

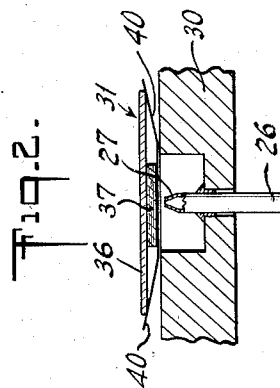
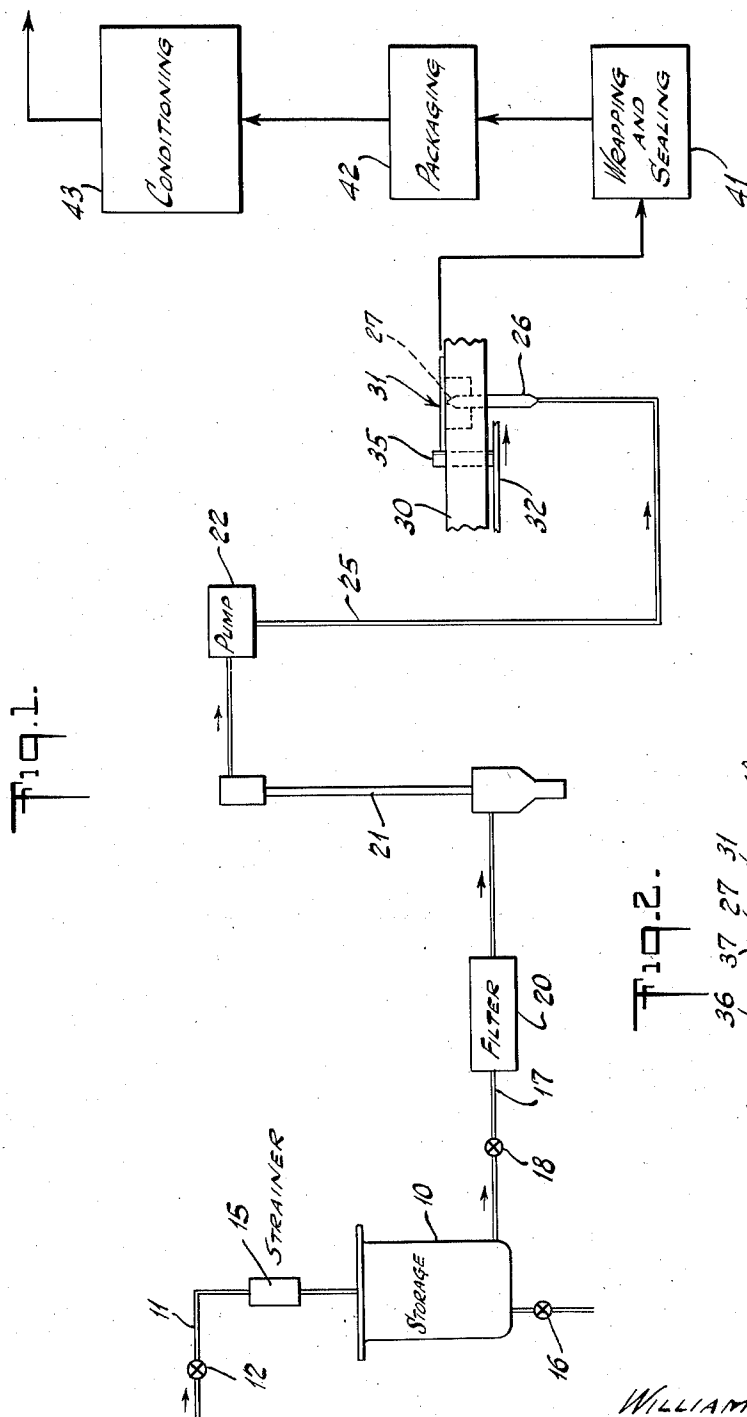
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STERILIZATION OF SURGICAL DRESSINGS

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STERILIZATION OF SURGICAL DRESSINGS

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3 Claims. (Cl. 21—58)

This invention relates to sterilization of fibrous materials with vapors of water and formaldehyde, and more particularly to a method of applying the sterilizing agent in the form of a liquid under critical conditions to avoid deterioration of the fibrous materials, and is a continuation-in-part of my previous application Serial No. 266,201, filed Jan. 12, 1952, now abandoned.

Sterilization by means of vapor of water and formaldehyde is well known and has achieved considerable commercial success. One method for carrying it out is by introducing the material to be sterilized in an autoclave or the like vessel. If the material to be sterilized is pre-wrapped, the wrapping must be porous. From the commercial viewpoint, this method is undesirable since it is carried out in a batch fashion and is relatively slow and cumbersome. The art is confronted by the problem of providing an economic and convenient method for applying these sterilizing agents to wrapped fibrous materials, especially to such material having desirable loft which is susceptible to deterioration upon prolonged wetting with aqueous liquid.

