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METHOD FOR STERILIZING ARTICLES

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This invention relates to a method for sterilizing articles for the purpose of delivering them to the point of ultimate use in a sterile condition. While the method has broad application, it is particularly valuable in the medical field where instruments and medicines are to be delivered to the user in a state free from bacteria ready for immediate use. Thus, for example, in the case of cartridges for hypodermic syringes or injectors it has heretofore been the practice to deliver these cartridges to the user in unprotected condition. These cartridges consist of a glass tube filled with the injection liquid and closed at one end of a piston and at the other end by a cap or seal. When the cartridge is inserted into position in the injector the cap is adapted to be pierced by the rearward extension of the cannula or hypodermic needle. When the injector is operated, pressure is applied to the small piston end of the cartridge to discharge the liquid through the needle. It is of the utmost importance that the cartridge generally, and particularly the piercing cap, be absolutely free of bacteria organisms, for otherwise there results the possibility of infection which may result in considerable pain and delay in healing.

It is therefore the principal object of this invention to provide a commercially feasible means whereby such cartridges and similar articles may be delivered to the user in a condition of absolute sterility.

The method which is here employed comprises two fundamental steps and several auxiliary steps which may be employed, depending upon the specific conditions. The two fundamental steps consist in subjecting the article to ultra violet radiations (as, for example, from a Westinghouse Sterilamp) and to packing the article in a sealed container. The ultra violet light destroys the bacteria, and the sealed container, made of material which is impervious to bacteria, will maintain the sterile condition. According to one method of our invention, we may subject the article to ultra violet light before the article is inserted in the envelope. The method then consists in subjecting the article to ultra violet light, inserting it in the envelope which is impervious to bacteria, and then sealing the article.

We have found that if the envelope is made of material which may be heat sealed, there is a definite beneficial sterilizing advantage in such heat seal. Therefore, when applying this method to cartridges for hypodermic syringes, we insert

the cartridge with the plunger end adjacent the closed end of the envelope. Heat sealing of the open end of the envelope thus provides an additional sterilizing effect adjacent the piercing cap, which is the most important area to be maintained sterile.

In a modification of the fundamental method, the article may be inserted in the envelope before being subjected to ultra violet light. The envelope is then sealed, and preferably heat sealed. The envelope is made of material which is impervious to bacteria but pervious to ultra violet light which then renders both the article and the air within the envelope sterile. A suitable envelope material possessing these properties is Cellophane. If desired, a combination of both methods may be employed wherein the cartridge is partially inserted into the U. V. porous container so that the piercing end projects and is subjected to irradiation with ultra violet light; then the cartridge is pushed completely into the container which, after being heat-sealed, is irradiated with ultra violet light through the U. V. porous material to insure complete sterility of the enclosed cartridge.

An actual bacteria analysis of an article of the type described, namely, a cartridge for hypodermic syringes, was made before subjecting the same to the sterilizing process last described above, and another analysis was made after removing the cartridge from its envelope and after it had been subjected to the process, with the following results: Previous to U. V. sterilization the piercing cap end showed an average of 8 bacteria per tube. After irradiating, the tube was sterile both for aerobic and anaerobic bacteria. After exposure of the irradiated tubes for three months, a bacterial examination showed no growth at all in the various media employed.

Further to test the effectiveness of this method, 10 tubes were infected with a virulent *Staphylococcus aureus* and 10 with a fungus spore resistant to phenol. These cartridges were then irradiated before and after inserting into the U. V. porous, but air sealed envelopes. After two weeks these tubes were incubated and the tests showed that the tubes were completely sterile.

While we have described our improvements in great detail and with respect to preferred forms thereof, we do not desire to be limited to such details and forms since many changes and modifications may be made and the invention embodied in widely different forms without depart-

ing from the spirit and scope thereof in its broader aspects. Hence we desire to cover all modifications, forms and embodiments coming within the language or scope of any one or more of the appended claims.

Having described our invention, what we claim and desire to secure by Letters Patent is:

1. The method of forming a package consisting of an article requiring a sterilized end and an envelope completely enclosing such article, said method comprising inserting the article in an envelope having an open end and a closed end and formed of Cellophane, the article being positioned with the end to be sterilized inside of the envelope and adjacent the open end thereof, and heat sealing the open end of the envelope whereby the end of the article adjacent thereto is sterilized by the constituents liberated by the action of heat on said envelope material.

2. The method of forming a package consisting of a cartridge for a hypodermic syringe requiring a sterile end and an envelope completely enclosing the cartridge, said cartridge having a plunger at one end and a cap at the other end adapted to be pierced by the syringe needle, said method comprising inserting the cartridge in an envelope having an open end and a closed end and formed of Cellophane, said cartridge being positioned in said envelope with its cap inside the envelope and adjacent the open end thereof, and heat sealing the open end of the envelope whereby said cap is sterilized by the constituents liberated by the action of heat on said envelope material.

3. The method of forming a package consist-

ing of a cartridge for a hypodermic syringe requiring a sterile end and an envelope completely enclosing the cartridge, said cartridge having a plunger at one end and a cap at the other end adapted to be pierced by the syringe needle, said method comprising subjecting the cartridge to ultra violet light, inserting the cartridge in an envelope having an open end and a closed end and formed of Cellophane, said cartridge being positioned in said envelope with its cap inside the envelope and adjacent the open end thereof, and heat sealing the open end of the envelope whereby said cap is further sterilized by the constituents liberated by the action of heat on said envelope material.

4. The method of forming a package consisting of a cartridge for a hypodermic syringe requiring a sterile end and an envelope completely enclosing the cartridge, said cartridge having a plunger at one end and a cap at the other end adapted to be pierced by the syringe needle, said method comprising inserting the cartridge in an envelope having an open end and a closed end and formed of Cellophane which is pervious to ultra violet light, said cartridge being positioned in said envelope with its cap inside the envelope and adjacent the open end thereof, heat sealing the open end of the envelope whereby said cap is sterilized by the constituents liberated by the action of heat on said envelope material, and further sterilizing said cartridge by subjecting the envelope and its enclosed cartridge to ultra violet light.

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