Aug. 6, 1946. G. JOSH 2,405,216

PROCESS FOR PACKAGING SURGICAL STRING MATERIAL

Filed May 2, 1941

Fig. 1

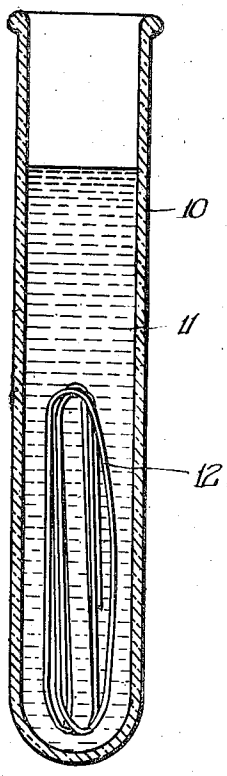


Fig. 2

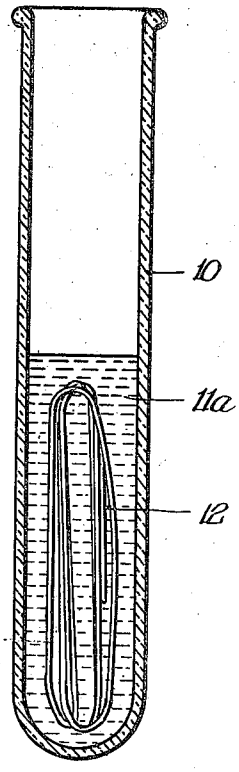


Fig. 3

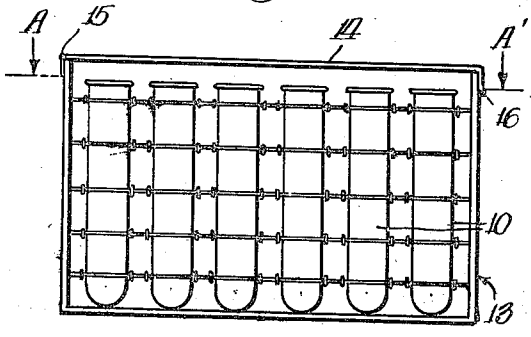
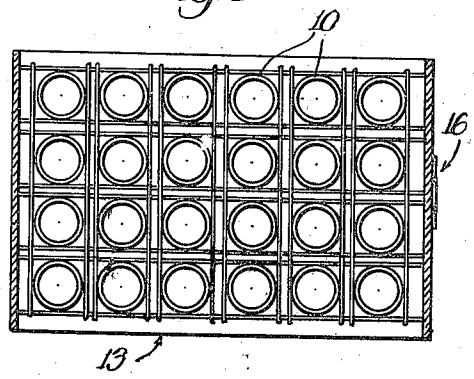


Fig. 4



INVENTOR.
George Josh,

BY

Carl C. Batz Atty.

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PROCESS FOR PACKAGING SURGICAL STRING MATERIAL

George Josh, Crown Point, Ind., assignor to Armour and Company, Chicago, Ill., a corporation of Illinois

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This invention relates to processes of packaging surgical string material, such as sutures and ligatures, and it is particularly concerned with processes in which the string material is dehydrated and sterilized in the presence of a water-immiscible fluid.

In the packaging of sutures and ligatures it is necessary to dehydrate surgical string material prior to "heat" sterilization and it is also necessary that the finished string be sterile and strong. Any traces of moisture left in the string interfere with sterilization and, when the string is held at sterilizing temperatures for a considerable time, weaken the string, or in other words, cause a decrease in the tensile and knot strength of the string.

It has been the practice in the art to treat the string material with heated air or with dried air to remove moisture, after which the string is immersed in a liquid and heated to effect sterilization. It is very difficult to remove the last traces of moisture in this way and the presence of such moisture causes weakness in the string upon sterilization, possibly due to hydrolysis of the collagenous matter present. Furthermore, the dried string material is quite hygroscopic and thus tends to reabsorb moisture when exposed to moisture-carrying atmosphere after dehydration.

It is an object of my invention to dehydrate the string material thoroughly and to sterilize the dehydrated string while it is immersed in a water-immiscible fluid. It is a further object of my invention to preserve the tensile and knot strength of the surgical string material by dehydration and by sterilization while the string is immersed in suitable liquids. Other objects and advantages of my invention will appear after the detailed description herein given.

