Sterilization manual for health centers

Authors:

Silvia I. Acosta-Gnass

Valeska de Andrade Stempliuk

Pan American Health Organization

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Preface

At the end of the XIX century, Joseph Lister made key contributions to solving one of the most significant problems that still faced surgery: infection. In those days, 30% to 50% of patients that underwent surgery died because of hospital gangrene, pyemia, erysipela and other infectious complications. The use of phenic acid for cleaning surgical material and the operating room environment made it possible for this proportion to decrease to 15% today. In the XXI century, the general public and health professionals are concerned about emerging pathogens such as *Helicobacter pylori, Escherichia coli* O157:H7, human immunodeficiency virus (HIV), Hepatitis C virus, the coronavirus responsible for severe acute respiratory syndrome (SARS), and multi-drug resistant *Mycobacterium tuberculosis.* Fortunately, it can be assured that the standard disinfection and sterilization processes described in this publication are adequate for sterilizing or disinfecting instruments or materials that are contaminated with blood or other fluids from people infected with these pathogens.

The preparation of this manual responds to a need expressed by countries, who are aware that only strict adherence to disinfection and sterilization guidelines can guarantee the safe use of invasive and non-invasive medical-surgical instruments. Therefore, the purpose of this publication is to facilitate the uniform application of practices that ensure the correct sterilization of these materials and equipment. The publication is targeted at the technical personnel who are responsible for these processes and, in turn, for guaranteeing the prevention of hospital acquired infections.

From within these pages, PAHO would like to extend an invitation for the critical reading of this manual, so that its implementation can be adapted to the different realities of health establishments. Each establishment should have written procedures that detail the processes that are used locally and that meet national regulations.

Thanks to the collaboration of the authors, Silvia Acosta-Gnass and Valeska de Andrade Stempliuk, this manual is available to bring about a positive impact on patient safety and on the safety of health professionals.

Jarbas Barbosa da Silva, Jr.
Area Supervisor
Health Surveillance and Disease Prevention and Control

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Contents

Introduction

Prior to World War II, the sterilization plant was the "right hand" of the operating room, the dressing room where primarily female hospital auxiliaries met to fold gauze and prepare bandages. During the postwar period, the need for a medical and surgical sterilization plant emerged in all hospitals. The plant's primary responsibility was the sterilization of instruments and devices, but with time, other functions were added (*Wenzel, R. 1993*).

Toward the end of the 1970s the following goal was proposed: the objective of the sterilization plant is to provide ***a service*** to improve patient care and maintain high standards of medical practice. It would also collaborate with hospital administration to protect personnel from infections or accidents, thus providing a safe environment for employees (*Wenzel, R. 1993*).

The sterilization plant plays a very important role in the prevention of hospital acquired infections, which have been associated with the inappropriate disinfection of reusable objects including endoscopic devices, respiratory care devices, transducers and reusable hemodialysis devices. There was a recent controversy concerning the reprocessing of expensive medical devices (for example, probes without lumen for cardiac electrophysiology) labeled by the manufacturer as "single use." If decision is made to re-use a disposable device, the responsible institution should demonstrate that the *safety*, *effectiveness* and *integrity* of the product have not been compromised in the process.

Sterilization plant services are also responsible for collecting and receiving the objects and devices used during patient care, and for processing, storing and distributing them throughout the hospital.

This manual has been published by the Headquarters of the Pan American Health Organization in order to inform health workers about the simple protocols and procedures that have been developed to prevent hospital acquired infections *inside* and *outside* the sterilization plant.

The guidelines included in this manual show the steps to follow in cleaning, preparing, sterilizing, storing and transporting hospital equipment so as to obtain sterile material. It is very important to be aware of this information in order to provide patients with safe health care.

Physical areas and personnel of the sterilization plant

The sterilization plant (SP), by definition, is the *service that receives, prepares, processes, controls and distributes textiles (clothing, gauzes, dressings), biomedical devices and instruments to all sectors of the hospital*, with the goal of providing a safe input to be used with the patient.

Advantages of centralization

The ***centralized sterilization*** system has the following advantages:

Efficiency: When duly organized, this system provides efficiency through supervision of the cleaning, maintenance and sterilization tasks. This system facilitates the standardization, uniformity and coordination of procedures since it requires the constant supervision of a person devoted to supervision.

Economy: A centralized service proves to be economical, since it avoids the duplication of expensive equipment (steam autoclaves, dry heat stoves, pouch sealers, etc). The life of the instruments is prolonged thanks to efficient manipulation (cleaning, preparation, sterilization) overseen by specialized personnel.

Safety: In the old decentralized sterilization systems (with unsupervised personnel), there was an increased probability of failures within processes. Examples include: materials exposed to improper sterilization methods (non-resistant elements exposed to high temperatures or destroyed due to processing by dry heat); or modification of the safety parameters of the process, such as an increase in the temperature of the process by using dry heat to empirically increase the safety of the process.

Infrastructure requirements

The SP has certain general requirements for all physical areas, which we will describe briefly:

Space requirements

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

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 cleaning and for filling the steam autoclaves, is recommended.

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 habitually used for cleaning.

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.

Ventilation

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 SP, since they generate high turbulence of dust in the air and microorganisms that are projected from the floor to the work tables.

Temperature and moisture

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

Sinks for washing instruments

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.

Fire extinguishing systems

The service should have at least two fire extinguishers based on CO_2 or ABC chemical powder in a visible, accessible location.

The physical areas of the SP are divided into: technical area (which has several spaces), administrative area and support area. Each area is physically divided and each one should maintain its integrity.

Technical area

Area for cleaning and decontamination of material (dirty area).

In the cleaning and decontamination area, the microbial load and organic matter of instruments and medical devices that enter for later processing are reduced. This area is separated by a physical barrier from the other areas of the SP (preparation, processing, deposit) and is easily accessible from an exterior corridor.

The importance of physical separation is based on the need to avoid the transport of aerosols, droplets and dust particles from the dirty to the clean area through air currents. This is key given that this sector generates a large quantity of aerosols (due to the type of work performed: brushing, ultrasound).

The floors, walls, ceilings and work surfaces should be constructed with non-porous materials that can tolerate frequent cleaning (daily, as a minimum) and humidity conditions.

All air from this sector should be expelled to the exterior without recirculation, thus preventing the introduction of contaminants that endanger the patient and personnel into clean areas.

The circulation of people is restricted and controlled and only adequately dressed personnel can enter.

This area should also have a compressed air terminal for drying elements with a lumen (catheter mount, trocars). Air should arrive clean and dry to the sector, which means that it should be treated appropriately with a silica gel air dryer or oil filtrate. Oxygen is also used for drying and is superior to other options since it does not present the moisture problems derived from compressed air. It is more expensive, however, in the form of cylinder containers.

This area should have negative air pressure relative to adjacent areas and should have an air extractor that functions continuously while working in the area (at a rate of 10 air changes per hour, with the air exit of air toward the exterior). Fans of any type should not be used within the area and windows should be closed permanently. If it is not possible to close the windows due to the heat produced by

the washing machines, ultrasound devices and hot water used to wash materials, windows should have a metal screen to avoid the entry of insects.

The environmental relative humidity should be between 35% and 50%.

Minimum necessary physical structure:

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.

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

The area for conditioning, packaging, preparation and sterilization of material should admit *completely clean, dry* objects. Here, instruments and devices are checked in order to safeguard their cleaning, integrity and functionality.

Transit of people should be strictly controlled and only adequately dressed personnel should enter the area.

Here, medical devices, boxes of instruments, clothing, etc. are prepared for the sterilization process.

Minimum necessary physical structure:

Washable floors and walls.

Bench made of washable material. It cannot be wooden.

Chairs.

Magnifying glasses for confirmation of the cleaning.

Sink for personnel.

Exit for compressed air.

Cabinets with doors to store non-sterile material and supplies.

Area for storage of material (sterile area).

The area for storing sterile material should admit only wrapped sterile devices or instruments, which should be placed on open shelves or in closed cabinets.

This area should be ventilated with at least 2 air changes per hour, with a temperature from 18 °C – 25 °C and environmental relative humidity between 35% – 50%.

All sterile packages should be stored at a minimum distance of 30 centimeters from the floor.

The transit of people is *prohibited* and only authorized, adequately dressed personnel should enter the area.

Minimum necessary physical structure:
Washable floors and walls.
Cabinets to store material after the sterilization process.
Prior to entry, a sink for personnel.

Administrative area

The SP should have an administrative area for carrying out administrative activities related to personnel and supplies that is adjacent to but separated from the technical area. Furthermore, all documentation generated by the SP should be kept in this area, such as: controls of sterilization cycles; controls of the number of materials, devices and supplies; personnel functions; and all other administrative processes of an SP.

Support area

The support area should be made up of, at a minimum:

A dressing area for changing out of street clothes and storing both clothes and personal objects.

A deposit area for chemical products, detergents and cleaning products. This area should have an additional sink to wash the accessories used to clean the environment.

Flow of material and personnel

Responsibility

All employees are responsible for maintaining and protecting each area for the function that was assigned to it and for respecting the established circulation.

Control of circulation

Access to the technical areas of the SP should be *strictly* for personnel that work in each area. Visits, technical personnel from other areas and suppliers should be received in the administrative area of the SP.

In order to have access to the processing area, every visitor or supplier should be dressed appropriately according to standards, including use of a gown, boots and cap, and accompanied by the person responsible for the SP.

Hospital personnel

Only authorized personnel should have access to the area for processing and sterilizing materials.

No individuals from outside of the service can enter the clean and sterile areas, unless the person has authorization from the Head of the SP and is appropriately dressed according to standards.

Material sterilized in another institution

The quality of the product used within a health institution is always the responsibility of the institution itself.

The quality of the material sterilized in another health institution can only be assured if the packaging is intact and with no stains or wrinkles.

In general, it is recommended that all material sterilized in another health institution be *washed, packaged and sterilized again*, unless there is knowledge and guarantee of the *process controls* carried out in the other institution.

Some health institutions outsource sterilization of their medical devices. However, it is the responsibility of the health institution to evaluate the quality of the sterilization processes by accessing the process controls carried out by the company in charge of sterilization.

Control and registration of the material from the sterilization plant

All medical equipment and instruments should be registered in order to control the process of reserves, maintenance and preventive substitution. Furthermore, certain characteristics of the material that enters or leaves the SP should be registered: type, quantity, conditions of conservation (if they are stained, oxidized or have operational deficiencies, etc.).

Boxes with surgical instruments should contain a description of the content in order to facilitate the work of organizing the boxes in the SP. They should be counted or reviewed in the operating room, before and after each procedure.

Human resources and training

Despite technological innovations in the arena of disinfection and sterilization with automated equipment, this equipment requires *trained operators* that should be informed about the sterilization processes they are performing (APEICH, 2003).

The centralization of cleaning and sterilization services from *the entire hospital* in the SP guarantees the quality of the processes, in addition to optimizing and economizing human resources and materials.

The number of SP employees will depend on the volume of the work carried out, but there should always be a minimum of stable 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 cleaning areas.

There should be an ongoing training program for all SP staff that includes: notions of microbiology; operation of equipment; principles of cleaning, disinfection and sterilization; selection and packaging of instruments; preparation of textile material; loading of autoclaves; control of processes; storage of sterile material; collection and distribution of material; and use of personal protective equipment (PPE).

Personal protective equipment

Personnel should work protected by PPE in order to critically prevent percutaneous and permucosal exposure to blood and other potentially hazardous materials.

Safe work practices, appropriate mechanics and engineering controls will also improve worker safety. Each type of activity requires a certain type of protection for implementation.

In the material cleaning and decontamination area, it is necessary to use the following PPE: eye or face protector; cap; mask; exclusive clothing; plastic apron; thick, long latex gloves; and rubber boots or waterproof footwear protectors.

In the material conditioning, packaging, preparation and sterilization area, the PPE will be divided by activity:

- For review of the cleaning and conditioning of medical instruments and devices, the following is necessary: simple latex gloves, cap and exclusive clothes.
- For professionals who work with autoclaves or stoves, the following is necessary: thermal protective gloves, cap and exclusive clothes.
- Other activities require a cap and exclusive clothes.

In the area for storage of sterile material, the following is required: exclusive clothes and a cap.

In the disinfection or chemical sterilization area, the PPE used will depend on the method used. See the specific PPE in the description of each method.

Hand washing

A measure that is important to diminishing environmental microbial contamination is that personnel meet adequate hygienic requirements for the functions they carry out.

Hand washing is the simplest, most effective method for stopping the spread of the infections

Always remove rings and bracelets; nails should be short and without nail polish; clothing or uniforms should have short sleeves. Hands should be washed with common soap or an alcohol solution, if they are not visibly dirty, on the following occasions:

1. When entering and leaving work.
2. Following contact with contaminated material, even if gloves or mitts have been used.
3. Before and after preparing instruments.
4. Before and after eating or drinking.
5. Before and after using the bathroom.
6. After removing gloves.
7. When passing from one area to another in the SP.

Hand washing with soap

Technique

1. If liquid soap is used, wet hands with running water.
2. If bar soap is used, pick it up with dry hands.
3. Apply soap and distribute it across the entire surface of hands and fingers.
4. Rub for at least 15 seconds away from running water.

5. Rinse thoroughly.
6. Dry completely with disposable paper towel.
7. Close the faucet with the paper towel.
8. Avoid the use of hot water, since it increases the risk of dermatitis.

Hand hygiene with alcohol solution

Technique

1. Apply a dose of alcohol solution (60% – 70% isopropyl or ethyl with emollients).
2. Distribute it across the entire surface of hands and fingers.
3. Rub until the skin on hands is dry.
4. The skin on hands *should not* remain wet with alcohol; if so, the asepsis was not effective.

In places where there is no water source or supply, alcohol solutions are indicated and achieve good antiseptic action. Below are four formulations of alcohol solutions that can be selected according to their convenience and availability at the health center.

Formulation for alcohol solution I

a. Ingredients:

96° Ethanol	833.33 ml
Glycerol 98%	14.5 ml
Hydrogen peroxide 3%	41.7 ml
Distilled or boiled water that has been cooled q.s.	1,000 ml

b. Technique:

In a 1,000 ml flask, add the ethanol, glycerol and hydrogen peroxide. Fill up to 1,000 ml with distilled or boiled water that has been cooled. Shake the flask softly in order to mix the content. Divide up. This formulation leads to the following final concentrations: ethanol 80% v/v, glycerol 1.45% v/v and hydrogen peroxide 0.125% v/v.

Formulation for alcohol solution II

a. Ingredients:

Isopropyl alcohol (99.8% pure)	751.5 ml
Glycerol 98%	14.5 ml
Hydrogen peroxide 3%	41.7 ml
Distilled or boiled water that has been cooled q.s.	1,000 ml

b. Technique:

In a 1,000 ml calibrated flask, add the isopropyl alcohol, glycerol, hydrogen peroxide and distilled or boiled water that has been cooled. Shake the flask softly in order to mix the content. Divide up. This formulation leads to the following final concentrations: isopropyl alcohol 75% v/v, glycerol 1.45% v/v and hydrogen peroxide 0.125% v/v.

Formulation for alcohol solution III

a. Ingredients:

Propylene glycol	161.3 ml
Glycerin	250 ml
Patent blue stain 1%	V drops
70° Alcohol q.s.	5,000 ml

b. Technique:

In a 5,000 ml flask, add one part of 70° alcohol, propylene glycol and glycerin and shake well until it is totally uniform. Complete the volume with 70° alcohol. Finally, add the stain and mix well until the color is uniform. Then, divide up.

Formulation for alcohol solution IV

a. Ingredients:

70° Alcohol	250 ml	1000 ml
Glycerin	8 ml	32 ml
Patent blue stain 1%	I drop	III drops

b. Technique:

In a 250 ml or 1,000 ml flask, add one part of 70° alcohol. Dissolve the glycerin in the alcohol. Complete the respective volume with 70° alcohol. Add the stain. Mix softly until the color is uniform. Then, divide up.

Utilization of hand washing products

- If the soap is in bar form, cut it into small pieces and discard after each use.
- If the soap is in dispensers, these should preferably be disposable.
- If the container is not disposable, it should be emptied every 24 hours and washed, rinsed and dried before filling it again with new soap. This practice is difficult to control and epidemics due to contamination of soaps in filled containers have been documented, even when the soaps are antimicrobial.
- Some common soaps have an added chemical agent that conserves the soap but does not have any type of antiseptic action.
- Sinks for hand washing should be deep and wide, with smooth, non-porous surfaces that are made of stainless steel insofar as it is possible since this is a high-quality material whose finish does not chip or split. It should also have rounded edges.
- Faucets should provide lukewarm water. If the temperature regulator is not centralized, they should have mixing valves since very cold or very hot water facilitates skin irritation.
- Towels should be made of disposable, resistant paper and placed in adequate dispensers that permit extraction or cutting without the need to handle the towels.

Cleaning of materials

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.

General principles of cleaning

Dirt acts by protecting microorganisms from contact with lethal agents (disinfectants, sterilizers), reacting to and inactivating cleaning agents.

Physical cleaning eliminates large quantities of organisms that are associated with dirt.

Safe cleaning practices are important to reducing the microbial load on the surfaces of medical devices. Manufacturer recommendations always need to be taken into account when devices are cleaned.

Handling of contaminated objects should be kept to a minimum.

A necessary requirement for cleaning is that each object be *completely disassembled* prior to beginning.

Factors involved in cleaning activities

- *Chemical energy: detergent*
- *Thermal energy: temperature*
- *Mechanical energy:* friction

Water

Water that contains dissolved minerals such as calcium, chlorine, magnesium and phosphates is called *hard water*.

When boiling this type of water, the aforementioned minerals will be deposited inside the washing or sterilizing container, forming a layer known as plaque or caliche.

This layer, which is composed of a type of calcareous stone, is not a good heat conductor and reduces the effectiveness of the washer or sterilizer since more heat will be needed to overcome this difficulty and therefore more energy

(either gas or electric) will be consumed.

This process also produces mineral deposits on the valves or filters, which will stop functioning correctly as a consequence of this action.

Water that does not contain minerals or only has a small number is called *soft water*.

Soft water and especially demineralized or distilled water does not cause calcium deposits and is *recommended* for cleaning materials.

Identification of the quality of softened water can be carried out by measuring the pH (which should be neutral) and conducting a chemical study to measure the level of salts, minerals and phosphates.

Selection of the type of water is very important for determining the type of washing.

Given the high cost of maintaining water treatment, soft water should be used in the cleaning process only in the final rinse of the material, in order to guarantee that all of the salt residues are gone and thus avoid damage to the material.

Cleaning products

There is no single cleaning agent that removes all types of dirt. Dirt includes a variety of ingredients: soluble in water, insoluble in water, organic and inorganic.

A cleaning product should carry out the following tasks:

- **Emulsification of fats**: This is the process in which fats are suspended in water.
- **Saponification of fats**: This is the process in which fats are made soluble in water.
- **Surfactation**: This is the process in which the superficial tension of water is reduced in order to permit greater penetration into dirt.
- **Dispersion** (defloculation): This is the breakage of dirt aggregates into small particles.
- **Suspension**: This is the process for maintaining insoluble particles suspended in water.
- **Peptization**: This is the rupture of proteins.
- **Water softening**: This is the removal of calcium and magnesium ions while maintaining their insolubility. Inorganic agents (sequestration) or organic agents (chelation) are used. These agents should sometimes be added to the product.

Detergent

This is a cleaner composed of an agent that diminishes superficial tension, a cleaning agent that is the active ingredient, or a chelating or sequestering agent.

***Considerations when selecting a detergent**:*

- Follow manufacturer recommendations for the type of dirt against which the detergent is effective.
- Follow manufacturer recommendations about the device or instrument to be cleaned.
- If a mechanical cleaner, such as an ultrasonic cleaner, is used, follow the recommendations for using the device.
- Take into account the degree of water hardness.

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.

Steps in the process for cleaning materials

- Reception
- Classification
- Prewashing or soaking
- Manual washing
- Mechanical cleaning (if there is access)
- Rinse with water
- Rinse with alcohol
- Drying
- Lubrication

Reception

This is carried out in the dirty (decontamination) area or red area.

Using a pass thru window, the materials and instruments should be confirmed in terms of number, state in which received and point of origin, and recorded in the respective registry.

Their entry will be recorded manually (in notebooks or forms) or through computerized systems.

During reception, personnel should use PPE (thick gloves, plastic apron, etc.) and use great caution to avoid dropping or spills.

Transfer of material between different services or areas should be carried out taking into account the necessary biosafety standards. It is important to consider that the transport cart should be used *only* to transport dirty or contaminated material.

Classification

After carrying out the reception of the material, it will be classified according to type of material, which can be:

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

Prewashing, soaking or decontamination of the material

Classification is followed by prewashing or decontamination. This is known as a physical process or method designed to reduce the number of microorganisms (bioburden) of an inanimate object in order to make it safe for handling.

It is important to mention that prewashing or decontamination is one of the principal tasks within the cleaning of articles and *precedes any other related task*.

This process is carried out by submerging the material in a tray or container that is perforated with an enzymatic detergent (according to the time recommended by the manufacturer) and then passing the material under a stream of running water.

Prior to every cleaning, materials should be completely disassembled.

The next step is the manual prewashing of the instrument or device, through submersion in a solution of enzymatic detergent 0.8% (see manufacturer recommendations) in running water whose temperature is not higher than 45 °C.

Then soak the device until all of the organic matter is dissolved and has been eliminated. *At least 1 minute* of soaking is recommended and the soaking time should be extended for devices with adhered organic matter. Materials that are non-stainless steel or carbon steel, and chromium plated materials that have lost their integrity (even if they have minimal erosion), *should not* be exposed to the enzymatic detergent for more than 5 minutes in order to prevent corrosion.

Thus, the removal and reduction of the bioburden are achieved through entraining, without any type of handling, so that the operator can carry out the

manual cleaning safely.

An issue that warrants mention is that in reality and in almost all cases, the material used in a procedure or during surgery is not taken immediately to the SP. This results in a bioburden (blood, organic matter or others) that dries and further hinders washing, particularly when it is carried out without adequate prewashing or soaking.

Once they are classified and prewashed (soaking or decontamination), articles will then be washed, taking into account their characteristics and uses.

Pour diluted enzymatic detergent solution (according to manufacturer recommendations) through all of the channels.

With a soft, non-metal bristle brush or a soft cloth and water at a temperature from 40 °C – 50 °C, mechanically clean all of the surfaces of medical devices.

Brushing should be carried out *underwater*. If it is carried out outside of the water, it will create aerosols that contain microorganisms and are dangerous for the operator.

