 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.
- The shelf life depends on: handling after sterilization; storage conditions; transport conditions; and amount of handling. A wrapped pack can be considered sterile as long as it remains intact and dry for no more than three months from date of processing, and from supplier should be stored as per the supplier expiry date
- Label accurately with contents, date of processing and expiration date and store wrapped materials in the open rack shelving area
- When in doubt about the sterility of a pack, consider it contaminated and re-sterilize the items
- 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
- 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
2.6 Commercially Prepared Items

- Grossly soiled or damaged stock should not be accepted as contents may be compromised
- Dust must be wiped from store pack before opening to prevent contamination of inner items
- Remove sterile items from the store pack before bringing them into the clean area
- Inspect unit packs or their contents for cleanliness or damage before use
- If the package is intact the expiring date should be considered valid

2.7 Release of Sterile Items

Sterile items should be released by educated and authorized staff. The following requirements should be met before releasing the item:

- All sterilization parameters should be met, i.e. temperature, pressure, time based on the batch documentation
- Evaluation of the chemical batch control
- Visual inspection of the integrity of packaging. Look for the following: holes or tears, wetness or stains, broken seals, dust, evidence of crushing, labeling, and indicators
- DO NOT release items where the indicator is missing or has not changed colour

2.8 Transportation of Contaminated Equipment and Sterile Supplies

Transportation of sterile supplies must be in a clean and dry trolley which is closed to outside contamination.

2.8.1 General Design Features for Trolleys and Transport Containers

Equipment must be dedicated for this purpose, i.e. separate equipment for the transportation of contaminated and sterile items. The trolleys should have the following characteristics:

- Should be covered or closed with a solid bottom shelf
- Can be cleaned, dried and disinfected
- Should be in a good working condition
- Should be easily maneuvered and fitted with brakes if possible

The Transport containers should be:
• Puncture-resistant
• Leak-proof
• Made of either plastic or metal, with a lid or liner that can be closed and cleaned and disinfected

2.8.2 Transport of Sterile Supplies

The maintenance of sterility depends primarily on the conditions of storage and the frequency of handling. All items transported should be delivered in a clean container and trolley dedicated for that purpose.

To guarantee sterility of items transported the following procedures should be followed:

• Containers and trolleys used for the transportation of sterile goods should be dedicated and must not be used for non-sterile goods, e.g. transportation of food or garbage
• Transport containers/systems must allow articles to be handled with care and be inspected as necessary
• Boxes or bags used should not be overloaded
• All transportation equipment should be maintained in a clean, dry condition and must be in good working order
• All sterile items for distribution outside the health care facility must be securely packed and protected against damage and contamination during transportation
• There must be a regular cleaning program for all sterile storage areas, including all containers and trolleys

2.9 Waste Management at CSSD

Anyone responsible for generating waste has a responsibility to dispose it off safely. When hazardous waste is not handled properly and is disposed off in landfill sites, it can expose the community, environment and animals to highly contagious infections.

During the decontamination cycle at CSSD, a wide range of waste may be produced. The clinical waste commonly produced at CSSD will be in form of packaging from returned medical devices and personal protective equipment (PPE).

Examples of the waste include; wrapping papers, gloves, aprons, masks, blood or body fluids, used swabs, drugs and other pharmaceutical products, sharps like needles and blades, and human tissue may also be present.

Responsibility of CSSD staff in waste management:

- Segregation of waste: waste should be segregated properly in the different colour coded bags to ensure that it ends up where it is supposed to be. The key to effective management of waste is to separate it at the source where it is generated
- Clearly mark the waste bags with labels
- Handling, storage, transport and dispose of waste should be done correctly, according to the facility set procedures and MoHSS IPC and Medical Waste Management Guidelines

2.10 Quality Assurance and Monitoring

It is important to have an effective management control system in place at the CSSD to cover all aspects of decontamination.

The quality management system should ensure the following:

i. Monitoring is carried out to ensure all systems are performing to the required standards
ii. Records are produced and maintained to demonstrate that activities comply with the stated requirements
iii. The correct protocols are in use
iv. The protocols are adhered to and there is documented evidence of adherence
v. Standard operating procedures (SOPs) are in place for the different activities of CSSD
vi. Adequate supplies of satisfactory quality are available at all times

2.10.1 Proper Care of Surgical Instruments

- Inspect each instrument for proper function and condition
- Make sure that scissor blades glide smoothly all the way (blades must not be loose when in closed position)
- Check that forceps tips are properly aligned
- Make sure that the hemostats and needle holders do not show light between the jaws, that they lock and unlock easily, and that the joints are not too loose
- Check needle holder jaws for wear and tear
- Examine cutting instruments and knives to be sure their blades are sharp and undamaged
- Use lubricant and silicone sprays when appropriate

2.10.2 Proper Care for CSSD Packs

- Basins and Bowls: Check for sharp edges and cracks
- Baskets and Trays: Check for sharp edges, damaged corners and open ends
- Linen, Towels and Gowns: Check for tears and holes in the material
- **Table surfaces**: Check for rough, sharp edges

*All these factors could tear the sterilization paper and therefore compromise the sterility of the packs. In case of damages, report to the supervisors for the necessary repairs and replacement.*

### 2.11 Risk Management

- Refer to MoHSS Post Exposure Prophylaxis & Integrated Health Care Waste Management Plan, 2012 (pg. 71)
- Orientation of new staff on hazards e.g. fire, different chemicals etc. is important
- Provide regular refresher trainings to the staff in the unit

### 2.12 Auditing and Validation

- Ensure regular Stock taking
- Identify instruments that need replacement
- Availability of Inventory registers
CHAPTER 3: STANDARD PRECAUTIONS

Standard precautions are safe work practices required to minimize the risk of infection to both patients and staff. They include good hygiene practices, particularly hand hygiene, the use of, appropriate handling and disposal of waste, adherence to the principles of asepsis and maintenance of a clean environment. Refer to the MOHSS Infection Prevention Control Guidelines 2nd Edition 2015 (Chapter 4) for more details.

3.1 Personal Protective Equipment (PPE)

Protective clothing should be worn during equipment processing to protect the health care worker from contact with blood and body fluids. It is also worn in this setting to avoid contributing to the bio-burden on articles during their preparation for sterilization or subsequent storage.

