July 25, 1961 H. F. ZOLLER ET AL 2,993,589

SURGICAL PACKAGE

Filed Aug. 15, 1958

Fig. 1.

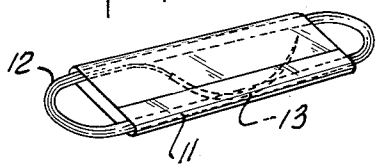


Fig. 2.

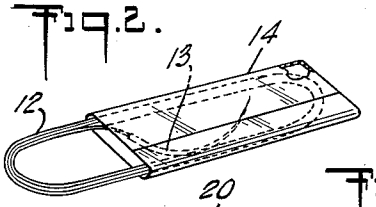


Fig. 3.

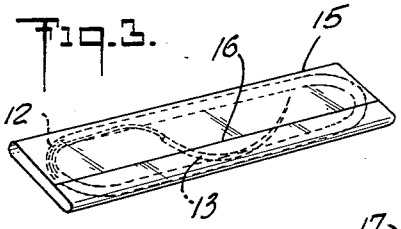


Fig. 4.

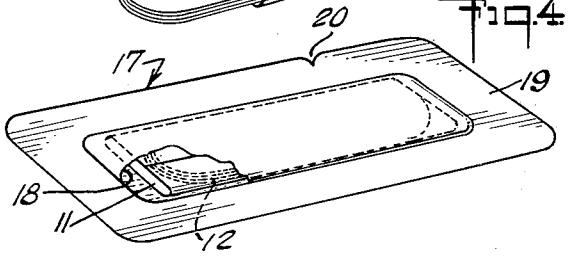


Fig. 5.

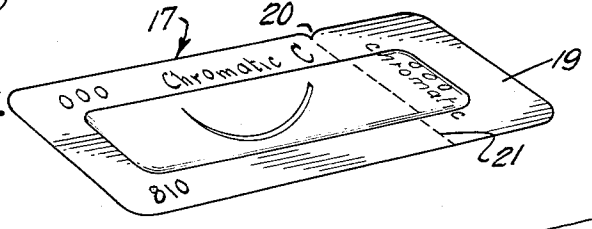
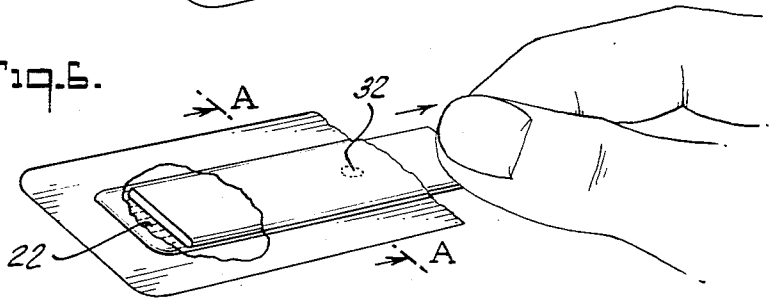


Fig. 6.



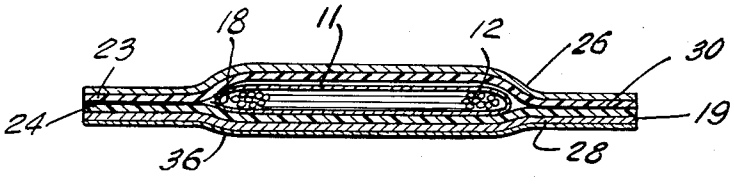


Fig. 7.

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SURGICAL PACKAGE

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Filed Aug. 15, 1958, Ser. No. 755,199
8 Claims. (Cl. 206—63.3)

This is a continuation-in-part of our copending application Serial No. 651,778, filed April 9, 1957.

This invention relates to an improved packaging arrangement for surgical materials. More particularly, the invention concerns an aluminum foil package having disposed therein a shield of flexible material.

Recent developments in the field of packaging have all but removed the glass tube from the industrial suture packaging scene. Aluminum foil and aluminum foil compositions are now almost exclusively used for packaging surgical materials. One method is to utilize aluminum foil in the form of an envelope which can be folded on one side and sealed on three sides. Alternatively, the envelope can be constructed by superposing two sheets of aluminum foil, or aluminum foil composition, and sealing the four sides. Finally, the package may be constructed of tubular material sealed only on the ends, or in any other manner which would result in a sealed envelope. The seal may be effected either by bonding with a suitable adhesive or by heat sealing.

