Dec. 7, 1965 D. R. BOWES ETAL 3,221,873

NON-SLIP SURGICAL PACKAGE

Filed June 28, 1963

Fig. 1.

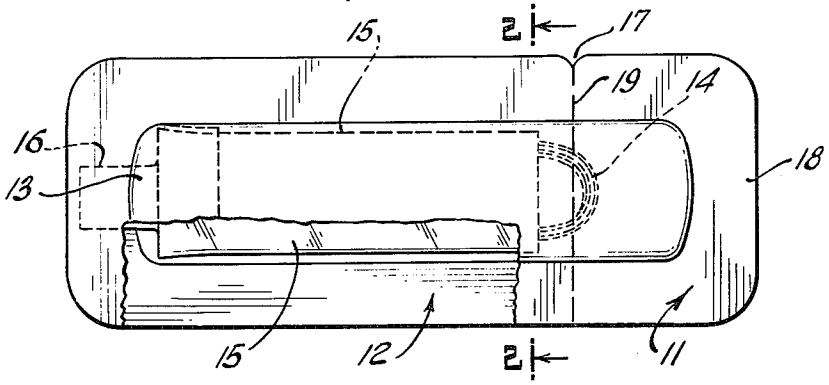


Fig. 2.

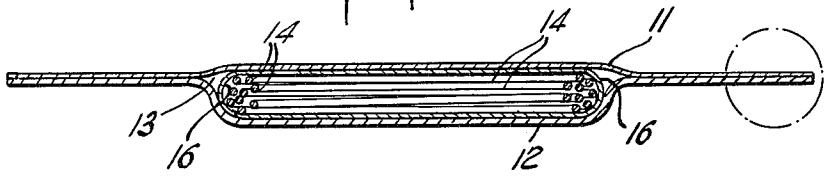


Fig. 3.

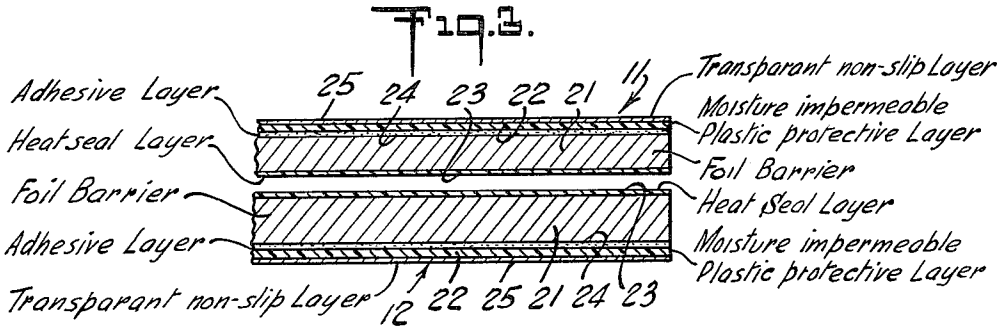
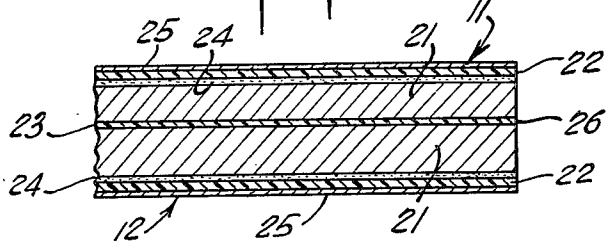


Fig. 4.



INVENTORS:
DONALD R. BOWES
OLIVER T. SMITH
BY
Charles A. Harris
ATTORNEY.

United States Patent Office 3,221,873 Patented Dec. 7, 1965

3,221,873

NON-SLIP SURGICAL PACKAGE

Donald R. Bowes, 214 Vinton Circle, Fanwood, N.J., and Oliver T. Smith, 17010 Melgrave Ave., Cleveland, Ohio

Filed June 28, 1963, Ser. No. 291,339
6 Claims. (Cl. 206—63.3)

The present invention relates to surgical packages of the type which are used to contain sterile absorbable catgut sutures and other sutures and surgical products.

