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V. C. EGLER ETAL
SUTURE LIGATING PACKAGE

3,062,372

Filed June 3, 1958

Fig. 1.

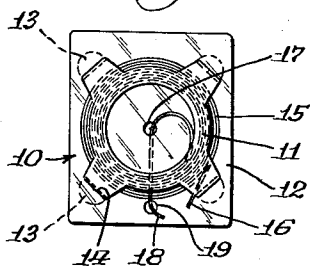


Fig. 2.

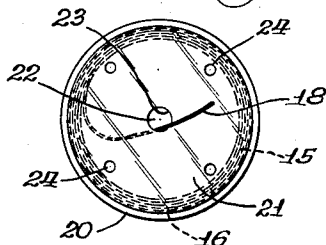


Fig. 3.

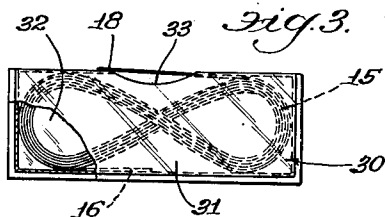


Fig. 5.

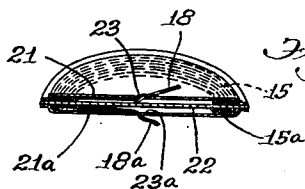


Fig. 6.

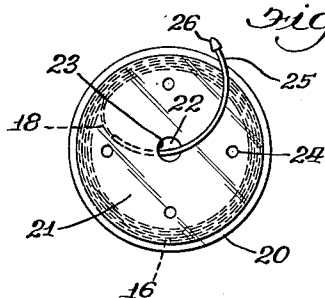


Fig. 4.

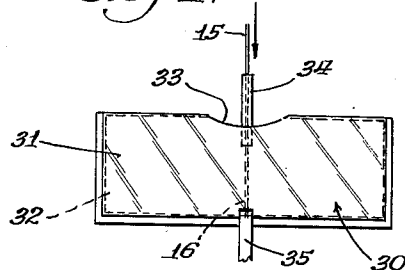


Fig. 4A.

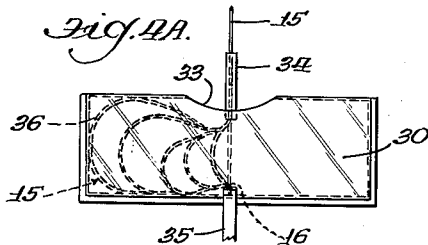


Fig. 4B.

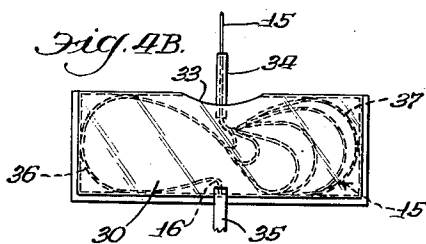


Fig. 7.

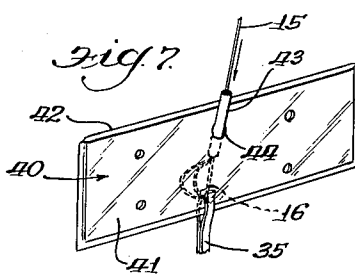
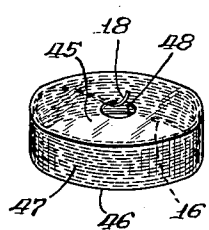


Fig. 8.



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3,062,372

SUTURE LIGATING PACKAGE

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5 Claims. (Cl. 206-63.3)

This invention is concerned with packages for coils of relatively stiff resilient suture strands. More particularly it is concerned with relatively flat suture coil packages which, in addition to dispensing the suture progressively without entanglement and with a minimum of kinking, have particular utility in surgical ligating procedures.

The surgical field has long been in need of a device which could eliminate time consuming practices and curtail a great deal of the handling of sutures in preparation for ligating. The practice today is one involving removing the suture from the reel, stretching it to remove the bends, severing it into short lengths to prevent tangling, coiling these short lengths loosely so that the surgeon can hold the loose coil in his hand or alternatively winding the length onto a bobbin which the surgeon holds in his hand. All of this must be done under aseptic conditions. Thereafter the surgeon uses each short length until it is too short to make strong knots after which perhaps as much as $\frac{1}{4}$ of the original length is discarded.

There have been some early previous attempts to solve this ligating problem, one of which is illustrated in U.S. Patent No. 2,284,724 to Cleminson. Cleminson had to resort to undesirable heat-setting of his suture into a spring-like coil in order to prevent tangling since his suture is dangling free in the tube. Furthermore, the Cleminson device is impractical for ligating purposes because the sharp broken edges of the tube would cut the surgeon's glove and hand if held in the palm for ligating.

