United States Patent [19]

Poncy

[11] **3,847,280**

[45]***Nov. 12, 1974**

[54] **STERILE PACKAGE FOR CLINICAL THERMOMETERS AND THE LIKE AND METHOD OF MAKING IT**

[75] Inventor: **George W. Poncy,** Chatham, N.J.

[73] Assignee: **Johnson & Johnson,** New Brunswick, N.J.

[*] Notice: The portion of the term of this patent subsequent to Jan. 5, 1988, has been disclaimed.

[22] Filed: **Aug. 31, 1972**

[21] Appl. No.: **285,255**

Related U.S. Application Data

[63] Continuation of Ser. No. 77,917, Oct. 5, 1970, Pat. No. 3,732,975, which is a continuation-in-part of Ser. No. 736,218, June 11, 1968, Pat. No. 3,552,558.

[52] **U.S. Cl.** **206/306,** 206/498, 93/35, 128/260, 206/212

[51] **Int. Cl.** **A61b 19/02**

[58] **Field of Search** ..... 206/16.5, 63.2 R, 306, 206/498, 212; 128/260; 229/48 T; 93/35

[56] **References Cited**

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Primary Examiner—William T. Dixson, Jr.
Attorney, Agent, or Firm—Lane, Aitken, Dunner & Ziems

[57] **ABSTRACT**

An improved sterile, disposable, sheath and sheath cover for thermometers and the like, and method of making it, packaged so as to preserve the sterility of the sheath during handling and storage, the sheath cover comprising the packaging material being strippable from the sheath along a tear seal to expose the same for clinical use when a thermometor or the like is inserted into the sheath. In some applications the sheath is covered on its outer surface during manufacture with a lubricant, medicated or otherwise, to facilitate insertion into a body cavity. The package is particularly designed for economical mass production.

