June 9, 1964 S. L. STACY ETAL 3,136,418

STERILE PACKAGE

Filed June 14, 1961 2 Sheets-Sheet 1

Fig. 1.

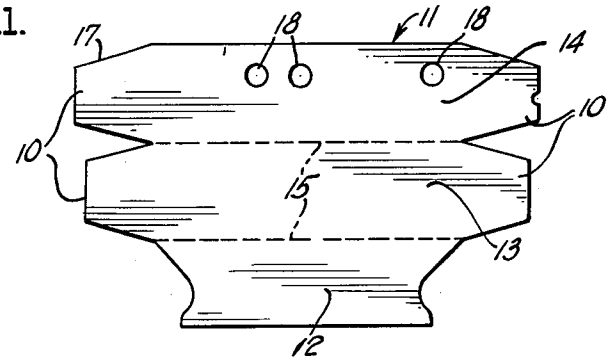

Fig. 2.

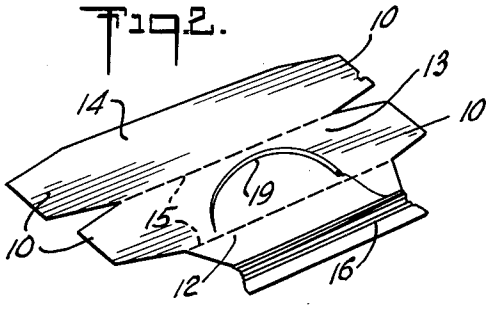

Fig. 3.

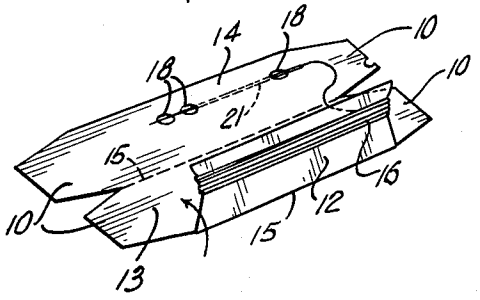

Fig. 4.

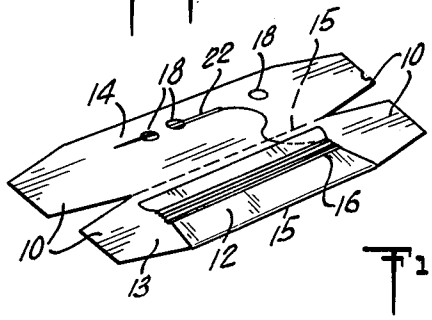

Fig. 5.

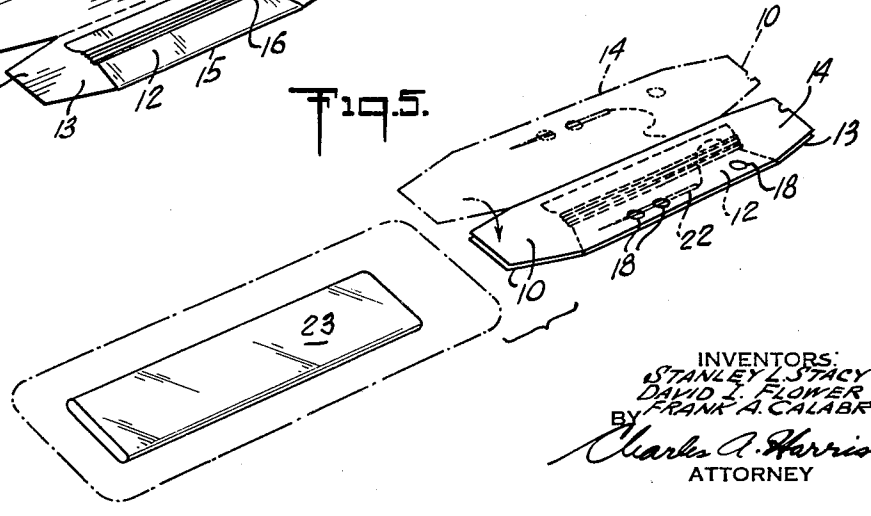

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Fig. 6.

