Sultanate of Oman
Ministry of Health

Medical Devices
Reprocessing Manual

Version 1- 2024

Center for Disease Control and Prevention
Department of Infection Prevention and Control

Ministry of Health, Sultanate of Oman

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Message from
H.E. the Minister of Health

We are privileged to benefit from the advancement of health care system particularly in the realms of diagnostics, preventive and therapeutic services. However, this advancement has brought about increased the complexities in our tools and processes, consequently amplifying some of the pre-existing challenges such as Healthcare Associated Infections (HAIs).

The increase in HAIs is multifactorial, encompassing the gaps in; knowledge (policies/guidelines), the implementation of best practices, capacities, and/or patient related factors.

Globally, HAIs especially in the era of Antimicrobial Resistance are adversely impacting the quality of care, patient safety, universal health coverage and increasing financial burden of care delivery.

As part of our collective responsibility to build a safe healthcare environment and ensure capacities for the prevention of Healthcare Associated Infections, the Ministry of Health considers the risks, from inappropriate reprocessing and sterilization of medical and surgical equipment, very seriously. The Ministry strives to develop resources to engage effectively and efficiently.

Hence, the Manual of Medical Devices Reprocessing in Healthcare Facilities, First Edition, provides evidence-based practices and standards that enhance the knowledge and practices of the health care workers facing the current and future threat of healthcare associated infections.

I extend my sincere thanks and congratulations to the national team that worked on this manual and I offer my best wishes for its successful implementation in all the healthcare facilities.

Dr. Hilal Al Sabti
Minister of Health

Foreword:

Contaminated medical and surgical devices are known sources for Healthcare Associated Infections (HAIs) which can be serious and lead to death in addition to its financial burden on health care system. Ensuring an effective reprocessing and sterilization program goes hand-in-hand with infection prevention and control of HAIs especially Surgical Site Infection (SSI). However, the reprocessing and sterilization of reusable medical and surgical devices is a complex process that requires qualified and competent staff, policies, and guidelines to standardize the practice and unify the assessment of processes and outcomes.

The development of this manual comes in response to the needs of the healthcare facilities in Ministry of Health and in recognition that adherence to evidence based and best practices guidelines for cleaning, disinfection and sterilization can guarantee the safe use and reprocessing procedures of invasive and non-invasive medical-surgical instruments.

This manual is written by the national experts and reviewed by WHO consultants adopting the international standards, including evidence based recommendations and best practices while ensuring that it can be implemented in Oman healthcare facilities.

I trust, that this Medical Devices Reprocessing Manual clearly describes protocols and procedures to be implemented at the health care facilities. We are proud that this manual in its first edition has been written by a national team of experts. The final draft was reviewed by WHO consultants, to ensure applicability for implementation in our local healthcare system while adopting the international standards in practice.

The healthcare facilities are expected to provide all the necessary support for the dissemination, successful implementation and monitoring for the use of this manual overseen by the facility and central infection prevention and control program.

I thank and congratulate the Department of Infection Prevention and Control, Sterilization Services Section and the national experts from different hospitals in the governorates for their dedication and valuable contribution for this highly needed reference manual. We will remain committed to provide all the support needed for the implementation, follow-up, and monitoring process.

Dr. Amal Al Maani
Director General
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Acronyms

AAMI	Association for the Advancement of Medical Instrumentation
ABHR	Alcohol-Based Hand Rub
ACH	Air Change per Hour
AER	Automated Endoscopy Reprocess
ATP	Adenosine Triphosphate
BI	Biological Indicator
CDIPC	Central Department of Infection Prevention and Control
CI	Chemical Indicator
CJD	Creutzfeldt–Jakob Disease
CLSI	Clinical & Laboratory Standards Institute
CSS	Central Sterilization Services
CSSD	Central Sterilization Services Department
CDCP	Center for Disease Control and Prevention
DGHS	Directorate General of Health Services
DGMS	Directorate General for Medical Supplies
DGQAC	Director General of Quality Assurance Centre
DI	Deionization
EO	Ethylene Oxide
EPA	Environmental Protection Agency
ERCP	Endoscopic Retrograde Cholangiopancreatography
FIFO	First-In, First-Out
HAI	Healthcare Associated Infections
HCF	Health Care Facility
HEPA	High Efficiency Particulate Air
HLD	High-level Disinfection
HSE	Health Safety and Environment
HVAC	Heating, Ventilation, and Air Conditioning
IAP	Inspection, Assembly and Packing
IFU	Instructions for Use

IPC	Infection Prevention and Control
IQ	Installation Qualification
IUSS	Immediate Use steam Sterilization (IUSS) or “flash” sterilization
LCS	Liquid Chemical Sterilization
MDR	Medical Device Reprocessing
MDRT	Medical Device Reprocessing Technician
MEC	Minimum Effective Concentration
MIFU	Manufacturer’s Instructions For Use
MoH	Ministry of Health
MRC	Minimum Recommended Concentration
NCG	Non-Condensable Gas
OQ	Operational Qualification
OR	Operating Room
PCD	Process Challenge Device
PHC	Primary Health Care
PPE	Personal Protective Equipment
PPM	Periodic Preventive Maintenance
PQ	Performance Qualification
QMS	Quality Management System
RO	Reverse Osmosis
RSCS	Rigid Sterilization Container System
SDS	Safety Data Sheet
SOP	Standard Operating Procedures
SSI	Surgical Site Infection
SUD	Single Use Devices
TDS	Total Dissolved Solids
TOC	Total Organic Carbon
UV	Ultraviolet
WHO	World Health Organization

Definitions

Administrative Area	Office space for the department supervisor and support personnel.
ATP assessment	Method using adenosine triphosphate (ATP) to indirectly measure viable microbial load.
Auditing	Periodic auditing where inspections are made of the processes, procedures and staff in the department
Automated Endoscope Reprocess (AER)	Machines designed to assist with the cleaning and disinfection of endoscopes.
Bioburden	The number of microorganisms on a contaminated object; also called bio-load or microbial load
Biofilm	Refers to the matrix of different types of bacteria and extra cellular material that can tightly adhere to the interior surfaces of endoscopes
Biological Indicators (BI)	A biological indicator contains viable, non-pathogenic microorganisms (e.g., spore-laden strips or vials) providing a defined resistance to a specified sterilization process. It verifies the lethality of the sterilization process
Chemical Indicators	Assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. There are six classes of chemical indicators
Contact Time	The defined time for which surfaces of the medical device are exposed to a chemical or thermal disinfection process to achieve the appropriate level of disinfection
Containment Device	Reusable rigid sterilization container, instrument case, cassette, or organizing tray intended for use in health care facilities for the purpose of containing reusable medical devices for sterilization
Contamination	State of having been actually or potentially in contact with microorganisms.
Decontamination	The use of physical or chemical methods to remove, inactivate or destroy microorganisms, rendering them safe for handling
Decontamination Area	Decontamination area – area of health care facility designated for collection, cleaning of soiled and/or contaminated items it could include receiving area.
Disinfection	The destruction of pathogenic (disease causing) microorganisms, usually by thermal or chemical means.
Endoscope	Refers to a flexible device used to visualize the interior of a hollow organ.
Enzymatic Cleaner	A pre-cleaning agent that contains detergent and protease enzymes that break down proteins such as blood, body fluids, secretions and excretions from surfaces and equipment.
Exposure Time	The defined period for which the critical variables are maintained within their specified tolerances in the sterilization chamber
Final Rinse Water For Endoscopes	Should be free from bacteria or in acceptable limit
High-Level Disinfection (HLD)	The processes that destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores.
Housekeeping Equipment Storage Area	Area or space where housekeeping items are stored

Immediate Use Steam Sterilization (IUSS)	A special steam sterilization process designed and used for the emergency sterilization of surgical goods when routine sterilization cannot be done. Also known as 'flash' sterilization. Used for surgical instruments in an unwrapped condition.
Implant	The FDA defines an implant as a "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also implants
Labeling	Any legend, work, or mark attached to, included in, belonging to, or accompanying any medical device or product
Minimum Effective Concentration (MEC)	Refers to the lowest concentration of active ingredient necessary to meet the label claim of reusable HLD
Pack Density	Refers to the ratio of weight to volume and is affected by how textiles are arranged within a pack and by how tightly the pack is wrapped before sterilization.
Personnel Support Area	Area providing toilet, shower, and locker facilities for employees.
Physical Monitors	A physical monitor is a device that monitors the physical conditions in a chamber during sterilization (e.g. time, temperature and pressure). These are recorded (as a printout or electronic record) on each cycle.
Physical Monitors	Verify that the parameters of the sterilization cycle have been met
Preparation and Packaging Area	Area or space where decontaminated instruments, clean instruments, and other medical and surgical supplies are inspected; are assembled into sets and trays; and are wrapped, packaged, or placed into rigid sterilization container systems for sterilization.
Process Challenge Device (PCD)	A process challenge device contains a BI and/or CI. During routine monitoring of sterilizers, the PCD is placed in the sterilizer according to the PCD and sterilizer manufacturer's instructions. It is intended to challenge the sterilization process in a manner that is equal to or greater than, the challenge posed by the most difficult item that is routinely processed
Quality Audit	A systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.
Reprocessing	Refers to the cleaning and high-level disinfection or sterilization of reusable endoscope devices either by manual or automated methods.
Reusable Medical Device	A device intended for repeated use on different patients, with appropriate decontamination and other processing between uses
Reverse Osmosis (RO)	Reverse Osmosis Is a water treatment method that removes most ionic species from the water. It also removes microorganisms, endotoxins, organic compounds, and colloids effectively.
Risk Management	Ensures that non-conformances, incidents and errors are identified promptly, investigated, evaluated and documented
Shelf life	Term is used with respect to a sterilized, medical device and the period of time during which the item is considered safe for use

Sterile Storage Area	Area of a health care facility designed to store clean and sterile items and protect them from contamination
Sterilization	A process by which all viable forms of microorganisms (including spores) are destroyed.
Sterilization Area	Area of a health care facility where sterilization activities take place.
Storage Drying Cabinet For Endoscope	A medical device designed for storage of flexible endoscopes that circulates continuous HEPA-filtered air through each endoscope channel and within the cabinet
Textile Assembly Area (Pack Room)	Area or space where clean reusable textiles are inspected, patched, folded, assembled into packs, and wrapped
Total Organic Carbon	Is one of chemicals test for water that is used as a control indicator for the pre disposition of biofilm formation

Introduction

There are hundreds of millions of people worldwide are affected yearly by preventable infections in healthcare facilities with the health care-associated infections (HAIs). Modern healthcare facilities employ many types of invasive devices and procedures to diagnose and treat patients. These medical devices predisposed patients to more than 850 000 device-related infections annually due to inadequate sterilization procedures of surgical instruments and disinfection of reusable patients care items e.g., endoscopic devices, respiratory care devices, and reusable hemodialysis devices. The improper sterilization and disinfection of medical devices are influenced by a complex design of some instruments, gaps in policies, infrastructure, organization, and staff knowledge and work behavior.

Medical devices are used in nearly every health care procedure. Patients and health care professionals expect these medical devices to be functionally and microbiologically safe. The safety of medical devices begins with the manufacturer and is supported and maintained by a system of National Standards and government regulations that includes medical device licensing, construction and performance standards, and incident reporting systems. Health care settings develop policies and procedures that are based on several inputs, including government regulation, National Standards, and the specific requirements that make up the quality system of the individual organization.

Within this structure, areas or departments that reprocess medical devices within or for a health care setting play an essential role and face unique challenges including working with a wide array of medical devices manufactured by different companies, and receiving devices in varying states of cleanliness and repair.

It is the responsibility of the Central Sterilization Services Department (CSS) to decontaminate, inspect, perform necessary maintenance of, and disinfect or sterilize each medical device using the medical device manufacturer's validated instructions. The goal is to provide medical devices that perform as intended by the manufacturer and are safe for reuse.

The Ministry of Health (MOH), Central Department of Infection Control is committed in addressing issues in the sterilization services ensuring the healthcare facilities are applying standardized reprocessing procedures of instruments and devices under stringent quality control standards for patient safety.

Purpose

This manual provides guidance in planning and designs, reprocessing procedures and practices, quality control, staff training, dealing with contaminated and disposal of hazardous materials including audit tools for sterilization services.

Scope

This Standard is intended to address the safe, effective, and reliable reprocessing of reusable medical devices at each phase of the reprocessing workflow. This guideline is applicable to all private and government healthcare facilities that perform disinfection and sterilization services.

Structure

The structure of this document is based on the sequence of work in reprocessing medical devices including all aspects of cleaning, disinfection and sterilization processes.

Chapter 1:

Physical Structure

Chapter 1: Physical Structure:

1. Central Sterilization Services (CSS)

The CSS may be laid out depending on the size of the population it serves, the number of operations it has to support, and the distance from the service delivery to the point of use. The most effective and appropriate layout should be based on workload, staffing and financial resources, but the basic functioning and integrity of the department must not be compromised. The best practices around the world are the centralization of Sterile Services.

Advantages to Centralization of Sterile Services:

- Efficiency: The staff's knowledge and experience are maximized, thus improving safe reprocessing and productivity. All levels of the staff are working as a team towards improving efficiency.
- Economy: The processing equipment, such as washer-disinfectors and sterilizers, can be used optimally and improve cost effectiveness. Surgical instruments can undergo a properly documented rotation, thereby prolonging the life of instruments.
- Safety: The systems can be upgraded and modernized, which will improve patient safety. The staff will be trained and educated in the use of processing equipment including the implementation of guidelines; these measures will ensure personal and patient safety.
- Validation: this allows the reprocessing systems to be standardized, monitored and audited to improve QA measures
- Quality Assurance: Reprocessing practices can be monitored and audited to validate each step in the reprocessing cycle has been completed and documented

Smaller units may be decentralized e.g. in in operating theatres (TSSU), endoscopy units or diagnostic departments. These units must be well controlled with complete systems of validation in place and preferably under the supervision of CSS.

A theatre sterile services unit (TSSU) is no longer accepted practice unless there are specific reasons, such as remotely located operating theatre suites with limited devices, surgical trays, processing equipment and resources, including transportation.

2. Traffic Control and Workflow

CSS work areas shall be made up of distinct and separate work areas based on the service provided and generally include areas for:

a. receiving contaminated medical devices;
b. decontamination of medical devices;
c. HLD if applicable;
d. preparation and packaging;
e. sterilization and storage; and
f. a pass-through window between the main decontamination room to the negative pressure AER room

Areas that perform reprocessing tasks outside the CSS, are required to comply with the design and environmental requirements of this standard.
Traffic in all reprocessing areas shall be restricted to authorized personnel and general traffic restricted. Criteria for the entry of authorized personnel not involved in reprocessing shall be outlined in CSS policies and SOPs that include requirements for attire and hand hygiene practices. Personnel not involved CSS shall be given access to the CSS in accordance with these policies and SOPs.
CSS departments shall be clearly identified at each entry door and signs posted to indicate the restrictions to access and the requirements for protective attire and hand hygiene.

Workflow in CSS shall be unidirectional (dirty to clean) and incorporate the following:

- Restrict the traffic in decontamination, preparation and packaging, sterilization processing, sterile storage and distribution by authorized personnel only.
- Prevent visitors to enter the area, in cases it is necessary; visitors should comply with the attire.
- Close the doors along the corridors at all times except for movement of supplies and equipment.
- Avoid passage of contaminated instruments and equipment in clean areas.
- Transport the contaminated instruments in closed containers, bags or covered trolley to the decontamination areas.
- Transport the clean and sterile instruments in a covered or enclosed cart with solid bottom shelf to maintain cleanliness and sterility.
- Bring the used instrument in the CSS receiving area and transfer in the decontamination area.
- Allow the instrument to pass thru assembly and packing windows.
- Remove the instrument from clean side of the autoclave to the sterile area.
- Place the instrument in designated areas allowing to cool down and check sterility.
- Release the sterile items via the sterile room issuing window, if applicable and deliver the sterile items to its respective units.
- Ideally, CSSs should be divided into areas that are physically separated with a clear unidirectional workflow from dirty to clean-add.

Figure 1: Example of Physical Layout of CSS to Support Appropriate Workflow

Adapted from: The Asia Pacific Society of Infection Control Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities

3. General Requirements

3.1. Size of CSS area:

The space for CSS shall be large enough to accommodate the anticipated activities and workload for the service as determined by the following factors:

a) Service model of the reprocessing services (e.g., centralized [including case carts] versus decentralized and number of transport carts);
b) Type and number clinical services supported;
c) Volume and type of procedures performed;
d) Medical devices used, reused, and disposed of;
e) Degree of automation and manual reprocessing within the services;
f) Type, size, and number of reprocessing equipment;
g) Storage space for sterile storage areas sufficient;
h) Separate room for receiving and opening/unboxing/unpackaging supplies;
i) Reprocessing hours of the area;
j) A standby emergency electrical power supply system

3.2. Entrance and corridors (public areas) shall consist of:

- PPE Donning area for staff to don PPE prior to entering work areas
- Dirty area receiving of used medical devices
- Inspection, assembly and packing (clean area)
- Sterilization area (clean area)
- Sterile store (cooling and short-term storage)
- Administration and staff rest and changing areas (essential to be away from work areas)
- Storage for devices, chemicals and packaging stores (raw material and CSS products)
- Presence of a dedicated housekeeping rooms for cleaning equipment

3.3. Ceilings, Walls and Floors

Ceilings, walls, and other vertical surfaces shall be constructed:

a) of cleanable non-porous, non-shedding materials;
b) With recessed, enclosed pipes and fixtures to create a flush surface;
c) Without fissures, open joints, or crevices that can retain or permit passage of dirt particles, facilitating frequent cleaning;
d) Resistant to humidity in spaces where steam and moisture are encountered.
e) Solid walls and other vertical surfaces shall be rendered to a hard, smooth finish to facilitate cleaning and repair. Epoxy coating or a sprayed paint finish is appropriate in CSS areas.

Note: *A finished ceiling with enclosed fixtures limits condensation, accumulation of dust, and other possible sources of contamination.*

Floors shall:

a) Have welded seams and be coved at all walls;
b) Be cleanable and maintainable without toxic stripping and finishing;

c) Provide the necessary stability and traction for foot traffic and wheeled traffic, as appropriate;
d) Resist damage by water, chemicals, and use; and
e) Limit the transmission or reflection of sound and vibrations where noise control is needed.
f) Floors in the decontamination and case cart washing areas shall be anti-skid or slip-proof.
g) All floors shall be constructed of materials able to withstand wet mopping, mechanical cleaning, and the application of cleaning agents.

3.4. Doors:

a) Doors will be self-closing or automatic external and internal doors should be used to optimize environmental conditions between areas within the CSS.
b) Should be made of cleanable materials and
c) Maintained in good repair

3.5. Work Surfaces:

Work surfaces in CSS shall meet the following criteria:

a) be large enough to provide sufficient work space;
b) be flat, cut-resistant, seamless, and composed of a non-porous material so that they can be
c) cleaned, disinfected, and dried
d) not be made of particulate-type materials (e.g., particle board) and materials that could shed fibres
e) not be made of laminated materials unless they are specified by the manufacturer as providing a chemical-resistant surface (e.g., suitable for laboratory use)

3.6. Equipment Automation

The CSS should consider the following equipment automation options:

a) Return conveyors for washer-disinfector accessories with an integral pass-through window at the barrier wall between soiled and clean sides (if applicable);
b) Automated loading and unloading systems for washer-disinfectors or sterilizers;
c) Height-adjustable trolleys for washer-disinfectors or sterilizers;
d) Height-adjustable shelving and/or storage systems;
e) Height-adjustable sinks and preparation and packaging tables;
f) Automatic faucets for sinks and hand wash stations;
g) Pass-through windows and doors between soiled and clean areas; and
h) Cleaning agent dispensers.

Notes: *A pass-through window or door is an integral part of the barrier wall separating soiled and clean areas. To minimize the potential for area cross-contamination and the negative impact to the balancing of the HVAC system airflow and room temperatures, any openings such as pass-through windows or doors in the barrier wall need to be kept closed during periods of inactivity.*

3.7. Hand Hygiene

- **Hand Wash Sinks**
  a) Provide dedicated hand washing facilities (foot control or electronic sensor, if possible) in entrances, exits, in decontamination, personnel support areas e.g. toilets and lounges
  b) Consider the use hands free equipment for sinks towel dispenser and soap dispenser during the design of new facilities. If electronic sensors are used, provide backup system during power failure.
- **Alcohol-Based Hand Rub (ABHR)**

  Wall-mounted ABHR dispensers and portable dispensers with products containing 60% to 90% alcohol shall be:

  a) Made available in all areas; and
  b) Not be placed adjacent to a hand-washing sink.
  c) Located in all change rooms and throughout the CSS
  d) Made available inside the IAP and sterile areas where water or wet areas are not recommended. It shall not be placed close to sterile or packaged items.

  Always follow the health care facilities Hand Hygiene policy and procedures.

3.8. Eye Wash and Emergency Shower Stations

- Install in location adjacent to the hazardous chemicals (e.g. decontamination area).
- Provide plumbed or gravity fed/self-contained eye wash stations.
- Avoid using bottle type eyewash units.
- Monitor the water temperature = between (13°C-38°C).
- Provide hands free, stay open feature once activated emergency shower equipment

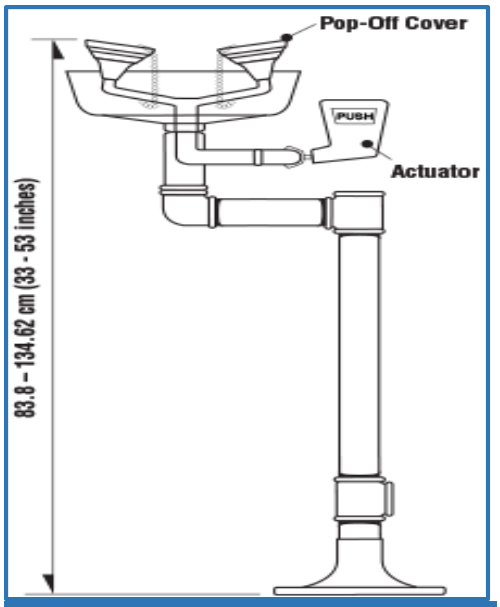


Figure 2: Eye Wash Station Requirements

Reference: Canadian Centre for Occupational Safety

4. Decontamination Areas

- **General Requirements for Decontamination Areas**
  a) Accessible from a service corridor.
  b) Functions under negative air pressure
  c) Cleaning accessories are available including water thermometer, medical grade air and mineral-free water (for flushing lumens)
  d) Pass-through windows separating the decontamination area from adjoining clean spaces remained closed.
  e) Automated decontamination equipment that supports automatic unloading of decontaminated devices to the clean side (two door) is recommended (passthru)
  f) For new construction, dedicated lift (elevator) to the transport of contaminated items only, if possible.
  g) Only utilized to process medical/surgical instrumentation and equipment.

- **Decontamination Sinks**

Decontamination sinks shall be:

- Stainless steel and designed with surfaces that are resistant to water and disinfecting chemicals;
- Designed with (3) compartments to facilitate soaking, washing and rinsing adjacent to waterproof counter tops and a backsplash preferred
- Double or triple sinks for manual cleaning and disinfecting, three sinks if manual cleaning will take place, and two sinks to prepare items for an automated system. One three-sink system should be available for use in an emergency when automated cleaning equipment is out of service
- Ensure sinks are deep to allow complete immersion of larger devices and instruments and large to accommodate trays or baskets of instruments and do not have an overflow
- Ensure it is appropriate height level so workers use them without bending or straining – preference to height adjustable sinks and work areas
- Provide water ports for the flushing of instruments if lumens instruments are used.
- Provide three functionally separate areas, if possible:
- Area for items that will require additional processing after decontamination and before patient reuse and/or drying equipment (eg. Drying cabinets for respiratory equipment etc.)
- Area for items (e.g., powered equipment) that require manual disinfection after cleaning to render them safe for handling in the preparation and packaging area
- Area for items that will not require additional processing

5. Inspection, Assembly and Packing Areas (IAP)

Equipment required in IAP areas includes:

a) Computers, if used, along with computer accessories (e.g., printer, bar code printer, scanner data ports, etc.);
b) Magnifying lights
c) Heat sealers
d) Instrument storage for replacement inventory and instruments requiring repair
e) Transfer carts
f) Processing tables made of nonporous materials (e.g., stainless steel) should be ergonomic and preferably height adjustable for Inspection, lubrication, sorting, assembly, and packaging
g) Testing equipment – e.g. continuity testing equipment
h) Battery rechargers – if applicable
i) Hand washing facilities (near exit of area)
j) Hand rub - accessible
k) Medical air for drying lumens
l) Drying cabinet

6. Sterilization Area

The area where sterilization is preformed shall have the following elements:

- Adjacent to the preparation and packaging area,
- Away from high traffic areas, scrub sinks, clinical sinks or hoppers, wash sinks or waste container.
- Space for all type of sterilizers, sterilizer carts, storage of long heat-resistant gloves, sterilizer cleaning supplies, record-keeping supplies, incubator, computer work stations
- Cooling area – not directly under air supply

7. Sterile Storage Areas

- **Clean and sterile storage areas shall be:**
  a) Dedicated to the storage of clean and sterile supplies;
  b) Located in an enclosed, limited-access area. The dedicated function of this area shall be the storage of sterile and clean supplies;
  c) Protected from
     i. moisture and dust contamination;
     ii. the entry of dust from adjacent areas and ventilation systems; and
     iii. the entry of vermin;
  d) Provided with adequate storage space to prevent crushing or damage to packages; and
  e) Equipped with appropriate environmental controls

Notes: *Maintaining the sterility of medical devices at the point of use is essential. Most packaging does not provide an absolute microbial barrier; therefore, it is important that environmental contamination be minimized to avoid compromising the sterility of medical devices during storage.*

- **Shelving:**
  All shelving shall be made of materials that are:
  a) Non-porous on all surfaces;
  b) Non-shedding and easily cleanable;
  c) Free of burrs and sharp or rough edges; and
  d) Solid on the top and bottom shelves.

  Shelving used on open shelving units for storage of clean and sterile medical devices and supplies shall be at a minimum:
  – 25 cm off the floor;
  – 45 cm from the ceiling; and
  – 5 cm from an outside wall.

  Note: *The use of solid plastic liners is appropriate for the top and bottom shelves. A solid top shelf will prevent dust from accumulating on sterile packages.*

8. Environmental Controls: Ventilation, Temperature and Humidity Requirements

General CSS shall establish documented requirements for environmental conditions and shall have documented procedures or work instructions on how to monitor and control environmental conditions such as humidity and temperature.

- Mechanical or controlled ventilation is required for CSS areas as they are demarcated into dirty and clean areas and have different ventilation requirements in each of these sections.
- Turbulent air flow and the use of portable fans are not allowed in any area of the CSS because rapid, uncontrolled air circulation can spread contamination.
- Ventilation systems must be cleaned, tested and maintained according to the manufacturer's instructions.
- There must be a clear policies and procedures in each CSS to ensure that the ventilation air-handling unit functions optimally AND meeting the requirements listed below.

Table 1: Environmental Controls for CSS:

Temperature

LOCATION	TEMPERATURE
Designated Clean Area	(18-23C)
Decontamination Area	(18-20C)
Sterile Storage and Support Area	(15-25C)

Humidity Requirements

LOCATION	RELATIVE HUMIDTY
All general areas	between 40%-50%
Humidity levels above 70% can adversely affect the sterile barrier system *Immediate action is required if humidity levels exceed 60%*	

Ventilation requirements

Area	Airflow	Minimum number of exchanges per hour	Air exhausted directly to the outdoor
Dirty area/ Decontamination	Negative	10 *	Yes *If no - Minimum of 20 ACH for mechanical ventilation
Clean area	Positive	12	No

Adapted: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

Chapter 2:

Staff Requirements and Qualifications

Chapter 2: Staff Requirements and Qualifications

1. Staffing Ratios:

There are no clear published guidelines on calculating staffing ratios in CSS. However, rough calculations with crude examples for the number of staff based on two parameters as shown in the example below.

- The number of operations or consultant episodes – calculated at 3000 per year per staff member.
  - The number of operating theatre (surgical) trays processed.
  - If there are automated wash processes, a rough guide would be one member of staff for every 1500-2000 trays per year.
- Another method is a time and motion study of a broad range of complexities (from simple to single Reusable Medical Devices (RMD)or complex tray) and specialties'.
  - Determine the mean, e.g. 10 minutes' labor for reprocessing.
  - Multiply by the number processed in a month e.g. 30,000 = 300,000 minutes = divide by 60 = 5000 hours = divide by 8 = 625 shifts for months and then work out staffing levels.

2. Training and Education:

- CSSD technicians must be qualified by owning certain certifications, training or experience and have comprehensive knowledge in all aspects of sterile processing.
- CSSD staff must be well trained on all infection prevention & control protocols including aseptic technique during biohazard transportation, decontamination, inspection, packaging, sterilization & storage.
- CSSD 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.
- CSSD staff must fully understand their roles and responsibilities with efficient implementation of all policies and procedures in order produce high quality sterile equipment for patient use.
- Infection Preventionists (IPs) should be a part of the interdisciplinary team that collaborates to provide safe, efficient, cost-effective, and high-quality reprocessing.
- If formal courses from recognized institution are available, the staff from heath care facility should be encouraged to do it.

The hospital should coordinate with vendors or company distributors to conduct education and training for new purchased instrument, devices and equipment

- All staff reprocessing medical devices should be knowledgeable about the following:
  - **A. Quality Management System (QMS) elements that apply to daily practice, including**

    i) monitoring;
    ii) testing
    iii) reporting;
    iv) corrective action; and
    v) documentation;
  - **B. IPC principles, including**

    i) basic microbiology concepts related to CSS;
    ii) Spaulding classification system;
    iii) one-way workflow;
    iv) maintaining a clean and uncluttered work surface and area;
    v) standard precautions;
    vi) hand hygiene;
    vii) selection and use of PPE;
    viii) handling of sharps and waste management;
    ix) body fluids exposure including prevention and actions to take should an exposure occur; and
    x) contamination and cross-contamination.
  - **C. Health Safety and Environment HSE including**

    i) engineering and environmental controls; HSE including
        1) the product identifiers of hazardous substances used in their health care setting; and
        2) how to read and interpret the information disclosed on labels and SDSs;
    iii) prevention of exposure to sharps;
    iv) prevention of exposure to chemicals;
    v) SOPs for the safe storage, use, handling, and disposal of hazardous substances and solutions;
    vii) hazard assessment;
    viii) post-exposure interventions, including the use of:
        1) eyewash stations;
        2) deluge showers; and
        3) spill kits;
  - **D. Decontamination, including**

    i) safe receipt of contaminated items;
    ii) selection and use of appropriate decontamination agents and methods;
    iii) types, function, and use of decontamination equipment (e.g., washer-disinfector, cart-washer);
    iv) collection, transportation, and receiving of soiled medical devices; and
    v) manual decontamination of used medical devices;

E. HLD, including

i) identification of medical devices that require HLD;
ii) use and selection of high-level disinfectant chemicals and equivalent processes;
iii) manual high-level disinfectant;
iv) types and functions of HLD equipment (e.g., AERs); and
v) automated HLD including thermal processes as applicable;

F. Assembly, including

i) sorting, inspecting, and functionality testing of reusable medical devices;
ii) differentiating among single-use, reusable, and limited reuse medical devices;
iii) operating assembly area equipment (e.g., heat sealers, tracking systems);
iv) instrument set assembly; and
v) packaging and wrapping items and sets for sterilization;

G. Packaging, including

i) suitability of the barrier systems for the sterilization process to be employed;
ii) maximum weight and load limitations in accordance with the IFUs; and
iii) distribution of medical devices in order to achieve sterilant contact on all instrument surfaces;

H. **Steam and low-temperature sterilization of medical devices,** including a demonstrated, comprehensive knowledge and use of each type of sterilization system(s) used, including the following:

i) the function of the main components and controls of the sterilizer systems;
ii) medical device compatibility or restrictions;
iii) barrier systems;
iv) system operation including sterility assurance monitoring, and interpretation of results;
v) understanding of critical parameters;
vi) loading and unloading of sterilizers and cycle operation;
vii) immediate post-sterilization handling of processed products;
viii) replacing the chemical supply (e.g., tank, cartridge, cup, or other container);
ix) routine and preventive maintenance;
x) SOPs for handling incidents (e.g., recalls, spills);
xi) safety measures for chemical systems used, including interpretation and understanding of the SDS, product label, potential hazards, and instructions for use;
xii) use of appropriate PPE as specified by the sterilant manufacturer;
xiii) use of environmental monitoring systems (if applicable);
xiv) chemical storage requirements;
xv) location and understanding of expiry date coding;
xvi) disposal of unused chemicals;
xvii) emergency responses to spills and leaks, e.g., hazard assessment, evacuation, use of showers and eyewash stations and use of spill kits and immediate first aid measures.

I. Storage, Transportation, and distribution;

i) storage and inventory management for reusable and single-use medical devices;
ii) transportation and distribution of clean and sterile supplies including case cart systems;
iii) unpacking and stocking;
iv) the importance of product integrity and damage prevention;
v) inspection;
vi) repacking;
vii) record-keeping;
viii) quality assurance;
ix) principles of sterility and stock rotation (FIFO);
x) environmental control (e.g., temperature and humidity, keeping doors closed); and
xi) safe receipt of sterile items;

J. Flexible endoscopes:

i) reprocessing flexible endoscopes and their accessories;
ii) documentation of transport time and key reprocessing stages;
iii) cleaning verification testing; and
iv) drying verification testing;

K. Waste management, including

i) biological waste;
ii) toxic waste;
iii) recycling waste; and
iv) anatomical waste

3. Competency Assessment:

Staff working in CSS should be appropriately qualified for their grade of work. Health-care facilities should consider the competencies required for the level of staff grade and ensure that the education program corresponds. Staff who's primarily role involves reprocessing should obtain and maintain competency in each area of reprocessing they are responsible for. There should be a process in place to ensure competency is continually assessed and continuing education is provided at regular intervals and all orientation, training, continuing education and competency assessments are documented.

The CSS Quality Management policy should set out requirements for ongoing competency assessment of staff performing and/or responsible for reprocessing. Competency of CSS staff shall be assessed annually and the review shall be based on defined performance criteria's:

- Quality assurance in sterile processing
- Manual and mechanical cleaning methods
- Processes of chemical and thermal disinfection
- Principles and methods of sterile packaging
- Principles of sterilization
- Operation of all sterilizing systems &equipment
- Storage, Transportation, and distribution
- Manufacturers standard operating procedures
- Tracking system and batch recall
- Infection Prevention and Control principles
- Health and safety principles

Chapter 3:

CSS Functions

Chapter 3: CSS Function

1. Items classification and disinfectant levels

Spaulding's Classification System

"Spaulding classification" is used to categorize reusable medical devices according to its intended use and the subsequent level of reprocessing required to render the medical device safe for reuse.

