Dec. 22, 1964 P. E. REGAN, JR 3,162,307

SURGICAL PACKAGE

Filed July 10, 1963 3 Sheets-Sheet 1

Fig. 1.

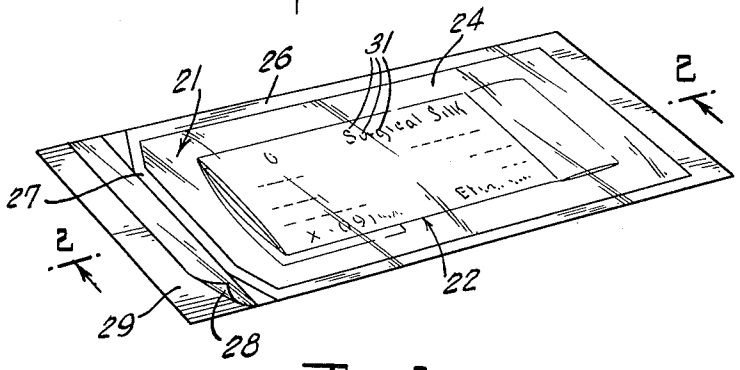


Fig. 2.

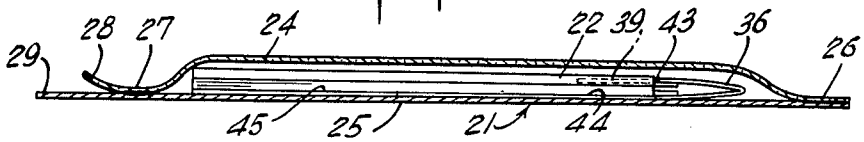


Fig. 3.

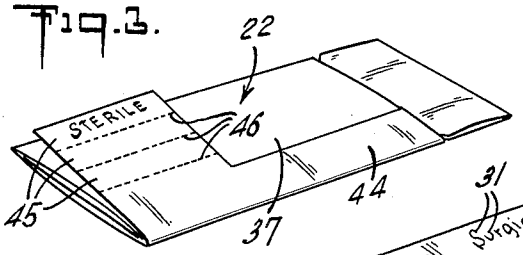


Fig. 4.

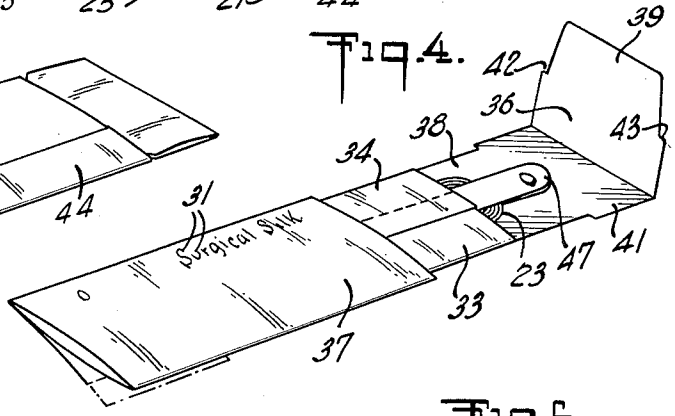


Fig. 5.

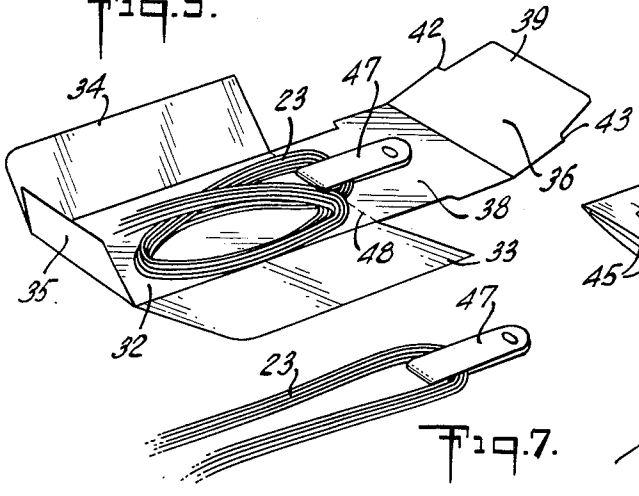


Fig. 6.