5 Claims, 10 Drawing Figures

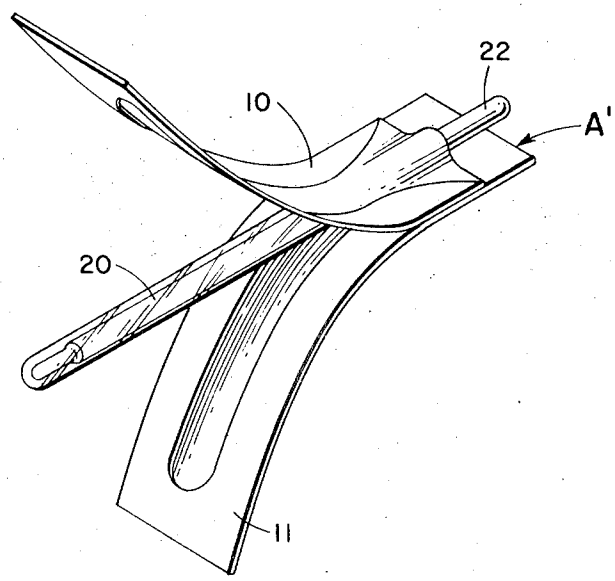


FIG. 1

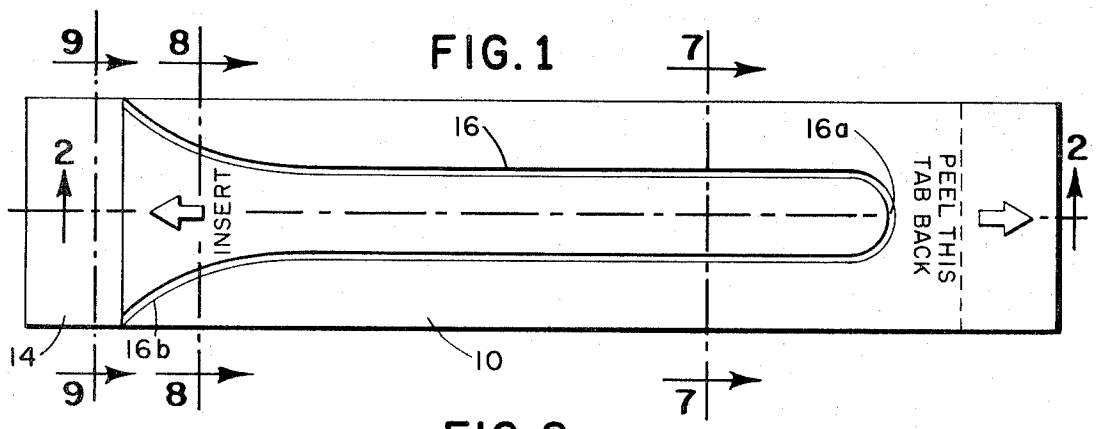


FIG. 2

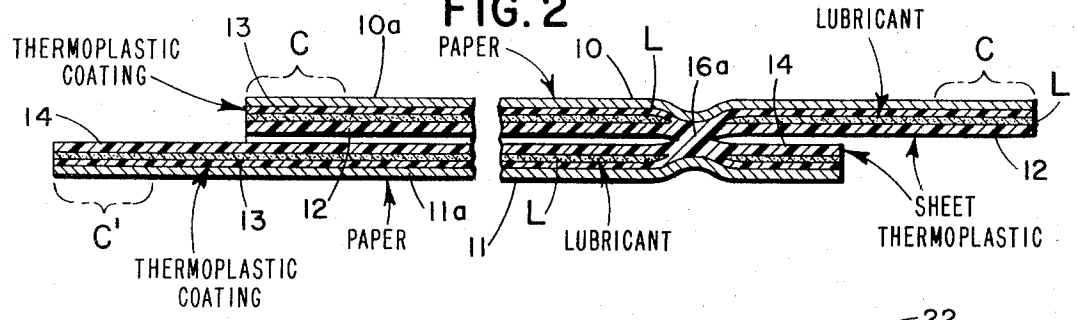


FIG. 3

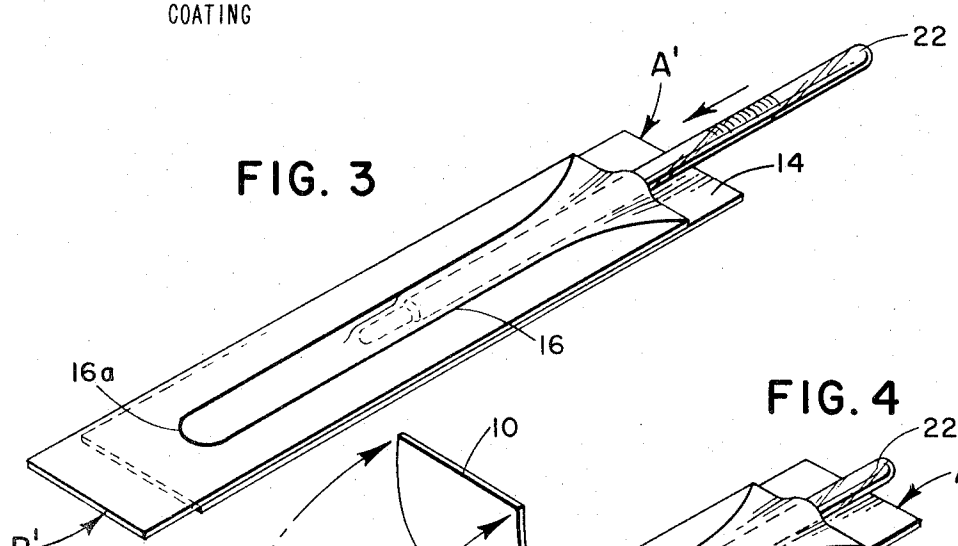


FIG. 4

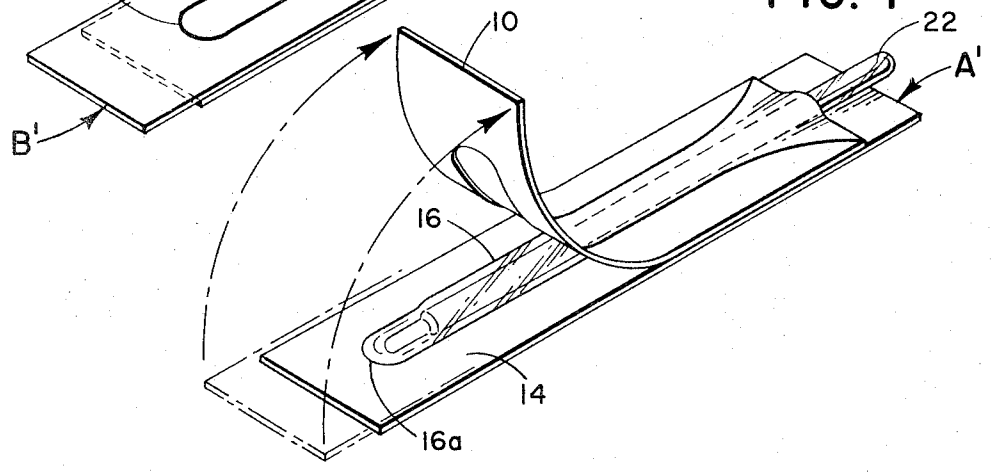


