



Government of the Republic of Trinidad and Tobago  
Ministry of Health



# GUIDELINES

## Cleaning, Disinfection and Sterilization of Medical Devices

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3rd Edition





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# Preface

The Government of the Republic of Trinidad and Tobago through the Ministry of Health has implemented a comprehensive Health Sector Reform Programme. This Programme is aimed at improving the quality of health care by introducing new organizational structures and systems, re-engineering ineffective systems and shifting expenditure to health promotion and disease prevention initiatives.

In keeping with one of the main goals, which is to improve and maintain the quality of health care delivered to the population, the ministry has introduced a sector-wide comprehensive Continuous Quality Improvement [CQI] Programme. Key elements of the CQI Programme include Accreditation and Licensing; Monitoring and Audit; Training and Capacity Building; Risk Management; Quality Management Information Systems [QMIS]; Systems Re-engineering and Evaluation.

In the context of the accreditation and risk management systems of the Quality Programme, the Ministry of Health has introduced a structured programme for the prevention and control of infection since it maximizes patient outcomes and is part of the Ministry's strategy for providing safe, effective and efficient quality health services.

In Trinidad and Tobago, like many other countries in the world, increasing numbers of different organisms are developing resistance to greater numbers of available antibiotics. Increased global travel is bringing more persons into contact with diseases, which are incubating; additionally, there are greater numbers of persons in a state of immune suppression who are more susceptible to invasion by pathogens [organisms causing diseases] or those usually considered non- pathogenic.

It is also well recognized that poor infection prevention and control practices result in patient dissatisfaction, increases patient stay and overall costs including litigation. It is therefore imperative that a holistic approach be instituted to the prevention and control of infection in Trinidad and Tobago. To achieve this goal public and private sector partnership has become absolutely essential. It is also mandatory that all health care facilities implement the infection prevention and control policies and guidelines in order to reduce the risks and improve quality.

The scope of the 3rd Edition of the Infection Prevention and Control Policies and Guidelines for Healthcare Services has been updated in four guidelines:

- **Guideline 1 – Prevention and Control of Healthcare-associated infections**
- **Guideline 2 – Occupational safety and health**
- **Guideline 3 – Sterilization and Disinfection**
- **Guideline 4 – Environmental cleaning**
- **Guideline 5 – Healthcare-associated infections surveillance – To be released at a later date**

As Minister of Health, I give the assurance that patient safety is of utmost importance and that the necessary infrastructure and resources will be made available and I feel confident that you the health care professionals, managers, and support staff will ensure that the goals of the programme are achieved and maintained. We thank the Pan American Health Organization (PAHO) for partnering with us to achieve this revision of our manual.

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**Chief Medical Officer**

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**Minister of Health**



# Introduction

Health care facilities contain a reservoir of infectious agents. Contamination of hospital equipment, medications, and water supplies by hospital pathogens is a well-known cause of epidemics.

Maintaining safe, clean, and hygienic health care facilities and minimizing microbial contamination on surfaces, objects, and equipment are essential for reducing the risks of health-care-associated infections.

The fundamental principles and requirements of basic cleaning and disinfection remain the same regardless the different types of patients, diseases, and medical interventions.

The purpose of this guide is to standardize cleaning and disinfection procedures in all health care settings, in order to ensure and maintain optimal conditions of hygiene and biosafety for patients, visitors, and for the health care facility's staff.

The recommendations presented here represent best practices developed with the goal of helping health care facilities reduce infections. These recommendations are intended to apply to all health care facilities, whether public, private, for-profit, or non-profit, and include hospital care, outpatient consultations, community health centers, doctors' offices, dental offices, and the private offices of other health care professionals.

The instructions and procedures discussed in this document should be adopted in all health care facilities and health services, following the guidelines applicable to specific areas, and based on the size and complexity of the facility and the services supplied. These measures should also be taken into consideration by health authorities responsible for certifying and accrediting health care facilities.

# 1. HUMAN RESOURCES

## 1.1. NUMBER AND QUALIFICATION

The number of Sterilization Department (SD) employees will depend on the volume of the work carried out, but there should always be a minimum number of employees. The area for the cleaning and decontamination of material (dirty area) should have one exclusive professional. Each remaining area should have one or more professionals that can perform activities in the different clean areas. The technical coordination should be performed by a nurse or other professional with at least an associate's degree.

## 1.2. TRAINING

Every Sterilization Department professional need be trained in service. The in-service training must include at least:

- Basic microbiology;
- Principles of cleaning;
- Sterilization;
- Preparation of textile material;
- Control of disinfection and sterilization processes;
- Collection and distribution of material;
- Waste management.
- Operation of equipment;
- Disinfection
- Selection and packaging materials;
- Loading of autoclaves;
- Storage of sterile material;
- Use of personal protective equipment (PPE); and

## 1.3. SAFETY

For each area of SD, it is necessary that a different personal protective equipment be worn in order to prevent the exposure to biological and chemical hazardous. As well mechanics and engineering control will improve the safety.

## 1.4. CLEANING AND DECONTAMINATION AREA

- Eye or face protector;
- Mask;
- Plastic apron;
- Rubber boots or waterproof footwear protectors.
- Cap;
- Exclusive clothing;
- Thick, long industrial type gloves; and

## 1.5. REVIEW OF THE CLEANING & CONDITIONING OF MEDICAL INSTRUMENTS & DEVICES

- Simple latex gloves
- Cap
- Exclusive clothes

## **1.6. AUTOCLAVES**

- Thermal protective gloves,
- Cap
- Exclusive clothes

## **1.7. STORAGE OF STERILE MATERIAL**

- Exclusive clothes
- Cap

## **1.8. DISINFECTION OR CHEMICAL STERILIZATION AREA**

- PPE used will depend on the method used

## **1.9. OTHER ACTIVITIES**

- Exclusive clothes
- Cap

## 2. PHYSICAL AREA

### 2.1. CENTRALIZED STERILIZATION DEPARTMENT (CSSD)

The Sterilization Department, by definition, is the service that receives, prepares, processes, controls and distributes textiles (clothing, gauzes, and dressings), medical devices and instruments to all sectors of the hospital, with the goal of providing a safe input to be used with the patient. The sterilization department should be centralized in an exclusive area with restriction of number of professionals where standardized, coordinated, and supervised cleaning; disinfection and sterilization procedures are done.

### 2.2. MINIMAL SPACE AND AREAS

The areas of the sterilization department are:

- Entrance and corridors (public areas);
- Gowning points to wear exclusive cloths and PPE for staff prior to entering working areas
- Cleaning room (receiving, dirty area)
- Inspection, Assembly and Packing area (IAP) (clean)
- Disinfection area (disinfection process performed)
- Sterilization area (location of sterilizers)
- Sterile store (cooling and short-term storage)
- Administration and staff rest and changing areas (offices are to be separated from work areas)
- Storage for devices, chemicals, packaging stores (raw material and sterilization department products)

### 2.3. MINIMAL GENERAL REQUIREMENTS

#### 2.3.1. SPACE REQUIREMENTS

These vary significantly according to the processes that the SD will carry out and are always calculated during planning. The general recommendation is one square meter per hospital bed.

