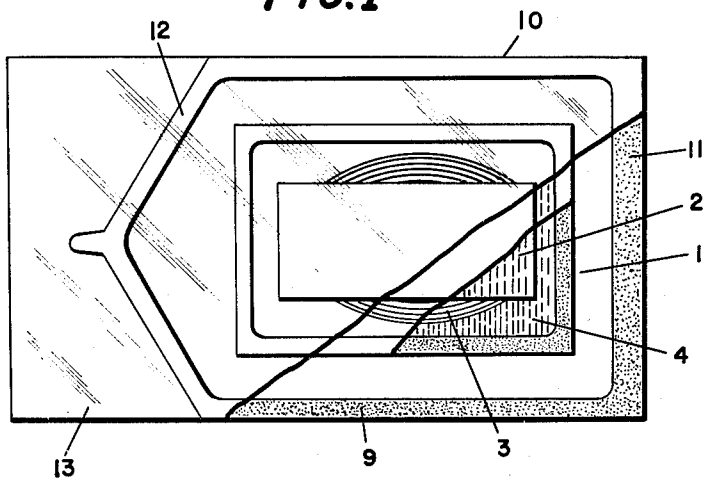
June 21, 1966 L. D. KURTZ 3,256,981

STRIPPABLE PACKAGE FOR SUTURES

Filed Nov. 1, 1962 2 Sheets-Sheet 1

FIG. 1



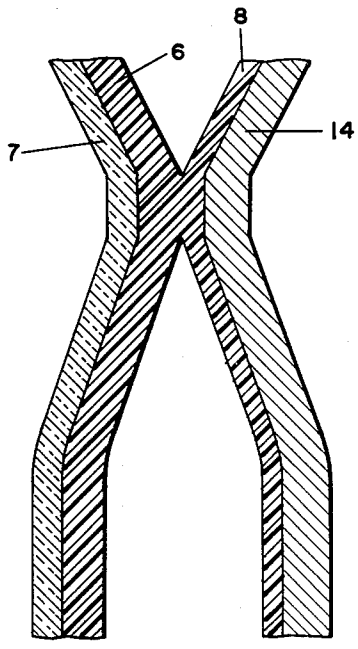


FIG. 2

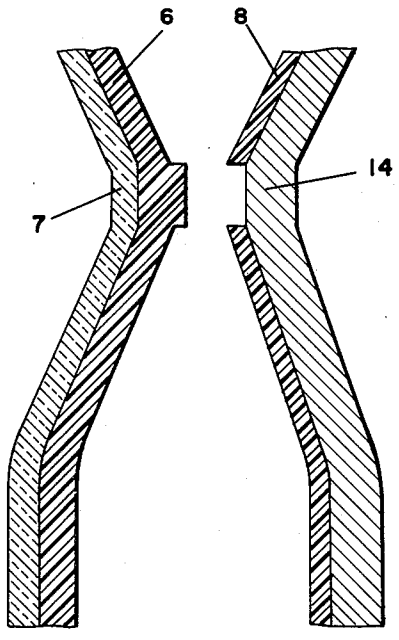


FIG. 3

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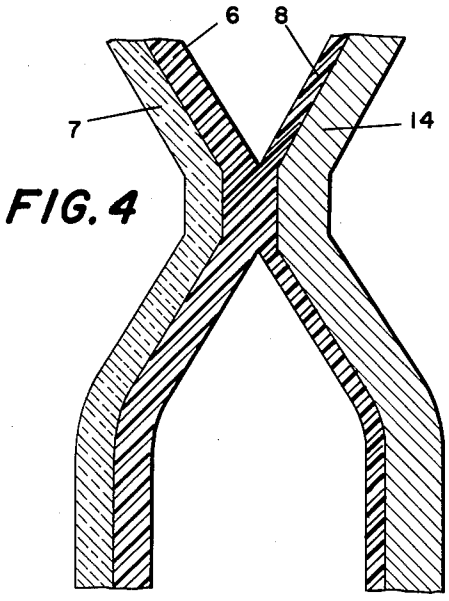