FIG. 5

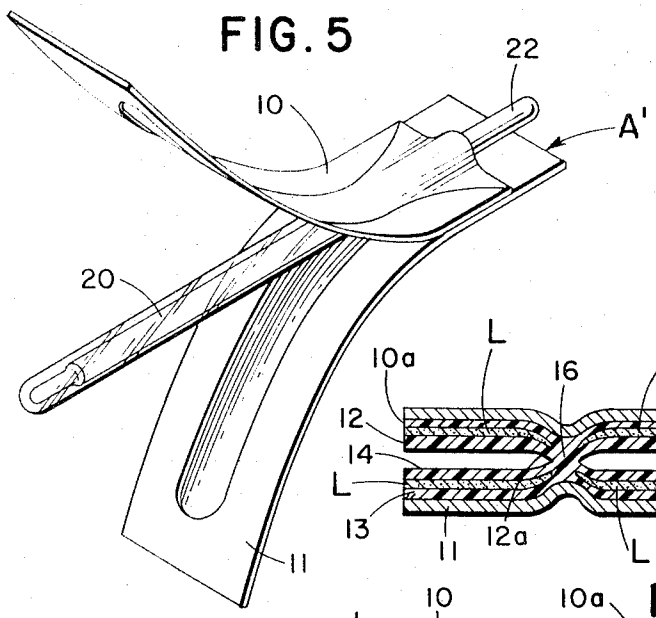


FIG. 7

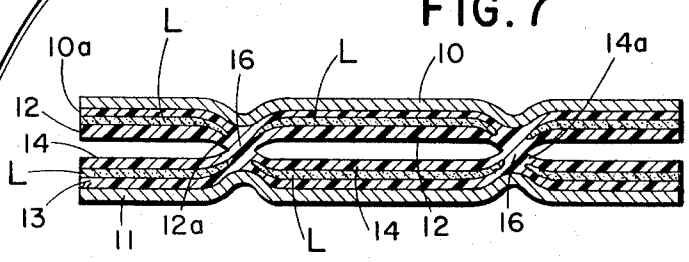
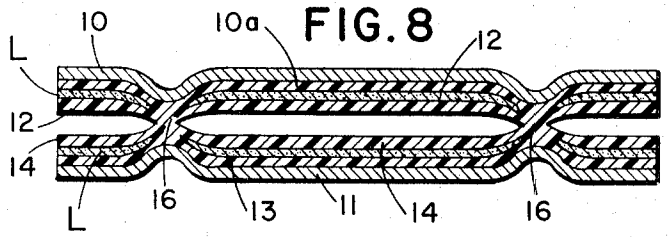


FIG. 8



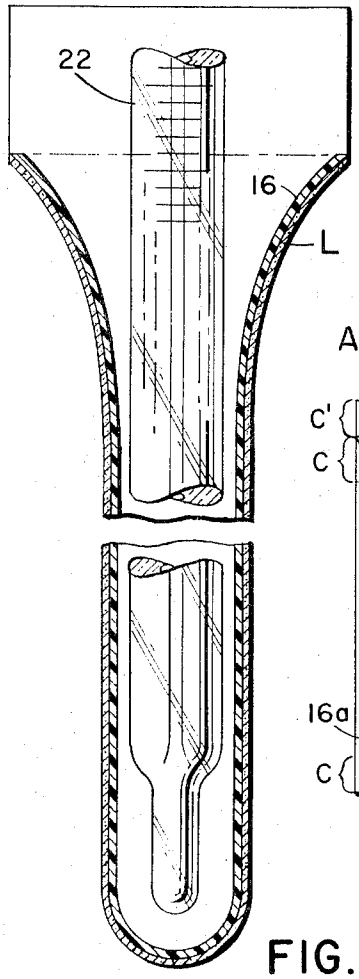
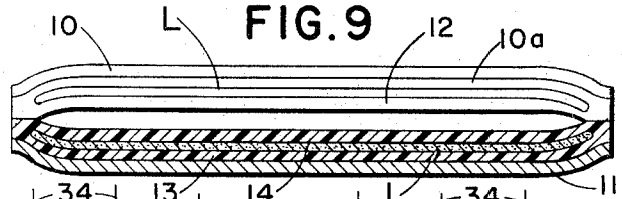


