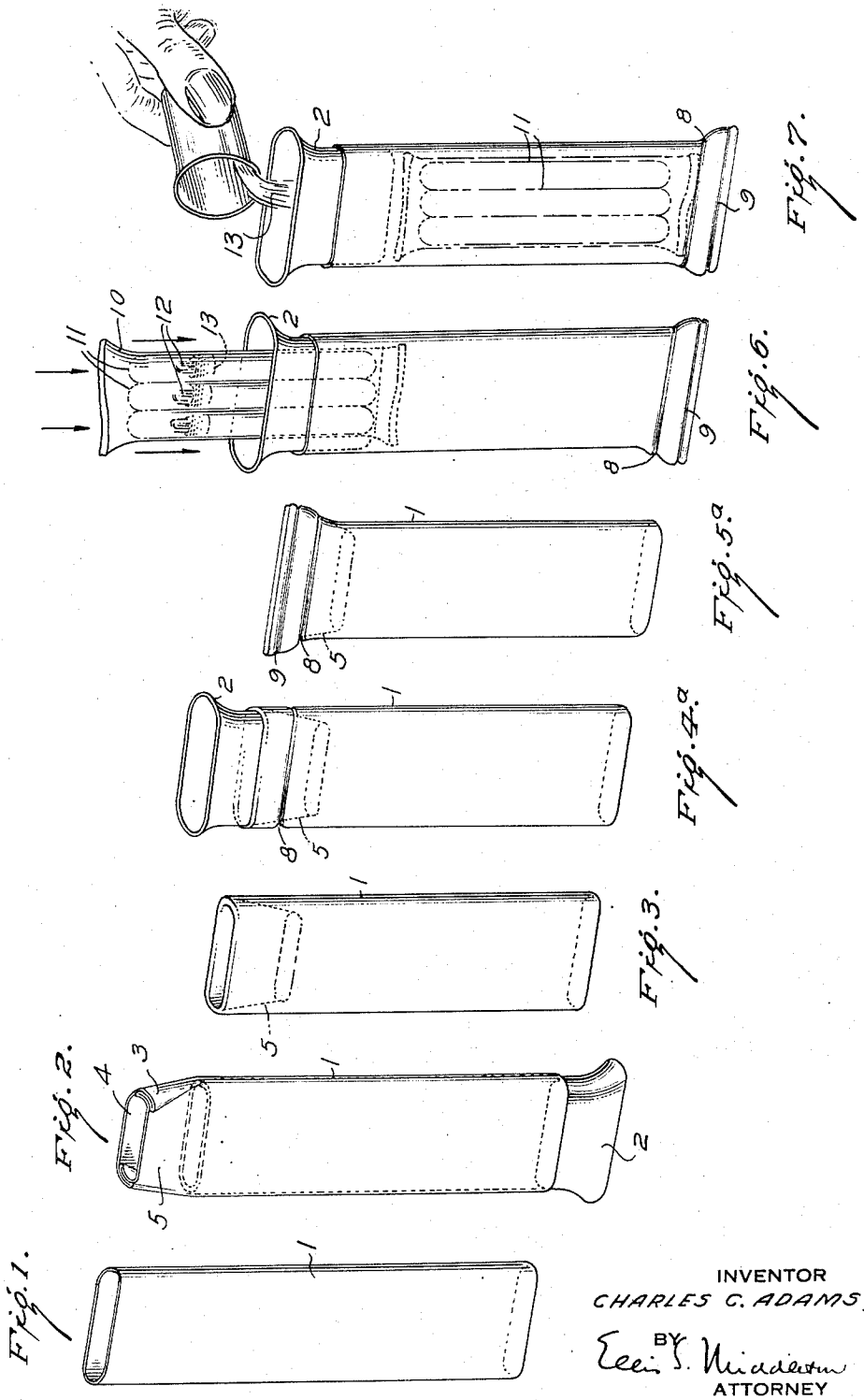
April 17, 1951 C. C. ADAMS 2,549,040

STERILE SUTURE TUBE PACKAGE

Filed Jan. 4, 1950 2 Sheets-Sheet 1



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STERILE SUTURE TUBE PACKAGE

Filed Jan. 4, 1950 2 Sheets-Sheet 2

Fig. 8.