Surgical packages intended for use in the sterile zone in hospital operating rooms must meet the exacting requirement of being sterile both inside and out. Under some circumstances, the exterior of the package is maintained sterile prior to use by immersing the package in a formaldehyde sterilizing solution enclosed in a secondary container. Often this type of package is packed by the manufacturer in a formaldehyde containing secondary unit of this type. When surgical gut is involved, a suture softening solution, which normally is alcohol-based, is included inside the package. Thus, the individual package must be capable of preventing permeation of the formaldehyde sterilizing solution into the package and leakage of the suture softening solution out of the package. If the sterilizing solution reaches the suture inside the package, the suture is hardened and may become nonabsorbable. On the other hand, if the softening solution leaks out, the gut becomes brittle and nonuseable. It is necessary, then that surgical packages of this type be capable of resisting the permeation of such fluids for an indefinite period of time since one cannot determine how long it will be before one of the packages is used.

For a number of years, sealed glass tubes were used for this purpose. While they were capable of resisting the permeation of these fluids, they were fragile and often broke in transit. Perhaps more importantly, they were opened by breaking the glass. This was, not only difficult, but dangerous and a source of possible contamination.

It has been proposed to use envelopes of various materials for this purpose. The only single plastic sheet material which is capable of resisting the permeation of these fluids for the length of time required is polychloro-trifluoroethylene. However, the cost of this material for this purpose is prohibitive and it also becomes brittle during sterilization by irradiation. Recognizing that a film of a single material is not satisfactory for this purpose, laminates of various materials have been employed. None of these have been completely satisfactory.

The most commonly used laminate is one comprising an outside layer of aluminum foil and an inside layer of a heat sealable film of a thermoplastic material such as polyvinyl chloride. Packages formed from this type of laminate are satisfactory up to a point. For instance, aluminum foil of the proper thickness makes a perfect barrier to the permeation of formaldehyde containing sterilizing solutions and alcohol-based suture softening fluids. However, aluminum foil is very susceptible to moisture induced electrolytic corrosion and to heavy metals attack. Quite often foil packages of this type are washed in water to remove blood stains, or the like. This can and does cause holes to be corroded through the foil. Obviously, once the holes appear, permeation of the fluids begins and then becomes increasingly worse. Another disadvantage of the aluminum foil on the exterior of the package is that the foil, itself, has very little capacity for elongation and therefore is susceptible to being broken or punctured during removal of the packages from the secondary container with the various forceps in use for this purpose. It also has been common in foil-plastic packages of this type to use a laminating film on the inside of the package for the additional reason that the film provides a secondary barrier to permeation through the package in case a pin hole is formed in the foil. Such films normally are plasticized to give them the necessary flexibility. Thus another problem occurs because the alcohol in the suture softening solution leaches out the plasticizer in the film and the plasticizer contaminates the suture.

In accordance with the present invention, a surgical package is provided which solves all of these problems. This package comprises opposed panels of an impervious laminate secured to one another around their edges to completely enclose and hermetically seal off a central space in which the panels are unattached to one another, and a surgical product such as a sterile suture enclosed in said space. Normally the laminate is impervious to formaldehyde and other sterilizing components. Each of the panels comprises an inner layer of aluminum foil and an outer layer of a tough, moisture impermeable transparent plastic film. The aluminum foil layer normally provides an effective barrier to all gases and fluids with which the package might come in contact, and the plastic film protects the foil from external moisture induced electrolytic corrosion and heavy metals attack and from mechanical damage during handling. At the same time, the foil-film laminate is capable of being torn easily for opening the package along a tear line adjacent one end thereof. In addition, the plastic film acts as a secondary barrier to penetration or permeation of the package by gases and fluids. Furthermore, the package according to this invention is sterilizable by irradiation, using an electron beam or similar means, without degradation of any of the materials making up the package.

Preferably, the plastic film is a polyester such as polyethylene terephthalate sold as Mylar film by E. I. Du Pont de Nemours & Co. Inc. and the film possesses a tensile strength of at least about 15,000 p.s.i. and a puncture resistance of at least about 25 kilometers per centimeter to give it the desired toughness to protect the foil from mechanical damage and chemical attack.

The plastic film of the package of this invention is transparent and the inner surface of the transparent film of at least one of the panels is printed in reverse to describe the contents of the package in such a way that the printing can be read from the outside of the package through the printed film. This protects the printing from being scuffed off the package or reacting with the sterilizing solution and thereby assures accurate description of the contents of the package at all times.