The discoveries associated with the invention relating to solution of the above problems, and the objects achieved in accordance with the invention as set forth herein include: a provision of the process for sterilizing a fibrous surgical dressing by treatment with vapors of water and formaldehyde in a wrapping which is bacteria impermeable but permeable to said vapors, which dressing is susceptible to undesirable loss of loft upon prolonged wetting with an aqueous liquid, in which process the sterilizing material is applied to the fibrous material as aqueous formaldehyde liquid in an amount and concentration to provide formaldehyde in an amount and a range of 0.4 to 1.5% based on the weight of the dressing plus the wrapping and water in an amount in the range of 3 to 10% based on the weight of the dressing, then wrapping the dressing within one sec. to 3 min. in the above-mentioned wrapping material, and maintaining it at a temperature in the range of 50 to 200° F. and a moisture content in the range of 3 to 10% for a time in the range of 1 hour to 3 weeks; the provision of such a process using a formaldehyde concentration range of 0.48 to 1.0% and a temperature range of 50 to 170° F. the provision of such a process using formaldehyde concentration range of 0.6 to 1.0%, a water concentration of 4.8% and the temperature range of 100 to 150° F.; and other objects which will be apparent as details or embodiments of the invention as set forth hereinafter.

The invention will be described by reference to the accompanying drawing, in which Fig. 1 is in the nature of a flow diagram and Fig. 2 is a vertical section taken through the portion of the equipment in which the concentrated aqueous formaldehyde solution is applied to the dressing.

Referring for the present to Fig. 1, number 10 represents a storage vessel into which the aqueous formaldehyde solution is introduced through pipe 11, control valve 12, and strainer 15. Pipe and valve 16 may be used to

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drain tank 10 when this is desired. The solution flows through pipe 17, control valve 18, and filter 20, and through rotameter 21 or other suitable apparatus for measuring and controlling flow of liquid material at a very low rate. Constant displacement pump 22 forces solution through pipe 25 into nozzle 26, which is illustrated on a larger scale in Fig. 2. The aqueous formaldehyde solution emerges from nozzle 26 at tip 27, at which point the liquid is in the form of a droplet above the tip. 30 represents a horizontal track which carries and on which is supported a surgical dressing, such as adhesive bandage 31. A portion of continuous belt or chain is indicated at 32, which belt is moving in a horizontal direction from left to right. Belt 32 carries a lug 35 which urges bandage 31 along its path on top of track 30.

Bandage 31 is formed from the usual backing strip and adhesive layer 36, having secured thereto a surgical dressing 37, having high loft. A pair of overlapping protective strips made, for example, of crinoline, are shown at 40.

Just after the aforementioned droplet disposed on the top of tip 27 is formed, bandage 31 moves over the tip in its path from left to right, contacts this droplet and removes it from the tip. Within a relatively short period of time, the solution becomes dispersed through the dressing. The bandage passes immediately to wrapping and sealing means shown diagrammatically at 41, where it is wrapped and preferably sealed in paper such as glassine or other low porosity super-calendered paper. The wrapped dressings are thereafter assembled in packages at 42, the packages are transferred to suitable conditioning zone 43, where the aqueous formaldehyde treated and wrapped bandages are maintained at a suitable temperature for time to accomplish sterilization.

By controlling the rate of flow of aqueous formaldehyde solution through nozzle 26, the concentration of formaldehyde in the solution, and the number of dressings passing tip 27 per minute, the amount of formaldehyde as HCHO introduced per dressing is maintained above about 0.4 percent by weight based on the dressing plus the wrapping material.

In order to facilitate a clear understanding of the invention, the following preferred specific embodiments are described in detail.

Example 1

Aqueous formaldehyde solution containing 20 percent HCHO is passed from storage tank 10 through pipe 17, rotameter 21, pump 22 and pipe 25 into nozzle 26 at a rate controlled, in conjunction with the frequency at which adhesive bandages 31 are manufactured and passed over tip 27, so that each bandage, weighing on the average, about 0.4 gms., including the wrapper, absorb about 0.003 to 0.0035 parts of HCHO. The bandages are formed from a fabric adhesive-coated backing, in the adhesive a surgical dressing made up of nonwoven cotton or rayon fibers wrapped in a gauze and having high loft, and overlapped layers of crinoline (or if desired, smooth facing material) protecting the adhesive and the pad. The aqueous formaldehyde is applied to the crinoline side of the bandage. After treatment, the adhesive bandage is wrapped and sealed in about 1 to 3 seconds in low porosity super-calendered glassine paper. Twenty samples are analyzed individually for HCHO, taken immediately after wrapping, one about every hour over a period of operation of one day. The HCHO content of the bandages ranges from 0.73% to 0.96%, based on bandage plus wrapper. The moisture content of the wrapped bandages is about 6½% based on the bandage alone and exclusive of wrapper. A total of about 300 bandages, taken at uniform time intervals throughout