Table 2: Spaulding's Classification of Medical Devices and Required Level of Processing/ Reprocessing

Classification	Definition	Level of Processing / Reprocessing	Example
Critical Equipment/ Device	Equipment/device that enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	•Surgical instruments Implants • Biopsy instruments • Eye and dental equipment
Semi critical Equipment/ Device	Equipment/device that comes in contact with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by High Level Disinfection (as a minimum) Sterilization is preferred	•Respiratory therapy equipment • Anesthesia equipment • Tonometer foot plate •Endoscope
Noncritical Equipment/ Device	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by Low-Level Disinfection (in some cases, cleaning alone is acceptable)	•ECG machines • Oximeters • Bedpans, urinals, commodes •Blood pressure cuff

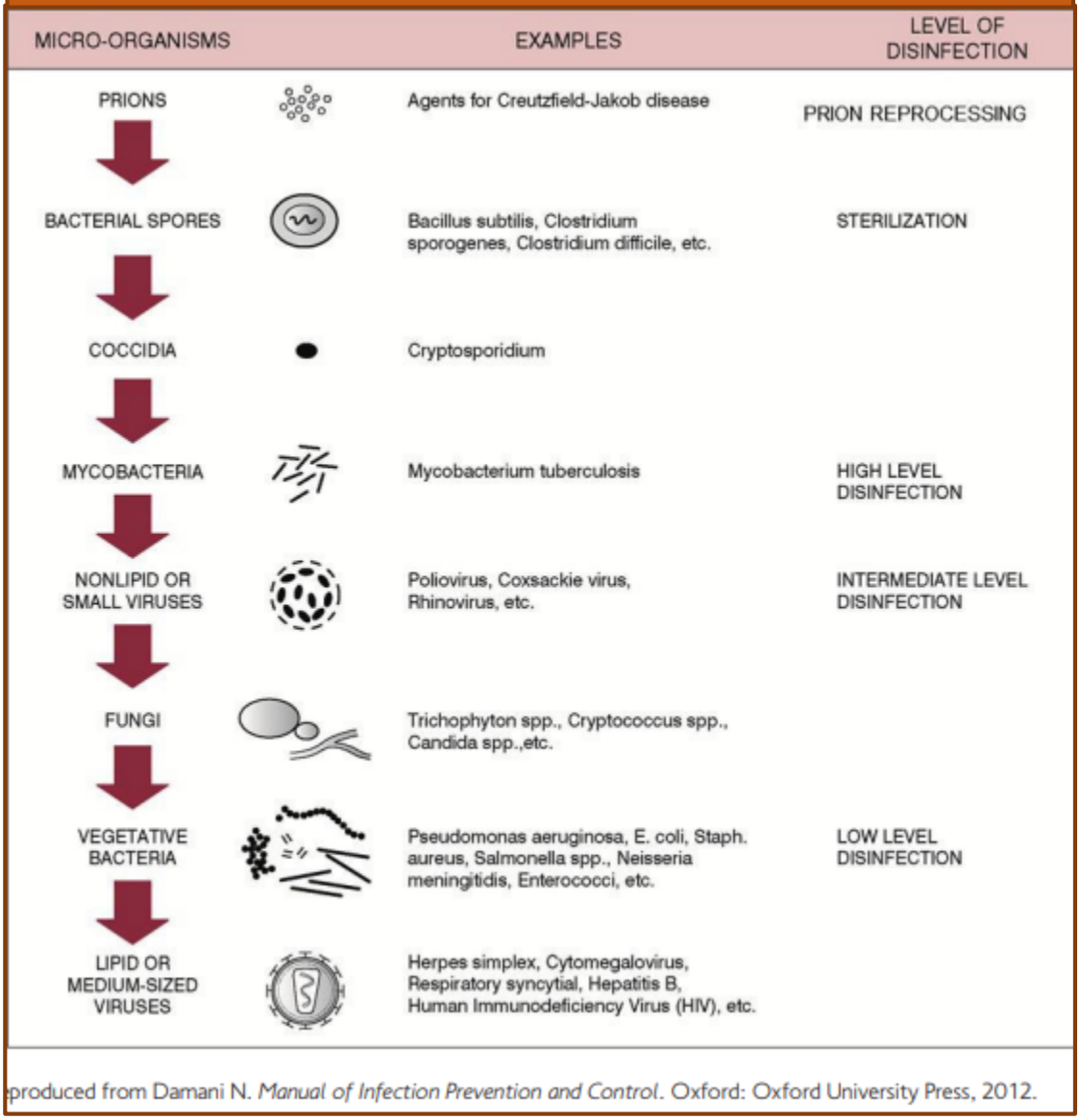
Reference: Best Practices for Cleaning, Disinfection and Sterilization of Medical Equipment/Devices in All Health Care Settings, 3rd edition, Provincial Infectious Diseases Advisory Committee (PIDAC), 2013

Levels of Disinfections:

Disinfectants can be classified as high-, intermediate-, or low-level disinfectants based on their ability to kill various microorganisms, including vegetative bacteria, mycobacteria, bacterial spores, fungi, and viruses.

- High-Level- process that kills all microorganisms, except bacterial spores
- Intermediate-Level - process that utilizes an agent that kills viruses, mycobacteria, fungi, and vegetative bacteria, but not bacterial spores
- Low-Level process that utilizes an agent that kills vegetative forms of bacteria some fungi and lipid viruses

Figure 3: Hierarchy of Disease Producing Agent and Destruction Agents



produced from Damani N. *Manual of Infection Prevention and Control*. Oxford: Oxford University Press, 2012.

Selecting the appropriate disinfectants:

- Should be approved by product evaluation team (MOH) or by international Environmental protection agency (EPA).
- Demonstrated efficacy for the intended use
- Compatibility with the device as per manufacturers IFU's
- Methods to be used for monitoring the products concentration, efficacy, temperature, and contact time
- Recommendations for rinsing (e.g., water quality, volume, time)
- Safety for use, with minimal toxic and irritating effects to/for staff
- Environmental safety, biodegradability and availability of disposal method in the healthcare facility.
- Method of use e.g. manual immersion, automated repressor, ultrasonic cleaner.
- Follow the manufacturer's recommendations pertaining to:

- Usage and compatibility, shelf life & storage, appropriate dilution/concentration, water requirements, temperature and contact time

An ideal disinfectant:

- Must have high germicidal activity
- Will rapidly kill a wide range of microorganisms, including spores
- Is chemically stable
- Is effective in the presence of organic compounds
- Is compatible with the surface being disinfected
- Is inexpensive (preferably) and aesthetically acceptable

Types of commonly-used chemical disinfectants

- **Ortho-phthaladehyde**
- **Glutaraldehyde**
- **Formaldehyde**
- **Peracetic acid**
- **Hydrogen peroxide**
- **Alcohol**
- **Chlorine dioxide**

Factors that affect the effectiveness of the disinfection process:

- Quantity of the Microorganisms Present on the Device: As the bioburden increases, the amount of time that a disinfectant need to act also increases. Therefore, it is essential to effectively clean of all the surfaces of instruments. Instruments with complex components should be disassembled and cleaned and disinfected part by part.
- Organic Matter: The presence of biofilms and/or organic matter, such as serum, blood, pus, feces or other organic substances, has the ability to inactivate the antimicrobial activity of disinfectants, and prevent contact with the disinfectant and therefore compromise its effectiveness.
- Resistance of microorganisms to the chemical agent: This refers primarily to the spectrum of antimicrobial activities of the various agents.
- Concentration of the agents: This refers to the concentration required of each disinfectant to produce the expected antimicrobial action. Higher concentrations may have deleterious effect on the material, e.g. corrosion.
- Physical and chemical factors: Some disinfectants have optimal antimicrobial activity at a certain temperature and/or PH.
- Duration of exposure: Each disinfection method and agent is associated with a specific amount of time that is necessary to achieve the desired result.
- Stability: Some disinfectants are unstable at use concentration, e.g. chlorine-releasing agents, and should be discarded as recommended by the disinfectant manufacturer/supplier.

2. Attire, Personal Hygiene, Personal Protective Equipment (PPE)

- Wear a clean prescribed uniform and shoes daily as per hospital policy. Wear closed shoes and not open sandals as they might accidentally injure themselves
- It is not recommended for the staff to wear street clothes in CSS
- Change the uniform when wet, grossly soiled or visibly contaminated with blood.
- Reusable contaminated uniforms must be laundered in laundry facility, if available.
- Avoid nail polish, wearing jewelry and wristwatches
- Avoid bringing handbags or work bags
- Provide containers for donning and removing attire.
- Use the appropriate PPE appropriate for the different areas within CSS.
- Remove PPE before leaving the decontamination area preventing contamination of the clothing beneath or the skin and discard the PPE and hair coverings when leaving the area.
- Reusable PPE should be decontaminated at least daily or between employees according to the manufacturer's instructions.
- Discard deteriorated PPEs (punctured, peeling, cracking) and if its integrity compromise safety.
- Provide disposable gown, head cover and shoes cover for other support personnel to wear upon entering the CSS.

Table 3: PPE Requirements in Different Areas

Areas	PPE
Decontaminated area	• Prescribed uniform • Fluid resistant long sleeve gowns • Face mask/goggles/full length face shields, or other devices to prevent splashing exposure in all angles. • Gloves – Disposable, long, heavy duty, water proof, puncture resistant (if available) • Hair covering/surgical cap • Shoes- Sturdy, nonskid closed toe/heel and washable
Packing, sterilization area, sterile storage (Restricted areas)	Prescribe uniform, facial and hair covering
Outside CSS or when going between buildings located on separate campuses	Uniform cover and outdoor shoes

Adapted from: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

3. Point of use/Pre-Cleaning

Point-of-use preparation helps to prolong the life of surgical instruments as dried blood and saline can cause the decomposition of stainless steel and make surgical instruments much more difficult to clean. Before any decontamination can take place, used devices are pre cleaned and prepared at the point of use. This procedure is not a substitute for cleaning.

Preparing devices at the point of use does not replace the cleaning process - it is the beginning

Procedure:

- Transport of contaminated devices post-procedure should be sent to a designated decontaminated area as soon as possible and secured in closed, leak and puncture-resistant containers/trolley with tamper-proof locks and security tags.
- Wear appropriate PPE as per personal risk assessment
- Remove any linen and disposable items and dispose of these items appropriately.
- Segregate sharps that can cause injury to health-care workers. Discard sharps, such as knife blades and needles in sharp container
- Remove gross soil from the instruments by wiping with a damp clean dry cloth or pre- clean (soaking with enzymatic solution or spray) and lumens flushed, preventing soil from drying on devices.
- Use MOH only approved cleaning products and approved by the device manufacturer
- If detergent-based products are used, ensure that they are correctly diluted. Avoid prolonged soaking of devices.
- Do not use saline as soaking solution and chlorine base disinfectants as it damages medical devices
- Keep the soiled instruments moist by:
    - Spray with an enzymatic spray or
    - Cover with a moist towel with water (not saline) or foam, spray, or gel specifically intended for this purpose
    - Do not transport in containers with water, as water is a splash hazard

4. Handling, Collection and Transport of Contaminated Items

Soiled medical devices shall be handled and transported in a manner that reduces the risk of exposure and/or injury to HCW and patients, or contamination of environmental surfaces. The transportation system must be enclosed and designed to minimize the risk of exposure to blood-borne and other disease-producing organisms and the possibility of damage to the instruments and other items being transported.

Procedures:

- Contaminated devices shall be transported to a designated decontamination area as soon as possible after use.
- Items contaminated with blood and other potentially infectious materials should be placed in a container that is puncture-resistant, leak-proof on the bottom and sides, labeled as bio hazardous, and sealed.
- Transport in closed, preferably locked, transport containers

- Decontaminate transport container before and after transport
- Transportation of contaminated instruments should avoid high (public) traffic areas and areas designated for storage of clean or sterile supplies
- Sterile and soiled devices shall not be transported together, dedicated trolleys for clean and contaminated instruments should be used.
- Scopes and other delicate instruments should be protected from damage.
- Hand washing and appropriate use of PPE should be practiced during the procedure.

5. Disassembly, Sorting and Pre-treatment:

5.1. Disassembly

Disassembly facilitates access of the cleaning agent.

- Following the recommended procedures for disassembly and reassembly ensures that it can be accomplished without loss of time or damage to important equipment.
- Care should be taken to ensure that defective instruments are not mixed with functional instruments during the cleaning process.
- For rigid sterilization containers follow manufacturer's IFU for removable, reusable filters (disassembly, cleaning and replacement)
- Remove process indicators, disposable labels, and disposable locks before any cleaning of the rigid sterilization container system.

5.2. Sorting:

Sorting medical devices keeps medical devices/instruments that belong to a set together and identify missing items for prompt investigation

- Sort devices into groups of like products requiring the same processes.
- Segregate reusable sharps and/or delicate devices to prevent injury to personnel and damage to the device.
- Avoid putting hand inside the container to retrieve reusable sharps that might be hazardous and contaminated with blood or other potentially infectious material
- Ensure that all small parts (e.g., screws, nuts, and washers) are contained to prevent loss.
- Keep together the non-interchangeable components of assemblies, such as parts of a metal stopcock, to ensure correct reassembly.

5.3. Pre-treatment/Soaking:

- Pretreatment can be done by soaking of instrument with enzymatic detergent. This process will loosen soil that may remain on devices, and it makes them easier to clean. It is requirement before cleaning.

Kinds of Enzymes:

- **Protease – Breaks down blood, mucous, feces, and albumin**
- **Lipase – Breaks down fatty deposits such as bone marrow and adipose tissue**
- **Amylase – Catalyzes (changes) starch**
- **Monitor water temperature and check manufacturer instructions for specific temperature requirements because temperatures above 45°C can affect chemical reactions**
- **Cool temperatures may not activate the enzyme**

- **Factors to consider when selecting an enzymatic detergent:**
  - Should be approved by product evaluation team (MOH) or by international Environmental Protection Agency (EPA)
  - Water hardness and room temperature in the decontamination area
  - Useful life and stability of the product
  - Expiration date of the product
  - Compatibility of the device to be cleaned

Factors to consider achieving effective cleaning process:

- **Water quality**
- **Quality, concentration, and type of detergent or enzymatic cleaner**
- **Acceptable washing method**
- **Proper rinsing and drying**
- **Correct preparation of items**
- **The time and temperature parameters**
- **Load capacity of the equipment**
- **Operator performance**

Procedure:

- Dilute the chemicals properly by calculating the volume of water used in the cleaning sink or other cleaning container (e.g., transport bin, basin, etc.) following manufacturers recommendation.
- Avoid prolonged soaking of devices.
- Completely submerge immiscible items
- Do not use saline as a soaking solution as it damages some medical devices.
- Process the instruments either manually or mechanically after pretreatment

6. Cleaning and Disinfection

The first and most important step before disinfection / sterilization is thorough cleaning. Cleaning process removes rather than kills microorganisms before disinfection. The cleaning products should be appropriate for medical devices and approved by the device manufacturer. If detergent based products are used, ensure that they are mixed to the correct in-use dilution.

Choose cleaning agents that are compatible with medical devices. Consider the following characteristic:

- **Nonabrasive**
- **Low-foaming**
- **Free-rinsing;**
- **Biodegradable**
- **Rapidly dissolve/disperse soil**
- **Nontoxic**
- **Be efficacious on all types of clinical soil**
- **Have a long shelf life**
- **Cost-effective**

There are two types of processes for cleaning; manual and mechanical cleaning:

6.1. Manual Cleaning

Adequately clean and prepare devices for sterilization with effective manual cleaning processes. It is important that all devices be disassembled so that all surfaces may be cleaned and disinfected, irrespective of the cleaning method chosen. This kind of cleaning method cannot be validated. Manual cleaning can be done only when there is no mechanical cleaning units (mechanical washer and disinfector and ultrasonic cleaners).

Indications for manual cleaning:

- Follow IFU for each type instrument and considerations taken for complex instrumentation.
- Medical devices that cannot be immersed (i.e. electrical or battery-powered devices)
- Devices that require special cleaning (i.e. narrow bore lumen or delicate devices)
- Pre-cleaning step prior to mechanical cleaning in ultrasonic and or washer-disinfector

Cleaning procedure:

- Fill sink or any other appropriate basin with lukewarm water and recommended amount of detergent solutions (at temperatures that do not to exceed 60°C [140°F]) and that follow manufacturers IFU to completely immerse the device.
- Log the temperature of the soaking solution
- Avoid using abrasive cleaning compounds and metal scouring
- Clean the device under the surface of the water so that aerosols are not produced
- Use appropriate brushes (nylon bristle) brushes to properly clean box locks, lumens and other hard-to-clean areas
  - Use soft (nylon) bristle brushes so that the surface of the instrument is not damaged
  - Brushes used to clean lumens must be the same diameter as the instrument to ensure that all internal surfaces can be reached
  - Brushes must also be long enough to exit the distal end of the instrument.
  - Decontaminate the reusable brush at least daily
- In another sink or basin, completely immerse the device in clean purified water and rinse the device thoroughly
- Mechanically dry; if this not available or not recommended by the manufacturer, air-dry or hand-dry using a disposable clean, non-linting cloth.

Rinsing:

Rinsing the instruments /devices following cleaning is necessary to remove loosened soil and residual detergent.

- Rinse the device whether manual or mechanical cleaning has been performed, use large amount of water for primary rinsing, use treated water for the final rinse
- Rinse thoroughly all the devices to remove debris and detergent residues.
- Flush the lumened items with the cleaning solution preferably with treated water.
- Avoid using physiological saline for final rinsing, as the salts in this solution will remain on the device and cause deterioration of the surfaces of surgical instruments
- Ensure regular maintenance of water treatment or reverse osmosis process.

6.2. Mechanical Cleaning

The use of mechanical cleaning equipment is to remove soil and microorganisms through an automated cleaning and rinsing process Automated washers are a very effective method for cleaning and disinfecting instruments because of the detergents and thermal action used.

Types of mechanical cleaner equipment:

- Ultrasonic cleaners
- Automated washers or washer-disinfectors
- Automated cart washers

6.2.1. Ultrasonic washers:

An ultrasonic cleaner should be used for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean.

- Follow the ultrasonic cleaner manufacturer's written IFU for proper use.
- Perform and document cleaning efficacy test each day before ultrasonic is used (example foil test).
- Remove the gross soil before placing in the ultrasonic cleaner.
- Submerged completely equipment/devices in the washing solution.
- Rinse thoroughly the equipment/devices after cleaning prior to further reprocessing.
- At a minimum, change daily the ultrasonic washing solution or more frequently if visibly soiled.
- If an ultrasonic cleaner is not available, try to reach the more inaccessible parts with different sized brushes.
- Ensure that ultrasonic cleaning will not damage the device and should be followed by thorough rinsing
- Drain and thoroughly clean ultrasonic at the end of each day.

6.2.2. Automated washers and disinfectors

Automated washer-disinfectors are designed for medical equipment/devices that can withstand mechanical cleaning and thermal (A value 3000) disinfection, to achieve the required exposure for cleaning and to reduce potential risk and rendering items safe to handle.

- Ensure that the washer-disinfectors meet the requirements of the AAMI, ISO and other international accrediting bodies.
- Follow the manufacturer's instructions for the use and routine maintenance, cleaning and calibration of the washer-disinfector.
- Do not use the washer-disinfectors for high-level disinfection.
- Read and follow the manufacturer's IFUs of the washer and disinfector.
- Perform cleaning efficacy testing and document each day before the automated washer/disinfector is used.
- Remove gross soil before placing in washer disinfector.
- Multi-level trays should be placed separately on racks with lids removed and in a manner that will not allow water to pool inside the tray.
- Arrange the instrument in the appropriate tray.
- Do not overload the washer disinfector.

- Ensure the spray arms can rotate freely without touching the instrument trays.
- Choose the appropriate program for the instruments in the cycle.
- It is also important that automated washer is tested for proper functioning before initial use, at a minimum weekly and after service and documented.

6.2.3. Cart washers

Trolley or cart washers are used for the cleaning of carts, rigid containers, surgical basins and other medical devices. It operates similarly to automated washers, but the cycle does not have the enzymatic wash or the lubrication steps

- Surgical instruments should not be processed in a cart washer unless it has been validated by the equipment manufacturer)
- Not all wheels are designed to be cleaned in a cart washer.
- Refer to manufacturer's instructions prior to washing wheeled carts when using this method and rigid

6.3. Drying:

Drying is an important step that prevents microbial growth and dilution of chemical disinfectants, which may render them ineffective.

- Follow the manufacturer's instructions for drying of the equipment/device.
- Equipment/devices may be air-dried or dried by hand with a clean, lint-free towel.
- Dry the lumens with compressed medical grade air that has been filtered.
- Dry stainless steel equipment/devices immediately after rinsing to prevent spotting or rusting.
- Drying cabinet may be used for certain types of medical equipment such as respiratory equipment (e.g., laryngeal masks).

6.4. Verification for Cleaning Process

The most common method of verifying the manual cleaning process is by visual inspection using magnifying glass. All medical devices must be inspected during assembly and packaging prior to sterilization.
The validation of automated washer-disinfector process is performed by using a commercially manufactured cleaning efficacy test that mimics dried blood. Failure of this quality check- indicates that the washing equipment is improperly operating or that cleaning chemicals are not feeding in properly. The cycle parameters of washer disinfectors should be checked also to ensure that the validated parameters have been met for each cycle - this must be documented. "A passing check does not prove that instruments are clean".

6.4.1. Monitoring of Mechanical Cleaning/Washers Equipment

Verification tests is required to ensure that mechanical cleaning equipment is working properly and according to the manufacturer's specifications
Testing results can be verifying by the following:

- Digital readouts are reviewed for each cycle
- Cycle printouts are reviewed and initialed
- Results of post-maintenance testing, following major repair

Table 4: Examples of Efficacy Testing for Washer-Disinfectors:				
Test Method	**Soil component**	**Limit of detection**	**Limitations**	**Results**
Visible test soil **Paint colored paste onto medical device.**	Artificial soil (not linked to specific soil components) detected as color being present or absent	Not indicated	Introduction of foreign material to medical devices that will subsequently be used on patients after cleaning	Visual Inspect the device to confirm removal of soil 1 min
Coagulated blood test. **Metal coupon with strip of coagulated blood soil.**	Blood and protein detected as visible red(blood) or visible "fil" (fibrin, protein)	Not indicated	Valuable as a quality assurance indicator for functionality of washer-disinfector but not for cleaning verification for specific medical devices in the washer	
Peroxidase reaction.	Hemoglobin	0.1 µg/swab	Applicable to blood soiled surfaces such as instruments and instruments with lumens. Not applicable if oxidizing substances are used for disinfection (cannot detect "bleached" hemoglobin)	Swab device, immerse in reagent and assess for color change 30 seconds
Protein test pyromol-test	Protein	0.1 µg/swab	Applicable to protein –soiled surfaces e.g. instruments with lumens. Rust or non proteinous discoloration on the swab will interfere with the color change	Swab device, immerse in reagent & assess for color change 15 minutes
Blood test soil pre – applied to thin metal coupon in reusable holder. ○ **Lumen version available**	Water insoluble protein with physical properties similar to blood fibrin; detected as visible red	Not indicated	Valuable as a quality assurance indicator of functionality of washer-disinfector but not for cleaning verification of specific medical devices in the washer.	Provides feedback and permanent record. 1 minute
Foil test for ultrasonic washers	None	Not indicated	What is the possible effect of known or potential variations in foil on foil perforation? Subjective results	Immerse foil in ultrasonic and run a full cycle.

7. Inspection, Assembly and Packaging (IAP) Process

Preparation and sterilization of surgical instrumentation needs to be carried out in a controlled environment by personnel who have knowledge and training in proper reprocessing procedures. These include various methods and techniques used in packaging area, like inspection, testing, lubrication, assembly, wrapping and labeling.

7.1. Visual Inspection and Testing:

- Cleanliness and functionality of all medical devices shall be verified by visual inspection. Testing for cleanliness and functionality shall be performed when indicated by the MIFUs to check the hidden parts of medical devices for invisible organic soils.
- Internal surfaces or parts that are difficult to see (e.g., lumens) shall be flushed or inspected using a borescope or similar optical inspection device to ensure cleanliness of the internal surface.
- If inspection cannot be performed, a single-use medical device shall be used.
- Soiled medical devices shall be returned to the decontamination area to be reprocessed.
  Note: *Soil on a medical device can harbor pathogens and impede disinfection and sterilization*

Inspection Criteria

Inspection shall occur under appropriate visual conditions, such as good task lighting and, where necessary, magnification. The type of lighting and magnification shall be appropriate for the medical device being examined. Lighting and magnification requirements shall also take into consideration the

a) Visual acuity of the area staff;

b) Degree of surface reflection in the inspection area; and

c) Complexity of the medical device(s) being examined.

7.2. Verification of Function

Decontaminated medical devices shall be reassembled before inspection for functionality unless the manufacturer IFUs specify otherwise. Reassembly shall take place in a clean and dry area.

Inspection for damage, integrity, and functionality shall include, but is not limited to, the examination of:

a) Hinge and joint action
b) Jaw and teeth alignment
c) Ratchet alignment and function
d) Cutting edge sharpness
e) Lens clarity
f) Materials integrity, including
g) Damage such as wear, corrosion, chips, burrs, dents, loss of finish, or other damage
h) Insulation integrity
i) Bends or kinks

Note:

1) *Visual inspection is particularly important for plastic and rubber medical device components, given their susceptibility to cracking, crazing, or deformation, and the possibility that adhesives will fail.*
2) *Chips on the surface can harbor soil. Burrs and chips can damage tissue and gloves. Worn medical devices can corrode.*
3) *Consult the manufacturer IFUs for inspection and test information.*
4) *Medical devices that are damaged or in poor working condition shall be removed from service, labelled, and segregated from usable medical devices.*
5) *The label shall indicate that the medical device is out of order, the date it was removed from service, the problem and the action to be taken.*
6) *Damaged medical devices shall either be repaired or disposed of in accordance with the documented policies and SOPs*.

7.3. Disassembly

Medical devices shall be disassembled to their simplest component parts for inspection for cleanliness.
If manufacturer IFUs require the medical device to be disassembled for sterilization, then the medical device shall be:

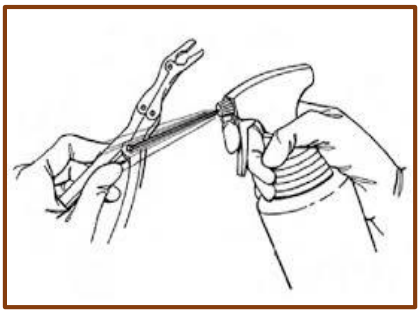
a) Assembled during inspection;
b) Checked for functionality; and
c) Disassembled for sterilization.

7.4. Lubrication

The purpose of a lubricant approved for medical devices is to protect the medical device; it is applied to the instruments before performing functional testing.
The device manufacturer's instructions shall be followed with regard to:

- Components requiring lubrication (e.g. instrument with joints)
- Specific lubricant(s) to be used (do not use an oily substance for lubrication). Should be water-soluble.
- Lubricate (proper technique, proper oil) and assemble

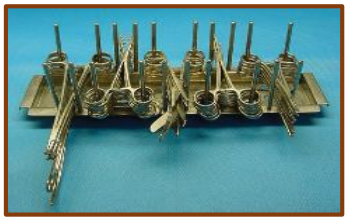
Note: *Incompatible lubricants can inhibit sterilization and damage instruments*



7.5. Assembly

The purpose of assembly and checking is to ensure that all devices are present in accordance with the surgical tray list, assembled correctly in accordance with the manufacturers' instructions and are placed in the correct tray in a manner that ensures ease of use by the end user and assembled in a manner that allows the sterilant to reach all surfaces on instruments within sets. The area where assembly and checking takes place should be designated and controlled to minimize contamination of the sets.

Assembling of surgical sets is prepared in partnership with medical or surgical users. There should be an agreed upon way to assemble surgical sets that include instruction that specify:



- The items belonging to the set and quantity of each item
- The type of tray (mesh, perforated, thermoformed) and size (large enough to permit equal distribution of weight and metal mass)
- As needed, the arrangement and protection of accessories to be used (e.g., protection of sharp and fragile items, wedges to avoid shift or shocks during transport, tray liners, etc.)
- As needed, the position of a medical devices, as required for safe extraction at point of use.

Surgical sets shall be inspected and assembled in the following manner:

- Instruments are clean and dry
- Jointed instruments are open and unlocked and as per manufacturers IFU
- Concave devices are placed in a way that does not collect condensate
- Heavy items are placed so not to damage delicate items
- When placing instrument in peel pack, the curved tip should always face the plastic side of the pack
- Sharps are protected using tip protectors that have been validated for sterilization method used
- Perform function check (according to manufacturer's guidelines)
- Multi-part devices are disassembled in accordance with manufacturers IFU's
- Use of tray liners validated by manufacturer
- Type 5 or higher chemical indicator is preferred for surgical instrumentation
- At a minimum Type 4 or higher chemical indicators are added appropriately to validate the sterilization process for all other packaged medical devices.

7.6. Packaging for Sterilization

Packaging for sterilization shall take the following considerations into account:

- For weight and size,
  a) The assembled packs shall not exceed the maximum specified by the sterilizer MIFUs;

  Note: *Some sterilization systems (e.g., tabletop, older generation steam sterilizers or chemical sterilizers) have weight limitations based on chamber size and load configurations.*

  b) Unless the sterilizer or RSCS manufacturer specifies otherwise, the mass of medical devices shall be distributed uniformly throughout the sterilization tray or RSCS; and
  c) Consideration shall be given to weight limitations to ensure that EH&S guidelines are met.

The size, weight, and weight distribution of the set shall allow personnel to use proper lifting techniques when lifting or moving sterile barrier systems. To ensure the safety of personnel, the combined weight of the package contents and sterile barrier system shall not exceed 10 kg.

- Contents should be arranged for order of use where possible (e.g., linen packs).
- Mixing metal items and textiles (e.g., gowns and drapes) in the same package shall be avoided.
- For steam sterilization, where there is potential for pooling, touching/nesting surfaces shall be separated with low-linting textile.
  Note: For chemical sterilization, separation of touching surfaces with low-linting textiles is not required.
- Contents should be evenly distributed in a single layer within the package validated to have more than one layer.
- A packaged item shall not be placed inside another package unless:
  a) This configuration is supported by the medical device manufacturer (e.g., an additional protective container);
  b) The internal packaging has been validated by the packaging material manufacturer for this use; or
  c) The internal packaging has been validated for this use by an external agency that performs validation.
- CI tape, if used, shall be used only on the exterior of the package as a process indicator.
  Note: *Indicator tape is the most common closure for wrapped packages, and there are different kinds of tape based on the method of sterilization.*
- When assembling packs of textiles,
  a) Packs should be tested for density.
  Note*: A simple calculation for density of textile packaging is provided in Annex A*

7.6.1. Packaging and wrapping materials:

Devices require packaging prior to sterilization. The packaging material and techniques are designed to hold and protect the devices in order to facilitate sterilization, maintain sterility and allow aseptic removal of contents at the point of use. The material selected depends on the recommended method of sterilization.

The HCF shall have SOPs in place for the evaluation, selection, pre-purchase testing, and inspection of packaging and wrapping materials. In addition, packaging policies and SOPs shall be based on the MIFUs from the medical device manufacturer, sterilizer manufacturer, and sterilization packaging manufacturer, as well as incorporating input of user departments as to arrangement of contents and aseptic presentation requirements

The sterile packaging process should:

- Allow penetration of the steam or any sterilants into the packaging and be compatible with any other requirements of the process such as drying
- Maintain the sterility of the package contents until it is opened
- Create a package that can be opened aseptically
- Permit identification of contents (written or visual)

Factors to take into account when selecting the packaging material:

- Packaging is validated for the method of sterilization
- Can maintain the sterility of the package contents after sterilization

- Allow adequate air removal from and steam penetration into the package contents
- Provide an adequate barrier to microorganisms or their vehicles (resist tearing or puncture)
- Allow a method of sealing that results in a complete seal that is tamper-evident and provides seal integrity
- Allow for ease of aseptic removal
- Free of toxic ingredients and non-fast dyes
- Non-linting
- Cost-effective

Types of packaging materials:

This section will look at the types of packaging materials available and requirements for specific sterile barrier systems

- **Packaging System Requirements:**

  The packaging system manufacturer shall supply:

  a) A documented statement of test methods validating sterility maintenance capabilities for the packaging systems intended use; and

  b) Written instructions regarding how to maintain sterile integrity to point of use.

  All packaging materials should be stored at room temperature and at a relative humidity ranging from 30% - 60% for a minimum of 2 hours before use for heavy sets and 30 minutes for individual lighter and items.

- **Disposable Sterilization Packaging:**

  a) Paper/Plastic Combinations

  Used for steam, hydrogen peroxide gas plasma and ethylene oxide sterilization. The plastic side allows visibility of pack contents, and the paper side allows sterilant penetration. Contains no cellulosic materials and is therefore compatible with gas plasma sterilization processes.

  b) Kraft-type Papers

  Medical-grade paper approved for use as sterilization packaging it is used for small items.

  c) Nonwoven Wrap

  Available in a wide variety of sizes and weights and used for various items from small single item packs, to entire instrument trays.

- **Reusable fabric packaging materials:**

  a) Muslin

  Broad term describing a wide variety of plain-weave cotton or cotton/polyester fabrics having approximately 140 threads per square inch.

  Note: *Canvas not recommended be used as a sterile packaging material because of its weave that makes steam penetration and drying difficult.*

b) Rigid Sterilization Container Systems (RSCS)

They are used for the moist heat sterilization of large sets of surgical instruments. They are made from diverse metals, aluminum, high-density polymers, or metals and plastic in combination. Perforations in the base and lid are lined with a steam-permeable HEPA material. After use, containers should be disassembled and cleaned by washing with detergent and water and dried before sterilization. Container systems must be validated before use and ensure that additional layers added are validated by manufacturer (cannot be overloaded and overfilled).

7.6.2. Wrapping/Packaging Methods:

7.6.2.1. Wrapping:

When wrapping packages for sterilization, the following shall apply:

a) The assembly surface area for wrapping shall be flat, smooth, of adequate size, well-lit, and clean.

b) Wrapper configuration shall provide a tortuous pathway to impede microbial migration into the sterile barrier system.

Note: *A wrapping technique may be used if the manufacturer has demonstrated the efficacy of this technique and recommends it for this application. Examples of wrapping methods are shown in Figure 4-5*

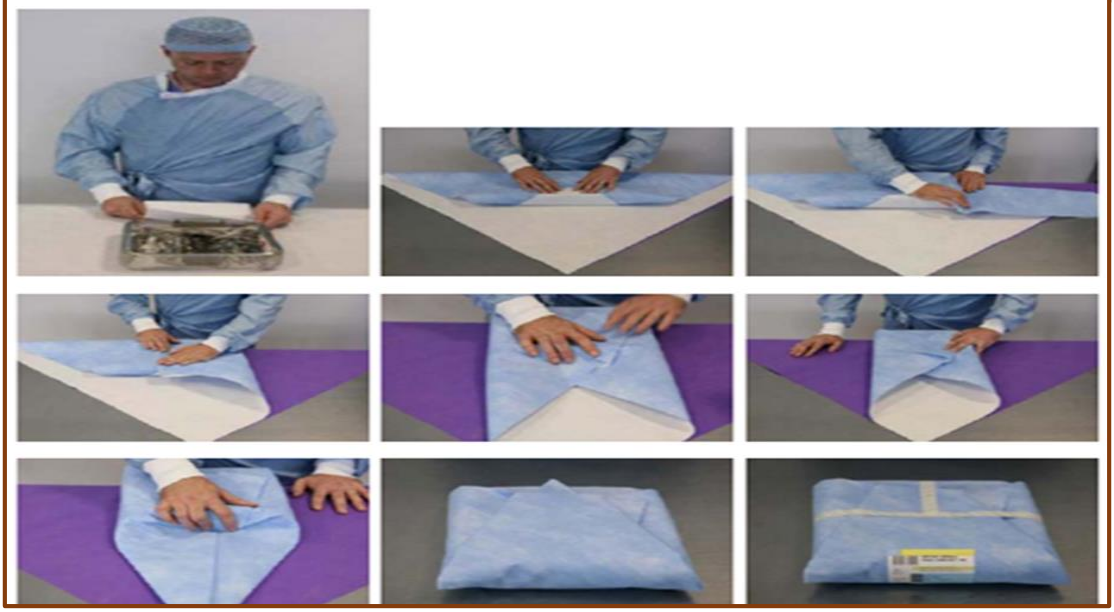
c) The sterilization wrapping method shall ensure that the opened wrapper will drape away from the sterile field.

d) The wrapped package shall be designed in a manner so that all edges are secured and do not interfere with aseptic presentation into the sterile field.

e) The methods and materials used when wrapping a pack or medical device for sterilization shall not inhibit sterilization or the maintenance of sterility, and shall permit aseptic presentation of the product at the point of use.