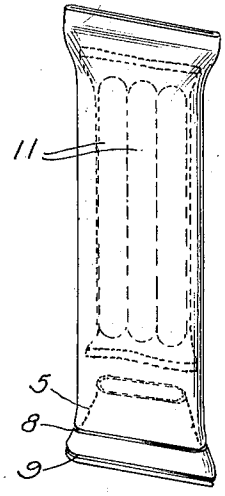


Fig. 9.

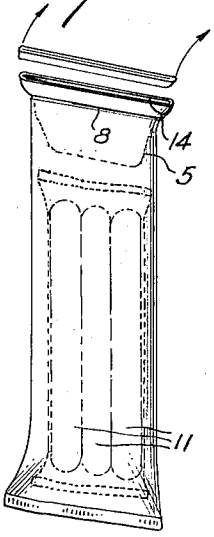


Fig. 10.

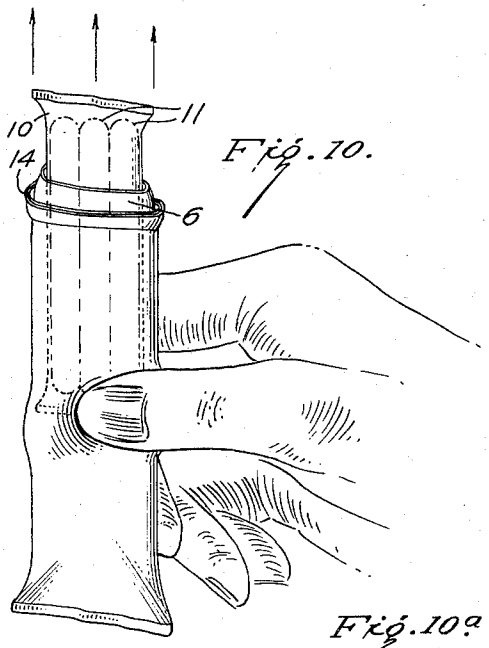


Fig. 10a.

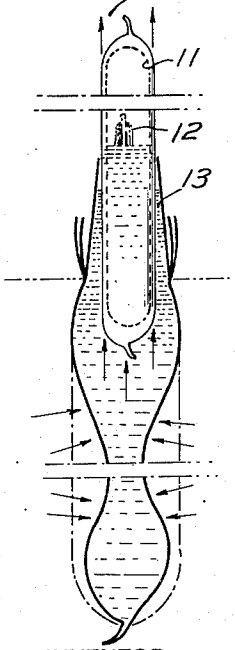


Fig. 7a.

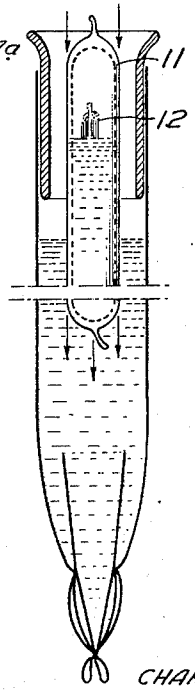
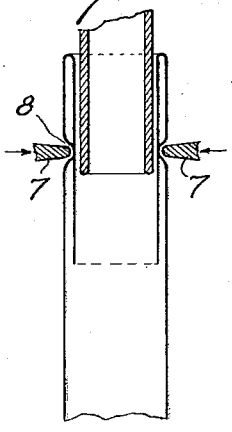


Fig. 4.



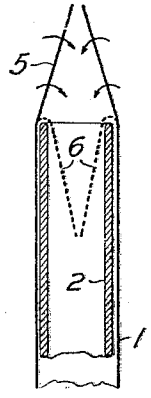


Fig. 3a.

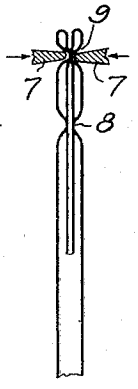


Fig. 5.

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STERILE SUTURE TUBE PACKAGE

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Application January 4, 1950, Serial No. 136,808

4 Claims. (Cl. 206—63.3)

1

The present invention relates to a double envelope package containing a sterile surgical article such as sutures in tubes.

The principal object of the invention is to provide such a package which will reduce the danger of contamination of the contained sutures when they are removed from the package.

Still another object is the provision of a cheap, readily manufactured, composite package of the type described which will deliver to the user one or more sterile suture tubes in a sterile, flexible, sealed envelope, sterile on the inside and outside, and which carries a self-contained protective skirt which absolutely assures that when the inner envelope is removed from the outer one, it will only contact sterile surfaces.

