

[54] **SHEATH-PACKAGE AND METHOD**

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Related U.S. Application Data

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[58] Field of Search **206/16.5, 63.2 R, 56 AA; 229/48 T, 3.5 R; 128/260; 93/35**

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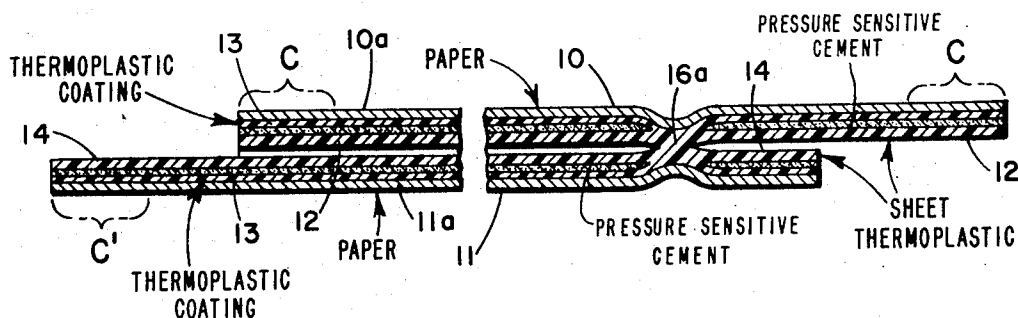
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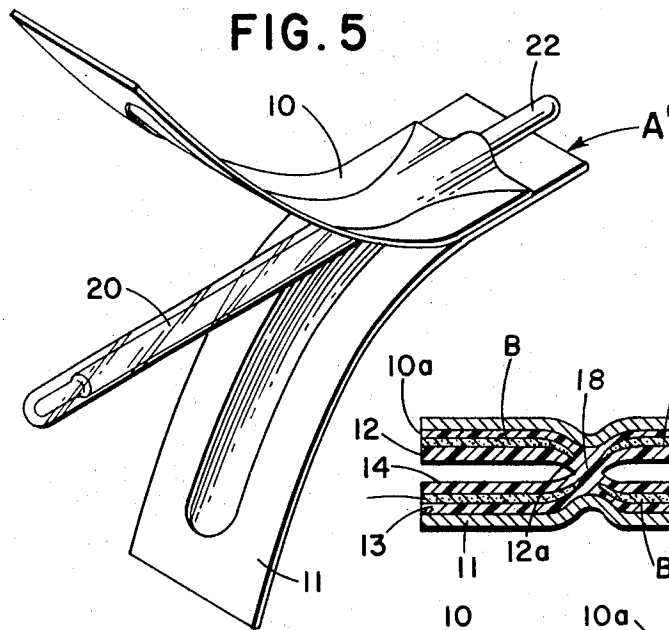
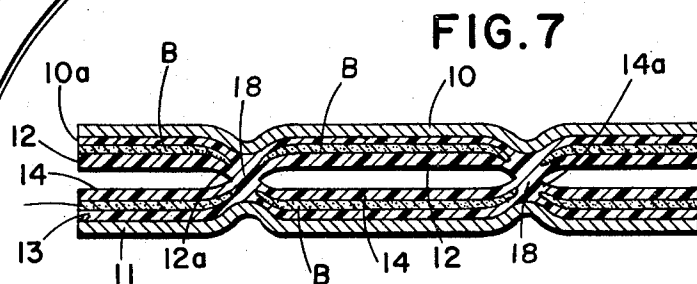
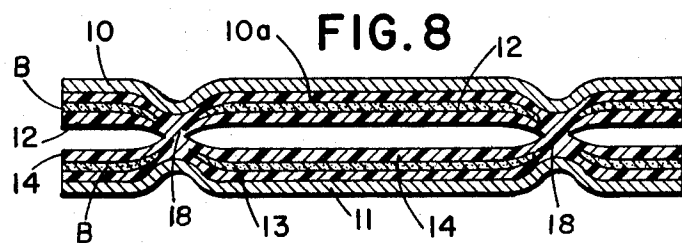
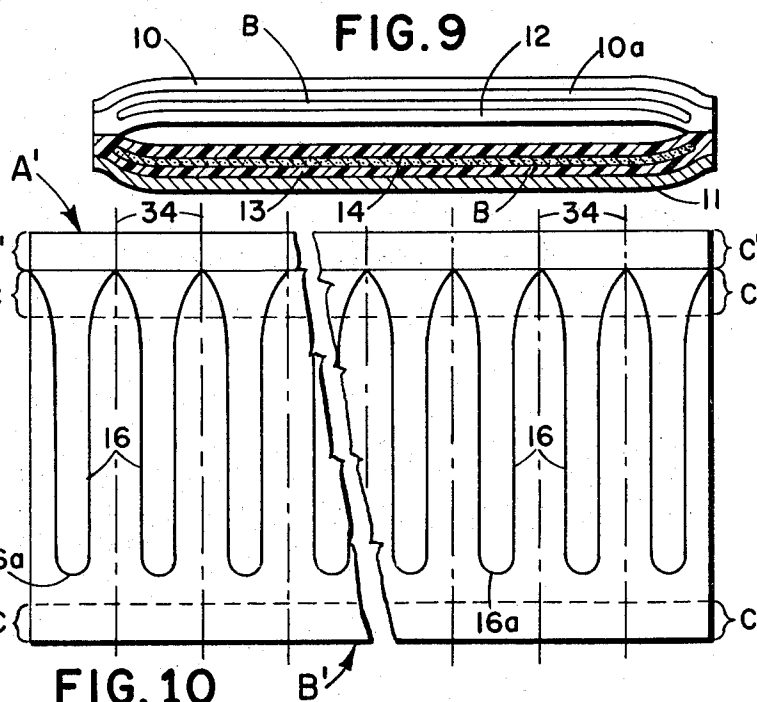
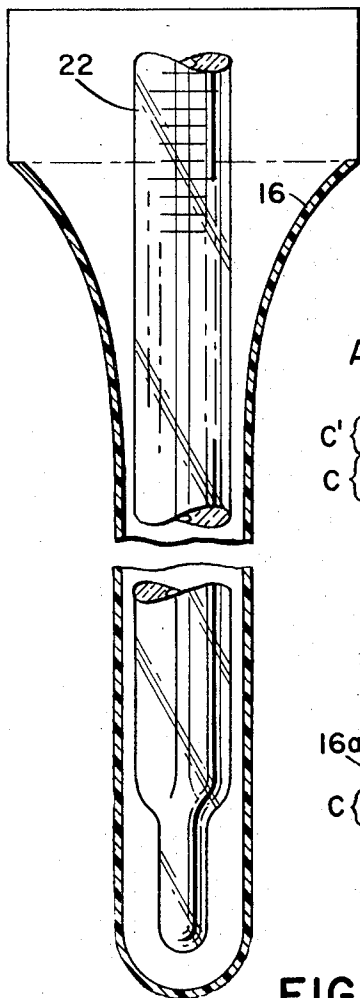
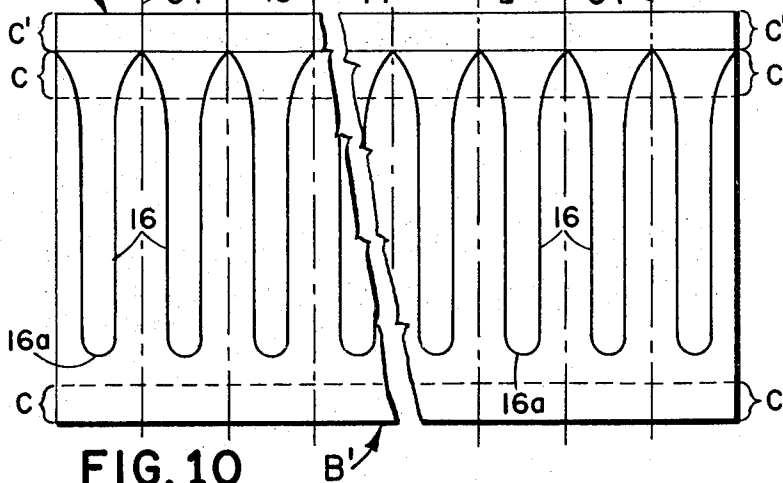
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ABSTRACT

