وزارة الصحة
Ministry of Health

الإدارة العامة لمكافحة عدوى المنشآت الصحية

General Directorate of Infection Prevention and Control in Healthcare Facilities

(GDIPC)

Sterilization Services Manual

V.1 2024

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In the name of ALLAH, Most Gracious, Most Merciful

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Table of Abbreviations:

CSSD	Central sterilization service department
IPC Department	Infection prevention and control department
HLD	High level disinfection
IFU	Instructions for use
PPM	Planned Preventive Maintenance
OPA	Ortho-phthalaldehyde is a chemical compound commonly used as a high-level disinfectant in healthcare settings. It's effective against a wide range of microorganisms, including bacteria, viruses, and fungi
IPC	Infection prevention & control
SSU	Sterilization service unit
ERU	Endoscopy reprocessing unit
HLD	High level disinfection
IFU	Instructions for use
AER	Automated endoscopy preprocessor
IPC committee	Infection control committee

Table of Abbreviations:

Shelf Life

Length of time a stored or in-use product/solution can remain active and effective. Also refers to the length of time a sterilized product (e.g., sterile instrument set) is expected to remain sterile.

Event-related Shelf-Life

a storage practice that recognizes that a package and its contents should remain sterile until the package is potentially contaminated through rough handling or evidence of moisture (e.g., discolored, or stained packaging or dropping).

Spaulding Classification

Strategy for reprocessing contaminated medical devices. The system classifies a medical device as critical, semi-critical, or non-critical based on risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilization, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical).

Spore

Relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions.

Sterile or Sterility

State of being free from all viable microorganisms. In practice, usually described as a probability function, e.g., as the probability of a viable microorganism surviving sterilization being one in one million.

Sterilization

Level of reprocessing required when processing critical medical devices. It results in the destruction of all forms of microbial life including bacteria, viruses, spores, and fungi.

Sterilizer, Pre-Vacuum Type

Type of steam sterilizer that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air. This method of operation results in shorter cycle times for wrapped items because

of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (135–132oC). This type of sterilizer generally provides for shorter exposure time and accelerated drying of drape and packaged loads by pulling a vacuum during the exhaust (drying) phase.

Bactericidal

Agent that kills bacteria.

Bowie-Dick Test

Diagnostic test of a sterilizer's ability to remove air from the chamber of a steam sterilizer with dynamic air removal. The air-removal or Bowie-Dick test is not a test of sterilization.

Chemical Indicator (CI)

A non-biological indictor test system designed to respond with a chemical or physical change to one or more of the conditions in the sterilizing chamber. CI is categorized according to their intended use, i.e., differentiation between unprocessed and processed items, specific tests and or procedures; assess the attainment of the process parameters. CIs are expressed in six types and categories (see section on routine monitoring for further information).

Biological Indicator (BI)

a device to monitor the sterilization process that consists of a standardized, viable population of microorganisms (usually bacterial spores) known to be resistant to the mode of sterilization being monitored. Biological indicators are intended to show whether the conditions were adequate to achieve sterilization. The biological indicator must match the type of sterilization process. Geobacillus stearothermophilus spores are used for steam while Bacilllus atrophaeus is appropriate for dry heat sterilizers.

Detergent

Cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipophilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.

Disinfectant

Usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens. It refers to substances applied to inanimate objects.

Disinfection

Thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).

Enzymatic Detergent

A cleaning agent that contains enzymes (e.g., protease, amylase, lipase) that break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment. They are used to loosen and dissolve organic substances prior to cleaning. The agent may use a single enzyme or multiple types of enzymes.

Exposure Time

Period in a disinfection or sterilization process during which items are exposed to the disinfectant or sterilant at the specified use parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.

High-level Disinfection (HLD)

Destruction of vegetative bacteria, viruses, fungi, and mycobacteria in or on devices, except for small numbers of bacterial spores.

Low-level Disinfection (LLD)

Level of disinfection that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some non-lipid viruses, and some fungi, but not bacterial spores.

Personal Protective Equipment (PPE)

Specialized clothing or equipment worn by a healthcare worker (HCWs) for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts) not intended to function as protection against a hazard is not considered to be PPE. PPE includes thick general-purpose gloves, fluid resistant covering with long sleeves, fluid resistant mask, eye protection and hair covering.

Physical Monitoring

Use of a mechanical device to monitor the physical conditions of the sterilization process (e.g., graphs, gauges, printouts).

Prions

Transmissible pathogenic agents that cause a variety of neurodegenerative diseases of humans and animals, including sheep and goats, bovine spongiform encephalopathy in cattle, and Creutzfeldt-Jakob disease in humans. They are unlike any other infectious pathogens because they are composed of an abnormal conformational isoform of a normal cellular protein, the prion protein (PrP). Prions are extremely resistant to inactivation by sterilization processes and disinfecting agents.

Reusable Medical Device (RMD)

Devices intended for repeated use on different patients with appropriate decontamination and other processing between uses.

Barrier

An impervious material that prevents the penetration of microorganisms, particulates, and fluids.

Biofilm

Microbial communities that are characterized by cells attached to a substrate or to each other, are embedded in a matrix of extracellular polymeric substances (glycocalyx) and exhibit increased resistance to dislodgment during cleaning and disinfection and to the effects of antimicrobial agents.

Engineering Controls

Controls that isolate or remove a hazard from the workplace (e.g., sharps disposal containers, safer medical devices such as sharps with engineered sharps injury protections such as self-sheathing needles or scalpels).

Medical Waste (Regulated)

Waste sufficiently capable of causing infection during handling and disposal (e.g., blood-soaked or saliva-soaked cotton rolls, sharp items such as needles, and surgically removed hard and soft tissues) to merit special handling and disposal.

Physical (Mechanical) Indicator

Automated devices (e.g., graphs, gauges, printouts) that monitor the parameters of the sterilization process.

Spatter

Visible drops of liquid or body fluid that are expelled forcibly into the air and settle out quickly, as distinguished from particles of an aerosol, which may remain airborne indefinitely.

Peracetic Acid

Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. Peracetic acid removes surface contaminants (primarily protein) on endoscopic tubing .An automated machine using peracetic acid to disinfect medical, surgical, and dental instruments chemically (e.g., endoscopes, arthroscopes).

Rigid Endoscope

Rigid endoscopy is a medical procedure that involves using a rigid tube-like instrument, called an endoscope, to visually examine the interior of the body, typically through natural openings or small incisions. It's often used for diagnostic and surgical purposes, allowing physician to view and sometimes treat various conditions within the body.

Flexible Endoscope

A flexible endoscope is a medical device that consists of a long, thin, flexible tube with a light and camera attached to its tip. It is used to visualize and examine the internal structures of the body, such as the gastrointestinal tract, respiratory system, or other cavities, without the need for invasive surgery. The flexibility of the endoscope allows it to navigate through curves and bends, providing real-time images to healthcare professionals for diagnosis and treatment.

Manual Cleaning

Manual cleaning for surgical instruments refers to the process of physically removing visible dirt, debris, blood, tissue, and other contaminants from surgical instruments by using specialized brushes, sponges, and detergents. This initial step is crucial to ensure that instruments are thoroughly cleaned before undergoing further sterilization or disinfection processes.

Cleaning Solution

For cleaning endoscopes, a specialized cleaning solution such as enzymatic cleaner or enzymatic detergent is commonly used. These cleaners are designed to break down and remove organic debris, such as blood, tissue, and mucus, from the surfaces of endoscopes effectively. A cleaning agent that contains enzymes (e.g., protease, amylase, lipase) They are used to loosen and dissolve organic substances during cleaning. The agent may use a single enzyme or multiple types of enzymes.

HLD Solution

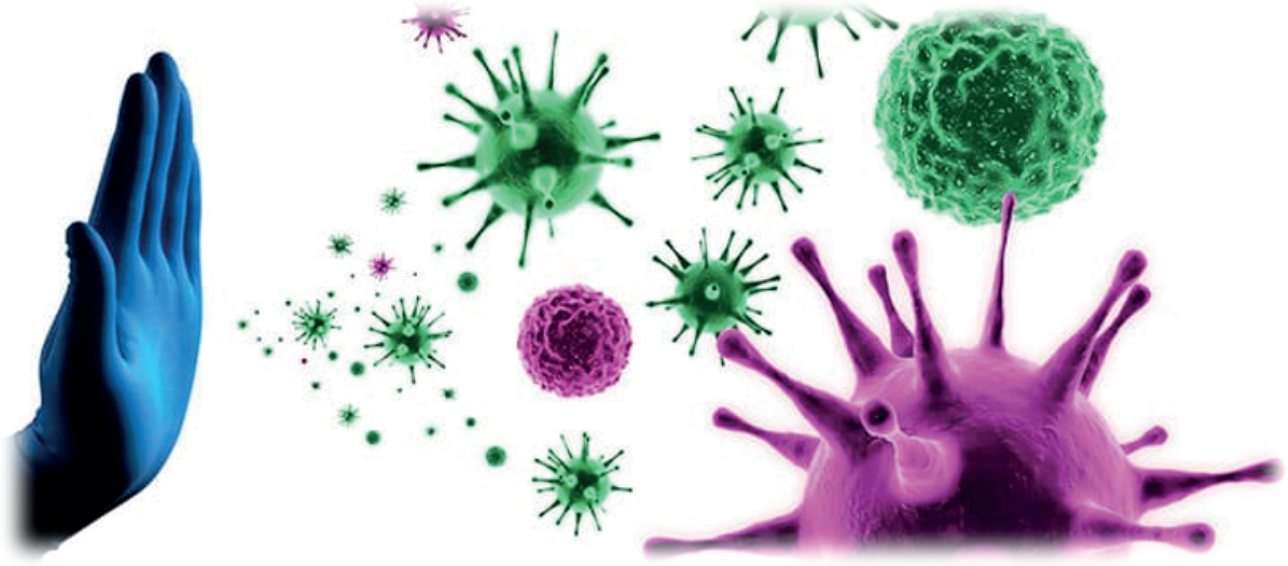
High-level disinfection solutions are a chemical substance are commonly used in healthcare settings to disinfect critical and semi-critical medical equipment and instruments that come into contact with mucous membranes or non-intact skin. It is an important process to prevent the transmission of infections and maintain patient safety.

Transportation Container

Transportation containers for endoscopy equipment are specialized cases designed to securely transport delicate and sensitive endoscopic instruments, cameras, and accessories. These containers typically have custom compartments that provide cushioning and protection to prevent damage during transportation. The usage of this container to transfer the endoscopes from and to the ERU.

CHAPTER I

Basic Infection Prevention & Control Measures in Sterilization Services



Applying infection prevention & control is crucial as it plays a vital role in preventing the spread of infections. It helps maintain a safe and healthy environment, protects individuals from infections, and minimizes the risk of healthcare associated infections outbreaks in various healthcare settings. Accordingly, effective infection prevention & control measures are essential for safeguarding patients and healthcare workers among healthcare facilities. Considering this, implementing these measures extends to the sterilization departments and units within healthcare facilities to ensure the quality and safety of both patients and healthcare workers.

Standard Precautions:

Implementation of infection prevention protocols for patients undergoing invasive surgical procedures is extremely important in preventing surgical site infections (SSIs). These are initiated in sterilization unit by maintaining a hygienic environment and achieving adequate sterility of reusable medical devices (RMD). To achieve this goal, we need to apply the standard precautions which are the minimum infection prevention practices that apply to all patient care or related measures, regardless of suspected or confirmed infection status of the patient, in any setting where health care is delivered. These practices are designed to both protect patients and healthcare workers which include following:

Hand Hygiene (HH):

- Hand hygiene stations including hand washing sinks with hands-free controls, soap, hand sanitizer dispensers, and paper towels should be located in or near to all work areas including changing rooms, and in the entrance of the decontamination area and inspection, assembly and packaging area (IAP) etc.
- Not allowed to have hand washing stations inside IAP area and sterile storage area.
- Staff must perform hand hygiene before entering of the sterilization services unit (SSU) & starting the work shift.
- In case of gloves tear with accumulation of fluid inside the gloves or visible contamination on hands during the decontamination process, sterilization services unit staff must immediately remove gloves and perform hand washing with antiseptic soap & water.

o To enable effective hand hygiene:

  - Nails must be kept clean and short.
  - Artificial nails or nail enhancements must not be worn.
  - Hand and arm jewelry, including watches, must be removed before performing hand hygiene.

- Sterilization services unit technician should keep fingernails short and clean at all times.
- For female staff, nail polish or acrylic nails are not allowed during the duty hours.

Personal Protective Equipment (PPE):

- In the sterilization services units, wearing the PPE should be strictly followed based on infection prevention and control standards which are as the following;
  - Sufficient and appropriate personal protective equipment's (PPEs) are available in adequate amount, types, and sizes with proper qualities & easily accessible to the healthcare workers. (Heavy duty gloves, face shields /eye goggles, impermeable gowns/aprons etc).

- Full PPE should be worn in the decontamination area.
- SSUs technician must be trained on the correct donning and doffing practices including sequence, technique, safety & disposal.
- In the Inspection, assembly, packaging area and sterile storage, head cover and clean scrub suite are required.

When choosing PPEs, the following points need to be considered:

- Gloves should be long enough to cover wrists and forearms, sufficient weight to be highly tear-resistant, and allow adequate dexterity of the fingers.
- Gown should protect skin and clothing from the hazardous chemicals. Secured gown that cover torso, neck to knee, and arm to the end of wrists must be used.
- Mask should be fit covering mouth, nose, chin properly and N95 respirator should be fit tested every 2 years or according to national regulation.
- Face shield / goggles must fit properly, face shield should cover the eye, forehead and extend below the chin. Must possess features of anti-fog to help maintain clarity of vision.
- Dedicated shoes with appropriate fit must be used to serve as a barrier against accidental splashes.

- All personal protective equipment (PPE) must be of high-quality material to ensure protection against potential contact with respiratory secretions, chemicals fumes and vapors, and blood or body fluids etc.
- SSU staff should never touch face or adjust PPE with contaminated gloves and minimize unnecessary touching of items & surfaces.
- PPE is removed on completion of the task for which it was indicated before leaving the reprocessing area followed by hand hygiene.

Dress Code:

- SSU technicians should wear clean medical attire (scrubs), dedicated shoes, disposable hair caps.
- Attire should be changed daily, after each shift or as needed if visibly contaminated with blood or other potentially infectious material.
- Scrubs should be laundered appropriately after each use.
- SSU staff should not wear jewelry (rings, bracelets, watches etc.) during duty hours.
- SSU staff should change their medical attire upon leaving the department.
- Visitors dress code in the clean area are (yellow-gown, head-cover, dedicated shoes) and for dirty area full PPE.

Environmental Hygiene:

- Environmental cleaning and disinfectant agents must be approved by MOH to be used in the healthcare facilities.
- Environmental cleaning is not allowed during sterilization process due to possibility of spread dust to reusable medical devices (RMD).

1. Environmental Cleaning Methods:

- Floor are swept & wet mopped at least after each decontamination procedure in the decontamination area or when required.
- Floor are swept and wet mopped at least after each shift in the cleaning area or when required.
- All areas must be free of dust, and insects etc.
- The process of cleaning should be from clean areas to dirty areas, from high areas to low areas (i.e., top of walls to floor) and from least contaminated to most contaminated.

- In case of hazardous biological spill etc. disinfection must be performed immediately using the spill kit according to the steps of biological spill management.
- In case of hazardous chemical spill, the appropriate management should be based on the hospital internal policy and based on the approved references.
- High touch horizontal surfaces must be cleaned and disinfected at the beginning and end of each shift & more frequently during the shifts or when required e.g., tabletops, counter tops etc.
- Decontamination sink should be cleaned after each shift and more frequently as needed.
- Worktables preferably cleaned before starting the sorting process in the decontamination area & Inspection process in the inspection & packaging (IAP) area or when required.
- Shelves, cabinets, racks, wall, and ceiling are cleaned based on regular cleaning schedule using a checklist.
- Offices, changing /locker room etc, are cleaned at least daily or when required.
- Light fixtures, and air vent should be cleaned at least every six months or as necessary, and the air vent filters must be changed based on the manufacturer instructions.

2. Environmental Cleaning Equipment:

- Cleaning equipment's are separate and dedicated for each area. (e.g., mops and bucket).
- Cleaning equipment must be kept clean and dry & are appropriately stored after use.
- Mop heads must be appropriately laundered after each use or disposed of if single use.

3. Environmental Cleaning Schedule:

- All cleaning activities must be performed according to the approved cleaning schedule with specified frequency for each area.
- Cleaning activities must be documented using a checklist that include cleaning frequency, responsible worker, used agents, methods & environmental surfaces intended to be cleaned.
- Quality of the cleaning activities should be regularly monitored by SSU supervisor & environmental services supervisor.

WASTE MANAGEMENT:

- Yellow hazard waste container, sharp containers, and regular black container should be available in sufficient numbers, and to be in a place that is easy to reach and access.
- If single-use sharp objects are received, they should be disposed into the sharp container.
- Biological indicator vails, empty plasma cassettes, and single use instrument are disposed appropriately based on the approved national medical waste regulations.
- Personal protective equipment's (PPEs) and regular waste disposed into the black regular waste container and based on the approved national medical waste regulations.
- Waste should be segregated accurately that no medical waste inside the regular waste container or regular waste inside the yellow medical waste container.

Sterilization Services Unit Staff Qualification & Safety:

Training and Education:

- SSU technicians must be qualified by owning certain certifications, training or experience and have comprehensive knowledge in all aspects of sterile processing.
- SSU staff must be well trained in all infection prevention & control protocols including biohazard transportation, decontamination, inspection, packaging, sterilization & storage.
- SSU staff must be knowledgeable about updated infection prevention & control standards to be followed during all stages of sterile processing.
- Functional analysis, risk factors, and best practices will achieve successful productivity.
- SSU staff must fully understand their roles and responsibilities with efficient implementation of all policies and procedures in order to produce a high-quality sterilization measure for patient use.
- The SSU must be a member of the IPC committee that include interdisciplinary team that collaborates to provide safe, efficient, cost-effective, and high-quality reprocessing.

Occupational Health and Safety:

An occupational health and safety review is recommended for all protocols for reprocessing of medical equipment / devices to verify that staff safety measures are followed and are based on the national occupational health and safety regulations and guidelines, this review will verify the following:

1. Fire Safety:

- Attention must be paid on the fire safety guide inside the SSU for the electrical and chemical hazards that may occur during sterilization processes.
- SSU technicians should be trained to deal with fire incident plan by knowing the fire alarm, emergency code, and the emergency exits.
- SSU technicians should be trained to use the fire extinguisher that belong to the SSU.

2. SSU Staff Health:

- According to the occupational safety and health administration (OSHA) regulations, and the national guidelines of the occupational health program that all employees who are dealing with potentially contaminated items should receive hepatitis B immunization.

- Occupational health clinic should offer certain vaccines for HCWs including SSU technicians for the purpose of diseases prevention as per institutional policy (mumps-measles-rubella, varicella, influenza, tetanus-diphtheria, etc.) and other vaccines based on the national regulations & standards.

3. Sharp Injury:

- All sharp injuries from sharp instruments including sharp skin hook, broken metal instruments etc… must be reported.
- Sharp needles and blades should not be received in SSU; If incidentally have been sent, so they need to be placed in sharps container.