In the surgical article art and particularly the surgical suture field, it is common practice to supply the trade with sutures immersed in a sterilizing liquid such as ethyl alcohol, aqueous formaldehyde, "Zepherin" or the like in a sealed transparent tube. Thus when the doctor or surgeon desires to use the suture, he has only to rupture the same and remove the suture which is in a sterile condition and ready for use.

It has been customary in the trade to include a plurality of such tubed sutures in cardboard containers but one of the objections thereto is that the outside of the suture tube is not sterile which requires a separate and additional sterilizing operation on the part of the customer.

It has also been customary to enclose a plurality of suture tubes in a tin can containing sufficient sterilizing liquid to completely immerse the tubes. This package has the advantage that the customer receives tubes completely sterile on the outside. However, the cans are open to the objection that they are extremely heavy which increases the transportation costs and such containers are expensive.

It has also been proposed to seal a suture into an envelope and enclose the first envelope into a second and outer envelope, all in a dry, sterile condition. Thus when the outer envelope is opened, the outside of the inner envelope remains sterile and the danger of contaminating the sterile suture in the inner envelope when the latter is opened is lessened. Such a proposal, while theoretically good, is open to the objection that it is impractical to satisfactorily dry heat sterilize either the sutures or the envelopes under those conditions and moreover no satisfactory transparent or translucent material was available which would resist the solvent or deteriorating action of the usual liquid sterilizing mediums or

2

satisfactorily hold such volatile mediums in storage or over long periods of time.

With the advent and commercial availability of thermoplastic resins such as the polyethylenes, trifluorochloroethylene polymers, polyvinyl chloride either alone or copolymerized with vinyl acetate, rubber, latex or the like, all of which are available as flexible, heat sealable, transparent or translucent sheets, it now becomes possible to supply the lack in the prior proposal and provide a transparent or translucent, flexible package for tubed sutures which may be readily heat sealed and contain the necessary quantities of the usual sterilizing liquids without fear of leakage or package deterioration.

One of the difficulties encountered in developing such a dry, double envelope package has been the provision of a satisfactory method of opening the same in order to make the contents accessible. While it is possible that surgical scissors be used to cut off the end, it must always be borne in mind that the outside of the outer envelope is unsterile and the act of shearing offers the possibility of carrying contaminations onto the previously sterile inner envelope and so to the tubes and sutures therein.

All of the above objections are overcome and the stated and other objects accomplished by the present invention which contemplates the provision of an inner envelope containing one or more suture tubes, each of which carries a suture and sterilizing liquid, with a sterilizing liquid in the inner envelope, the latter being enclosed in an outer sealed envelope with additional sterilizing liquid. The top of the outer envelope is provided with a downwardly depending skirt of less width than the width of the inner envelope and terminating short of the top of the inner envelope so that when the top portion of the outer envelope is severed even with unsterile scissors, the outer envelope in the act of being removed turns the sterile skirt inside out so that the inner envelope slips past completely sterile surfaces without danger of contamination. The invention contemplates that the material of which the envelopes are made shall be of a flexible, thermoplastic, heat sealable resin composition and substantially transparent or translucent.

The invention is further illustrated in the drawings in which

Fig. 1 is a perspective view of a section of endless tubing made of any of the well known thermoplastic, heat sealable, flexible, transparent or translucent resin compositions.

Fig. 2 is a similar view showing a flared mandrel

inserted through the open bottom of the tubing with the edges of the top portion heat sealed together.

Fig. 3 is a similar view showing the top portion of the tube tucked inside the mandrel to form a depending skirt.

Fig. 3*a* is an enlarged fragmentary sectional view showing the tucking in operation.

Fig. 4 is a similar view showing the previous mandrel removed and re-inserted from the other end with heating element sealing means sealing the side wall of the tube to the depending skirt.

Fig. 4*a* is a perspective view showing the completed operation.

Fig. 5 is an enlarged fragmentary sectional view showing the mandrel of Fig. 4 removed, the envelope collapsed and heating elements sealing one end of the envelope.

Fig. 5*a* is a perspective view showing the operation completed.

Fig. 6 is a similar view showing the thus sealed tube inverted, the mandrel inserted into the open end and a sealed envelope containing suture tubes inserted therein.

Fig. 7 is a similar view showing the addition of sterilizing liquid.