Figure 4: Example of Parcel Wrapping Method:

Figure 5: Example of Envelope Wrapping Method



Reference: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

7.6.2.2. Package Closures/Sealing:

When sealing a wrapped package, the following shall apply:

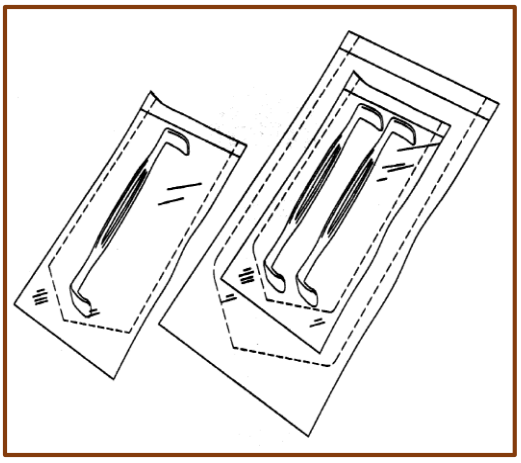
a) Closure systems shall show evidence of tampering:
   i. Closures that compress the package or medical device shall not be used (e.g., ropes, strings, elastic bands, paperclips, staples, or similar items).
   ii. Elastic bands used to close textile packs shall not compress the textile pack, shall allow the sterilant of choice to penetrate the pack, and shall be latex free.

   Note: *Elastic bands used by linen/laundry providers differ from the elastic bands mentioned above as closures for medical devices and are acceptable for use.*

b) Packages shall be sealed using banding that has been validated by the manufacturer for use in sterilization.
c) String ties, masking tape, and devices that puncture materials (e.g., pins and staples) shall not be used for closing a wrapper.
d) Medical devices containing latex shall not be used for closures.
e) The sterilization tape used for sealing packages shall
   i. Be validated for use with the sterilization process and cycle and the wrap material; and
   ii. Contain an indicator.
f) If flexible bands are used, they shall be:
   i. Of a type that is easy to unfasten without tearing;
   ii. Latex-free and validated by the manufacturer for use in sterilization;
   iii. Not ordinary rubber bands
   iv. Not reused
   v. Indicate whether a flexible band closure has been opened to prevent tampering; and
   vi. Not compressing the pack.

7.6.2.3. Packaging Paper–Plastic Pouches:

The following requirements shall apply when using sterilization pouches and reels:



a) The size of the pouch and the strength of the materials shall adequately contain and protect the medical device to be packaged**.**

   Note: *Sterilization pouches are normally used for small, lightweight, low-profile items (e.g., one or two clamps). Items that are too large for a pouch or have sharp edges put extra pressure on the seals and the materials, causing rupture.*

b) Unless otherwise specified by the manufacturer, the pouch shall be filled only to a maximum of 75% of the inner surface area of the porous side, in order to facilitate closure without creating .

c) Wrinkles in the seal. Care shall also be taken to ensure that the distance from the seals is increased for products of greater height.

d) If double pouching has been validated by the pouch manufacturer for the sterilization process,

   i. The inner pouch shall be able to move within the outer pouch.

   Note: *This allows penetration of the sterilant and prevents the pouches from sticking together during the sterilization process.*

   ii. An inner pouch shall not be folded in order to fit into the outer pouch.

   iii. The plastic side of the inner pouch shall face the plastic side of the outer pouch.

   Note: *This will minimize stressing or damage to the inner pouch and ensure proper sterilizing agent penetration. The plastic-to-plastic configuration allows for identification of content and permeation of sterilant.*

   iv. Specified requirements for seal width and seal strength shall be met.

e) Sealing procedures shall ensure that folds and closures are not skewed or wrinkled, and care shall be taken to ensure that both corners are well sealed, in order to ensure a complete closure across the entire end. Non-validated sealing methods shall not be used to seal pouches (e.g., autoclave tape, indicator tape, paper clips, and staples).

f) The sealer shall be capable of attaining the sealing conditions provided by the pouch manufacturer. Only sealing devices manufactured and intended for pouch systems shall be used.

g) Sealing devices shall be able to control and monitor critical process parameters (e.g., temperature, pressure, sealing time/speed). Operators shall not be able to modify the process parameters outside of these validated conditions.

h) The filled pouch shall allow for aseptic presentation (e.g., the grip of the medical device should be placed toward the opening end; multiple, loose items should be contained). Peel open characteristics shall be continuous, in the direction of the opening stated by the manufacturer and without delamination or tearing that can affect aseptic presentation.

   Note: *Seal areas are considered non-sterile when opened.*

i) The pouch shall show, by design, in which direction the package should be opened (e.g., arrow sign, shape of seal).

j) Pouches shall be inspected for intact seals and barrier integrity before and after sterilization and before use.

k) In accordance with the manufacturer IFUs there shall be adequate space to ensure seal closure.

l) If a heat sealer is used, it shall create at least one seal having a minimum width of 3 mm. If the seal is less than 3 mm wide, two rows of seal shall be required.

   Note: *Taping for closure of pouches shall not be used*

7.6.2.4. Rigid Sterilization Container Systems (RSCS)

RSCSs are designed to hold medical devices and accessories and maintain their sterility during transport and storage. They are sterilized without exterior wrapping.

A rigid sterilization container systems (RSCS) shall consist of a bottom or base and a lid that is secured to the base by a latching mechanism and may contain a basket or tray to hold medical devices.

Note: RSCS are designed to hold medical devices and accessories and maintain their sterility during transport and storage. They are sterilized without exterior wrapping.

7.6.2.4.1. Requirements for RSCS:

a) Sterilization container filters shall be carefully inspected for integrity and shall be properly secured by the filter retention system.
b) Only filters recommended by the RSCS manufacturer for the method of sterilization (e.g., steam, EO) shall be used.
c) Sterilization container valves (if equipped) shall be inspected and prepared in accordance with the RSCS manufacturer IFUs.
d) Tamper-evident devices shall be secured in accordance with the RSCS manufacturer IFUs. Tamper-evident devices shall be appropriate for the sterilization process.
e) If the tamper-evident device is broken, indicating that someone or something might have compromised the RSCS, the RSCS shall not be used and shall be reprocessed.
f) Each RSCS shall have a visible external CI to clearly identify a reprocessed RSCS from an unprocessed, identification label and information card. The external CI, identification label and information card shall be appropriate for the sterilization process.

7.6.2.4.2. Tamper-Evident Devices

When used, tamper-evident devices appropriate for the sterile barrier systems such as RSCS, and sterilization processes shall be secured in accordance with the system MIFUs.

They shall indicate that the package has not been opened intentionally or accidentally.

Note:

i. The contents of a package that has become unsealed before use could be exposed to contamination.
ii. Tamper-evident devices are used for RSCS.

7.6.3. Package Labelling:

Labelling systems shall:

a) Remain clear, remain intact, and adhere to packaging until packages are used;
b) Be validated for the sterilization process; and

c) Have print/ink that:
    i. is non-toxic
    ii. is not transferred to medical devices; and
    iii. does not react with packaging materials

7.6.3.1. Labelling Principles and Practices:

The CSS's labelling SOP for a packaging system shall incorporate the following principles and practices:

a) For pouches,
    i. When used, a label shall be placed on the transparent portion of the packaging and shall not conceal the medical device; and
    ii. Printing or writing shall be placed outside the area enclosed by the outside dimensions of the seals.
b) Care shall be taken when applying labels to packages so as not to damage packaging materials or contents.
c) Writing on wrapped packages shall be on the closure tape, not directly on the wrappers.
d) Labels validated for use in a specific sterilization process, shall be written on in accordance with the MIFUs. If these labels are used, they shall not impede the sterilization process (i.e., they shall not block the breathable area of the package).
e) Labelling shall remain securely adhered to the package throughout the sterilization process and storage until the point of use.
    Note: *If paper labels are used on hydrogen-peroxide sterilized packages, they may be applied after the sterilization process as the packages are being removed from the sterilizer.*
f) Adhesives in labels or closure tapes used as labels shall be approved for medical use.
g) Only a permanent, soft-tipped marker that has been validated for use with the chosen sterilization process shall be used.
h) Ballpoint pens or any writing instrument shall not be used as these do not meet the criteria for labelling and carry the potential for puncturing the sterile barrier system.

7.6.3.2. Labelling Information

Packages shall be labelled with at least the following information:

a) Package identification (package code or name);
b) Identity of the person who assembled the package (unless automatically recorded in the system); and
c) Sterilizer load identification, including the
    i. Sterilizer number;
    ii. Load number in that sterilizer; and
    iii. Sterilization date

7.6.3.3. Event Related Statement

Sterile packages should also be marked with the following statement (or its equivalent): “Product is not sterile if packaging is open, damaged, or wet. Check before using.”

8. Sterilization:

Proper sterilization of instruments and materials is a critical aspect of infection control. Sterilization is the elimination of all disease-producing microorganisms, including bacterial spores. Steam sterilization (pre-vacuum) is most preferred method used on heat-resistant critical medical devices and, whenever possible, semi-critical medical devices. It should be done in central reprocessing unit.

8.1. Steam Sterilization:

Steam sterilization is a process that uses saturated steam under pressure as the sterilants. It is the preferred method for sterilizing critical medical devices. The removal of air is essential to ensure an efficient sterilization process – sterilization cannot occur in the presence of air. Conditions necessary for effective steam sterilization are contact, time, and moisture temperature).

Advantages of Steam Sterilization:

Low cost, fast cycles, relatively simple technology, leaves no chemical residues or by-products behind.

8.2. Types of Steam Sterilizers:

There are different types of steam sterilizers that utilize different methods to remove air from packages and the chamber, e.g. dynamic air removal (pre vacuum) and steam-flush pressure-pulse sterilizers, or passive air removal (e.g. gravity). The steam sterilizers vary in chamber size from small tabletop to large floor-loading models.

8.2.1. Pre vacuum Sterilizers:

Uses a vacuum pump or water ejector to remove air from the chamber and packaged devices during the preconditioning phase and prior to sterilization. Operate at (132ºC to 135ºC).

8.2.2. Steam-flush Pressure-pulse:

Uses a repeated sequence of a steam flush and pressure pulse to remove air from the chamber and packaged items. Operate at (121ºC to 123 ºC; 132 ºC to 135º C; or 141ºC to 144 ºC). (primarily used in dental practice).

8.2.3. Gravity Sterilizers

Gravity is used to displace the air from the sterilizer chamber and packaged devices. Operate at (121ºC) or higher.

8.2.4. Table Top Sterilizers

These sterilizers are designed for small instruments, such as dental instruments, and not recommended for any lumen instruments. The wrapped instruments take about 14 minutes to be sterilized and dried.

Written, validated, device-specific instructions from the device manufacturer and sterilizer efficacy testing from the sterilizer manufacturer must be obtained before utilizing any sterilization method.

Remember unwrapped instruments will not remain sterile once they have been removed from the sterilizer.

8.2.5. Immediate Use Steam Sterilization IUSS (Flash Sterilization):

IUSS is a special high-speed, short cycle sterilizer usually used for emergency use and not used as a routine method of sterilizing medical devices or use with implantable equipment/devices.
IUSS is normally located in the operating theatre in order to process unwrapped instruments and instruments for immediate urgent use.

The HCF shall ensure that personnel operating reprocessing equipment performing IUSS:

a) Are knowledgeable, trained, and have current demonstrated expertise in the use and application of the steam sterilization process
b) Have current competency documentation in the operation of steam sterilizers
c) Are aware of the hazards associated with steam sterilizers
d) Wear appropriate scrub attire, including PPE
e) Verify that sterility assurance components used in IUSS produce acceptable results before placing the medical device on the sterile field
   Note: *The BI test results will not be known prior to use of IUSS but the Type 5 or 6 CI result will be known along with the first BI testing performed without a medical device in the load.*
f) Are able to aseptically transfer the sterilized medical devices to the point of use;
g) Are familiar with all aspects of the IUSS SOP at the health care setting; and
h) Meet the requirements for sterilizer operation and monitoring (sterility assurance).

Use of IUSS requires written policies, validated device-specific instructions from the device manufacturer and sterilizer efficacy testing must be performed and documented by log book as well as the patient's record. IUSS should be tested in accordance with testing guidelines for steam sterilizers. The same quality assurance measures are required for IUSS as are required for steam sterilization.

8.3. Sterilization Methods for Heat-Sensitive Devices:

Devices that are not able to withstand steam sterilization, the following sterilization methods are appropriate:

- ETO gas
- Hydrogen peroxide gas
- Hydrogen peroxide gas plasma
- Formaldehyde gas
- Ozone
- Dry heat

8.4. Unacceptable methods of disinfection or sterilization:

- Boiling
- Chemical (formaldehyde vapour)
- Formaldehyde chemical
- Glass bead sterilization
- Microwave oven
- Ultraviolet irradiation

8.5. Sterilizer Loading:

The health care setting shall have written SOPs for sterilizer loading and operation. These SOPs shall follow the sterilizer manufacturer IFUs.

See figures 6,7,8,9 for examples of correct sterilizer loading.

The contents of each load processed in the sterilizer shall be documented and records shall be maintained in accordance with the health care settings polices and SOPs and shall follow national regulations and/or licensing body's requirements.

The sterilizing agent shall contact all surfaces of the medical devices.

Proper loading of the sterilizer shall be performed for successful sterilization.

Note: *Proper loading is also important for the drying process.*

8.5.1. Package Placement:

Packages shall be placed in the sterilizer chamber in a manner that facilitates air removal, sterilizing agent penetration, sterilizing agent evacuation, and drying (e.g., steam sterilization).

In addition, the following requirements shall apply:

a) Packaged items shall not contact the interior walls of the sterilizer chamber, as contact can damage the wrapper and can also impede sterilizing agent circulation.

b) Pouches and wrapped packages shall not be stacked or compressed.

c) There shall be adequate space between packages to ensure effective sterilizing agent penetration, evacuation, and drying. A package may be leaned against another package when placed on its edge and a single contact point or edge with 1 to 2 cm of space shall be made between packages and away from the contact point.

8.5.2. Pan or Tray Placement

Pans or trays that have mesh or perforated bottoms shall be placed flat unless otherwise advised by sterilizer MIFUs and shall not be stacked (Figure 6). Only those trays with validated instructions to be stacked shall be stacked during sterilization.

PQ of the tray configurations shall be performed prior to stacking of the trays.

Note: *Flat placement can help to prevent wet packs and uneven distribution of metal mass within a set, refer to sterilizer MIFUs.*

During steam sterilization, surfaces that could collect water, such as solid-bottom basins, trays, and similar items, shall be placed on edge to allow steam to contact all surfaces and to allow for drainage of water and condensate unless otherwise specified by the manufacturer.

8.5.3. Pouch Placement

Steam sterilization pouches shall be placed in a vertical orientation (i.e., on edge). Pouches shall not be stacked. When sterilizing multiple pouches, pouches shall be placed with the transparent surface of the pouch facing the non-transparent surface of the adjacent pouch (see Figure 7).

If it is not possible to place a pouch in a vertical orientation, the sterilizer and pouch MIFUs for pouch orientation shall be followed.

For low-temperature sterilization, pouches shall be placed in accordance with sterilizer MIFUs.

Note:

a) Air and most sterilants only pass through the non-transparent surface of paper/plastic pouches.

b) A vertical orientation for steam sterilization facilitates air removal, sterilizing agent contact, and drainage/evaporation of sterilant.

c) *Racks, baskets, and holders designed for holding pouches in a vertical orientation during sterilization are available.*

Figure 6: Wrapped medical devices in perforated or wire-mesh-bottom tray

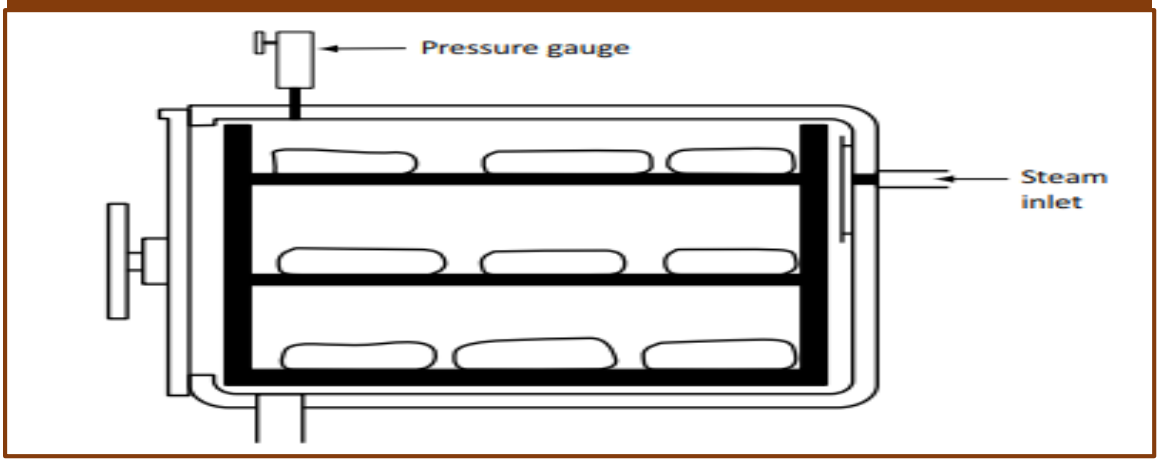
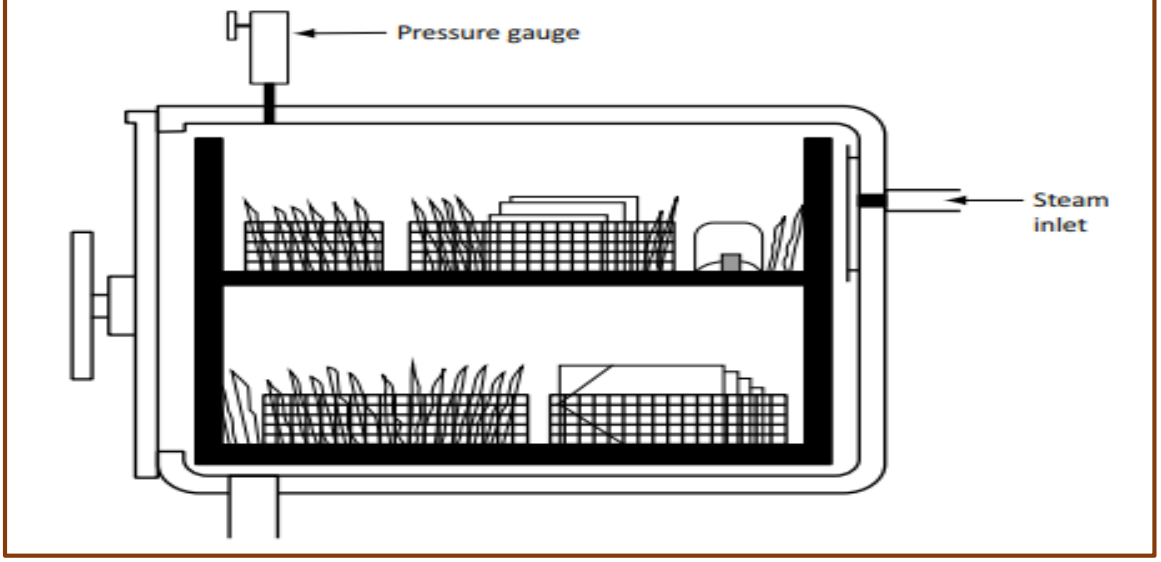


Figure 7: Load of paper/plastic peel pouches using wire-type baskets

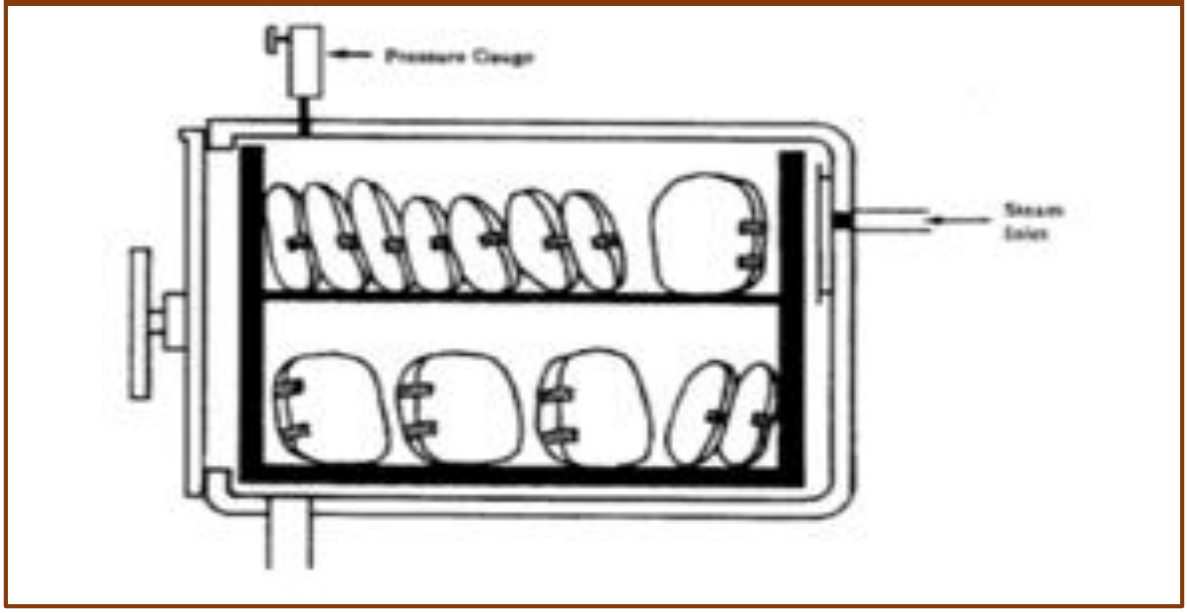


8.5.4. Reusable Textile Packs:

Reusable textile packs shall be loosely loaded and positioned standing on edge and shall not be stacked (see Figure 8).

Reusable textile packs shall not be sterilized using VH2O2 sterilizers.

Figure 8: Load of reusable textile packs



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8.5.5. Mixed Loads

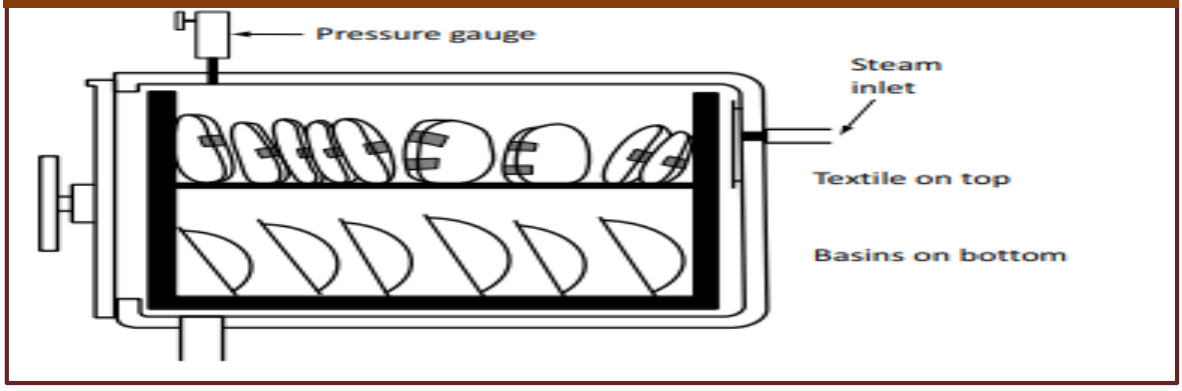
If mixed loads are required, users shall ensure that:

a) The sterilization cycles for the different items are compatible; and

b) Textile packs are positioned above metal medical devices on the loading cart due to the potential for wetting of the textile.

Note: *It is preferable not to have mixed textile and metal loads due to the potential for condensate from metal products to cause wetting of the textile*.

Figure 9: Mixed Loads



8.6. Sterilizer Operation:

The sterilizer MIFUs for the operation of the sterilizer shall be followed.

If more than one sterilization cycle is available on a given sterilizer, the medical device manufacturer, the sterilizer manufacturer, and/or the CSS written SOPs shall describe the criteria and SOP for correct cycle selection and operation.

8.6.1. Steam Sterilization Cycles

If the medical device manufacturer's recommended cycle different from a standard steam sterilization cycle, the health care setting shall consult with the sterilizer manufacturer to ensure that the equipment can effectively deliver that cycle.

If the validated sterilization cycle conditions for the medical device do not meet the validated conditions delivered by the sterilizer.

Prior to purchase or evaluation of a new medical device, the health care setting shall review how the sterilization cycle will be monitored.

Note: *Examples of validated standard steam sterilization parameters include, but are not limited to:*

a) Dynamic air removal: 132 °C, 4 min;
b) Dynamic air removal: 135 °C, 3 min; and
c) Gravity displacement: 121 °C, 30 min.

Drying Cycle:

For steam sterilization, a drying phase shall be included in all sterilization cycles for packages unless the medical devices will be used immediately in IUSS.

For steam sterilization, the drying time shall be established based on the following considerations:

a) Instructions of the sterilizer manufacturer and the sterile barrier system manufacturer;
b) Size, weight, and type of packages
c) Size, weight, and type of load in the sterilizer
d) Steam quality
e) Characteristics of the sterilizer
f) Medical device MIFU's

8.7. Low-temperature sterilization:

For low-temperature sterilizers, only chemical sterilants validated and labelled for that particular sterilizer shall be used. The HCF shall ensure that the chemical sterilant used in the sterilizer has and follow the appropriate manufacturer IFU's.

8.8. Chemical Sterilants:

The chemical sterilant and cartridges shall be labelled with an expiry date and shall not be used beyond the in-use life limit or the expiry date, whichever comes first.

Expired chemical sterilants and cartridges shall be disposed of in accordance with the sterilant/cartridge manufacturer and for further direction consultation with the government regulations.

8.9. Sterilizer Unloading:

Before removing sterilized items from the sterilizer cart or racks, the operator shall check the results of external CI. In the event of failure, follow the recall section of this document.

8.9.1. Inspection Requirements:

During unloading, packs shall be inspected for:

a) Evidence of potential contamination
b) Package integrity
c) Dryness
d) An intact seal, if used
e) The correct change in an external CI
f) Presence of a load control label

If a package does not meet the inspection criteria, the contents shall be reprocessed.

If moisture is detected on the load, a log shall be completed to identify information such as the packages contained within the load, packages with moisture, positioning of packages, sterilizer, and time of day, and person who loaded and prepared the packages.

Note: *This information can be used to assess moisture issues within the CSS to determine possible causes, looking at patterns which might occur over time.*

Sterilizers shall be unloaded in accordance with manufacturer instructions, including recommended door opening and inspection practices.

At the conclusion of a sterilization cycle and before the load is removed, the operator shall check the printout.

Once it is confirmed that the required parameters (e.g., time, temperature, pressure, sterilant and chemical concentrations) and all phases of the sterilization cycle including aeration (if required) were met, and that no errors are apparent, the operator shall sign the printout.

If the printout indicates a failure of any parameter or if there is any other indication of error, the operator shall not release the load and shall follow the health care setting's applicable policies and SOPs.

In a paperless system, the operator confirmation may be recorded manually or electronically; however, the manual or electronic record shall clearly identify the person making the entry (e.g., by means of personnel login identification and password or initials if manual documentation).

Note: *If another load is not going to be processed in the sterilizer immediately after the load is removed, the door should be closed to maintain stand-by temperatures.*

8.9.2. Cool-Down Requirements

There shall be an SOP for the cool-down phase e in accordance with sterilizer and medical device manufacturer IFUs.

Thermal protection shall be worn when removing hot carts or racks from the steam sterilizer.

For vapor systems, care shall be taken to ensure that there is no moisture or droplets in the chamber or on packages. Any visible moisture shall be considered chemical sterilant. Specific SDS shall be referenced for instructions and PPE.

Precautions should be taken to avoid sudden changes in temperature or relative humidity particularly exposure to cool air that can cause condensation.

Loads should be removed immediately from the sterilizer following the completion of the sterilization cycle unless aeration is required.

Note: *a) Sterilizer manufacturers can have specific instructions for opening the door during the cool-down period.*

b) For consistency, temperature guns may be used for controlling the temperature of load before unloading

8.9.3. Handling Sterile Packages after Unloading:

When the load is removed from the steam sterilizers, it shall be placed in a draft-free location where it will be undisturbed.

For sterilizers using loading carts, the carts shall be approved by the sterilizer manufacturer.

Sterile packages shall not be touched, removed from carts, or otherwise handled until the load is cooled to room temperature (18 to 24 °C).

Warm items shall not be transferred from the cart to cold metal racks or shelves for cooling, and items shall not be placed within dust covers before they are completely cooled.

Sterilized packages should not be stacked or placed on surfaces (e.g., air vents, cool metal counters, workstations, and air diffusers) where sudden cooling can occur as condensate can form beneath, between, and within stacked packages when exposed to a cool surface.

Note: *A warm package:*

a) Might still contain moisture that can wick microorganisms from hands; and

b) If placed on a cool surface, can create condensation that can also wick external microorganisms into the package

9. Quality Assurance

Each process of reprocessing cycle is crucial; any mistake during the steps may lead to HAIs, huge financial costs and endangered the life of the patients and staff. It is important to have a quality assurance (QA)/management system in CSS, which provides a framework for documentation and control. The validation must be documented and the records shall be kept up to 5 years depending on the medical/legal requirements of each facility.

Documentation is very important in the sterilization process. (If not documented not done)

9.1. Sterility Assurance:

Sterility assurance applies to all sterilization systems and shall include:

a) Careful adherence to written SOPs (e.g., decontamination, sterilization, handling, and storage of medical devices)
b) Testing and monitoring of critical points in the process to ensure that SOPs and processes are working correctly
c) Accurate documentation
d) An effective recall SOP so that problems can be quickly identified, appropriate action taken, and patient safety assured

9.1.1. Sterilization SOPs:

The CSS SOPs shall outline the configuration of specific load types that have been verified as producing consistent and effective results through PQ of loads.

The sterilizer SOP shall include guidelines and illustrations as necessary to communicate the correct configuration of loads for each type of sterilizer as described in the sterilizer IFUs

9.1.2. Validation of Sterilizers:

Validation usually applies to equipment or procedures used for reprocessing medical devices as part of the QA programmer.

The CSS can adapt the ISO 90011 (general quality) and European norm (EN) ISO 134852 (quality of the installation and maintenance of health products) standards to evaluate its system and to guide the steps for its improvement.

Sterilization validation should be carried out upon installation and revalidation at least once a year by manufacturer's technical service representative.

Validation testing should be performed upon:

- Installation/performance/quality
- Installation before using a new sterilizer
- Relocation
- After major repairs and sterilization failures
- Malfunctions
- Maintenance operations are carried out

For new sterilizer:

- **Consult experts (e.g. medical device reprocessing, infection prevention and control, physical plant, biomedical engineering) before a purchasing**
- **Verify proof of certification or international approval during evaluation and prior purchase of sterilization equipment, accessories or supplies.**
- **Install, operate and maintain sterilization equipment according to the sterilizer manufacturer's instructions.**
- **Consult sterilizer manufacturer if the test fail. Do not approve sterilizer for use if any of the tests fail.**

Validation Testing Should Include:

- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance or process qualification (PQ)
- Microbiological performance qualification (MPQ)
- Documented results
- Validation and reports

Installation Qualification (IQ):

IQ confirms that the sterilizer has been installed and connected to the required services in accordance with the sterilizer manufacturer's specifications and local regulations:

- Verify the correct installation of connections: water, steam, electricity, compressed air, ventilation, etc. as per manufacturer's specifications.
- Verify the correct operation of the equipment's different security functions, according to standards e.g. doors and seals, leaks, etc.
- Ensure that the machine has the adequate technical documentation, i.e. installation plans, technical/operational user manual, etc.

Operational Qualification/Requalification (OQ):

The installation of equipment operates within predetermined limits when used in accordance with its operational manual.

Pre vacuum autoclave:

- Calibrate the regulators and control elements
- Perform a cycle with the vacuum test and with the Bowie-Dick test

For a displacement autoclave

- Calibrate the regulators and control elements

- OQ has the following two aspects:
  - It verifies that the sterilizer meets the manufacturer's operating specifications, which includes calibration of temperature and pressure sensors as well as verification of safety features and alarms.
  - It also verifies that the sterilizer consistently produces the necessary process conditions for sterilization by testing using a BI in a PCD.
- Operational requalification shall be performed to demonstrate that the sterilizer will deliver the specified sterilization process.

Requalification Testing:

Requalification shall take place at least annually and may be performed by the health care setting (or designate) or sterilizer manufacturer (or designate).

Requalification testing shall also be performed in response to any of the following events or conditions:

- Major sterilizer repairs (that could affect sterilizer performance), including:
  a) Replacing sterilizer controls;
  b) Replacing plumbing packages;
  c) Major rebuilding, including weld repairs of the pressure vessel; or
  d) Installation of major new components, including a chamber door, a vacuum pump, and major piping assemblies;

  Note*: Normal preventive maintenance, such as the rebuilding of solenoid valves, pressure reducing/regulating valves or the replacement of gaskets, is not considered a major repair.*
- Sterilizer relocation;

  Note: *Relocation means moving a sterilizer to any new location (e.g., transporting a sterilizer to a different health care setting or a different area within the same health care setting), and/or disconnection from an electrical source and reconnection to a different electrical outlet/source.*
- Unexplained sterilization failures; and
- For steam sterilization,
  a) Any major interruptions in steam supply or delivery; or
  b) Any change in utilities servicing sterilizer (e.g. disruption in water supply, changes in static and dynamic steam pressure).

Performance Qualification (PQ):

The installation of equipment is proper and operates in accordance with manufacturers manual

- Conduct three consecutive biological tests with PCD for each type of load and obtaining the temperature profile at all points for each one.

Validation of the Steam Sterilization:

Sterilization by moist heat should be validated in order to guarantee the safety, adaptation and effectiveness of the process.

- Verify correct installations including the physical structure itself, temperature, and installed networks of steam, ventilation and compressed air.
  - For hydraulic installation - the water hardness should be noted.
  - For electrical installations- the voltage, protective devices, installation to the source itself, and quality of the steam should be observed.
- The structure for the installation should be confirmed, including its physical adaptation, integration, and ventilation near the doors of the autoclave, and minimum distances between walls and the equipment in order to facilitate maintenance.
- Ensure that there is availability of operational manual, a registry of the replaced parts, information registered by the technical service, and certification operation of the equipment.