After the thick dirt is removed, an ultrasonic cleaner can be used to clean the "difficult to reach" parts of an instrument. If an ultrasonic cleaner is not available, try to reach the more inaccessible parts with different sized brushes.

Surfaces should never be rubbed with household cleaning powders, abrasives, steel wool, metal sponges, wire brushes, etc., since these scratch and damage metals and increase possibilities of corrosion.

Do not spatter the physical environment or other people while carrying out the washing process.

Rinsing should be carried out only when the operator is certain that all of the dirt has been removed.

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 enzymatic 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.

Mechanical cleaning

Some centers may have the assistance of machines for mechanical cleaning. These could include:

- Ultrasonic washer
- Washer-disinfector
- Lavador-desinfectador

Manual washing and rinsing of the material

Washing machines should be in a *perfect state of hygiene* for their use, to be determined by the cleaning standards of the institution for each type of equipment. This is important since these machines often act as contamination vectors (biofilm) for the elements being washed.

Both the ultrasonic washer and the washer-disinfector carry out the complete process (wash, rinse and dry) within the chamber of the machine or in successive modules. This process can be considered safer since it avoids cuts and scrapes to personnel, water splatters in the washing area, etc.

When using washing machines (disinfector or ultrasonic), manufacturer instructions for installation and use should be followed strictly.

Ultrasonic washer

Action

Electric power is transformed into a high frequency sound wave and transmitted to the liquid by transducers located under the sink. The high frequency sound waves are converted into mechanical vibrations. Two types of waves are generated: high-pressure and low-pressure.

The low-pressure waves flow through the solution, causing the formation of millions of 0.001 mm microscopic bubbles on the surface and cavities of the instrument. The high-pressure waves cause the bubbles to expand until they become unstable and collapse.

The implosion produces localized vacuum areas that are responsible for cleaning the surfaces of the objects. This process is called cavitation.

Soluble particles are dissolved in the solution inside the tank, which includes a detergent that facilitates the process.

Insoluble dirt is deposited on the bottom of the tank.

Advantages

This process can clean dirt from areas that are inaccessible to manual cleaning due to the design of the equipment.

Disadvantages

The equipment requires preventive maintenance and attention to the operational procedure.

If the ultrasonic cleaner does not have a rinse cycle, loose particles can remain in the devices. These should be rinsed by hand.

Delicate objects can be damaged.

Considerations during ultrasonic cleaning

Ultrasonic cleaning cannot be used for optical instruments (because it removes glue from glass), rubber, PVC, wood, different types of metals at the same time, or metals and plastics at the same time.

This cleaning does not remove encrusted dirt. It is a supplement to manual cleaning.

The wave frequency utilized does not produce microbial death and if the cover of the tank is not closed, it can produce polluting aerosols.

Devices that go through ultrasonic cleaning should be aired out prior to cleaning, in order to eliminate all gases. Otherwise, the process of cavitation will decrease since gases will be introduced into the steam bubble, diminishing the energy of the implosion.

Technique

Elevate the instrument relative to the base of the tank by placing a rack on the floor of the tank.

The instrument should be open and the operator should make sure that larger-sized instruments do not produce “shade areas” over smaller instruments.

The water temperature should not be higher than 55 °C, since this would cause large instead of micro steam bubbles.

The established times are: 5 minutes for 20-25 KHz transducers and 3 minutes for 35 KHz transducers.

Increasing the amount of time is not favorable since the dirt tends to get re-deposited. The greatest percentage of dirt is removed in the first 15 seconds.

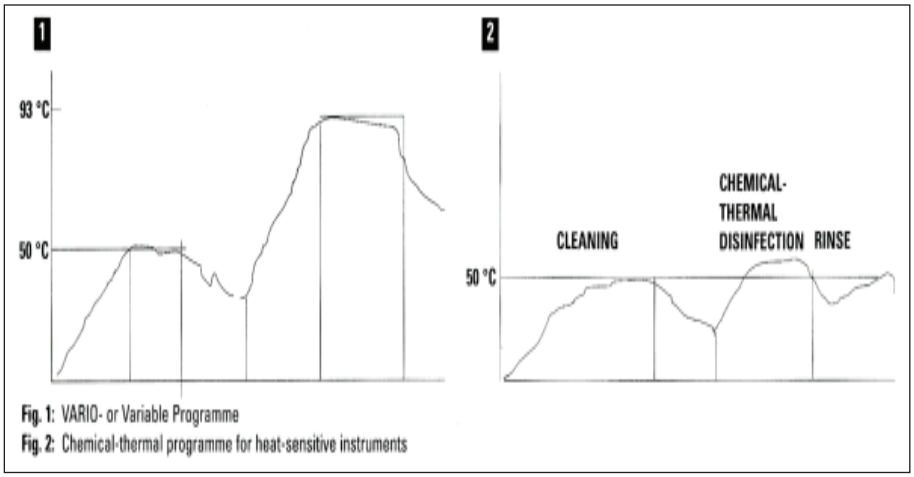
Washer-disinfector

Action

Ten minutes of a combination of detergent and water at 93 °C, and vigorous cleaning through *streams of water*, guarantee the cleaning and disinfection of articles. The cycle is divided into three stages: cleaning, disinfection and drying.

Disinfection (at 93ºC, maintained for at least 10 minutes) is carried out after repeated washings with detergent and water. It guarantees action that is bactericidal, fungicidal and tuberculocidal, inactivating viruses including Hepatitis B virus.

1. Cycle of the thermodisinfection process.



Adapted from http:/www.wfhss.com/index_en.htm

Advantages

This equipment facilitates the work routine and diminishes the contact of professionals with infective agents once the material is placed within the equipment and at the conclusion of the cycle, since the material will be clean and disinfected at that point.

Disadvantages

The equipment requires preventive maintenance and care during operation. If the machine does not have a dry cycle, the instruments and devices should be dried with compressed air. The latter increases instrument handling and possibilities of recontamination.

This can only be used for heat-resistant devices because thermosensitive material does not tolerate temperatures of 93 °C.

Water quality is important for guaranteeing the effectiveness of the process.

Considerations for the washer-disinfector

Surgical instruments or critical devices emerge ready for packaging and sterilization. Semi-critical devices (e.g., respiratory assistance) are ready for use at the conclusion of the process. This type of cleaning replaces manual cleaning.

The water used in the disinfection stage should undergo microbiological controls and should be free from *Pseudomonas aeruginosa, Legionella* and atypical mycobacteria.

Technique

Place the instruments in the equipment, making sure that all parts are in contact with the stream of water.

The instruments should be open and the operator should make sure that larger-sized instruments do not impede the smaller instruments' contact with the water.

The water should circulate freely throughout the machine.

Cycle

Cold rinse: water at 25°C, 3 minutes, 2 times.
Wash with detergent: see table below.

Type of detergent	Wash temperature	Exposure time
Alkaline	60 °C	5 minutes
Enzymatic	40 °C	10 minutes
Neutral	50 °C	7 minutes

Adapted from http:/www.wfhss.com/index_en.htm

Hot rinse: water at wash temperature, 3 minutes, 2 times.
Disinfection: water at 93 °C, 10 minutes, 1 time.
Drying: follow manufacturer recommendations for the equipment or validate the drying process.

Cleaning of special articles

Instruments have significant material value within a hospital's total investments. Thus, a series of recommendations should be taken into account depending on the material used:

Washing of metal materials

Cuvettes, drum trays, kidney trays, sinks, etc.

Manual washing

Any remnants of adhesive tape should be removed.

The materials should be placed in the sink with enzymatic detergent for the amount of time and at the dilution specified on the product's instructions.

They should be rinsed with abundant water, eliminating all residues from the detergent solution.

A final rinse should be carried out.

The corresponding brushing should be carried out if necessary.

The materials should be dried with a clean cloth.

Mechanical washing

The instructions for the washing machine should be followed. The operator should be sure not to overload the chamber with instruments in order to avoid problems when closing the doors.

Washing of surgical instruments

Tweezers, scissors, etc.

Before proceeding to wash the instruments, it is necessary to thoroughly check the instrument received according to its description (number of parts and state of conservation of each part).

It is sometimes necessary to open and disassemble tweezers.

The instruments should be placed in order at the bottom of the container made of metal or perforated plastic, starting with the heaviest one.

Manual washing

To carry out decontamination, place the instruments in a perforated tray and submerge them in a container with enzymatic detergent.

This container should be located in the wash sink.

Then put the container under the stream of water to eliminate the maximum amount possible of bioburden.

Proceed with brushing, placing special emphasis on the toothed bars and internal spaces of the tweezers.

Rinse with abundant water, eliminating all residues from the detergent solution.

Carry out a final rinse.

Dry the materials with a clean cloth.

Mechanical washing

Place the perforated trays in the washer-disinfector of instruments and turn it onto the automatic cycle, which varies according to the brand.

Once the manual or mechanical washing period is complete, place the instruments on the drying table.

Then, take the instruments through the pass thru window toward the clean or blue area for their preparation, conditioning and packaging.

Washing polyethylene, rubber, plastic and latex material

When washing polyethylene, rubber, plastic and latex material we should follow the following steps:

During washing, it is important to have cuvettes, trays, or perforated containers.

Remove any remnants of adhesive tape that are stuck to the surfaces (for example, adhesive tape) using cotton impregnated with white benzine.

Then submerge the material in an enzymatic detergent.

In the case of tubular-shaped material, use a 60 cc. syringe with a cone point to fill the entire lumen with the 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.

Let it drain into the environment and then dry.

If it is possible, use compressed air (less expensive) or drying chambers for corrugated materials that contain filtered air.

It is important to note that there are currently washing machines that are specially designed for washing material or devices with lumens such as endoscopes, bronchoscopes, etc.

The cleaning process for latex gloves is not recommended or mentioned since in recent years, various cost-effectiveness studies have demonstrated a high reprocessing cost. Moreover, mechanical reprocessing is difficult and this material is not made to be reused.

Washing of glass material, jars and syringes

Manual washing

Submerge the material in a solution with enzymatic detergent.

It should be taken into account 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.

Recommendations for the deep cleaning of material with accumulated dirt, organic matter and others.

Instruments that have a lumen, hinges, articulations and grooves run a greater risk of accumulating dirt or organic matter. Therefore, the immersion of these instruments in enzymatic detergent for a longer period of time than usual is recommended.

If surgical steel instruments accumulate carbonized organic matter through heat-based sterilization, varnish, minerals, or oxide stains, the use of an oxide and corrosion *removal solution* that is specifically for surgical steel is recommended. The active ingredients in this solution are phosphoric acid and ether-propyl-glycol.

It is also recommended that this activity be programmed regularly, according to the specific needs of each material.

Rinse with 96° alcohol

After exhaustive rinsing with water, rinsing the material with pure alcohol (96°) is recommended, especially hollow, tubular, corrugated, etc. devices.

The purpose of this rinse is to increase the drying speed.

Drying the material

Drying instruments, devices and other hospital use articles constitutes a fundamental part of the cleaning process.

It is very important to dry the instruments immediately after rinsing, in order to prevent later contamination.

When drying materials, it is necessary to take into account the degree of moisture of the articles, since it could interfere in the disinfection or sterilization process.

Drying can be manual and automatic.

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.

Automatic drying should have a specific tube for each lumen.

The principal advantage of automatic drying is the speed of the process, which reduces work time and costs.

At present, special chambers for drying tubular and corrugated materials are available. The cycle lasts approximately 25 minutes to 2 hours, depending on the type and amount of materials to dry.

The specific connection should be taken into account for different lumens.

Different lumen materials can be placed in the drying chamber, always ensuring that that they have the same characteristics.

Lubrication

Following cleaning, instruments can become rigid and difficult to manage and present stains or other imperfections. This is why lubrication after cleaning and before sterilization is important.

This is only carried out for 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.

Validation of the cleaning process

The process to validate the cleaning carried out can be done through:

- verification of compliance with procedural guidelines (protocols)
- visual inspection after the process, and
- the presence of implemented water irrigation systems.

The validation of the cleaning process is subjective given that it is not possible to visualize the bioburden (defined as the number and type of viable microorganisms that an article contains after cleaning) of each article and for each cleaning procedure.

Thus, it is important to adopt cleaning protocols that seek to standardize the validation of this process.

When validating the procedural guidelines (protocols), data on the following should be clearly indicated: dilution of the products used; length of immersion time; mode of rinsing; and the technique that should be used to disassemble the articles and instruments.

Furthermore, an important part of validating the cleaning process is visual inspection after washing, when the operator should carefully observe whether there are any signs of dirt, particularly in toothed bars.

If there is any doubt in this regard, a magnifying glass is useful.

Another indispensable requirement for validating the cleaning process is that the red area be equipped with water irrigation systems with pressurized devices for articles with lumens. Without these devices, optimal and safe cleaning cannot be achieved.

In addition, there are chemical controls to validate the effectiveness of mechanical cleaning: the visible dirt test and the disinfection test.

The visible dirt test uses a powder reagent that simulates blood when mixed with water. This reagent is applied to the instrument in order to visualize possible organic matter residues.

In the clean area (blue area) / area for material preparation, it is important to have a magnifying glass for visual inspection.

Validation of functionality

Both the hygiene and functionality of the device or instrument should be controlled. Once dry, do a thorough inspection of the material by:

- Cleaning
- Drying
- Functionality of closures
- Absence of cracks or tears (for glass material, clothing and instruments)
- Absence of lint or fibers
- Correspondence of parts (arm/piston; body/cover)

The medical device is now ready for high-level disinfection or sterilization.

Important

- Discard the solutions when used or when visibly dirty.
- Rinse the solution into the drain with abundant water.
- Do not use to store devices.
- Take into account that the enzymatic detergent should be used together with PPE because it irritates the eyes and skin. It is also toxic when inhaled (therefore an exhaust fan should be used continuously) and harmful if ingested.
- Store the enzymatic detergent at a controlled temperature (15 °C – 30 °C). Avoid excessive heat (more than 40 °C). Rinse the container well before discarding.
- Use it prior to the expiration date (see the lower part of the container).
- Cleaning brushes, once used, should be disinfected at the end the day. Disinfection can be carried out using a sodium hypochlorite solution (1:10) for 15 minutes.
- Personnel who work specifically in cleaning are fundamental to its success. They should be neat and meticulous.
- Personnel should be vaccinated against Hepatitis B.

Preparing and packaging materials

Every article to be sterilized, stored and transported should be packaged in packaging that is selected to guarantee the sterile conditions of the material processed.

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.

Preparation of materials, packaging and methods

Once articles are processed in the red (contaminated or dirty) area, they will be taken through the pass thru window to the blue (clean) area according to the condition and use for their preparation.

This stage includes the inspection and verification of the articles, selection of the packaging, packaging of the article, sealing and labeling of the package, and evaluation of the package.

Inspection and verification of articles

The inspection and verification of articles should precede the preparation stage in order to detect deficiencies in the cleaning process, as well as the conditions of integrity and functionality of the articles.

In order to complete this activity and avoid the contamination of the materials, thus guaranteeing that they are in perfect conditions for use, personnel should use a cap and latex gloves and have a well-illuminated environment, lubricants and a magnifying glass.

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 that are 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.

General principles of packaging

This refers to objects that are sterilized and later stored, such as instruments, drapes, accessories, or devices.

The purpose of any type of packaging system is to hold these objects and protect them from contamination by dirt, dust and microorganisms.

The package should preserve the sterility of its content until the time it is opened, which is when it will be used in a sterile area.

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.

The packaging material selected and used should maintain the sterility of the package contents after sterilization.

The preparation and conditioning of packages should be carried out in such a way that the sterilization process is effective (e.g., the sterilizer [ethylene oxide, steam or dry heat] should have the capacity to penetrate the package and make contact with the object to be sterilized).

The objects should be packaged in such a way that the wrapping can be opened and the object removed without contamination and while maximizing the convenience of the user.

The preparation and content of a package should respond to the need for use, ease of use and safety of the procedure.

A package should contain the necessary amount of material for a single procedure or visit.

A package should be designed to permit the easy use of its content, in terms of its size, internal arrangement, aseptic opening, etc.

Packaging materials

Factors to take into account when selecting the packaging material:

- It should meet national and/or international standards or another regulation that is in effect.
- It should be adequate for the method of sterilization used and should permit the penetration of the sterilizing agent.
- It should be a reliable biological barrier and should not be a vehicle for bacteria.
- It should be durable.
- It should be efficient when used.
- It should have integrity.
- It should be resistant to abrasion, breakage and moisture.
- It should be water repellent.
- It should be liquid-resistant.
- It should be easy to open.
- It should be flexible.
- It should be free of even the smallest perforations.
- It should be free from toxins or stains and should not release lint or fibers.
- It should not react with the sterilizing agent.
- It should be permeable to the sterilizing agent.
- It should not react with the material that will be packaged.
- It should not release any type of odor.
- It should be inexpensive and readily available.

The use of the following should be prohibited:

- Metal drum trays.
- Newspaper.
- Packages made from recycled material.

Criteria for selecting a packaging system

Since the market offers many products, it is necessary to first evaluate and select the product that fulfills the majority of needs.

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.

The following criteria can be helpful when choosing a suitable, efficient packaging material.

Porosity / permeability

The packaging material should make it possible for the sterilizing agent to penetrate and leave the package while also providing a highly effective bacterial barrier.

The flow of air or permeability is expressed in ***liters per minute every 100 cm²***. Air flow is necessary for ensuring the sterility of the contents in the package. A lower measure is equivalent to lower air flow and a higher measure means that the result will be better (more sterile).

Good penetration of steam and ethylene oxide, for example, allows the achievement of improved sterility conditions in the materials. On the other hand, kraft, crepe, parchment and other similar types of paper are closely woven and do not allow adequate flow of the steam or gas used.

A very simple test is to exhale cigarette smoke through an unwoven cloth and repeat the experience with a piece of paper. This will make it possible to observe the differences.

Strength

The factors that should be considered for measuring the strength of a certain type of packaging for sterilization are three: **resistance to bursting**, **tearing** and **abrasion**.

Burst resistance refers to possible punctures or pricks produced by the corners of instrument trays or packaged instruments.

Burst resistance is measured through the Mullen Burst Test. This test uses an apparatus with an expansive 1 ¼ rubber diaphragm that pushes the material upward progressively until it, literally, bursts. The pressure required is measured in pounds per square inch (PSI). Higher values correspond to better resistance by the material.

Tear resistance is not as important as burst resistance since the tests of tear resistance (Elmendorf Test) only measure the strength that is necessary to apply

in order to propagate the tear, but once the tear has already occurred.

Abrasion resistance, on the other hand, is very important in two aspects: the resistance that the material offers to abrasion; and lower release of lint or microparticles. If the sterilization packaging wears away with friction, the material weakens and is more vulnerable to holes and tears.

Lint or particles

A product or material that does not release lint should be selected. Lint microparticles should be minimized in areas where patients undergo surgical procedures.

Sterilization packaging made from materials with high lint release is a potential risk for patients since lint serves as a vehicle for transmitting microorganisms. If lint penetrates a patient's critical tissues, it will cause a foreign body reaction. If it penetrates the bloodstream, it can cause an embolism.

As mentioned earlier, abrasion is an important source of lint. Another source is the mechanical extraction of fibrous elements. For example, removing the tape that seals the package produces lint release. The ideal is a material that has a *zero coefficient for microparticle or lint release*.

Repellency

Sterilization packaging should be repellent to liquids such as water or saline solution. This is in order to prevent its penetration by liquids and to maintain the sterility of the contents.

The normal test to measure the degree of repellency is the Mason jar test, which simulates critical use. The capacity of penetration by liquids into the material is tested by placing saline solution in a glass jar (mason jar) and covering the mouth of the jar with the material being examined. The bottle is then inverted over a glass base and the *time required by the liquid* to penetrate the material is measured.

A longer amount of time, measured in minutes and seconds, is equivalent to a more efficient protective barrier. At least *30 minutes* are required in order to be considered acceptable.

In addition to *water* repellency, the packaging should demonstrate resistance and repellency to *alcohols*. This aspect should be considered since the most commonly used solutions in hospitals contain alcohol.

A very common procedure consists of placing three drops of an alcohol solution on the material. After five minutes, the material is observed to see if there

has been penetration. The initial solution *should not* contain alcohol; then it should increase by 10% alcohol for every five minutes of exposure.

Alcohol repellency is measured in the solution with the highest percentage of alcohol that *does not penetrate* the cloth within a period of five minutes. A solution with *70% alcohol* (range 7) for *five minutes* is considered acceptable.

Memory

Once the package has been processed and is ready to be opened in the sterile area, the opening process should be both easy and maintain the asepsis of its contents. All packaging has memory, or the ability to remain where it is placed. During its opening, the extremes of the packaging should remain where they are placed, without the edges caving in onto the content of the package (bad memory).

Ease of handling

Unwoven packaging materials should be easy to handle during all of the processes related to their use. The material should be soft, ductile and permit packaging without resistance. Softness is important for preventing irritation of the skin of the professional who handles many packages per day. Materials that are hard and have low ductility have sharp edges that can cause small cuts, which constitute a source of contamination both for the professional and for the patient.

Types of materials used and instructions for use

The type of packaging should be selected according to the required sterilization method. At the global level there is no doubt that in order to package biomedical articles, *only* products manufactured for this purpose *should be used.* This refers to products that meet the conditions for being considered *medical grade*.

As mentioned earlier, it is very important *to eliminate the use* of: drum trays, newspaper, and recycled paper made from mixtures that are uncontrolled and of very low quality.

Sterilization packaging is classified according to its origin or manufacturing as medical grade, non-medical grade and rigid container materials. Within these different types, there are materials that are disposable and others that are reusable.

The term *medical grade* is used by the sterilization packaging industry to designate materials that are specially designed for packaging and whose preparation is standardized. This type of packaging has a controlled porosity no higher than 0.5 microns and water repellency.

For packaging that is not medical grade, its preparation is not standardized and it may not fulfill the principal characteristics required for ensuring the sterile conditions of articles. Usually this type of packaging does not have quality assurance with respect to controlled permeability, resistance or porosity given that it was not designed specifically as sterilization packaging. Therefore, it may not constitute an adequate barrier. This refers to materials made of natural woven fibers such as cellulose, cotton, linen, or a mixture of cotton and polyester.

Woven cloths

Appropriate cloths are those made of cotton and cotton with polyester with a count of 55 threads/cm^2 distributed in the following way: warp, 28 threads/cm; weave, 27 threads/cm; total, 140 threads/inch^2, 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^2) 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^2) 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^2) 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.

Given that this type of material is susceptible to deterioration and experiences changes when used, it should be rigorously examined prior to each use. In the case of holes or tears, adhesive patches should be used. Mending is not appropriate since it may alter the weave and allow the passage of particles.

