



THE APSIC GUIDELINES
FOR DISINFECTION AND STERILISATION OF INSTRUMENTS IN HEALTH
CARE FACILITIES

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Glossary

Activation of a sterilant: process of mixing the contents of a chemical sterilant that comes in two containers (small vial with the activator solution; container of the chemical); keeping the two chemicals separate until use as this extends the shelf life of the chemicals.

Aeration: method by which ethylene oxide (ETO) is removed from ETO-sterilised items by warm air circulation in an enclosed cabinet specifically designed for this purpose.

Antimicrobial agent: any agent that kills or suppresses the growth of microorganisms.

Antiseptic: substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.

Asepsis: prevention of contact with microorganisms.

Automated endoscope reprocessor (AER): machines designed to assist with the cleaning and disinfection of endoscopes in a consistent and reproducible manner

Bactericidal: agent that kills bacteria.

Bioburden: number and types of viable microorganisms with which an item is contaminated; also called *bioload* or *microbial load*.

Biofilm: accumulated mass of bacteria and extracellular material that is tightly adhered to a surface and cannot be easily removed.

Biological indicator (BI): test system containing viable microorganisms providing a defined resistance to a specified sterilisation process, (e.g., *Geobacillus stearothermophilus* for steam and hydrogen peroxide sterilising processes).

Bowie-Dick test: diagnostic test of a steriliser's ability to remove air from the chamber of a steam steriliser with dynamic air removal. The air-removal or Bowie-Dick test is not a test of sterilisation.

Ceiling limit: concentration of an airborne chemical contaminant that should not be exceeded during any part of the workday. If instantaneous monitoring is not feasible, the ceiling must be assessed as a 15-minute time-weighted average exposure.

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

Contact time: time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.

Culture medium: substance or preparation used to grow and cultivate microorganisms.

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

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

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

D value: time or radiation dose required to inactivate 90% of a population of the test microorganism under stated exposure conditions.

Endoscope: an instrument that allows examination and treatment of the interior of the body canals and hollow organs.

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

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

Fungicidal: agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.

Germicidal: agent that destroys microorganisms, especially pathogenic organisms.

High efficiency particulate air (HEPA) filter: a type of high efficiency particulate air filter with an efficiency of 99.97% in the removal of airborne particles 0.3 microns or larger in diameter.

High-level disinfection (HLD): destruction of vegetative bacteria, viruses, fungi and mycobacteria in or on devices, except for small numbers of bacterial spores.

Inanimate surface: non-living surface (e.g., floors, walls, furniture).

Incubator: apparatus for maintaining a constant and suitable temperature for the growth and cultivation of microorganisms.

Infectious microorganisms: microorganisms capable of producing disease in appropriate hosts.

Inorganic and organic load: naturally occurring or artificially placed inorganic (e.g., metal salts) or organic (e.g., proteins) contaminants on a medical device before exposure to a microbiocidal process.

Immediate use steam sterilisation (previously known as flash sterilisation): a process in which sterilised devices are transferred aseptically to the sterile field in the shortest practicable time after removal from the steriliser (most commonly items are unwrapped and must be used immediately).

Implantable device: 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

Lipid virus: virus surrounded by an envelope of lipoprotein in addition to the usual core of nucleic acid surrounded by a coat of protein. This type of virus (e.g., HIV) is generally easily inactivated by many types of disinfectants. Also called an *enveloped* or *lipophilic virus*.

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

Medical device: instrument, apparatus, material, or other article, whether used alone or in combination, including software necessary for its application, intended by the manufacturer to be used for human beings for diagnosis, prevention, monitoring, treatment or alleviation of disease.

Microorganisms: animals or plants of microscopic size. As used in health care, generally refers to bacteria, fungi, viruses, and bacterial spores.

Minimum effective concentration (MEC): the minimum concentration of a liquid chemical germicide needed to achieve the claimed microbiocidal activity as determined by dose-response testing. Sometimes used interchangeably with *minimum recommended concentration*.

Mycobacteria: bacteria with a thick, waxy coat that makes them more resistant to chemical germicides than other types of vegetative bacteria (e.g., *M. tuberculosis*, agent that causes tuberculosis).

Non-lipid viruses: generally considered more resistant to inactivation than lipid viruses. Also called non-enveloped or hydrophilic viruses.

Pasteurization: process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77°C (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.

Permissible exposure limit (PEL): time-weighted average maximum concentration of an air contaminant to which a worker can be exposed, according to OSHA standards; usually calculated over 8 hours, with exposure considered over a 40-hour work week.

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

Parts per million (ppm): common measurement for concentrations by volume of trace contaminant gases in the air (or chemicals in a liquid); 1 volume of contaminated gas per 1 million volumes of contaminated air or 1¢ in \$10,000 both equal 1 ppm. Parts per million = $\mu\text{g/mL}$ or mg/L .

Physical monitoring: is the use of a mechanical device to monitor the physical conditions of the sterilisation process (e.g. graphs, gauges, printouts).

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

Process challenge device (PCD): item designed to simulate product to be sterilised and to constitute a defined challenge to the sterilisation process to assess the effective performance of the process.

Recommended exposure limit (REL): occupational exposure limit recommended by the National Institute for Safety and Health NIOSH as being protective of worker health and safety over a working lifetime, frequently expressed as a 40-hour time-weighted-average exposure for up to 10 hours per day during a 40-hour work week.

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

Small steam steriliser: also known as a tabletop steriliser is a compact steam steriliser that has a chamber volume of not more than 2 cubic feet (60 L) and generates its own steam when distilled or deionized water is added.

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

Spore: relatively water-poor round or elliptical resting cell consisting of condensed cytoplasm and nucleus surrounded by an impervious cell wall or coat. Spores are relatively resistant to disinfectant and sterilant activity and drying conditions (specifically in the genera *Bacillus* and *Clostridium*).

Spore strip: paper strip impregnated with a known population of spores that meets the definition of biological indicators.

Steam quality: steam characteristic reflecting the dryness fraction (weight of dry steam in a mixture of dry saturated steam and entrained water) and the level of non-condensable gas (air or other gas that will not condense under the conditions of temperature and pressure used during the sterilisation process). The dryness fraction (i.e., the proportion of completely dry steam in the steam being considered) should not fall below 97%.

Steam sterilisation: sterilisation process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilising agent.

Sterile or **Sterility:** state of being free from all viable microorganisms. In practice, usually described as a probability function, e.g., as the probability of a viable microorganism surviving sterilisation being one in one million.

Sterility assurance level (SAL): probability of a single viable microorganism being present on a product unit after sterilisation. Usually expressed as 10^{-6} ; a SAL of 10^{-6} means $\leq 1/1$ million chance that a single viable microorganism is present on a sterilised item.

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

Sterilisation area: area of a health-care facility designed to house sterilisation equipment, such as steam ethylene oxide, hydrogen peroxide gas plasma, or ozone sterilisers.

Steriliser: apparatus used to sterilize medical devices, equipment, or supplies by direct exposure to the sterilising agent.

Steriliser, gravity-displacement type: type of steam steriliser in which incoming steam displaces residual air through a port or drain in or near the bottom (usually) of the steriliser chamber. Typical operating temperatures are 121–123°C and 132–135°C.

Steriliser, pre-vacuum type: type of steam steriliser that depends on one or more pressure and vacuum excursions at the beginning of the cycle to remove air.³ This method of operation results in shorter cycle times for wrapped items because of the rapid removal of air from the chamber and the load by the vacuum system and because of the usually higher operating temperature (132–135°C). This type of steriliser generally provides for shorter exposure time and accelerated drying of drape and packaged loads by pulling a vacuum during the exhaust (drying) phase.

Steriliser, steam-flush pressure-pulse type: type of steriliser in which a repeated sequence consisting of a steam flush and a pressure pulse removes air from the sterilising chamber and processed materials using steam at above atmospheric pressure (no vacuum is required). Like a pre-vacuum steriliser, a steam-flush pressure-pulse steriliser rapidly removes air from the sterilising chamber and wrapped items; however, the system is not susceptible to air leaks because air is removed with the sterilising chamber pressure at above atmospheric pressure. Typical operating temperatures are 121–123°C, 132–135°C.

Terminal sterilisation: The process in which a product is sterilised within its packaging and sterility is maintained until point of use.

Vegetative bacteria: actively growing / reproducing bacteria that are devoid of spores and usually can be readily inactivated by many types of germicides.

Virucidal: Germicide that inactivates viruses

References

1. CDC Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008
2. Best Practices for Cleaning, Disinfection and Sterilisation of Medical Equipment/Devices in All Health Care Settings, 3rd edition. Provincial Infectious Diseases Advisory Committee (PIDAC). May 2013.

Introduction

General principles

The goals of effective and safe reprocessing of medical equipment/devices include:

- a) Preventing transmission of microorganisms to personnel and clients/patients/residents;
and
- b) Minimizing damage to medical equipment/devices from foreign material (e.g. blood, body fluids, saline and medications) or inappropriate handling.
- c) Protecting health-care personnel from injury through use of hazardous germicides (e.g., glutaraldehyde)
- d) Present each device to the required level of disinfection or sterilization as required for safe reuse

Sterilisation refers to a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods. Steam under pressure, dry heat, ethylene oxide gas, hydrogen peroxide gas plasma, and liquid chemicals are the principal sterilising agents used in health-care facilities.

Disinfection refers to a process that eliminates all pathogenic microorganisms, except bacterial spores, on inanimate objects.

In general, Spaulding Classification System is used in determining appropriate method of reprocessing of patient-care items and equipment. The system classifies a medical device as critical, semi-critical, or non-critical on the basis of risk to patient safety from contamination on a device. The system also established three levels of germicidal activity (sterilisation, high-level disinfection, and low-level disinfection) for strategies with the three classes of medical devices (critical, semi-critical, and non-critical).

Best practices in reprocessing medical equipment/devices must include the following:

- a) Adequate review by all parties whenever new equipment/devices are being considered for

- purchase (e.g. reprocessing committee);
- b) A centralised area for reprocessing (Central Sterile Supplies Department, CSSD) or an area that complies with the requirements for reprocessing;
 - c) Written policies and procedures for reprocessing each type of medical equipment/device;
 - d) Training of all staff who perform reprocessing at initiation of employment and at least yearly with yearly competency testing (written and observation);
 - e) Verification of cleanliness, decontamination or sterility and function of the reprocessed equipment/device;
 - f) Continual monitoring of reprocessing procedures to ensure their quality;
 - g) A corporate strategy for dealing with single-use and single-patient use medical equipment/devices;
 - h) Management and reporting of medical incidents;
 - i) Management and reporting of safety-related accidents;
 - j) Complete and proper documentation of all reprocessed items for traceability, recall of improperly reprocessed devices and legal purposes.; and
 - k) Procedures to be followed in emergency situations (e.g. utilities shutdowns, compromised packaging, biological indicator (BI) testing failures).

Decisions related to reprocessing medical equipment/devices should be made by a multi-disciplinary Infection Control Committee that includes the individuals responsible for purchasing the equipment/device, reprocessing the equipment/device, maintaining the equipment/device, infection prevention and control, occupational health and safety, and the end-user of the equipment/device.

It is strongly recommended that, wherever possible, reprocessing should be performed in a centralised area that complies with the physical and human resource requirements for reprocessing.

When formulating written policies and procedures, the following steps in reprocessing must be included:

- a) Collection at point-of-use, containment and transport in an appropriate container with a biohazard label;
- b) Initial cleaning to remove all blood, protein and debris before transport for further cleaning and disinfection or sterilization
- b) Disassembly (if required);
- c) Inspection;
- d) Cleaning;
- e) Disinfection/sterilisation (including establishment of the level of reprocessing required for items, based on Spaulding's Classification and manufacturer's instructions) – sterile items should be packaged in an appropriate container/wrap to maintain sterility – ideally high level disinfected items should be placed in an appropriate container/wrap to maintain cleanliness
- f) Rinsing (following disinfection);
- g) Drying/aeration;
- h) Inspection, reassembly, functional testing, proper labelling and packaging (where required);
- k) Clean transportation; and
- l) Storage and handling in manner that prevents recontamination.

It is essential that an overall inventory of all reprocessing practices within the healthcare setting is done, including documentation as to where, how and by whom all equipment/devices are being reprocessed and whether current standards are being met, as set out in this document. All processes must continue to be audited on a regular basis (e.g. at least annually), with clear and known consequences resulting from non-compliance.

As new reprocessing technologies and processes become available, they must be evaluated against the same criteria as current methodologies. Verify that:

- a) The process is compatible with the equipment/device being reprocessed;
- b) The process is compatible with the cleaning products being used;
- c) Environmental issues with the process have been considered (e.g. odours, toxic waste

products, toxic vapours);

- d) Occupational health issues with the process have been considered (e.g. is PPE or special ventilation required);
- e) Staff education and training is available (provided by the manufacturer);
- f) The facility is able to provide the required preventive maintenance;
- g) The process can be monitored (e.g. there are physical, chemical and biologic monitors and indicators available);
- h) Quarantine of non-implantable items in processed loads pending results of biological indicator (BI) testing (if load quarantine is not possible, evaluation of a Type 5 or 6, category i chemical indicator (CI) and specific cycle physical parameters may be used to justify the release of loads); and
- i) Quarantine of each load containing implantable devices pending results of BI testing.
- j) Is cost effective compared to other technologies.

Single use devices

Health care settings must have written policies regarding single-use medical equipment and devices. Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done according to institutional and governmental policy.

Health care settings that wish to have their single-use medical equipment/devices reprocessed should ensure that the facilities and procedures have been certified by a regulatory authority or an accredited quality system auditor to ensure the cleanliness, sterility, safety and functionality of the reprocessed equipment/devices. In order to have critical or semi-critical medical equipment/devices reprocessed by one of these facilities, there must be processes for:

- a) Tracking and labelling equipment/devices;

- b) Recalling improperly reprocessed medical equipment/devices;
- c) Assuring proof of sterility or high-level disinfection;
- d) Testing for pyrogens;
- e) Maintenance of equipment/device functionality and integrity;
- f) Quality assurance and quality control;
- g) Reporting adverse events; and
- h) Provision of good manufacturing procedures.

Whereas reusable medical equipment/devices are sold with instructions for proper cleaning and sterilisation, no such instructions exist for single-use medical equipment/devices. Furthermore, manufacturers of single use equipment/devices often have not provided data to determine whether the equipment/device can be thoroughly cleaned, whether the materials can withstand heat or chemical high-level disinfection or sterilisation, or whether delicate mechanical and electrical components will continue to function after one or more reprocessing cycles. In circumstances where the manufacturer does not approve of reuse, the facility will bear the brunt of legal responsibility in establishing when and under what conditions reuse of medical equipment/devices presents no increased risk to patients and that a reasonable standard of care was adhered to in the reuse of the equipment/device. This would involve written policies, extensive testing of reprocessing protocols and strict adherence to quality assurance investigations. This is a detailed and expensive process and should only be undertaken if there is a compelling reason to do so.

Periodic regular infection control rounds to areas using sterilisers to standardize the steriliser's use may identify correctable variances in operator competence; documentation of sterilisation records, including chemical and biological indicator test results; steriliser maintenance and wrapping; and load numbering of packs. These rounds also may identify improvement activities to ensure that operators are adhering to established standards.

Factors Affecting the Efficacy of the Reprocessing Procedure

Policies and procedures for disinfection and sterilisation must include statements and information relating to factors that might affect the effectiveness of reprocessing. These procedures must be readily accessible to staff doing the reprocessing.