- Check that there is evaluation and assessment of effectiveness and efficiency. These includes physical parameters, types of packaging, types of loads, types of materials (quantity and volume), and the arrangement of the materials within the chamber and its capacity, use of biological and chemical indicators.

Validation for Hydrogen Peroxide Plasma:

- Follow the validation qualifications as per manufacturers IFU
- Use a microprocessor to evaluate the physical parameters, must be perform during three consecutive days and with loads.
- Use the test package for the specific biological and chemical indicators (see the manufacturers IFU)
- The CI indicates that hydrogen peroxide has been introduced into the sterilization chamber.
- The biological indicator consists of a paper strip containing spores specific for IFU of low temperature (hydrogen peroxide plasma) in a cellulose free package such as Tyvek®.

Validation Documentation Requirements:

HCFs do not conduct validation testing; however, they shall ensure prior to purchase that manufacturer of medical devices, sterilizers, and sterile barrier systems have provided documentation that a sterilization process is effective.

9.1.3. Commissioning Requirements

Commissioning shall include IQ and OQ as the process of installing the sterilizer and confirming that the sterilizer operates with all its accessories according to specified performance criteria.

This includes the steps needed to confirm that the equipment meets the necessary requirements and that the utilities that are connected to the equipment meet the manufacturer's specifications.

Commissioning shall include the following:

a) Checking sterilant supply and capacity
b) Checking water supply and capacity
c) Checking sewer capacity and drain configuration
d) Ensuring that the installation location is straight, square, and level and meets architectural specifications
e) Measuring clearance around equipment and services
f) Measuring water quality, water pressure, and volume of flow
g) Checking the installation against drawings, code requirements, and environmental specifications
h) Ensuring that all environmental conditions are satisfied (i.e., lighting, HVAC, and physical facilities [flooring, ceiling, and walls] are correctly provided)
i) Ensuring proper electrical connections
j) Evaluating steam quality
k) Measuring steam quality both static and dynamic

9.2. Sterilization Documentation Requirements for HCF:

A SOP shall be established to ensure that documents and records required by the QMS are reviewed and approved at least every 3 years or sooner if new information becomes available.

The QMS program shall be:

a) Documented and include record keeping
b) Remain legible
c) Readily available
d) Easily identifiable
e) Retrievable

Note: *The extent of the QMS documentation can differ from one health care setting to another due to the size of the HCF, the type of activities, and the complexity of processes and their interactions*

Each HCF should ensure that sterilization services have the following documents related to sterilization:

- Results of the sterilization process quality control testing (including CI and BI monitoring)
- Records of recall investigations and actions taken during sentinel events.
- Tracking system (manual or electronic)
- Training, competencies audit tool checklist & reports
- Written manufacturer instructions (IFU) of medical devices, surgical instruments and sterilization cycles parameters
- Environmental controls monitoring (air exchange, temperature, humidity)
- Water quality monitoring
- Machine periodic preventive maintenance (PPM) and monitored parameters of mechanical washers
- Safety data sheets of chemicals used

Sterilizer Logbook:

- Lot number of BI
- Specific contents of the lot or load, including quantity, department, and a specific description of the items (e.g., towel packs, type/name of instrument sets);
- Exposure time and temperature, if not provided on the sterilizer printer or electronic record
- Name or initials of the operator
- Results of biological testing, if applicable
- Results of Bowie-Dick testing, if applicable
- Response of the CI placed in the PCD (BI challenge test pack, BI challenge test tray, or CI challenge test pack), if applicable
- Any reports of inconclusive or nonresponsive CIs found

9.3. Monitoring Indicators for Sterilization:

During the steam sterilization the use of physical, chemical and biological monitoring shall be routinely performed to verify the effectiveness of sterilizers and the sterilization process to ensure high probability of absence of microbes on processed items, detect failures as soon as possible, remove medical devices involved in failures before patient use and improve patient safety outcomes.

Table 5: Sterilization Monitoring Methods		
Monitoring method	**Conditions**	**Purpose**
Physical - (Cycle's printout)	Each load	Verifies that the parameters of the sterilization cycle have been met
Chemical indicators (external and internal)	Each package For dynamic air removal-type sterilizers (e.g. "pre-vacuum" or vacuum assisted), an air removal test with a Class II chemical indicator (e.g. Bowie Dick) shall be performed every day the sterilizer is used.	Verifies that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load.
Biological indicators	Preferably each day or at least weekly Each type of cycle that is used that day All loads containing implants	Verifies that the conditions at a location within the load were adequate to kill a population of microorganism's resistant to the sterilization process and demonstrate the lethality of the sterilization process.
Other routine test (diagnostic)	Specified by manufacturers	

Reference: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

Routine Monitoring:

This verifies that the sterilization process is working as expected. It involves the assessment of physical parameters of the sterilizer cycle, chemical indicators and biological indicators.

Routine monitoring shall include assessment of:

a) physical parameters of the sterilizer cycle (e.g., time, temperature, pressure), shown on gauges and displays during each cycle and documented manually, on a printout, or electronic record at the end of each cycle;

b) Chemical Indicators:
   i. external indicators, Type 1, on each package unless internal indicators are visible through packaging materials;

c) BI as part of the PCD.
   Note: These may be in the form of a Type 1 CI affixed to:
   i. paper-plastic pouches;
   ii. indicator tape;
   iii. indicator label;
   iv. container identification cards; or
   v. tamper-evident devices.
      - Type 4, Type 5, or Type 6 internal CI inside each package;
      - Type 5 or 6 internal CI as part of a BI or CI; and

Notes:

1) *Type 1 process indicators are intended for use with individual packages to indicate that the packages have been exposed to the sterilization process and to distinguish between processed and unprocessed packages.*
2) *Type 4 multi critical process variable indicators are designed to react to two or more of the critical process variables and intended to indicate exposure to a sterilization process at SVs of the chosen critical process variables.*
3) *Type 5 integrating indicators are designed to react to all critical process variables. The SVs are generated to be equivalent to, or exceed, the performance requirements given in the -ISO 11138 series of Standards for BIs.*
4) *Type 6 emulating indicators are designed to react to all critical process variables for specified sterilization processes and are cycle specific.*

Note: *Routine monitoring verifies that the health care setting's systems and equipment are supplying conditions necessary for sterilization.*

A type 4 CI shall not be used for release of loads in the absence of BI result.

The use of CIs is part of an effective quality assurance program; they should be used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile, only that the item has gone through the sterilization cycle.

Use of Sterilization Indicators

- Use according to the indicator manufacturer's IFUs
- Use only for the sterilizer type and cycle for which it was designed and validated
- Interpret only by qualified staff who have been trained to do so
- Don't use beyond the expiration date
- Store in accordance with the manufacturer's instructions

9.3.1. Physical Monitoring of Sterilization Cycles

- Interpret and record the results of physical parameters
- Review physical monitoring parameters for each operation (e.g., printed or electronic records)
- Document any malfunction and appropriate action taken
- Test filter systems for leakage
- Validate gas sterilization units for such factors as gas concentration, temperature, and relative humidity
- Conduct three consecutive tests with the air detection test pack (bowie-dick) for sterilizers of the dynamic air removal type
- Do not use a sterilizer without a recording device. It is important that the chart or printout is readable and verify the printer if it is functioning properly.
- Ensure the pen is functioning properly and that when the chart is inserted, it is marked with the correct date, operator and sterilizer number. If there is no printer or electronic monitoring, the sterilizer operator shall monitor and document the physical parameters of the sterilization process.
- Record the cycle identification number.

- Examine and interpret the chart or printout at the end of the cycle before unloading the items from the sterilizer and initial it.
- Monitor and keep the record (paper or electronic) of the time, temperature, and pressure recorders, displays, digital printouts, and gauges, label the tape with date; it must be reviewed and signed by the operator.
- Keep all the records of repair and preventive maintenance for each sterilizer
- Record the sterilizer load identifier on the patient chart or the patient name on the sterilizer logbook records.
- A leak test is performed according to the sterilizer manufacturer's instructions for use (applicable to pre-vacuum sterilizers)
- Avoid releasing the loads if the interpretation of the physical monitors suggests inadequate steam processing and inform to the designated supervisor for appropriate investigation and follow up.

Sterilizer Leak Testing

When the leak rate test is performed, a sterilizer shall exhibit an average leak-rate that meets manufacturer specifications.

The leak-rate test frequency shall be in accordance with to sterilizer IFU.

9.3.2. Chemical Indicator Monitoring

- An internal type 5 or higher chemical indicator shall be placed inside each package, container or bundle in the area judged to be least accessible to steam penetration. Not necessarily be at the center of the package
- Choose the type of indicator based on the parameters being measured and the degree of precision that is needed.
- Each package or container shall have an externally visible Type I chemical indicator, which is examined immediately after sterilization to ensure that the item has been exposed to the sterilization process.
- For the dynamic air removal-type sterilizers, an air removal test with a Type II chemical indicator (bowie-dick) shall be performed every day and after cooling process has occurred (sterilizer allowed to cool with time between uses).

Table 6: Classes Of International Chemical Indicators (CI)	
(Type 1) Process indicators	These indicators are intended for use with packs or containers to indicate that they have been directly exposed to the sterilization process and to distinguish between processed and unprocessed units
(Type 2) Specific indicators	These indicators are intended for use in specific test procedures, such as, the Bowie Dick test for air removal
(Type 3) Single variable	These indicators are designed to react to one of the critical sterilization variables, e.g. time and temperature, and are intended to indicate exposure to a predetermined sterilization process variable, e.g. 134 °C
(Type 4) Multi variable	These indicators are be designed to react to two or more of the critical sterilization variables, e.g. time and temperature, and are intended to indicate exposure to predetermined sterilization process variables, e.g. 134 °C, 3 minute
(Type 5) Integrating	These indicators are designed to react to all critical variables of the sterilization process, e.g. time, temperature and presence of moisture, and are intended to be equivalent to or exceed the performance requirements given in the ISO 11138 series for biological indicators
(Type 6) Emulating	These indicators are designed to react to all critical variables of the sterilization process, e.g. time, temperature and presence of moisture, and are intended to match the critical variables of specified sterilization cycles

Bowie-Dick Testing

Bowie-detects evidence of air leaks, ineffective air removal with other air removal techniques that do not utilize a deep vacuum, and the presence of non-condensable gases (i.e., air or gases from boiler additives).

- Perform the Bowie-Dick test each day as per sterilizer manufacturer IFU before the first processed load Ensure that the correct Bowie Dick test is purchased for the type of sterilizer used.
- If the sterilizer is used continuously, the test may be performed at any time, but should be performed at the same time every day.
- Place the test pack horizontally in the front, bottom section of the sterilizer rack, near the door and over the drain, in an otherwise empty chamber.
- Remove and interpret the test sheet from the pack and document results.
- Check for any unexpected color change, such as the center of the test sheet being paler or a different color than the edges (i.e., there is a non-uniform color change), this indicates that there was an air pocket present during the cycle because of sterilizer malfunction.
- Report to the designee any test results that do not conform to the recommended color standards provided by the manufacturer of the test sheet

Figure 10: Bowie Dick test Results Example

Sample Monitoring Documentation: Bowie-Dick Test

Healthcare facility _____ Date: _____

Autoclave Name/ number	Serial number	Cycle
AFFIX BOWIE DICK TEST		
Date	**Time**	
Name of operator	**Signature**	

9.3.3. Biological Indicator Monitoring:

- Shall be used to test the sterilizer with each type of cycle that is used that day.
- Implantable devices shall be quarantined until the results of the BI test are available, if quarantine pending BI results is not possible, evaluation of a Type 5 chemical indicator and the specific cycle physical parameters may be used to justify the release of routine loads; however, the BI should continue to be incubated.
- Sterilization cycles using ethylene oxide; a BI shall be included in every load.

Table 7: Biological Indicator Sample Record

Autoclave Number	Cycle Type	Load Number	BI Lot #	Date	Time	Operator Name and Signature	Supervisor Name and Signature
Reading							
Time	**Date**	**Result**		**Operator**		**Supervisor**	
		Pass	**Failed**	**Name**	**Signature**	**Name**	**Signature**
Note: *When a positive BI is noted, please see the recall policy and procedures for action to be taken.*							

Process Challenge Device (PCD) Testing

A BI contained within a PCD shall be used to test the sterilizer for each type of cycle used (e.g., dynamic air removal, gravity) and at the shortest exposure time for each cycle type, in accordance with the sterilizer manufacturer's recommendations.

Routine BI testing shall be conducted following the sterilizer and PCD MIFUs.

Note: *A PCD may be a user-assembled challenge test pack or test tray or a commercially available, disposable, pre-assembled challenge test pack– see figure 10 below*

Generally, the procedure is as follows:

- The BI PCD shall be placed in the location as designated by the PCD and sterilizer manufacturer, as follows:
  a) For steam sterilization, a standard cycle with a typical load shall be run with the BI PCD placed in a full load in the area of the sterilizer chamber above the drain. (See Figure 12).
  b) For low-temperature sterilization, the most challenging cycle(s), which is usually the shortest, as recommended by the manufacturer shall be used.

- On cycle completion, including any needed post-process residual removal such as an aeration cycle, the BI shall be removed from the sterilized load and documented. This includes date and time of sterilization, sterilizer number, and cycle number.
- The BI shall be incubated in accordance with the IFUs. Results of incubation shall be documented and
- A daily control BI from the same lot number and unexposed to sterilant shall be incubated in accordance with the IFUs.

Note: *Control BI is used to verify the viability of the bacterial spore population, the ability of the growth media to promote growth, and the proper functioning of the incubator.*

- The BI's are intended to demonstrate whether the conditions were adequate to achieve 10^{-6} log reduction.
  - The HCF must select BIs that consist of spores of (for steam sterilization), that comply with ANSI/AAMI/ISO 11138-3, and that are suitable for use in the specific sterilization method.
  - The BI should be used within process challenge device (PCDs) at least weekly, but preferably every day when sterilizer is in use and with each load that contains implants.
  - A "control" test with the same lot number of the biological indicator t is used and is matched to the biologic indicator test.

Figure 10: Preparation of the 16 towel PCD (BI Challenge test pack)

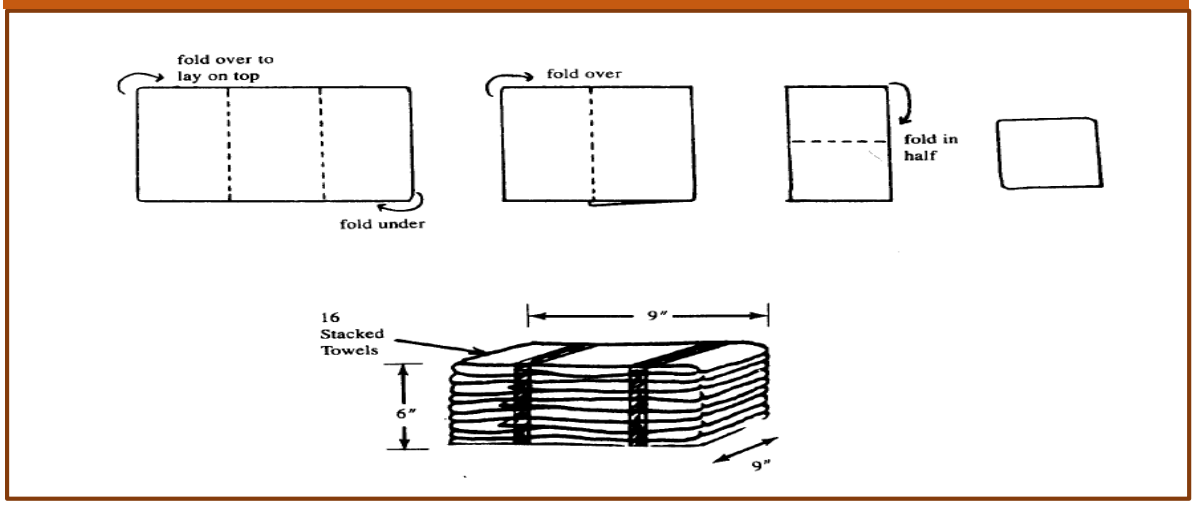


Figure 11: Placement of the 16 Towel PCD (BI Challenge Test Pack) Qualification

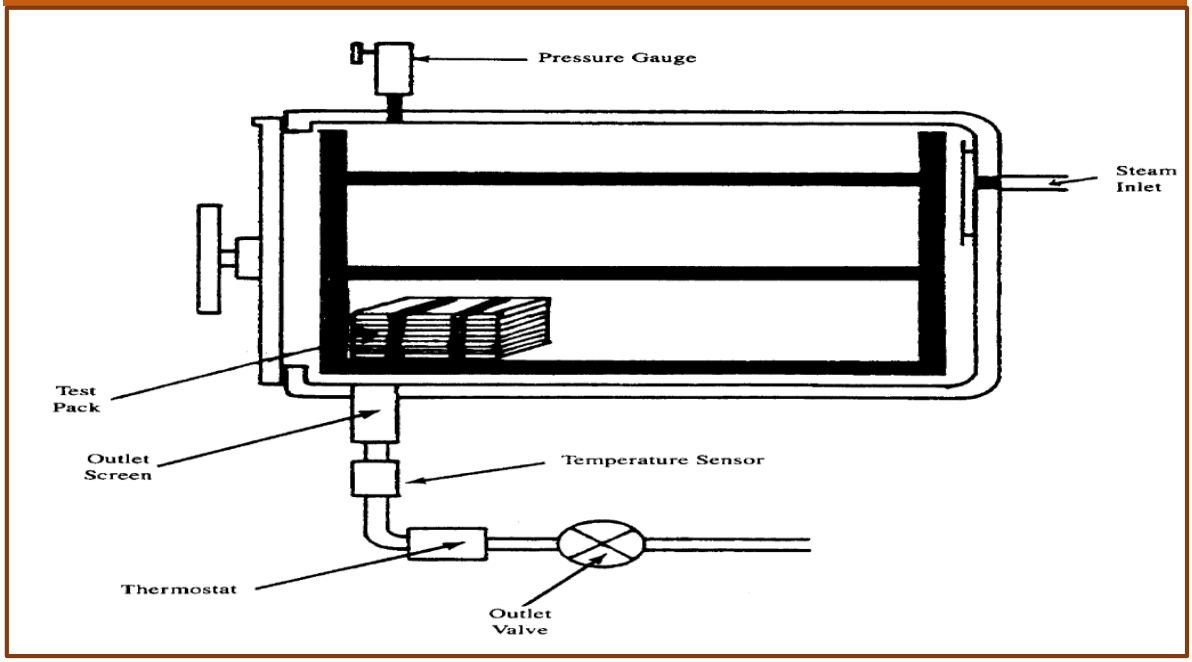
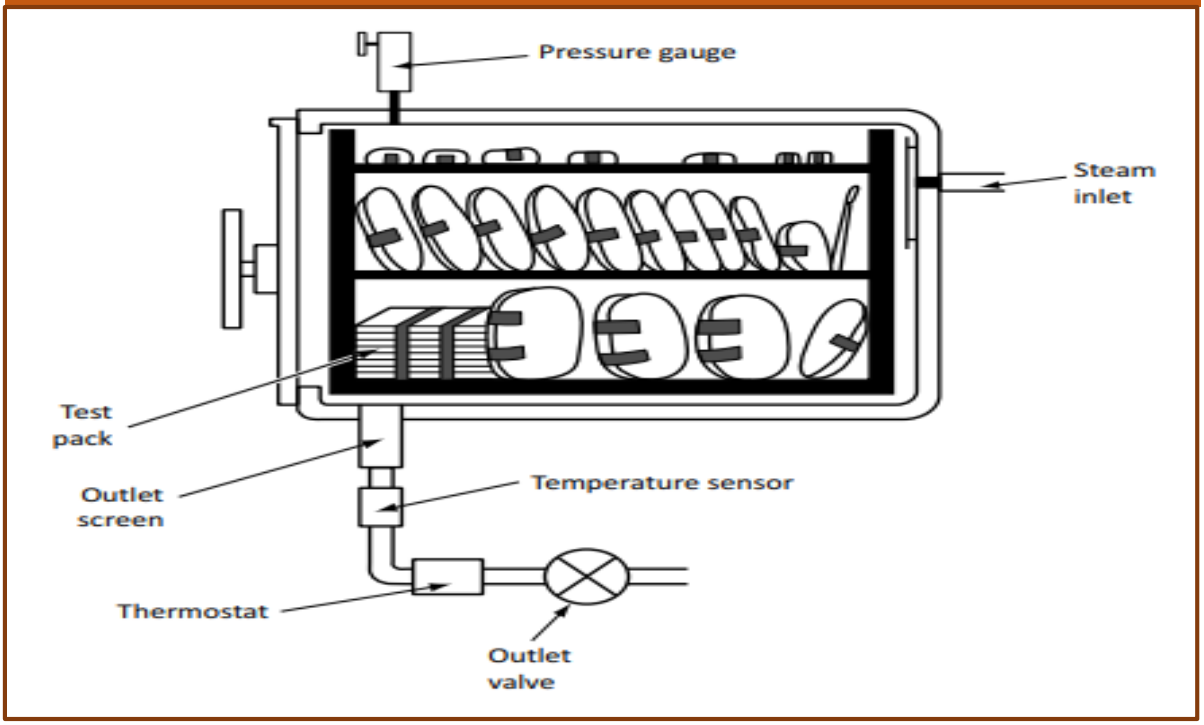


Figure 12: Placement of the 16 towel PCD (BI challenge test pack) for routine biological monitoring of sterilizers larger than 2 cubic feet



Reference: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

9.4. Implantable Device Sterilization:

- Every load containing implantable medical devices shall be monitored using a BI PCD.
- Implants shall be validated by the manufacturer for the type of sterilization process to be used.
- The health care setting shall only sterilize implants if the manufacturer IFUs provide validated cleaning and sterilization instructions as well as the number of reprocessing cycles that can be performed.

Note:

1) *Implants include, but are not limited to*
   a) *Ligating clips*
   b) *Gastric staples*
   c) *Orthopedic internal fixation medical devices such as Screws (Plates, Staples, Wires)*
   d) *Joint replacement prostheses*
   e) *Cardiac valves*
   f) *Mesh*
2) *Due to the length of time that an implant is in contact with a patient (client), the risk of infection from a non-sterile implant is greater than from a typical medical device used during a typical procedure.*
3) *Some chemical sterilizers are not validated for the sterilization of implants, or might only be validated for limited types of implants. Follow the sterilizer IFUs.*

Release of Loads Containing Implantable Medical Devices (If Used):

- Implantable medical devices shall be quarantined until the results of the BI test are available.
- Early release of implants shall only be done in emergency situations where there is an emergent, life or limb unplanned need (e.g., trauma-related medical devices).
- Early release of implants shall not be used to compensate for inventory shortages or re-scheduling of procedure. If an implant must be released before the BI test results are available, the following shall apply:
  a) Evaluation of a Type 5 or Type 6 CI in the BI PCD, the specific cycle physical parameters, and any visible CI shall be assessed and the results

  Note: *Consideration needs to be given to use of new BI technology that provides a result in under an hour.*

  b) Information identifying the implant and the patient (client) it was used on shall be documented.
  c) A report (e.g., incident report) shall be prepared, reviewed, and maintained in accordance with the health care setting's risk management policy and shall contain the:
     - Patient's (client's) identifier
     - Implant identification number
     - Surgeon's name
     - Time and date of the procedure
     - Results of any physical or CI used in the sterilization process
     - Results of the BI once they are known
     - Reason for release

Release of Loads without Implantable Medical Devices:

Physical parameters and internal CI results shall be used as part of the justification to release routine loads (i.e., loads without implantable medical devices) in the absence of BI results.

A PCD containing a Type 5 or Type 6 CI or a BI PCD should be used for increased assurance of sterility in all steam sterilization processes.

Note: *If a routine load is monitored with a BI PCD, it is preferable to not release items in the load until all test results are known*

Table 8: Checklist for sterilizer records for implant and non-implant loads

Non Implant	Implant	Elements
√	√	Lot number (sterilizer identification number or code, cycle number, and date of sterilization)
√	√	Specific contents of the lot or load (including quantity, department, specific description of items)
√	√	Exposure time & temperature (if not provided on sterilizer recording chart)
√	√	Name or initials of operator
√	√	Results of Bowie-Dick testing, if applicable
Daily	**√**	Results of biological testing (test and control);
Optional Daily	**√**	PCD challenge results (BI challenge test pack or test tray, or CI challenge test pack)
√	**√**	Reports of inconclusive or nonresponsive CIs found later in the load
√	**√**	Time & temperature recording chart, printer, or tape should be dated, reviewed and signed by operator

Table 9: Sterilization Monitoring Schedule Example

Healthcare Facility:							**Region:**						
Month	**Physical Monitors**			**Bowie-Dick Test**			**Leak Test**			**Biological Test**			**Remarks**
Day	Every load			Daily			Weekly			**Weekly**			
	P	F	Signature	P	F	Signature	P	F	Signature	P	F	Signature	
Day 1													
Day 2													
Day 3													
Day 4													
Day 5													
Legend : P- passed ; F – failed													
Reviewed by :							**Signature:**						

Table 10: Time and temperature parameters for the gravity –displacement steam and pre-vacuum sterilization cycles				
Item	**Exposure time/ minutes**			**Drying Times/ mins**
	121 C (250 F)	132C (270F)	135 C (275 F)	
Wrapped Instruments	30 min	15 min		15-30 min
			10 min	30 min
Textile packs	30 min	25 min		15 min
			10min	30 min
Wrapped Utensils	30 min	15 min		15-30 min
			10 min	30 min
Unwrapped non porous items		3 min	3 min	0-1 min
Unwrapped non porous items in mixed load		10 min	10 min	0-1 min

Adapted from: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

Table 11: Minimum cycle times for dynamic air removal steam sterilization cycles			
Item	**Exposure time /minutes**		**Drying time Minutes**
	132°C (270°F)	135°C (275°F)	
Wrapped Instrument	4 minutes		20-30
		3 minutes	16
Textile packs	4 minutes		5-20
		3 minutes	3
Wrapped utensils	4 minutes		20
		3 minutes	16
Unwrapped non porous items	3minutes	3minutes	NA
Unwrapped non porous and porous items in mixed load	4 minutes	3minutes	NA

Adapted from: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

9.5. Extended Steam Sterilization Cycle Requirements:

- For all medical devices that require an extended steam sterilization cycle, the health care setting shall request a validated, written reprocessing protocol from the medical device manufacturer.
- In the absence of an alternative validated reprocessing protocol, the health care setting shall:
  - Request recommendations from the medical device manufacturer for means to monitor an extended steam sterilization cycle; and
  - Ensure that all sterile barrier systems, indicators, sterilizers, and other components are compatible with the sterilization conditions used.

    Note: *Preference is for the manufacturers to provide validation using standard steam sterilization cycles.*

- When an extended steam sterilization cycle is required, the health care setting should limit the number of cycles used to allow for the monitoring of critical process parameters.

Performance Qualification:

For all groups of medical devices that require an extended steam sterilization cycle, the health care setting shall conduct PQ of products and product loads (i.e., verification testing of products and loads).

Monitoring Extended Steam Sterilization Cycles:

Examples of extended steam sterilization parameters include

a) Dynamic air removal: 132 °C (270 °F), 10 min; and
b) Dynamic air removal: 132 °C (270 °F), 20 min.

Monitoring Tools for Extended Steam Sterilization Cycles

The HCF shall ensure that BI and CI are validated for the extended steam sterilization cycles in which they are used.

CI shall be designed for monitoring of process parameters specific for the cycle being used.

Notes: *Manufacturers need to provide documentation of validation for indicators used under different sterilization conditions.*

Process Challenge Device Requirements for Extended Steam Sterilization Cycles:

When PCDs are used to monitor extended steam sterilization cycles, they shall be specifically designed and validated for the cycle being tested.

9.6. Water Quality for Steam Sterilizers (also see Annex D & E):

The water supply, steam generation equipment, and pipelines serving steam sterilizers must be designed, built, and maintained to produce a reliable supply of controlled quality steam. Some sterilizers have independent steam generation systems.

- The HCF should monitor the quality of its water supply. The water should meet the required quality to ensure that the device is not damaged and that the patient will not be injured by contact with the device. If the water does not meet the requirements, the facility shall implement the necessary treatment process to bring the water within specifications.
- The water quality monitoring includes microbial and chemical testing according the annex table D-2
- Furthermore, the HCF should have a written reprocessing contingency plans in place that address loss of potable water e.g., during the natural calamity and contamination of water source.

9.7. Steam Quality (Also see Annex E)

The HCF shall ensure that the characteristics of steam quality are assessed and documented.

Steam Condensate:

- The HCF or designate (i.e., third-party service provider) shall have the steam sterilizer condensate evaluated to ensure that the steam does not contain contaminants in quantities that can impair the steam sterilization process, or harm or contaminate the sterilizer or its load.
- Steam sterilizer condensate shall meet the sterilizer manufacturer specifications. If the steam sterilizer condensate does not meet manufacturer specifications or the recommended.

- Parameters listed below, the HCF shall implement the necessary treatment process, modifications, or repairs to ensure that the steam is suitable for sterilization.
- Steam sterilizer condensate shall be sampled from the condensate return.

Steam Evaluation:

- Proper steam quality will prolong the life of medical devices by reducing adverse effects from water impurities.
- The water impurities, lime, rust, chlorine and salt can be left as deposits on medical devices which lead to stress corrosion, pitting and discoloration that have negative effects (less effective) to the sterilization process.
- The health care setting or designate shall have the CSS steam evaluated in the following instances/ frequencies:
  - upon commissioning of new equipment in CSS area and annually or as per manufacturer's IFUs;
  - following a change from one sterilizer to another;
  - following an issue where staining of equipment/medical devices has occurred; and
  - Following wet loads after steam sterilization.

    Note: *Steam is vapourized water that is produced from a treated water source by a centralized boiler or a generator or heat exchanger at point of use. Water vapour (steam) is used directly within the sterilization system as the sterilizing agent and will come in contact with the medical device. When cooled down below the saturation temperature, steam is transformed into steam condensate*
- The HCF should ensure steam quality by:
  - monitoring, controlling, and documenting the process of generating steam;
  - testing steam against the following critical variables:
    - Steam dryness between 97% to 100% to avoid wet steam
    - Non- condensable gases (e.g., air) at a level (less than 3.5% v/v condensate) that will not impair steam penetration into sterilization loads,
    - Superheat of steam (not acceptable)

9.8. Chemical Disinfection (High-level disinfection- HLD) Monitoring:

The frequency of testing should be based on how frequently the solutions are used (i.e., test daily if used daily); at a minimum, test according to manufacturer's IFU.

- Do not use products beyond the expiration date.
- Disinfection practices shall be audited on a regular basis and a quality improvement process must be in place to address any deficiencies/concerns identified.
- Prepared solutions shall not be topped up with fresh solutions
- HLD container shall be covered during use and wash, rinse and dry when the solution is changed.

Records shall be kept and shall include, but are not limited to the following:

a) High-level disinfectant solution documentation:
   - Product name
   - Lot number

- Expiry date of high-level disinfectant in use
- Date of solution change
- Initials of staff doing the preparation and documentation

b) High-level disinfectant test strip documentation:
- Name of test strip
- Lot number
- Expiry date
- Quality control test results (each time a new test strip bottle opened)
- Routine test strips results: minimum effective concentration (MEC) pass or fail
- Initials of staff doing the testing and documentation

c) Medical device name or type documentation:
- Medical device name or type
- Unique identifier (serial number)
- Date and time of disinfection
- Contact time of the high-level disinfectant
- Temperature of the high-level disinfectant (if applicable)
- Results of electrical leak test (if applicable)
- Initials of staff doing the reprocessing

d) Reprocessor documentation:
- Date of any maintenance performed
- Fault codes recorded and corrective actions taken
- Filter changes, if appropriate
- Cycle printouts
- Resetting or verification of correct cycle parameters following repair
- Maintenance, if appropriate
- Results of the MEC testing (if applicable), including
  - Signature of the person conducting testing;
  - Quality assurance of strip testing in accordance with the MIFUs, if appropriate;
  - Lot number and name of disinfectant; and
  - Date the new disinfectant was installed or activated, if high-level disinfectant is reusable

10. Sterile Storage and Shelf Life:

The sterile storage area in the facility should be appropriately designed for the storage of medical devices and supplies.

- It should be located nearby to the sterilization area, preferably in a separate, enclosed, limited-access area and away from external doors and windows.

- Sterile storage areas should be kept clean and dried, the sterile items should be stored under environmentally controlled conditions in a manner that reduces the potential for contamination.
- It is essential to ensure that all sterilized items been maintained and stored in such a way that sterility is maintained until it is used.
- Procedures for routine daily cleaning of the sterile storage area must be clearly defined to prevent the contamination of sterile items.
- Pest free – once there is evidence of presence of any pests, the stored items are considered to be contaminated and should undergo for reprocessing.
- Access to hand hygiene products (ABHR) at entrance to the area.

10.1. Storage of sterile items:

- Implement first in first out (FIFO) principle
- Identification of sterile items should be clear and visible
- Store on open shelving and at least 8 to 10 inches above the floor, at least 18 inches below the ceiling or the level of the sprinkler heads, and at least 2 inches from walls
- Store in such a way that wrapped packages are not stored under rigid sterilization containers on the same shelf so that packaging is not crushed and compressed
- Sterile items, including those packaged in rigid sterilization container systems, should not be stored next to or under sinks, or in any location where they could become wet.
- Elastic bands or tapes should not be used to bundle item
- Closed or covered cabinets are recommended for sterile storage if open shelving is used it requires special attention to traffic control and area ventilation
- Avoid using any storage containers that are not moisture-resistant and cleanable (i.e., corrugated cardboard boxes)
- For safety and ease of handling, heavy instrument trays should be stored on middle shelves; transport trays with solid or perforated bottoms may be used to prevent tears in wrappers during handling.
- Access to the sterile storage area should be restricted to authorized personnel (traffic control).
- Ensure that the storage areas are clean, dry and protected from moisture and pest.
- Prohibit any unauthorized personnel, entering the sterile storage room.
- Ensure proper signs and labels are posted in the storage shelves
- Minimize handling of sterile items to maintain sterility integrity

10.2. Sterility maintenance & Shelf life

- The shelf life of a sterile package shall be event related or time related.
- For an event-related shelf life, where the integrity of the package has been compromised
- (e.g., damaged, torn, dropped on the floor) or is questionable, the package shall be considered non-sterile and the contents reprocessed.
- Product labelling for sterile manufactured medical devices shall be referred to, and where this is not available, event-related sterility (e.g., reprocessed products) shall be used.
- The health care setting shall assess event-related shelf life based on the concept that items that have been decontaminated, wrapped, sterilized, stored, and handled in accordance with the SOPs established by the HCF will remain sterile indefinitely unless the integrity of their packaging is compromised.
- The following events that can compromise the sterility of a sterile item includes:
    - Holes or torn wrappers
    - Securing tapes or locks that have been tampered with or removed
    - Broken or incomplete seals on laminated pouches including taping on seal
    - Items that have been dropped/placed on a dirty surface
    - Exposure to blood, body fluids or any type of moisture.
    - Writing on sterile packages etc.