It should be taken into account that textile material is not water repellent, which means that precautions to avoid moisture should be maximized by securing and protecting the packaging with a plastic cover if it is going to be stored for a

long time. The cover also constitutes protection from penetration by dust.

Unwoven cloths

These cloths are a combination of cellulose and synthetic fibers or 100% synthetic fibers joined by methods other than traditional weaving. They are joined by the fusion of fibers and resins that are later dried. They are disposable, compared to reusable cloths, eliminating the need for washing and inspection.

Instructions for use:

Unwoven cloths are resistant to liquids and have good penetration by steam and ethylene oxide. Since they can retain moisture, the drying time should be increased.

Paper

It is important to discuss all existing types of paper and which ones are appropriate for the sterilization process.

Wrapping paper

This material is used for sterilization by steam autoclave. 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 it composition.

Newspaper

Newspaper is of very poor quality. The ink resins mask spores and contain toxic salts (Pb and Hg). Furthermore, newspaper has very little resistance to tears and stains.

Recycled papers

This includes sulphite and wood paper, which are both of similar quality. Preparations are made of paper that is recycled and bleached with sodium sulphite (Na_2SO_3). During preparation, the pH, moisture, starch concentration (microbial food), resistance to tearing and porosity are all uncontrolled.

Kraft paper

White, monolucid kraft paper is made from cellulose. The difference with wrapping paper is that kraft paper has controlled porosity and its manufacture

is standardized with regard to additives, water repellency and resistance. It is a paper with high mechanical resistance, obtained from the chemical paste made of bleached wood.

The accepted grammage is 60 to 80 g/m^2, with a moisture of 8%. It has a porosity of less than 0.3 micras, which means that it represents a good antimicrobial barrier under adequate storage conditions. It has a rough side (exterior) and a glossy side (interior), which means that it does not release lint.

The term "kraft paper" only applies to the material that brings together the aforementioned characteristics, as certified by a regulatory agency.

Instructions for use:

Double wrapping is recommended. It can be used for steam and ethylene oxide. It is a better barrier than muslin. It wrinkles easily. It should not be reused.

Surgical grade or medical grade paper

This is the ideal paper for the sterilization process. Its porosity of 0.1 micras is controlled. It should have no less than 55% long fibers (the rest are short fibers) made of pure cellulose (British Standards 6255:1989).

Optical bleaches are not added during the preparation of this paper. The grammage is 60 to 65 g/m^2, its pH is neutral and it is highly resistant to tearing. 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^2 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, but its capacity for protection decreases in successive sterilization processes.

Instructions for use:

It can be used for steam and ethylene oxide. It should not be reused.

Surgical grade crepe paper

This paper is made with cellulose paste and has a porosity of 0.1 micras, a grammage of 60 to 65 g/m^2 and neutral pH. It is used instead of cloths to prepare high-volume packaging. Its characteristics of flexibility and resistance make it adequate for this use. Its characteristics have been defined in British Standards (SW 6254:1989). It is accommodative, liquid repellent, does not release lint,

does not irritate the skin, is resistant and does not have memory.

Instructions for use:
It can be used for steam and ethylene oxide. It wrinkles easily. It should not be reused. It is used most commonly as the inner wrapping of packages.

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.

Rigid containers
There are a wide range of containers on the market with different characteristics and compatible with different sterilization methods. They should be used according to manufacturer instructions.

They can be made from aluminum, stainless steel, plastic, or plastic-metal combinations. Some contain bacterial filters and others have valves that provide a biobarrier. They are very effective since they do not break, do not release fibers, do not become contaminated, and are easily transported.

Rigid containers without filters
These include closed stainless steel boxes that transmit heat through conduction.

Instructions for use:
These are used exclusively for dry heat.

Rigid containers with filters
Rigid containers, in order to be compatible with other sterilization methods, should be perforated. Some of these perforated containers have an incorporated filter that

permits their use without exterior packaging. These filters should be examined and replaced periodically according to manufacturer instructions in order to ensure their effectiveness.

Perforated containers without an incorporated filter should be packaged externally with packaging that is compatible with the selected sterilization method.

Instructions for use:
These are used for steam.

Polymers
Polymers are an absolute barrier against microorganisms and dust. Therefore, storage using these materials as a barrier can be very prolonged. Since they are transparent, they are also useful for visualizing the contents. There are various types:

Polyethylene
Since this is a thermolabile material, it can only be used at low temperatures. It is useful for ethylene oxide or ionizing radiation. The most adequate is low-density polyethylene (0.076 mm). A problem arises during its use since it is a material that is waterproof, which impedes the humectation of the material when sterilized by ethylene oxide (moisture is an essential factor in this process). The entrance of water (in the form of steam) into the package being sterilized by ethylene oxide would be solved through the use of a Pouch, also called a peelable bag or window package. The Pouch consists of one folio (film) side and one paper side. The folios are made using a pure petroleum base as raw material (non-chlorinated, as is the case with PVC), which means that they can be burned or stored since they do not produce dioxanes or furans. The folio behaves neutrally in groundwater in rubbish dumps and does not release toxic substances during thermal elimination. The folio is waterproof to liquids, air and gases and therefore blocks bacteria.

Film bags of medical grade polyethylene
These are temperature-stable and permeable to steam, but they do not tolerate vacuum gaps.

PVC (Polyvinyl Chloride)
This material is not recommended since it is labile to temperature and to ionizing radiation, forming ethylene chlorohydrin (a non-volatile fixed substance) as a response.

PVC absorbs large amounts of ethylene oxide and eliminates it very slowly. For example, the time needed to eliminate the substance at room temperature is 1 to 2 weeks. It is not recommended as packaging for sterilization.

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 140 °C – 150 °C). Since they can retain moisture, the drying time should be increased.

Polypropylene is the packaging of choice for sterilization with hydrogen peroxide plasma.

Nylon (poliamide)

This material is temperature-stable and permeable to steam, but does not tolerate vacuum gaps. Therefore, it breaks when used in steam autoclaves. It is not appropriate for sterilization by ionizing radiation. It has low permeability to ethylene oxide. There is a poliamide that tolerates up to 180 °C and can be used with dry heat.

Tyvek®

This material is a synthetic polymer and a spunbonded olefin that is made essentially of polyethylene fibers in a sheet that is similar to paper. It has excellent shielding characteristics. Its mechanical stability is high and it does not release fibers when opened. Its porosity is controlled for permeability to air, ethylene oxide or any other sterilizing gas. It is moisture resistant. It is durable and flexible at -73 °C. It shrinks at 118 °C and melts at 135 °C. In general, it should not be used above 65 °C.

This material is optimal for gas sterilization: it leaves 100 times less EtO and formaldehyde after sterilization, which reduces the desorption time. It is a material with a never-ending amount of polyethylene fibers. It is impermeable to water and alcohol, can be heat-sealed and has an incorporated chemical indicator. The heat-seal temperature is lower than 120 °C. Correct sealing will be opaque and non-transparent.

Instructions for use:

This is the packaging of choice for sterilization with hydrogen peroxide plasma. It is also compatible with sterilization by ethylene oxide.

Packaging selection and evaluation

The procedures for packaging selection should be in accordance with the sterilization methods available in the establishment. Before incorporating new packaging, there should be an evaluation and validation with regard to compatibility, ease of use and cost/benefit of the material at the local level.

A program for continuous supervision should exist in order to evaluate packaging options. The supervision should confirm the integrity of the external layer, the integrity of the seals, compatibility with the sterilization method, the chemical indicator gauge, and the expiration date.

Type of packaging recommended for each type of sterilization process

Packaging	Moist heat	Dry heat	Ethylene oxide	Formalde-hyde	Hydrogen peroxide plasma
Metal boxes or containers, WITHOUT perforations, with hermetic cover	NR	R	NR	NR	NR
Metal organizer boxes WITH perforations	R	NR	R	R	R
Metal organizer boxes with filter	R	NR	R	NR	R *
Plastic boxes WITH perforations and heat-resistant	R	NR	R	R	R
Plastic organizer boxes with filter and heat-resistant	R	NR	R	NR	R *
Glass jars with hermetic cover	NR	R	NR	NR	NR
Glass jars and tubes with gauze and paper stopper	R	NR	NR	NR	NR
Medical grade paper	R	R	R	R	NR
Double-sided bags (pouches) with medical grade / polyethylene paper	R	NR	R	R	NR
Muslin: 140 threads/inch^2 or double cotton	R	NR	NR	R	NR
Polypropylene and polycarbonates	R	NR	R	R	R
Poliamide	NR	R	NR	NR	NR
Crepe paper	R	NR	R	R	NR
Tyvek	NR	NR	R	R	R

Adapted from APECIH 2003-2 Ed. and http:/www.wfhss.com/html/educ/educ.php
R: recommended. NR: not recommended. * : Boxes with filter lacking cellulose or cotton

Packaging techniques

An adequate packaging technique provides adequate protection, identification and maintenance of sterility, in addition to facilitating transport, management by the user, and opening and transfer of the sterile material with aseptic techniques. All of these enable safe utilization.

Conditioning materials for sterilization

Materials	Conditions
Clothing	Not compressed. In equipment for clothing, what will be used first will be placed on top. Prepare with surgical fold. Do not overload. Maximum size 30x30x50 cm. Maximum weight 3 kg.
Thermosensitive plastic tubes	Sizes over 45 cm., place in spiral form.
Rubber tubes	Sizes over 45 cm., place in spiral form, but first moisten the lumen with distilled water.
Glass syringes	Separate arm and piston. Optional: assembled, if sterilized with dry heat, but monitor the heating times for the material.
Talcum	In small envelopes of 1 or 2 grams.
Vaseline	In glass jars with hermetic cover. Maximum quantity: 30 grams.
Oils	In neutral glass jars with hermetic cover. Maximum quantity: 30 grams.
Test tubes	When sterilized with moist heat: use gauze stopper and paper cap. When sterilized with dry heat: use with corresponding cover that is hermetic and heat-resistant.
Gauzes	For surgery: the fold should be made maintaining the edges inwards, without leaving loose threads and lint. Design the necessary measures. Prepare them with hydrophilous gauze.
Dressings	Prepare them with hydrophilous gauze and cotton.
Aqueous contents	Load to only 70% of the capacity of the container. With semi-open hermetic cover and paper cap.
Boxes of instruments	Do not overload. Maximum weight 3 kg. Arrange internally for surgical use.

Elements used for packaging

Packaging material to use:

- Adhesive tape with external chemical control according to the sterilization method to be used.
- 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.

Packaging models

The manual preparation of the following models is recognized worldwide for the packaging of medical use products in the SP:

- **Envelope type**: This type is for small, rounded and light elements. The opening is made on the operator's hand.
- **Rectangular type**: This type is for large and heavy elements (boxes of instruments and packages of clothing). The opening is made on the table.
- **Paper bags**: There is a considerable range of sizes, all of which need to be folded and sealed with tape or heat-sealed by machines. They should be made of medical grade paper, with bellows that facilitate aseptic opening, have a glossy interior side. If it has a printed chemical witness, it should be indelible to steam. The adhesive part of the bags should be resistant to sterilization processes.
- **Pouch or window package** (paper - film): consists of a transparent folio or film front side that is sealed to the paper using heat. The folios can be made from polyester and polyethylene, or polyester and polypropylene.

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. If packages of 25 x 25 x 20 cm are used, exposure and drying times can be reduced. The weight should not exceed 4 to 5 kg.

For sterilization by dry heat:

Metal boxes should not contain more than 30 articles. It is not recommendable to use boxes made from common aluminum, since they can release aluminum particles into the instruments at high temperatures.

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.

Pouch or window package

- These packages should only be filled to ¾ of their capacity. Otherwise, effective sealing cannot be carried out and the container will be at risk of bursting.
- Regardless of the sterilization method used, recall that when adjusting the pouches or packages in the sterilization chamber, each polymer side should be placed against another polymer side, since the exchange of air, steam, or gases happens only through the paper.
- One precaution related to sealing is that in the case of a very high resistance by the sealing cord, there can be problems opening the bag and possible bursting of the package. Do not forget to always confirm the sealing cord and reduce its resistance by lowering the temperature of the seal.

Sealing

The purpose of hermetic sealing is to maintain the sterility of the content of the packages after the preparation, sterilization, storage and distribution processes, both prior to and at the moment of use.

The sealing of the package should be very secure and avoid any type of opening.

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

Do not use the following for sealing:

- Clasps
- Pins
- Other sharp elements

All of these elements could break the package.

Materials and machines used in heat-sealing

- Mixed or simple packaging with polyethylene
- Adhesive tape with an external chemical control
- Internal chemical indicator or integrator
- Machine sealer

Practical recommendations

- Observe the integrity of the package by looking for wrinkles and burned areas.
- The sealer should be regulated at an adequate temperature level for effective sealing.
- When carrying out the sealing process, allow a minimum margin of 3 cm. from the edges of the package in order to permit later aseptic opening of the package.
- Sealing of paper and folios (film) made of plastic or polyethylene should guarantee the hermetic seal of the packaging.
- There are two types of machines for sealing materials for sterilization: manual and automatic.

Identification or labeling of the package

The labeling should be clear, easy to interpret and familiar to the users. It can be:

- Manual
- Mechanic

Mechanical labeling is carried out by machines or templates that are produced for this use.

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)

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

Adequate labeling of the package allows for identification of the contents, storage and expiration period. It also enables the tracking of sterilized packages in the event of technical problems with the device or an infectious event that is attributed to deficiencies in the sterilization process.

Adhesive labels or adhesive tape (masking tape), a bar code or a manual label maker can be used.

A registration system for the storage and distribution of articles should be developed and all users should be knowledgeable about the system.

Evaluation of the packaging process

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

The timing and human resources (external auditors) for evaluation of the packaging process should be established.

Opening techniques

Double fold of paper or cloth

When removing the product, we should avoid the contamination of the external face of the interior container.

This position has consequences for the extraction technique in the operating room.

The instruments should not rub the external face of the container.

The exterior container or second packaging should be opened by the assistants of the instrument handler, who will touch only the sterile material.

One of the most common ways to contaminate the interior container, when opening the exterior one, is by dragging the powder from the flaps of the external container.

What causes pouch holders to break?

- A container that is too small for the dimensions of the material can cause breakage since this exerts pressure on the sealing cord and opens the pouch.
- A very profound vacuum gap during sterilization can cause the holder to burst.
- Packaging of textiles in pouches tends to break these holders because textiles retain air for longer in the pouch. When the vacuum gap is broken, the container swells like a balloon and can break. It is for this reason that it is advisable to use only paper containers since they are completely permeable to air. In the case of the pouch, only the paper face – which makes up 50% of the package – is permeable.

Issues to take into account

- Never use metal clasps since they perforate the packaging that protects the material.
- When paper-paper (entirely paper bags) or paper-plastic (pouch or window package) are sealed, fibers can be released during opening and produce adverse reactions if they make contact with human tissue. As a result, a great deal of attention should be paid when opening these packages.
- The ideal situation is to leave a flap to make opening more practical.
- The seal of the package should always be inspected prior to sterilization and immediately prior to opening in order to evaluate its integrity.

Basic guidelines for disinfection and sterilization

All instruments that are used during a specific procedure in a patient need to be sterilized or disinfected. Therefore, it is advisable to identify different types of instruments according to their use and determine the steps for managing the different groups.

Guideline criteria for disinfection or sterilization

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:

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.

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.

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.

Classification of medical instruments for their correct processing and use in patient care

Classification of objects	Examples	Method	Procedure
Critical They penetrate sterile tissues, including the vascular system and normally-sterile cavities.	Surgical and treatment instruments. Vascular, skeletal and other prostheses. IV and angiography catheters. Urinary catheters, syringes, needles, forceps, implants.	Autoclave or poupinel sterilization; ethylene oxide with sterilization and aeration equipment. Use before the expiration time. Chemical and biological controls according to standards. Continuous maintenance and review of equipment.	Sterile technique: Sterile drape, gloves and cloths. Sterile instruments and materials in individual packages. Hand washing before and after the procedure.
Semi-critical They come into contact with mucous membranes and non-intact skin. They should be free from vegetative bacteria.	Respiratory assistance devices. Anesthesia devices. Endoscopes, laparoscopes, bronchoscopes, endotracheal cannulas, probes, aspiration tubes; tongue depressor; rectal thermometers.	Sterilize (if possible) or high-level disinfection.	Aseptic technique: Hand washing before and after the procedure. Separation of aseptic area and contaminated area.
Non-critical They only come into contact with healthy skin.	Phonendoscopes, sphygmomanometers and sleeves, as well as objects for patient use: glasses, plates, silverware, bedpans, urinals and bedclothes.	Intermediate-level and low-level disinfection. Personnel are informed about cleaning and disinfection standards, which are always available for their review.	Concurrent disinfection (daily) and terminal disinfection (at discharge of patient). Separation of clean objects and materials from dirty ones.

Disinfection

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 orthophthaldehyde, glutaraldehyde, peracetic acid, chlorine dioxide, hydrogen peroxide and formaldehyde, among others.

Intermediate-level disinfection (ILD): This is carried out using chemical agents that eliminate vegetative bacteria and some bacterial spores. This includes the phenol group, sodium hypochlorite, cetrimide and benzalkonium chloride.

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.

Factors that affect the effectiveness of the disinfection process

- **Quantity and location of the microorganisms**. As the bioburden increases, the amount of time that a disinfectant needs to act also increases. Therefore, it is fundamental to carry out a scrupulous cleaning of the instruments' surfaces. This holds particularly true for instruments with multiple components, which should be disassembled and cleaned part by part.
- **Resistance of microorganisms to the chemical agent**. This refers primarily to the spectrum of action of the method or agent used.

- **Concentration of the agents**. This refers to each agent's potential strength to produce the expected action. Concentrations vary with respect to disinfecting agents and can be related in some cases to a deleterious effect on the material (corrosion).
- **Physical and chemical factors**. Some disinfectants specify the temperature at which they need to be used in order to be effective. The pH level favors the action of disinfectants.
- **Organic matter**. The presence of organic matters such as serum, blood, pus, stool, or other organic substances can inactivate the action of some disinfectants and compromise their effectiveness.
- **Duration of exposure**. Each disinfection method and agent is associated with a specific amount of time that is necessary for achieving the desired result.
- **Presence of extracellular material or biofilms**. Many microorganisms produce thick masses of cells and extracellular material or biofilms, which generate a barrier against the disinfection process. For this reason, disinfectants should first saturate the biofilms, in order to eliminate the microorganisms they contain.

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.

Boiling

This method uses boiling water at very high temperatures to achieve disinfection. For example, during HLD instruments are boiled in a covered container for 15 to 20 minutes, measured from the time the water starts to boil. The objects should be covered completely by the boiling water and no other objects should be added while it is boiling. The heat should be low, since high heat causes

objects to bounce, decreases the water level and consumes more gas. The use of longer boiling times is recommended for locations at high altitude above sea level. Objects should be air dried or dried with a sterilized towel before reusing or storing them. This method is not used in the hospital environment.

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.

Ultraviolet radiation (UV)

This method inactivates microorganisms in the range of 240–280 nm. It acts through the denaturation of nucleic acids, but its effectiveness is influenced by factors such as the potency of UV tubes, presence of organic matter, wavelength, temperature, type of microorganisms, and the intensity of the UV, which is affected by the distance and dirtiness of the tubes. UV radiation does not disinfect or sterilize water. The use of UV radiation as a disinfectant in the operating room environment is currently under debate due to lack of clinical evidence that it reduces infection rates. Furthermore, it is necessary to take into account that it induces keratoconjunctivitis in patients and professionals exposed to radiation.

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: orthophthaldehyde, glutaraldehyde, chlorine and chlorinated compounds, formaldehyde, hydrogen peroxide, peracetic acid, phenols and quaternary ammoniums.

It is important to mention that not all disinfectants are available in all countries.

Actions of different disinfectants

Compound	Concentration	Level of disinfection	B	LV	HV	M	F	S	Mechanism of action	Uses
Chlorine	2:1000 (100 ppm)	Intermediate/ low	+	+	+	+	+		EI, PD, INA	floors
Iodine	30-50 ppm	Intermediate	+	+	+	±	±	-	RP	hemoculture bottles, medical devices
Hydrogen peroxide	3-25%	Intermediate	+	+	-	+	+	-	ROH	contact lenses
Alcohols	60-95%	Intermediate	+	+	-	+	+	-	PD	thermometers, endoscopes, external surfaces
Phenols	0.4-5%	Intermediate/ low	+	+	±	-	±	-	EI	
Quarternary ammoniums	0.4-1.6%	Low	+	+	-	-	±	-	EI, PD	floors, furniture
Peracetic acid	0.001-0.2	High	+	+	+	+	+	+	Oxidant	dialysis equipment
Chlorhexidine	0.05%	Low	+	+	±	-	+	-	Cytoplasmic	antiseptic
Glutaraldehyde	2%	Chemical sterilizer	+	+	+	+	+	+	Alkylation of DNA, RNA	thermolabile instruments

Legend: ppm = parts per million, B = bacteria, LV = lipophilic virus, HV = hydrophilic virus, M = mycobacterium, F = fungus, S = spore, EI = enzymatic inactivation, PD = protein denaturation, INA = inactivation of nucleic acids.

Orthophthaldehyde

This chemical agent is new and is used for high-level disinfection (HLD). It corresponds to the group of inorganic aldehydes and contains benzenecarboxaldehyde 1.2.

Mechanism of action: It causes the alkylation of cellular components and acts directly on nucleic acids.

Spectrum: Studies have demonstrated its excellent microbicidal activity and higher activity than glutaraldehyde for mycobacteria. It is a mycobactericide and viricide.

Advantages and disadvantages: The principal advantage is that it has excellent stability in a broad range of pH (3-9) and as a result does not require activation. It also has excellent compatibility with any type of material or article and has chemical indicators. It is not carcinogenic, but it is recommendable to use this compound in ventilated areas since it still has not been determined if it can pro-

duce irritation in the eyes and nostrils. At this time, its high cost seems to be the principal disadvantage for its use.

Instructions for use: The time required for high-level disinfection varies according to the following standards and manufacturers:

American standard (Food and Drug Administration – FDA) (10 to 12 minutes at 20 °C)
Standard in Canada (10 minutes)
Standard in Europe (5 minutes)
In our environment, the recommendation is 10 to 12 minutes.

Concentrations for use: A concentration of 0.55% is recommended. The solution can be reused for 14 days and has a shelf life of two years.

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: In our environment we have a 2% solution. A time of 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%.

In Europe, there are concentrations of 1.5% with longer immersion times. The threshold limit value (TLV/exposure value) of glutaraldehyde is 0.02 ppm. (parts per million) to 0.05 ppm. in 8 work hours.