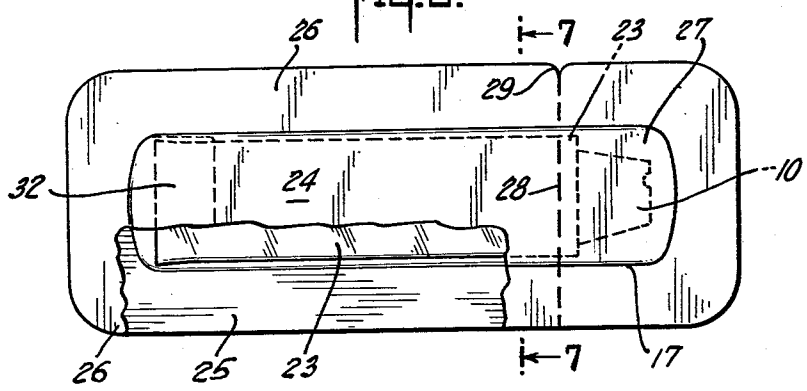

Fig. 7.

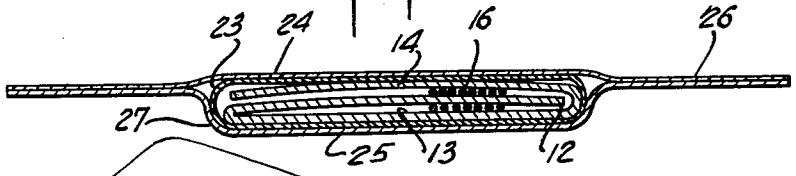

Fig. 8.

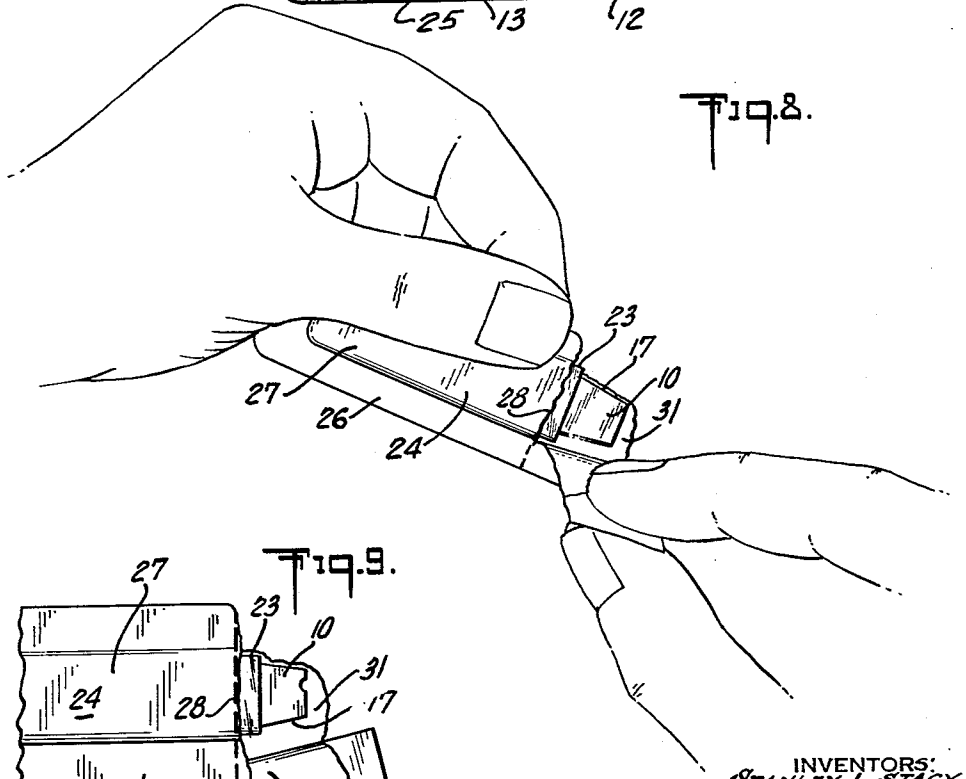

Fig. 9.