The sheath-package comprises an outer cover and an inner sheath formed of heat sealable material, with a layer of releasable bonding material sandwiched between the cover and sheath for releasably bonding them to each other over substantially the entire outer surface of the sheath. The cover and sheath have an opening through which an instrument can be inserted into the sheath. The sheath is formed from two sheets joined along a seal line which defines the sheath. The cover is strippable from the sheath upon the insertion of an instrument therein, whereupon the sheath and sheathed instrument are exposed for use.

15 Claims, 10 Drawing Figures





SHEATH-PACKAGE AND METHOD

This application is a continuation-in-part of copending application Ser. No. 77,917, filed Oct. 5, 1970 now Pat. No. 3,732,975, and of the application Ser. No. 736,218, filed June 11, 1968, which issued on Jan. 5, 1971 as U. S. Pat. No. 3,552,558, and which is the parent of application Serial No. 77,917 and was copending therewith.

The method of making sheath-packages includes applying a pressure-sensitive adhesive to one side of each of two continuous sheets of cover material and feeding each of them into contacting relationship with a corresponding continuous sheet of thermoplastic material, the pressure-sensitive adhesive being adjacent to the sheet of thermoplastic material. Enough pressure then is applied to each of the sheets of cover material and their respective corresponding sheets of thermoplastic material to effect a releasable bond between them for forming first and second layers of the sheath-package. The first layer is brought into contact with the second layer with the thermoplastic sheets in facing contact. The joined layers are then subjected to the action of a die to form successive spaced seals in the thermoplastic sheets for sealing them together along the line formed by the die with the die line defining an enclosure, open at one end, between the thermoplastic sheets.