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 viricide, fungicide and bactericide (mycobactericide).

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.

Formula to prepare a hypochlorite solution:

cc = Liters of water x ppm / Purchase concentration

Where:
cc: cubic centimeters of sodium hypochlorite to add to the preparation.
Liters of water: quantity of final solution to prepare.
ppm: parts per million (final concentration to prepare).
Purchase concentration:

- Household 5.25%.
- Concentrated 10%.
- Pools 12%.

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.

Formaldehyde
Formaldehyde is an aqueous solution with a penetrating odor that is polymerized, forming a white deposit inside containers when found in high concentrations and on the articles themselves after prolonged immersion (even in lower concentrations like 37% to 40% formalin).

Mechanism of action: It produces the inactivation of microorganisms through the alkylation of the amino and sulfhydryl groups of proteins and of the nitrogenous ring of puric bases. This causes alterations in the synthesis of nucleic acids.

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

Disadvantages: It presents a disagreeable odor, in addition to irritating the mucous membranes. It is considered potentially carcinogenic. Occupational exposure precautions should be taken when this element is used.

Indications: Its use is limited to hemodialysis filters and the conservation of pathological anatomy parts. Due to its toxic and irritant effects, formalin under any presentation has been excluded from the list of disinfectants in the United States of North America since 1996.

Hydrogen peroxide
Hydrogen peroxide is an oxidant agent used for HLD.

Mechanism of action: Its antimicrobial action is performed through the production of hydroxyl free radicals that damage the lipid membranes, DNA and other

cellular components.

Spectrum: It is a bactericide (mycobactericide), fungicide, viricide and sporicide in concentrations from 6% to 7%.

Advantages and disadvantages: It does not damage glass or plastic articles. It is an oxidant for metal articles. It presents ocular toxicity and can also produce pseudomembranous colitis due to poor rinsing during HLD.

Instructions for use: It is indicated in the use of HLD for endoscopes given its compatibility with this material.

Concentrations for use: Its presentation ranges between 3% and 7.5%. In order to carry out high-level disinfection, the indication is for 6% to 7.5% for 30 minutes. The solution can be reused for 21 days.

Peracetic acid

Also known as peroxiacetic acid, this is an oxidant agent that acts similarly to hydrogen peroxide.

Mechanism of action: It produces the denaturation of proteins, altering the permeability of the cell wall.

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

Advantages and disadvantages: The greatest advantage of this element is that it does not produce toxic waste and does not require activation. It can corrode copper, bronze or galvanized iron. This corrosion can be controlled with pH additives. It produces ocular toxicity and irritation of the mucous membranes.

Instructions for use: There are formulations associated with hydrogen peroxide that are indicated for the capillary reprocessing of hemodialyzers.

Concentrations for use: In low concentrations of 0.1% to 0.2% and in 10 to 15 minutes, it takes fast action against microorganisms (including spores). The solution lasts for 14 days.

Phenols

Phenol derivatives that are commonly found as the active ingredient of formulations are: ortho-phenyl-phenol and ortho-benzil-para-chlorophenol. Phenol compounds are produced through the substitution of one or two atoms of aromatic hydrogen from phenol with a functional group (alkyl, phenyl, benzyl, halogen).

Mechanism of action: In high concentrations, they break the cell wall, penetrating the cell and precipitating cytoplasmic proteins. In low concentrations, they cause the death of microorganisms by inactivating the enzymes in the cell wall.

Spectrum: It is a bactericide (mycobactericide), fungicide and viricide. It has

little action in small viruses such as echovirus, poliovirus and coxsackievirus. Phenols are inactivated when organic matter is present.

Disadvantages: Phenols can be absorbed by porous materials such as plastic, leaving waste that produces irritation in the mucous membranes.

Instructions for use: Phenolic derivatives are indicated mainly in the disinfection of non-critical articles and on smooth surfaces. Its use is not indicated in semi-critical articles due to the absence of data on its germicidal effectiveness. Furthermore, its utilization is contraindicated when cleaning incubators and other surfaces in areas for neonates since it generates hyperbilirubinemia. Currently, due to its low effectiveness and to the risks described, it is not recommended for use in the hospital environment.

Concentrations for use: The concentrations vary with the presentation of the product.

Quaternary ammoniums

The compounds most commonly used in hospital establishments are alkyl-dimethyl-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 viricides against only lipophilic viruses. 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.

Recommendations for the use of disinfection processes

Since high-level disinfection is commonly used outside the SP (endoscopy and dentistry services and surgical areas), it is essential for the professional responsible for the SP to participate jointly with the institution's Infection Control Service in the implementation of high-level disinfection processes and to take responsibility for their supervision.

This assertion justifies that the efficacy and safety of disinfection processes requires strict monitoring of written parameters and procedures that detail work operations. Additionally, the *chemical controls* (control of the concentration with chemical reaction strips) and *physical controls* (temperature and exposure time) performed on the disinfectant solution should also be registered.

These controls should have the same degree of rigor that applies to the sterilization processes carried out within the plant.

General guidelines for performing high-level disinfection

The disinfectants used for high-level disinfection should have ANMAT (National Administration of Medicines, Food and Technology–Argentina) authorization for commercialization (Provision 4324/00 or other provisions that are currently in effect).

The disinfectants that are currently used for medical use products are: glutaraldehyde, ortoftalaldehyde, formaldehyde and peracetic acid.

Independent of the product used, adequate monitoring of the *critical parameters of the process* should be carried out:

- concentration of the disinfectant agent
- temperature
- exposure time

The validity date of the solution should also be controlled.

It is fundamental to confirm the physical and functional compatibility of the instrument with the disinfectant product, as stated in manufacturer instructions.

The ventilation conditions required in the work area should be respected in order to avoid the exposure of personnel to vapors in concentrations higher than the limits established by occupational health agencies.

The disinfection area should have forced ventilation, broad work benches and two sinks for the washing and elimination of the disinfectant from the instruments through rinsing (Standards of the AAMI – Association for the Advancement of Medical Instrumentation, or other standards that are currently in effect).

As was previously mentioned, the international tendency is to consider high-level disinfection as part of a set of operations designed to guarantee the adequate reprocessing of medical products.

As a result, the full treatment for complete high-level disinfection, including the stages prior to and following disinfection itself, should be understood as the following.

These stages are:

- *Washing*
- *Rinsing*
- *Drying*
- *Disinfection itself*
- *Rinsing of the disinfecting agent*
- *Drying*

Washing

- Prepare a solution of enzymatic detergent in potable water in the washing tray, respecting the proportion and temperature of water indicated by the product manufacturer.
- Submerge the endoscope fully in the solution (for non-submersible models, the head is not immersed).
- Make the solution of diluted enzymatic detergent circulate through the channels of the endoscope until the organic remains are completely eliminated.
- Leave the instrument submerged and the channels full of solution for the time indicated by the manufacturer of the cleaning product.
- In non-submersible models, the head should be cleaned with a cloth impregnated with an enzymatic detergent solution.
- Discard the enzymatic detergent solution.
- Rinse the washing tray used with potable water.

Rinse

- Place the washing tray in the washing sink.
- Make an abundant amount of water circulate through the channels of the endoscope.
- Proceed with the rinse of the instrument's exterior.
- Confirm that both the exterior and interior rinses have completely eliminated the remains from the cleaning agent.
- Discard the water in the sink after each rinse.

Drying

- Carry out a final rinse of the channels and external surfaces of the endoscope with 70° alcohol.
- Carry out drying by runoff, with a clean disposable cloth and/or with compressed air at low pressure (less than 12 pounds per square inch).

Disinfection itself

- 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.

Drying

- Carry out a final rinse of the channels and external surfaces of the endoscope with 70° alcohol.

- Carry out drying by runoff or with filtered compressed air, which should be free from oils and water and at low pressure (less than 12 pounds per square inch).
- Store the endoscope in a sealed plastic bag or pouch within 40 minutes and until its later use. If more than 40 minutes passes, it should be disinfected again prior to use.
- In the case of a sealed pouch for storage of the instrument, label the pouch "DISINFECTED" in order to indicate the validity of the process.

Automatic disinfection

The use of automated equipment for washing and high-level disinfection decreases procedural variability and errors. There is currently equipment that is appropriate for many of the available commercial products.

In spite of being automated processes, written internal institutional protocols for their use should be developed in order to facilitate training and guide the technical personnel in charge of operating each type of equipment.

Equipment used in automatic disinfection should be in a perfect state of hygiene, according to the institutional cleaning standards that will be applied for each type of equipment.

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

Disinfection process for endoscopes

What to do	How to implement
1. Clean	Immediately after the procedure, submerge and review the external surfaces and internal channels with brushes, a water solution and enzymatic soap.
2. Rinse	Rinse the exterior and all channels with abundant water and with adequate syringes. Subsequently drain the water.
3. Dry	After rinsing and before disinfection, treat the internal channels with forced air and the exterior with a clean compress.
4. Disinfect	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 at least 20 minutes.
5. Rinse	Rinse the endoscope and channels with sterile water. If this is not possible, use faucet water, followed by an alcohol rinse.
6. Dry	After disinfection and prior to storage, treat the internal channels with forced air and the exterior with a clean compress.
7. Store	The endoscope should be stored in a place that prevents recontamination.

- If the endoscope cannot be sterilized, a high-level disinfection (HLD) process should be carried out immediately prior to its use with the patient.
- **One-time use elements:** Also called disposable elements, the manufacturer provides these elements sterile. Opening of the sterile package implies its immediate use. Once used, they should be discarded and should not be reused under any circumstance.
- The process for the cleaning and disinfection of **arthroscopes** and **laparoscopes** is the same as the process for endoscopes, with the exception that the rinse should be carried out with **sterile water without any exceptions**. The area and timing for carrying out this procedure is the operating room, prior to the surgical procedure. Drying should be carried out with sterile compresses.

Bronchoscopes

Endoscopes, light sources and tweezers should be inspected before commencing the procedure in order to confirm their correct functioning or state of conservation.

The bronchoscope should receive high-level disinfection (HLD) prior to the first study of the day and immediately following each study.

All of the removable parts should be disassembled for mechanical cleaning. The inside and outside of the bronchoscope should be cleaned vigorously with enzymatic detergent.

The channels should be brushed. The parts that have been removed should be submerged in a neutral enzymatic detergent during a period of time that will depend on the detergent used. The head of the non-submersible bronchoscope should be cleaned with gauze soaked in detergent.

Disinfection should be carried out through the complete immersion of the device in a container with a 2% glutaraldehyde solution without surfactant (being particularly careful when filling the working channels) for 20 minutes.

In the case of non-submersible endoscopes, a rigid tube can be used, making it possible for the entire moveable part to be submerged. The device should be aspirated through the channel using a syringe while maintaining the syringe attached to the aspiration channel. This ensures that the channel it is in contact with the glutaraldehyde during the entire disinfection period.

The activity of the glutaraldehyde solution should be controlled and the containers should be adequately labeled in order to confirm the activation date.

Rinsing should be carried out with abundant common water (or preferably

distilled sterile water; a physiological solution should not be used) on the exterior cover and the working channels.

The final drying is carried out with oxygen or filtered compressed air.

At the end of the day, the bronchoscope should be kept (preferably hung) in a dry, dust-free location.

Biopsy forceps or foreign-body forceps should be washed with enzymatic detergent and subsequently sterilized in an autoclave.

The brushes for cytological and bacteriological studies should be discarded.

During the study, the light source should be covered with a disposable sheet of plastic in order to avoid contact with the biological materials. Afterward, it should be cleaned with a piece of gauze soaked in detergent.

Advice:

The immersion of the endoscope in glutaraldehyde for **60 minutes** is advised when the study will be conducted in a patient with a compromised immune system.

Frequent monitoring of the pH of the glutaraldehyde is advised, given that the time needed for the activity is variable depending on the quantity of studies carried out. Its estimated duration time is 14 days.

Routine bacteriological control of the endoscope is not advisable, except in the case of a suspected cross-infection. In these cases, the best method of bacteriological isolation is the brushing of the channel.

In the case that persistent contamination of the endoscope channel is confirmed, it should be ***sterilized with ethylene oxide following exhaustive washing***.

Non-compliance with these standards makes both the operator and the institution where the procedure was carried out jointly responsible for ensuing accidents due to the transmission of pathogens to patients or intervening personnel.

Tonometers, diaphragm rings and cryosurgery instruments

The disinfection strategies for these elements are highly varied and few studies have demonstrated their effectiveness.

Although these are semi-critical elements, many of the studies conducted used

alcohols and chlorated compounds, which are intermediate-level disinfectants. The microorganisms that we are interested in inactivating are primarily Hepatitis viruses, HIV, adenovirus and herpes. However, these disinfectants were not tested for all of these viruses.

Currently, disinfection with isopropyl 70% or ethyl-alcohol is used for 15 minutes (after an exhaustive cleaning with enzymatic detergents, rinsing and drying). The effectiveness of this practice, however, has not been verified.

HLD also needs to be used for cryosurgery instruments.

Vaginal sonography probe

In gynecology, one or two condoms are used to cover the vaginal explorer in sonographic scanning studies. Nevertheless, this small object can fail and, as a result, HLD is required between patients. HLD should be carried out with glutaraldehyde 2% that is allowed to act for 20 minutes.

Dental instruments

Increased scientific articles and publicity about the potential transmission of infectious agents in the dental practice focused the attention of professionals in this discipline on dental instruments as possible agents of disease transmission.

The ADA (American Dental Association) issues the reminder that every surgical element or elements that normally penetrate soft tissue or bone (forceps, scalpels, surgical aspiration elements, bone chisels, etc.) are classified as critical. The ADA recommends that they be sterilized between uses or discarded.

Instruments that do not penetrate tissues or bone (amalgam condenser, air/water syringe, etc.), but are in contact with the oral cavity, are considered semi-critical. They should also be sterilized between every use.

Handheld instruments that do not tolerate high temperatures should be replaced by others that can be exposed to heat.

Disinfection processes should not be used in critical or semi-critical dental elements.

Implantable objects

Implantable objects for articulations should come sterile from their procurement from the manufacturer.

Implantable objects such as **bones**, **screws**, **plates** and **meshes**, which are

not sterile, should be sterilized in an autoclave and maintained in the service until the biological indicator is negative. HLD cannot be carried out on implantable objects.

Anesthesia masks

Anesthesia masks and intranasal airways should be cleaned and disinfected after each use.

Wash the internal and external parts of anesthesia masks with a brush, soft detergent and water.

In order to clean the interior of intranasal airways, a round, flexible brush should be used.

Inspect the masks in order to confirm their integrity. If the rubber is broken or cracked, parts of the mask are missing, or the rubber around the edge is missing, the mask should be discarded.

Clean by sonication for 10 minutes.

Rinse with water.

Dry.

Submerge the masks and intranasal airways in glutaraldehyde for 10 minutes.

Remove the objects, rinse with clean water and allow them to air dry.

Adequate reprocessing of reusable anesthesia materials is the responsibility of the Sterilization Plant.

Disinfection of elements contaminated with HBV, HIV or *Mycobacterium tuberculosis*

Semi-critical biomedical elements contaminated with the blood of patients with HBV or HIV or with the respiratory secretions of patients with tuberculosis should receive high-level disinfection since experimental studies have demonstrated the inactivation of these germs with disinfectants of this type.

It is necessary to mention that many patients are asymptomatic carriers of these germs and that it is not possible to separate biomedical elements in order to give them additional treatment. Therefore, it is very important to always respect the steps of disinfection processes.

Inactivation of *Clostridium difficile*

Endoscopes such as colonoscopes can serve as vehicles of transmission. It is therefore important to reemphasize that the patient can be endangered if all steps of the disinfection process are not fulfilled.

Inactivation of pathogenic agents from blood on equipment and in the environment

The emergence of HIV raised awareness concerning all of the pathogenic microorganisms that are transmitted through blood. However, national and international recommendations related to the elimination of these germs on the surfaces of the environment do not seem to be very useful.

Studies conducted on disinfectants point out that an immersion time of 10 minutes is required. However, items such as equipment, floors and beds cannot be submerged. On the other hand, the majority of disinfectants become inactivated in the presence of organic matter and if some of their concentrations are increased, they can be caustic or toxic.

Alternatively, it would be advisable to use chlorine-based products to carry out cleaning of equipment and the environment, resulting in early elimination of blood and visible dirt. This practice also eliminates viruses and reduces the time, corrosion and toxicity of the disinfection process.

Blood and dirt can also be eliminated by first cleaning and later using alcohol 70% for disinfection.

The adequate selection of the disinfectant will depend on: the type of element, the corrosion factors and the possibilities of submerging the element.

In general, the recommendations are regulated in the following manner:

"Eliminate or minimize the risk of occupational exposure to pathogenic microbes that are transmitted through the blood by first cleaning and then decontaminating with an appropriate disinfectant."

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. *This is the principal method used in a SP*.

Every heat-resistant material that is incompatible with moisture should be sterilized by dry heat.

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

Sterilization by immersion in liquid chemical methods, which are carried out manually, will always be the last method of choice. These processes are difficult to control, have major possibilities of recontamination during rinsing or drying, and do not allow for storage.

The sterility of a medical instrument cannot be guaranteed if the instrument does not enter the sterilization process following prior cleaning. Our objective is to obtain sterile inputs that can be used safely with the patient.

Nature of what is sterile

Risk of non-sterility: the sterile or non-sterile state of an object cannot be shown through conventional analytical techniques. This condition can be estimated by calculating the number of residual microorganisms that exist in an article subject to a given sterilization method. The residual number depends on:

Initial contamination (**Co**) (concentration, volume or mass) of the articles that will be sterilized.

Volume (**V**) or **Surface** (**S**) of the articles that will be sterilized.

Effectiveness (E) of the sterilization, expressed in the number of decimal

reductions. For example, if sterilization has permitted the reduction of the initial population of 10^n microorganisms to a population of 10^m, the effectiveness is:

$$E = n - m$$

After sterilization, the **average number (R)** of microorganisms per object is equal to:

$$R = Co \times V \text{ (or S)} \times 10\ E$$

Where R also represents the **probability** that an article is non-sterile or the **risk of non-sterility of the article**.

R should be as small as possible.

R is never null.

The European and American pharmacopeia have set 10^{-6} as the maximum limit for the risk R of non-sterility.

Sterility of a lot of medical articles is a relative notion. According to analytical techniques, this is the level of quality that should be analyzed for 1 million sterilized articles.

Factors that impact the effectiveness of sterilization processes

Factors that affect the effectiveness of sterilization processes are:

- number of microorganisms
- organic matter
- time
- temperature
- relative humidity
- standardization of the load.

Keene (1996) and Rutala (1993) described these factors, which should be taken into account in order to carry out an adequate sterilization process.

Number of microorganisms (Co). This is a fundamental factor since it is one of the two factors that measure the effectiveness of different sterilization processes. The R or D value refers to the time needed for the sterilization method

to achieve elimination of 90% of the microorganisms. It is used to evaluate the different methods.

Organic matter (S). The presence of organic matter hinders the elimination of microorganisms but is one of the most easily modified factors. These two factors, **Co** and **S,** justify the importance of *CLEANING* prior to sterilization, in order to always guarantee a reduction in the risks that affect the sterilization process.

Time. This is another factor that is used to evaluate the performance of sterilization methods. Value **F** is the time needed for a suspension with a temperature of 121 °C to eliminate all bacterial spores. It is also used as a reference value in the evaluation of sterilization methods.

Temperature. An increase in temperature during a specific sterilization process increases its effectiveness when the level is higher than the optimal temperature needed for the growth of a microorganism. This usually induces microorganism death.

Relative humidity (RH). RH is defined as the fraction of water vapor pressure in a system with respect to another system at maximum pressure (100% saturated) and at the same temperature. Higher relative humidity is associated with higher water content in the cells or spores and a better (faster) end sterilization result.

Standardization of the load. Packages should meet the international standards for measurements (28 x 28 x 47 cm.) and types of packaging. The load to be sterilized is very variable. It can change with regard to the number and size of instruments, the volume of the load and the content of the packages. It is important to standardize the sterilization processes according to the different articles being sterilized since the effectiveness of the method can vary in relation to the articles.

Resistance of microorganisms

The susceptibility of different microorganisms to inactivation processes relates to the aforementioned factors. However, microorganisms have an intrinsic or innate resistance to sterilization processes. The nature of this resistance resides primarily in the composition of the cell wall, which regulates the penetrability of disinfecting and sterilizing agents.

Diagram of the susceptibility of microorganisms to sterilization processes (*Maillard, 2004*):

1. Prions
2. Bacterial spores
3. Mycobacteria (*M. tuberculosis, M. avium, M. chelonae*)
4. Protozoans (Cysts: *Giardia, Cryptosporidium*))
5. Small viruses without sheath (*Picornavirus*, *Poliovirus* *Parvovirus* and some *Rotavirus*, Hepatitis A and E, *Norovirus*)
6. Large viruses without sheath (*Adenovirus*)
7. Fungal spores (*Aspergillus, Absidia*)
8. Bacterial and fungal vegetative forms
9. Large viruses with lipid sheath (HIV, HCV, HBV, Herpes, Chickenpox, Rubella).

Sterilization methods

Physical methods: dry heat and moist heat.
Chemical methods: liquids and gases (ethylene oxide).
Physical-chemical methods: low-temperature steam (formaldehyde) and gas plasma (hydrogen peroxide).

Physical methods

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. It is usually used at 170 °C for 60 minutes or 150 °C for 150 minutes.

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.

Types of stoves or Poupinell

There are two types of stoves that are commonly used: the gravity convection stove and the mechanical convection stove (forced air circulation).

Gravity convection stove

This stove consists of a covered chamber with electric resistance on its interior wall and a channel or orifice for air drainage on its upper wall. Circulation depends on the currents produced by the rise in temperature and shock due to differences in temperature. For these reasons, its process is slower and less uniform.

Mechanical convection stove

This stove has a device that produces the rapid movement of a large volume of hot air, facilitating the transmission of heat directly to the load or package. Less time is used and it offers thermal balance.

Instructions for use:

- It can only be applied when materials do not support the action of moist heat.
- Its recommended use for the sterilization of certain materials derives from its facility to penetrate solids, non-aqueous liquids and closed cavities.
- Its behavior with metal is less corrosive but more oxidant.
- It does not erode glass, as is the case with steam.
- Although its use is limited for petrolates and liquids, the following instruments, materials and substances can be sterilized in dry heat:
- Sharp stainless steel instruments (scissors and tweezers).
- Needles, crystal syringes, tubes, glass pipettes, heat-stable powders.
- Liquids and substances that are liposoluble and water-resistant such as oils, silicone, paraffin, vaseline, creams and talcum powders.