Many factors affect the efficacy of reprocessing, particularly when chemical reprocessing is used. These factors include:

a) Cleanliness of the surface of the equipment/device:

- i. Many chemical disinfectants/sterilants are inactivated by organic material; cleaning must always precede further processing;
- ii. If there is bioburden present, the equipment/device cannot be disinfected or sterilised effectively;
- iii. Pitting corrosion can give greater risk of infection since microorganism can be trapped inside the corrosion. In addition, pitted instruments may cause injury to patients (e.g., fine instruments used in ocular surgery)

b) Characteristics of equipment/device:

- i. Long, narrow lumens and channels are difficult to clean;
- ii. Materials such as rubber and plastic may require special treatment;
- iii. Rough or porous surfaces may trap microorganisms (e.g. ridges, ribbing, grooves, and articulations); and
- iv. Hinges, cracks, coils, valves, joints, clamps, crevices on the equipment/device may impede successful disinfection/sterilisation.

c) Type and concentration of the product:

- i. Products used for disinfection and/or sterilisation must be prepared according to the manufacturer's recommendations in order to achieve the correct dilution; if the concentration of the disinfectant is too low, the efficacy will be decreased; if the

concentration is too high, the risk of damage to the instrument or toxic effects on the user increases;

- ii. Dry equipment/devices after cleaning, before immersing in disinfectant, to prevent dilution of the disinfectant;
- iii. Discard solutions on or before expiry date; diluted products are inherently unstable once mixed and the manufacturer's directions as to duration of use must be followed;
- iv. Use chemical test strips for all high-level liquid disinfectants to assess their efficacy; during each reuse, the concentration of active ingredients may decrease as dilution of the product occurs and organic impurities accumulate;
- v. Use the appropriate disinfectant/sporicide for the task; infection prevention and control must approve disinfectants and their application; and
- vi. Some microorganisms are more intrinsically resistant to disinfectants/sporicides, and this must be taken into consideration when choosing the product/process.

d) Duration and temperature of exposure to the product:

- i. Use Spaulding's Classification (see Table 2) for the level of disinfection/sterilisation required for the intended use of the equipment/device and minimum exposure time to disinfectants/sterilants to achieve this level;
- ii. Use manufacturer's recommendations for temperature and for exposure time required to achieve the desired level of disinfection/sterilisation; do not exceed the manufacturer's maximum exposure time, as some chemicals may cause damage to the medical equipment/device if used for extended periods of time;
- iii. All surfaces of the article must be in direct contact with the disinfectant/sterilant; and
- iv. Contact may be compromised by the complexity of the article and the ability of the disinfectant to penetrate lumens etc.

e) Physical and chemical properties of the reprocessing environment:

- i. Water hardness can affect some disinfectants;
- ii. Excessive humidity may compromise sterile wrappings; and
- iii. The pH of the solution may be an important consideration, as extremes of acidity or alkalinity affect growth of microorganisms or alter the activity of disinfectants and sterilants.

f) Post disinfection treatment:

Some disinfectants have to be removed following exposure to prevent harm to the patient and user. Sterile water should be used for thorough rinsing to make sure the device is not re-contaminated.

Unacceptable methods of disinfection/sterilisation

The following methods of disinfection/sterilisation are **NOT** recommended.

A. Boiling

The use of boiling water to clean instruments and utensils is not an effective means of sterilisation. Boiling water is inadequate for the destruction of bacterial spores and some viruses.

B. Ultraviolet Irradiation

The germicidal effectiveness of ultraviolet (UV) radiation is influenced by organic matter, wavelength, type of suspension, temperature, type of microorganism and UV intensity. The latter is affected by distance and dirty tubes. The application of UV light in the health care setting is limited to the destruction of airborne organisms (e.g. ventilation ducts) or inactivation of microorganisms located on surfaces (e.g. laboratory hoods). It is not an acceptable method of disinfection/sterilisation for medical equipment/devices.

C. Glass Bead Sterilisation

Glass bead sterilisers use small glass beads and high temperature for brief exposure times to inactivate microorganisms. Glass bead sterilisers are difficult to monitor for effectiveness, have inconsistent heating resulting in cold spots, and often have trapped air which affects the sterilisation process. The U.S. Food and Drug Administration has determined that a risk of infection exists with this equipment because of their potential failure to sterilize dental instruments and has required their commercial distribution cease until the device has received FDA clearance. Glass bead sterilisation is not an acceptable method of sterilisation for medical equipment/devices.

D. Chemiclave

Unsaturated chemical-vapour sterilisation ('chemiclave') involves heating a chemical solution of primarily alcohol with 0.23% formaldehyde in a closed pressurized chamber. Because of the environmental risks associated with formaldehyde, this method of sterilisation is discouraged. If used, it must be closely monitored and local regulations for hazardous waste disposal must be followed and air sampling for toxic vapours may be indicated.

E. Microwave Oven Sterilisation

Microwave ovens are unreliable and difficult to monitor for effective sterilisation. Home microwaves have been shown to inactivate bacteria, viruses, mycobacteria and some spores, however there may not be even distribution of microwave energy over the entire device. More research and testing is required to validate the use of microwave ovens for sterilisation. The use of microwave ovens for sterilisation of medical equipment/devices is not currently acceptable.

Recommendations

1. Critical medical and surgical devices and instruments that enter normally sterile tissue, body space or vascular system must be sterilised before use. (IA)

2. Steam sterilisation is the preferred method for sterilising critical medical and surgical devices and instruments that are not damaged by heat, steam, pressure, or moisture. (IA)
3. High-level disinfection is required for semi-critical patient care equipment. (IA)
4. Noncritical patient care devices are disinfected when visibly soiled and on regular basis. (IIB)
5. Standard sterilisation and disinfection procedures are adequate for patient care equipment used on patients with blood-borne pathogens, MDRO including multiply resistant *Mycobacterium tuberculosis* except prions. (IA)
6. The following methods are not acceptable for achieving disinfection/sterilisation: (IIIB)
 - Boiling
 - Ultraviolet light
 - Glass bead sterilisation
 - Microwave ovens
 - Chemiclave sterilisation
7. Needles must be single-use and must not be reprocessed. (IA)
8. The health care setting must have written policies regarding single-use medical equipment/devices. (IIIA)
9. Critical and semi-critical medical equipment/devices labelled as single-use must not be reprocessed and re-used unless the reprocessing is done by a licensed reprocessor. (IIA)
10. It is strongly recommended that catheters, drains and other medical equipment/devices with small lumens (excluding endoscopy equipment) be designated single-use and not be reprocessed and re-used, even if designated as reusable by the manufacturer. (IIA)
11. It is strongly recommended that, wherever possible, reprocessing should be performed in a centralised area that complies with the physical and human resource requirements for reprocessing. (IIIB)
12. Persons performing high-level disinfection and/or sterilization should be trained on the science and methods of disinfection/sterilization at initiation of employment and at least yearly. They should

undergo competency testing (written and observation at the initiation of employment and at least yearly).

13. Persons performing high-level disinfection and/or sterilization should be trained on the proper use of personal protective equipment relevant to the method being used. The health care facility should make available appropriate personal protective equipment.

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Figure 1

Decreasing order of resistance of microorganisms to disinfection and sterilisation and the level of disinfection or sterilisation (Reference: CDC Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008)

Resistant Level	Level / method of disinfection & sterilisation
Resistant	
↓ Prions (Creutzfeldt-Jakob Disease)	Prion reprocessing
↓ Bacterial spores (<i>Bacillus atrophaeus</i>)	Sterilisation
↓ Coccidia (<i>Cryptosporidium</i>)	
↓ Mycobacteria (<i>M. tuberculosis</i> , <i>M. terrae</i>)	High
↓ Nonlipid or small viruses (polio, Cocksackie)	Intermediate
↓ Fungi (Aspergillus, Candida)	
↓ Vegetative bacteria (<i>S. aureus</i> , <i>P. aeruginosa</i>)	Low
↓ Lipid or medium-sized viruses (HIV, herpes, hepatitis B)	
Susceptible	

Facility design: Environmental Requirements for Reprocessing Areas

A. Physical Space

There must be a centralised area for reprocessing medical equipment/devices. Reprocessing performed outside the centralized area must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space. If centralised reprocessing is not possible, consistent policies and procedures between locations are to be in place. In smaller settings, such as clinics or offices in the community, this refers to any segregated area where reprocessing of equipment/devices takes place, away from clients/patients/residents and clean areas.

The CSSD size is appropriately designed with regard to anticipated volume. The central processing area(s) ideally should be divided into at least three areas: cleaning, packaging, and sterilisation and storage. Physical barriers should separate the cleaning area from the other sections to contain contamination on used items.

In the cleaning area, reusable contaminated supplies (and possibly disposable items that are reused) are received, sorted, and decontaminated. The recommended airflow pattern should contain contaminants within the cleaning area and minimize the flow of contaminants to the clean areas.

The American Institute of Architects recommends negative pressure and no fewer than six air exchanges per hour in the cleaning area (AAMI recommends 10 air changes per hour) and 10 air changes per hour with positive pressure in the packaging and steriliser equipment rooms.

The environment where cleaning is performed must:

- a) Have adequate lighting;
- b) Have adequate space for the cleaning process and storage of necessary equipment and supplies;
- c) Be distinctly separate from areas where clean/disinfected/sterile equipment/devices are handled or stored (i.e., separation of clean and dirty areas);
- d) Have easy access to hand hygiene facilities separate from the sinks used to clean devices ;

- e) Have surfaces that can be easily cleaned and disinfected;
- f) Have slip-proof flooring that can withstand frequent wet mopping and hospital-grade cleaning and disinfecting products; and
- g) Have restricted access from other areas in the setting and ensure one-way movement by staff;
- h) Have a spill kit in a readily accessible position; and
- i) Have adequate ventilation to remove fumes from disinfectants used in high level disinfection.

Cleaning work areas shall be physically separated from clean and other work areas by walls or partitions to control traffic flow and to contain contaminants generated during the stages of cleaning. Walls or partitions should be cleaned regularly and be constructed of materials that can withstand cleaning and disinfection.

Cleaning sinks should:

- a) Be designed and arranged to facilitate soaking, washing and rinsing of equipment/devices with minimal movement or delay between steps;
- b) Be adjacent to waterproof counter tops and a backsplash;
- c) Drain freely and not have an overflow;
- d) Be at a height that allows workers to use them without bending or straining;
- e) Be large enough to accommodate trays or baskets of instruments;
- f) Be deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning;
- g) Be equipped with water ports for the flushing of instruments with lumens, if appropriate; and
- h) Have three compartments for soaking, cleaning and rinsing.
- i) Not be used for hand washing

The packaging area is for inspecting, assembling, and packaging clean, but not sterile equipment or

devices.

The sterile storage area should be a limited access area with a controlled temperature (may be as high as 24°C) and relative humidity (30-60% in all work areas except sterile storage, where the relative humidity should not exceed 70%).

The floors and walls should be constructed of materials capable of withstanding chemical agents used for cleaning or disinfecting. Ceilings are flush surfaces and not made of materials that are of a particulate or fibre-shedding composition.

Hand hygiene facilities should be located in all personnel support areas and at all entrances to, and exits from, the cleaning area. Hand hygiene facilities should include:

- a) Accessible hand washing sinks with hands-free controls, soap dispensers and paper towels;
and/or
- b) Alcohol-based hand-rub (ABHR).

Table 1 Design parameters (Example from ANSI/ASHRAE/ASHE standard 170-2008)

Location	Pressure relationship to adjacent areas	Minimum outdoor ACH	Minimum total ACH	All room air exhausted directly to outdoors	Air re-circulated by means of room units	Relative humidity (%)	Temperature (°C)
Cleaning room	Negative	2	6	Yes	No	No requirement	22-26
Clean workroom	Positive	2	4	No requirement	No	No requirement	22-26
Sterile storage	Positive	2	4	No requirement	No requirement	Maximum 60	22-26
Steriliser equipment room	Negative	No requirement	10	Yes	No	No requirement	No requirement

The area used to reprocess endoscopes must include:

- a) Adequate space for the storage and holding of clean and soiled equipment/devices that is separate from other activities and controlled to prohibit public contact;
- b) Dedicated processing room(s) for cleaning and disinfecting endoscopes and accessories that are physically separated from clean areas, client/patient/resident care areas and procedure rooms;
- c) Within processing/cleaning rooms, utility sink(s) appropriate to the volume of work and method of disinfection;
- d) Dedicated hand hygiene sink(s);
- e) Eye-washing facilities;
- f) Sufficient cleanable counter space to handle the volume of work;
- g) Space and utility connections for automatic endoscope reprocessor(s) (AER), if used;
- h) Ventilation system that will remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents;
 - i. The vapour concentration of the chemical disinfectant used shall not exceed allowable limits (e.g., 0.05 ppm for glutaraldehyde);
 - ii. Air-exchange equipment (e.g., ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapours;
 - iii. In-use disinfectant solutions must be maintained in closed, covered, labelled containers at all times; and
 - iv. Air quality should be monitored on a scheduled basis to ensure control of vapours; and
- i) Clean equipment room(s), including storage, should protect the clean equipment from contamination.

B. Air Quality

Occupational exposure limits such as ceiling exposure value (CEV) for chemical agents (e.g. glutaraldehyde, ethylene oxide) are to be complied with in accordance to local environmental law. A CEV

is the maximum airborne concentration of a chemical agent to which a worker is exposed at any time. If control measures are not available during reprocessing involving a chemical agent, air sampling may be required to ensure that the regulated limit has not been exceeded for the chemical being used. (Reference: CDC Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008)

The health care setting must have air changes; temperature and humidity appropriate to the process/product being used. In health care settings where there are dedicated central reprocessing areas, negative pressure airflow must be maintained in cleaning areas and positive pressure airflow must be maintained in clean areas and be monitored.

C. Water Quality

The health care setting should be aware of the quality of its water supply and develop policies to address known problems. There should be written reprocessing contingency plans in place that address loss of potable water, boil water advisories and other situations where the water supply becomes compromised. The health care facility should have a written policy on how to manage a water spill including potable water and contaminated water.

D. Environmental hygiene

The housekeeping (i.e., environmental service) department should consult with the management of the CSSD and infection prevention and control to establish policies and procedures for cleaning practices and cleaning frequency. As a minimum:

- a) The facility shall have written cleaning procedures with clearly defined responsibilities for all areas in the facility where decontamination is performed;
- b) All work areas, stands, tables, countertops, sinks and equipment surfaces shall be cleaned with hospital approved agents and disinfected at least daily when in use;
- c) Floors shall be cleaned at least daily;

- d) If a spill occurs, the affected area shall be cleaned immediately and disinfected if contaminated;
- e) Sinks shall be cleaned each shift at a minimum and more frequently as necessary;
- f) Sinks used for cleaning endoscopes and respiratory equipment shall be cleaned between each use;
- g) The sequence of cleaning shall be from clean areas to dirty areas, from high areas to low areas (i.e., top of walls to floor) and from least contaminated to most contaminated;
- h) Cleaning staff shall not move back and forth between clean and dirty areas; and
- i) Cleaning equipment used in the dirty area shall not be used in any other area.

Recommendations

1. The cleaning work area must be physically separated from clean areas by walls or partitions. (IIA)
2. Reprocessing performed outside the CSSD must be kept to a minimum and must be approved by the Infection Control Committee or those accountable for safe reprocessing practices and must conform to the requirements for reprocessing space. (IIIB)
3. Wherever chemical disinfection/sterilisation is performed, air quality must be monitored when using products that produce toxic vapours and mists. (IA)
4. There must be a regular schedule for environmental cleaning in the CSSD that includes written procedures and clearly defined responsibilities. (IIB)

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Policies and Procedures

A. Introduction

Policies and procedures must be established to ensure that the disinfection and sterilisation processes follow the principles of infection prevention as set out by CDC, WHO or the country Ministry of Health. Completed policies and procedures should be reviewed and approved by the Infection Prevention and Control Committee. They must be readily accessible to staff doing the reprocessing. Review of reprocessing policies and procedures must take place at least annually.

Reprocessing policies and procedures shall include the following:

- a) Written protocols for each component of reprocessing: the cleaning, disinfection and/or sterilisation processes that are based on the manufacturer's recommendations and established guidelines for the intended use of the product;
- b) Documentation and maintenance of records for each process; on-going audits of competency and procedures (who, when, how);
- c) Procedures for the recall and reprocessing of improperly reprocessed medical requirements for internal or external subcontractors, if applicable written a protocol that prevents the release of loads containing implantable devices pending results of BI testing equipment/devices;
- d) Selection of product/process for reprocessing; and
- e) Procedures for procurement of medical devices.
- f) The Safety data sheet (SDS) {may be referred to as the material safety data sheet {MSDS} or product safety data sheet {PSDS}} for each chemical used (e.g., peracetic acid) should be readily available.