BACKGROUND OF THE INVENTION

This invention relates to improved sheath-packages for products which are required to be sterile, including tools or instruments such as clinical thermometers, tongue depressors, probes, catheters and like instruments, used by the medical profession and other scientific personnel. While the sheath-package is adaptable for use with a variety of objects, it will be described and illustrated in connection with a clinical thermometer.

While it is well known that the thermometer used in taking temperature readings must be in a state of sterility in order to avoid recontamination of the patient in subsequent readings, or contamination of another patient, it is not as well known among laymen that present practices in hospitals or by doctors in their private practices do not afford a sterile thermometer in most instances. The cross-contamination that can occur when the same thermometer is used on different patients is a constant hazard.

The shortcomings of this practice with regard to sterility of thermometers was well recognized by the medical profession which, while cognizant of the dangers of such practice, did not have available a practical and economical means of facilitating the use of a thermometer which is sterile at each use.

The inventions of my U. S. Pat. No. 3,552,558 and my copending application Ser. No. 77,917 filed Oct. 5, 1970, provide, in a sterile expendable package, a sterile disposable sheath for instruments such as clinical thermometers. The package is designed so that a thermometer can readily be inserted by anyone so that the thermometer enters directly into a transparent sheath which has previously been sterilized and maintained in a sterile condition within the package in those areas which come into contact with the body of a patient. The package can be stripped to expose the sterile sheath, whereupon the sheathed thermometer may be inserted into a body cavity, and a reading subsequently taken through the sheath. The sheath can then be dis-

carded, or it may first be discarded, so that the reading can be taken directly from the thermometer.

The thermometer may then, for subsequent use, be inserted into a new package and sheath without the necessity of sterilizing the thermometer itself after each use. This results in a substantial saving of time in the handling of the thermometer, and in the saving of money for the materials and supplies heretofore used to sterilize such objects. The use of such a sterile-package will also serve to reduce the total number of thermometers required to be available.

In addition, those inventions also provide a transparent sheath for a thermometer in which the exterior of the sheath is sterilized and is maintained in a sterile condition by its enclosing package, which is also sterilized at those portions which come into contact with the sheath.

The sterile package is disposable and can be mass produced in very substantial quantities in a short space of time at such low cost that it will be competitive with prior devices and methods for using thermometers and other devices which must be kept sterile in use to prevent contamination of patients.

This design has proved highly satisfactory during normal use when an instrument such as a thermometer is inserted into the sheath immediately prior to use and the packaging material is then stripped to expose the sterile sheath so that the instrument can be put to its intended use. However, it has been found that the sterile package can be used other ways such as, for example, to insert a number of thermometers at one time into their respective sheath-packages, which can either be deposited in a receptacle for future use or transported to another area. In addition, whenever instruments other than thermometers, such as, for example, catheters, are used in conjunction with the sheath-package gradual stripping of the packaging material over a considerable length may be required.

For these applications of the inventive sheath-package, the additional handling of the package with the instrument inside may cause the strippable seal enclosing the sheath to break prematurely and thereby expose the sterile surface to possible contamination before the instrument is used. Similar problems arise when instruments that are bulky or irregular in shape are inserted into the packaged sheath.

SUMMARY OF THE INVENTION

In accordance with the invention, these problems are solved by providing a layer of release-type, pressure-sensitive adhesive between the cover material and the thermoplastic sheath material so that they are releasably bonded to each other substantially over the entire surface area of the sheath. In this way, the outer cover is anchored in place which operates to reduce the strain on the seal that protects the sterility of the sheath, thereby reinforcing the seal and preventing the sterile outer surface of the sheath from premature exposure and possible contamination. The term "release-type," when applied to pressure-sensitive adhesives, is commonly used to refer to those coatings which permit a clean and easy separation, preferably the separation is achieved without leaving a residue on the surface to which the coated article was bonded.

The improved sheath-packages can be manufactured almost as cheaply by continuous methods as the sheath-package where the outer cover material is not releas-

ably bonded to the sheath. The method for manufacturing the improved sheath-packages includes applying a pressure-sensitive adhesive to the inner surface of a cover material which is preferably coated with a thermoplastic material. The cover material is then fed into contacting relationship with a corresponding sheet of thermoplastic material used to form a sheath, the pressure-sensitive adhesive being adjacent to the contacting sheets to effect a releasable bond therebetween. Upper and lower, bonded, composite layers are then brought together with their thermoplastic sheets in facing contact. The layers are then subjected to the action of a die to form successive, spaced seals in the thermoplastic sheets thereby sealing them together along a line formed by the die. The die line defines an enclosure which is open at one end between the thermoplastic sheets and which is capable of sheathing the thermometer or like instruments.