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STERILE PACKAGE

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5 Claims. (Cl. 206—63.3)

The present invention relates to sterile suture packages of the type which are adapted to be opened by tearing off one end of the package, more particularly to such packages wherein the suture is wound upon a flat reel enclosed in the package.

When used herein, the term suture, or sutures, includes surgical sutures of catgut, silk, nylon, etc., as well as materials of the same general type which are intended for use as ligatures. In the preferred form of this invention, the suture is attached either to a straight or to a curved surgical needle which is protected by the package.

Heretofore, such packages have been formed by placing the reel containing the suture between two sheets of tearable packaging material and the sheets are sealed to one another along their edges to form the package. With absorbable sutures which must be packaged with a liquid called tubing fluid, the package normally is sealed on three sides to form an envelope with one end open and the tubing fluid is added through the open end before this end is sealed. Packages of this type have been marked with a tear line extending across one end of the package. Commonly the point at which the tear is to be initiated is indicated by a notch formed in one of the sealed edges of the package. Thus, the package is opened by tearing it from the notch in the direction of the tear line.

Heretofore, when the reel holding the suture has been extended beyond the tear line, it either interferes with tearing off the end of the package or is distorted, damaged, or, itself, torn when the end of the package is removed.

If the reel was sufficiently stiff and tear-resistant to preserve its integrity, it interfered with removal of the end of the package. On the other hand, if it was formed from a flexible material which would not interfere with removal of the end of the package, it was likely to be distorted or torn when the package was opened.

One approach to solving this problem is to provide a longer package wherein the reel does not extend beyond the tear line. However, this approach has the obvious disadvantage that the nurse or surgeon is obliged to "fish" inside the sterile package to find the suture reel and remove it for use after the package is opened. This is highly undesirable.

Often, in packages of this general type, the reel carrying the suture is included inside a tubular sleeve of flexible material. Such sleeves assure that the reel is properly positioned in the package to minimize the possibility that the reel will protrude into the sealing area around the edge of the package and be sealed into the package by mistake. Such sleeves cooperate to some extent with the material of the reel to prevent distortion or tearing of the reel, but again if the combination of the reel and sleeve is too stiff, it interferes with removal of the end of the package. On the other hand, if it is sufficiently flexible to avoid this difficulty, it is not strong enough to protect the reel, itself, when the end of the package is removed.

The present invention contemplates a tearable suture package of the type generally described above and which comprises a flat suture reel formed of a relatively stiff and tear-resistant sheet material. The reel, in turn, comprises an elongated protective portion and a suture holding portion and is positioned in the package in such a way that one end of the protective portion of the reel extends a substantial distance beyond the tear line marked on the outside of the package. The side edges of the end portion extending beyond the tear line are beveled inwardly toward the end of the reel beyond the tear line, to facilitate tearing off the end of the package.

When a tear is initiated at one end of the tear line in a package according to this invention and the end to be removed is pulled frontwardly away from the remainder of the package, the front side of the package tears off easily, more or less along the tear line, and the rear side of the package tears off easily, more or less along the beveled top edge of the end of the reel. As soon as the tear in the back side of the package reaches the end of the reel, it proceeds downwardly from the reel to allow the end of the package to be removed. The end of the package of this invention is easily removable and the tear proceeds in the manner described in every case so that the package may be opened easily and in a controlled manner.

The package of this invention is adapted to hold and protect sutures secured to straight or curved needles without changes in the dimensions in any of the parts of the package. Preferably, the sleeve according to this invention comprises a pair of double ended elongated protective portions and a shorter "reel-like" suture holding portion, all formed in one piece of a relatively stiff tear-resistant material, such as cardboard. In this case, two folds are formed in the reel so that the reel may be folded to superimpose the protective portions and the suture holding portions and form a flat folded reel enclosing the suture and the needle.

