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2,832,664

STERILIZATION OF SURGICAL CATGUT
SUTURES AND LIGATURES

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This invention relates to sterilization of surgical catgut sutures and ligatures and particularly relates to a method of sterilization in which catgut sutures and ligatures, hermetically sealed in containers in the presence of an aqueous alcoholic fluid, are sterilized by the application of heat. The term "sutures" as used hereinafter in the description of the invention is meant to include both sutures and ligatures.

Surgical catgut sutures are composed mainly of collagen which has the property of shrinking or contracting when heated in the presence of water. A catgut suture which has undergone substantial shrinkage or contraction has markedly diminished tensile strength, is irregular in diameter, and consequently has little or no value for use in suturing or ligating. It is because of the property of collagen, of shrinking or contracting when heated in the presence of water, that heat sterilization of surgical catgut strands to be tubed with an aqueous alcohol tubing fluid, as heretofore and currently practiced, entails a complicated procedure involving the dehydration under stringently controlled conditions before the application of heat of sufficient intensity to kill all microorganisms in vegetative or spore form. In the conventional sterilization procedure, catgut strands of desired lengths are wound into coils and placed in individual glass tubes prior to dehydration and then dehydrated by a carefully controlled heat treatment in which the intensity of the heat is gradually raised until the temperature reaches 100° C. During the course of the heat treatment hot air is circulated over the mouths of the open glass tubes to facilitate removal of water vapor. An inert anhydrous fluid, such as an aliphatic hydrocarbon having a boiling point above 160° C., is added to the tubes in an amount sufficient to completely cover the strands and the dehydrated strands are sterilized by heating the tubes for a period of about one hour at a high temperature, usually 150° C. to 160° C. The inert anhydrous fluid is drained from the hot tubes under aseptic conditions, an aqueous alcoholic tubing fluid is added to each individual tube, and the tubes are sealed under aseptic conditions.

Although the procedure described above for sterilizing surgical catgut strands is widely practiced and surgical catgut strands sterilized according to the procedure have achieved wide acceptance, the process is attended with numerous disadvantages and shortcomings. Since the surgical catgut strands are sterilized in open tubes, stringent measures and precautions must be taken to prevent recontamination during the steps of the process following the heating of the strand in the presence of an inert anhydrous fluid and until the tubes have been sealed. Aseptic manipulations are required in aseptic areas during the steps subsequent to sterilization and this requires that all manufacturing operators undergo a procedure comparable to that necessary for personnel participating in surgical operations in an operating theatre. A procedure of this nature requires that the operators be trained in aseptic techniques and continually alert to the dangers of contamination. Even if all the precautions are taken, acci-

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dental contamination of individual tubes occurs and a relatively large number of sterilized suture tubes must be routinely opened and tested bacteriologically for sterility in order to minimize the possibility of unsterile sutures being used.

It is an object of this invention to provide a method for the sterilization of surgical catgut strands in which the strands are sterilized by the application of heat to a hermetically sealed container containing a catgut strand and an aqueous alcoholic tubing fluid.

It is another object of this invention to provide a process for the sterilization of surgical catgut strands in which the strands are not dehydrated before sterilization.

It is still another object of this invention to provide a simple method for the sterilization of surgical catgut strands immersed in an aqueous alcoholic solution which does not require the expensive equipment and the time-consuming operations necessary when sterilization is performed under aseptic conditions.

It is another and further object of the invention to provide a method of sterilizing surgical catgut strands which provides strands of improved hand, pliability, and tensile strength.