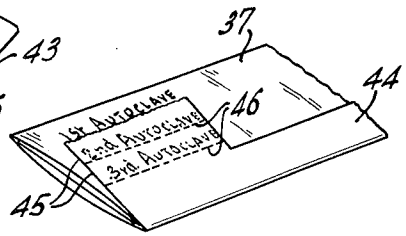


Fig. 7.

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Fig. 8.

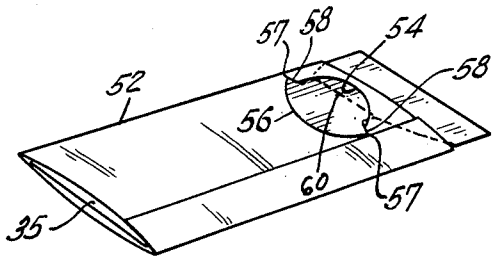


Fig. 9.

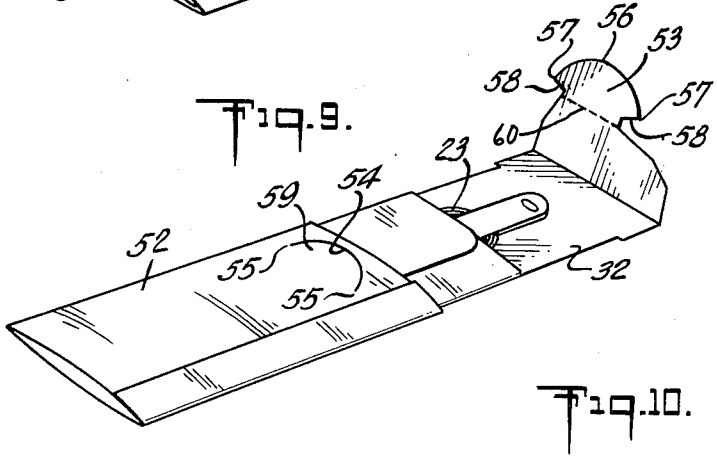


Fig. 10.

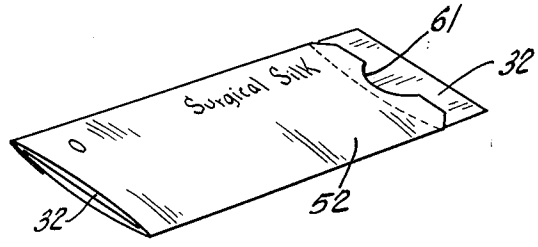
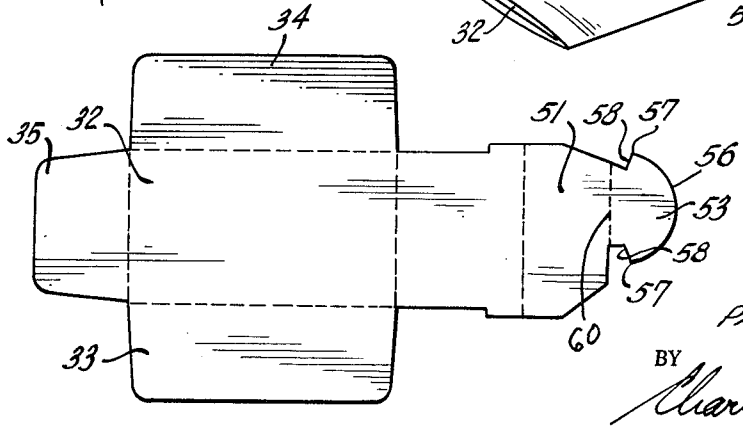


Fig. 11.



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Fig. 12.