Continuous non-releasable, or in other words permanent, seals are formed along both edges of the upper layer and along one edge of the lower layer so that there is no danger of the thermometer being inserted between the outer surface of the sheath and the cover material and so that the portion of the thermoplastic material outside the seal line will be grasped and peeled away along with the cover material after an instrument is inserted in the sheath. In addition, the upper and lower layers are offset so that tabs are provided to facilitate removal of the outer cover and insertion of an instrument into the sheath.

During the continuous process, the combination of the releasable seals and non-releasable seals along the edges of the layers can be formed simultaneously either by using the same pressure-sensitive adhesive that is coated over the total area of the non-releasable seal and over less than the total area of the releasable seal, or two different adhesives with different degrees of adherence can be used which would be sealed at the same time upon the application of pressure. The permanent seals can also be formed by applying heat between thermoplastic layers when the cover material is coated with a layer of thermoplastic material, while the releasable seal could be formed by a pressure-sensitive adhesive.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the invention, reference may be had to the following description of a preferred embodiment, taken in conjunction with the accompanying drawings, in which:

FIG. 1 is a plan view of the package, in strip form, showing the sheath within it;

FIG. 2 is a substantially enlarged, central, longitudinal sectional view of FIG. 1, taken along line 2—2 thereof, showing in particular the layers of pressure-sensitive adhesive;

FIG. 3 is a perspective view of the sheath-package with a thermometer partially inserted therein;

FIG. 4 is a perspective view of the package similar to that of FIG. 3, but with the upper strip partially peeled to expose the sheathed thermometer;

FIG. 5 is a perspective view of the sheath-package, with a thermometer inserted therein, and with both front and back strip portions of the package partially stripped away to expose the sheathed thermometer;

FIG. 6 shows the sheathed thermometer after both the front and back strip portions of the package have been fully stripped or peeled away from the sheath;

FIG. 7 is an exaggerated and enlarged transverse sectional view taken along the line 7—7 of FIG. 1, showing the several separate layers of materials used, and a portion along which a seal is made to form the sheath;

FIG. 8 is a view similar to the one in FIG. 7, taken along the line 8—8 of FIG. 1;

FIG. 9 is a view similar to the ones in FIGS. 7 and 8, taken along the line 9—9 of FIG. 1;

FIG. 10 is a plan view of a continuous sheet illustrating the method of making the sheath-package by mass production and showing the composite web from which the individual strips are cut.

DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

As best shown in FIGS. 1 and 2, a preferred embodiment of the invention comprises a plurality of layers of sterilizable strips of impervious paper and impervious films of thermoplastic materials joined by sealing in a manner to be explained. The front and back or upper and lower sheets 10 and 11, respectively, are thin sheets of strips of paper, preferably glassine, each coated over one entire surface 10a, 11a, with a very thin coating of thermoplastic material 13. This coating is preferably of the order of one-half mil or less in thickness.

The intermediate sheets 12 and 14 are thin films or sheets of an impervious, transparent, thermoplastic material, each of the order of about one mil in thickness. The strips so formed are all substantially equal in length and width, the sheets 10 and 12 forming a first or upper layer and the sheets 11 and 14 forming a second or lower layer. When assembled, the two layers are combined as shown in FIG. 2 with the thermoplastic strips being sandwiched between the glassine strips, the ends of the upper composite layer being offset with respect to the ends of the lower composite layer, so as to form a tab at each end of the combined layers.

Preferably, each of the thermoplastic strips 12 and 14 has a thickness less than that of the glassine strips 10 and 11. The thickness of the several sheets and coatings are exaggerated in the drawings for clarity of illustration.

Adjacent strips 10 and 12 are bonded to each other in a way that permits the strip 10 to be peeled or stripped away from the strip 12. The strips 11 and 14 are similarly bonded. The bonding is accomplished by applying a coat of pressure-sensitive adhesive or cement B to the inner face of the thermoplastic coating 13 and then pressing the adjacent strips together with a sufficient pressure to effect the bond. The cement is of a known variety that forms a releasable-type bond between the adjoining strips, but permits the cover strip to be peeled away from the strips 12 and 14 and preferably without leaving any residue on the strips 12 and 14.

The strips 10, 12 are permanently sealed or welded to each other at both ends, over the areas indicated at C in FIG. 2. The strips 11, 14 are similarly sealed to each other at one end, over the area indicated at C'. The seals designated by C, C' are such that there is a non-peelable or permanent bond between the strips at the places indicated.