- Take care when handling glass and other fragile objects.
- In case of needle stick injuries incidents, the following procedure must be followed:
  - Do not be panic.
  - Stop immediately the procedure you perform.
  - Dispose properly the contaminated gloves.
  - Dispose the sharp instrument in the sharp container.
  - Encourage the wound to bleed, ideally by holding it under running water.
  - Clean the wound with running water/ soap.
  - Apply waterproof dressing.
  - In case of splashes to the eyes, nose or mouth irrigate with clean water, saline, or sterile irrigants.
  - Identify the patient involved for an appropriate management.
  - Immediate reporting.

4. Chemical Hazards:

- Chemicals must be labeled, stored, and handled appropriately under the supervision of the safety department.
- Use Safety Data Sheets (SDS) and keep it readily available.
- Use defined, written procedures and methods for handling and storage of process chemicals.
- Clearly identify chemicals that should not be stored together.
- Store chemicals below shoulder height and choose the correct size of safety cabinets.
- All personnel who handle detergents, rinse aids, disinfectants, or any chemical solutions must be aware of the hazard classification of each chemical use and take a full training course on this subject.
- Follow emergency procedures and protocols and manage hazardous materials for spill hazard as per policies & procedures for spill management:

- Get help and put warning signs in place where the incident has occurred.
- Collect the spill kit.
- Follow protocol precisely.
- Check the material safety data sheet if indicated.
- Put on PPE and assemble cleaning equipment.
- Clean the spill.
- Dispose of waste appropriately.
- Replenish supplies.
- Complete an incident or adverse occurrence report.

5. Emergency Eyewash Station:

- An eyewash station, separate from other cleaning facilities/sinks, is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent and it should be in decontamination area.
- It must be available with unobstructed access for immediate use within a travel time of 10 seconds or accessible within 30 meters of areas of potential chemical exposure.
- The American national standard Institute and sterilization services national standard established a minimum specification for eyewash station:
  - It should permit hand-free operation and have a stay-open feature to flush both eyes.
  - It should be tepid, not too hot, or too cold to prevent burn to the eyes.
  - It must be regularly tested and documented.
  - Technicians must follow the SDS instructions for a chemical reaction.
- If blood or blood products contact eyes, rinse the eyes gently but thoroughly, for at least 30 seconds, with water.
- If blood or body fluids are sprayed into the mouth, spit out and then rinse the mouth with water several times.

CHAPTER II

Central Sterilization Services Department (CSSD)

Central sterilization services department (CSSD) is an area responsible for reprocessing instruments and other reusable medical devices (RMD) among hospitals. The process involves handling, collecting, transporting, sorting, disassembling, cleaning, disinfecting, inspecting, packaging, sterilizing, storing, and distributing reprocessed items. The goal is to provide safe, functional, and sterile instruments and medical devices and reduce the risk for healthcare associated infections.

General Principles of CSSD Best Practices:

- CSSD is a centralized area for reprocessing surgical instruments and equipment's.
- Written policies and procedures for reprocessing each type of reusable medical device (RMD).
- Training of all staff who perform reprocessing at initiation of employment and at least yearly.
- The scope of service in the CSSD should be for the RMD that needs to be sterilized or high-level disinfection only. Other devices requiring low or intermediate-level disinfection or other processes are not the CSSD responsibility.
- Verification of cleanliness, decontamination or sterility and function of the reprocessed equipment and device.
- Continual monitoring of reprocessing procedures to ensure their quality.
- Management and reporting of medical incidents and safety-related accidents.
- Complete and proper documentation of all reprocessed items for traceability, recall of improperly reprocessed devices and legal purposes.
- Procedures to be followed in emergencies (e.g., utilities shutdowns, compromised packaging, biological indicator testing failures).

National Criteria for CSSD Staffing Level:

IPC committee	Required Number of CSSD Staff
Hospitals with bed capacity >100 beds	One CSSD staff for every **50 beds.**
	An additional 1 CSSD staff per average of **100 Surgical Procedures done per month.**
	Minimum required numbers is **5 CSSD** staff at least.
Hospitals with bed capacity ≤ 100 beds	One CSSD HCW for every **20 beds.**
	An additional One CSSD HCW per average of **100 Surgical Procedures done per month.**
	Minimum required numbers is **3 CSSD** staff at least.

CSSD Design / Infrastructure :

Design Layout:

CSSD construction requires an in-depth knowledge of operational CSSD experts, biomedical engineers, Infection control expertise with collaboration & approval of infection control committee. CSSD infrastructure should be developed under specific approved standards and MOH guidelines must be reviewed before any planned CSSD construction.

- Sterilization services MUST be centralized in one UNIT/ Department and none of the sterilization activities are carried out by individual departments outside CSSD. In general, there must be a centralized area for reprocessing of reusable medical devices (RMD)
- Adequate space in CSSD is critical to provide for a good workflow and efficient and effective processes that promote staff safety, standardize procedures, minimize environmental contamination, and maintain the sterility of processed items.
- The size of the CSSD should be appropriate for the volume of work being performed, the processes being conducted, the types of services provided, and the amount of equipment required to perform the required tasks.
- CSSD must have physical barriers with clear demarcation for clean and dirty areas. There must be complete physical separation between the clean areas (i.e packaging, sterilization & storage areas) and decontamination area with demarcation signs posted for each zone (2 or 3 zones).
- Ideally, the decontamination area should have a three-section sink for cleaning (one section for cleaning, one for initial rinsing, and one for final rinsing). The sinks should be approximately 36 inches from the floor and 8 to 10 inches deep. The sink should be large enough to place a tray or container basket of instruments flat in the sink and the area should have a source of critical water for the final rinse

- Walls should be constructed of non-particulate, non-fiber shedding materials to withstand cleaning & disinfection etc.
- The ceiling in the restricted area should be constructed of enclosed fixtures hold all pipes and ductwork.
- The door should be made of a durable, smooth, and cleanable material.
- Doors should open easily following the one-way directional workflow.
- Floors should be level and constructed of non-particulate, non-fiber shedding materials to withstand daily cleaning & disinfection activities.
- The work surfaces should be covered with a nonporous material that can withstand frequent cleaning with germicides.
- Lighting fixtures should put into a selected position to facilitate the work.

Traffic Control and Workflow:

- CSSD should be away from the main traffic pattern and restricted to the authorized personnel identified ONLY based on the facility's policies and procedures.
- Visitors must be accompanied by authorized personnel during their professional visit to the CSSD restricted areas (e.g., decontamination, preparation, packaging, sterile processing, and sterile storage).
- Healthcare workers in these areas should wear medical attire (scrubs) and dedicated shoes, and their head and facial hair (except eyebrows and eyelashes) should be covered.
- Areas, including locker rooms, break rooms, meeting rooms, offices, and sterilizer service access rooms may be limited based on the facility's policies and procedures.
- CSSD areas must be physically separated at least two zones to prevent cross-contamination.
- This arrangement reduces the risk of cross contamination of areas and the items being sterilized, which both improves safety and increases the efficiency of sterile processing operations. In hospitals, the decontamination, packaging, sterilization, and sterile storage area/rooms should be physically separate to eliminate environmental contamination.

- The workflow processes allow items to move progressively from the dirty phase to the high disinfection phase. Then from the safe handling phase to the final phase.
- CSSD technicians should be organized so that activities and objects flow in a unidirectional way & sterilization process is never circumvented.

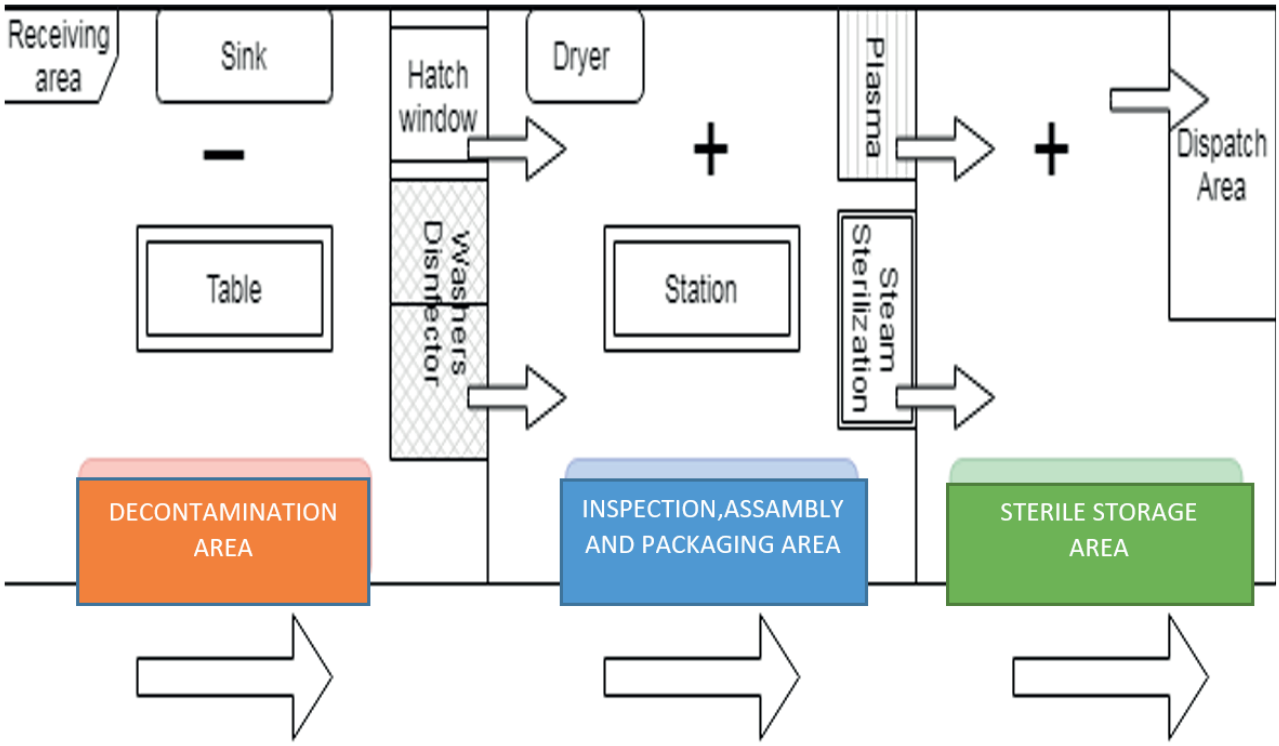


Figure 1: CSSD Workflow, Design, Area's Pressure

Environmental Control Parameters:

AREAS	TEMPERATURE	PRESSURE	EXCHANGES/HOUR	HUMIDITY
Decontamination Area	°16C - °18C	Negative	A Minimum 10 AirExchanges/Hour	30%-60%
Inspection, Assembly, & Packaging (IAP) Area	°20C – 23 °C	Positive	A Minimum 10 Air Exchanges/Hour	30%-60%
Sterile Storage	°20C – 23 °C	Positive	A Minimum 4 Air Exchanges/Hour	30%-60%

Table1: CSSD Environmental Control Parameters

CSSD procedure cycle distribute the sterile reused medical devices and supplying sterilized products to various departments such as operation theatres, critical care departments, emergency department and wards etc.

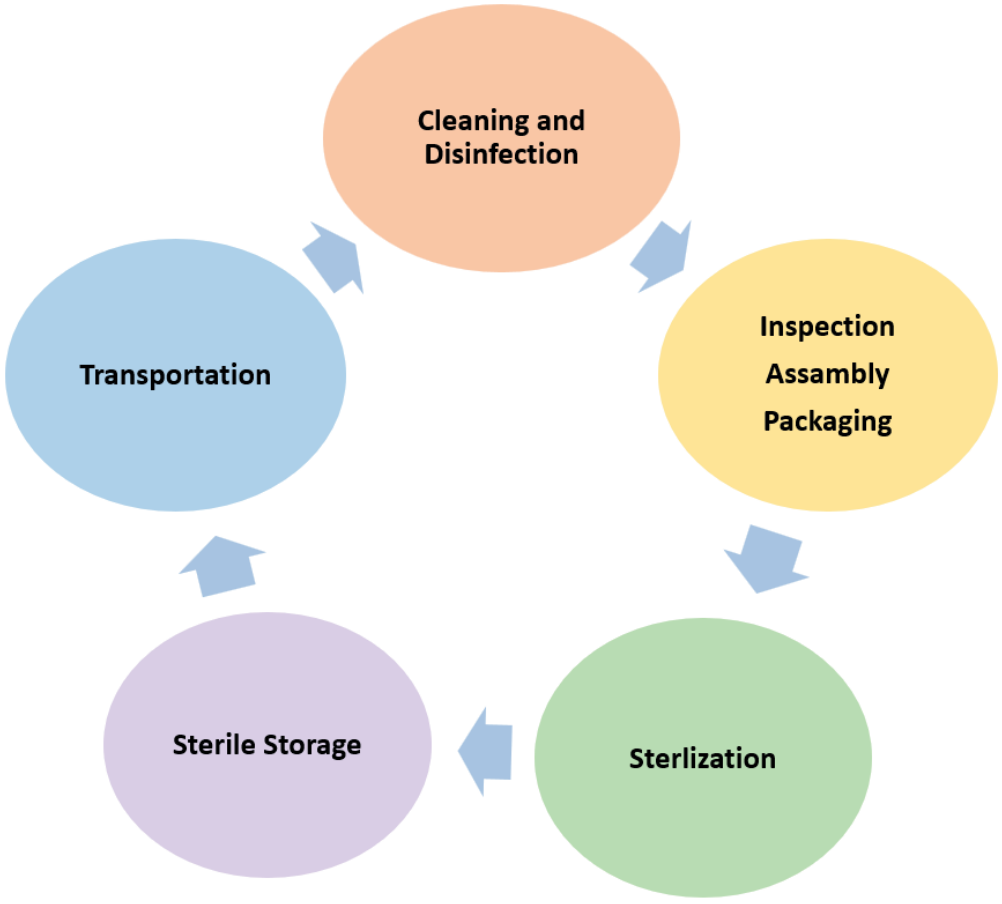


Figure 2: The CSSD procedure cycle

Safe and effective handling of reusable medical devices (RMD) will ensure the following:

- Prevent transmission of microorganisms to patients and health care workers.
- Minimize damage to RMD from foreign material (e.g., blood, body fluids, saline and medications etc) or inappropriate handling.
- Protect health-care workers from injury during use of hazardous chemicals.
- Produce high quality RMD/ end product to the required level of sterilization / disinfection for safe reuse.

Point of Use Cleaning / Pre-Cleaning:

- The reprocessing of contaminated equipment or instruments for sterilization begins at the point of use. Assigned staff must separate instruments into reusable items to be sent for the CSSD, single-use items to be disposed of in a proper waste container with a biohazard label.
- The end user is responsible for the immediate pre-treatment by removing gross soil and debris by spraying with transform gel in operation set to reduce the risk of dried gross soil including tissue, body fat, blood, and other substances.
- RMD that need repair should be identified by tag before sending it to the CSSD and notified.
- Containers must be located in a soiled utility room that has controlled access, and clearly identified with biohazard labels to identify the risk associated with carrying dirty instruments.
- Before contaminated items are transported to CSSD, they should be placed in puncture-resistant leak proof sealable containers and visibly labeled as biohazardous.

Transportation of Contaminated RMD to CSSD:

All contaminated Items must be transported to the CSSD for reprocessing in a covered container or closed cart with ideal characteristic such as:

- Transportation carts should be equipped with a secured lid to prevent spread of infection & instruments from falling over.
- Carts should be Leak-proof to prevent accidental spillage of contaminated fluids.
- Transportation carts should be easily cleaned, disinfected, and dried to prevent recontamination in the second rotation.
- Contaminated instruments should be transported on a rotational basis by direct routes far from public traffic or through dedicated elevators.

- Transportation staff must consider the risk associated with hazardous items & wear the proper PPE.
- PPEs and biohazards material spill kits should be available in the vehicle, and if only one vehicle is available, it must be decontaminated before using again to transport clean or sterile items.
- Keep the cart closed at all times except during loading and unloading.
- During transportation, never leave the trolley or transportation cart unattended

The Transportation Policy and Procedures of Reusable Medical Devices (RMD) Out-Side The Hospital:

Transportation of reusable medical device (RMD) from CSSD facility to another CSSD facility out of hospital, need to be monitored and controlled under strict conditions to prevent cross contamination and to assure that items are securely contained without spillage or damage. CSSD worker must consistently follow safe transportation procedures. A clear agreement or formal document should be announced and approved by all involved hospitals higher authorities to clarify the situation and notify the frequency of collection and transportation and follow the agreed measures.

1. Protocols for Outside Transportation of Soiled RMD are as the Following:

- From the point of use to the planned holding area, transportation can be done in two ways:
  - Hand transport in a puncture-resistant, leak-proof, biohazard sign, and sealed containers that should be carried in a position parallel to the floor.
  - Cart /Trolley transport that can prevent falling over during transport, secured and closed, easy and smooth wheels, and withstand frequent disinfection.
- Place containers in the planed holding area organized and secured for the pick-up.
- Transporters must wear gloves, protective gown and mask at soiled utility room while handling the containers to load it in the transportation cart.

- Responsible staff must wear appropriate PPE & perform hand hygiene.
- Count the number of items that are being transferred.
- At the time of transfer of contaminated RMD, a biohazard label sign should be tagged on the cart.
- Transporter should use the service corridors or service elevators (avoid use the patients and visitor hallway) to reach the vehicle.
- Place contaminated containers and packages in an organized secure way in the transportation vehicle with strict adherence to the safe handling precautions (glove, mask) & perform hand hygiene subsequently.
- Driver must be instructed to drive gently and carefully to avoid spillage or damage to the RMD.

2. Protocols for Outside Transportation of Sterile RMD are as the Following:

- The transporter must perform hand hygiene before handling sterile items.
- After sterilization process assigned technician should minimize the handling to maintain sterility of sterile packs and containers.
- Transporter must disinfect the trolley before transporting the sterile packages and sets.
- During transportation outside, possible negative impact of environmental temperature and humidity that may compromise the integrity of the packages MUST be considered.
- For small packs it is recommended to cover it with dust cover and for big packs it is prefer to put the RMD inside designated bin or closed trolley.
- In case of any negative impact including wet pack the entire packs/sets must be returned back to the reprocessing area (decontamination area).

3. Vehicles Specifications:

- Provide complete separation of contaminated items from sterile items.
- Allow for ease of loading and unloading items.
- Allow for easy cleaning and disinfection after use with no seats.
- Always remain closed except during loading and unloading and should not be left unattended in unsecured areas.

Decontamination Area:

Receiving Contaminated Instruments:

- **Once the CSSD technician receives the instrument, the following must be ensured:**
  - All items/instruments must be clearly identified with a label stating the name of the sending department/s.
  - Quantity needs to be documented manually or by the tracking system.
  - Manual or electronic system is available for all received items. Information MUST include: Sender / Receiver ID, Department's name, RMD sets and packages names, Date, Time & quantities etc
  - Sorts disassemble, and segregate the RMD according to IFU.
  - Report any damage, missing, or defected RMD. Accidental sharp objects must be reported & safely disposed of in sharp containers.

Manual Cleaning:

1. Cleaning Technique:

- Cleaning is the removal of foreign material from objects and is normally accomplished using water with detergents or enzymatic products. First and the most important step in reprocessing reusable medical devices is thorough cleaning and rinsing.
- Cleaning must be performed immediately once the instruments are received to reduce the formation of biofilm that adheres to surfaces of the instruments and presoaking if applicable.
- All visible and non-visible soil that adheres to the surfaces of instruments interferes with the effectiveness of disinfection and sterilization if not cleaned.
- Manual cleaning must be done before any mechanical cleaning to remove all visible soil for effective disinfection and sterilization.