Protective attire worn during cleaning of used equipment includes:

- Waterproof outer wear (gown or apron with impermeable arm protection)
- Heavy-duty gloves
- Safety glasses and masks, or face shields if manual cleaning is undertaken
- Staff should wear closed shoes with non-slip soles, strong enough to protect against injury if articles are dropped accidentally
- Consideration may be given to staff wearing ear protection but this will be dependent on the noise levels within the area

3.2 The Role of Infection Control Teams

The role of infection control team is primarily to prevent healthcare associated infections. This necessitates a close working relationship of CSSD staff and Infection Control Coordinators.

The establishment of committee structures, e.g. Theatre Users Committee, IPC Committee and other means of formal and informal communication between infection control and sterilizing services staff will ensure the adequate and timely provision of properly processed equipment in health care facilities.

Ensure that the sterilizing service department is aware of local and nationwide infection control policies that may affect the service they provide.

The CSSD should have a responsibility for achieving consistent production and management standards in the reprocessing of reusable instruments and equipment.
The following infection control measures should be observed by all CSSD staff:

- Change out of street clothes into CSSD uniform (theatre scrubs)
- Staff should always wash their hands after glove removal
- All cuts and skin abrasions are to be covered with a waterproof dressing
- Hair and beards should be covered with face mask at all times
- Wearing of jewelry, artificial nails and nail polish should be discouraged. Rings and watches when on duty should be removed
- All staff members working in the CSSD should be immunized against Hepatitis B.
- Post exposure prophylaxis (PEP) guidelines should be readily available at the CSSD and staff should know the steps to follow in case of accidental injuries

For more details on infection transmission and management refer to the MOHSS IPC Guidelines 2nd Edition 2015 (Chapter 1).

3.3 **Adverse Events**

Strong detergents and disinfectants may have adverse effects on the skin. Any skin contamination should be washed off immediately and managed as per the Material Safety Data Sheet instructions.

Events including sharp injuries should be managed according to the recommendations in the MoHSS National Guidelines on PEP for HIV, HBV and Tetanus 2010 (page. 19).
CHAPTER 4: RISK OF INFECTION FROM MEDICAL EQUIPMENT

4.1 Classification of the Risk from Medical Equipment

The classification system developed by Spaulding divides medical equipment/devices into three categories based on the potential risk of infection involved in their use:

Table 1: Spaulding’s Classification of Medical Equipment/Devices and Required level of Processing

<table>
<thead>
<tr>
<th>Classification</th>
<th>Definition</th>
<th>Level of Processing/Reprocessing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical (High Risk) Equipment/device</td>
<td>Equipment/device that enters sterile tissues, including the vascular system.</td>
<td>Cleaning followed by sterilization</td>
</tr>
<tr>
<td>Semi-critical (Intermediate Risk) Equipment/device</td>
<td>Equipment/device that comes in contact with non-intact skin or mucous membranes but do not penetrate them.</td>
<td>Cleaning followed by high level disinfection or sterilization if indicated</td>
</tr>
<tr>
<td>Non critical (Low risk) Equipment/device</td>
<td>Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the client / patient / resident.</td>
<td>Cleaning followed by low level disinfection (in some cases, cleaning alone is acceptable)</td>
</tr>
</tbody>
</table>

Placing instruments and equipment into one of the above 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.

4.1.1 Low Risk (Noncritical Items)

Low risk (noncritical) items are items that come into contact with intact skin but not mucous membranes, examples of these include: stethoscopes, BP cuffs, crutches and thermometers.

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Cleaning with a detergent and drying is usually adequate. Stethoscopes are usually cleaned and in rare cases they should be disinfected if used on an infectious patient or highly susceptible patient.

After cleaning, they should be stored in a clean and dry place.

4.1.2 Intermediate Risk (Semi-critical Items)

Intermediate (Semi-critical) items are items that make contact directly or indirectly with intact mucous membranes or non-intact skin. Examples include: endoscopes, laryngoscopes, specula and endotracheal tubes.

Cleaning followed by high level disinfection (HLD) is usually adequate. They should be well stored to protect from environmental contamination and stored for only up to one week.

4.1.3 High Risk (Critical Items)

High risk (critical items) items are items entering sterile tissue, the body cavity, the vascular system and non-intact mucous membranes. Examples include: surgical instruments, intra-uterine devices, vascular catheters and implants. 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, preferably heat, is required.

4.1.4 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.

Re-sterilization of single use items should be avoided and discouraged - it is illegal. If such as process has to be undertaken for cost reasons, very clear direction from a well experienced group of experts should advice on how to undertake the reprocessing safely and how many times a medical device can be reprocessed without jeopardizing its integrity or function.
Figure 2: Summary of Decontamination Process

- **Disposable Items**: e.g. gloves, needles
  - Dispose
  - Clean
  - Dry and Store

- **Non-critical Items**: e.g. stethoscopes, BP cuff, thermometer
  - Clean
  - Dry and Store

- **Semi-critical Items**: e.g. endoscopes, laryngoscope
  - Clean
  - High Level Disinfection or Sterilization
  - Dry and Store

- **Critical Items**: e.g. surgical instruments
  - Clean
  - Sterilization
  - Dry and Store
CHAPTER 5: INSTRUMENT PROCESSING (CLEANING PROCESS)

There are several steps when reprocessing medical devices that are used during clinical and surgical procedures which are summarized here (Fig. 3) of which cleaning is the most important one. Once a medical device is thoroughly cleaned, it can either be disinfected or sterilized depending on its resistance to heat.

**Figure 3: Shows the Decontamination Steps**

5.1 **Cleaning Process**

Cleaning is the removal of all foreign material (dirt and organic matter) from the object being reprocessed. **This is the first and the most important step.**

No disinfection or sterilization should be done without thorough cleaning.

**Two key components of cleaning are:**

- Rubbing or brushing to remove foreign matter
- Use of fluids to remove or rinse away contamination

Cleaning is essential for penetration of disinfectants or steam and therefore must precede all reprocessing.
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.

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.

Studies have shown that thorough cleaning alone can provide a major reduction in contaminant microbes from endoscopes. Cleaning can be very effective in removing microbial contaminants from surgical devices.

