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3,043,067

SUTURE PACKAGE

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Fig. 1.

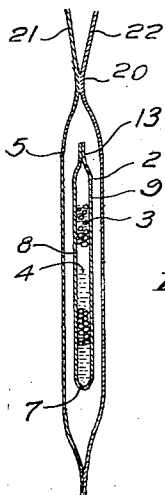
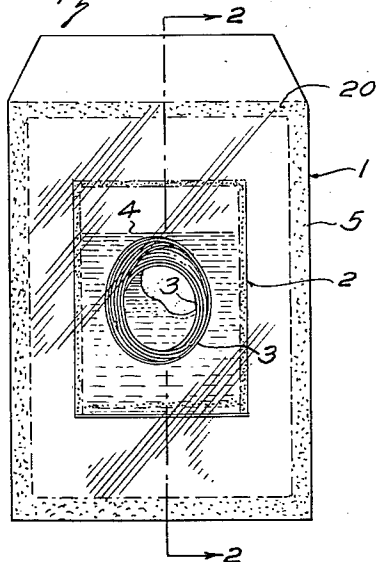


Fig. 2.

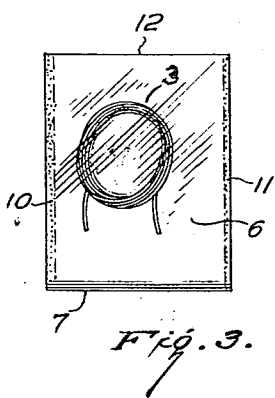


Fig. 3.

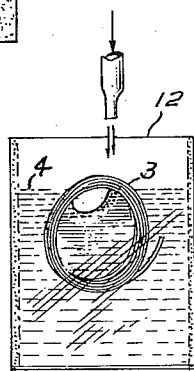


Fig. 4.

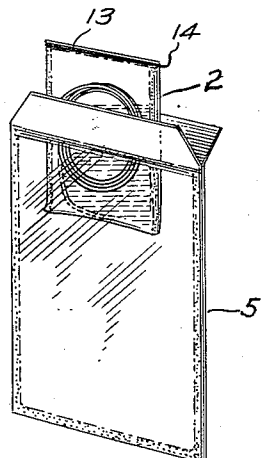


Fig. 6.

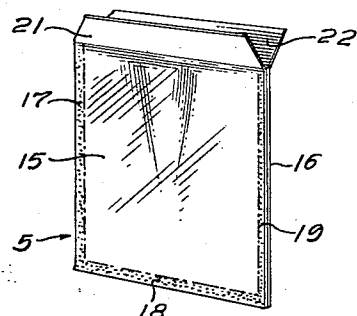


Fig. 5.

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SUTURE PACKAGE

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3 Claims. (Cl. 53—27)

This invention relates to a light-weight plastic package for surgical sutures and has for its principal object the provision of such a package that will permit delivery of a liquid-immersed surgical suture packet to the operating room in a completely sterile condition.

Heretofore surgical sutures have been packaged by the manufacturer in sealed glass tubes containing, in addition to the suture itself, an alcoholic conditioning fluid known as a tubing fluid. These glass tubes are relatively bulky, being about 4 to 5 inches long and about 1/2 an inch in diameter, and are also fragile and subject to premature breakage during shipment. They are also troublesome to open in the operating room, since they must be broken open under completely sterile conditions. Frequently small slivers of glass from a broken tube become attached to the suture, and may introduce undesirable foreign material if not carefully removed before the suture is used.

The glass suture tubes are accepted by the medical profession, in spite of the disadvantages noted above, because they have provided a reliable means of delivering sutures to the operating room in a sterile condition. However, upon receipt of the suture tubes in the hospital, it has been necessary to sterilize their outer surfaces before they can be opened safely. The established sterilizing practice was to wash the tubes with soap and water and then to place them in a sterilizing solution for some 18 hours. More recently the tubes have been packed by the manufacturer in a jar or can containing the sterilizing solution, so that sterilization by the hospital is unnecessary. However, this procedure adds even more to the bulk and weight of the suture package; so much so, in fact, that the weight of the glass tubes, sterilizing liquid and rigid outer container is many times the weight of the sutures themselves. Thus, for example, a sealed can containing three dozen sutures packed in this manner will weight about three pounds, whereas the sutures themselves weigh less than one ounce.