The contents of reprocessing policies and procedures shall include the following:

- a) Statements and information relating to factors that might affect the effectiveness of reprocessing;
- b) Responsibilities of management and staff;
- c) Qualifications, education and training for staff involved in reprocessing;

- d) Infection prevention and control activities;
- e) Health care personnel health and safety activities;
- f) Preventive maintenance requirements with documentation of actions;
- g) Provision for annual review of policies and procedures with updating as required; and
- h) Management and reporting to administration or appropriate regulatory body of incidents where healthcare workers and patient safety may have been compromised.
- i) A biohazard label should be placed on any container used to transport or store devices or equipment that may be contaminated with blood or body fluids capable of transmitting a blood borne pathogen (i.e., HIV, HBV, HCV).

B. Selection of Product/Process for Reprocessing

The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device. The process and products used for cleaning, disinfection and/or sterilisation of medical equipment/devices must be compatible with the equipment/devices:

- a) Compatibility of the equipment/device to be reprocessed to detergents, cleaning agents and disinfection/sterilisation processes is determined by the manufacturer of the equipment/device; and
- b) The manufacturer must provide written information regarding the safe and appropriate reprocessing of the medical equipment/device.

Reprocessing Process

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

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

Classification	Definition	Level of Processing/ Reprocessing	Examples
Critical	Equipment/device that enters sterile tissues, including vascular system	Cleaning followed by sterilisation	Surgical instruments, biopsy instruments
Semi-critical	Equipment/device that comes into contact with non-intact skin or mucous membranes but do not penetrate them	Cleaning followed by high-level disinfection (at a minimum). Sterilisation is preferred	Respiratory therapy equipment, anaesthesia equipment, tonometers
Non-critical	Equipment/device that touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by low-level disinfection	ECG machines, oximeter, bedpans, urinals, commodes, blood pressure cuffs, crutches, computers, bed rails, bedside tables, patient furniture and floors

All medical equipment/devices that will be purchased and/or will be reprocessed must have written device specific manufacturer's cleaning, disinfection and/or sterilisation instructions. If disassembly or reassembly is required, detailed instructions with pictures must be included. It is recommended that hospitals or healthcare facilities follow the written, updated instruction (e.g. Instructions for Use [IFU], Product Insert) provided by the device manufacturers on how their devices should be cleaned, disinfected or sterilised. To achieve this, staff training must be provided on these processes before the medical equipment/device is placed into circulation.

Reprocessing Products

Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilisation) must be:

- a) Appropriate to the level of reprocessing that is required for the use of the medical equipment/device;
- b) Approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise (e.g., facility's

infection prevention and control professionals, public health staff with training in infection prevention and control, regional infection prevention and control network).

C. Continued Monitoring and System Failures Recalls

Reasons for recall can be as a result of improperly sterilised product being used in an event.

A written procedure must be established for the recall and reprocessing of improperly reprocessed medical equipment/devices.

All equipment/devices in each processed load must be recorded to enable tracking in the event of a recall. The recall procedure should include:

- a) Outline the circumstances for issuing a recall;
- b) Designation of department and staff responsible for executing the recall;
- c) Identification of the medical equipment/devices to be recalled; if recall is due to a failed BI, the recall shall include the medical devices in the failed load as well as all other devices processed in the steriliser since the last negative growth BI;;
- d) Assessment of client/patient/resident risk;
- e) Procedure for subsequent notification of physicians, patients, other facilities and/or regulatory bodies, if indicated; and
- f) Involvement of the facility's risk manager, if applicable.
- g) Actions to be carried out;
 - a. Include all items processed back to the last negative BI
 - b. Identify the sterilisation lot numbers and devices to be recalled
 - c. Recording of the items recalled and specify the action to be taken by the person receiving the notification

Health care facilities shall have a process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies.

Health care facilities shall have a policy for evaluation of exposure events in which a potentially inadequately disinfected or sterilized device or instrument was used on a patient (See Weber DJ, RutalaWA. Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. Am J Infect Control. 2013 May;41(5 Suppl):S67-71).

Following completion of the recall a report should be written that includes:

- a) The circumstances that prompted the recall
- b) Specification of the corrective actions taken to prevent it happening again
- c) Identification of the total number of devices intended to be recalled and the number actually recalled
- d) Verification that the recalled items were reprocessed or destroyed as appropriate.

D. Procedures for Procurement of Medical Devices

Procedures for procurement of medical devices should be pursuant to EN ISO 17664 to ensure the possibility of reprocessing prior to purchase.

Procedures for procurement of medical devices should include:

- a) Factors that will be considered during the selection process;
- b) Department where medical device is to be used;
- c) Manufacturers;
- d) Medical device designation; and
- e) The methods that can be used for reprocessing.

Factors considered during the selection process should based on

- Clinical need;
- Clinical suitability;
- Whole life costs;

- Maintenance processes;
- Disinfection and sterilisation processes;
- Cost and availability of consumables;
- Cost and availability of spare parts;
- Supplier product support; and
- User and service training provision.

A checklist for procurement of medical devices should be filled with the signature of manufacturers, users, Infection Prevention and Control officers and CSSD managers signature e.g. the World Federation for Hospital Sterilisation Sciences (WFHSS) checklist (Guideline No.02 November 2011).

E. Loaned instruments

It is common practice for medical devices to be brought into the CSSD on loan with the purpose of

- Trial or evaluation;
- Provided for research;
- To replace devices that are being repaired;
- Provided as part of a disposable procurement arrangement; and
- Provided as devices that are lacking and have not been bought.

Medical devices loaned are subject to the same risks for patient and user safety as medical devices sited in CSSD and must therefore be managed appropriately.

The procedures should include the following:

- Ensuring loan instruments are properly reprocessed prior to use, that the company supplying have an indemnity agreement if required, and the set(s) of instruments are uniquely identified to ensure traceability.

- All loaned devices must only be used by staff who have been trained adequately in the use of the equipment. Adequate user instructions should be available to allow for the safe use of the device.
- All loaned devices being returned to a manufacturer/supplier must be reprocessed prior to release.
- All loaned devices must be delivered a minimum of 24 hours prior to use to allow for reprocessing before use. If the suppliers have reprocessed the devices, the supplier must provide documentation that decontamination has been performed.
- A comprehensive delivery note/checklist (received and returned) should be performed between the suppliers and receivers.

Recommendations

1. The health care facility will, as a minimum, have policies and procedures for all aspects of reprocessing that are based on current recognized standards/recommendations and that are reviewed at least annually. (IIIA)
2. All policies and procedures for reprocessing medical equipment/devices require review and approval by the Infection Prevention and Control Committee. (IIIA)
3. Procedures for disinfection and sterilisation must include statements and information regarding the type, concentration and testing of chemical products; duration and temperature of exposure; and physical and chemical properties that might have an impact on the efficacy of the process. These procedures must be readily accessible to staff performing the function. (IIA)
4. The reprocessing method and products required for medical equipment/devices will depend on the intended use of the equipment/device and the potential risk of infection involved in the use of the equipment/device. (IIIA)
5. A procedure should be established for the recall of improperly reprocessed medical equipment/devices. (IIA)

6. The recall procedure should include assessment of client/patient/resident risk and a procedure for subsequent notification of physicians, clients/patients/residents, other facilities and/or regulatory bodies if indicated. (IIA)
7. A process for receiving and disseminating medical device alerts and recalls originating from manufacturers or government agencies should be described. (IIIA)
8. Products used for any/all stages in reprocessing (i.e., cleaning, disinfection, sterilisation) must be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise. (IIIA)
9. Products used for any/all stages in reprocessing must be appropriate to the level of reprocessing that is required for the use of the medical equipment/device. (IIIA)
10. The process and products used for cleaning, disinfection and/or sterilisation of medical equipment/devices must be compatible with the equipment/devices. (IIA)
11. All medical equipment/devices that will be purchased and will be reprocessed must have written device-specific manufacturer's cleaning, disinfection and sterilisation instruction. If disassembly or reassembly is required, detailed instructions with pictures are highly recommended. Staff training must be provided on these processes before the medical equipment/device is placed into circulation, (IIA)

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Occupational Health and Safety for Reprocessing

An Occupational Health and Safety review is recommended for all protocols for reprocessing medical equipment/devices to verify that staff safety measures are followed and are in compliance with the local Occupational Health and Safety Act. This review will verify that:

- a) Sharps are handled appropriately and disposed of correctly at point of use;
- b) Local exhaust ventilation systems adequately protect staff from toxic vapours;
- c) Chemicals are labelled, stored and handled appropriately, and Safety Data Sheets (SDS) are readily available;
- d) An eyewash fountain, separate from other cleaning facilities/sinks, is installed to prevent a potential hazard to the eye due to contact with a biological or chemical agent; and
- e) Personal protective equipment such as elbow length impervious insulated gloves for unloading the autoclave is present and complies with regulatory requirements. Procedures must be in place for immediate response to staff exposure to blood and body fluids or injury from sharp objects. All staff working in reprocessing must be immune to Hepatitis B or receive Hepatitis B immunization.
- f) National fire safety regulations are complied with.
- g) Personnel who read color-coded test strips have appropriate vision (i.e., are not colour blind)
- h) If latex gloves are used, new staff should be assessed for latex allergy

A. Routine Practices

Routine practices must be part of all staff education and training to prevent exposure to body substances. Routine practices in reprocessing areas include:

- a) A policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics or and handling contact lenses in the reprocessing area;
- b) No storage of personal effects, including food and drink, in the reprocessing area;
- c) Hand hygiene facilities located at all entrances to, and exits from, reprocessing areas and:

- d) Faucets should be supplied with foot-, wrist- or knee-operated handles or electronic sensors;
- e) Hands are cleaned before beginning work, before breaks and upon completion of work; after removing gloves; and whenever hands are contaminated with body substances if there is visible soil on the hands, hand hygiene is performed with soap and water; if there is no visible soil on the hands, staff may use either soap and water or an alcohol-based hand rub (ABHR);
- f) Hand and arm jewellery, or artificial nails are not worn;
- g) Provision for, and wearing of, appropriate PPE for all reprocessing activities; and
- h) Dedicated staff for the decontamination area.

B. Personal Protective Equipment (PPE)

Standard precautions are to be complied with by all staffs. Staff involved in reprocessing must be trained in the correct use, wearing, limitations of and indications for PPE:

- a) PPE worn for cleaning and handling contaminated equipment/devices includes gloves appropriate to the task, face protection (full face shield or fluid-impervious face mask and protective eyewear) and impermeable gown or waterproof apron;
- b) When choosing gloves, the following points need to be considered:
 - i) Cleaning gloves must be long enough to cover wrists and forearms;
 - ii) Cleaning gloves must be of sufficient weight to be highly tear-resistant;
 - iii) Cleaning gloves must allow adequate dexterity of the fingers;
 - iv) Disposable cleaning gloves are recommended; if reusable gloves are used, they must be cleaned and disinfected daily and inspected for tears and holes.
- c) PPE is removed on completion of the task for which it was indicated and before leaving the reprocessing area;
- d) Staff must be trained in management of a blood or body fluid spill; and
- e) 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.

C. Safe Handling & Proper Disposal Sharps

Procedures shall be in place to prevent injuries from sharp objects. When working with sharps, staff in the decontamination area shall:

- a) Use appropriate PPE (see section B);
- b) Place disposable sharp objects in puncture-resistant containers;
- c) Take care when handling glass and other fragile objects;
- d) Discard chipped or broken glass devices or arrange to have them replaced;
- e) Not recap used needles or other sharps unless using a recapping device; and
- f) Not manually bend or break needles.

D. Work Restrictions

Reprocessing staff are subject to some work restrictions:

- a) Staff who have respiratory problems (e.g., asthma) should be assessed by occupational health and safety staff prior to working with chemical disinfectants or cleaning agents; and
- b) Staff who have exudative lesions or weeping dermatitis on exposed areas of the body (i.e., arms below the elbow, face or neck) shall refrain from handling client/patient/resident care equipment until the condition is resolved.

Recommendations

1. Occupational Health and Safety for the healthcare setting will review all protocols for reprocessing medical equipment/devices to verify that worker safety measures and procedures to eliminate or minimise the risk of exposure are followed and are in compliance with the Occupational Health and Safety Act of the country. (IIA)
2. There is a policy that prohibits eating/drinking, storage of food, smoking, application of cosmetics

or/and handling contact lenses in the reprocessing area. (IIA)

3. Appropriate personal protective equipment (PPE) should be worn for all reprocessing activities. (IA)
4. All staff working in reprocessing shall be offered Hepatitis B immunization unless they have documented immunity to Hepatitis B. (IA)
5. Measures and procedures shall be written to prevent and manage injuries from sharp objects. (IA)
6. Measures and procedures shall be in place for immediate response to worker exposure to blood and body fluids. (IA)
7. Health care personnel should also be offered vaccines for vaccine preventable diseases as per institutional policy (e.g., mumps-measles-rubella, varicella, influenza, tetanus-diphtheria or tetanus-diphtheria-acellular pertussis). (IIA)

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Handling and Transportation of Used Medical Equipment / Devices

The goals of transportation and handling of soiled medical equipment/ devices are:

1. To prepare soiled items so that they will not be damaged after use
2. To transport the soiled items without cross-contaminating the environment between point of use area and the reprocessing area
3. To assure that all individuals who may come in contact with soiled items remain safe.

To reduce potential cross contamination and damage to the equipment/device some special instruments should not be processed with general surgical instrument, e.g. ophthalmic viscosurgical devices. Solutions used in these surgeries can dry very quickly on eye instruments. To prevent Toxic Anterior Segment Syndrome (TASS) the instrument should be wiped clean with a lint free sponge moistened with sterile water during the procedure. Intraocular instruments may need to be immersed in sterile water at the end of the surgical procedure to reduce the formation of a biofilm that adheres to surfaces of these instruments. They are then transported to the CSSD for full reprocessing in a covered container or closed bag and if contaminated in a container with a biohazard label.

Procedure for handling and transport of used items

1. Remove gross soil immediately after use at point of use. Gross soil refers to tissue, body fat, blood, and other body substances.
2. Remove disposable components using proper disposal methods. Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point of use.
3. Medical equipment/device that needs repair should be identified (e.g. tags).
4. Used items should be kept moist. Spraying or soaking with an approved pre-treatment product or placing a moist towel over used items in a closed container can accomplish this. Always refer to equipment/device and product manufacturer's instructions.
5. Transport items using closed carts or covered containers that are secured, designed to prevent items from falling over and prevent the spill of liquids, with easily cleanable surfaces. Carts and containers shall be cleaned after each use.

6. Used items shall be transported by direct routes, avoiding high traffic or public areas. Preferably, dedicated elevators (or lifts) with direct access to the cleaning area are designated to transport the used items.

Used items for reprocessing should be considered contaminated. The person who transported used items for reprocessing should wear a protective gown over their attire, and wear cleaning gloves to handle the items as they are picked up and placed into the transport cart. The gloves should then be removed and hands washed. Any person who may be coming into contact with used items must be educated about the dangers associated with biohazardous items.

Recommendations

1. Gross soil should be removed at the point of use. (IA)
2. Disposable components shall be disposed prior to transportation. Disposable sharps shall be disposed of in an appropriate puncture-resistant sharps container at point of use, prior to transportation. (IIA)
3. Used items should be kept moist. (IIA)
4. Used items must be handled in a manner that reduces the risk of exposure and/or injury to personnel and clients/patients/residents, or contamination of environmental surfaces. (IIA)
5. Used items should not be transported through high traffic (public) areas, designated areas for storage of clean or sterile supplies, or client/patient/resident care areas. (IIIA)
6. Sterile/ clean and used items shall not be transported together. (IIA)
7. Transport carts shall be cleaned and dried between uses. There should be a physical barrier between the bottom shelf and the floor. (IIIA)

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Cleaning and Verification of Reusable Medical Equipment/Devices

Policies and procedures for cleaning medical equipment/devices shall be based on the manufacturer's instructions and must be developed in consultation with Infection Prevention and Control, Occupational Health and Safety, Biomedical Engineering and Environmental Services. Full PPE shall be worn for handling and cleaning contaminated equipment/devices.