10.3. Inventory Management of Sterile Items:

- Inventory Management prevents supply chain issues, providing equal patient care and to control operating costs.
- Each health care setting shall establish policies and SOPs for inventory control and shelf life.
- The health care setting's policies and SOPs shall address the following issues:
    - Sterilization load indicators for traceability purposes;
    - Sterilization date for stock rotation purposes (e.g., FIFO);
    - Adequate spacing of packages;
    - Easy visibility and retrieval of packages;
    - Visual inspection of all packaging before use; and

      Note: *The probability of contamination increases with handling and environmental stresses.*
    - Storage conditions.
- Infrequently used sterile packages should be stored in closed or covered cabinets or dust covers.

11. Distribution and Transportation of Sterile Items:

Note: *Transportation refers to off-site and distribution refers to on-site.*

- Transportation SOPs shall take into account the manufacturer's recommendations for the conditions of transportation, including temperature and relative humidity, handling requirements, and restrictions on agitation, bumps, and other movement.

  Note: *Medical devices that have been removed from their shipping containers need extra care to prevent damage during transportation*.

- Routine distribution of clean and/or sterilized medical devices to different areas in the HCF shall be performed using clean and either enclosed or covered transportation carts, bins, and totes, or plastic bags.
- Carts, bins, and plastic totes that are used for transportation of sterile goods shall be cleaned in accordance with HCF policy.
- Due to the risk of cross-contamination, single-use and reusable medical devices or supplies shall be transported and stored separately from soiled medical devices and soiled laundry.
- Uncased clean single-use and reusable medical devices or supplies shall be contained (e.g., in a tote, plastic bag) during transportation and distribution to protect them from damage and/or contamination.

11.1. Transportation (off-site):

- Vehicles used for the transportation of single-use and reusable medical devices or supplies shall not compromise the condition of the sterile medical devices or supplies.
- To minimize damage to sensitive medical devices, the pneumatic suspension of the vehicles used for transporting clean and sterile single-use or reprocessed medical devices or supplies shall be assessed by the health care setting to ensure damage to medical devices does not occur during transport.

Cleaning and Maintenance:

- Vehicles used for transportation shall be clean and maintained.
- Extremes of temperature and humidity, as well as large fluctuations, shall be prevented during the transportation of medical devices.

  Notes: *Compliance with this requirement will help to reduce the risk of condensation and potential contamination of the medical devices.*

Vehicle Compartment Cleaning:

A compartment in a vehicle that has carried contaminated medical devices shall be cleaned and disinfected before being used to transport clean or sterile medical devices.

11.2. Distribution (on-site)

- Carts, bins, boxes, and plastic bags used for routine distribution of single-use and reusable medical devices or supplies within a HCF shall be cleaned in accordance with SOP.
- Sterile single-use and reusable medical devices and sterile supplies, shall be enclosed or covered during distribution.

  Note: *If distribution is carried out entirely within a clean, dedicated system (e.g., dedicated clean, sealed elevators); there is no need for enclosure or covering of medical devices.*
- Clean and sterile medical devices shall not be transported through soiled areas (i.e., decontamination areas, soiled elevators, or soiled utility rooms).
- Scheduled distribution on public elevators should be timed during low-traffic times and not when garbage or soiled linen is being transported on the elevator.

Reusable Covers:

Reusable covers for protecting medical devices, carts, or containers during transport shall be cleaned regularly in accordance with an established schedule.

12. Tracking and Recall

The healthcare facilities should have tracking systems to facilitate identification of patients and the devices/ instruments used during their procedures. A written procedure must be established for the recall of improperly reprocessed medical equipment/devices. All the instruments/devices in each processed load must be recorded to enable tracking in the event of process failure or a recall.

12.1. Tracking System:

A good system *(*Manual or Electronic*)* should enable the identification of patients on whom instrument sets have been used. Traceability can be accomplished by recording the sterilizer load identifier on the patient chart or the patient name on the load record (label). Ideally, every reprocessed medical device, especially an implant, should be fully traceable to the patient on whom it is used or in whom it is implanted.

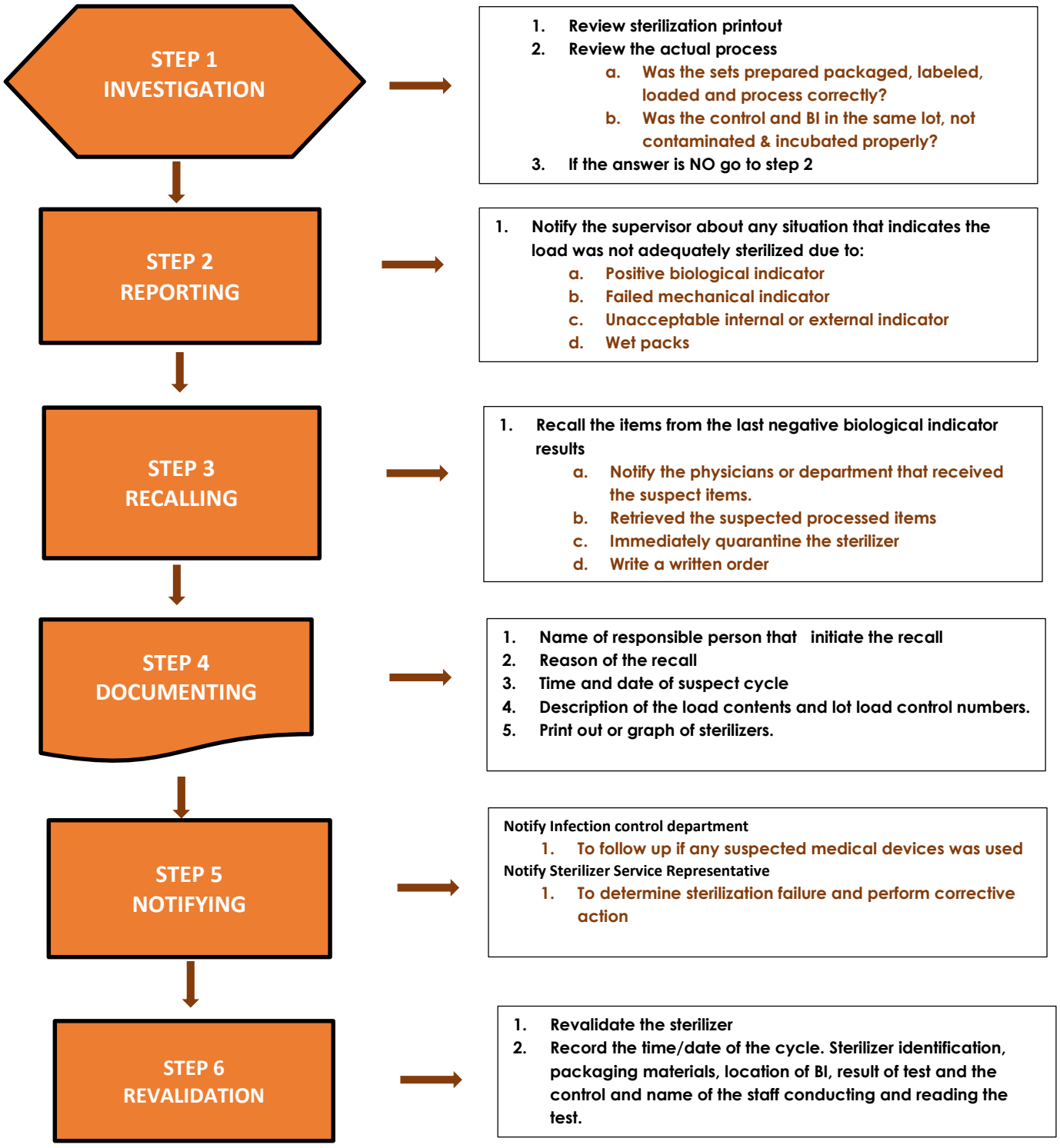
12.2. Recall Policy:

Each healthcare facility should develop a policies and procedures for the recall of items in collaboration with the infection prevention and control committee and the Quality department.

Note: *See Figure 13: Flow Chart for Product Recall*

- In the event of sterilization failure, such as positive biological indicators/failed load Controls or sterilizer malfunction, items from that test and previous loads after the last known passed test must immediately be recalled.
- All recalled materials need to be contained / quarantined until the process has been completed; if this is not practical, reprocess the identified instruments immediately
- The department head or designee should decide when a recall of processed supplies should be implemented.
- Whenever there is evidence of a sterilization failure, the infection prevention and control professional should be notified so that follow-up surveillance of patients can be conducted.

Figure 13: Flow Chart for Product Recall



Adverse event:

- An adverse event is one that creates doubt that all required reprocessing steps were performed correctly.
- Examples of reprocessing adverse events include (but are not limited to):
  - Incorrect reprocessing method used
  - Reprocessing parameters not met
  - Positive biological indicator
  - Failed chemical indicator
  - High level disinfection failure
  - Release of a non-sterile medical device(s)
  - Wet sterilization load
  - Medical device alert
- All adverse events shall be followed up with including:
  - Investigation- to determine what further actions (if any) are required;
  - Documentation and reporting of findings according to facility policy (e.g. notification to risk manager)
  - An action plan based on risk assessment (e.g. recall)
  - Evaluation of action plan effectiveness; and
  - Further intervention as required in response to feedback.

13. Loaner Medical Devices:

Sterility assurance "begins at the loading dock," from the time that items are received into the HCF until they are used. Where possible, loaner equipment should be received 48hrs prior to the surgical procedure to ensure adequate time for identifying any discrepancies with loaned or leased medical devices.

The HCF shall be able to reprocess the loaner medical device in accordance with the Manufacturer's IFU.

Reprocessing methods within the Manufactures IFU shall include validated reprocessing equipment and cycles available in the CSS.

The health care setting shall base their reprocessing decision on its written policies and SOPs and the expertise of its health care professionals.

Note:

1) Health care professionals include all those involved in the selection of medical devices i.e. physicians, nurses, CSS personnel, biomedical engineers, microbiologists, and IPC.

2) A medical device is considered unsafe to use if soiled, damaged, modified, altered, or malfunctioning.

13.1. Documentation and Records of Loaned Equipment

Records for loaned medical devices shall be maintained by both receivers and senders.

Each organization in its capacity as receiver or sender shall have mutually accepted policies for the maintenance and availability of records for the purpose of traceability.

Accompanying Documentation:

Documentation accompanying a loaned, reusable medical device shall include, as applicable,

a) The manufacturer's written and validated instructions for reprocessing, including any specific reprocessing instructions before return;
b) An itemized list of all parts and components, along with any illustrations and identifying numbers that allow for confirmation of set contents;
c) Documentation of any known malfunctions or breakage; and
d) Packing and shipping instructions.

13.2. SOPs for Receiving, Inspecting, Reprocessing, and Releasing:

SOPs shall be in place for receiving, inspecting, reprocessing, and releasing of a loaned, reusable medical device.

These SOPs shall specify the necessary documentation and checklists for this activity.

The sender shall provide the medical device in the agreed-upon timeline to allow the receiver to follow its SOPs for inventorying the set contents, in-servicing, inspecting, and reprocessing before the scheduled date of the operative procedure.

The minimum timeline shall be two (2) working days.

If this is the first time receiving the loaned, reusable medical device and/or if it requires an extended cycle, the minimum timeline shall be three (3) working days allowing for verification that the HCF can:

a) Follow the MIFUs;
b) Have the resources available on-site; and
c) Complete PQ, if required.

13.3. Timing Requirements:

HCF's shall not accept any medical device for use that does not arrive in sufficient time to allow the health care setting to follow its SOPs for inventorying, in-servicing, inspecting, and reprocessing, except in an emergency as defined in its policies and SOPs.

Before use, all loaned, reusable medical devices received shall be inventoried and inspected for functionality and documented.

All consumables required for the operation of the medical devices and for the procedure shall be present. Medical devices shall be reprocessed in accordance with the Manufacturer's IFUs and the HCF's policies and SOPs.

Reprocessing methods shall include functional sterilization methods available at the facility, if applicable.

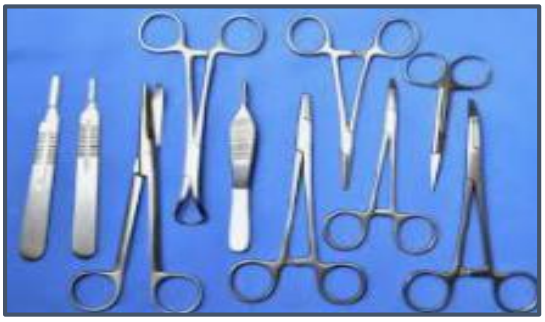
Note: *Depending on the complexity of the medical device, and whether it is electrically powered, compliance with the SOPs could require inspection and testing by qualified personnel (e.g., manufacturer's representative, biomedical or clinical engineering personnel).*

Chapter 4:

Maintenance of CSS Equipment and Care of Instrument

Chapter 4: Maintenance of CSS Equipment and Care of Instruments

The care and maintenance for CSS equipment and instruments is critical to their performance during surgery and help in prolong equipment's life and save the functional ability and value of these instruments and to help reduce the cost and expenses associated with surgical instruments. The equipment manufacturer (including sterilizers, washers, disinfectors, heat sealers etc…) should provide written IFU for preventive maintenance of the equipment. This maintenance should be carried out by a qualified individual on a regular schedule as determined by the manufacturers IFU.



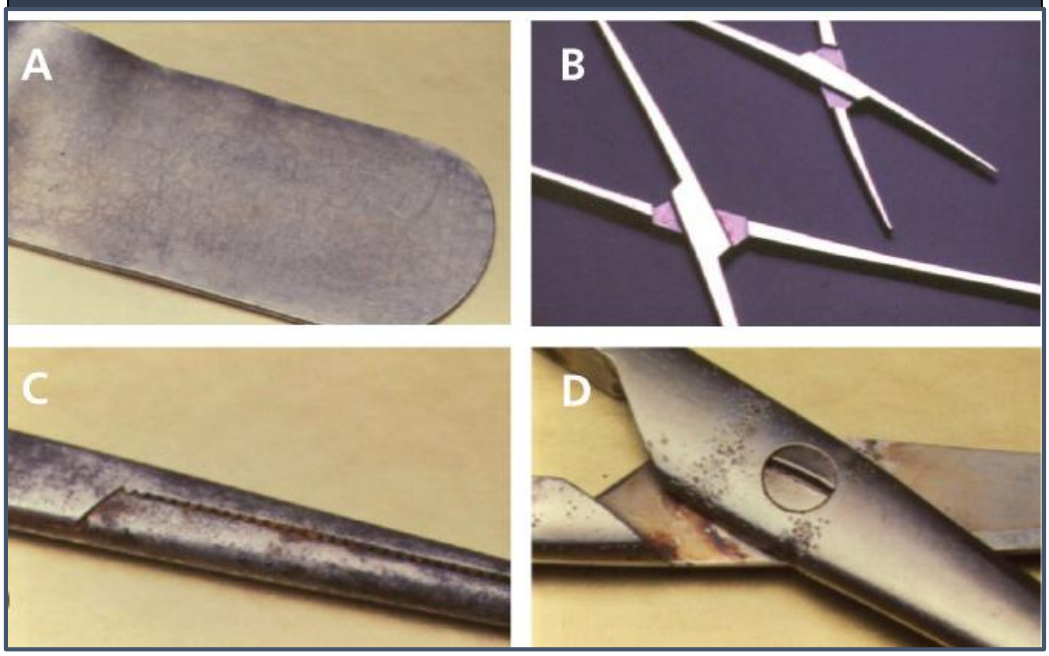
1. Care of Instruments:

- Inspection and functionality testing shall be carried out to ensure that instruments still function as they should.
- Lubrication helps prevent the friction of metal on metal which would lead to rusting or corrosion.
- To prevent damage and secondary corrosion due to metal abrasion, never use metal brushes or abrasive materials to remove stains.
- Monitor water quality. An impure water source (may cause staining, rusting and corrosion), improperly maintained sterilizer, or improperly processed surgical wrappers are all major sources of the impurities which can stain and corrode instruments.
- Ensure good quality steam at the correct pressure is used and maintained, as recommended by the manufacturer.
- Ensure proper drying cycles and strict adherence to the equipment manufacturer's recommendations are carried out to prevent the formation of excessive moisture and the resulting water spotting which will lead to staining and corrosion.
- Never lock an instrument during autoclaving. This will prevent the steam from reaching and sterilizing the metal-to-metal surfaces. Furthermore, heat expansion during autoclaving can cause cracks in hinge areas.

2. Stain and Corrosion

Approximately 75% of all surgical instruments used are made of stainless steel. It resists rust, can be honed to a fine point and retains sharp edges. There is really no "stainless" type of steel. Although it is corrosion resistant, it can still rust and/or stain if handled improperly. To determine if a discoloration is rust or just a stain; if there is pitting in the metal under the discoloration - it is corrosion. If the discoloration is removed- it is a stain.

Figure 14: Examples of Staining and Corrosion on Surgical Instruments:



Reference: MDRAO Medical Device Reprocessing Manual Third Edition, 2012

Sometimes good quality steam is delivered to the sterilizer but staining and corrosion still develop. The linen wraps used in the preparation of trays for sterilization may cause these problems. The washing, rinsing and final treatment of linen used for this purpose must be understood and the best possible methods strictly adhered to.

Table 12: Stain Guide for Stainless Steel	
Stain Color	**Causes**
Brown/Orange	High pH
Dark Brown	Low pH
Bluish/Black	Reverse plating due to mixed metals during cleaning process
Multicolor	Excessive heat
Light/Dark Colored Spots	Water droplets drying on the surface
Black	Contact with ammonia
Gray	Excessive use of rust remover solution
Rust	Dried on blood or bio debris

Adapted from: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

3. Inventory Management:

The CSS policy should have a procedure on how to investigate instruments missing from a set or parts of instruments / scopes and escalated as appropriate to individuals who have the authority to replenish. All sterile set should be complete prior to sterilization.

The following are suggestions to prevent missing instruments:

- When the CSS staff identified that there is a missing instrument or part of an instrument, immediately isolate the tray and contact the end user.
- Check all wash baskets, transport trolleys, washer disinfectors, floor areas, linen, etc.
- If the missing item is located - return it to circulation.
- The incident must be fully recorded.

4. Purchasing Medical Devices/Consumables:

Before purchasing reusable medical devices, reprocessing equipment, and reusable wrappers, decisions shall involve representatives from the departments in the HCF that will procure, use or be affected by, reprocess, and maintain the devices, equipment, or reusable wrappers. These meeting and subsequent decisions shall be documented.

The following departments should be involved as appropriate to the complexity, risk class, and intended use of the medical device:

- CSS;
- Purchasing;
- OR or other units/departments that will use the medical device;
- Quality;
- IPC;
- HSE;
- Biomedical engineering;

4.1. Validated Manufacturer IFUs:

Before considering reusable medical devices, reprocessing equipment, or reusable wrappers for purchase, the health care setting shall ensure that it is supplied with validated written IFUs specific to the item, for

- intended applications and limitations;
- storage instructions before use;
- maintenance of sterility and package integrity;
- environmental conditions for transport and storage (i.e., temperature and humidity) and measures to be taken if these limits are exceeded;
- sterility process to be utilized and
- use of the product;

5. Maintenance of Packaging Systems:

There should be SOP's in place for the maintenance of packaging systems that include:

- Validation of reusable rigid containers for reuse according to manufacturers' IFU
- Planned preventative maintenance in accordance with ISO standards, manufacturers' instructions and/or local national policies
- Heat sealer efficiency, integrity and strength testing should be performed on each heat sealer daily
- Routine monitoring of processed heat-sealed products by checking the quality of the output
- Annual service on Heat sealers should be conducted annually at a minimum (based on frequency of use and IFU) This service includes temperature calibration, heat seal integrity and strength of seal.

6. Preventative Maintenance (PM) of Reprocessing Equipment:

Preventative maintenance should be planned and all processing equipment must be evaluated for performance, checked and maintained to ensure it is in good working condition according to manufacturer's guidelines and departmental maintenance schedules.

Manufacturer instructions for maintenance and inspection shall be followed for all CSS equipment, connected equipment, and accessories, wherever located.

The HCF or designate shall ensure that the necessary utilities are provided in the quality and quantity required, and continue to meet the specifications of the equipment manufacturer for proper operation.

Maintenance and inspection SOPs shall be performed only by personnel trained to provide such services. The health care setting's SOPs shall specify the actions to be taken, including backup plans, when CSS equipment is shut down for any reason.

Maintenance Program:

The HCF shall formulate a maintenance service contract or an in-house inspection and maintenance program shall be formulated by the health care setting.

An in-house inspection and maintenance program shall be based on the equipment MIFUs and performed by qualified personnel.

SOPs:

The HCF shall have an SOP requiring a record of maintenance and inspection of reprocessing equipment and the SOPs shall:

- Be maintained in accordance with health care setting policy;
- Be kept current and copies kept in the CSSD;
- Be readily available to the CSS management; and
- Contain, but not be limited to, the following information:
    a) The date on which an inspection, a correction, or a maintenance was initiated and completed;
    b) The name of the person who carried out the inspection or maintenance;
    c) Components that were inspected and the extent of any maintenance ;

d) The date that any required tests were performed, the results of the tests, the signature of a qualified service technician for handing over the equipment, and the signature of a qualified CSS person acknowledging receipt of the equipment and if any follow-up testing is required or an electronic means to track these steps; and
e) The model, serial number, and location of the equipment.

A maintenance record (either paper or electronic format) should be kept and maintained for each sterilizer.

Table 13: Example of Maintenance and Repair Checklist

No	Checklist Maintenance and Repairs	Performance
1	Date service was requested	
2	Model and serial number of sterilizer	
3	Location of the equipment (hospital identification, if applicable);	
4	Name of individual who requested and authorized the service	
5	Types and quantities of parts replaced	
6	Name of person who performed the service	
7	Date work was completed	
8	Signature and title of person who acknowledged completion of the work	
9	Results of any post-maintenance testing performed, if needed, before sterilizer was returned to service	

Chapter 5:

Risk Assessment in Sterile Services

Chapter 5: Risk Assessment in Sterile Services

Ongoing quality assurance and Risk assessment helps to identify the potential risk of sterilization failures and other defects in reprocessing practice. It allows identification and implementation of procedures for risk avoidance or mitigating strategies to be put in place that can reduce the overall likelihood of a risk. The HCF should have systematic and contingency plans in place to deal with sentinel events. The quality processes can be enhanced by audits that are conducted on a regular basis for verifying compliance with procedures. The information from these activities should be summarized and shared between CSS staff, stakeholders, and IPC team and appropriate actions developed for improvement.

Five steps of risk assessment (IDERR©):

Step 1 - Identify the hazards

Step 2 - Decide who might be harmed

Step 3 - Evaluate the risk and precautions

Step 4- Record your findings

Step 5 - Review your assessment and update if necessary

Adapted from: CHAS 2013 Ltd 2022

Important and common factors that needs risk assessment:

1. Classification of Patient Care items (Spaulding's Classification – Table 2)
2. Supply Chain issues
3. Reprocessing of Single use items
4. Storage shelf life
5. Wet Packs
6. Sterilization failures
7. Immediate-Use Steam Sterilization IUSS

1. Classification of Patient Care Items:

It is important to understand the differences between cleaning, disinfection and sterilization to ensure that the patient care items are appropriately and safely reprocessed preventing harm to the patients. The classification of the instruments/devices should follow the Spaulding classification and reprocess the patient care items according to proper disinfection levels.

Table 14: Differences between Cleaning, Disinfection and Sterilization	
Cleaning	The physical removal of body materials, dust or foreign material to reduce the number of microorganisms as well as the soil, therefore allowing better contact with the surface being disinfected or sterilized and reducing the risk of soil being fixed to the surface
Disinfection	The destruction or removal of microorganisms at a level that is not harmful to health and safe to handle. This process does not necessarily include the destruction of bacterial spores.
Sterilization	The complete destruction or removal of microorganisms, including bacterial spores. A validated process used to render a product free from viable microorganisms.

Reference: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

2. Reprocessing of Single Use Devices (SUD):

The judgment to reprocess and reuse of SUD is complex, with little or poor data to provide clear direction. The HCFs considering this practice must understand the limitations and its risk. There are health risks in reusing depending to a great extent on the type of device and the way it interacts with the patient's body and sterilization method and number of times reprocessed. The SUDs are patient care items intended to be used once on an individual patient during a single procedure and then discarded. If the HCF considers reprocessing SUD, manufacturer IFU's must be taken into consideration, and following local guidelines and standards and the infection prevention and control team on appropriate decontamination methods.

Health-care facilities shall have written policies regarding single-use medical devices. Critical and semi-critical medical devices labelled as single-use are not to be reprocessed and reused unless performed by a licensed third party reprocessor.

Single-use medical equipment/devices are usually labelled by the manufacturer with a symbol:

Risks of Reprocessing Single-Use Devices:

Reusing single-use devices carries the obvious risk of cross-patient infection, but also the increased probability that the device could malfunction due to the adverse effects of reprocessing on materials or delicate components in addition to the following:

- May not be designed to allow thorough reprocessing.
- Reprocessing may alter device characteristics, and performance may be compromised as a result.
- They do not undergo extensive testing validation and testing for reuse.
- May cause cross-infection due to design that is difficult to reprocess (e.g., Fine bores of tubes).
- Inadequately cleaned SUDs can carry bacterial endotoxins, which remain after bacteria are killed.
- Some materials can absorb certain chemicals, which can gradually leach from the material over time.
- Chemicals and heat may corrode or change the device materials. The device material may experience stress during reuse and may fail, stretch, or break.

3. Wet Packs (also see Annex E):

Sterility is considered compromised and the package contents considered contaminated when wet packs are found. Packages are considered wet when moisture in the form of dampness, droplets or puddles are found on or within a package. There are two types of wet packs; those with external wetness and those with internal wetness. Visible moisture left in (interior) or on (exterior) a package after sterilization and the proper cooling period should be considered a wet pack. If moisture is present on or in two or more packages the load should be considered a wet load. The moisture can be in the form of visible dampness, droplets, or puddles of water on or within a pack. If wet packs are observed in the processing area, they should not be released. If wet packs are observed in the user area (e.g., in the OR) they should not be used. Any wet packs should be reprocessed following measures taken to help ensure that excess moisture/condensation does not occur.

Moisture found on the outside of a package can be caused by condensate dripping from the sterilizer cart railings or shelves, collection of condensation in improperly trapped steam lines, or condensation dripping from metal items on a shelf above other items. Moisture found on the inside of a package can be caused by positioning items in a way that will trap moisture or as a result of other pack preparation techniques, including:

a) heavy or dense instrument sets;
b) absence of low-linting absorbent material to wick moisture between basin sets;
c) textile packs wrapped too densely; or
d) improperly prepared items (e.g., items wrapped while moist).

In addition, the composition materials (e.g., plastic) of containment devices can cause wet items.

Wet packs are a concern because the moisture on or within a package can create a pathway for microorganisms to migrate from the outside to the inside of a package. Investigation should be conducted to discover and diagnose the problem.

Occurrence and Causes of Wet Packs:

The occurrence of wet packs should be documented. Finding the cause and cure of wet packs and/or wet loads is not always easy. Many factors need to be taken into consideration. A team should be formed to help solve the wetness issues because of the complexity of the issue. This team can be made up of the sterile processing technicians and managers, infection preventionists, health care technologists, facilities managers, and equipment repair personnel.

The investigation process is a multiple step process. It should start with a series of questions related to the occurrence of wetness. Some of the questions that need to be asked are as follows:

a) Did any change in the sterilization process happened recently?
b) Did the wet packs/pouches happen at a certain time of day?
c) Did they happen on a certain shift?
d) Are the wet packs/pouches happening at a certain time of the year or with the change of seasons?
e) Are the wet packs/pouches happening only with certain trays? Orthopaedic trays? Basins? Certain RSCS? Wrapped trays?
f) Is the wetness concern taking place in a specific sterilizer?
g) Is the wetness appearing on a certain level or location of the sterilizer cart?
h) Is the wetness appearing in a certain location of the sterilizer chamber?
i) If using textiles, do the trays appear to be wrapped too tightly?
j) Are trays produced by a specific employee experiencing a higher incidence of wet packs?
k) What is the humidity in the area where the wrapping and assembly is taking place?
l) Is the wetness appearing on the outside of the item? Inside? Or inside and outside at the same time?
m) Is water draining from lumens?

4. Sterilization Failure:

Risk assessment to identify potential sterilization failures should include:

- Identifying the sources of likely sterilization failures;
- Estimating the likelihood that such a sterilization failure will occur;
- Assessing the consequences if sterilization failure occurs; and
- Assessing how prepared the facility is to manage the failure and the creation of contingency plans in the event a failure takes place.

SOPs shall be in place for the actions to be taken following a failed BI test, a failed air detection test, a failed PCD, or an unexplained parameter change that occurs during routine sterilizer or load monitoring

An overall assessment shall be conducted using risk management principles to determine what further action is needed.

Notes: *A failed BI test is defined as a BI that is positive for growth following a sterilization cycle.*

Investigating Sterilization Failures:

If the BI test, Type 5 or Type 6 CI PCD, or air removal test fails during routine monitoring, the following actions shall be performed and documented:

- The supervisor shall be notified with the following information:
  a) time and date of the questionable sterilizer cycle;
  b) description of the sterilizer and load, including lot control number;
  c) measured physical parameters, results from CI tests, and PCDs (if applicable) from the load; and
  d) other relevant information for an investigation.
- If the cause of the BI test failure is immediately identified (usually operator error) and confined to one load, the cause of the failure shall be corrected, the test repeated, and the load, if present (e.g., BI monitored load), reprocessed.
- If the cause of a BI test failure is not immediately identified, the following shall take place:
  a) quarantine of all items from the load in question and every previous load from that sterilizer back to the last negative BI test, until the investigation is complete;
  b) immediate removal of the sterilizer from service, pending further investigation;
  c) notification of relevant personnel (e.g., IPC, maintenance and service personnel, CSS manager);
  d) initiation of a formal investigation of the failed test, performed and documented in accordance with written SOPs and specifying job titles of those who will be involved;
  e) recall of any medical devices that could have been inadequately sterilized, in all loads back to the last negative BI; and
  f) reprocessing of all medical devices in loads that could have been inadequately sterilized.

The sterilizer shall not be used until the incident has been thoroughly investigated, any necessary corrective action has been taken, and subsequent requalification testing has confirmed that the sterilizer is operating properly.
While the sterilizer is out of service, it shall be clearly marked with a warning sign.
The sign shall include the name and number of the person who can be contacted for information regarding the sterilizer and recently processed loads.

Note: *A sterilizer that fails the air removal test cannot be made functional by merely increasing the holding time*

5. Immediate-Use Steam Sterilization (IUSS):

It is a process designed and used for the emergency sterilization of surgical goods in an unwrapped condition, when routine sterilization cannot be done. It is also known as 'flash' sterilization.

This sterilization method should be avoided and used only in urgent situations as the instruments are sterilized unwrapped g and does not have a drying cycle. As a result, there is a high risk of contamination of the instruments once removed from the sterilizer.

IUSS testing and documentation should be in accordance with testing guidelines for steam sterilization which includes traceability back to the patient it was last used on.

Immediate-use sterilization should NOT be performed on the following devices; implantable devices, suction tubing, cannulas, lumened devices or any other products not specifically validated for the IUSS process as per the HFC policies.

6. Reprocessing of Instruments Exposed to Creutzfeldt-Jakob Disease:

Creutzfeldt-Jakob disease (CJD) - is a degenerative neurological disorder of humans. Currently, there is no sterilization procedure known to be completely effective against prions and prion-related diseases. Moreover, the vast majority of health-care-associated transmission cases have resulted from use of contaminated tissues or grafts.

Please refer to international for guidance on CJD or other prion-related diseases.

7. Contingency and Emergency Situations

The HCF shall have policies and/or SOPs in place that include contingency plans for emergency situations that could impact quality of CSS functions and include, but are not limited to,

- loss of staff;
- loss of or decrease in supply chain or inventory;
- loss of utilities including utility water;
- loss of reprocessing equipment;
- loss of or damage to sterile storage and/or laundry areas; and
- spills of hazardous substances

Chapter 6:

Infection Prevention and Control

Chapter 6: Infection Prevention and Control

1. The Role of Infection Prevention and Control:

The main role of infection prevention and control and CSS is important to prevent the contamination of instrument during the reprocessing process that may lead to an increase likelihood of hospital acquired infection related to medical devices. It is essential that the identified roles will be performed by the designated department, units and staffs in healthcare facilities and in central level. The organizational structure of Central department of Infection Prevention and Control (CDIPC) includes the overseeing of the Central Sterile Services (CSS) services in the country. The Infection Prevention and Control department (IPCD) in hospitals and the Infection Preventionists (IP) assigned in different regional healthcare facilities is tasked to monitor the CSS, identify areas of improvements in operations and ensure that policies and procedures are implemented and followed.

The Role of IPC & CSS Department/Section/Unit in HCF:

- Writes internal policy for disinfection & sterilization according to the local set up and resources adopting the national guidelines
- Conducts training for the CSS staff about the policy and the best practices according to CSS and IPC guideline
- Conducts the centralized and decentralized assessments and review of practices and policies for sterilization services every 6 months using the attached audit checklist
- The frequency of audit may increase based on the assessment outcomes for the corrective actions.
- Ensure follow-up for the assessment recommendation with the concern departments
- The audit report should be submitted to the hospital administration annually to central DIPC.
  Conduct competency assessment for the CSS staff on an annual basis, the frequency should be based on the assessment outcome.

The Role of Infection Prevention and Control Team At the Governorate DGHS:

- Writes internal unit specific policy for disinfection & sterilization adopting national guidelines.
- Conducts the assessment for the Reprocessing & Sterilization Service in the primary care facilities on annual basis using the attached audit checklist.
- Submit assessment report to the Director of Communicable Diseases in DGHS and concerned facility.
- Prepare and submit an annual report that includes all audited HCF to the director of communicable diseases in DGHS and Director of CDIPC.
- Ensure appropriate follow-up for the recommendation and areas of improvement.
- Conduct annual education and training for the Reprocessing and Sterilization Services staff in the governorate level.
- Conduct competency assessment for the staff on annual basis.

The Role of Infection Prevention and Control Team at the CDIPC:

- Ensures that IPC policy and procedures is properly implemented in different health care facilities.
- Develop annual audit plans for all sterilization services in the health care facility and communicate with the HCF.
- Review the submitted audit reports from the HCFs and generate the national reports for sterilization services.
- Ensure adequate supply for sterilization services with coordination with DGMS in case of hospital complain and emergencies.
- Ensures that continue education and training are provided for sterilization services
- Conducts the audit as per the risk assessment based on submitted reports with the local team in the facility. Submit final reports to the team in the local facility.

2. Hand Hygiene:

- The staff in CSS should perform hand hygiene to prevent infections from the soiled instruments and the cross contamination.
- Wash hands when visibly soiled, after gloves are removed for any reason, after the removal of other PPE, after touching contaminated materials, and in accordance with hospital hand hygiene policy.
- Perform hand hygiene correctly (hand washing or hand rubbing) and understand the importance to dry hands thoroughly before donning gloves or carrying out a task.
- Artificial nails, nailpolish, shellac, gel, nail adornments or hand and wrist jewelry is not permitted when performing any reprocessing tasks.
- Visible wall-mounted posters demonstrating the correct method for hand washing and hand rubbing should be visible in all areas of CSS.

