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STERILIZATION OF HOSPITAL AND PHYSICIANS' SUPPLIES

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The present invention relates to the sterilization of certain hospital and physicians' supplies for the purpose of completely eliminating bacteria, molds and yeasts, and their spores. It is applicable to a wide variety of hospital materials including hemostatic gauze sponges, hemostatic dusting powder, cotton rolls and balls, rolled gauzes, gauze bandages, catgut (animal source) sutures, medicated gelatin films of burns, synthetic sutures, surgical dressings, cotton swab applicators, disposable diaper liners and diapers, obstetrical pads for hospital use, nursing pads and other hospital products, many of which items are variously medicated. These are comprehended by the term hospital and physicians' supplies of animal and vegetable origin.

In recent years, with the necessity for complete sterilization of various types of supplies used by physicians and hospitals, there has been need for a more rapid process for positive sterilization of these products and in many instances, the old classical method of heat-sterilization in an autoclave has become outmoded. The use of ethylene oxide gas for sterilization has been found to be tremendously effective and satisfactory for the complete elimination of microorganisms and organic life which are always present on or in these materials. It has been found that undiluted ethylene oxide not only is exceedingly efficient but also does not contribute toxicity or change in the composition or physical characteristics of the materials herein described.

Since the gas used in the present invention is ethylene oxide gas, certain other standards are applied for the performance of the present invention. It is known that ethylene oxide may be used under conditions to effect a sterile product, but less drastic use thereof may be practiced to produce a product just short of sterile. It is also known that ethylene oxide has insecticidal and bactericidal action and reactivity in the presence of moisture by combining with water to form ethylene glycol, the latter having these properties. Ethylene oxide is reactive with some materials, such as certain proteins, and the present process uses low temperatures to minimize and prevent such reaction. It is known that in using ethylene oxide on dry materials lacking moisture whereby to use the function of ethylene oxide rather than the function of ethylene glycol, that prior processes discharge material with residual traces of ethylene oxide sorbed by the material. Such materials on standing acquire moisture and the residual ethylene oxide reacts therewith to form the glycol, and in some cases reacts with the material involved.

The items to be sterilized in accordance with the present invention may be characterized as merchandise. As such, they are commonly manufactured, processed or packaged at one place, then shipped and stored until use. According to the present invention the materials may be sterilized prior to storage for use. One or more

items or a quantity of material is placed in a container which protects the sterilized content from contamination by physical contact in the interval of time between sterilization and use, yet in a protective container which is permeable to the sterilizing gas. Preferably a single-use amount of the item or substance is present in an individual container. These individual containers may be collectively housed in a larger container for shipment and storage, and preferably such a larger container is one which is a protective one which is permeable to the gas, so that a packed larger container may be an entity to be subjected to the gas.

Among the materials for the present invention are some which are medicated for use, for examples, adhesive tapes, dressings, gauze and swabs. The process is carried out under conditions of low temperature and low moisture content, not only to prevent affecting the medication but also to minimize or prevent reaction to form ethylene glycol. Although some of the materials contemplated for sterilization may be sterilized without damage by use of temperatures higher than specified, the process as a general one is limited so that mixed goods of the general class may be sterilized in one operation.

The present invention concerns a sterilizing process wherein the materials in gas-permeable protective containers are placed in a retort and treated in the following manner:

(1) Preheat time—from a limit of 70° F. to 100° F. for 45 minutes or longer.

(2) Draw first vacuum to at least 29 inches of mercury and exposed for at least 45 minutes.

(3) Introduce ethylene oxide gas in amount from 30 to 65 pounds per 1000 cu. ft.

(4) Exposure of material to gas from one-half hour to four hours.

(5) Draw second vacuum to at least 29 inches of mercury.

(6) Flush with sterile filtered dry air to attain atmospheric pressure.

(7) Remove the containers.

The process is so effective that the material may be sterilized within containers such as paper bags, fiber drums, cellophane or other plastic film envelopes, corrugated cartons and the like, of course not hermetically sealed. The products are free from a toxic residue of gas and free of ethylene glycol formed from the gas.

The following Table I illustrates the infestation of certain commercial hospital and physicians' supplies now available on the market.

Table I

Material	Days				
	1	3	5	7	10
Hemostatic Gauze Sponges	+	+	+	+	+
Cotton Gauze Bandages	−	+	+	+	+
Catgut Sutures	+	+	+	+	+
Surgical Dressings	+	+	+	+	+

(+) Bacterial growth.
(−) No bacterial growth.
NOTE.—Used fluid thioglycollate culture medium with incubation t30°-32° C.

After sterilization by the present invention the same materials similarly tested for 14 days show no bacterial growth.

Table II shows the shelf life of certain supplies sterilized by the present invention.

Table II

Material	Storage in Weeks			
	4	8	12	24
Hemostatic Gauze Sponges	[1] —	—	—	—
Hemostatic Dusting Powder	—	—	—	—
Gauze Bandages	—	—	—	—
Catgut Sutures	—	—	—	—

[1] (—)=No bacterial growth.
NOTE.—Used fluid thioglycollate culture medium for testing, at incubation temperature of 30°-32° C.

The present invention is not limited to or by the listing of materials herein, other items being contemplated.

The first heating and evacuating step in the process frees the surface and intercellular spaces of the material of adsorbed and absorbed gases, including some moisture and air. The lower temperature assures adequate heating from a chilled condition of the goods to be sterilized, as may be encountered in winter. The process is hastened by temperature above 70° F. but not over 100° F. for preserving the required character of some items. The material is thus considered to be activated so that the ethylene oxide can act on the microorganisms probably by increasing the concentration locally by sudden changes in the osmotic tension of the organisms so that the gas acts upon the cells. The entire process takes approximately four to seven hours in large retorts depending upon the material being treated.

I claim:

1. The method of sterilizing hospital and physicians' supplies of animal and vegetable origin, which comprises subjecting the material enclosed in a gas-permeable protective container therefor at a temperature in the range from 70° F. to 100° F. to a vacuum of at least 29 inches of mercury in a closed chamber for at least 45 minutes, admitting into said evacuated chamber substantially undiluted ethylene oxide gas in amount in the range from 30 to 65 pounds per 1000 cu. ft. of chamber space, thereafter subjecting the material to the action of said gas for a time in the range from one-half to four hours, then increasing the vacuum to at least 29 inches of mercury and thereby withdrawing free ethylene oxide gas, then flushing the chamber with sterile filtered dry air to establish atmospheric pressure in the chamber, and then removing from the chamber the material within its closed gas-permeable container, whereby all of the organic life in the article and within the container is killed.

2. The process of claim 1 in which the material is cotton.

3. The process of claim 1 in which the material is catgut suture.

4. The process of claim 1 in which a plurality of the initial containers are enclosed in a larger protective gas-permeable container for subjection to said gas, whereby the larger container in being shipped or stored provides a supply of substantially sealed packages of sterilized content.

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