**Cleaning may be carried out by the following means:**

i. Manual

ii. Mechanical

5.1.1 Manual Cleaning

**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
- When Items with narrow lumens need to be cleaned (endoscopes)

Manual cleaning must be done with extreme caution.

**The staff should follow these set procedures:**

i. All items requiring disinfection or sterilization should be taken apart before cleaning.

ii. Cold (Luke warm temperature, not above 45 degrees) 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

iii. 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

iv. 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)
### Table 2 Steps to follow during the Cleaning Process

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Wear heavy-duty rubber gloves, a plastic apron, eye protection, mask and closed shoes during cleaning.</td>
</tr>
<tr>
<td>2.</td>
<td><strong>Disassemble</strong> instruments and other items with multiple parts, and be sure to brush in the grooves, teeth, and joints to items where organic materials can collect and stick.</td>
</tr>
<tr>
<td>3.</td>
<td>Soak the instruments in normal tap water containing a detergent and diluted according to manufacturer’s guidelines.</td>
</tr>
<tr>
<td>4.</td>
<td>Scrub instruments and other items vigorously to completely remove all foreign material using a soft brush, detergent, and water. Hold items under the surface of the water while scrubbing and cleaning to avoid splashing.</td>
</tr>
<tr>
<td>5.</td>
<td>Flush through lumens with an adapted water jet.</td>
</tr>
<tr>
<td>6.</td>
<td>Rinse items thoroughly with clean water to remove all detergent. Any detergent left on the items can be toxic and can reduce the effectiveness of further processing.</td>
</tr>
<tr>
<td>7.</td>
<td>Inspect items to confirm that they are clean.</td>
</tr>
<tr>
<td>8.</td>
<td>Allow items to air dry or dry them with a clean towel. This is to avoid diluting the chemical solutions used after cleaning and as preparation for storage or sterilization.</td>
</tr>
</tbody>
</table>
Things to 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. Only use a recommended detergent for cleaning.
- Always wear utility gloves, a mask, eye protection and closed shoes when cleaning instruments.
- Do not use abrasive materials that scratch or pit instruments. Scratches, pits, or grooves can harbor microorganisms and promote corrosion (Don’t use metal brushes).
- Automatic washing machines are preferable to washing by hand.

5.1.1.1 Soaking of Instruments Prior to Cleaning

Sometimes the level of contamination of the instrument makes it necessary to soak items prior to cleaning. A deep container, e.g. a bucket, containing a wire-mesh basket can be filled with water and detergent only. The instruments are placed in the wire basket and soaked for 3-5 minutes, and then lifted out. Instruments still need proper cleaning prior to drying, inspection, packing and sterilizing.

NEVER SOAK MEDICAL DEVICES IN DISINFECTANTS PRIOR TO CLEANING!

5.1.2 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 ≥55°C. This is followed by a 10-second hot water rinse at 80-90°C and then by drying at 50-75°C.
- **Washer/disinfector**: The washer/disinfector is used for anesthetic equipment. It runs a 45-minute cycle of washing with a detergent solution and cleaning plus a 2-minutes disinfection cycle with water at 80-100°C.
- **Ultrasonicator**: the ultrasonicator is a sophisticated and expensive but extremely efficient piece of equipment. It uses high-power output of 0.44 W/cm³ and dislodges all organic matter on metallic surfaces. Do not use it on plastic items.

5.1.3 Proper Care of Surgical Instruments

After the cleaning process the instruments should be checked for the following:

- Inspect each instrument for proper function and condition.
- Make sure that scissor blades glide smoothly all the way (blades must not be loose when in closed position).
- Check that forceps tips are properly aligned
- Make sure that the hemostats and needle holders do not show light between the jaws, that they lock and unlock easily, and that the joints are not too loose
- Check needle holder jaws for wear and tear
- Examine cutting instruments and knives to be sure their blades are sharp and undamaged
CHAPTER 6: DISINFECTION PROCESS

Disinfection refers to inactivation of vegetative (non-sporing) organisms using either heat or water (thermal) or by chemical means like glutaraldehyde 2%.

Thermal disinfection is preferred whenever possible because of the following:

- It is generally more reliable than chemical processes
- Leaves no residues
- More easily controlled
- 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 the disinfectant. The larger the number of microbes present, the longer it takes to disinfect. Thus thorough cleaning before disinfection is of greatest importance.

6.1 High Level Disinfection (HLD) - Semi-critical Items

There are two methods of HLD:

1. Use of moist heat at 70-100°C
2. Chemical disinfection

When sterilization is not available, HLD is the only acceptable alternative for instruments and other items that will come into contact with the bloodstream or tissues under the skin. Flaming is not an effective method of HLD because it does not effectively kill all microorganisms.

6.1.1 HLD by Boiling

High-level disinfection is best achieved by moist heat such as boiling in water (100°C for 10 minutes holding time), which kills all organisms except for a few bacterial spores. However it cannot be adequately controlled and should not be used instead of controlled validated sterilization.

It is important to note that boiling equipment items in water will not achieve sterilization.
Guidelines to follow during HLD by boiling:

- Instruments and other items must be completely covered with water. Disassemble items with multiple parts.
- Always boil for 10 minutes. Start counting the one minute when the water reaches a continuous boiling. 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.
- 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. Dry and store in a manner that protects them.

6.1.2 HLD by Mechanical - Thermal Disinfection

Disinfection by hot water can also be performed in specially constructed washing machines in which 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 shortens disinfection times.

If machines are used they should be regularly maintained and checked for efficacy. Low to high-level disinfection is achieved depending on the type of machine and the complexity of the items.

6.1.3 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. These include:

a. Glutaraldehyde 2% for 10 minutes to half an hour
b. Hydrogen peroxide 6% - 7.5% for 20 – 30 min
c. Peracetic acid 0.2-0.35% for 5 min
d. Ortho-phthalaldehyde (OPA) for 5-12 min

The following procedures should be followed:

- 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 dried thoroughly and stored properly

**Steps to be followed during use of chemical HLD:**

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. Fresh solution should be made each day (or sooner, if the solution becomes cloudy). Follow the manufacturer’s instructions
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. Disassemble items with 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 based on the manufacturer’s guidelines

**6.1.3.1 Notes on Disinfectants:**

The use of disinfectants is covered in the Disinfectant Policy in the IPC Manual and is summarized here.