In actual practice, particularly on a rapid production basis, the closure of an aluminum foil package by heat sealing presents certain difficulties, especially in cases where it is desired to enclose a coil of suture material in the package. For example, if the package is formed by heat sealing the four sides of two sheets of aluminum foil superposed on each other, the ends of the suture have a tendency to escape from the confines of the package so that the final sealing operation catches the ends of the suture material in the seal. This results in a defective package, because on opening the suture cannot be removed readily, it being securely fixed on the sealed skirt. Secondly, the tendency of the ends of the suture to escape necessitates the use of reels for winding the suture material and fixing the ends thereon. This adds to the cost of operation and results in an overall slowdown in production, since the operator must be more diligent in seeing to it that the suture ends are securely fixed on a reel or within the coil itself.

It has now been found that the inclusion of a flexible shield within the aluminum foil package confines the coil of surgical material within its prescribed limits, eliminates the undesirable affixation of the suture ends to the skirt of the package during the heat-sealing or bonding operation, permits automatic loading of packages, and facilitates the unimpeded removal of the suture from the package at the time of use. Moreover, although the shield may be used for surgical materials wound on a reel, it is more especially useful in cases where a loose coil of surgical material, without a reel, is intended to be packaged, thus eliminating entirely the need for a reel.

As used herein the term "surgical material" is meant to include sutures such as catgut, silk, nylon, etc. with or without attached surgical needles. It is to be understood that sutures are used under circumstances different from ligatures, but the word "suture" is used herein as a matter of convenience to indicate either sutures or ligatures.

The objects and advantages of this invention will be apparent from the following description and the accompanying drawings in which similar characters of reference indicate similar parts throughout the several views.

Referring to the drawings,

FIGURE 1 represents a view in perspective of a shield containing surgical material, the shield being shorter in length than the coil of surgical material and centrally disposed between the end portions thereof.

FIGURE 2 represents a view in perspective of a shield in the form of an envelope with three sides closed, the coil of surgical material protruding from the open end of the shield.

FIGURE 3 represents a view in perspective of the shield in the form of an envelope, the length of the shield being approximately equal to or greater than the length of coiled surgical material.

FIGURE 4 represents a view in perspective of a surgical package constructed of an aluminum foil-plastic laminate and containing a coil of surgical material centrally disposed within a shield.

FIGURE 5 represents a plan view of a surgical package.

FIGURE 6 represents a plan view of the surgical package of FIGURE 5 with parts broken away and showing the package torn open and the contents partially removed.

FIGURE 7 represents a view in cross section of the surgical package of FIGURE 6 along line A—A.

Referring first to FIGURE 1, there is shown a shield **11**, as a sleeve, having disposed therein a coil of suture **12**, having on one of its ends a needle **13**. Alternatively, as shown in FIGURE 2, the shield may be in the form of an envelope **14**, sealed on three sides with the suture **12** protruding from one end or, as shown in FIGURE 3, in the preferable form of a complete wrapper **15** having open ends. The suture can be removed therefrom either by slipping the wrapper off or by opening the fold **16**.

FIGURES 4 and 5 show a preferred form of the surgical package, indicated generally at **17**, which contains a coil of suture **12**, enclosed in a sleeve shield **11**, in a cavity **18**, the package being fabricated of two sheets of aluminum foil or aluminum foil-plastic laminate material and heat sealed or bonded with adhesive at the skirt **19**, a notch **20**, being formed to facilitate easy opening across tear line **21**.

FIGURE 6 shows the contents being partially removed from a surgical package containing a quantity of tubing fluid such as ninety percen isopropyl alcohol solution, a sterilizing agent such as ethylene oxide, or a mixture of both, indicated generally at **22**.

FIGURE 7 shows a cross section of the surgical package shown in FIGURE 6 across sectional line A—A containing a coil of suture material **12**, a shield in the form of a sleeve **11**, hermetically sealed within a cavity **18**, in a package fabricated of two sheets of aluminum foil **23** and **24**, laminated to two sheets of plastic **26** and **28**, the two sheets of plastic being sealed together. The bond **30**, along the skirt **19**, is formed by means of a glutinous bonding agent or a heat seal. If desired, a paper backing **36** may be bonded to aluminum foil after the plastic has been laminated thereto and before the package is assembled. The preferred paper is water resistant.

Although aluminum foil per se may be employed as the packaging material for constructing the novel package arrangement of this invention, the preferred material is an aluminum foil-plastic laminate composition. The package is formed by superposing the plastic of the sheets and heat sealing to provide a hermetic seal capable of withstanding the solvent effect of an aqueous alcohol solution. The aluminum foil-plastic laminate is 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 ad-

hesive 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. The material to be enclosed in the packages, i.e. a coil of suture confined within a shield of flexible material, is placed in each cavity. If the suture is catgut a tubing fluid such as ninety percent aqueous isopropyl alcohol solution may be added. A second sheet of aluminum foil-plastic laminate formed in the same way as the first sheet is then superposed on top of the first sheet which contains the suture material, the plastic side of the second sheet being in contact with the plastic side of the first sheet, and the second sheet is heat sealed to the first sheet by passing the assembly through heated rollers or dyes which contain cavities which mesh with the cavities containing the surgical material. The surgical packages are then die-cut from the sheet containing the filled cavities.