It has previously been proposed to package a dry suture in an envelope, the suture and envelope then being heat-sterilized and enclosed in an outer container. However, this sterilizing procedure cannot be applied to a wet-packed gut suture, for the tensile strength of the gut is markedly reduced by heat-sterilizing it in the presence of some alcoholic and aqueous liquids. It has also been proposed to pack the suture in a paper envelope containing a germicidal sterilizing solution, a number of these envelopes then being immersed in an outer jar or can containing additional liquid germicide. Such direct contact of the suture with a germicide is very undesirable, however, since the character of the suture is always changed thereby. Gut sutures are hardened by formaldehyde-containing germicides and are not readily absorbable after the incision has healed; substantial quantities of mercury-containing and phenol-containing germicides make the suture irritating to the wound. Furthermore, the liquid-filled outer container presents the problem of bulk and unnecessary weight that is discussed above.

Our present invention retains all the advantages of the liquid-containing glass suture tube packages, including delivery of an externally-sterilized suture container to the operating room, but avoids completely the unnecessary bulk and weight incident to the use of glass tubes.

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Essentially, the invention consists in the provision of a light-weight, completely sterile, liquid-containing plastic suture packet that is dry-packed in an internally sterile sealed outer envelope, the outer envelope being so constructed that it can be pulled apart and the inner suture packet discharged therefrom without its contacting an unsterile portion of the outer envelope. The invention also includes a number of additional important structural features of our novel suture package, as well as a novel procedure for preparing and sterilizing the suture and its container, as will hereinafter be more fully described with reference to the accompanying drawing and pointed out in the appended claims.

Referring to the drawing:

FIG. 1 is a front elevation of a complete suture package constituting an embodiment of the invention.

FIG. 2 is a vertical section on the line 2—2 of FIG. 1.

FIGS. 3 and 4 are detailed views showing, respectively, the insertion of a coiled dry suture into the inner envelope or cachet and the addition of a conditioning liquid after dry sterilizing the suture and inner envelope.

FIG. 5 is a perspective of a preferred form of the outer envelope, and

FIG. 6 is a perspective showing the insertion of the externally sterile, heat-sealed inner suture packet or cachet into the internally sterile outer envelope before heat-sealing the latter.

Referring to FIGS. 1 and 2, the suture package designated generally by reference numeral 1 comprises a sealed inner envelope or packet 2, containing a suture 3 immersed in a sterile conditioning liquid 4 in contact with the inner surfaces of the envelope 2, this packet being dry-packed in a sealed outer envelope 5. By "dry-packed" we intend to emphasize, as one important feature of the invention, that no substantial quantity of liquid is introduced into the outer package or envelope so that the space between the inner and outer envelope is simply gas-filled. This contributes materially to the extremely light weight and flexibility of our suture package both because it eliminates the weight of a sterilizing liquid and because the thickness and strength of the walls of the outer envelope can be correspondingly decreased.

The absence of a substantial quantity of liquid in the outer envelope is important for an additional reason; namely, because it would be a source of contamination of the outer surface of the inner envelope 2 upon opening the package. It will readily be understood that, upon opening the outer envelope 5 in the manner hereinafter described, such a liquid would flow out and contact its outer unsterile surfaces, and would thereby become non-sterile. Portions of this contaminated liquid could then easily contact the inner envelope 2 while it is being discharged from the package. It will be further understood, however, that this problem would not arise if only a small quantity of liquid, such as a few drops, is present in the outer envelope. Therefore the presence in the outer envelope of a very small amount of liquid, such as a few drops of pyrogallol solution for detecting leakage in the seal, is contemplated within the broad scope of the invention.

A preferred form of the inner envelope 2 is shown in FIG. 3 of the drawings. The envelope is made of a strip of thin cast or extruded synthetic plastic material 6 that is folded as at 7 to form a pair of side walls 8 and 9 (FIG. 2). These side walls may be joined together at their outer edges by seals 10 and 11, leaving an open end 12 for insertion of the suture 3. After dry-sterilizing the open-ended envelope and the suture therein, and after introducing the sterile conditioning liquid 4, the edge 12 may be sealed as at 13 (FIG. 6), preferably by heat-sealing to form the completely sealed, sterile plastic packet that constitutes a principal feature of the inven-

tion. If desired a tear string 14 with a projecting end may be placed in the open end 12 before sealing it, to facilitate opening the packet.