To be acceptable in the hospital environment, the disinfectant must be:

- Easy to use
- Non-volatile *(does not evaporate rapidly)*
- Not harmful to equipment, staff or patients
- Free from unpleasant smells
- Effective within a relatively short time

In using a disinfectant, manufacturer’s recommendations must always be followed. Disinfectants should always be stored in a cool, dark place. They should never be stored in direct light or excessive heat.

### Table 3 Different Types of Disinfectants, their Actions and Limitations

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Actions</th>
<th>Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde 2%</td>
<td>Broad range of microbial activity. Easily kills bacteria, fungi and viruses but it is slow in killing spores.</td>
<td>Dangerous, toxic and irritant. Maximum exposure time needed.</td>
</tr>
<tr>
<td>Peracetic acid 0.2 to 0.35%</td>
<td>Broad range of microbial activity. Generally rapid acting including mycobacterium and spores.</td>
<td>May be slightly corrosive or damaging.</td>
</tr>
<tr>
<td>Alcohol 70% isopropyl alcohol or 60 to 80% ethyl alcohol (ethanol)</td>
<td>Rapidly acting against most bacteria and viruses. Main use is for rapidly disinfecting clean surfaces. The alcohol evaporates quickly to leave surfaces dry.</td>
<td>Since alcohol is flammable, it cannot be used in large amounts. Soil prevents penetration. Not sporicidal and has poor penetration.</td>
</tr>
<tr>
<td>Hydrogen peroxide solution</td>
<td>Fast virucidal and bactericidal but slow sporicidal and fungicidal. It is non-irritant when mixed and user friendly.</td>
<td>Corrosive to some metals.</td>
</tr>
<tr>
<td>Chlorine releasing agents. Commonly used is sodium hypochlorite (Bleach)</td>
<td>Rapid and broad range of antimicrobial activity. Useful in decontaminating blood and body fluid spills and have a wide range of environmental applications, e.g. disinfecting worktops, baths, toilets and sinks.</td>
<td>Hypochlorite can damage and bleach many fabrics and causes pitting of metal. High concentrations are required for direct application to spills as it is readily inactivated by dirt.</td>
</tr>
</tbody>
</table>
CHAPTER 7: STERILIZATION PROCESS

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

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 the 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.

7.1 **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.

Autoclaves use steam as a carrier of thermal energy or heat. Steam is a much more efficient carrier of heat than air. The steam softens the outer layer of microorganisms, which permits the thermal energy or heat to enter the organism and come in contact with the proteins in the organisms. The proteins are then denatured thus become unable to do their normal function in the cell leading to cell death.

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

The **autoclave cycle involves the following:**

- Removing all air from the autoclave
- Introducing steam at a required pressure
- Achieving required temperature
- Maintaining the temperature for the required time
- Removing condensation/water
- Introducing warm filtered air
- Drying the instruments
7.1.1 Types of Steam Sterilizers

a) 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
- Not suitable for surgical packs and wrapped instruments

b) Portable steam sterilizer:
- These can be adapted for processing critical devices in low resource settings
- In addition, pressure cookers can provide adequate steam sterilization in situations where conditions and resources are severely limited
- Not recommended for surgical packs and wrapped instruments
- Dental equipment and open trays only

c) 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 15 minutes or 134 °C for 3-4 minutes
- Cannot be controlled or properly validated. Not recommended

d) 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
- Only for unwrapped items
- It should NEVER be used for sterilization of surgical trays or packs

e) High-speed pre-vacuum 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
- Ideally used for wrapped items and porous loads (fabrics, swabs, instruments with lumens)
7.1.2 Sterilization Times

Table 4: The Sterilization Times for the Different Types of Sterilizers

<table>
<thead>
<tr>
<th>Type of Instruments to be Sterilized</th>
<th>Sterilization Time (Holding Time)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Gravity Sterilizer</strong></td>
<td></td>
</tr>
<tr>
<td>Unwrapped 121 ºC (1.036 Bar)</td>
<td>15 minutes</td>
</tr>
<tr>
<td>Unwrapped: 134 ºC (2.026 Bar) (metal and glass only)</td>
<td>3 minutes</td>
</tr>
<tr>
<td>Unwrapped: 134 ºC (2.026 Bar) (e.g., rubber)</td>
<td>10 minutes</td>
</tr>
<tr>
<td>Wrapped 121 ºC (1.036 Bar)</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Wrapped 134 ºC (2.026 Bar)</td>
<td>15 minutes</td>
</tr>
<tr>
<td><strong>High-speed Vacuum Sterilizer</strong></td>
<td></td>
</tr>
<tr>
<td>Wrapped: 134 ºC (2.026 Bar)</td>
<td>4 minutes</td>
</tr>
</tbody>
</table>

**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.

7.1.3 Wrapping Instruments and Other Items for Autoclaving

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 or cotton fabric however paper is preferred to allow steam penetration.**

Make points in the wrapping material while wrapping the instruments and other items so that the packs can be easily opened without contaminating their contents (see Fig. 3 below).
The wrapping systems for sterile items should meet the following criteria:

- Should provide an adequate barrier to particulate matter
- Withstand physical conditions of the sterilization process
- Provide an adequate barrier to fluids
- Permit adequate air removal
- Allow penetration and removal of the sterilants
- Protect package content from physical damage, resist tears and punctures
- Be free of holes and free of toxic ingredients
- Have a low lint content
- Be used according to the manufacturers’ written instructions
- Be dated

**Figure 4 Steps for wrapping instruments and other items**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Place the instrument or other item in the center of the top wrapper.</strong> Items should be positioned so that the points and not the flat edges are at the top, bottom, and sides.</td>
<td><strong>Fold the bottom section of the top wrapper to the center, and fold back the point.</strong></td>
<td><strong>Fold the left section to the center, and fold back the point.</strong></td>
<td><strong>Fold the right section to the center, and fold back the point.</strong></td>
</tr>
</tbody>
</table>

![Step 1 Diagram](image1)

![Step 2 Diagram](image2)