3. Employee Health and Safety:

While it is the responsibility of the employer to provide appropriate protection and a safe working environment for CSS workers, it is equally the responsibility of the staff to ensure that policies and procedures are followed once training has been provided.

CSS staff shall be trained in the following:

- How to handle sharps appropriately and ensure that there is provision for safe disposal of sharps
- How to wear PPE appropriately according to the correct indications
- How to deal with accidents occurring in the CSS (e.g. chemical exposures)
- Document all accidents through HCF Incident Reporting System, no matter how minor.

CSS staff shall be responsible for the prevention of any accidents in the department. They must adhere to the following:

- Visible posters and other information should be available to staff to serve as constant reminders in the workplace.
- Observe standard precautions.
- Avoid eating and drinking in processing areas.

- Do not attempt to catch falling sharps object.
- Wash thoroughly with soap and water the hands and other skin surfaces that are contaminated with potentially infectious materials.
- Observe proper body mechanics all the time while performing any activities
- Avoid lifting heavy materials, ask for help.
- Familiarize for the location of fire alarm and fire extinguisher; and memorize emergency telephone numbers.
- Attend periodic hospital internal and external disaster plan
- Report to the designated department any defective, malfunction equipment e.g. frayed wires.
- Switch off all the electrical equipment immediately after use.
- Use safety ladder to access high shelves.
- Turn off any steam leak (autoclave), if possible and inform the senior staff to call the biomedical department immediately
- Staff must be trained in management of a blood or body fluid spill.
- Where there is the risk of exposure to biological and/or chemical agents, eye wash stations must be provided and staff must be trained in their use.

Chemical Safety:

There should be a comprehensive system for providing health and safety information on hazardous products intended for use, handling, or storage for each HCF that includes:

- Appropriate chemical storage and clearly label containers with the manufacturer's instructions on safe handling, dilution and disposal.
- Access to safety data sheets from the suppliers for any chemicals used.
- Exhaust systems requirements to remove physical smell of chemicals vapor, noxious gases and allow for dilution of biological hazards.
- Safe handling guidelines to prevent spillage and accidental splashing when preparing solutions.

Personal Protective Equipment (PPE):

All staff are required to wear proper PPE when handling contaminated instruments/equipment in reprocessing areas.

- Staff must be trained in accordance with Infection Control in the correct donning, doffing and indications use of PPE
- Adequate numbers of PPE must be available at each gowning area before entering the main reprocessing sections, e.g., decontamination, IAP, sterilization area and storage
- PPE includes gloves appropriate to the task, face protection (i.e., full face shield or fluid-impervious face mask and protective eyewear) and impermeable gown or waterproof apron.
- Containment of hair including facial and body hair. (e.g., hair covering, beard covering).

Safe Handling of Sharps and Healthcare Waste Management:

- Follow the blood and body fluid exposure management policy including sharp management
  Ensure sharps container is available in decontamination and assembly area
- Collect any sharps in the puncture resistant sharp containers
- Call the designated department when the sharp container is ¾ full
- Report any accidental sharps injury immediately to your superior
- Complete the log of sharps recovered from surgical trays

The waste management policy in CSS will follow the National Healthcare Waste Management Guidelines.

Staff Health:

There should be a policy and procedure for healthcare screening and vaccination of healthcare workers that the CSS follows.

All staff participating in clinical procedures must follow the MOH vaccination requirements and be vaccinated against hepatitis B and against vaccine-preventable diseases.

Work Restrictions:

Any staff who has the following health conditions should report to staff clinic:

- Skin rashes, boils or open wounds
- Diarrhea or gastroenteritis
  Respiratory illness, either allergic or infectious

4. Environmental Hygiene in the CSS:

There shall be written environmental cleaning policies for the CSS that is clearly defined with SOPs agreed between the housekeeping staff, the IPC, management and the CSS manager. The procedures, responsibilities for cleaning practices and cleaning frequency must be clearly stated.

Cleaning shall be performed in a manner that minimizes air turbulence and excess moisture.
The cleaning sequence for surfaces and equipment shall move from higher to lower and from the least contaminated to the most contaminated.

Spills:

All work areas shall be cleaned immediately if a spill occurs as per the health care setting's SOPs.
Note: *Daily cleaning controls microbial contamination and dust.*

Cleaning Frequencies:

A regular cleaning and disinfection schedule shall be established, posted, and documented.

Cleaning After Sentinel Event:

Additional cleaning and disinfection of all areas shall be performed after any event such as
a) flood;
b) renovation;
c) removal of temporary hoarding barriers;
d) repair that creates dust; and
e) chemical spills

Acceptable Cleaning Methods for CSS:

Cleaning equipment used in CSS shall not be used in other areas of the health care setting and cleaning equipment used in decontamination area shall only be used in the decontamination area.

Patient Care Equipment:

Portable or fixed, reusable, non-invasive patient (client) care equipment shall be cleaned and disinfected by designated personnel after each use in accordance with the IFUs.

Storage of Cleaning Equipment:

Environmental cleaning equipment shall be stored in the CSS dedicated housekeeping storage room.

Cleaning Equipment Manufacturer IFUs"

Equipment used for cleaning and disinfection shall not be used when damaged, broken, torn, dirty, or worn (e.g., wipes/cloths, handles, brushes).

Note: *Brooms are only to be used when dealing with sharps/glass.*

Duration of use and cleaning and disinfection of these items shall be followed in accordance with the MIFUs.

Mechanical Equipment:

If mechanical cleaning equipment is used, it shall be of the wet-scrubber type. Dry scrubbers shall not be used. The cleaning attachments of automated floor cleaning machines shall be designated for a specific area (e.g., reprocessing, clean/sterile area, within the CSS) and shall not be used in other areas.

Note: Dry scrubbers stir up dust and microorganisms that can contaminate stored medical devices or work surfaces.

Floor Cleaning with Sprayers:

Mechanical floor-cleaning equipment with sprayers should not be used unless single-use and reusable medical devices are stored high enough to be out of range of the overspray.

Vacuum Cleaners:

Vacuum cleaners shall be equipped with HEPA filter.

Chapter 7:

Reprocessing in Primary Health

Chapter 7: Reprocessing in Primary Health care and Dental setting

1. Reprocessing Reusable Dental Instruments:

Increased body of evidence shows the potential for transmission of infectious agents in dentistry caused by improperly processed dental instruments.

Where possible, all dental instruments should be processed centrally in the CSS or a dedicated area within the dental practice setting not in the procedure rooms. Processing of instruments related to dental practice require a written infection prevention and control policy to ensure that all procedures are in place for the decontamination and sterilization of dental instruments.

The goals of safe reprocessing of reusable patient-care items (dental instruments, handpieces, devices and equipment) include:

- preventing transmission of micro-organisms to staff and patients;
- minimizing damage to patient care items from foreign material or inappropriate handling;
- safe handling of chemical disinfectants

All reusable instruments must be properly cleaned, rinsed, dried and inspected prior to either disinfection or sterilization. These steps are essential, as residual debris will compromise the disinfection and sterilization process.

Compliance and Best Practice Requirements:

The following are minimum practice recommendations for reprocessing reusable medical devices in a dental setting:

- Dedicated space for reprocessing dental instruments that clearly delineates clean and dirty spaces and supports one way, dirty-to-clean workflow.
- Availability and implementation of unit specific policy and procedures including infection control, decontamination and sterilization procedures and transport of instruments.
- A designated person is appointed and trained in the prevention and control of infection and reprocessing of medical devices.

Staff working in dental practice, all new staff who will be responsible for reprocessing will:

- Attend a course or participate in training for infection prevention and control and decontamination of medical devices. In addition, they should be able to provide proof of continuing professional development training courses in each of these areas.
  Ensure that all policy and procedures including a do not reuse single use policy and are updated and followed. A regular audit should be carried out to ensure compliance
- Establish and implement quality assurance systems that cover the use of effective measures of decontamination, sterilization and infection control by the use of audit tools.

- Audits should be done at a minimum of every six months and frequency can be reviewed dependent to the outcomes. Audit reports and actions to address areas for improvement should be kept and maintained according to the HCF policy.
- Use of dedicated cleaning accessories for reprocessing
- Use of validated washer-disinfector with adequate capacity is preferred but if not available a 2 step manual cleaning and disinfection process is required.
- Dedicated hand washing facilities are available for use.
- Cleaning and inspection with the use of magnifying light are key parts of dental instrument reprocessing.
- Search for an alternative if the instruments are difficult to clean this will include but is not limited to matrix bands, saliva ejectors, aspirator tips and three-in-one tips. Use of disposable instruments is recommended if possible.
- Endodontic reamers and files are designated reusable; they should be treated as single patient use or single use – regardless of the manufacturer's recommendations.
- Exercise care in the cleaning of re-usable endodontic reamers and files. If automated washer–disinfectors are used, the risk of cross-contamination to other instruments would be very low, in view of the dilution factors. They do not need to be processed on a separate cycle. Due to the variability in dilution during manual washing, they should be washed separately from other instruments
- Suitable dedicated area (enclosed if in procedure area) for storage of sterile instruments is available to reduce risk of contamination.
- Preventive maintenance and validation of equipment used for reprocessing to ensure it is functioning correctly and is documented
- National healthcare waste management SOP is followed.

Table 15: Spaulding's Classification for Reprocessing Dental Instruments:

Risk categories	Procedures	Example of instruments	Comments
Critical item Entry into sterile tissue, cavities or bloodstream	Surgical dental procedures, such as the removal of a fully impacted tooth, extraction, and endodontic procedures on vital pulp tissue	• Needles and syringes • Dental forceps and elevators • Flap retractors and surgical burrs • Instruments for placement of implants, implantable items including mini-implants and surgical dental hand pieces	• Must be sterile at the time of use and either be "single-use disposable" or capable of being steam sterilized • Critical items must be used immediately after sterilization or stored in bags until use. • If the bags are damaged, the devices must be re-sterilized before use
Semi-critical item Contact with intact non-sterile mucosa or non-intact skin	General dental procedures	• Mouth mirrors • Restorative instruments • Dental tweezers and probes • Metal impression trays • Other non-critical items when used occasionally in the mouth, e.g. Lecron carver	• Instruments are sterilized between patients or are "single-use" (disposable) • After processing, devices should be bagged and kept in closed drawers or in dedicated containers, such as instrument cassettes, until required • Rarely, thermal disinfection for example, thermal disinfection of denture polishing buffs, may be acceptable as these are unlikely to be contaminated with blood
Non-critical item Where there is contact with intact skin		• Prosthetic gauges and measuring devices • Face bows • Protective eyewear • Bib chains • Dappen dishes • Willis gauges	• Cleaning with detergent and water is generally sufficient but in some cases thermal disinfection with heat and water may be indicated • After processing, these instruments should be stored in the same way as semi-critical instruments to prevent contamination prior to use

Reference: Decontamination and Reprocessing of Medical Devices for Health-care Facilities, WHO, 2016

2. Reprocessing Reusable instruments in Primary Health care:

The instrument reprocessing areas must have separate areas (outside of the treatment area):

- Transport
- receiving, cleaning and decontamination
- rinsing and drying;
- preparation and packaging;
- sterilization;
- storage

Transport:

- Clean and contaminated instruments must be separated for transport. There should be a process in place to identify items that have been reprocessed and items waiting to be reprocessed (e.g. labelling).
- Observe safety precautions during transport of contaminated instruments to decontamination areas. If instruments cannot be transported promptly to decontamination areas, immerse in potable water or use commercial gel/spray to prevent drying.
- Enclosed transport containers are used to protect both the product during transit and the handler/environment from inadvertent cross-contamination.
- Transport containers should be:
    - rigid
    - leak-proof and puncture resistant
    - easy to clean
    - close securely
    - should contain instruments, preventing accidental damage during transport and sharps injury
    - Designated transport containers for clean and dirty items, should be clearly identified and kept visibly clean.
- When transporting sterilized instruments, it is preferable that they are wrapped or inside their cassette or container that has been sterilized.

Receiving, Cleaning and Decontamination:

- Reusable instruments must be received and disassembled in accordance with the manufacturer's IFU's, sorted and cleaned in one section of the reprocessing area.
- A puncture-resistant sharps container must be available in this area for disposal of any sharps.
- Cleaning involves the removal of debris (e.g. organic and inorganic matter). This is achieved either by Manual cleaning scrubbing with a detergent formulated for medical device reprocessing or an enzymatic cleaner, or by an automated process (e.g. ultrasonic cleaner or automated washer with a cleaning solution).
- Gross debris must be removed from instruments prior to placement in an ultrasonic cleaner. In addition, ultrasonic cleaning solutions must be changed daily or more frequently if they become visibly soiled.
- Ultrasonic cleaners with a basket are preferred over manual cleaning. The ultrasonic cleaner should contain a detergent, which should be disposed of at the end of each clinical session or sooner if it appears to be heavily contaminated. Once a cleaning cycle has begun, it should not be interrupted and more instruments should not be added.
- Automated washers may not require presoaking or scrubbing of instruments. Refer to the manufacturer's IFUs for the automated washer.
- Two dedicated sinks with separate or shared water supply is required, if two sinks is not available use one sink with a removable bowl/basin.
    - Use a dedicated bowl for washing/cleaning and the other is used for rinsing.
    - Clean water in each sink/bowl should be changed between each item that is cleaned.
    - Care should be taken when removing/emptying or lifting the removable bowl preventing splash or spillage.

- Use of validated washer-disinfector with adequate capacity is preferred but if not available a 2 step manual cleaning and disinfection process is required.

Rinsing and Drying:

- After cleaning, instruments must be rinsed with water to remove detergent residue, dried (e.g. lint-free cloth) and visually inspected to ensure all debris has been removed.

Preparation and Packaging:

- In a dedicated area within the reprocessing area, cleaned and dried instruments must be inspected, assembled into sets or trays, and packaged for sterilization.
- Critical and semi critical instruments must be reprocessed in a manner that will maintain sterility during storage. Suitable packaging materials include wrapped perforated instrument cassettes, peel pouches of plastic or paper, and woven or nonwoven sterilization wraps.
- Packaging materials must be designed for the type of sterilization process being used.
- Instruments should be evenly distributed in a single layer within the package or container, unless the container is designed and validated to allow for more than one layer.
- Hinged instruments must be reprocessed open and unlocked.

As in CSS, labels, chemical indicator tapes, and handwritten or printed inks must be compatible with the packaging system and colourfast, so as not to degrade, run, leach, fade or become illegible with exposure to the sterilization process.

Sterilization:

All instruments must be sterilized by either steam under pressure (i.e. autoclaving), which is dependable and economical. Chemiclaves and bead sterilizers are NOT acceptable methods of sterilization.

All sterilization must be performed by using medical sterilization equipment registered by appropriate licensing bodies e.g. FDA. Sterilization times, temperatures and other operating parameters recommended by the manufacturer of the equipment used, as well as IFU's and placement of containers, wraps, and chemical or biological indicators, must be followed.

The sterilization area should include:

- the sterilizer(s) and related supplies,
- adequate space for loading, unloading and cool down.
- may also include an area for biological indicators and incubators storage and testing,
- as well as enclosed storage for sterile and single-use (disposable) items.

3. Monitoring of Sterilization:

- Monitoring of sterilization must be conducted through a combination of physical, chemical and biological means, which evaluate both the sterilizing conditions and the procedure's effectiveness.
- The dental setting and primary health care must have written policies and procedures for monitoring the sterilization process.

- **Physical indicators** include the gauges or displays on the sterilizer for cycle time, temperature and pressure. Some tabletop sterilizers have recording devices that print out these parameters or store them electronically.
    - Sterilizers with recording devices are preferred. All new sterilizers must have this feature. If a sterilizer does not have a recording device, consideration should be given to replacing it in a reasonable time.
    - Physical indicators (printout) must be checked and validated for each load. If the sterilizer has a recording device, the physical parameters must be checked at the conclusion of the sterilization cycle for each load. This is to verify that the pre-programmed cycle operated correctly, and that the required conditions for sterilization were achieved.
    - If the sterilizer does not have a recording device, the physical parameters must be checked during the sterilization cycle for each load and documented.
- **Chemical indicators** (i.e. internal and external) are designed to provide a chemical or physical change as a result of exposure to a defined sterilization process.
    - Each package sterilized should have a Type 1 chemical indicator on the outside of each instrument package in addition to a Type 4, Type 5 or Type 6 chemical indicator inside each package. Some pouches incorporate Type 1 external and Type 4 internal chemical indicator on the package.
- **Biological indicators** (BIs or "spore tests") the following requirements apply to biological monitoring:
    - A BI must be placed in a PCD and used to test the sterilizer each day that it is used AND for each type of cycle that is used. The manufacturer's IFU's concerning the appropriate placement of the BI in the sterilizer must be followed.
    - A BI must be placed in a PCD and included in every load containing implantable devices (e.g. dental implants, temporary anchorage devices, surgical screws/plates/staples). Implantable devices must be quarantined until the BI test results are known. Commercially prepared PCD's are recommended.
    - For failed BI result – follow same process as CSS (chapter 6 section 4 Sterilization Failures)

4. Table Top Sterilizers:

The table top model is the most commonly used steam sterilizer in outpatient, dental clinics. They are defined as a sterilizer that has a chamber volume of not more than two cubic feet, which generates its own steam using distilled or deionized water that is added by the user.

Figure 15: Examples of Common Table Top Sterilizers:

Reference: WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities, 2016

These sterilizers are designed for small instruments, such as dental instruments, and not recommended for any lumen instruments with a gravity sterilizer. The ability of the sterilizer to reach the physical parameters necessary to achieve sterilization should be monitored by mechanical, chemical and biological indicators.

Tabletop sterilizers undergo frequent use, and wear and tear. The manufacturer IFU's must be consulted for guidance on use, weight limitations, load configurations and a preventive maintenance program, including regular inspection of gaskets and seals. The preventive maintenance, servicing and repair of all reprocessing equipment must be documented and retained according to clinic policy.

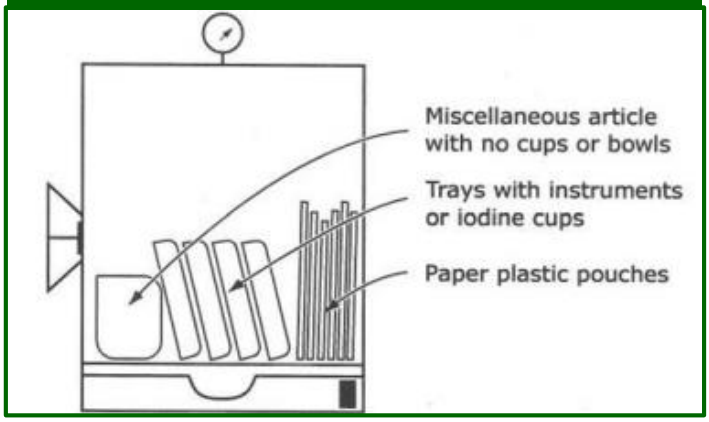
Manufacturer's directions include:

- Daily, weekly, and monthly cleaning
- Monitoring cycle parameters of time, temperature, and pressure
- Type of water to be used (deionized, reverse osmosis, distilled or sterile)
- Loading of items (follow the rack directions if not using a rack, be sure to place the pouches on the tray plastic up or down)
- Use chemical indicators according to manufacturer's recommendation
- Use biological indicators for implants

- During sterilization, the steam must circulate freely around each pack and have the unrestricted ability to penetrate into and exit from each pack. Paper/plastic packages, linen packs, and any packs with a solid bottom must be placed on their sides. This will ensure air removal, contact with steam and allow any condensation to be drained (Figure 16).
- When placed side-by-side, paper/plastic packages must be placed with the plastic side facing the paper side of the next package. Air and steam only pass through the paper side of a paper/plastic package.

- No package should come into contact with the chamber wall as this contact promotes staining and will damage the package; the free circulation of steam will be also significantly impaired.

Figure 16: Proper Loading of Table Top Sterilizer



Reference: WHO Decontamination and Reprocessing of Medical Devices for Health-care Facilities, 2016

Table 15: Type of Sterilizers In Accordance With EN 13060 (European Standard) On Small:

Cycle type	Type of load	Comments
N	Unwrapped, solid items	Simplest type of cycle. Cannot assure sterilization of hollow instruments or those with lumens Not suitable for wrapped loads (e.g. items in pouches). The product does not remain sterile beyond the end of the sterilization cycle.
B	Wrapped or unwrapped solid items or hollow items	Has the widest range of applications? Can be used for the sterilization of lumened instruments as per the manufacturer. A post-sterilization drying stage is essential for wrapped items. This increases the total cycle time.
S	Only suitable for the types of loads specified by the manufacturer	Some but not all sterilizers can sterilize wrapped and/or hollow items. Compatible with sterilization of unwrapped, wrapped or hollow items only if the sterilizer manufacturer specifies. Some have rapid cycle times but a post sterilization drying stage is essential for wrapped items. This increases the total cycle time. Some sterilizers have instrument cassettes that allow transport of sterile instruments.

Reference: EN 13060 European Standards for Small Steam Sterilizers 2018

Wrapping before Sterilization when using a Vacuum Sterilizer:

- Dental materials adhering to instruments (such as filling materials or phosphoric acid-based cement removers) must be removed immediately after use to prevent hardening on the instrument and/or cause corrosion.
- Dental cement must be removed with a swab or cellulose cloth immediately after use. Move this section to pre-cleaning.
- Handpieces, angle pieces and turbines should be placed separately and preferably machine reprocessed in accordance with the manufacturer's instructions, should not be treated in an immersion or ultrasonic bath.

Some manufacturers mark headpieces with the symbol to indicate that they can be cleaned in a washer-disinfector.

5. Physical Structure:

It is essential that a dedicated decontamination area, away from the procedure area be identified and designed to allow a dirty to clean workflow of instruments as described for the CSS and include.

- Sufficient flat, cut-resistant, seamless, and nonporous work surfaces that can be cleaned, disinfected, and dried to handle the volume of work.
- At least two dedicated sinks with separate or shared water supply, if two sinks are not available use one sink with a removable bowl. Use a dedicated bowl for washing/cleaning and the other is used for rinsing.
- A designated reprocessing area that is separated into distinct areas for:
    - receiving, cleaning, and decontamination;
    - preparation and packaging;
    - sterilization; and
    - storage.

    These areas can be achieved through physical or visual barriers.

Storage of Sterile Items:

Sterile and single-use (disposable) items should be stored in an enclosed space, such as closed or covered cabinets, or drawers. They must NOT be stored under sinks, on counters adjacent to sinks or in other locations where they might become wet or contaminated.

Mechanical Systems:

- A system for water distillation or demineralization, which will be used both for cleaning and for filling the steam autoclaves, is recommended.
- Ventilation systems should be designed so that the air flows from the clean to dirty areas and is then released into the exterior or into a filtered recirculation system.
- There should be no less than 10 air changes per hour. Fans are not permitted in the sterile processing areas, since they generate high turbulence of dust in the air and microorganisms that are projected from the floor to the worktables.
- Temperature and moisture: 18 ºC – 25 ºC and a relative humidity of 35% – 50%.
- Floors and walls in reprocessing areas should be constructed with washable materials that are non-porous and do not release fibers or particles and that are resistant to chemical agent.
- Ceiling ideally, should be smooth and non-porous to facilitate ease of cleaning and minimize dust dispersal.

6. Education and Training:

All staff responsible for reprocessing tasks should undergo a general reprocessing orientation with a qualified CSS technician until competency has been demonstrated. Staff must complete annual reprocessing refresher courses and competency testing. The records of orientation and training must be kept and maintained.

The topics must include the following:

- Unit specific Infection control policy and procedures
    - Basic Infection Control course
    - Standard precautions
    - Transmission based precautions
    - Chain of transmission
    - Procedures in the event of accident or personal injury

- Decontamination process including:
    - Transporting of contaminated instruments
    - Dismantling of instruments
    - Selecting the correct cleaning and decontamination method for each instrument,
    - Assembly and packaging
    - Sterilization

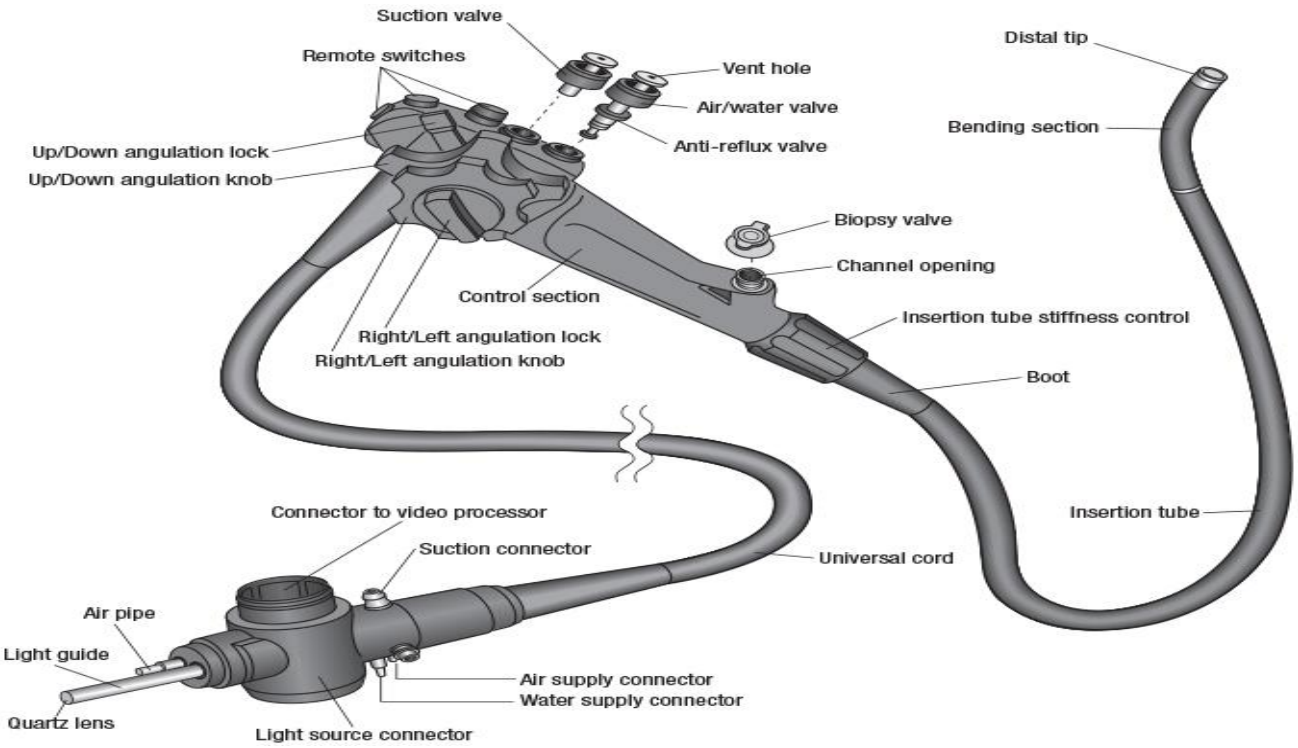
Chapter 8:
Endoscopy

Chapter 8: Endoscopy

There is a global concern for the outbreaks of infection transmission due to contaminated flexible endoscopes and suboptimal reprocessing and infection control practices during endoscopy. Studies shows that despite of rigorous reprocessing techniques of endoscopes, organic residues are not completely removed because of the complex design of flexible endoscope.

The endoscopy reprocessing services in healthcare facilities shall be supervised by Infection Prevention and Control staff and CSSD technician.

Figure16: Diagram of Endoscope:



Source: Public Health Ontario Annex a—Minimizing the risk of bacterial transmission from patient to patient when using duodenoscopes. Annexed to: Best practices for cleaning, disinfection and sterilization of medical equipment/devices in all health care settings- 2013.

The reprocessing involves five main steps: bedside cleaning, leak testing, manual cleaning & pre – rinsing, HLD or sterilization & final rinsing, drying and storage.

The lapses or gaps of these process leads to endoscopy related contamination risk that can potentially cause patient injury or death.

Bedside Cleaning: Removes organic matter. This will help to reduce the possibility of drying of organic matter causing channel blockages, especially if there is a delay before manual cleaning takes place.

Leak Testing: Ensures the integrity of the endoscope. Any damage to the outer surface could allow body fluids or chemicals into the internal workings of the endoscope.

Manual Cleaning: Brushing of accessible channels and flushing of all channels to remove organic matter. This stage will also allow the detection of channel blockages.

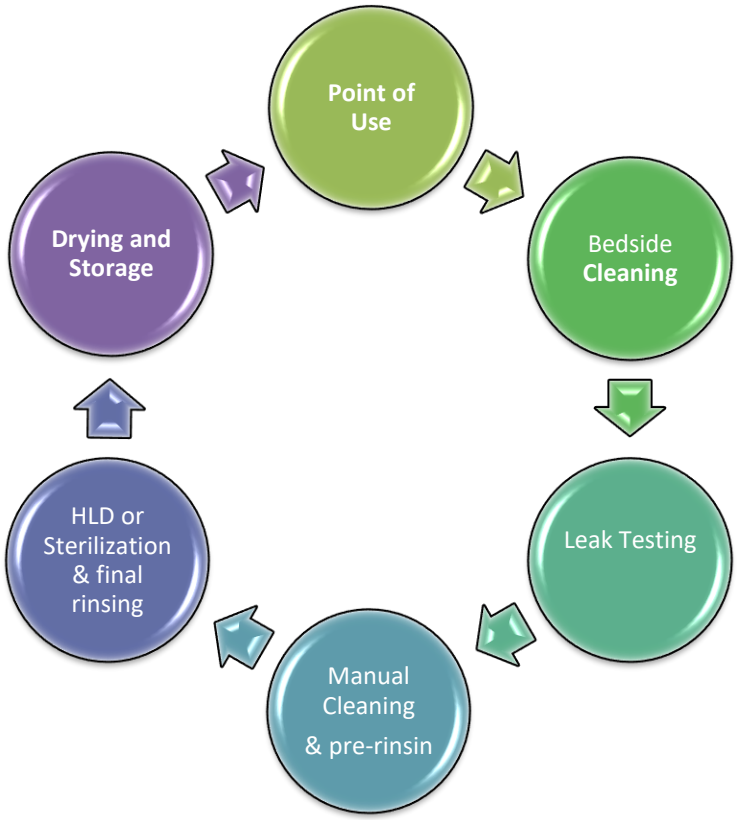
Rinsing #1: To remove detergent residues that may affect the performance of the disinfectant

Drying #1: To expel excess fluid that may dilute the disinfectant

Disinfection: To eradicate potentially pathogenic microorganisms, i.e. bacteria, including mycobacteria and viruses

Rinsing #2: To remove disinfectant residues that could cause a harmful effect to the patient.

Drying #2: To expel excess fluid before use on the patient or storage.



1. General requirement for Reprocessing Endoscopes:

1.1. Personal Protective Equipment (PPE):

The following PPE is required for staff safety when reprocessing endoscopes:

- Gowns: Water-resistant, have long sleeves that fit snugly around the wrist, and wrap to cover as much of the body
- Gloves: Chemicals-resistant (see SDS), no tears or holes, should be long to extend up the arm to protect forearm or clothing from splashes and seepage, Vinyl gloves are not approved as they are damaged by enzymatic solutions.
- Eye / face protection: A face shield or safety glasses with a facemask allowing ventilation is recommended.

1.2. Physical Design and Materials:

Decontamination of rigid endoscopes is preferable within the CSSD as the process controls and validation are already in place. Use of the CSSD is not so practical for endoscopes with a rapid turnaround, (e.g. gastrointestinal endoscopes), and these are often processed at the point of use. It is important that if decentralized reprocessing of endoscopes is carried out, the following shall be adhered to including;

- Dirty to clean work flow (from receipt of used endoscope to cleaning, disinfection and storage) and complete physical separation between dirty and clean areas, where possible, and the procedure room
- Medical air or filtered controlled air that is used for drying the lumens.
- Two sinks (in appropriate size to prevent coiling of endoscopes) when reprocessing and with hot and cold water supply.
- Dedicated hand hygiene sink, water supply and sewage system.
- Non-porous, cleanable counter space without seams large enough to handle the volume of work without overcrowding.
- Negative ventilation system in cleaning and decontamination area with a minimum of (10) air exchange per hour.
- Hepafilters are a suitable alternative to negative air pressure to create inward directional air flow if ducted to outside or exhaust system in the facility.
- Positive pressure for clean holding areas and storage
- Flexible endoscopes should be stored, preferably hung, to allow drainage of channels in a dust-free environment. Lockable hepafiltered storage cabinets are available and used in accordance with IFU for storage cabinet in relation to shelf life.
- Even and no joint floors and walls (easy to clean and disinfect materials) reword
- Construct ceilings with non-particulate non fiber shredding materials.
- Doors made of durable, non-porous material
- No exterior doors or windows in reprocessing area
- Suitable eye washing stations.
- Adequate lighting and appropriate electrical system.
- The unit should be restricted to authorized personnel only.

2. Procedure for Cleaning Endoscopes:

Bedside Procedure (pre-clean):

- Immediately after use on the patient, the insertion tube of the endoscope should be wiped with freshly prepared detergent solution and a single-use cloth and detergent sucked through the suction biopsy channel.
- An adaptor is fitted to the air/water channel port and the air/water channel is flushed with water from the water bottle.

Transportation of contaminated

- Use a system for trolleys or other transport devices to keep clean and dirty scopes separate. Label or use a color coded transport container for identification the clean and dirty. The surfaces and furnishings must be kept clean, made of impermeable material and easy to clean
- Transport contaminated endoscope immediately in dirty reprocessing area in close or covered container to the procedure to prevent drying.
- Do not transport with the lumen full fluid to prevent spillage
- The transport system should not be reused for clean transport.

Leak Test:

- This should be carried out prior to the manual cleaning following the manufacturer's instructions. If a leak is detected, the decontamination procedure must not proceed. The endoscope should be sent for repair.

Manual Cleaning:

- A sink large enough to accommodate the endoscope without excessive coiling is required.
- The detergent solution should be prepared at the correct concentration and temperature.
- A neutral pH or enzymatic detergent may be used, but must be endorsed by the endoscope manufacturer as being compatible.
- The detergent must be specific for medical devices and not one used for general housekeeping purposes
- The accessible channels, i.e. suction/biopsy, must be brushed before flushing with detergent. This will dislodge adherent material. The brush must be passed along the entire length of the channel and repeated until the brush is visibly clean.
- The material must be removed from the brush and under fluid to reduce the risk of aerosols before withdrawing the brush.
- After brushing, all channels must be flushed with freshly-prepared detergent solution using the irrigation device supplied with the endoscope. The detergent solution must be discarded after use.

Rinsing (first):

Freshly drawn potable tap water must be used to remove detergent residues.

Disinfection:

- The disinfectant must be compatible with the endoscope and used at an effective concentration for the recommended contact time.
- The endoscope should be placed in a container with sufficient capacity to allow it to be completely submerged and with a lid in place at all times to reduce the risk of release of disinfectant vapour. The most widely used disinfectants are 2% glutaraldehyde and peracetic acid.
- The critical parameters for effective disinfection are concentration, temperature and contact time, which should be measured and recorded. It is also important to ensure that the disinfectant is in contact with all accessible surfaces/channels.
- Some disinfectants are single-use and discarded after each use. Multi-use disinfectants are widely used and test strips/kits are available to establish that the concentration is still effective within the required contact time, i.e. the minimum effective concentration.