Reusable medical equipment/devices shall be thoroughly cleaned prior to disinfection or sterilisation. An item that has not been cleaned cannot be assuredly disinfected or sterilised.

If an item is not cleaned, soil (e.g., blood, body fluids, dirt) can protect the microorganisms from the action of the disinfection or sterilisation process making it ineffective, as well as inactivate the disinfectant.

Factors that affect the ability to effectively clean medical equipment/devices shall be considered prior to cleaning. The cleaning process for a medical device depends on:

- a) The device manufacturer's written instruction for use;
- b) Cleanliness of the surface of the equipment/device, whether the device was possibly exposed to prions;
- c) Characteristics or the design of equipment/device;
- d) Other characteristic or type and concentration of the cleaning product;
- e) Duration and temperature of exposure to the cleaning product; and
- f) Physical properties of the reprocessing environment.

A. Pre-Cleaning

Gross soil (e.g., faeces, sputum, and blood) shall be removed immediately at point-of-use.

If cleaning cannot be done immediately, the medical equipment/device must be kept moist by spraying or soaking with a pre-treatment product or placing a moist towel over used items to prevent organic matter from drying on it. Always follow manufacturer's recommendations.

Once medical equipment/devices have been received in the reprocessing area they must be disassembled, sorted and cleaned:

a) **Disassembly** – Facilitates access of the cleaning agent, disinfectant and/or sterilant to device surfaces:

- i. Equipment/devices (e.g. instrument, device, rigid container) shall be disassembled prior to cleaning if there is one or more removable part, unless otherwise recommended by the manufacturer; and
- ii. Manufacturer's recommendations shall be followed when disassembling medical equipment/devices prior to cleaning;

b) **Sorting** – items should be kept organised for safety reasons and to discourage instrument loss or misplacement:

- i. Reusable instruments that are sharp must be segregated from other instruments and confined in a puncture resistant container at point of use, to prevent injury to personnel and damage to the equipment/ device;
- ii. Equipment/devices should be sorted into groups of like products requiring the same processes; and
- iii. Equipment/devices identified for repair should remain segregated and tagged.

c) **Soaking** – prevents soil from drying on equipment/devices and makes them easier to clean:

- i. Saline shall not be used as a soaking solution as it damages some medical equipment/devices;
- ii. Soaking equipment/device must be placed in a hospital approved instrument soaking solution;
- iii. Soaking solution includes detergent based products with or without enzymes, and should always be used according to the equipment/ device manufacturer; and
- iv. Avoid prolonged soaking (e.g., overnight) of equipment/devices as this causes damages.

B. Cleaning

Cleaning is the removal of foreign material (e.g. soil and organic material) from objects, and it is normally accomplished using water with detergents or enzymatic products.

Cleaning may be done manually or using mechanical cleaning machines (e.g., washer-disinfector, ultrasonic washer) after gross soil has been removed.

Automated machines may increase productivity, improve cleaning effectiveness, reduce aerosol generation and decrease staff exposure to blood and body fluids. Manual cleaning may be required for delicate or intricate items.

The equipment/device manufacturer's cleaning instructions shall be followed, including specifications for detergent type, water temperature and cleaning methods. The following procedures are included in the cleaning process:

a) Cleaning Product

- i. Products shall be approved by the committee/ team responsible for product selection; by an individual with reprocessing expertise and infection prevention expertise;
- ii. Products used in the cleaning and/or disinfection processes must be compatible with equipment/ device to be reprocessed and used according to manufacturer's instructions;
- iii. Manufacturers must provide written instructions and safety consideration (product data bulletin and safety data sheets [SDS]);
- iv. Manufacturer's instructions shall be accessible by staff;
- v. Detergents and other chemicals should be stored in chemical storage; and
- vi. Chemical spills management procedures, including spill kits, should be developed in accordance with SDS or local policies;

b) Manual Cleaning – Friction and Fluidics

- i. Completely submerge immersible items during the cleaning process to minimize aerosolisation of fluids and microorganisms and assist in cleaning;

- ii. Minimize the production of aerosols when cleaning non-immersible equipment/devices;
- iii. Clean equipment/devices that have lumens with a brush, according to the manufacturer's instructions, then manually or mechanically flush with a detergent solution and rinse;
- iv. Check equipment/devices with lumens for obstructions and leakage;
- v. Friction by brushing should be done under water level;
- vi. Fluidics by spraying water under pressure to remove soil and debris; and
- vii. Sinks should be large enough to contain large instruments soaked and allow a tray or container basket to be placed flat.
- viii. Disinfect brushes per manufacturer's instructions after each use

c) Mechanical Cleaning

Whenever possible, equipment/devices shall be cleaned by mechanical means:

- i. Use mechanical cleaners in accordance with the manufacturer's instructions;
- ii. Ensure that the equipment/device to be cleaned is compatible with the mechanical cleaning equipment and chemical solutions that are being used;
- iii. Remove heavy soiling before mechanical cleaning;
- iv. Ultrasonic washers are strongly recommended for any semi-critical or critical medical equipment/device that has joints, crevices, lumens or other areas that are difficult to clean:
 - a. Ultrasonic washers removes soil by cavitation and implosion;
 - b. The manufacturer's instructions must be followed for use and routine cleaning and maintenance of the ultrasonic washer;
 - c. Equipment/devices shall be completely immersed in the cleaning solution;
 - d. After cleaning, equipment/devices shall be rinsed thoroughly prior to further reprocessing;
 - e. The ultrasonic cleaning solution should be changed at least daily or more frequently if it becomes visibly soiled or if the manufacturer's instructions specify more frequent changes; and

- f. Rubber and polyvinyl chloride (PVC) cannot be cleaned ultrasonically because these materials absorb ultrasonic vibration.
- v. Washer-disinfectors (WD) are strongly recommended for medical equipment/devices that can withstand mechanical cleaning, to achieve the required exposure for cleaning and thermal disinfection and to reduce potential risk to personnel:
 - a. WD removes soil by water circulation and detergents;
 - b. Includes thermal disinfection at the end of process;
 - c. The WD manufacturer's instructions must be followed for the use
 - d. Washer-disinfectors may be used for low-level disinfection; and
 - e. Washer-disinfectors are not to be used for high-level disinfection.

d) Care of Cleaning Tools

- i. Cleaning tools (e.g., brushes, cloths) should be capable of thermal disinfection or be single use only;
- ii. Inspect brushes and other cleaning equipment for damage after each use, and discard if necessary;
- iii. Adequate supplies should be available for frequent changing; and
- iv. Cleaning tools should be cleaned, disinfected and stored dry.

e) Rinsing

Rinsing following cleaning is necessary, as residual detergent may neutralize disinfectant, cause damage to the equipment/device or harm to the patient (ie. TASS):

- i. Rinse all equipment/devices thoroughly after cleaning with water to remove residues which might react with the disinfectant/sterilant or be transferred to the patient;
- ii. Final rinse should be performed with treated water that does not contribute to staining or contamination; and

- iii. Perform the final rinse for semi critical equipment/devices containing lumens (e.g. flexible endoscope) with commercially prepared sterile, pyrogen-free water (note: distilled water is not necessarily sterile or pyrogen-free).

f) Drying

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

- i. Follow the manufacturer's instructions for drying of the equipment/device;
- ii. Equipment/devices may be air-dried using compressed instrument grade air or dried by hand with a clean, lint-free cloth;
- iii. Dry lumens with 70% isopropyl alcohol or ethanol followed by compressed instrument grade air that has been filtered (oil and dust free) and dried;
- iv. Dry stainless steel equipment/devices immediately after rinsing to prevent spotting; and
- v. Drying cabinets should be used with equipment/device manufacturer's recommendation.
- vi. Instruments such as flexible endoscopes should have lumens dried with 70% isopropyl alcohol or ethanol then compressed instrument grade air and then be hung vertically and not touch the sides or the bottom of the cabinet.

C. Post-Cleaning

Once medical equipment/devices have been cleaned, there must be a process to ensure that they can be differentiated from equipment/devices, that have and have not been cleaned and disinfected.

The following procedures must be included following the cleaning process:

a) Reassembly and Inspection

- i. Visually inspect all equipment/devices once the cleaning process has been completed and prior to disinfection/sterilisation to ensure cleanliness, dryness and integrity of the equipment/device (e.g., cracks, defects, adhesive failures, missing parts);
- ii. Repeat the cleaning process on any item that is not clean; and
- iii. Do not reassemble equipment/device prior to disinfection/sterilisation; if the equipment/device manufacturer's instructions specify reassembly at this stage in the reprocessing, it shall take place in a clean area and be performed in accordance with the manufacturer's instructions.
- iv. Cleaning process verification should be done regularly (e.g. monthly) by artificial soil, protein, endotoxin, blood, or adenosine triphosphate bioluminescent.

D Practice Audits

- i. Cleaning verification by users should include visual inspection combined with other verification methods (e.g. ATP, protein residue, etc.) that allow assessment of instrument surfaces and channel.
- ii. Cleaning processes must be audited on a regular basis on selected samples, weekly at a minimum, or preferably daily.
- iii. Monitoring of mechanical cleaning equipment should be done upon installation and on regular basis and recorded; and
- iv. Quality improvement process must be in place to deal with any irregularities/concerns arising from the audit.

Recommendations

1. Reusable medical equipment/devices must be thoroughly cleaned prior to before disinfection or sterilisation. (IA)

2. Factors that affect the ability to effectively clean medical equipment/devices shall be considered prior to cleaning. (IIA)
3. Personnel must use appropriate PPE whenever cleaning reusable medical equipment/ devices. (IA)
4. The process for cleaning shall include written protocols for disassembly, sorting, soaking, manual or mechanical cleaning, rinsing and drying. (IIIA)
5. There shall be a process to ensure that item which have been cleaned can be reliably differentiated from equipment/devices which have not been cleaned (e.g., colour coding). (IIIA)
6. Products shall be approved by the committee/ team responsible for product selection; by an individual with reprocessing expertise and by infection prevention expertise. (IIIA)
7. Products that are used in cleaning process must be compatible with equipment/ device to be reprocessed and used according to manufacturer's instructions. (IIIA)
8. Audits of the cleaning process shall be done on a regular basis. (IIA)

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Instrumentation Inspection, Preparation & Packaging

After reusable medical equipment/devices have been cleaned they are then inspected, assembled into sets and trays, and packaged for subsequent terminal sterilisation. Most facilities use a variety of packaging materials including peel pouches, sterilisation wraps and rigid containers.

A. Inspection

Equipment/devices should be carefully inspected for;

- a) Cleanliness and dried before packaging, flaws or damage.
- b) Check for rust, pitting, corrosion, burrs, nicks, cracks, chipping of plated surfaces. Lighted magnifying glass should be available for equipment/device inspection function:-
 - i) Cutting edges are sharp;
 - ii) Moving parts move freely, without sticking.
 - iii) Instruments needing repair are taken out of service for repair or replacement.
 - iv) Assess optics (if present in the device)
- c) Lubrication after cleaning or prior to sterilisation.
- d) Follow IFU for instruments requiring lubrication after cleaning or prior to sterilisation.

B Lubrication

- i. Follow the manufacturer's guidelines for lubrication; lubrication is not recommended for implants
- ii. Equipment/devices requiring lubrication shall be lubricated prior to sterilisation;
- iii. Lubricants shall be compatible with the device and with the sterilisation process; and
- iv. Discard lubricants on expiry date or when visibly soiled or contaminated.

C. Preparation and Assembly

- a) The preparation and assembly of surgical instrumentation is a complex process, and various packaging methods are used. Preparing instruments in the manner described helps ensure that there will be adequate contact by the sterilising agent with all surfaces and reduces the potential for sterilising residues(e.g. wet packs).
 - i) Delicate/sharp instruments are protected while being handled/ assembled for sterilisation. (*May use special holders, tip guards, or foam sleeves*). Tip protectors should be fit for purpose and permeable to the sterilising process.
 - ii) Instruments that open (e.g. scissors, haemostats) are held in unlocked, open positions.
 - iii) Multi-part instruments are disassembled prior to sterilisation, ensuring all parts are easily accessed for aseptic assembly
 - iv) Lumened devices - Remove styles /plugs, such as catheters, needles, and tunings.
 - v) Complex instruments (e.g., air-powered, endoscopes, having lumens or channels) are prepared according to written IFU from device manufacturers.
 - vi) Low-linting absorbent material may be placed in trays to help facilitate drying. Tray liners or other absorbent materials may be used to alleviate drying problems during steam sterilisation.
 - vii) Basins: Graduated basins should differ in diameter by one inch. Use low-linting absorbent material between nested basins. Wrapped basin sets should not exceed 3 kg.
 - viii) Rigid container sets with instruments should not exceed 11kg.

D. Packaging:

Personnel should understand how the sterilisation method and the items being sterilised affect the selection of the appropriate packaging method, how the packaging method affects achievement of sterilisation parameters and maintains the sterility of the contents until the package is opened, and to

provide for the removal of the contents without contamination. Equipment/devices that are to be sterilised require wrapping prior to sterilisation (except for IUSS). The selection of packaging material should be as follows:

- a) Packaging materials are held for at least 2 hours prior to use at room temp (21°C-24°C) and at a relative humidity ranging from 30-60%. This is needed to permit steam sterilisation and prevent superheating.
- b) Packaging materials are examined for defects before use (i.e. holes, stains).
- c) Wrappers should be kept snug, but not wrapped too tightly as strike-through could occur.
- d) Paper/plastic pouches - labelling is done on plastic side only.
- e) Wrapped packs - write only on indicator tape or affixed labels.
- f) Perforated, wire-mesh-bottom trays, and rigid organizing trays are inspected prior to each use to ensure there are no sharp edges, nicks, or loose wire-mesh.
- g) Tape (other than sterilisation indicator tape) should not be used to secure packages, nor should safety pins, ropes, paper clips, staples, rubber band or other sharp objects.
- h) Seal verification test to be done for heat sealer at a set frequency, weekly at a minimum, preferably daily.
- i) Heat sealing: select preformed pouches in accordance with the size of the medical device, which may occupy at most 75% of the pouch. Upper end must be at least 3 cm. to allow for unimpeded peeling as well as aseptic withdrawal.
- j) The rigid container system should be large enough to allow the metal mass of instruments and devices to be distributed equally in the basket and the chemical indicator should be placed inside the rigid container, one in each of two opposite corners of the inside basket. The filter is inspected at every use and replaced when indicated.

Recommendations

1. Reusable medical equipment/devices must be thoroughly inspected, prepared before packaging and

sterilised ready to use and ensure patient safety. (IIA)

2. Effective packaging materials for sterilisation should, as a minimum, allow adequate air removal, sterilising agent penetration, provide an adequate barrier to microorganisms, resist tearing or puncture, provide complete seal and integrity, free of toxic ingredients, non-linting and cost-effective. (IIA)
3. Rigid container systems should be cleaned after each use. All components including filters should be disassembled for proper cleaning following manufacturer's IFU. (IIA)

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Disinfection of Reusable Medical Equipment/Devices

Disinfection is the inactivation of disease-producing microorganisms. Disinfection does not destroy bacterial spores or prions. Disinfection of medical equipment/devices falls into two major categories – low-level disinfection and high-level disinfection.

