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Decontamination and Reprocessing of Medical Devices for Health-care Facilities

World Health Organization

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Abbreviations

ABHR	alcohol-based hand rub
AER	automated endoscope reprocessor
AS	Australian standard
Cfu	colony-forming units
CDC	Centers for Disease Control and Prevention
CHA	Canadian Health-care Association
CHRISP	Centre for Healthcare related Infection Surveillance and Prevention
CMS	Central Manufacturing Standards
SSD	Sterile service department
EN	European norm
ERCP	endoscopic retrograde cholangiopancreatography
ETO	ethylene oxide
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
HBN	Health Building Note
HEPA	high efficiency particulate absorption
HIV	human immunodeficiency virus
IAP	inspection, assembly and packing
IQ	installation quality
ISO	International Standardisation Organisation
IUS	immediate use steam (sterilization)
NaDCC	sodium dichloroisocyanurate
OH&S	Occupational health and safety
OPA	ortho-phthaladehyde
OQ	operating quality
PAHO	Pan American Health Organization
PHC	primary health centres
PPE	personal protective equipment
PPM	parts per million
PQ	process quality
PSBS	preformed sterile barrier system
PVC	polyvinyl chloride
QA	quality assessment
RMD	reused medical devices
RO	reverse osmosis
RSUD	reprocessed single-use device
SAL	sterilization assurance level
SOP	standard operating procedures
SSD	sterile services department
SUD	single-use device
SWOT	strengths, weaknesses, opportunities and threats (analysis)
TSSU	theatre sterile services unit
WHO	World Health Organization

Glossary of terms

Alcohol-based hand rub: A liquid, gel or foam formulation of alcohol (e.g. ethanol, isopropanol), which is used to reduce the number of microorganisms on hands in clinical situations when the hands are not visibly soiled. They contain emollients to reduce skin irritation and are less time-consuming to use compared with hand washing.

Assessment (or Audit): A comprehensive review of reprocessing practices to identify gaps in compliance with best practice standards.

Autoclave: An autoclave or sterilizer is a device used to sterilize equipment and supplies by subjecting them to high pressure and steam at 121°C or above. For the purposes of this document, the term autoclave refers to a large industrial sterilizer used in a central sterile services department.

Automated endoscope reprocessor: Machine designed to assist with the cleaning and disinfection of endoscopes.

Bioburden: The number of viable organisms that contaminate a device.

Biological indicator: Test systems containing viable bacterial spores providing a defined resistance to a sterilization process.

Chemical indicator: Test systems that reveal a change in one or more predefined variables based on a chemical or physical change resulting from exposure to the process e.g. colour change.

Cleaning: The first step required to physically remove contamination by foreign material, e.g. dust, soil. It will also remove organic material, such as blood, secretions, excretions and microorganisms, to prepare a medical device for disinfection or sterilization.

Contamination: The soiling of inanimate objects or living material with harmful, potentially infectious or unwanted matter.

Decontamination: Removes soil and pathogenic microorganisms from objects so they are safe to handle, subject to further processing, use or discard. (Centers for Disease Control and Prevention [CDC] Guidelines for Disinfection and Sterilization in Healthcare Facilities, 2008).

Detergent: A cleaning agent that increases the ability of water to penetrate organic material and break down greases and dirt. Detergents are needed to allow effective cleaning to take place.

Disinfectant: A chemical agent that is capable of killing most pathogenic microorganisms under defined conditions, but not necessarily bacterial spores. It is a substance that is recommended for application to inanimate surfaces to kill a range of microorganisms. The equivalent agent, which kills microorganisms present on skin and mucous membrane, is called an **antiseptic**.

Disinfection: A process to reduce the number of viable microorganisms to a less harmful level. This process may not inactivate bacterial spores, prions and some viruses.

Dispersion: Breaking up of dirt aggregates into small particles.

Emulsification: The breakdown of larger fat globules into smaller uniformly distributed particles.

Invasive procedure: Any procedure that pierces skin or mucous membrane or enters a body cavity or organ. This includes surgical entry into tissues, cavities or organs.

Medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, intended by the manufacturer to be used in humans for the purpose of the diagnosis, prevention, monitoring, treatment or alleviation of - or compensation for - an injury or handicap.

Monitoring compliance and effectiveness: A process of audit carried out by the infection prevention and control team or a similar group in order to measure the level of compliance with the policy outlined in this document. The audit activity will review both the environment and processes related to equipment decontamination in community health-care settings. Feedback will be supplied to managers to promote compliance with the policy.

Original device: A new, unused single-use device.

Parametric release: A system of release that gives the assurance that the product is of the intended quality based on information collected during the manufacturing process and in compliance with specific Good Manufacturing Practice requirements related to parametric release.

Prion: A small proteinaceous infectious unit that appears to cause transmissible spongiform encephalopathies. These are rare, fatal neurodegenerative disorders that occur in a wide variety of animals, including humans, and are highly resistant to disinfection and sterilization.

Quality assurance: A programme for the systematic monitoring and evaluation of the various aspects of a service e.g. decontamination, to ensure that standards of quality are being met.

Quality control: A system of maintaining standards by testing a sample against a defined specification.

Reprocessed single-use device: A reprocessed single-use device is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.

Reprocessing: All steps that are necessary to make a contaminated reusable medical device ready for its intended use. These steps may include cleaning, functional testing, packaging, labelling, disinfection and sterilization.

Saponification: A chemical process that produces soap usually from fats which are soluble in water.

Single-use device: A device intended for one use only or on a single patient during a single procedure.

Sterilisation: A validated process used to render an object free from viable microorganisms, including viruses and bacterial spores, but not prions.

Surfactant: An agent that will increase the penetration of dirt by reducing the surface tension.

Suspension: Maintaining insoluble particles suspended in water.

Validation: Documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently disinfect and sterilize instruments and other medical devices.

Verification: Confirm through the provision of objective evidence that specified requirements have been fulfilled.

Water softening: The removal of cations present in hard water. The softened water is more compatible with detergents and extends the lifetime of plumbing and equipment.

Introduction

Globally, hundreds of millions of people are affected every year by avoidable infections in health care (health care-associated infections, HAIs). The determinants of HAI are influenced by a complex combination of gaps in policies, infrastructure, organization and knowledge, defects in health-care workers' behavior, and patient-related factors. Through knowledge, best practices and infrastructures improvement, infection prevention and control (IPC) aims to prevent harm due to HAI to patients and health workers.

Sterilization and decontamination of instruments and medical devices play a very important role in the prevention of HAIs. Indeed, defective sterilization of surgical instruments and disinfection of reusable objects including endoscopic devices, respiratory care devices, and reusable hemodialysis devices still occur in many settings and lead to HAIs. In addition, in many low-resource settings inappropriate reuse of disposable medical devices is common practice and the procedures to clean and decontaminate these devices are inadequate and not standardized. The processes of sterilization and decontamination are complex, require specific infrastructure and equipment and involve several steps that need to be correct, from devices collection, receipt by the unit, processing, storage and distribution them throughout the facility. Of utmost importance are also quality control procedures to assess the correct functioning of the equipment.

Most common HAIs caused by harmful device reuse practices or inadequate sterilization/decontamination procedures are surgical site infections (SSI), hepatitis B and C, HIV infection, urinary and vascular catheter associated infections, and ventilator-associated infection.

Following recent threats caused by widespread epidemics and increasing awareness about the spread of antimicrobial resistance, several countries are paying more attention and investing resources to strengthening IPC infrastructures and improving practices. In this context, this manual is a very important instrument to provide guidance to health managers and health workers on required infrastructures and standard procedures for effective sterilization, and decontamination reprocessing of medical devices. This edition of the manual represents a thorough revision and update of the Sterilization Manual for Health Centers issued by the Pan American Health Organization in 2009 and it is the result of a close collaboration between the IPC Global Unit at the Headquarters of the World Health Organization, the Pan American Health Organization, and a group on international experts.

WHO Decontamination and Sterilization Working Group

In response to the lack of guidance in sterile services, particularly for low- and middle-income countries, the current Pan American Health Organization (PAHO) manual was written by two very knowledgeable colleagues, Drs Silvia I Acosta-Gnass and Valeska de Andrade Stempliuk, who worked tirelessly to produce a working document for PAHO/WHO. The manual has been revised in close collaboration with the Infection Prevention and Control Global Unit of the World Health Organization (WHO) Headquarters to expand its scope to a global context in recognition of countries where sterile services departments (SSD) either do not exist or are inadequately run. The aim of this manual is to provide guidance in improving standards in sterile services across health-care facilities worldwide.

The Working Group comprises international experts in the sector of reprocessing of medical devices with a vast experience and knowledge related to the legislation, processes and outcomes of well-established sterile services.

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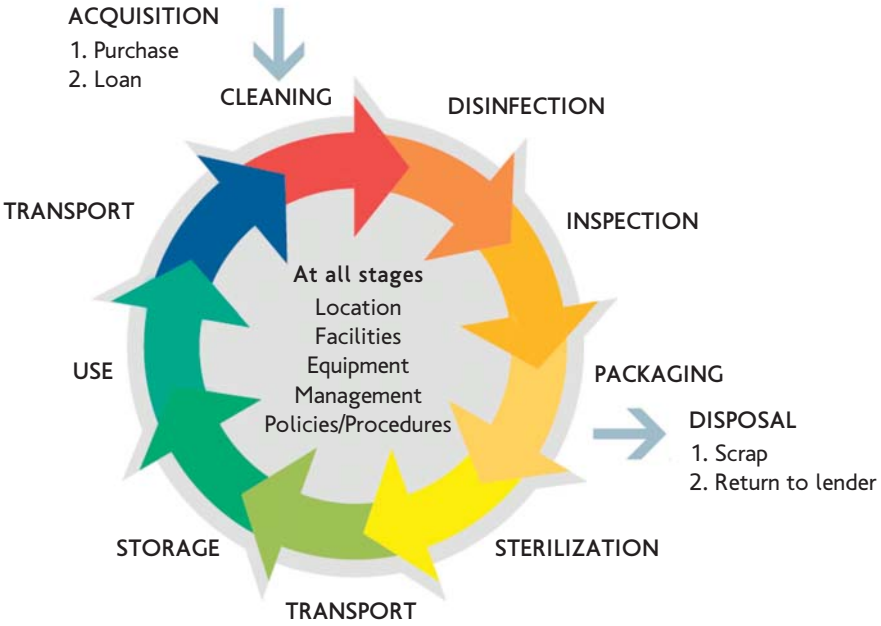
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General aspects of sterilization

The life cycle of decontamination illustrates the salient features of decontamination, each step being as important as the next (Figure 1). This section describes three important features for a sterile service: risk assessment, quality assurance and environmental cleaning. Further sections will deal with specific aspects of sterile services.

Figure 1. **The decontamination life cycle**



Source: Health Building Note 13 (HBN13), Department of Health, United Kingdom, 2004

QUALITY ASSURANCE

Introduction

Each step of the sterile supply cycle is crucial to the good and safe use of a sterile reusable medical device/instrument during a surgical intervention. An error during any of the stages of the decontamination cycle may lead to huge costs, serious suffering and endanger the lives of patients and staff.

It is essential to have a quality assurance (QA)/management system in place which provides a framework for documentation and control. Pivotal to quality assurance is validation of each step of the reprocessing cycle; records are kept usually up to 5 years, depending on the medico-legal requirements of each country.

Essential elements of quality management systems

Documentation and record-keeping: of all stages of the decontamination cycle should include the following aspects:

- Personal protective equipment (PPE) for the following procedures (see also section on *PPE*):
  - Instrument cleaning: waterproof gown, hair cover, visor, closed footwear, heavy-duty gloves
  - Inspection, assembly, packing/wrapping: hair cover, clean lint-free uniform
  - Sterilization area: clean uniform, hair cover, heat-resistant gloves, closed footwear
- Sterilizer monitoring: use of biological and chemical indicator controls.
- Product sterility release criteria: parametric release to ensure that the processed medical device has met the validate process parameters.
- Record-keeping: all activities should be documented and maintained for the requisite (national legal period) length of time.
- Device and process tracking and traceability: manual or computerized system for tracing and tracking to enable tracing from the patient back to the processor in the event of a medical device recall.
- Storage and transport.
- Preventative maintenance procedures, schedules and contracts.
- Procedural or material change standards and policies.
- Infection prevention and control within the decontamination facility:
  - Hand hygiene
  - PPE
  - Dress code and personal hygiene
  - Safe sharp disposal
  - Incidents and reporting
  - Waste management
  - Ventilation control testing using air movement detection
  - Environmental cleaning

Occupational health and safety (OH&S): policies and procedures (see section on OH&S).

Education and training: internal and external staff (see section on *Education*).

- Numeracy, literacy and dexterity are essential to perform the duties required.
- Effective and appropriate training and assessment programmes must be put in place to assist staff development.

Risk management: ensures that non-conformances, incidents and errors are identified promptly, investigated, evaluated and documented.

Knowledge of international and European standards: relevance to quality management systems

- International Standards Organization (ISO): ISO 13485 (2003) relates to medical devices, quality management systems and requirements for regulatory purposes.

Auditing: periodic auditing where inspections are made of the processes, procedures and staff in the department.

- Audits can be detailed and conducted by the departmental manager or by an independent person within the health-care facility or by local government agencies.

What should quality assurance include?

- QA includes Implementation of a recognized QA system.
- Resources and training.
- Policies and procedures.
- Regular service and validation of sterilization and decontamination equipment.
- Tracking and traceability of process and medical devices from the processor back to the patient.
- Good Manufacturing Practice (GMP) requirements:

  - Guard against litigation
  - Promote customer confidence
  - Continuous evaluation
  - Risk evaluation
  - Ongoing evaluation and treatment of risks
- Successful service is based on understanding and co-operation.
- Positive process:
  - Enables to see issues as challenges and not problems
  - Creates a learning and supportive role and not a climate of blame

Validation

Validation usually applies to equipment or procedures used for reprocessing medical devices. Each step of the decontamination cycle will require validation as part of the QA programme and will be addressed in each relevant section. While it is accepted that not all sterilization service departments (SSDs) will be able to achieve such high standards of validation, best practice is the aim of this document.

Validating a process consists of systematically carrying out the process in a specific manner in order to improve it by planning: establish temporary programmes and checklists, validation protocols with criteria for acceptance/rejection, resource needs and risk analysis.

Evaluation of sterilizing methods

The ISO 9001[1] (general quality) and European norm (EN) ISO 13485[2] (quality of the installation and maintenance of health products) standards make it possible for a facility to evaluate its system and to guide the steps for its improvement. In the case of sterilization, the sterilization assurance level [SAL] 10^{-6} should be ensured so that the sterilization process generates a product or service according to its predetermined validated specification and in keeping with established quality characteristics.

> Note: The European standard, EN 46001 1997[3], defines that a medical device determined to be "sterile" should reach a SAL of 10^{-6} colony-forming units (cfu) when it undergoes a validation process.

A common requirement of ISO 13485, the European Central Manufacturing Standards (CMS), and the United States (US) GMP and Food and Drug Administration (FDA) is the use of validated processes as mentioned above.

Validation of the sterilizer process

The validation process consists of verifying in a certified and clearly documented manner that a process meets the requirements for which it was designed. In the case of sterilization, labelling a health product with the word "sterile" is only permissible when a validated sterilization process has been used.

Validation should consist of the following:
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance or process qualification (PQ)
- Documentation
- Microbiological performance qualification (MPQ)
- Validation report and certificates

In this way, the sterilization process can demonstrate in a documented manner that the parameters of temperature, time and pressure reached throughout the process were within the validated parameters determined by three consecutive successful cycles.

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1 EN ISO 9001:2008 Quality management systems. Requirements
2 EN ISO 13485:2003 Quality managements systems – regulatory compliance for medical devices
3 BS EN 46001:1997 Specification for application of EN ISO 9001 to the manufacture of medical devices
4 ISO/TS 11139: 2006 Sterilization of healthcare products - Vocabulary

Installation qualification (IQ): Is a process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification[4].

IQ consists of verifying that the equipment has been adequately installed and is safe to operate following the manufacturer's specifications and the standards applied in each country.
The following steps should be taken:

- Verify the correct installation of connections: water, steam, electricity, compressed air, ventilation, etc. This process verifies that the different parameters meet the manufacturer's specifications and the regulations that apply.
- Verify the correct operation of the equipment's different security functions, according to standards.
- Confirm that the machine is equipped with the adequate technical documentation, i.e. installation plans, technical/operational user manual, etc.

Operational qualification (OQ): A process of obtaining and documenting evidence that the installed equipment operates within predetermined limits when used in accordance with its operational procedures[4].
This consists of verifying that the sterilizer's different measurement and control elements function correctly and within the ranges specified by the manufacturer. Furthermore, it aims to verify that the temperature distribution in the chamber is uniform and within the parameters designated by the country standards. To achieve this, the following steps should be taken for a pre vacuum autoclave:

- Calibration of the regulation and control elements
- Carry out a cycle with the vacuum test
- Carry out a cycle with the Bowie-Dick test
- Implement three thermometric tests in an empty chamber in order to obtain the temperature profile at all points of the chamber

For a displacement autoclave

- Calibration of the regulation and control elements
- Implement three thermometric tests in an empty chamber in order to obtain the temperature profile at all points of the chamber

> Note: This is the crucial phase of fine-tuning the process during which its robustness and reliability should be demonstrated when facing the worse-case scenario.

Performance qualification (PQ): A process of obtaining and documenting evidence that the equipment as installed and operated in accordance with operational procedures consistently performs in accordance with predetermined criteria and thereby yields a product meeting its specification.

> Note: This final phase examines the replicability of the process, the precise training and qualifications for its operators, including work instructions that are definitive and put into action.

The quality of the process is demonstrated by carrying out three thermometric tests for each type of load and obtaining the temperature profile at all points for each one.

Validation of loads for sterilizers

It is important to validate the process at all points (especially where contamination may occur). These include cleaning, inspection, wrapping and packaging, and the loading and unloading of medical devices. These parameters are validated by PQ and documentation of the evaluation criteria should be checked by the user.

Technique and material

Documented evidence contributes to a high degree
of safety of the process, during which the following aspects should be taken into account:

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4 ISO/TS 11139: 2006 Sterilization of healthcare products - Vocabulary

- Position of the articles within the load
- Packaging of the load
- Selected cycle
- How to unload
- Repeated three times

Components of sterilization validation

Audit
This process is designed to demonstrate, document and confirm that the equipment meets the performance specifications according to its specific design and technical characteristics following its installation in the place of use.

Certification to operate
This process demonstrates that a review of the equipment has confirmed its ability to produce acceptable products when operated according to the specifications of the process. The following will have to be demonstrated:
- Certification of the equipment
- Test of the effectiveness of the equipment
- Monitoring of the equipment's operational routine
- Validation if an alteration in the routine is identified

Types of sterilizers and methods of validation

Validation of the sterilization process by dry heat

Ensure that sterilization by dry heat is adequate, safe and effective. The validation process to demonstrate evidence of sterilization by dry heat will guarantee that this is always carried out in the same way and with the same quality. The purpose is to guarantee the pre-established parameters for sterilization by means of dry heat.

Technique and material
The validation of this process consists of meeting the minimum stages and evaluation criteria by the user. Furthermore, documented evidence contributes a high degree of safety to this process during which the following aspects should be taken into account:
- Equipment quality: the electrical installations (voltage), structure, dimensions and ventilation should be confirmed.
- OQ: confirmation that all components of the equipment function according to the operation manual and maintenance instructions. Similarly, a report of the most common parts replaced and the technical service carried out should be generated.
- PQ: verification of the established physical parameters, types of packaging, types of loads and their registries, types of materials (quantity and volume), arrangement of the materials within the chamber and its capacity, and the adequate use of registries for chemical indicators.

Validation of the sterilization process by steam

Sterilization by moist heat should be validated in order to guarantee the safety, adaptation and effectiveness of the process. The validation process to demonstrate evidence of sterilization by moist heat will guarantee that this is always carried out in the same way and with the same quality. The purpose is to guarantee the pre-established parameters for sterilization by means of moist heat.

All of these verifications can be defined by IQ, OQ and PQ as described above.

IQ: this consists of verifying that the equipment has been adequately installed and is safe to operate according to the manufacturer's specifications and the standards applied in each country. The following steps should be taken:

- Verify the correct installation of connections: water, steam, electricity, compressed air, ventilation, etc. This process verifies that the different parameters meet the manufacturer's specifications and the regulations that apply.
- Verify the correct operation of the equipment's different security functions according to published standards.
- Confirm that the machine is equipped with the adequate technical documentation, i.e. installation plans, technical/operational user manual, etc.

OQ: This consists of verifying that the sterilizer's different measurement and control elements function correctly and within the ranges specified by the manufacturer. Furthermore, it aims to verify that the temperature distribution in the chamber is uniform and within the parameters designated by the country standards. To achieve this, the following steps should be taken for a pre vacuum autoclave:
- Calibration of the regulation and control elements
- Carry out a cycle with the vacuum test.
- Carry out a cycle with the Bowie-Dick test
- Implement three thermometric tests in an empty chamber in order to obtain the temperature profile at all points of the chamber

For a displacement autoclave
- Calibration of the regulation and control elements
- Implement three thermometric tests in an empty chamber in order to obtain the temperature profile at all points of the chamber

PQ: This procedure documents and verifies that the parameters of temperature, pressure and case-fatality reached within the load throughout the sterilization process are within the criteria defined by national standards. The quality of the process is demonstrated by carrying out three thermometric tests for each type of load and obtaining the temperature profile at all points for each one.

Technique and material

This validation should be carried out by confirming the quality of the following elements:
- **Environment**. The installations should be verified. The physical area includes the structure itself, climate control dimensions, and installed networks of steam and compressed air. With regard to the hydraulic installation, water hardness should be noted. With regard to the electrical installations, the voltage, protective devices, installation to the source itself, and quality of the steam should be observed.
- **Equipment**: The structure for the installation of the autoclave should be confirmed, including its physical adaptation, integration, and ventilation near the doors of the autoclave, and minimum distances between walls and the equipment in order to facilitate maintenance.
- **OQ**. The existence of an operational manual should be confirmed, as should a registry of the most commonly replaced parts, information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **PQ**. This should be evaluated by assessing effectiveness and efficiency. Established physical parameters, types of packaging, types of loads and their registries, types of materials (quantity and volume), the arrangement of the materials within the chamber and its capacity, and the adequate use of registries for biological and chemical indicators should all be confirmed.

In pre-vacuum autoclaves, three cycles should be checked with the Bowie-Dick test, followed by three complete cycles with biological and chemical controls during three consecutive days and with loads.
In gravitational autoclaves, the test should be carried out with an empty chamber. A frequent problem is that preventive maintenance is not carried out on machines and the most common attitude is to wait until equipment failure occurs and then take action. To prevent equipment failure, regular servicing at least once a year is recommended.

Validation of sterilization by ethylene oxide (ETO)

Validation should be determined and provided by the manufacturer of ETO autoclaves (see above-mentioned section on QA).

Technique and material

This validation should be carried out by confirming the quality of the following elements:

- **Environment.** The installations should be verified. The physical area includes the structure itself, climate control dimensions, and the need for an installation to extract environmental gas toward the exterior. Furthermore, the electrical installations, voltage and protective devices should be observed.
- **Equipment.** The structure for the installation of the autoclave should be confirmed, including its physical adaptation, integration, ventilation and minimum distances between walls and the equipment in order to facilitate maintenance. The existence of a device to measure the quantity of residual ETO in the environment should be confirmed also.
- **OQ.** The existence of an operational manual should be confirmed, including a registry of the most commonly replaced parts, information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **PQ.** This should be evaluated by assessing effectiveness and efficiency. Established physical parameters, types of packaging, types of loads and their registries, types of materials (quantity and volume), the arrangement of the materials within the chamber and its capacity, and the adequate use of registries for biological and chemical indicators should all be confirmed.

Three complete cycles should be confirmed with biological and chemical controls during three consecutive days and with loads.

Validation of hydrogen peroxide plasma

Technique and material

This validation should be carried out by confirming the quality of the following elements:

- **Environment.** The installations should be verified. The physical area includes the structure itself, climate control dimensions, and the need for an installation for extraction toward the exterior. Furthermore, the electrical installations, voltage and protective devices should be observed.
- **Equipment.** The structure for the installation of the autoclave should be confirmed, including its physical adaptation, integration, ventilation and minimum distances between walls and the equipment in order to facilitate maintenance.
- **OQ.** The existence of an operational manual should be confirmed, including a registry of the most commonly replaced parts, information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **PQ.** A microprocessor should be used to evaluate the physical parameters. In addition, a test package has been developed for the specific biological and chemical indicators. It consists of a plastic tray with a restricted dissemination opening that ends in a closed compartment containing both indicators. The chemical indicator indicates that hydrogen peroxide, an essential part of the sterilization cycle, has been introduced into the sterilization chamber. The biological indicator consists of a paper strip containing 106 spores of *Bacillus subtilis* var. Niger in a Tyvek® bag.

The physical parameters should be confirmed with a test package, followed by three complete cycles with biological and chemical and controls, during three consecutive days and with loads.

Summary of validation activities of all machines

- Create a multifunctional validation team
- Plan the approach and define the requirements
- Identify and describe the processes
- Specify the parameters of the process and the desired outcome
- Create a master validation plan
- Select the validation methods and tools
- Create validation protocols

- Carry out IQ, OQ and PQ and document the results
- Determine continuous process controls
- Prepare the final report and ensure administrative approval
- Provide continuous control of the process.
- Create a plan of education and training

When should sterilization validation be carried out?

- Sterilization validation should be carried out prior to first use and periodically thereafter, at least once a year is recommended.
- Once the equipment is installed, a test should be carried out jointly by the centre's staff and the manufacturer's technical service.
- This test confirms that the equipment works correctly in the specified environment and should be repeated whenever:
- Damage is repaired
- Maintenance operations are carried out
- Packaging material is modified
- The composition of the load is modified substantially

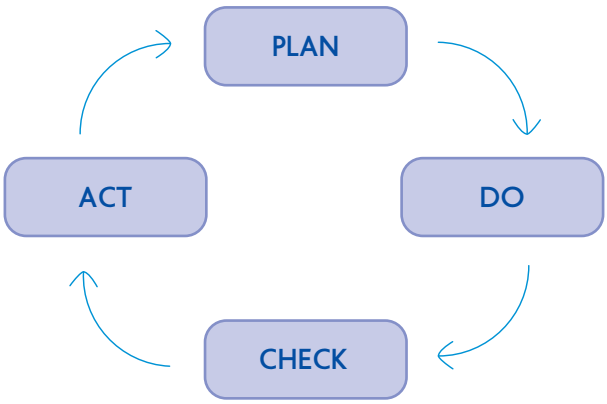
RISK MANAGEMENT IN DECONTAMINATION AND STERILIZATION

Risk management serves to identify, analyse and evaluate the risks of the SSD processes. It addresses the following issues:

- Definition of criteria by which risks are assessed and evaluated
- Methods of risk assessment
- Responsibilities for risk decisions
- Provision of resources assigned to risk prevention
- Internal and external communication regarding identified risks (reporting)
- Qualifications of staff dedicated to risk management

Risk management is viewed as an ongoing process in the planning, implementation, monitoring and continuous improvement to take place (Deming cycle "Plan-Do-Check-Act").

Figure 2. **Deming cycle "Plan-Do-Check-Act"**



RISK ASSESSMENT IN STERILE SERVICES

Medical devices

To determine the level of decontamination required for a particular medical device, it is important to understand the differences between cleaning, disinfection and sterilization.

Table 1. **Level of decontamination**

Cleaning	The physical removal of body materials, dust or foreign material. Cleaning will reduce the number of microorganisms as well as the soil, therefore allowing better contact with the surface being disinfected or sterilized and reducing the risk of soil being fixed to the surface. Removal of soil will reduce also the risk of inactivation of a chemical disinfectant and the multiplication of microorganisms. The removal of contamination from an item to the extent necessary for further processing or for intended use. [ISO/TS 11139]
Disinfection	The destruction or removal of microorganisms at a level that is not harmful to health and safe to handle. This process does not necessarily include the destruction of bacterial spores.
Sterilization	The complete destruction or removal of microorganisms, including bacterial spores. **Sterility** State of being free from viable microorganisms. **Sterilization** Validated process used to render a product free from viable microorganisms.

With these definitions in mind, risk assessment to determine the level of decontamination can be applied. This is known as the "Spaulding classification". This system should be applied to categorize a reused medical device (RMD) according to its intended use and the subsequent level of reprocessing required to render the RMD safe for reuse.

RMDs shall be categorized as follows:
- Critical
- Semi-critical
- Non-critical

Table 2. **Policy for the local decontamination of reusable equipment according to the Spaulding classification**

Risk category	Recommended level of decontamination	Examples of medical devices
High (critical) Items that are involved with a break in the skin or mucous membrane or entering a sterile body cavity	Sterilization	Surgical instruments, implants/prostheses, rigid endoscopes, syringes, needles
Intermediate (semi-critical) Items in contact with mucous membranes or body fluids	Disinfection (high level)	Respiratory equipment, non-invasive flexible endoscopes, bedpans, urine bottles
Low (non-critical) Items in contact with intact skin	Cleaning (visibly clean)	Blood pressure cuffs, stethoscopes

A series of questions can then be asked to establish the method to be used. This will depend on the use of the medical devices, the heat tolerance of the item, available resources/facilities and the time available for reprocessing.