#### 2.3.2. MECHANICAL SYSTEMS

In addition to mechanical, energy, water and steam requirements, sterilization processes habitually require pressurized systems such as compressed air, nitrogen, and vacuum systems.

A system for water distillation or demineralization, which will be used both for final rinse after cleaning and for filling the steam autoclaves, is recommended.

#### 2.3.3. FLOORS AND WALLS

Floors and walls should be constructed with washable materials that do not release fibers or particles and that are not affected by the chemical agents that are used for cleaning.

#### 2.3.4. CEILINGS

Ceilings should be constructed so that there are no exposed angles and only one surface (sanitary angles) in order to avoid condensation by moisture, dust or other possible causes of contamination.

### 2.3.5. VENTILATION

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Ventilation systems should be designed so that the air flows from the clean to the dirty areas and is then released into the exterior or into a filtered recirculation system. There should be no less than 10 air changes per hour. Fans should not be allowed in the SD, since they generate high turbulence of dust in the air and microorganisms that are projected from the floor to the worktables.

### 2.3.6. TEMPERATURE AND MOISTURE

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The ideal environment will maintain a stable temperature from 18oC – 25oC and a relative humidity of 35% – 50%. Higher temperature and moisture benefit microbial growth and lower levels can affect sterilization and disinfection parameters, such as the penetration of the sterilizing agent.

### 2.3.7. SINKS FOR WASHING INSTRUMENTS

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The sinks should be deep, in order to avoid splatters during the task and permit the correct immersion of the elements, a key factor for the correct cleaning of instruments.

## 2.4. WATER

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The water used in SD should be at potable and filtered, but ideally it should be demineralized or distilled water. If not enough demineralized or distilled water is available, it can be used for the final rinse and to produce steam for the autoclaves.

## 2.5. TECHNICAL AREAS- MINIMUM NECESSARY PHYSICAL STRUCTURE

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### 2.5.1. AREA FOR CLEANING AND DECONTAMINATION OF MATERIAL (DIRTY AREA)

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- Washable floors and walls.
- Two deep sinks.
- Bench made of washable material. It cannot be wooden.
- Lavatory or toilet to discard large amounts of organic matter.

### 2.5.2. AREA FOR CONDITIONING, PACKAGING, PREPARATION AND STERILIZATION OF MATERIAL (CLEAN AREA)

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- Washable floors and walls.
- Bench made of washable material. It cannot be wooden.
- Chairs.
- Magnifying glasses for confirmation of the cleaning.
- Sink for personnel hand washing.
- Exit for compressed air.
- Cabinets with doors to store non-sterile material and supplies.

### 2.5.3. AREA FOR STORAGE OF MATERIAL (STERILE AREA)

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- Washable floors and walls.
- Cabinets to store material after the sterilization process.
- Prior to entry, a sink for personnel hand washing.

## 3. CHEMICAL SOLUTIONS AT SD

At SD only hospital-grade and efficacy proved chemical solution must be used.

### 3.1. DETERGENTS

Must be used following the manufactures recommendation for dilution and time of contact. In SD use only hospital-grade detergents or hospital-grade cleaning products for cleaning of medical devices.

For instrument cleaning, a neutral or near-neutral pH detergent solution commonly is used because such solutions generally provide the best material compatibility profile and good soil removal. Enzymatic , usually proteases, sometimes are added to neutral pH solutions to assist in removing organic material (CDC, 1998), and alkaline detergent solution can also be used as cleaning product at SD.

Enzymatic cleaners and detergents are not disinfectants, so need to be prepared fresh at each shift (6 hour).

### 3.2. LUBRICANTS

A lubricant is a solution used to protect instruments. It should not be oily, sticky or toxic, but it should be soluble in water.

### 3.3. DISINFECTANTS

Disinfectants are the chemical or physical components active against vegetative microorganisms, the disinfectants can be used only in INANIMATED objects (section below).

### 3.4. ANTISEPTIC

Antiseptics are not discussed in this guideline; it is dedicated to antiseptics of skin and mucous membranes. It is not for use in surfaces or medical devices. Examples of antiseptic solution are: chlorhexidine, benzalkonium chloride, Iodine, PVPI, triclosan, PCMX or alcohol 70% (the only one can be also used as disinfectant)

### 3.5. STERILIZERS

Sterilizers are the physical or chemical components active against all forms of life, including spores. Sterilization process will be used in inanimate objects (medical devices) or substances, no surface or live tissue can be sterilized (section below).

## 4. CLEANING OF MEDICAL DEVICES

Cleaning of every material that is used in the hospital should be carried out prior to the disinfection or sterilization process. Cleaning is an essential component in the reprocessing of medical devices and sterilization can never be achieved without a complete cleaning.

Steps in the process for cleaning materials:

- a) Reception
- b) Classification
- c) Prewashing or soaking
- d) Manual washing and
- e) Rinsing with water
- f) Drying
- g) Lubrication

### 4.1. RECEPTION

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**Area:** This is carried out in the dirty (decontamination) area or RED area.

**PPE required:** thick gloves, plastic apron, eye or face protector, cap; exclusive clothing, rubber boots or waterproof footwear protectors.

Activities performed:

- check of dirty materials (number and quality state in which received and point of origin)
- record of material received
- Take care and check for the possibility of sharps

### 4.2. CLASSIFICATION AND DISASSEMBLY

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**Area:** This is carried out in the dirty (decontamination) area or red area

**PPE required:** thick gloves, plastic apron, eye or face protector, cap; exclusive clothing, rubber boots or waterproof footwear protectors.

Activities performed:

Classification of medical devices according to type of material, which can be:

- metal (ideally stainless steel)
- polyethylene
- rubber
- plastic
- glass

Remove any remnants of adhesive tape that are stuck to the surfaces

Open and disassemble the medical devices. All instruments and medical devices need to be disassembled before the following steps:

### 4.3. PREWASHING OR SOAKING

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**Area:** This is carried out in the dirty (decontamination) area or red area

**PPE required:** **thick gloves**, plastic apron, eye or face protector, cap; exclusive clothing, rubber boots or waterproof footwear protectors.

Activities performed: This process is carried out by submerging the material in a tray or container that is perforated with a hospital-grade detergent and then passing the material under a stream of running water. **AVOID THE USE OF CLORO based disinfectant or other DISINFECTANT or antiseptic to perform the prewashing step**

### 4.4. MANUAL WASHING AND RINSING WITH WATER

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**Area:** This is carried out in the dirty (decontamination) area or red area

**PPE required:** **thick gloves**, mask, plastic apron, eye or face protector, cap; exclusive clothing, rubber boots or waterproof footwear protectors.

Material Required:

Pour diluted hospital-grade detergent solution (according to manufacturer recommendations)

through all of the channels and devices surfaces.

- A soft, non-metal bristle brush or a soft cloth and
- Water at a temperature from 40oC – 50oC,
- Potable water

Activities performed:

- Brushing should be carried out underwater.
- Rinse the medical device vigorously with potable running water, passing the water through all of the channels in order to remove possible traces of the hospital-grade detergent.
- Carry out the final rinse of the material with soft water in order to guarantee that all of the salt residues are removed and thus avoid damage to the material.
- The materials should be dried with a clean cloth.