The above objects of this invention are accomplished by a sterilization process in which non-sterile surgical catgut strands are hermetically sealed in containers, such as glass tubes or plastic envelopes or tubes, in the presence of an aqueous isopropanol solution and heated. The concentration of the aqueous isopropanol solution is required to be within the range of from about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water respectively. If the water content of the aqueous isopropanol solution is more than about 10% by weight, the tensile strength of the surgical catgut strands is substantially decreased during a heat treatment which will render them sterile and, if the water content of the aqueous isopropanol solution is less than about 7.5% by weight, the sterile surgical catgut strands are stiffened during the heat treatment to the extent that they are not acceptable in suturing and ligating without conditioning by the application of moisture before use. The temperature and time of the sterilizing heat treatment applied to surgical catgut strands hermetically sealed in containers with an aqueous alcoholic tubing fluid must be carefully controlled if satisfactory sterile strands are provided: the temperature is required to be within the range of from about 90° C. to about 95° C. for a period of at least two hours. If the temperature is less than about 90° C., or if the duration of the heating period is less than two hours, some catgut strands may not be sterilized, particularly strands contaminated with heat resistant bacterial spores. If the temperature is above about 95° C., the tensile strength of the strands is substantially decreased. The duration of the heating period may be as long as six hours without resulting in a substantial decrease in the tensile strength of the strands. It is preferred that the heat treatment be conducted at a temperature of from 91° C. to 94° C. Heating at 94° C. for a period of two hours is the specific preferred condition for sterilizing surgical catgut strands hermetically sealed with an aqueous alcoholic tubing fluid.

The following examples illustrate various conditions with respect to temperature, time and concentration of aqueous isopropanol satisfactory for use in the sterilization of surgical catgut strands of various sizes according to the invention.

Example I

150 five-foot lengths of non-sterile surgical catgut strands containing approximately 3% by weight of water were each coiled and inserted in individual glass tubes. The strands had a diameter of 19.5 mils which comes within the range of diameter specified by the U. S. Phar-

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macropoeia for size 2 surgical catgut strands. Tubing fluid consisting of 90% by weight isopropanol and 10% by weight water was added to each glass tube in an amount sufficient to completely immerse the coiled strand, and the glass tubes were hermetically sealed. Fifty of the tubes were immersed in a heating bath maintained at a temperature of 90° C. for a period of three hours, fifty of the tubes were immersed in a heating bath maintained at a temperature of 92° C. for three hours, and fifty of the tubes were immersed in a heating bath maintained at a temperature of 94° C. for three hours.

Ten randomly selected tubes from each of the fifty tube groups were opened and tested for sterility by immersion of the strands in sterile culture media and incubation of the media at 34° C. for ten days. At the end of the ten-day incubation period there was no bacterial growth in any of the tubes containing the surgical catgut strands. Ten randomly selected strands from each of the fifty tube groups were tested for straight tensile strength and knot tensile strength. The strands heated at 90° C. had an average strand tensile strength of 22.7 pounds, and an average knot tensile strength of 13.8 pounds. The strands heated at 92° C. had an average straight tensile strength of 20.4 pounds and an average knot tensile strength of 12.2 pounds. The strands heated at 94° C. had an average straight tensile strength of 18.6 pounds and an average knot tensile strength of 13.2 pounds. The straight tensile strength and knot tensile strength specified for size 2 surgical catgut sutures by the U. S. Pharmacopoeia is 13 pounds and 9 pounds respectively.

Example II

The sterilization procedure of Example I was repeated with 50 surgical catgut strands of the same size, but in this instance the aqueous isopropanol solution containing 91% by weight of isopropanol and 9% by weight of water and the hermetically sealed tubes were immersed in a heating bath maintained at a temperature of 94° C. for three hours. The average straight tensile strength of the strands tested was 18.6 pounds and the average knot tensile strength was 12.8 pounds. There was no evidence of microbial contamination in sterility tests of the strands subjected to the heat treatment.

Example III

Fifty five-foot lengths of non-sterile surgical catgut strands having a diameter of 16.0 mils, corresponding to size 0 which had a diameter specification in the U. S. Pharmacopoeia within the range of 16.0 to 19.5 mils, were treated according to the sterilization procedure of Example I, but in this instance the aqueous isopropanol solution contained 90% by weight of isopropanol and 10% by weight of water and the hermetically sealed tubes were immersed in a heating bath maintained at a temperature of 90° C. for three hours. The average straight tensile strength of the strands tested was 15.3 pounds and the average knot tensile strength was 8.4 pounds. The U. S. Pharmacopoeia specifies that surgical catgut sutures of size 0 have a straight tensile strength of seven pounds and a knot tensile strength of five pounds. There was no evidence of microbial contamination in sterility tests of strands subjected to the heat treatment.