Table 3. **Establishing the method to be used**

Questions to be asked	Assessment to be carried out
1. What is the purpose of the device?	Is it an invasive device
2. Manufacturer's reprocessing instructions	In contact with mucous membranes, skin, body fluids or potentially infectious material Table 2 will assist in assessing the level of decontamination required
3. Can the item be reprocessed?	Can it be cleaning properly and has the SSD the available resources for cleaning and sterilization of the item
4. Are the resources and facilities required for cleaning, disinfection or sterilization available locally?	Look at what is available. If possible, do not compromise on the level of decontamination required due to the lack of resources/facilities.
5. How soon will the device be needed?	Can the item be sent to a central department for processing, such as an SSD, or does it have to be processed at the point of use? Are there sufficient devices for the number of patients requiring its use

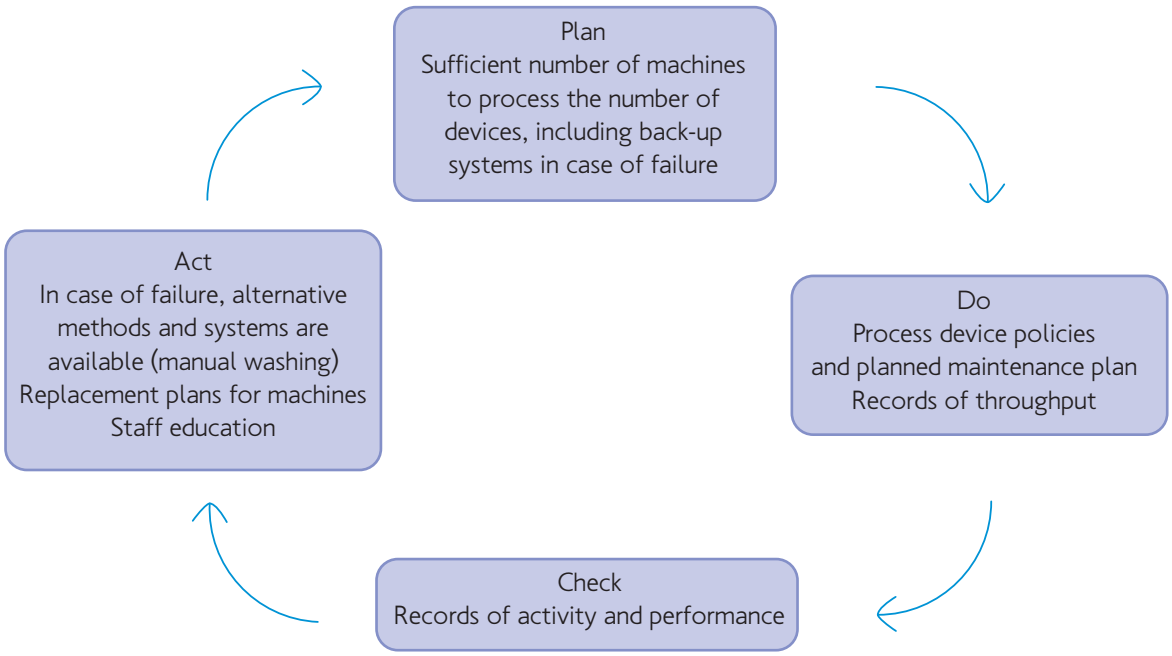
Processing equipment or machines

All processing equipment must be evaluated for performance and to ensure that the correct medical devices are processed in the correct machine. This is essential to ensure:

- Proper use and maintenance of the processing equipment
- Appropriate cycles for the medical devices being reprocessed
- Manufacturer's guidelines are followed for the installation, commissioning and use of the processing equipment
- Provision of alternative methods for processing should the machines fail or are not functional
- Availability of appropriate planned preventative maintenance and regular servicing

In addition, the SSD manager must undergo training to recognize essential elements of risk management. The local team should also be educated and trained to recognize faults and carry out minor repairs without jeopardizing the manufacturer's guarantee.

Figure 3. **An example of risk assessment for washer-disinfectors**



Controls/test procedures and checks

The SAL is defined as the probability of a single unit being sterile after it has been subjected to the sterilization process. Tests are conducted to determine if the sterility levels have been obtained, once the device has been sterilized.

Table 4. **A summary of decontamination processes and measurements for validation and their application**

PROCESS	WHAT IS MEASURED AND WHEN?	
Cleaning	Daily Use of detergent and disinfectant	Per item Cleaning results by visual control or by using a cleaning test
Disinfection	Daily Use of disinfectant by concentration, temperature and pH of disinfectant	Per load Time of exposure
Chemical sterilizers		Per process Biological indicator Chemical indicators Physical indicator Per item External indicators
Moist heat (steam sterilizers)	Daily Bowie-Dick test for steam penetration in porous loads (pre- vacuum autoclave) (Helix test for hollow lumen instruments, if available.) Clean the chamber every week	Per process Biological indicator Chemical indicators Physical parameters met as per PQ Per item External indicators

Maintenance

Define when and which parts should be controlled and/or replaced in agreement with the reprocessing equipment manufacturer. For guidance purposes:

- every 6 months: limited preventive technical control of all critical machines
- annually: extensive technical control followed by validation

All machines classified as critical according to the risk management analysis require a structured plan of maintenance and replacement, such as sterilizers, steam generators and washer-disinfectors.

Auditing

The auditor assists in ensuring that all sterilization processes are implemented according to national and international standards. An important part of the audit is to check compliance with local procedures and sterilization standards and to recommend process improvements.

Staffing in the SSD

STAFFING LEVELS

Education and training

Sterile services or "decontamination sciences" as they are often called, have gained recognition as a speciality in their own right in most high-income countries. In low- to middle-income countries, the SSD still falls under the nursing hierarchy and it is considered as an appendage of the operating theatre complex.

Many SSDs are managed by professional staff that have qualified and specialized in operating theatre practice, but essentially trained in procedures and not systems or processes. This practice is still common in many countries where there is no career path or staffing structure for sterile services.

The best situation is when SSD managers, irrespective of their initial training, are retrained in decontamination sciences. Regardless of the person managing the SSD, each level of staff must be competent in delivering against a defined job description. For this reason, a strong training and education programme is essential. The curriculum should contain certain essential concepts and the performance of the operators and supervisor should be checked against these standards. Regular updates, not only in practices, but also related to new developments in equipment and technology, should be introduced for SSD staff.

It is *not* recommended that housekeeping staff be involved in cleaning medical devices unless they have been trained and certified and moved into the SSD staffing structure.

An example of the levels of competence is shown below.

Educational requirements and qualifications
Entry level operator: high school leaving certificate
Two-year trained operator: completion of the basic SSD curriculum
Five-year trained operator or supervisor: completion of the intermediate SDD curriculum
More than 8 years of training or manager level: completion of the advanced SDD curriculum

Staff should be appropriately qualified for their grade of work. However, the local health-care facilities should consider the competencies required for the level of staff grade and ensure that the education programme corresponds. "Staff who is primarily involved in reprocessing obtains and maintains their qualifications. There should be a process in place to ensure continued competency, including continuing education provided at regular intervals and periodic competency assessment, and all orientation, training and continuing education is documented."[5] If formal courses from recognized institution are available staff from heath care facility should be encouraged to do it.

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5 *British Columbia Ministry of Health. Best practice guidelines for cleaning, disinfection and sterilization of critical and semi-critical medical devices in BC Health Authorities 2011. Available from: http://www.health.gov.bc.ca/library/publications/year/2011/Best-practice-guidelines-cleaning.pdf.* (Accessed 20 August 2015).

Table 5. **Educational requirements and qualifications**

LEVEL	CERTIFICATE	COURSES
Entry level operator	High school leaving certificate	Basic curriculum in SSD
Supervisor		Intermediate curriculum in SSD
Manager		Advanced curriculum in SSD

Basic curriculum for the SSD

All staff reprocessing medical devices should be aware of the risk to self, the patient, medical devices and the environment. Standard precautions or routine practices should be part of staff education to prevent exposure to blood and body fluids.

Objectives[6]

- Designed to familiarize sterile service operators and managers with the basic principles of sterile services
- To ensure an understanding of the principles of sterilization and decontamination in health-care facilities and applications in the workplace
- To select appropriate candidates for further studies in sterile services
- To establish a previously unrecognised career path in sterile services

Contents

- Introduction to microbiology, types of microbes and routes of transmission
- Conducting a risk assessment in sterile services related to the daily work
- Means of preventing transmission both in general and in sterile services
- Decontamination and cleaning of medical devices – significance and importance
- Evaluation of cleaning methods as part of risk assessment
- Inspection, assembly and packaging (IAP) as part of risk assessment
- Chemical disinfection of medical devices and best practice.
- Principles of sterilization, "do's and don'ts"
- Loading and unloading a sterilizer
- Purchasing equipment and validation procedures

Intermediate SSD curriculum

Objectives

- Demonstrate an extensive in-depth knowledge and understanding of the principles of decontamination and sterilization
- Work at managerial level to improve decontamination and sterilization of clinical equipment so as to render it safe for patient use
- Improve sterile services and ensure improved patient care
- Establish a career path in sterile services via a diploma or equivalent qualification. The top students on this course will have the opportunity to progress to the advanced SSD course in sterile service management

Content

- Introduction to decontamination by a team comprising a SSD manager and an engineer
- In-depth review and evaluation of the sterile supply cycle
- Methods of physical disinfection
- General infection control concepts for staff to ensure compliance and safety
- Disinfection – general use and abuse
- Endoscopy unit and disinfection
- In-depth knowledge of sterilization, including designing a sterilizer

6 Unit for Infection Prevention and Control, Stellenbosch University, Cape Town. South Africa. http://www.sun.ac.za/uipc. Accessed 20 August 2015

- Alternative methods to heat sterilization
- Reuse of single-use products As per instruction for use (IFU)
- Sterilization kinetics – physics
- Packaging and transportation
- Tracking and traceability
- Validation, testing and maintenance – record-keeping and documentation
- International standards and references
- Case studies – batch recall
- Introduction to productivity

Advanced SSD curriculum

Objectives

- Demonstrate extensive in-depth knowledge and insight into decontamination and sterile services from a managerial point of view
- Perform system analysis and project management in order to improve sterile services and ensure improved patient care

Content

- In-depth discussion on ISO standards
- Change management
- Leadership styles – strengths, weaknesses, opportunities and threats (SWOT) analysis
- Productivity management
- Department layout, staffing and quality management – optimizing available facilities
- Financial management
- Contingency planning
- In-depth validation
- Product release procedure
- Presentation on implementing a quality manual
- Role play for managers

Staffing ratios

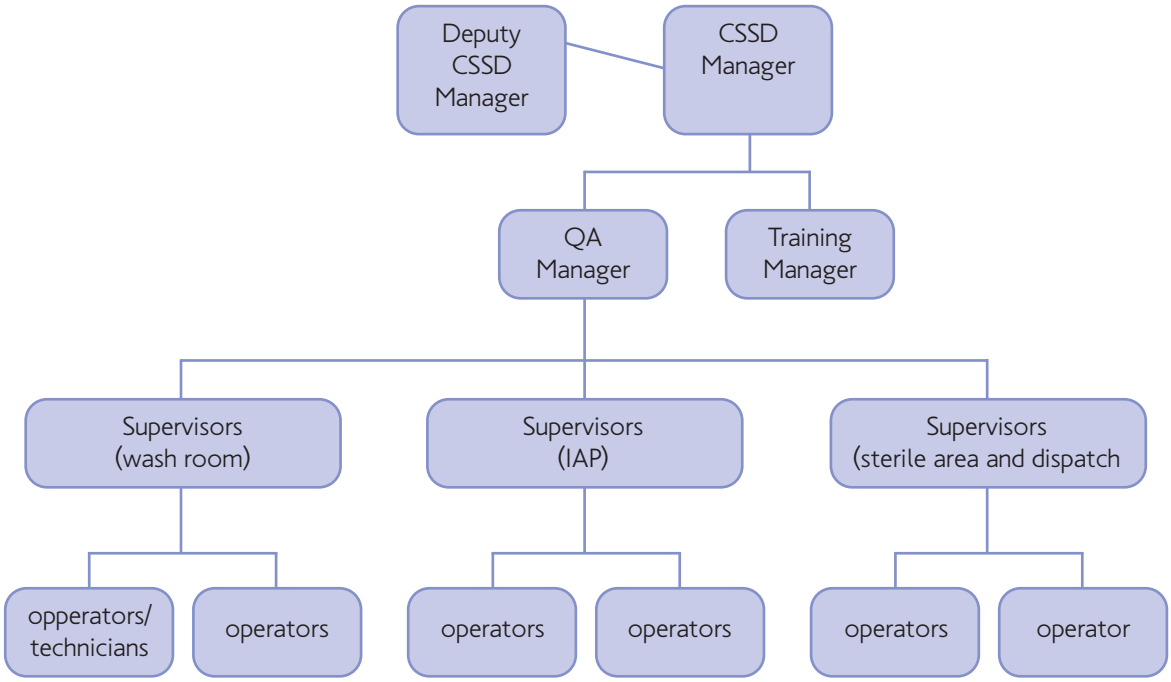
The structure and number of staff vary greatly and as yet there are no clear published guidelines on how to calculate staffing ratios. However, rough calculations with crude examples for the number of staff based on two parameters are shown below.

- The number of operations or consultant episodes – calculated at 3000 per year per staff member.
- The number of operating theatre (surgical) trays processed. If there are automated wash processes, a rough guide would be one member of staff for every 1500-2000 trays per year.
- Another method is a time and motion study of a broad range of complexities (from simple to single RMD or complex tray) and specialities. Determine the mean, e.g. 10 minutes labour for reprocessing. Multiple by the number processed in a month e.g. 30,000 = 300,000 minutes = divide by 60 = 5000 hours = divide by 8 = 625 shifts for months and then work out staffing levels.
- Staffing levels will depend also upon the facility financial investment in SSD services. If the SSD operators are also used as porters to transport clean and used equipment, it provides a point-of-use service.

The recommendations on structure differ slightly from one system to another. However, an example of a basic structure is shown in Figure 4. In smaller SSDs, the quality assessment manager and the training manager might be a combined post, unlike a larger SSD where these are two separate posts.

Supervisors work in shifts and oversee the performance of the operators working in that particular area or station. The minimum requirement is at least one supervisor each for the dirty area and clean areas, but more may be necessary in larger SSDs.

Figure 4. **Example of a staff structure in the SSD**



It is difficult to calculate the number of staff required to work in a SSD. In the case of a primary health centre (PHC) sterilization area, the tasks are usually performed by clinical staff. There are many factors that influence the number and use of staff in the SSD, some of these are mentioned below.

Workflow and work environment

The work environment and workflow influence the number of staff and the best use of staff time. The number of staff required at each shift will depend on several parameters.

- The peak time when operations and theatre are functioning influences the number of staff and the number of shifts per 24 hours.
- The number of surgical trays and devices available for each list of operations. The fewer the number of instruments, the more cycles have to be run, and more staff will be required not only during the day, but also at night.
- If the surgical trays are being transported over long distances to be processed, then the shifts during the day and the night will have similar workloads. In hospitals with specialized surgery, there will be different types of medical devices and possibly more of them to be reprocessed.

The Sterile Services Department (SSD)

INTRODUCTION

Decontamination and sterile services are essential and highly specialised processes controlled by GMP not is all countries GMP is for manufacturers of single use items, by which all medical devices are or should be reprocessed. The SSD is where this demand-led service is delivered by qualified trained staff and all of its functions are governed by validated processes with recognized codes of practice based on national and international standards.

Medical devices processed outside the SSD cannot be controlled and are considered unsafe unless these processes are under the supervision of highly-trained staff of a similar calibre to those in the SSD.

The **primary aim** of the SSD is to provide safe, reprocessed, reusable, invasive medical devices for clinical procedures, carried out on wards, critical care areas, ambulatory surgery, nutrition, dialysis and endoscopy.

The **fundamental role** of the SSD is to receive, clean, decontaminate, package, sterilize and distribute medical devices. These devices are reprocessed in reprocessing equipment, such as washer-disinfectors and sterilizers that are routinely maintained and validated in order to prevent cross-contamination and infection in patients. This is achieved by well-trained and knowledgeable staff working in the SSD under the supervision of experienced and trained SSD managers who understand and implement strategies of risk management and QA (Figure 1).

STRUCTURE OF A STERILE SERVICES DEPARTMENT

The SSD may be laid out in various configurations, depending on the size of the population it serves, the number of operations it has to support, and the distance from the service delivery to the point of use. It is advisable to choose the most effective and appropriate layout based on workload, staffing and financial resources, but the basic functioning and integrity of the department must not be compromised.

Advantages and disadvantages of a SSD

The SSD is a centralized service provision that deals with all the necessary reprocessing of devices in a designated area or site that has been specifically built and run for that purpose. Over time, such departments have developed skills, knowledge, and experience in the field of sterile services and the efficient use of reprocessing equipment and safe transportation of reprocessed devices.

There are several **advantages** to centralization and many countries have adopted this concept.

- *Efficiency*: by centralizing SSD services and consolidating staff of all levels, knowledge and experience are maximized, thus improving safe reprocessing and productivity. Every individual will play a vital role as a member of the team, which is geared towards improving efficiency.
- *Economy*: the initial outlay for capital equipment is high, but the processing equipment, such as washer-disinfectors and sterilizers, can be used optimally and improve cost effectiveness. Often, devices such as surgical instruments can undergo a properly documented rotation, thereby prolonging the life of instruments, particularly if these have been correctly labelled for tracking.
- *Safety*: by centralizing SSD services, systems can be upgraded and modernized, which will improve patient safety.

SSD staff will be trained and educated in the use of processing equipment and, together with the production of guidelines and standard operating procedures (SOP), these measures will ensure personal and patient safety.
- *Validation:* this allows processing systems to be standardized, resulting in improved QA programmes.

The **disadvantages** are:
- Initial capital outlay is high for both the processing equipment and the number of medical devices purchased to ensure that adequate supplies are available at the point of use.
- A very efficient transportation system, both internal and external, is required to ensure delivery to all points of use. The SSD should have its own transportation collection and delivery system. Access to alternative transportation in the case of a breakdown is also to be considered.
- Point-of-use operating theatre lists and emergency systems have to be documented to allow an adequate supply of devices.
- In some countries, SSD are privately owned and the work is contracted out to them by the users. In this case, it is essential that the same validation and QA systems apply also to these entities.

Layout of the SSD

Ideally, SSDs should be divided into areas that are physically separated with a clear unidirectional workflow from dirty to clean.

There should be physical barriers, such as walls or double-door (pass-through) washer-disinfectors between the decontamination and the packing area, and double-door (pass-through) sterilizers between the packing and the sterile storage area. There should be no crossover of staff or devices unless specifically indicated, such as returning devices that have not been properly cleaned. The space shall be designed to ensure a one-way movement of staff and devices from contaminated to clean areas to minimize the bioburden and particulate contamination.

Basic criteria are:
- Entrance and corridors (public areas)
- Gowning points for staff to don PPE prior to entering work areas
- Dirty area receiving of used medical devices (dirty area)
- Inspection, assembly and packing [IAP] (clean)
- Sterilization area (sterilizers)
- Sterile store (cooling and short-term storage)
- Administration and staff rest and changing areas (essential to be away from work areas)
- Storage for devices, chemicals and packaging stores (raw material and SSD products)

Smaller specialized sterilization units

Smaller units may be decentralized and could be located in operating theatres, endoscopy units or diagnostic departments. A theatre sterile services unit (TSSU) is no longer accepted practice unless there are specific reasons, such as remotely located operating theatre suites with limited devices, surgical trays, processing equipment and resources, including transportation. However, if such smaller units do exist, these must be well controlled with complete systems of validation in place as in larger SSDs and preferably under the supervision of the latter.

Ten Rules for the SSD location

1. The SSD is designed so that it is physically separated from all other work areas and does not interfere with routine clinical practice.
2. The SSD is not an integral part of any other service user or treatment area, such as operating theatres.
3. The SSD is not to be used as a thoroughfare.
4. The SSD is purpose-specific and built for reprocessing devices with clearly demarcated areas.
5. The SSD is designed to allow segregation of “dirty” and “clean” activities.
6. The SSD is designed to facilitate a unidirectional flow from the “dirty” area to the “clean” area.
7. The SSD will have a dedicated staff area in proximity for changing into work wear, which includes a shower, toilet facilities and lockers.

8. Access to the dirty and "clean" areas, such as the IAP room, should be through separate, dedicated gowning rooms provided with hand hygiene facilities.
9. The dirty area, IAP, sterilizing and sterilizer unloading area should be free from windows that can be opened, ledges and difficult-to-clean areas.
10. The dirty area, clean area room, IAP area and sterilizing area should be designed to minimize the ambient sound levels within the rooms. This will require particular attention to the installation of equipment, building finishes and maintenance of machines.

Space planning

There are several aspects to be considered when planning space within the SSD. Each health-care facility may have special or general requirements but, essentially, the dirty and clean areas must be clearly demarcated and separated without allowing crossover of staff or devices during a shift. This will have an impact on the space required, number of staff employed and those working a particular shift.

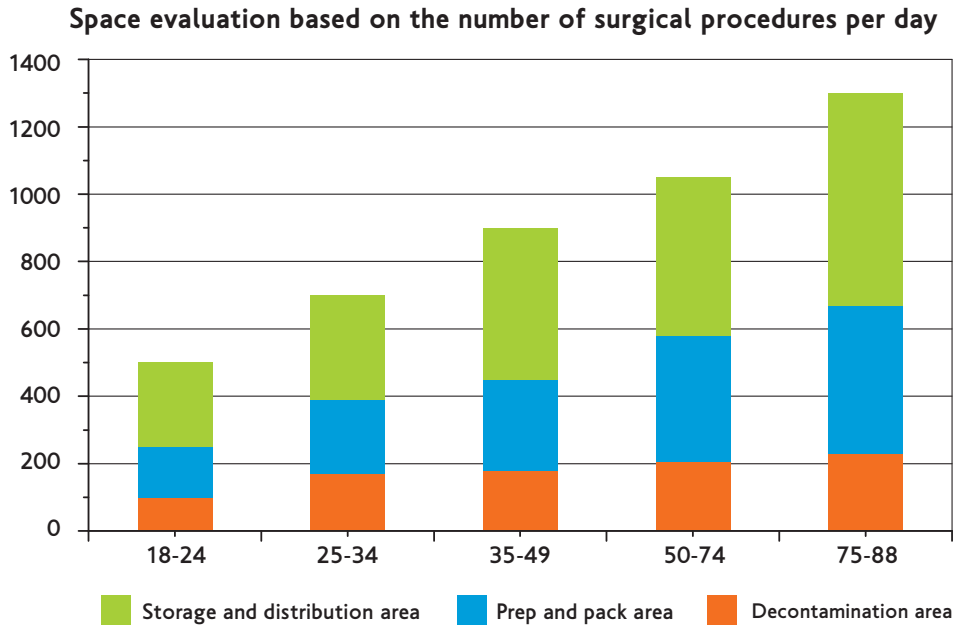
Size of SSD

The size of the spaces intended for the reprocessing of medical instruments depends upon a number of factors. Although no strict regulations or criteria exist, there is some legislation[7] that provides a rough guide of space measurements required and it is recommended to follow the national regulations, when available.

The space (SSD) estimate might be based on some or all of the following:

- Size of the institution (classification: small, medium, large[8])
- Average number and type of surgical procedures per day
- Number of beds relying on the supply from SSD
- Examples of other indicators are:
  - What is the frequency of the use of single medical devices or other equipment requiring reprocessing?
  - Is endoscope reprocessing carried out in that space?
  - Is low temperature sterilization used? If so, which type?
  - The use of containers rather than wraps which will require more space for reprocessing and storage

Figure 5. **An example of space evaluation based on the number of surgical operations**



7 HBN13, Health building note: sterile services department. Leeds: NHS Estates, 2004

8 In general, small size refers to a facility with no inpatient services; medium size to a community hospital; and large size to a medical centre or large community hospital with satellite services

Within the SSD, the calculation for space should include:

- Cleaning methods for reprocessing. Are these mainly manual or automated? Manual cleaning might require a larger allocated area than automated systems.
- The distribution of processed packs to the point of use could either be via lifts (elevators) or trolleys (carts). The space required for these systems needs to be calculated to include storage, cleaning and parking of carts.
- Number of shifts per day and the number of employees per shift. This will influence the work area, staff rest areas and movement between the various demarcated areas.
- Quality and size of the equipment used to reprocess medical devices, e.g. whether these are front- loading or the pass-through type with double doors.
- Central supply of high quality water, medical quality of air, and pre-generated steam. These are essential elements and the space to house or produce these must be included in the calculation for space.

Design of the SSD

When building new SSDs or renovating existing facilities, the project team must take into account national and international recommendations to ensure the best possible design, workflow, and safety of staff and patients. However, the SSD is often an afterthought and located in the least accessible and well supported part of the health-care facility, or it is situated in an essential thoroughfare. There must be restricted access to the SSD, especially the decontamination area. A well-designed SSD will ensure good workflow, ease of transportation to and from the place of use and delivery of necessary supplies. The same principles, standards and specifications applied to SSD are valid also for decentralized units and for small settings in dental medicine and primary health-care.

Utilities for the SSD

Air quality for drying

Air supplied to the SSD should be of medical quality. This means that the air will be free of bacteria, chemicals and large particles of dirt.[9]

Compressed air contamination

Contaminants originate from three general sources.

1. Contaminants in the surrounding ambient are drawn into the air system through the intake of the air compressor. Ingested contaminants appear in the form of water vapour, hydrocarbon vapours, natural particles and airborne particulates.
2. As a result of the mechanical compression process, additional impurities may be introduced into the air system. Generated contaminants include compressor lubricant, wear particles and vaporized lubricant.
3. A compressed air system will contain in-built contamination. Piping distribution and air storage tanks, more prevalent in older systems, will have contaminants in the form of rust, pipe scale, mineral deposits and bacteria.

The ISO 8573 air quality standards and ISO 12500 compressed air filter standards make the basis for air treatment product selection much easier. To achieve the recommended ISO 8573.*1 Class 2* (classification for solid particulate removal), a 1.0 micron particulate filter is recommended. The particulate filter will enhance also the service life of high-performance coalescing filters by minimizing solid loading.

Water quality for cleaning and sterilization

The quality of water is integral to the cleaning process, as well as the steam produced for sterilizers. Routine water testing is often conducted by engineering staff and/or engineering contractors in the SSD. In modern SSDs, the possible interactions between very hard water and water with elevated levels of dissolved chemicals justify the attention required concerning the quality of water used for cleaning of salts and other elements dissolved in the water. Water hardness is determined by the amount of calcium and magnesium ions present in the water.

9 Air quality standards ISO 8573.1 & ISO 12500

The disadvantages of hard water

- Water hardness reduces the rate of kill of certain disinfectants
- It generally reduces the efficiency of cleaning chemicals because divalent cations (e.g. magnesium and calcium) interact with some chemicals to form insoluble precipitates
- It reduces the conductivity of heat during sterilization
- It deposits and blocks valves, such as safety valves, stopcocks and filters, thus interfering with essential internal systems in the reprocessing machines
- A white-grey residue is left on the instruments after drying
- It damages instruments irreparably and they need to be replaced

Ideally, water used in the SSD should be soft, which means that the mineral and salt content is low and does not affect devices or processing equipment. Water can be softened by several methods:

- **Filtration** selectively removes minerals and salts
- **Reverse osmosis** (RO) is required to remove chlorides. A RO system is sometimes recommended by manufacturers of modern and highly sophisticated washer-disinfectors and sterilizers. Of note, it is worth checking this before purchasing equipment, particularly if the budget is restricted.

Since the processing of water can be expensive, it is recommended that soft water be used only for the final rinse if that is all that is affordable. Water and resource economization should not take precedent over operational imperatives, such as water quality and critical parameters for processes.

When the water is purified, a special control of its quality and eventual contamination should be undertaken. A microbiological control of this water must be performed. No large reservoir can be used to store the water. In addition, the reservoir must be cleaned at least each two months to guarantee no bacterial contamination of rinse water. The water in the reservoir should be maintained at all times at a temperature able to prevent bacterial growth.

Water quality

Water quality for steam sterilizers

The water supply, steam generation equipment, and pipelines serving steam sterilizers must be designed, built, and maintained so that they produce a reliable supply of controlled quality steam. Some sterilizers have independent steam generation systems, which produce steam according to the requirements of the machines. The steam used for sterilization shall not interfere with the sterilization process or damage the medical devices being sterilized.

Proper steam quality will prolong the life of reprocessed medical devices by reducing adverse effects that water impurities can have on device materials. Lime, rust, chlorine and salt can all be left as deposits on devices if demineralized water is not used. These compounds can lead to stress corrosion, pitting and discolouration of the device. Pitting, corrosion and precipitates must be avoided as their formation provides areas where organisms can readily accumulate and be protected from the killing effects of the steam process, i.e. increased risk of infection transmission due to inadequate sterilization.

The steam line feeding the sterilizer shall be taken off the top of the main steam line. The steam supply system must include steam traps or filters, if needed, to remove contaminants contributed by the pipeline. The health-care facility should have its water supply evaluated by water professionals to ensure that it meets the steam equipment manufacturer's specifications. If the water does not meet the requirements of this clause, the facility shall implement the necessary treatment process to bring the water within specifications. If the manufacturer's specifications are incomplete or unavailable, the water supply shall be evaluated and treated as necessary to meet the criteria outlined in ISO 17665[10]. The treated water should be periodically monitored to ensure it meets the criteria indicated.