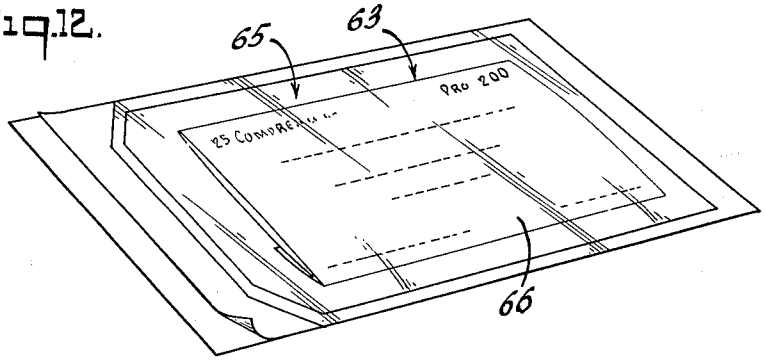


Fig. 13.

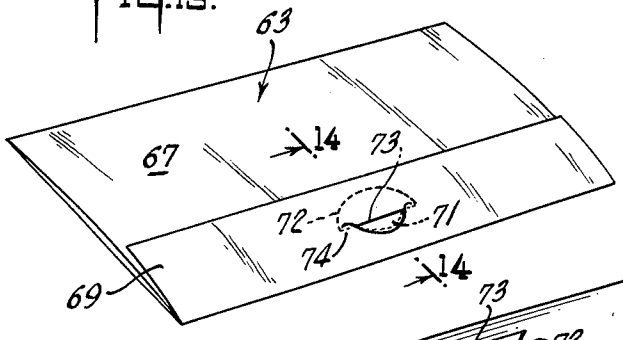


Fig. 14.

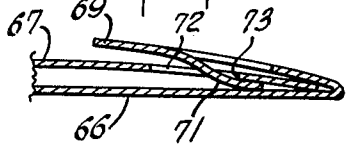
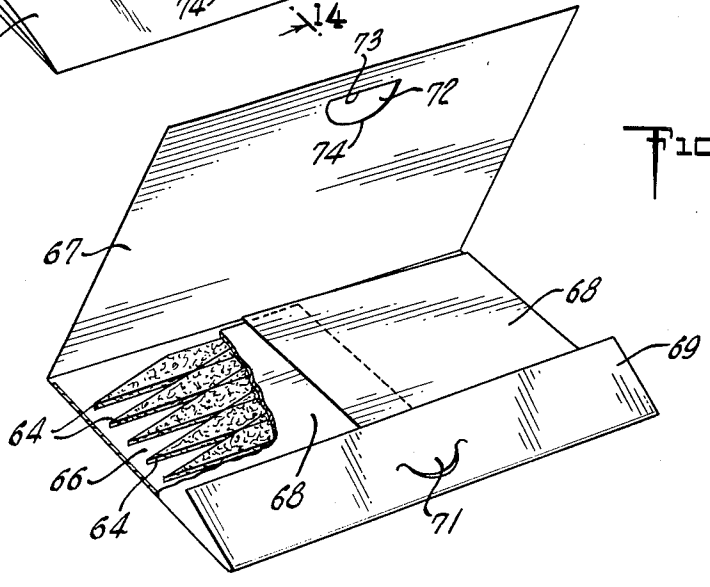


Fig. 15.



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United States Patent Office 3,162,307 Patented Dec. 22, 1964

3,162,307
SURGICAL PACKAGE

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Filed July 10, 1963, Ser. No. 293,969
13 Claims. (Cl. 206—63.3)

The present invention relates to sterile surgical packages, more particularly to sterilized and sterilizable packages for surgical products such as sutures, needles, and the like.

Surgical products of this type commonly have been packaged in double enclosures both of which are hermetically sealed. At one time it was most common to package products, such as sutures, inside sealed glass tubes which, in turn, were enclosed within a sealed can or jar. This type of package has been virtually replaced wtih sealed double envelopes, i.e., the sterile product is sealed inside an inner envelope and the inner envelope containing the product is sealed inside a second or outer envelope.