The line 16 in FIG. 1 indicates a crease which extends through the several layers, the impression and seal along the line 16 being made by an electronic die (not shown) in a high frequency heat sealing press (not shown). The line 16 forms on the inner strips 12 and 14 the outline of an elongated sheath or pocket that is closed at one end 16a and open at the other end to the atmosphere. The sheath has a flaring or funnel-like mouth 16b adapted to receive a thermometer or the like, or other instrument. This seal along the line 16 makes a visual impression on the paper strips 10, 11 and forms a tear seal, between the paper strips, in the thermoplastic strips 12, 14, which are thus joined together in a weld when subjected to the heat and pressure mentioned above. This unites the several layers along the line 16, as best shown in FIGS. 7 and 8, where the thermoplastic coatings 13 and the adjacent portions of the thermoplastic layers 12, 14 all flow together under the influence of the heat induced in the material by the high frequency current and the pressure of the die (not shown) to weld or fuse these together into one coherent mass, as shown in the enlarged and exaggerated areas 18 in these views. The thickness and curvature of the materials in FIGS. 7, 8 and 9 are enlarged and exaggerated for the purpose of clarity of exposition. The sheath-package is actually a thin flat strip in its finished form, as will be evident from the material thicknesses previously described.

The action of the die (not shown) has the effect of weakening the thermoplastic material along the line 16 of the seal formed by said die so that the plastic portions thereof outside of the boundary of the sheath formed by the seal 16 can be torn away, the remaining portions of the thermoplastic material adhering to the strip 11 along the edge of the line formed by the seal. This tearing of the thermoplastic material along the seal line 13 to separate the waste portions of the thermoplastic strips 12 and 14 outside of the seal line from the portions of the strips 12 and 14 inside the seal line comprising the sheath walls can be readily effected by inserting an instrument into the sheath and against the leverage afforded by the instrument pulling on the end of the strip 12 opposite the closed end of the sheath. The seal is designed so that the tearing occurs right down the middle of the seal leaving the strip 12 permanently sealed to the strip 14 along the perimeter of the tear both inside the tear to form the sheath and outside the tear joining the waste portions of the strips 12 and 14 together. Thus, the seal between the strips 12 and 14 along the seal line 16 is a permanent seal that is readily tearable right down the middle along the line of the seal. The perimeter along the seal line 16 between the cover strip 10 and the thermoplastic strip 12 and between the cover strip 11 and the thermoplastic 14 are peelable so that the cover strips 10 and 12 can be peeled away from the sheath.

In the sheath-package of the above mentioned co-pending applications, it was these peelable perimeter seals along the seal line 16 which alone protected the outer surfaces of the sheath from contamination. By respectively bonding the adjacent strips 10 and 12 and 11 and 14 together by pressure-sensitive sealable adhesive, the cover material is anchored to the sheath material, thereby reinforcing the peelable perimeter seals along line 16 between the cover strip 10 and the thermoplastic strip 12 and between the cover strip 11 and the thermoplastic strip 14. As a result, the chances of

the seals protecting the sheath breaking prematurely and allowing the sheath to become contaminated are substantially reduced. With this bonding feature, a sheath-package is provided that can withstand rough handling, successive manipulation, and relatively high stress without danger of breaking the protective and outer seals protecting the sheath and without sacrificing the easy and fast peelability of the outer cover.

The upper and lower paper strips 10 and 11 act as buffers between the die and the bed of the press. To some extent the strips 10 and 11 prevent the total destruction of the thermoplastic material by the heat induced therein, and because the strips are bonded to the sheath material they actually become a part of the sheath-package itself. The coating 13 on the paper strips additionally forms a protective surface or barrier against sheath contamination which might possibly occur due to any porosity which may exist in the paper used. The visible seal line 16 also serves as a visual guide for the insertion of the thermometer or instrument into the sheath-package.

The adjacent or meeting faces of the strips 10 and 12, and those of the strips 11 and 14, respectively, and the pressure-sensitive cement may be sterilized by subjecting them to ultraviolet exposure right up to the moment the surfaces are joined during assembly. This sterilization may be carried out on the facing surfaces of the strips 10, 11 after they have been coated with the coating 13 and the pressure-sensitive cement. Sterilization may be carried out during the manufacturing process, as just described, or after the package has been completely fabricated such as by permeation by sterilizing gas or by ultraviolet light. Sterilization both during manufacture and after may be used, if desired, to completely insure sterilization.

In some applications, it may be desirable to use cloth fabric as a cover material substitute for the glassine paper, in which event the coating 13 would seal the fabric to render it impervious.

The application of the die to the superimposed sheets of material results in the formation of the sheath 20 from the two strips 12, 14 (see FIGS. 5 and 6), with the result that the sheath is thus fully enclosed in a sterile atmosphere. Only the interior surfaces of the sheath are exposed to the atmosphere, at the mouth 16b thereof, with the mouth being open.

The material of the facing coating 13 on the outer paper strips 10, 11 and the material of the sheath may be of any suitable thermoplastic, preferably vinyl, and more particularly ethylene-vinyl-acetate, this particular formulation having been found to be most suitable for the purposes of this invention.