According to this invention, a package of the above type is provided wherein a transparent non-slip layer having a high wet coefficient of friction is provided on the outside surface of each of the plastic film outer layers of the package to assure that the package can be handled accurately and torn properly to open the package and expose its contents when desired. When the plastic film is a polyester, it is preferred that the non-slip layer comprise a dispersion of silica particles in a transparent polyester base. This non-slip layer including the silica particles is transparent so that the printing on the inside surface of the plastic film can be read easily through the non-slip layer.

Copending application Serial No. 291,482 filed June 28, 1963, in the name of Donald R. Bowes claims the specific aluminum foil-polyester laminated package described herein. This application is directed in particular to the aforesaid non-slip feature.

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

FIG. 1 is a partially broken away plan view of a sterile suture package according to one embodiment of this invention;

FIG. 2 is an enlarged sectional view taken along the line 2—2 of FIG. 1;

FIG. 3 is a greatly enlarged sectional view of the encircled portion of FIG. 2 showing the adjacent top and bottom panels of the package before they are heat sealed to one another;

FIG. 4 is a greatly enlarged sectional view of the panels of FIG. 3 after they are heat sealed to one another.

Referring to the drawings, there is shown a sterile suture package comprising a top panel **11** and a bottom panel **12** of a formaldehyde impervious laminate. Said panels **11** and **12** are superimposed and sealed to one another along their edges to completely enclose and hermetically seal off a central space **13** in which the panels are unattached to one another. A coiled sterile surgical suture **14** inside a paper sleeve **15** is enclosed within the central space **13**. A tab **16** at one end of the sleeve **15** fits between the panels **11** and **12** at one end of the package and is thereby sealed to the panels. If the suture **14** is of absorbable surgical gut, a small amount of a suture softening, or pliabilizing, solution, not shown, is included within the central space **13**. A typical softening fluid for this purpose is a 90% solution of isopropyl alcohol in water. The suture package, itself, may be enclosed within an outer container, not shown, and immersed in a formaldehyde containing sterilizing solution for maintaining the exterior of the package sterile. A tearing notch **17** is located adjacent one end **18** of the package along its top edge and a tear line **19** is marked on one side of the package extending from the notch **17** to the opposite side thereof. The package is intended to be opened by gripping it on opposite sides of the notch **17** and tearing downwardly along the tear line **19** to remove the end **18** of the package.

As shown most clearly in FIGS. 3 and 4, both the top and bottom panels of the package are made up of an inner aluminum foil barrier layer **21** and an outer moisture-impermeable transparent plastic protective layer **22** of a tough material such as a polyester film. The inside of the foil layer is coated with an alcohol resistant heat sealable layer **23** and the outer surface of the foil layer is coated with an adhesive layer **24**. When the plastic protective layer **22** is a polyester film, the adhesive **24** is a polyester adhesive. The outermost layer of the panel laminate is a waterproof and chemical-resistant transparent non-slip layer **25** having a wet coefficient of friction. Again, when the plastic protective layer **22** is a polyester film, the non-slip layer **25** comprises a dispersion of silica particles in a transparent polyester base.

As shown in FIG. 4, the top and bottom panels **11** and **12** are placed together and heat sealed by the application of heat and pressure in such a way that the two heat sealable layers **23** adhere and more or less blend into one another in the sealed areas. The edge **26** of the blended heat sealable layers is so thin and presents such a small area to the outside of the package and the width of the seal, i.e., the distance between the edge **26** and the cavity **13** is comparatively so great, that there is virtually no opportunity for permeation of fluids through the seal itself. Elsewhere, the foil plastic laminate described makes a perfect barrier to the permeation of fluids inwardly or outwardly of the package, and the plastic protective layer **22** protects the foil layer **21** from external moisture induced electrolytic corrosion and heavy metals attack, and from mechanical damage. As mentioned hereinbefore, the plastic film **22**, itself, preferably possesses a low permeability to gases and fluids and acts as a secondary barrier to penetration of the package in case any holes should be formed in one of the foil layers. In this connection, it should be noted that preferably the foil layer in the panel which is distorted the most to form the central space or cavity **13** in the package is somewhat thicker than the foil layer in the other panel in order to provide additional strength in the panel and minimize the likelihood of cracking the foil. In the embodiment shown, the foil layer **21** of the bottom panel **12** is somewhat thicker than the foil layer **21** of the top panel **11** for this reason.