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 ac-

cording 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.
- Times: 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.

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

Adapted from Block – 5th edition

Equipment:

- Sterilizing stoves that meet the standards for the organization and operation of plants for the sterilization and processing of medical use products in health facilities should be used. Standards are produced by the National Program for Quality Assurance in Medical Care.

Implementation of the method:

- The preparation and arrangement of the load should be carried out taking into account that dry heat is a mass sterilizing agent.
- Procedure and quality manuals should contain the guidelines that will be followed by each institution and that are approved by the Health Authority.
- During the sterilization cycle, the door of the sterilizer should not be opened.

- When the material to sterilize is a poor heat conductor (talcum), it should be used in a thin layer in the quantity necessary for a single use.

Advantages and disadvantages of the method:

- *Advantages*: It permits the sterilization of vaselines, fats and heat-resistant powders, which cannot be processed by moist heat.
- *Disadvantages*: It requires long exposure periods, is a difficult process to certify or validate, and accelerates the process of destruction of the instrument.

Basic principles to prevent errors:

- Validate the equipment and ensure the efficient calibration of the instruments.
- Sterilization will be efficient when the coldest point registers 170 °C, after two hours of exposure. As a result, the user should have precise information.
- The selection of the packaging material should be made based on its thermal conductivity. Textiles or paper should not be sterilized or used.
- Burden sharing: Make sure that the packages do not touch the walls and that there is sufficient space between each package in order to obtain good circulation.
- Adequate packaging materials such as metal boxes and refractory glass jars should be used.
- Carry out chemical and biological controls in order to guarantee the effectiveness of the process.

Moist heat or 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.

The efficiency of steam as a sterilizing agent depends on:

- moisture
- heat
- penetration
- the mixture of steam and pure air (and other impurities it could contain).

Types of steam sterilizers

Gravity displacement or gravitational autoclaves

In this type of machine, the air is removed by gravity since cold air is denser. The air tends to leave when the steam is admitted, exiting through a channel placed in the lower part of the chamber. This process is very slow and favors the residual permanence of air.

These machines vary in size, from small models that are placed on the table and used in clinics and physician's offices to large units capable of handling carts for transporting materials.

Penetration time becomes prolonged when there is incomplete exit of air and, accordingly, sterilization times are longer. This type of equipment is obsolete. There is currently much more sophisticated equipment available. Although they operate using the same principle, the newer equipment facilitates functioning and increases security through automatic controls, vacuum pumps and microprocessors.

Pre-vacuum sterilizers

This equipment has a vacuum pump, or Venturi system, to remove air from the chamber rapidly in the form of pulses, so that the steam enters the chamber at greater speed. This improves the efficiency of the autoclave since it eliminates air bubbles and increases the speed of the process, even when they operate at

the same temperature as gravity displacement sterilizers (121 °C or 132 °C). It represents a much more efficient system than other systems.

The advantage of this system is that the penetration of the steam is practically instantaneous, even in porous materials. Furthermore with this method, sterilization periods are shorter due to the rapid removal of air both from the chamber and from the load and due to the higher temperature to which it is possible to expose the materials. Autoclaves with a vacuum pump function at temperatures of 121 °C – 132 °C in periods that last 4 to 18 minutes.

Instantaneous (flash) autoclaves

These are special high-speed sterilizers that are usually located in the operating room in order to process *unwrapped instruments* and instruments for *extremely urgent* use. These sterilizers operate at 134 °C for 3 to 4 minutes.

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

Components of a basic autoclave

A steam sterilizer has the following principal components:

High-pressure vessel with attached cover

The solid container or vessel where water will be heated using pressurized steam is called an autoclave.

The space where the objects to be sterilized are placed is called a sterilizing chamber. In order to avoid leaks between the container and the cover, the sterilizer has a seal joint between the two.

Furthermore, it has a lock mechanism with screws or a bayonet-type system composed of small, portable autoclaves.

Pressure control valve

The pressure control valve is located on the base in order to maintain the level of desired steam. If necessary, it will allow the escape of a certain quantity of steam. In modern units, this instrument has a pressure sensor for steam and a temperature sensor for heat.

Safety valve

This is useful in the event that the control valve does not work well. If this occurs, the escape of the steam will not take place and the pressure of the autoclave could rise and eventually burst. In that situation, the safety valve would permit the escape of steam. In some countries this safety valve is compulsory by law.

Mechanism for air expulsion

This is also called a *drip trap*. Modern autoclaves are equipped with an air expulsion system that operates through a piece or bellows that is filled with a mixture of water and alcohol.

General control parameters for autoclaves

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

Steam pressure: Saturated steam with a degree of 0.95 (95% steam and 5% condensated) 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.

For example, in gravitational and pre-vacuum autoclaves, where the material is protected with simple packaging, we will use:

Type of sterilizer	Type of load	Temperature (ºC)	Time (minutes)
Gravitational	Porous or non-porous surface	121	30
		134	25
	Liquid	134	30
Pre-vacuum	Porous or non-porous surface	121	15
		134	4
	Liquid	134	30

Adapted from Rutala and Weber 2002; and the MAC Manual July 2002

Instructions for use:

Textiles: This includes cotton, thread, synthetic fibers, etc. The porosity (stiffness) of the weave can hinder the passage of steam and the suction of air through the vacuum pump. Therefore, in the case of new clothes, carrying out a *prior washing* to diminish this risk is recommended.

- **Metals:** This includes instruments, sinks, kidney trays, drum trays, etc. Metal material requires washing and drying prior to sterilization.

- **Glass or crystal:** On some occasions, sterilization by dry heat is preferable, but it is also feasible to use saturated steam.
- **Liquids:** This refers to distilled water and pharmacological solutions whenever they do not change their composition. As a guideline, it should be taken into account that the container should not be filled to more than 2/3 of its total capacity.
- **Heat-resistant rubbers and plastics:** These materials should be clean and dry in order to ensure the elimination of organic matter.
- **Inactivation of the Creutzfeldt-Jakob disease (CJD) agent:** The CJD virus requires special recommendations. It has been transmitted iatrogenically through cerebral electrodes that were disinfected with 70° alcohol and formaldehyde after their use with patients known to have CJD. The contagion was also observed in corneal and human hormone receptors. The need for special recommendations is based on the high resistance of the virus when it is protected by tissues or skin. Washing followed by steam sterilization at 132 °C for one hour is the *preferred method* for the contaminated material. Disinfectants such as sodium hydroxide 1 N, for one hour and at room temperature, kill the virus but are caustic. Items unrelated to the patient, such as floors or autopsy tables, do not require special recommendations since they are not considered potential transmission agents. A chlorate can be used (dilution 1:10) on these surfaces. In order to inactivate the virus in patient *tissue* samples, *formalin-formic acid* is required.

Sterilizing agent:

- Saturated steam at a pressure that is higher than the normal level.

Mechanism of action:

- It acts by microbial death due to the denaturation of proteins, which is produced by the action of the temperature and saturated steam.
- Saturated steam is a surface sterilizing agent, which is the reason why materials should be placed in a way that ensures close contact of all of their components with the steam; e.g.: open tweezers, adequately conditioned textile.

Conditions of the process:

- The conditions to take into account are *temperature* and *exposure time,* which will be established during the validation of the equipment and processes.

- For saturated steam, there is equivalence between temperature and pressure (AAMI/96).
- The following table is presented as general guidance:

Type of sterilizer	Temperature (°C)	Exposure time
Gravitational	121-123	15 to 30 minutes
	132-135	10 to 25 minutes
Pre-vacuum	121-123	15 to 30 minutes
	132-135	3 to 4 minutes

- The application of the procedure known as *"Flash"* is accepted under the following conditions in accordance with AAMI/96:

Type of sterilizer	Temperature (°C)	Exposure time
Gravitational	1. Only metal, non-porous articles (without lumens).	3 minutes
	2. Metal articles with lumens and metal, porous articles, sterilized together.	10 minutes
Pre-vacuum	1. Only metal, non-porous articles (without lumens).	3 minutes
	2. Metal articles with lumens and metal, porous articles, sterilized together.	4 minutes

- It should be ensured that the later transfer of the material to the place of use is carried out in aseptic conditions.

Prostheses should never be sterilized using the flash procedure.

Equipment:

- Steam autoclaves that meet the standards for the organization and operation of plants for the sterilization and processing of medical use products in health facilities should be used. Standards are produced by the National Program for Quality Assurance in Medical Care.

Implementation of the method:

- The type of load should be taken into account when programming the sterilization cycle. For each type of load, the corresponding validation should be carried out in order to achieve and be able to document valid results using process indicators.
- Procedure and quality manuals should contain the guidelines that will be followed by each institution and that are approved by the Health Authority.

Advantages and disadvantages of the method:

- *Advantages*: This method is considered the most economical and most rapid. It has no adverse effects since it does not leave residues from the sterilizing agent.
- *Disadvantages*: It is not suitable to apply in materials that do not support the conditions of the process.

Factors that affect sterilization by autoclave

Factors that affect sterilization by autoclave are:

- **Incomplete elimination of the air in the sterilizer:** This produces a reduction in temperature, which affects sterilization. The air bubbles trapped in packages act by impeding the diffusion and expansion of the steam. This occurs because of deficiencies in the vacuum pumps or in gravity displacement autoclaves due to the incomplete elimination of air.
- **Overheated steam:** This can affect the microbicidal power since it loses moisture and acts only as *hot air*.
  - This can occur when the steam is not in contact with the water from which it is formed. It is completely dry and cannot be used in autoclaves. Its temperature rises rapidly.
  - Saturated steam can also overheat when there is a rapid reduction in pressure (abruptly, by more than 50%), causing higher pressure and temperature in the jacket than in the chamber.
  - Another reason is over-drying, produced by the passage of steam through materials that have lower than 50% relative humidity (as is the case of some textiles that are stored at high temperatures).
- **Inadequate preparation of the material:** The preparation of the material with regard to the type of articles, packaging or wrapping, size and location within the chamber are also important factors in sterilization. They can affect the elimination of air, the diffusion of heat and steam, and the preheating of the chamber.

Diagram for the preventive maintenance of autoclaves

Frecuencia	Actividad	Responsable
Daily	Cleaning of the internal chamber	Operator
Monthly	Cleaning of drainage filters	Operator
Quarterly	Discharge of the generator	Engineer or technician
	Verification of the cleaning of electrodes	Engineer or technician
	Lubrication of the heating system	Engineer or technician
	Confirmation of pitfalls	Engineer or technician
Biyearly	Verification of the operating and safety systems	Engineer or technician
	Confirmation of the water inlet filters	Engineer or technician
Yearly	Cleaning of the steam generator	Engineer or technician
After 3 years, the operation of the control instruments will be evaluated		

All heat-resistant material that is compatible with moisture should be autoclaved.

Chemical methods

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

Liquid chemicals

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.

Automated equipment increases the safety of the sterilization process. However, this equipment requires controls and operators who are well-trained in their use and management. Some hospital infection outbreaks have been related to the use of automated equipment without the appropriate supervision.

Glutaraldehyde

- This disinfectant, which can be acidic or alkaline, is used as a high-level disinfectant and can be used at a concentration of 2% for sterilization purposes. The duration of the contact time necessary for sterilization is approximately 10 hours. It has a wide spectrum of antimicrobial activity, is

active in the presence of organic matter, and rapidly inactivates microorganisms, except spores. It is easy to used and relatively non-corrosive.

Hydrogen peroxide

- This disinfectant is used very little since it does not exist commercially on the market. In general, hydrogen peroxide at a concentration of 6% is sporicidal but very corrosive when used for delicate instruments and optical fiber endoscopes.

Formaldehyde

- The use of formaldehyde is indicated for all materials that are used for hemodialysis. Sterilization is achieved at 8% concentration and 24 hours of immersion. Formaldehyde has been questioned recently due to its high toxicity.

Peracetic acid

- This agent, which can be considered as a derivative of hydrogen peroxide, has microbial activity that was identified at the beginning of the century. In this regard, it is necessary to mention the existence of recommended formulations of peracetic acid with hydrogen peroxide that, in high concentrations (40%), are inflammable. This element should be handled with extreme precaution since it constitutes a very corrosive and unstable solution. It can be used, alternatively, for sterilization of hemodialysis equipment. A new technology approved in 1999 by the FDA is the combination of peracetic acid 35%, hydrogen peroxide and neutralizing solutions that eliminate their corrosive effect. It is usually indicated for submersible, heat-sensitive material at temperatures that fluctuate between 50 °C and 56 °C, at a neutral pH of 6.4, and at a final concentration of 0.2%. It is ideal for materials and parts that require rapid re-use since the cycle lasts from 25 to 30 minutes. Moreover, it has a system of chemical and biological controls or monitors. Its principal disadvantage is that it cannot sterilize instruments that are not submersible, for example, older flexible endoscopes with heads or video chambers that are not submersible.

Gaseous chemicals

Chemical sterilization by ethylene oxide

Indication:

- In general any thermolabile article can be sterilized by ethylene oxide (EtO). The only recommendation is that the aeration process should be controlled if the article is porous.

Sterilizing agent:

- Ethylene oxide, or ether 1-2 epoxy-ethane, is an alkylating agent. The process by which ethylene oxide destroys microorganisms is by alkylation: replacing the hydrogen atom in a molecule of the organism with an alkyl group and thus preventing the cell from metabolizing or reproducing. Its presentation is liquid and it volatizes to form a gaseous compound. Pure EtO is inflammable and explosive. EtO gas is colorless, is heavier than air, has an ethereal odor, is detectable between 230 to 700 ppm., and is soluble in water and in the majority of solvents. The characteristics of EtO make the sterilization of materials in special, controlled conditions possible. It is only considered effective if the equipment used guarantees the parameters necessary for sterilization such as temperature, moisture, exposure time, pressure and concentration of the agent.

Physical properties:

Solubility in water	Very soluble
Solubility in organic solvents	Soluble in almost all solvents
Boiling point	10.4ºC at 760 mmHg
Odor of the gas	Perceptible above 700 ppm

Chemical properties:

EtO is a highly reactive substance:

- Reacts with water to form ethylene glycol
- Reacts with chloride ions to form ethylene chlorohydrin
- Has alkylating properties and can be combined with different chemical groups such as sulfhydryl, amino, carbonyl, etc.

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. The following table is presented as general *guidance:*

Concentration of the gas:	300-600 mg/l. There are ranges of up to 450 to 1500 mg/l of gas mixture, depending on the requirements of the sterilizer.
Temperature:	37-55ºC. Increases in temperature shorten the sterilization process.
Relative humidity:	Optimal moisture: 50% (range of 40% to 60% relative humidity). This is necessary for the penetration of EtO into the microbial cell. There is no way to measure the level of relative humidity inside the majority of sterilizers.
Sterilization time:	The time is affected by the gas concentration, temperature and moisture. Cycle timing (from when the door closes to when it opens) is from 3 to 6 hours.

Note: The parameters depend on the type of equipment used and manufacturer recommendations for the use of the equipment.

- The pressure of the chamber should be sub-atmospheric throughout the cycle when pure EtO is used. In the case of authorized mixtures, the pressure will be at higher than normal values.
- The aeration stage should be included in the validation of the process, in order to guarantee that the sterilized materials do not contain residual ethylene oxide in concentrations higher than the recommended levels.
- For materials that have higher fixation of EtO (PVC, latex), the recommended estimated aeration times are between 12 and 16 hours depending on the work temperature.

Equipment:

- EtO sterilizers that meet the standards for the organization and operation of sterilization plants in health facilities should be used. Standards are produced by the National Program for Quality Assurance in Medical Care.

Implementation of the method:

- Procedure and quality manuals should contain the guidelines that will be followed by each institution and that are approved by the Health Authority.

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 periOperative 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.
- The proposed aeration time for all materials is:

Air in the room		Aeration chamber	
Temperature	Time	Temperature	Time
20 °C	7 days	49 °C – 50 °C	12 hours
-	-	60 °C – 62 °C	8 hours

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.
- **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 recom-

mended 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 1 million parts of air (1 ppm), for an 8 hour work day (according to Resolution 444/91 – Ministry of Labor).
- MAXIMUM LEVEL PERMITTED FOR MEDICAL DEVICES: 5 ppm (according to Resolution 255/94 – Ministry of Health and Social Action).
- 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 us-

ing 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.

The use of glass vials containing pure EtO should be ruled out completely.

- 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.

Physical-Chemical Methods

Gas with formaldehyde steam (FO) or Low temperature steam formaldehyde (LTSF)

Indications:

- Formaldehyde gas (methanol or formic aldehyde) is an alternative to sterilization by EtO for the sterilization of equipment and materials that do not resist high temperatures.

Sterilizing agent:

- Formaldehyde 2% with steam at low temperature.
- Formaldehyde gas (FO) is a colorless gas with a spicy odor that is highly soluble in water and reacts with water to produce formalin. Formalin is used in variable concentrations. The common preparation of formaldehyde

is 40% and it is prepared with a dilution of 1:10 or 1:20 as a preservative or sterilizer.

Mechanism of action:

- Its mechanism of action is similar to EtO, by the alkylation of hydrogen atoms from functional groups of structural proteins, enzymes and nitrogenous bases of nucleic acids in synergism with the lethal action of steam at low temperature.

Conditions of the process:

- The parameters of the process are:

Concentration:	**2%**
Temperature:	50 °C – 65 °C
Relative humidity:	100%
Exposure time:	2 to 6 hours
Pressure:	Sub-atmospheric throughout the cycle

- Sterilization occurs through the action of FO in the presence of saturated steam.
- This is obtained by making a formalin solution pass through a vaporizer and has four stages:
  - air elimination
  - injection of FO
  - humid stage
  - washing of the chamber
- The gas is removed from the chamber through repeated vacuum pulses and steam in order to then carry out a drying phase and an aeration phase.

Equipment:

- Sterilizers for formaldehyde with steam that meet the standards for the organization and operation of plants for the sterilization and processing of medical use products in health facilities should be used. Standards are produced by the National Program for Quality Assurance in Medical Care.

Implementation of the method:

- Procedure and quality manuals should contain the guidelines that will be followed by each institution and that are approved by the Health Authority.

Advantages and disadvantages of the method:

- *Advantages*: Speed, absence of toxic waste, easy installation.
- *Disadvantages*: Incompatible with moisture-sensitive materials. FO is considered to be a potentially carcinogenic and mutagenic toxic product.

Toxicity:

- Contact of the product with the conjunctiva can cause permanent injury to the cornea.
- In very low environmental concentrations (between 0.1 and 5 ppm.), it can cause irritation of the eyes and respiratory tract.
- In concentrations over 10 to 20 ppm., it can cause coughing, precordial oppression, tachycardia and headache.
- Exposures between 50 and 100 ppm. can cause pulmonary edema, pneumonia and death.

Measurement and control of FO:

- Residual levels of FO are variable depending on the materials. Papers and woven cloths are not compatible with this sterilization method.
- It has a wide biocidal spectrum (viruses, fungi, TB bacilli, etc.).
- Its sporicidal action is low at room temperature, which is why it should be combined with heat at temperatures of 50 °C – 75 °C.
- This method also requires work with an automated system to avoid and prevent occupational exposure.
- The permissible exposure limit (PEL) is 0.75 ppm. in 8 work hours.

General recommendations:

- Recommendations are the same as for ethylene oxide.
- In many countries, sterilization with FO is prohibited in the absence of adequate equipment and installations.
- At present, paraformaldehyde (formalin) tablets are no longer used since they represent a procedure that does not guarantee disinfection or sterilization.

Hydrogen peroxide plasma

- This method uses hydrogen peroxide as a plasma precursor. Plasma, which is considered to be a fourth state of matter that is different from liquid, solid and gas, is composed of reactive ions, electrons and neutral atomic particles.

Indications:

- Hydrogen peroxide in its plasma phase has sterilizing properties at low temperatures. It is useful for the sterilization of equipment and materials that do not resist high temperatures.

Sterilizing agent:

- The sterilizing agent is hydrogen peroxide vaporized in aqueous solution at 58% of the plasma state.

Mechanism of action:

- There is synergism between the oxidant action of hydrogen peroxide in the vapor state and the alkylating activity of free radicals.

Conditions of the process:

The parameters of the process are:

Concentration:	**6 ppm**
Temperature:	< 50 ºC
Total cycle time:	45 to 75 minutes
Pressure:	Sub-atmospheric throughout the cycle

- The sterilizing equipment operates through the injection of hydrogen peroxide 58%. By means of the emission of radiofrequency energy, it creates an electromagnetic field in the chamber, which generates plasma. It is in this state that sterilization takes place.
- Subsequently, the radiofrequency is cut and the atmospheric pressure returns through the introduction of filtered air.
- The complete process lasts approximately 75 minutes.
- Currently, a smaller chamber has been designed, which means that the processing time would be shorter.
- At these concentrations and conditions of use, hydrogen peroxide is not corrosive for metals and is compatible with a large number of materials.

- The diffusion of hydrogen peroxide in lumens less than 1 millimeter in diameter and more than 1 meter long is difficult.
- It is recommendable to not include any material that contains *cellulose*, as is the case with cotton, paper and wood.

Equipment:

- Sterilizers for hydrogen peroxide gas plasma that meet the standards for the organization and operation of plants for the sterilization and processing of medical use products in health facilities should be used.

Implementation of the method:

- Over the course of the cycle, the vacuum, injection and diffusion of the sterilizing agent take place prior to the plasma stage, during which the reactive chemical radicals are formed from the vaporized solution.

Advantages and disadvantages of the method:

- *Advantages*: Absence of toxic waste, easy installation, speed of the process. Compatible with moisture-sensitive materials.
- *Disadvantages*: It has low penetration power. Materials derived from cellulose cannot be sterilized. It requires special non-cellulose packaging for the composition.

Correctly loading the sterilizer

In order for the sterilization procedure to be correct, the following points should be taken into account:

- The chamber should be in a perfect state of cleanliness.
- Burden sharing should permit the free circulation of the sterilizing agent in the chamber.
- Each package should be separated from its neighbors and it should not be in contact with the walls, floor and ceiling of the sterilizer.
- The load of the sterilizer should be constituted preferably by similar materials and should not surpass 80% of the total capacity of the chamber.

Daily care of the sterilizer:

- Remove lint and sediments on the meshes with a brush. It is through the meshes that air and condensation are removed.
- All accessible surfaces of the cart should be washed with a damp cloth using a smooth detergent, moving from the top down. The baskets should be cleaned last.
- All objects that are sterilized by steam should be adequately wrapped or packaged with the corresponding indicator.