I have found that the disadvantages of the prior art are overcome and an improved surgical string package is produced by heating the surgical string material in an open container while covered with a water-immiscible fluid containing a lower boiling liquid and a higher boiling liquid until at least part of the lower boiling liquid has been evaporated off and then sterilizing the string by heating it, immersed in a water-immiscible liquid which has a boiling point above the sterilizing temperature. The sterilized string material is then stored, suitably in a sealed tube containing any desired storing or holding fluid.

The fluid in which the string is immersed during the first heating step comprises a low boiling liquid having a boiling point higher than the boiling point of water, for example, a lower boiling

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hydrocarbon such as toluene, a xylene, ethyl benzene and the like, or a water-insoluble ketone or the like, and a higher boiling liquid having a boiling point higher than the sterilizing temperature, for example, a higher boiling hydrocarbon such as mesitylene, cymene, decane and the like, or a water-insoluble ketone or the like. The fluid mixture is made up of liquid constituents which are miscible with each other. A mixture readily obtained on the market which contains lower and higher boiling constituents, such as kerosene, may also be used, so long as part of the mixture has a boiling point higher than that of water and is vaporizable below the sterilizing temperature and part of the mixture has a boiling point higher than the sterilizing temperature.

In the case of non-boilable sutures or ligatures, I have found that an improved surgical string package is produced by immersing the string material in a container in a water-immiscible fluid mixture as described above, heating to vaporize the lower boiling liquid and to dehydrate the string, heating to sterilize while the string is immersed in the remaining higher boiling liquid, cooling, pouring off the sterilizing liquid, adding a suitable tubing or storing fluid and sealing the container. In the case of boilable sutures, the string material is placed in a container and covered with a water-immiscible fluid comprising a low boiling liquid and a higher boiling liquid as described above, and heated to vaporize the low boiling liquid and with it the moisture contained in the string material. The higher boiling liquid which remains and in which the string is immersed is removed, and tubing or storing fluid, for example, a liquid hydrocarbon, is added, and thereafter the container is sealed off in the customary manner and sterilized.

The attached drawing will help to illustrate the process of my invention.

Figure 1 is a longitudinal sectional view of one embodiment of the invention, showing a glass tube containing a coiled surgical string and the water-immiscible fluid prior to the first heating step; Figure 2 is a longitudinal sectional view of the tube and contents after the first heating step; Figure 3 is a view of a basket having a hinged lid and containing a number of tubes within which are disposed coils of surgical string material; Figure 4 is a sectional view of the basket containing the tubes, the section being taken on the line A—A' of Figure 3.

Referring to the drawing in detail, 10 is a glass tube containing surgical string 12; 11 is a water-immiscible fluid comprising a lower boiling liquid

and a higher boiling liquid and enough of this starting liquid mixture is present so that at the end of the first heating stage there is sufficient liquid 11*a*, as shown in Figure 2, left to cover the string. The liquid 11*a* comprises predominantly the higher boiling constituent of the starting liquid but smaller amounts of the low boiling constituent may, of course, still remain.

The tubes are conveniently held in a framework or wire basket 13 which is fitted with a lid 14, such as a wire mesh lid, fitted by a hinge 15 to the top of one wall of the basket and held by a clamp 16 which secures it to the top of the opposite wall of the basket. The mesh lid permits drainage of liquid from the tubes when the lid is held shut and the basket is inverted. The basket and lid may also be made of perforated sheet metal which allows drainage. In the process the tubes containing the coils of string are placed in the basket and are filled with the mixture of lower and higher boiling liquids. The basket is then heated as described, thereafter the lid of the basket is clamped in place, the basket is inverted until the remaining liquid is drained out of the tubes, the basket is then placed right side up, the lid opened, and the desired tubing fluid added to the tubes.

Example

As an example of the preparation of my surgical string package, the surgical string material, such as a suture or ligature, is coiled and inserted into the glass tube 10. A number of these glass tubes containing the coiled strings are placed in a wire basket so that each tube is maintained in an upright position, the tubes are filled with a liquid consisting of about 25% toluene and about 75% of a commercial cumene fraction having a boiling point of about 330° F. and the lid is placed on the basket. The basket containing the filled tubes is now heated to about 320° F. At the end of this time substantially all of the toluene will have boiled off, the volume of the liquid being thereby reduced, as shown in Figure 2 and the string material will be dehydrated.