Another attempt to solve the ligating problem is illustrated in Figs. 3 and 4 of U.S. Patent No. 1,334,916 to Lukens. The tight coils which the tubes illustrated in this patent (and in the Cleminson patent) impose upon the contained suture invite excessive kinking particularly when the suture is dispensed from the side.

We have found that it is characteristic of catgut and other relatively stiff resilient suture strands to kink when pulled longitudinally from a generally circular or helical coil if the coil is too small in diameter. By "kink" we mean a very tight loop in a suture strand resembling the written letter *e* which tends upon longitudinal pulling on the strand to retain its loop form but become smaller to the point where the strand is damaged. We have found that with circular and helical coils smaller than two inches in circumference kinking is commonly encountered particularly with relatively flat packages with side dispensing. There is a natural tendency with side dispensing of suture strands from circular and helical coils to reduce the diameter of the immediate coil loop to the point where a kink is formed if the loop cannot turn over.

The Cleminson and Lukens devices which were designed to be contained in glass suture tube outer containers, have not, therefore, been widely accepted by the surgical profession. Glass suture tube packages, instead, have generally contained sutures wound upon H shaped reels typically illustrated in U.S. Patent No. 2,253,287 to Davis, et al. A modification of the H reel has three prongs at each end with the suture wound around the middle two prongs so as to lie generally in a plane parallel to the plane of the reel body.

These latter, relatively flat reels together with a reel having four circumferential prongs projecting from a flat face, with the suture assuming a roughly circular coil parallel to the face, have reduced the kinking problem considerably particularly the four prong, circular coil

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reel. Furthermore, their flat nature makes them more suitable for insertion into relatively flat envelope type suture outer packages which are currently preferred by many surgeons to standard glass tubes. But none of these presently utilized reels have solved the ligating problem because when the prongs of these reels are bent or broken to make the suture available, the entire coil loosens and thereby tends to come off the reel at once.

It is one of the objects of this invention to provide a combination suture-dispensing and ligating package for suture coils which is relatively flat so as to fit comfortably in the surgeon's palm and which will dispense catgut or other relatively stiff resilient suture strands progressively as needed without entanglement and with a minimum of kinking.

It is another object of the invention to provide relatively flat suture coil packages with dual utility in dispensing sutures and for ligating procedures which in some forms may be suitable for use with glass tube suture outer packages, but which are particularly suitable for use in relatively flat envelope type suture outer packages.

Other objects and advantages of the invention will be apparent from the detailed description and the accompanying drawings in which:

FIG. 1 illustrates, in plan, one type of suture coil package of this invention in which initially flat panels comprising the package faces are joined by interfitting flaps of one panel into slots in the other.

FIG. 2 illustrates, in plan, a preferred form of the invention in which circular superimposed initially flat panels are sealed together around their peripheries to form the coil package and wherein the contained suture assumes a roughly circular coil form.

FIG. 3 illustrates, in plan, partly cut away, a coil package of this invention showing a relatively stiff resilient organic suture strand coiled in figure-eight form.

FIGS. 4, 4A, and 4B illustrate, in plan, the successive positions which the relatively stiff resilient organic suture strand assumes, as the suture is fed in parallel to or at an acute angle with the package faces, to form the initial figure-eight of the suture coil of FIG. 3.

FIG. 5 illustrates, partly in cross-section, an isometric view of a modification of FIG. 2 in which a two compartment coil package holds a suture strand in each compartment.

FIG. 6 illustrates a plan view of the coil package of FIG. 2 with a needle attached to the contained catgut suture.

FIG. 7 illustrates a method of filling a modification of FIG. 3.

FIG. 8 illustrates a further embodiment of the invention wherein the package has somewhat greater thickness.

In the drawings, FIG. 1 illustrates one type of suture package 10 which consists of two initially flat separate panels, 11 and 12 having interfitting tabs 13 and slots 14. After its assembly, the package may be filled with the suture 15 by inserting the suture end 16 through the filling and dispensing hole 17 and wedging it between the panels or into one of the slots 14, whereupon the suture may be fed endwise through the hole 17 and guided to form a circular coil. The suture end 18 may be left protruding from hole 17 or it may be tucked into another hole 19 or into one of the slots 14 if desired. Preferably the hole 17 is centrally located in panel 12 from which position the suture may be loaded and dispensed more evenly.