Normally, double envelope packages of the type referred to above have employed thermoplastic materials and have been sealed by heat or by a thermoplastic adhesive. In most cases this means that the packages can be sterilized only by irradiation or by sterilizing gases. After sterilization by the manufacturer, all parts of the package are sterile with the exception of the exposed surfaces of the outer envelope. Just prior to use, the outer envelope is opened to enable the sterile inner envelope to be placed in a sterile zone in a surgical area. If the inner envelope is not opened at all, it remains as a sterile enclosure for the product. However, its outer surface must be resterilized before it can again be placed in a sterile zone. Since most hospitals have only heat sterilizing equipment such as a steam autoclave, the inner envelope must be returned to the manufacturer for resterilization.

It may be desirable to enclose a quantity of sterile products such as several suture lengths, needles, surgical sponges, or the like, in one inner envelope. However, if this is done the inner envelope must be capable of being reclosed prior to resterilization in order to protect the product. This is not possible with the conventional sealed inner envelope.

According to the present invention, a double envelope package for sterile surgical products is provided which has an inner envelope which is resterilizable whether or not it is opened; and which is re-useable because it can be reclosed and resterilized after it is opened. The package of this invention comprises a conventional outer envelope and a stiff fiber-board inner envelope. The outer envelope preferably includes one transparent panel for viewing the inner envelope and reading printing presented on one side of the inner envelope. The outer envelope is hermetically sealed by the manufacturer to provide a sterile package, and the inner envelope is detachably closed by mechanical means.

The inner envelope comprises a panel on which the product is adapted to be positioned and which covers one side of the product, a flap foldably connected to one edge of the panel and adapted to be folded over the product to sandwich the product between the panel and the flap, and detachable mechanical means for holding the flap and the panel in their folded over positions with respect to one another. Means also are provided for holding the product on the panel and preventing movement of the product beyond the panel in a direction parallel to the above referred-to folding edge. Preferably, these holding means are in the form of holding flaps at opposite ends of the panel which fold inwardly over the panel at right angles to the first-mentioned flap.

In one embodiment, the detachable mechanical means may be in the form of a slot and a detent presented by corresponding flap and panel portions. The detent or the slot may extend from an additional latching flap foldably connected to the panel or one of the other flaps.

In a preferred embodiment of this invention for suture packages, the first-mentioned flap is foldably connected to the bottom edge of the panel and is adapted to cooperate with a top flap foldably connected to the top edge of the panel for holding the product. In this embodiment, the panel has a dispensing section at one end and the top and bottom flaps terminate short of the dispensing section. Opposite side flaps also are provided and the side flap attached to the dispensing section, hereinafter sometimes called "the opening flap," preferably terminates short of the top and bottom flaps. All of the flaps are adapted to be held in their folded down position by a fiber-board sleeve which slides over the panel and the flaps. When the sleeve is moved with respect to the panel to uncover the opening flap only, this flap may be folded upwardly to expose one end of the sterile product positioned on the dispensing section of the panel for ready access thereto. One of the advantages of this embodiment is that a sterile product such as a coil of sutures may be placed on the panel and fixed in position very easily merely by folding down the flaps, and then the flaps may be held in position merely by inserting the panel into the sleeve.

In still another embodiment of this invention, the package just described is modified by the addition of means for securing the panel in the sleeve to provide a tamper-proof feature. The opening flap on the panel may be modified to present a detent adapted to cooperate with a slot defined in one side of the sleeve to form the latch. The detent is designed so that it is easily inserted in the slot but is difficult to remove. Thus, the inner envelope normally is opened by breaking off the end of the detent, thereby giving a clear indication that the envelope has been used or tampered with.