When the cart is loaded/unloaded, use the following instructions:

- Place all of the packages on their side and arrange the load in the chamber so that resistance to the passage of steam through the load is minimal.
- Place the instrument trays on the side, with the longer side on the shelf.
- In mixed loads where there are textiles, place large equipment on the lower shelves. This prevents cloths from getting damp if condensation drips from the equipment.
- Do not overload the shelves or compress the packages.
- Do not allow wrapped packages to come into contact with the sterilization chamber. Leave at least 7.5 cm between the upper part of the sterilizer and the highest part of the load.
- Never place packages on the floor of the chamber.

- Place “pouch” (plastic/paper) type packages in a metal mesh basket. The packages should be placed on their side with the plastic side of one pouch facing the paper side of the other pouch. All the packages should be tilted slightly, with the paper side facing downward, in order to prevent the moisture from becoming trapped.
- Sterilize liquids separately from other materials.
- When the sterilization cycle is complete, do not place the load near air conditioning or a cold air fan.
- Visually control the exterior part of the packages in order to verify whether they are dry.
- An instrument tray that has drops of water or visible moisture on the exterior part of the package, or on the adhesive tape used to wrap it, is not considered sterile.
- Sterilized objects should remain in the cart and should not be handled until the content has reached room temperature. Depending on the objects and the environment, this can take approximately 1 to 3 hours.
- When all of the objects have cooled, remove them from the cart carefully, making sure not to damage the packaging.
- Storage of sterile articles should be arranged in a location that avoids risks of contamination and favors rapid, easy movement and identification of the articles.
- Adequate storage of the material will be reflected in how well their sterility is maintained.
- The effectiveness of this stage of the sterilization process will generate an impact of cost-related savings for the institution, reflected in expenditures on packaging, time used by personnel, and duration of the usage cycles for sterilization equipment. Re-sterilization without reason will be prevented, resulting in a reduced workload, better inventory management, and evidence of recently sterilized elements.

Handling, transporting and storing materials

Sterile material should be stored in conditions that ensure their sterility. The shelf life of a sterile product is the time that elapses from when it is processed until it is used or reaches the expiration date. At that point, it should be removed in order to be re-sterilized if it is reusable or discarded if it is a single-use product.

The shelf life of a sterile product depends directly on the following fundamental aspects: ***manipulation***, ***transport***, ***storage*** and ***correct use***, independent of the sterilization method used.

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.

Transport

Materials should never be taken directly by hand to the shelves.

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 SP to the destination area.

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, 45 cm. from the ceiling and 5 cm. 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 °C – 28 °C 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.

Shelf life

It is accepted universally that the validity of the sterilization process is conditioned on the events to which the medical use product is exposed. For this reason, it is important to have a reliable control of the product in the SP and in the sectors where it is used.

Expiration of sterilized articles (shelf life)

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

The AORN and the AAMI established that the shelf life of a sterile material is related to the events that it experiences.

In 1993, AAMI established:

Shelf life: "The shelf life of a sterile material will depend on the events, the quality of the packaging, the storage conditions, the transport conditions, and the number of times handled."

Expiration date: "The items that should be used when sterile should be labeled with a lot number, a control date for rotation of stock, and the following message: 'This product is not sterile if the package is opened, damaged or moist. Please review before using.'"

Furthermore, different studies have demonstrated that correctly packaged materials can remain sterile indefinitely.

Regarding storage, we should also take into account that closed shelves are for storing articles or packages that have low rotation and that open shelves are for articles or packages with high turnover.

Calculation of the shelf life of a package

For general guidance, we have reproduced a table for the estimated calculation of the shelf life of a package, including an explanatory example:

Packaging	Crepe paper	Unwoven cloth	Paper bag	Medical grade paper pouch made of polyester / polypropylene	Pouch of pressed polyethylene / polypropylene	Container
First package	20	40	40	80	100	100 (with filter)
Second package	60	80	80	100	120	250

If the material has protective wrapping in addition to the packaging, then add the following points:

Protective wrapping	Points
Sealed polyethylene bag	400
Protective container or wrapping	60

According to the storage environment, it should have the following points:

Storage environment	Points
Drawers	0
Open cabinets	0
Closed cabinets	100

According to the storage location, then add the following points:

Storage location	Points
Patient room	0
Nursing office	50
Material deposit	75
Sterile material deposit	250
Deposit in operating room or sterilization plant	300

Scoring or scale list:

Score	Duration
1-25	24 hours
26-50	1 week
51-100	1 month
101-200	2 months
201-300	3 months
301-400	6 months
401-600	1 year
601-750	2 years
751 or higher	5 years

Example:

Conditions:	Product A	Product B
Double paper / polypropylene pouch	80+100	80+100
Protective wrapping	-	-
Storage in open cabinet	0	-
Storage in closed cabinet	-	100
Storage in operating room	300	300
Total score	480	580
Expiration date	1 year	1 year

Distribution

- The sterilized medical use product should be distributed while preventing dropping and unnecessary manipulation.
- The discharge of the product should be documented in the discharge registry.
- Clean bags or containers should be used to distribute the sterilized medical use product to different sectors of the institution.
- Once distribution is complete, the necessary mechanisms for the rapid replenishment of stock should be implemented.

What causes contamination?

Sterility can be compromised by:

Deficiencies in the sterilization process.

Packaging materials that do not provide an adequate barrier: Technical documentation regarding the barrier's quality, permeability, resistance to tearing, porosity, etc. should be reviewed.

Handling: It is recommendable to not handle packages more than 3 or 4 times from when it leaves the sterilizing equipment until it arrives at the patient.

Transport: Transfer standards that minimize or eliminate accidental contamination should be established.

Storage conditions: Environmental factors such as microbial pollution, air movements, temperature and humidity should be reviewed continually.

Crushing the packages when they are being stored should be avoided.

Whether the materials will be stored on open or closed shelves should be established.

The AAMI also establishes that storage on open shelves requires greater care, that the area should be ventilated, and that the transit of people and speaking should be avoided.

Application of an event-related policy

An event-related policy is a method for improving the efficiency and reducing the costs of reprocessing. Communication strategies should be developed to provide training and discussions to strengthen this policy.

Ultimately, the application of an event-related policy is based on eliminating the entities that compromise sterility:

- Events that require reprocessing should be specified, for example: tears, moisture.

- Items that need expiration dates should be determined and rotation policies should be established. Both should then be monitored.

"The packaging form and technique of every article should guarantee and maintain the sterile content during storage and transport."

Practical recommendations

- Sterile articles should be handled carefully and the least number of times possible.
- Register the movement of articles at entry and exit.
- Carry out periodic inventories of the articles stored in reserve (to ensure sufficient quantity).
- After sterilization, packages should remain at room temperature before being stored in order to avoid the formation of any steam condensation within the cabinets.
- Establish the frequency of cleaning needed for this area.
- Store and distribute the packages according to the chronological order of their sterilization lot number, trying to arrange for old lots to be distributed prior to new lots.
- In this case, a basic rule should be used: **F.E.F.L.**, which means:

"The first one to enter is the first one to leave"

Summary

The implementation of events related to shelf life is synthesized here:

- This practice recognizes that the product should be kept sterile until certain events contaminate it (such as breakages, moisture, falls to dirty surfaces like the floor, etc.).
- In other cases, the expiration date of 6 months can be used to ensure available inventory and conserve storage space.

In order to change the labeling of the expiration date, the following should be carried out:

- First, carry out an inventory of all articles that are not used for 6 months.

- For articles sterilized in January, the expiration date should be July. For articles sterilized in February, the expiration date should be August. The same pattern should be followed for other dates.
- If this system is used, different storage locations can be supervised 12 instead of 365 times a year.

Storage processes should be reevaluated if:

- Storage is not being carried out well. This could happen if recently sterilized packages are stored on top and as a result are the first to be used.
- The quantity of a single article requested is exaggerated.
- There are some articles that are probably never used.
- There are sterilized articles whose use is unknown to all personnel.

Once these steps have been analyzed and overcome, analyze:

- Which conditions can be used to store the articles required for each service, while trying to meet the storage standards mentioned above.
- Analysis of any changes should be carried out together with the Infection Control Committee.
- The costs associated with the change in packaging, including no reprocessing and the time used by personnel for reprocessing, should be analyzed.

Methods for controlling the sterilization process

Control is carried out by verifying that what is planned according to the standards of the service is fulfilled. The process should be controlled at every stage and this control should be recorded. In order to adequately control sterilization processes, it is necessary to have in-depth knowledge of:

- the way the equipment works,
- its current state,
- deficiencies that it can have,
- ways to control it, and
- its tolerance to materials.

In order to approach a control method we should first ask ourselves:

Was it processed?

Was it processed correctly?

A control system should meet the following objectives:

- Identify each material.
- Confirm that the process was carried out using a chemical control.
- Establish an acceptable operating point.
- Detect deficiencies in the equipment beforehand.

Control of the process includes the control of inputs used at each stage, the raw material (gauze, paper, cotton, ethylene oxide capsules, etc.), biological monitors, chemical indicators, etc.

When the result of the control is satisfactory, it will pass to the following stage.

Sterilizing equipment is validated both in a chamber that is empty and in a loaded chamber at least once a year and whenever it is repaired.

Such repairs should be carried out by trained personnel. A plan for corrective and preventive maintenance is recommended.

User manuals (in the appropriate language) for each type of equipment should be on hand in the SP.

The reading instrument should be exact, which is why it is necessary to calibrate it periodically.

The sterilization process is complex. We can discuss a degree of reliability in the processed material only when strictly respecting the conditions involved in each stage.

Sterility cannot be ensured only through tests. It is obtained through a system of total control throughout the process.

A good infection control program involves the continuous validation of the conditions of the process.

Validation can be defined as *"a systematic, documented study that provides a high degree of certainty that a procedure, piece of equipment, process, material, activity or system will actually behave within certain predefined limits*."

The validation and observation of good manufacturing practices are the fundamental pillars of quality assurance.

In order to obtain sufficient safety, the program should include: adequate training of personnel and adequate preparation of the location, the equipment and the system for circulating materials. Equipment should also be adequately monitored.

The air filters, the water for washing, the measures of biosafety, the physical plant, the clothing of the personnel, the quality of the steam, etc., also integrate quality control.

The Bowie Dick (specific indicator) test is carried out before the first sterilization cycle each day and for each steam autoclave with:

- a standard package according to predetermined standards (AAMI, CEN – European Committee for Standardization).
- a single-use commercial package adjusted to the characteristics of the cycle, or
- an independently-prepared package that adjusts to the requirements of the test.

	Types of controls	Detect
Sterilization controls	Physical indicators	Mechanical operation
	Chemical indicators	T°; steam; exposure time
	Microbiological indicators	Destruction of microorganisms and spores

Physical monitors

- These are measurement elements that are incorporated into the sterilizer, such as thermometers, pressure manometers (barometers), chronometers, load censors, parameter registry valves and systems, among others.
- They allow visualization if the equipment reaches the parameters required for processing. Many types of equipment currently have a microprocessor that prints the characteristics of the process at all stages. These monitors, however, can present errors or not reflect what really occurs with the process.
- This is particularly certain due to the existence of other factors that affect sterilization, such as the size of the load and the presence of organic matter, which cannot be detected by physical monitors.
- Physical monitors are very useful, but they are not sufficient as sterilization indicators. Additionally, they should be calibrated periodically in order to guarantee the information they provide.

Periodicity of use:

- During every sterilization cycle.

Temperature:

- The temperature of the chamber and of the interior of the packages are recorded through temperature sensors that are made specifically for the apparatus and through other external sensors (thermocouples, etc.).

Pressure:

- Through manometers, manovacuometers or pressure sensors that should be calibrated periodically.

Time:

- According to the clock that is part of the equipment, which should be calibrated periodically.

Maximum thermometer:

- This indicates the highest temperature that has been reached, but not its duration.
- For sterilization by moist heat, it is necessary to take the precaution of wrapping the thermometer in surgical clothing in a way that does not form channels that hinder the arrival of the sterilizing agent.

At the end of the cycle, confirm fulfillment of the parameters with the values required for the total sterilization cycle. The printed registries that can be issued by the equipment should be used.

These registries should be filed with the rest of the documentation of the process.

Chemical indicators

Periodicity of use:

- In every cycle and/or package.
- The chemical indicators used for each process should meet the following conditions:
  - printed on non-toxic tapes.
  - stable over time.
  - easy to read and interpret.
  - permit the replicability of the process.

Classification of chemical indicators (ISO 11140-1)

Type of indicator:	Controls:
Class I: Process indicators.	They distinguish between processed and unprocessed units.
Class II: Indicators for use in specific tests.	Bowie Dick Test.
Class III: Simple parametric indicators.	They respond to one parameter. For example, temperature.
Class IV: Multi-parametric indicators.	They respond to more than one critical parameter, such as temperature and climate.
Class V: Integrating indicators.	They respond to all of the critical parameters and are adjusted to the response of biological indicators.
Class VI: Emulating indicators.	They respond to all of the critical parameters and are adjusted to those of a known cycle.

Process indicators

Adhesive tape - Class I

- These are adhesive tapes that are impregnated with thermochemical ink that changes color when it is exposed to a given temperature.
- Their purpose is to demonstrate that the article was exposed to the sterilization process and to distinguish between processed and unprocessed articles.
- These devices are based on chemical reactions and are sensitive to the

parameters of different sterilization methods (by saturated steam, temperature and time).

- They are presented in the form of paper strips printed with ink and other non-toxic reagents that change color when the established requirements for the process are fulfilled.
- It is important to emphasize that these products change if a key element is fulfilled, for example temperature, and not necessarily the three elements mentioned at the same time.

These controls can be internal and external:

- Internal controls are placed inside of the packages. Their principal advantage is that they provide immediate information on the results, although they do not present definite proof of sterility.
- External controls indicate that the process has undergone sterilization control, but do not show whether or not it was effective. These controls are presented as adhesive tapes.
- Chemical indicators differ according to the process used (dry heat, moist heat or gas) and should be selected according to the parameters that need to be measured.

Simple parametric indicator - Class III

- This is an indicator for only one parameter. In this case, it only indicates that the package was exposed to a given temperature, according to the AAMI (1994).
- This is carried out to verify the temperature during the sterilization process.
- It is important to mention that new indicators currently exist. These indicators are no longer being used in our arena.

Multi-parametric indicator - Class IV

- This is a type of indicator for multiple minimum parameters (time and temperature) of the sterilization process.
- This consists of a strip of paper impregnated with termochromic ink, which changes color when it has been exposed to the necessary minimum conditions of the method.

Integrating indicator - Class V

- These are indicators designated to react to all of the critical parameters of the autoclave sterilization process (temperature, time, quality of the steam) within a specific interval of the sterilization cycle.
- These indicators are much more precise than those in Class IV.
- They should be used inside each package as an internal indicator.

Simulation indicators for cycle verification - Class VI

- These are also known as simulation indicators since they are designated to react to all critical parameters within a specific interval of specific sterilization cycles.
- They function when 95% of the specific cycle has concluded.
- Their performance and reading is similar to Class V integrating indicators.

Specific indicator

Bowie Dick Test - Class II

- This is a method for evaluating the effectiveness of the vacuum system in the pre-vacuum autoclave. Its purpose is to demonstrate the absence of air or other uncondensed gases in the sterilization chamber that can impede the rapid, uniform penetration of steam within the load.
- The test package will be formed by pure cotton cloths or towels, folded so that they reach the measure of 30 x 22 x 25 cm. and an approximate weight of 6.5 kg. A Bowie Dick test sheet will be placed in the center of the package and everything will have its corresponding packaging.
- This package will be placed in the lower part of the chamber, near the door and in a horizontal position (the sheet should be parallel to the base of the sterilizer).
- A cycle should be carried out at 134 °C with an exposure time of 3.5 to 4 minutes (Rutala, 1996, AORN 1994, Scali 1997).
- At the end of the cycle the package will be removed and the results will be interpreted:
- *Correct test:* The indicator will have turned toward the other tonality uniformly across its entire length.
- *Incorrect test:* This is expressed through a color that is fainter than the one indicated by the manufacturer or through the appearance of spots or areas of different color or color density.
- There are currently factory packages that replace the ones just discussed.

- *Critical aspects:* If the test indicates incorrect sterilization (it is positive), it should be repeated. If incorrect sterilization is confirmed, the operation of the equipment should be interrupted and maintenance assistance should be requested (review of drip traps, solenoids and the vacuum pump). After the review, perform the test again in order to corroborate its functioning.

Biological indicators

Biological controls are currently the only means available to confirm the sterilization of an article or to determine the effectiveness of the sterilization process.

Periodicity of use:

- **Moist heat:** one per week.
- **Ethylene oxide:** one in each load.
- **Steam - formaldehyde:** one in each load.
- **Hydrogen peroxide gas plasma:** one in each load.
- **Dry heat:** one per week or according to the periodicity of its use.

Furthermore:

- Each time the **equipment is repaired.**
- Whenever the equipment is used to sterilize **prostheses or implants.**

Each biological indicator should specify:

- quantity of spores
- lot number
- expiration date
- D value

Biological controls should meet current national or international standards.

Placement of the controls:

- **For control of the chamber:** Place them in locations that are as inaccessible as possible to the sterilizing agent, inside of a syringe and with double wrapping.
- **For control of packages:** Place the control in the center of a package that will be placed in a location that is as inaccessible as possible to the sterilizing agent.

Biological references:

- **Moist heat:** *Geobacillus stearothermophilus*.
- **Dry heat:** *Bacillus atrophaeus*.
- **Ethylene oxide:** *Bacillus atrophaeus*.
- **Steam - formaldehyde:** *Geobacillus stearothermophilus*.
- **Hydrogen peroxide gas plasma:** *Geobacillus stearothermophilus*.

Biological indicators are prepared to contain a sufficient charge of microorganisms that are highly resistant (*Geobacillus stearothermophilus, Bacillus atrophaeus* and others) to sterilization and whose destruction, when exposed to a given cycle, indicates that it has been satisfactorily implemented.

They are designed in such a way that their reading and interpretation is very easy and rapid, in order to confirm the presence or absence of viable microorganisms after the sterilization process.

These indicators should be introduced into the interior, and at the midpoint, of the largest, heaviest packages of the load.

Different controls should be used in the different cycles of each piece of equipment.

In 1996, Rutala classified biological indicators into: first, second and third generation, according to the order of growth, speed and rapidity of results.

First generation: These appeared in the seventies in very simple form as paper strips with spores. They had to be transported to the laboratory in order to incubate them, which took 2 to 7 days.

Second generation: These are vials with the dry content of spores, in which the final reading is taken after 48 hours. They have a portable incubator. These indicators are not available for dry heat.

Third generation: These are quick-read biological indicators.

At present, a new biological indicator has been designed based on the detection of an enzyme associated with microorganic spores.

The method allows for results to be attained in three hours (autoclave), compared to the 48 hours needed for the traditional biological control.

Evaluations of the method have concluded that the method is even more sensitive than the biological indicators used to date.

The latest generation incubator has an ultraviolet light lamp (fluorescence) in order to accelerate the reading process.

Basic procedure for using biological indicators

Place a biological indicator in the center of a package (surgical clothing), labeling its position, the lot number of the load, the date and number of the autoclave, with a full load in a normal work cycle.

Afterwards, place the package in the central part of the chamber and begin the cycle.

The frequency of use can be daily (AAMI 1994, AORN 1999) or weekly (CDC 1985).

After the cycle is complete, it should be taken to an incubator at 56 °C for indicators used in an autoclave (*G. stearothermophilus*) and an incubator at 37 °C for indicators used in ethylene oxide (*Bacillus atrophaeus*).

The internal vial will break before placing it in the incubator, so that the culture medium remains in contact with the spores.

At 48 hours, register the results:

Negative result: When the indicator does NOT change color according to the protocol – EO (green) and autoclave (violet), it means that the sterilization process was correct or adequate.

Positive result: If the sterilization process was inadequate, the indicator will change to a yellow color, which indicates that the bacilli are still alive and developed in the culture. In this case, report and immediately follow up on all of the packages sterilized in that lot in order to reprocess them.

"All sterilization processes should be controlled by means of physical monitors and chemical and biological indicators."

The disadvantage of these indicators is the waiting period for results, since the reading is taken after the first 12 hours and at a maximum of 72 hours.

Reactive strips for determining the minimum effective concentration of glutaraldehyde

Use of the strips

- The strips are a semi-quantitative method for determining if the glutaraldehyde concentration is above or below the minimum effective concentration (MEC).
- They should NOT be used to validate the sterilization or disinfection process.

Instructions for use

- Submerge the end of the reactive strip in a container with Cidex solution for one second and remove it. Do not leave the strip in the solution for more than one second or "stir" the strip in the solution. If it is submerged for more than one second or moves vigorously in the solution, it will wash the reagents off the strip. This can cause a deficiency in the formation of a yellow color (error) when the solution would normally pass the test.
- Remove the excess solution from the strip by touching the longer edge with a paper towel. Do not shake the strip after removing it or "dry it" on a towel paper facing downward, because it would remove the reagents and the same effect described in item 1 would occur.
- Read the results of the color reaction between 5 and 8 minutes after the strip has been removed from the solution. If it is read prior to 5 minutes, there can be false negative reactions. Do not read the strip after 8 minutes since the color vanishes, making interpretation difficult. The strip should remain completely yellow in order to indicate that the solution is effective. Any tone of yellow is acceptable; the intensity varies according to variations in concentration. If white residue remains on the strip, the Cidex solution is ineffective and should be discarded. Refer to the original bottle to facilitate the visual interpretation of results by comparison.
- Write down the results obtained in the file provided. Keep a record of each test that is carried out.

Quality control

- Prepare a control solution of positive and negative Cidex, in order to confirm the quality of the strips.
- Activate the Cidex solution. This activated solution, as of that point, will be used as a positive control.
- Dilute one part of the activated solution with one part of water. This will be the negative control.
- Following the previous steps for use, submerge three strips in each solution. The strips submerged in the positive control should be completely yellow within 5 to 8 minutes. The strips submerged in the negative control should be completely white or present an incomplete yellow color when they are read at 5 to 8 minutes.
- If the results obtained are not satisfactory, discard the remaining strips and do not use them in the test.