FIG. 4

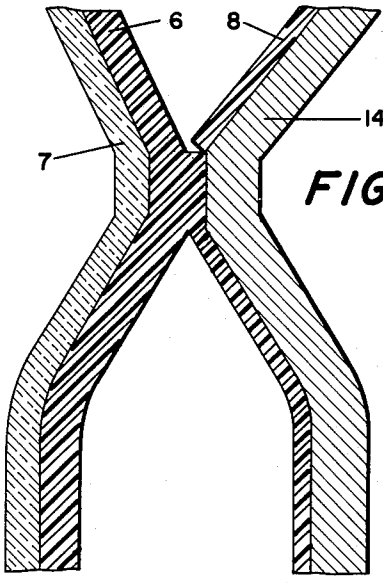


FIG. 5

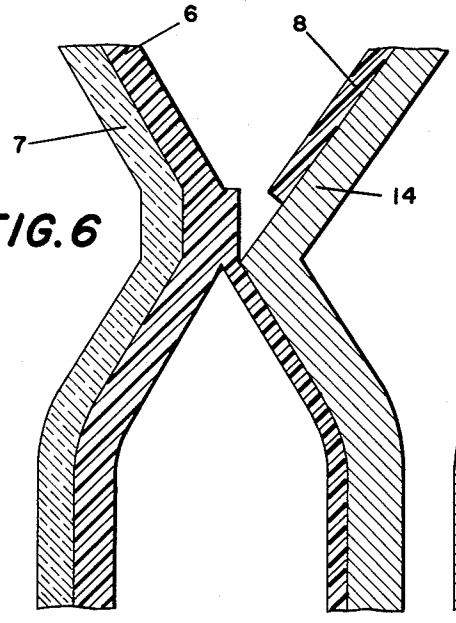


FIG. 6

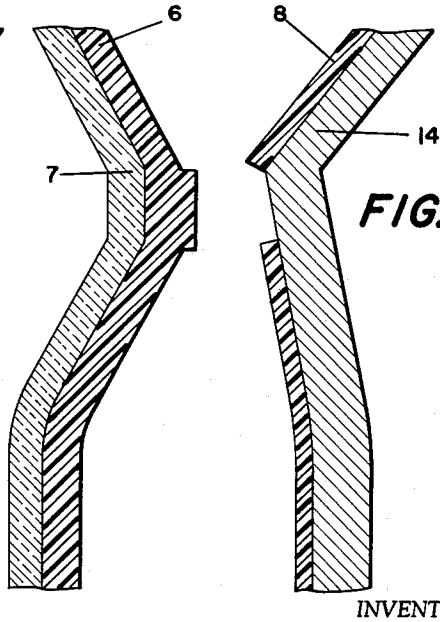


FIG. 7

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3,256,981

STRIPPABLE PACKAGE FOR SUTURES

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Filed Nov. 1, 1962, Ser. No. 234,791
8 Claims. (Cl. 206—56)

This invention relates to packages for surgical sutures.

There are at present two generally accepted methods for packaging surgical sutures. One of these methods is known as the "wet" method wherein the suture packages are disposed in a jar of sterilizing solution and the individual suture packages are removed from the jar and passed into the sterile area. At the present time in the art, it is common practice to package the surgical sutures in a plastic or foil pack. At the operating room table, these sterile packs are opened by tearing or by scissors. The use of the scissors has the obvious disadvantage of requiring an instrument in order to open the sterile pack to obtain the sterile contents. Tearing of the pack does not render the contents readily accessible. It is necessary to extract the suture by instrument or by hand from the enveloping ruptured package. It would, therefore, be desirable to perfect a method of opening a sterile pack using no instrument and eliminating the necessity of fishing or groping for the contents of the ruptured pack. It would be desirable to provide a method wherein the complete exposure of contents can be accomplished by peeling the package open.

The other commonly accepted method for packaging sutures is known as the "dry" method. According to this method the sutures are packaged in a sterile inner package and this sterile inner package is in turn packaged in an outer package. Strippable packages are being used for the dry technique. The circulating nurse peels the outer pack so that she can pass the sterile inner pack directly to the scrub nurse in the sterile area. The package passed into the sterile area, at the present time, cannot be peeled open by the scrub nurse, it must be cut or torn. Similarly, when the sterility of packages is maintained in a formaldehyde solution bathing the outer walls, the passage of the sterile package into the sterile area still forces the scrub nurse to open the pack by cutting or ripping. There is an obvious need for the sterile pack passed to the sterile nurse to be peeled rather than ripped or cut. The packages presently available do not accomplish this aim.

The problem of the outer package is similar in many respects to the suture package itself. It must be impermeable to all contaminating organisms. It must be peeled back in such a way that transfer from circulating nurse to the scrub nurse can be achieved with good sterile technique. This means that the package must open or "peel" along predetermined lines. If the package were to peel badly with the lines of cleavage leaving the predetermined lines, the contents could be entrapped or difficult to remove making the transfer impractical. This has been experienced when perfect seals were made of plastic. In these cases, attempts to open the package have invariably resulted in unpredictable cleavage lines.