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

FIG. 1 is a view in perspective of a sterile package according to a preferred embodiment of this invention for packaging sutures;

FIG. 2 is a somewhat enlarged view, partly in section and partly in elevation, taken along the line 2—2 of FIG. 1;

FIG. 3 is a view in perspective of the back of the inner envelope of the package of FIG. 1;

FIG. 4 is a view in perspective of the front of the envelope of the package of FIG. 1 showing the positioning panel partially removed therefrom with its opening flap folded upwardly to expose the end of a coil of sutures;

FIG. 5 is a view in perspective of the positioning panel and flaps of the envelope of the preceding figures showing all of the flaps folded open;

FIG. 6 is a view in perspective of the back of one end of the envelope of the preceding figures showing the removal of the first resterilization tab;

FIG. 7 is a view in perspective of the tied end of the suture loop after the sutures have been straightened out;

FIG. 8 is a view in perspective of the back of an inner envelope according to a somewhat different embodiment of the invention and showing a latch for securing the positioning panel to the sleeve;

FIG. 9 is a view in perspective of the embodiment of FIG. 8 and showing the detent presented by the opening flap before it is inserted through the slot in the sleeve;

FIG. 10 is a view in perspective showing the front of the envelope of FIG. 8;

FIG. 11 is a plan view of the positioning panel and flaps of the envelope of FIG. 8 showing all of the flaps open;

FIG. 12 is a view in perspective of a package according to a still different embodiment of this invention;

FIG. 13 is a view in perspective of the inner envelope of the package of FIG. 12;

FIG. 14 is an enlarged sectional view taken along the line 14—14 of FIG. 13 and showing the latch for holding the flaps down over the positioning panel of the envelope;

FIG. 15 is a partially cut-away view in perspective of the envelope of the preceding figures showing the top and bottom flaps partially open.

Referring to FIGS. 1–7 of the drawings, there is shown a package according to a preferred embodiment of this invention for packaging sutures, which comprises a hermetically sealed outer envelope **21**, a stiff fiber-board inner envelope **22** and a sterile surgical product, i.e., a coil of sutures **23**, inside the inner envelope. The outer envelope **21** comprises a transparent top panel **24** and a bottom panel **25** sealed together along their edges to provide a hermetically sealed strippable sterilizable enclosure for the sleeve **22** and its contents. The top and bottom panels **24** and **25** may be formed of any sheet materials which will act as the desired barriers for a sterilizable package of this type and which may be sealed together as shown and stripped apart as will be described hereinafter. Typically, the transparent top panel **24** is a laminate of Mylar and polyethylene and the bottom panel **25** is a laminate of foil and paper held together by a polyethylene adhesive. The top and bottom panels **24** and **25** are superimposed with the polyethylene side of the top panel **24** in contact with the paper side of the bottom panel **25** and the panels are heat sealed to one another along a strip **26** which forms a shallow peak **27** at one end of the package. The peak **27** is spaced somewhat from the adjacent ends of the panels to provide stripping flaps **28** and **29** for opening the package. The flaps **28** and **29** are pulled apart to separate the panels and break the seal when it is desired to remove the inner envelope **22** from the outer envelope **21**. Printing **31** is applied to one side of the inner envelope **22** to identify its contents and the inner envelope is inserted so that it may read through the transparent side **24** of the outer envelope **21**. The resulting package may be sterilized by irradiation after the outer envelope is sealed, or by the use of a sterilizing gas such as ethylene-oxide which enters the mouth of the outer envelope before it is sealed, or by any other suitable means.

The inner envelope **22** is formed from relatively stiff sterilizable sheet material such as virgin paperboard approximately 0.01 inch thick, and the exterior of the inner envelope preferably is treated so that it is water and blood-stain resistant. The inner envelope **22** comprises a positioning panel **32** on which the sutures are adapted to be positioned and which covers one side of the sutures, a bottom flap **33** foldably connected to the bottom edge of the panel **32** and adapted to be folded over the sutures **23** to sandwich the sutures between the panel **32** and the flap **33**, and a top flap **34** foldably connected to the top edge of the panel for cooperating with the bottom flap **33** in holding the sutures in position on the panel. A first side flap **35** and an opening flap **36** also are foldably connected to the opposite side edges of the positioning panel **32**. All of the flaps are adapted to be folded down over the panel **32**, and a fiber-board sleeve **37** is provided for fitting over the panel **32** and holding the flaps in their folded down positions thereon, as shown in FIGS. 1 and 3.