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10 EN ISO 17665-1:2006 Sterilization of health care products – moist heat – Part 1:Requirements for the development, validation and routine control of a sterilization process for medical devices

An example of the minimum condensate requirements[10]

Bacteria (cfu/mL)	‹ 200
Total organic carbon (mg/L)	‹ 1.0
Hardness (ppm $CaCO_3$)	‹ 1.0
Resistivity (MΩ-cm)	› 1.0
Total dissolved solids (mg/L $CaCO_3$)	‹ 0.4
Ionic contaminants	
Chloride (mg/L)	‹ 1.0
Iron (mg/L)	‹ 0.2
Copper (mg/L)	‹ 0.1
Manganese (mg/L)	‹ 0.1

Colour and turbidity: colourless, clear, no residues

ISO TS 17665 Part 2 recommends more stringent standards for steam condensate, which could be used if the facility has a water treatment plant available.

The SSD environment

Surfaces

All surfaces in the reprocessing space must be smooth, straight and easy-to-clean without cracks and pores and be able to withstand chemical disinfection. They must be made from waterproof materials that are compatible with cleaning agents used. Wood and laminates are not recommended because they absorb water and chemical solutions. Stainless steel is recommended for work surfaces, sinks and equipment coating as these are easiest to clean.

Ceilings

All ceilings must be smooth, straight, without cracks and should be moisture-proof. Panel ceilings are not recommended directly over the clean and sterile working areas as these release dust and debris when disturbed.

Walls

Walls should be continuous as far as is practical, smooth (no peeling of paint), straight and coated with washable paint or material. The corners should be protected with metal ridging or similar to prevent damage from carts and trolleys.

Floors

All floors should be straight, smooth, without cracks and able to withstand the load of heavy carts transported across them. The floor should be continuous with a non-slip finish, especially in the decontamination and cart washing areas. The corners should be covered and the flooring should rise up along the wall to ensure easy and complete cleaning. There should be no sharp corners that allow the collection of moisture, dirt and dust.

Ventilation[11]

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

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11 HBN13, Health building note: sterile services department. Leeds: NHS Estates, 2004.

Air changes per hour

In general, it is recommended that there should be no less than a total of 20 air changes per hour when using controlled ventilation in the SSD. In the absence of mechanical ventilation, direct access to the outdoor air is found in some SSDs. In this case, a minimum of 10 to 20 air changes per hour for the dirty area and 12 to 20 air changes per hour for the clean area has been recommended. What is important is that the pressure in the wash roomis negative to the IAP room.

Pressure relative to the surrounding areas

In the dirty area or dirty area, the air should be extracted towards the outside so that it is under *negative pressure* compared with the clean area. The clean areas will be under *positive pressure* so that air flows away from clean surfaces towards the dirty area dirty area or the outside. Air from the SSD can be vented outside to the atmosphere with minimal risk to the surrounding area because of the dilution. If extracted for recycling, it has to be filtered and well maintained.

Relative humidity

The relative humidity is recommended to be 40-50%, but in hot and humid tropical countries it may rise to 70%, which can adversely affect the sterile barrier system. In the absence of controlled ventilation, working conditions become unbearable, affecting also the integrity of the sterile barrier. Where possible, humidity in the SSD must be mechanically controlled.

Ambient temperature

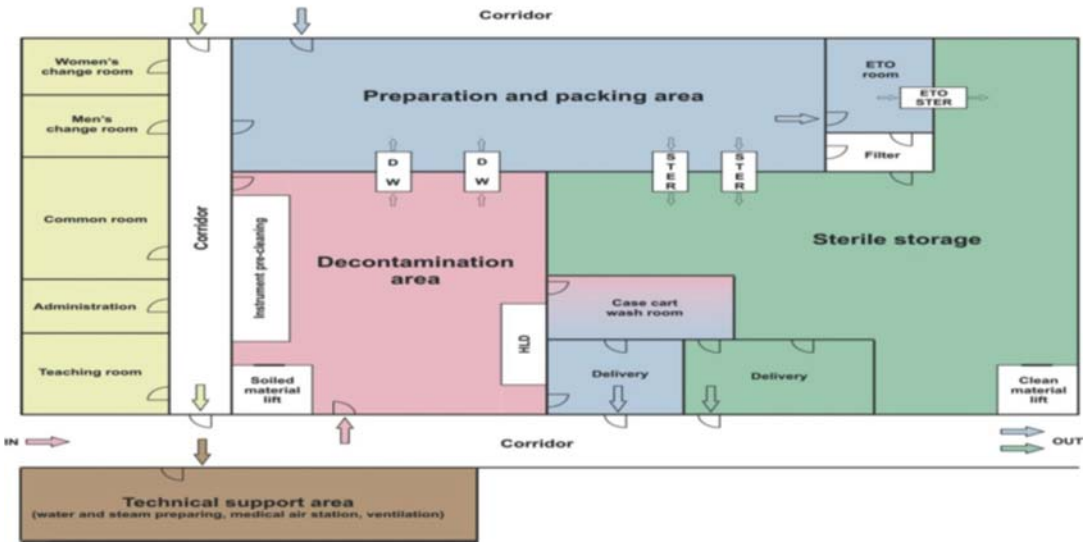
Comfortable ambient temperatures are essential for the staff to function efficiently and to ensure that the heat generated by the processing equipment is dissipated to prevent an increase in temperature. The following temperatures have been recommended in temperate countries and cooler storage is required in hot countries where the ambient temperatures are higher:

- Decontamination area 18-20°C
- Clean areas 18-23°C
- Sterile storage 15-25°C

Specific areas within the SSD

Each area of the SSD, including the entrance and exit, must be carefully considered according to its purpose, space and function. This section will deal with the function and layout of individual areas within the SSD.

Figure 6. **An example of a SSD layout***



*Note the flow of staff and devices

Entrance and corridors

Signage for the SSD must be clearly visible from all points of the health-care facility and access should be strictly controlled either manually or electronically. The entrances, including corridors, are the main areas of contact with the SSD. The staff entrance should lead directly to the staff changing areas. From there, a corridor should lead to the dirty area and the clean areas, such as IAP and sterilization. All entries must have a security-controlled entrance.

The staff tea room and conference/seminar/visitors' rooms should be located in the vicinity of the staff areas with no access into the SSD working areas.

Used devices, such as surgical trays, are transported to the SSD for reprocessing and these require also an access via a corridor or entrance. This entrance into the SSD is directly linked to the dirty area only and should have no direct contact with the clean areas of the SSD (Figure 6). The corridors should be wide enough to take trolleys and human traffic without congestion. Some institutions may have dedicated lifts that go directly to the operating theatres.

Staff changing rooms

All SSD must have separate changing rooms for men and women with lockers for storage of personal items, such as mobile phones, handbags and valuables and, if possible, hanging space for clothes. An adequate number of toilets and showers with hot and cold running water should be provided. Hand hygiene facilities with liquid soap, paper towels and alcohol-based hand rub (ABHR) should be available for staff use.

A rack of freshly-laundered uniforms or clothes for staff to change into before going to the designated work areas should be available and restocked regularly. Note that these areas should be separate from the gowning areas. Ventilation must be comfortable and the rooms should feel and smell clean and fresh. A large notice board with work schedules, essential occupational health rules and recent notices should be available.

Gowning areas

There must be a clearly demarcated area outside the dirty area and the IAP where the staff put on the appropriate PPE prior to entering the work area with an adequate availability of PPE for all staff, including cleaners.

Equipment

- A rack for PPE
- Hand hygiene facilities
- Bin for disposal of used PPE

Dirty Area

This is the area that receives soiled and used devices and it is usually the first point of contact in the SSD. The dirty area must be secured to ensure that no entry is possible without permission. The area must be physically separated from the clean areas, such as the IAP area, as well as the sterile store. Return instrument trolleys are either pushed directly into the wash area via a hatch or self-closing door, or are unloaded in a waiting area and then moved across manually. Either way, there must be enough space to allow trolleys to be unloaded in the dirty area without causing harm to staff.

Cart or trolley cleaning area

There must be provision for cleaning trolleys (carts) in the wash area once the devices have been unloaded. The trolleys or carts can be washed, cleaned and pushed through to the sterile store for sterile pack transportation. If trolleys are used for used RMDs and then intended for the transport of sterile RMDs, they must be thermally disinfected between use or separate trolleys provided. In some SSDs, there are dedicated lifts that receive and return surgical trays and other items from the point of use.

The environment of the dirty area should:

a) Be distinctly separate from areas where clean/ disinfected/sterile devices are handled or stored
b) Have restricted access from other areas in the setting
c) Ensure one-way workflow of staff, as well as medical devices
d) Have adequate space for the cleaning process and storage of necessary equipment and supplies
e) Have surfaces that can be easily cleaned and disinfected
f) Have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products
g) Have easy access to hand hygiene facilities

Cleaning (reprocessing) equipment

Provision must be made for the following equipment in the wash (dirty) room as follows:

- Table or surfaces for registering and sorting the devices
- Sinks for manual cleaning and disinfection – double sinks with flat surfaces on either side to allow the devices to dry
- Cold water jet guns
- Medical quality air as used in the health-care facility (for drying lumens)[12]
- Sluice as dispenser of organic matter
- Shelves (open slatted or wire racks) for storage of chemicals and cleaning items

Decontamination sinks: these are designed specifically for the purpose of cleaning medical devices[13] and should be:

- Designed and arranged to facilitate the soaking, washing and rinsing of devices with minimal movement or delay between steps
- Adjacent to waterproof countertops and a backsplash
- Without an overflow
- At a height that allows workers to use them without bending or staining
- Large enough to accommodate trays or baskets of instruments
- Deep enough to allow complete immersion of larger devices and instruments so that aerosols are not generated during cleaning.
- Equipped with water ports for the flushing of instruments with lumens, if required
- Equipped with a section for air drying medical devices

Hand hygiene: wash basins (at least one) should be located at a visible and convenient place, preferably at the entrance to the wash area, and should be supplied with mixer taps, liquid soap and paper towels.

Preparation and packing area

After devices have been cleaned, they are passed to the preparation and packing area, also known as the IAP area. Here, the clean devices can be handled safely and inspected, assembled, replaced and packed for sterilization. This is a clean area and the equipment required is to facilitate the sorting, packaging and wrapping of devices. All of which are manual activities. Once the trays have been packaged they are moved to the steam sterilizer or low temperature sterilizer.

General equipment required for the IAP area

- Work tables for:
  – Sorting
  – Assembly
  – Packaging and wrapping
  – Record-keeping

12 Where medical air could come into direct contact with the load, such as when used for drying the load or testing the free passage of lumens it should be oil-free (i.e. should have no more than 0.5mg of oil per cubic metre of free air measured at 1013 mbar and 20°C (see ISO 554). It shall be filtered to an efficiency of at least 95% when tested in accordance with BS3928 and be free of bacteria.

13 Canadian Standards Association (CAN/CSA Z314 8-08)

- Shelves
- Racks
- Heat sealer work station
- Medical quality air (for drying lumens)
- Chairs
- Magnifying lens with light
- Closed cabinet to store clean instruments and medical devices and packing supplies

The environment of the IAP area should:
a) Be distinctly separate from areas where clean/ disinfected/sterile devices are handled or stored
b) Have restricted access
c) Ensure one-way work flow of staff, as well as medical devices.
d) Have adequate space for the packing process and storage of necessary equipment and supplies
e) Have surfaces that can be easily cleaned and disinfected
f) Have slip-proof flooring that can withstand wet mopping and hospital-grade cleaning and disinfecting products
g) Have easy access to hand hygiene facilities

Sterilization area

This area is usually joined with the IAP area, without any physical barrier between the two areas.

Specialized equipment required:
- Steam sterilizers
- Low temperature sterilizer(s)
- Chemical sterilization processes
  – Separate room for ETO
  – Plasma sterilization

Sterile storage

Once the packs have been removed from the sterilizer, they should be moved to an area where they are allowed to cool. When the packs are cooled, they are then placed in a sterile store until delivery to the point of use. The storage area needs to be a restricted area and away from any windows or traffic. Sterile items should be handled as little as possible.

Equipment required
- Tables for placement of packs
- Open shelving that allows good air circulation
- Desk for record-keeping prior to dispatch
- A dispatch and transportation system for sterile packs

All spaces used for the reprocessing of medical instruments must be equipped with hand hygiene facilities at the entrance and exit points.

Sterile storage at point of use

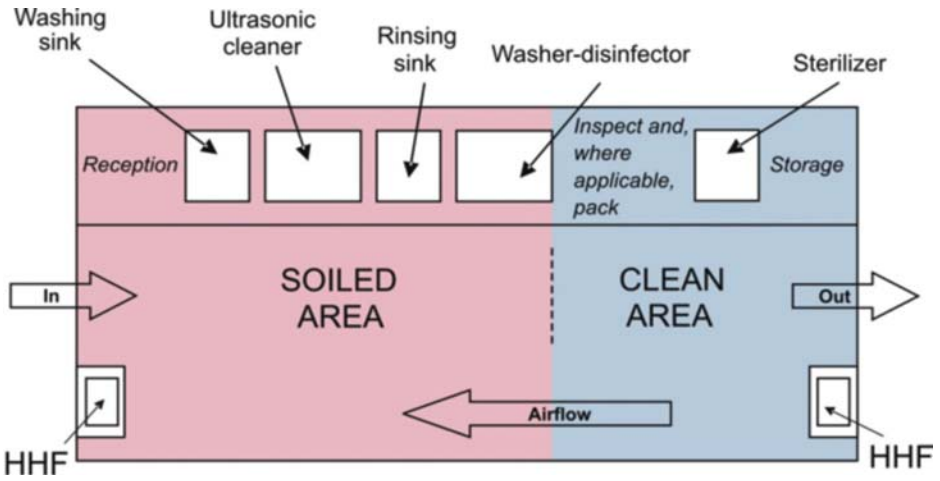
Upon arrival at the point of use, it is essential to store sterile packs in a dry, well-ventilated area with open racks for air circulation and moderate temperatures and humidity. Avoid storage in closed cupboards in busy clinical areas and stock packs in a separate store. There should be a procedure in place to check expiry dates and apply the rule of “first-in, first-out” so that stock is adequately rotated and wastage is kept to a minimum.

The principles and procedures applicable to SSDs apply also to primary health-care clinics (PHCs), and the only difference is the scale of production and a rapid turnover of devices. It is essential that vigilance is maintained while cleaning, disinfecting or sterilizing material.

Sterilization area in special units

In dental clinics and PHCs, the sterilization area is smaller and refers to any separate areas where reprocessing of devices takes place away from clients/patients/residents and from clean areas. An example of a layout is shown in Figure 7. The workflow is the same and the dirty and clean areas are demarcated if possible.

Figure 7. **Example of a dentistry one-room layout**



HHF = hand hygiene facility

Environmental cleaning in the SSD[14]

The environmental cleaning policy in the SSD must be clearly defined in a written policy with standard SOPs agreed between the housekeeping staff, the infection prevention and control team, management and the SSD manager. The procedures, responsibilities for cleaning practices and cleaning frequency must be clearly stated.

The minimum standards for cleaning are:

- SSD cleaning must be carried out by dedicated equipment and well-trained staff
- Floors are polished (as specified in the contract), but not less than twice a week
- Training of housekeeping staff must be provided by the infection prevention and control team or the SSD managers
- All work areas, stands, tables, countertops, sinks and equipment surfaces (but not the inside of processing equipment) are cleaned and disinfected **at least once a day**, depending on the workload
- Floors are **cleaned daily** using clean water and a neutral detergent; the surfaces must be dried
- If spillage or any other accident occurs, it must be **cleaned immediately**
- Sinks are cleaned once at the beginning of each shift or more frequently if required
- Sinks used for cleaning endoscopes or respiratory equipment are cleaned after each use
- The sequence of cleaning starts at the cleanest areas and works towards the contaminated areas. If separate cleaning teams are involved, the decontamination and clean areas are the responsibility of the individual teams assigned to these areas
- No crossover between the various areas – either of staff or cleaning equipment
- Provision for storage of cleaning equipment, such as mops and buckets, where equipment is washed, cleaned and dried (cleaned mops and buckets are stored inverted) or packed to send to the laundry.
- Separate cleaning equipment for the cleaning and clean areas

14 Guidelines for environmental infection control in health-care facilities. Centers for Disease Control and Prevention. http://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf . Accessed 20 August 2015.

Procedure

Floor

- **Dry method or static sweeping:** This consists of passing a synthetic barrier that is lightly impregnated with an electrically-polarized substance (magnetic effect) across the floor so that it retains all types of particles that are possible carriers of microbe particles. It represents a hygienic adaptation of the broom that it replaces and is ideal for avoiding the dispersion of dust in the environment. It will eliminate dirt that is not stuck to the floor in order to then apply the moist method.

- **Moist method**: This includes two techniques, the use of a double or a single bucket.
  – *Double bucket procedure*: The most common method and the method of choice. It is carried out using a two-bucket system, one for the disinfectant or detergent solution, and the other with clean water for rinsing. This method minimizes the recontamination of areas.
  – *Single bucket procedure:* When this method is used, the solution should be changed 1) when it is dirty, even if the cleaning of the area is not complete, and 2) before moving to another area.

Surfaces

- All shelves should be cleaned weekly with a clean cloth and 70% alcohol to remove dust. At that time, the expiration date and the integrity of the packaging of sterile medical equipment should be reviewed.

Occupational health and safety

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

- Adequate numbers of PPE must be available at each gowning area before entering the main reprocessing sections, such as decontamination, IAP, sterilization area and storage
- Visible posters and other information should be available to staff to serve as constant reminders in the workplace. Where language is a barrier, pictograms can be used to display the correct information
- Chemical stores should be provided and all containers must be clearly labelled with the manufacturer's instructions on handling, dilution and final delivery. Material safety data sheets must be provided for all cleaning chemicals and updated when a change occurs or every 5 years
- Exhaust systems should be functioning up to the standard required to remove noxious gases and chemicals and allow for dilution of biological hazards
- Staff should have hepatitis B immunization when they start working in any health-care facility. If possible, staff should be aware of their own human immunodeficiency virus (HIV) and hepatitis B status. All workplace accidents, such as splash or sharp injuries, must have first aid assistance with documentation of the incident in a register or logbook

The OH&S representatives should review all policies to ensure that work practices are compliant with the national health and safety at work act, which exists in most countries. Whether inside or outside the SSD, this will require that all staff reprocessing medical devices must:

- Be trained (preferably formal) to the appropriate level of knowledge for the grade of work to ensure both self-protection and patient safety
- Learn to handle sharps appropriately and ensure that there is provision for safe disposal of sharps
- Know how to wear PPE appropriately according to the correct indications
- Understand the risks of transmission of blood-borne viruses in the decontamination area
- Learn how to handle chemicals safely with appropriate PPE
- Know how to deal with accidents occurring in the SSD, such as ETO noxious gas exposure
- Document all accidents, no matter how minor

SSD dress code

All SSD staff should be provided with uniforms laundered at work (not taken home to wash), which they change into when arriving at work and remove before leaving. They should be advised to wear closed shoes and not open sandals as they might accidentally injure themselves. It is not recommended that SSD staff work in their street clothes.

Hand hygiene

All staff should learn how to perform hand hygiene correctly, whether this is hand washing or hand rubbing and understand the importance to dry hands thoroughly before donning gloves or carrying out a task. The correct method is shown in several WHO guidelines and documents and details are beyond the scope of this manual. Wall-mounted posters demonstrating the correct method for hand washing and hand rubbing should be visibly displayed.

Hand wash basins should be provided at the entrance to the dirty area and the IAP areas. The hand wash basin should have a mixer tap, liquid soap in a closed container and paper towels, including a foot-operated peddle bin to discard used paper towels. ABHR can be made available inside the IAP and sterile areas where water or wet areas are not recommended.

Appropriate use of PPE

PPE should be provided and the staff must be trained in its correct use and disposal. Table 6 outlines the tasks and the suggested PPE to be worn.

Table 6. **Indications for the use of PPE in the SSD**

PPE indication	Gloves	Face cover/visors	Headgear	Aprons/ gowns	Closed shoes
Decontamination area • Handling used medical devices • Removal and disposal of sharps • Manual cleaning	Domestic gloves (heavy duty); long; disposable or tear-resistant if reused if available use nitrile gloves	Cover mucous membranes and eyes • Mask with integrated visor • Full visor • Face mask with goggles	Yes	Yes	Yes
IAP • Inspection after cleaning • Assembly • Packaging	Not indicated	Not indicated	Yes	Optional	Yes
Sterilization • Loading • Emptying sterilizer	Heavy duty heat-resistant gloves	Not indicated	Yes	No	Yes
Sterile stores • Loading shelves • Taking inventory • Documentation	Not indicated	Not indicated	Optional	No	Yes
Transportation • Delivering sterile pack	Not indicated	Not indicated	Optional	No	Yes
• Returning used medical devices	Yes – domestic gloves (heavy duty)	Only when handling open wet trays		Yes	Yes

Safe handling of sharps and waste management

Most surgical trays contain sharps. All SSD staff must know how to handle sharps safely.

- Place a sharps' container not more than at arm's length or close to the place of work
- Carefully examine each surgical tray and concentrate on its contents
- Remove the sharps carefully, preferably without physically touching them
- Discard immediately in the sharps' container
- Do not recap or try to separate the needle from the syringe
- Report any accidental sharps' injury immediately to your superior
- Complete the log of sharps recovered from surgical trays

The waste management policy in the SSD will follow the established colour coding for segregation of waste as defined by the health-care facility or health-care waste management services in the institution.

Staff health

Any member of the SSD who has the following should report to the OH&S or medicine clinic:

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

In the absence of a staff health clinic, report to the SSD manager. The member of staff should be placed on sick leave until his/her health has improved. A certificate is required to return to work.

Cleaning of medical devices

WHY SHOULD ALL MEDICAL DEVICES BE THOROUGHLY CLEANED BEFORE PROCESSING?

Instruments and materials used during an operation will be covered with blood and tissue remains. They may have been in touch also with chemicals and fluids, dirt and dust. Hinged instruments may have remnants of blood and tissue from the operation. The tubing of hollow instruments may be also full of these soiled materials.

Before any decontamination can take place, used devices are prepared for reprocessing at the point of use to ensure their safe transport and a minimal risk to SSD staff. This procedure is not a substitute for cleaning.

Figure 8. Sequence of events for cleaning: from point-of-use to inspection



rinse off at point of use



sort



manual cleaning



inspection

POINT-OF-USE PREPARATION OF DEVICES FOR DECONTAMINATION

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

Point-of-use preparation helps to prolong the life of surgical instruments as dried blood and saline can cause the decomposition of stainless steel and make surgical instruments much more difficult to clean.

The following guidelines should be followed **before** sending instruments to SSD for cleaning:

- Wear PPE to protect yourself
- Remove any linen and disposable items and dispose of these items appropriately
  - Sharps, such as knife blades and needles, should be correctly discarded
  - Segregate sharps that can cause injury to health-care workers
- Remove gross soil from instruments by wiping with a damp clean dry cloth. Pre-cleaning (e.g. soak or spray) prevents soil from drying on devices and makes them easier to clean
- Cleaning products used should be appropriate for medical devices and approved by the device manufacturer
- If detergent-based products are used, ensure that they are mixed to the correct in-use dilution
- Avoid prolonged soaking of devices

- *Do not use saline as a soaking solution as it damages some medical devices*
- Contaminated items should be contained in dedicated, fully enclosed, leak-proof and puncture-proof containers prior to transport
- Soiled instruments should be opened and kept moist
  – Spray with an enzymatic spray
  – Cover with a moist towel with water (**not saline**) or foam, spray, or gel specifically intended for this purpose
  – Do not transport in containers with water as water is a splash hazard

Figure 9. **Example of a prepared tray with surgical instruments ready for transportation to the SSD**



Soaking of instruments in disinfectant prior to cleaning

Soaking of instruments in 0.5% chlorine solution or any other disinfectant before cleaning is ***not recommended*** for the following reasons:

- It may damage/corrode the instruments
- The disinfectant may be inactivated by blood and body fluids, which could become a source of microbial contamination and formation of biofilm
- Transportation of contaminated items soaked in chemical disinfectant to the decontamination area may pose a risk to health-care workers and result in inappropriate handling and accidental damage
- May contribute to the development of antimicrobial resistance to disinfectants

FUNDAMENTAL ROLE OF CLEANING

Cleaning is the first and most essential step before any process of disinfection or sterilization can be carried out.

- Cleaning is the first step in reprocessing a device after use
- Failure to properly clean an instrument may allow foreign material (e.g. soil and organic materials, including microorganisms and inorganic materials and lubricants) located outside and inside of the device to hinder disinfection and/or sterilization processes
- Cleaning is accomplished by manual cleaning with cleaning chemicals (detergent) and water, brushing or flushing, or by using ultrasonic and or washer disinfectors to remove foreign material.[15] Not every facility has a high level of resources (i.e. mechanical cleaning equipment), but medical devices must be thoroughly cleaned prior to disinfection or sterilization, irrespective of available resources.

15 International Association of Healthcare Central Service Materiel Management (IAHCSMM) Central Service Technical Manual 7th ed. (2007). (https://www.iahcsmm.org/publications/central-service-technical-training.html, Accessed 20 August 2015

One can clean without sterilizing, but one cannot sterilize without cleaning!

By following the necessary cleaning protocols, devices can be cleaned adequately even if resources are minimal, thereby protecting staff and patients from the risk of contamination.

What is cleaning?

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

Effects of not dismantling and cleaning devices

- Residue of blood and body fluids with a risk of blood-borne virus transmission (e.g. human immunodeficiency virus (HIV), hepatitis B and hepatitis C). There is a particular risk with highly infectious viral diseases, such as Ebola
- Sputum and mucous residue (tuberculosis and other bacterial pathogens)
- Biofilm formation in the lumens, thread of screws and difficult to reach areas; biofilm protects bacteria by covering them with an impenetrable layer of mucous and deposits (e.g. *Pseudomonas aeruginosa)*
- Hard water and mineral and calcium deposits devices lose efficiency and function.
- Not removing detergent and chemical build-up lead to the destruction of integrity of the device or its coating.
- Devices cannot be disinfected or sterilized in the presence of dirt and organic matter as poor penetration of chemicals occurs
- Inactivation of some disinfectants by organic matter
- Allergic reactions in patients
- Endotoxin and pyrogen release

Summary of cleaning

- Medical devices should be disassembled to allow effective cleaning
- Physical cleaning reduces the bioburden or the microbial load sufficiently to allow the process of sterilization or high-level disinfection to be effective
- Dirt protects microorganisms from contact with the disinfectants, steam and other chemicals, thereby rendering the process ineffective
- Some chemicals used for reprocessing devices are inactivated in the presence of organic matter
- Some chemicals used for reprocessing are inactivated when mixed with other chemicals (incompatible)
- The life of the instruments is prolonged if soil and debris are removed regularly

Factors that affect cleaning

There are several factors that can affect the efficacy of the cleaning process.

- Amount and type of soil present.
  - Cleaning chemicals can become diluted or ineffective in the presence of soil
- Water quality and temperature (see previous section on water quality).
  - Some cleaning chemicals are designed to be used at specific temperatures
  - If clean water is not available, the water itself might deposit toxins on medical devices
  - Water hardness (the presence of excess dissolved minerals) can alter the effectiveness of cleaning chemicals and can cause spotting and leave deposits on medical devices
- Availability and use of cleaning chemicals.
  - If cleaning chemicals are not available, cleaning must be accomplished with the use of water and friction alone.
  - It is important to follow the manufacturer's instructions for use regarding the chemical to water dilution rate as the dilution rate (high or low) has a direct effect on the efficacy of the cleaning process.
- Staff training.

– It is essential that staff performing the cleaning process is adequately trained in the use of all equipment, chemicals and tools, such as brushes
– Staff must be familiar with medical devices so as to know which method of cleaning is appropriate and how to adequately clean each specific device (e.g. lumens, disassembly and re-assembly of items)

CLEANING PRODUCTS

There is no single cleaning agent that removes all types of bioburden. Bioburden is made up of a variety of matter, which may be soluble or insoluble in water and can be organic or inorganic.

Properties associated with ideal cleaning agents

- Emulsification
- Saponification
- Surfactation
- Dispersion and suspension
- Peptization
- Water softening
- Free rinsing
- Non-toxic

Selection of cleaning agents

Deposits of dust, soil and microbial residue on equipment can contribute to healthcare-associated infections. Cleaning agents remove organic, inorganic and microbial contaminants. No single compound has all the properties that are required to remove all soil deposits. The first step in cleaning is the use of surfactants or surface active agents to reduce surface tension, which assists in soil being held in the cleaning solution.[16]

Enzymatic (proteolytic) cleaners

Gross soil should first be removed by rinsing with detergent and water. If blood or exudates have dried or hardened, soaking in a warm solution of an enzymatic cleaner is required. Cleaning agents containing enzymes to break down proteinaceous matter may be used for sensitive equipment if the equipment manufacturer approves their use.