A. Low-Level Disinfection (LLD)

Low-level disinfection eliminates vegetative ('live') bacteria, some fungi and enveloped viruses. LLD is used for non-critical medical equipment/devices and some environmental surfaces. Low-level disinfectants include 3% hydrogen peroxide, 0.5% accelerated hydrogen peroxide, some quaternary ammonium compounds (QUATS), phenolic and diluted sodium hypochlorite (e.g., bleach) solution

LLD is performed after the equipment/device is thoroughly cleaned; rinsed and excess rinse water is removed. The container used for disinfection must be cleaned, rinsed and dried when the solution is changed. Non-critical medical equipment/devices require decontamination using a low-level disinfectant.

B. High-Level Disinfection (HLD)

High-level disinfection eliminates vegetative bacteria, enveloped viruses, fungi, mycobacteria (e.g., tuberculosis) and non-enveloped viruses but many eliminate small number of spores. High-level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide and 0.55% ortho-phthalaldehyde (OPA). Refer to Table 3 for contact time required for HLD. Pasteurization also achieves high-level disinfection. HLD is performed after the equipment/device is thoroughly cleaned, rinsed and excess rinse water is removed. Semi-critical medical equipment/devices require at a minimum, HLD after each patient use, but sterilisation is preferred.

Table 3 Indicative disinfection and sterilisation times for chemical agents

	High level disinfection claim	Sterilisation claim
Hydrogen peroxide 7.5%	30 mins at 20°C	6 hours at 20°C
Peracetic acid 0.2%	NA	12 mins at 50-56°C
Glutaraldehyde ≥2%	20-90 mins at 20-25°C	10 hours at 20-25°C
Ortho-phthalaldehyde 0.55% (OPA)	5 mins at 20°C, 5 mins at 25°C in AER	None
Hydrogen peroxide / peracetic acid (7.35% / 0.23%)	15 mins at 20°C	3 hours at 20°C

C. Methods of Disinfection for Semi-critical Medical Equipment/Devices

There are two major methods of disinfection used in health care settings – liquid chemicals and pasteurization.

1. Liquid Chemical Disinfection

When selecting a disinfectant for reprocessing medical equipment/devices in the health care setting, consideration needs to be given to:

- a) Efficacy for the intended use;
- b) Compatibility with the equipment/device and surfaces to be disinfected;
- c) The intended end use of the equipment/devices to be disinfected;
- d) The method for monitoring the product concentration;
- e) Recommendations for rinsing following disinfection (e.g., water quality, volume, time);
- f) Safety for use, with minimal toxic and irritating effects to staff; and
- g) Environmental safety and biodegradability.

The manufacturer's recommendations for chemical disinfectants must be followed pertaining to:

- a) Usage - disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used;

- b) Contact time (NOTE: where the manufacturer recommends a shorter contact time with a particular product than is required to achieve the desired level of disinfection/sterilisation, an infection prevention and control professional must be consulted for advice);
- c) Use life;
- d) Proper disposal;
- e) Storage;
- f) Appropriate dilution; and
- g) Required PPE.

The process of HLD requires monitoring and auditing:

- a) Chemical test strips should be used to determine whether an effective concentration of active ingredients is present, despite repeated use and dilution:
 - i) The frequency of testing should be based on how frequently the solutions are used (i.e., test daily if used daily);
 - ii) Chemical test strips must be checked each time a new package/bottle is opened to verify they are accurate. See manufacturer's recommendations for appropriate controls;
 - iii) Test strips must not be considered a way of extending the use of a disinfectant solution beyond the expiration date;
 - iv) If the test strips have an expiration time once opened per the manufacturer, the date the strip bottle was opened and the expiration date should be written on the outside of the bottle containing the test strips

- b) A permanent record of processing shall be completed and retained according to the policy of the facility; this record shall include, but not be limited to:
 - i) The identification of the equipment/device to be disinfected;
 - ii) Date and time of the clinical procedure;
 - iii) Concentration and contact time of the disinfectant used in each process;
 - iv) Results of each inspection (and, for endoscopes, each leak test);
 - v) Result of each testing of the disinfectant; and
 - vi) The name of the person completing the reprocessing.
- c) Disinfection practices shall be audited on a regular basis and a quality improvement process must be in place to deal with any irregularities/concerns resulting from the audit;
- d) Prepared solutions shall not be topped up with fresh solution;
- e) If manual disinfection is performed, the container used for disinfection shall be kept covered during use and washed, rinsed and dried when the solution is changed; and
- f) Rinsing of medical equipment/devices following chemical disinfection requires three separate rinses, using sterile water, and the rinse solutions must be changed after each process.

2. Pasteurization

Pasteurization is a process of hot water disinfection (minimum 71°C for 30 minutes), which is accomplished through the use of automated pasteurizers or washer disinfectors. Semi-critical medical equipment/devices suitable for pasteurization include equipment for respiratory therapy and anaesthesia.

Advantages of pasteurization include:

- a) No toxicity;
- b) Rapid disinfection cycle; and
- c) Moderate cost of machinery and upkeep.

Disadvantages of pasteurization include:

- a) May cause splash burns;
- b) Difficulty in validating the effectiveness of the process; and
- c) Pasteurizers and related equipment can become contaminated without a good preventive maintenance program and careful monitoring of processes.

The manufacturer's instructions for installation, operation and on-going maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated:

- a) The process must be monitored with mechanical temperature gauges and timing mechanisms for each load, with a paper printout record; pasteurizing equipment must have, or be retrofitted for, mechanical paper printout;
- b) Water temperature within the pasteurizer should be verified weekly by manually measuring the cycle water temperature;
- c) Cycle time should be verified manually and recorded daily;
- d) Calibration of pasteurization equipment will be performed according to the manufacturer's recommendations;
- e) Daily cleaning of pasteurizing equipment is required following the manufacturer's recommendations; and

- f) Following pasteurization, medical equipment/devices should be inspected for wear, cracks or soil. Damaged equipment/devices shall be handled according to facility procedures.

Following pasteurization, medical equipment/devices shall be handled in a manner that prevents recontamination. Equipment/devices shall be transported directly from the pasteurizer to a clean area for drying, assembly and packaging. Medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and is used exclusively for the drying of pasteurized equipment/devices. A preventive maintenance program for drying cabinets must be implemented and documented. Printed records of each cycle (i.e., temperature, time) shall be retained in accordance with the health care setting's requirements.

Recommendations

1. Non-critical medical equipment/devices are to be cleaned then disinfected using a low-level disinfectant. (IIA)
2. Semi-critical medical equipment/devices require at a minimum, high-level disinfection but sterilisation is preferred. (IA)
3. The chemical disinfectant used for disinfecting medical equipment/devices must be compatible with both the equipment/device manufacturer's instructions for disinfection and the cleaning products involved in the reprocessing of the equipment/device. (IA)
4. Disinfectant manufacturers must supply recommended usage for the disinfectant to ensure that it is compatible with the medical equipment/devices on which it will be used. (IIIA)
5. The process of high-level disinfection requires monitoring and auditing. If a chemical product is used, the concentration of the active ingredient(s) must be verified and a logbook of daily concentration test results is to be maintained. (IA)

6. Manufacturer's instructions for installation, operation and on-going maintenance of pasteurizing equipment must be followed to ensure that the machine does not become contaminated. (IA)
7. A preventive maintenance program for pasteurizing equipment must be implemented and documented. (IIIA)
8. Following the pasteurizing cycle, medical equipment/devices shall be thoroughly dried in a drying cabinet that is equipped with a high efficiency particulate air (HEPA) filter and that is used exclusively for the drying of pasteurized equipment/devices. (IIIA)
9. A log of contents, temperature and time is to be maintained for each pasteurizer cycle. (IIA)

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Sterilisation of Reusable Medical Devices

This section provides guidance on sterilisation, the testing and monitoring of the sterilisers and verification of the sterilising process as an integral part of preventing transmission of infection. The sterilisation method chosen must be compatible with the item to be sterilised to avoid damage and must be able to achieve the sterility assurance level (SAL) of 10^{-6} for terminally sterilised devices. The steriliser manufacturer's instructions should be followed for correct loading and operation of individual sterilisers. Chemical and biological methods of monitoring are to be designed for the purpose and stored and used in accordance with the indicator manufacturer's instructions for use. Sterilisation is a process not an event.

Sterilisation

Sterilisation involves the complete destruction of all forms of microbial life, including bacteria and spores. Sterilisation must be preceded by thorough cleaning. All critical devices and, whenever possible, semi-critical medical devices shall be sterilised by a steam sterilising process. Critical devices have to be sterile at time of use. Where critical devices are not compatible with steam sterilising they need to be sterilised using a validated low temperature sterilising process (i.e. ethylene oxide, peracetic acid and hydrogen peroxide).

Note: Prions (CJD, vCJD) are not susceptible to routine sterilisation parameters and separate processes need to be established to manage devices suspected of or that have been exposed to prion-infected tissue. Refer to CDC and SHEA guidelines on sterilisation of these instruments.

There are various sizes and types of steam steriliser. The type is identified by the method of air removal from steriliser and load. Large steam sterilisers are either downward/gravity displacement or dynamic air removal (pre-vacuum and above atmospheric). Small steam sterilisers are classified by the types of cycles they are able to process (B, N and S) [see Table 4].

Table 4 **Small steam sterilisers**

Type	Description of intended use
B	For products that lie within the limits specified for the relevant test loads, this includes solid products, porous products and lumen devices, packaged or non-packaged devices
N	Sterilisation of non-packaged, non-complex solid devices

Type	Description of intended use
S	The sterilisation of products as specified by the manufacturer of the steriliser including non-packaged solid products <u>and at least one</u> of the following: porous products, small porous items, lumen devices, bowls and receivers, single-layer wrapped products, multiple-layer wrapped products.

Table adapted from BS EN 13060

Semi-critical devices that cannot withstand the sterilisation methods of steam, dry heat or low temperature sterilisation may be reprocessed using liquid chemical disinfectants with sterilisation claims. However, there are limitations with liquid chemical sterilisation and it is recommended that their use is limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilisation methods.

Immediate use steam sterilisation (IUSS)

Immediate use sterilisation, formerly known as flash sterilisation, should only be used when there is insufficient time to process by the preferred documented method. IUSS should not be used as a substitute for sufficient instrument inventory. IUSS should not be used for implantable devices except in cases of defined emergency when no other option is available. It is essential that all steps including cleaning and preparation for sterilisation when IUSS is used to ensure appropriate infection prevention and control practices are maintained. The IUSS procedure should include the following criteria:

- a) Once cleaned and prepared for sterilisation the device/s should be placed within a container or package intended for IUSS;
- b) Cycle time and parameters should be according to the steriliser manufacturer's instructions for use;
- c) Identification that there is little or no drying time and the items processed are assumed wet at the end of the sterilising cycle and the item is hot while being transferred to point of use;

- d) The processed devices are transferred from the steriliser to the actual point of use immediately in a manner that minimizes the risk of contamination.

Records should be maintained on all devices processed under the IUSS procedure to monitor the type and volume as part of quality monitoring.

Loading the steriliser

Sterilising agents need to be able to penetrate the packaging to contact the load items to achieve sterility. In addition to loading the carriage within the steriliser manufacturer's specifications the following should be given consideration:

- (a) Similar items requiring the same cycle parameters should be grouped together.
- (b) The devices are to be positioned on the steriliser carriage to allow removal of air from the chamber and load content, penetration of the sterilising agent and exhaust of sterilising residues, including condensate.
- (c) Solid-bottom pans, bowls, and trays are tilted on edge and oriented in the same direction. Paper-laminate pouches should be on edge or flat with paper-side down, instrument sets in trays should be placed flat.
- (d) Light load items are placed on the carriage above heavy items. For mixed loads, place metal items on the loading cart below textiles and paper-plastic pouches (to prevent condensate from dripping onto lower packs).
- (e) The requirements of monitoring each cycle, test and load cycles, are documented.

Unloading the steriliser

Following completion of the selected sterilising cycle care should be taken to make sure the risk of recontamination is reduced. Sterilised devices should only be handled with clean hands. Sterilised devices should be removed from the steriliser at the end of the cycle and placed in an area of low traffic and away from air-conditioning or cold air vents.

Devices sterilised by steam should be left on the sterilising carriage until packages are cool to touch before being transferred to the sterile storage.

Devices sterilised by ethylene oxide should be aerated in the sterilising chamber and should not be removed until the aeration is complete.

All packs must be checked for dryness, that seals are intact, external indicators colour change is correct and steriliser parameters are correct and complete. Wet items are considered contaminated even if not touched. All checks and monitoring results should be documented as part of the traceability of devices and quality management.

Testing and monitoring sterilisers

The purpose of testing a steriliser is to prove it is functioning as intended by the steriliser manufacturer and it will sterilize the devices in use in the health care facility. The tests carried out depend on the type of steriliser and sterilising method. Some tests require a test product to be included to prove the function of the steriliser such as the Bowie & Dick type test for sterilisers with dynamic air removal. The Bowie-Dick testing is completed daily in pre-vacuum sterilisers with an empty chamber containing a PCD that includes a Type 2 chemical indicator before the first processed load. It is processed at 132°-134°C for 3.5 to 4 minutes. The steriliser manufacturer's instructions for use should be followed.

The purpose of monitoring is to verify the steriliser is achieving the required parameters to deliver an SAL 10^{-6} for terminally sterilised devices. Monitoring is used per load of instruments processed through a steriliser to provide confirmation of parameters being met and microbial death. Three types of monitoring are used, physical, chemical and microbiological. Each provides information on the achievement of sterilising parameters.

Routine monitoring

Routine monitoring (physical, biological and chemical monitoring) is done to verify the function of sterilisers and the sterilisation process. Monitoring is done when a steriliser is first installed before it is put into general use and to assess routine performance thereafter. Performance monitoring using all three

types of monitors must be completed in all sterilisers to ensure that effective sterilisation has been achieved.

Routine monitoring consists of monitoring every package and sterilisation load, steriliser efficacy and periodic product quality assurance testing.

As a minimum the following monitoring should be carried out for loads including medical devices;

- a) Physical monitoring - includes printouts, digital readings, graphs, gauges to verify the parameters of each cycle have been met. Printouts should be stored safely per institutional policy.
- b) Chemical monitoring - chemical indicators should be placed on the outside and inside of every package. External indicators (Type 1, Category e) identify processed from non-processed items. Internal indicators (Type 3, 4, 5, 6, Category i) verify the sterilising agent has reached the contents of the package and critical variables of the process have been met. The variables monitored will depend on the specific type of internal chemical indicator. For loads containing implants, a PCD containing a biological indicator and Type 5 integrating indicator must be included in each load.
- c) Biological monitoring – is to be included in the first instrument load of the day and is optional for the remaining loads of the day not containing implants. PCDs containing a BI are required for each load containing implants.

Table 5 International Classification of Chemical Indicators

Type	Category	Description	Intended use
1	e1	Exposure or process indicator	Indicates exposure to a process, allows differentiation between unprocessed and processed, i.e. indicator tapes or labels
2	s2	Special indicator	Indicators for use in special applications, i.e. Bowie-Dick test
3	i3	Internal single variable indicator to indicate when 1 critical variable	For pack control - but not as useful as Class IV or V indicators; for exposure control monitoring, i.e. temperature tubes for dry heat sterilising

Type	Category	Description	Intended use
4	i4	Internal multi-variable indicator that reacts to more than 1 critical variable in sterilisation cycle	For pack control, i.e. chemical impregnated paper strips
5	i5	Internal integrating indicator that reacts to all critical variables in the sterilisation process (i.e. for steam sterilisation - time, temperature, presence of steam) and has stated values that correlate to a BI at 3 time/temperature relationships	For pack control or as additional monitoring for loads that contain implants, i.e. PCD containing a type 5 CI
6	i6	Internal emulating indicator that reacts to all critical variables (i.e. for steam sterilisation - time, temperature, presence of steam) for specified sterilisation cycle	For pack control, i.e. chemical impregnated paper strip

1. Physical Monitors

A physical monitor is a device that monitors the physical parameters of a steriliser, such as time, temperature and pressure that are measured during the sterilisation cycle and recorded (as a printout or electronic record) on completion of each cycle. Every steriliser has physical monitoring devices built-in as a required component.