Summary of quality control of the sterilization process

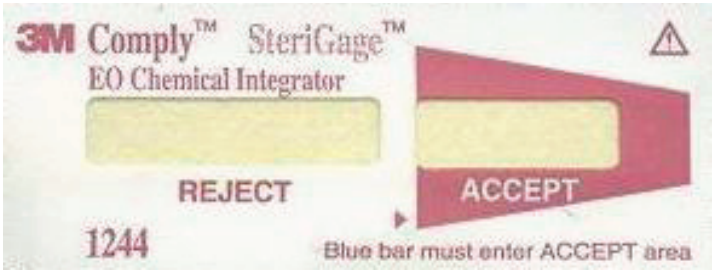
Identification of the product	Registration of the load of every cycle and the expiration date of the material	Verification of every cycle
Physical controls	Temperature Time Steam pressure Concentration	Verify for every cycle
External chemical identifiers	Indicate whether it has passed the physical conditions.	Verify for every package (upon exiting chamber and prior to use)
Internal chemical indicators	Indicate whether the interiors of the containers and packages have achieved the conditions of the process.	In the interiors of packages or containers > 30 liters. Verify before using.
Biological indicators	Document the effectiveness of the sterilization process.	At least 1 per week in steam and 1 per cycle in EtO. Verify before using.
External chemical controls	Adhesive tape or ink. Verify in all packages.	
Internal chemical controls	In packages without external chemical control or in which the volume or composition make it difficult for the sterilizing agent to pass (container). Verify one or all parameters (integrator). These exist for all systems. Verify before using.	
Biological controls	Spores: Bacillus atrophaeus for EtO and Geobacillus stearothermophilus for steam. Types: Fast reading (hours) and slow reading (days).	

Examples of controls for the interiors of boxes:

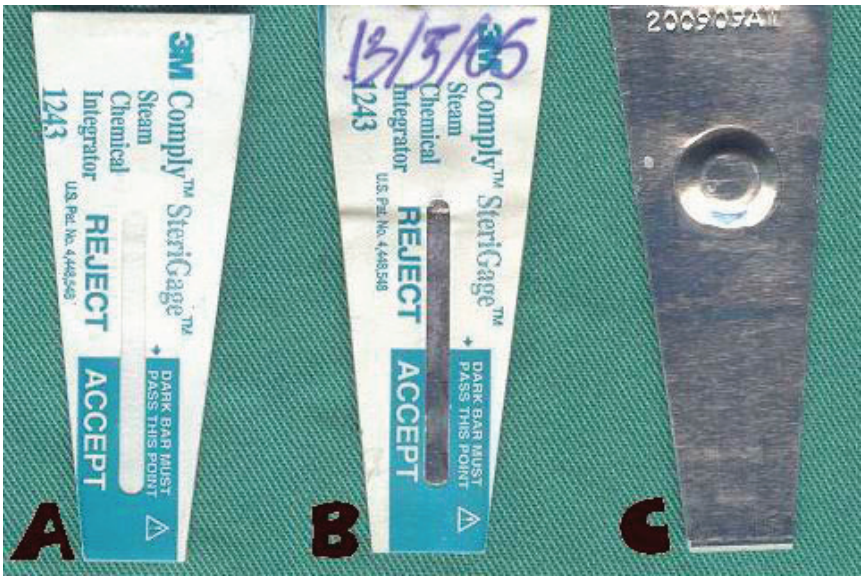
1. Non-sterile:

2. Sterilized:

3. If sterilization is correct, the bar should be blue:



Examples of controls for the interiors of boxes:



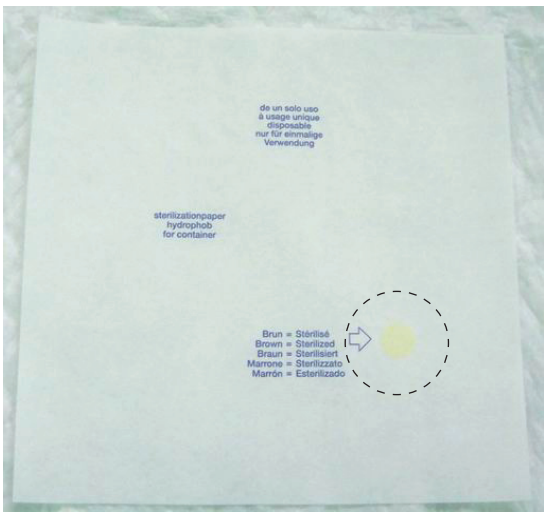
A: Non-sterile **B: Sterile** **C: Back side**

Adapted from: Enfermera de Quirófano, Spain, 2006

Examples of controls for the exteriors of boxes or bags:

1. In the controls for the exteriors of boxes and on tapes, we should also put the date that that the box was sterilized.
2. We should also take advantage of the tape in order to note whether a certain part, clamp, etc. is missing.

3. Tape (once sterile, the lines should turn black).



4. The yellow point should turn brown once sterilized.

Adapted from: Enfermera de Quirófano, Spain, 2006

Failures in the sterilization process

In the event that the sterilization process fails and for the management of sterile equipment that have an expiration date, the following recommendations should be used:

- All sterile materials whose expiration date has passed are not considered safe for use with patients and should be removed from the service.
- Objects that are processed in the hospital should return to the SP. In the SP, the boxes should be opened, the cotton towels replaced and a new chemical indicator placed in their interior. Prior to re-sterilization, the objects should be packaged in new packaging. Objects wrapped in plastic or paper should be removed from the previous package and replaced with new packages. New chemical indicators should be placed in each package in order to re-sterilize it. All sterilization parameters that are appropriate for the reprocessing of medical equipment should be followed.
- Products sterilized by the manufacturer should not be re-sterilized unless the trade name provides written instructions for their re-sterilization. There are standards for the re-sterilization of medical use materials.
- In the event that a sterilizer fails, revealed by a change in color in the biological indicator, it should be taken out of service immediately and the maintenance service should be notified in order to repair it. All objects that have not been used in this load should be collected and re-sterilized. Patients exposed to sterile objects from the deficient lot should be monitored. Infection Control personnel should be notified about the deficiency of the sterilizer in order to follow up with the patients.

Responsibility

- The SP technician is responsible for the results obtained from the biological indicators in each load, both in autoclaves by steam and by ethylene oxide. If the biological indicator suggests a deficiency in the sterilizer, the technician should report this immediately to the department supervisor and

take the sterilizer out of service.

- The department supervisor should notify the maintenance service about the repair of the sterilizer. This cannot be placed in service again until the verification procedures are carried out.
- All hospital staff should review the sterile packages routinely and organize them on the shelves according to their expiration date. Objects with an earlier expiration date should be placed up front. If the expiration date has passed, the package should be removed from the service and sent to the SP for reprocessing. This is the responsibility of each department.

Summary

If there is a potential sterilization failure, the following steps should be undertaken:

- The SP technician should notify the supervisor at the first sign that a biological indicator is positive (this normally takes 48 hours, but positive results could potentially be obtained in 24 hours).
- The sterilizer that fails should immediately be taken out of service.
- The lot number of the batch affected should be reviewed and all objects listed under the lot should be removed from patient care areas and sent to the SP for reprocessing.
- It should be assumed that objects that have not been located have been used with patients. All possible efforts to identify which patients were affected should be made.
- The head of the SP should be the one in charge of reporting the possible failure of the sterilizer immediately to Infection Control personnel.

Validating the sterilization process

Quality is a basic tool for improving processes and services. The ISO 9001 (general quality) and EN ISO 13485 (quality of the installation and maintenance of health products) standards make it possible for us to evaluate our system and guide the steps to improve the system.

In the case of sterilization, an adequate level of sterilization (SAL: Sterilization assurance level) should be ensured so that the specific process generates a product or service according to its predetermined specification and in keeping with established quality characteristics.

The European Standard, 1994, defines that: a medical device that is determined to be "*sterile*" should reach a SAL of 10^{-6} when it undergoes a **validation** process.

A common requirement of ISO 13485, Correct Manufacturing Standards (CMS) from Europe, Good Manufacturing Practice (GMP) and the FDA is the use of *validated processes*.

Validating a process consists of systematically carrying out the process in a specific manner in order to improve it, using the following phases:

Planning: Establish temporary programs and checklists, validation protocols with criteria for acceptance/rejection, needs for resources, risk analysis.

Installation qualification (IQ): This phase is associated with installation by the service provider and includes the calibration of measurement and control elements, documentation, plans, and work instructions.

Operational qualification (OQ): This is the crucial phase of fine-tuning the process, during which its robustness and reliability when facing the worst cases should be demonstrated.

Provisional or functional qualification (PQ): This final phase examines the replicability of the process, including the precise formation and qualifications for its operations and work instructions that are definitive and put into action.

Validation of the sterilization process

Validation	**Qualification of the equipment**	Installation qualification
		Operational qualification
		Provisional or functional qualification
	Qualification of the load	Parameter tests
		Microbiological tests
		Others

The validation process consists of verifying in a certified and sufficiently documented manner that a process meets the requirements for which it was designed.

In the case of sterilization, labeling a health product with the word **"sterile"** is only permissible when a validated sterilization process has been used.

As a result, validation should consist of the following points:

- Installation qualification
- Operational qualification
- Process qualification
- Documentation
- Case-fatality calculation
- Validation report and certificates

In this way, the SP can demonstrate in a sufficiently documented manner that the parameters of temperature and pressure reached throughout the sterilization process of a load were within the criteria defined by the standards, and for repeated loads.

The validation of a process is the documented procedure of evidence with regard to the equipment and its operation.

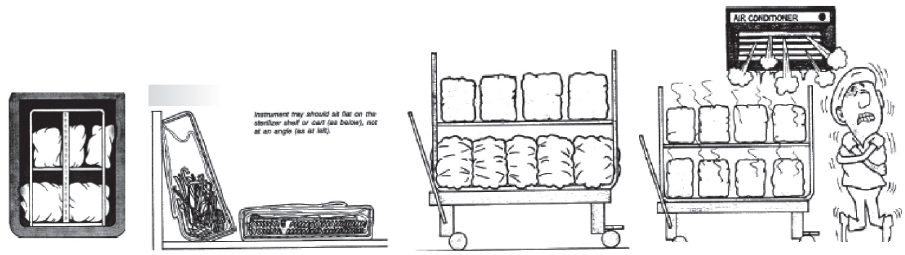
Validation of loads

It is important to validate the process at all points: washing, loading/unloading of the material, and the sterilization process itself. In the case of loading/unloading of the material, the validation of this procedure consists of meeting the minimum stages and evaluation criteria that the user should handle.

Technique and material

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

- Position of the articles within the load.
- Packaging of the load.
- Cycle selected.
- How to unload.
- Repeat three times.



Components of sterilization validation

Audit

This process demonstrates, documents and confirms that the equipment meets the performance specifications as they were designed following their installation in the place of use.

Certification to operate

This process demonstrates that the equipment, following review, will produce acceptable products when it is 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.

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 that the user should handle.

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 electric installations (voltage), structure, dimensions and ventilation should be confirmed.
- **Operational quality:** This should confirm that all of the 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 will be generated.
- **Performance quality:** This should verify the 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 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 with the terms: IQ (installation quality), OQ (operational quality) and finally, PQ (process quality).).

- **IQ Installation quality:** This consists of verifying that the equipment has been adequately installed and is safe to operate, following manufacturer specifications and the standards applied in each country. 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 manufacturer specifications as well as 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: installation plans, technical/operational user manual, etc.
- **OQ Operational quality:** This consists of verifying that the sterilizer's different measure 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 standards. To achieve this, the following steps should be taken:
  - 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.
- **PQ Process quality:** This procedure documents that the parameters of temperature, pressure and case-fatality reached within the load throughout the sterilization process and in repeated cases are within the criteria defined by the country's 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. This verification ensures that the parameters of temperature, pressure and case-fatality are within the parameters designated by the country's standards.

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, the water hardness should be observed. With regard to the electric installations, the voltage, protective devices, installation to the source it-

self, and quality of the steam should be observed.

- **Equipment:** The structure for the installation of the autoclave should be confirmed, including its physical adaptation, harmony, ventilation near the doors of the autoclave, and minimum distances between walls and the equipment in order to facilitate maintenance.
- **Operation:** The existence of an Operational Manual should be confirmed, as should the registry of the most commonly replaced parts, the information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **Performance:** Performance 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 chemical and biological 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 chemical and biological 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, since what is most common is to wait until the machine fails.

Validation of sterilization by ethylene oxide

Validation should be determined and provided by the manufacturer of EtO autoclaves.

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 electric installations, voltage and protective devices should be observed.
- **Equipment:** The structure for the installation of the autoclave should be

confirmed, including its physical adaptation, harmony, ventilation, and minimum distances in order to facilitate maintenance. The existence of a device to measure the quantity of residual EtO in the environment should also be confirmed.

- **Operation:** The existence of an Operational Manual should be confirmed, as should the registry of the most commonly replaced parts, the information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **Performance:** Performance 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 chemical and biological indicators should all be confirmed.

Three complete cycles should be confirmed with chemical and biological 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 electric installations, voltage and protective devices should be observed.
- **Equipment:** The structure for the installation of the autoclave should be confirmed, including its physical adaptation, harmony, ventilation, and minimum distances in order to facilitate maintenance.
- **Operation:** The existence of an Operational Manual should be confirmed, as should the registry of the most commonly replaced parts, the information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **Performance:** A microprocessor should be used to evaluate the physical parameters. Additionally, there are specific chemical indicators and a biological indicator test package that consists of a plastic tray with a restricted

dissemination opening that ends in a closed compartment that contains a chemical indicator and a biological indicator. 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 10^6 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 chemical and biological controls, during three consecutive days and with loads.

Validation of low temperature steam formaldehyde (LTSF)

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 electric installations, voltage and protective devices should be observed.
- **Equipment:** The structure for the installation of the autoclave should be confirmed, including its physical adaptation, harmony, ventilation, and minimum distances in order to facilitate maintenance.
- **Operation:** The existence of an Operational Manual should be confirmed, as should the registry of the most commonly replaced parts, the information registered by the technical service, and a voucher that certifies the operation of the equipment.
- **Performance:** A microprocessor should be used to evaluate the physical parameters. There are also specific chemical indicators (the strips should be introduced within the test package). The parameters that these chemical indicators measure in different sterilization methods are: presence of formaldehyde, concentration of formaldehyde, temperature and climate. The biological indicator consists of a vial with a paper strip containing 10^6 spores of *Geobacillus stearothermophilus*, which should be placed within the test package.

The physical parameters should be confirmed with a test package, followed

by three complete cycles with chemical and biological controls, during three consecutive days and with loads.

Management areas and critical points

Direct observation can be used to determine *the type of mistakes made* and *the critical points* (risk areas). A multidisciplinary team with knowledge about the field of sterilization should be created to implement this. There are eight critical points (work areas), which can be divided into five areas (Criado Álvarez, 2006):

Management areas	Critical points
Preparation	Prepare protocols and work procedures Provide training for personnel
Management of the process	Ensure correct selection and allocation of resources Ensure adequate working conditions Safeguard the safety of the user and the environment
Supervision system	Guarantee correct execution and control and continuous surveillance
Organization of resources	Carry out operational, efficient planning
Verification of the process	Ensure documented validation and accreditation

Summary of validation activities

- 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

When should sterilization validation be carried out?

- Sterilization validation should be ***initial*** and ***periodic***.
- Once the equipment is installed, a test should be carried out jointly by the

center's personnel and the manufacturing company's technical service.
- This test confirms that the apparatus works correctly in that environment.

This test should be repeated whenever:
- Damages are repaired
- Maintenance operations are carried out
- The packaging material is modified
- The composition of the load is modified substantially

Quality indicators for the sterilization plant

Criteria for verifying the effectiveness of the sterilization process

The sterilization process should be effective and neutralize any life form that is present. It has to be confirmed through a correct result on the physical, chemical or biological indicators.

Indicators

No. of loads per autoclave, with a verification sheet, with the correct sterilization indicators per week.
——————————————— x 100
Total No. of loads per autoclave during the week.
Quality standard: 99%

No. of loads with EtO, with a verification sheet, with the correct sterilization indicators per week.
——————————————— x 100
Total No. of loads with ethylene oxide during the week.
Quality standard: 100%

No. of loads with gas plasma, with a verification sheet, with the correct sterilization indicators per week

_____ x 100

Total No. of loads with gas plasma during the week.

Quality standard: 99%

Criteria for sterilization expiration time

Every sterilized product needs a printed label that shows the expiration time of the sterilization.

Material that needs to be re-sterilized due to an expired time should be kept to a minimum.

Indicator

No. of re-sterilized products that passed the expiration time.

_____ x 100

Total No. of sterilized products.

Quality standard: less than 1%

Criteria for adequate packaging of material to be sterilized

Indicator

No. of errors or defects in the packaging of materials to be sterilized per week.

_____ x 100

No. of sterilization loads during the week.

Quality standard: 0%

Criteria for safety in the sterilization plant

The sterilization plant needs to work with standardized, safe procedures in order to guarantee a minimum frequency of work-related accidents.

Accident indicator

No. of accidents that take place in the sterilization plant in a month.
_____ x 100
No. People / day working during the month.

Quality standard: 0%

Incident indicators

No. of incidents that take place with the autoclave in a month.
_____ x 100
No. of loads by autoclave carried out during the month.

Quality standard: less than 1%

No. of accidents that take place with ethylene oxide in a month.
_____ x 100
No. of loads by ethylene oxide carried out during the month.

Quality standard: 0%

No. of accidents that take place with gas plasma in a month.
_____ x 100
No. of loads by gas plasma carried out during the month.

Quality standard: less than 2%

Criterion for the satisfaction of the internal client

Indicator

N° of claims or complaints due to delays, deterioration or losses received by the SP per month.

_____ x 100

No. of sterilization loads carried out during the month.

Quality standard: less than 1%

Re-use of a single use medical device

Re-used is currently understood as: *the repeated use of any medical device, including those that are reusable or labeled as single use, with the corresponding reprocessing between uses.*

Reprocessing is understood as: *all the operations necessary for reusing contaminated single-use or reusable materials.* The steps include: cleaning, functional testing, packaging, labeling and sterilization.

The reuse of single-use medical devices (MD) should be authorited by specific national regulation. Despite this, the practice of re-use in many health centers is indiscriminate and disobeys regulations, in the majority of cases due to ignorance. The situation that countries experience suggests the need to implement a re-use program that is sustainable over time.

When intending to re-use a single-use MD, one should first demonstrate that there will be savings. This should be done while also evaluating operational issues such as the functionality and integrity of the MD, the risk of infections, the risk of endotoxic reactions, personnel safety, and legal and ethical responsibility.

Manufacturers of MD that are labeled as single-use maintain the position TO NOT RE-USE, alleging that the products have not been designed or validated by clinical data that support multiple re-uses. They consider that re-use goes against the recommendation of the label and implies risks to the parties involved, primarily the patient.

The first devices to be analyzed are usually costly MD, which in general turn out to be critical or high-risk. The evaluation of low-cost, high-consumption MD, which are usually medium- or low-risk, is often overlooked.

According to the FDA, single-use MD are classified as:

- **CLASS I or low-risk:** These devices are considered to pose a low risk for patients. These require *"general controls."*
- **CLASS II or medium-risk:** These devices can have some risk for patients, which means that they need *"special controls."*
- **CLASS III or high-risk:** These products are considered to pose a high risk for patients. These require *"rigorous controls."*

Although the washing, packaging and sterilization of "reusable" medical devices are *normal* functions of the SP, the reprocessing of devices labeled as single-use is not.

Therefore the methodology or protocol that should be used to *DEVELOP AND MAINTAIN A PROGRAM FOR RE-USE* should simulate the practices of the industry. It should establish the procedures step by step through quantifiable, documented and replicable results.

It is therefore important to initiate contact with the manufacturer in order to ask, for example: *what polymers does the device contain?, does it have lubricants?, can certain disinfectants, contrast media, drugs, etc. be aggressive and incapacitate reprocessing?*

As a result, the requirements that should be met in order to reuse single-use medical devices are:

Cleaning: The design and manufacture of a device should permit the cleaning of all surfaces. Cleaning is defined as the total removal of all visible dirt from the surfaces, crevices, joints and lumens of the device. For the cleaning procedure, enzymatic cleaners, brushes and/or automatic cleaning equipment should be used, in order to remove the dirt from all contaminated surfaces without leaving toxic residues or causing damage to the device.

Inspection: Following cleaning, tests of functionality and physical integrity should be carried out in order to confirm that the device is safe to be reused. The level of inspection will depend on the complexity of the device and its later use. The inspection process can be by a simple visual check in order to ensure that all visible dirt has been eliminated and/or by a complex process that requires adequate equipment.

Packaging: The same quality of packaging that was used for the original product should be used at this stage, taking into account that the device will experience a subsequent sterilization process.

Sterilization: The sterilization process should demonstrate a sterility safety coefficient (CSE) of 10^{-6}, the coefficient that is accepted for devices that will have contact with tissue. Ethylene oxide is the most commonly used sterilizer for thermosensitive products, although all possible alternatives should be evaluated. s, de todas formas deberían evaluarse todas las alternativas que se poseen.

Validation of the processes to reuse materials

The validation of the processes for reusing MD should be carried out through:

- Verification of the effectiveness of the cleaning.
- Verification of the effectiveness of the sterilization processes.
- Verification of the absence of toxic waste.

Verification of the absence of toxic waste is not simple to carry out in health centers. More complex centers should carry out the primary development work and then give this information to centers of lower complexity.

The development costs of the protocols can be reduced if hospitals collaborate on the creation of each section.

The results can then be applied to devices from the same manufacturer, duplicating the procedures and using the same sterilizer equipment, as long as they operate according to manufacturer specifications.

Evaluation of the cleaning

The initial analysis for the development of the protocol should include a test for each level of re-use since waste and biofilms can go unnoticed and accumulate in a device with each subsequent use.

Sample size

The sample size or number of MD that need to be tested should be sufficiently large to ensure that the process can be duplicated successfully. In a previously published study (Reichert 1985), industrial practices were emulated and thirty devices, in three samples of ten, were tested.

For example, if the MD will be reused twice, a sample of thirty MD should be tested after each level of use, for a total of *sixty tests*. This test is focused on *cleaning* and the *sterilization process*.

Analysis of the sterilization process

The effectiveness of the cleaning procedure can be demonstrated with MD after they are used in clinical procedures. These stained devices should be cleaned using the procedure developed.

The ***first phase of analysis*** at each level of re-use is a visual inspection of the device after cleaning it. This inspection is carried out to verify that all visible dirt has been removed. Small lumen devices like catheters should be cut and opened in order to examine the internal lumen. If the device is not visibly clean, the cleaning procedure should be repeated until acceptable results are obtained.

The ***second phase of analysis***, once the effectiveness of the cleaning procedure has been verified, is the test of the sterilization process. At each level of re-use, the devices are cleaned, prepared and sterilized. After sterilization, the MD is sent to the microbiology laboratory where bacterial sterility is confirmed by culture. The sterile culture medium should be placed in contact with all of the surfaces of the MD. Devices that are lumens, such as catheters, have to be cut and opened to make sure that the culture medium is in contact with all surfaces.

Results. If there is no growth, the test confirms that the cleaning procedure was sufficiently effective for reduce the microbial charge to a level that can be destroyed during the sterilization process. If there is growth, the procedure should be repeated and the MD reexamined.