- Cleaning solution and water must be change when it is visibly soiled, which might be after one use to prevent soil particles from re-depositing on instruments.
- For all powered surgical devices, including Electric-Powered, Pneumatic-Powered, Battery-Powered, and other complex instruments including lumen and reamers, delicate eye devices, lenses, and fiber optic devices, it is critical to follow exactly the specific manufacturer's IFU.
- Similar devices may require very different processing procedures for cleaning.
- A technician should separate general operating instruments and utensils from delicate instruments that require special handling.
- Disassemble all complex devices and open all jointed instruments.
- Whether done manually or mechanically, it must involve friction to physically remove debris through wiping, brushing, spraying, or flushing the items.
- Use soft bristle brushes to clean serrations and box locks.
- Cleaning should be under the surface of the water to reduce the risk of aerosol production and in to and fro motion.

Ideally, the decontamination area should have a three-section sink for cleaning (one section for cleaning, one for initial rinsing, and one for final rinsing).

- The first sink for cleaning. Sink should be filled with water having temperature range of °27C - °44C, enzymatic detergent solution.
- The second sink for initial rinsing with plain or softened (de-ionized) water that should be changed frequently.
- Third sink for the final rinsing that should be with de-ionized or reverse osmosis (RO) water to allow instrument spotting.

2. Sink Features:

Cleaning sinks should:

- Be designed and arranged to facilitate soaking, washing and rinsing of RMD with minimal movement or delay between steps.
- The sinks should be approximately 36 inches from the floor and 8 to 10 inches deep.
- Drain freely and not have an overflow.
- Be at a height that allows workers to use them without bending or straining.
- Be large enough to accommodate trays or baskets of instruments.
- Be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning.
- Be equipped with water ports for the flushing of instruments with lumens, if appropriate.
- Have three compartments for soaking, cleaning, and rinsing.
- Not be used for hand washing.

3. Cleaning Tools:

- Brushes with various shapes and sizes are available in the area & used appropriately.
- Reusable cleaning tools should be cleaned and disinfected after each shift collect reusable cleaning tool in mesh basket before inserted in washer disinfector, reusable cleaning tool should be capable of thermal disinfection.
- Inspect brushes and other cleaning equipment for damage, discard if necessary.
- Adequate supplies should be available for frequent changing.
- Cleaning tools should be cleaned, disinfected, and stored dry.

4. Cleaning Detergents:

There are six different types of cleaning detergents:

- **Multi-enzymatic detergents** which contain protease to break down proteins in blood, mucous, feces and albumins, lipase to break down fat, bone marrow and tissue, and amylase to change the structure of soil from reforming can clean all type of soil.
- **Alkaline detergents** Known as cleaning detergent agents contain Emulsifiers to dissolve the uncombined substances, Surfactants to increase the solubility of organic substance, and chelating agents to hold hard water minerals.
- **Pre-cleaning agent** commonly contain: enzymatic detergent, and combination enzyme-germicide detergent to keep soil moist and loosen dried soil.
- **Stain and rust removers** contain acid-based compounds to remove hard water deposits, rust scale, and discoloration from RMD.
- **Lubricants** for instrument maintenance for RMD integrity and good function, used after cleaning as final step of mechanical wash or can be applied manually.
- **Descaler** to remove substances appears on the wall of equipment, washer, or sinks due to the scale interfere with the cleaning abilities.

- For choosing an effective agent, some criteria and features should be present long with the machines and instruments like manufacturer's instruction & compatibility.
- Agents must be environmentally friendly, rapidly dissolve soil, nontoxic, low-foaming, non-abrasive, free-rinsing.
- Factors affect the level of cleaning purity of the surgical instruments which should be highly considered are:

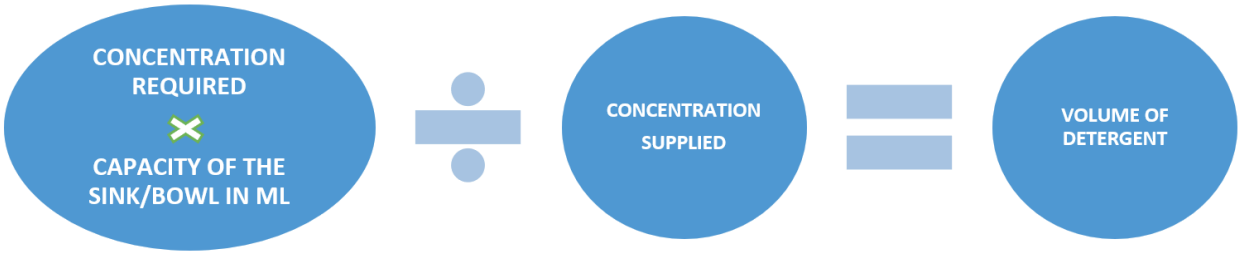
- Cleanliness of the surface of the RMD.
- Characteristics or the design of RMD.
- Type and concentration of the cleaning product.
- Contact time (Duration) and temperature of exposure to the cleaning product.
- Physical properties of the mechanical action.
- The device manufacturer's written instruction for use (IFU).
- Water Quality including water hardness, and water PH.

5. Water Quality:

- Water used in all phases must be purified for high-quality instruments outcome.
- Poor water that contains minerals, dissolved soil, particles, bacteria, algae, and parasites will shorten the life of instruments by harming their finish and rusting them, and lead to corrosion.
- Purified water in the final rinsing phase releases the instruments from the high PH of many chemicals used for cleaning and disinfecting.
- CSSD personal must be acknowledged of the water quality that supplies their department.
- There are three types of purified water used in CSSD: Distilled, Deionized, Reverse osmosis (RO).
- A regular water quality test should be done with the collaboration with hospital public health department.
- Since water is an effective factor in the cleaning process, some criteria should be followed:

  - Correct dilution is required for affective cleaning - more water is not always better
  - Specific water quality hardness and PH
  - Correct concentration, the correct volume of concentrated detergent must add to the correct volume of water at the correct temperature.

The following calculation can be used for right concentration:



Disinfection of RMD:

The disinfection process kills and destroys the majority of remaining microbes except for spores, some mycobacteria, and prions, which may not be inactivated by the disinfection process.

1. Disinfection Methods:

- Thermal by using of moist heat at °70C °100-C in the automatic washer disinfector.
- Chemical by using of chemical disinfectant the Low /Intermediate level disinfectant for minimum treatment recommended for reprocessing non-invasive medical devices, and the High-level disinfectant (HLD) for maximum treatment recommended for reprocessing invasive medical devices for use in critical site.

2. Disinfectant Types:

Low / Intermediate Level Disinfectant:

- Alcohol %70 (isopropyl): Rapidly acting against most bacteria and viruses, but it cannot be used in large amounts due to its flammability.
- Chlorine (Hypochlorite): Useful in decontaminating blood and body fluid spills, but it can cause damage, bleach and pitting of metal. Inactivated by organic soil.

- Quaternary Ammonium (Quats): Kills some bacteria, fungi, and viruses unless Super quats mix use, but it can absorb by cotton, surface must be wet for 10 min to disinfect.
- Phenolic: Kills bacteria, fungi, and lipophilic viruses, but it can cause skin burn if not rinse, and damage plastic instruments.

High-Level Disinfectant:

- Glutaraldehyde %2: Easily kills bacteria, fungi, and viruses, but it is slow in killing spores, dangerous, toxic, and irritant.
- Hydrogen peroxide %7.5-%6: Fast viricidal and bactericidal, but it causes corrosive to some metals, and slow in killing fungi and spores.
- Ortho-phthalaldehyde (OPA): Broad range of microbial activity, generally rapid, no odor, but it is poor sporicidal agent, Expensive. Skin irritant
- Peracetic acid %0.35 - %0.2: Kill wide range of microbe, mycobacterium, spores, but it may cause slight corrosive or damage.

The Approved Disinfectant in the Hospital Environment Must Be:

- Easy to use with a light scent smell.
- Does not evaporate rapidly.
- Not harmful on RMD, staff, or patients.
- Disinfect within a relatively short time.
- Disinfectants should never be stored in direct light or excessive heat.
- Material safety data sheet must be provided.

For instruments that need to be manually disinfected by high-level disinfectant chemicals after manual cleaning, processes must be applied by following the steps below:

- Clean and dry all items to be high-level disinfected.
- Prevent dilution of chemical solution that may occur from wet instruments.
- Fresh solution should be checked each day and must change whenever visibly dirty.
- Change solution if did not pass the minimum effective concentration test (MEC) to determine if the solution is still effective.
- Add the solution in a clean container with a lid and mark the container with the preparation date and expiration date.
- The technician must cover the container and allow items to be soaked for the exact duration stated in the disinfectant manufacturer's instruction.
- Rinse thoroughly with purified water to remove the chemical residue.
- After chemical expired the chemical should be carefully disposed and the container should be cleaned and dried.

Automatic Cleaners and Disinfectors:

1: Washer Disinfector:

Washer disinfector allows instruments to be cleaned and disinfected by exposing them to spray force and thermal action during several stages:

- First step is a cool pre-rinse to wet the instruments and prevent the coagulation of proteins; the chamber is filled with cold water.
- Second step is a detergent cycle with water and is heated to about °60C to maximize the effectiveness of the detergent action.
- Third step is rinsing, followed by a pure rinse cycle to remove any remaining detergents.
- Some washers also provide a lubrication cycle during the rinse cycles.
- The disinfection step allows the chamber to filled for a final time again with filtered or RO water but this time, the temperature is raised to °80C - °93C and held for a predetermined time (usually °90C for 5 minutes) to ensure effective disinfection.

- Final step will allow instruments to dry.
- Manufacturers design different cycles to serve the instrument material without damaging.
- Technician should use anesthesia rack for the anesthesia cycle.
- Washer racks should never be overloaded, and spray arms should move freely during operation.
- Trays or sets with multiple levels should be opened, and each tray should be placed separately on the washer's rack; keep them together to avoid missing.
- Hinged instruments should be opened to permit direct contact of the water and detergent.
- Trays with lids/covers should be opened so contents may be exposed to the washer spray.
- Delicate and small instruments may be dislodged from the racks due to the blunt force of the spray action so, should be confined in small perforated baskets with approved lids.
- Instrument washer racks and conveyor systems should be inspected daily.
- Routine cleaning of washers should include inspection and cleaning of spray arms, washer jets, strainers, and surface.
- Washer detergent levels should be frequently monitored. If detergent drums are allowed to run dry, feed lines can deliver air instead of detergent.
- Document all maintenance schedules and visits for all machines.
- It is important to put an identification password for each washer settings dashboard to avoid changes in the parameters after repair or maintenance by manufacturers.
- To verify that the washer-disinfector cycle process parameters met including time, temp, spray coverage, chemistry in all phases of the cleaning cycle use mechanical test and recorded result in a logbook (protein check, water PH, water hardness, water temperature).

2: Ultrasonic Cleaners:

- Ultrasonic cleaners are used for fine cleaning, not for disinfection or sterilization.
- They are used to remove soil from joints, crevices, lumens, and other areas that are difficult to clean by other methods.
- Hospital sonic cleaners produce from 20,000 to 38,000 vibrations per second.
- Bath temperatures for cleaning instruments should be between 80 F to 109 F (°27C to °43C) unless specified by the equipment or detergent manufacturer.
- Temperatures above 140 F (°60C) will coagulate protein, making them difficult to remove.
- Ensure that the manufacturer's recommendations are followed regarding the ultrasonic cleaner detergents are compatible.
- Technicians should be using a suitable enzymatic detergent that is effective at low temperatures.
- If the tank has a heater, set the temperature control to be comparable with the detergent manufacturer's recommendations.
- An ultrasonic unit may have one, two, or three chambers: first chamber is for the detergent bath, second is for rinsing, and third is for drying.
- Some of the single-chamber ultrasonic have a raising and drying cycle so, a technician must be aware of their machines IFU.
- For cannulated instruments, it should be flushed and brushed before load in the ultrasonic.
- Instruments should be placed in trays that are designed for use in the machine.
- Typical trays should be in small wire construction with at least eight openings per inch to allow the transmission of sonic energy.
- Instruments must be submerged in the solution completely, so they are exposed to the cavitation.
- Hinged instruments placed in the sonic cleaner should be opened.
- Trays must not be overloaded.

- Check the ultrasonic IFU for load limitations.
- There are some items that should not be placed in a sonic cleaner include: Chrome-plated instruments, Plastic, Glass, Wood, Rubber, Fiber-optic instruments.
- Ultrasonic energy can loosen the tiny screws of delicate instruments so, staff should inspect RMD before and after ultrasonic processing.
- Maintenance for the sonic electrical part is always important as any other powered mechanics.
- Water should be changed when it is visually soiled or at regularly scheduled intervals to prevent soiled particles from re-depositing on instruments.
- The unit's tank should be cleaned, and the drain should be checked for debris of each water change.
- Ultrasonic Water must be degassed daily and after changing sonic cleaner for 5 to 10 minutes.
- De-gassing is the process of releasing dissolved air bubbles within the cleaning solution.
- Ultrasonic check should be used daily and record the result for the machine verification.

3: CART WASHER:

- They are designed to clean carts used for transport of all devices and instruments.
- Several manufactures provide accessories that help to process rigid containers and other miscellaneous items.
- It is operating in a manner similar to an automated washer disinfector but on a large scale.
- Spray nozzles will deliver high-temperature water and detergents.
- A high rainwater volume will remove the residue out of the cart's surface.
- A hot air-drying cycle will then run as a final step.
- Do not process individual instruments in the cart washer due to lost, and damage.
- Only use chemical cleaning detergents that are recommended by the manufacturers.
- Regularly clean its strainers and surfaces with a descaler.
- Cart washer also needs to document all its maintenance reports.
- Send HLD instrument through the hatch window to the IAP area.

Inspection, Assembly and Packaging Area:

Unloading of RMD:

- The cycle selection should be checked before unloading to ensure that correct cycle was used.
- The printout should be saved for a year as per MOH recommendations.
- Check that the chart record for the cycle confirms the information established during validation and that all recorded variables are within the parameters permitted.
- Allow items on rack to cool down before dragging to prevent CSSD from burn injury.
- **Reject load if:**
    - Visible soiling on instruments, and failure in the protein test.
    - Any blockage in the spray arm.
    - Incorrect cycle, and if cycle canceled for any mechanical issues.
- Whether RMD received manually or unloaded out of the washer-disinfector, both must be dried to prevent microbial growth, and reduce spotting.
- Follow IFU for drying RMD.
- Drying cabinets should be used unless not recommended by the instruments IFU so, air-dried using compressed instrument grade air, or hand dried using a lint-free cloth.

Inspection of Reusable Medical Devices (RMD):

1. Instruments Inspection for Cleanliness:

- Each set should be inspected separately.
- Lighted magnifying should be available at workstations to assist with detailed inspections.
- Box joints, serrations, and crevices should be critically inspected for cleanliness.
- Check/reject policy in the department.
- Cannulated devices should be checked to ensure that the channels are patent and free of soil.

2. Instruments Inspection for Function:

- Hinges on devices, such as artery forceps and clamps, should be checked for ease of movement.
- Jaws and teeth should be checked for alignment.
- Ratchets should be checked for security.
- Multi-part instruments should be assembled to ensure that all parts are complete and working.
- Multi-part instruments should be assembled as per IFU.
- Any damaged, incomplete, or malfunctioning devices should be reported immediately to the supervisor and documented.
- Cutting edges on devices should be checked for sharpness:
  - For Scissors: Red test material for scissors measuring 4.5" and larger.
  - For Scissors: Yellow test material for scissors measuring 4" and smaller.
  - For Rongeurs /cutter: Index card
  - For Chisels/ Curettes: Plastic dowel rod
- Hinges on devices, such as artery forceps and clamps, should be checked for ease of movement and lubricate the hinge box if necessary.
- Each device should be checked to ensure free movement of all parts, and that joints do not stick, a water-based lubricant may be used if required.
- All screws on jointed devices are tight and have not become loose.

Assembly of Reusable Medical Devices (RMD):

- Each device should be checked against the surgical list specific to the tray being assembled.
- Any device missing in this phase from a tray should be reported to the supervisor.
- Any extra devices found while assembling a tray should be reported to the supervisor for further action, and non-conformance documented.

- The purpose of assembly and checking is to ensure that:
  - All devices are present in accordance with the surgical tray list.
  - All devices are assembled correctly in accordance with the IFU.
  - All devices are placed in the correct tray in a manner that ensures ease of use by the user.
- Jointed instruments must be placed in an unlocked position to allowed sterilizer penetration.
- Multi-part should be disassembled unless otherwise indicated by the IFU.
- Devices with concave surfaces must be flipped upside down to prevent condensation.
- Heavy items arrange at the bottom of the tray, so they will not damage delicate items.
- Sharp instruments should be capped with tips protected without being too tight.
- Devices with ratchets should be closed on the first ratchet only for steam penetration.
- Similar devices should be kept together when placing them in the tray.
- Tray liners should be placed at the base of the surgical tray.
- Devices should be spread evenly by weight over the tray surface.

Packaging of Reusable Medical Devices (RMD):

- The preparation and assembly of surgical instrumentation is a complex process, and various packaging methods are used. Preparing instruments in the manner described helps ensure that there will be adequate contact by the sterilizing agent with all surfaces and reduces the potential for sterilizing residues (e.g., wet packs).
- Delicate/sharp instruments are protected while being handled/ assembled for sterilization. Tip protectors should be fit for purpose and permeable to the sterilizing process.
- Instruments that open (e.g., scissors, haemostats) are held in unlocked, open positions.
- Multi-part instruments are disassembled prior to sterilization, ensuring all parts are easily accessed for aseptic assembly.

- Lumened devices - Remove styles /plugs, such as catheters, needles, and tunings.
- Complex instruments (e.g., air-powered, endoscopes, having lumens or channels) are prepared according to written IFU from device manufacturers.
- Tray liners are used to alleviate drying problems during steam sterilization.
- Follow the policy and procedure of wrapping, and pouching technique indicated by the department.
- Every package should have a compatible external chemical indicator and compatible internal chemical indicators.
- Protect package contents from physical damage.

1. Packages Material Standard:

- The type of material used must allow the sterilant to reach the contents of the packing.
- The material must provide a good barrier to all types of microorganisms.
- The pack must be able to be opened without contamination.
- Withstand normal handling, resistant to tears, punctures, and proven tamperproof seal.
- The packaging material must comply with the IFU recommendations of RMD.

2. Packaging Methods:

The choice and type of packing material will depend on the type of sterilization process used:

- **Packing Type for Steam Sterilizer**
  - Woven wraps (crape paper)
  - Non-woven wraps (SMS)
  - Paper-plastic pouch (peel pouch)
  - Rigid Container System
- **Packing Type for Plasma Sterilizer**
  - Non-woven wraps (SMS)
  - Spun-bond polyolefin- plastic pouch (Tyvek)

3. Paper–Plastic Pouch:

- The paper–plastic pouch should be used, filled, and opened according to the pouch IFU.
- Sealed smoothly without folds, bubbles, or wrinkles.
- Double packaging in paper-plastic pouches should only be performed if the pouch manufacturer has validated the product for this use.
- If the item needs to be double packaged, two sequentially sized pouches should be used.
- The pouches should be positioned so that plastic faces plastic.
- When pouching leave 1 inch after sealing and write in plastic side.
- The use of paper–plastic pouches with heavy metal instruments could result in inadequate drying of the package after sterilization.
- Heat sealing or self-sealing should be used on their shelf life.
- Each facility should evaluate what works best for its situation including ease of use by staff, and the highest quality standard for patients.
- The temperature is adjustable for the type of material being sealed, either for a paper-plastic pouch or Tyvek pouch.
- Follow the prepare packing, sealing, and visual inspection methods for avoiding any defects.
- Recommended sealing temperatures and pressures and other technical advice should be followed carefully.
- Heat sealer should be safety tested annually by the biomedical departments.