Other and further advantages of this invention will be apparent from the following description and claims taken together with the drawings wherein:

FIG. 1 is a plan view of a suture reel according to this invention before it is folded,

FIG. 2 is a slightly reduced view in perspective of such a reel still in its open, or unfolded, position with a suture and a curved needle attached thereto in position on the reel,

FIG. 3 is a view similar to FIG. 2, showing a suture and a long straight needle attached thereto in position on the reel and the suture holding portion of the reel as it is being folded over the adjacent elongated protective portion thereof,

FIG. 4 is a view similar to FIG. 3 with a suture and a short needle attached thereto in position on the reel folded down upon the adjacent elongated protective portion thereof,

FIG. 5 is a view in the same order of magnitude as FIGS. 2–4 showing the reel of FIG. 4 after the other elongated protective portion thereof is folded down over the remainder of the reel so that the reel is ready for insertion into a tubular sleeve for positioning in the package,

FIG. 6 is a partially broken away plan view of a suture package according to this invention with the reel and sleeve in position therein,

FIG. 7 is an enlarged sectional view taken along the line 7—7 of FIG. 6,

FIG. 8 is a pictorial view demonstrating how the package tears as the end of the package is being removed therefrom, and

FIG. 9 is a partially reduced plan view of a portion of a package of FIG. 6 illustrating the tear at the end of the package just before removal of the torn end.

Referring particularly to FIGS. 1–5 of the drawings, there is shown a suture reel 11 according to this inven-

tion formed from a single sheet of relatively stiff tear-resistant sheet material such as cardboard approximately 10 mils thick and sold by the Strathmore Paper Company, under the name Strathmore Number 140. The sheet may be cut or stamped in the shape shown in FIG. 1. The reel is divided into a suture holding portion 12, a first, or adjacent, elongated protective portion 13, and a second, or remote, elongated protective portion 14 by fold lines 15 located between the respective portions. For ease in folding, the cardboard preferably is scored along the fold lines.

The suture holding portion 12 is "reel shaped" to facilitate winding a length of suture 16 thereon. Each of the elongated protective portions 13 and 14 of the reel is considerably longer than the suture holding portion 12 and is adapted to extend beyond the tear line in the package when the reel is folded together and positioned therein. Each end 10 of each of the protective portions has beveled edges 17 to facilitate tearing the package as described above. Preferably, the remote elongated protective portion 14 is somewhat longer than the adjacent protective portion 13 at each end of the reel to facilitate unfolding of the reel. When it is desired to unfold the reel, either end of the remote protective portion 14 may be grasped easily for unfolding since it extends beyond the adjacent protective portion 13.

Means are provided in the remote protective portion 14, preferably in the form of a series of perforations 18 for holding a straight needle in position in the reel.

The reel of this invention is ideally suited for packaging sutures attached to curved or straight needles. FIG. 2 illustrates how a suture 16 attached to a curved needle 19 would be positioned on the reel and FIGS. 3 and 4 illustrate how sutures 16 attached to straight needles 21 and 22 would be positioned on the reel.

The curved needle 19 is placed over the adjacent protective portion 13 of the reel with only a short length of suture 16 extending from the end of the needle to the remainder of the suture wrapped around the suture holding portion 12 of the reel. When a curved needle is positioned on the reel in this fashion, the possibility of displacement of the needle end-wise of the reel is minimized.

As shown in FIG. 3, when a long straight needle 21 is to be packaged, it is passed through two of the holes, or perforations 18, in the remote protective portion 14 of the reel in such a way that the point of the needle and its opposite end attached to the suture will be located inside the reel when the reel is folded. The same is true of the arrangement of the short straight needle 22 on the reel as illustrated in FIG. 4. The long straight needle 21 is passed through two of the holes 18 which are separated from one another by a substantial distance, whereas the short straight needle 22 is passed through the closest two holes 18 in the remote protective portion 14 of the reel.

As illustrated most clearly in FIGS. 3–5, the suture holding portion 12 of the reel is first folded down upon the adjacent protective portion 13 thereof and then the remote protective portion 14 of the reel is folded down upon the suture holding portion of the reel to form a flat folded reel 11 containing a suture and a needle inside the reel. This folding reel then may be slid into a tubular sleeve, or envelope, 23 for positioning inside a package according to this invention. If desired, the reel 11 containing the suture may be packaged without a sleeve 23 but a sleeve is preferred to protect the reel from being sealed accidentally to the package.