The positioning panel **32** has a dispensing section **38** at one end thereof, and the top and bottom flaps **34** and **33** terminate short of the dispensing section. The opening flap **36** is attached to the panel at the end of the dispensing section **38** so that the opening flap **36** is adapted to fold down over the dispensing section **38**. However,

when folded down on the panel **32**, the opening flap **36** terminates short of the top and bottom flaps **34** and **33** so that the opening flap **36** does not tuck under the top and bottom flaps **34** and **33** and therefore is capable of being folded in and out of position over the dispensing section **38** independently of the top and bottom flaps. However, when the positioning panel **32** is fully inserted in the sleeve **37**, the sleeve covers the leading end **39** of the opening flap. The leading end **39** of the flap **36** is tapered so that it fits easily into the sleeve **37** and the outermost portion **41** of the dispensing section **38** and a corresponding portion of the opening flaps **36** are widened to prevent the sleeve **37** from passing completely over the dispensing section **38**. Thus, top and bottom portions **42** and **43** of the opening flap immediately adjacent the inclined leading end **39** thereof are adapted to engage the top and bottom edges of the sleeve **37** when the sleeve is pressed over the panel **32** to hold the sleeve in position with respect thereto.

The sleeve **37**, itself, is formed from a single sheet of paperboard which is folded and secured together by an adhesive along a folded strip **44** facing the back of the sleeve. Also attached to the folded strip **44** is a set of three sterilizing tabs **45**. The tabs **45** are part of a flap which extends over one end of the sleeve and are formed by three spaced perforated tear lines **46** which are adapted to be used for detaching the tabs **45** successively from the sleeve. The top tab is printed with the word "sterile," meaning that the sleeve and contents is sterile and in the condition in which it is received from the manufacturer. Underneath the first, second and third tabs on the face of the sleeve **37**, the designation "first autoclave," "second autoclave," and "third autoclave," are printed. Each time the inner envelope **22** is sterilized one of the tabs **45** is removed to expose the appropriate designation and thereby indicate how many times the envelope has been resterilized.

In use, the outer envelope **21** is stripped open and the inner envelope **22** is deposited in a sterile zone in an operating area. At this point the inner envelope **22** is sterile inside and out. If the sutures **23** inside the inner envelope are needed, the sleeve **37** may be drawn partially off the panel, as shown in FIG. 4, to uncover the end of the opening flap **36**. Then, the opening flap **36** is folded back to expose the end of the suture loop **23** or a holding tab **47** attached thereto. For convenience at this point, a perforated fold-line **48** is provided in the panel itself at the inner end of the dispensing section **38** so that the dispensing section and the opening flap **36** may be folded under the remainder of the positioning panel **32** in a reverse bend to present the holding tab **47** at the end of the suture loop free of any package structure. The loop of sutures **23** then may be removed easily from the package by drawing it outwardly by the tab **47**. In the package shown in FIGS. 1–7, several sutures **23** are included in the loop. In use the suture loop may be held by the tab **47** and then stretched or shaken so that one or more of the sutures may be removed easily therefrom. If all of the sutures **23** are not used, those remaining may be looped and placed on top of the positioning panel **32**, as shown in FIG. 5, and positioned on the panel by folding the first side flap **35** and the bottom and top flaps **33** and **34** successively down over the loop. Then the opening flap **36** is folded down over the panel **32** and the panel is inserted in the sleeve **37**. At this point, the sutures **23** are completely enclosed inside the inner envelope **22** and the inner envelope **22** is ready for resterilization. After resterilization as described above, the sutures **23** are protected against contamination by the inner envelope.

Referring to FIGS. 8–11, there is shown a somewhat different embodiment of an inner envelope according to this invention. The positioning panel **32**, the top flap **34**, the bottom flap **33**, and the first side flap **35** are substantially identical with the same parts of the envelope **22** of the embodiment of FIGS. 1–7. However, a modified

opening flap 51 and sleeve 52 have been incorporated. The purpose of this modification is to provide means for latching the positioning panel 32 in position in the sleeve 52 and provide a tamper-proof feature. Since in this embodiment it may not be desirable to resterilize the inner envelope, the sterilization tabs of the sleeve of FIGS. 1–7 and corresponding indicia also have been removed from the sleeve 52.