![Step 3 Diagram](image3)

![Step 4 Diagram](image4)

<table>
<thead>
<tr>
<th>Step 5</th>
<th>Step 6</th>
<th>Step 7</th>
<th>Step 8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fold the top section to the center, and fold back the point.</strong></td>
<td><strong>Fold the bottom section of the bottom wrapper to the center, and fold back the point.</strong></td>
<td><strong>Fold the left section to the center, and fold back the point.</strong></td>
<td><strong>Fold the right section to the center, and fold back the point.</strong></td>
</tr>
<tr>
<td>Step 9</td>
<td>Step 10</td>
<td>Step 11</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>---------</td>
<td>---------</td>
<td></td>
</tr>
<tr>
<td>Fold the top section to the center, and fold back the point.</td>
<td>Tuck the point under the right left sections.</td>
<td>Fasten the folds securely, using autoclave tape, if available.</td>
<td></td>
</tr>
</tbody>
</table>

**Storage of sterile items** should be according to these guidelines as in Chapter 2 section 2.5.

**7.1.3.1 Preparation of Other Items e.g. Cotton Swabs, Gauzes for Sterilization**

The preparation is done according to the health facilities standard operating procedures as determined by the CSSD.

**7.1.4 Steps for Pressure Steam Sterilization (Autoclaving)**

1. **Correct loading of the autoclave:**
   - Items should be loaded within the boundaries of the loading tray so that they do not touch the chamber walls or fall off when the load tray is in transit
   - Ensure there is sufficient room between items to allow circulation of steam
   - Do not overload the chamber
   - Racks may be used to allow for adequate separation of packaged instruments
o Packs of hollow-ware and trays of instruments should not be placed above textile packs or soft goods in order to avoid wetting caused by condensation from items above
o Do not load the heavier packs on the top shelf as it is easier to unload the packs from the bottom shelf without dragging it

2. **Follow the manufacturer’s instruction for operating the autoclave.** Adjust time, temperature and pressure according to *Table 4*. It is best to use a timer, which helps ensure that the appropriate timing is achieved.

3. 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

4. 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.

5. **Unloading of the Autoclave:**
   o Remove packs, drums, or unwrapped items from the autoclave using sterile pick-ups to handle unwrapped items
   o The operator should wear heat resistant gloves to prevent burning as the packs come out of the autoclave hot
   o The packs of equipment should come out of the autoclave dry. Wet packs must be considered non-sterile
   o On removal of the load, the operator should check the print-out or fill in details about the cycle on the record sheet to indicate the required parameters have been met
   o Cooling items will not be placed on solid surfaces as condensation from vapor (still within the pack) may result. They should be placed on the cooling rack
   o Do not drag the packs along surfaces as this may result in tears in the packs and compromise the sterility of the pack
   o Do not store packs, drums or unwrapped items until they cool to room temperature. This may take several hours
   o Sterile items should be stored and handled in a manner that maintains the integrity of packs and prevents contamination from any source as described in section 2.5
**Things to remember:**

- *Clean all items to be sterilized*
- *Instruments may be autoclaved individually or in sets*
- *Unlock all instruments and sterilize them in open position*
- *Place heavy instruments on bottom of set*
- *Never lock instruments during autoclaving. This will prevent the steam from reaching and sterilizing the metal-to-metal surfaces. Furthermore heat expansion during autoclaving can cause cracks in hinge areas*
- *Sterilized packs should always have the date of sterilization as well as the expiry date clearly written*

**7.1.4.1 Shelf Life and Rotation of Stock**

- **Unwrapped items:** use immediately after removal from the autoclave or keep them in a covered, dry, sterile container for up to one week.
- **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. The shelf life depends on:
  - Handling after sterilization
  - Storage conditions
  - Transport conditions and
  - Amount of handling

A wrapped pack can be considered sterile as long as it remains intact and dry. It is however recommended that items entering sterile organs should be stored for a maximum of 3 months.

- Instruments packed in steri-pouches remain sterile for up to a year as long as these are not punctured.

*Rotation of stock should be done on a regular basis by rotating your packs from top to bottom, back to front and left to right.*

**7.1.4.2 Determination of sterility of a set:**

1) Set must be dry
2) Wrapping should be intact i.e. not torn
3) Properly wrapped
4) Expiry date checked: sets expire after 3 months
5) Indicator strips showing that sterility was achieved

**7.1.5 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
CHAPTER 8: MONITORING EFFECTIVENESS OF STERILIZATION AND AUTOCLAVE MAINTENANCE

8.1 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. These include mechanical, chemical and biological indicators.

8.1.1 Mechanical Indicators (Physical)

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.

8.1.2 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.

The advantage is that chemical indicators are visible to the user. The disadvantage is that some chemical indicators can change without going through a complete sterilization process.

8.1.3 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.

8.1.4 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.
- Perform the Bowie Dick test for air removal each day before starting the sterilization cycle.
- Place heat-and steam-sensitive chemical indicators, on the outside of each pack.
- Perform testing with biological indicators daily or weekly if used.
- Indicators should be in the middle of the item reprocessed (the most difficult part of the load).
- A thermocouple could be put in the most difficult part of the load where air removal is hard and is usually performed by the engineers.

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). Thermocouples are only used if the sterilizer has been serviced or is faulty.

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.

8.1.5 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.
- If correct use of the unit has been documented and monitoring still indicates 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 non-sterile and must be processed again with the unit that is functioning properly.
8.2 Contaminated Supplies

Contaminated supplies are totally unsuitable for use. Items should be closely monitored by visual inspection looking for contamination as part of a quality management program.

Any contaminated or opened packaging should be considered unfit for use and discarded or decontaminated if they are re-usable items.

Items are considered contaminated when:
- They are wrapped incorrectly or inadequately
- Packaging is damaged or opened
- Comes in contact with a wet surface
- An item is placed or dropped on a dirty surface like floor or sink
- Has no indication of having been through a sterilizing process for example the chemical indicator has not changed colour (see chapter 6)
- Incorrect or inadequate cleaning procedures in the storage area
- Stored at incorrect temperature
- Excessive exposure to sunlight or ultraviolet light
- Evidence of pests and insects
- Evidence of incorrect handling when transporting items

8.3 Autoclave Maintenance

The autoclave should be checked by the operator or supervisor 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. If there is a fault, report it to the supervisor or manager and call out the engineer to correct the fault. A fault log must be recorded and kept for medico legal reasons.

