

MANUAL STERILIZATION USING AMPOULES

A. FOUR CONDITIONS TO BE TAKEN INTO ACCOUNT WHEN STERILIZING

- o Room temperature: at least 20° C.
- o Relative humidity: not less than 30%.
- o The sterilization cycle shall last 12 hours or more.
- o The ventilation of the sterilized items shall last 24 hours minimum.

C. ADDITIONAL PRECAUTIONS

- o The Biolene® ampoule is designed to be used only with the retaining bag provided.
 - o It shall not be used for sterilizing food-stuff nor drugs.
 - o This gas does not penetrate metal, glass or aluminum.
- The ampoule must be stored out of direct sunshine and in a cold place.

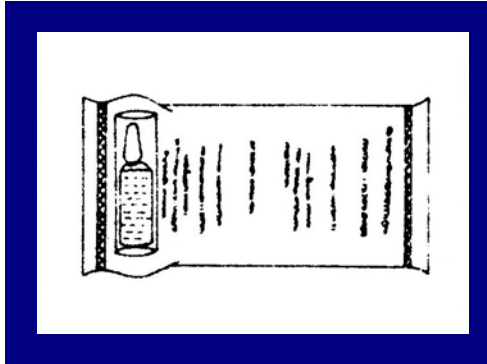
B. PRECAUTIONS TO BE CONSIDERED WHEN USING THE BIOLENE® GAS AMPOULE

- o The gas inside the ampoule shall be liquid.
 - o The ampoule has the ETO gas in its liquid state; it is extremely combustible. Thus, you shall take into account the following precautions in the place the sterilization is being carried out:
 - a) The place shall be ventilated.
 - b) Keep away from flames.
 - c) There must not be many people in that place.
 - o If liquid E.O. comes in contact with your skin, you shall flush yourself with plenty of cold water.
 - o As E.O. gas adheres to rubber and to the PVC, the items sterilized of this material shall be ventilated for a minimum of 30 hours.
- Should you have any doubt, call the distributor.

D. EXPLANATIONS AS REGARDS THE EVAPORATION OF THE AMPOULE



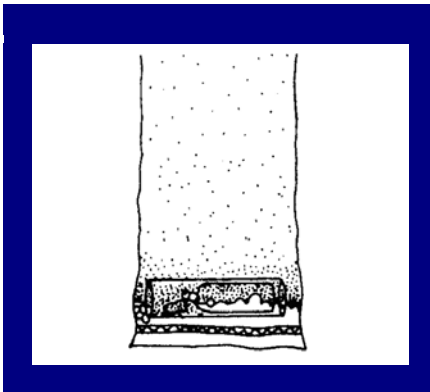
1. The ampoule is delivered in a plastic shield which prevents broken glass from the open ampoule from puncturing the gas release bag or from hurting one's hands.



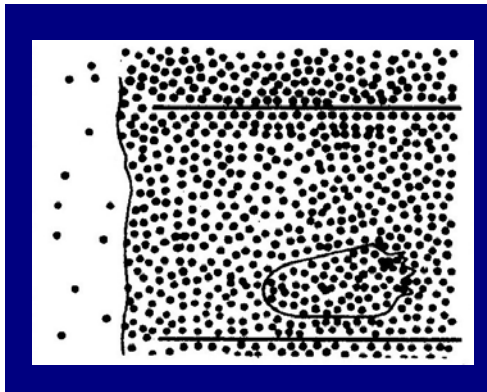
2. The plastic bag, in which are sealed the ampoule and the shield, is a gas diffusion membrane of known permeability which function is to contain the gas given off by the ampoule and to keep the temperature so as to facilitate the sterilization cycle.



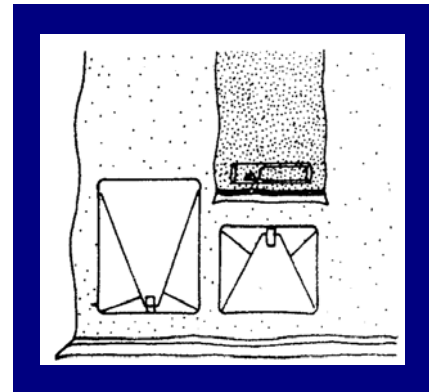
3. Grasp the ampoule through the bag and the protective shield and snap the top of the ampoule.



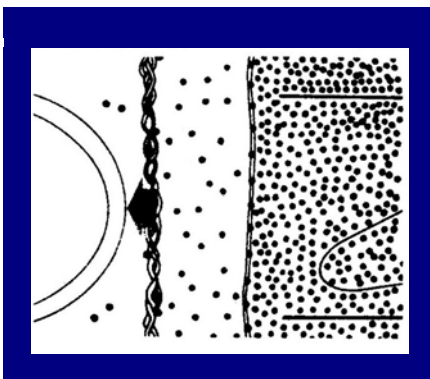
4. The ampoule should not be removed from the bag. The evaporation will begin through the top of the ampoule, flowing at 250-500 mg per hour. You should not wrinkle the bag.



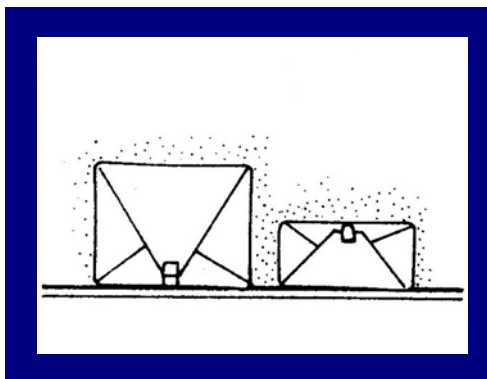
5. The force of the E.O. gas molecule runs through the bag which detains the diffusion of the gas to its exterior. The evaporation starts when the bag blows up like a balloon.



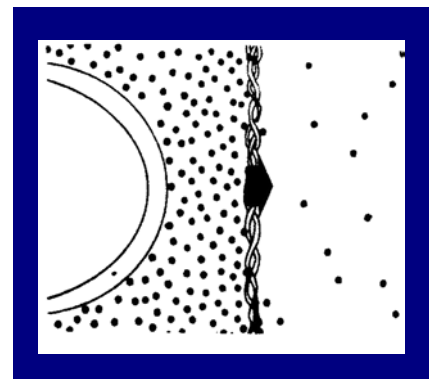
6. This graphic is to show the displacement of the molecules in the container.



7. The E.O. gas is powerful enough to penetrate into the membranes sterilizing their contents.



8. Once the cycle of sterilization is over, the packets should be left in a cool place and they should be ventilated for 24 hours or more before use. If the material is to be used in the human body, it should be ventilated for not less than 72 hours before use.



9. This graphic is to illustrate the way in which the gas residues emigrate from the sterilized materials, running in this way through the wrapping that covers it during the ventilation period.