In an alternative embodiment of the invention, the strips 10, 11 need not include the thin coating of thermoplastic material 13, and the pressure-sensitive cement can be applied directly to the strips 10, 11. The sheath-package is then formed substantially the same way as described above. In such an embodiment, the entire protection of the sheath would be provided by the by the seals provided by the pressure-sensitive adhesive between the outer cover strips and the thermoplastic strips.

The sheath, being a very thin transparent film enclosing the thermometer and formed from the welded layers 12, 14 provides negligible insulation against heat transfer, yet has sufficient strength for the intended purpose and permits an accurate reading of the ther-

monometer. In practice, however, the sheath as shown in FIG. 6 is preferably slipped off the instrument after use and is discarded before a reading is taken.

The sheathed thermometer 22 has the additional advantage that should the thermometer break in the body of a patient, as sometimes occurs, removal of the entire contents is simplified by the fact that the broken glass is held by the sheath. In addition, the material of the sheath has a greater tensile strength than that of the glassine cover so that the body of the sheath is resistant to tearing as the cover is stripped away (see FIG. 5).

It will be understood that a variety of tools and instruments requiring sterilization in use can be encapsulated by accommodating the configuration and dimension of the tear seal substantially to the outline of the desired object.

In use, the sheath-package may be grasped by the tab A' or along either side and the thermometer or other instrument 22 may be inserted into the mouth of the sheath at 16b and pushed inwardly until it fully occupies the sheath and is stopped by the end seal 16a. Of course, the thermometer is inserted mercury bulb first. The paper strips 10, 11 and the respective cohering waste portions of the thermoplastic strips 12, 14 are then stripped or peeled away from the sheath along the line 16 against the leverage afforded by the inserted thermometer, by gripping and pulling the tab at the opposite end B', separation taking place along the center of the tear seal line 16, leaving the sterile exterior surfaces 12a, 14a of the sheath exposed as at 20 in FIG. 5. Then the stripped portions may be discarded, or they may be retained as in FIG. 5 and used to grip the instrument as it is inserted into a body cavity, thus avoiding contact of the hand of the user with the body of the patient.

The thermometer is thus covered with a transparent sheath which is entirely sterile along its entire exposed surface to avoid transmission of disease or infection, and through which the graduations on the thermometer may be read with ease, if so desired. After use, the sheath is easily slipped off the instrument and disposed of. The same thermometer is immediately available for reuse on the same or another patient without sterilization, by inserting it into another sheath-package according to this invention and stripping the outer cover therefrom as described above.

Instead of inserting the thermometer or other instrument into the sheath-package just before the outer cover strips are peeled away, it is sometimes desirable to insert several instruments at one time in the different sheath-packages for later peeling and use. The sheath-packages with the inserted instruments may be deposited in a convenient receptacle until they are to be used or they may be transhipped to another location for later use. Some instruments, such as a long catheter, may require a gradual stripping of the sheathed instrument commensurate with venal insertion over a considerable catheter length. In such instances, extensive handling and manipulation of the sheath package with the instrument inserted would be expected and if the outer surface of the sheath were protected only by a peelable perimeter seal along the line 16, such handling or manipulation might cause premature penetration of the peelable perimeter seal and thus expose prematurely the sterile surface of the sheath. In the improved sheath package of the present invention, this danger is eliminated because the cover strips 10 and 11 are

bonded to the thermoplastic strips over the entire surface area of the strips rather than just along the line 16 and this seal over the entire surface area firmly anchors the cover strips in place and prevents undue handling or manipulation from prematurely exposing the sterile surface of the sheath. Yet, because the seal between the outer cover strips 10 and 11 and the thermoplastic layers 12 and 14 is peelable except in the areas C and C', the cover strips 10 and 11 can be readily peeled away to expose the sterile sheath surface. The use of the seal over the entire surface of the strips also eliminates the danger of premature exposure of the sheath when the instrument or object to be sheathed is bulky or irregular in shape such as to be likely to cause substantial strain on the peelable seal between the cover strips and the thermoplastic layer when the object is being inserted in the sheath-package or when the sheath-package is being subsequently handled.

Experience has shown that some users attempt to strip the cover strips from the sheath by peeling them away from the wrong end of the strip. Stripping should be accomplished from the end opposite that where the thermometer is inserted. To eliminate the possibility of stripping the covers from the wrong end, the tab B' at the end opposite the opposite end of the sheath can be marked with an appropriate legend to indicate that stripping takes place at that end.

The foregoing sheath-package is particularly designed so as to enable it to be manufactured in large quantities by mass production methods so that the cost of the individual sheath-package is reduced to a negligible (fraction of a cent) amount. Thus, the sheath-package may be used and expended freely without regard to cost. In the manufacture of the sheath-package, the four layers of material 10, 11, 12, 14, in superimposed or in face to face relation, are simultaneously fed in continuous sheet or strip form to a high frequency electronic sealing press (not shown) which is well known in the art. The method of making the strips shown in FIGS. 1 and 2, which comprise four separate sheets of material, is as follows.