Note the recommendations of the manufacturer of the enzymatic solution for dilution, temperature and time

> **REMEMBER**
> **Enzymatic cleaners are not disinfectants; they only remove protein from surfaces.**
> **Rubber or nitrile gloves are recommended when handling enzymatic solutions - enzymatic cleaners will degrade latex gloves**

Cleaning chemicals (detergents)

These agents have a function of reducing surface tension and cut through fat and organic matter.

Considerations when selecting a detergent

- Follow the manufacturer's recommendation for the type of soiling against which the detergent is effective
- Follow the manufacturer's recommendations for compatibility with the device to be cleaned
- Select the appropriate cleaning agent to use with an ultrasound cleaner
- Degree of water hardness – choose the appropriate detergent based on the manufacturer's guidelines
- Do not substitute unless approved by the manufacturer

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16 A guide for selecting cleaning agents can be found in AS/NZS 4187:2003. Cleaning, disinfecting and sterilizing r eusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.http://www.saiglobal.com/pdftemp/previews/osh/as/as4000/4100/4187.pdf. Accessed 20th August 2015.)

A mild alkaline detergent is preferred for manual cleaning, ultrasonic cleaning, or one of the several types of instrument washers. Mild alkaline detergents (pH range, 8.0 – 10.8) are more efficient cleaning agents for surgical instruments than neutral pH detergents or surfactant-based detergents. It is recommended that facilities work with chemical suppliers to determine the best detergent required as this will be dependent on the facilities' water quality.

Chemical residue has the potential to cause tissue irritation.

REMEMBER
Only use appropriate detergents for instrument cleaning in the SSD. Detergents used for home cleaning or laundry use are not suitable for the cleaning of medical devices or instruments.

Preparation of detergent solutions

Chemicals, like disinfectants and detergents, function best at their optimal dilution - making a stronger solution does not necessarily mean it will be more effective.

- For effective cleaning it is essential that the detergents are prepared at the concentration recommended by the manufacturer/supplier. To achieve the correct concentration, the correct volume of concentrated detergent has to be added to the correct volume of water at the correct temperature. The following calculation can be used:

$$\frac{\textit{volume of detergent or chemical (supplied)} = \textit{concentration required} \times \textit{capacity of the sink/bowl (in ml)}}{\textit{Concentration supplied}}$$

For example, if a 1% solution of detergent is required and the sink/bowl capacity is 10 litres (10,000 ml) and the concentration supplied is 100%: volume of supplied detergent $= \frac{1 \times 10{,}000}{100} = 100$

Therefore, 100 ml is used and made up to 10 litres to achieve a 1% solution. The detergent does not have to be measured precisely each time, but a fill line can be placed on the sink/bowl as shown in Figure 10 and a galipot or jug used to measure the detergent.

Think this section could be written to reduce repetition

Figure 10. **Detergent preparation using precise measurement of water and concentrated detergent for dilution**





Lubricants

The purpose of a lubricant is only to protect the medical device. Lubricants should be soluble in water. Devices requiring lubrication shall be lubricated according to the manufacturer's instructions, prior to sterilization. The device manufacturer's instructions shall be followed with regard to:

- Components requiring lubrication
- Specific lubricant(s) to be used
- Proper preparation and application of the lubricant, including the amount of lubricant to use and the immersion time, if applicable

Incompatible lubricants can inhibit sterilization, create harmful by-products, and damage the device or the sterilizer. Devices shall be decontaminated and free of visible soil and rust before they are lubricated.

- Lubricants must be compatible with the device and the steam sterilization process[17]
- Avoid the re-use of containers to store lubricants
- Lubricants shall be discarded if they are past their expiry date or if they appear visibly soiled
- Make up the lubricant according to the manufacturer's guidelines and avoid contamination

CLEANING METHODS

Manual cleaning

Facilities with minimal resources can adequately clean and prepare devices for sterilization with effective manual cleaning processes. However, it is vital that all devices be disassembled so that all surfaces may be cleaned and disinfected, irrespective of the cleaning method chosen.

- Ensure that the device to be cleaned is compatible with the chemical solutions used in the facility
- Completely submerge immersible items during the cleaning process to minimize aerosolization and to assist in cleaning
- Remove gross soil using tools, such as brushes and single-use cloths
- Minimize the production of aerosols when cleaning non-immersible devices
- Clean devices that have lumens with an appropriate brush, then manually or mechanically flush with a detergent solution and rinse with potable water
- Check devices with lumens for obstructions and leakage

Validation

Manual cleaning cannot be validated; a clear SOP is required.

Indications for manual cleaning

- Medical devices that cannot be immersed (i.e. electrical or battery-powered devices)
- Devices that require special cleaning (i.e. narrow bore lumen or delicate devices)
- Pre-cleaning step prior to mechanical cleaning in ultrasonic and or washer-disinfector

Immersion method

- Fill sink or any other appropriate basin with sufficient warm water for complete immersion of the device
- Add the appropriate quantity of detergent following the manufacturer's instructions for dosage
- Clean the device under the surface of the water so that aerosols are not produced
- Use appropriate brushes to properly clean box locks, lumens and other hard-to-clean areas
  - Use soft (nylon) bristle brushes so that the surface of the instrument is not damaged
  - Brushes used to clean lumens must be the same diameter as the instrument to ensure that all internal surfaces can be reached
  - Brushes must also be long enough to exit the distal end of the instrument

17 Canadian Standards Association. CAN/CSA-Z314.3-09. Effective sterilization in health care facilities by the steam process. Rexdale, Ont.: Canadian Standards Association, 2009

Note: Brushes should be thermally disinfected and dried at the end of the day. If this is not possible, they should be cleaned and left dry. Brushes must be replaced when damaged. Remove all visible soil from the device.

- In another sink or basin, completely immerse the device in clean purified water and rinse the device thoroughly
- Mechanically dry; if this not available or not recommended by the manufacturer, air-dry or hand-dry using a disposable clean, non-linting cloth

Non-immersion method

- Clean the device by wiping surfaces thoroughly with a disposable, clean, non-linting cloth and detergent ensuring that moisture does not enter critical areas of the device (e.g. power connections) until all visible soil is removed
- Rinse the device by wiping surfaces thoroughly with a damp, disposable, clean, non-linting cloth until all detergent residue is removed
- Mechanically dry; if this is not available or not recommended by the manufacturer, air-dry or hand-dry using a disposable clean, non-linting cloth. Disposable cloths should be discarded after each use
- Cleaning solution and water should be changed at each cleaning session and when visibly soiled.

Chemical disinfection prior to cleaning is unnecessary, ineffective and of little value in the presence of organic matter.

Rinsing

Rinsing following cleaning is necessary to remove loosened soil and residual detergent. Rinse all devices thoroughly after cleaning with water to remove residues, which might react with the disinfectant/ sterilant. Perform the final rinse of lumens of intravascular/ intrathecal devices with commercially-prepared, sterile, pyrogen-free water or reverse osmosis processed water.

Note: Distilled water is not necessarily sterile or pyrogen-free.

Drying

Drying is an important step that prevents microbial growth and dilution of chemical disinfectants, which may render them ineffective. Devices should be air-dried or dried by hand with a clean, non-linting cloth preferably single use.
Dry lumens with compressed medical grade or high-efficiency particulate absorption (HEPA)-filtered air at a pressure specified by the device manufacturer. Use a regulator to control pressure.
Dry stainless steel devices immediately after rinsing to prevent spotting.

Care of cleaning tools

- Cleaning tools need to be cleaned, disinfected and dried after every shift
- Inspect brushes and other cleaning equipment for damage after each use and discard if necessary
- The use of single-use cleaning tools is recommended. If reusable tools are used, they should be disinfected at least daily

MECHANICAL CLEANING

Mechanical cleaning equipment may be available and do provide controlled and uniformly reliable results if the equipment is well maintained. Equipment used for the mechanical cleaning of medical devices include:

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

Whenever possible, clean devices by mechanical means:

- Use mechanical washers in accordance with the manufacturer's instructions
- Manually clean heavily soiled devices before mechanical cleaning if necessary
- Ensure that the device to be cleaned is compatible with the mechanical cleaning equipment, cycle parameters and cleaning chemicals that are being used
- Ultrasonic washers are strongly recommended for any semi-critical or critical medical device that has joints, crevices, lumens or other areas that are difficult to clean
- Washer-disinfectors are strongly recommended for medical devices that can withstand mechanical cleaning to achieve the required exposure for cleaning and to reduce potential risks to staff

When the equipment is available and devices are designed for an automated process, the advantages of using such a process for the cleaning and thermal disinfection of medical devices include faster throughput of devices, greater consistency of results, and higher standards for cleaning that can be validated and less risk to staff.

Important considerations when using mechanical cleaning equipment include staff training, water quality, cleaning chemicals' dilution rates and ensuring that the equipment is in proper working condition. Washer-disinfectors and ultrasonic cleaners are only effective when they are operated, loaded and serviced in compliance with the manufacturer's instructions for use.

Ultrasonic cleaners

Ultrasonic cleaners are a mechanical cleaning method that is effective for hard-to-reach parts of surgical instruments, such as box locks, serrations, hinges and lumens. In brief, ultrasonic vibrations pass through the cleaning solution and create bubbles. As the bubbles become larger, they become unstable and implode, a process called *cavitation*. This creates a vacuum in the solution that draws the debris from the instruments into the surrounding fluid. Some newer machines have an automated filling and draining capacity.

Requirements

- Instruments must be pre-cleaned of gross soil prior to using the ultrasonic cleaner
- Water temperature should be between 27° C (80F) and 43° C (109F) and never above 60° C (140F) because proteins coagulate above that temperature
- The manufacturer's recommendations for the dosing and temperature of the cleaning solution should be followed
- Water should be changed daily and each time it is visibly soiled
- The ultrasonic unit should be degassed each time it is filled to remove excess bubbles. This is done by filling the unit, closing the lid and running a cycle for 5-10 minutes
- Instruments should be opened and completely submerged and lumens completely filled
- The lid must be closed prior to running to prevent aerosol production
- Refer to the instrument manufacturer's recommendations for specific cleaning information prior to placing the device in an ultrasonic cleaner
- After cleaning with an ultrasonic machine, instruments need to be rinsed and dried
- The ultrasonic cleaner needs to be cleaned at the end of each day

Validation process

- The ultrasonic process needs to be validated daily as follows and the results documented to ensure that devices are safe to use:
- Visual inspection of all devices removed
- Foil test
- Commercial tests at least once a year)

Automated washers

Washer-disinfectors work on the principle of impingement, i.e. the use of pressurized water to physically remove the bioburden. Automated washers are a very effective method for cleaning and disinfecting instruments because of the detergents and thermal action used. Multiple steps are includedin the cycle including pre-rinse, enzymatic wash, detergent wash, and lubrication. A final rinse at a temperature that thermally disinfects using de-ionized water will help to prevent mineral deposits and spotting and improve drying.

Recommendations

- Washer racks should never be overloaded and instruments should be in an open position and contained within the basket
- Multi-level trays should be placed separately on the washer rack and all lids removed
- Spray arms should be inspected daily to ensure that they are in good working order
- It is usually not necessary to pre-clean instruments prior to placing in an automated washer, which saves time and is safer for staff as they do not have to handle contaminated instruments

Cart washers

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

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

Cleaning verification and quality control

The most common method of verifying the cleaning process is by visual inspection. All medical devices must be inspected during packaging prior to sterilization. The efficacy of the automated washer-disinfector process can be verified with a commercially-manufactured product that mimics dried blood. Failure of this quality check can indicate that the washing equipment is not operating properly or that cleaning chemicals are not feeding in properly, but a passing check does not prove that instruments are clean. Reference ISO 15883:5 The cycle parameters of washer disinfectors should be checked also to ensure that the validated parameters have been met for each cycle. This should be documented.

Cleaning is the most complex and important step in the processing of medical devices because if a device is not clean it cannot be disinfected or sterilized.

The cleaning action

All cleaning action requires a solvent (warm water) and friction or rubbing to remove the dirt using a detergent to suspend the dirt and exposure time to the detergent. Warm water increases the activity of some chemicals. There is always a minimal exposure time required to obtain the maximum benefit from the detergent and the cleaning process as observed with hand hygiene.

Figure 11. **Cleaning circle: all factors are essential**[18]



18 Sinner's Circle (Dr Herbert Sinner, 1959)

PREPARATION FOR CLEANING OF MEDICAL DEVICES

Summary of recommendations

- Disposable sharps shall be disposed of in an appropriate, puncture-resistant, sharps' container at the point of use prior to transportation.
- Soiled medical devices shall be handled in a manner that reduces the risk of exposure and/or injury to staff/visitors/patients/residents or contamination of environmental surfaces.
- Contaminated devices shall not be transported through areas designated for the storage of clean or sterile supplies, visitor/patient/resident care areas or high-traffic areas.
- Sterile and soiled devices should not be transported together.
- Reusable medical devices must be thoroughly cleaned before disinfection or sterilization.
- If cleaning cannot be done immediately, the medical device should be pre-treated to prevent organic matter from drying on it.
- The process for cleaning (decontamination) shall include written protocols for disassembly, sorting, pre-treatment, physical removal of organic material, rinsing and drying.

It is strongly recommended that catheters, tubing, and other medical devices with small lumens that are very difficult to clean be designated as single-use material and not be reprocessed and reused.

Do's and don'ts of cleaning

Do

- Ensure detergent is prepared at the correct concentration and temperature and used for the recommended contact time
- Keep instruments moist and clean as soon as possible after the procedure
- Disassemble instruments prior to cleaning
- Open hinged/jointed instruments to ensure access to all surfaces
- Use appropriate sized brushes to clean lumened items
- Use soft bristle brushes to clean serrations and box locks
- Inspect instruments after cleaning
- Clean instruments under the surface of the water to reduce the risk of aerosol production
- Follow manufacturer's instructions for the cleaning of all medical devices

Don't

- Use metal brushes or any abrasive item when cleaning instruments
- Clean instruments under running water because this can produce aerosols
- Overload trays in a washer–disinfector
- Obstruct spray arms in a washer-disinfector
- Submerge power equipment or electrical items (unless they have a waterproof cap)
- Use a detergent that is not intended for medical devices

Preparation and packaging for reprocessing

INTRODUCTION

The inspection, assembly and packaging (IAP) of reused medical devices (RMDs) in the SSD is where medical devices are visually inspected and function-tested by trained staff.

Following testing, devices are reassembled, sorted and packed either as a set of medical devices or as a single medical device packed in a transparent pouch or wrapped in appropriate wrapping material. Some RMDs are disassembled for sterilization as per the manufacturer instructions for use.

Records should be kept of all inspected and tested devices.

All devices are assembled, checked and scanned (where computerized traceability is installed). Where manual traceability is in place, medical devices are documented on an instrument tray list.

All medical devices should be inspected in a place designated and controlled to optimize the effect of the sterilization process and minimize contamination. Use a bright light with a magnifying or a magnification light.

Figure 12. **Assembly and packing with computerized traceability**



INSPECTION

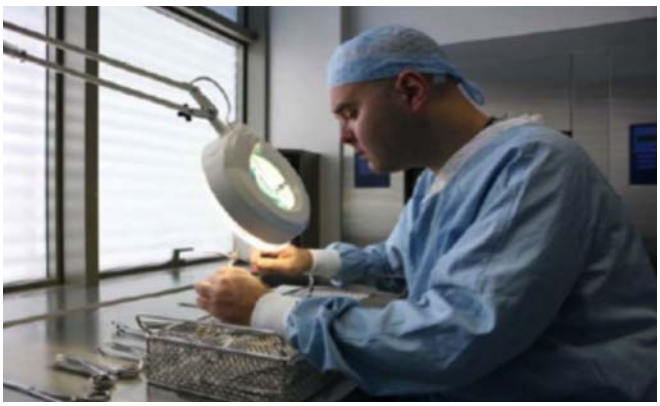
Post-cleaning inspection and function test area

- Equipment
- Procedure
- Documentation on post-automated cleaning
- Inspection and function testing
- Assembly
- Packaging

Equipment

- Workbench
- Magnifying inspection glass
- Fibre optic light source
- Insulation testing equipment; diathermy pinhole tester
- Autoclave tape dispenser
- Wrapping material holder
- Baskets for medical devices (autoclave baskets)
- Heat sealing machine (for preformed sterile barrier systems [PSBS])
- Tracking and traceability scanner and computer (computerized traceability – optional)
- Raw materials (daily stock)

Figure 13. **Inspection of cleaned medical devices***



*Note magnifying glass for close inspection

Recommended practices

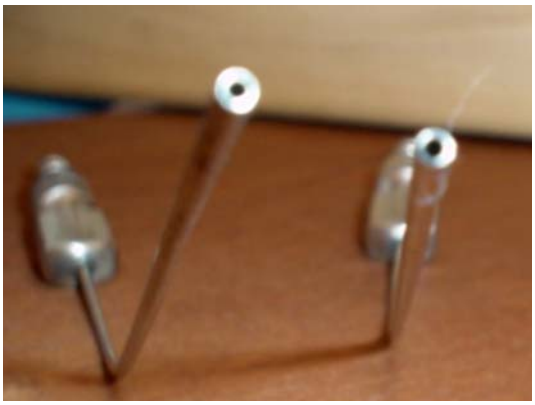
- Perform hand hygiene before carrying out this activity
- Maintain the workbench in good condition, both in terms of hygiene, with disinfection between sessions, and organization
- Do not use an oily substance for lubrication
- Do not allow a staff member with any type of dermatological lesion to carry out this activity

Inspection and function testing (post-cleaning)

- Each set should be inspected separately
- Box joints, serrations and crevices should be critically inspected for cleanliness
- Hinges on devices, such as artery forceps and clamps, should be checked for ease of movement
- Jaws and teeth should be checked for alignment
- Ratchets should be checked for security
- Multi-part instruments should be assembled to ensure that all parts are complete and working
- Multi-part instruments should be assembled or disassembled for sterilization as per manufacturers' instructions
- Any damaged, incomplete or malfunctioning devices should be reported immediately to the supervisor
- Cannulated devices should be checked to ensure that the channels are patent
- Telescopes and light cables should be function-checked according to the manufacturers' instructions
- Each device set should be checked for completeness and defects
- Cutting edges on devices, such as scissors, rongeurs, chisels and curettes, should be checked for sharpness.
- Hinges on devices, such as artery forceps and clamps, should be checked for ease of movement.
- Devices that have an outer insulation coating,e.g. diathermy forceps, require close inspection to ensure that the insulation remains intact. Insulated devices should be checked using an insulation diathermy pinpoint tester. In accordance with manufacturer's instruction to ensure safe use of equipment. Damaged

surfaces not only will allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and service users
- Each device should be checked to ensure free movement of all parts and that joints do not stick.A water-based lubricant may be used if required
- Each device should be checked after each cleaning cycle to ensure that all screws on jointed devices are tight and have not become loose during the cleaning process

Figure 14. **Example of lumen inspection**



Placing devices in surgical trays

Devices shall be prepared for sterilization in the following manner:
- Clean and dry
- Jointed instruments in the open or unlocked position
- Multi-part or sliding pieces disassembled, unless otherwise indicated by the device manufacturer
- Devices with concave surfaces that will retain water must be placed in such a manner that condensate does not collect.
- Heavy items arranged so as to not damage lighter more delicate items
- Sharp instruments with tips protected[19] without being too tight

ASSEMBLY

The purpose of assembly and checking is to ensure that:
- All devices are present in accordance with the surgical tray list.
- All devices are assembled correctly in accordance with the manufacturers' instructions
- All devices are placed in the correct tray in a manner that ensures ease of use by the user

Space for assembling medical devices

The area where assembly and checking takes place should be designated and controlled to optimize the effect of the sterilization process and minimize contamination of the sets.

- When preparing devices for packaging and sterilization, it is essential that all surfaces are presented to the sterilization media (i.e. steam).
  – It is equally important that devices to be sterilized are disassembled and presented in this state
- Devices with ratchets should be closed on the first ratchet only to ensure that steam can penetrate to all surfaces.
  – Similar devices should be kept together when placing in the tray, e.g. artery forceps can be placed on a device pin together

19 CSA Z314.0-13 Medical device reprocessing – General requirements.

- The device tray is selected so that devices can preferably be placed in one single layer
- Tray liners should be placed at the base of the surgical tray
- Devices should be spread evenly by weight over the tray surface; this helps to prevent condensate flowing together
- Each device should be checked against the surgical list specific to the tray being assembled
- Plastic items should be evenly placed in the tray; avoid placing them in one section of the tray
- Ensure that sharp devices are assembled correctly to avoid penetration of the outer packaging to avoid overheating
- Protectors to be placed on sharp devices should be validated for steam penetration
- Ensure that delicate devices are placed in the tray in a manner, which will not cause damage to them
- Any device missing from a tray should be reported to the supervisor for further action and non- conformance documented
- Any extra devices found while assembling a tray should be reported to the supervisor for further action and non-conformance documented

Figure 15. **Example of an instrument tray assembly***



*Note the error of placing the tray list inside tray; as it is made of paper, this generates paper lint that can be transferred to instruments and cause patient harm.

PACKAGING AND WRAPPING MATERIAL

Devices require packaging prior to sterilization. Packaging material and techniques are designed to hold and protect the devices in order to facilitate sterilization and to maintain sterility and permit aseptic removal of contents at the point of use. The material selected depends on the recommended method of sterilisation and must comply with international standards[20].

General principles for wrapping

The choice and type of wrapping material will depend on the type of sterilization process used[21].

- Packaging should be selected according to the sterilization method and the devices to be prepared

20 EN 868-2:1999; EN 868-3:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5). Requirements and test methods. EN 868-4:1999 Packaging materials and systems for medical devices which are to be sterilized. Paper bags. Requirements and test methods.
EN 868-5:1999 Packaging materials and systems for medical devices which are to be sterilized. Heat and self-sealable pouches and reels of paper and plastic film construction. Requirements and test methods.

21 Materials used should comply with EN ISO 11607-1: 2006 Packaging for terminally sterilized medical devices Part 1. Requirements for materials, sterile barrier systems and packaging systems. ISO 11607-2 (2006) and EN 868, parts 2-10. ISO 16775 inclusive.

- Every package should have an external chemical indicator (internal chemical indicators are optional) and an identification or label of the content, lot number, expiry date and initials of the operator
- Devices may be packaged in any of the following sterile barrier systems (SBS): PSBS, ssterilization wrap, rigid reusable containers
- When selecting a packaging system, the capability of each specific product to meet predetermined requirements and criteria should be evaluated
- An appropriate size of wrapping material should be chosen to achieve adequate coverage of the item being packaged
- Hollow ware and RMDs or dressings should not be placed in textile (linen) packs as difficulties may be experienced in drying the combined pack materials and sterilization may be compromised as the temperature increases in these materials at different rates
- Single-use wraps should be used once only and discarded after use in the appropriate health-care waste stream
- Device packs should be packed in a manner that prevents damage to delicate items
- Trays used for packaging devices should be perforated to allow for penetration of the sterilant
- Hollow ware items packaged together should be separated by non-porous material to permit efficient steam circulation
- Hollow ware should be packaged so that all openings face the same direction
- Only a minimum of raw materials commensurate with daily production should be stocked within the clean room
- Compatibility of the packaging material with the sterilization process should be established
- If chemical indicators are used inside the pack, they should be compatible with the pack
- Sequential wrapping using two barrier-type wrappers is recommended as it provides a tortuous pathway to impede microbial migration

Requirements for packaging systems

- Packaging systems must be appropriate to the ***items being sterilized***. They should:
  – Permit identification of contents
  – Permit complete and secured enclosure of items
  – Protect package contents from physical damage
  – Permit delivery of contents without contamination
  – Maintain sterility of package contents until opened
  – Facilitate aseptic technique at all times, including opening of the package

- Packaging systems must be appropriate ***to the method of sterilization***. They should:
  – Provide adequate seal integrity
  – Provide an adequate barrier to particulate matter and fluids
  – Be compatible with and able to withstand physical conditions of the sterilization process
  – Allow penetration and removal of sterilant
  – Maintain integrity of the pack
  – Permit use of material compatible (i.e. non-degradable) with the sterilization process

- Packaging systems must be used ***according to the manufacturers'*** *instructions* with the following attributes:
  – Resistance to punctures, tears and other damage that may break the sterile barrier and cause contamination
  – Resistant to penetration by microorganisms from the surrounding environment
  – Free of holes
  – Free of toxic ingredients
  – Lint-free (or low linting)
  – Tamper-proof and able to seal only once
  – Provide an adequate barrier to particulate matter and fluids

Packaging materials

- Packaging materials should be stored at room temperature 18°C to 22°C and at a relative humidity of 35% to 70%. Temperature and humidity equilibrium of packaging material is important to maintain the integrity of the product

- Packaging materials should not be stored adjacent to external walls or other surfaces, which may be at a lower temperature or a higher temperature than the ambient temperature of the store room
- Packaging materials should be stored on shelves 10 inch/28 cm above floor level[22]
- Packaging material should be rotated to ensure that it does not exceed its shelf life ("first in, first out")

Requirements for packaging material

- Packaging materials must be validated for method of sterilization used
- Contain no toxic ingredients or dyes
- Capable of withstanding high temperatures
- Allow air removal from packages and contents
- Permit sterilant contact with package contents
- Permit drying of package and contents and prevent the entry of microbes, dust and moisture during storage and handling
- Proven tamperproof seal
- Capable of withstanding normal handling, resistant to tears or punctures and allow for aseptic presentation
- Cost effective
- The packaging material must comply with the manufacturer's recommendations for the type of reprocessing equipment which is used
  – Packaging manufacturers' instructions for use should be followed to obtain the best results.

Types of packaging material

Sterilization wraps

Sterilization wraps including bleached crepe paper and wraps combining cellulose and synthetic fibres are commonly used packaging materials for steam, dry heat and ETO sterilization. They are permeable to steam, air and chemical vapours and provide an effective barrier if the packs are stored in clean, dry conditions. Medical grade paper is free from loose particles, but frees particles if packs are opened by tearing, cutting or by opening a fibre tear seal.

It is important that the sterilization wraps used in the facility are used in accordance with the manufacturer's recommendations. The use of double Paper-based sterile barrier systems (PSBS) is not recommended as a wrapping method as this increases the probability that the steam may not penetrate the packing material (refer to ISO 16775 for further guidance). Paper-based sterile barrier systems are unsuitable for use in the hydrogen peroxide plasma method of sterilization as they absorb the hydrogen peroxide vapour from the chamber space, thus interfering with the subsequent generation of hydrogen peroxide plasma during the cycle.

Rigid reusable containers

Rigid reusable containers are used for the moist heat sterilization of large sets of surgical instruments. They are made from diverse metals, aluminium, high-density polymers, or metals and plastic in combination. Perforations in the base and lid are lined with a steam-permeable HEPA material. Containers should be properly loaded in terms of density to avoid problems of moisture retention and increased drying times. After use, containers should be disassembled and cleaned by washing with detergent and water and dried before sterilization. Routine inspection and maintenance is essential to ensure their ongoing effectiveness. Container systems must be validated before use.

Reusable fabrics

Reusable woven cotton or cotton/polyester material can be used for heavy packs that are sterilized in pre-vacuum or downward displacement steam sterilizers. They are less resistant as a bacterial barrier than sterilization wraps.

22 CSA Z314.0-13 Medical device reprocessing – General requirements.

Two layers of reusable fabrics with the textile configured as an inner wrap should always be used, or one layer of reusable fabric and one disposable sterilization wrap. Defects in the fabric render the wrap ineffective, such as holes and threadbare patches. All reusable fabric outer wraps should be of double thickness. The performance of reusable fabrics (cotton or polyester/cotton materials) as microbial barriers is not as good as the many single-use sterilization wraps, but reusable fabric wraps should maintain sterility for several weeks under clean, dry storage conditions.

If reusable fabrics (woven cotton/polyester materials) are used, there should be facilities and procedures in place to inspect and access the quality and suitability of such fabrics for use and reuse. Very tightly or thick woven materials may impede air removal and steam penetration and should not be used. The exception is the introduction into the Australian market of "recyclable barrier fabrics" made from completely synthetic materials. These are very durable and thus attractive for use, but validation of the attainment of sterilization conditions and reliable drying should be locally established before they are adopted in a facility. When reusable fabrics are used as a sterilization wrap, there are additional requirements to ensure the suitability of the wrap prior to each use[23].

Non-perforated containers of glass or metal

Glass tubes closed with non-absorbent cotton wool plugs or crimped foil caps may be used only for dry heat sterilization of glass syringes and needles. As glass is a poor conductor of heat, heat penetration investigations need to be performed. Needles should be supported so that the tip does not contact the wall of the container.

Glass bottles, vials and ampoules may be used for the steam sterilization of aqueous liquids by laboratories, and lidded jars may be used for dry heat sterilization of oils. Non-perforated metal containers are only suitable for dry heat sterilization.

Aluminium foil may be used as a wrapping material for large articles, such as surgical drills, which are sterilized by dry heat. Pinholes may occur in the creases and thus a grade of foil thicker than the common "domestic" grade needs to be selected (~75 µM). Metals are impervious to steam and gas sterilizing agents.

Single-use packaging

- Medical device regulations include a requirement that sterile devices should be designed, manufactured and packed in a non-reusable pack and/or according to appropriate procedures to ensure that they are sterile
- A clearly stated preference for single-use packaging as the primary packaging for sterile devices is now observed
- Double wrapping is recommended for medical devices used in the operating theatre

Selection of packaging material

Packaging materials are selected according to size, shape, weight and the intended sterilization process. See Table 7.