FIG. 9



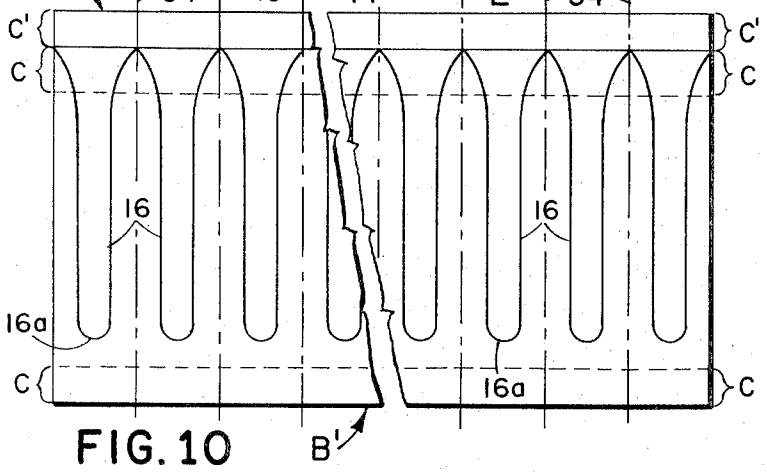


FIG. 10

FIG. 6

STERILE PACKAGE FOR CLINICAL THERMOMETERS AND THE LIKE AND METHOD OF MAKING IT

This is a continuation of application Ser. No. 77,917, filed Oct. 5, 1970, now U.S. Pat. No. 3,732,975 which is a continuation-in-part of my prior application Ser. No. 736,218, filed June 11, 1968, now U.S. Pat. No. 3,552,558.

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, merely by way of example, 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 re-contamination of the patient in subsequent readings, or contemination 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 the present practice with regard to sterility of thermometers is well recognized by the medical profession which, while cognizant of the dangers of such practice, does not have available a practical and economical means of facilitating the use of a thermometer which is sterile at each use. The various attempts to solve this problem, as evidenced by the prior art, has not been successful.

A principal object of the invention, therefore, is to provide, in a sterile, expendable package, a sterile, disposable sheath for such objects as clinical thermometers. Another object is to provide such a package into which a thermometer can readily be inserted by anyone, just prior to use thereof, 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, and from which 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 therethrough through said sheath, which may then be discarded, or the sheath 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. It will also serve to reduce the total number of thermometers required to be available.

Another object of the invention is to 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.

A further object is to provide such a device which 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.

Still a further object of the present invention is to provide a lubricant for the sheath to facilitate its entry into a body cavity when in use, thus providing a prepackaged, sterile, lubricated sheath for thermometers and the like, the lubricant including medication where required for treatment. This eliminates the necessity of on-the-spot lubrication of the instrument by a physician, nurse or other technician, with consequent necessary cleansing and wiping of hands. The lubricant is applied to the sheath during the manufacture thereof, as will be explained.

The following specification and accompanying drawings describe and illustrate a preferred embodiment of the invention.

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.

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** is a perspective view of 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 similar view taken along the line **8—8** of FIG. **1**.

FIG. **9** is a similar view 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 web from which the individual strips are cut.