FIG. 2 shows a preferred form of the invention wherein the suture package 20 is formed of circular initially flat panels 21 and 22 sealed together around their peripheries. In addition to the centrally located dispensing hole 23, one or both of the panels may also be provided with circulation holes 24 which permit ingress and egress of

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air and suture fluid. The end 16 of the suture coil 15 wedges itself at some point into the acute angle formed by the two panels where they join around their peripheries and the coil automatically forms itself as the suture is fed endwise normal to panel 22 and into the hole 23. The suture end 18 may be tucked into one of the circulation holes 24 if desired.

FIG. 3 illustrates a suture package 30 of this invention in which the suture strand is in the form of a figure-eight. It will be noted that the filling and dispensing hole 33 is located at one of the edges where the panels 31 and 32 join. This is the preferred location for such a hole in packages containing figure-eight coils, but as will be explained hereafter the hole may be in the face of only one of the panels as is illustrated in FIG. 7.

FIG. 4 illustrates a method of filling the package of FIG. 3. The relatively stiff suture strand is fed endwise parallel to or at an acute angle to the face of the package 30 through the stationary guide 34. As the suture enters the package, the suture end 16 strikes the point of the package opposite the filling and dispensing hole where the panels 31 and 32 meet. At this point, end 16 is held by a temporary externally applied clamp 35. The progressive formation of the initial loop of the suture strand 36 is illustrated in FIG. 4A. In FIG. 4B the progressive enlargement of loop 37 is shown. As more of the suture strand is fed into the package, a second loop is formed to the left followed by a second loop formed to the right etc., until only the end portion 18 of the suture remains in the guide 34. At this point, the guide is removed, as is the clamp 35 and the ends 16 and 18 assume the position shown in FIG. 3.

In FIG. 5 a modification of FIG. 2 is illustrated in which the panel 22 of FIG. 2 becomes a common separation and middle panel for a two compartment suture package with a panel 21 on one side and a similar panel 21a on the other side. This modification contains a suture 15 in one of the two compartments and another suture 15a in the other.

In FIG. 6 is shown another modification of FIG. 2 in which a needle 25 is shown attached to the end 18 of the suture. The needle is shown with a protecting tip 26 of dipped wax, polyethylene or other plastic material which may be easily removed and which furnishes protection for the needle tip as well as for the outer suture container if the latter is capable of being damaged by the sharp point.

In FIG. 7 is illustrated a method of making a figure-eight catgut suture coil in a package of this invention which package has a hole 44 in panel 41 instead of a hole in the edge of both panels 41 and 42. A curved stationary guide may be used with this modification, especially with fine sutures, in making a figure-eight coil, but stiffer sutures may be more readily coiled into figure-eight configuration with a straight guide 43 inserted at an acute angle.

In FIG. 8 is illustrated a suture package of this invention wherein the top panel 45 and the bottom panel 46 are joined at their peripheries by an intervening wall 47. With this type of package, the suture assumes a true helical winding with the entering suture end 16 forming a circular loop against the wall 47 and on the bottom panel and each succeeding loop lying against the wall 47 and atop the preceding loop. The dispensing end 18 of the suture projects from the filling and dispensing hole 48.

Various commercial products of my invention include resilient suture strands of natural or synthetic material in the stiffness range of monofilament strands varying from .001 to .05 inch in diameter and having initial moduli of elasticity ranging from 200,000 to 1,200,000 pounds per square inch as calculated from the stress-strain curve obtained on the Instron Tensile Tester manufactured by Instron Engineering Company, Quincy 71, Massachusetts. Initial modulus is stress over strain where stress is the load in pounds divided by the cross-sectional area in

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square inches, and strain is the elongation in inches divided by the initial length in inches. The initial modulus of a monofilament strand and its cross-sectional area are variable factors which determine the stiffness of the strand. Where the strand is a multifilament, it should have the same relative stiffness and resiliency as any of the monofilaments in the given ranges, to facilitate filling the suture package and to permit the strand to be withdrawn therefrom without kinking or tangling. In general, the suture's resiliency and stiffness for the packages of this invention should be such that when the strand is formed into a bend and the bending force is removed, the suture strand should have a definite tendency to return to its unbent condition.

The relatively stiff resilient organic strand material for the coil packages of this invention is preferably of a digestible proteinaceous nature such as the surgical suture made of sheep's intestines commonly known as "catgut," but other organic strand material with stiffness and resiliency comparable to monofilament strands within the given diameter and initial modulus ranges are suitable for the coil packages of the invention whether the strands are natural or synthetic in origin. A list of suitable materials which is representative, but by no means exclusive, includes polyamides such as various nylons, polyesters such as polyethylene terephthalates and vinyl polymers and copolymers of vinylidene chloride, vinyl acetate and vinyl chloride, polyolefins such as polyethylene, polypropylene and the like, and acrylics such as acrylonitrile polymers.