Rinsing (second):

This stage is essential to remove disinfectant residues, which could be harmful to the patient if not removed. One of the major causes of post-endoscopic infection or pseudo-infection is due to recontamination during the final rinse. Infections with Pseudomonas species and atypical mycobacteria have been reported.

The higher risk procedures where recontamination may be an issue are cystoscopy, bronchoscopy and ERCP. The use of filtered or sterile water is recommended for these endoscopes. To avoid the build-up of disinfectant residues, this rinse water should be discarded after each use.

Drying:

Flushing air down the channels will remove excess fluid, but will not completely dry the channels. This is desirable before storage and may be achieved with medical grade air and flushing the channels with 70% alcohol followed by air.

The use of 70% alcohol to flush all channels reduces this risk and is recommended prior to storage.

Endoscope Accessories:

Many accessories used in endoscopy, (e.g., biopsy forceps, diathermy, etc...), some are invasive items and graded as high risk therefore sterilization is the preferred option for decontamination. Most items are heat tolerant and ideally should be sent to the CSS for steam sterilization. If this is not possible due to lack of instruments or available facilities, then immersion in a high-level disinfectant is acceptable or reprocessed in an AER with the endoscope. Single-use may be the preferred option for invasive accessories. Cleaning of these items is difficult, but essential prior to steam sterilization or exposure to chemicals.

Accessories used for the cleaning of endoscopes should be cleaned and disinfected after each use.

3. Endoscope Storage:

Flexible endoscopes should be stored, preferably hung, to allow drainage of channels in a dust-free environment.

Lockable storage cabinets are available. HEPA filtered drying cabinets are preferred as they feed filtered air down the channels to facilitate drying and allow for prolonged storage times.

Transportation of high-level disinfected endoscopes

- Disinfected endoscopes can become re- contaminated by hands and or communication with surfaces while being handled and transported.
- After reprocessing the endoscope should be protected from recontamination by:
- Don new exam gloves before removing the endoscope from the storage cabinet
- Transport the endoscope using an impervious barrier method that will prevent re-contamination.
    - Examples would be a clean plastic bag, endoscope transfer system (scope in a tote bin with a cover), or similar method. The endoscope should be loosely coiled to prevent damage.
- If transporting endoscopes off site, the inner receptacle must be transported inside a rigid lidded leak proof container.

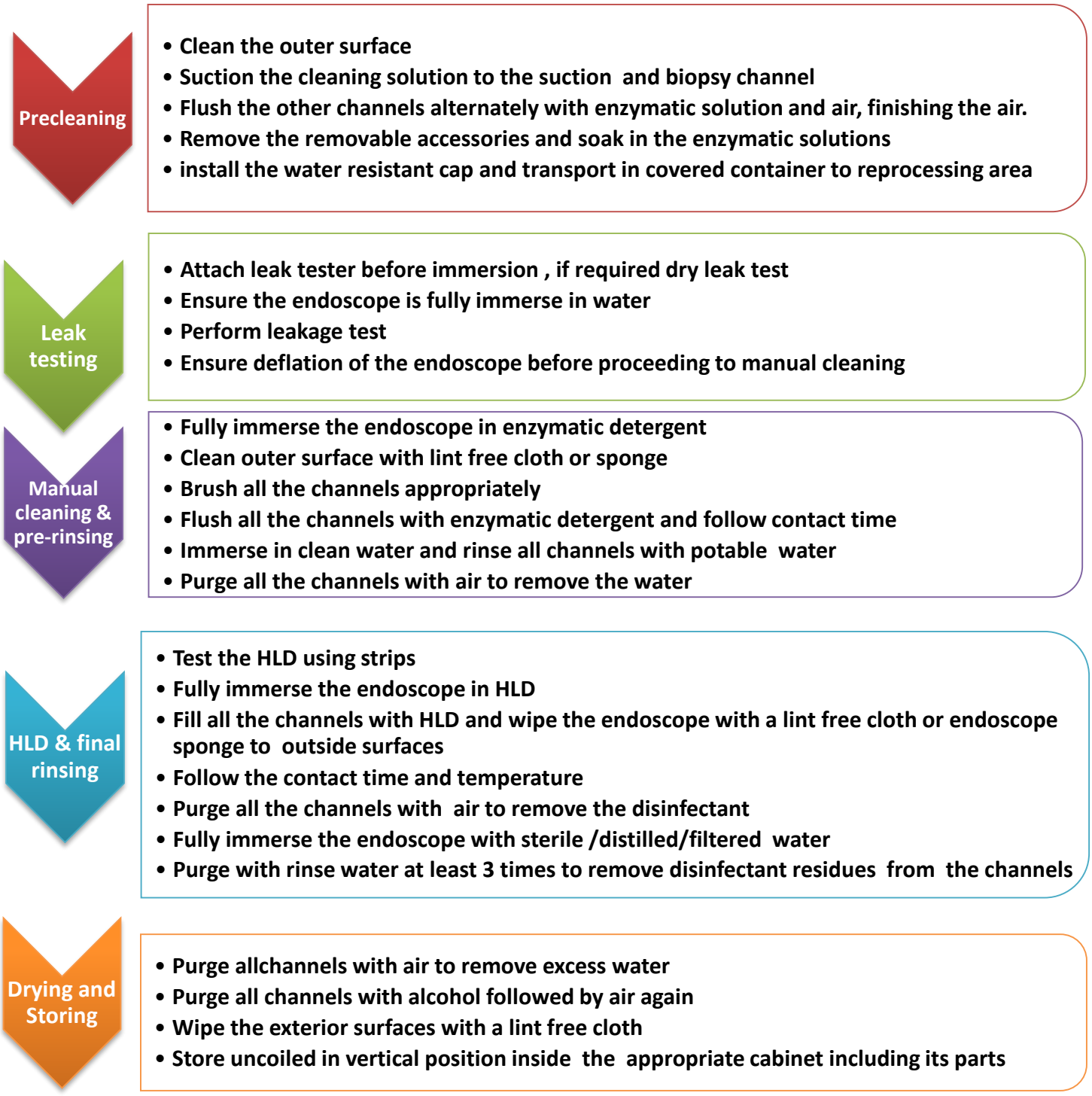
4. Automatic Endoscope Reprocessors (AER):

The use of an AER does not remove the need for the leak test or the bedside and manual clean. The AER should comply with ISO EN 15883 parts 130 and 431 or a national regulation. These standards describe the design of an AER and also the tests that should be carried out to validate and verify its efficacy. It is important that these tests are carried out at the time of installation (PQ) to establish the performance of the machine and to provide a baseline for comparison when periodic tests are performed.

Water may remain within the washer, which may become a source of contamination and lead to the formation of a biofilm, particularly with Pseudomonas spp. Therefore, a daily machine disinfection cycle and monitoring is recommended.

Recently, FDA cleared several specific AERs having label claims that manual cleaning is not necessary because the AER has a wash cycle that provides cleaning equivalent to manual cleaning. It should be noted that many currently marketed AERs with wash cycles have not been cleared by the FDA as providing cleaning; therefore, devices still require manual cleaning before being processed in the AER (Source: AAMI TIR34:2014/(R)2017).

Figure 17: Summary Endoscopy Reprocessing:



5. Flexible Endoscopes with Elevator Channels (Duodenoscopes):

Recent outbreaks have demonstrated that adherence to current guidelines for endoscope reprocessing may not be sufficient to prevent bacterial transmission following the use of endoscopic retrograde cholangiopancreatography (ERCP) endoscopes (i.e., duodenoscopes). Design features inherent to all currently available duodenoscopes make effective cleaning and disinfection challenging. Health care facilities where duodenoscopy is performed need to be aware of the risk of bacterial transmission associated with duodenoscopes and should ensure guidelines for reprocessing endoscopes are strictly followed.

Gastrointestinal endoscopes are challenging to reprocess due to their narrow and angulated internal lumens and irregular, hard to reach surfaces, combined with the high levels of bacterial contamination that occurs following routine use. Duodenoscopes are side-viewing endoscopes that differ from other gastrointestinal endoscopes in having an elevator mechanism and elevator recess at the distal end of the endoscope that allow accessories to be moved into and out of the endoscope field (Figure 18). Duodenoscopes also have an elevator channel that connects the distal elevator mechanism to the operator controls at the proximal end of the endoscope which are difficult to access for cleaning and the elevator mechanism contains complex mechanical parts including hinges.

Figure 18: Distal End of Duodenoscope - Elevator Mechanism:

Source: Public Health Ontario Annex A—Minimizing the risk of bacterial transmission from patient to patient when using duodenoscopes

It is essential that all facilities review their duodenoscope reprocessing policies and protocols to ensure that:

- They are consistent with current best practice guidance and updated manufacturers' instructions and national guidelines.
- They provide appropriate education and training to all individuals involved in endoscope reprocessing.
- They implement a quality assurance program to ensure that best practices are applied consistently and maintained over time.
- All aspects of duodenoscope reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel.

- Health care facilities where duodenoscopy is performed shall have a mechanism in place to link duodenoscopes to the patients for whom they were used in order to facilitate trace-back investigations in the event of an outbreak or reprocessing failure.

Health care facilities where duodenoscopy is performed must ensure that all essential steps required for duodenoscope reprocessing are performed consistently including:

- pre-cleaning
- manual (mechanical) cleaning
- high-level disinfection or sterilization
- drying
- storage and transport

Cleaning is an essential step without it disinfection or sterilization will not be effective. Efforts to enhance cleaning of the elevator mechanism, recess and channel are therefore a central focus of manufacturers' and others' recommendation to reduce bacterial transmission in duodenoscopes related to recent outbreaks. These recommendations include additional cleaning processes including raising and lowering the elevator mechanism throughout the cleaning process to facilitate cleaning on both sides of the mechanism, and careful inspection of the mechanism and recess for organic debris. Facilities may consider a double cleaning process, during which the duodenoscope is manually cleaned twice, ideally by a second trained cleaner.

5.1. Accessories: Water Bottle, Cap, Flushing Pump, and Connecting Tubing:

An ERCP procedure shall include a sterile water bottle, cap, and connecting tubing to hold and deliver the sterile water during this invasive procedure.

On completion of the ERCP, all accessories shall be replaced with clean or sterile supplies, depending on the requirements of the case to follow.
The water bottle, cap, and connecting tubing shall be cleaned and sterilized following the MIFUs.

Note: *Flexible endoscope contamination with Pseudomonas aeruginosa has been associated with patient (client) infection. As tubing is difficult to clean, disposable tubing should be considered.*

For procedures other than the ERCP, the water bottle, cap, and connecting tubing shall be removed and replaced with sterile supplies at the following times:

a) at the beginning of each day (at minimum);
b) before any procedure that invades sterile tissue; and
c) if the bottle becomes contaminated (i.e., visible turbidity in the liquid).

Sterile water shall be used in the water bottle.

If using a single-use water bottle, cap, and tubing, they shall be discarded in accordance with the MIFUs. It shall be verified with the accessory manufacturer that the water bottle, cap, and tubing have been indicated for use with the endoscope.

If using disposable irrigation tubing for the water jet function on the endoscope, a single-use endoscope connector with backflow prevention features shall be used.

Notes:

1) *There have been reported cases of cross-contamination when the endoscope manufacturer-validated reusable connector for the auxiliary water channel was not used or used incorrectly.*
2) *A backflow valve prevents patient (client) fluid from contaminating the water bottle. Failure to use one can potentially pose an infection control risk.*
3) *Refer to FDA letter from April 18, 2018 on Risk of Cross-Contamination from 24-Hour Multi-Patient Use Endoscope Connectors — Letter to Health Care Providers and Staff at Health Care Facilities Performing Gastrointestinal Endoscopy Procedures.*

5.2. Strategies to Enhance Effective Cleaning for Duodenoscopes:

Enhanced strategies specific to the elevator recess and mechanism include the use of a magnifying glass or borescope to carefully inspect for gross soil, and to ensure that such soil is removed, prior to disinfection. Additionally, several manufacturers have recommended the use of specific brushes for cleaning hard-to-reach areas specific to duodenoscopes. These brushes should be disposable; if reusable brushes are used, they must be cleaned and high-level disinfected between uses and discarded if damaged.

5.3. Auditing the Cleaning Process for Duodenoscopes:

It may be useful to consider the use of an audit tool designed to assess the adequacy of the cleaning process. A variety of tests designed to detect adenosine triphosphate (ATP), protein, carbohydrate and hemoglobin are currently available. If using these tests, it is important to test the areas of the duodenoscope of concern (e.g., elevator recess and mechanism, elevator channel if accessible). Any one of these tools could be considered for use either on a routine (i.e., for every duodenoscope reprocessed) or periodic (e.g., all scopes weekly or monthly) basis.

5.4. Surveillance Culturing of Duodenoscopes:

Current Canadian, US and European guidelines recommend that culturing of endoscopes is appropriate when epidemiological analysis links exposure to endoscopes with transmission of bacterial pathogens. As Carbapenemase-producing Enterobacterales (CPE) and other multidrug-resistant bacterial outbreaks associated with duodenoscope use are increasingly being reported, all facilities performing duodenoscopy should have protocols in place to allow culturing of endoscopes, particularly duodenoscopes. Developing a protocol for duodenoscope sampling and laboratory protocols for testing requires collaboration with the microbiology laboratory that will be performing the testing. Any duodenoscope used on a patient known to be colonized or infected with CPE should be removed from use, reprocessed, and then cultured for CPE.

6. Validation Testing for Manual Cleaning, HLD and AER:

Table 16: Testing Frequency Chart:

Activity	Testing	Frequency
Manual cleaning	ATP; Protein and hemoglobin swabs; flush method (combination test strips protein, carbohydrates and hemoglobin	Routine monitoring including one scope per week preferably
HLD	*MEC Test strips	Daily
Machine-AER	Follow manufacturer IFU for cleaning and disinfection efficiency test	Daily

* Do not use expired disinfectants or if the MEC fails

6.1.1. Water Quality Monitoring: (bacterial and chemical testing):

- Conduct bacteriological testing at least monthly
- Should be free from Coliform, Pseudomonas, and organisms subject for risk assessment e.g. Legionella and Mycobacteria
- See Annex D

Water type	Normal value
Tap Water supply	≤ 100 cfu/ml
Final rinse water from AER	≤ 10 cfu/ml

Follow the manufacturer's guidelines for chemical water quality to prevent damage of endoscope and AER, and may impact to the cleaning and disinfection process. See annex - Table D.3

7. Tracking System and Documentation

Records shall include, but not be limited to, the following:

a) the daily schedule of procedures; (table 18)
b) for every endoscope and diagnostic medical device reprocessed
   - date and time of the procedure;
   - patient (client) identification details;
   - instrument identification details;
   - AER identification number;
c) unique identifier (e.g., signature, initials) of the person who is responsible for point-of-use cleaning at the bedside; and manual cleaning, including
   - leak testing;
   - brushing; and
   - rinsing
d) Maintain records of repair of endoscopes and reprocessing equipment (e.g., leak testers, automated endoscope reprocessor.
e) Endoscope disinfection records (Table 19).

Table 18: Sample Procedure Record Documentation

Patients Name	Inpatient number	Date and Time	Type of procedure	Endoscopist	Serial number of endoscope	Comments

Table 19: Sample Endoscope Disinfection Records

Endoscope serial no.	Date and time	Disinfectant used HLD and Lot #	Contact time	T°	MEC results Pass/fail	Operator	Comments

7.1. Inventory

Information reviewed for each endoscope should include but is not limited to the:

- Endoscopes manufacturer serial No and model
- Location of use
- Number of procedures performed
- Location of the endoscope manufacturer's IFUs
- Location for endoscope reprocessing
- Equipment used for HLD and/or sterilization
- Status of the endoscope (i.e., condemned, out for repair, in use)

8. Education and Training:

Managers, supervisors and staff responsible for reprocessing shall have completed formal education on medical device reprocessing and orientation, training and competency testing on basic reprocessing principles and how to reprocess instruments at the following intervals:

a) when first employed;
b) with any authorized change in process;
c) when a new medical device/equipment is purchased; and
d) when a new processor is purchased.

Manager and staff responsible for reprocessing are required to:

- Demonstrate reprocessing competencies initially and at specified predetermined intervals.
- All education, training, and competency testing is documented.
- There is an audit and follow-up process in place for ongoing observation and evaluation of reprocessing with documented action plans and resolutions.
- Appropriate personnel and IPC are notified when follow-up is required
- Training and competency assessment for the staff are completed upon initial hiring and annually thereafter,

Competency assessment should be conducted internally (every 6 months) and externally (yearly).

9. Roles and Responsibilities:

Endoscopist:

- Schedule the procedure to allow sufficient time for reprocessing.
- Verify that the endoscopes are high level disinfected before using to other patients by checking the AER print out or a manual check sheet.

Endoscopy staff

- Adhere to this policy and procedures.
- Perform correctly the endoscopy reprocessing procedures
- Attend relevant trainings and required competency testing
- Operate AER systems as per the manufacturer's recommendations.
- Carry out validation testing on a regular basis.
- Carry out a diagnostic testing to AER prior to instruments being loaded.
- Use the correct amount or dilution of chemicals required for each load.
- Read and understand the safety data sheets of chemicals used in the unit.
- Manage if there is chemical spill
- Observe the standard precautions at all times

Endoscopy Supervisor

- Supervise the day to day operation in the unit
- Conduct the periodic staff competency testing
- Maintain and organize the manufacturers IFUs
- Maintain sufficient inventory of endoscopes to meet the demand
- Report to IPC and CSS department /unit for any relevant issues
- Ensure that the AER complies with the standards and evaluates reprocessing cycle.
- Collaborate with designated department or manufacturer representative to: collect water samples (supply water and the final rinse water in AER), change water filters, validation of AER (cleaning and disinfection efficacy) and PPM
- Keep and maintain any relevant documents
- Ensure that the staffs are aware about the SDS and the unit policy, and it should be accessible to them.

Hospital Administrator

- Provide infrastructure support for the endoscopy services e.g. appropriate physical designs, sufficient number of endoscopes and trained personnel, appropriate supply and updated technology.
- Coordinate with suppliers to provide endoscopy reprocessing training in accordance with the installation and commissioning agreement.

Hospital Engineering Department

- Received the equipment's and inform the department for the installation of the equipment.
- Checking the status of the equipment every month.
- In case of any failure, department should be aware to avoid any misuse from the staff.
- Doing PPM for the equipment every 3 months or 6 months, and should follow the procedure of PPM.
- Contact with authorized dealer if they need any clarification from the manufacturer.

Hospital Infection Prevention and Control and CSS Department

- Monitor the proper implementation of this policy and procedures.
- Review and approve the products related to infection prevention and control
- Collaborate with relevant department for education and training
- Review and interpret the results of water sample and collaborate with designated departments to conduct necessary actions in cases of unacceptable limits.
- Conduct reprocessing audit according to the local policy and procedures.
- Collaborate with Central Department of Infection Prevention and Control if needed for any consultation e.g. (review and approve the sketch plan of the endoscopy unit and type of dust barrier control during construction and renovation)

Central Department of Infection Prevention and Control

- Review and approve the sketch plan of the endoscopy unit and dust barrier control during construction and renovation
- Update periodically this policy and procedure
- Coordinate with various stakeholders for the implementation of policy and procedures
- Conduct yearly audit to the healthcare establishments.

Appendix

Appendix

Annex A: Specifications and Calculations for the Density of Reusable Textile Packages:

Calculating density

The formula for calculating density of a textile package is where:

$$D = \frac{M}{V}$$

Or

$$D = \frac{M}{L \times W \times H}$$

DI = density, kg/m3
MI = mass, kg
VI = volume, m3
LI = length, m
WI = width, m
HI = height, m

Density is a key factor related to the sterilization of items. The more densely items are packed, the greater the percentage that the sterilant will not contact the surface areas of all items, and drying will be inadequate causing a wet load.

Reference: CSA Z314:22 Canadian medical device reprocessing in all health care settings

Annex B: Endoscopy Competency Checklist:

Note: *This tool is a sample template designed for competency testing for the reprocessing staff. If the procedures listed are not met, identify the opportunity for improvement. If the staff is not competent. Write an action plan.*

Verification method (VM):

(DO) Direct observation

(DEM) Demonstration

(V) Verbalization

(DR) Document review

Procedure	Verification	MET		Opportunity for improvement
	DO, DEM. V, DR	Yes	No	
PPE				
Perform hand washing and don appropriate PPE whenever needed in each procedures				
Remove PPE and perform hand washing after each procedures				
Bedside Cleaning				
Prepare a fresh solution of the cleaning product recommended by the manufacturer				
Clean the endoscopes immediately after each procedure to prevent drying.				
Wipe the external surfaces with lint free cloth or endoscope sponge				
Place the distal end in the cleaning solution and suction the solution through the endoscope				
Suction the enzymatic cleaning solution to the suction and biopsy channel				
Flush the other channels alternately with enzymatic cleaning solution and air, finishing with air.				
Inspect for damage				
Discard the cleaning materials and solution after each use.				
Contain the accessories separately				
Transportation				
Transport to the designated decontamination area				
Keep the endoscope damp, but not submerged in the cleaning solution.				
Transport the endoscope and accessories (that are keep separately) together in closed container				
Use designated clean or dirty trolleys and appropriate container.				
Leak testing				
Refer to manufacturer's recommendation for dry leak test before immersion leak test, if required. If dry leak test fails , it should not undergo the immersion leak test				
Perform leak testing prior to manual cleaning				
Read the manufacturer's instructions				
Remove all the port covers and function valves				
Place in loose configuration				
Pressurized to recommended pressure				

Manipulate all moving parts, including elevator and angulating the bending section of distal end and video switches				
Maintain pressure and observe for minimum of 30 seconds for continues bubbles				
Deflate the endoscope before manual cleaning				
Remove the damaged endoscopes immediately from service when leak test fails				
Manual cleaning				
Read the endoscope manufacturer's IFUs				
Prepare fresh enzymatic cleaning solution and document the temperature monitoring.				
Submerge the endoscope below the solution surface level at all times.				
Clean the exterior surfaces with a single use lint free cloth or sponge.				
Brush the valves, cylinders, openings and forceps elevator housings				
Brush all the channels until there is no visual debris.				
Flush and rinse all exterior surfaces with potable water until all cleaning solution is visibly removed.				
Repeat the cleaning, brushing and rinsing process until there is no visible debris or solution residues.				
Soak , brush and rinse the accessories				
Flush the channels with cleaning solution				
In case the automatic flushing is used, ensure its compatibility and follow the manufacturer's IFU.				
Preliminary Rinsing				
Remove its components and rinse all surfaces and channels				
Rinse thoroughly until the debris are removed and there is no traces of disinfectants. Use fresh water on each rinse.				
Dry the exterior surface with soft , lint –free cloth or sponge and purge air to the channels				
Inspection				
Use a lighted magnification to inspect: the cleanliness, missing parts, damage (cracks, corrosion, and discoloration) and check the integrity of fiber optics.				
Remove defective endoscopes, accessories and equipment and send for repair or replacement.				
Dry completely the endoscope and accessories prior to sterilization, or remove the excess water prior to disinfection.				
High Level Disinfection (HLD) or Sterilization				
Ensure that the HLD and Sterilants used is compatible with endoscopes.				
Monitor and document the efficacy of HLD or Sterilants as per IFU				
Completely immerse the endoscope and its components in the solution and ensure all channels are perfused				
Use 30 cc syringe to flush the HLD to purge air from all channels				
Soak the endoscope in HLD at recommended time and temperature				
Flush the air through the channels using adaptor (suction cleaning adaptor) to remove the HLD				
Final Rinsing and Drying				
Ensure to immerse completely the endoscopes in rinse water				
Rinse the endoscope and flush the channels with filtered or sterile water completely to prevent chemical residues that may cause toxic reactions.				
Discard rinse water				
Follow by a 70-80% ethyl or isopropyl alcohol rinse				
Purge the channels with air				
Dry all removable parts and accessories				
Send the reusable accessories e.g. biopsy forceps and cutting devices for steam sterilization				
Automated Endoscopy Reprocessor				
Read the manufacturer's IFU and recommended HLD				
Check the expiration date of HLD or Sterilants				
Check MEC of HLD efficacy				
Verify that the endoscope and its components are compatible with AER				
Ensure that the connectors are labeled and connected properly on the site of the AER and the endoscope.				
Place the brushes and instruments used to clean the endoscope in the AER				
Monitor the mechanical processing cycle to verify the program is completed.				

Repeat the cycle if interrupted or not completed.				
Do not open or stop the AER once started to ensure the proper disinfection/sterilization.				
Remove the endoscope after the final cycle completion				
Manual Drying				
Dry the external surface with clean lint free cloth.				
Purge clean filtered air in all the channels for 10 minutes or more until completely dried with pressure controlled air.				
Flush with 70-80% ethyl or isopropyl alcohol to facilitate drying.				
Flush again all the channels with filtered & pressure controlled air				
Record keeping (log the following)				
Patient name and number				
Date and time of the procedure				
Type of procedure				
Name of Endoscopist				
Endoscope serial number				
AER serial number, if available				
Name of person performing the reprocessing				
Lot number of processing solutions and MEC results				
Storage				
Wear clean, low protein, powder free gloves when handling processed endoscopes or removing them in the cabinets.				
Store in accordance of storage / drying cabinet manufacturers IFU				
Hang vertically in a manner that minimizes contamination or damage				
Store with all valves open.				
Store the disconnected caps, valves and other detachable components with the endoscopes in small bags or similar device tied in the endoscopes.				
Prevent disinfected endoscopes to coil, touch the sides and the floor or bottom of the cabinet while hanging, and don't store back in their cases				
Document the cleaning activity of storage cabinets (at least weekly)				
Reprocess the flexible endoscopes if storage exceeds the shelf life.				
Reprocess before use, the bronchoscopes that are not used on a routine basis.				
Store sterile items in a sterile storage area as per hospital policy				
Competency Test Result		**Yes**	**No**	**Action Plan**
Competent				

The staff had named below has completed the required competency testing related to reprocessing of flexible endoscopes.

Employee Name: _____
Employee Signature: _____
Date: _____
Evaluator Name: _____
Evaluator Signature: _____
Date: _____
Endoscopy Unit Head: _____
Manager Signature: _____
Date

Annex C: Laundering of Reusable Gowns, Drapes and Wrappers

Laundering of reusable hospital linens is a complex process involving design of the laundering areas, purchasing of specialized laundering equipment, water quality, and appropriate cleaning, drying and preparation of reusable linens which requires detailed policy and procedures to be created and followed.

The following criteria can be used by the HCF to gather and analyze information about internal laundries that reprocess gowns, drapes, or wrappers to help guide the policy and procedure development:

1. Quality systems in place for monitoring:
    a) soiled sort;
    b) quality of sort processes; and
    c) adherence to load size specifications;
2. Wash floor (laundry area):
    a) control of water hardness, which can affect textile life, wash formula, and quality;
    b) measurement and consistency of chemical titrations; and
    c) monitoring of finishing pH levels;
3. Laundry departments — KPI's:
    a) stain %;
    b) reject %; and
    c) mending %;
4. Reusable surgical textiles reprocessing area:
    a) inspection SOPs and guidelines — monitoring and compliance with load size specifications;
    b) patching/repair protocol;
    c) tracking and identification; and
    d) sterility assurance protocol (where applicable) — correct use and interpretation of CI,
    e) mechanical, and BI;
5. Cart makeup:
    a) ward cart delivery;
    b) bulk cart delivery; and
6. Describe the performance against other quality benchmarking criteria, such as the following:
    a) return rate for linen items whose defects are due to stains, tears, holes, etc. (i.e., less than 1%); and
    b) fill rate (i.e., 97% or higher).
7. Are there programs that are designed to decrease usage patterns and accompanied by benchmark peer reports?
    a) Will the IPC set up a schedule of routine visits to provide unit-level service communications and problem solving?
    b) What types of new products are being developed or introduced to enhance patient care and reduce operating costs?

8. Define the linen specifications to be delivered:
    a) size;
    b) weight;
    c) colour;
9. Describe the ongoing service analysis of the reusable surgical textile program:
    a) product evaluation;
    b) staff in-servicing;
    c) complaint handling and follow-up; and
    d) surgical pack review process

Annex D: Water Quality

Notes:
1) This Annex was adapted from ANSI/AAMI ST108 with permission of Association for the Advancement of Medical Instrumentation, Inc. © 2021 AAMI, https://www.aami.org.

Background information
Water quality is an important consideration in all stages of CSS. Ensuring adequate water quality in CSS requires collaboration between the personnel who reprocess medical devices and the personnel who establish and maintain the water treatment system.

Because the needs of these two groups are distinct, this Annex contains:
a) Guidance for personnel involved in CSS on the selection of the appropriate water quality for each stage of medical device processing for each category of medical device (see Table D.4); and
b) Technical information for water maintenance personnel (e.g., personnel who are involved in water treatment and distribution in the health care setting) to guide them in setting up and monitoring water treatment systems (see Table D.1)

Water can be treated by a variety of methods, which yield different levels of water quality. Water quality can vary seasonally depending on the source and level of treatment applied. In general, microbial water quality at the point of use is worse than at the point of treatment due to the potential for growth of biofilms in the pipes used for its distribution. In health care settings, including CSSs, the system should be closely monitored to prevent microbial overgrowth. Gram-negative bacteria, including legionellae and pseudomonas, and Gram-positive bacteria, including nontuberculous mycobacteria, can grow in any type of water, including potable, softened, deionized, RO treated, and distilled water.

The rate of growth and the microbial levels attained are a function of the amount of organic and inorganic contaminants in the water. The importance of monitoring water quality to prevent problems with microbial overgrowth cannot be overemphasized.

There are three categories of water quality suitable for CSS (see Clause D.4). This Annex describes the water treatment processes that can be used to obtain appropriate water quality. To provide optimal water for CSS personnel and water maintenance personnel should collaborate with administrative personnel to implement the SOPs listed in Table D.1.

Risk analysis

Water impurities can have adverse effects on medical device processing. The recommendations in this Annex are intended to mitigate the risks associated with water identified to be of inadequate quality. It is important that personnel responsible for processing medical devices or using them in patient procedures understand the importance of water quality and how water quality failures contribute to adverse patient (client) events and outcomes. They should be aware of some of the indicators that suggest that there could be problems with the water quality. As part of the water management program, monitoring water quality is a prospective process meant to confirm that control strategies are working properly. Monitoring is performed in order to detect when control strategies might require review or remedial action. Some of the potential effects are listed, but not limited to, below:

- Adverse effects to the **medical device**:
  - – corrosion, pitting, scaling;
  - – biomass build-up; and
  - – increased microbial load or endotoxin content;
- Adverse effects to the **process**:
  - – decreased effectiveness of detergents; and
  - – degradation of the water system or processing equipment (biofouling, scaling, or foaming);
- Adverse effect to the **patient (Indirect)**:
  - i) infection (e.g., water-borne pathogens); and
  - ii) toxicity (e.g., toxicity of residual chemicals, exposure); and
- Adverse effects to **Staff**:
  - – Environmental Health and Safety (e.g., chemical handling, exposure and disposal, injury by high pressure water, electrical hazards).

Evidence has shown that water quality issues can contribute to adverse patient events and outcomes. This Annex helps health care personnel to be aware of some of the gross indicators that suggest that there might be problems with water quality (Kremer, et. al, 2020). Monitoring water quality is a process meant to confirm that control strategies are working properly.

In the preparation of water for use in medical device processing, four general characteristics need to be considered:

- the microbial level in water;
- inorganic and organic contaminants of water;
- the pH of the water; and
- conductivity of the water.

Each facility should be responsible for delivering water to health care setting without potential to cause adverse human health effects. See National Water Quality Guidelines for drinking water for more information.

Each drinking water system should have a baseline range of Total Viable Count (TVC) bacteria levels depending on the site specific characteristics as unexpected increases in the TVC baseline range could indicate a change in the treatment process, a disruption or contamination in the distribution system, or a change in the general bacteriological quality of the water.

Water used for medical device processing should continue to deliver water of this quality level to the point of use. Specific microorganisms of concern for patient safely (e.g., Legionella) should be considered for lower levels.
A risk analysis for water quality should be completed prior to water system installation and the resulting evaluation plan conducted periodically to assess the continued performance of the water system.

Effects of adverse water quality on medical device processing
The primary objective of medical device processing is to prepare a device for use on a patient.
Adverse patient events and outcomes to which inadequate water quality can contribute include:

a) Device malfunction during a patient procedure (e.g., corrosion of a surgical instrument could result in breakage of the device inside the patient when stress is applied to the device; mechanical movement of the device could be obstructed by residual debris or corrosion inside the mechanism; degradation of optical and metal surfaces negatively impacting function);
b) Toxic effects and tissue irritations results from residuals on a device or implant that was processed using water of inadequate quality;
c) Risk of patient infection resulting from the use of contaminated devices; and
d) Ineffective cleaning/disinfection due to water contaminants interfering with device processing chemicals.

Table D.1 Multi-Disciplinary/Cross Functional Team Responsibilities

Step	SOP	What to do	Who is responsible
1	Assessment of water quality	The utility water from the public utility source should be analyzed by an accredited facility with appropriate expertise in water quality to determine whether the water requires treatment and, if so, what type of treatment. This analysis should take into account seasonal variations in water quality. It is advisable to consult with Department of Environmental & Occupational Health to better understand potential problems and water quality variations.	Water maintenance personnel
2	Implementation of water treatment	On the basis of the assessment in Step 1 and in consultation with an accredited facility with appropriate expertise in water quality, personnel should ensure that treatment processes are implemented to provide the type of water quality needed for the MDR needs of the health care setting. Consideration should be taken for preventing particulates from being carried with the water flow. Water filters (recommended 5 to 20 µm) should be installed on the main water supply line to the hospital. Self-contained water treatment options can be of benefit to smaller health care settings that are installed on a distribution loop that is off the main water supply line.	Water maintenance personnel in conjunction with MDR personnel
3	Assurance of proper water quality for the various stages in MDR	MDRAs should be audited to determine whether water of the appropriate quality is being used for the medical devices being reprocessed in each area. If not, the water treatment should be modified as necessary	MDR personnel in conjunction with engineering personnel
4	Ongoing monitoring of water quality and recording of results	Where applicable, monitoring SOPs should be established to ensure that the treated water is of adequate quality for MDR. Water maintenance personnel should communicate effectively to ensure that appropriate action is taken when inadequate water quality is detected.	Water maintenance personnel in conjunction with MDR personnel

Reference: CSA Z314-22 Canadian medical device reprocessing in all health care settings, 2022

MDR=CSS

Water Pre-treatment

Water provided by the public utility source can be variable in its quality. Consequently, water pre-treatment might be necessary before the more refined water treatment techniques are employed.
Sediment filters may be utilized to remove relatively coarse particulate material from the incoming water. These filter systems contain multiple layers, each layer retaining progressively smaller particles.

Water containing calcium or magnesium can form relatively hard deposits and is termed hard water.

Water softeners employ a technique where a sodium, ion exchange will remove calcium and magnesium from the water. The primary use of softeners in water system is to prevent hard-water deposits from damaging sensitive RO membranes and to prevent calcium deposition onto the reprocessed device.
Carbon absorption systems, often referred to as carbon filters, are the principal means of removing both free chlorine and chloramine. Free chlorine degrades some RO membranes.