Special materials

- **For tubular-shaped material**, use a 60 cc. syringe with a cone point to fill the entire lumen with the detergent solution. Remove and rinse with abundant water. If possible, use high pressure water guns or specialized cone-shaped pressurized water pipes to pressure in different sizes or diameters to wash the lumen of catheters, extension tubes, connector tubes, corrugated tubes, etc. Carry out the final rinse of the material with water.
- Washing of glass material, jars and syringes
- Submerge the material in a solution with enzymatic detergent. It should be considered that when cleaning the interior of the jar, the type of brush that is used with feeding bottles or swabs should be used according to the required size. Rinse repeatedly under a stream of running water. Dry the outside with a cloth, but never dry the inside with a cloth, in order to avoid the introduction of foreign bodies like lint.



## 4.5. DRYING

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**Area:** Area for conditioning, packaging, preparation and sterilization of material (clean area)

**PPE required:**

- Cap
- Exclusive clothes.
- Simple latex gloves

**Activities performed:** Manual drying should be carried out with a cloth or compressed air

- Dry the devices well by hand with soft cloths made from very absorbent material or cellulose fiber. Make sure that lint or fibers do not remain on the surface or interior of the materials.
- Do not dry the corrugated and tubular material hanged in room temperature air, to avoid recontamination of this material it must be dried inside the dryer machine with hot air.

## 4.6. LUBRICATION

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**Area:** Area for conditioning, packaging, preparation and sterilization of material (clean area)

**PPE required:**

- Cap
- Exclusive clothes
- Simple latex gloves

**Activities performed:** Apply the lubricants solution on the surgical instruments.

- The lubricant solution utilized should be water soluble and made specifically for sterilization. Mineral, silicone or machine oils should not be used since they do not allow the sterilizing agents to fully penetrate and as a result, microorganisms are not destroyed. There are lubricants that contain an oxide inhibitor that is useful for preventing the electrolysis of the ends and edges. The use of lubricant is the first step in the preventive maintenance of instruments.

## 5. PREPARING AND PACKAGING MATERIALS

Every material needs to be packing in order to be sterilized; stored and transported. The package will guarantee the sterile condition until the final use. Unpacked material cannot be storage.

Some materials undergo high-level disinfection and are stored for later use, such as: laryngoscopes and anesthesia masks. After the disinfection process, these materials should be kept in a simple plastic bag in order to avoid their recontamination.

Packaging should be selected according to the sterilization method and the article to be prepared.

Every package should have an exposure control and an identification or label of the content, service, lot number, expiration date, and initials of the operator.

This stage includes:

- a) Inspection and verification of the article
- b) Selection of packaging
- c) Packing of material
- d) Sealing
- e) Labeling of the package
- f) Evaluation of the package

### 5.1. INSPECTION AND VERIFICATION OF THE ARTICLES

**Area:** Area for conditioning, packaging, preparation and sterilization of material (clean area)

PPE required:

- Cap
- Exclusive clothes
- Simple latex gloves

**Activities performed:** The visual inspection of each article should be carried out by observing deficiencies in the cleaning process, corrosion and other damage like cracks. The functional inspection of each article should also be carried out, confirming that scissors are able to cut, confirming the fit of the teeth in dissecting forceps, and confirming the catch system for the toothed bars of hemostatic forceps. Their lubrication conditions should also be verified. Articles not ready for use will be withdrawn and replaced in the shortest amount of time possible.

Recommended practices

- Use the hand washing technique before carrying out this activity.
- Maintain the work table in good conditions both in terms of hygiene and organization.
- Do not use an oily substance for lubrication.
- Do not allow a worker with any type of dermatological lesion to carry out this activity.

## 5.2. SELECTION OF THE PACKAGING

### 5.2.1. AREA

Area for conditioning, packaging, preparation and sterilization of material (clean area)

PPE required:

- Cap
- Exclusive clothes
- Simple latex gloves

### 5.2.2. ACTIVITIES PERFORMED

The principal purpose of any packaging material is to hold the objects, maintain the sterility of the content, and provide an aseptic presentation. At the same time, it should be economically effective and cost-saving for the institution.

Many possibilities of packing are available, the quality as microbial barrier will have impact at the expiration date of the packed.

The use of the following should be prohibited:

- Metal drum trays.
- Newspaper.
- Packages made from recycled material.
- Wrapping paper - This material is used for sterilization by steam autoclave. But it is not considered to be an efficient barrier since it has memory, is not waterproof, generates lint, and does not have standardized porosity. Furthermore, given that in some cases its manufacture is not standardized, it can contain toxic waste as part of its composition.

Note: metal drum trays only can be used as a secondary packing, for examples, to hold a small packages of gaze or cotton.

### 5.2.3. AVAILABLE PACKING PRODUCTS AND IT USES

#### 5.2.3.1. Linen Or Woven Cloths

Appropriate cloths are those made of cotton and cotton with polyester with a count of 55 threads/cm<sup>2</sup> distributed in the following way: warp, 28 threads/cm; weave, 27 threads/cm; total, 140 threads/inch<sup>2</sup>, in double wrapping. These are used for heavy packages that need resistant packaging. The cloth should be washed after each process and discarded in the case of any holes.

Instructions for use:

Cotton or cotton-polyester cloth packaging (140 threads/inch<sup>2</sup>) should be using with double wrapping. This is the least effective bacterial barrier. It can be used for ethylene oxide steam. It should be washed, free from lint and inspected prior to use.

- “Jean” type cloth packaging (160 threads/inch<sup>2</sup>) should be used with double wrapping. It can be used for ethylene oxide steam. It should be washed, free from lint and inspected prior to use.
- Cloth barrier (272 to 288 threads/inch<sup>2</sup>) is resistant to liquids and has good penetration by steam and ethylene oxide. Since they can retain moisture, the drying time should be increased. It should be washed, free from lint and inspected prior to use.

Woven cloths should be washed between each use in order to restore the moisture content and ensure the filtration capacity of the fibers. Continuous washing of textiles reduces their efficiency as a barrier, which means that their storage time may be reduced.

### 5.2.3.2. Polypropylene And Polycarbonates

These are both heat-resistant materials that are formed by 3 layers that are thermally joined (SMS):

- Spunbond: formed by long fibers that provide strength.
- Meltblown: formed by short, disordered fibers that provide a barrier.

They are accommodative, non-toxic and water repellent.

Instructions for use:

They can be used in steam sterilization (resistant up to approximately 140oC – 150oC). Since they can retain moisture, the drying time should be increased. Polypropylene is the packaging of choice for sterilization with hydrogen peroxide plasma.

### 5.2.3.3. Papers

- Surgical grade or medical grade paper

This is the ideal paper for the sterilization process. This paper does not release lint, but it does release fibers if the paper is broken by the hand during opening. A grammage of 60 to 80 g/m<sup>2</sup> guarantees mechanical resistance. Thicker paper guarantees protection against the entry of bacteria. During sterilization, especially by steam, the structure of the paper fibers undergoes strong pressures. This paper is safe and blocks bacteria following one sterilization, it is disposable

**Instructions for use:** It can be used for steam and ethylene oxide. It should not be reused.

- Mixed paper

This paper is a combination of medical grade paper and a transparent polymer. It represents the most common packaging in sterilization services. It consists of a transparent sheet that allows the article to be seen and an opaque sheet (medical grade paper). It is resistant to tension, bursting and tearing, heat sealable, easy to open and has incorporated chemical indicators. The presentation of this material is in the form of sleeves that are adaptable to materials of different sizes and envelopes.