If it is desirable to prevent removal of the shield member simultaneously with the removal of the suture after the package is opened, it is essential to fix the shield member to at least one of the two inner walls of the package. This can be readily accomplished either by placing a small quantity of suitable non-toxic adhesive such as fish glue or a vegetable base glue on the inner wall of the package immediately prior to placement of the shield member containing the surgical material therein; or, preferably, by heat sealing the shield within the cavity during the heat-sealing operation. Advantageously, this may be done by exposing a small area of the package, indicated generally at **32** in FIGURE 6 in the attached drawing, to heat. The preferred embodiment comprises a loosely-imbedded shield enclosing a coil of suture which can be readily removed after tearing the package at notch **20** across tear line **21**, and unwrapping the fold **16**.

The shield assembly may suitably 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. A preferred fabrication is one of glassine having a polyvinyl chloride coating. Alternative materials equally suitable for use as a shield include paper, aluminum foil, aluminum foil-plastic laminate, cellophane, "Saran," [1] "Mylar," "Kel-F," [2] or plasticized polyvinyl chloride. The shield is formed either by folding a rectangular sheet of suitable material so that its ends overlap, preferably tucking the overlapping ends and flattening the resulting tube to the desired shape.

It will be observed that the packing improvement described herein is especially suitable in combination with an aluminum foil-plastic laminate tearable envelope, since it does not require the use of a tab around the coil of suture to facilitate its removal either from the package, from within the shield, or both.

[1] Vinylidene chloride copolymer.
[2] Trifluorochloroethylene copolymer.

What is claimed is:

1. A hermetically sealed tearable surgical supply envelope which comprises a top sheet and a bottom sheet super-imposed one upon the other in edge-to-edge relationship, each of said sheets comprising an outer layer of aluminum foil and an inner thermoplastic layer, the sheets being arranged with the inner thermoplastic layers facing and in contact with one another along a sealing strip extending around the package adjacent the edges of the sheets, said sheets being heat sealed together along said strip to provide a hermetic seal adjacent the edge of the package and completely enclosing its contents, at least one of said sheets being recessed just inwardly of said strip to form a cavity bordered by said strip, a flattened sleeve formed from a thin sheet of sleeve material confining a coil of suture in said cavity, the sleeve being slightly narrower than the cavity so as to confine the suture within the cavity and prevent it from entering between the sheets in the area of the strip, and means adjacent one end of the envelope for facilitating tearing of the envelope along a tear line extending across the envelope, one end of said sleeve extending beyond said tear line when the sleeve is in position in the cavity.

2. A hermetically sealed tearable surgical supply envelope according to claim 1 wherein the sleeve is made up of a thin sheet of glassine.

3. A hermetically sealed tearable surgical supply envelope according to claim 1 wherein the sleeve is made up of a thin sheet of aluminum foil.

4. A hermetically sealed tearable surgical supply envelope according to claim 1 wherein the sleeve is made up of a thin sheet of cellophane.

5. A hermetically sealed tearable surgical supply envelope according to claim 1 wherein the sleeve is made of a flexible thermoplastic material.

6. A hermetically sealed tearable surgical supply envelope according to claim 5 wherein the sleeve is open at both ends.

7. A hermetically sealed tearable surgical supply envelope according to claim 5 wherein the sleeve is affixed to one of the inner walls of the envelope by a heat seal.

8. A hermetically sealed tearable surgical supply envelope according to claim 5 wherein the thermoplastic material of the sleeve comprises a vinylidene copolymer.

References Cited in the file of this patent

UNITED STATES PATENTS

1,878,306	Whittier	Sept. 20, 1932
1,962,900	Hirsch	June 12, 1934
2,121,988	Salfisberg	June 28, 1938
2,179,864	Scott	Nov. 14, 1939
2,402,981	Beal et al.	July 2, 1946
2,760,630	Lakso	Aug. 23, 1956
2,824,642	Stoltz	Feb. 25, 1958
2,870,906	Harkness et al.	Jan. 27, 1959

FOREIGN PATENTS

1,496	Great Britain	1909
747,162	Great Britain	Mar. 28, 1956

UNITED STATES PATENT OFFICE

CERTIFICATE OF CORRECTION

Patent No. 2,993,589 July 25, 1961

Howard F. Zoller et al.

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.

Column 2, line 53, for "23 and 24" read -- 26 and 28 --; lines 53 and 54, for "26 and 28" read -- 23 and 24 --; column 3, line 22, for "dyes" read -- dies --.

Signed and sealed this 2nd day of February 1965.

(SEAL)
Attest:

ERNEST W. SWIDER
Attesting Officer

EDWARD J. BRENNER
Commissioner of Patents