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the day are marked for sterility tests, but processed with the other bandages. The individually wrapped bandages are placed in cartons, about 4,000 per carton. The carton is then placed in a conditioning zone maintained at 120° F. for 15 hours. After conditioning for a total of 15 hours, the above-mentioned marked bandages are examined and found to be sterile (U. S. Pharmacopoeia method).

Example 2

Adhesive bandages of the above type are inoculated with the following:

Bacillus subtilis
Clostridium sporogenes
Escherichia coli
Staphylococcus aureus
Staccaromyces cerivisiae
Aspergillus niger

Another species of *Aspergillus* mold having known high resistance to HCHO

These contaminated adhesive bandages are then treated with aqueous formaldehyde solution containing 17.7% HCHO on the apparatus and in the manner described in Example 1. The relative humidity of the air during aqueous formaldehyde treatment and wrapping is 60%. 0.5% HCHO is added to each bandage (based on the weight of bandage plus wrapper), 2.2% water (based on bandage, exclusive of wrapping) is added in the aqueous formaldehyde solution, and the total moisture content of the wrapped bandage is 5.7%. The wrapped bandages packaged as described in Example 1 are conditioned at 110° F. for 15 hours. The conditioned bandages are then examined and found to be sterile.

Example 3

Adhesive bandages of the above type are inoculated with bacteria. These contaminated adhesive bandages are then treated with aqueous formaldehyde solution containing 10.0% HCHO on the apparatus and in the manner described in Example 1. The relative humidity of the air during aqueous formaldehyde treatment and wrapping is 75%. 0.48% HCHO is added to each bandage (based on the weight of bandage plus wrapper). 4.2% water is added in the aqueous formaldehyde solution, and the total moisture content of the wrapped bandage (based on bandage alone) was 8.3%. The wrapped bandages, packaged as described in Example 1, are conditioned at 140° F. for 1 hour. The conditioned bandages are then examined and found to be sterile.

Example 4

Adhesive bandages of the above type are inoculated with bacteria. These contaminated adhesive bandages are then treated with aqueous formaldehyde solution containing 10.0 percent HCHO on the apparatus and in the manner described in Example 1. 0.48 percent HCHO is added to each bandage (based on the weight of bandage plus wrapper). 4.2 percent water is added in the aqueous formaldehyde solution, and the total moisture content of the wrapped bandage (based on bandage alone) is 7.5 percent. The wrapped bandages, packaged as described in Example 1, are conditioned at 160 to 170° F. for 1 hour. The conditioned bandages are then examined and found to be sterile.

Example 5

Adhesive bandages of the type described in Example 1 are inoculated with the bacteria specified in Example 2. These contaminated adhesive bandages are then treated with aqueous formaldehyde solution containing 20 percent HCHO, 32 percent methyl alcohol, and 48 percent water, on the apparatus and in the manner described in Example 1. The relative humidity of the air during aqueous formaldehyde treatment and wrapping is 38 percent. 0.48 percent HCHO is added to each bandage (based on the

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weight of bandage plus wrapper. 1.0 percent water is added in the aqueous formaldehyde solution, and the total moisture content of the wrapped bandage (based on bandage alone) is 3.1 percent. The wrapped bandages, packaged as described in Example 1, are conditioned at 70° F. in 20 percent R. H. ambient air for 2 weeks. The conditioned bandages are then examined and found to be sterile.

Example 6

Adhesive bandages of the type described in Example 1 are inoculated with the bacteria specified in Example 2. These contaminated adhesive bandages are then treated with aqueous formaldehyde solution containing 17.7 percent HCHO on the apparatus and in the manner described in Example 1. The relative humidity of the air during aqueous formaldehyde treatment and wrapping is 38 percent. 0.48 percent HCHO is added to each bandage (based on the weight of bandage plus wrapper). 2.2 percent water is added in the aqueous formaldehyde solution, and the total moisture content of the wrapped bandage (based on bandage alone) is 4.3 percent. The wrapped bandages packaged as described in Example 1 are conditioned at 70° F. in 20 percent R. H. ambient air for 2 weeks. The conditioned bandages are then examined and found to be sterile.