Packaging material for use in sterilizers must:

- Be compatible with the sterilization process
- Be suitable for closing and sealing
- Free from loose fibres and particles
- Free from toxic ingredients and non-fast dyes
- Be compatible with pack contents under the proposed sterilization conditions

The requirements of a packaging material include:

- Permeability to air, steam and gaseous sterilants, i.e. allows removal and penetration to steam. (This does not apply to dry heat or ionising radiation.)
- Resistance to penetration by microorganisms following sterilization

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23 ISO 11607-1:2006, 5.1.11 and 5.1.12

In relation to microbial penetration, non-porous materials are solid barriers, while porous materials are effectively "filters" manufactured to have good control over the probability of penetration by microorganisms as long as the packaging is kept dry, even at low rates of air flow through the material.[24]

Recommendations for packaging material

Recommended

- **Sterilization wrap** made from cellulose fibres and non-wovens made from a combination of cellulosic and synthetic fibres may be used. Both types are suitable for porous-load steam sterilization and most gas processes because they are permeable to air, steam and other gases
- **Rigid reusable sterilization containers** should be suitable for the method of sterilization used and compatible with the cleaning method and cleaning agent
- **Transparent pouches** should be placed paper to plastic for sterilization. Single instruments only should be packed in pouches

Not recommended

- **Metal (sterilization) drum trays** with holes that can be opened and closed manually. These do not guarantee sterility of its contents
- **Newspapers, brown paper bags** and other products that do not allow air removal or penetration of steam must not be used
- **Recycled material packaging** because these have lost their integrity and the bacterial barrier and do not allow adequate air removal or steam penetration

In some parts of the world, linen is used for strength and packaging. It is possible to use linen provided that it is placed between two layers of non-woven material before being used to wrap surgical trays.

> **The total weight of instrument sets and their packaging should not exceed 10 kg and the total weight of wrapped basin sets should not exceed 3 kg.**

Packaging techniques

Devices may be packaged in any combination of **flat wrapping material** (sheets, bags, pouches or reels) or **containers** to maintain the integrity of the product. Devices wrapped with sheet material using either the **envelope** or **parcel fold** technique. Devices are wrapped in a manner which minimizes the risk of contamination during opening and removal of contents.

Equipment required

- Packaging material
- Sterilization chemical indicator tape
- Marking pen
- Label (where applicable)
- Tray liners

Types of wrapping

- Flat wrapping material
  - Parcel fold wrapping method
  - Envelope wrapping method
- Containers
- Pouches

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24 *Australian/New Zealand guidelines. Disinfection & sterilization infection control guidelines.* Centre for Healthcare related Infection Surveillance and Prevention (CHRISP), 2006. Available from: www.health.qld.gov.au/chrisp/ [Accessed 20 August 2015].

Table 7. **Various types of packaging systems available and their appropriate use in sterile services**

TYPE OF PACKAGING	USES	ADVANTAGES	DISADVANTAGES	COMMENTS
Paper (medical grade) Bleached crepe paper; cellulose & synthetic fibres	Steam Dry heat ETO	• Penetration of steam, air, chemicals • Effective barrier in dry clean conditions • Free from loose particles; single use only	• Fibres and loose particles if torn or shredded • Not to be used for hydrogen peroxide plasma - absorbs hydrogen peroxide • Do not facilitate aseptic opening	• Use manufacturers' guidelines; double wrap may- reduce steam penetration • Paper bags are not very strong; unable to see inside
Reusable rigid containers - metals, aluminium, high density polymer or a combination of metal and plastic	Steam sterilization for large sets of surgical devices	• Keeps the devices safe after sterilization and during transportation	• Containers must be loaded properly to avoid problems of moisture and increasing drying times	• Lid and base are perforated to allow steam penetration; disassemble and clean after each use • Require routine inspection and maintenance • Container systems must be validated before use
Woven fabrics. Two layers of cloth or one each of cloth and paper. Primary packaging	Steam prevacuum or downward displacement (gravity)	• Heavy pack • Stronger - resistant to tearing; reusable	• Poor bacterial barrier. • Holes in the fabric render them ineffective Impede air penetration and air removal if thick or tight • Cannot be used alone • If too dry, will cause overheating of steam and failure of sterilization • "Sterile" wound infections from lint	• Store clean and dry. • Need to be inspected carefully and assess quality during use and reuse • Not recommended for primary packaging alone, must have another (secondary or layered) cover with it
Synthetic woven fabrics	Steam sterilization	• Durable and good to use	• Need to be validated for sterilization and reliable drying in the facility	• Validation required for sterilization
Non-perforated containers of glass or metal	Dry heat sterilization	• Sterilization of needles	• Poor conductor of heat - increases drying time	• Not recommended -
Glass bottles, vials and ampoules for liquids	Dry heat sterilization of liquids and oils	• For sterilization of liquids and oils	• Limited use if any	• Less often used
Aluminium foil Thicker grade than domestic (about 75_M)	Dry heat	• Used for larger items like drills	• Impervious to steam and gas	• Not recommended for routine use

TYPE OF PACKAGING	USES	ADVANTAGES	DISADVANTAGES	COMMENTS
Transparent pouches • Polymers • Polyethylene • PVC • Polypropylene & polycarbo-nates • Nylon	Steam ETO Steam Hydrogen peroxide plasma Dry heat only	• Good antimicrobial and dust barrier • Single items (one medical device per pouch); maintain sterility; contents easily visible	• Can tear or perforate • Need to be properly heat sealed without leaks to maintain sterility • Some impede steam removal and increase air removal time	• Use for single devices or light materials. • Some polyethylene pouches do not tolerate vacuum - • PVC & nylon pouches are not recommended
Tyvek™-bonded polyethylene Superior bonded, paper like non-woven	Steam ETO Low temperature steam formaldehyde Hydrogen peroxide plasma;	• Robust, good barrier properties, low absorption of chemical sterilants, can be heat sealed, and has an incorporated chemical indicator	• None, but expensive • Not widely available	• Good non-woven substitute for linen

Table 8. **Some examples of devices and the primary packaging systems that can be used***

ITEM	RECOMMENDED	ALTERNATIVE
Textile packs	Two sheets of packaging materials; parcel-fold or envelope fold	Container, laminated film pouch
Small quantities of textile and/or bandages/swabs	Laminated film pouch, possibly in dual laminated film pouches	Container
Instrument sets in trays/ baskets	Two sheets of packaging materials: parcel fold or envelope fold	Container, laminated film pouch
Individual devices	Laminated pouch, possibly in dual laminated film pouches	Container
Bowls and trays (small)	Laminated film pouch; paper sheet, paper bag	Container
Catheters, tubing, hoses	Laminated film pouch, if appropriate in dual laminated film pouches	Two sheets of packaging material, paper bag, container
Scopes	Special container, laminated film pouch, possibly in dual laminated pouches, laminated film pouch from roll	Two sheets of packaging material, paper bag
Fine surgical devices (individual as well as in sets)	Dual laminated film pouches, special container, two sheets of packaging material in combination with a support system/rack	Container
Breast prosthesis	Sheet of packaging material in pouch	Container, laminated film pouch

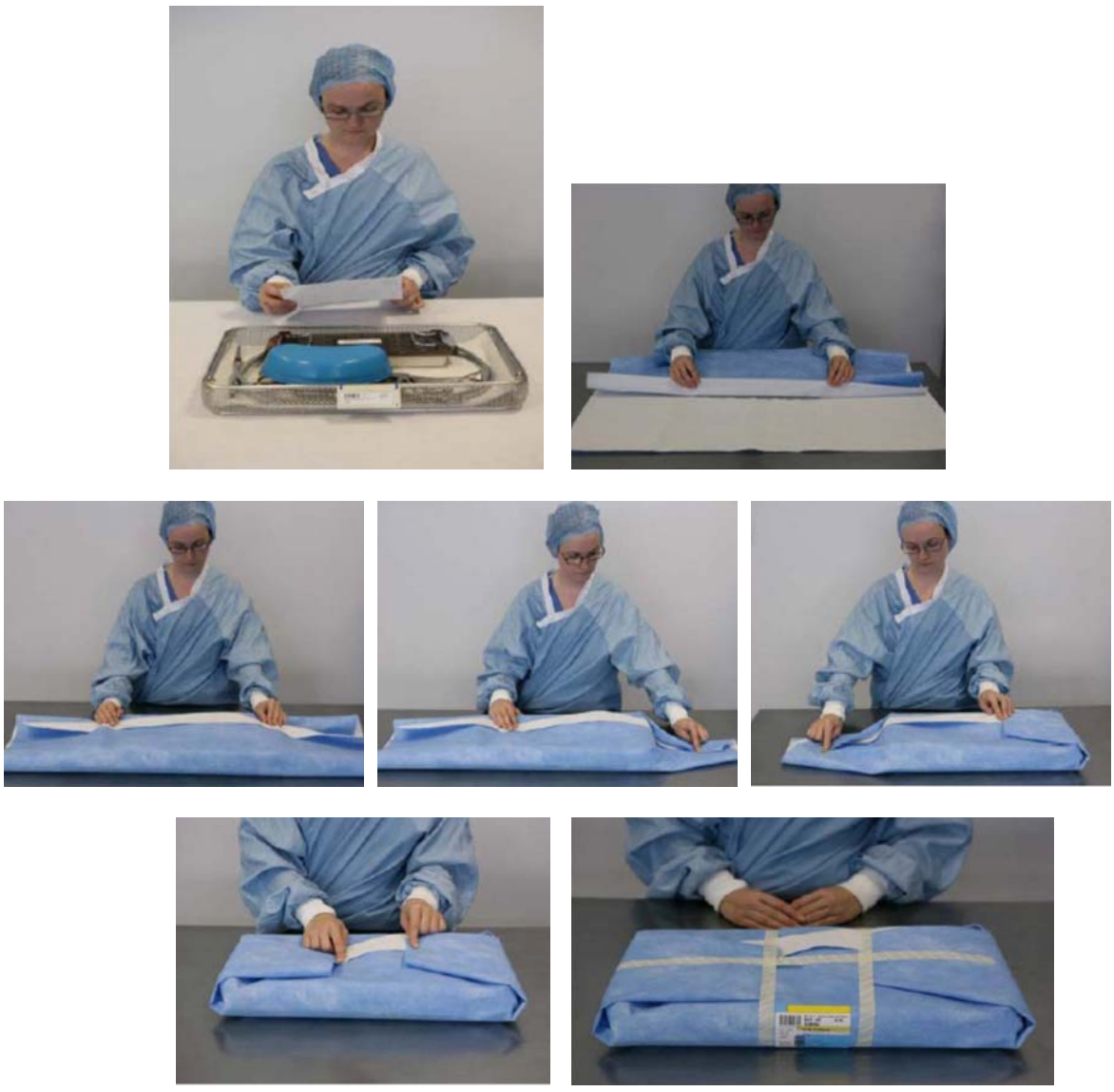
* Adapted from Huys, J. Sterilization of Medical Supplies by Steam. Volume 1 – General Theory, 2nd edition. Renkum: Heart Consultancy, 2004

Parcel fold wrapping method

Select appropriate packaging material and place on work top. The device set is placed on the wrap, approximately in the centre of the packaging material. Verify the accuracy of the device identification label with the device or device set, i.e. ensure that it corresponds to the device list/internal tray label. A step-by-step guide to the method is illustrated below in Figure 16.

The long edge of the tray should be aligned parallel to the long edge of the wrap. One of the long edges of the wrap is folded over the pack contents to the base of the tray and the edge of the wrap is turned back on itself. The opposite side of the wrap is then folded over the pack contents to overlap the centre line (and the side already folded over the pack contents), and the edge is turned back on itself. The ends beyond the short side of the contents are then folded to a point and each is then folded over the contents. The same procedure may then be repeated for an outer wrap(s). The wrap is secured in position using sterilization indicator tape. It is important to wrap the item securely to avoid gapping, billowing and the formation of air pockets, which could compromise sterility. The device identification label is placed on the outside wrap.

Figure 16. **Example of the parcel fold wrapping method**

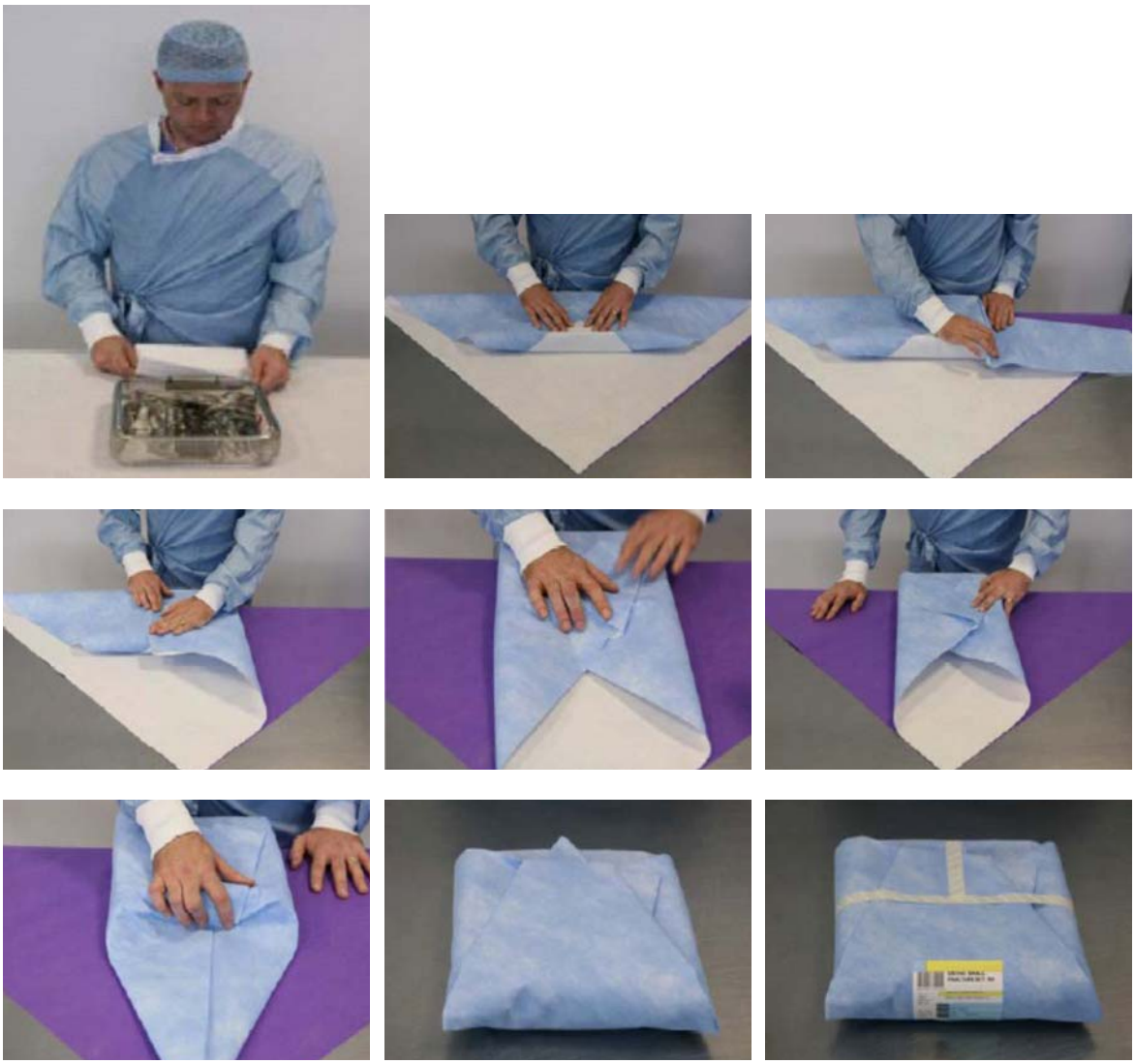


Envelope wrapping method

Select appropriate packaging material and place on worktop. The device set is placed on the wrap diagonally and slightly off the centre line. Verify the accuracy of the device identification label with the device/device set, which should correspond to the device list/tray internal label. A step-by-step guide to the method is illustrated below in Figure 17.

The section of the wrap with the shorter corner-to-pack length is folded over the contents by bringing the corner to the centre. This is repeated with the corners to the right and left of the first folded corner. In each case the corner is turned back to provide a flap for opening. Finally, the larger fold is brought over the top and tucked in under the earlier folds with a corner protruding to facilitate aseptic opening. The same procedure may then be repeated for an outer wrap(s). The wrap is secured in position using sterilization chemical indicator tape. It is important to wrap the item securely to avoid contamination, which could compromise sterility. The device identification label is placed on the outside wrap.

Figure 17. **An example of the envelope wrapping method**



Sealing of packs and bags

Heat sealing equipment is essential in all SSDs that use the pouch system for individual devices. The use of alternatives, such as rubber bands and glue or paste, is not acceptable. The sealer does require electricity to run and it should be maintained regularly to ensure optimum performance.

Equipment required

All equipment must be serviced at least once a year if not sooner.

- Heat seal pouches
- Heat sealer
- Marking pen
- Label (where applicable)

- Select an appropriate size of heat seal pouch
- Place device(s) in the pouch. Ensure that creases in the packaging material are removed as this can result in inadequate or uneven seal
- Remove as much air as possible from the pouches before sealing
- Air acts as a barrier to heat and moisture
- Expansion of air during the sterilization process may cause the bag to rupture
- Place open end of pouch in the heat sealer
- Apply heat and pressure to the surface of the open end of the heat seal pouch
- Checks should be made that the seal is complete, especially over the gusset folds of the pouches
- A weak point in the heat seal of paper bags may often be found in the corners where the paper is folded back on itself, and in gusseted packs where four thicknesses of material become two
- This latter problem can be minimized by reverse folding the gusset in the area to be heat sealed before sealing

Heat sealers

- Heat sealers are used to seal paper to paper (e.g. bags or pouches), film to paper (e.g. laminates, flexible packaging systems) and plastics.
  - Heat sealing involves pressing the lacquered surfaces between heated plates. The temperature, pressure and contact times must be constantly monitored.
  - Creases, thickness and type of material used may result in faulty seals.
  - Seals should always be checked on opening to ensure that the seal has been maintained
- Heat sealers shall undergo a complete mechanical service, including temperature calibration, at regular intervals not exceeding 12 months
- Test pieces for each type of packaging material used should be processed daily on each heat sealer and examined for integrity and strength of seal before and after being subjected to a steam sterilization process.
- Various types of heat sealers are available[25] (refer to Australian standard [AS] 4187). Heat sealers are either of the jaw-type or of the continuous type.
  - For each type of heat sealer, the operator must perform a daily check of the following items:
- Ensure that the machine is in a clean condition with no loose fibres or lint present
- Ensure that element covers, where fitted, are in a good condition and replaced immediately when damaged
- Verify the effect of the sterilization process on the seal. Heat seals are weakened during steam sterilization, but usually return to the normal condition on cooling.
  - Sterilization by ETO, hydrogen peroxide plasma or radiation does not have a significant effect on seals
- In addition, every three months, the operator should check and adjust the gap between the heating elements to ensure that it is within the manufacturer's recommendations

25 *Australian/New Zealand guidelines. Disinfection & sterilization infection control guidelines.* Centre for Healthcare related Infection Surveillance and Prevention (CHRISP), 2006.

Sealing, indicators and labelling

Adhesive tapes, such as sterilization indicator sealing tape, are commonly used to fasten wrappings and incorporate a chemical indicator. The chemical indicator is visible as diagonal stripes that darken or change in colour during the sterilization process. Tape adhesive must be stable under the conditions occurring during sterilization and be permeable to the sterilizing agent.

Heat sealing of flexible packaging materials is the best method for these materials. Seal the laminate to the paper with a continuous adhesive seal of 3-15 mm. In the event of breakdown of the heat sealer, a seal may be formed by first folding the corners of the open end inwards, then making two or three width-wise folds of the entire open end of the pack, followed by securing of the folds with adhesive tape (which could be autoclave indicator tape).

The heat sealing process should be undertaken with care. Creases in the packaging material can result in an inadequate or uneven seal. When double-wrapping using heat seal pouches, the packages should be used in such a way so as to avoid folding the inner package to fit into the outer package. Edges of inner heat seal pouches should not be folded as air may be entrapped in the folds and inhibit sterilization. When double-wrapping using paper/plastic heat seal pouches, the paper portion should be placed together to ensure penetration and removal of the sterilant, air and moisture. This also enables the devices to be viewed. It is important to wrap the devices securely to avoid contamination, which could compromise sterility. Use an adhesive device identification label, ***do not write on the paper side of the pouch***. The device identification label is placed on the outside packaging.

When loading paper/plastic pouches into the sterilizer, the packages should be placed in the same direction, (i.e. paper/plastic, paper/plastic). If one heat seal pouch is placed inside another, care should be taken to select the appropriate sequential sizing.

Self-sealing packages are to be used in accordance with the manufacturers' instructions.

Staples must never be used because they perforate the packaging material.

Figure 18. **Example of a heat sealing work station**



Specific guidelines for packaging for low temperature processes

Low temperature sterilization processes have special requirements or limitations for packaging materials. Brief descriptions are provided below.

ETO

Many porous packaging materials and sealing styles may be used in ETO sterilization, except for cotton or polyester/cotton textiles, which absorb moisture needed to reliably kill microorganisms. Sealed containers must not be used. Different packaging materials (as well as the goods being sterilized) will absorb differing amounts of ETO during sterilization. Removal of this absorbed gas is a slow process requiring a specific aeration stage and equipment. Packaging materials can have a significant effect on the efficacy of the sterilization process and any change requires that the process be revalidated.

Hydrogen peroxide plasma

Only purely synthetic packaging materials can be used in hydrogen peroxide plasma sterilization. This is because there is no absorbed moisture in the packaging material as very small quantities would interfere with the attainment of the deep vacuum and the generation of plasma used in this process. Suitable materials may be selected from the range of non-woven wraps and non-cellulose flexible packaging materials available and should be sealed at 120°C.

Peracetic acid

Peracetic acid sterilization uses a liquid sterilant. Therefore, porous packaging materials cannot be used as they would be completely saturated with liquid at the end of the process. This process is intended for the sterilization of unwrapped instruments with only a very short distance for transport of goods from the sterilizer to the point of use. For this purpose, the load-carrying "cassette" offers some protection following sterilization, similar to the way packaging materials function, but these machine-specific, load-carrying systems are not intended to maintain sterility longer than a few minutes after sterilization.

Labelling

Packages to be sterilized should be labelled before sterilization. The information on the label should include the following:

- Name of product
- Name of wrapper
- Expiry date and/or sterilization date
- Where appropriate, the word "sterile"
- Load number

Label information should be documented on sterilization chemical indicator tape or label and not on the packaging material. Plastic/paper pouches can be labelled outside the heat seal line and on the clear (laminate) side as the ink may penetrate the paper on the plastic portion. Marking pen used to label the pack should be indelible, non-bleeding and non-toxic. Sharp-tipped, water-based or ballpoint type pens should not be used as these may compromise the integrity of the pack. The label fixed to the surface of the packaging should be able to withstand exposure to the sterilization process. Commercially-prepared, self-adhering labels may be used, with the advantage that they may be pre-printed and/or computer-generated. The labels should remain on the package until the point of use. Of note, the ink and adhesive should be toxin-free.

Policies, procedures, protocols and guidelines for wrapping and labelling and sealing of devices to be sterilized should be developed, reviewed periodically and readily available within the department.

A piggyback batch control label system or computer-generated system is to be used on all items that are to be used as a sterile product[26]. This label is to be placed in the patient's procedural record by operating theatre staff to assist with the ability to recall items.

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26 "Recommendations for manual batch labelling and manual tracking of instruments trays for Operating Suite". Accessed 20th August 2015.) https://www.health.qld.gov.au/chrisp/

Minimum labelling requirements[27] include:

- Sterilizer identification number or code
- Date of sterilization
- Cycle load or number
- Expiry date

Monitoring and control during labelling

The following should be monitored during labelling:

- Ensure the general appearance of the packaging material
- Ensure that packages are complete
- Ensure that the correct products and packaging material are used
- Ensure that the labelling is correct on the product
- Ensure correct sealing
- Ensure the correct performance of packaging equipment, e.g. temperature gauge reading on heat-sealing equipment
- There should be no open seals, bubbles or other breaks in the integrity of the seal
- Material should be checked for tears and holes
- Container seals and filters should be checked
- Containers should be checked for damage and tamper evidence that may interfere with maintaining sterility

Maintenance of packaging systems

- Reusable rigid containers should be validated periodically for reuse according to manufacturers' instructions
- Planned preventative maintenance should be undertaken in accordance with ISO standards, manufacturers' instructions and/or local policies, procedures, protocols and guidelines
- Heat seal efficiency, integrity and strength testing should be performed on each heat sealer daily
- Routine monitoring of processed heat-sealed products should be undertaken by checking the quality of the output
- Heat sealers should be serviced yearly. This service includes temperature calibration and heat seal integrity and strength of seal
- Preventative maintenance should be planned and performed for all equipment and utilities in accordance with documented procedures, as recommended by the manufacturers' instructions
- The procedure for each planned maintenance task and the frequency at which it is carried out should be specified and documented
- Records of all maintenance, validation and servicing should be maintained for a period of time according to national regulations
- A nominated qualified person should review the planned maintenance procedures

27 A guide for selecting cleaning agents can be found in AS/NZS 4187:2003 .Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities. http://www.saiglobal.com/pdftemp/previews/osh/as/as4000/4100/4187.pdf. Accessed 20th August 2015.)

Chemical disinfectants

INTRODUCTION

Various chemical agents are used to disinfect items or equipment in a health-care setting. This section deals specifically with the use of chemical disinfectants after heat labile devices have been cleaned.

AN IDEAL DISINFECTANT

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

Antimicrobial activity to particular disinfectants is summarized in Table 7. The descending order of resistance to germicidal activity of chemical disinfectants against various microorganisms is illustrated in Table 9.

Factors that affect the effectiveness of the disinfection process

Quantity of the microorganisms. As the bioburden increases, the amount of time that a disinfectant needs to act also increases. Therefore, it is essential to carry out a scrupulous cleaning of all the surfaces of instruments. Instruments with multiple components should be disassembled and cleaned and disinfected part by part.

Organic matter. The presence of biofilms and/or organic matter, such as serum, blood, pus, faeces or other organic substances, has the ability not only to inactivate the antimicrobial activity of disinfectants, but also to prevent contact with the disinfectant and therefore compromise its effectiveness.

Resistance of microorganisms to the chemical agent. This refers primarily to the spectrum of antimicrobial activities of the various agents (see Table 7).

Concentration of the agents. This refers to the concentration required of each disinfectant to produce the expected antimicrobial action. Higher concentrations may have deleterious effect on the material, e.g. corrosion.

Physical and chemical factors. Some disinfectants have optimal antimicrobial activity at a certain temperature and/or pH.

Duration of exposure. Each disinfection method and agent is associated with a specific amount of time that is necessary to achieve the desired result.

Stability. Some disinfectants are unstable at use concentration, e.g. chlorine-releasing agents, and should be discarded as recommended by the disinfectant manufacturer/supplier.

Types of commonly-used chemical disinfectants

Table 9. **Chemical disinfectants***

Chemical	Mode of action	Advantages	Disadvantages
Ortho-phthaladehyde Ortho-phthaladehyde (OPA) (Cidex OPA®) is a chemical agent used for high-level disinfection. It corresponds to the group of inorganic aldehydes, which contains benzene-carboxaldehyde. *Instructions for use* The time required for high-level disinfection varies according to the national standards and manufacturers. For example, the United States FDA standard requires 10 to 12 minutes at 20°C, the Canadian standard requires 10 minutes, and the European standard requires 5 minutes immersion time. *Concentrations for use* A concentration of 0.55% is recommended. Once opened, the solution can be reused for 14 days; if unopened, it has a shelf life of two years.	Kills microorganisms by alkylation of cellular components and acts directly on nucleic acids.	• Excellent stability in a broad range of pH (3-9) and as a result does not require activation. • Fast-acting with excellent material compatibility and does not coagulate blood or fix tissues to surfaces. • Barely perceptible odour and requires no activation. • Not carcinogenic, but it is recommended that it be used in ventilated areas (similar to all chemicals) as the effects on health are not fully understood	• More expensive than glutaraldehyde and no claims for sporicidal activity are made. • A potential disadvantage is that it may cause eye irritation and stains proteins grey including unprotected skin, mucous membranes, clothing and environmental surfaces. Therefore **caution must be exercised** when handling the solution and PPE (e.g. gloves, eye and mouth protection, fluid-resistant gowns) is necessary during it use. • In addition, **equipment must be thoroughly rinse**d to prevent discolouration of a patient's skin or mucous membrane. • Disposal must be undertaken in accordance with local regulations as OPA solution may require neutralization before disposal to the sanitary sewer system. • Not recommended for use on cystoscopes used on patients who are post-surgery for bladder carcinoma due to the risk of anaphylactic shock associated with residue. • Aldehyde-based disinfectants are fixatives and items must be scrupulously clean before immersion. • Test strips are available for some products to check that the solution is at an effective concentration.