The nature of the plastic material of which the inner envelope 2 is composed is extremely important. It must be impervious to water and to the aqueous alcoholic solutions that are used as conditioning fluids; i.e., the plastic must be insoluble in and unattacked by these liquids and must contain no pores through which the liquid can pass. For this reason a fibrous material such as paper or a porous plastic such as regenerated cellulose cannot be used. The plastic should be tough, have a melting or softening point well above the highest temperatures used for dry sterilizing (300–320° F.), flexible and non-breakable, and transparent so that the suture can be inspected. The material should also be heat-sealable; i.e., two adjacent films should be capable of being fused together to a non-leakable seal by the application of heat. Also the plastic should preferably be relatively inexpensive.

We have discovered a class of plastic films possessing all of the above characteristics, and sterile, liquid-immersed sutures sealed in plastic envelopes composed of this film constitute another important feature of our invention. The material of which the film is composed is a highly polymeric linear terephthalic ester of a polyethylene glycol, as described in U.S. Patent No. 2,465,319, dated March 22, 1949. The polymeric terephthalates sold commercially in filament form as "Dacron," and which are polyethylene glycol terephthalates, constitute the preferred materials. Films of these polymers are produced by melting the polyethylene glycol terephthalate in a jacketed melting vessel at about 285° C., preferably in an inert atmosphere, and forcing the molten polymer through an extrusion press, a sand filter pack and a stainless steel disk containing a narrow slot orifice. The resulting extruded ribbon of molten polymer is passed through pinch rolls which stretch it to the desired thickness (about 0.006–0.008 inch) and then into a quenching bath of cold water. The film is then drawn between two pairs of pinch rolls operating at speeds of 120 and 600 revolutions per minute, respectively, these rolls being enclosed in a bath of mineral oil heated to 70° C. The final drawn film has a thickness of about 0.003 inch. The film so produced is now being sold commercially as a base for motion picture film, and is known as "Mylar."

Drawn films of approximately the same thickness composed of poly-trifluoromonoethylethylene and films of poly-tetrachlorethylene have also been tested. Both films can be used to prepare suture packets having most of the above-described characteristics, including particularly the properties of flexibility, transparency and imperviousness to aqueous alcoholic conditioning fluids, but they are much higher in price. Moreover, they are not so easily heat-sealed as is Mylar, and therefore are less desirable.

The construction of the outer envelope 5 constitutes a particularly important factor in the suture package of our invention. The interior of this envelope must remain completely sterile during shipment of the package and until it is opened in the operating room of the hospital. The envelope must therefore be completely sealed. However, a permanent seal requiring cutting or tearing of the outer envelope and extraction of the inner one would subject the inner packet to the danger of contamination by the outer, unsterile portions of the outer envelope. Our invention avoids this danger of contamination by providing an outer envelope having walls joined by a strippable seal; i.e., a seal having a cross-sectional tensile or tearing strength that is less than the tearing strength of the walls themselves. Such a seal permits the walls to be pulled apart and the inner suture packet discharged without contacting any unsterile portion of the envelope.

Referring to FIG. 5 of the drawings, the outer envelope 5 will be seen to consist of a front wall 15, preferably

composed of transparent plastic material, and a back wall or backing strip 16 which is preferably but not necessarily composed of thin metal foil such as aluminum foil. When a metal foil backing strip is used its inner surface is preferably coated with a thermoplastic resin such as Vinylite resin to assist in forming a gas-tight package. The front wall 15 is preferably composed of Mylar film, or of some other film of impervious, transparent thermoplastic material capable of being heat-sealed to the backing strip by a strippable seal. Such a seal is preferably formed along three of the outer edges 17, 18 and 19 of the envelope before the inner packet is inserted therein. After sterilizing the open outer envelope and inserting the packet, as shown in FIG. 6 of the drawing, the last strippable seal is made some distance inwardly from the remaining edges of the front and backing strips, as at 20 on FIG. 1. By locating a seal in this manner, a pair of separable projecting edges 21 and 22 is provided that can be grasped between the fingers and pulled apart, thus permitting the outer envelope to be stripped open without danger of contamination of the inner packet.