The surgical catgut strands sterilized according to the above three examples did not undergo any shrinkage or acquire irregularities of diameter as a result of the sterilization process.

Collagen and particularly surgical catgut strands shrink and thicken when immersed in water at about 60° C. but dehydrated strands do not shrink significantly when heated at 150° C. to 160° C. in an anhydrous medium. If only a slight amount of water is present in the surgical catgut strands, considerable thickening occurs at 150° C. to 160° C. and significant thickening occurs even at a much lower temperature. Heating of dehydrated surgical catgut strands at a temperature of 150° C. to 160° C. or

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below does not result in shrinkage but the temperature at which such strands shrink in the presence of water is substantially lowered. Dehydrated surgical catgut strands which have been heated at 155° C. exhibit substantial shrinkage at 53° C. when immersed in water. The medium in which collagen is immersed while the shrinkage temperature is measured has a very marked effect on shrinkage. In an anhydrous non-polar fluid such as an aliphatic hydrocarbon, shrinkage of surgical catgut strands is negligible at a temperature not higher than 160° C. The shrinkage temperature of surgical catgut strands immersed in a solution containing 75% by volume of glycerine and 25% by volume of water is 30° C. to 40° C. higher than the shrinkage temperature of surgical catgut strands immersed in water only.

Surgical catgut strands sterilized according to the above examples have a higher shrinkage temperature in water or aqueous alcoholic solution than surgical catgut strands sterilized in a dehydrated form by heating at 150° C. to 160° C. while immersed in an aliphatic hydrocarbon. Consequently, surgical catgut strands sterilized by the method of this invention are less susceptible to thermal damage than surgical catgut strands sterilized by the conventional procedure of heating dehydrated strands immersed in an aliphatic hydrocarbon at a temperature of 150° C. to 160° C. Surgical catgut strands which have been sterilized according to conventional procedures shrink markedly at about 70° C. when immersed in a solution containing 90% by weight of isopropanol and 10% by weight of water, whereas the surgical catgut strands sterilized according to the method of this invention and immersed in a solution containing 90% by weight of isopropanol and 10% by weight of water shrink to a comparable degree only when heated to 100° C. The higher shrinkage temperature, which is characteristic of surgical catgut strands sterilized according to the method of this invention, indicates damage to the surgical catgut strands is significantly less than the damage resulting from sterilization according to the conventional procedure.

Since certain changes may be made in the conditions of the sterilizing process, it is intended that all matter contained in the above description shall be interpreted as illustrative and not in a limiting sense, but the invention is to be limited only by the scope of the appended claims. What is claimed is:

1. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of at least two hours at a temperature within the range of from about 90° C. to about 95° C.

2. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in glass tubes with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of at least two hours at a temperature within the range of from about 90° C. to about 95° C.

3. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of at least two hours at a temperature within the range of from about 91° C. to about 94° C.

4. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of at least two hours at a temperature of about 94° C.

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5. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of from two to six hours at a temperature within the range of from about 90° C. to about 95° C.

6. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of from two to six hours at a temperature within the range of from about 91° C. to about 94° C.

7. A process for sterilizing surgical catgut sutures comprising heating surgical catgut sutures hermetically sealed

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in a container with an aqueous isopropanol solution containing about 90% to about 92.5% by weight of isopropanol and about 10% to about 7.5% by weight of water for a period of from two to six hours at a temperature of about 94° C.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 2,832,664

April 29, 1958

Alfred Bloch

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

In the grant, lines 2 and 12, and in the heading to the printed specification, lines 4 and 5, name of assignee, for "Ethicon Suture Laboratories Incorporated" read -- Ethicon, Inc. --.

Signed and sealed this 29th day of July 1958.

(SEAL)
Attest:

KARL H. AXLINE

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Commissioner of Patents