Chemical	Mode of action	Advantages	Disadvantages
Glutaraldehyde This is an aldehyde compound and available as acidic or alkaline solutions. The acidic solutions are stable and do not require activation, but they are slower in activity than alkaline buffered solutions. For this reason, they are not as widely used as solutions with an alkaline pH. *Instructions for use* Immersion times vary between countries, but 10 minutes is a minimum requirement for bactericidal activity, 20 minutes for tuberculocidal activity, and longer contact times (>3 hours) for sporicidal activity. *Concentrations for use* A 2% concentration at alkaline pH is recommended for high-level disinfection. Alkaline solutions are provided as an acid solution, which is activated by the addition of an alkaline buffer. Once activated, it has an alkaline pH, which reduces the shelf life to 14 days post-activation. There are also formulations that allow a longer shelf life of 28 days.	Acts on microorganisms by causing alkylation of cellular components that alters the protein synthesis of DNA and RNA.	• 2% glutaraldehyde is widely used to disinfect heat-sensitive items, such as flexible endoscopes. Most preparations of glutaraldehyde have the following properties: • Non-corrosive to metals and other materials. • Inactivation in the presence of organic matter is minimal. • Alkaline solutions have a wide range of antimicrobial activity, including bacterial spores.	• Irritancy and potential toxicity. • Once activated, it tends to produce vapours that may cause occupational asthma and contact dermatitis. – Latex gloves may be worn and discarded after use if the duration of contact with glutaraldehyde is brief, i.e. less than 5 minutes. For a longer duration, nitrile gloves must be worn. • It should be stored away from heat sources and in containers with close-fitting lids. • Use in a well-ventilated area and appropriate PPE (e.g. eye protection, a plastic apron and gloves) must be worn when glutaraldehyde liquid is made up, disposed of, or when immersing instruments. • Concentrations of glutaraldehyde in the environment should be monitored and the occupational exposure standards (threshold limit value/exposure value) of glutaraldehyde should be 0.02 ppm (parts per million) to 0.05 ppm in 8 work hours. – Respiratory protection must be available in the event of a spillage. • Aldehyde-based disinfectants are fixatives and items must be scrupulously clean before immersion. Test strips are available for some products to check that the solution is at an effective concentration.

Chemical	Mode of action	Advantages	Disadvantages
Formaldehyde Formaldehyde (formalin is a stabilised 40% solution of formaldehyde) is an aqueous solution. *Indications* Due to its toxic and irritant effects, formalin under any presentation has been excluded from the list of disinfectants in North America since 1996. *The use of formaldehyde in solutions should be discouraged due to the hazardous health effects of this chemical*.	Produces the inactivation of microorganisms by alterations in the synthesis of nucleic acids.	• None	• Penetrating odour. • Irritating to mucous membranes. • Potentially carcinogenic. • Formaldehyde is a potent eye and nasal irritant and may cause respiratory distress and allergic dermatitis. – Appropriate PPE (gloves, goggles, aprons and respiratory protection) should be worn when preparing and disposing of formaldehyde solutions. – Occupational exposure monitoring is required as per local guidelines. – Use of formaldehyde or formalin solutions must only be carried out by fully trained staff.
Peracetic acid Peracetic acid is an oxidizing agent that acts similarly to hydrogen peroxide. It is available in liquid and powder form and the pH varies between manufacturers. *Instructions for use* Automated machines using peracetic acid are available to chemically "sterilize" medical, surgical and dental instruments, including endoscopes and arthroscopes. Solutions are available for manual immersion of items after cleaning. *Concentrations for use* It is used in concentrations of 0.1% to 0.2% with a contact time of 5 to 15 minutes. It is considered unstable, particularly when diluted. Once prepared, the current manufacturer's recommendation is that it should be used within 24 hours. Biological indicators are not suitable for routine monitoring. Test strips are available for some products to check that the solution is at an effective concentration.	Denatures the proteins and alters the permeability of the cell wall.	• Broad spectrum of antimicrobial activity (including spores). • Very rapid mode of action. • Does not produce toxic waste. • Does not require activation. • Remains effective in the presence of organic matter. • Sporicidal even at low temperatures. • Does not coagulate blood or fix tissues to surfaces. • More effective than glutaraldehyde at penetrating organic matter, such as biofilms.	• Corrosive to copper, brass, bronze, plain steel and galvanized iron, but these effects can be reduced by additives and pH modifications. • Can cause eye and skin damage (especially concentrated solutions) and cause irritation of the mucous membranes.

Chemical	Mode of action	Advantages	Disadvantages
Hydrogen peroxide Hydrogen peroxide is an oxidizing agent used for high- level disinfection. *Instructions for use* Commercially-available 3% peroxygen compound is a stable and effective disinfectant when used on inanimate surfaces. It has been used in concentrations from 3% to 6% for the disinfection of soft contact lenses, tonometer, biprisms and ventilators. Due to compatibility concerns with brass, zinc, copper and nickel/silver plating, the manufacturer's approval should be obtained before using on equipment where corrosion may present problems, such as endoscopes or centrifuges. Hydrogen peroxide has not been widely used for endoscope disinfection because of concerns that its oxidizing properties may be harmful to some components of the endoscope. *Concentrations for use* Its presentation ranges between 3% and 7.5%. In order to carry out high-level disinfection, the indication is for 6%–7.5% for 30 minutes. The solution can be reused for 21 days.	Kills microorganisms by the production of destructive hydroxyl free radicals that can attack membrane lipids, DNA, and other essential cell components.	• Active against a wide range of microorganisms, including cryptosporidium. • Under normal conditions, hydrogen peroxide is extremely stable when properly stored (e.g. in dark containers) • Hydrogen peroxide and peroxygen compounds have low toxicity and irritancy. • No activation required and removes organic matter. • Does not coagulate blood or fix tissues to surfaces. • No odour, does not cause irritation. • Does not require special disposal. • Does not damage glass or plastic articles.	• It is an oxidant for metal articles. • A chemical irritation resembling pseudomembranous colitis has been reported in a gastrointestinal endoscopy unit with use of 3% hydrogen peroxide. • As with other chemical sterilants, dilution of hydrogen peroxide must be monitored by regularly testing the minimum effective concentration (i.e., 7.5%–6.0%). • Can cause serious eye damage with contact.

Chemical	Mode of action	Advantages	Disadvantages
Chlorine-based compounds Chlorine-based disinfectants are available as a liquid (sodium hypochlorite "bleach" or as a solid (calcium hypochlorite or sodium dichloroiso-cyanurate [NaDCC]). NaDCC tablets are stable and the antimicrobial activity of a solution prepared from NaDCC tablets may be greater than that of sodium hypochlorite solutions containing the same total available chlorine. Aqueous solutions of sodium hypochlorite are widely used as household bleach. *Concentrations for use* Hypochlorites are the most widely used chlorine disinfectants and are available as household products. The most widely used concentrations with examples are shown in **Table 8.** The minimum concentration to eliminate mycobacteria is 1000 ppm (0.1%) for 10 minutes on a clean surface. Objects should not be submerged for more than 30 minutes due to the element's corrosive activity	Produces the inhibition of enzymatic reactions, denaturation of proteins and inactivation of nucleic acids.	• Fast acting. • Low cost. • Broad spectrum of antimicrobial activity (including bacterial spores). • Does not leave toxic residues. • Unaffected by water hardness. • Very active against most viruses and the disinfectant of choice for environmental decontamination following infectious cases and other items (refer to Table 8). • It is important to remember that the following factors affect the stability of chlorine: – Presence of heavy metal ions. – Incompatible with cationic detergents. – Decreased efficiency with an increase in pH of the solution. – Temperature of the solution. – Presence of biofilms. – Presence of organic matter (particularly if used in low concentrations). – Ultraviolet radiation. – Decomposition and deterioration of hypochlorite is accelerated by light, heat and heavy metal. It is also polymerized by sun rays and needs to be protected in opaque containers. – Evaporation of hypochlorite causes the concentrations of available chlorine to decline substantially. Hypochlorite solutions should not be stored in uncovered containers. It is important that diluted hypochlorites solutions should be freshly prepared daily and kept in opaque containers to prevent degradation.	• Corrosive to metal, damaged plastic, rubber and similar components on prolonged contact (› 30 minutes), or if used at an incorrect concentration. • Bleach fabrics, carpets or soft furnishings • Efficiency also diminishes with decreased concentration, presence of organic matter and an increase in pH. • Hypochlorites can cause irritation to the mucous membranes of the skin, eyes and lungs, especially if used frequently in a poorly ventilated area. – Appropriate PPE must be worn when hypochlorite is handled, whether in liquid or powdered/granulated form. • Sodium hypochlorite should *not* be mixed with ammonia or acid or acidic body fluids (e.g. urine) as it releases toxic chlorine gas, especially in a confined space. • They should *not* be used in the presence of formaldehyde as some of the reaction products are carcinogenic.

Chemical	Mode of action	Advantages	Disadvantages
Alcohol *Concentrations for use* If concentrations are given in fractions of 100 ("percent"), they must be clearly defined as percentage by weight (g/g or w/w) or by volume (ml/ml or v/v). Alcohol (ethanol or propanol) is commonly used at concentrations of 60%–70%.	The bactericidal/ virucidal mechanism of action is dissolution (dissolving) of the cell membrane (phospholipid bilayer).	• An important feature for their usability in antisepsis is the miscibility of alcohols with water. – Only short-chained alcohols, such as methanol, ethanol and the propanols, are completely miscible. – Of the large chemical group of alcohol substances, three are mainly used in disinfection and antisepsis: ethanol, iso-propanol (or 2-propanol) and n-propanol (or 1-propanol). • Alcohol has a broad spectrum of activity, including viruses and mycobacteria. • Alcohol evaporates so no rinsing to remove residues is required.	• Alcohol does not penetrate well into organic (especially protein-based) matter, and should therefore be used to disinfect only physically- cleaned hard surfaces *or* equipment. • Alcohol should be stored in a cool place. • Alcohol solutions are flammable, so care should be taken when it is used for skin preparation prior to the use of diathermy. • Do not leave uncapped bottles of alcohol as it releases vapours and irritates mucous membranes, especially in an enclosed space. • May cause eye and skin irritation if used in a large quantity in an enclosed space, therefore its use should be avoided in a poorly ventilated area. • If inhaled in large quantities, it may cause headache and drowsiness. • Alcohol is not sporicidal and should not be used for hand disinfection when *Clostridium difficile* is known or suspected.

Chemical	Mode of action	Advantages	Disadvantages
Chlorine dioxide Chlorine dioxide was first used at a spa in Ostend, Belgium, as a water disinfectant. Since the 1950s, it has been used to disinfect drinking water, for the treatment of waste water and for slime control. Some products are now available for instrument and environmental disinfection. *Concentrations for use* High level disinfection can be achieved in 5 minutes; however, 10 minutes are required for sporicidal activity. Before using on any items, (flexible endoscopes, etc.), user acceptance and instrument and processor compatibility must be established. Test strips are available for some products to check that the solution is at an effective concentration.	Chlorine dioxide (ClO_2) is a neutral compound of chlorine in the +IV oxidation state. It disinfects by oxidation; however, it does not chlorinate.	• Products are available to disinfect heat-sensitive instrument e.g. flexible endoscopes. • Wide range of antimicrobial activity. • Stable in diluted solutions in a closed container in the absence of light.	• May be damaging to some metals and plastics.

Note: The chemical disinfectants shown in this table may be used for reusable medical devices. Of note, only high-level disinfectants are cited here. Other chemicals, e.g. chlorhexidine and povidone iodine, are antiseptics and are ***not*** suitable for decontamination of medical devices and their intended use is for use on hand and skin only.

Table 10. **Uses of chlorine and recommended solution strengths**[28]

Use	Available chlorine ppm*
Blood spills	10,000
Laboratory discard jars	2,500
General environmental disinfection	1,000
Disinfection of clean instruments	500
Infant feeding bottles and teats	125
Food preparation areas and catering equipment	125
Eradication of Legionella from the water supply system, depending on exposure time	5-50
Hydrotherapy pools	
Routine	1.5-3
If contaminated	6-10
Routine water treatment	1.5-1

* Undiluted commercial bleach products is usually available between 5.25% or 6.00%–6.15% sodium hypochlorite depending upon the manufacturer.
* Sodium dichloro-isocynaurate (NaDCC) tablets are also available and may be used for the preparation of chlorine solutions.
* There are test strips available for measuring the level of available chlorine in diluted bleach solution to ensure the desired concentration as outlined above.

USE OF CHEMICAL DISINFECTANTS–SAFETY OF HEALTH-CARE WORKERS

Disinfectants are chemical agents and may be harmful, irritant or corrosive and may cause damage by contact with eyes or mucous membranes, by inhalation of vapours or by absorption through the skin. In addition, environmental disinfectants can damage fabrics, metals and plastics.

The employer has a duty to *inform*, *instruct* and *train* employees and non-employees on his premises in relevant safety matters; this includes the use of chemical disinfectants.

- Concentrated disinfectants should always be stored and handled with care wearing appropriate PPE, such as gloves, aprons, respiratory and eye protection
- Whenever possible, disinfectants should be stored in and dispensed from a closed container to reduce the risk of vapour release
- Storage containers should never be left open to the atmosphere for longer than absolutely necessary
- Work should be carried out in an area with easy access to running water, eye wash bottles and adequate ventilation (e.g. an extractor fan or open window)
- It is essential that a risk assessment be carried out when disinfectants are selected in health-care facilities
- Users must follow the manufacturer's instructions and, where necessary, the exposure of employees and others should be monitored according to recommended guidelines.

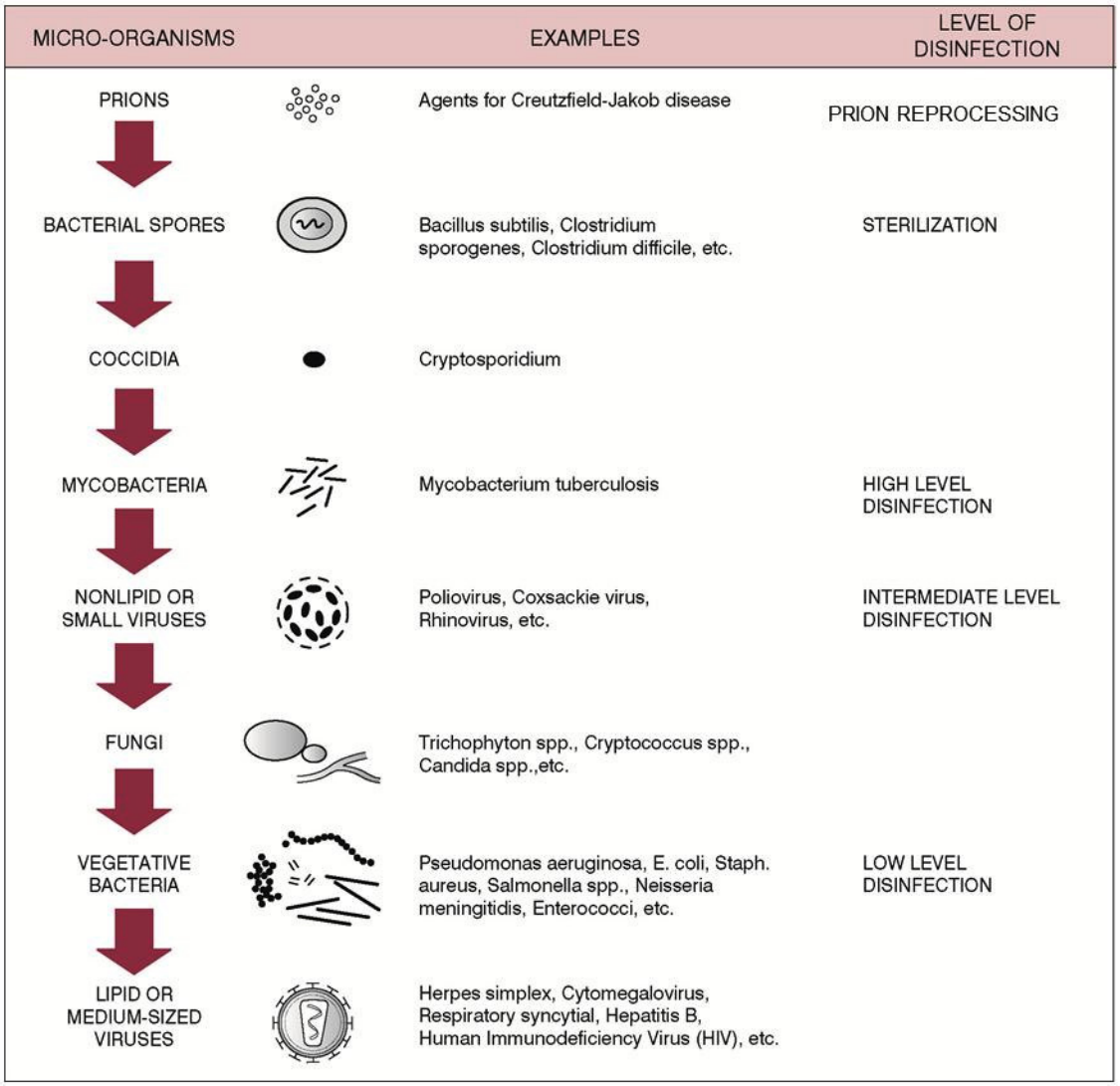
Some individuals may be more sensitive or allergic to disinfectants and may develop skin rashes, contact dermatitis, or in rare cases, difficulty in breathing (asthma). These individuals must inform their line manager who should refer them to the occupational health department for assessment and appropriate action.

The following points should be kept in mind when using chemical disinfectants:
- The efficacy of chemical disinfection is often uncertain and difficult to control/standardize, so wherever possible, disinfection by heat is preferable to chemical methods

28 Reprinted with modification from Fraise AP, Bradley C, eds. *Ayliffe's control of healthcare-associated infection. A practical handbook*. 5th ed. London, Hodder Arnold, 2009

- All chemical disinfectants must be clearly labelled and used within the expiry date. They should be freshly prepared and used at the correct concentration and stored in an appropriate container.
  – Chemical disinfectant solutions must not be mixed or detergents added unless they are compatible
- Disinfectant or detergent solutions must not be prepared and stored in multi-use containers for occasional use. Solutions prepared and stored in this manner may become easily contaminated with microorganisms and the use of such solutions will readily contaminate a surface rather than clean it
- Disinfectants can be corrosive and may damage fabrics, metals and plastics. Manufacturer's instructions must be consulted on compatibility of materials with the method of sterilization or disinfection
- Disinfectants must be disposed of in accordance with the manufacturers recommendations and local guidance

Figure 19. **Descending order of resistance to germicidal activity of chemical disinfectants against various microorganisms**



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

Antimicrobial activity and summary of properties of disinfectants

Table 11. **Summary of the antimicrobial activity of commonly-used disinfectants and their recommended concentrations and properties**

Disinfectant	ANTIMICROBIAL ACTIVITY					OTHER PROPERTIES			
	Bacteria	Mycobacteria	Spores	Viruses		Stability	Inactivation by organic matter	Corrosive/ damaging	Irritant/ sensitizing
				Enveloped	Non-enveloped				
Alcohol 60–70% (ethanol or isopropanol)	+++	+++	–	++	++	Yes (in closed container)	Yes (fixative)	Slight (lens cements)	No
Chlorine-releasing agents (0.5–1% available chlorine)	+++	+++	+++	+++	+++	No No (‹1 day)	Yes	Yes	Yes
Clear soluble Phenolics (1–2%)	+++	++	–	++	+	Yes	No	Slight	Yes
Glutaral-dehyde (2%)	+++	+++	+++	+++	+++	Moderate (14–28 days)	No (fixative)	No	Yes
Peracetic acid (0.2-0.35%)	+++	+++	+++	+++	+++	No (‹1 day)	No	Slight	Slight
Peroxygen compounds* (3–6%)	+++	±	±	+++	±	Moderate (7 days)	Yes	Slight	No

Activity: +++ = Good; ++ = Moderate; ± = Variable; – = no activity or insufficient activity.
*Activity varies with concentration.

Decontamination of endoscopes

An increasing number of diagnostic and therapeutic procedures are now being carried out using rigid or flexible endoscopes. The risk of infection can be classified according to the degree of invasiveness of the procedure. Effective decontamination will protect the patient from infection, ensure the quality of diagnostic procedures and samples and prolong the life of the equipment. The source of infection may be due to:

- The previous patient or inadequate decontamination of the endoscope before reuse
- Endogenous skin, bowel or mucosal flora
- Contaminated lubricants, dyes, irrigation fluid or rinse water
- Inadequate decontamination of the reprocessing equipment

An awareness of the sources of infection will help in the formulation of decontamination policies.
There is often a shortage of instrumentation due to the cost of the instruments and accessories and a rapid turnaround is required between patients. This puts pressure on the staff carrying out the decontamination procedure so lists should be planned to allow sufficient time between patients. Staff should be aware of the complexities of the endoscopes they are processing to ensure that the construction of the endoscope is fully understood. Failures in decontamination, particularly for flexible endoscopes, have been reported due to failure to access all channels of the endoscope. Irrespective of the method of disinfection or sterilization, cleaning is an essential stage in the decontamination procedure and the manufacturers' instructions should be followed at all times. An endorsement of compatibility of the endoscope with the decontamination process is essential.

TYPES OF ENDOSCOPE

Rigid endoscopes

These endoscopes (Figure 20) are relatively easy to clean, disinfect and sterilize as they do not have the sophistication of functionality, construction and channel configuration and compatibility issues that exist with flexible endoscopes (Figure 21). Most suppliers have now introduced autoclavable endoscopes, thus eliminating the need for chemical disinfectants (Figure 22). Where possible, all reprocessing of autoclavable endoscopes and their accessories should take place in a SSD.

Figure 20. **Example of a rigid endoscope**



Flexible endoscopes

These endoscopes (Figure 21) are heat sensitive, and range from endoscopes with no channels e.g. nasendoscopes, single-channel endoscopes, e.g. bronchoscopes, to the more complex multi-channelled endoscopes. e.g. colonoscopies, duodenoscopes. These usually require chemical disinfection (or low temperature disinfection).

Figure 21. **Example of a flexible endoscope**



Figure 22. **Example of an endoscope with the manufacturer's stamp to certify that it can be autoclaved**



Type of procedure

An increasing number of investigative and therapeutic procedures are carried out using an endoscope. Table 13 illustrates the type of procedures that are considered using an endoscope and the recommended method of disinfection.

Table 12. Types of endoscopic procedures

Types of endoscopes	Rigid endoscope example	Flexible endoscope example	Level of decontamination
Invasive – passed into normally sterile body cavities or introduced into the body through a break in the skin or mucous membrane	Arthroscope Laparoscope Cystoscope	Nephroscope Angioscope Choledochoscope	Sterilization by steam or a low temperature method e.g. gas plasma
Non-invasive in contact with intact mucous membrane, but does not enter sterile cavities	Bronchoscope	Gastroscope Colonoscope Bronchoscope	High-level disinfection, e.g. immersion in glutaraldehyde, peracetic acid, chlorine dioxide

FACILITIES FOR DECONTAMINATION

Decontamination of rigid endoscopes is preferable within the SSD as the process controls and validation are already in place. Use of the SSD is not so practical for endoscopes with a rapid turnaround, e.g. gastrointestinal endoscopes, and these are often processed at the point of use. It is important therefore that staff responsible for reprocessing these endoscopes be aware of the need to follow the recommendations for their decontamination.

- Decontamination of flexible endoscopes should take place in a dedicated room away from the patient/clinical room
- There should be adequate ventilation to remove potentially harmful disinfectant vapour
- The room should be equipped with a sink with sufficient capacity to accommodate the largest endoscopes and a dedicated hand wash basin equipped with soap and disposable paper towels
- There should be a flow within the room from dirty to clean to avoid the possibility of recontamination of decontaminated endoscopes from those just used on a patient
- A system should be in place to indicate which endoscopes are ready for patient use. This could be a printout from the automated endoscope reprocessor (AER) or a manual check sheet
- More up-to-date units will have a two-room system with pass-through washer-disinfectors to provide a separation between clean and dirty
- Storage of endoscopes should be in an area that will not allow recontamination of processed endoscopes
- There should be sufficient storage for the consumables used during the decontamination procedure, e.g. PPE, chemicals, cleaning brushes and sufficient capacity for waste disposal

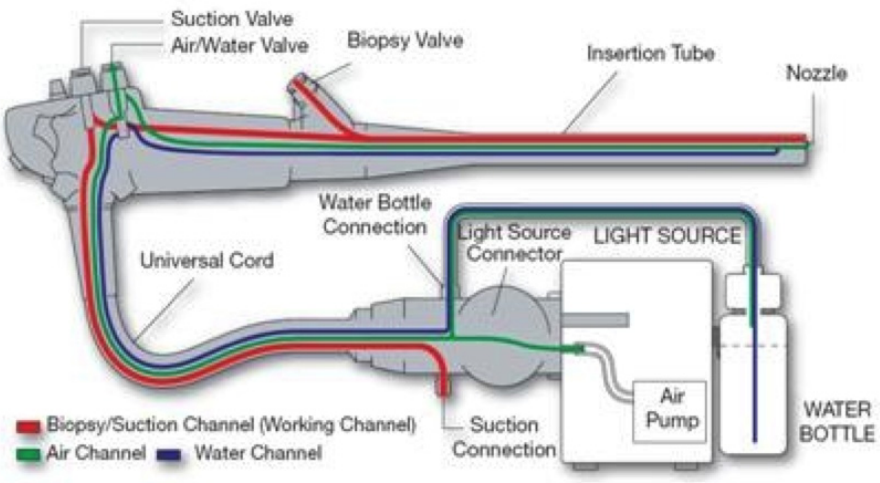
Decontamination of rigid endoscopes

The endoscope and accessories should be fully dismantled and all accessible surfaces cleaned with freshly-prepared detergent. All accessible channels should be brushed with a soft brush. The instruments should then be rinsed and dried before inspection and packaging for sterilization in accordance with local procedures. Automated systems are available to facilitate the cleaning of rigid endoscopes.

Decontamination of flexible endoscopes

A typical channel configuration of a flexible endoscope is shown in Figure 22.

Figure 23. **Anatomy of an endoscope showing channels that require cleaning and penetration of disinfectants**



Source: Courtesy of Olympus KeyMed, United Kingdom

An assurance of access to all channels during the cleaning, disinfection and rinse stages of the decontamination procedure is essential. Endoscopes used for endoscopic retrograde cholangiopancreatography (ERCP) have a raiser bridge channel, which is very narrow and a dedicated adaptor is required to flush this channel. For all stages of the decontamination procedure, the manufacturer's instructions should be followed. The procedure should ideally take place in a dedicated room separate from the clinical area. Table 14 illustrates the stages of reprocessing for flexible endoscopes.

Table 13. **Stages of reprocessing for flexible endoscopes**

Stage	Why
Bedside procedure (pre-clean)	To remove readily detachable organic matter. This will help to reduce the possibility of drying and causing channel blockages, especially if there is a delay before manual cleaning takes place
Leak test	To ensure the integrity of the endoscope. Any damage to the outer surface could allow body fluids or chemicals into the internal workings of the endoscope
Manual clean	Brushing of accessible channels and flushing of all channels to remove organic matter. This stage will also allow the detection of channel blockages
Rinsing	To remove detergent residues that may affect the performance of the disinfectant
Drying	To expel excess fluid that may dilute the disinfectant
Disinfection	To eradicate potentially pathogenic microorganisms, i.e. bacteria, including mycobacteria and viruses
Rinsing	To remove disinfectant residues that could cause a harmful effect to the patient
Drying	To expel excess fluid before use on the patient or storage

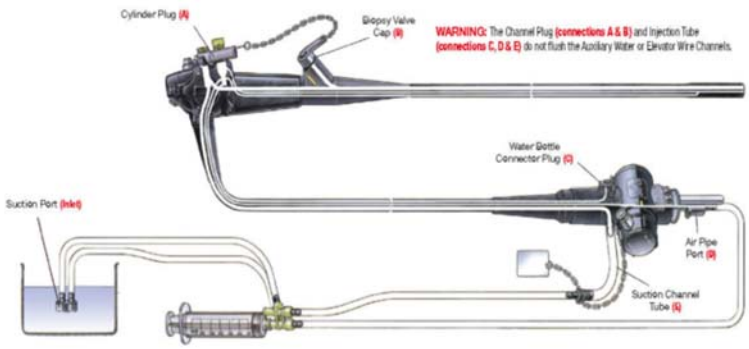
Bedside procedure (pre-clean)

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

Leak test

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

Figure 24. **Example of an irrigation device**

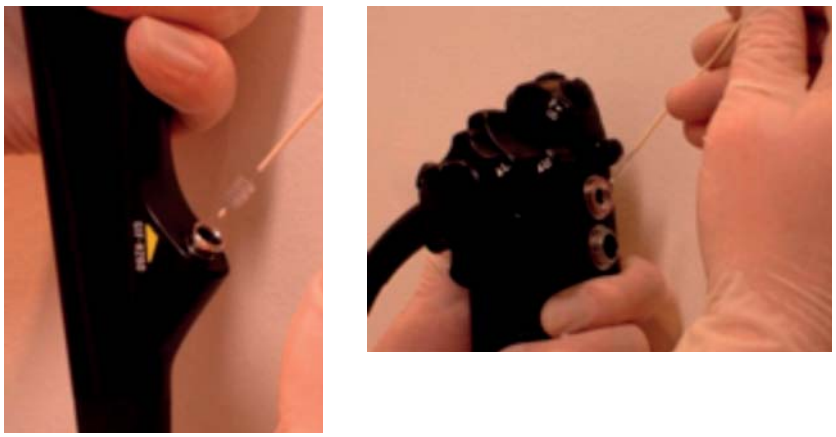


This irrigation device is used for all stages of the decontamination procedure where flushing of the channels is required (Figure 24).