Deionization (DI)

DI can produce a large volume of water on demand and has a relatively low initial capital cost; however, DI resins should be periodically regenerated or replaced. In some cases, DI tanks are provided by a vendor and replaced by that vendor when the resistivity reaches a certain level. Conductivity monitors should be used with DI tanks to continuously monitor water quality. DI removes both positively and negatively charged ions very effectively. Of the three most common treatment processes (DI, RO, and distillation), DI produces water with the lowest conductivity. Conductivity of water decreases in proportion to the removal of ions, so low conductivity indicates that there has been efficient removal of ions. DI does not effectively remove non-charged or weakly charged species, such as some organic compounds and silica, nor does it remove microorganisms or endotoxins. Poor maintenance of the DI system can lead to microbial overgrowth that result in increased levels of microorganisms and endotoxins in the water. Additional treatment steps are needed after DI to ensure the microbiological quality of the treated water (e.g., filtration treatments that remove pyrogens, submicron filters that remove microorganisms, ultrafilters).

Ultrafiltration

Ultrafilters are membrane-based separation devices that can be used to remove particles as small as 1000 Daltons; thus, ultrafilters are well suited to remove both bacteria and endotoxins. Ultrafilters should be placed in water systems at locations downstream of DI, if DI is the last process in a water treatment system or following UV irradiation.

Reverse osmosis (RO)

RO removes most ionic species from the water. The initial conductivity might not be as low as that achieved by DI, but it is sufficient for most CSS needs. RO also removes microorganisms, endotoxins, organic compounds, and colloids effectively. A two-pass RO system, in which the first RO system feeds the second RO system, produces water of very high quality. Another approach widely used is a first-pass RO followed by DI. RO does produce purified water relatively slowly, so a storage tank might be needed. RO systems should be regularly tested and disinfected to minimize bacterial growth.

Distillation

Distillation relies on the vaporization and condensation of water to remove dissolved and suspended substances. Distillation effectively removes microorganisms, endotoxins, organic compounds, and colloids. Various styles of stills are available. This water treatment method generally requires more energy to operate than RO or DI. Distilled water is produced relatively slowly, so a storage tank is needed and should continuous flow to the distribution loop. Care should be taken to prevent scaling or coating with colloidal material. Normally, soft water or deionized water is used to feed a distillation unit to keep the amount of scaling to a minimum.

UV irradiators

UV irradiators can be used to control bacterial proliferation in purified water storage and distribution systems. UV irradiators contain either a low or medium pressure mercury lamp or a light emitting diode (i.e., LED) that emits UV light at a wavelength between 200 to 280 nanometers. The lamp is contained inside a transparent quartz sleeve that isolates it from direct contact with the water. The dose of radiant energy provided by the lamp should be at least 30 watt-s/cm2.

UV radiation is not effective in water containing large amounts of organic substances or colloids and, therefore, is not suitable for use in controlling bacteria in the pretreatment section of a water
purification system. Because killing bacteria with UV irradiation increases the level of endotoxin in the water, UV irradiators should be followed by an ultrafilter.
The use of sublethal doses of radiation could lead to the development of resistant strains of bacteria; therefore, UV irradiators should be equipped with an online monitor of radiant energy output that activates a visible alarm when the lamp should be replaced.

Distribution

After water has been treated, it is necessary to maintain its quality and prevent microbial contamination and growth. Maintenance of water quality is generally accomplished by routine disinfection of the distribution loop and by continuous recirculation of the water through the distribution system. Piping should be constructed from stainless steel or a sanitary polymer that will provide a smooth surface to inhibit the formation of biofilm and to allow sanitization. There should be no dead legs (i.e., piping that is more than six times as long as its diameter and that does not have constant water flow). A constant water flow of more than 0.9144 m/s will minimize the formation of biofilm on the piping. Providing a slight slope to the water distribution system will enhance water quality by enabling the water to drain out without pooling, thereby minimizing the formation of biofilm caused by improper drainage. Water flowing through the distribution system can be disinfected by UV treatment. The distribution pipes can be sanitized or disinfected with hot water, ozone, or various chemicals, such as sodium hypochlorite (bleach), hydrogen peroxide, or peracetic acid.

Note: *Treatment agents need to be used with caution. For example, chemical disinfectants containing chlorine might not be compatible with materials and filters within the distribution system and, consequently, could cause premature degradation. It has been demonstrated that residual chlorine is extremely difficult to neutralize and remove from a water system. Therefore, all sanitizers and disinfectants used on water distribution systems should be evaluated for material compatibility before they are used.*

Table D-2—Overview of water quality monitoring

Characteristic	Type of testing	Sample site	Samples taken and analyzed by	Suggested frequency of testing
Bacteria	Heterotrophic plate count [1)]	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel	Monthly
Endotoxins	LAL test	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel	On installation, modification, or repair of the Critical Water treatment system or when persistent increased microbial levels are detected by heterotrophic plate count, ATP, or TOC
Total organic carbon	TOC test	Reprocessing area	Maintenance personnel	Monthly or quarterly
pH	pH meter Colorimetric dipsticks	Reprocessing area Reprocessing area	Maintenance personnel/ Reprocessing personnel	Monthly Monthly
Water hardness	Determination of ppm $CaCO_3$ Colorimetric dipsticks	All main water feedlines into the facility Reprocessing area	Maintenance personnel/ Reprocessing personnel	Annually [2)] Annually [2)]
Resistivity meter	Resistometer	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel (reprocessing personnel if point-of-use water treatment is used)	Monthly
Ionic contaminants	Specific tests for chloride, iron, copper, manganese	All main water feedlines into the facility	Maintenance personnel	Annually [2)]
Color and turbidity	Visual inspection	Reprocessing area, storage tanks (if used), immediately downstream of water treatment process	Maintenance personnel and reprocessing personnel	Daily

Source: AAMI TIR34: 2014/(R)2017

NOTE 1—The specifications presented in this table should be tested to the parameters specified in Table D-3, where applicable.

NOTE 2—This characteristic should initially be monitored quarterly for one year or until there are four consecutive quarters with no out-of-specification readings. Monitoring should be conducted annually thereafter or as appropriate based on the assessment of the previous year's validation.

NOTE 3—The recommendations for frequency of testing in this table are the recommended minimum frequency. If problems or issues arise with the water quality, it might be necessary to increase the frequency until they are resolved.

Categories of water quality for medical device processing

The water quality needed for the various stages of medical device processing is determined by the type of medical device and by the disinfection or sterilization process used. For example, the processing of stainless steel surgical medical devices that are steam sterilizable has different water quality issues than the processing of flexible endoscopes, which require HLD or low-temperature sterilization.

Three categories of water quality

There are three categories of water quality in terms of the characteristics that are important for medical device processing and the level of treatment that might be needed:

1) Utility water: water as it comes from the tap that might require further treatment to achieve the specifications. This water is mainly used for flushing, washing, and intermediate rinsing.

Note: *The decision regarding the need to treat incoming tap water to provide adequate water for medical device processing should be undertaken in every facility that processes medical devices*

Utility water is predominantly used for medical device processing with the exception of final rinse, where critical water is recommended. At the point of production, water should meet the requirements as specified in Table D.4. This might require tap water to be treated to meet these requirements.

2) Critical water: This type of water is extensively treated (usually by a multistep treatment process that might include a carbon bed, softening, DI, and followed by either RO or distillation) to ensure that the microorganisms and the inorganic and organic material are removed from the water; a final submicron filtration can also occur as part of the treatment process. This water is mainly used for the final rinse after HLD and/or for critical medical devices prior to sterilization.

Note: *Using critical water for all stages of medical device processing can be unnecessary and costly and can cause damage to equipment.*

3) Steam: Vapourized water that is produced from a treated water source by a centralized boiler or a generator or heat exchanger at point of use. When the steam is tested as a condensate, it must meet specified criteria for specific applications in medical device processing.

Note: *Critical water might not be compatible with all boilers and black iron piping.*

Table D.3 —Categories and recommended levels of water quality for medical device reprocessing

Type of Water		**Utility Water**			**Critical Water**
Water Use		**Flushing/Washing/Rinsing**			**Final Rinse/Steam**
Specifications:					
	Units				
Hardness	mg/L	< 150			< 1
Conductivity (mg/L = ppm)	µS/cm	< 500			< 10
pH		6 – 9			5 – 7
Chlorides	mg/L	< 250			< 1
Bacteria	cfu/mL	n/a	<10		< 10
Endotoxin	EU/mL	n/a	<20		< 10

Source: AAMI TIR34: 2014/(R)2017

Table D.4 Categories and PQ Levels of Water Quality for Medical Device Processing

Water quality measurement	Units	Utility water	Critical water	Steam*
pH @ 25 °C:	pH	6.5–9.5	5.0–7.5	5.0– 9.2†
Conductivity	µSiemens/cm	<500	<10	<10
Total alkalinity	mg $CaCO_3$/L	<400	<8	<8
Hydroxide alkalinity	mg $CaCO_3$/L	<40	<1	<1
Carbonate alkalinity	mg $CaCO_3$/L	<400	<8	<8
Bicarbonate alkalinity	mg $CaCO_3$/L	<400	<8	<8
Chloride	mg/L	<250	<1	<1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Iron	mg/L	<0.1	<0.1	<0.1
Copper	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Aluminum	mg/L	<0.1	<0.1	<0.1
Zinc	mg/L	<0.1	<0.1	<0.1
Total Hardness	mg $CaCO_3$/L	<150‡	<1	<1
Bacteria	cfu/mL	N/A§	<10	N/A
Endotoxin	EU/mL	N/A§	<10	N/A
TOC	mg/L	N/A	<1.0	N/A
Colour and turbidity	Visual	Colourless, Clear, no residues	Colourless, clear, without sediment	Colourless, clear, without sediment

Source: *ANSI/AAMI ST108.*

** Values for steam condensate utilizing critical water as feed water. Values will be different for house steam utilizing utility water as feed water.*

† For boiler-treated steam, most boilers should be treated to maintain a pH of 7.5 to 9.2.

‡ If hardness is greater than 150 mg/L, a water softener should be used unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness.

§ Unless used after chemical HLD as a final rinse, then bacteria should be <10 CFU/mL and Endotoxin should be <20 EU/mL

Rationale for Table D.4

The following provide rationale and other considerations for Table D.4:

1. Bacteria: Critical water should be bacteria-free if tested at the point of generation. However, because most facilities will transport water to the site of use through pipes and because collection could result in low levels of bacteria being detected, the bacterial level has been defined as10 cfu/mL. This rationale is similar to that stated by CLSI for its recommended bacterial level for RO water used in laboratories (CLSI, 2006).
2. Endotoxins: Only critical water is derived by a process that would be expected to remove endotoxins. Although RO treatment should significantly reduce endotoxins, some endotoxins might be detected because of passage of the water through tubing that is not endotoxin-free. If the final rinse of a medical device is done with critical water containing less than 10 EU/mL, the amount of endotoxins left on the medical device would be expected to be only a fraction of that amount so the medical device would have far less than 20 EU remaining on its surface, which is the limit specified by USP testing for transfusion and infusion assemblies and similar medical devices (USP 161). Because either tap water or utility water is produced by a process that removes endotoxins and because neither tap water nor utility is used for the final rinse of critical medical devices that contact the patient's (client's) bloodstream, endotoxin testing of such water is unnecessary.

   Note: *Adverse effects have been demonstrated when 1 to 4 ng/kg of purified endotoxins (1 ng/kg equals 2 EU/kg) are injected (Suffredini et al., 1999). However, the threshold amount of endotoxins in rinse water that would lead to sufficient residuals on a reprocessed medical device to cause an adverse patient reaction is not clearly defined in the literature. There are no published data or guidelines for endotoxin levels in water used to reprocess medical devices. The above-mentioned 10 EU/mL value was adopted by committee consensus because it was thought unlikely to result in sufficient residual endotoxins on a medical device to cause an adverse patient (client) reaction.*
3. TOC: Only critical water is derived by a process that removes microorganisms and organic materials. Softened or deionized water would be expected to have total organic carbon levels that are no worse than tap water; therefore, the TOC value of <1.0 mg/L for critical water and N/A for utility water.

   Note: *No studies have been published that establish how much organic material is needed to interfere with the disinfection and sterilization processes*.
4. PH: Water having an acidic or alkaline pH can cause pitting of the medical device surfaces. In addition, it can interfere with the efficacy of cleaning agents and disinfectants. Tap water is expected to have a pH in the range of 6.5 to 8.5 (EPA Secondary Drinking Water Regulations). Tap water is typically in the higher portion of this range.
5. Water hardness: Tap water is generally considered "hard" if it has a calcium and magnesium level higher than 150 ppm; therefore, this level is given as the upper limit for utility water. Avoiding excess hardness prolongs the life of washer sprayers, reduces the risk of hard-water deposits on medical devices during reprocessing, and helps ensure the efficacy of cleaning agents. For softened water, however, 10 mg/L is a typical value; if the CaCO3 content exceeds 10 mg/L, the softener should be serviced. For critical water, the RO or distillation process would be expected to remove solutes and produce water that has a CaCO3 content of less than 1 ppm. Because critical water is used for the final rinse of critical medical devices that will contact the bloodstream, reducing the likelihood of hard-water deposits on such medical devices is desirable. Deionized water is often used for steam, EO, and ozone sterilization.

6. Ionic contaminants and conductivity: Conductivity and resistivity measurements are electrical measurements of the ionic concentration in water. These measurements are mathematical inverses of one another (e.g. > 0.1 MΩ*cm resistivity is equal to <10 µSiemens/cm). Conductivity was selected as the measurement as it is expressed as an upper limit. Ionic contaminants in water used in CSS can corrode medical devices. Because the process that produces critical water removes the majority of ionic contaminants, the value for chloride and iron is < 0.2 mg/L and the value for copper and manganese is < 0.1 mg/L (i.e., these are the levels achieved by the water treatment process). Such low levels of ionic contaminants will minimize the risk of corrosion. Similarly, tap, softened or deionized water should have low levels of chloride, iron, copper, and manganese to ensure that there is no staining or corrosion of medical devices during reprocessing.
7. Colour: Tap water is expected to be colourless and clear and contain no residues. Because all categories of water are expected to be equivalent to or better than tap water because of removal of ions and organic material, the same criteria for colour apply to all categories.

Cleaning

Manual cleaning/Point-of-use cleaning and rinsing

Utility water is suitable for use in point-of-use cleaning and for rinsing a medical device immediately after patient (client) use to remove gross debris. The temperature of the water used for this purpose should not exceed 45 °C to prevent coagulation of blood and other proteins.

Notes:

1) Uncontrolled water is not appropriate to contact medical devices during any rinsing stage. Tap water refers to the location from which the water is obtained as the tap, faucet, or fixture and may not meet the requirements for utility water.

2) Water supply to the sinks used for manual endoscopes cleaning (prior to AER) should be passing through a filtration system (recommended minimum 5 µ). This will prevent potential debris from damaging the scope channels.

Cleaning

Utility water may be used for the cleaning state if it continuously meets the requirements in Table 4 of ANSI/AAMI ST108 and if its characteristics are compatible with appropriate cleaning agents used for CSS (in accordance with the MIFUs). It is important that the utility water be analyzed to determine its characteristics and allow the user, in consultation with the cleaning agent manufacturer, to ensure that a compatible cleaning agent is used.

Automated Cleaning by Medical Washers and Medical Washer-Disinfectors

Automated washers, washer-decontaminators, and washer-disinfectors are used to clean and decontaminate surgical medical devices and medical devices that are intended for being reused that will withstand contact with cleaning agents in an automated cleaning process that can reach temperatures up to 93 °C.

Water is used directly in the automated cleaning, rinsing, and thermal disinfection of medical devices before further handling and preparation for terminal sterilization. The types, quality, and number of water sources depend on the size and type of medical washer or medical washer-disinfector. To achieve the cleaning and disinfection results validated by the manufacturer, the quality of water is important in all stages of the cleaning and disinfection process.

Medical washers and medical washer-disinfectors are equipped with at least one control valve for hot water and one control valve for cold water. A separate control valve for final rinse water is standard on most models and optional on others.

Automated control is provided in medical washers and medical washer-disinfectors that have processing cycles constructed in a progression of treatment stages. The parameters of each treatment stage within a given cycle can vary depending on the medical devices to be processed. All treatment stages require water, and potable water is the minimum acceptable quality. At each treatment stage, the water quality should be compatible with:

a) the material of construction of the medical washer or medical washer-disinfector;
b) the items being processed;
c) the cleaning agents used;
d) the disinfectants used; and
e) the process requirements at each stage.

Note: *Drying as a treatment stage, though important, is not addressed in this Annex.*

Water Quality Factors for Medical Washers and Medical Washer-Disinfectors

The key water quality factors to consider for each cycle stage are as follows:

a) Water hardness: Most medical washers and medical washer-disinfectors can be operated with water having a hardness value of up to 400 ppm as CaCO3, but will tend to be more effective and efficient when the water has a hardness value of less than or equal to 150 ppm as CaCO3. Some medical washers and medical washer-disinfectors are fitted with internal water treatment systems and some cleaning chemistries are formulated to contain chelating agents which are used to protect devices against hard water conditions.

b) Conductivity: Conductivity and resistivity measurements are electrical measurements of the ionic concentration in water. These measurements are mathematical inverses of one another (e.g. > 0.1 MΩ/cm resistivity is equal to <10 µSiemens/cm). Conductivity was selected as the measurement as it is expressed as an upper limit. Ionic contaminants in water used in medical device processing can have a negative impact on medical devices. Because the process that produces Critical Water removes the majority of ionic contaminants, the value for chloride is < 1mg/L and iron is < 0.2 mg/L and the value for copper and manganese is < 0.1 mg/L (i.e., these are the levels achieved by the water treatment process). Such low levels of ionic contaminants will minimize the risk of damage (e.g., discolouration, visible deposits or corrosion). Similarly, utility water should have low levels of chloride, iron, copper, and manganese to ensure that there is no staining or corrosion of medical devices during processing. For steam, it is especially important that chloride ion concentration be minimized to prevent device corrosion; therefore, water used for steam sterilization should have less than 1.0 mg/mL of chloride ions.

   Monitoring the conductivity is a good way to ensure that the ion concentration is not beyond the level expected for that quality of water.

c) pH level: pH for utility water (used for all but the final rinse) at 6.5 – 9.5 while critical water (final rinse) is 5.0 – 7.5. Water that is either too acidic (the pH is less than 6) or too alkaline (the pH is more than 8) can cause pitting and staining of medical devices and shorten their useful lives. The appropriate pH level during the cleaning agent stages (e.g., enzyme, neutral pH, high alkaline wash, neutralizing [acidic] rinse) is specified by the product manufacturer. The manufacturer's directions should be followed.

d) Water temperature: The temperature at which water is supplied to each stage of the process has a major effect on the effectiveness of the process. The user should always consult the manufacturer's specific instructions, because these instructions vary from product to product, even when products are supplied by the same manufacturer.

e) Ionic contaminants (e.g., chloride, heavy metals): Critical Water used in the automated cleaning and disinfection of medical devices should have a chloride concentration less than <1 mg/L to avoid the risk of corrosion. Because chloride concentrations higher than 250 mg/L can cause pitting, the chloride level in the utility water should be kept well below 250 mg/L.

f) Microbial level: The purpose of the decontamination process is to remove soil and reduce the microbial contamination to an acceptable level for the further processing or intended use of the medical devices. The water used at each stage of the medical washer or medical washer-disinfector cycle should not increase the bioburden of the items in the load. The acceptable extent and nature of the microbial contamination in the water supplied to the equipment depends on the stage in the process cycle at which it is used and on the intended use of the decontaminated load at the end of the process. For items that are intended to be used without additional processing, the nature and extent of the microbial population in the final rinse water should not present a potential hazard to the patient (client) (e.g., cause an infection or lead to misdiagnosis). Appropriate treatment to control or reduce the microbial contamination in the water might be required.

g) Bacterial endotoxins: Bacterial endotoxins can be present in utility water because these categories of water will have had no treatment that would remove bacteria or endotoxins. If the incoming water to the washer-disinfector is of this quality, medical devices processed through the cleaning and rinsing process could have residual endotoxins. Medical devices for which residual endotoxins might be a problem should receive a final rinse with critical water, which may be accomplished either by supplying high-purity water to the washer-disinfector for the final rinse or by manually rinsing the medical device with critical water after the washer- disinfector cycle has been completed.

It should be noted that steam quality is affected by the quality of the incoming water. Pre-treatment of the incoming water might be needed to ensure that the steam produced does not cause deposition of residuals when used for steam sterilization of medical devices. As pointed out in a review of water for steam generation in steam sterilization (Arbeitskreis Instrumenten-Aufbereitung, 2004), water used to generate "saturated steam" for steam sterilization needs to be closely monitored to ensure that ions, carbon dioxide, other gases, silicates, and conductivity are at safe levels. Although concerns have been raised regarding endotoxins in steam (Martin and Dailey, 2001; Kober, 2006; Steeves and Steeves, 2006), studies by Flocard et al. (2005) and Whitby and Hitchins (2002) have demonstrated that despite microbial contamination of the water used to generate steam, medical devices exposed to the steam and the steam condensate did not have significant endotoxin levels. Therefore, routine monitoring of endotoxin levels in water used to generate steam is not warranted.

For critical medical devices, pyrogenic reactions are a significant consideration. Duffy et al. (2003) found that when water treatment systems were improved to include DI, filtration, and RO, the pyrogenic reactions associated with the use of reprocessed intravascular critical medical devices dropped from 7.8% to 0.5%. The improvements in water treatment, along with changes in personnel training and in reprocessing and water treatment maintenance procedures, led to a more than 300-fold decrease in endotoxin levels and a five-fold decrease in bacterial counts. It was not possible to isolate the benefit from improvements in water treatment from the benefit gained from changes in reprocessing procedures or personnel training. The pyrogenic reactions observed in this study could have been associated with elevated endotoxin levels in the rinse water, or they could have been caused by the cleaning agent bath, which was noted to be overgrown with bacteria. However, materials containing endotoxins (or other organic residues) or inorganics have been associated with toxic anterior segment syndrome TASS (see Annex N of ANSI/AAMI ST79). The FDA has expressed concern that endotoxins might contribute to TASS (FDA, 2006b), and the American Society of Cataract and Refractive Surgery (ASCRS) and the American Society of Ophthalmic Registered Nurses (ASORN) have recommended that sterile water or deionized/distilled water be used to rinse ophthalmic surgical medical devices (ASCRS and ASORN, 2007). Many manufacturers of ophthalmic surgical medical devices also recommend that medical devices used for cataract surgery be thoroughly rinsed with sterile distilled water. Therefore, it is prudent to ensure that critical water of the recommended quality (see Table D.4) is used for the final rinse of ophthalmic surgical medical devices before steam sterilization.

Not all medical devices require such stringent water quality for reprocessing. However, it is important that the water used in reprocessing be appropriate for the category of medical device being reprocessed.

Water Quality Considerations during Cycle Stages in A Medical Washer or Medical Washer-Disinfector

Note: The following Clauses describe specific water quality requirements for typical cycle stages in a medical washer or medical washer-disinfector. When critical water is not available, utility water (e.g., water meeting the recommendations of Table D.4) can be used in all stages in accordance with the instructions of the equipment manufacturer.

Cleaning and Rinsing Stage

Cold utility water is typically used for the manual cleaning stage to hydrate microbial soil. Water of the appropriate temperature is important for this stage. Water that is too hot during the cleaning stage could cause coagulation of proteins and “fixing” of proteinaceous soil to the medical device surfaces.

The temperature of the water used to pre-clean soiled medical devices should not exceed 45 °C.

Enzymatic Pre-Wash Stage

Provided that the water meets the enzymatic cleaning agent manufacturer's criteria, the water used for the enzymatic pre-wash stage may be utility water. It might be necessary to use treated water for the cleaning stage if the utility water in the area has excessive dissolved minerals or other undesirable characteristics that make it incompatible for use with the cleaning agents recommended for CSS. Critical water is not necessary for this stage of cleaning. The need for treated water in this stage varies from location to location — and possibly from season to season — and the water treatment system manufacturer should be consulted to ensure that the treatment process will be adequate for the specific characteristics of the incoming utility water. Enzymes are biologically active proteins that are sensitive to various environmental conditions, including pH level and water temperature. Users should be aware that product labelling might not supply the optimal range of pH and temperature, but only the pH and temperature at which complete deactivation of the enzymes occurs. Users should consult the manufacturer about the optimum water temperature range and the optimum pH range.

Wash Stage

The cleaning agent selected should be compatible with utility water. Cleaning agent additives are formulated to compensate for variations in the hardness level. The cleaning agent MIFUs should be consulted before critical water is used in main cleaning agent wash stages. Cleaning agent effectiveness is heavily influenced by water temperature and pH level. The cleaning agent manufacturer's recommendations should be followed closely.

Disinfection Stage

Chemical disinfectants should always be used in accordance with the disinfectant MIFUs for time, temperature, and any other conditions specified. If dilution of LCSs or high-level disinfectants is necessary, critical water may be used, provided that the manufacturer of the liquid chemical has validated its use for this purpose.

Most washer-disinfectors primarily provide thermal disinfection. The washer-disinfector MIFUs should be consulted for the target temperature for thermal disinfection. Thermal disinfection is delivered by heated water; the drying cycle in a washer or washer-disinfector contributes to cumulative heat exposure but is not considered the primary basis for thermal disinfection.

Rinse Stages

The water used for the final rinse is very dependent on the category of the medical device. The medical device MIFUs should be consulted before rinsing the medical device. Some manufacturers of medical washers and medical washer-disinfectors recommend that utility water be used for the initial rinse, followed by critical water for the final rinse of all categories of medical devices (see Table D.4). However, if the quality of the water could cause corrosion, tarnishing, or salt deposits, it might be necessary to use various water treatment processes (e.g., softening, DI) to ensure that medical devices are not damaged and that the ensuing disinfection or sterilization process will be effective. For medical devices that will contact the bloodstream or other sterile areas of the body, the final stage in rinsing requires water that does not have excessive levels of organics (e.g., endotoxins or other microbial constituents); therefore, critical water should be used.

The maximum temperature of the rinse water should be compatible with the items being processed.
Some medical devices are temperature-sensitive and can be damaged if the rinse temperature is too high. Despite the costs involved in treating water, using the appropriate water quality for each stage is usually cost-effective.

Automated Cleaning by Ultrasonic Cleaners

Ultrasonic cleaners are used to facilitate the cleaning of jointed and serrated stainless steel medical devices and other medical devices as recommended by the medical device manufacturer.

Ultrasonic cleaning may be used in conjunction with manual cleaning and with medical washers or washer disinfectors.

The key water quality factors to consider for ultrasonic cleaning are

a) water hardness;
b) water temperature;
c) ionic contaminants (e.g., chloride, heavy metals);
d) microbial level; and
e) bacterial endotoxins.

The temperature of the water is also an important factor in ultrasonic cleaning. The equipment MIFUs should be consulted for specific recommendations.

The level of monitoring required for each factor varies with the type of equipment. For example, if the ultrasonic cleaner does not provide a final rinse, the medical device MIFUs for manually rinsing the medical device should be followed. Water quality can be impacted over the period of use and water changes should be performed.

Disinfection and sterilization — General considerations

Water quality is a factor in all disinfection and sterilization processes. If the quality of the water used for steam generation for steam sterilization or thermal disinfection is inappropriate, residues that condense out of the steam onto the medical device can lead to staining or corrosion of medical devices. Furthermore, the quality of water can affect the efficacy of LCSs or high-level disinfectants that are diluted to achieve the correct use-dilution.

The post-disinfection rinse applies only to liquid chemical processes that include a final rinse to remove any residual LCSs or high-level disinfectants. For medical devices processed with LCSs or high-level disinfectants, it is important that the final rinse does not recontaminate the medical device. Therefore, selecting the quality of water for the final rinse must take into account not only the removal of inorganic residuals but also the need to avoid recontamination of the medical device with microorganisms or organic residuals (e.g., endotoxins or other microbial constituents).

The water supply to sterilizers may be used directly or indirectly in the sterilization process to accomplish several vital functions, including the following:

a) As part of the conditioning stage of a steam sterilization cycle, steam may be introduced for the purpose of load conditioning (e.g., air removal and temperature distribution).
b) Water may be used to convey thermal energy to microbial cells to cause denaturation and coagulation within the cells, resulting in bacterial death or sterilization.

Steam sterilizers used in health care settings fall into two general categories: table-top sterilizers and fixed-installation sterilizers.

Table-top steam sterilizers are used extensively in office-based practices and in specialty areas conducting only incidental sterilization activities. Table-top steam sterilizers usually have self-contained water reservoirs that recirculate the water from cycle to cycle within the sterilizer. Because recirculating water reservoirs can become contaminated, strict attention should be given to cleaning the reservoirs and replacing the water supply.

For table-top steam sterilizers that have non-recirculating water systems, a fixed number of cycles can be run before the reservoir water must be replaced. Chemicals in the supply water can affect the materials from which the sterilizer is constructed, so users should carefully follow the sterilizer MIFUs for water quality and quantity. See also ANSI/AAMI ST55.

Fixed-installation systems are provided with integral steam generators or are connected directly to the building steam supply. Steam sterilizers with integral steam generators are usually connected to the building water supply system. The chemistry of the local water supply often varies seasonally. The local water supply is usually chemically treated by the local water authority, which should provide a complete water chemistry analysis on request. Compliance of the local water with the requirements for the steam generator should be verified at installation and re verified periodically over the life of the equipment.

Fixed-installation sterilizers connected directly to the setting's steam distribution system can be viewed as having a relatively large steam supply, but that steam supply is generated and maintained economically for purposes having little in common with steam sterilization needs. The steam boilers in most hospitals, for example, are designed to efficiently generate high-temperature and high-pressure steam to serve HVAC systems and laundry and food-service applications. Steam sterilizers use relatively low-temperature, low-pressure steam at low volumes.

Hospital boiler water treatment might not be ideal for sterilization purposes. Carryover of boiler water treatment chemicals can create unacceptable chemistries within a steam sterilizer.

The water for steam production should be free from contaminants in concentrations that could impair the sterilization process, damage the sterilizer, and damage the medical devices to be sterilized, or leave toxic residues on medical devices. Therefore, integral steam generators are preferable and generally, softened or deionized water is used, but critical water could be used if readily available.

Critical water can be very aggressive and manufactures should be consulted to determine if the sterilizer chamber and piping are appropriate for use with critical water.

It should be noted that many sterilization methods do not completely inactivate endotoxins on a medical device. Therefore, critical water should be used to rinse critical medical devices before sterilization to help reduce the amount of endotoxins on the sterilized medical device and to lessen the chance of a pyrogenic or other adverse patient reaction.

Adapted from CSA Z314-22 Medical Device Reprocessing in Canadian Healthcare Facilities – Annex G

Annex E (informative) Steam Quality:

Notes:
1) This Annex was adapted from ANSI/AAMI ST79 with permission from the Association for the Advancement of Medical Instrumentation, Inc. © 2017 AAMI, https://www.aami.org.

Introduction
This Annex provides guidelines on how to achieve and maintain adequate steam quality for steam sterilization processes.

In table-top sterilizers, critical water is used as the feed water as per MIFUs and steam is generated within the table-top sterilizer. Steam quality
(e.g., steam dryness and levels of non-condensable gas NCGs) for table-top sterilizers is not adjustable by the end user.

General Considerations
Steam systems should be designed to ensure that a continuous and adequate supply of saturated steam is available to the sterilizer. The critical variables are the dryness of the steam, expressed as a dryness fraction and the level of NCG (such as air), expressed as a fraction by volume.

Steam dryness should be at a value between 97% and 100%, and the level of NCG should be at a level at which it will not impair steam penetration into sterilization loads.

Steam pipework should be insulated, and it should be designed so that any condensate flows by gravity in the same direction as the steam, except for vertical rises between floors. This general principle applies equally to steam mains, branch connections, and pipework on the sterilizer itself, especially in situations where the steam is generated in a location remotely located from the sterilizer. Air vents and steam traps should be fitted at each vertical rise. Steam traps should be selected for the specific application, sized and spaced accordingly (e.g., every 60.96 m along the horizontal steam line), or as recommended by steam designs. Care should be taken to trap, drain, and return any condensate that might be collected in pockets in the pipework. Dead legs should be avoided. (A “dead leg” is a section of pipe that leads nowhere and does not form part of a constant circulation system; in a steam line, condensate can form in a dead leg and become stagnant.)

Branch steam lines should exist from the top of the main lines to reduce condensate carryover. The accumulation of condensate during the periods when the sterilizer is not in operation should be avoided, particularly in any part of the pipework and fittings between the take-off from the manifold and the sterilizer chamber. This can be achieved by the correct declination of each portion of pipework and by adequate trapping throughout the steam distribution system.

At installation, an assessment of the steam quality should be made and documented. Steam quality should be maintained by monitoring and controlling the process of generating steam; maintaining steam traps, boilers, and generators in good working order; and periodically assessing sterilization loads for wet packs. A steam separator should be used to remove entrained water and increase the degree of steam saturation, and it should be placed in the steam supply piping as close as possible to the sterilizer.

Steam Dryness

The dryness of the steam is of vital importance to the performance of any steam sterilizer. Excess moisture can cause damp loads in porous materials and uneven temperature distribution in nonporous materials, particularly those containing a large number of small items. Sterilizing conditions might not be attained if the moisture contained in the steam supply is insufficient to prevent the steam from becoming superheated when it expands into the chamber.

Significant deviations in steam dryness are likely to cause the following problems:

a) wet loads, resulting from a dryness value that is too low;

b) superheating (sudden increase in temperature over the saturation point), resulting from either a dryness value that is too high before the pressure-reducing system or from excessive pressure reduction through the valve (superheating can be severe if both conditions are present simultaneously); or

c) difficulties with operation of the pressure-reducing system, resulting from a low pressure-reduction ratio, water hammer, water logging, and/or dirt and other carryover delivered in the steam.

Note: A low dryness value could also lead to sterilization failures due to low temperature readings.

Feed Water

Modern compact, high-rated boilers and steam generators are particularly sensitive to the quality of feed water and are much more likely to prime than boilers of traditional design. Priming or foaming (which results in carryover of boiler water) can result from

a) Under sizing the boilers. The boilers should be designed for, at a minimum, the required peak demand for all steam equipment running at the same time (including washers, cart washers, etc.);

b) treating feed water incorrectly;

c) setting the boiler water level too high;

d) forcing a boiler that needs internal cleaning;

e) violent boiling under fluctuating load conditions; or

f) a high level of TDS (typically 2000 ppm).

Superheated steam is an unsuitable medium for steam sterilization and can cause failure to sterilize, scorching of textiles and paper, and rapid deterioration of rubber. Superheat conditions within the load and chamber could result from adiabatic expansion, exothermic reaction, or both.

Non-condensable Gas (NCGs)

NCGs are defined as gases that cannot be liquefied by compression under the conditions of temperature and pressure used during the sterilization process. They can be simplistically described as air in a steam supply. Low levels of NCGs contained in steam supplied to sterilizers can markedly affect the performance of the sterilizer and the efficacy of the process and lead to inconsistencies in the performance of the sterilizer and in air removal test results.

The most effective way of driving off dissolved air, carbon dioxide, and other NCGs is to degas the boiler feed water before use by heating it in a vented tank (a hot well). This process will also break down bicarbonate ions, driving off more carbon dioxide. For the degassing to be effective, it is important that the temperature of the feed water remain high.

Adapted from CSA Z314-22 Medical Device Reprocessing in Canadian Healthcare Facilities – Annex H

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