In some applications, lubricant may be provided within the sheath-package as disclosed in the above identified copending application Ser. No. 77,917. With the lubricant applied, the pressure-sensitive cement will still bond together to form a peelable bond between the cover strips and the thermoplastic strips. This bonding occurs at tiny spaced points with the lubricant filling the spaces between the points.

The strips 10 and 12 are continuously fed in web form from supply rolls towards a press (not shown) with the strip 10 over the strip 12. Simultaneously, the strips 11 and 14 are similarly fed towards a second press with the strip 14 facing upwardly. The adjoining or contacting surfaces of the strips 10 and 12 and the strips of 11 and 14, respectively, are subjected to the action of ultraviolet rays before they are brought into contact with one another, but after the coating 13 and pressure-sensitive cement B have been applied to the strips 10, 11.

The pressure-sensitive cement B is applied in a continuous manner by any suitable coating mechanism such as a roller, knife or other coater mechanism (not shown), supplied by a reservoir (not shown), and subjected to the action of ultraviolet rays. As the webs of the material are fed past the sterilizing mechanism (not shown), the parts are exposed to such rays. The pres-

sure-sensitive cement B in the reservoir is constantly exposed to such rays and the webs move through them at a speed and for a sufficient time duration as to ensure satisfactory sterilization. Alternatively, this sterilizing step may be omitted and the completed package may be effectively sterilized after manufacture by subjecting the completed package to permeation by a sterilizing gas or to the action of ultraviolet rays in a well known manner for a time sufficient to effect complete sterilization.

After the inner surface of the web of covering strips 10 has been coated with the pressure-sensitive cement B, it is brought into contact with the web of thermoplastic strips 12 used to form the sheath. The webs of the strips 10 and 12 are then passed between a pair of pressure rollers so that they are releasably bonded to each other over their entire adjoining surface area.

The seals or non-peelable bonds C and C' can be formed at the same time the covering and thermoplastic strips are bonded together, or the seals can be formed afterwards. When these seals are formed by using pressure-sensitive cement there are two basic methods that can be employed, both of which can be used to form the permanent seals simultaneously upon bonding of the remaining portion of the strips together.

First, the same pressure-sensitive cement can be applied over the entire surface of the covering strip, including the area where the permanent seal is to be located. However, the area of the permanent seal is totally coated with the cement while the area of the releasable bond has less than total coating such as, for example, by stippled, dotted or stripped deposits of the cement. This can be done by providing a roll for applying the cement, which is engraved with the appropriate pattern so that the cover material can be selectively coated or imprinted with cement. Thus, when the strips are passed through the pressure rolls the two strips will be bonded to each other with varying degrees of strength. The marginal areas where a total coat of cement has been applied will be permanently bonded, while the remaining area where there is a less than total coat will be releasably bonded.

Alternatively, the different degrees of adherence can be achieved by applying two different types of pressure-sensitive cement to the covering material, one for the permanent bond and one for the peelable or releasable bond. This can be done in a manner similar to two-color printing where one type of cement is applied to the area where the permanent bond is desired and a second type of cement in the remaining area.

In addition, the seals C and C' can be formed after the bonding step by not coating the seal areas with the pressure-sensitive cement and fusing the coating 13 with the adjoining thermoplastic layer when heat is applied to form the line 16.

After the cover material and the adjoining thermoplastic material are bonded together, the strips 10 and 12, forming the upper web, are then placed over the strips 11 and 14, forming the lower web, in such fashion that the side edges of the upper web are offset laterally from the adjacent edges of the lower web to achieve a relationship between the webs (best shown in FIG. 2), wherein tabs A', B' are provided, one at each opposite end of the superposed strips. The combined webs are then subjected to the repeated action of a die in the press mentioned to form the composite web shown in

FIG. 10, where they are joined or welded together along the die line 16. The individual sheath-packages, as shown in FIG. 1, are then formed by cutting the web of FIG. 10 along the lines 34. After cutting, each strip will have a tab A', B', respectively, at its ends, as described above.

In use, the strip is gripped at the tab A' at the open end of the sheath and a thermometer is inserted into the sheath. The tab B' is then peeled or stripped away as shown in FIG. 4. The remaining strip is then peeled or stripped away as shown in FIG. 5, leaving the sheath exposed for use.

Thus, there is provided in accordance with the invention an improved sheath-package which has a reinforced sealable perimeter seal around the sheath so that the chances of the sterile sheath being exposed prematurely are greatly reduced. There is also provided a method which can be used to continuously produce the sheath-packages cheaply and in large quantities. The embodiments of the invention described herein are intended to be merely exemplary, and those skilled in the art will be able to make additional modifications and variations without departing from the spirit and scope of the appended claims, all such modifications and variations being contemplated as falling within the scope of the claims.