2. Biological Indicators (BI)

A biological indicator is a test system containing viable microorganisms (e.g., spore-laden strips or vials) providing a defined resistance to a specified sterilisation process. The BI is generally contained inside a process challenge device (PCD) that simulates the in-use challenges presented by packaged devices. Once sterilised, a BI is incubated to see if the microorganism will grow, which indicates a failure of the steriliser. The steriliser manufacturer's instructions regarding the type of BI to be used in a particular sterilising process should be followed. The recommended test microorganisms generally used as BIs are:

- a) *Geobacillus stearothermophilus* spores for sterilisers that use steam, hydrogen peroxide gas plasma or peracetic acid and

b) *Bacillus atrophaeus* spores for sterilisers that use dry heat or ethylene oxide.

The recommended frequency of BI testing for steam sterilisation is daily whilst for gaseous sterilisation (Ethylene oxide sterilization and hydrogen peroxide gas plasmas sterilization) are for every load with BI testing.

The BI is incubated according to the indicator manufacturer's instructions. Most BIs require up to 48 hours of incubation before the test is complete. Recently, however, rapid readout biological indicators have become available that provide BI results in one hour. These indicators detect enzymes of *Geobacillus stearothermophilus* (the test organism for steam sterilisers) by reading a fluorescent product produced by the enzymatic breakdown of a non-fluorescent substrate. Studies have shown that the sensitivity of rapid-readout tests for steam sterilisation (1 hour for 132°C-135°C vacuum sterilisers) parallels that of the conventional sterilisation-specific BIs.

3. Chemical Indicators (CI)

A chemical indicator is a system that responds to a change in one or more predefined process variables with a chemical or physical change. There are six types of chemical indicators (see Table 2, 'International Classification of Chemical Indicators').

4. Process Challenge Device (PCD)

A process challenge device (PCD) is a test device intended to provide a challenge to the sterilisation process that is equal to, or greater than, the challenge posed by the most difficult item routinely processed. Examples include BI test packs, which contain a biological indicator, or CI test packs, which contain a Type 5 integrating indicator. During routine monitoring of sterilisers, the BI and/or CI is usually placed within a PCD and placed in the steriliser.

A PCD can be commercially manufactured or prepared in-house by the user (see Appendix 3 method for user prepared PCDs). Hollow load PCD test is not recommended for use in hospitals for routine monitoring; this is normally used only for validation by manufacturers.

The PCD should be placed in the area representing the greatest challenge, normally the identified cold point in the chamber. The steriliser manufacturer should advise on the cold point. This does vary but is normally in the front near the door and bottom section of the chamber near the drain. The commercially prepared PCD should be positioned as guided by the PCD manufacturer's instructions for use. The user prepared PCD should be placed flat so the layers of towels are horizontal.

The use of internal chemical indicators do not necessarily indicate that a device is sterile but does indicate that the package has been processed through a sterilisation cycle and internal indicators can give information on the parameters met. Chemical indicators do not replace the need to use a biological monitoring as part of routine monitoring.

5. Product testing

Standardised PCDs provide a known challenge to the sterilising process that may not reflect the same challenge as items processed in the normal course of the day. Testing to verify that the products (medical devices / instruments) being sterilised are achieving SAL 10^{-6} should be carried out routinely. Product testing should always be completed when changes are made to packaging and load configuration (e.g. weight and dimensional changes). Product testing should be considered when evaluating new or loan sets to determine if the established cycles will achieve SAL 10^{-6} .

The testing should include the use of BI and CI (type 4, 5 or 6) and post sterilisation moisture content. The number of BIs and CIs used will depend on the size and configuration of the product being tested and overall size of the complete load. The indicators should be placed at the points in the load most difficult to sterilise. Examples of placement of the BIs and CIs are;

1. Textile packs – place the indicators between the folded layers of the material
2. Basin sets – place the indicators in locations where air pockets could form such as between nested basins.
3. Instrument set – place the indicators at each end of the tray among the instruments
4. Rigid containers – place the indicators in locations as recommended by the manufacturer of the container.

The whole process needs to be documented and the configurations and test results stored for reference when retesting is carried out or a change is required.

Documenting the sterilising process

Procedures are needed for identification and traceability of semi-critical devices undergoing HLD and critical devices. The requirements of HLD documentation are identified under the disinfection section of the guidelines. At a minimum the traceability system should enable the identification of a patient where a recall is necessary.

Sterilising records should include:

- a) Date of sterilising and process cycle number
- b) Identification of the steriliser
- c) Identification of the type and number of devices in the load
- d) Identification of the person responsible for loading the steriliser
- e) Documented evidence of the processing parameters having been met and the person releasing the load
- f) Other records include, but are not limited to, results of performance tests, results of chemical and biological monitoring and where required the sterilising agent batch number and expiry date (i.e. hydrogen peroxide gas plasma sterilisation).

Recommendations

1. Policies and procedures for sterilising processes, including loading and unloading the steriliser, operation of the steriliser, testing and monitoring, are documented and available. (IIA)
2. Steriliser manufacturer's written instructions for use are available and loading configurations and cycle parameters are followed. Safety data sheets are available for chemical sterilisation. (IIIA)
3. Medical device manufacturer's instructions for use, including sterilising type and cycle parameters are available, including for loan sets. (IIIB)

4. Policies and procedures specific to immediate use steam sterilisation (IUSS) are documented and available. Records are maintained, reviewed and demonstrates use of IUSS is restricted and not used for implantable devices. (IIA)
5. Procedure for loading shall ensure similar items requiring the same cycle parameters are grouped together. Loading configuration of steriliser carriages includes;
 - a. Allowing space between packs;
 - b. Carriages are not overloaded;
 - c. Packages do not touch the steriliser chamber walls;
 - d. Metal items are placed below textiles and pouches;
 - e. Hollow ware, i.e. bowls are placed on edge to allow condensate to drain;
 - f. Paper-plastic pouches arranged in a basket on edge or on steriliser carriage with paper side down in a single layer for large items; and
 - g. Rigid containers placed on carriages according to the manufacturer's recommendations. (IIIB)
6. Devices shall be removed from the steriliser at the completion of the cycle and shall remain on the carriage for at least 30 minutes or until the outside is cool to the touch. For small sterilisers the load shall be removed from the chamber and placed on a rack to cool. Sterilised devices are cooled in low traffic areas with no air conditioning. (IIIB)
7. Sterilisation loads, including IUSS, are documented, results of load indicators recorded and parameters achieved verified and load released for use. Checks made are:
 - a. Parameters verified by reviewing the printout and signing exposure time and cycle completion;
 - b. Bowie Dick test completed daily;
 - c. Biological monitoring completed at least daily, in every load containing implants and each load for gaseous sterilisation methods;
 - d. Internal chemical indicator placed in each package; and
 - e. External indicators achieved correct change (IIA)

8. A policy and procedure is in place for the recall of improperly reprocessed medical devices. Records demonstrate adherence to policy and procedure. Policy must include requirement for review of all recalls required. (IIA)

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Release to sterile storage and distribution to point of use

This section will provide guidance on the activities required to release sterilised devices into storage and then transported to the point of use. All policies and procedures need to be documented and include infection prevention and control best practice to minimise the risk of contamination of the sterile packs.

Release of sterile devices

Procedures for the review of records and release of the medical devices from the sterilising processes are to be specified and documented. The following visual checks need to be completed at a minimum;

- a) Packaging used is suitable for the sterilising process and is the correct size for the device sterilised
- b) The pack is labelled correctly to identify the contents, the seal is intact and the processing chemical indicator has a correct change
- c) The cycle parameters are achieved and signed as having been checked
- d) Loads containing biological indicators are quarantined until the results are known and recorded.

The load can be released when there is a no growth result on the processed BI PCDs if used, are read and correct

- e) There is no visible moisture or droplets.

No device should be released if criteria have not been met. The recall policy and procedure must be followed where there are non-conforming sterilised devices.

Information collected as part of the release of sterilised devices should form part of the traceability records so that the patient can be tracked back to the process. IUSS devices should be released in the same way as devices going through the usual processes.

Storage of reprocessed medical devices

Following release from the sterilising process the device is removed from the sterilising carriage and placed in sterile storage awaiting use. All sterile devices should be visually inspected before being

placed on the shelf. Handling should always be done with clean hands and kept to a minimum to reduce the risk of contamination.

Sterile Storage Areas

The sterile storage area should be located adjacent to the sterilisation area, preferably in a separate, enclosed, limited-access area. Requirements for this area include:

- a. Containers used for storage of sterilised devices should be moisture-resistant and easily cleaned.
Brown cardboard is not suitable for use as a container as they shed lint;
- b. Devices are stored in a well ventilated, clean, dry, dust-free area (closed shelves preferably), not at floor level, and at least one meter away from debris, drains, moisture and vermin to prevent contamination;
- c. Sterile items are stored at least 20-25cm above the floor, at least 45cm below the ceiling or sprinkler heads, and at least 5cm from outside walls.
- d. Supplies and materials used for reprocessing will not be stored in sterile storage area.
- e. Storage containers should be kept dust free.

Shelf life

The shelf life of a sterile package is event-related rather than time-related. Event-related shelf life is based on the concept that items that have been properly cleaned, packaged, sterilised, stored correctly in a controlled environment and handled with clean dry hands will remain sterile indefinitely, unless the integrity of the package is compromised (i.e., open, wet, dirty).

Batch labels for event related sterility have a manufacturing date, not an expiry date.

Sterile stock needs to be rotated so that the oldest supplies are used first. This is known as a first in first out (FIFO) stock rotation system.

Maintaining sterility

Health care settings must have procedures for storage and handling of clean and sterile medical devices that include:

- a. Medical devices purchased as sterile must be used before the expiration date, if one is given;
- b. Reprocessed medical devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage;
- c. The sterile storage area should have temperature and humidity control to assist with maintaining a long shelf life of terminally sterilised devices;
- d. Devices must be handled in a manner that prevents recontamination of the item; and
- e. Sterile packages that lose their integrity shall be repackaged and re-sterilised prior to use.

Using sterile devices

At point of use, upon opening the reprocessed medical device, a check must be made for integrity of the packaging and the device. Those performing this inspection must be provided with education that includes:

- a) Validating results of chemical tape and internal chemical indicators, if present;
- b) Visually inspecting the device for discoloration or soil; if present, the item is removed from service and reprocessed;
- c) Checking for defective devices and removing them from use;
- d) Checking for dampness or wetness (e.g., high humidity); if present, reprocessing may be required; and
- e) Reassembly of device, if required.

Recommendations

1. Written policies and procedures are available for storage, handling, rotation and labelling of sterile packs. (IIA)
2. Reprocessed medical devices shall be stored in a clean, dry location in a manner that minimizes contamination or damage. Traffic in the sterile storage area is controlled to limit access; no external shipping cartons are present. Shelving is at least 20 – 25cm above the floor, at least 45cm from the ceiling or sprinkler heads, and at least 5cm from outside walls. Supplies are only stored on designated shelving, counter and carts (not on windowsills, floors etc.). (IIA)
3. Sterile storage area is generally $\leq 24^{\circ}\text{C}$, relative humidity does not exceed 70%, minimum air changes per hour of 4 downward-draft type. (IIB)
4. Rotation of stock is maintained on a first in first out (FIFO) basis. (IIA)
5. At point of use, upon opening the reprocessed medical device, check for integrity of the packaging and the device; validate results of chemical monitors if present; and reassemble device if required. (IIA)

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Calibration and maintenance of reprocessing equipment

The on-going effectiveness of processes shall be checked regularly to make sure reprocessing equipment is delivering the process within specification. Reprocessing equipment includes but is not restricted to washer disinfectors, ultrasonic bath, heat sealers and sterilisers, Planned maintenance reduces the risk of malfunction of critical components that can cause failures in the efficacy of reprocessing.

The maintenance program may be in-house or contracted to the equipment manufacturer or a qualified service company. The individual performing the services should have sufficient training to understand the operation and calibration of the equipment being maintained. Records of calibration and maintenance shall be maintained.

Installation

Equipment should be installed according to manufacturer's instructions to ensure that the equipment will meet user's requirements and perform correctly. The equipment manufacturer will provide specific, written instructions on the utilities (i.e. water, electricity, compressed air, steam) required for the successful use of their equipment. The health service facility, in discussion with the equipment manufacturer, shall identify any deficiencies and rectify them before installation is carried out. Any deficiency with supply of utilities can significantly impact on the efficiency of use and overall production in the reprocessing environment.

Qualification test

Input from a professional with infection prevention and control expertise must be obtained prior to the purchase of reprocessing equipment. The equipment manufacturer should be specific as to what type of medical devices can be processed and the recommended parameters and accessories (i.e. racks, carriages, cleaning, disinfecting and sterilising agents) to make sure equipment that is fit for purpose is purchased.

Following purchase, new equipment must go through a validation process. This process proves the equipment has been installed to the manufacturer's requirements, is operating correctly and there has been no damage during transportation and verifies that the equipment can deliver effectively and reproducibly the results required for the devices being processed.

All equipment must undergo a qualification test before being put into routine service after new installation and requalification following relocation, major repair, change of processing products (for WD and AER) (ie cleaning and or disinfecting products) or other environmental changes to make sure the required processing parameters are being achieved for the loads and cycle selected.

Washer disinfectors must pass 3 consecutive loads per carriage type per cycle the carriage is used in. A wash challenge is to be included in each cycle as an additional verification of the cleaning efficacy, in addition to visual inspection.

Sterilisers must pass at least 3 consecutive cycles with the appropriate challenges (i.e. biological, chemical) placed in an empty steriliser, as well as at least one cycle challenged with a full test load. A pre-vacuum steam steriliser will need 3 consecutive Bowie Dick tests prior to the challenge loads. A steriliser shall not be approved for use if the biological indicator (BI) yields a positive result on any of the tests.

Calibration

Instrumentation used to control or monitor reprocessing equipment, e.g. timers, gauges and temperature monitoring devices, shall be recalibrated regularly to prove their accuracy, at least annually and immediately prior to requalification.

Planned preventive maintenance

Preventative maintenance should be carried out in accordance with the equipment manufacturer's instructions for use. To achieve this, a qualified individual should carry out maintenance of the equipment. Particular attention should be given to inspection, maintenance and replacement of

components subject to normal wear and tear such as recording devices, filters, steam traps, drain pipes, valves and door gaskets.

Maintenance records

A schedule for maintenance and the work carried out shall be maintained for each piece of reprocessing equipment. The records should provide a history of routine maintenance as well as unscheduled maintenance and repairs. Records should include the following information;

- a) Identity of the equipment by model, serial number and location;
- b) The date the maintenance or repair was carried out;
- c) The reason for maintenance or repair and a description of what was undertaken;
- d) Details of the parts replaced; and
- e) The name of the person completing the work and the person releasing the equipment back to use.

These records should be maintained by the supervisor responsible for the equipment and whoever else is deemed appropriate by the health care facility.

Recommendations

1. A schedule and maintenance record is kept and available for each piece of reprocessing equipment.
These demonstrate planned preventive maintenance is being undertaken according to the equipment manufacturer's instructions for use. (IIIA)
2. Calibration of instruments used to control and monitor the equipment is carried out periodically according to the equipment manufacturer's instructions for use and at other times where a replaced component requires it. (IIIA)
3. A qualification test is to be done after new installation, relocation, major repairs and any other environmental changes. The process must be fully documented, all test results documented and the documentation reviewed. (IIA)

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3. Association of periOperative Registered Nurses. Guidelines for perioperative practice. Denver, CO 2016.

Reprocessing Endoscopy Equipment/Devices

For the purposes of this document, endoscopes will be considered to be of two types:

- I. **Critical Endoscope:** Endoscopes used in the examination of critical spaces, such as joints and sterile cavities. Many of these endoscopes are rigid with no lumen. Examples of critical endoscopes are arthroscopes and laparoscopes.
- II. **Semi-critical Endoscope:** Fibreoptic or video endoscopes used in the examination of the hollow viscera. These endoscopes generally invade only semi-critical spaces, although some of their components might enter tissues or other critical spaces. Examples of semi-critical endoscopes are laryngoscopes, nasopharyngeal endoscopes, transesophageal probes, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes and enteroscopes.