Instructions for use:

It is compatible with sterilization by autoclave with steam, ethylene oxide and formaldehyde steam.

**Table 1 -Type of packaging recommended for each type of sterilization process**

<b>TYPE OF PACKAGING</b>	<b>USES</b>	<b>ADVANTAGES</b>	<b>DISADVANTAGES</b>	<b>COMMENTS</b>
Paper (medical grade) Bleached crepe paper; cellulose & synthetic fibres	Steam Dry heat ETO	<ul style="list-style-type: none"> <li>• Penetration of steam, air, chemicals</li> <li>• Effective barrier in dry clean conditions</li> <li>• Free from loose particles; single use only</li> </ul>	<ul style="list-style-type: none"> <li>• Fibres and loose particles if torn or shredded</li> <li>• Not to be used for hydrogen peroxide plasma - absorbs hydrogen peroxide</li> <li>• Do not facilitate aseptic opening</li> </ul>	<ul style="list-style-type: none"> <li>• Use manufacturers' guidelines; double wrap may- reduce steam penetration</li> <li>• Paper bags are not very strong; unable to see inside</li> </ul>
Reusable rigid containers - metals, aluminium, high density polymer or a combination of metal and plastic	Steam sterilization for large sets of surgical devices	<ul style="list-style-type: none"> <li>• Keeps the devices safe after sterilization and during transportation</li> </ul>	<ul style="list-style-type: none"> <li>• Containers must be loaded properly to avoid problems of moisture and increasing drying times</li> </ul>	<ul style="list-style-type: none"> <li>• Lid and base are perforated to allow steam penetration; disassemble and clean after each use</li> <li>• Require routine inspection and maintenance</li> <li>• Container systems must be validated before use</li> </ul>
Woven fabrics. Two layers of cloth or one each of cloth and paper. Primary packaging	Steam prevacuum or downward displacement (gravity)	<ul style="list-style-type: none"> <li>• Heavy pack</li> <li>• Stronger - resistant to tearing; reusable</li> </ul>	<ul style="list-style-type: none"> <li>• Poor bacterial barrier.</li> <li>• Holes in the fabric render them ineffective Impede air penetration and air removal if thick or tight</li> <li>• Cannot be used alone</li> <li>• If too dry, will cause overheating of steam and failure of sterilization</li> <li>• "Sterile" wound infections from lint</li> </ul>	<ul style="list-style-type: none"> <li>• Store clean and dry.</li> <li>• Need to be inspected carefully and assess quality during use and reuse</li> <li>• Not recommended for primary packaging alone, must have another (secondary or layered) cover with it</li> </ul>
Synthetic woven fabrics	Steam sterilization	<ul style="list-style-type: none"> <li>• Durable and good to use</li> </ul>	<ul style="list-style-type: none"> <li>• Need to be validated for sterilization and reliable drying in the facility</li> </ul>	<ul style="list-style-type: none"> <li>• Validation required for sterilization</li> </ul>
Non-perforated containers of glass or metal	Dry heat sterilization	<ul style="list-style-type: none"> <li>• Sterilization of needles</li> </ul>	<ul style="list-style-type: none"> <li>• Poor conductor of heat - increases drying time</li> </ul>	<ul style="list-style-type: none"> <li>• Not recommended -</li> </ul>
Glass bottles, vials and ampoules for liquids	Dry heat sterilization of liquids and oils	<ul style="list-style-type: none"> <li>• For sterilization of liquids and oils</li> </ul>	<ul style="list-style-type: none"> <li>• Limited use if any</li> </ul>	<ul style="list-style-type: none"> <li>• Less often used</li> </ul>
Aluminium foil Thicker grade than domestic (about 75_M)	Dry heat	<ul style="list-style-type: none"> <li>• Used for larger items like drills</li> </ul>	<ul style="list-style-type: none"> <li>• Impervious to steam and gas</li> </ul>	<ul style="list-style-type: none"> <li>• Not recommended for routine use</li> </ul>

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

**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

Source: Decontamination and reprocessing of medical devices for health care facilities.

I. World Health Organization. II. Pan American Health Organization. ISBN 978 92 4 154985 1

## 5.2.4. PACKAGING OF THE ARTICLE

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### a) Elements and packing material:

- Adhesive tape with external chemical control according to the sterilization
- Adhesive tape for identification of the package (masking tape).
- Internal chemical indicator or integrator.
- Gauze or protectors for sharp, pointed instruments.
- Sealer in the case of mixed or polyethylene packaging.

### b) Packaging models:

- Envelope type
- Rectangular type
- Paper bags
- Pouch or window package

### c) Size of the package

- For sterilization by steam (autoclave):
- The size of the packages should not be larger than: 28 x 28 x 47 cm. The weight should not exceed 4 to 5 kg.

### d) Techniques or procedures for preparing packages

#### Envelope type

- Position the material diagonally in the center of the packaging.
- Place the internal chemical indicator or integrator in the center of the package.
- Fold the end facing the person who is preparing the package in such a way that it reaches the center of the package and covers the article.
- Then make a fold with the point facing outward.
- Fold the sides into the center of the package in the form of an envelope, always making a fold at the point. Carry out the same procedure on the other side so that they both cover the article.
- Complete the package by lifting the fourth and final point toward the center of the package and seal the entire package with process indicator tape.
- The control tape should not measure less than 5 cm.

#### Rectangular type of surgical clothing

- For quality implementation of surgical activities, it is important that the surgical textile material be prepared in packages that contain the quantity of articles that are necessary for the type of intervention to be performed.
- Taking into account that the sheets, compresses and scrubs are dense enough to serve as a barrier to penetration by steam, it is advisable to wrap these elements in packages that do not exceed 30 x 30 x 50 cm. Otherwise, they should be wrapped separately.
- If the packages are larger, they run the risk of blocking the flow of the sterilizing agent inside the autoclave, preventing elimination of air and sterilization of the packages.

### 5.3. SEALING

Paper bags will be folded twice and then sealed with adhesive tape, which will be applied vertically at the closure. Boxes (metal or plastic) should not be sealed with any type of adhesive tape.

The sealing should permit later opening that is aseptic and allows the use of an easy technique that prevents dropping or breakage of the material. Sealing can be carried out according to the following techniques:

- With adhesive tapes
- Bundled with strings or cotton thread
- Manual folding
- Heat-sealed

### 5.4. LABELING OF THE PACKAGE

Manual labeling should be done on self-adhesive labels or on the fold or flap of the package, making sure not to perforate the package and that the writing ink does not stain the medical use device.