The latching means comprises two parts, i.e., a detent 53 presented by the opening flap 51, and a cooperating slot 54 in one side of the sleeve. In the embodiment of FIGS. 8–11, the slot 54 is cut in the back side of the sleeve 52 adjacent one end thereof. The slot 54 is curved in the shape of a C with its convex side adjacent the end of the sleeve. Thus, the slot 54 is inclined away from its ends 55 toward the end of the sleeve. The detent 53 is positioned on the opening flap 51 so that it will be aligned with the slot 54 when the flap 51 and the sleeve 52 are brought together. The detent has a convexly curved leading edge 56 which is inclined from its center toward each of its ends 57, and presents trailing latching portions 58 behind the ends 57 of its leading edge 56. The slot 54 in the sleeve is wider across its ends 55 than the detent 53 is across its ends 57, so that the detent may be inserted easily into and through the slot when the panel 32 is inserted in the sleeve 52 with its flaps folded down. Preferably, the detent 53 is inserted through the slot 54 from the underside of the slot so that the detent appears outside the sleeve 52 when the panel is latched to the sleeve, as shown in FIG. 8.

After the detent 53 passes through the slot 54, the tongue-like portion 59 of the sleeve defined by the slot tends to press the detent 53 outwardly above the level of the sheet making up that side of the sleeve, as shown in FIG. 8. When it is attempted to remove the panel from the sleeve, the latching portions 58 of the detent 53 catch on the inclined curved edge of the slot 54 and prevent further outward movement of the panel. Because of the upward pressure of the tongue-like portion 59 on the detent 53, it is very difficult to remove the dentent 53 from the slot 54 without tearing the detent. To provide a tamper-proof feature, instructions may be printed on the sleeve 52 indicating that the detent 53 should be torn to allow removal of the panel 32 from the sleeve 52. Obviously, if the detent 53 is torn, it will be a clear indication that the package has been used or tampered with. A perforated tear line 60 is provided to facilitate tearing off and removing the detent 53. A crescent shaped recess 61 is provided in the leading edge of the opposite side of the sleeve 52 to that containing the slot 54 to facilitate gripping the panel 32 for removing it from the sleeve.

For some uses, it might be advisable to fold the opening flap 51 down over the top of the sleeve 52 and secure the detent 53 to the sleeve by applying a piece of adhesive tape, not shown, over the end of the detent. In this case, the envelope would be opened by tearing along the line 60 to allow the sleeve 52 to be separated from the panel 32

A still different embodiment of the package of this invention is shown in FIGS 12–15. A folded fiber-board inner envelope 63 containing a number of compressed cellulose sponges 64 is packaged inside a hermetically sealed sterilizable strippable outer envelope 65 of the type shown in FIGS. 1 and 2 and described hereinbefore. As described in connection with the embodiment of the preceding figures, the inner envelope 63 preferably is formed from a relatively stiff sterilizable sheet material such as virgin paperboard approximately 0.01 inch thick and treated to be water and blood-stain resistant. The inner envelope 63 comprises a positioning panel 66 covering one side of a layer of sponges 64, a top flap 67 foldably connected to one edge of the panel 66 for preventing movement of the sponges longitudinally of the panel, and detachable mechanical means for holding the top flap 67 and the holding flaps 68 in their folded over position with respect to one another and with respect to the panel 66. As shown in FIG. 15, the holding flaps 68 are adapted to be folded down over the sponges 64 and the top flap 67 is adapted to be folded over the holding flaps to secure them in position. The above-referred-to detachable mechanical means comprises a relatively short latching flap 69 foldably connected to the edge of the positioning panel 66 opposite to the edge connected to the top flap, a detent 71 presented by the latching flap, and a corresponding cooperating slot 72 in the top flap 67 for receiving the detent 71 when the latching flap is folded down over the top flap, as shown in FIGS. 13 and 14. The cooperating slot 72 has one straight edge 73 adjacent the top edge of the top panel and a semicircular curved edge 74 connected thereto. The detent 71, which is defined by a C-shaped cut in the latching flap 69, is adapted to be inserted easily in the cooperating slot 72 merely by pressing the detent 71 downwardly with one finger to advance it beyond the straight edge 73 of the slot. Similarly, the detent 71 may be removed from the slot simply by bending the portion of the latching flap between the detent and the edge of the flap so as to swing the detent out of the cooperating slot. The latching means may be operated in this manner any number of times for opening and closing the inner envelope 63 to provide access to its contents and for resterilizing the envelope and the products remaining therein.