Due to the complexity of their design, flexible fibreoptic and video endoscopes ('semi-critical endoscopes') require special cleaning and handling.

Since flexible bronchoscopes and cystoscopes are entering a sterile cavity, it is highly recommended that these be sterilised; however, if they are not compatible with sterilization, high-level disinfection is the minimum requirement.

A. Education and Training

All staff in any setting (hospital, clinic, ambulatory care and physician's office) where endoscopy is performed must adhere to infection prevention and control principles that will maintain a safe environment free from the possibility of spreading disease to patients and co-workers.

Individuals responsible for reprocessing endoscopes require training and must meet the health care facilities written endoscope processing competency requirements, which include on-going education and training:

- a) Staff assigned to reprocess endoscopes must receive device-specific reprocessing instructions to ensure proper cleaning and high-level disinfection or sterilisation;

- b) Competency testing of personnel reprocessing endoscopes shall be performed at initiation of employment and at least annually and
- c) Temporary personnel shall not be allowed to reprocess endoscopes until competency has been established.

Each individual who reprocesses instruments should complete the initial infection prevention and control orientation and reprocessing competency. Competency review and infection prevention and control updates should be validated and documented annually.

B. Cleaning Procedures

Each health care setting in which endoscopic procedures are performed shall have written detailed procedures for the cleaning and handling of endoscopes. Endoscopic cleaning shall take place immediately following completion of the clinical procedure, as soil residue in endoscope lumens dries rapidly, becoming very difficult to remove.

Bedside Clean: Immediately following completion of the endoscopy procedure:

- a) Flush and wipe the endoscope at point-of-use;
- b) Use a freshly prepared enzymatic cleaning solution; and
- c) Place the endoscope and accessories in a covered, leak proof container with a biohazard label and transport to the designated cleaning area.

Cleaning: The following steps must be included in the cleaning procedure:

- d) Follow the manufacturer's recommendations for cleaning and cleaning products;
- e) Perform leak testing after each use, prior to cleaning:
 - i. Verify the potency and integrity of the endoscope sheath through leak testing, performed prior to, and during, immersion of the endoscope;
 - ii. Perform the leak test according to the manufacturer's instructions;

- iii. An endoscope that fails the dry leak test should not undergo the immersion leak test;
- iv. Soak and manually clean all immersible endoscope components with water and a recommended cleaning agent prior to automated or further manual disinfection or sterilization;
- v. Disconnect and disassemble endoscope components (e.g., air/water and suction valves) as far as possible and completely immerse the endoscope and components in enzymatic cleaner;
- vi. Flush and brush all channels and lumens of the endoscope while submerged to remove debris and minimize aerosols;
- vii. Ensure that brushes used for cleaning lumens are of an appropriate size, inspected before and after use, and discarded or cleaned, high-level disinfected and dried following use;
- viii. Consider irrigation adaptors or manifolds that may be recommended by the manufacturer to facilitate cleaning;
- ix. Thoroughly rinse endoscope and all components with clean filtered water prior to disinfection/sterilisation and remove excess rinse water;
- x. Identify damaged endoscopes and immediately remove from service;
- xi. Discard enzymatic cleaner after each use;
- xii. Discard disposable cleaning items or thoroughly clean and high-level disinfect/sterilise non-disposable items between uses.

C. Special cleaning for duodenoscopes

The duodenoscope is a complex endoscopic instrument for Endoscopic Retrograde Cholangiopancreatograph (ERCP) that features a specific channel, which allows the manipulation of a guide wire at the terminal end of this channel. This separate channel is the elevator channel that is complex in design and has crevices that are difficult to access with a cleaning brush. Outbreaks related to duodenoscopes involving carbapenemase-resistant *Enterobacteriaceae* (CRE) and other multiple drug

resistant organisms (MDROs) have been reported. Meticulously cleaning duodenoscopes prior to HLD should reduce the risk of transmitting pathogens but may not entirely eliminate it. Thus, it is important to follow manufacturer's instruction to clean the elevator parts and using appropriate connectors and brushes are also critical to achieve thorough cleaning. Regular review of staff in the endoscopy unit on the competency of cleaning the duodenoscope is important.

D. Endoscope Disinfection and Sterilisation

Procedures for disinfection and sterilisation of endoscopes must ensure that a minimum of high-level disinfection is used for all endoscopes and their accessories, excluding biopsy forceps and brushes (which require sterilisation). The following steps must be included in the disinfection/sterilisation procedure:

- a) Choose a disinfectant that is compatible with the endoscope;
- b) Monitor the efficacy of the disinfectant before each use with test strips available from the product manufacturer;
- c) Maintain a written log of monitoring test results;
- d) Do not use disinfectants past their expiry date;
- e) Carefully follow the manufacturer's directions regarding the ambient temperature and duration of contact for the disinfectant (e.g., 2% glutaraldehyde for 20 minutes at 20°C);
- f) Completely immerse the endoscope and endoscope components in the high-level disinfectant/sterilant and ensure all channels are perfused; and
- g) Following disinfection, rinse the endoscope and flush the channels with filtered or sterile water.
- h) High-level disinfection of cystoscopies should be followed by rinsing with sterile water and rinse water must be discarded after each use/cycle.

A disposable sheath placed over the endoscope during use reduces the number of microorganisms on the scope but does not eliminate the need of cleaning, disinfection and sterilisation between uses.

E. Special disinfection and sterilisation processes for duodenoscope

To minimise the immediate risk, it is recommended to adhere to current endoscope reprocessing guidelines with any one of the following methods for reprocessing duodenoscopes (priority ranked):

- a) Ethylene oxide sterilization after HLD with periodic microbiologic surveillance
- b) HLD done twice with periodic microbiologic surveillance
- c) HLD with scope quarantine until negative culture
- d) Liquid chemical sterilant processing system using peracetic acid (rinsed with extensively treated potable water) with periodic microbiologic surveillance
- e) Other FDA-cleared low-temperature sterilization technology (provided material compatibility and sterilization validation testing performed using the sterilizer and endoscope) after HLD, with periodic microbiologic surveillance
- f) HLD with periodic microbiologic surveillance

Follow CDC interim protocol regarding surveillance for bacterial contamination of duodenoscopes after reprocessing using a special culture method and test. It is recommended to test each duodenoscope either once a month or after 60 ERCP procedure.

F. Biopsy Forceps and Brushes

Because of the difficulty cleaning biopsy forceps/brushes, it is strongly recommended that disposable items be used. Reusable biopsy forceps and brushes that break the mucosal barrier must be sterilised after each use. Reusable biopsy forceps/brushes must be meticulously cleaned prior to sterilisation using ultrasonic cleaning.

G. Automated Endoscope Reprocessor (AER)

To achieve consistency in endoscope reprocessing (disinfection), it is recommended that automated endoscope reprocessor (AER) be used. The following must be included in the procedure:

- a) Follow the manufacturer's instructions for use of the AER;
- b) Ensure that the endoscope and endoscope components to be reprocessed are compatible with the AER used;
- c) Ensure that channel connectors and caps for both the AER and the endoscope are compatible;
- d) Place brushes and instruments used to clean the endoscope in the AER for disinfection;
- e) Do not open or stop the AER once started; if an AER cycle is interrupted, high-level disinfection cannot be assured;
- f) Implement and document preventive maintenance program(s) for the AER(s).

F. Drying and Storage of Endoscopes

Steps in the final drying of semi-critical endoscopes include:

- a) Initial flushing of all channels with medical or filtered air;
- b) Flushing all channels with 70% isopropyl alcohol (IPA) to aid in the drying process; and
- c) Second flushing of the channels with instrument grade air or drying in a HEPA-filtered drying cabinet.

Storage procedures must include the following:

- a) Remove caps, valves and other detachable components during storage and reassemble just before use; store close to the endoscope in a manner that minimises contamination;
- b) Store semi-critical endoscopes by hanging vertically in dedicated closed, ventilated cabinet outside of the decontamination area and procedure room;
- c) HEPA-filtered channel purge drying cabinet should be used for storage;

- d) Store endoscopes that have been sterilised in their sterilisation containers;
- e) Do not allow endoscopes to coil, touch the sides, floor or bottom of the cabinet while handling, or be stored in their cases;
- f) Ensure that endoscope storage cabinets are constructed of non-porous material that can be cleaned;
- g) Clean and disinfect endoscope storage cabinets at least weekly with an approved low-level disinfectant.

Colonoscopes have a maximum shelf life of 7 days, if stored dry. There are no recommendations regarding shelf life of other types of endoscopes.

G. Equipment Used for Cleaning During Procedure

The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during the ERCP (endoscopic retrograde cholangiopancreatography) procedure, should be cleaned and receive high-level disinfection or sterilisation at least daily following manufacturer's instruction. Sterile water shall be used to fill the water bottle.

H. Record-keeping

An accurate, permanent record of endoscope use and reprocessing will assist in tracking endoscopes and clients/patients/residents in the event of a recall or follow-up:

- a) For each procedure, document the client/patient/resident's name and record number, the date and time of the procedure, the type of procedure, the endoscopist, and the serial number or other identifier of both the endoscope and the AER (if used) to assist in outbreak investigation;
- b) Record the endoscope number in the patient record; and
- c) Retain records according to the policy of the facility.

Recommendations

1. Individuals responsible for reprocessing endoscopes shall be specially trained and shall meet the facility's written endoscope processing competency requirements, including ongoing education and training and annual competency testing (IA)
2. Each health care setting in which endoscopic procedures are performed shall have written, detailed procedures for the cleaning and handling of endoscopes. (IIA)
3. Critical endoscopes shall be sterilized prior to use. (IA)
4. Semi-critical endoscopes require a minimum of high-level disinfection prior to use. (IA)
5. Adequate ventilation is required to remove toxic vapours generated by, or emitted from, cleaning or disinfecting agents. (IA)
6. Endoscope cleaning shall commence immediately following completion of the clinical procedure. (IA)
7. Patency and integrity of the endoscope sheath shall be verified through leak testing, performed after each use. (IA)
8. Endoscopic equipment/devices shall be rinsed and excess water removed prior to disinfection or sterilization. (IIA)
9. Endoscopic accessories (e.g., biopsy forceps and brushes) that enter sterile tissue or the vascular system shall be disposable or sterilized after each use. (IA)
10. Final drying of semi critical endoscopes shall be facilitated by flushing all channels with filtered air, followed by 70% isopropyl alcohol, followed by forced air purging of the channels. (IA)
11. Semi critical endoscopes shall be stored in a dedicated, closed, ventilated cabinet outside of the reprocessing area and procedure room. (IIA)
12. The water bottle and its connecting tube, used for cleaning the endoscope lens and irrigation during ERCP (endoscopic retrograde cholangiopancreatography) procedures, shall be cleaned and sterilized following manufacturer's instructions. (IIIA)
13. A preventive maintenance program for automated endoscope reprocessor (AER) shall be implemented and documented. (IIIA)

14. Healthcare settings shall have policies in place providing a permanent record of endoscope use and reprocessing, as well as a system to track endoscopes and clients/patients/residents that includes recording the endoscope number in the client/patient/resident record. (IIIA)
15. Enhancement in methods for reprocessing duodenoscopes should be followed and documented. (IIA)
16. Regular surveillance for bacterial contamination of duodenoscopes after reprocessing using a special culture method and test is recommended. (IIA)

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Education and Training

The manager and all supervisors involved in reprocessing must, as a minimum, have completed a recognised qualification/certification course in reprocessing practices. A plan must be in place for each person involved in reprocessing to obtain this qualification. It is strongly recommended that continuing education and or re-certification be obtained at a regular interval.

It is the supervisor's responsibility to ensure that:

- a) Any individual involved in the cleaning, disinfection and/or sterilisation of medical equipment/devices is properly trained and their practice audited on a regular basis to verify that standards are met;
- b) Training includes information on cleaning, disinfection and sterilisation, occupational health and safety issues, and infection prevention and control;
- c) Orientation and continuing education is provided and documented for all personnel involved in reprocessing of medical equipment/devices; and
- d) Feedback is provided to reprocessing staff in a timely manner.

The policies of the health care setting specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices and will ensure that:

- a) All staff who are primarily involved in reprocessing obtain and maintain certification;
- b) Any individual involved in any aspect of reprocessing obtains education, orientation and training specific to the medical equipment/device to be reprocessed (e.g., dental hygienists, radiation technologists, nurses in long- term care, nurses in physician offices);
- c) There is a process in place to ensure continued competency, including continuing education;
- d) Supervisory staff must be competent through education, training and experience in the reprocessing of reusable medical equipment/devices.

All staff involved in reprocessing of medical equipment/devices must be supervised and shall be qualified through education in a formally recognized course for sterilisation technology, training and experience in the functions they perform shall be provided at regular intervals and periodic competency assessment all orientation, training and continuing education is documented.

Recommendations

1. The policies of the healthcare setting shall specify the requirements for, and frequency of, education and training as well as competency assessment for all personnel involved in the reprocessing of medical equipment/devices. (IIA)
2. All aspects of reprocessing shall be supervised and shall be performed by knowledgeable, trained personnel. (IIA)
3. Managers, supervisors and staff involved in reprocessing have completed a recognized qualification/certification course in reprocessing practices. (IIA)
4. A plan must be in place for each person involved in reprocessing to obtain certification qualification. (IIIA)

References

1. Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings | May 2013 (PIDAC).

Appendix 1

Table 6 Categories for strength of each recommendation

Categories for strength of each recommendation	
CATEGORY	DEFINITION
A	Good evidence to support a recommendation for use.
B	Moderate evidence to support a recommendation for use.
C	Insufficient evidence to support a recommendation for or against use
D	Moderate evidence to support a recommendation against use.
E	Good evidence to support a recommendation against use.
Categories for quality of evidence on which recommendations are made	
GRADE	DEFINITION
I	Evidence from at least one properly randomized, controlled trial.
II	Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies, preferably from more than one centre, from multiple time series, or from dramatic results in uncontrolled experiments.
III	Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies, or reports of expert committees.