The medical use product should be identified with the following information:

- Name of the material
- Destination (in the event that it is needed)
- Preparation and/or sterilization date
- Code of the person responsible
- Lot number
- Any other clarification that is considered necessary (expiration date)

### 5.5. EVALUATION OF THE PACKAGE

Packages should undergo continuous evaluation in order to confirm the following:

- Integrity of the external layer of the material
- Integrity of the seals
- Correct identification
- Gauge of the chemical indicator
- Reading of the expiration date



## 6. DISINFECTION

In 1968, Earl Spaulding established the first criterion for disinfection with the objective of rationalizing guidelines for processing materials and instruments. Spaulding considered the level of infection risk that the utilization of these articles would represent and classified them

in the following way:

a) **Critical articles:** Critical articles are instruments that come into contact with cavities or sterile tissues, including the vascular system. These articles pose a high risk of infection if they are contaminated with any microorganism, which means that they should **always** be **sterile**.

This includes, for example, surgical instruments, cardiac probes, catheters and prostheses.

b) **Semi-critical articles:** Semi-critical articles are instruments that come into contact with the mucous membrane of the respiratory, genital and urinary tracts and with skin that is not intact. Although mucous membranes are usually resistant to infections by bacterial spores, they can present infection when they are contaminated with other microbial forms. For this reason, they should be **sterile**, or at the least, they should be submitted to **high-level disinfection** (HLD). This includes, for example, respiratory assistance devices, anesthesia and endoscopic devices.

c) **Non-critical articles:** Non-critical articles refer to all instruments that only come into contact with intact skin. In this case, healthy skin acts as an effective barrier to keep out the majority of microorganisms. As a result, the level of disinfection needed is lower. In general, only adequate cleaning and drying are required, with the need for **intermediate - or low-level level disinfection** on some occasions. Some examples of this type of instruments are sphygmomanometers, bedclothes, incubators, mattresses and furniture.

**Disinfection** -is the physical or chemical process that **eliminates vegetative microorganisms from inanimate objects without ensuring the elimination of bacterial spores**. Every semi-critical article that cannot be sterilized should be disinfected according to the guideline criteria and the validated protocol.

Levels of disinfection

These levels are based on the microbicidal effect of the chemical agents on the microorganisms and can be:

- **High-level disinfection (HLD):** This is carried out with liquid chemical agents that eliminate all of the microorganisms. Examples are Ortho-phthalaldehyde (OPA), Glutaraldehyde-based formulations, peracetic acid, hydrogen peroxide.
- **Intermediate-level disinfection (ILD):** This is carried out using chemical agents that eliminate vegetative bacteria and some bacterial spores. This includes the phenol group, Ethyl, or isopropyl alcohol (70-90%) and sodium hypochlorite.
- **Low-level disinfection (LLD):** This is carried out by chemical agents that eliminate vegetative bacteria, fungi and some viruses within a short period of time (less than 10 minutes). One example is the group of quaternary ammoniums.

## 7. DISINFECTION METHODS

Disinfection is one of the oldest procedures in the hospital environment. It was originally used to eliminate microorganisms from the environment and to sanitize hands.

There are two disinfection methods: physical and chemical.

- Physical methods:
- **Pasteurization** - This method was originally used by the French Louis Pasteur. This process is used to carry out HLD, by bringing water to 77 °C for approximately 30 minutes. This destroys all microorganisms except bacterial spores.
- **Water and water jet disinfectors** – This equipment is used to clean and disinfect objects that are used for patient care in the hospital room. Water jet disinfectors are used to empty, clean and disinfect objects such as bedpans and urinals through a process that eliminates manual washing and, in some cases, uses a minimum quantity of chemical germicides. It uses temperatures over 90 °C.
- **Liquid chemical methods** - This is the most frequently utilized method in our hospital system and multiple germicidal agents exist in liquid form. This method requires many controls during execution. Since it is a method that is carried out for the most part manually, all stages of the protocol recommended by the manufacturer and validated should be followed closely. Deficiencies in the disinfection process can result in serious infectious or inflammatory complications in patients who come into contact with these articles. The principal disinfectants used in the hospital area are: ortho-phthaldehyde, glutaraldehyde, chlorine and chlorinated compounds, formaldehyde, hydrogen peroxide, peracetic acid, phenols, and quaternary ammoniums.

### 7.1. HIGH LEVEL DISINFECTANTS

#### 7.1.1. GLUTARALDEHYDE

This is an aldehyde compound that is presented as aqueous, acidic and alkaline solutions. The acidic solutions are not sporicidal, but when an alkalinizing agent is used as activator, this product becomes sporicidal. Once activated, it has an alkaline pH, which is drastically reduced starting 14 days post-activation. There are also formulations that allow a longer shelf life of 28 days.

**Mechanism of action:** Its action is the result of the alkylation of cellular components that alters the protein synthesis of DNA and RNA acids.

**Spectrum:** It is a bactericide, fungicide, viricide, mycobactericide and sporicide.

**Advantages and disadvantages:** It is not corrosive. For HLD (45 minutes) at room temperature, it has germicidal activity in the presence of organic matter. The great disadvantage of glutaraldehyde is its toxicity: once activated, it tends to produce vapors that irritate the mucous membranes, respiratory system and skin. Therefore, it should be used in highly ventilated environments and with personal protective equipment. There are currently workspaces for HLD that protect the operator.

**Instructions for use:** It is indicated for the HLD of endoscopes when sterilization is not possible. It is also indicated for the use of metal articles or materials such as speculums, ear, nose and throat and dental instruments, and the slides for laryngoscopes.

**Concentrations for use:** For 2% solutions. A time of 30-45 minutes is required to carry out HLD at a temperature of 20°C. There are other formulations of glutaraldehyde in concentrations that range from 2.4% to 3.4%, but the same contact time is required between 30-45min for HLD.

## 7.2. LOW-LEVEL DISINFECTANTS

### 7.2.1. CHLORINE AND CHLORATED COMPOUNDS

Chlorine-based disinfectants are usually available in liquid form as sodium hypochlorite (bleach) or in solid form as calcium hypochlorite (sodium dichloroisocyanurate).

**Mechanism of action:** It produces the inhibition of enzymatic reactions, denaturation of proteins and inactivation of nucleic acids.

**Spectrum:** It is a virucide, fungicide and bactericide (mycobactericidal).

**Advantages and disadvantages:** Its action is fast, low-cost and easy to manage. It has deodorizing properties and microbicidal activity attributable to the undissociated hypochlorous acid. The dissociation of this acid, and consequently the smaller activity, depends on the pH. Its efficiency diminishes with an increase in pH. It has corrosive activity, becomes inactive in the presence of organic matter, produces irritation of the mucous membranes, is polymerized by sun rays, and needs to be protected in opaque containers. Chlorine solutions should not be conserved in uncovered containers for more than 12 hours due to the evaporation of the active product. Evaporation causes the concentrations of available chlorine to decline from 40% to 50%.

**Concentrations for use:** The minimum concentration to eliminate mycobacteria is 1,000 ppm (0.1%) for 10 minutes. Objects should not be submerged for more than 30 minutes due to the element's corrosive activity. Abundant rinsing is also recommended to prevent chemical irritation from possible waste. It is important to point out that there are many factors that affect the stability of chlorine, such as the presence of heavy ions, the pH of the solution, the temperature of the solution, the presence of biofilms, the presence of organic matter, and ultraviolet radiation.

Concentrations for use in the hospital area:

10,000 ppm = 1% = Concentration for disinfection of spills, following cleaning.