The suture coil packages of this invention are formed of two or more preferably initially flat superimposed panels, with immediately adjacent panels being joined in at least three points spaced about the panel peripheries to form a compartment. The coil package comprises one or more of such compartments each having a filling and dispensing aperture or hole, in one of the superimposed panels, from which an end of the contained strand or an extension of the strand (such as an attached needle), projects.

Preferably the flat superimposed panels of the suture coil packages of this invention meet at their peripheries (as is illustrated in FIG. 2) for reasons of economy and convenience in use. Such packages may be made of soft pliable material such as polyethylene in thin sheets. However, in some embodiments of the invention, the superimposed panels may be joined at their peripheries by an intervening wall which provides somewhat greater thickness to the package as is illustrated in FIG. 8. In any event, when the coil is substantially circular as opposed to figure-eight shape, the filling and dispensing hole is preferably centrally located in one of the superimposed panels so that it lies near the axis of the coil. As the filling and dispensing hole is moved toward the periphery of the panel, the possibility of kinking during suture dispensing is increased with circular coils, and this is true of packages of the kind illustrated in FIG. 8 where the depth of the package is not more than one-fourth of the coil circumference.

We have found that catgut or other relatively stiff resilient organic sutures may be introduced into the coil packages of this invention preferably progressively lengthwise into the filling and dispensing hole in one of the superimposed panels whereupon the stiffness and springy nature of the strand will cause it to bend and conform itself to the inside dimensions of the coil package in such a way that consecutive bends tend to be of maximum possible diameter depending upon the angle of introduction, the size and shape of the package and the stiffness of the strand. This characteristic of relatively stiff organic sutures permits their subsequent progressive lengthwise withdrawal from the packages of this invention without entanglement. For example, when the end of a catgut suture is introduced perpendicularly to the panel 21

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into the filling and dispensing hole 23 of FIG. 2, and progressively inward lengthwise suture motion is continued, the end portion bends and moves toward the package edge where the end wedges itself into the space where panels 21 and 22 meet. With further progressive lengthwise introduction of catgut, the bight within the package conforms itself by winding (in this case) into the largest circle possible contacting the package walls, with the initial loop of catgut wedging into the restricted space near the points where the panels meet. If the external end of the catgut is not free to rotate, a single turn of twist is introduced opposite to the direction of coiling into each loop as it coils (and an opposite untwist is introduced as it is uncoiled). With continued introduction of catgut further loops are formed, each succeeding loop expanding into the available space consistent with its stiffness winding in contact with the walls of the package. As a consequence of this tendency of resilient suture strands to expand as much as possible into contact with the package walls each loop stabilizes itself as it is formed so that the package, with its contained suture, tends to remain stable with very little tendency for the individual catgut loops to become entangled.

Where catgut or other relatively stiff resilient organic strand material is wound helically onto a turning mandrel to form a coil, no twist is normally introduced by the coiling. When the coil is removed from the mandrel and placed in a dispensing package where the helical coil is not free to turn, however, a longitudinal pull on the strand will introduce a full twist in the direction of coiling for each loop uncoiled. Obviously where the loop circumference is small, a high degree of accumulated twist is introduced which resists further twisting. This resistance may reach the point where the immediate loop instead of disappearing, by introducing a further twist, merely becomes smaller and smaller until a kink is formed. Where the dispensing hole is so located that the suture material as withdrawn from the coil is in a line, which is substantially parallel to the axis of the coil, then the tendency to kink is at a minimum. The farther away from parallelism the axis of the coil and the withdrawn line of the suture are, the greater the tendency is to kink especially where the loop being uncoiled is confined so that it cannot turn to bring the line to the dispensing hole more nearly into parallelism with its axis. We have found, however, that where the dispensing hole is centrally located near the axis of the coil and the coil is at least two inches in circumference, the tendency to kink on dispensing is virtually eliminated.

Catgut or other relatively stiff resilient organic strands may be dispensed in full 60 inch length from the packages of the invention, through the filling and dispensing hole readily and efficiently as needed without the user's touching the portion still remaining in coiled condition or removing it from the package. The package may thus be held in one hand while ligating blood vessels and the like, the outer end portion of the strand being used in tying off, after which the attached suture strand may be severed near the knot, thus attaining one of the primary advantages of this invention. By tying the knot in ligating before severing the strand end from the coil, any waste of suture material on the coil side is confined to the end portion of the 60 inch strand.