If an outer envelope composed entirely of a plastic such as Mylar is used it may be similar in form to the inner envelope 2 and may be made by folding an oblong sheet of film and heat-sealing the edges.

Our invention includes certain improved methods of making, sterilizing and assembling the elements which constitute our new suture package. While a number of manufacturing methods may be used, the following procedures possess the important commercial advantages that will be indicated below.

The inner envelope may be made from a single strip of Mylar or other suitable film. As shown on FIGS. 2 and 3 of the drawings, such a strip may be folded as at 7 and the opposing edges sealed as at 10 and 11, forming an envelope having an open upper edge 12. The suture 3 is inserted through the open end of this envelope after which the envelope and suture are dehydrated and sterilized. Dehydration is carried out by heating the open envelope containing the suture in an oven at 105° C. for about 8 hours; the step is necessary to remove all moisture that might hydrolyze and deteriorate the gut during the subsequent high-temperature sterilization if it were present. After dehydration, the temperature of the oven is raised to 135° C. and the envelope and suture are heated at this temperature for 3 hours. The sterilization may be carried out at 155° C. for about 1–2 hours, or temperatures between 135° C. and 155° C. may be maintained for an intermediate length of time.

After sterilizing, a quantity of conditioning fluid sufficient to soften the dry suture is introduced through the open end of the envelope as illustrated on FIG. 4 of the drawing. The particular conditioning fluid may vary with the type of suture, but will usually consist of a water soluble alkanol of 1–4 carbon atoms; i.e., methanol, ethanol, isopropanol or tertiary butanol, or a mixture of two or more of such alkanols, together with a small amount of water. In most cases the quantity of water will range from a minimum of about 0.2% to a maximum of about 8–10% of the composition, the balance consisting substantially of the alcohol or alcohols. A very small quantity, such as about 0.025% of phenyl mercuric benzoate or comparable quantities of other germicide may be included if desired. The ratio of water to alcohol is preferably that which forms an azeotropic mixture so that the composition will remain constant if any vaporization should occur. After the suture has been immersed in conditioning liquid by this procedure, the open edge 12 of the inner envelope 2 is sealed under sterile conditions, thereby forming a completely sealed packet that is both internally and externally sterile.

The packet may be made by other procedures. Thus, for example, a seamless tube of Mylar film may be cut into suitable lengths, each length being sealed at one end,

the suture inserted and the package sterilized, after which the conditioning fluid is introduced and the opposite end is sealed under sterile conditions. Alternatively a catchet may be formed by sealing three opposing edges of two separate strips or pieces of Mylar film, followed by insertion of the suture 3, sterilizing, introducing the conditioning liquid and sealing.

As has been stated above, the outer envelope 5 is preferably formed by sealing together a sheet of thin metal, such as aluminum foil, and a sheet of plastic such as Mylar film. The two sheets are preferably placed in opposition and sealed together along their side edges 17 and 19 and bottom edges 18 as shown on FIG. 5 of the drawings. The envelope so formed may then be sterilized by steam autoclaving, preferred conditions being for 30 minutes under 15 pounds pressure or for 15 minutes under 20 pounds of steam pressure. The sterile inner envelope 2, prepared and sealed as described above, is then introduced into the sterilized outer envelope 5 as shown on FIG. 6 of the drawings, after which the open end of the outer envelope is sealed as at 20 on FIG. 1 of the drawings.

We have developed a chemical sterilizing procedure suitable for use in sterilizing and filling the outer envelope 5 that is particularly adapted for large scale commercial manufacture. A chemical sterilizing agent may be applied in this manner either before or after inserting the inner envelope 2, since it does not require a heating step that would deteriorate a gut suture in contact with an aqueous conditioning liquid. We find that by subjecting the open-ended outer envelope 5 to an ethylene oxide-containing atmosphere a complete sterilization of the envelope and its contents may be obtained.

Ethylene oxide is an explosive gas with a wide range of explosive limits, and must therefore be diluted with an inert gas such as nitrogen or carbon dioxide. We find, however, that complete sterilization can be obtained with a gas mixture composed of about 10% to 20% by weight of ethylene oxide and about 80% to 90% carbon dioxide, nitrogen or a mixture thereof. We therefore expose the open-ended envelope 5 to this gas mixture, with or without first inserting the inner envelope 2, for a time sufficient to obtain complete sterilization which is several hours. The outer envelope is then sealed as described above, and a completely sterilized package is obtained.