4. Sterilization Wrap:

- Sterilization wraps Sterilization wraps including:
  - Crepe paper suitable only for steam sterilizer.
  - Non-woven wrap (SMS) is suitable for porous-load steam sterilization and plasma.

There are two types of wrapping technique:

Sequential Wrapping refers to when two layers of wrap material are wrapped individually using a fold technique. A single layer is folded completely and then sequentially followed with a second sheet of wrap material and repeating the wrap sequence to form a package within a package.

Simultaneous Wrapping refers to when both layers of wrap material are wrapped together simultaneously.

Two single-layer wrappers or one bonded double-layer wrapper can be used.

There are also two techniques for wrapping packages and both are used with the sequential and simultaneous wrap methods:

- **Envelope Fold Technique** The items to be wrapped are placed on the table in a diamond shape to the wrapper. This method is frequently used for smaller items.
- **Square Fold Technique** The items to be wrapped are placed on the table parallel to the wrapper. This method is generally preferred with heavier items.

5. Rigid Container System:

- Containers vary in size and intended for use in various sterilization methods.
- Containers consist of a solid bottom, inner basket, silicone gaskets, latches, load cardholder with engravable ID tags, and lid.
- Filter retention plates and its valves should be checked for cleanliness, and function with no sign of damage or leak.

6. Package labeling:

- Packages should be labeled before sterilization.
- Package labels should be visible and legible.
- Consist of non-toxic materials and ink.
- Write only on the non-porous side of the pouch.
- Write on indicator tape or affixed labels.
- Indicate a description list of the contents with identification of lot number, sterilization date and initials of the operator.

7. Product Identification and Traceability:

- Each package should be labeled with a lot-control identifier that lists the sterilizer identification number, cycle and lot numbers, and date of processing.

8. Loading Considerations:

- To achieve sterility of packages and containers, loading policy and procedure must be followed.
- Technicians should be aware of their sterilizer's IFU loading considerations.
- Documentation should be done manually or by printing an informative adhesive card out of the tracking system including:
  - Cycle parameters
  - Tests results
  - Loaded items and quantity
  - Sterilizer cycle and load number
  - Date of sterilization
- The load control number must be attached to any item intended for use as a sterile product.
- The name or initials of the sterilizer operator must be stated in the package or checklist.
- Light items should be placed above, and heavy metal should be below if mixed load.
- Items should be loaded within the boundaries of the loading tray, do not overload the chamber.
- Ensure there is sufficient room between items to allow the circulation of steriliant.

Sterilization of reusable medical devices (RMD):

Sterilization indicates all forms of microbial life including spores. Sterility assurance level considers sterile if there is less than a one in a million chance of microorganism survival. Bacteria population decreases measured with log; sterility happened when 10^{-6} of bacteria population are killed. -1log reduction means that 90% of the spores have been killed. Each successive log reduction results in an additional 90% kill until there is less than one microorganism surviving.

- **Spaulding Classification:**

Sterilization of reusable medical devices depends on their instruction of use and subjected to the Spaulding classification.

The minimum acceptable level of decontamination of surgical instruments based on the risk associated with the procedures and the surgical sites.

Device Classification	Minimum Inactivation Level	Patient Contact
Critical Items	Sterilization (Steam or Plasma)	RMD enters tissue or blood stream
Semi-Critical Items	High-level disinfection (HLD)	RMD comes into contact with non-intact skin or mucous membrane
Non-Critical Items	low-level disinfection (LLD)	RMD touch only intact skin and does not directly touch the patient

Table 2: Spaulding classification for processing the RMD

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Steam Sterilizers:

1. The Components of Prevacuum Steam Sterilizers:

- Jackets: heat the interior chamber wall.
- Insulation: prevent condensation from forming around the jacket.
- Door: has a safety locking and unlocked only when pressure is exhausted.
- Door Gasket: maintain a tight seal that prevents steam from escaping and air from entering.
- Chamber Drain: to release steam must be cleaned for effective steam flow.
- Thermostatic Trap: automatically controlled by a senior to allow flow of air and steam.
- Gauges and Controls: Gauges allow visual pressure which set at zero, and when steam injected it must reach 14.7 pound per square inch (PSI) to start the exposure sterility time.

2. The Principles of Prevacuum Cycle:

Conditioning:

- Steam enters at the upper back portion with saturated steam which holds many tiny water droplets in suspension, the relative humidity of the saturated steam is 97% to 100%.
- Air displaced through drain.
- Pressure and temperature begin to rise.

Exposure:

- After temperature is reached and all air removed from the autoclave.
- Sterilizer's control system begins timing the cycle's exposure phase.

Exhaust:

- Chamber's drain the steam through the discharge line.
- Filtered air is gradually reintroduced into the chamber and chamber decrease to room pressure.
- Drying the instruments for a specific time can be programmed.

3. Sterilization Process Monitoring:

Sterilization process monitoring includes the use of physical monitors, CIs, BIs, and documentation of results. By monitoring every load for all sterilization processes, personnel can detect operator errors, ensure that each cycle type and all implant loads are monitored, simply staff training, and provide a universal standard of patient care.

- This approach reduces the cost and other consequences of recalls, lowers the risk of HAIs, and improves patient safety.
- CSSD, OR, and infection prevention and control staff should be involved in determining the sterilization process monitoring protocol for all sterilizers used in the healthcare system.

TYPES OF INDICATORS / QUALITY ASSURANCE TESTING

PHYSICAL MONITORS	- Physical monitors are the visible monitors (time, temperature, and pressure recorders, digital printouts, and gauges) on equipment that enable the operator to promptly determine whether the correct sterilizing parameters were met. - They are the first monitoring tool used to detect a sterilization process failure and initiate a recall. Sterilizers that do not have recording devices should not be used. - The CSSD staff should verify all sterilization parameters (e.g., time, temperature, pressure, humidity, sterilant concentration) were met by reading the results on the digital printouts, recording charts, displays, or gauges at the end of the cycle and initial. - CSSD staff should not release a load for use if the physical monitoring results are incorrect for the load contents.
BOWIE-DICK TEST	- A Bowie-Dick test is used to rapidly assess whether dynamic-air-removal steam sterilizers properly remove air from the chamber and prevent air entrainment. - Test should be done every day that the sterilizer is used, “before the first processed load or at the same time each day, and during sterilizer qualification testing. - The Bowie-Dick test pack should be run in an empty preheated chamber (run a shortened cycle by omitting the drying phase) and placed horizontally on a cart or shelf (not on the floor), over/near the drain but should not obstruct it. - Following the Bowie-Dick test pack manufacturer’s IFU, the test exposure time should be 3.5 to 4 minutes at °134C (°273F). - If sterilizer does not pass the Bowie-Dick test, personnel should remove it from service and determine whether it should be retested, serviced, or returned to service.
EXTERNAL CHEMICAL INDICATORS	- CIs are devices used to detect potential sterilization process failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. - These external CIs check whether a package has been processed or exposed to the sterilization process. - The external CI should be read when unloading the sterilizer, dispensing, or issuing the item for use, and before the item is opened in the OR - Personnel should not dispense or use a package whose external CI indicates improper processing. If the package is dispensed , it should be returned to CSSD unused with the load identification and the CI intact.

INTERNAL CHEMICAL INDICATORS	- At least one internal CI should be placed in each healthcare facility-prepared package, tray, or containment device in the area considered the most challenging to sterilant penetration. - These internal CIs are used for pack control to determine that the sterilant penetrated each package, tray, or containment device.
BIOLOGICAL INDICATORS	- BIs are the only process indicators that directly monitor the lethality of a given sterilization process. - Compared with the bioburden found on medical devices or instruments, the spores used as BIs demonstrate increased resistance to the sterilizing agent used in a sterilization process. - It is important to follow the BI manufacturer's written IFU to determine which BI challenge test packs (PCD) to use to monitor a specific sterilization process and cycle, how to use positive controls, the correct incubation temperature and time, how to interpret results, and optimal storage conditions.

Monitoring the Effectiveness of Steam Sterilization:

- Monitor the sterilization process to detect equipment or operator errors or malfunctions that prevent sterilization.
- To ensure that sterilization has been successful, the process of sterilization is tested by measuring various aspects of the process through different **physical and mechanical indicators:**
- Written record of all conditions Date, time, type of cycle, temperature, dry time, exposure time, pressure showed in the display screen are provided in print out paper or digital copy in the computer.
- The printout should be saved for a year (MOH recommendation).

Vacuum leak test should be performed daily

- Determine the air-tight integrity of a Prevacuum autoclave's chamber and plumbing system.
- A typical Vacuum Leak Test Cycle will consist of three vacuum/pressure pulses
  - o followed by 15-minutes of dwell period at deep vacuum.
- leak rate will be displayed on the autoclave's control screen in an average leak rate of 1mmHG/min or less.
- Regularly perform a Vacuum Leak Test that allows greater confidence in the integrity of the chamber and plumbing.

Bowie Dick Test should be used daily before any sterilization processes performed.

- The **Bowie-Dick test pack** should be placed in a preheated chamber on a cart or shelf, over the drain and placed horizontally.
- Select the cycle specified by the sterilizer manufacturer.
- The exposure time should be 3.5 to 4 minutes, not exceed 4 minutes at °134C.
- At the end of the cycle, open the test pack carefully because it might be hot.
- Fail results should be reported as defined in facility policy, and a determination made as to whether the sterilizer should be retested, serviced, or remain in use.
- The test sheet should be saved for a year as per MOH recommendation.

External chemical indicator Process indicator should be present on the external surface of each package or rigid container in the form of indicator tape, an indicator label, a container identification card, or a tamper-evident device.

Internal chemical indicators: Type 6 indicator is preferable because the chemical indicator changed only at specific parameters of the cycle.

- It provides the user with more information on the critical steam sterilization parameters.
- Internal CIs should be visible to the person opening the package and placed in the area considered least accessible to steam penetration.

- If the chemical indicator does not pass:
  - The contents of the package should not be used.
  - At the point of use, the nurse should inform the CSSD supervisor and return the complete, unused package including load identification and the CI, to the sterile processing area.
  - The department head should then decide whether to recall that load or not.
  - The results of internal CIs of another set in the same load can help.

Biological Indicators (BIs) should consist of spores of Geobacillus stearothermophilus comply with ANSI/AAMI/ISO 3-11138 standard, as stated in both IFUs of the BI manufacturer and the sterilizer manufacturer.

- These indicators use the heat-resistant bacterial endospores (Geobacillus stearothermophilus) to demonstrate whether or not sterilization has been achieved.
- Various types of BIs are available, each with different response characteristics and incubation requirements. The appropriate BI must be chosen for the steam sterilization cycle being run and used correctly in accordance with the manufacturer's written IFU.
- Biological indicators should be used minimum weekly, preferably daily, and must use in each implant load and after mechanical maintenance performed.
- Self-contained BIs include incubation media with the spore carrier in a single vial.
- Biological indicators then must place in its compatible incubator for periods of time depending on the specific production time until it is determined whether the microorganisms grow or fail to grow, which means killed by the sterilization process.
- The test BI vial and a control BI vial should be from the same lot to ensure that the control will read the appropriate time.
- Biological indicators should be placed in an incubator at the IFU temperature, time.
- The typical temperature is 55C to 60C.
- If positive BI is indicated, a recall process must be followed.
- The documentation of BI result should be saved for a year as (MOH recommendation)

Recalls :

- A written policy & procedure must be established for the recall and reprocessing of improperly reprocessed medical instruments.
- Protocols should be followed for necessary actions when BIs, CIs, or Physical Monitors Indicate a Failure). Sometimes, a processing failure is confined to one load or one item in the load. For example, a single load could fail if an operator ran the wrong sterilization cycle, or a single item could fail because it had an unresponsive internal CI.
- Reasons for recall can be as a result of improperly sterilized product being used in an event.
- All RMD in each processed load must be recorded to enable tracking in the event of a recall.
- The recall procedure should include:
  - Outline the circumstances for issuing a recall.
  - Designation of department and staff responsible for executing the recall.
  - Identification of the medical instruments to be recalled; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the sterilizer since the last negative growth BI.
  - Assessment of patient safety risk.
  - Procedure for subsequent notification of IPC committee and Biomedical Departments.
- Actions to be carried out:
  - Include all items processed back to the last negative BI.
  - Identify the sterilization lot numbers and devices to be recalled.
  - Recording of the items recalled and specify the action to be taken by the person receiving the notification.
- Following completion of the recall a report should be written that includes:
  - The circumstances that prompted the recall.
  - Specification of the corrective actions taken to prevent it happening again.
  - Identification of the total number of devices intended to be recalled and the number actually recalled.
  - Verification that the recalled items were reprocessed appropriate.
  - Surveillance of patients must be traced in case of nonsterile instruments used.

Steam Sterilizer Failure:

1. Contact Failure :

- Inadequate cleaning before sterilization.
- Sets are too dense.
- Packages wrapped too tightly.
- Crowded unorganized loads.

2. Mechanical Failure :

- Defective steam traps.
- Clogged exhaust lines.
- Steam delivery system problems
- Any mechanical malfunctions.

3. Parameters failure :

- Inadequate exposure time.
- Unsaturated steam.

Plasma Sterilizers:

- Plasma sterilization is the process that is used to deactivate all microorganisms on devices / equipment that are heat and moisture sensitive.
- Hydrogen peroxide gas plasma sterilizes a wide range of instruments including single-channel flexible endoscopes, rigid endoscopes, cameras, batteries, light cords, and power drills by using 59% sterilant against a broad spectrum of pathogens include bacteria, mycobacteria, non-e nveloped viruses, enveloped viruses, fungi, and protozoa.
- Hydrogen peroxide gas plasma depending on

- **Concentration**
- **Contact time**
- **Process temperature.**

The Principle of Plasma Cycle:

- Vacuum phase: air will remove from the chamber and pressure will reduce to below atmospheric pressure.
- Injection phase: Hydrogen peroxide will be pumped from the cassette into vaporizer bowl to the chamber.
- Diffusion phase: vapor into small crevices and lumens of devices.
- Plasma phase: a vacuum decreases the pressure and radio frequency energy which ionizes the hydrogen peroxide creating hydrogen peroxide gas plasma, the injection and plasma phase are repeated a second time.
- Vent phase: air vented into the chamber through bacterial high efficiency particulate air (HEPA) filters, the chamber will return to the atmospheric pressure and the process byproducts are only water vapor and oxygen.

- The cycle time varies with the sterilizer model and the temperature varies from 113F, (45C) not exceed 131 F, (55C).
- Sterilization should be monitored with suitable biological indicators at least daily, every load containing implantable items.
- Chemical indicators must be suitable for plasma and placed inside each package.
- Physical indicators of each cycle.
- Refer to the recall section in case of CI, BI, and Physical Failure.
- To minimize the hydrogen peroxide risk, be attention should be given to:

    - Hazards associated with the sterilant.
    - Storage, handling, and disposal of the sterilant cassettes.
    - Handling canceled cycles.
    - Adherence to standards and Safety Data Sheet (SDS).
    - Appropriate use of use of PPE.

Sterilizers Maintenance:

- The maintenance program may be in-house or contracted with the equipment manufacturer or other qualified service company.
- A validation test with a documented report must be provided for every installed machine.
- Particular attention should be given to the inspection, maintenance, and replacement of components such as filters, steam traps, drainpipes, valves, and door gaskets.
- Scheduled maintenance including lubrication of appropriate parts and replacement of expendable parts should be performed as needed by qualified personnel.
- Certain maintenance tasks after warranty years that require special tools or calibration equipment not available in the health care facility should be performed by the manufacturer's representative or another qualified service provider.
- In the event of a sterilizer malfunction, repair, or replacement of any component affecting sterilizer performance, appropriate recalibration should be performed.
- A maintenance record, in either paper or electronic format, should be kept for each sterilizer including:

    - The date of the service request
    - The model and serial number of the sterilizer
    - The name of the requested service person
    - The reason for the service request
    - Description of the service performed
    - The types and quantities of parts replaced
    - Biological testing records
    - Name and signature of the controller
    - The scheduled date for re-testing
    - Re-testing results

Sterile Storage Area

Unloading and Release of Reusable Medical Devices (RMD):

- Sterilized items should be allowed to cool to room temperature before handling in order to avoid wet packs after unloading of sterilizers.
- The time allowed for cooling should be taken into consideration:
  - The type of sterilizer being used.
  - The design of the device being sterilized.
  - The temperature and humidity of the ambient environment.
  - The type of packaging used.
- During cooling, the sterilizer cart should be placed in a low-traffic area and away from air-conditioning or other cold-air vents, doors & windows etc.
- RMD damage, no change of the external indicator, dust, debris, or moisture (wet packs) should be returned to the decontamination area for reprocessing.

Storage Area Specifications & Maintaining Sterilities:

- Sterile storage should be located adjacent to the sterilization area, preferably in a separate, enclosed, limited-access area, the only function of which is to store sterile and clean supplies.
- The sterile storage area is maintained under positive pressure, with 4 air changes per hour at least, temperature ranges from °20C to °23C and relative humidity with limit of 70%.
- The relative humidity in the sterile storage area should be maintained at the level recommended in the instrument and packaging manufacturer's IFU.

- Storage Shelves: Must be designed to hold items safely, and ideally, the top and bottoms shelves should be solid or covered to reduce or prevent dust accumulation.

- Sterile storage shelves are clearly labelled, free from dust & away from sprinklers and air vents.
- Items are arranged appropriately in the storage shelves with lighter items on the top shelves & heavier items on bottom shelves.
- Sterilized items should be stored far enough away from the floor, the ceiling, and outside walls to allow adequate air circulation, ease of cleaning etc. Storage shelves are placed following appropriate distance recommendations:
  - **Walls: packs/sets must be at least 5cm from walls to reduce condensation risks.**
  - **Floors: packs/sets should be kept at least 30-25cm above the floor to prevent contamination from floor cleaning, spills, and dust.**
  - **Ceiling: packs/sets should be at least 45cm between the highest package and the ceiling or fire sprinkler heads.**
- The products stored in the sterile storage area should be removed from shipping cartons or processed on site prior to storage.
- Correct handling: minimize touch with instruments and carefully pick it do not drag or push items against surfaces causing friction or abrasion.
- Use handling technique by lifting the front of the package underneath with one hand, place the other hand midway under the package and lift the whole item free from the shelf.

Storage Shelf Life / Event- Related Sterility:

- Shelf life of facility sterilized items is event-related. CSSD personnel should follow policy and procedure for shelf life of sterilized items based on:
  - The quality of the packaging material.
  - The storage conditions.
  - The methods and conditions of transport.
  - The amount and conditions of handling.

- With event-related sterility, items are considered sterile unless the integrity of the packaging is compromised (e.g., torn, soiled, wet, or showing evidence of tampering).
- **Conditions that may alter the integrity of the packaging include the following:**
  - Environmental sources of contamination (e.g., moisture, vermin, and air movement associated with traffic or transportation).
  - The barrier properties of the packaging material (e.g., the integrity of its seals and its resistance to tearing).
  - Storage and distribution practices (e.g., open versus closed shelving and transport units)
  - Stacking of sterile items that could result in packaging being torn.