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 replaced
- Steam comes out from under the lid or around the door. If this happens, the gasket must be cleaned and dried or replaced
- Items emerge wet - the steam is incorrectly delivered. There is condensation along the chamber walls
- Items emerge dry and crisp - steam is over heated
- Water marks on the packs - poor water quality
- Indicators fail - poor air removal, leaks or incorrect processes.
To ensure that the autoclave is properly maintained, ensure the following:
- Regular maintenance must be performed and documented according to the manual.

8.3.1 Cleaning of the autoclave
Cleaning of the autoclave should be done according to the manufactures recommendation.

8.4 Record Keeping
Record keeping helps in tracking what happens during any particular process. In case a problem arises during decontamination process or after, records can help to analyze what caused the problem.

The following are some of the importance of record keeping:
- Helps to check if sterilization cycle parameters have been met for every cycle. If a problem is identified, any unsterile packs can be stopped from going out to the theatre and wards
- Helps monitoring processes in the CSSD while they are occurring and if something goes wrong, it can be corrected immediately
- If a problem is picked up after the packs have been issued, the use of load identification numbers will help to identify which packs are faulty
- Sterilization records help staff to determine whether reprocessing must be repeated and the extent, if, any to which a recall is needed
- Properly maintained records help to verify that the department has met or exceeded quality goals

8.4.1 Types of Records
Regardless of the type of sterilization methods used, several basic records must be maintained for each sterilization cycle that is performed. These records will allow the tracking of sterilized items to the patient.

a) Load control number: must be attached to any item intended for use as a sterile product. It must identify the sterilization date, sterilizer equipment used; cycle number and expiration date if applicable
b) General contents of the load in each sterilization cycle
c) Biological and chemical indicator test results
d) Exposure time and temperature and pressure (if applicable) of the sterilization process
e) Name or initials of the sterilizer operator
The following autoclave maintenance records must be maintained for all sterilization:

- Date of service
- Model and serial number
- Reason for maintenance
- Location
- Descriptions of replaced parts
- Biological testing records
- Name and signature of controller
- Scheduled date for re-testing
- Re-testing results

Follow the manufacturer's instructions whenever possible since autoclave maintenance varies depending on the type of autoclave.
Endoscopes are medical devices used to examine the inside of the body. They are made of a long thin tube that is passed into the body and are widely used in a number of surgical specialties. There are two types, i.e. flexible and rigid endoscopes.

They are problematic to clean, disinfect and sterilize because of the complexity of their design (long narrow channels, complex internal design, etc.). They are also expensive and easily damaged.

Processing of Endoscopes

The complete cycle of endoscope processing includes several stages:

- Cleaning
- Rinsing
- Disinfection or sterilization
- Rinsing if only disinfection was done
- Drying

9.1 Endoscope Cleaning

Preparations for endoscopes cleaning and disinfection:

Ensure the following items are in place:
- PPE
- 4 basins each containing the following:
  - Endozyme solution
  - Distilled or sterile water
  - Ortho-phthalaldehyde – OPA (Cidex)
  - Distilled or sterile water
- Endoscope cleaning brushes
- Syringe 50ml
- Drying / wiping sterile cloths (lint free) according to the manufactures instructions
- 70% - 90% ethyl or isopropyl alcohol
- Lubricating oil
- Leakage test device
- Flushing valves
9.1.1 Cleaning and Disinfection of Flexible Endoscopes

The following is recommended:

- Immediately on removal of the instrument from the patient, the endoscope should be wiped from control head to distal tip using a clean cloth soaked in clean water and enzymatic cleaning solution (diluted as per manufacturers’ instructions). It is impossible to adequately disinfect or sterilize an endoscope when organic material has been allowed to dry on the endoscope.
- The internal suction channel should be aspirated with enzymatic solution, depressing and releasing suction button to promote debris dislodgement.
- Depress and release air/water buttons to flush water through water channel and air through air channel (where applicable use air/water cleaning adaptors as per manufacturers’ instructions).
- Prior to disassembly and further cleaning of the endoscope the leak test should be performed as per manufacturer’s instructions. In the case of video endoscopes the protective cap should be applied prior to leak test.
- The flexible endoscope and all reusable accessory items should be disassembled as far as practicable.
- The components should be cleaned with an enzymatic solution (diluted as per manufacturers’ instructions).
- Any taps should be opened and the channels/lumens of the endoscope should be brushed to remove any adherent debris.
- If the cleaning brush has obvious debris, it should be washed prior to being withdrawn through the channel.
- Sites such as nozzles, flaps, hinges, crevices and joints of accessory items should be cleaned with a soft brush to remove any adherent debris. This cleaning process should continue until the endoscope, its channels, buttons and valves and accessory equipment are completely clean.
- Accessory items, including buttons should be placed in an ultrasonic washer according to manufacturers’ instructions. It is mandatory for spiral coiled accessory equipment to be thoroughly cleaned in the ultrasonic washer.
- Thorough flush rinsing should be carried out to remove any traces of enzyme/detergent from all channels.
- All channels should then be purged with medical air to expel as much water as possible, and the external surface is dried with a lint free cloth prior to disinfection.
- Brushes used in the cleaning process for each endoscope shall be cleaned and thermally disinfected after each use.
Important things to remember when cleaning ENDOSCOPES:

1) Rinse scope through with soap water
2) Soak scope with endozone solution for 3-5 minutes
3) Brush scope and dissembled parts
4) Rinse scope with soap water, brush, flush
5) Rinse scope in sterile water, flush through with sterile water. Flush with air, because water will dilute CIDEX, and will therefore make it ineffective
6) Flush CIDEX through scope and immerse scope in it for 5 minutes
7) Rinse with sterile water, flush scope with water, then air. Wipe dry with towel and hang on stand to dry
8) Discard solutions after 24 hours or when there are too many visible particles

9.1.2 Cleaning of Rigid Endoscopes

The cleaning steps as for the flexible endoscope above should be followed. The following should however be noted:

- Rigid endoscopes and accessories, which do not have any fibre-optic light carriers or cables, may be dried in a drying cabinet
- On completion of the cleaning, rinsing and drying process, the rigid endoscope and associated instruments should be reassembled, inspected and checked to ensure they are not damaged and are in working order, and then disassembled prior to sterilization

9.2 Endoscope Disinfection

Glutaraldehyde/OPA disinfectant has a wide range of antimicrobial activity and is effective against viruses including HIV, Hepatitis B and C and the majority of bacteria, although spores and mycobacteria species are relatively more resistant.