In the case of non-boilable sutures, the tubes containing the remaining cumene liquid and the string material are now sterilized, suitably by heating at about 320° F. for about an hour. The sterilized tubes, disposed within the basket, are now cooled as quickly as desired and the basket is inverted, the lid being held firmly in place, so that the sterilizing fluid is drained from the tubes into any convenient receptacle, whence it may later be recovered. Storing fluid is now added, under aseptic conditions to the sterilized tube and the tube is then sealed off in the usual manner. Any storing fluid ordinarily used with non-boilable surgical strings may be employed, as, for example, a fluid comprising about 95% to 98% alcohol and 2% to 5% sterile water with, if desired, a small amount of germicide such as potassium mercuric iodide. In the case of boilable surgical strings, the fluid containing dissolved fat and the like is drained out of the tubes at the end of the first heating stage, a storing fluid for boilable strings, such as cumene or xylene, for example, is added and the tubes are sealed off and sterilized, after which the package is ready for storage or marketing. Sterilization of the sutures in sealed tubes may be effected by heating the tube and its contents to sterilization temperature of the suture in any convenient way.

In the above described process it is advantageous to carry out the heating step while the tubes and their contents are disposed within the basket or perforated container. However, it is not necessary that a basket be used and the tubes containing the string and fluid may be subjected to the heating step in any other desired manner.

During the first heating stage of my process, I find it convenient to heat the tube assembly in an enclosed space provided with a fan to carry the solvent vapors off to the outer atmosphere and to prevent building up a concentration of these vapors in the room where the operators work. Under these conditions, heating takes place under a slight vacuum. However, I can heat at ordinary pressures or under any degree of vacuum, which would accelerate the process. The vapors may be condensed and the solvent vapors recovered for re-use, if desired. It is an advantage of my process that cotton plugs are not necessary in the tubes nor do the tubes have to be sealed off from the atmosphere before the sterilizing step. The string material is covered with a water-immiscible liquid or with a layer of water-immiscible liquid at temperatures below the vaporization point of such liquid, thereby preventing contact of the string with moisture-laden air and reabsorption of moisture.

While I have described specific ways of carrying out my process it will be understood that other specific ways may be employed, and various changes and modifications may be made in the practice of this process without departing from the spirit of this invention. The foregoing detailed description of the process and means for carrying it out has been given for purposes of explanation only and no unnecessary limitations should be understood therefrom.

Having now described my invention what I wish to claim is:

1. The process of preparing a sterilized surgical string package which comprises heating surgical string disposed within an open container, said string being immersed in a water-immiscible fluid containing a lower-boiling liquid having a boiling point higher than that of water and being vaporizable below the sterilization temperature and a higher boiling liquid having a boiling point higher than the sterilizing temperature, until a substantial portion of said lower-boiling liquid is vaporized, thereafter heating to sterilize the said surgical string immersed in the remaining liquid, removing the remaining liquid, adding a storing fluid to the container and sealing said container.

2. The process of preparing a sterilized surgical string package which comprises heating surgical string disposed within an open container, said string being immersed in a fluid comprising a lower boiling liquid hydrocarbon having a boiling point higher than that of water and being vaporizable below the sterilization temperature and a higher boiling liquid hydrocarbon having a boiling point higher than the sterilization temperature, until a substantial portion of said lower-boiling hydrocarbon is vaporized, thereafter heating to sterilize, removing the remaining fluid, adding a storing fluid to the container and sealing said container.

3. The process of preparing a surgical string package which comprises heating a surgical string disposed within an open tubular container, said string being immersed in a liquid comprising toluene and a cumene fraction having a boiling point of about 330° F., until the toluene is substantially vaporized, and then sterilizing the surgical string immersed in the remaining cumene liquid, removing the cumene liquid, add-

ing a storing fluid to said container and sealing the container.

4. The process of preparing a sterilized surgical string package which comprises heating a surgical string disposed within an open container, said string being immersed in a water-immiscible fluid comprising a lower boiling liquid having a boiling point higher than that of water and being vaporizable at temperatures below the sterilization temperature and a higher boiling liquid having a boiling point higher than the sterilization temperature, until a substantial portion of the said lower boiling liquid is vaporized, removing the remaining liquid, adding a non-aqueous storing fluid to said container, sealing said container and sterilizing.

