

Following find the steps for sterilization:

1. We control the sterilization technical parameter first:
in the sterilization cupboard:
 - Temperature: 38Degree +_ 2 degree
 - Vacuum: -30 Kpa
 - EO density : 600mg/L +-30mg/L
 - Wet: 30% RH - 80%RH
2. Put the needles in the sterilization cupboard for more than 8 hours
3. After 8 hours, take out the cartons, and put the needles in a well-ventilated analysis chamber for seven days to reduce the residue of the EO gas

Following find the steps for proper storage of EO Gas Sterilized items:

- Store items properly. Proper Storage is as important as the sterilization process itself:
- **Wrapped items.** *Under optimal storage conditions and with minimal handling*, properly wrapped items can be considered sterile as long as they remain intact and dry. For optimal storage, place sterile packs in closed cabinets in areas that are not heavily trafficked, have moderate temperature, and are dry or of low humidity. When in doubt about the sterility of a pack, consider it contaminated and re-sterilize it.

What is the ethylene oxide?

The ethylene oxide is a colorless and odorless gas which special chemical properties permit:

- A good diffusion in porous materials
- A good diffusion and absorption in most of the heat sensitive plastic materials.
- a good action on the surface of heat-sensitive metallic instruments.
- a good care of the elements since the gas does not damage the material which constitutes the items to be sterilized by this method. Therefore this method can be used without risks.

The combination of these features triggered its widespread use, since the method allows to:

- penetrate in the sheets and those inaccessible parts of complex elements
- sterilize between 25°C and 55°C. it guarantees that the elements to be sterilized will not be either damaged or destroyed
- pass through the membranes of the packing containing the elements (especially the polyethylene film).
- No reacciona ni deteriora la mayoría de los materiales que constituyen los elementos a esterilizar por este método, lo que permite su uso sin riesgo.

3.- What is the ethylene oxide sterilization?

It is a type of chemical sterilization based on the use of a sterilizing agent named ethylene oxide. This method has been used in the medical area for more than 60 years. Moreover, the ethylene oxide sterilization is recommended as an alternative for those elements that cannot be sterilized by the traditional techniques of heat and/or vapor.

Up to present no other technology has been able to offer better features than the sterilization by ethylene oxide. Consequently it is still considered the best choice to sterilize heat-sensitive elements.

As a result of the development of new raw materials and products a lot of new techniques and procedures, a great deal of new drugs and several instruments of internal and external use have been produced with non traditional heat-sensitive materials. One of the activities benefitted by this trend is the medical field.

In view of that, the sterilization processes had to be updated to keep up with the development of new elements for medical use and to satisfy the needs of the medical industry as well as the health institutions.

In addition to the traditional techniques of dry heat sterilizers and steam autoclaves, low-temperature sterilization methods were required, such as: radiation of gamma rays and the chemical sterilization by ethylene oxide. This last method is known as cold sterilization since it works with temperatures lower than 60 degrees.

In this way this method allows to sterilize those elements that should be discarded because they can not be recyclable with maximum safety and guarantee required by Health care organizations, or because the heat may damage them or reduce its useful life.

4.- Where may the ethylene oxide be useful? ?

Health Institutions (public and private hospitals; health care centers, clinics) may find useful: loads of ethylene oxide gas as supplies for sterilizers, packing materials to wrap elements to be sterilized with ethylene oxide.

Manufacturers of heat-sensitive medical products (orthopedic products, instrumental for ophthalmology, etc.) may find useful: the packing materials and loads of ethylene oxide gas to safely sterilize their products.

Emergency health service facilities (first aids units, sanitary units, etc.) may find useful: ampoules of ethylene oxide for sterilization without a special equipment.

Pet shops and agricultural companies may find useful: ampoules of ethylene oxide for the control of plagues, and for the sterilization of their instrumental.

Libraries and antique dealers may find useful: ampoules of ethylene oxide to control insects and larvas which may grow in incunabula books and articles of high historical value.

5.- What elements can be sterilized with ethylene oxide?

Yes they can be sterilized:

- Plastics
- Sensitive Rubbers
- Optical Instruments
- Electrical devices
- Sensitive Instruments
- Implants
- Protesis

Elements that should not be sterilized with ethylene oxide:

- All those that can be sterilized by other traditional techniques.
- Aquous Solutions
- Fat
- Fabrics
- Oils
- Powders

6.- What are the advantages of the ethylene oxide sterilization method?

- Highly effective as fungicide and antimicrobial.
- Best to sterilize biomedical heat-sensitive materials (which are very expensive). Since the ethylene oxide sterilize at low temperatures, the non - deformation or destruction of the elements is guaranteed.
- Good diffusion of the gas through the sheets and parts of difficult access of the elements to be sterilized.
- Elements that otherwise should be discarded, can be sterilized and used again improving the cost-process relation.
- The ethylene oxide can be neutralized with water.

7.- What are the disadvantages of the ethylene oxide sterilization method?