Factors affecting the efficiency of a disinfectant include:

- Water carried over from the washing and rinsing process reduces the concentration of glutaraldehyde
- Organic matter may inactivate glutaraldehyde
- Repeated use of the disinfectant may also cause a reduction in the concentration of the solution

The following is recommended during disinfection:

- Instruments soaked in the solution must be cleaned thoroughly and dried prior to immersion
• Manufacturer's recommendations on the management of glutaraldehyde should be followed. The solution is at a 2% concentration initially. It is undesirable for this to fall below 1.5%
• Change of the glutaraldehyde solution will depend on usage
• Where endoscopy is being performed infrequently, the glutaraldehyde solution should be disposed of at the end of the day
• Chemical indicators should be used to ascertain the concentration of glutaraldehyde. These processes must be documented and monitored
• The methods for the soaking and rinsing of the endoscope must be conducted in an aseptic manner

9.2.1 Disinfection of Flexible Endoscopes

The following steps should be followed:
• The flexible endoscope shall be leak tested, clean and dry prior to placement in the liquid disinfectant solution
• Manual disinfection—totally immerse the endoscope, valves and buttons in the disinfectant solution (diluted as per manufacturer's instructions)
• Use a syringe to flush the disinfectant solution down all lumens and channels, to remove airlocks and to ensure all internal surfaces are in contact with the disinfectant
• The endoscope should be soaked as per recommended guidelines dependent on the type of endoscope, strength and temperature of the solution
• Disinfectant solution should be monitored for concentration levels daily or immediately prior to use
• Flexible endoscopes other than bronchoscopes should be totally immersed in 2% glutaraldehyde/ ortho-Phthalaldehyde (OPA) for a minimum of 10 MINUTES between cases and prior to and end of each list
• Bronchoscopes should be totally immersed in 2% glutaraldehyde for a minimum of 20 MINUTES between cases and prior to and at the end of each list

Note: OPA is not to be used for processing of urological instruments due to a rare risk of anaphylaxis noted in patients with a history of bladder cancer.

Automated flexible endoscope reprocessing units:

The endoscope is placed into and connected to the machine and the appropriate disinfection cycle chosen in accordance with manufacturer’s instructions dependent on the type of endoscope.

The reprocessing machine should be routinely monitored as per recommended guidelines and manufacturer’s instructions.
9.2.2 Disinfection of Rigid Endoscopes
Disinfection is not a sterilizing process and shall not be used to prepare items intended for entry into sterile body cavities, or which penetrate the mucosal barrier.

Rigid endoscopes are critical items and shall only be steam sterilized prior to reuse.

9.2.3 Post Disinfection Rinsing
- Water for the final rinse of all gastrointestinal endoscopes should be of high quality, filtered and free from microorganisms able to cause clinical disease e.g. Pseudomonas
- Endoscopes processed in an automated reprocessing unit may not require rinsing on completion of cycle, check manufacturer’s instructions and description of cycle used

9.3 Decontamination and Disinfection of Endoscopes

9.3.1 Decontamination of Flexible Endoscopes
- Most flexible endoscopes (check manufacturer’s instructions) can withstand a process capable of sterilization using low temperature (≤55°C)
- These processes include ethylene oxide, hydrogen peroxide and peracetic acid.
- Accessory items capable of withstanding steam sterilization should be processed by this method

9.3.2 Sterilization of Rigid Endoscopes
- A rigid scope with external detachable optics can and should be sterilized by steam.
- Any scope that the manufacturer declares to be suitable for sterilization should undergo steam or other appropriate sterilization method (e.g. ethylene oxide and peracetic acid)
- Where sterilization is by a wrapped process, the packaging material or system used shall be in accordance with the method of sterilization used (as per manufacturers’ instructions)
- Consideration as to the ability of the endoscope to withstand steam/low temperature sterilization should be given prior to purchase of rigid scopes

Note: If items used for surgery will not tolerate sterilization, consideration should be given to the purchase of rigid scopes that can undergo a sterilization process, or single use items.
9.4 **Storage of Endoscopes**

9.4.1 **Storage of Flexible Endoscopes**

- The endoscopes must be thoroughly dry before being stored. Sterile isopropyl alcohol 70% or dry clean air should be used to assist forced air-drying of channels. This reduces bacterial growth during storage.
- Denatured alcohol, e.g. Methylated spirit should not be used for drying as it can damage components of flexible endoscopes. Some manufacturers do not recommend the use of alcohol, in which case it should not be used.
- Endoscope storage is preferably, by hanging at full length with insertion tube as straight as possible, on appropriate support structures, rather than coiled in a case.
- The storage conditions should be as recommended in (Chapter 1) for sterile items.
- After storage all endoscopes must be disinfected / sterilized prior to use.

9.4.2 **Storage of Rigid Endoscopes**

Rigid endoscopes that have undergone sterilization as a wrapped item shall be stored in accordance with [Chapter 2 (storage of sterile items)](https://example.com).
CHAPTER 10: LINKAGE WITH OTHER DEPARTMENTS

10.1 Laundry Services

See the IPC Manual for more details - the laundry services for the CSSD are summarized here.

Laundering of OT linen

Careful handling and reprocessing of soiled linens prevents the transmission of infectious agents. Therefore, all reusable gowns and drapes must be washed, disinfected and subsequently sterilized.

Where laundering of OT linen is on site, the CSSD is a significant stakeholder in the standard being routinely attained by those laundry processes, despite the laundering occurring ‘outside’ the CSSD. It follows that the CSSD needs to be able to refer to the appropriate guidelines if available and the Namibian Standards governing these laundry practices and ensure that all linen products meet the requirements.