5,000 ppm = 0.5% = Disinfection of materials, following cleaning.

1,000 ppm = 0.1% = Disinfection of critical areas, following cleaning.

100 to 500 ppm = 0.01 to 0.05% = Disinfection of non-critical areas.

### 7.2.2. QUATERNARY AMMONIUMS

The compounds most commonly used in hospital establishments are alkyldimethyl-benzyl-ammonium chloride, alkyl-didecyl-dimethyl-ammonium chloride and dialkyl-dimethyl-ammonium chloride.

**Mechanism of action:** They produce the inactivation of energy-producing enzymes, denaturation of cellular proteins and rupture of the cellular membrane.

**Spectrum:** They are fungicides, bactericides and virucides against only lipophilic viruses (Enveloped). They are not sporicides or mycobactericides and cannot act against hydrophilic viruses.

**Advantages and disadvantages:** These elements are good cleaning agents due to their low toxicity. Gauze and cotton remnants can affect their action.

**Instructions for use:** Due to their low toxicity, they can be used to disinfect surfaces and furniture.

**Concentrations for use:** The concentrations for use vary according to the combination of quaternary ammonium compounds in each commercial formulation.

## Table 2- Actions of different disinfectants

### 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
Glutaraldehyde (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.

Source: Decontamination and reprocessing of medical devices for health care facilities. World Health Organization. II. Pan American Health Organization.

### 7.3. DISINFECTION PROCESS

- The disinfecting agent should be contained in a disinfection tray with a cover, on which the preparation date and validity of the solution should be clearly and legibly indicated.
- In the case that the product requires it, the disinfecting agent should be previously activated by the addition of the activating solution during the preparation of the solution.
- The tray should be opaque in the case that the product used is photosensitive.
- Confirm the concentration of the disinfecting agent with reactive strips that are specific to the product used at the beginning of the day or after every 10 immersions or procedures. Confirm that the temperature of the solution is the minimum recommended for the disinfection time utilized.
- Confirm the expiration or validity date of the solution.
- If the product validity date has passed, or the product was diluted or inactivated (shown in that the reactive strips did not reach the final point), discard the solution.
- If the product is apt, submerge the endoscope completely (except for the head in the non-submersible model) and make the disinfectant solution circulate through the channels of the endoscope repeatedly.
- Cover and leave the instrument and channels in contact with the solution for the minimum amount of time specified for disinfection in the institution's internal procedures.
- Remove the endoscope from the solution.
- Cover the disinfection tray for later use, without discarding the disinfectant solution.

#### Rinse of the disinfecting agent

- Place the tray in the rinsing sink.
- Make an abundant amount of potable quality running water circulate through the channels of the endoscope.
- Proceed with the rinse of the instrument's exterior.
- Carry out successive rinses of the instrument in order to eliminate all of the toxic remains from the chemical agent used.
- Discard the wastewater after each rinse.

### 7.4. DISINFECTION PROCESS FOR ENDOSCOPES

The recommendations for the cleaning and disinfection of endoscopes are summarized in the following table.

**Table 3 - Cleaning and disinfection of endoscopes**

What to do	How to implement
1. <b>Clean</b>	Immediately after the procedure, submerge and review the external surfaces and internal channels with brushes, a water solution and enzymatic soap.
2. <b>Rinse</b>	Rinse the exterior and all channels with abundant water and with adequate syringes. Subsequently drain the water.
3. <b>Dry</b>	After cleaning and before disinfection, treat the internal channels with forced air and exterior with a clean compress.
4. <b>Disinfect</b>	Submerge the endoscope in a high-level disinfectant, making sure that it penetrates through the channels of air, water, suction, and biopsy. Leave it for 20 minutes.
5. <b>Rinse</b>	Rinse the endoscope and channels with sterile water. Of this is not possible, use faucet water, followed by an alcohol rinse.
6. <b>Dry</b>	After disinfection and prior to storage, treat the internal channels with forced air and the exterior with a clean compress.
7. <b>Store</b>	The endoscope should be stored in a place that prevents recontamination

## 8. STERILIZATION

Sterilization refers to the set of operations that are developed to eliminate or kill all forms of living beings that are contained in an object or substance. Every critical article should undergo some type of sterilization method according to its compatibility. Every heat-resistant material that is compatible with moisture should be autoclaved.

### 8.1. STERILIZATION METHODS

Physical methods: dry heat and moist heat (steam).

Chemical methods: gases (ethylene oxide).

#### 8.1.1. STEAM STERILIZATION

Steam sterilization is the most common sterilization procedure (except for materials that cannot resist heat and moisture). The equipment used is called an autoclave. The action mechanism for moist heat is the denaturation of proteins. This method should be considered as the top choice whenever the materials permit it. It has the advantages of rapidly producing elevated temperatures, having short sterilization times, and not leaving toxic waste in the material.

General control parameters for autoclaves

The control parameters are: steam pressure, time and temperature.

Sterilizing agent: Saturated Steam

**Steam pressure:** Saturated steam with a temperature of 121 to 132 °C (approximately: 95% steam and 5% condensed water) and free of impurities, using soft or treated water.

**Time and temperature:** These will have a direct relationship with the thickness or type of packaging, defined according to the standards established by international agencies.

#### **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).

#### 8.1.2. 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 OC to 135 OC.

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 OC to 123 OC, 132 OC to 135 OC, or 141 OC to 144 OC.

Gravity sterilizers

Gravity is used to displace the air from the sterilizer chamber and packaged devices.

Operate at 121 OC or higher.

## 8.2. DRY HEAT

It is important to always take into account that the microbicidal action of heat is conditioned by the presence of organic matter or dirt on the materials. This applies, for example, to oil or fat for cases in which the microorganisms are protected from heat-based action.

Dry heat penetrates slowly in materials, which means that long exposure periods are required. Hot air is not corrosive but the process is slow. This system eliminates microorganisms through coagulation of the proteins in the microorganisms. Its effectiveness depends on:

- the diffusion of the heat
- the quantity of heat available and
- the levels of heat loss.

Sterilizing agent: Hot air.

**Mechanism of action:** Microbial death occurs as a consequence of energy transfer and oxidation mechanisms.

Conditions of the process: Institutional procedure manuals should establish working conditions according to the load, volume, weight and thermal resistance of the material. It is indispensable to respect the parameters obtained during the validation of the procedure.

**Temperature:** the temperature of sterilization by dry heat should stay between 160°C – 170°C.

**Time:** the total exposure time of the material is determined through the corresponding validation of the cycle. It is important to point out that the exposure time should be recorded after the required temperature is reached and not from the time that the sterilizer is charged since a prolonged time could be required to reach the sterilization temperature.

Table 5 -Relationship between time – temperature for sterilization by dry heat

Temperature (°C)	Exposure time
180 °C	30 minutes
170 °C	1 hour
160 °C	2 hours
150 °C	2 hours and 30 minutes
140 °C	3 hours
121 °C	12 hours

## 9. CHEMICAL METHODS

These methods are used only in the case of materials that do not tolerate heat, but do tolerate chemicals.

### 9.1. ETHYLENE OXIDE (ETO)

**Mechanism of action:** It acts as an alkylating agent for functional groups of structural proteins and enzymes and for nitrogenous bases of nucleic acids.