Fig. 7*a* is a sectional view showing the inner envelope and sterilizing liquid poured into the outer envelope.

Fig. 8 is a perspective view showing the completed composite package.

Fig. 9 is a similar view showing the skirt end of of the composite package having been cut as by scissors to remove the contents.

Fig. 10 is a similar view showing the inner envelope being removed from the outer envelope.

Fig. 10*a* is a sectional view showing the inner envelope being removed from the outer envelope.

Referring now to the embodiments illustrated, there is shown at **1** a section of endless tubing of one of the thermoplastic resin compositions above mentioned from which the envelopes may be made. A flared mandrel **2** is then inserted through the open bottom to a point near the top of the tube, triangular portions of the tube at the side of each end portion collapsed upon themselves and heat sealed as at **3**. This has the effect of producing a reduced opening **4**. The thus reduced end portion **5** of the tube is then tucked into the mandrel **2** as shown in Fig. 3*a* to form a depending skirt **6** on the inside of the tube **1**. The mandrel **2** is then withdrawn, re-inserted into the inside of the skirt from the other end as shown in Fig. 4 and a pair of heating elements **7** pressed against the doubled thickness of the envelope and skirt from each side so as to form a heat sealed joint **8**. The article thus far produced is shown in Fig. 4*a*. The mandrel is then withdrawn, the entire tube collapsed and heat elements **7** again brought together in pressure relation so as to completely seal the entire top of the tube in a joint **9** where all four surfaces are fused together as in Fig. 5. The article at this stage is shown in Fig. 5*a*.

It will, therefore, be seen that in the first sealing operation, the skirt was simply sealed to the side walls of the tube whereas in the second sealing operation, all four surfaces of the tube were sealed together and at a point somewhat separated from and above the skirt juncture.

The envelope at this stage is then inverted as shown in Fig. 6, the mandrel 2 re-inserted and

an inner sealed envelope **10** containing one or more suture tubes **11** containing sutures **12** and sterilizing liquid **13** inserted. This inner envelope **10** may be simply made by first heat sealing one end thereof in a manner similar to that shown in Fig. 5, the suture tubes inserted, sterilizing liquid added and the top heat sealed in the same way. Additional sterilizing liquid **13** may then be added as shown in Fig. 7. The mandrel **2** is then removed and the end of the outer envelope heat sealed as, for instance, by the mechanism of Fig. 5. We thus have the completed package as shown in Fig. 8.

Where it is desired to remove the sutures from inside this composite package without contamination, it only becomes necessary to clip off that end of the outer envelope which is adjacent the depending skirt as shown in Fig. 9. It is to be remembered that while the outside of the outer envelope is unsterile, yet the depending skirt is sterile inside and out, the inner envelope is sterile inside and out, and the suture tubes are sterile inside and out. Therefore, even if unsterile scissors are used to clip the end of the outer envelope as in Fig. 9, the only part of the entire assembly which would be contaminated thereby is the upper edge **14** of the outer package. The inner envelope may now be squeezed upwardly against the depending skirt **6** which is turned inside out and the inner envelope removed. In sliding through the restricted opening in the skirt, the inner envelope only comes in contact with sterile surfaces and then may be either taken by the sterile and gloved hand of the surgeon or his nurse or received onto a sterile towel. Thereafter it only remains to sever the end of the inner package as by means of sterile scissors and remove the suture tubes, break them and remove the sutures. This can be done in a simple manner without in any way introducing contamination.

It is important to note in Fig. 9 that the top of the inner envelope is below the bottom of the depending skirt. This causes the inner skirt to be turned inside out in order for the inner envelope to be removed therethrough and assures the protecting of the inner envelope by sterile surfaces.

While the invention has been described with particular reference to specific embodiments, it is to be understood that it is not to be limited thereto but is to be construed broadly and restricted solely by the scope of the appended claims.

What is claimed:

1. In combination, a sealed suture tube within an inner flexible envelope of a thermoplastic, heat sealable resin composition, an outer sealed envelope of similar material, said outer envelope having an inner skirt depending from one end and a sterlizing liquid in both envelopes.

2. The combination of claim 1 in which the inner envelope is sealed.

3. The combination of claim 1 in which the depending skirt terminates short of the top of the inner envelope.

4. The combination of claim 1 in which the depending skirt is provided with a bottom opening of less width than the width of the inner envelope.

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No references cited.