In the flatter packages of this invention panels of geometrically equilateral configuration or of circular shape are preferred because suitable packages can be attained with a shorter package sealing periphery and the least amount of packaging material and the bends in the suture coils contained in such packages conveniently may be relatively large thus further minimizing the tendency to kink. In the packages of this invention containing circular suture coils, we prefer that the suture make a complete turn in slightly more than 3.5 inches.

The shape assumed by the coils of resilient suture

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strands in the packages of this invention is determined largely by the stiffness of the suture, the angle of introduction of the suture into the package and the shape of the package.

Packages containing circular coils of resilient suture strands may be made in accordance with this invention by progressively moving a suture lengthwise into an aperture or hole in one of the two panels forming the faces of the package in such a way as will permit the suture to form itself freely into the package in a circular coil around the hole. Depending upon the stiffness of the resilient suture strand, the hole in the package may approach the edge of a panel rather closely and still a circular coil will be produced especially if a rotating guide is utilized which turns as the suture forms the circular coils. However, figure-eight coils will be produced if the suture is unable to form freely into a circular coil as when a stiff suture is introduced at an acute angle or too near the panel edge. The simplest procedure, therefore, and that which is preferred, is to locate the hole roughly centrally of one of the panels and use a fixed guide with the suture guide channel thereof normal to the face of the panel.

Packages of this invention having oval coils of relatively stiff resilient strands may be formed in the same manner as those containing circular coils, but the package in such cases should be slightly elongated preferably being either rectangular or oval shaped.

Whereas circular coils are preferred in the packages of this invention, it is possible also, especially where it is advantageous to use a narrow rectangular package, to have the relatively stiff resilient suture assume the form of a figure-eight coil. With such coils it is highly desirable that the inner end of the suture assume a position near the mid-portion of the package where the two panels meet, as is illustrated in FIG. 3, rather than near the outer edge of the loops since in the former position it is almost impossible to cause entanglement whereas in the latter position entanglement occasionally does occur. At any rate, packages with figure-eight suture coils may be made which are efficient in dispensing sutures without entanglement and which are almost as readily usable as those with oval or circular coils. Such figure-eight packages are highly useful in ordinary glass suture tubes.

Packages of this invention containing figure-eight coils may be made in the manner preferred for circular coils by making the angle of introduction acute either at the edge or center of the top panel. Because of the difficulty of controlling the entering end of catgut, however, it is preferred in forming figure-eight coils, to temporarily clamp the end of the suture utilizing the methods illustrated in FIG. 7 or that illustrated in FIGS. 4, 4A and 4B.

We claim:

1. A catgut suture package comprising two superimposed flexible sheet panels heat sealed together in flat face-to-face relation along their peripheries to form a compartment therebetween, a coil of catgut suture disposed within said compartment and permanently retained therein so long as it is in coiled form, an aperture in one of said panels communicating with said compartment, the outermost convolution of said coil terminating in one end of the suture, at least a portion of said convolution being wedged between said panels at the boundary of said compartment, the suture spiralling generally inwardly from said convolution and terminating in the other end portion, said other end portion projecting through said aperture, whereby said suture may be dispensed progressively lengthwise through said aperture without entanglement of the convolutions of said coil with said one end and without breaking the seals of said compartment, the seals of said compartment preventing removal of said suture in coiled form.

2. A suture package comprising two superimposed sheet panels sealed together in flat face-to-face relation near

their peripheries to form a compartment therebetween, a resilient organic suture disposed in a connected repeating series of geometric configurations to form a coiled structure within said compartment and permanently retained therein so long as it is in coiled form, an aperture in said package sufficiently restricted as to prevent removal of the suture in coiled form and communicating with said compartment, the outermost configuration of said coil terminating in one end of the suture, at least a portion of said configuration being wedged between said panels at the boundary of said compartment, the suture winding inwardly from said configuration in progressively shorter paths and terminating in the other end portion, said other end portion projecting through said aperture, whereby said suture may be dispensed progressively lengthwise through said aperture without entanglement of the configurations of said coil with said one end and without breaking the seals of said compartment.

3. The package of claim 2 wherein the panels are sealed together along their peripheries.

4. The package of claim 2 wherein the suture is disposed in the package in the form of a coiled structure

comprising a repeating series of connected figure-eight configurations.

5. The package of claim 2 wherein said other end portion is attached to a surgical needle which needle constitutes the portion projecting through said aperture.

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