As best shown in FIGS. **1** and **2**, the invention comprises a plurality of layers of sterilizable strips of impervious paper and impervious films of thermoplastic materials joined by heat sealing in a manner to be explained. The front and back, or upper and lower sheets **10, 11**, respectively, are thin sheets of strips of paper, preferably glassine, each coated over one entire surface **10***a*, **11***a*, with a very thin coating of thermoplastic material **13**. This coating is preferably of the order of ½ mil, or less. In those applications where this is necessary or desirable, a lubricant L is applied over the coating **13**, the lubricant being of the viscous type such as gel, salve or ointment, or even a powdery material having lubricating properties. An example of the viscous

type may be petrolatum or a petroleum jelly such as vaseline, and the powdery material may be a talc which is used in the making of lubricants. Such lubricant may be medicated as the occasion requires.

The intermediate sheets **12, 14,** are thin films or sheets of 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, and when assembled, the two layers are combined as shown in FIG. **2,** the ends of the upper strip being offset with respect to the ends of the lower strip, so as to form a tab at each end of the combined layers.

The thermoplastic strips **12, 14,** each preferably have a thickness less than that of the glassine strips **10, 11,** and are sandwiched between the latter. The thicknesses of the several layers are exaggerated in the drawings for clarify of illustration.

The strips **10, 12** are sealed or welded to each other at one end, over the area indicated at C in FIG. **2.** The strips **11, 14** are sealed or welded to each other over the area indicated at C'. The remaining areas of the strips are, or may be, in physical contact, but are not sealed to each other except as indicated below. The line **16** in FIG. **1** indicates a crease which extends through the several layers, the impression and seal being made by an electronic die (not shown) in a high frequency heat sealing press (not shown) and forms from the intermediate strips **12** and **14** the outline of an elongated sheath or pocket closed at one end **16***a*, and open at the other end to the atmosphere with a flaring or funnel-like mouth **16***b*, 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** and **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. This tear seal also maintains the sheath in fixed position with respect to its container. The thickness and curvature of the materials in FIGS. **7, 8, 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. The upper and lower paper strips act as buffers between the die and the bed of the press, and to some extent prevent the total destruction of the thermoplastic material by the heat induced therein, and these buffer strips 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 impression line **16** also serves as a visual guide for the insertion of the thermometer into the sheath-package. The layer or coating of the lubricant L does not substantially affect the making of a good seal, and the seal so made is just as good and as strong as if a lubricant had not been used.

The adjacent or meeting faces of the strips **10** and **12,** and those of the strips **11** and **14,** respectively, may be sterilized by subjecting these surfaces to ultra-violet exposure right up to the moment these surfaces are joined during assembly, and this sterilization is preferably carried out on the facing surfaces of the strips **10** and **11** after they have been coated with the coating **13.** Sterilization may be carried out during the manufacturing process, as just described, or after the package has been completely fabricated. Both methods 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,** FIGS. **5** and **6,** from the two strips **12** and **14,** 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 **16***b* thereof, the mouth being open, the exterior surfaces **12***a*, **14***a* as shown in FIG. **7,** being closed to the atmosphere along the sides and at one end by the seal **16,** and at the ends of the strips by the seals C, C', as best shown in FIGS. **2, 8** and **9.**

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. The coating on the paper strips, alternatively, may be of a pressure sensitive type cement.

The sheath-package may be freely handled without special precautions as to the outer surfaces of the sheath **20,** FIG. **5,** are wholly enclosed within the sterile surfaces of the outer cover strips **10, 11,** until the cover is stripped away as disclosed in FIGS. **4, 5** and **6,** to expose the sterile sheath for insertion into any body cavity. 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 thermometer. 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 sheated thermometer **22** has the additional advantage that should the thermometer break, as sometimes occurs, in the body of a patient, removal of the entire contents is simplified by the fact that the broken glass pieces are held by the sheath. 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, FIG. **5,** is stripped away.

It will be understood that a variety of tools and instruments requiring sterilization in use can be encapsulated in a similar manner 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 object **22** may be inserted into the mouth of the sheath at **16***b* and pushed inwardly until it fully occupies the sheath and is stopped by the end seal **16***a*. 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 tear seal line **16,** leaving the irradiated and sterile exterior surfaces **12***a*, **14***a* of the sheath, FIG. **7,** exposed, as at **20,** FIGS. **5** and **6.** 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. In some applications the sheath will be lubricated and may be medicated along its exposed surface. After use, the sheath is easily slipped off the instrument and disposed of. The same thermometer is immediately available for re-use on the same or another patient without sterilization, by insertion into another sheath-package according to this invention and stripping the outer cover therefrom as described above.