**Conditions of the process:** The values of gas concentration, temperature, humidity, exposure time and aeration should be the same as those that result from the corresponding validation of the cycle.

**Equipment:** EtO sterilizers that meet the standards for the organization and operation of sterilization plants in health facilities should be used.

**Advantages and disadvantages of the method:** **Advantages:** EtO is a substance with a high level of diffusion and penetration, which permits high versatility for the sterilization of heat-sensitive materials. **Disadvantages:** It is highly toxic to living things and can cause local reactions on skin and mucous membranes and systemic toxic effects with clinical manifestations such as dyspnea, cyanosis, gastrointestinal disorders, hemolysis, necrosis, mutagenesis and carcinogenesis. Due to these adverse effects, it is considered a highly dangerous substance and its use should be restricted to adequately trained personnel. It is a slow process that requires environmental and residual controls of the materials. There are no chemical indicators that can monitor the concentration of EtO during the sterilization cycle. It requires packaging materials that are permeable to EtO. It is a high-cost method.

#### Stages of sterilization by EtO:

- Conditioning and humidification
- Entrance of the gas
- Exposure to the gas
- Evacuation
- Aeration
- Sterilization temperatures range from 35°C – 55°C and exposure times range from 1 hour 20 minutes and 4 hours.
- The aeration process that should be implemented is carried out at 40°C – 60°C for 6 to 12 hours (times suggested by the AORN – Association of peri Operative Registered Nurses – and the AAMI). This results in a total duration for the entire process of 8 to 16 hours.
- It is worth pointing out that implementation is carried out under the premise that lower temperatures require longer aeration times.
- Sterilization by EtO is recommendable provided that it is automated.

#### Aeration:

- The aeration of objects sterilized by EtO permits the desorption of the gas.
- Metal objects do not require aeration. However, the packaging used does.



## Measurement and control of EtO:

For better monitoring and control of exposure to EtO, OSHA (Occupational Safety and Health Administration) and NIOSH (National Institute for Occupational Safety and Health) recommend environmental monitoring, engineering controls and certain ventilation strategies of the United States of America (USA), should be referred to.

### Environmental monitoring:

- This can be carried out with passive monitors with brand names as: Dupont Proteck®, Amsco ETO Self Scan®, 3M 3551®, Ken Medical ETO Track®, available for periods of 8 hours and 15 minutes.
- Eight-hour controls should be carried out twice a year.
- Fifteen-minute controls should be carried out 4 times a year.
- This instrument or monitor, which looks like a dosimeter, should be placed as close as possible to the operator's face, as if it were an "identification card."
- Subsequent to exposure, the monitor should be sent for the corresponding reading of the limit value of exposure.
- Other materials that exist – but that are not available in all countries – include infrared analyzers, photoionization equipment, electromechanical equipment (Gas Technologies Inc.®, Etox Catalyst Research®, Intercom Gas Track®), gas chromatographs (HNO Systems®, Foxboro®, Envirogard III®), and detector tubes ( Draeger®).

### General recommendations:

- Place the equipment in ventilated areas and far from the circulation of personnel and the public.
- Use protective barriers.
- Carry out periodic controls (environmental monitoring).
- If anyone presents hypersensitivity to EtO, the person should avoid exposure.
- Guaranteed removal of EtO in work environments and materials is achieved with the adequate functioning of ventilation and extraction equipment in rooms where this equipment operates and with the fulfillment of all recommended technical specifications. Such removal is necessary in order to avoid exposures that can carry serious consequences for the health of personnel or patients.
- The ventilation system should expel air directly toward the exterior. The extraction channel should be at or below the level of the door and the equipment's drainage area.
- The room should have 10 air changes per hour, be at 21 °C and have a relative humidity of 50%.
- **MAXIMUM ENVIRONMENTAL LEVEL ALLOWED:** 1 part of EtO per 1million parts of air (1 ppm), for an 8 hour work day
- **MAXIMUM LEVEL PERMITTED FOR MEDICAL DEVICES:** 5 ppm
- It is necessary to monitor the levels of EtO gas in the room.
- Discharge the sterilizer immediately after finalizing the cycle. Open the door of the sterilizer by 5 to 10 cm. and leave the area immediately for at least 15 minutes. This may not be necessary in sterilizers with purge systems.
- Storage of EtO cylinders should be in a vertical position, including during transport.

Symptoms associated with exposure to ethylene oxide:

- Initially: irritation of the eyes, respiratory tract, nose and throat, with a “peculiar taste.”
- Late: headache, nausea, vomiting, dyspnea, cyanosis, pulmonary edema, weakness, EKG abnormalities, urinary excretion of biliary pigments.
- Skin irritation and burns through direct contact.
- Elevated absolute white blood cell count and decline in hemoglobin values following intermittent exposures over several years.
- In the case of exposure to high concentrations of EtO for a short period of time, a high number of chromosomal abnormalities were observed.
- The union of EtO and water produces a toxic compound called ethylene glycol, which depresses the central nervous system and has renal toxicity.

Protective measures for personnel:

- Personnel should have a biyearly medical exam.
- The employer has the obligation to inform the worker about the risks of using EtO. The employer should document the corresponding instructions; the list of exposed workers; annual consumption of the gas; and the result of the biyearly measurements of environmental EtO.
- Such documentation should be in addition to the Inspection Book for Occupational Health and Safety and should be overseen and reported to the oversight body by a specialized engineer.
- Work with EtO is prohibited for any individual who has blood dyscrasia or is pregnant.
- Personnel should have a mask with a specific filter for EtO gas or organic vapors, a gown and protective gloves (neoprene, nitrile rubber or similar material) whenever participating in the sterilization process with ethylene oxide.
- The work environment should be controlled periodically and whenever there is suspicion of a gas leak.
- Containers with EtO should be kept in deposits far from the processing area and in environments that meet the conditions for the deposit of inflammable material.

## 9.2. LIQUID CHEMICAL METHODS

Sterilization by manual immersion in chemical agents will always be the last method of choice. These processes are difficult to control, have a high probability of recontamination during rinsing or drying, and do not allow later storage. Agents can be used as chemical sterilizing: Glutaraldehyde. (See disinfection section, particularly HLD)

## 10. HANDLING

Product handling begins from the time that the material comes out of the sterilizer. Handling should always be kept at the minimum amount necessary.

Before touching containers that contain sterile products, it is important to take the following into account:

- Allow them to cool prior to removing them from the sterilizer in order to avoid condensation.
- Hands should be clean and dry.
- If the operator carried out another activity prior to the current one, carry out exhaustive hand washing.
- Take off gloves used for the other activity and wash hands.
- Transport materials in carts, if the volume requires it, and never resting against work clothes.
- Work clothes should be clean.

## 11. STORAGE

Although the storage of sterile products is carried out in different areas of the health center, the conditions should always be the same.