Manual cleaning

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

Figure 25. **Example of an irrigation device**



Rinsing (first)

Freshly drawn potable tap water[29] must be used to remove detergent residues.

Disinfection

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

29 WHO guidelines for drinking water quality, 4th ed. Geneva, World Health Organization, 2011.

Rinsing (second)

This stage is essential to remove disinfectant residues, which could be harmful to the patient if not removed. One of the major causes of post-endoscopic infection or pseudo-infection is due to recontamination during the final rinse. Infections with *Pseudomonas* species and atypical mycobacteria have been reported. The higher risk procedures where recontamination may be an issue are cystoscopy, bronchoscopy and ERCP. The use of filtered (0.22 µm) or sterile water is recommended for these endoscopes. To avoid the build-up of disinfectant residues, this rinse water should be discarded after each use.

Drying

Flushing air down the channels will remove excess fluid, but will not completely dry the channels. This is desirable before storage and may be achieved with medical grade air or flushing the channels with 70% alcohol followed by air. This process is not recommended in countries where prion disease may be an issue due to the fixative properties of alcohol. A "3-hour" rule is observed in many countries in that endoscopes have to be used within three hours of processing as this is the window in which microorganisms present in the final rinse water may multiply to numbers that potentially may initiate infection. The use of 70% alcohol to flush all channels reduces this risk and is recommended prior to storage. This practice is not recommended in the United Kingdom due to the fixative properties of alcohol and the potential for transmission of prion-related disease.

Endoscope storage

Flexible endoscopes should be stored, preferably hung, to allow drainage of channels in a dust-free environment. Lockable storage cabinets are available. Some are described as drying cabinets as they feed filtered air down the channels to allow for prolonged storage, i.e. up to 30 days.

Automated endoscope processors (AER)

These are now becoming more widely available and will provide a standardised and reproducible decontamination procedure, while protecting staff from exposure to chemical disinfectants. Some AERs have fume extraction to remove disinfectant vapour. The use of an AER does not remove the need for the leak test or the bedside and manual clean. The AER should comply with ISO EN 15883 parts 1[30] and 4[31] or a national regulation. These standards describe the design of an AER and also the tests that should be carried out to validate and verify its efficacy. It is important that these tests are carried out at the time of installation (PQ) to establish the performance of the machine and to provide a baseline for comparison when periodic tests are performed. Water may remain within the washer, which may become a source of contamination and lead to the formation of a biofilm, particularly with *Pseudomonas spp.* Therefore, a daily machine disinfection cycle is recommended.

Accessories

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

30 EN ISO 15883-1: 2006 Washer-disinfectors – Part 1: General requirements, definitions and tests.

31 EN ISO 15883-4: 2008 Washer-disinfectors – Part 4: Requirements and test for washer disinfectors employing chemical disinfection for thermolabile endoscopes

Example of an audit tool for endoscope decontamination

	Question	Yes	No	N/A	Comment
Pre-clean procedure					
1	Are all channels flushed and external surfaces wiped with a detergent solution immediately after removal of the endoscope from the patient?				
Manual cleaning					
2	Are all valves and detachable parts removed before cleaning?				
3	Does manual cleaning take place in a dedicated sink?				
4	Is a leak test carried out before manual cleaning is undertaken?				
5	Are staff aware of the action to be taken if a leak is detected?				
6	Is the detergent solution accurately prepared in accordance with the manufacturer's instructions?				
7	Are all accessible ports and channels brushed with a suitable brush during cleaning?				
8	Are all accessible channels flushed and external surfaces wiped with detergent?				
9	Are all internal channels and external surfaces rinsed with water?				
10	Is there evidence that checks are made to ensure that the endoscope is visibly clean after manual cleaning?				
Disinfection					
11	If the disinfectant is reusable, is the minimum effective concentration tested and recorded?				
12	If the disinfectant is single use, is it accurately prepared and discarded after each use?				
13	Are all channels and external surfaces exposed to the disinfectant for the manufacturer's recommended contact time?				
Rinsing					
14	Are all channels and external surfaces of the endoscope rinsed with water of adequate quality?				
Use of an AER					
15	If an AER is used, are checks made to ensure the flow of fluid down all channels?				
16	If an AER is used, is the water tested to guarantee microbial safety to ensure that the quality of water is adequate?				
Storage					
17	Are endoscopes stored in an area that will protect them from contamination and/or damage?				
Health and safety					
18	Is appropriate PPE worn throughout the decontamination process?				
19	Is the disinfectant stored in a manner that will reduce the risk of vapour being released into the work environment?				

Sterilization of reusable medical devices

Sterilization is the elimination of all disease-producing microorganisms, including bacterial spores (e.g. *Clostridium* and *Bacillus* species). Prions are not susceptible to routine sterilization.

Sterilization is used on critical medical devices and, whenever possible, semi-critical medical devices.

The preferred method for sterilization of heat-resistant critical devices is steam/moist heat sterilization (pre-vacuum sterilization is preferred).

Most medical and surgical devices used in health-care facilities are made of materials that are heat stable and therefore undergo heat, primarily steam, sterilization.

For heat-sensitive devices that cannot withstand steam sterilization, some examples of chemical sterilants available are:
a) ETO gas
b) Hydrogen peroxide gas
c) Hydrogen peroxide gas plasma
d) Formaldehyde gas
e) Ozone
f) Dry heat

Choosing the correct sterilization process is important so as not to cause damage to the item or compromise sterility. Sterilization and the provision of a sterile device for a patient procedure is dependent on the whole cycle of decontamination, including cleaning, packaging, sterilization, storage/transport, and even to the point of preparing and using the device on a patient.

If you cannot clean a device, you cannot sterilize it.

STERILIZATION PROCESS

Risk assessment as discussed in Section 1 applies here. In summary:

- Medical devices that have contact with sterile body tissues or fluids are considered critical items. All critical medical devices shall be cleaned and then sterilized because microbial contamination could result in disease transmission
- Critical items (i.e. those that will enter a sterile body cavity) include, but are not limited to, surgical instruments, implants, foot care equipment, endoscopes that enter sterile cavities and spaces, colposcopy equipment, biopsy forceps and brushes, eye and dental instruments
- Whenever possible, semi-critical medical devices should be sterilized. (Semi-critical medical devices are in contact with non-intact skin or mucous membranes, but do not penetrate them.)

Device compatibility

For a medical device to be deemed compatible with a particular sterilization method, it must be able to be effectively sterilized and at the same time remain functional following sterilization.

Among other considerations, the ability of the sterilization system to effectively sterilize the medical device will depend on component materials and device design, as well as the level of bioburden (cleanliness) prior to sterilization.

Functionality is the ability of a medical device to withstand the sterilization process and to remain within operating specifications. The device manufacturer will test its functionality after processing through repeated sterilization cycles.

STEAM STERILIZATION

Steam sterilization is a process that uses saturated steam under pressure as the sterilant. It is the preferred method for sterilizing critical medical devices. The removal of air is essential to ensure an efficient sterilization process – sterilization cannot occur in the presence of air.

Types of steam sterilizers

There are several types of steam sterilizers that utilize different methods to remove air from packages and the chamber, such as dynamic air removal (e.g. prevacuum) and steam-flush pressure-pulse sterilizers, or passive air removal (e.g. gravity).

Prevacuum sterilizers

- Use a vacuum pump or water ejector to remove air from the chamber and packaged devices during the preconditioning phase and prior to sterilization.
- Operate at 132°C to 135°C

Steam-flush pressure-pulse

- Use a repeated sequence of a steam flush and pressure pulse to remove air from the chamber and packaged items
- Operate at 121°C to 123°C, 132°C to 135°C, or 141°C to 144°C

Gravity sterilizers

- Gravity is used to displace the air from the sterilizer chamber and packaged devices
- Operate at 121°C or higher

Steam sterilizers vary in chamber size from small table top models to large floor-loading models. The recommended practices described in this document apply to all types and sizes of steam sterilizers, including table top sterilizers.

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

Steam sterilization methods

The following types of loads/cycles have been developed and tested by steam sterilization manufacturers:

- Wrapped devices (non-porous cycles)
- Textile packs (porous cycles). Porous refers to the ability to trap air/liquid within the lumen, channel or hollow devices (e.g. dental hand pieces and rigid scopes may require special cycle conditions, depending on the length and diameter of the lumen)
- Utensils and glassware
- Combination of porous and non-porous loads
- Liquids and solutions
- Immediate use steam sterilization (IUSS)

Porous and non-porous cycles/loads

- Steam sterilization is achieved via direct contact of the steam with all surfaces of the medical device(s)
- Direct contact can only be achieved after all air has been removed from the devices, the packages and the chamber
- Non-porous items, such as stainless steel forceps, needle holders, scissors, and retractors, do not trap air and thus allow surface contact to be readily achieved
- Porous items, such as textiles, wrappers, paper, rubber or plastic items, items with lumens or with sliding parts that can trap air/liquid and/or present a challenge to surface contact by the sterilant, require longer exposure times to ensure adequate steam penetration. Porous loads are often a challenge to sterilize by steam
- Longer cycle times for porous items are particularly important for sterilizers that rely on gravity displacement to remove air
- In all instances, users must follow, monitor and record the sterilization time and temperature requirements specified by the manufacturer when sterilizing non-porous and porous medical devices

Monitoring of the sterilization cycle

Monitoring of each sterilization machine and every cycle is essential to ensure sterility of the reprocessed medical devices. The available means of monitoring are as follows:

- Physical (notebook, displays and printout)
- Chemical (internal and external indicators)
- Biological

If the sterilizer does not have a conjugated printer, the operator should control the physical parameters of sterilization process. See Table 15 for an example of a log to record each cycle.

Table 14. **Manual control of physical parameters for steam sterilization**

Date	Autoclave number	Load number	Start cycle	Start sterilization time	End of sterilization time	End cycle time	Signature

Chemical indicators for sterilization

ISO 11140 classifies chemical indicators into six groups, according to their intended use. They are further subdivided within each of these classifications by the sterilization process for which they are designed to be used. The classification structure is solely to describe the characteristics and intended use of each type of indicator and has no hierarchical significance.

Table 15. Chemical indicator types

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

Loading

Steam sterilizers shall be loaded in the following manner to ensure sterilant contact and penetration:

- Package placement to avoid overloading
- Non-perforated tray and container placed on their edge
- Packages away from chamber walls
- Concave devices on an angle to avoid condensate pooling
- Textile packs perpendicular to the sterilizer cart shelf
- Steri-peel on its edge with multiple packages being placed paper to plastic
- Rigid containers shall not be stacked unless validated by the manufacturer for that configuration

The operator responsible for loading and initiating the cycle should be documented.

Unloading

Upon completion of the cycle, the operator responsible for unloading the sterilizer must

- Review the sterilizer printout for the following:
- Correct sterilization parameters
- Cycle time and date
- Verify that the cycle number matches the lot control label for the load
- Verify and initial that the correct cycle parameters have been met
- Examine the load items for:
- Any visible signs of moisture
- Any signs of compromised packaging integrity

Printed records of each cycle parameters (i.e. temperature, time) shall be retained in accordance with the health-care setting's requirements.

Load cool-down

Upon removal of the sterilized load, the operator should:

- Visually verify the results of the external chemical indicators
- Allow the load to cool to room temperature. The amount of time for cooling depends on the devices that have been sterilized
- Ensure that cool-down occurs in a traffic-free area without strong warm or cool air currents

Troubleshooting – wet pack problems

Packages are considered wet when moisture in the form of dampness, droplets or puddles are found on or within a package. There are two types of wet packs; those with external wetness and those with internal wetness. When wet packs are found, sterility is considered to be compromised and the package contents contaminated. There are several causes of wet packs.[32]

IMMEDIATE USE SYSTEM STERILIZATION (IUSS) / "FLASH" STERILIZATION

What is IUSS?

IUSS or "flash" sterilization is a common term that describes the practice of fast sterilization of non-porous and/or non-cannulated surgical instruments in an unwrapped condition in downward displacement steam instrument sterilizers located close to the point where the instruments will be used immediately. In the past, IUSS was the predominant way of providing sterile instruments for surgery.

Special high-speed sterilizers are usually located in the operating room in order to process unwrapped instruments and instruments for extremely urgent use. For example, the only available hand piece is dropped on the floor in the middle of the procedure and this single instrument needs to be sterilized in a hurry. These sterilizers operate at 134°C for 3-10 minutes. IUSS delivers the instruments wet and very hot into the operating room environment.

> **This sterilization method should be avoided as the material is sterilized *without packaging* and the cycle eliminates *drying*. As a result, the possibility of recontamination of the material increases.**

Indications for the use of IUSS

If a IUSS sterilizer must be used, it should be used only after all of the following conditions have been met:

- Work practices should ensure proper cleaning, inspection, and arrangement of instruments before sterilization
- Physical layout of the area ensures direct delivery of sterilized items to the point of use
- Procedures are developed, followed and audited to ensure aseptic handling and staff safety during transfer of the sterilized items from the sterilizer to the point of use
- Items are needed for use immediately following IUSS and as soon as the device cools so as not to burn the patient

IUSS versus pre-pack

The alternative approach to IUSS is to provide instruments in a wrapped, dry and cool condition (temperature depending on the time since steam sterilization). This is possible when there is a sufficient inventory of instruments and equipment to allow for a "turnaround" time for reprocessing (such as pre-vacuum sterilizers with fast cycles) in a well-appointed and staffed SSD. In smaller surgical facilities, SSD activities often occur in the operating room area. However, this represents a compromise of several desirable standards of control of particulate and microbial contamination in the area where sterile packs are being produced.

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32 Centre for healthcare related infection surveillance and prevention. Queensland Health Infection Control Guidelines, 2006. https://www.health.qld.gov.au/chrisp/sterilising/section_appendix.pdf Accessed 20th August 2015

There is now a strong movement towards the routine preparation of sterile instruments in a wrapped, dry and cool condition for use in the operating room for the following reasons:

- Immediate advantages to case-by-case organization of sterile instruments by operating theatre staff
- The typical operating theatre is not designed or equipped to clean instruments as reliably and consistently as a properly appointed SSD and there are concerns regarding the adequacy of cleaning and drying of instruments in the operating theatre prior to using IUSS processing
- Sterility of sets of instruments can be uncertain following the use of sterilizers designed and intended only for single dropped instruments; they should not be used for routine sterilization of instrument sets
- The sterilizer may not be located in an area immediately adjacent to the operating theatre; thus, the delivery of IUSS-sterilized devices to their point of use compromises their sterility
- Patient injury has occurred from IUSS-sterilized items, including full thickness burns resulting in permanent scars, *P. aeruginosa* meningitis from IUSS-sterilized implantable devices and surgical site infection.

A compromise is the commercially-available method of delivery of IUSS-sterilized devices in an enclosed container with valves that automatically close at the end of steam sterilization (FLASH-PAK™)[33]. Manufacturer's recommendations should be observed in relation to the minimum temperature exposure time. Inspection and maintenance of such systems should be carried out on a regular basis as recommended by the manufacturer.

IUSS recommendations

- Restrict use to emergencies, such as unexpected surgery, or dropped instruments
- In most emergency situations, the risk/benefit ratio is low enough to justify the use of IUSS- sterilized objects
- In non-emergency situations, the risk/benefit ratio is higher, particularly when implantable devices are involved
- IUSS sterilizers must never be used for implants, suction tubing or cannulars or any other product not specifically validated for the IUSS process.

Minimizing IUSS sterilization

The following points should be considered for action to minimize routine IUSS sterilization:

- Increase the available inventory of certain instruments, particularly rigid endoscopes
- Replace older devices with newer ones designed for steam sterilization
- Provide more instrument sets in wrapped form, focusing on the advantages this provides both during surgery and for the management of the operating theatre
- Ensure the appropriate design of the SSD or sterile processing area to optimize the production and timely delivery of wrapped instrument packs
- Manage operating theatre case lists in a way that optimizes use of the available instruments in association with their sterile processing requirements

TABLE TOP STERILIZERS

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

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

Ensure that items or packs removed from the sterilizer are visibly dry as moisture will wick contaminants into the package contents. Unwrapped items are vulnerable to contamination.

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33 A guide for selecting cleaning agents can be found in AS/NZS 4187:2003 .Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.http://www.saiglobal.com/pdftemp/previews/osh/as/as4000/4100/4187.pdf. (Accessed 20th August 2015.)

Figure 26. **Examples of table top sterilizers**



The widespread use of tabletop sterilizers outside primary health or dental clinics is discouraged.

These "pot-style" sterilizers look and operate just like a pressure cooker. Distilled or deionized water is poured into the bottom to the required level. Clean, unwrapped instruments are placed in the basket, lowered into the sterilizer and placed on a support that keeps the basket above the water reservoir. The sterilizer is then sealed and turned on.

As with other types of tabletop sterilizers, the water is boiled into steam, forcing out air until the sterilizer valve closes. Pressure is increased until the desired temperature and pressure are achieved (Figure 25). This process usually takes less than 5 minutes. The complete sterilizer cycle lasts approximately 16 minutes, with an additional 10 minutes for the pressure to drop to normal, after which the lid can be opened.

TABLETOP STERILIZERS WITH A CASSETTE CHAMBER

Some steam sterilizers have a reusable cassette that is, in effect, the chamber (Figure 26). The cassette is a metal container that may vary in size, depending on the size of the sterilizer. It consists of a tray, lid and some form of gasket to seal the unit. In the base of the cassette, there are two apertures that allow for the movement of steam and air through the cassette; one is an inlet and the other is an exit. Always make sure that these openings are clean and free from obstruction.

A quantity of instruments (which may be wrapped if desired) is placed in the cassette, which is then closed and put into the sterilizer. Wrapped instruments take about 14 minutes to be sterilized and dried; unwrapped instruments will take less time.

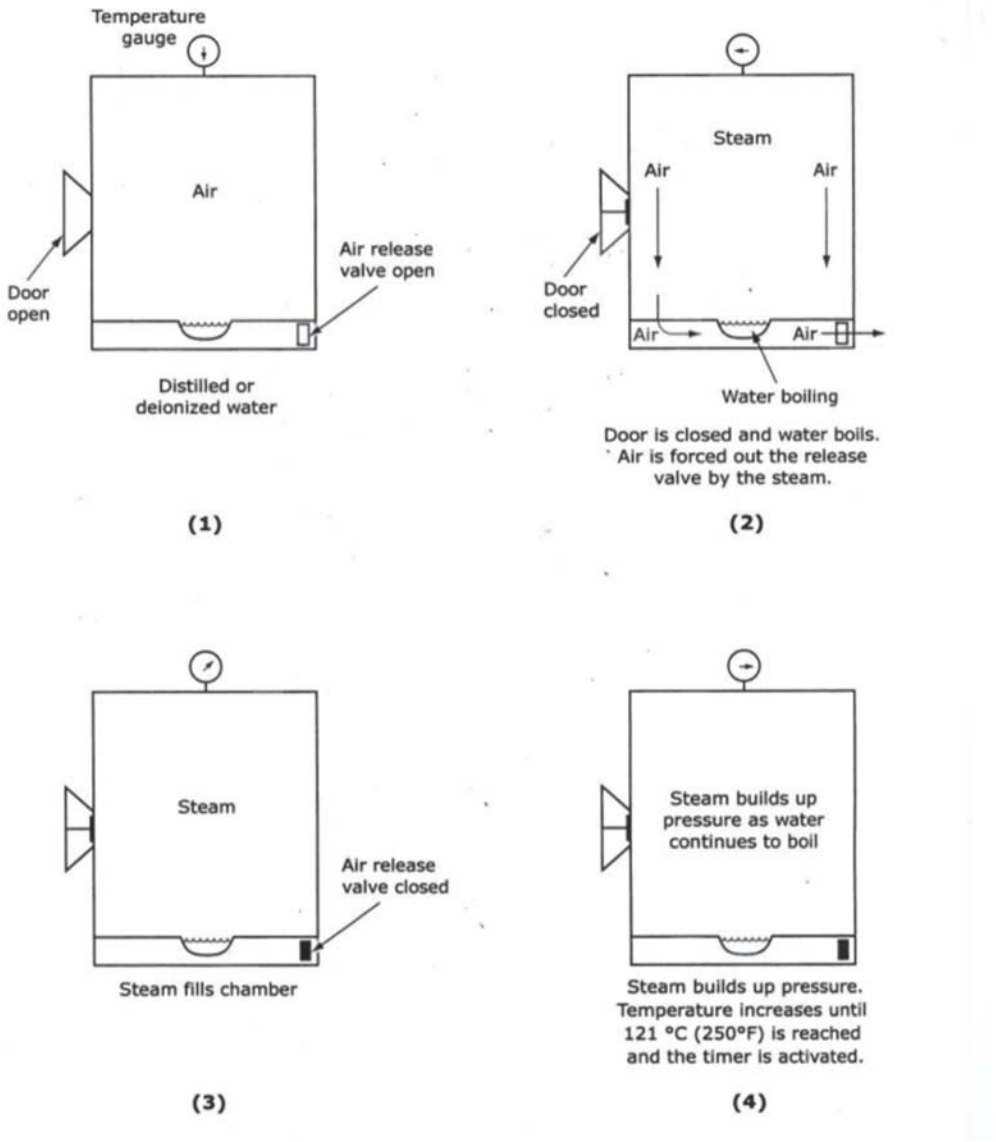
A drying cycle is an optional feature and, therefore, devices come out wet after being processed and are not acceptable for use on a patient. Be aware that unwrapped instruments will not remain sterile once they have been removed from the sterilizer. The instruments must be handled carefully to minimize contamination.

As with all equipment, follow the manufacturer's instructions for use, e.g. certain devices could be sensitive to contaminants in the water, hence the manufacturer's recommendation to use only distilled water in the reservoir.

Figure 27. **Example of a cassette-type, table top steam sterilizer**



Figure 28. Example ofthe operation of a table top sterilizer



Loading a tabletop sterilizer

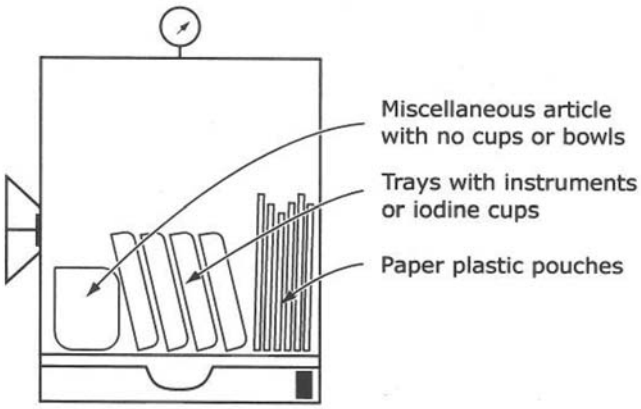
During sterilization, the steam must circulate freely around each pack and have the unrestricted ability to penetrate into and exit from each pack. Paper/plastic packages, linen packs, and any packs with a solid bottom must be placed on their sides. This will ensure air removal, contact with steam and allow any condensation to be drained (Figure 28).

When placed side-by-side, paper/plastic packages must be placed with the plastic side facing the paper side of the next package. Air and steam only pass through the paper side of a paper/plastic package.

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

If the user intends to sterilize other products, apart from a hard-surfaced device, e.g. a liquid, the manufacturer should be contacted to confirm if the sterilizer supports this use, and if so, how to do it. Normal cycles and techniques cannot be used for this application.

Figure 29. Loading a table top sterilizer



Unloading a table top sterilizer

Do not handle sterile packages until they are cool. When touched, hot packages act as wicks for moisture, which destroys the barrier quality of the package. The microorganisms from your hands could then easily contaminate the package. Check the available indicators to make sure that the essential requirements for sterilization have been achieved. Carefully inspect the packs for wetness; if wet, the package must be reprocessed. Warm packs must not be placed on cool surfaces (e.g. metal counters) or near drafts (e.g. air vents). This will cause condensation to form that could contaminate the contents. Any sterilized item that becomes wet or is dropped, torn, compressed or otherwise mishandled should be considered contaminated and must be reprocessed.

CHEMICAL (LOW TEMPERATURE) STERILIZATION METHODS

Chemical gas (low temperature) sterilization is used to sterilize heat- and moisture-sensitive medical devices. Written policies and procedures for chemical sterilization should include:

- Staff qualification, education/training and competency assessment
- Preparation and packaging of medical devices
- Sterilizer operating procedures
- Monitoring and documenting of chemical or cycle parameters
- Workplace health and safety protocols specific to the chemical sterilant
- Handling, storage and disposal of the sterilant. Consult sterilant manufacturer's instructions for use and local regulations

Sterilization with gaseous chemical methods should be carried out in chambers with automated cycles that provide safety for the user and guarantee the processes.

Device compatibility will vary with each low temperature sterilization method. The user should obtain written functional compatibility information from the device manufacturer and sterilizer efficacy information from the sterilizer manufacturer. Low temperature (gas) sterilization can be achieved using a number of different chemicals including:

- ETO
- Hydrogen peroxide gas/plasma
- Ozone
- Low temperature steam formaldehyde
- Chemical disinfection (not recommended)

Ethylene oxide (ETO)

ETO is a colourless gas that is flammable and explosive. The use of ETO evolved when few alternatives existed for sterilizing heat- and moisture-sensitive medical devices. The four essential parameters (operational ranges) are: gas concentration; temperature; relative humidity; and exposure time. These influence the effectiveness of ETO sterilization. Within certain limitations, an increase in gas concentration and temperature may shorten the time necessary for achieving sterilization.

- ETO is absorbed by many materials. For this reason, items must be thoroughly aerated prior to handling or use following sterilization, according to the device manufacturer's recommendations.
- The aeration cycle **must not** to be interrupted for any reason. Do not open the chamber to retrieve devices for use.
- Similar to all sterilization processes, the effectiveness of ETO sterilization can be altered by lumen length, lumen diameter, inorganic salts and organic materials.

Hydrogen peroxide gas (plasma)

Depending on the concentration and contact time, peroxide gas is considered an effective antimicrobial, including rapid bactericidal, fungicidal, virucidal and sporicidal activity. The gas is safe for use on most device and material types, including electrical components and electronics. Hydrogen peroxide gas sterilization activity is primarily dependent on the gas concentration, exposure time, as well as the process temperature. Materials and devices that cannot tolerate high temperatures and humidity, such as some plastics, electrical devices, and corrosion-susceptible metal alloys, can be sterilized by hydrogen peroxide gas.

Ozone only or hydrogen peroxide and ozone gas

Ozone is a potent antimicrobial chemical and requires high levels of humidity.

The sterilizer creates its own sterilant internally from United States Pharmacopoeia (USP) grade oxygen, steam-quality water and electricity. The sterilant is converted back to oxygen and water vapour at the end of the cycle by passing through a catalyst before being exhausted into the room. Duration of the sterilization cycle is approximately 4 hours 15 minutes. The ozone process is compatible with a wide range of commonly-used materials, including stainless steel, titanium, anodized aluminium, ceramic, glass, silica, PVC, teflon, silicone, polypropylene, polyethylene and acrylic.

This process is safe for use by the operator as there is no handling of the sterilant, no toxic emissions, no residue to aerate, and a low operating temperature means that there is no danger of an accidental burn. There are some limitations on material compatibility (e.g. aluminium, brass and polyurethane), as well as not being able to be used to sterilize liquids, textiles and cellulose-based materials (including paper packaging systems).

The hydrogen peroxide and ozone gas combination versus only ozone has the benefit of a shorter cycle time and greater lumen penetration capability.

Formaldehyde gas or low temperature steam formaldehyde

Formaldehyde gas is considered to be biodegradable over approximately two hours in the environment. However, it is known to be a toxic, irritating and allergenic chemical; it is also referenced as a suspected carcinogen. Low temperature steam formaldehyde is indicated for all materials used for hemodialysis.

Liquid chemical sterilization

- Not recommended
- Mostly used as a high-level disinfectant
- Rarely used as a sterilant
- Processes are difficult to control, have a high probability of recontamination during rinsing or drying and do not allow later storage
- Automated equipment increases the safety of the sterilization process. However, this equipment requires controls and operators who are well-trained in its use and management

Disadvantages

- Cannot be used for moisture-sensitive or non-immersible items
- Thorough rinsing is challenging
- Takes a long time to achieve sterilization
- Must be used immediately and cannot be stored.