Frequency of the analysis. The test should be carried out: initially, when the product changes (e.g.: another manufacturer), when the process equipment is modified or changed, or when the cleaning agents are changed.

Analysis of pyrogens

The test of pyrogens should be used for any product that comes into contact with blood and bodily fluids and as a result could contain bacterial endotoxins that cause a pyrogenic response. Products like catheters can be visibly clean and sterile and still be hazardous to the patient due to high pyrogen levels.

Limulus amebocyte lysate (LAL) analysis is used to determine the endotoxin level and is available in a commercial kit.

Sample size

A sample size of 10 MD for each level of re-use should be carried out in order to test for the presence of pyrogens when developing the preliminary protocol.

Waste analysis

Although there are no standards for waste levels, the standards published by the FDA have been used as acceptable standard levels for the industry.

Recognized acceptable levels of waste for EtO and by-products

Medical Device	Ethylene oxide	Ethylene chlorohydrin	Ethylene glycol
Implant	-	-	-
Small, 10 g	250 ppm	100 ppm	25 ppm
Environment, 10 g to 100 g	250 ppm	100 ppm	25 ppm
Large, >100 g	5,000 ppm	2,000 ppm	500 ppm
Intrauterine device	5 ppm	10 ppm	10 ppm
Intraocular glasses	25 ppm	25 ppm	500 ppm
Devices in contact with mucous membrane	250 ppm	250 ppm	5,000 ppm
Devices in contact with blood and tissues	25 ppm	25 ppm	250 ppm
Devices in contact with skin	250 ppm	250 ppm	5,000 ppm
Sponges for surgical washing	25 ppm	250 ppm	500 ppm

Source: Federal Registry 43, no. 122 (23 June 1978), United States.

Integrity and functionality of MD

As a final step in the design of the protocol, it should be demonstrated that the reprocessed MD is functionally similar to the original MD.

The test should aim to confirm the specific characteristics of the MD. For example, if a MD needs to have flexion during regular use, a demonstration that it can be folded would be important.

Environmental cleaning and disinfection of the sterilization plant

The environmental cleaning and disinfection of the sterilization plant should be carried out daily. Floors and horizontal work surfaces should be cleaned at least once a day. Other surfaces (shelves, ceilings, windows, walls) should be cleaned periodically, according to the regular program created by the supervisor.

During the cleaning procedure, personnel should be very careful to not alter the integrity of the containers and materials that have already been processed.

Cleaning should always be carried out from "clean" areas to "dirty" areas, in order to avoid contaminant transfer.

It is ideal to have cleaning utensils (rags, cloths, sponges) that are differentiated by areas: dirty and clean.

Personnel should be trained to fulfill the standardized protocol, taking into account the following aspects:

- Carry out the cleaning procedures exhaustively, placing greater emphasis on floors and surfaces where the amount of dirt and microorganisms is more concentrated.
- Walls should be free from stains and splatters and should be cleaned completely when dirt or fungi are present.
- The utilization of water aspirators is recommended for improved disinfection of floors, although this equipment is not available in the majority of health institutions.
- Cleaning materials should be placed in mobile carts in the corridors.
- Dry sweeping with a broom should never be done, since this induces the movement of microorganisms from the floor into the air. There, they will remain suspended for several minutes until being deposited once again on the horizontal surfaces in the area.
- The use of air aspirators is not recommended for the same reason.
- Rags with dust should not be shaken out and surfaces should not be cleaned with dry rags.

Procedure

Cleaning and disinfection will be carried out from the ***green area*** (cleanest or most sterile) to the ***blue area***, in order to finish in the ***red area.***

Floors

- **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 subsequently apply the moist method.
- **Moist method:** This includes two techniques, the use of a double bucket, or the use of a single bucket.
  - **Double bucket procedure:** This is 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 alcohol 70% in order to remove dust. At that time, the expiration date and the integrity of the packaging for sterile medical equipment should be reviewed.
- A cloth or rag treated with disinfectant, which can be sodium hypochlorite (1:100), should be used to clean the surfaces. A clean rag should be used for each area.
- Alternatively, surfaces can be sprayed with a sodium hypochlorite solution, diluted at 1:100, and then rubbed vigorously with a clean rag saturated in the solution.

Hygienic and biosecure

In order for a SP to be a hygienic and biosecure place, the following recommendations should be followed:

- Corresponding measures to avoid or minimize the generation of drops or aerosols should be taken.
- The use of liquid soaps is recommended in order to prevent contamination and clogged plumbing.
- Wash hands before and after each procedure.
- Deposit the materials in completely dry places.
- Avoid air currents or movements within the areas of the SP.
- Fulfill the requirements of the institution's de-infestation program.
- Avoid all types of construction or un-programmed renovations in the area.
- Personnel should use the complete uniform provided by the institution (suit, cap, etc.) according to the standards of the SP.
- The use of nail polish, cosmetics and jewelry is prohibited.
- The use of feather dusters and brooms is prohibited.
- Eat or drink only in designated areas.
- Avoid the unnecessary handling of processed medical use products.

Ocupational hazards

The health team that works in a hospital establishment is exposed to countless risks that are capable of inducing work-related alterations or pathologies.

Sterilization services are not an exception to the occurrence of occupational risks. On the contrary, the SP constitutes a work area with high occupational risk.

The risks can be of a different nature or etiology, of which these are the most common:

Physical hazards: These are hazards caused by equipment, whose use involves risks such as noise and vibrations that can induce sound trauma and high temperatures that can induce burns.

Chemical hazards: These are hazards caused by aerosols, gases, vapors and organic dusts that can be natural or synthetic and inorganic. The chemical sterilizing agents with the highest risk are: ethylene oxide, glutaraldehyde, peracetic acid, hydrogen peroxide and formaldehyde.

Biohazards: These hazards are induced by the presence of microorganisms (fungi, viruses, bacteria, etc.).

Ergonomic hazards: These hazards are directly related to the design of the equipment, stress, workload, fatigue, repetitive tasks, monotony, etc.

Adverse effects of some chemical compounds

Isopropyl alcohol: This is used to dry rubber and latex materials and material with lumens. Isopropyl alcohol can irritate the eyes and mucous membranes. Its permissible limit is 400 ppm.

Sodium hypochlorite: This is used to disinfect environments. The sodium hypochlorite solution can irritate the eyes, nose and respiratory tract. Its permissible exposure limit is 0.5 ppm.

Phenols: This is used as a surface disinfectant. It can irritate the eyes, mucous membranes and skin. It can also affect pigmentation and generate skin necrosis. Its permissible limit is 5 ppm.

Glutaraldehyde: This is a disinfecting agent that produces toxicity by inha-

lation, causing cough, headache, difficult breathing and nausea. In the case of cutaneous exposure, it can produce reddening and irritation.

Ethylene oxide: The routes of entry into the body are through breathing (more frequent), the skin and digestion (less frequent). It is rapidly absorbed through the respiratory tract and highly soluble in blood. It is distributed rapidly in the body and ¾ of it is eliminated through urine within 48 hours. It can produce acute and sub-acute toxicity by inhalation of high concentrations in a short time (greater than 100 ppm). It produces irritation of the eyes and respiratory tract (with dyspnea, cyanosis and even pulmonary edema), digestive symptoms (nausea, vomiting, diarrhea), and neurological symptoms (headache, somnolence, lack of coordination and in exceptional cases, convulsions). In a liquid state and in solutions, its irritant effect is greater and can trigger allergic dermatitis. Cases of carcinogenesis, mutagenesis and teratogenesis have been demonstrated in animals in experimental studies. It is for this reason that EtO is classified as a type C2 substance. According to OSHA, the permissible exposure limit (PEL) is 0.8 ppm or 1.4 mg/m^3 in 8 work hours.

Hydrogen peroxide: This is a colorless liquid that is water miscible and can be decomposed by numerous organic solvents. It can produce acute toxicity and irritates the skin and mucous membranes at high concentrations. Contact with solutions over 35% can produce phlyctenas on the skin. The inhalation of hydrogen peroxide vapors or mist can induce severe inflammation of the upper respiratory tract. If over-exposure continues, it could result in pulmonary edema.

Formaldehyde gas: The principal means of occupational exposure is through the ocular mucous membrane, upper respiratory tract and cutaneous contact. After being inhaled, it is absorbed in the upper part of the respiratory tract due to its hydrosolubility. It is soluble in blood, distributed rapidly in the body – and more commonly in highly vascularized organs – has rapid cellular renewal, and has high protein synthesis. Its elimination is very variable. It can produce acute and sub-acute toxicity. Its principal effect is to produce primary irritation in eyes, nose and throat. Irritation increases when the environmental concentration surpasses 50 ppm. It can produce severe bronchiospasm. With regard to chronic exposure, studies have demonstrated that exposed people present subjective signs of irritation of the ocular mucous membrane and respiratory tract that can cause chronic respiratory pathology. Since its carcinogenic, mutagenic and teratogenic effects have been demonstrated in *in vitro* cells, it has been recognized as a type C2 agent. According to OSHA, its permissible exposure limit (PEL) is 0.8 ppm or 0.9 mg/m^3 in 8 work hours.

General recommendations

Physical hazards

In the case of physical hazards that can usually be modified and solved, it is recommendable to take into account:

- Internal training, communication and regulation as the main strategies to prevent physical hazards.
- Close monitoring of adequate temperature control and ventilation in environments such as machine rooms and adequate use of personal protection in high-risk areas (contaminated areas).
- Train human resources in what to do in accidents such as burns, cuts and injuries.
- Have an emergency kit adequately set up for emergencies.
- These should all be adapted to health and safety policies in the workplace and current electric safety.
- Transport carts should have rubber wheels.
- Personnel should use footwear with rubber or anti-slip soles.
- Fire distinguishers should be in a perfect state of use.
- Personnel that work with steam sterilizers or stoves should use antithermic gloves or mitts. Asbestos gloves should never be used.
- Equipment to cut off electric currents should be available.
- Gauze cutting machines should have a frontal safety switch.
- Personnel that work with textile cutting machines should use protective metal gloves.
- The SP should have easily accessible emergency exits.
- A water shower or bath should be available in the case of a spill with ethylene oxide or other chemical substances.

Chemical hazards

With regard to the prevention and treatment of the chemical risks detailed above, it is recommendable to take into account:

- When glutaraldehyde, EtO, FO and hydrogen peroxide are used, we should consider well-ventilated environments, personal protection according to possible contact (gloves, goggles, mask), the use of chambers designed to prevent exposure, and automated equipment.
- In the case of sodium hypochlorite, it should never be mixed with ammonia

(substance that is used to clean toilets).

- In the case of an EtO leak (some people are able to detect the leak if there is a sweet odor), it can cause signs of eczema and pruritus. In this case, the area should be evacuated and ventilated immediately and an expert should be contacted. In addition, the gas should be eliminated with pulverized water and the water jets should not be allowed to drip.
- When EtO, FO and glutaraldehyde are used, environmental control is important.

Biological hazards

Biological hazards occur when there is contact with contaminated materials and when both infectious and noninfectious waste of human origin from isolation areas is handled, such as tissues and bodily fluids, including blood and plasma. Other hazards derive from handling the contents of contaminated sharp, pointed instruments used in operating rooms, laboratories, etc. The recommended measure is the application of the biosafety principles detailed below:

- Universality means that every material that has organic matter is handled as highly infectious material. A label that says that the material is contaminated should not be necessary. The aforementioned clean-up and decontamination protocols should be applied.
- The use of physical barriers for personal protection is very important when contaminated materials and instruments are handled and when disinfection is carried out with chemical agents.
- The use of a mask for the preparation of textiles in the blue area is compulsory.
- For proper waste management, especially in the case of sharp, pointed instruments, it is important to segregate the waste material. This process should be carried out by the external user.
- It is important to take into account the classification of waste according to the standards of the General Environmental Sanitation Bureau.

Ergonomic hazards

With regard to ergonomic risks, it is recommendable to take into account:

- Maintain a direct relationship with the work team in order to rapidly identify environmental factors (moisture, steam, heat) that affect the normal limits of comfort.
- Train personnel on adequate positions for working and on the natural movements that should be used when transferring loads, lifting weight, etc. The use of aids such as transfer carts or adequate mechanical equipment should be employed in order to prevent fatigue and musculoskeletal disorders.
- Work furniture (chairs, tables, footstools and others) should be equipped in such a way that they permit postural ergonomics.
- Establish a rotation of activities between personnel in order to avoid monotony at work.
- Human resources should determine their own pace for producing activities. This should not be subject to a total dependency on machines or other people.
- When the organization of teamwork, participation, the pace of work and automation are maintained, problems of stress or psychosocial ergonomics will be avoided.
- The personnel in charge of waste collection should wear waterproof, resistant gloves and wash their hands whenever they take off the gloves. In addition, they should be vaccinated against Hepatitis B and tetanus.

Waste management

Classification

In a health institution waste is classified as: pathological or infectious; and household, chemical and radioactive types.

- **Infectious waste:** This type of waste can transmit infectious diseases and is also referred to as pathological waste. It includes primarily:
  - Laboratory materials, cultures, blood and derivatives.
  - Pathological anatomy material and material from operating rooms.
  - Sharp, pointed elements: all devices that have sharp rigid corners, edges, or protuberances capable of cutting, including needles, scalpels, and broken glass.
  - Patient elements with communicable diseases.
  - Waste from dialysis, including arterial tubes and dialysis membranes.
  - Waste with blood and/or bodily fluids and everything that is used with the patient.
- **Household waste:** This type of waste does not carry organic matter from patient treatment. It includes primarily:
  - Food scraps
  - Kitchen elements
  - Paper
  - Boxes
  - Cardboard
  - Packaging
  - Every disposable element that does not contain blood or biological liquids
  - Administrative waste
- **Chemical waste:** This includes chemical products and anti-neoplastic drugs, which should be discarded according to national laws.
- **Radioactive waste:** This includes radioactive products, which should meet the federal regulations for their disposal.

Disposal and final treatment

- **Sharps:** They should be placed in disposal containers that have been approved by infection control at the time of their use. When these containers reach their maximum capacity (3/4 full), they should be closed and placed in red bags with other pathological waste. The final treatment is incineration.
- **Contaminated liquids:** These should be discarded in toilets, which drain into the sewage system.
- **Household type waste:** Its final disposal is in containers for household waste companies and will follow the same path as household waste.

The waste bags contained in the waste receptacles should be closed with a safety seal to prevent accidents. They should then be placed in other receptacles identified as pathological or common waste, for their transportation and circulation through the institution.

All waste receptacles should be washed once a day and whenever they are visibly dirty. This should be done in the sector designed for that purpose.

The waste receptacles located at the nursing stations should be used for large quantities of pathological waste, for example major treatments.

No waste receptacle should exceed its content.

Waste storage

This is the place where waste will be placed temporarily. This location should be adequate for this function and should guarantee its temporary isolation, personal protection and environmental safety.

This sequence has *three stages*:

- **Primary storage:** This is carried out in baskets equipped with plastic bags.
- **Intermediate storage:** This is carried out in larger size containers, where the bags will be placed after removing them from primary storage and until being transported for their final storage and treatment. These are restricted access areas, in order to avoid contact with the general public.
- **Final storage:** This is the physical space where the waste generated in the establishment's different services is deposited until the time it is removed for final treatment and disposal.

Recommended standards and practices for infectious waste management

- All infectious waste should be discarded separately from other waste.
- Infectious waste should be discarded as close as possible to the site where it was generated.
- Infectious waste should be contained in red plastic bags, common waste in black plastic bags, and sharps in rigid containers.
- The micronage of the bags should be: 40 to 60 microns for small bags, 60 to 80 microns for medium bags, and 100 to 120 microns for large bags.
- The sizes should be analyzed and adapted to the quantity of waste that is generated by the sector or service.
- These bags should be closed, tied firmly and collected by housekeeping personnel when they are ¾ full.
- The use of a double red bag is not routinely required.
- Prior to contact with excretions, blood and bodily fluids, personnel should put on gloves, as stipulated in the standard precautions.
- Hands should be washed completely after removing the gloves.
- Sharp elements should be discarded in rigid containers provided in the nursing units. Needles should not be recapped, bent, or broken.
- Patients should be encouraged to discard dirty paper tissues in bags or receptacles located next to the bed.
- Dressing changes should be carried out using aseptic techniques and dirty dressings should be discarded in a red plastic bag that is closed prior to discarding.
- The infectious waste generated during the treatment of patients who require isolation precautions should be placed in receptacles with red plastic bags.
- Precautions not to mix other dangerous waste (e.g., cytotoxic drugs, mercury, etc) with infectious waste should be maximized.
- Liquid waste can normally be thrown in the toilet or similar object. This can be used to eliminate blood, stools, vomit, urine, sputum, secretions and other body fluids. Personnel should wear resistant gloves or mitts in order to handle liquid residue, avoid spattering their clothes and wash their hands. They should be particularly careful when pouring liquids not to stain the walls, toilets, furniture, floor, etc.
- Disposable containers should be closed hermetically in order to avoid spillage.

- Do not place explosive material (alcohol, solvent, aerosols) or glass in bags being sent for incineration. They should be treated as special waste, placed in rigid boxes and labeled.
- Human pathological waste (breasts, uterus, placenta, amputations, etc.) should be placed in well-closed bags and if necessary a double bag in order to avoid spillage. They should be placed in closed rigid boxes and labeled: BIOHAZARD.
- In the case of long lower limbs, they should be placed in a double bag, closed and labeled: BIOHAZARD.
- Pay attention when discarding pathological waste to not mix it with the rest of the waste, even when everything is headed to the incinerator. Label and discard it without delay.
- The circulation and transport of waste should be programmed. The frequency of the collection should be according to the need for the services. Waste transport should not be carried out when meals, medical visits, public visits, or patient transfer are scheduled.
- The closed bags should be placed in primary containers located in each sector. These will be removed by designated personnel, if necessary twice per shift.
- All waste should be transported to the designated storage areas in closed carts.
- Personnel that handle and collect waste should use adequate clothing and elements. They should use gloves made of a resistant material, a plastic apron (washable) and adequate footwear (rubber boots or similar).
- At the conclusion of the task, personnel should wash the carts used with water and detergent, rinse with running water and then disinfect with sodium hypochlorite 0.05% (dil. 1:100 of commercial bleach).
- Finally, personnel should take off the protective elements, wash and disinfect them. Then, they should take off their gloves and wash their hands and forearms.

Terms related to sterilization

- **Antisepsis:** process that destroys the majority of pathogens located on moving surfaces.
- **Antiseptic:** chemical agent that inhibits the development of microorganisms, or destroys them, and that is used on live tissue.
- **Area for preparation and packaging** where clean, dry elements are inspected, arranged in sets or boxes, and adequately wrapped or packaged for the selected sterilization process.
- **Area for raw material deposit:** an environment to store inputs such as textiles, packaging material and other clean products.
- **Area for reception and cleaning:** where reusable elements (instruments, equipment, etc.) are received, registered and undergo a cleaning process.
- **Area for support:** bath, showers, office and other facilities for personnel.
- **Area for sterilization:** where steam autoclaves, ethylene oxide (EtO) autoclaves, dry heat stoves and any other sterilizing equipment such as formaldehyde or hydrogen peroxide plasma are located. This includes the space for loading and unloading the carts.
- **Area for storage of sterilized material:** where the already sterilized materials are placed prior to their distribution.
- **Area for textile preparation:** where clean reusable textiles (surgical linen) and different hydrophilous materials (gauzes, bandages, etc.) are inspected, arranged and packed in their process packaging.
- **Bactericide:** chemical method or agent that is capable of killing or destroying bacteria.
- **Bacteriostatic:** chemical method or agent that is capable of inhibiting bacterial growth, but not necessarily killing bacteria.
- **Biological control:** method that determines the presence of pathogenic bacteria in objects subject to a sterilization process.
- **Broad-spectrum disinfectant:** disinfectant that has activity against a wide range of microorganisms.
- **Cavitation:** process by which air bubbles implode (break inwards), liberating dirt particles or tissue remains.
- **Cleaning:** process that eliminates organic and inorganic dirt or any other foreign material.

- **Contaminated:** this refers to every surface, moving or unmoving, that it is known to house microorganisms.
- **Decontamination:** this is the process for the removal of pathogenic microorganisms from objects and equipment in order to make them safe for handling.
- **Disinfection:** this is the process by which the majority of pathogenic microorganisms, with the exception of bacterial spores, are killed or destroyed. Disinfectants are used on inanimate objects.
- **High-level disinfection:** disinfection process that kills vegetative bacteria, tubercle bacilli, fungi and viruses, but not necessarily a high number of bacterial spores.
- **Intermediate-level disinfection:** disinfection process that kills vegetative bacteria, the majority of fungi, tubercle bacilli and the majority of viruses, but does not kill resistant bacterial spores.
- **Low-level disinfection:** process that kills the majority of vegetative bacteria, some fungi and some viruses, but does not kill *Mycobacteria* or bacterial spores.
- **Terminal disinfection:** process through which an area or object is disinfected after some type of contamination has occurred.
- **Ethylene oxide gas:** highly inflammable toxic gas capable of sterilizing an object.
- **Fungicide:** chemical agent capable of killing fungi.
- **Germicide:** chemical agent that destroys microorganisms. It may destroy pathogenic microorganisms, but not necessarily resistant bacterial spores. It can be used on live tissues (antiseptics) or inanimate objects (disinfectants).
- **Glutaraldehyde:** chemical agent capable of sterilizing objects.
- **Inanimate:** non-living.
- **Peracetic acid:** chemical agent capable of sterilizing objects.
- **Sanitation:** process that results in a reduction in the microbial population on an inanimate surface at a safe or relatively safe level.
- **Shelf life:** time period that a packaged object will remain sterile after undergoing a sterilization process.
- **Sporicide:** chemical agent capable of killing spores, especially bacterial spores.
- **Sterilization:** process by which all types of microorganisms are destroyed.

- **High vacuum sterilizer:** type of steam sterilizer that mobilizes the air in the vacuum chamber.
- **Steam sterilizer:** sterilizer that exposes the objects to steam at high pressure.
- **Gravitational displacement sterilizer:** type of sterilizer that mobilizes air using gravity.
- **Sterilization control verifier:** method that determines whether a process has been completed. It does not indicate if the objects subject to this method are sterile.
- **Tuberculocide:** chemical agent capable of killing *Mycobacterium tuberculosis*.
- **Ultrasonic cleaner:** equipment for cleaning instruments using cavitation.
- **Virucide:** chemical agent capable of killing viruses.
- **Washer-disinfector:** equipment that washes and sterilizes surgical instruments after an operation.

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