Another suitable sterilizing procedure consists in irradiating the inner envelope 2 or the outer envelope 5, or both, with ionizing radiations such as cathode rays, X-rays or gamma rays. This type of sterilization may be applied to the Mylar or other plastic film and to the aluminum foil before they are made into envelopes or it may be applied after the envelopes are made. It may also be used to sterilize both the contents and the outer surfaces of the filled and sealed suture packet 2 or of the filled and sealed outer envelope 5. Tests have been made wherein sutures suspended in liquid in sealed containers were subjected to irradiation by high voltage X-rays after which the sutures were removed aseptically and placed in large culture tubes containing nutrient broth enriched by adding 0.5% sodium chloride and 0.1% dextrose. The cultures were incubated for one week at 37° C. and then inspected. It was found that complete sterilization of the sutures was obtained with dosages of 1.5 to 2 million roentgens. A roentgen is the amount of radiant energy which, when passing through one cubic centimeter of air at standard temperature and pressure, will release one electrostatic unit of charge.

Cathode rays are inherently more efficient than X-rays for sterilizing purposes, since all of their emergent energy can be directed into the material undergoing treatment and expended in ionization processes. Voltages within the range of from 500 to 3,000 kv. and dosages similar to those used with X-rays are recommended.

Because of their great depth of penetration gamma rays are particularly suitable for sterilizing the contents of the outer envelope 5 after it has been filled and sealed. Dos-

ages of $1.5-2.0 \times 10^6$ r.e.p. (roentgens equivalent physical) are recommended for this purpose.

From the foregoing it will be seen that our invention provides a light-weight, completely sterile, liquid-containing plastic suture packet that is dry-packed in an internally sterile sealed outer envelope having a strippable seal permitting it to be easily opened in the operating room. While the packet is probably of greatest utility in the packaging of non-boilable gut sutures it can also be used for the packaging of boilable gut sutures, in which case a non-aqueous conditioning fluid such as absolute alcohol, xylene and the like would be employed. It can also be used with non-absorbable sutures such as those composed of silk and the like. All these sutures may and frequently do have needles attached, and may be wound upon a reel or frame, and it will be understood that these adjuncts are included in the term "suture" as used in the appended claims.

Although heat-sealing is by far the best method of sealing the edges both of the inner packet 2 and of the outer envelope 5, it will be understood that other sealing procedures may be used. Thus, in the case of the outer envelope 5, an adhesive having the proper bond strength to provide the necessary seal for the envelope, while still remaining strippable, may be employed; the pressure-sensitive rubber cements that are now used on cellophane tape are representative of such adhesives. It will be understood therefore that modifications of the preferred embodiments of the invention, and substitutions of equivalents therefor, may be resorted to within the scope of the appended claims.

What we claim is:

1. A method of manufacturing a sterile suture package which comprises enclosing a suture in an open-ended plastic envelope, dry-sterilizing the suture and envelope, introducing a sterile conditioning liquid into the envelope and sealing the envelope to form a liquid-tight, sterile suture packet, bringing two sheets of side wall-forming material into alignment and sealing together by a strippable seal at least one but less than all of their outer edges to form an open outer envelope, sterilizing said outer envelope and introducing said sterile suture packet therinto under sterile conditions, and sealing together the outer unsealed portions of said outer envelope by a strippable seal.

2. A method of manufacturing a sterile suture package which comprises enclosing a suture in an open-ended plastic envelope, dry-sterilizing the suture and envelope, introducing a sterile conditioning liquid into the envelope and sealing the envelope to form a liquid-tight, sterile suture packet, forming an open-ended outer envelope, sterilizing said envelope by contact with ethylene oxide gas and introducing said sterile suture packet therinto under sterile conditions, and sealing said outer envelope.

3. A method of manufacturing a sterile suture package which comprises forming an open-ended, heat-sealed, transparent envelope from a polymeric polyethylene terephthalic ester film, inserting therein a suture, dehydrating and sterilizing the suture containing envelope, introducing a sterile conditioning liquid into the envelope, and heat-sealing the open end of the envelope to thereby form a liquid-tight, sterile suture packet.

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