The sleeve 23 suitably may be formed from any flexible material, preferably having thermoplastic properties, e.g. a polyvinyl chloride coating to permit easy bonding, especially by heat sealing, to the inside wall of the aluminum foil package so that when the reel 11 is removed the sleeve 23 will remain in the package. Thus, the suture 16 will be ready for use immediately on removing the reel 11 from the package without the necessity of

removing the sleeve 23. A preferred sleeve material is one of glassine having a polyvinyl chloride coating. Alternative materials equally suitable for use as a shield include paper, aluminum foil, cellophane, vinylidene chloride copolymer, polyethylene terephthalate, polymerized trifluorochloroethylene, or plasticized polyvinyl chloride. The shield may be formed by folding a rectangular sheet of suitable material so that its ends overlap, tucking the overlapping ends, and flattening the resulting tube to the desired shape.

Referring to FIGS. 6–9, there is shown a hermetically sealed sterile package according to this invention comprising two sheets 24 and 25 of a tearable packaging material sealed together along their edges 26 to completely enclose the contents of the package. Whereas two separate sheets of the same size are illustrated, it will be understood that a package of this type may be formed easily from one longer or wider sheet, not shown, folded in the center to superimpose the two halves formed by the fold and then heat sealed along the three superimposed edges thereof to form a hermetically sealed enclosure.

A reel 11 according to this invention folded together to enclose a suture 16 attached to a needle in the manner described hereinbefore is positioned inside a sleeve 23 of the type described above in a cavity 27 located centrally of the package. For the purposes of clarity, the needle is not shown in FIGS. 6–9 and the suture is shown only in FIG. 7. It will be seen that the reel 11 is enclosed well within the sleeve 23 so that it is unlikely that the reel could become sealed between portions of the tearable sheets 24 and 25 during sealing of the package.

A tear line 28 is clearly marked on the outside of at least one face of the package extending across one end of the cavity 27 and a notch 29 is provided at one end of the tear line 28 to indicate the point where tearing should be initiated to remove the end of the package. The end of the package is removed by grasping the body of the package in one hand and the end to be removed in the other. Tearing may be accomplished either by drawing the end to be removed toward the user or away from the user. If the end is drawn toward the user, the front side of the package will tear more or less along the tear line 28 and the back side of the package will tear down the tear line to the reel 11 and then along the beveled top edge 17 of the reel to the end of the reel and more or less straight downwardly therefrom until the end of the package is removed. If the end is torn off in the opposite direction, the back side of the package will tear along the tear line 28 and the front side of the package will tear along the beveled edge 17 of the reel.

As illustrated in FIGS. 1–5, 6, 8 and 9, the ends 10 of the elongated protective portions 13 and 14 of the reel are beveled inwardly toward the end of the reel at an angle in the range of about 15° to the fold lines 15 in the reel to form the beveled side edges 17. The beveled ends 10 of the reel extend a substantial distance beyond the tear line 28 and a substantial length of the beveled end 10 of the reel extends beyond the end of the sleeve 23. Preferably, the sleeve 23 does not extend appreciably beyond the tear line 28 but if it does, it is sufficiently flexible so as not to substantially interfere with the tearing of the package along the beveled end 10 of the reel extending beyond the tear line 28.

That portion of the torn body of the package which tears along the beveled edge 17 of the protruding reel, i.e., the remaining portion of the back side of the package in FIG. 9, acts as a tab 31 which may be turned back away from the reel 11 to facilitate gripping of the end 10 of the reel for removal of the reel from the remainder of the package. Preferably, the sleeve 23 is attached by a heat seal 32 to the opposite end of the package during sealing of the package so that the sleeve remains with the package and the reel 11 is removed from the sleeve

23 at the same time as it is removed from the package. Thus, the suture and needle may be presented for use merely by unfolding the reel after it has been removed from the package.