- Use maintenance covers when needed.
- Inspect package integrity and the external CI before the item is dispensed.
- Document storage conditions that could result in contamination of sterile items.

Distribution Policy and first in first out (FIFO) Consideration:

- Inventory should be rotated on a first-in-first-out (FIFO) basis. Accordingly, the first item in is the first item out (place newer items in the back part of the storage area to promote rotation of items).
- To avoid contamination of sterile items, extreme care should be taken during transport to uncontrolled environments.
- A covered or enclosed cart with a solid bottom shelf should be used for transport, and packages should not be dragged, slid, crushed, bent, compressed, or punctured.
- Carts should be decontaminated before they are reused for transporting sterile supplies.
- Follow the department's policy and procedure for transportation.
- Tracing systems and documentation should be used for dispatching items either manually or by the tracking system.

Documentation / record keeping:

- All cleaning, disinfection, and sterilization processes and monitoring results, as well as equipment maintenance and repairs MUST be documented & records are kept where they can be retrieved easily and when necessary.
- Maintain thorough records that can be used if an infection needs to be traced. Records should cover every step from the initial cleaning through high-level disinfection and sterilization processes and including patient use.
- Implant sterilization and monitoring should be traceable to the specific patient. Scope disinfection or sterilization monitoring should be traceable to the specific patient.
- Verification Documents are kept for one year: sono check, protein test, water PH and hardness & washers' temperature test etc, according to manufacturer's IFU.
- Records for sterilization monitoring are kept for one year including: • Sterilization physical parameters (print out from sterilizer / manual documentation of sterilization parameters by the operator)
- Results of sterilization process monitoring should be documented & kept for 1 year. (Bowie dick test, biological indictors (BI) etc.
- There should be a computerized system for tracking & tracing system (or at least manual process for documentation & filing) with implemented policies & procedures for recall of unsterilized items.
- Logbooks or implemented system is available for all received and dispatched items. Information includes: Sender / Receiver ID, department's name, RMD sets and packages names, date, time & quantities etc.
- Environmental Parameters monitoring documents should be available for one year: Daily monitoring record of each area for temperature, humidity, pressure, and air exchange by CSSD staff & quarterly monitoring record checked by maintenance department.

CHAPTER III

Sterilization Services Unit (SSU)

Sterile Services Unit (SSU) is the service unit responsible for reprocessing the reusable medical devices in the primary healthcare centers and dental clinics under strict infection prevention & control measures for the patients and staff safety. The process in the SSU involves collecting, transporting, sorting, disassembling, cleaning, disinfecting, inspecting, packaging, sterilizing, storing, and distributing reprocessed items.

Instrument Reprocessing: Cleaning, Disinfection and Sterilization:

Sterilization of contaminated reusable instruments that have been cleaned is the most important component of an asepsis program. An initial distinction must be made between the antimicrobial outcomes of sterilization and disinfection. As presented earlier, sterilization is defined as the destruction of all forms of life, with reference to microbial forms.

The limiting requirement and basic criterion for accomplishment of sterilization is the destruction of high numbers of bacterial and spores, the most heat- resistant microbial forms. In contrast, the term disinfection refers only to the inhibition or destruction of most organisms; spores are not killed during disinfection procedures.

A standard system of classification to determine whether items should be sterilized, undergo high-level disinfection, or only require surface disinfection was first proposed by Spaulding. This system was originally devised for classifying hospital instruments according to their use and degree of contamination and was adapted to include dental instrument and surgical equipment.

Care items and equipment are categorized as critical, semi critical, or noncritical depending on the potential risk for infection associated with their intended use (see Table 1). Critical items used to penetrate soft tissue or bone have the highest risk of transmitting infection and should be sterilized by heat. Examples include scalers, burs, and scalpel blades or surgical instrument used in most PHC centers. Recent studies have indicated that debris remains on 94 to 100 percent of dental burs and endodontic files after cleaning, regardless of the cleaning method. The characteristic small size and multiple crevices of endodontic files and dental burs contribute to the difficulty cleaning these devices

Instrument Transportation:

Composite materials should be removed from all instruments prior to transport to prevent adherence and instrument corrosion. Procedure trays and instruments should be transported from the operatory in a puncture resistant, leak proof container, securely closed, clearly marked as biohazardous.
Instruments must be kept moist until reprocessing occurs to prevent hardening of bioburden which increases cleaning difficulty. One option is to cover instruments with a product designed to keep instruments moist (e.g., enzymatic gel) until they can be cleaned if the instruments can't be processed immediately.

Overview of Sterilization Services Unit Structure:

Adequate space in sterilization service unit (SSU) is critical to provide appropriate workflow, efficient, and effective processes that promote staff safety, standardize procedures, minimize environmental contamination, and maintain the sterility of processed items.
The size of the SSU should be appropriate for the volume of work being performed, the processes being conducted, the types of services provided, and the amount of equipment required to perform the required tasks. The space requirements for the SSU area can be affected by the storage and delivery systems employed by the healthcare facility.

SSU Design/Infrastructure:

Design Layout:

- SSU infrastructures should be done under specific standards according to Facility Guidelines Institute (FGI), and MOH-Health Care Facility standards. It must be reviewed before any possible project or reconstructive work by the infection prevention and control committee, or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space.

- The size of the SSU should be appropriate for the volume of work being performed, the processes being conducted, the types of services provided, and the amount of equipment required to perform the tasks.
- SSU include decontamination, preparation and packaging, sterilization, and storage areas.
- The design of the unit must follow the one-way workflow direction from dirty to clean area.
- A clear demarcation between soiled and clean work area must be maintained.
- SSU must have physical barriers between the decontamination area and packaging and sterilizing area, it should be smooth, non-particle, non-shedding, washable with clear demarcation for clean and dirty areas.
- Walls should be constructed of non-particulate, non-fiber shedding materials to stand cleaning.
- Windows are not allowed in both areas.
- The ceiling in the restricted area should be constructed of enclosed fixtures that hold all pipes and ductwork.
- The door should be made of a durable, smooth, and cleanable material.
- Floors should be flat and constructed of non-particulate, non-fiber shedding materials to withstand daily mope cleaning.

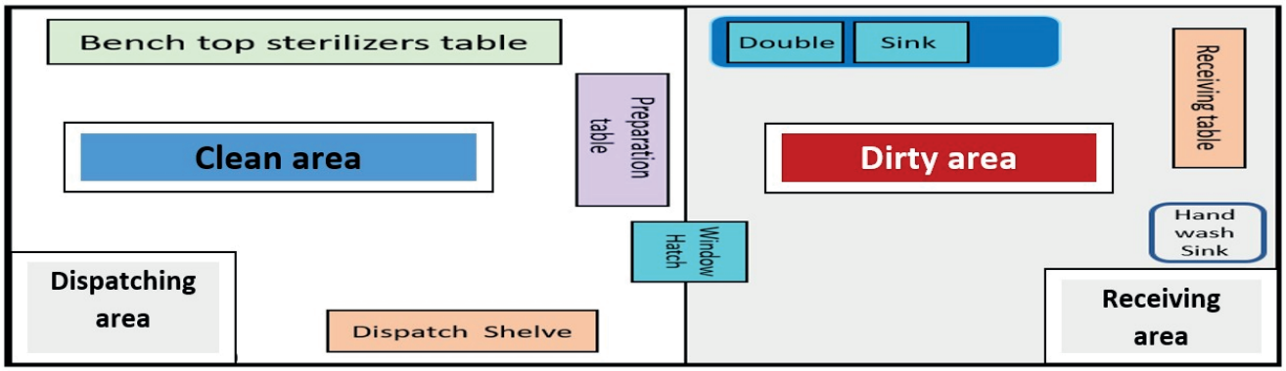


Figure 3: The SSU Design

Traffic Control and Workflow:

- Reprocessing of reusable medical devices must be done in the SSU and none of the cleaning, disinfecting, and sterilizing processes is done in the clinics.
- SSU should be divided into 2 areas with complete physical separation between these areas (dirty area), (clean area), in case the center has sterile storage area follow the sterile storage requirements in CSSD section.
- SSU should be away from the main traffic pattern, it should be restricted area for authorized personnel, and with a clear sign posted on the SSU entrance. To be specific, the SSU should not be next to the patient waiting area, or located between clinics, or next the cafeteria or main entrance or exit gates and should not be located under the stairs.
- SSU staff should be organized so that activities and objects flow in a unidirectional way.

Environmental Control Parameters of SSU:

AREAS	TEMPERATURE	PRESSURE	EXCHANGES/HOUR	HUMIDITY
Dirty Area	16°C - 18°C	Negative	A Minimum 10 Air Exchanges/Hour	30°C - 60°C
Clean Area	20°C - 23°C	Positive	A Minimum 10 Air Exchanges/Hour	30°C - 60°C
Sterile Storage	20°C - 23°C	Positive	A Minimum 4 Air Exchanges/Hour	30°C - 60°C

Table2: SSU Environmental Control Parameters

SSU Functions:

Point of Use Treatment /Pre-Cleaning:

- Instruments should be kept moist until they are cleaned by using an enzymatic pretreatment spray.
- Repeat the spray process as needed If the sterilization process will be applied after 2 hours or more.
- It is recommended NOT to use saline to wipe or moisturize instrument surfaces.
- These procedures help prevent material and debris from drying on instruments.
- Single-use instruments, disposable blades, and body fluids must be disposed of according to MOH specifications for medical wastes and discarded at the point of use.
- In case of receiving the single-use items in SSU dispose according to the MOH specifications of medical wastes procedure should be followed and incident report should be implemented.
- The containers that contain soil instruments in the clinics must be closed and clearly identified with biohazard labels to identify the risk associated with carrying dirty instruments.

Transportation of Contaminated RMD to SSU:

- Items must be transported to the SSU for full reprocessing in a closed container or cart with ideal characteristics such as:
    - It must be labeled and marked with a biohazard label.
    - Secured lid to prevent infection spread.
    - Robust to prevent falling over and protect instruments from damage.
    - Containers should be puncture resistant.
    - Containers should be leak-proof to prevent liquid spillage.
    - Containers used for holding contaminated items should be made of material that can be easily cleaned and effectively decontaminated.
    - Containers and carts must be dried after cleaning and disinfection to prevent recontamination.

- Contaminated instruments should be transported on rotation basis by direct routes far from public traffic.
- Personal protective equipment's (PPE) and biohazard spill kits should be available for the transportation process.
- Contaminated instrument container should not be used to transport sterile instruments.
- If only one transportation trolly or cart is available, it must be decontaminated and disinfected before using again to transport clean or sterile items.
- Keep the cart always closed except during loading and unloading.
- During transportation, never leave the trolley or transportation cart unattended with biohazard labels in Arabic and English.
- All instrument coming from procedural areas is considered contaminated and must be contained properly when transported to the decontamination room.

Decontamination Area:

Manual Cleaning:

- Manual cleaning is defined as the removal of all visible and non-visible soil, and any other foreign material from medical instruments.
- It is a pre-requisite step to the disinfection or sterilization step.
- When instruments are received in the decontamination area, it must be inspected for any sharp objects before handling them to prevent any possible injures.
- Cleaning must be performed immediately once the instruments are received to reduce the formation of biofilm that adheres to the surfaces of the instruments.
- All soil that adheres to the surfaces of instruments interferes with the effectiveness of disinfection and sterilization if not cleaned.
- Cleaning solution and water must be change when it is visibly soiled, which might be after one use to prevent soil particles from re-depositing on instruments or it should be changed according to manufacture instructions.
- It is important that the water temperature is in the range recommended by the detergent manufacturer for the most effective cleaning, range of temperature is 80 F̊ to 110̊ F (°27C – 44 °C) to prevent coagulation, if the temperature of the solution does not meet what is required, it should be changed.
- Disassemble all instruments and open all jointed instruments.
- When performing manual cleaning, technicians must involve friction to physically remove d ebris through wiping, brushing, spraying, or flushing the items.
- Use soft or stainless-steel bristle brushes to clean serrations and box locks, avoid using the stainless-steel brush if the instrument's IFU not recommend it.

- Cleaning should be under the surface of the water to reduce the risk of aerosol production.
- Factors that affect the level of cleaning purity of the reusable instruments which should be highly considered are:
    - Cleanliness of the surface of the reusable medical instruments.
    - Characteristics or the design of reusable medical instruments.
    - Type and concentration of the cleaning product.
    - Contact time (duration) and temperature of exposure to the cleaning product.
    - Water quality including water hardness, and water PH which should be monitored.

Sink Features:

- Cleaning sinks should be designed and arranged to facilitate soaking, washing, and rinsing of medical devices.
- The sinks should be approximately 36 inches from the floor and 8 to 10 inches deep, deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning.
- The sink should be at a height that allows workers to use them without bending or straining.
- The sink should be large enough to accommodate trays or baskets of instruments.
- The sink should not be used for handwashing.

Cleaning Tools and Detergents:

- Cleaning solution must be compatible with the instruments and follow the cleaning product manufacturers for proper dilution, concentration, temperature, and contact time.
- Brushes with various shapes and sizes are available & used appropriately.
- Using the correct size brush will ensure adequate cleaning the first time; this will eliminate re-cleaning and will also eliminate possible contamination of other instruments.

- Reusable brushes should be cleaned after each use, disinfected, or sterilized at least once a day.
- Discard of damaged brushes or if their bristles are bent or will not come clean.
- Single-use cleaning tools should be discarded after each use.
- Adequate supplies should be available for frequent changing.
- The multi-enzymatic detergents should be used which contain protease, lipase, and amylase to clean all types of soil for manual cleaning.
- Stain and rust remover detergent contain acid-based compounds to remove hard water deposits, rust scale, and discoloration from instruments should be available.
- They should use a transport spray agent which commonly contains an enzymatic detergent with an enzyme-germicide detergent to keep the soil moist and loosen.
- Detergent agents must be environmentally friendly, rapidly dissolve soil, nontoxic, low-foaming, non-abrasive, and free-rinsing.

Decontamination Area:

Transfer the Reusable Instruments to the Packaging Area:

- Reusable instruments received in this area must be dried before packed to prevent microbial growth, reduce spots, and allow steam to reach the instrument's surfaces.
- Instruments can be hand dried using a lint-free cloth.

Instruments Inspection for Cleanliness and Function:

- If possible, the lighted magnification lens can be used to help detect residue on instruments.
- Each instrument should be inspected separately.
- Devices should be inspected for flaws, damage, debris, detergent residue, and completeness, then dried.

- Box joints, serrations, and crevices should be critically inspected for cleanliness.
- Hinges on devices, such as Artery forceps and Clamps, should be checked for free movement.
- Jaws and teeth should be checked for alignment, so jaws or teeth must be in correct relative position.
- Ratchets should be checked for security.
- Multi-part instruments (e.g. dental handpieces) should be assembled to ensure that all parts are cleaned, complete and working as per IFU.
- Any damaged, incomplete, or malfunctioning devices should be reported immediately and documented.
- All screws on jointed devices must be tight and have not become loose.
- Place devices in an open position to allow the sterilant to meet all surfaces.
- Sharp instruments should be checked for broken parts and packed carefully without damaging the pouch.
- Devices with ratchets should be closed on the first ratchet only, for steam penetration.

Packages Material Standard:

- The type of material used must allow the sterilant to reach the contents of the packing.
- The material must provide a good barrier to all types of microorganisms.
- The pack must be able to be opened without contamination.
- It should withstand normal handling, resistance to tears and punctures, and proven tamperproof seal

Paper–Plastic Pouch:

- The paper–plastic pouch should be used, filled, and opened according to the pouch IFU.
- Sealed smoothly without folds, bubbles, or wrinkles.
- When pouching, leave 1 inch after sealing and write on the plastic side.
- Pouches shelf life is affected by sterilization, storage conditions, and time.
- Follow the proper packing, sealing, and visual inspection methods for avoiding any defects.
- Heat sealer should be safety tested annually by the biomedical departments.

Packing labeling:

- Packages should be labeled before sterilization.
- Package labels should be visible and legible.
- Consist of non-toxic materials and ink.
- Write only on the non-porous side of the pouch.
- Indicate the lot number, sterilization date, and initials of the operator.

Loading Considerations:

- Technicians should be aware of their sterilizer's IFU loading considerations.
- Ensure there is sufficient room between items to allow the circulation of steam.
- Do not overload the chamber, this can cause wet packs and condensation to the set during sterilization.
- Wrapped instruments should be placed side by side.

Sterile Process Monitoring, Documentation, and Recalls

Cycle Parameters:

- Visible monitors for the table sterilizer to determine whether the correct sterilizing parameters were met must be done.
- Dental SSU HCWs should not release a load for use if the physical monitoring results have failed.
- All related documents should be saved for a year as per (MOH recommendation).

Tests Results:

- A Bowie-Dick test is used to rapidly assess whether steam sterilizers properly remove air from the chamber and prevent air re-entrainment.
- The test should be done at least once weekly and should be run in an empty preheated chamber. If the sterilizer does not pass the Bowie-Dick test, personnel should remove it from service and determine whether it should be retested, serviced, or returned to service.
- The test sheets should be saved for a year as per MOH recommendation.
- Biological indicator (BI) uses the heat-resistant bacterial endospores (Geobacillusstearor the mophilus) to demonstrate whether sterilization has been achieved or not.
- Biological indicators then must be placed in its compatible incubator for periods depending on the specific production time until it is determined whether the microorganisms grow or fail to grow, which means killed by the sterilization process.
- The test BI vial and a control BI vial should be from the same lot to ensure that the control will read the appropriate time. If positive BI is indicated, a recall process must be followed.
- The documents of BI results should be saved for a year as per (MOH recommendation).
- If the center have an agreement to apply the BI incubation outside the center the result should be received and documented immediately.
- Internal chemical indicators must be placed in each package, they are used for pack control to determine that the sterilant has penetrated each package.
- If the chemical indicator does not pass, the contents should not be used.

Distribution of Sterile Items:

- Before unloading from the sterilizer, sterilized items should be allowed to cool down before handling to avoid wet packs after unloading of sterilizers.

- Thoroughly inspect the package, inspect the item and packaging for any signs of compromise such as but not limited to the following: staining or watermarks on the packaging, proof of sterility, worn areas, tears-regardless of size, improper packaging (wrong type, wrong method of wrapping or containment) expiration date.
- Return any compromised sterile items for processing (e.g., damage, debris, dust or soiled)
- Transport sterile items in a manner that will prevent the package from puncture or contamination from moisture, excessive humidity, condensation, insects, vermin, dust and dirt, and excessive pressure.
- Extreme care should be taken during transportation, make sure to transport in controlled condition.
- An enclosed cart or box with a solid bottom shelf should be used for transportation, where packages should not be dragged, slid, crushed, bent, compressed, or punctured.
- Ensure your transfer cart, or other device has been properly disinfected before placing items ready to be transferred.
- Return transfer cart, for subsequent cleaning and disinfection after items are issued.
- Do not put sterile packages in pockets or carry them outside the facility or staff break areas.
- Assume an item is contaminated if it is dropped on the floor or an unclean surface. Do NOT use it.

Instrument Storage in The Clinics:

- The clinic room must be controlled under specific environmental monitors (Humidity from 60%-30%, temperature from 23 - 20 °C) to maintain the sterility of the packages.
- The sterile packages set inside the cabinet and drawers in the clinics.
- Sterilized packages should be used on a rotational basis so the process of using these sterile packages follows the FIFO (first in first out) methods.
- Rotate sterile items from "first-in" to "first-out" by placing the newest items towards the storage bin area's back.