Comparable results to the foregoing may be achieved with the various modifications thereof including the following. The formaldehyde concentration should be in the range of 0.4 to 1.5%, desirably 0.48 to 1% and preferably 0.6 to 1%, based on the weight of the dressing plus the wrapping, and the water concentration in the range of 3 to 10% based on the weight of the dressing. Lower contents of formaldehyde do not give adequate or reliable sterilization. Higher amounts are generally not necessary for the sterilization, and may give rise to undesirable odor problems. In addition, the higher contents of formaldehyde are avoided for economic reasons. Lower contents of water do not give adequate or reliable sterilization; and higher or excessive amounts are to be avoided in order to avoid undesirable deterioration of the loft or absorbency of the dressing.

The water may be introduced with the formaldehyde desirably as aqueous formaldehyde above about 8% by weight formaldehyde concentration, and preferably about 37%. The treated dressing may contain some moisture, and in such a case, only the needed additional amount is added. The relative humidity of the atmosphere surrounding the wrapped bandages may be controlled to regulate the moisture content within the desired range, i. e., 3 to 10%. A desirable relative humidity is above about 20%.

The temperature of the wrapped materials is maintained in the range of about 50 to 200° F., desirably 50 to 170° F. and preferably 100 to 150° F. The bandages are maintained at this temperature for a time in the range of about 1 hour to three weeks, the higher temperatures requiring the shorter times for adequate sterilization, and vice versa.

As the term is used herein, aqueous solutions are intended to cover all solutions containing water. Preferably, the aqueous solvent for the HCHO contains a major proportion, i. e. 50% or more, water. However, in certain instances, it may be desirable to replace more of the water of the aqueous formaldehyde with alcohol or other non-aqueous solvent, for example, to reduce "bleeding" of mercurochrome dressings or dressings treated with similar water soluble medicaments. According to this embodiment, which is within the scope of the invention, water content of the solvent (exclusive of HCHO solute) may be reduced to not less than about 15% by weight, the remaining 85% being non-aqueous solvent.

The wrapped and packaged individual dressings which, of course, have been treated with the aqueous formaldehyde are preferably assembled in a relatively large num-

ber in a large size carton during conditioning. This affords not only efficiency of space utilization in the factory, but also facilitates handling problems since the bandages may be sterilized in the packages in which they are distributed and sold. Formaldehyde tends to adhere to the dressing and hence the invention method enjoys the prolonged sterilizing effect of the residual formaldehyde remaining in the wrapped bandage.

The bacteria impermeable wrapping which is permeable to the sterilizing vapors may be glassine or the like super-calendered paper or it may be of other material including known micro-porous plastic materials. The invention is applicable to so-called round or surgical sponges, cotton tips, and similar materials made up of fibrous material, each of which has desirable loft and absorbency, which properties are susceptible to undesirable loss or deterioration upon prolonged wetting with an aqueous liquid.

The aqueous formaldehyde may be applied to the bandages or other materials at any point in their manufacture, preferably, however, it is applied just before the wrapping. The time lack between application of the aqueous formaldehyde and the wrapping should be within the range of about 1 sec. to 3 min. Further, the apparatus described in Figs. 1 and 2 is but one illustration of means for contacting the aqueous formaldehyde solution with the dressing, which means is subject to variation. For example, instead of applying the solution on the bottom of the dressing, it may be sprayed or otherwise introduced onto the top of the dressing, either before or after the continuous strip of process material is severed into individual bandages.

In view of the foregoing disclosures, variations or modifications thereof will be apparent, and it is intended to include within the invention all such variations and modifications except as do not come within the scope of the appended claims.

I claim:

1. In the method of sterilizing a fibrous surgical dressing by treatment with vapors of water and formaldehyde in a wrapping which is bacteria-impermeable but permeable to said vapors, which dressing is susceptible to undesirable loss of loft upon prolonged wetting with an aqueous liquid, the improvement which comprises providing in said dressing aqueous formaldehyde liquid in an amount and concentration to provide formaldehyde in an amount in the range of 0.4 to 1.5% based on the weight of the dressing plus the wrapping, and water in an amount in the range of 3 to 10% based on the weight of the dressing, wrapping the said dressing within 1 sec. to 3 min. and maintaining at a temperature in the range of 50 to 200° F. at a moisture content within the said range of 3 to 10% for a time in the range of one hour to 3 weeks, whereby there is obtained a non-deteriorated fibrous surgical dressing which is sterile and individually wrapped in bacteria-impermeable material.

2. The method of claim 1 wherein the formaldehyde concentration is in the range of 0.48 to 1.0% and the temperature is in the range of 50 to 170° F.

3. The method of claim 2 wherein the formaldehyde concentration range is 6.0 to 1.0%, the water concentration range is 4 to 8% and the temperature range is 100 to 150° F.

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