General considerations

- The storage area should be separated from other materials, primarily dirty clothes and waste.
- Access to the area should be restricted.
- Packages should be placed on shelves or in cabinets. If they are small packages, they should be placed in drawers or baskets. It is recommended that the storage containers not be wooden.
- They should be located at a minimum distance of 30 cm. from the floor, 45cm. from the ceiling and 5cm. from the wall.
- The material should be far from sources of moisture or heat.
- Air exchange should be carried out in such a way that it meets 10 changes per hour.
- The presence of steam plumbing, potable water or wastewater should not be permitted in this area.
- There should be an adequate level of illumination.
- The material should be placed in a position that makes it simple to label and visualize the expiration date indicated on the container.
- Materials should be grouped homogeneously, well-differentiated and, whenever possible, placed vertically.
- Other materials should not be touched when removing the one that is needed.
- They should be identified.
- Every container, when being stored and prior to being released should be inspected in order to verify that it meets the requirements of a sterile product.
- Shelving and cabinets for storing sterile products should always be in optimal conditions in terms of order and cleanliness.

Requirements that the storage location should fulfill

- It should be large enough for the amount of material that needs to be stored there.
- The walls should be smooth and easy to clean.
- It should have adequate environmental conditions in terms of both temperature and moisture: 15 oC – 28 oC and 30% – 50%.
- Shelving or cabinets should be selected based on the rotation of the materials and of personnel access to the area.
- Open shelving should be made of racks in order to avoid condensation of moisture and concentration of dust.
- Closed cabinets should be used when the material will have infrequent rotation or when personnel access is not restricted.
- Accessory baskets that are used should be placed on shelving or cabinets whenever the material is unstable or the basket could slide or fall.
- It is advisable for furniture to have wheels in order to be able to move them away from the walls for cleaning.
- Rigid containers should be stored in a way that their expiration date can be identified and controlled without having to moving them.
- When the content is heavy or has protruding edges, cardboard containers or a plastic interior, protection with a double bag is suggested.

### 11.1. SHELF LIFE

Shelf life is the maximum time that a sterile package can be stored.

The shelf life needs to be validated at the local facility. Must be included at Facility SOP, based on the calculation done by the facility condition of storage and packing material used.

## 12. TRANSPORT

For their transport, carts that are easily cleaned, have smooth surfaces and are preferably made of heat-resistant plastic polymers should be used. This type of cart produces less temperature difference in materials than stainless steel carts and the possibility of condensation is also lower.

Depending on the route that the cart would need to follow, the following can be used:

- Open carts
- Protected carts (with protective cover)
- Closed carts

In any of these cases, carts should be taken directly from the SD to the destination area.

## 13. QUALITY CONTROL

### 13.1. VALIDATION

Validation is a procedure documented to demonstrate that a process defined, such as cleaning, disinfection and sterilization is effective, replicable and provides products of a previously specified quality. All SD process needs to be validating at least once a year. Validation is a time consuming process but is the only methodology to prove the efficacy of SD process.

Question to make before start the validation process:

- What should it be validated?
- How will it be validated?
- Who is going validate it?
- Who going to approve the validation?
- When should it be ratified?

### 13.2. VERIFICATION

Verification is the daily process to demonstrate the validated process is occurring as expected, the process steps were complied; the equipment is working properly and identify the opportunity for corrective actions.

### 13.3. CLEANING

Verification of cleaning process:

**Every day:** Visual inspection

**Periodically:** Detection of organic waste, detection of adenosine triphosphate (ATP)

### 13.4. DISINFECTION

Verification of disinfection process will monitor the critical physical chemical parameters of the process.

The parameters need to be logged in a logbook specific for Chemical disinfection.

At beginning of workday check or before every cycle:

- Temperature
- pH,
- Effective minimum concentration of the disinfectant

During every cycle

- Exposure time

Controls of the high-level disinfectants:

The effective minimal concentration is controlled with chemical indicators through reactive strips that detect the effective minimum concentration (EMC) of the principle active.

## 13.5. STERILIZATION

For sterilization methods the critical parameters need to be monitoring ideally every cycle or at least every day. The gold standard challenge for the sterilization process is the biological test, and it need to be done weekly.

### 13.5.1. STEAM STERILIZATION

The Steam Sterilization is the main process to be used at any SD, the quality control of sterilization process need to cover: equipment control, control of exposure, control of package and control of load.

Critical parameters:

- Time of exposition
- Temperature
- Quality of steam
- Pressure

Equipment control

- Bowie-Dick Test (to pre vacuum autoclave) – daily, first load of day
- Physical or mechanical control – each cycle, log the time, temperature and pressure

Control of the exposure

- External chemical control – each package

Control of the package

- Internal chemical control – each package or at least one challenge package per cycle

Control of the charge

- Biological control – daily, or weekly. Every cycle with implants

### 13.5.2. DRY HEAT

Dry heat is the least option of physical sterilization option, with few controls of quality.

Critical parameters:

- Time of exposition
- Temperature

Equipment control

- Physical or mechanical control – each cycle, log the time, temperature

Control of the exposure

- External chemical control – each package

Control of the package

- Internal chemical control – each package or at least one challenge package per cycle

Control of the charge

- Biological control – daily, or weekly. NEVER put implants at dry heat

### 13.5.3. ETHYLENE OXIDE

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Ethylene oxide can only be performed at an automatic machine. It is a good option for a non-thermo-resistant material, but need to follow strictly the environmental and staff control

Critical parameters:

- Time of exposition
- Temperature
- Humidity
- Ethylene oxide concentration

Equipment control

Physical or mechanical control – each cycle, log the time, temperature and humidity

Control of the exposure

– External chemical control – each package

Control of the charge

– Biological control – each load

### 13.5.4. LIQUID CHEMICAL METHODS

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Use the same control as for disinfection methods but the contact time is longer.

Usually: 10 hour for Glutaraldehyde 2%

## ANNEXES

### ANNEX 1 – STANDARD OPERATING PROCEDURES – SOP TEMPLATE

DATE
Procedure Name
Purpose of Procedure
Description of Procedure
Material Required
Potential Hazards
Personal Protective Equipment
Related Documents













## ANNEX 7 – LABEL FOR STERILE PACKING

OBS: the label must be enough to keep the traceability of device

Name of the material	
Sterilization Date	
Autoclave number (OPTIONAL)	
Load number	
Expiration date	
Area of destination (OPTIONAL)	
Operator name	
Operator signature	

## **ANNEX 8 – TECHNICAL DESCRIPTION OF CHEMICAL PRODUCTS FOR CLEANING AND DISINFECTION OF MEDICAL DEVICES**

### **Enzymatic Detergent**

Enzymatic detergent containing at least 3 basic groups of enzymes: amylase, protease and lipase. Nonionic, pH between 6 and 8, 100% biodegradable, safe for contact with skin and mucous membrane.

### **Neutral Detergent Hospital Grade**

Liquid, nonionic detergent, neutral pH, fully biodegradable, non-corrosive, non-toxic, safe for contact with skin and mucous membrane.

### **Glutaraldehyde**

Minimal concentration of 1.7% of neutral or alkaline glutaraldehydes solution (pH 7.5–8.5) or glutaraldehyde-phenol-sodium phenate, potentiated acid glutaraldehyde, stabilized alkaline glutaraldehyde, with use-life of minimally 14 days to 28, 30 days. And with monitor strips available for test of minimum effective concentration.

Glutaraldehyde Monitor Strips for test of minimum effective concentration

Monitor strips to measure of the minimum effective concentration (MEC) of glutaraldehyde.

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