- Sterilized packages must be returned to the SSU and prohibited to use if there is any evidence of wet packages, tears, burn pouch, missing indicator, or missing identification of the sterilization date shown.
- Cabinet and drawers used for storing sterilized instruments are free from dust, not stacked arranged.
- Not overcrowding bins or cabinets.
- Not using rubber bands or clips to bind items together or hang them to "fit them all in".
- Reducing the risk of contamination is achieved through minimal handling.
- Protective packaging for sterilized items that could be subjected to environmental challenges or multiple handling before use.
- Do not transport sterile items on a dirty cart or store them with used or contaminated items.
- Do not store items in sterile packaging under sinks

SSU Supplies Storage:

- Supplies storage is available nearby or next by the SSU for providing the sterilization process products including cleaning detergents, cleaning check tools, sterilization quality check, packaging materials.
- The products stored in the supply's storage should be removed from shipping cartons and arranged by categories.
- The room/store area must be controlled under specific conditions to ensure that SSU supplies are in good condition to use:
    - Avoid any external conditions such as humidity, temperature, dust, and sunlight.
    - Avoid wiping packages with disinfectants.
    - Supplies storage shelves are properly cleaned, free from dust and the room has no windows.
    - Items are arranged appropriately in the storage shelves with lighter items on the top shelves and heavier items on the bottom shelves.

Storage Period:

event-related shelf-life which means the product should remain sterile indefinitely unless some event causes it to become contaminated (e.g., torn or wet packaging, excessive handling). If packaging is compromised, the instruments must be unwrapped and go through the cleaning process prior to repackaging.

Documentation:

Receiving form, dispatching form, sterilization logbook, bowie dick test result form and biological indicator test result form should be available and implemented to ensure high quality outputs.

Supplies and Equipment:

This topic guides the PHC centers and dental clinics on how to determine the Sterile Service Unit's need for supplies, equipment, and accessories.

SSU Supplies:

Cleaning Brush for Manual Washing:

- Regular cleaning brush with two thick and thin ends Regular cleaning brush, double-ended, high quality white medical grade soft nylon bristles, end 1 ,1# x 3.5cm, end 0.5 ,2# x 2.5cm, total length 20- 15 cm, disposable, plastic handle.
- Regular cleaning brush, single-ended, high-quality white medical grade soft nylon bristles, overall length 20-15 cm, bristle diameter length -7inch, disposable, non-sterile.
- Metal cleaning brush for instrument cleaning, high quality, toothbrush-style, stainless steel, disposable, non-sterile.

Cleaning and Disinfection Detergents:

- Enzyme solution 5-3 liter capacity (direct in washer-disinfector or manual washing) Concentrated enzymatic cleaner, contains multiple enzymes (amylase, protease, lipase), effective on hard-to-clean soils, dissolves completely in hard or soft water, easy to rinse, low foaming, suitable for manual cleaning, low dilution, compatible with instruments materials (stainless steel, plastic, soft metals, aluminum), enhanced corrosion inhibitor properties to protect instruments from the harmful effects of water and water impurities, 1 manual dosing pump for every 30 gallons, biodegradable, EPA registered, suppler provide EPA/CE certification, Safety data sheet (SDS) should be provided, 3 – 5 L.
- Spray for dirty instruments, transfer Spray. Transport agent for point of use, ready to use surfactant and or enzymatic formula that clings to soiled instruments to maintain the moisture during transport up to 72 hours, the dose does not perform oily film, dye-free formula to prevent stain and soiled sharps visibility, neutral PH, contains corrosion inhibitors for instruments (safe for aluminum, soft metals, gold handles), rinses easily (no need for special rinsing before automated processing and compatible with all types of washers), easy to rinse even when dried, conforms to relevant iso standards, Safety data sheet (SDS) should be provided, size: 600ml - 1000ml.
- Neutralizer detergent solution for removing rust -5–3liter (washer-disinfector and manual) Neutralizer detergent, acidic formula, for rust and scale removal, a phosphate-free formula that restores and maintains the protective passive layer integrity of stainless steel surfaces, resistant to corrosion and pitting, removing stains, rust, hard water scale deposits, easy to rinse leaving the residue-free surface, it can be used for manual and automated process 3-5L.
- Surgical instruments lubricant spray, ready to use, safe formula, for manual application, contains corrosion inhibitors that prevent rust, does not interfere with steam or plasma sterilant, does not leave any oily residue, neutral PH, compatible with all types of metal instruments, non-silicon based, phosphate-free, contains a preservative to ensure that the product will not support the growth of microorganisms, Safety data sheet (SDS) should be provided, spray bottle of 250 - 500 ml.

Cleaning Indicators:

Enzymatic indicator for efficiency of manual cleaning of surgical instruments Indicator, for enzyme activity, for use in monitoring the enzyme activity of enzyme detergents, used in a manual bath, compatible with ANSI⁄AAMI ST 79 – colour of the indicator is directly compared to color blocks on bottle labeled, clearly labeled with lot number and expiration date.

Steam Sterilization Indicators:

- Steam penetration indicator (Bowie-deck test). Bowie-deck test pack, designed for daily monitoring of the performance of pre-vacuum steam sterilizers operating at 134C / 3.5 minutes and 121C / 12 minutes, in addition to detecting air leaks, inadequate steam penetration, and vacuum pump failures. The test can detect wet steam, superheated steam and non-condensable gases problems conform to EN iso 4-11140 and EN285. The test uses thermochromic ink formulation, free from lead or any toxic materials. The indicator reagent should be uniformly distributed on the test sheet to cover not less than 30 % of the surface area of the sheet, with the distance between adjacent areas of indicator reagent should not exceed 20 mm and sufficient strength to withstand steam sterilization. The difference in reflectance density should not be less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer, must be laminated. The back of the test sheet should include inquiries about department, machine number, cycle number, 120 x 30 mm. Indicator should give remarkable colour change.
- Rapid Biological Indicator for steam sterilizers (Daily) Biological indicator, individual vials for steam sterilizers, super rapid readout incubation time less than 30 min, self-contained biological indicator with external chemical indicator type 1, comply with ISO 11138, safety data sheet must be provided with it, the biological vial must comply with the MOH incubator auto reader machine and supplier must provide one auto-reader machine for free for every MOH facility.

- Class 6 chemical indicator Type 6 Emulating Indicator, Steam sterilization cycle verification strip chemical indicator that confirms exposure to certain critical variables (temperature, exposure time, and saturated steam) for a specified sterilization cycle, the product is an internal pack Indicator that can be used routinely invalidated pre-vacuum cycles (Dual Temperatures Indicator: 121 °C for 12 minutes - 134 °C for 4 minutes). Conform to EN 1-867 Class D and ISO 1-11140 Type 6) standards, the indicator ink is non-toxic and free of lead or heavy metals and provides the permanent colour change that indicates specified sterilization parameters have been met, with endpoint colour standard on each strip to facilitate colour comparison, a short strip with fully laminated from both sides, Safety data sheet (SDS) should be provided.
- Adhesive Label rolls for printing cycle data Label rolls, strong, adhesive, keeps label withstand steam sterilization, eliminating the need for relabeling, the label provides 2 lines of information with up to 10 characters per line (one line for load and sterilizer numbers and the second line for sterilization Gregorian dating, labels comes printed with the red area "sterilized" in-between the 2 lines and the statement "sterile unless the package is opened or damaged" labels/ roll: 1200 - 500, with label size, not less than 15 mm x 30mm, Supplier should provide one printing machine as per approved specifications for free for every 5000 rolls.
- Printing machine (Date, Cycle Number, Sterilizer Number) Applicator, for CSSD label, well adhesive labels to sterilization & wrapping packages & pouches and record sheets, durable, high-quality printout on the label, 2line labels: lot/ cycle number and machine number, Georgian print of date of sterilization, Supplier should provide one printing machine for free for every 5000 rolls.

Transportation Box:

- Transportation box (300 X 200 X 120MM) Box, for transportation, propylene, with reversible delivery label pocket lockable and autoclavable, size 300 X 200 X 120MM
- Transportation box (400 X 300 X 220MM) Box, for transportation, propylene, with reversible delivery label pocket lockable and autoclavable, size 400 X 300 X 220MM.

Steam Sterilization Pouches:

- Gusseted precut sterilization steam pouch, information printed in the pouch as per EN 5-868 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 9x5x12.5 cm. or dental pouch size: 9cmx10cm
- Regular precut sterilization steam pouch, information printed in the pouch as per EN 5-868 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 10x20 cm. or dental pouch size: 11.5cmx23cm
- Regular roll sterilization steam pouch, information printed in the pouch as per EN 5-868 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 15CMX100M. or dental pouch size: 16.5cmx25.5cm
- Regular precut sterilization steam pouch, information printed in the pouch as per EN 5-868 and ISO 11607, medical garde paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 20x40 cm.
- Gusseted precut sterilization steam pouch, information printed in the pouch as per EN 5-868 and ISO 11607, medical grade paper face porous material and one laminated polyester and polypropylene face transparent film, should be printed at distance not more than 15 cm, size: 25x8x40 cm.

SSU Equipment:

- Bench Top Steam Sterilizer: for Wrapped or unwrapped solid or hollow items porous loads, chamber material is Stainless steel, allow for Bowie & Dick Test and Vacuum Test, have Special user-programmable cycle, alert for low water level alarm, have a cycle finish alarm, alert for cycle malfunction, LCD or touch screen cycle status display, chamber capacity is from 150 – 40 Liters approx, loading from front door single, cycles 134 ,121 flash, , Manual or Automatic water fill and continuous direct drain, power supply 220 V, 60 HZ, regulatory compliance CE and FDA approved.
- Work Table in decontamination area: Frame and a top surface made of Stainless steel, dimensions are 120-80cm (L) x 65 -60cm (W) x 90 (H), with all other accessories needed.
- Inspection and cleaning Table: Frame and a top surface made of Stainless steel, dimensions are 210-200cm (L) x 100-60cm (W) x 90cm (H), with all other accessories needed.
- Double Manual Washing Sink: Used for manual washing in decontamination zone in CSSD, double sink, made of stainless steel, sink dimensions 180-60cm W X 80-40cm L X 30-25 cm D, 90cm (H), with one mixer faucet for hot and cold water, with overhead shower, the lower cabinet closed with 2 doors, work flow from right to left or left to right according to zone layout drawing, with air gun/pressurized water faucet, with glass protection from water splashes, accessories should be provided (nozzles holder, brushes holder).

- Cart Transport Cleaning: Frame and a top surface made of Stainless steel, dimensions are 100-60(L) x 60-40(W) x 90-75 (H), three shelves, with wheels and have 2 brakes, with all other accessories needed.
- Water Distiller Machine: with self-rinsing system to serve steam sterilizer, capacity 12-5 liter/hr.
- Shelves: Used to store sterile instruments and other sterilized items, made of Stainless steel, at least five shelves, easy to clean, no hidden parts, 120-100(L) x 90-60(W) x 160-150 (H).

- Heat Sealer: Used to seal sterilization pouches for steam and plasma sterilization, table top, fully automated microprocessor control, temperature range from 99- 0 degree centigrade, sealing length 120 – 500 mm, has over heat protection mechanism, provided with pouch printer to print date/batch number / personal code/department name, with accessories roll wheels and cutting devices, 220volt/60Hz.

CHAPTER IV

Endoscopy Reprocessing Unit (ERU)

The Endoscopy reprocessing unit (ERU) is responsible of reprocessing endoscopes, and to ensures that the endoscopes reprocessing is effective in reducing infection risks. This requires a well-established framework for training, competence, quality assessment, and management within all reprocessing measures.

The following chapter is provided to assist healthcare facilities to achieve a reliable, high-quality reprocessing approaches among endoscopes.

Flexible Endoscopy Types & Components:

Flexible Endoscopes are Consist of:

- Handle assembly (control section).
- Light source connector.
- Flexible shaft (Insertion tube).
- The handle features control knobs that, when actuated, cause the distal end of the endoscope shaft to move.
- Small-diameter flexible endoscopes generally allow movement in two directions (up and down).
- Large-diameter flexible endoscopes allow movement in four directions (up, down, left, and right).

Flexible endoscopes can be classified as either fiber optic endoscopes or video scopes, the difference between the two is how the image is captured and transmitted by the endoscope.
A fiber optic flexible endoscope gathers the image via a series of lenses at the distal end of the endoscope. The image is transmitted to the eyepiece via a fiber optic bundle. Video flexible endoscopes require a power source and a video system to view the image. The image is captured and transmitted as an electrical signal to the viewing monitor. The internal components are contained and protected by an external sheath. The sheath is made of materials that can withstand exposure to body fluids, and they allow easy insertion and withdrawal.

Flexible endoscope lengths range from a typical esophagogastroduodenoscope (about 36" long) to colonoscopes (usually 60" or longer). Like rigid endoscopes, flexible endoscopes can also be described as either diagnostic or operative.

Operative flexible endoscopes have a working channel that allows the passage of a surgical instrument (i.e., biopsy forceps or diagnostic brushes for scrapings). These scopes may also have a channel(s) for suction, irrigation, and insufflation to stretch the organ for better viewing. Different caps are used to protect from damage during various phases of reprocessing. If protective water caps are supplied, these must be in place whenever the scope is at risk of having water enter the scope.

Flexible endoscopes may also come with a venting cap to the outside environment. The venting cap is used to allow sterilant, such as ETO and hydrogen peroxide, to enter and exit the scope channels. It is also used for shipping scope, (particularly via air flight) to equalize pressure within and outside the scope.

Types of Flexible Endoscopes:

- **Bronchoscope:**

  Bronchoscope is used to directly visualize the tracheobronchial tree (bronchus) and allows:

  - **Diagnosis**

    to get uncontaminated secretion for culture, to take a biopsy, or to find out the cause of cough or hemoptysis (spitting up blood).

  - **Treatment**

    to remove a foreign body, excise a small tumor, apply a medication, aspirate the bronchi, or provide an airway during a tracheotomy.

- **Gastroscope/ Esophagoscopy:**

  Gastroscope is used to visually inspect the upper digestive tract (including esophagus, stomach, and duodenum), with aspiration of contents and biopsy, if necessary.

  Esophagoscopy is the direct visualization of the esophagus using a gastroscope.

- **Colonoscope/Sigmoidoscope:**

Colonoscopy involves the visual inspection of the entire large intestine with a colonoscope.

Sigmoidoscopy involves the visual inspection of the lower part of the large intestine with a sigmoidoscope.

These are important diagnostic tools and may used for biopsy and removal of polyps and to control bleeding ulcers.

- **Cystoscope/Ureteroscope:**
  - A flexible cystoscope is used to visualize the urethra and bladder.
  - A flexible ureteroscope is used to visualize the ureter and kidney.
  - It is passed through the urethra and bladder to the ureter/kidney to look for obstructions, such as strictures or kidney stones and tumors.

- **Rhino-Laryngoscopes:**

Rhino-laryngoscopes are used to visualize and perform procedures within the nose, sinus cavity or upper gastrointestinal tract (GIT).

Flexible Endoscopes Accessories:

- Flexible Endoscopes Instruments: All reusable flexible endoscope instruments should be carefully reprocessed following the manufacturers' IFU. These items usually encounter sterile tissues; therefore, they must be cleaned and sterilized prior to reuse.

Endoscopy Reprocessing Unit Layout:

- The reprocessing area should be in a space that is separate from the patient procedural area.
- Review the physical setting to ensure a “one-way” workflow that separates contaminated workspaces from clean workspaces.
- If a separate room is used for manual cleaning of endoscopes, ensure a directional airflow that maintains negative pressure within that room relative to adjoining spaces.

- Ensure that heating, ventilation, and air conditioning parameters are appropriate for the chemicals and equipment in use.
- Staff should have access to a handwashing sink that is separate from the reprocessing sink(s).
- Install eyewash stations within the endoscopy reprocessing room where chemicals that are hazardous to the eyes are used. Eyewash stations should not be installed in a location that requires flushing of the eyes in the decontamination sink.
- Ensure that the manufacturer's instructions for reprocessing of the endoscopes and use of the ERU and associated chemicals are readily available.
- Provide designated space to enable access to files electronically (e.g., computer) or hard copy (e.g., in binders for IFUs and safety data sheets for chemicals used to reprocess flexible endoscopes.

ERU Environmental Control Parameters:

AREAS	TEMPERATURE	PRESSURE	HUMIDITY
Dirty Area	16°C - 18°C	Negative	30%-60%
Clean Area	20°C - 23°C	Positive	30%-60%

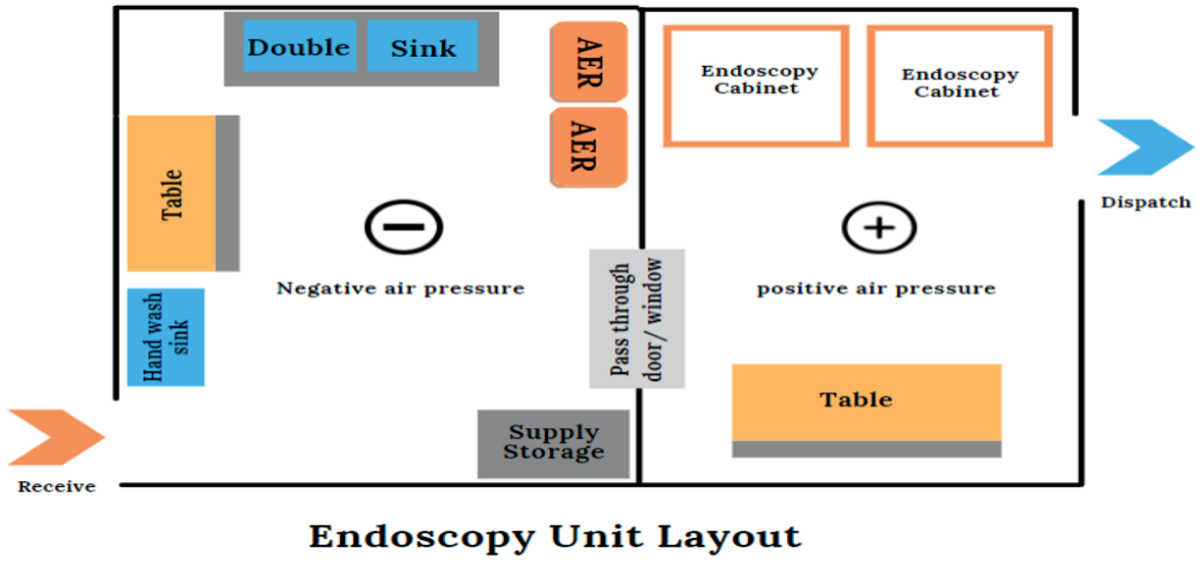
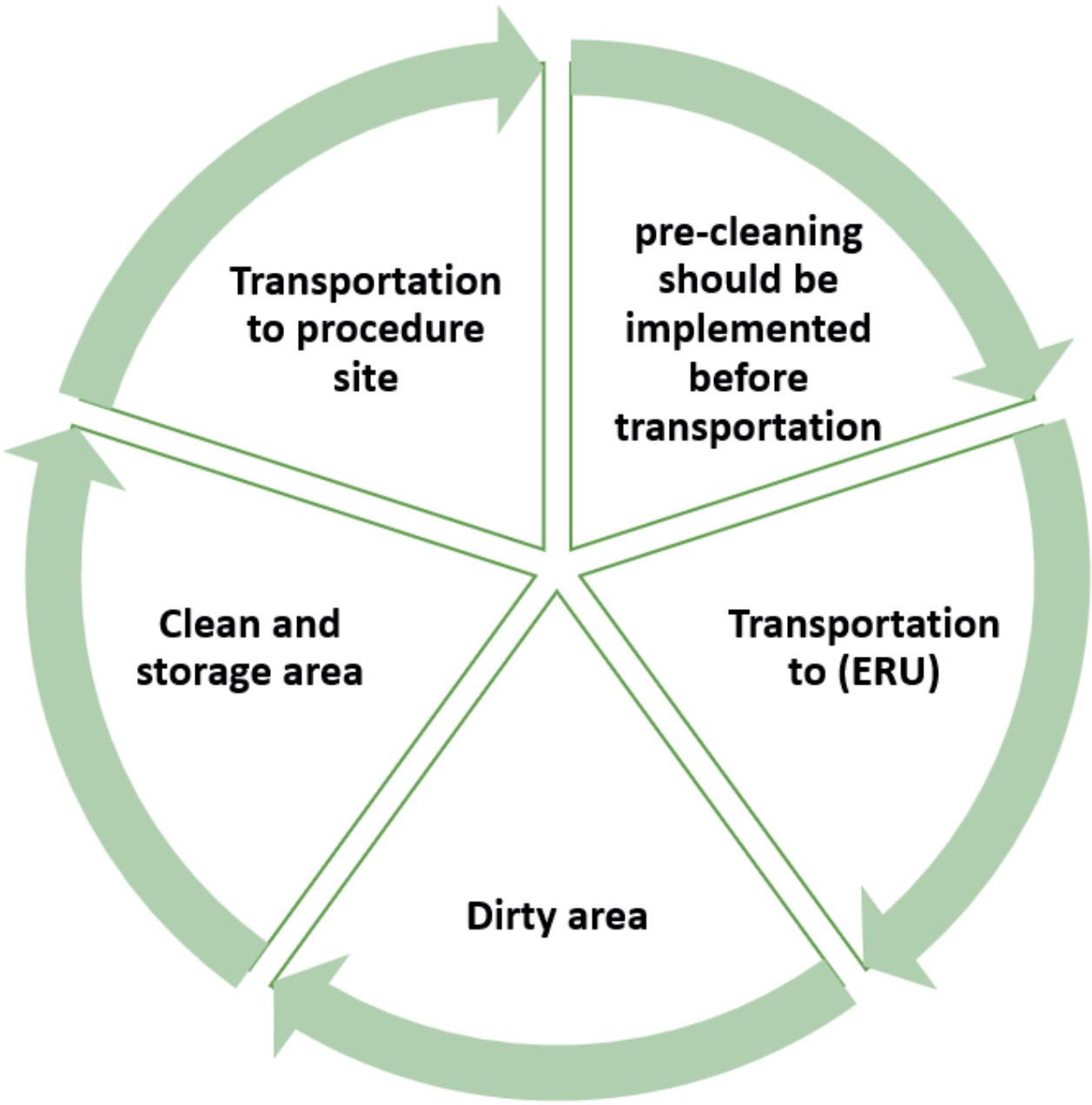