- It is a slow process since in addition to the sterilization time it must be taken into account the ventilation time of the sterilized elements. The ventilation time may depend on the type of the sterilized material (metal, glass, plastic, etc.) and on whether they will be used intra-corporal or extra-corporal.

- A bad handling may cause adverse health effects.

8.- How to use the ethylene oxide?

The Oxide of Ethylene is sold pure or in mixtures.

The most common mixtures may consist of: Carbon dioxide and Freons. However, at present the use of freons is banned as they are harmful to the environment.

The Ethylene oxide may come in the following way:

- small doses: glass ampoules (for manual sterilization) and metallic disposable cartridges (to be used in small and medium sterilizers).
- In bulk: cylinders or tanks, intended for large capacity chambers.

According to either the technology applied or to the type of gas used, ethylene oxide sterilizers may be divided into two groups:

- Ethylene oxide in mixtures: they work under positive pressure..
- Pure ethylene oxide: they work under negative pressure. (*).

The safer and most reliable way to sterilize using this gas is by using [sterilization equipment](#) which not only prevent the operator from contacting the gas but they also guarantee to maintain the working place and the environment safe. The use of sterilizers also help to improve the sterilization process by setting the right parameters, such as: gas concentration, humidity, time of exposure and temperature. These conditions may vary according to the manufacturer's instructions for each of the sterilizers on the market.

Los equipos de la línea **Bio-Gas** sterilizers have been built to run under negative pressure confirming our concern in terms of safety

A suitable Ethylene Oxide sterilizer should feature the following sequences::

- Heating of the chamber upto the chosen temperature
 - Initial vacuum
 - Humidification
 - Injection of the gas
 - Countdown of the chosen sterilization time.
 - Extraction of the ethylene oxide gas from the chamber. (In Biogas sterilizer this is done by taking out the gas into bubbling water so the ethylene oxide becomes etilenglicol, a neutral gas; then the clearing of the chamber is done by alternate cycles of vaccuum and entrance of filtered air).
 - Final ventilation of the sterilized material. (In Biogas sterilizers the sterilization and ventilation are carried out inside the same chamber avoiding the handling of non-aereated material. Moreover, the ventilation program can be set from 1 to 20 hours.).
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Another way of using the ethylene oxide is the method which consists in the use of glass ampoules placed inside a containing bag. This simple and practical system can be carried out anywhere and specially where there would be not enough resources available to install a sterilizer.

Even though there is, currently, a trend towards the use of sterilization equipment due to that they provide safety for the operator, It is important to highlight that the sterilization system with ampoules is the ideal method to be used in emergency or catastrophe situations.

9.- Which are the variables involved in the process of the ethylene oxide sterilization?

The variables present in the sterilization process with ethylene oxide are:

- Concentration of gas: the gas is active in concentrations ranging from 300 mg/l to 600 mg/l and depending on the temperature, humidity and exposure time applied.

- Temperature: the gas is active in a temperature range that varies from 25° C to 55° C; it is important to remark that higher temperatures does not entail better results.

- Humidity: the best relative humidity (HR) to sterilize with ethylene oxide (EO) ranges from 30% to 50%. The antibacterial activity of the ethylene oxide decreases at higher HR values since the E.O. polymerizes with water and loses its action. This activity also decreases at lower HR values due to that the microorganism does not receive a good humidification and therefore the spores become more resistant to the penetration of the EO.

- ExposureTime: the times will depend on the type and size of the materials in the load; on the concentration; on the wrapping material used; on the temperature set; on the humidity value and on the initial microbial population

In order to carry out an effective sterilization, all the above mentioned variables must keep a proper relationship between them; A change in any of the variables may cause a change in the others and as a result affect the efficacy of the sterilization process. Another fact to bear in mind once the sterilization process has concluded is the ventilation time of the sterilized material. This time may vary according to the type of sterilized material, to the wrapping type and the features of the sterilizer.

10.- Which cautions should be kept in mind in handling the ethylene oxide?

El óxido de etileno es tóxico e inflamable; es por ello que se recomienda:

- Remember that the sterilization by ethylene oxide is an alternative method. Therefore the use of this gas should be reduced to those cases in which no other sterilization method can be used.
- Restrict the use of ethylene oxide to certain places. Provide with a forced extraction of air to guarantee a permanent airflow in the sterilization area.
- Evaluate and choose the most suitable sterilization equipment; Handle them properly and carry out preventive maintenance periodically.
- Comply with the transport and storage norms for the ethylene oxide.
- Keep any source of ignition (fire) away from the ethylene oxide, either in the working place or during the transport or in the storage place.
- Provide education training to the personnel who work in the sterilization area.
- Prepare an action plan in case of emergencies and catastrophes.
- If the ethylene oxide enters in contact with the operator, this person will have to wash the affected area with plenty of cold water.
- If the vapors of ethylene oxide are inhaled, the operator should be taken outdoors immediately.
- If the operator finds it difficult to breathe, he should be helped with oxygen while the doctor arrives.
- Seek for medical advice, after providing first aids treatment.