

UNITED STATES PATENT OFFICE

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SUTURES

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This invention relates to surgical sutures and particularly to the composition of the liquid in which sutures are customarily packed or tubed. The invention results from my discovery that the propyl alcohols, either pure or containing small quantities of water, have unexpected properties toward absorbable protein materials, such as animal tissues, which are of advantage in the tubing of absorbable sutures, such as surgical gut.

In order to provide surgeons with sutures which are sterile and ready to use, it has been the practice to pack the suture in a glass tube containing a preserving or conditioning liquid, called tubing fluid, the tube being sealed hermetically either before or after sterilizing the suture, depending on the nature of the suture and the particular tubing fluid used.

One of the problems attending the use of sutures is the sterilizing of the outside of the tube so that when it is handled to break the tube and remove the suture, the suture will not be contaminated. One method of accomplishing this is to boil the suture tube, or place it in a steam sterilizer before the tube is opened. This requires a tubing fluid which is inert with respect to the suture material at temperatures up to at least 212° F., and usually as high as 250° F. Sutures packed in such tubing fluids are named and labeled boilable. As a matter of fact, when boilable tubing fluid is used, the suture is customarily sealed in the tube and thereafter sterilized by heating for an hour or more to a temperature of about 315° F. Therefore, boilable tubing fluids should be inert to the suture material at this temperature.

The most extensively used sutures are made from animal tissues, especially the sub-mucosa lining of the small intestines of sheep (called surgical gut). Previous attempts to tube boilable sutures in alcoholic or other solutions containing water have been unsuccessful because previously known tubing fluids containing even small quantities of water as well as previously known alcoholic tubing fluids (containing ethanol or methanol) ruin the gut at boiling temperatures. Thus xylol and similar anhydrous hydrocarbons have been used for boilable sutures in spite of their known disadvantages among which are irritation of the tissue, stiffness or elastic wiriness of the suture, and the difficulty of removing the tubing fluid from the fibers of the suture, which results in difficulty in softening or requires prolonged exposure to water or other softening liquids.

I have discovered that sutures tubed in the propyl alcohols can be boiled without damage to

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the suture even when the propyl alcohol contains as much as about 2% water.

In accordance with my invention, sutures are prepared in the usual manner including drying and polishing and placing in open glass tubes. I then partially fill the tube with my novel tubing fluid, seal the tube, and subsequently heat it to sterilizing temperature. The tubing fluid, according to my invention, consists of between about 98% and about 100% of a propyl alcohol, the remainder being water. I can use either normal propyl alcohol or isopropyl alcohol, but I prefer the latter.

When the suture is to be used, the tube is broken and the suture soaked in sterile water or is placed in a wet sterile towel to render it sufficiently pliable for use. In prior practice, as much as ten minutes exposure to moisture might be required to render the suture sufficiently pliable. This was partly due to the presence of the previously known boilable fluids, which were not miscible with water, and which acted somewhat as waterproofing impregnants. This prolonged exposure not only caused undesirable delay, but subjected the suture to the risk of contamination. I have found that sutures tubed in a propyl alcohol, or a solution having a concentration above about 98% propyl alcohol, are softened after exposure to moisture of only about half the time formerly required. The propyl alcohols are miscible in water in all proportions, so that the tubing fluid rapidly dilutes and dissolves into the water, giving the water instant access to the fibers. Moreover, the presence of the water produces a suture somewhat more pliable initially than a suture tubed in a completely anhydrous liquid.

Another advantage resulting from my invention, is the elimination of the irritation caused by traces of previously known hydrocarbons which remain in the suture even after soaking in water. Because these tubing fluids are not miscible in water, undesirable quantities remain in the fibers of the gut. These residual quantities of many tubing fluids, such as xylol, are irritating to human tissue and retard recovery of the patient. The propyl alcohols not only are less irritating, but less of the tubing fluid remains in the suture because of its solubility in water.

Still another advantage, resulting from using propyl alcohols, is the elimination of the brashy knots, which are experienced with previously known boilable sutures. This is a phenomenon attending stiff sutures, and results from splinter-

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ing of the suture or breaking of the fibers when sharply bent as in a knot. Boilable sutures must show definite tensile strengths over knots, as rigidly specified by the United States Pharmacopoeia for each size of suture. It is required that the sutures show these minimum strengths upon removal from the tube and without conditioning. Where the stiff suture is tied in a knot and the knotted string pulled to the test value of tension (e. g., 7 pounds for a No. 1 gut having a diameter between 16.0 and 19.0 mils), the small fibers of the gut at and near the outside are apt to break. This weakens the gut and causes it to fail the test. Gut tubed in the propyl alcohols, for some reason not fully understood, has less brashy knots than gut tubed in standard boilable fluids. The fibers at the outside break less and the sutures show improved knot tensile strength. The reduction of brashiness seems to improve with increase of water content up to the limit of water content which permits boiling of the suture, namely about 2%.

I claim:

1. As an article of manufacture, a suture of absorbable proteinaceous material, sealed in a container with a propyl alcohol between about 98% and about 100% and water between about 2% and about 0% said suture being stable at temperatures up to 100° C.

2. As an article of manufacture, a suture of absorbable proteinaceous material, sealed in a container with normal propyl alcohol between about 98% and about 100% and water between about 2% and about 0% said suture being stable at temperatures up to 100° C.

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3. As an article of manufacture, a suture of absorbable proteinaceous material, sealed in a container with isopropanol between about 98% and about 100% and water between about 2% and about 0% said suture being stable at temperatures up to 100° C.

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