Appendix 2

APSIC Checklist

Note: Yellow highlighted boxes refer to mandatory items

(A) Handling, Collection and Transport of Contaminated Instruments

	Item reviewed	Yes/No	Action Plan
1	Reusable items separated from waste at point of use		
2	Contaminated disposable items are discarded appropriately (including sharps.)		
3	Gross soil is removed from instruments at point of use if immediate transportation not possible		
4	Soiled items should be kept moist (moist towel, enzyme foam or spray product)		
5	Secured, dedicated containers are provided for soiled instruments		
6	Use of puncture resistant, leak-proof containers for soiled items		
7	Soiled items must be contained during transportation		
8	Transportation of soiled instruments avoids high (public) traffic areas		
9	Transportation carts should be covered and should prevent items from falling over or off		
10	Dedicated elevators (or lifts) with direct access to decontamination area.		
11	Policy and procedure in place for transportation of contaminated items between buildings, if applicable		

(B) Cleaning and Decontamination Processes

	Item reviewed	Yes/No	Action Plan
1	Written policies and procedures in place for all cleaning and decontamination processes.		
2	Instrumentation is disassembled (according to manufacturer's instructions) to expose all surfaces for cleaning		
3	Rigid container systems disassembled according to manufacturer instructions (filters, valves and interior baskets.)		
4	Cleaning agents are used according to manufacturer's instructions (dilution and temperature, etc.)		
5	Appropriate manual and mechanical cleaning methods are used according to manufacturer's instructions and IFU's are accessible to decontamination staff		
6	Appropriate personal protective equipment (PPE) are used		
7	Appropriate brushes/cleaning implements designed for use on medical devices are used.		
8	Brushes/cleaning implements are either disposable or if reusable, are decontaminated at least daily.		
9	Monitoring of mechanical cleaning equipment should be done upon installation and then weekly (preferably daily) and recorded		
10	Appropriate manual and mechanical rinsing methods are understood and are done according to manufacturer's instructions.		
11	Cleaning Agent (Enzymatic cleaner) should be compatible with the medical device to be cleaned.		
12	Chemical for disinfectants and terminal sterilisation are used according to manufacturer's instructions		
13	Ultrasonic cleaner solution is changed at specified frequency or sooner if needed		
14	Final rinse in washer disinfectant is done with treated water (deionized, distilled, or RO water)		

(C) Instrumentation Inspection, Preparation & Packaging

	Item reviewed	Yes/No	Action Plan
Instrument inspection			
1	Ensure instruments are cleaned and dried before packaging.		
2	Inspect instruments for flaws or damage. Check for rust, pitting, corrosion, burrs, nicks, cracks, chipping of plated surfaces. Lighted magnifying glass available for instrument inspection.		
3	Cleaning verification by users should include visual inspection combined with other verification methods (ATP) that allow assessment of instrument surfaces and channel		
4	Instruments: Ensure that <ul style="list-style-type: none"> - Cutting edges are sharp; - Moving parts move freely, without sticking. - Instruments needing repair are taken out of service for repair or replacement. 		
5	Follow MDMs instructions for instruments requiring lubrication after cleaning or prior to sterilisation.		
Preparation and Assembly:			
6	Delicate/sharp instruments are protected while being handled/assembled for sterilisation. (<i>May use special holders, tip guards, or foam sleeves</i>). <ul style="list-style-type: none"> - Tip protectors should be sterilant-permeable. 		
7	Instruments that open (e.g. scissors, haemostats) are held in unlocked, open positions.		
8	Multi-part instruments are disassembled prior to sterilisation, ensuring all parts are easily accessed for aseptic assembly.		
9	Lumened devices: <ul style="list-style-type: none"> - Remove stylets/plugs, such as catheters, needles, tubings. - Moistening of the lumen may be recommended; consult device manufacturer. 		
10	Complex instruments (air-powered, endoscopes, having lumens or channels) are prepared according to written instructions from device manufacturer.		
11	Non-linting absorbent material may be placed in trays to help facilitate drying. Tray liners or other absorbent materials may be used to alleviate drying problems.		

12	Basins: <ul style="list-style-type: none"> - Graduated basins should differ in diameter by one inch. - Use non-linting absorbent material between nested basins. - Wrapped basin sets should not exceed 3 Kg (7 lbs.). 		
13	Containerized instrument sets do not exceed 11kg (25 lbs.).		
Packaging:			
14	Packaging materials are held for a min. of 2 hrs. prior to use at room temp (21°F-24°F) and at a relative humidity ranging from 30-60%. <i>[This is needed to permit steam sterilisation and prevent superheating.]</i>		
15	Packaging materials are examined regularly for defects (i.e. holes, worn spots, stains).		
16	Wrappers should be kept snug, but not wrapped too tightly or strike-through could occur.		
17	Paper/Plastic Pouches: <ul style="list-style-type: none"> - Labelling is done on plastic side only. - Double peel pouch only if pouch is validated for this use. 		
18	Wrapped packs: write only on indicator tape or affixed labels.		
19	Perforated, wire-mesh-bottom trays, and rigid organizing trays are inspected prior to each use to ensure there are no sharp edges, nicks, or loose wire-mesh.		
20	Tape (other than sterilisation indicator tape) should not be used to secure packages, nor should safety pins, ropes, paper clips, staples, or other sharp objects		
21	Validation test to be done for heat sealer at set frequency.		

(D) Sterilisation and Monitoring

	Item reviewed	Yes/No	Action Plan
Follow Manufacturers' Guidelines:			
1	<u>Steriliser Manufacturers'</u> written instructions for cycle parameters are available.		
2	<u>Rigid Container Manufacturers'</u> instructions for cycle parameters are followed.		
3	<u>Medical Device Manufacturers'</u> written instructions for sterilisation cycle parameters are available/accessible for items to be sterilised, including Loaner sets		
Loading the Steriliser: (Follow steriliser Mfrs. Written instructions)			
4	Group together similar items requiring same cycle parameters.		
5	Steriliser Cart: - Allow space between packs - Do not overload - Packages should not touch chamber walls		
6	Mixed Loads - Place metal items on the loading cart below textiles and paper-plastic pouches (to prevent condensate from dripping onto lower packs).		
7	Solid-bottom pans, bowls, and trays are tilted on edge and oriented in the same direction.		
8	Paper-plastic pouches – Use baskets to facilitate placing pouches on edge.		
9	Rigid Containers: Stacking could interfere with air evacuation; follow container Manufacturer's Instructions.		
Unloading the Steriliser:			
10	Open steriliser door properly. - Door may be opened slightly at the end of the cycle (for some time) prior to removing the load.		
11	Load contents: There should be no visible signs of liquid, or water droplets. (Wet items are considered contaminated even if not touched.)		
12	Sterilised items remain on the cart to cool for a minimum of 30 minutes, and are not touched during the cooling process.		
13	Place cart in a low traffic area without proximity to air-conditioning or cold-air vents.		

	Item reviewed	Yes/No	Action Plan
14	Immediate Use “Flash” Items: Are used immediately and not stored for later use. (Assume condensate will be present.)		
Physical monitors, Chemical indicators, Biological indicators:			
15	Verify parameters of the cycle have been met by reviewing cycle printout tapes. Circle minimum temperature and exposure time, initial/sign, and date.		
16	Bowie-Dick Testing is done daily in pre-vacuum sterilisers before first processed load. Process Bowie-Dick at 132°-134°C for 3.5 to 4 minutes. One pack per load in an empty chamber. Record results.		
17	External process indicators (indicator tape, labels) are affixed to hospital-sterilised packages and containers.		
18	Internal chemical indicator(s) (Type 4, 5, 6) are placed inside every package in the most challenging location for sterilant to reach. (Refer to Rigid Container Manufacturers’ Instructions for CI placement).		
19	<u>Implant Loads:</u> Monitor with a BI PCD containing a Type 5 Integrating Indicator. Implants should be quarantined until BI results are known, except in emergency situations		
20	<u>Non-Implant Loads:</u> <i>Optional</i> monitoring with a PCD containing either: a BI, a BI and Type 5, a Type 5 integrating indicator, or a Type 6 emulating indicator.		
21	Routine steriliser efficacy testing with a BI PCD is done daily (if steriliser run daily): <u>Sterilisers larger than 60 L</u> –Place BI PCD in first load of items to be sterilised, on bottom shelf of steriliser cart over drain. <u>Table Top sterilisers:</u> BI PCD is run with first load of the day and generally placed in centre of load.		
Use appropriate BI PCD depending on type of steriliser:			
22	<u>Steam: daily (each day the sterilizer is used)</u>		
23	<u>Gaseous sterilization (e.g. EO, H₂O₂): BI should be used every load</u>		
24	<u>Sterilisers larger than 60 Litter.</u> Use commercially available FDA-cleared BI PCD or AAMI 16-towel pack. (M)		

	Item reviewed	Yes/No	Action Plan
25	<u>Table Top sterilisers</u> . BI PCD is a user assembled challenge test pack, which creates the greatest challenge (e.g., BI in peel pouch, BI in wrapped set) and contains items normally processed.		
BI Test/Control, and Results:			
26	<u>Control BI</u> : Incubate a positive BI control each day a test vial is incubated and in each Auto-reader or incubator. The Control BI needs to be from the same lot number as the Test BI. Record results.		
27	<u>Test BI</u> : Incubate Test BI according to BI Manufacturers' Instructions. Record results.		
Qualification Testing:			
28	For sterilisation process failures where the cause is not immediately identifiable, and after major steam or steriliser repairs, run 3 empty cycles with a BI PCD followed by 3 empty cycles with a Bowie-Dick test if prevacuum steriliser.		
Steriliser Maintenance:			
29	Steriliser "drain strainers" are inspected daily for debris.		
30	Steriliser external and internal surfaces are routinely cleaned.		

(E) Sterile Storage and Distribution

	Item reviewed	Yes/No	Action Plan
STERILE STORAGE:			
1	Written Policies and Procedures are available for storage, handling, rotation, and labelling of sterile packs.		
2	Traffic in the sterile storage area is controlled to limit access to sterile items.		
3	Outside shipping containers and corrugated cartons are not used as containers in sterile storage areas.		
4	Storage area temperature is generally less than 24°C and Relative Humidity should not exceed 70%.		
5	Sterile items are stored at least 20-25cm (8-10") above the floor, at least 45cm (18") below the ceiling or sprinkler heads, and at least 5cm (2") from outside walls.		
6	Shelving and storage carts have a physical barrier between the bottom shelf and the floor.		
7	Medical/Surgical items, including rigid containers, are not stored next to or under sinks, under exposed water/sewer pipes, or in any location where they may become wet.		
8	Supplies are stored only on designated shelving, counters, and carts (not on windowsills, floors, etc.)		
9	When stacking container systems, ensure they are firmly seated on one another.		
DISTRIBUTION:			
10	Supplies are distributed on a First In First Out (FIFO) basis		
11	Packaging is inspected visually for integrity, and labelling, prior to using items.		
12	Transport carts should have a physical barrier between the bottom shelf and the floor. - Reusable covers should be cleaned after each use.		
13	Carts are decontaminated/ dried before reused for transporting sterile supplies.		

(F) Documentation

	Item reviewed	Yes/No	Action Plan
EQUIPMENT & CYCLE DOCUMENTATION:			
1	Documentation for each mechanical washer is maintained: Monitor and verify cleaning processes (e.g. digital readouts, and cycle printouts)		
2	Documentation for each steriliser is maintained, and includes results from each load. (e.g. monitoring results; steriliser repair records)		
3	<u>For each cycle printout tape:</u> <ul style="list-style-type: none"> - Verify cycle start was initiated - Ensure cycle selected was appropriate for load contents - Verify correct Time & Temp. was met - Ensure there were no cycle aborts or warnings 		
4	<u>Record for each cycle:</u> <ul style="list-style-type: none"> - Lot number; - Load contents; - Exposure time/temp; *Name/initials of steriliser operator; - Results of BI testing, if applicable; - Results of Bowie-Dick testing, if applicable; - Results of CIs in test packs; reports of non-conclusive or non-responsive CIs found in the load 		
5	<u>An instrument tracking system or other type of computer system is used.</u>		
PRODUCT RECALLS:			
6	<ul style="list-style-type: none"> - Policies & Procedures are clear and concise - Records are maintained - Lot control labels are used, to include: Steriliser ID, lot number, sterilisation date, expiration date, name of pack and initials. 		
7	<u>Sterilisation Process Failure:</u> – When cannot immediately identify cause of failure (e.g. selected incorrect cycle setting), reprocess the load and recall/reprocess all items dating back to last load in steriliser with negative BI results.		

(G) Facility Design

	Item reviewed	Yes/No	Action Plan
1	All instrumentation reprocessing is centralized		
2	If centralized reprocessing is not possible, consistent policies and procedures between locations are in place.		
3	CSSD department size is appropriately designed with regard to anticipated volume		
4	Decontamination area facilitates proper workflow and provides adequate space for necessary equipment		
5	Decontamination area has space dedicated to donning and removal of PPE.		
6	Decontamination sink is of adequate size and has three compartments (for soaking, cleaning and rinsing)		
7	Handwashing sinks/hand hygiene facilities are appropriately located in department		
8	Emergency eyewash stations (required by OSHA) located within 10 seconds travel time of all chemical usage locations, with a continuous flush for at least 15 minutes. E.g., Decontamination area.		
9	Functional workflow pattern: clear distinction (i.e. physical wall) between dirty and clean		
10	Functional workflow pattern: pass-through window available to avoid hallways, and is not propped open		
11	Temperature and humidity monitoring controls in decontamination and clean areas		
12	Temperature and humidity monitoring is recorded daily		
13	Appropriate traffic control. Written policy and procedure in place for authorized entry and movement and attire.		
14	Floors and walls are constructed from materials that can withstand frequent cleaning		
15	Ceilings are flush surfaces and not of materials that are of a particulate or fibre-shedding composition.		
16	Doors close freely and do not have thresholds.		
17	Appropriate positive (clean areas) and negative (soiled areas) pressure ventilation systems in place		

	Item reviewed	Yes/No	Action Plan
18	Appropriate air-change in decontamination and storage area		
19	Lighting adequate for all work areas		

(H) Considerations

	Item reviewed	Yes/No	Action Plan
1	CS supervisory personnel meet minimum recommended qualifications		
2	CS supervisory personnel maintain competency and participate in departmental continuing education		
3	CS technicians meet minimum recommended qualifications		
4	All new CS personnel receive initial and comprehensive facility and department orientation.		
5	All CS personnel receive a minimum annual training on department policies and procedures All CS personnel demonstrate competency annually.		
6	Written policy on personal hygiene.		
7	Written policy and adherence to appropriate CS personnel attire.		
8	Written policy and adherence to appropriate PPE in decontamination area.		
9	Written policy and schedule for housekeeping		
10	Written policy and schedule for instrument and sterilizer machine maintenance		
11	Products used for any/all stages in reprocessing (cleaning, disinfection, sterilization) must be approved by the committee responsible for product selection, by an individual with reprocessing expertise and by an individual with infection prevention and control expertise		

Appendix 3

Construction of user prepared PCD

The PCD (Process Challenge Device) is a challenge test pack. Depending on the application as part of sterilisation process monitoring, the PCD may contain

- a) a BI,
- b) a BI and a Type 5 category i (integrating CI), or
- c) a Type 5 category e (integrating CI) or Type 6 category e (emulating CI).

The PCD (challenge test pack) should consist of 16 clean, preconditioned, surgical towels, in good condition, each measuring approximately 41 cm by 66 cm. Each towel is folded lengthwise into thirds and then folded width wise in the middle per the diagram below. After they are folded, the towels are placed one on top of another, with folds opposite each other, to form a stack that is approximately 23 cm by 23 cm by 15 cm.

Once the stack is formed the BI (one or more) is placed in the approximate geometric centre of the pack (between the eighth and ninth towels). The CI is positioned in a similar manner within the pack. The pack is then taped to secure the towels and contents. The pack is not wrapped as it is designed to present the challenge through the manner of folding and layering.

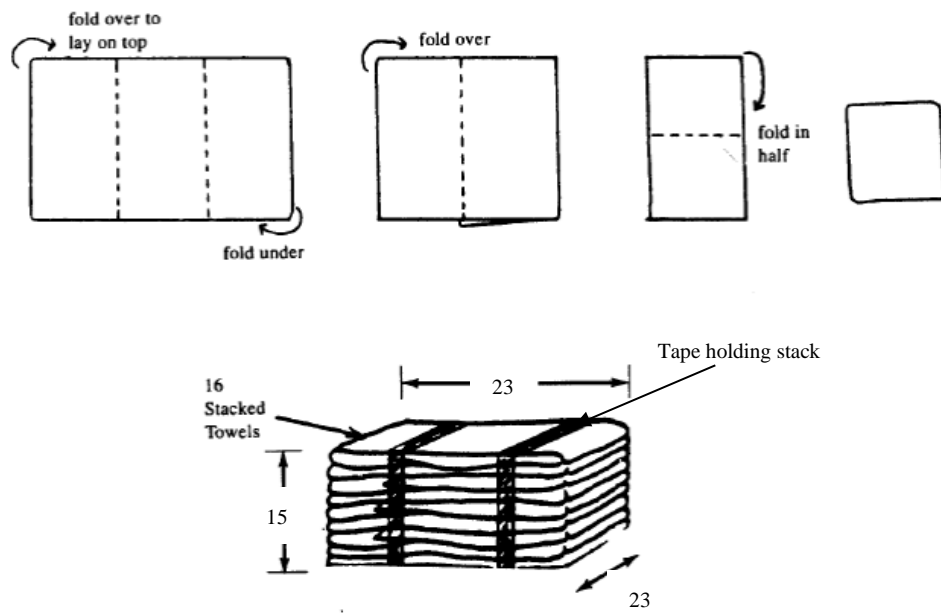


Figure amended from AAMI ST79