The inside surface of the transparent plastic protective layer **22** of the top panel **11** preferably is printed in reverse with material intended to describe the contents of the package and the printing, shown in part in FIG. 1, can be read through the protective layer **22** and through the transparent non-slip layer **25**. Thus, the printing, itself, and the ink used therefore, is completely shielded against reaction with chemicals and fully protected from scuffing.

In a typical package according to this embodiment of the invention, the bottom panel **12** is formed from a layer **21** of dead-soft, high purity aluminum foil approximately two mils thick and a protective layer **22** of Mylar polyethylene terephthalate film approximately 0.25 mil thick; whereas the top panel **11** is formed from a similar aluminum foil layer **21** approximately 1.5 mils thick and a protective layer **22** of the same Mylar polyester approximately 0.35 mil thick. The alcohol resistant heat sealing layer **23** in each case is applied in a first coat of about 3 pounds per ream of a primer comprising copolymers of vinyl chloride and vinyl acetate and a second coat of about 3 pounds per ream of an unplasticized heat sealing material which consists predominately of a copolymer of vinyl chloride and vinyl acetate. The adhesive **24** between the foil layer **21** and the Mylar polyester protective layer **22** is a polyethylene terephthalate adhesive. In the bottom panel **12** only about 3 pounds per ream of the polyester is applied, but in the top panel **11** the polyester adhesive **24** is pigmented white and applied in the amount of about 6 pounds per ream. The non-slip layer **25** is a similar transparent polyester adhesive with very small silica particles dispersed therein to achieve a high wet coefficient of friction. When the inside surface of the transparent protective layer of the top panel is reverse printed as described hereinbefore, the white pigment in the polyester adhesive provides a background for the printing so that it may be read more easily.

Various important qualities of this polyester protective film **22** have been described hereinbefore. For instance, the film should possess a tensile strength of at least about 15,000 p.s.i. and a puncture resistance of at least about 25 kilograms per centimeter to provide the desired toughness and impermeability. On the other hand, to provide good tearability which is necessary to facilitate removal of the end of the package by tearing as described above, moderate to low tear strength and elongation are required. For instance, a film possessing an elongation of about 70–100% combined with a tear strength of about 15 grams per mil should have ideal tearing qualities. One additional important feature when the package is to be heat sealed from the outside, i.e., the top and bottom, is that the polyester protective film **22** and the non-slip layer **25** be capable of resisting the temperature of the heat sealing shoes or dies employed. Polyethylene terephthalate films of the type described possess a melting point above about 350–380° F., which is satisfactory for this purpose. Furthermore, these films possess very low water vapor transmission rates and, perhaps more importantly, a low rate of moisture absorption. It is the combination of these qualities which protects the exterior surface of the foil from electrolytic corrosion. These films also possess excellent resistance to acids, bases, grease and oil, and for these reasons are ideal for protecting the foil barrier.

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 sterile surgical package which comprises opposed panels of a gas and liquid impervious laminate secured to

one another around their edges to completely enclose and hermetically seal off a central space in which the panels are unattached to one another, a sterile surgical product in said space, said panels each comprising an inner layer of aluminum foil and an outer layer of a tough, moisture impermeable transparent plastic film, and a transparent non-slip layer having a high wet coefficient of friction on the outside surface of each of said panels.

2. A sterile surgical package according to claim 1, wherein said sterile product is a surgical suture.

3. A sterile surgical package according to claim 1, wherein the inner surface of said transparent plastic film is printed to describe the contents of the package in such a way that the printing can be read through the film and through the non-slip layer.

4. A surgical package which comprises opposed panels of a gas and liquid impervious laminate secured to one another around their edges to completely enclose and hermetically seal off a central space in which the panels are unattached to one another, a surgical product in said space, said panels each comprising an inner layer of aluminum foil and an outer layer of a tough, moisture impermeable polyester film, and a waterproof and chemical-

resistant non-slip layer comprising a dispersion of silica particles in a polyester base on the outside surface of each of said panels.

5. A surgical package according to claim 4, wherein said polyester film comprises polyethylene terephthalate and said film is adhered to the foil by a polyester adhesive.

6. A surgical package according to claim 5, wherein the polyester film of at least one of said panels and its corresponding non-slip outside layer are transparent and the inner surface of said polyester film is printed to describe the contents of the package in such a way that the printing can be read from the outside of the package through the film and through the non-slip layer.

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FRANKLIN T. GARRETT, *Primary Examiner.*

GEORGE O. RALSTON, *Examiner.*