Finally, the dry technique has the additional problem of unused suture packs. All of the suture packs on the operating table are not used at the time of operation. The scrub nurse requires additional suture material as a safety precaution. These unused packs, under the wet technique, would be washed and put into the formaldehyde solution for 18 hours, after which they would be passed into a sterile area again. This is not the practice with the dry technique. These unused packs must be returned to the manufacturer to be repackaged. If the inner packs are made as strippable packages, it will not

be necessary to return the unused packs to the manufacturer for repackaging. The unused inner packs may be removed from the sterile area and when it is necessary to use the sutures the strippable inner pack is opened and the sterile suture passed into the sterile area.

In the attempt to achieve a practical package which will open along predetermined lines the seal has been weakened as disclosed in Patent No. 2,917,878 wherein the seal of the strippable outer package is formed by an incomplete fusion of the inner layers of the laminated sheet forming the package. Thus, a line of cleavage is provided so that when the side edges of the pack are pulled apart, the package will open along the line of cleavage through the incomplete seal. Difficulty has been experienced, however, due to the fact that there is no insurance with this type of package that a uniform seal is provided.

A true and complete seal rather than an incomplete fusion is desirable. According to the present invention a strippable package is provided having a true and complete seal. This strippable package is comprised of two sheets of laminated materials:

(1) One sheet consists of an outer layer comprising a laminate of a very thin layer of Mylar (polyethylene terephthalate polyester film) or cellophane covering an underlying aluminum foil. The purpose of this outer covering of Mylar or cellophane is to prevent cracking or crazing of the underlying aluminum foil. It may also decrease the possibility of transmission of injurious material into the package were any faults to appear in the aluminum foil. The inner layer of this sheet is polyethylene.

(2) the other sheet is composed of Aclar (fluorohalocarbon polymeric film) bonded to polyethylene. Neither the Aclar nor the aluminum foil participates in the seal. The seal is between the polyethylene layers of each sheet and these are completely fused one to the other.

By control of (1) the thickness or strength of the polyethylene layers in each of the opposing films and (2) the strength of the bonding agents in each of the opposing films, the line of cleavage of the package can be so controlled that they will always open along a predetermined path, completely exposing the contents in a satisfactory manner.

An object of the present invention is to provide a strippable package for surgical sutures wherein a completely uniform absolute seal is obtained and wherein the package is openable along predictable tear lines.

Another object of the present invention is to provide a strippable package which can be immersed in a formaldehyde solution or other sterilizing solution and yet be completely impermeable to alcohol and formaldehyde or other sterilizing agents and wherein the package is openable along predictable tear lines.

Other objects and many of the attendant advantages of the present invention will be readily appreciated upon consideration of the following detailed specification in regard to the accompanying drawings wherein:

FIG. 1 is a plan view partly in section of a surgical suture package manufactured in accordance with the present invention,

FIG. 2 is a partial sectional view showing the seal between the package sides,

FIG. 3 is a partial sectional view showing the package opened, and

FIGS. 4 to 7 are diagrammatic views showing the sequence of steps involved in opening the package.

Referring now more specifically to the drawing wherein like numerals indicate like parts throughout the sev-

eral views there is shown at 1 in FIG. 1 an inner package containing a sheath 2 having a coil of suturing material 3 disposed therein. There is shown at 4 the conditioning or sterilizing solution which may be present if needed within this inner pack.

The inner pack is disposed within a strippable outer pack which is formed from laminated sheets and a complete air tight package is obtained by heat sealing along the side edges 9 and 10 and across the ends as at 11 and 12. The portions 13 extend beyond the seal 12 and provide a means for grasping the outer pack when the pack is to be opened.

The inner and outer pack may be formed of a laminated material. As shown in FIG. 2 the outer pack comprises a laminated sheet of relatively thick polyethylene 6 and a layer 7 of Aclar or like material. The other film is composed of a relatively thin layer 8 of polyethylene and a layer 14 of aluminum foil. Additional protecting films may be used on the outside to protect the underlying film or give additional protective properties.

As shown in FIG. 2 the seal is formed by completely fusing adjacent inner layers of the laminated material. It can be seen that the inner layer 6 is fused to the adjacent inner layer 8 so that there is no line of cleavage between the layers at the point of the seal.

While the specific description herein relates to a strippable outer pack, it is apparent that the invention is applicable to a strippable inner pack or to the suture package employed in the wet technique.

With reference to FIG. 4 it can be seen that the sealing of two adjacent films forms a polyethylene pouch. It is desired to provide a predetermined line upon which the package will open. The line of rupture must first extend through the thin layer of polyethylene to the plane of lamination between the inner and outer layers as seen in FIG. 5. The line of rupture must then extend parallel to the polyethylene seal along the line of lamination. This rupture must extend to the base of the seal as shown in FIG. 6. The line of rupture must then extend back through the thin polyethylene layer into the cavity of the punch, FIG. 7. This last portion of the process may be termed re-entry.