Various sheet materials may be used for the tearable portion of packages according to this invention provided that they meet certain requirements. For instance, they must be sufficiently impermeable in themselves to provide a hermetically sealed package, they must be sealable along their edges for the same reason, and they must be sufficiently weak and rigid so that they are adapted to be torn easily when superimposed in the form of two sheets in the package described above. An aluminum foil laminated with a heat-sealable plastic material has been found to be ideal for this purpose. The laminate may be formed by coating aluminum foil with a solution of adhesive, for example butadiene acrylonitrile copolymer plasticized with a long-chain polybasic acid, such as adipic acid and a polyhydric alcohol such as glycerol. The solvent for the adhesive may be any suitable organic solvent such as benzene. The adhesive is allowed to dry and a film of plastic which is capable of withstanding the solvent effect of an aqueous alcohol solution and having a thickness within the range of from 0.8 to 1.4 mils is laid on the aluminum foil coated with the dry adhesive. The laminate is then passed through heated pressure rolls, the sheet is cut to proper width and cavities are formed by air pressure. A vinyl chloride-vinyl acetate copolymer plasticized with dioctyl phthalate is particularly suitable for laminating to the aluminum foil. Of course, in forming a package according to this invention, the plastic sides of the two sheets are arranged to face one another so that they may be heat sealed along their edges to provide the desired hermetically sealed package. Other materials suitable for this purpose include aluminum foil, itself, a laminate of paper and plasticized polyvinylchloride, plastic sheets, themselves, and laminates thereof, and other combinations of materials which meet the above described requirements.

Having now described the invention in specific detail and exemplified the manner in which it may be carried into practice, it will be readily apparent to those skilled in the art that innumerable variations, applications, modifications, and extensions of the basic principles involved may be made without departing from its spirit or scope.

The invention claimed is:

1. A sealed sterile suture package adapted to be opened by tearing off one end of the package, which comprises opposite tearable sheet portions sealed to one another along their edges in such a way as to form a cavity centrally located in the package, at least one of said sheet portions being marked with a tear line extending across one end of the cavity, a flat suture reel in said cavity, said reel being formed of relatively stiff and tear-resistant sheet material and comprising an elongated protective portion and a suture holding portion, said reel being folded to superimpose said protective portion and said suture holding portion, an end portion of said protective portion extending a substantial distance beyond said tear line, the side edges of said end portion being beveled inwardly toward the end of the reel beyond said tear line, and a suture mounted on said reel.

2. A sealed sterile suture package according to claim 1, which comprises a flexible sleeve in said cavity around said reel, a substantial length of the beveled end of said reel extending beyond said sleeve.

3. A sealed sterile suture package adapted to be opened by tearing off one end of the package, which comprises opposite tearable sheet portions sealed to one another along their edges in such a way as to form a cavity centrally located in the package, said sheet portions being marked with a tear line extending across one end of the cavity, a flat suture reel in said cavity, said reel being formed from one piece of relatively stiff and tear-resistant sheet material and comprising a suture holding portion, an adjacent elongated protective portion and a remote elongated protective portion, said suture holding portion, said adjacent protective portion and said remote protective portion being separated from one another by fold lines, said suture holding portion being folded down over said adjacent protective portion and said remote protective portion being folded down over said suture holding portion so that said suture holding portion is covered by said protective portions, a suture wound on said suture holding portion, and a needle attached to one end of the suture and positioned between said folded protective portions, the ends of said protective portions at one end of the reel extending a substantial distance beyond said tear line and being beveled inwardly toward the end of the reel along the side edges of the reel beyond said tear line.

4. A sealed sterile suture package according to claim 3, wherein the opposite ends of the elongated protective portions are identical in shape so that either end of the reel may be positioned to extend beyond the tear line in the package.

5. A sealed sterile package adapted to be opened by tearing off one end of the package, which comprises opposite tearable sheet portions sealed to one another along their edges in such a way as to form a cavity centrally located in the package, at least one of said sheet portions being marked with a tear line extending across one end of the cavity, and a flat reel in said cavity, said reel being formed of relatively stiff and tear-resistant sheet material and comprising an elongated protective portion, an end portion of said protective portion extending a substantial distance beyond said tear line, the side edges of said end portions being beveled inwardly toward the end of the reel beyond said tear line.

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