Figure 4: The ERU Design

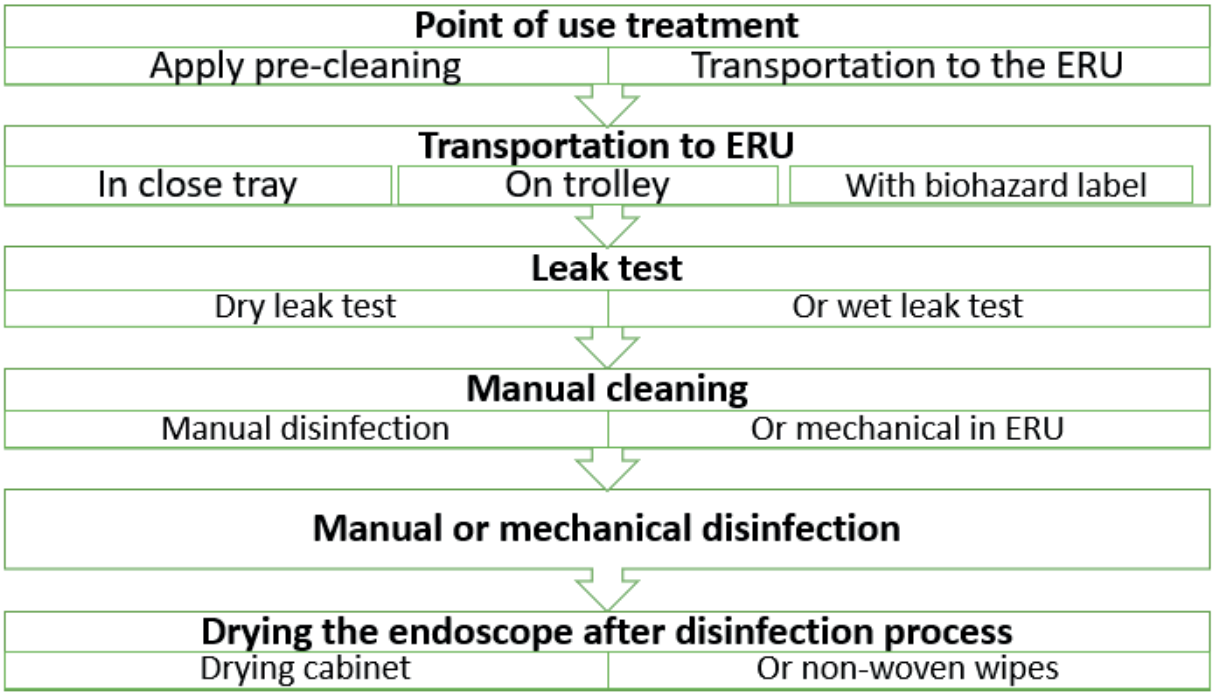
Reprocessing Flexible Endoscopes:

Reprocessing flexible endoscopes is critical in healthcare settings to ensure patient safety. These delicate instruments are used for various diagnostic and therapeutic procedures, such as gastrointestinal examinations.

Reprocessing involves thorough cleaning, disinfection, and sterilization to prevent cross-contamination and infections. Proper training, adherence to guidelines, and advanced reprocessing equipment are essential to maintain the integrity and effectiveness of flexible endoscopes. This cycle below briefly describes the reprocessing of endoscopes:


pre-cleaning should be implemented before transportation
Transportation to (ERU)
Dirty area
Clean and storage area
Transportation to procedure site

Another map that describes the whole process of reprocessing endoscopes procedure:



Proper reprocessing of flexible endoscopes is essential to prevent the transmission of infections between patients and to maintain the integrity and functionality of the equipment.

The reprocessing process typically involves the following steps:

Pre-cleaning :

Pre-cleaning of flexible endoscopes and accessories at the point of use should occur as soon as possible after the endoscope is removed from the patient (or the procedure is completed) and before organic material has dried on the surface or in the channels of the endoscope.

Designated personnel should wipe the external surfaces with a soft, lint-free cloth or sponge saturated with utility or sterile water and should suction water through the channels. Suction channels should be rinsed with clean water to remove as much blood and tissue debris as possible. The insertion tube should be wiped with an enzymatic detergent solution approved by the endoscope manufacturer.

Transportation to ERU:

- Contaminated flexible endoscopes and accessories should be transported to the endoscopy reprocessing unit as soon as possible after use.
- Endoscopes and accessories should be kept wet or damp but not submerged in liquid during transport.
- Contaminated endoscopes and accessories must be transported to dirty area in a closed container or closed transport cart.
- The container or cart must be leaking proof, puncture resistant, and large enough to contain all contents.
    - The container should be of sufficient size to accommodate the endoscope when the endoscope is coiled in large loops.
    - Flexible endoscopes should be transported in a horizontal position and not suspended.
    - The transportation container must be cleaned and disinfected according to IFU.
- Endoscope accessories should accompany the endoscope but should be contained separately.
- The processing of endoscopes and endoscope accessories should begin as soon as possible after transport to the endoscopy reprocessing unit or within the manufacturer's recommended time to processing.
    - When it is not possible to initiate the cleaning process within the endoscope manufacturer's recommended time to cleaning, the manufacturer's instructions for use (IFU) for delayed processing should be followed.
    - Flexible endoscopes should not be left soaking in enzymatic cleaning solutions beyond the endoscope manufacturer's designated contact time unless this is recommended in the manufacturer's IFU for delayed processing.
    - A procedure should be developed and implemented for recording the times that the procedure is completed, and cleaning is initiated.

Leak Test:

- Flexible endoscopes designed to be leak tested should be leak tested after each use; after any event that may have damaged the endoscope; and, if it is a newly purchased, repaired, or loaned endoscope, before use.
    - The majority of flexible endoscopes require a leak test be performed prior to submerging the device during cleaning, and prior to high level disinfection / sterilization.
    - Depending upon the manufacturer's IFU, leak testing may involve (Dry Leak Test) or testing the endoscope under water (Wet Leak Test). In either case, the endoscope is pressurized via a hand pump or automated system.
    - A leak test is necessary to ensure that the endoscope is watertight. A leaking endoscope cannot be disinfected or sterilized properly (i.e., it should not be used on any patient)
    - Damage from use, incorrect care and handling practices, or improper chemical exposure can lead to leaks in the covering or seals.
    - Leak testing is, therefore, required before further cleaning or disinfection can occur.
    - Most endoscope manufacturers require the use of specific leak testers. It is necessary to ensure that the leak test is performed using the correct tool.
    - Consult the manufacturer about the proper leak testing procedure and instructions for the specific endoscope.
    - **Dry Leak Test:** Some manufacturers recommend only a dry leak test to be performed. To perform this test:
        - Attach the leak tester and pressurize the scope. Do not place the scope in water.
        - Follow the IFU for pressure testing the endoscope to the prescribed pressure, then manipulate the movable parts of the endoscope by holding the parts in each direction for a minimum of 15 seconds.
        - Watch the leak tester gauge; if the pressure drops, the scope has a leak and should be sent for repair.

- Wet Leak Test: Some manufacturers recommend a wet leak test to be performed. To perform this test:
  - First, pressurize the scope and check the distal end by submerging only the distal end of the insertion tube into water. The water bath should be clear water (with no chemicals), so air bubbles will be easily seen.
  - Rotate the distal end of the endoscope (i.e., moving it in different directions). If no bubbles are observed exiting the bending section, then the endoscope is totally submerged.
  - After submerging the scope, use a syringe to flush water through all channels to remove any air that remains trapped within the channels.
  - Observe the exit area to see if air bubbles appear. If air bubbles are observed exiting the endoscope after previously flushing all air out of the channels, a leak has occurred.
  - The most common area for leaks is the bending rubber at the distal tip of the insertion tube.
  - Remove the endoscope from the water and drain.
  - Release pressure & verify deflation of the endoscope.
  - Disconnect the leak tester from the endoscope.
  - Never disconnect the leak tester or deflate the endoscope while it is submerged; water could enter the leak tester connector and invade the endoscope's interior.
- If the endoscope passed the leak test, it is watertight, and reprocessing may proceed.
- Any endoscope that fails a leak test should be immediately shipped to the manufacturer or an authorized company for repair.
- The flexible scope should be cleaned before being sent for repair as per manufacturer instructions.

Manual Cleaning:

Cleaning endoscopes requires careful attention to detail to ensure effective disinfection and prevent the transmission of infections between patients. While the specific cleaning protocols may vary depending on the endoscope model and manufacturer, here are some general steps to manually clean an endoscope:

- Manual cleaning should occur as soon as possible after leak testing.
- Manual cleaning should be performed using the type of water recommended by the endoscope manufacturer.
- Manual cleaning should be performed using a cleaning solution recommended by the endoscope manufacturer.
    - Manual cleaning should be performed using a freshly prepared cleaning solution. Cleaning solutions should be changed before they become cloudy or discolored and before there are visible particulates in the solution.
    - Cleaning solutions should be changed when the temperature of the solution does not meet the temperature specified in the manufacturer's instructions.
- The endoscope should be completely submerged in the cleaning solution during the cleaning process. Removable parts (e.g., valves, buttons, caps) should be detached from the endoscope and submerged if this is recommended by the endoscope manufacturer's instruction.
- All exterior surfaces of the endoscope should be cleaned with a soft, lint-free cloth or sponge saturated with the cleaning solution.
- All accessible channels and the distal end of the endoscope should be cleaned with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer. The endoscope valves should be manually actuated during cleaning.

- The elevator mechanism and the recesses surrounding it should be cleaned and brushed with a cleaning brush of the length, width, and material recommended by the endoscope manufacturer. The elevator should be raised and lowered throughout the manual cleaning process.
- A clean brush should be used for each endoscope cleaning. Brushes and other items used to clean endoscope channels should be visually inspected before use and should not be used if the integrity of the brush or other cleaning item is in question.
- The accessible channels of the endoscope should be brushed multiple times (at least 3 times or based on manufacturer instructions) until no debris appears on the brush. Debris should be removed from the brush before the brush is retracted through the channel and after each pass by swirling the brush in the cleaning solution and rinsing it.

- The channels of the endoscope should be flushed with cleaning solution. A cleaning adapter or automatic flushing system may be used when it is compatible with the endoscope.
- The exterior surfaces and internal channels of the endoscope should be flushed and rinsed with utility water until all cleaning solution and residual debris is removed.
- The exterior surfaces of the endoscope should be dried with a soft, lint-free cloth all channels purged with instrument air.
- Reusable parts (e.g., valves, buttons, port covers, tubing, water bottles), accessories (e.g., forceps), and cleaning implements (e.g., brushes, channel cleaning adapters) should be cleaned, brushed, rinsed, and high-level disinfected or sterilized according to manufacturer instructions.
- Water and irrigation bottles should be high-level disinfected or sterilized at least daily. There should be no residual water or moisture remaining in the water-bottle assembly.

- Single-use parts, accessories, and cleaning implements should be discarded after use and should not be reprocessed.

Check for Endoscope Integrity:

Flexible endoscopes, accessories, and associated equipment should be visually inspected for cleanliness, integrity, and function before use, during the procedure, after the procedure, after cleaning, and before disinfection or sterilization.

- Before use, all new, repaired, refurbished, or loaned endoscopes, accessories, and other equipment should be visually inspected and processed according to the manufacturer's IFU.
- Endoscopes, accessories, and equipment should be visually inspected and evaluated for: cleanliness, missing parts, clarity of lenses, integrity of seals and gaskets, moisture, physical or chemical damage functionally.
- Lighted magnification should be used to inspect endoscopes and accessories for cleanliness and damage.
- Internal channels of flexible endoscopes may be inspected using an endoscopic camera or borescope.
- Defective endoscopes, accessories, and equipment should be removed from service and repaired or replaced.
- Medical equipment being sent for repair must be decontaminated according to IFU to the fullest extent possible and a biohazard label attached before transportation.

High Level Disinfection (HLD):

After manual cleaning and when it is compatible with the endoscope manufacturer's IFU, flexible endoscopes and accessories either should be mechanically disinfected by exposure to a high-level disinfectant or a liquid chemical sterilant (low temperature sterilization) or manually disinfected.

- The minimum recommended practice for flexible endoscope disinfection is HLD with an approved disinfectant.
- To achieve adequate HLD, all internal and external surfaces must be in contact with that disinfectant, according to manufacturer's labeling instructions.
- Prior to selecting a disinfectant, the endoscope manufacturer must be consulted for IFU to ensure that the disinfectant is compatible with the endoscope.
- In addition, if an ERU is used, that manufacturer's IFU must also be checked.
- Several HLD solutions, including Ortho-Phthalaldehyde (OPA), and Peracetic acid solutions, are approved for endoscopes' disinfection.
- Testing the dilution of these chemicals is required daily.
- The ERU drain should be checked daily for cleanliness.
- Ensure that the monitoring processes and strips are correct for the brand and concentration of disinfectant selected.
- Solution test strip is designed to verify the high-level disinfectant solution prior to each use, to confirm that the concentration is above the MRC (Minimum Recommended Concentration). The steps for using the MRC test are as follows:
    - Dip the strip into the solution for just 2 seconds then remove it.
    - At 60 seconds, read result (Color Change).
    - If the color changed completely, the test is considered "Passed"

- An endoscopy reprocessing machine is that cleans, disinfects and rinses flexible endoscopes. The design permits the exterior of the scope and all lumens to be exposed to cleaning, disinfecting, and rinsing solutions.
- The labels of some disinfectants require elevating their temperature above room temperature to achieve HLD. Most endoscopy reprocessing machine has heater feature that conveniently and rapidly elevates the temperature to a pre-determined setting (i.e., they are typically enclosed systems).
- Endoscopy reprocessing machine limit staff exposure to liquid chemical disinfectants and their vapors.
- Endoscopes are placed in the endoscopy reprocessor after Initial manual cleaning & brushing.
- For flushing of the lumens, specific tubing connections must be connected.
- The disinfectant should not be diluted with any fluids.
- The endoscopes reprocessor should circulate fluids through all endoscope channels at an equal pressure without trapping air. Channel flow sensors provide an added measure of compliance.
- The detergent and disinfectant cycles should be followed by thorough rinse cycles and forced air to remove all used solutions.
- Endoscopes reprocessing machine should be self-disinfecting.
- No residual water should remain in hoses and reservoirs.
- Cycles for alcohol flushing and forced air drying are desirable.
- The reprocessing machine should also feature a self-contained or external water filtration system.
- Printing data verification for cycle completion is required.
- Some machines use enzymatic detergents and disinfectants (cleaner & disinfector), others use only disinfectants (disinfector).

- In either case, all steps of manual cleaning & brushing must be applied before inserting endoscope into the disinfection machine.
- Prepare the endoscope reprocessor according to manufacturer's guidelines. Set the machine for the appropriate time and temperature depending on the chemicals used.
- Dry the exterior of the endoscope with a soft, lint-free cloth and channels with air to prevent dilution of the chemical disinfectant if the reporocessor (disinfector) not provide drying phase.
- Place the endoscope in the reprocessor and attach all channel adapters according to manufacturer's IFU.
- The elevator channel of a duodenoscope has a very small lumen. Since most machines cannot generate the pressure required to force fluid through this lumen, manually reprocess the elevator channel unless the same machine is validated to perfuse this channel.
- You should check with the endoscope ‘s manufacturer for model specific information and IFU.
- Place valves, removable parts, and other accessories into the soaking basin of the disinfection machine.
- Unless the machine has a dedicated space for the endoscope's accessories, reprocess these items separately.
- If there is a cycle that uses enzymatic detergent, the product should be compatible with the disinfection machine and the endoscope.
    - Improper dilution or excess amounts of the enzymatic detergent may allow detergent residues to remain on the internal and external surfaces of the endoscope, and/or on the sink surfaces of the reprocessor.
    - Enzymatic detergent residues may interfere with the action of the high level disinfectant.
- Start the machine and allow it to complete all cycles/phases.
- If cycles/phases are interrupted, HLD cannot be ensured, and full cycle must be repeated.

Endoscopy Reprocessing Machine Phases:

- Cleaning phase spry arm start moving and provide high pressure channel.
- Detergent cleaning by the recommended enzymatic detergent solution.
- Rinsing from detergent residues.
- Drying phase (1).
- High level disinfection (HLD) will be applied with approved chemical disinfectant.
- Rinsing from disinfectant residues.
- Drying phase (2).