10.1.1 Laundering Standards

- Wherever operating room linen is laundered on-site, effective liaison and communication between the CSSD and laundry personnel will be of great importance in achieving the necessary standards
- Written protocols for the day to day functioning of laundries which process operating room linen need to be established
- Laundries should adopt thorough inspection procedures to ensure that cleaned OT linen has minimum staining and textile damage prior to sterilization
- Infection control principles should be followed when handling contaminated linen

The following procedure in sorting linen should be followed:

- Follow standard precautions, use PPE
- Handle contaminated linen as little as possible with minimal agitation
- Soiled linen should be sorted before being loaded into washing machine units. This will protect both the machine and linen from the effects of the objects that may be present in the linen

10.1.2 Cleaning and Sterilization of Theatre Linen

- Soaps and detergents are used to loosen soil and remove dirt
- A prewash rinse of 15 minutes will remove gross soilage
• Hot water washing at a temperature of at least 71°C, for a minimum of 25 minutes is recommended. This provides an effective means of destroying vegetative forms of bacteria but not spores
• Addition of mild acid to neutralize any alkalinity in the water supply, soap or detergent. This is the last action performed during the washing process. It helps in decreasing skin irritation and further reduces the number of bacterial present
• Hot air drying or drying in sunlight will also reduce the number of bacteria present, as will ironing with a hot iron
• Clean linen must be stored and transported in such a manner that cross contamination is avoided
• Linen to be sterilized must be properly wrapped before being sent to the sterile processing department.
• A function check of the sterilization machine must be performed before the sterilization process
• A validated process must be used to determine when reusable textiles have to be withdrawn from use.

Note:
- Low linting fabrics are preferred since lint may impair wound healing because of reactions to foreign bodies. Therefore non-woven fabrics are recommended.
CHAPTER 11: DISASTER MANAGEMENT

11.1 Purpose

To provide an emergency plan for internal emergencies that will ensure the safety of all staff, patients and visitors. All CSSD staff should be committed to a policy of emergency preparedness for the benefit of all occupants and visitors.

Disaster Committee

All internal and external disasters will be coordinated by the Disaster Committee.

The committee will consist of the following people:

- Senior Medical Superintendent (SMS) / Senior Medical Officer (SMO)
- Senior Control Registered Nurse in charge
- Control Administrative Officer
- Community Health Representative
- Environmental Health Officer
- Transport Clerk
- Representative from the local Fire Brigade Department

a) In order to cope with a disaster all staff should:
   - i) Be aware of what is required of them
   - ii) Know who is in control
   - iii) Know the location of all emergency equipment
   - iv) Know the emergency exits and evacuation routes
   - v) Be constantly aware of hazards
   - vi) Do not panic
   - vii) Not make statements to the press

b) Internal disaster
   - i) Important safety rules:
     - Keep all areas neat, especially storerooms.
     - Discourage loafers and vagrants
     - Control visitors
     - Ensure that contractors conform to safety regulations
     - Maintain equipment on a regular planned basis
     - Train staff to be aware of dangers
   - ii) Control of fire
     - It is important that every employee understands the dangers in the hospital as well as the procedures to be followed should a fire break out.
     - All personnel, patients and visitors have a responsibility to ensure the safety of others.
Fire hazards within a hospital
- High technology equipment (explosions) – autoclaves, computers
- Electrical equipment (electric fires) – polishers, medical equipment
- Linen – foam rubber mattresses
- Building in general – ceilings, oxygen ports and lines, cylinders
- Dangerous substances – theatre gases, cleaning fluid, alcohol

Techniques for extinguishing fires
- Smothering
  A fire is smothered by reducing or cutting off the oxygen through the use of blankets, sand, foam and dry powder fire extinguishers.
- Starvation
  A fire can be starved by either removing the source (material burning) or by moving the fire to a safe area.
- Cooling
  Burning material can be cooled to below its combustion point. Water is a suitable coolant.

Types of fire
- Class A
  General fire of wood, paper, etc. and can be extinguished with either water or foam.
- Class B
  Burning, flammable liquid, that can be extinguished with dry powder or foam.
- Class C
  Fires where electricity is involved must be extinguished with dry powder or foam.

NB: DO NOT USE WATER ON AN ELECTICAL FIRE
- Class D
  Gas fires that include products that release gasses when burning must be extinguished with dry powder or foam.

Using a fire extinguisher
All staff must be aware of the position of the nearest firefighting equipment.

- Remove from the fixture
- Break the seal
- Remove the safety pin
- Press the trigger to test
- Aim at the base of the fire and press the trigger
- Move from left to right

Recommended distance form fire is 3 to 4 meters.

- **Important aspects to remember when confronted by a fire**
  - Do not panic
  - Do not run
  - Do not turn your back on the fire
  - Move as low as possible
  - Contact the switchboard
  - Close all windows and doors
  - Attempt to control the fire
  - Activate the fire alarm if available

**iii) Evacuation procedure**

- **General guidelines**
  - An evacuation will follow as a result of a fire, flood, bomb or other disaster that requires patients to be moved to a safer environment
  - An evacuation will only take place on the instruction from the Disaster Committee
  - It must be done in an orderly fashion
  - Be familiar with all the possible routes and exits
  - All staff has to move to central points in their units
  - The area manager will then allocate tasks
  - All staff not allocated specific tasks must report to the assembly area to await further instructions
  - Patients are our responsibility and must be evacuated as a matter of priority
  - Do not panic

- **Responsibilities of the Area Manager**
  - Ensure calm evacuation of the area
  - Ensure safety of all patients
  - Ensure compliance with procedures
  - Ensure that all persons have left the building
Ensure that the second in command is aware of his/her function in the absence of the area manager

- **Specific Departmental Tasks**
  - Pharmacy must remove important stock to the assembly area
  - Emergency unit must set up a first aid post at the assembly area
  - Laundry staff must take all available bedding to the assembly area
  - Maintenance department must shut off power and gas supplies and supply portable oxygen
  - Financial officer must remove important financial documents
  - Human resources officer must take the current staff list of all on duty
  - Administrative staff must assist with the moving of patients
  - Kitchen staff must assist with the moving of patients
  - OPD staff and theatre staff must assist with patients arriving from the wards at the assembly point
REFERENCES