I claim:

1. A sheath-package comprising:

an outer cover, an inner sheath formed of heat sealable material, a layer of releasable, pressure-sensitive bonding material between said cover and said sheath, said layer of bonding material releasably bonding said cover and said sheath to each other over substantially the entire outer surface of the sheath, said cover and sheath having an opening for the insertion of an instrument into said sheath, said cover being strippable from said sheath upon the insertion of an instrument therein, whereupon said sheath and the sheathed instrument are exposed for use.

2. The sheath-package in claim 1, wherein said outer cover includes a coating of heat sealable material on its inner surface.

3. The sheath-package in claim 1, wherein said sheath-package includes an upper composite strip of said cover and said sheath material releasably bonded together and a lower composite strip of said cover material and said sheath material releasably bonded together with said opening being located between said composite strips at one end thereof.

4. The sheath-package in claim 4, wherein said cover and said sheath material comprising said upper composite strip are non-releasably bonded together at both ends thereof and said cover and said sheath material comprising said lower composite strip are non-releasably bonded together at the end of said strip at said opening.

5. The sheath-package in claim 4, wherein the non-releasable bonds at the ends of said composite strips are effected by means of a pressure-sensitive adhesive.

6. The sheath-package in claim 5, wherein the releasable and non-releasable bonds are effected by means of the same pressure-sensitive adhesive, the area of the non-releasable bond having a greater coverage of said pressure-sensitive adhesive than the area of said releasable bond.

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7. The sheath-package in claim 5, wherein the releasable and non-releasable bonds are formed of different types of pressure-sensitive adhesive with different degrees of adherence.

8. The sheath-package in claim 4, wherein said upper composite strip projects beyond the lower strip at the end opposite said opening and said lower composite strip projects beyond said upper strip at the end of said opening.

9. Means for sheathing an instrument comprising: an assembly having upper and lower layers of cover material, intermediate layers of heat sealable material disposed between said upper and lower layers, a coating of releasable pressure-sensitive bonding material between said upper layer and the adjacent intermediate layer and between said lower layer and the adjacent intermediate layer, each of said intermediate layers being releasably bonded to the respective adjacent layer of said cover material, each of said intermediate layers being also in direct contact with each other and united along a seal defining the outline of a sheath so that a sheath is formed by said intermediate layers within the line defining said seal, said sheath having an open end and a closed end, said upper and lower layers of cover material being strippable from said sheath and from each other to expose said sheath for use when an instrument is inserted therein.

10. The means in claim 9, wherein said upper and lower layers of cover material include a coating of heat sealable material on their inner surfaces, said pressure-sensitive adhesive is disposed between said coating and intermediate layers, and both of said intermediate layers are releasably sealed along said line defining said seal to the coating on the respective adjacent layer of cover material.

11. A method of making sheath-packages from a plurality of separate layers of sheet material comprising the steps of:

applying a pressure-sensitive adhesive to one side of a first continuous sheet of cover material;

feeding said first continuous sheet of cover material into contacting relationship with a first continuous sheet of thermoplastic material, said pressure-sensitive adhesive being adjacent to said first sheet of thermoplastic material; applying a pressure-sensitive adhesive to one side of a second continuous sheet of cover material;

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feeding said second continuous sheet of cover material into contacting relationship with a second continuous sheet of thermoplastic material, said pressure-sensitive adhesive being adjacent to said second sheet of thermoplastic material;

applying enough pressure to said first and second sheets of cover material and the corresponding sheets of thermoplastic material to effect a releasable bond therebetween for forming first and second layers of said sheath-package;

joining said first layer to said second layer with the thermoplastic sheets thereof in facing contact; and subjecting said joined layers to the action of a die to form successive, spaced seals in said thermoplastic sheets, thereby sealing said thermoplastic sheets together along the line formed by said die, said die line defining an enclosure, open at one end, between said thermoplastic sheets capable of sheathing an instrument therein.

12. The method in claim 11, wherein both of said sheets of cover material are coated with a layer of thermoplastic material before the step of applying a pressure-sensitive adhesive.

13. The method in claim 11, and further including the steps of forming a continuous non-releasable bond between the sheets forming said first layer along both edges thereof, and forming a continuous non-releasable bond between the sheets forming said second layer along one edge thereof, before the step of joining, wherein said layers are subjected to the action of said die between said edge bonds.

14. The method in claim 13, wherein said steps of applying a pressure-sensitive adhesive to said first and second sheets of cover material includes applying the same adhesive to substantially the entire surface area of said first and second sheets, a greater density of said adhesive being applied in the area of said non-releasable bonds than over the remaining area in order to provide said releasable bond in said remaining area.

15. The method in claim 13, wherein the steps of applying includes applying a first non-releasable pressure-sensitive adhesive in the area of said non-releasable bonds and applying a second releasable pressure-sensitive cement in the remaining area of said sheets of cover material.

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