- Many departments do not have automated equipment to disinfect flexible endoscopes, **so the manual disinfection should be implemented:**
  - Prepare the disinfectant solution for use according to the manufacturer's IFU and the dilution of the solution should be checked daily by using specific strip.
  - Place the clean endoscope into the appropriate container containing the HLD solution. Ensure that the scope is completely dry (to prevent dilution of the disinfectant solution) and fully immersed with removal of any air bubbles adhering to its surface.
  - Use a syringe, the cleaning adaptors or the supplied irrigation tubes to fill all channels with disinfectant solution until no bubbles are seen exiting these channels.
  - Place all valves and removable parts in the disinfectant.
  - Set the timer for the correct exposure time (Contact Time).
  - After disinfection is complete, remove the endoscope, valves and removable parts from the disinfectant solution and rinse them by completely immersing these items in treated water.
  - Flush lumens carefully according to the manufacturer's IFU.
  - Dry the endoscope according to the manufacturer's IFU.
  - Label the scope with the date processed or date to process, depending on the facility's scope storage policy.

- Document all information regarding the processing steps of flexible endoscope.
- Fulfill records related to flexible endoscope procedures for tracking purposes.

Records should include:

- Date & time of disinfection.
- Identification of the patient.
- Procedure name.
- Identification of the endoscope and its accessories used during the procedure.

Storage of Flexible Endoscopes:

Cabinets used for the storage of flexible endoscopes should be situated in a secure location in the clean workroom of the endoscopy processing area in a two-room design or in a separate clean area close to, but not within, the endoscopy procedure room.

- Storage cabinets should have doors and should be located at least 3 ft from any sink, It is preferable to wear gloves while hanging the endoscopes in a storage cabinet.
- Flexible endoscopes should be stored in a drying cabinet.
- If a drying cabinet is not available, flexible endoscopes may be stored in a closed cabinet with HEPA-filtered air that provides positive pressure and allows air circulation around the flexible endoscopes.
- Flexible endoscopes that have been mechanically processed should be stored in a cabinet that is either designed and intended by the cabinet manufacturer for horizontal storage of flexible endoscopes of sufficient height, width, and depth to allow flexible endoscopes to hang vertically without coiling and without touching the bottom of the cabinet.
- Flexible endoscopes should be stored with all valves open, and removable parts should be detached but stored with the endoscope.
- Flexible endoscopes should be clearly identifiable, with a distinct visual cue, as processed and ready for use.
- Flexible endoscopes and storage cabinets should be visually inspected for cleanliness before endoscopes are placed into or removed from storage.

- IPC committee that includes infection preventionists, endoscopy and perioperative nurses endoscopy processing personnel, endoscopists, and other involved personnel should establish a policy to determine the maximum storage time that processed flexible endoscopes are considered safe to use without reprocessing.
- IPC committee should establish a policy for removing and reprocessing the endoscope before use if the maximum storage time has been exceeded.
- The maximum interval of endoscope storage is required to be stated clearly in the policy and the length of time may depend on multiple factors as identified on organizational risk assessment that may include endoscope usage/turnover of endoscopes used and manufacturer's instructions-for-use, and all the previous mentioned recommendations must be constructed and approved by IPC committee, endoscopy unit staffs, preoperative staffs, and the endoscopes reprocessors, and in the same policy should be stated that the appropriate measures required if the required time of the storage interval exceeded.
- The endoscopy cabinet should be periodically maintained, and the periodic protective maintenance (PPM) should be documented.
- IPC committee should establish a policy to determine the cleaning frequency of the storage cabinet.
- The health care facilities should maintain records of flexible endoscope processing and procedures.
- Records related to flexible endoscope processing should include the
  - Date and time.
  - Identity of the endoscope and endoscope accessories.
  - Method and verification of cleaning and results of cleaning-verification testing.
  - Number or identifier of the mechanical processor or sterilizer and results of process efficacy testing.
  - Identity of the person(s) performing the processing.
  - Lot numbers of processing solutions.
  - Disposition of defective items or equipment.
  - Maintenance of water systems, endoscopes and endoscope accessories, and processing equipment.

- Records related to flexible endoscope procedures should include the
  - Date and time.
  - Identity of the patient.
  - Procedure.
  - Identity of the licensed independent practitioner performing the procedure.
  - Identity of the endoscope and endoscope accessories used during the procedure.

- The health care facility quality management program should evaluate the processing of flexible endoscopes.
- IPC committee should establish a policy to determine processes for monitoring and auditing facility water quality to ensure compliance with requirements for endoscope processing as specified in the endoscope, processing equipment, and processing products manufacturers' IFU. Water quality and water filtration systems should be assessed at established intervals and after major maintenance to the water supply system.
- Healthcare facilities should collaborate with manufacturer service personnel to determine schedules for preventive maintenance of flexible endoscopes, mechanical processors, and other equipment (eg, the drying cabinet) used for processing flexible endoscopes.
- Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (eg, after each use, daily).
- IPC committee should establish the type of cleaning-verification test to be performed.

Administrative in the ERU:

- Healthcare facilities where flexible endoscopes are used and/or reprocessed is accountable for:
  - Allocating sufficient human and material resources to ensure that the selection, use, and reprocessing of endoscopes and related accessories are managed in a manner that minimizes infection risk and supports patient and healthcare worker safety.

- Supporting and empowering the authority of those responsible for managing infection prevention & control practices to ensure effectiveness of the program.
- Ensuring that the essential elements of an endoscope reprocessing measures are followed and that endoscopes are reprocessed according to manufacturers' IFU.

- **Policies:**

- In all practice settings where endoscopy is performed, policies related to the reprocessing of endoscopes should be approved by an IPC committee.
- Policies should address the selection, use, transport, reprocessing, and storage of endoscopes and accessory devices to ensure compliance with endoscope and reprocessing equipment manufacturers' IFUs. In addition, policies should clearly include requirements for documentation of adherence to essential reprocessing steps, parameters regarding the physical setting where endoscope reprocessing occurs, staff education, training, and assessment of competency, ongoing quality assurance procedures, and protocols for responding to equipment and HLD/sterilization failures or breaches.
- Policies should include the management of "loaner" endoscopes (i.e., endoscopes that are not owned by the healthcare facility but are provided for temporary use by manufacturers, equipment suppliers or other healthcare facilities) to ensure adherence to the same reprocessing standards described above required for facility-owned equipment. This includes:
  - Assessing the condition (i.e., visual inspection, leak testing) of loaner endoscopes prior to use.
  - Cleaning and high-level disinfection or sterilization of loaner endoscopes supplied by the manufacturer or another healthcare facility prior to use.
- Policies should also take into consideration the standards and recommendations from international professional approved organizations and national guidelines.

- Management should ensure that:
  - Policies related to the reprocessing of endoscopes are in place and are reviewed on a regular basis as required. In addition, policies should be updated regularly when new equipment/products are purchased and when new information is published.
  - Occupational health needs are addressed that include but are not limited to the provision of hepatitis B vaccine, prevention of exposure to infectious agents (e.g., bloodborne pathogens, enteric pathogens) and availability of post-exposure prophylaxis when indicated, convenient access to and appropriate use of personal protective equipment (PPE), and monitoring for exposure to chemicals used for reprocessing when applicable.
  - Staff has access to infection prevention knowledge and training to support the development and implementation of infection prevention policies and procedures in the ERU.
  - All personnel involved in the reprocessing of endoscopes, including the supervisors and managers of reprocessing personnel, receive ongoing education, training and assessment of competency.
    - If personnel are responsible for reprocessing more than one type of endoscope, verify reprocessing competency for each type of endoscope, including the appropriate use of all equipment required for reprocessing.
  - At minimum, water used for reprocessing of endoscopes meets the specifications that are recommended by the device and reprocessing equipment manufacturers.
  - All the essential elements of an effective endoscope reprocessing measures are met and maintained.

Documentation:

- Documentation requirements vary depending upon the methods and the products that are used for HLD or sterilization.
- For all methods of reprocessing using HLD or sterilization, document endoscope and patient identifiers. Tracking is essential in the event of a disinfection failure and for responding to device or product recalls.
- Ensure that there is a process in place to record the procedure end time and the start time for manual cleaning. Recording these times enables reprocessing personnel to ascertain how long the endoscope has been awaiting reprocessing, to prioritize reprocessing of specific endoscopes, and to determine whether routine reprocessing within the manufacturer's recommended time to cleaning is achievable, and if not, to implement the manufacturer's procedures for delayed processing.
- Maintain documentation of the effectiveness of the products used for cleaning and disinfection (e.g., document the results of testing for effective concentrations of the chemical disinfectant, expiration dates for test strips and chemical disinfectants).
- Maintain records of periodic preventive maintenance (PPM) and repair of endoscopes and reprocessing equipment (e.g., leak testers).
- Documentation should include the investigation of critical or potential critical events such as HLD or sterilization process failures or equipment failures.

Inventory:

- Conduct an endoscope inventory to identify all endoscopes and method of reprocessing in use by the healthcare facility. Information reviewed for each endoscope should include but is not limited to the:
  - Endoscope manufacturer and model.
  - Location of use.
  - Number of procedures performed.
  - Location of the endoscope manufacturer's IFUs.
  - Location for reprocessing.
  - Equipment used for HLD and/or sterilization.
  - Status of the endoscope (i.e., retired, out for repair, in use)
- Ensure that each endoscope has a unique identifier to facilitate tracking. Tracking should include the ability to determine when specific endoscopes were used for specific patients, loaned to other units or healthcare facility, reprocessed, or repaired. Tracking is also essential for responding to device or product recalls.

Education, Training, and Competencies:

- Training and competency assessments should be based upon the endoscope manufacturer's IFUs as well as the reprocessing equipment and chemicals used. If more than one type/model of endoscope is used, staff should be able to demonstrate they are competent to reprocess each specific type of endoscope.
  - o Model-specific competency assessment check lists may be required.
  - o Post visual educational aids and standard operating procedures to reinforce best reprocessing practices.

- Education and training should also address decontamination, cleaning and sterilization of reusable accessories that breach the mucosal barrier (e.g., biopsy forceps).
- Ensure that trainers and managers are competent to reprocess endoscopes and can adequately train and verify the competency of their staff.
- Perform staff competencies:
    - Initially upon hire and periodically as required by healthcare facility policy. An educational update followed by direct observation of staff performing endoscope reprocessing is recommended.
    - Whenever a new model of endoscope, reprocessing equipment (e.g. machine or leak tester), or chemical is purchased.
    - Whenever there are updates to the manufacturer's IFUs.
    - That include essential steps of reprocessing from pre-clean to storage and documentation.
    - That include a review of procedures to be followed in the case of equipment failure (e.g., use of manual reprocessing methods as per manufacturer's IFU or use of an alternative automated reprocessor that is validated for the endoscope).
    - That include how and when to perform supplemental testing or other assessments of endoscope cleaning (e.g., tests that measure residual organic material or adenosine triphosphate) when those tests are used by the facility.
- Certification in reprocessing of endoscopes does not mitigate the need for orientation, ongoing education training/education and competency assessments.

Risk Assessment and Quality Assurance:

A risk assessment or comprehensive gap analysis should be conducted to ensure that:

- All essential steps of reprocessing and essential elements of an endoscope reprocessing approaches are met and maintained.
- Flexible endoscopes are precleaned at the point of use and transported safely to the reprocessing area.
- Staff competencies are verified.
- Sufficient numbers of reprocessing personnel are available when routine and/or emergency endoscopic procedures are performed.
- Manufacturer's IFUs are readily available and followed.
- Necessary reprocessing equipment and supplies are available.
- Physical space is adequate for reprocessing.
- Heating, ventilation, and air conditioning parameters are monitored and controlled.
- Storage of endoscopes is appropriate.
- Documentation providing complete traceability is maintained.

- When conducting the risk assessment or gap analysis, if an reprocessing machine is used, assess for documentation that the machine has been validated for reprocessing the endoscope and endoscope components. Obtain the model-specific reprocessing protocols for both the endoscope and reprocessor and verify compatibility.
- Perform periodic audits of healthcare facility reprocessing protocols and the completeness of documentation to monitor compliance. Gap analyses and risk assessments should be conducted periodically and whenever new endoscopes are purchased, manufacturer's IFUs change.

Disinfection/Sterilization Failure:

- Breaches in adherence to essential disinfection and sterilization steps can be a result of malfunctioning of equipment and/or human error. Each breach is a result of unique circumstances and should be evaluated to determine the risk of disease transmission.
- IPC should review each event carefully to determine the necessary corrective steps and the need for patient notification.
- There are several resources available to assist in a breach evaluation. The multi-disciplinary team should use one or more of these documents to guide their investigation.
- When a breach involves a suspicion of patient exposure to an improperly reprocessed endoscope, the decision to notify patients of their potential exposure should be made in consultation with an infection preventionist, healthcare facility administrative, and the health cluster administration.

References

1) Association for the Advancement of Medical Instrumentation: 1110 North Glebe Road, Suite 220, Arlington, VA 4890-525-703 4795-22201 Fax: 0793-276-703 **www.aami.org**

2) APIC Text of infection control & epidemiology: Chapter 108, Sterile Processing, Published April 2019.

3) Association of perioperative Registered Nurses 2170 South Parker Road, Suite 300 Denver, CO 2676-755-800 5711-80231 **www.aorn.org**

4) Canadian Standards Association 5060 Spectrum Way Mississauga, Ontario L4W 5N6 CANADA 6727-463-800 Fax: (2510-747 (416 **www.csa.ca**

5) Certification Board for Sterile Processing & Distribution 2 Industrial Park, Suite 3 Alpha, NJ 9555-454-908 08865 **www.sterileprocessing.org**

6) International Association of Healthcare Central Service Materiel Management 213 W. Institute Place, Suite 307 Chicago, IL 0078-440-312 60610 Fax: 9474-440-312 **www.iahcsmm.org**

7) World Health Organization and Pan American Health Organization ISBN 1 154985 4 92 978. **www.who.int**

8) CDC Works 7/24. (n.d.). Centers for Disease Control and Prevention. **https://www.cdc.gov/**

Appendix

Appendix 1:

RECEIVING AND DISPATCHING SHEET

Department: _____

Date Time	Sent by (Person Name)	Items	No. Of Pieces		Received by (Person name)	Delivered by	Received by
			Ward	CSSD		CSSD	Ward

Appendix 2:

DECONTAMINATION AREA CHECKLIST

1.

Weekly Ultrasonic Cleaner – Date: / / ☐ Not available								
Ultrasonic cleaners' number	1	2	3	4	5	6	7	Technician
Passed								
Failed								

2.

Weekly Automated Washer Disinfector Test–Date: / / ☐ Not available									
Washing machine number	1	2	3	4	5	6	7	Cart washer	Technician
Passed									
Failed									

3.

Weekly Filters Cleaning – Date: / / ☐ Not available									
Washing machine number	1	2	3	4	5	6	7	Cart washer	Technician
Passed									
Failed									

4.

Weekly Emergency Eyewash Safety Station Test – Date: / /		Technician
Working		
Not working		

Appendix 3:

DECONTAMINATION AREA CHECKLIST

- First Week

Daily disinfectant manual test – Date: / / ☐ Not available							
Date of solution filling: / /							
DAY	SUN	MON	TUE	WED	THU	FRI	SAT
Pass							
Failed							
Technician							

- Second Week

Daily disinfectant manual test – Date: / / ☐ Not available							
Date of solution filling: / /							
DAY	SUN	MON	TUE	WED	THU	FRI	SAT
Pass							
Failed							
Technician							

- Third Week

Daily disinfectant manual test – Date: / / ☐ Not available							
Date of solution filling: / /							
DAY	SUN	MON	TUE	WED	THU	FRI	SAT
Pass							
Failed							
Technician							

- Fourth Week

Daily disinfectant manual test – Date: / / ☐ Not available							
Date of solution filling: / /							
DAY	SUN	MON	TUE	WED	THU	FRI	SAT
Pass							
Failed							
Technician							

Head of the CSSD: _____

Appendix 4:

INAPECTION, ASSAMBLY AND PACKAGING AREA CHECKLIST

NO.	Day	Warm up	Leak test	Bowie-dick test	Technician
1			○ Pass ○ Failed	○ Pass ○ Failed	
2			○ Pass ○ Failed	○ Pass ○ Failed	
3			○ Pass ○ Failed	○ Pass ○ Failed	
4			○ Pass ○ Failed	○ Pass ○ Failed	
5			○ Pass ○ Failed	○ Pass ○ Failed	
6			○ Pass ○ Failed	○ Pass ○ Failed	
7			○ Pass ○ Failed	○ Pass ○ Failed	
8			○ Pass ○ Failed	○ Pass ○ Failed	
9			○ Pass ○ Failed	○ Pass ○ Failed	
10			○ Pass ○ Failed	○ Pass ○ Failed	

This form can be used before starting the sterilization process or in the beginning of each shift

STERILIZATION RECORDING SHEET

Appendix 6:

BIOLOGICAL INDICATOR TEST SHEET

Sterilizer Number	Load Number	Name of the Sets	Quantity	Ward	Cycle Start	Cycle End	Technician (Releasing)

Time/Date of inserting BI in incubator	Machine number	Load number	Type of sterilizer	Type of process	Technician initial	Time/Date of BI reading	BI result	Technician initial
			o Autoclave o Plasma	o Routine o Implant o After maintenance			o Positive o Negative	
			o Autoclave o Plasma o	o Routine o Implant o After maintenance o			o Positive o Negative	
			o Autoclave o Plasma o	o Routine o Implant o After maintenance o			o Positive o Negative	
			o Autoclave o Plasma o	o Routine o Implant o After maintenance o			o Positive o Negative	
			o Autoclave o Plasma o	o Routine o Implant o After maintenance o			o Positive o Negative	

Appendix 7:

Temperature, Humidity and Pressure Log Sheet For (Decontamination, IAP, & Sterile Storage) Areas

Date	Morning			Sign	Evening			Sign	Remarks
	T	H	P		T	H	P		
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

Appendix 8 :

CHECKLIST FOR DRYING AND STORAGE OF ENDOSCOPES

SCOPE NO.	DATE	SCOPE ID	PATIENT NAME	PERFORMED BY INITIAL & BADGE NO.	LOAD DATE/TIME	UNLOAD DATE/ TIME	TOTAL STORAGE TIME	REMARKS
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								

Appendix 9 :

CHECKLIST FOR REPROCESSING OF ENDOSCOPES AND ACCESSORIES

BY WASHER-DISINFECTOR

NO.	DATE	TIME	PATIENT NAME	PROCEDURE	TYPE OF SCOPE & IDENTIFIER	PRE CLEANING	Leak Test		Test Strip	TEMP	ENDOSCOPIST	PERFORMED BY: Initial & Badge no.	REMARKS
							1st	2nd					
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													
15													

Appendix 10 :

CHECKLIST OF ENDOSCOPES WASHER/DISINFECTOR SELF-DISINFECTION

NO.	DATE	TIME	RESULT		PERFORMED BY INITIAL & BADGE NO.	REMARKS
			Working	Not Working		
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						

Appendix 11 :

ENDOSCOPES WASHER-DISINFECTOR FUNCTIONAL CHECKING

NO.	DATE	TIME	RESULT		PERFORMED BY INITIAL & BADGE NO.	REMARKS
			Working	Not Working		
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						

Appendix 12 :

CHECKLIST FOR MANUAL REPROCESSING OF ENDOSCOPES

NO.	DATE	TIME	PATIENT NAME	PROCEDURE	TYPE OF ENDOSCOPE & IDENTIFIER	PRE-CLEANING	Leak Test		Test Strip	TEMP	ENDOSCOPIST	PERFORMED BY: Initial & Badge no.	REMARKS
							1st	2nd					
1													
2													
3													
4													
5													
6													
7													
8													
9													
10													
11													
12													
13													
14													

وزارة الصحة
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وزارة الصحة
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