5. The process of preparing a sterilized surgical string package which comprises heating a surgical string disposed within an open container, said string being immersed in a fluid comprising a lower boiling liquid hydrocarbon having a boiling point higher than that of water and being vaporizable at a temperature below the sterilization temperature and a higher boiling liquid hydrocarbon having a boiling point higher than the sterilization temperature, until the lower boiling hydrocarbon is substantially vaporized, removing the remaining fluid, adding a non-aqueous storing fluid to said container, sealing said container and sterilizing.

6. In a process for preparing a sterilized surgical string package, the steps which comprise heating surgical string immersed in a water-immiscible fluid comprising a lower boiling liquid having a boiling point higher than that of water and being vaporizable at a temperature below the sterilization temperature and a higher boiling liquid having a boiling point above the sterilization temperature, until a substantial portion of the said lower boiling liquid is vaporized, while maintaining the temperature of said fluid below sterilization temperature, and thereafter sterilizing the string immersed in a water-immiscible fluid having a boiling point above the sterilization temperature.

7. In a process for preparing a sterilized surgical string package, the steps which comprise heating a surgical string immersed in a liquid comprising toluene and a cumene fraction having a boiling point of about 330° F., until the toluene is substantially vaporized, while maintaining the temperature of said liquid below sterilization temperature, and thereafter sterilizing the surgical string immersed in the remaining cumene liquid.

8. In a process for preparing a sterilized surgical string package, the steps which comprise heating a surgical string immersed in a water-immiscible fluid comprising a low boiling liquid having a boiling point higher than that of water and being vaporizable at a temperature below the sterilizing temperature and a higher boiling liquid having a boiling point above the sterilizing temperature, until a substantial portion of the said lower boiling liquid is vaporized while the string remains immersed in fluid and while maintaining the temperature of said fluid below sterilization temperature, and thereafter heating to sterilize the string immersed in a water-immiscible fluid having a boiling point higher than the sterilizing temperature.

9. In a process for preparing a sterilized surgical string package, the steps which comprise heating a surgical string immersed in a water-immiscible fluid comprising a low boiling liquid having a boiling point higher than that of water and being vaporizable at a temperature below the sterilizing temperature, until a substantial portion of the said lower boiling liquid is vaporized while the string remains immersed in fluid and while maintaining the temperature of said fluid below sterilization temperature, and thereafter heating to sterilize the string immersed in the remaining fluid.

10. The process of preparing a surgical string package which comprises heating surgical string disposed within an open container, said string being immersed in a water-immiscible fluid comprising a lower boiling liquid hydrocarbon solvent having a boiling point higher than that of water and being vaporizable at a temperature below the sterilizing temperature and a higher boiling liquid hydrocarbon solvent, until the said lower boiling solvent is substantially vaporized, continuously withdrawing the solvent vapors, thereafter heating to sterilize the string immersed in the remaining liquid, removing the remaining liquid, adding a storing fluid to said container and sealing said container.

11. In a process for preparing sterilized surgical string the steps of dehydrating said string while immersed in a water-immiscible fluid comprising a lower boiling liquid having a boiling point higher than that of water and vaporizable at a temperature below the sterilization temperature and a higher boiling liquid having a boiling point above the sterilization temperature by maintaining said string at a temperature at least as high as the boiling point of said lower boiling liquid but below the sterilization temperature until at least a substantial portion of said lower boiling liquid is vaporized, and sterilizing the thus dehydrated string immersed in a water-immiscible liquid by heating said string while so immersed to sterilizing temperature.

12. A process as set forth in claim 11 wherein said dehydrating step is performed at a pressure at least as low as atmospheric pressure.

13. A method of dehydrating animal material adapted and intended for surgical purposes which includes heating the same to a water removing temperature in an organic liquid having a solubility for water no greater than 5.0% for a sufficient length of time to desirably dehydrate said material and then cooling, contact between said material and air being avoided during both the heating and the cooling steps.

14. A method of treating animal material to dehydrate and sterilize the same for surgical purposes which includes heating said material to a water-removing temperature which is below the sterilization temperature, in an organic liquid medium which comprises a liquid having a solubility for water no greater than 5.0% to desirably dehydrate said material, heating the dehydrated material to sterilization temperature in an organic liquid medium which comprises a liquid having a boiling point above the sterilization temperature and having a solubility for water no greater than 5.0% to desirably sterilize said material, and then cooling said material, contact between said material and air being avoided during each of said heating steps.

GEORGE JOSH.