Table 17. **Sterilization options *currently* available: indications for use, monitoring requirements, advantages and disadvantages**

Manufacturers' recommendations for product concentration and exposure time must be followed

PROCESS OPTION	CONTACT AND/ OR CYCLE TIME	COMMENTS
STERILIZATION		
Steam • Pre-vacuum sterilizers • Gravity displacement sterilizers • Small tabletop sterilizers	Cycle times will vary (3 to 18 minutes) depending on the sterilization temperature (121°C-135°C)	**Preferred method of sterilization** **Indications** • For critical devices and some semi-critical devices that will not be damaged by moisture or heat i.e., stainless steel instruments, stainless steel ware, e.g.,bowls, basins, trays **Monitoring** • Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) • All loads containing an implantable device shall be monitored with an additional biological indicator and should be quarantined until the results of that biological indicator testing are available • Additional monitoring of pre-vacuum sterilizers shall include a dynamic air removal test (daily) **Advantages** • Inexpensive • Fast • Effective, with a wide margin of safety • Penetrates medical packing, device lumens • Non-toxic – low environmental impact • Readily available • Sterilizers are available in many sizes for many applications • Cycle easy to control and monitor **Disadvantages** • Unsuitable for anhydrous materials (e.g. oils, powders), wood, and for heat- and moisture-sensitive materials • Some table top sterilizers lack a drying cycle and/or printers (for physical monitoring of each cycle) • May leave instruments wet, causing them to rust • Safe use of steam sterilizers requires a sound knowledge of their requirements. Not all settings have this expertise • Chrome stainless steel surgical blades and other related devices have developed pitting and dulling of the cutting edges after multiple sterilization cycles • Deleterious for heat-sensitive instruments • Microsurgical instruments damaged by repeated exposure • Potential for burns

PROCESS OPTION	CONTACT AND/ OR CYCLE TIME	COMMENTS
STERILIZATION		
IUSS (also known as "flash" sterilization)	Cycle times will vary depending on the sterilization temperature and the device containment system used (e.g. tray, container or wrapper)	**Not best practice for sterilization of medical devices** **Indications** • For emergency sterilization of critical devices that are heat- and moisture- tolerant • Not to be used for implantable devices or complete sets or trays of instruments • Any trays or wrappers that are used for IUSS sterilization must be validated for that purpose **Monitoring** • Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) • Biological indicator testing should include each type of cycle and load configuration (e.g. open tray, enclosed container, single wrapper) to be used that day. • Cycles shall be documented in such a way that the IUSSed device can be linked to the patient on which it was used should there be an adverse sterilization event. e.g. failed biological indicator **Advantages** • Fast **Disadvantages** • Devices cannot be stored because they are still wet on cycle completion • Requirement to follow all of the steps of safe sterilization practice (e.g., decontamination, sterilizer monitoring and maintenance, aseptic transfer to the sterile field) may be onerous or impossible to achieve in some settings.
Hydrogen peroxide vapour and gas (may also include plasma)	Cycle time and temperature will vary, depending on the brand and model of sterilizer Current times range from 28-70 minutes. Cycle temperatures are less than 60°C	**Indications** • For critical devices and some semi-critical devices that will be damaged by moisture or heat **Monitoring** • Sterilization should be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) **Advantages** • Fast compared to ETO. Some cycles are faster than steam sterilization (approximately 28-75 minutes) • Safe for the environment (water and oxygen end products) • Compatible with many medical devices (e.g., heat- and moisture-sensitive) • Absence of toxic waste • Easy installation and operation • Effective against a wide range of organisms • No staff monitoring currently required • No aeration required • No chemical residues

PROCESS OPTION	CONTACT AND/ OR CYCLE TIME	COMMENTS
STERILIZATION		
		Disadvantages • May be incompatible with some devices. Compatibility must be confirmed with both sterilizer and device manufacturers • Cannot sterilize materials that absorb hydrogen peroxide (e.g. linen, gauze, cellulose/paper, wood) • Low penetration power • Wraps and trays must be validated for hydrogen peroxide sterilization (e.g. polypropylene wrappers, Tyvek-backed peel pouches). • Medical devices must be dry before processing • Cellulose (paper), linens and liquids cannot be processed • Limitations to length of lumens of medical devices that can be effectively sterilized – Certain models of sterilizers require "boosters" of hydrogen peroxide to sterilizer lumens.
ETO gas	Combined sterilization and aeration (required) times commonly total approx 15 hours	**Indications** • For critical devices and some semi-critical devices that will be damaged by moisture and/or heat. e.g. electronic instrumentation **Monitoring** • Sterilization shall be monitored with biological indicators (each load), chemical indicators (each package) and physical indicators (each cycle) • A biological indicator with a 4-hour read-out time is available **Advantages** • Non-corrosive • Penetrates packaging materials, device lumens • Has some ability to penetrate some synthetic materials • Excellent material compatibility • Effective on a wide variety of microorganisms • Single-dose cartridge and negative-pressure chamber minimizes the potential for gas leak and ETO exposure • Simple to operate and monitor **Disadvantages** • Toxic/carcinogenic to humans • Lengthy cycle due to aeration requirements • Requires monitoring of the work areas • Requires control and monitoring of discharge into the environment • Flammable and explosive. Can be highly reactive with other chemicals • Expensive compared to steam • Incompatible with some materials, e.g. silicone • Requires packaging materials that are permeable to ETO • High-cost method

PROCESS OPTION	CONTACT AND/ OR CYCLE TIME	COMMENTS
STERILIZATION		
Ozone		**Not often available or used globally** <u>Indications</u> • For critical devices and some semi-critical devices that will be damaged by moisture or heat <u>Monitoring</u> • Sterilization should be monitored with biological indicators at least daily), chemical indicators (each package) and physical indicators (each cycle) <u>Advantages</u> • Fast compared to ETO • Safe for the environment (oxygen end products) • Compatible with certain medical devices <u>Disadvantages</u> • May be incompatible with some devices. Compatibility must be confirmed with both sterilizer and device manufacturers • Some material restrictions • Wraps and trays must be validated for ozone sterilization (e.g. polypropylene wrappers, Tyvek-backed peel pouches). • Limitations to length of lumens of medical devices that can be effectively sterilized
Formaldehyde gas or low temperature steam formaldehyde	Concentration and temperature: 8-16 mg/L is generated at an operating temperature of 70-75°C	<u>Monitoring</u> • Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) <u>Advantages</u> • Fast compared to ETO. • Cost per cycle relatively low • Compatible with certain medical devices • Absence of toxic waste • Easy installation • Wide biocidal spectrum (e.g. viruses, fungi, tuberculosis bacilli, etc.) <u>Disadvantages</u> • Known to be a toxic, irritating and allergenic chemical • Suspected carcinogen and mutagenic • Tight environmental controls are recommended for safe use - not to exceed 0.75 ppm (8 hours) or 2 ppm (15 minutes) • Incompatible with moisture-sensitive materials • Papers and woven cloths not compatible

PROCESS OPTION	CONTACT AND/ OR CYCLE TIME	COMMENTS
STERILIZATION		
Dry heat (Also known as hot air or oven sterilizers) • Gravity convection • Mechanical Convection	Exposure time and temperature vary, depending on the item being sterilized. Typically 170°C x 60 minutes or 150°C x 150 minutes)	**Not recommended as a best practice for the sterilization of medical devices** **Indications** • For critical devices that will be damaged by moisture, pressure and/or vacuum • Rarely used clinically for the sterilization of restricted types of material, such as glassware, oils, powders and instruments that are moisture-sensitive materials/devices **Monitoring** • Sterilization shall be monitored with biological indicators (at least daily), chemical indicators (each package) and physical indicators (each cycle) **Advantages** • Non-corrosive • Reaches internal parts that cannot be disassembled for direct sterilant contact (via heat conduction) • Inexpensive • Effective and safe for sterilization of dental metal instruments and mirrors • Does not dull cutting edges **Disadvantages** • Lengthy cycle due to slow heat conduction process (30 to 180 minutes depending on temperature) • Temperature can be variable especially in gravity convection ovens (141°C to 180°C) • Cooling of the load post-sterilization prior to safe handling is lengthy • High temperatures can damage some materials, i.e. melt or burn • Restrictions on the types of materials/devices that can tolerate dry heat sterilization • Poor penetration • Destroys heat-labile items • Cannot be used to sterilize liquids • Generally unsuitable for hand pieces (dental) • Not recommended
Liquid chemicals (e.g. glutaraldehyde, peracetic acid)		**Not suitable for sterilization – high-level disinfection only** **Advantages** None **Disadvantages** • Difficult to control • A high probability of recontamination during rinsing or drying, does not allow later storage • Requires controls and well-trained staff for its use and management • Cannot be used for moisture-sensitive or non-immersible items • Thorough rinsing is challenging • Takes a long time to achieve sterilization – 12 hours • Must be used immediately – cannot be stored

Sterilization audit

Examples of question for audit

Sterilization of reusable medical devices
Installation, validation and performance (IQ, OQ, PQ) records are documented and maintained according to local health authority policy for documents
Critical devices are sterilized by an approved sterilization process
Unacceptable sterilization methods include boiling, glass bead sterilizers, microwaves and ultraviolet light
Endoscopes and accessories that pass through normally sterile tissues are cleaned and sterilized before each use, e.g. arthroscopes, cystoscopes, laparoscopes
Cleaning always precedes sterilization.
A – Steam sterilization
General (including "flash" [USS] and tabletop sterilizers)
There is a system in place that clearly distinguishes a non-processed item from one that has been processed
Devices being sterilized are validated for the steam process and the cycle selected
Consumables in use are appropriate for the sterilization method to be used, e.g. biological and chemical indicator strips and tape
Consumables are used before the expiry date, e.g. biological and chemical indicator strips and tape
Preparation and packaging
Devices are prepared in a manner that facilitates sterilization and aseptic presentation, e.g. disassembled, stopcocks opened, standard wrapping methods, appropriate sized packaging materials
An internal chemical indicator is placed inside each package
Packaging materials are validated and approved for the selected process
Total weight of an instrument set (including container) to be steam sterilized does not exceed 10 kg
Total weight of a wrapped basin set to be steam sterilized does not exceed 3 kg
Sterilized items are labelled with a load/cycle number, sterilizer number and the date of sterilization
External process indicator is on the outside of each package
Loading, unloading and cooling
Package items are loaded in a manner that facilitates sterilization, e.g. not overcrowded, away from chamber walls, peel pouches on edge
Correct cycle is used for each load, including parameters, i.e. time and temperature
Printout is reviewed and initialled for critical elements on cycle completion, i.e. exposure time, exposure temperature, cycle pressure and cycle number matches the lot control label
Load is examined for visible signs of moisture and/or compromised packaging
Load cools to room temperature before items are handled
Cooling area is traffic-free and without strong air currents (warm or cool)
Steam – monitoring and documentation
General
The contents of each load are documented
The results of all monitoring tests are documented
Physical monitors
The printout is reviewed and signed/initialled for critical elements on cycle completion, e.g. time, temperature, pressure
Cycle number on printout matches the lot control label
A leak test is performed according to the sterilizer manufacturer's instructions for use

Chemical indicators
Bowie-Dick air removal test (high-vacuum sterilizers only) is performed daily
The external process indicator on the outside of each wrapped package is checked when package is unloaded
Biological indicators
Biological indicator test is run each day (minimum) that the sterilizer is used
Each type of cycle to be used is monitored with a biological indicator, e.g. high vacuum, gravity and extended cycles
Biological indicators are used for every load containing implantable medical devices
If the biological indicator is positive, loads are recalled and the positive test is investigated according to facility policy
A “control” test is run according to the biological indicator’s manufacturer's instruction for use, e.g. lot number of control matched the biological indicator test
B –IUSS
General
IUSS sterilization is only used in emergency situations
There is a system in place that clearly distinguishes a non-processed item from one that has been processed
Implantable devices are not IUSS sterilized
If implantable devices are IUSS sterilized for any reason, answer NO
Complete sets are not IUSS sterilized
If IUSS sterilization is done, all criteria are met from Sections 6 (Cleaning) and 10-1 (Steam sterilization), except packaging
IUSS sterilization incidents are reported in the Patient Safety Learning System
IUSS – monitoring and documentation
Each IUSS sterilization cycle is documented with the following information
• Sterilizer identification
• Devices(s) IUSS-sterilized
• Verified and initialled sterilizer printout
• Results of biological and chemical indicators (if applicable, i.e. with implant)
• Note in the patient’s chart describing devices(s) and reason for IUSS sterilizing
• The load documentation (above) is verified and initialled by the individual responsible for releasing the IUSSed items
• Biological and chemical indicators used to monitor the cycle are appropriate for IUSS sterilization
Physical
The physical parameters of each cycle are monitored and results are recorded, i.e. exposure time and temperature
A leak test is performed according to the sterilizer manufacturer's instructions for use (applicable to pre-vacuum sterilizers)
Chemical
Bowie-Dick air removal test (pre-vacuum sterilizers only) is performed daily and documented
An internal chemical indicator is placed inside each tray holding device(s) being sterilized
Biological
Biologic indicator test is run each day (minimum) that the sterilizer is used
Each type of cycle to be used is monitored with a biological indicator, e.g. high vacuum, gravity and extended cycles
Biological indicators are used for every load containing implantable items
If the biological indicator is positive, the positive test is investigated according to the facility recall procedure.
A “control” test is run according to the biological indicator’s manufacturer’s instructions for use, e.g. lot number of control matched the biological indicator test

Chemical (low temperature) sterilization methods

C – Hydrogen peroxide/vapourised hydrogen peroxide

General

There is a system in place that clearly distinguishes a non-processed item from one that has been processed

Devices being sterilized are validated for hydrogen peroxide system sterilization and the cycle selected

Correct cycle (including parameters) is selected, e.g. long cycle for flexible endoscopes

Consumables in use have not passed their expiry date, e.g. biological and chemical indicators, sterilant, tape

The vapourizer plate is changed every 30 days or 145 cycles and change is documented

Preparation and packaging

Devices are cleaned in accordance with Section 6 (Cleaning) and/or Section 9 (Endoscopes)

Devices are prepared in a manner that facilitates sterilization and aseptic presentation, e.g. disassembled, stopcocks opened, standard wrapping methods and appropriate-sized packaging materials

Internal chemical indicator is placed inside each package

Boosters are used when required (e.g. for implants) and applied correctly

Packaging materials and consumables are validated and approved for hydrogen peroxide system sterilization

External chemical indicator is on the outside of each package

Sterilized items are labelled with a load/cycle number, sterilizer number and the date of sterilization

Loading and unloading

Package items are loaded in a manner that facilitates sterilization, e.g. trays are flat, not overcrowded, away from chamber walls, peel pouches on edge, paper to plastic

Correct cycle (long or short) is used for each load

Load is examined for visible signs of moisture and/or compromised packaging

External chemical indicator results are verified

Hydrogen peroxide – monitoring and documentation

General

The contents of each load are documented

The results of all monitoring tests are documented

Biological and chemical indicators (including tape) are appropriate for hydrogen peroxide system sterilization

Physical

The printout is reviewed and initialled for critical elements on cycle completion, i.e. correct cycle, two repetitions of injection, diffusion, and plasma, and the words “cycle complete” at the foot of the printout

Cycle number on printout matches lot control label

Chemical

The external process indicator on the outside of each wrapped package is checked for colour change when the package is unloaded

Biological

Biological indicator test is run each day (at a minimum) that the sterilizer is used

Biological indicators are used for every load containing implantable items

Results of the biological indicator test are documented

If the biological indicator is positive, loads are recalled and the positive test is investigated according to facility policy

A “control” test is run according to the biological indicator’s manufacture’s instruction for use, e.g. lot number of control matched the biological indicator test

D – ETO

General

Devices being sterilized are validated for ETO sterilization

Consumables in use has not passed their expiry date, e.g. biological and chemical indicators, sterilant, tape

Ventilation, monitoring and ETO discharge comply with OH&S and Environment Canada guidelines

There is a system in place that clearly distinguishes a non-processed item from one that has been processed

Preparation and packaging
Devices are cleaned and dried in accordance with Section 6 (Cleaning)
Devices are prepared in a manner that facilitates sterilization and aseptic presentation, e.g., disassembled, stopcocks opened
Internal chemical indicator is placed inside each package
Packaging materials and consumables are validated and approved for use
External chemical indicator is on the outside of each package
Sterilized items are labelled with a load/cycle number, sterilizer number and the date of sterilization
Loading and unloading
Package items are loaded in a manner that facilitates sterilization, e.g. not overcrowded, away from chamber walls, peel pouches on edge
Correct cycle (if applicable) is selected
Load is examined for compromised packaging
External chemical indicator results are verified
ETO – monitoring and documentation
General
The contents of each load are documented
The results of all monitoring tests are documented
Chemical and biological indicators are appropriate for ETO
Physical
The printout is reviewed and initialled for critical elements on cycle completion, e.g. time, temperature and/or pressure
Cycle number on printout matches lot control label
Chemical
External process indicator on the outside of each wrapped package is checked when the package is unloaded
Biological
Biological indicator test is run in each load
Results of the biological indicator BI are documented
If the biological indicator is positive, loads are recalled and the positive test is investigated according to facility policy
A “control” test is run according to the biological indicator’s manufacture’s instruction for use, e.g. lot number of control matched the biological indicator test

Reuse of single-use medical devices

INTRODUCTION

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

Health-care facilities that wish to have their single-use medical devices reprocessed by a licensed reprocessor must ensure that the reprocessor's 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 devices. In order to have critical or semi-critical medical/devices reprocessed by one of these facilities, QA processes must be in place to ensure:

- Good Manufacturing Practice
- Maintenance of device functionality and integrity
- Proof of sterility or high-level disinfection
- Testing for pyrogens
- Tracking and labelling devices
- Recall of improperly reprocessed medical devices
- Reporting of adverse events
- Quality control

When purchasing sharps or devices with sharp components, ensure that these can be safely cleaned and reprocessed. Think carefully before reprocessing single-use devices or components bearing in mind the interests of staff and patient safety.

Users often justify the reprocessing of such devices on the basis of economic and environmental benefits. These perceived benefits are questionable as many of the processes required to ensure that the device is safe and fit for its intended purpose cannot be undertaken by the reprocessor, i.e. the person who undertakes the reprocessing of a medical device. Many single-use devices are reused without an adequate evaluation of the increased risk to patients.

SAFETY ISSUES

- Single-use devices may not be designed to allow thorough decontamination processes
- Reprocessing may alter device characteristics and performance may be compromised
- Single-use devices have not undergone extensive testing validation and testing for reuse
- Single-use device may present a potential for cross-infection through design, e.g. fine bores of tubes
- Some materials can absorb certain chemicals, which can gradually leach from the material over time
- Chemicals may cause corrosion or changes to device materials
- The material may experience stress during reuse and may fail, stretch or break
- Inadequately cleaned equipment can carry bacterial endotoxins, which remain after bacteria are killed

Any person who reprocesses or reuses a device intended by the manufacturer for single use bears full responsibility for its safety and effectiveness and becomes the manufacturer.

SINGLE-PATIENT USE

Some devices are identified as suitable for single-patient use only, e.g. urethral catheters supplied within the community for intermittent use and continence treatment equipment. A medical device may be used for more than one episode on **one patient only** and the device may undergo some form of reprocessing between each use. Advice must be sought from the manufacturer and the infection prevention and control team on appropriate decontamination methods.

Single-use medical devices are usually labelled by the manufacturer with the international symbol shown below (Figure 29).

Figure 30. International symbol for single-use medical devices



DO NOT REUSE.
Synonyms for this are
Single-use or Use only
once.

A reusable device, such as a surgical instrument, is designed to be used many times on different patients, and the manufacturer provides detailed instructions on how it can be safely reprocessed between each patient.

A single-use device is designed by a manufacturer to be used on a single patient only and then discarded. Emphasis is on a "single patient" and a device may be used multiple times on the same patient, depending on its design and manufacturers' instructions.

Much consideration needs to be taken when deciding to reprocess a single-use device. It needs to involve the highest level of administration in the health-care facility, as well as the infection prevention and control team, SSD, and biomedical experts.

RISKS OF REUSE

The health risks of reusing a single-use device depend to a great extent on the type of device and the way it interacts with the patient's body. Single-use devices are often classified as critical, semi-critical and non-critical, according to a set of criteria known as the Spaulding definitions. Under these definitions, critical single-use devices are those that are intended to contact normally sterile tissue or body spaces during use. Semi-critical single-use devices are intended to contact intact mucous membranes and not penetrate normally sterile areas of the body. Non-critical single-use devices are intended to make topical contact and not penetrate intact skin.

Most non-critical devices, such as compression sleeves, can be cleaned and reused with minimal risk. Opened, but unused, sterile instruments can sometimes be re-sterilized, provided that the materials can withstand the sterilization procedure. However, some invasive single-use devices, especially those with long lumens, hinged parts, or crevices between components, are difficult or impossible to clean once body fluids or tissues have entered them. Reusing single-use devices carries the obvious risk of cross-patient infection, but also the increased probability that the device could malfunction due to the adverse effects of reprocessing on materials or delicate components.

GUIDANCE DOCUMENTS ON REPROCESSING OF SINGLE-USE ITEMS

In 1996, Health Canada collaborated with the Canadian Dirty area Association (CHA) to provide guidance to hospitals in making decisions on reuse. The result was a CHA publication partially funded under a contract from Health Canada.[5] This guide has been used in Canadian hospitals and has been distributed in the USA by the Association for the Advancement of Medical Instrumentation. The CHA guideline does not take a position for or against reuse, but rather provides a framework to enable a facility to judge the merits of reuse and to establish the quality systems necessary to ensure that reprocessed single-use devices are safe.

The CHA guideline suggests that a quality system for reprocessing single-use devices should include the following components:

1. A reuse committee including members from the facility with responsibility for administration, risk management, epidemiology, infection prevention and control, biomedical engineering, medical device processing and procurement, medical departments and accounting. The committee should establish policies, ensure that protocols exist for each reprocessed device, and monitor adherence to approved procedures.
2. Written reprocessing procedures for each type of single-use device.
3. Validation of the effectiveness of reprocessing procedures to ensure both sterility and functionality of the device.
4. QA. This includes monitoring of control points and quality indicators, regular sampling and inspection of devices, and a periodic review of external factors that could affect the safety or function of reprocessed devices, such as changes in hospital use practices, changes in the supplier of the device, or changes in the design or materials of the device.

Don't do it, but if you do it, very good reprocessing systems must be in place

Summary of recommendations for reprocessing single use items

- Health-care facilities need to have written policies regarding single-use medical devices
- Critical and semi-critical medical devices labelled as single-use are not reprocessed and reused unless the reprocessing is done by a licensed reprocessor
- In the interests of staff and patient safety, devices that cannot be cleaned safely are not reused, e.g. burrs.
- Reusable devices with small lumens, such as catheters, drains and fine cannulae, should be designated for single-use only and not be reprocessed and reused
- Devices owned by the patient that are reused in their home must be adequately cleaned prior to reuse
- Home health-care agencies may consider reusing single-use, semi-critical medical devices for a single patient in their home when reuse is safe
- The health-care facility has a written policy and procedure regarding single-use medical device reprocessing
- Single-use critical and semi-critical medical devices are considered disposable and are discarded at point of use, except when reprocessed by an approved third party reprocessor

Transporting medical devices to and from a decontamination facility

INTRODUCTION

The basic principles of reprocessing are universal, irrespective of where a clinical procedure is performed or how and where reusable devices are transferred for decontamination.

HANDLING AND TRANSPORTATION OF CONTAMINATED DEVICES

Soiled medical devices should be handled in a manner that reduces the risk of exposure and/or injury to staff and clients/patients/residents, or contamination of environmental surfaces.

- Contaminated devices must be transported to a designated decontamination area as soon as possible after use.
- Contaminated devices should be transported in covered, fully enclosed, puncture-resistant containers that prevent spill of liquids. Containers must be decontaminated after each use.
- On-site transport for contaminated devices should follow designated routes to avoid high-traffic and patient care areas.
- All carts and containers containing contaminated devices must be clearly identified.
- Sterile and soiled devices must not be transported together, i.e. on the same cart, due to the risk of cross-contamination.

Post-procedural sorting, separating and accounting for contents of sets of devices is most important for several reasons.

- To ensure that all devices and their parts are present prior to cleaning
- To keep reusable devices in designated areas
- To inspect devices for signs of damage and make a note of any repairs necessary
- To allow for tracking and traceability of single devices or sets of devices/instruments, particularly in the case that the infection prevention and control team or operating department need to know on whom the device or devices have been used, e.g. concerns associated with Creutzfeldt-Jakob disease and other risks
- Transport of contaminated devices post-procedure should be sent to a designated decontaminated area as soon as possible and secured in closed, leak and puncture-resistant containers/trolley with tamper-proof locks and security tags
- Biohazard sign should be clearly visible
  – Internationally-recognized symbol or biohazard signage clearly identified in different colours – orange, yellow, red

There are various types of closed container systems available. These include trays, trolleys, impermeable bags, lidded bins and rigid container systems.

- Transport containers should protect both the equipment and the handler from accidental contact with blood or body fluids during transit. These containers may only be reused following cleaning
- Ideally, devices should be transported in moist conditions, without excess liquid

- Distances between procedure and reprocessing areas can often be long and on several floors in larger institutions, sometimes restricting safe and practical transport
- Devices should be carefully packed in the transport system, preferably lockable, with lighter instruments/devices on top of heavier devices. If shelving is used, lighter items below and heavier device sets placed where the handler can lift them without causing injury
  – Manual handling and health and safety procedures should be followed as per institution/facility policies and procedures
- Ideally, all transport trolleys should be segregated and identified as contaminated or decontaminated
  – In some facilities, trolleys are used alternately to transport contaminated and decontaminated items
    - Transport trolleys should be constructed from a material, which allows for proper cleaning to avoid cross-contamination

External/road transport

- When using off-site or outsourced reprocessing facilities, special care must be taken regarding containment of contaminated items
- Transport vehicles should be completely enclosed and allow for ease of loading
- If the vehicle is being used to transport both contaminated and decontaminated devices, a system should be put in place to segregate soiled from sterile devices to prevent the risk of cross-contamination
  – Contaminated and decontaminated devices should be placed in separate, secure areas of the vehicle
  – On-site transport for contaminated devices should follow designated routes to avoid high-traffic and patient care areas
  – All carts and containers transporting and containing contaminated devices should be clearly identified

Figure 31. **Trolley system showing transportation of sterile trays**



Processing of instruments in dental practice

INTRODUCTION

Where possible, all dental instruments should be processed centrally in the SSD. Processing of instruments related to dental practice require a written infection prevention and control policy to ensure that all procedures are in place for the adequate decontamination of dental instruments. A nominated person should be appointed to ensure that all policy and procedures are updated and followed and a regular audit should be carried out to ensure compliance.

STAFF HEALTH

Education and training

All dental staff needs to be trained in the prevention and control of infection. Prior to commencing work in a dental practice, all new staff must attend an induction programme in infection prevention and control and decontamination of instruments. In addition, they should be able to provide proof of attendance at continuing professional development training courses in these topics.

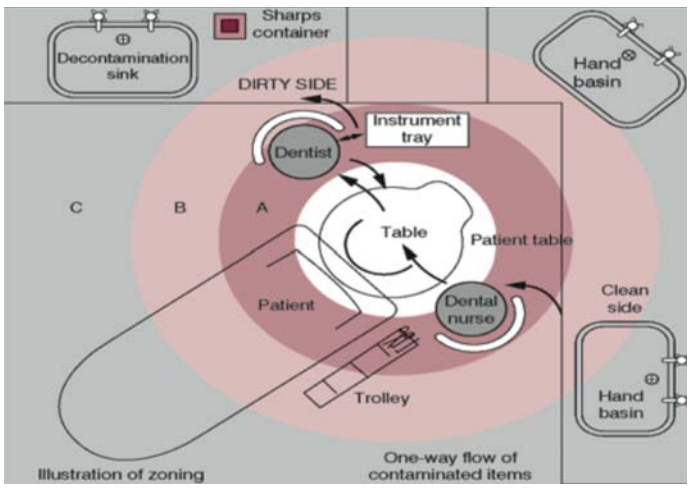
Immunization

All staff participating in clinical procedures must be vaccinated against hepatitis B and against vaccine-preventable diseases, particularly tuberculosis and rubella for women.

Surgery clothing

Surgery clothing should not be worn outside the surgery and must be removed before entering eating areas. All uniforms should be washed at 65°C.

Figure 32. Dental surgery area



DECONTAMINATION OF DENTAL EQUIPMENT

The Spaulding classification of risk categories of instruments used in dentistry are summarized in Table 18. All instruments that may have come into contact with any bodily fluids must be meticulously cleaned before sterilization. It is essential that a dedicated decontamination area be identified in the practice and designed to allow a dirty to clean flow of instruments as previously described for the SSD.

Table 18. **The Spaulding classification of risk categories according to items, procedures, and examples of instruments used in dentistry**

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

CLEANING OF INSTRUMENTS

Cleaning before decontamination can be achieved by:

Manual cleaning

Long-handled brushes should be used to remove debris and thick household gloves and protective eyewear should be worn. Cleaning brushes used for manual cleaning must be washed, rinsed and then stored dry. They should also be autoclaved regularly (see section on manual cleaning for method).

Ultrasonic cleaning

Ultrasonic cleaners with a basket are preferred (see section on ultrasonic cleaning). The cleaner should contain a detergent, which should be disposed of at the end of each clinical session or sooner if it appears to be heavily contaminated. Once a cleaning cycle has begun, it should not be interrupted and more instruments should not be added.

Washer-disinfectors

This is the most efficient method of cleaning and manufacturer's instructions must be followed. (For details, see section on cleaning of instruments.)

STERILIZATION OF INSTRUMENTS

Heat (using steam under pressure) is the preferred method for sterilization for all dental instruments. Ideally, this can be done by sending items to a SSD. Alternatively, a rapid turnover of patients will require rapid reprocessing in which case a portable tabletop steam sterilizer/autoclave is acceptable (see Table 18).

Dry heat sterilization and chemicals are **not** recommended for the routine sterilization of dental instruments and equipment. Ultraviolet light and boiling water do not sterilize instruments and must **not** be used.

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