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 must 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 open end of the sheath is 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, whereby to reduce the cost of the individual sheath-package to a negligible (fraction of a cent) amount, so that it 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 of FIGS. **1** and **2,** which comprises four separate sheets of material, is as follows.

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, 12** and **11, 14,** respectively, are subjected to the action of ultra-violet rays before they are brought into contact with one another, but after the coating **13** and lubricant L have been applied to the strips **10, 11.**

The lubricant L is applied by any suitable coating mechanism such as a roller or knife or other coater mechanism (not shown), supplied by a reservoir (not shown) subject to the action of ultra-violet rays. As the webs of the material are fed past the sterilizing mechanism (not shown) the parts are exposed to such rays. The lubricant 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 insure 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 the action of ultra-violet rays in a well known manner for a time sufficient to effect complete sterilization.

After the strips **10, 12** are brought into contact, a continuous marginal seal C, FIGS. **1** and **2,** is formed adjacent both edges. After the strips **11** and **14** are brought into contact, a continuous marginal seal C', FIGS. **1** and **2,** is formed adjacent one edge of the combined strips. The layers **10, 12** forming the upper strip, are then placed over the layers **11, 14,** forming the lower strip, in such fashion that the side edges of the upper layer or strip are offset laterally from the adjacent edges of the adjacent layer or strip to achieve a relationship between the strips as best shown in FIG. **2,** wherein tabs A', B' are provided, one at each opposite end of the superposed strips. The combined strips are then subjected to the repeated action of a die in the press mentioned to form the 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 strip of FIG. **10** along the lines **34.** After cutting, each strip will have a tab A', B', respectively, at its end, as discussed 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 pelled 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, coated with the lubricant, exposed for use.

I claim:

1. A sheath-package for surgical instruments and the like comprising superposed laminations of material formed into two separate layers, the inner layer of each lamination forming a sheath for the reception of an instrument, said sheath having an open end and a closed end, the outer portions of each lamination comprising a cover for said sheath, said laminations being joined together by a seal defining said sheath, said seal between said laminations being constructed so that said outer portions are strippable from said sheath along said seal upon the insertion of an instrument into said sheath.

2. The device of claim **1** wherein said laminations are formed into strips.

3. A flexible sheath package comprising a flexible sheath having an open mouth, and being of a size and shape to sheathe a thermometer, said sheath being formed from a first pair of strips of sheet material bonded together along a seal line to define said sheath, an outer cover enclosing outer surfaces of said sheath, said cover comprising a second pair of strips of differ-

ent sheet material than said first pair of strips, said first pair of strips being sandwiched between said second pair of strips to enclose said sheath, each of the strips of said second pair having an inner face in face-to-face contact with an outer face of the corresponding strip of said first pair, a surface area of the inner face of each of the strips of said second pair being bonded to a corresponding surface area of the outer face of the corresponding strip of said first pair across the ends of said strips at the mouth of said sheath, said cover being open at the mouth of said sheath so that the sheath package of said sheath and said cover is open to the interior of said sheath through the mouth thereof, whereby a thermometer may be readily inserted into such sheath while outer surfaces of said sheath are still enclosed by said cover, said cover having defined therein a separation line along which the material strength of said cover is weaker than remainder of said cover, said separation line comprising means causing severing of said cover along said separation line to expose said sheath when said cover is stressed in a predetermined manner after a thermometer has been inserted in said sheath.

4. A flexible sheath package as recited in claim **3** wherein the exterior surface of said sheath is sterile and said cover comprises means to protect the sterility of the exterior surface of said sheath until said sheath is exposed.

5. A flexible sheath package comprising two flexible layers sealed together along a seal line to define a sheath, a cover enclosing the outer surfaces of said layers within said seal line, the seal between said inner layers being constructed and said cover being fixed to said layers in a manner so that the outer portions of said flexible layers outside of said seal line is torn away from said sheath when said outer layer is peeled from said sheath with an instrument within said sheath.

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 3,847,280
DATED : November 12, 1974
INVENTOR(S) : George W. Poncy

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

Claim 5, line 8, "outer layer" should be --cover--.

Signed and Sealed this

Fifteenth Day of *August 1978*

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

DONALD W. BANNER
Commissioner of Patents and Trademarks