The thin polyethylene film 8 must be weaker than the Aclar, the thick polyethylene 6, or the foil 14. On pulling the films, the polyethylene thin film 8 should rupture as in FIG. 5. It should rupture into the plane of lamination between the polyethylene 8 and the foil 14. The foil strength should stop further extension along this path toward the outside of the film.

On further pulling of the external leaves, the line of rupture would extend downward parallel to the seal, FIG. 6. The plane of lamination is again the weakest region. The seal is extremely strong, the foil is strong, the line of rupture, therefore, occurs along the line of lamination. This would extend down to the base of the seal and now the problem of re-entry arises. On continued pulling apart of the leaves of the package the rupture line could go in two directions, it could extend along the line of lamination or it could rupture through the polyethylene film 8 back into the polyethylene bag as in FIG. 7. If the plane of lamination were stronger than the strength of the polyethylene film, the polyethylene film would rupture. This is precisely what has been achieved. In other words, the line of rupture follows the line of least resistance. On stressing the package in the first stage, the polyethylene ruptures since it is the weakest point. This places us in the plane of lamination. The plane of lamination then ruptures because it is the weakest in the region being torn.

After the rupture reaches the base of the plane of lamination at the seal, it once again encounters the polyethylene which is weaker than the plane of lamination and inevitably the rupture goes through the polyethylene wall into the bag.

In one specific embodiment of the invention the following materials were used—

Foil-polyethylene:
- Foil thickness equals 1.5 mils
- Foil disruption strength equals 30 to 35 lb. per inch
- Laminating bond strength equals 450 to 500 grams per inch
- Polyethylene rupture strength less than 450 to 500 grams per inch

Aclar-polyethylene laminate:
- Polyethylene rupture strength, 7.5 lb. per inch
- Laminating bond strength, 600 to 750 grams per inch
- Aclar disruption strength, 15 lb. per inch.

Polyethylene-polyethylene seal:
- Strength equals 1000 to 2000 grams per inch

If alcohol dissolves the laminating bond of the polyethylene-foil laminate, the strength of the laminating bond decreases to 150 to 250 grams per inch destroying re-entry.

Obviously, many modifications and variations of the present invention are possible in light of the above teachings. What is claimed as new and desired by Letters of Patent is:

1. A package comprising a laminar sheet having inner and outer layers bonded together, the inner layer being weaker than the bonding strength between layers and said outer layer being stronger than the bonding strength between layers, an opposing sheet disposed with an inner surface thereof facing the inner layer of said laminar sheet and forming a package therewith by a full strength complete fusion seal between the inner layer and inner surface without a line of cleavage therebetween to provide a seal for the package, said fusion seal being stronger than said bonding strength between the layers of said laminar sheet, said opposing sheet being stronger than said inner layer of said laminar sheet whereby, on separating said sheets, the package is opened along a line defined by a tear through said inner layer on one side of said fusion seal, a parting of the bond between said inner and outer layers adjacent said fusion seal, and a tear through the inner layer on the other side of said fusion seal.

2. A package according to claim 1 wherein said inner layer and said second sheet consist of polyethylene and wherein said second sheet is thicker than said inner layer.

3. A package according to claim 1 wherein said opposing sheet comprises a laminar sheet having inner and outer layers bonded together.

4. A package according to claim 1 wherein said inner surface and said inner layer consist of a plastic.

5. A package according to claim 1 wherein said outer layer is selected from the group consisting of polyester, aluminum foil and fluorocarbon polymers.

6. A package comprising a first laminated sheet having an inner layer of polyethylene bonded to an outer layer of a material selected from the group of polyester, aluminum foil and fluorocarbon polymer, said outer layer being stronger than the bonding strength between said layers and said bonding strength being stronger than said inner layer, a second opposing laminar sheet having an iner layer of polyethylene disposed facing and thicker than said inner layer of polyethylene on said first laminar sheet and forming a package therewith by a full strength complete fusion seal between the polyethylene layers without a line of cleavage therebetween to provide a seal for the package, said fusion seal being stronger than the bonding strength between the layers of said first laminar sheet whereby, on separating said laminar sheets, the package is opened along a line defined by a tear through the thinner polyethylene layer on one side of said fusion seal, a parting of said thinner polyethylene layer from the outer layer bonded thereto adjacent said fusion seal, and

a tear through said thinner polyethylene layer on the other side of said fusion seal.

7. A package according to claim 6 wherein the outer layer of said second sheet is selected from the group consisting of polyester, aluminum foil, and fluorocarbon polymer.

8. A package according to claim 6 wherein said outer layer is aluminum foil.

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