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 comprising an outer envelope, a stiff fiber-board inner envelope and a sterile surgical product inside said inner envelope, said outer envelope being hermetically sealed and comprising at least one transparent panel, and said inner envelope comprising

(i) at least one panel covering said product,

(ii) a flap foldably connected to one edge of said panel and adapted to be folded over said product to sandwich the product between the panel and the flap,

(iii) means for holding said product and preventing movement thereof beyond said panel in a direction parallel to said edge, and

(iv) detachable mechanical means for holding said flap and said panel in their folded over position with respect to one another,

the outside surface of at least one of the panels of said inner envelope bearing printing describing said product and said printing being readable through the transparent panel of said outer envelope, and said inner envelope being capable of being sterilized at temperatures of at least about 250° F. in the presence of live steam without deterioration or detracting from the effectiveness of said inner envelope.

2. A sterile surgical package according to claim 1, wherein said holding means comprise a pair of opposed holding flaps foldable inwardly from opposite edges of one of the panels of said inner envelope and said holding flaps also are adapted to be retained in their folded position by said detachable mechanical means.

3. A sterile surgical package according to claim 1, wherein said detachable mechanical means comprises a latching flap foldably connected to one of said first-mentioned panel and flap and presenting therewith a corresponding slot and detent for holding said first-mentioned panel and flap in their folded over position.

4. A sterile surgical package according to claim 1, wherein said detachable mechanical means is in the form

of a fiber-board sleeve which fits over said first-mentioned panel and flap to hold them in their folded over position.

5. A sterile surgical package according to claim 4, which further comprises a cooperating flap foldably connected to an edge of said first-mentioned panel opposite to the edge connected to said first-mentioned flap, and said holding means comprises opposed holding flaps foldable inwardly in a direction normal to the folding of said cooperating flap, said first-mentioned flap, said cooperating flap and at least one of said holding flaps overlapping one another when they are in their folded over position, and all of said flaps being held in their folded over position by said sleeve.

6. A sterile package according to claim 5 wherein one of said holding flaps does not overlap any of said other flaps and therefore is adapted to be folded independently of the other flaps to expose one end of the surgical product when the sleeve is partially withdrawn to uncover the said nonoverlapping holding flap.

7. A surgical package which comprises a stiff heat-sterilizable envelope and a surgical product inside said envelope; said envelope comprising a panel on which the product is adapted to be positioned; said panel having a dispensing section at one end; top and bottom flaps foldably connected to the top and bottom edges of said panel and terminating short of the dispensing section thereof; a first side flap foldably connected to the side edge of said panel opposite its dispensing end, said top and bottom flaps and said first side flap being adapted to overlap one another at least partially when they are folded down over said panel; an opening flap foldably connected to the side edge of said panel at the dispensing end thereof; and a sleeve adapted to slide over said panel and said flaps when the flaps are folded down over said panel and hold said flaps in their folded down position, whereby said sleeve may be moved with respect to said panel to uncover said opening flap and said opening flap may be folded upwardly to expose one end of the product positioned on said panel for ready access thereto.

8. A surgical package according to claim 7, wherein top and bottom portions of said opening flap are adapted to engage the top and bottom edges of said sleeve when said sleeve is placed over said panel to hold the sleeve in position with respect thereto.

9. A surgical package according to claim 7, wherein the dispensing section of said panel is adapted to be folded under the remainder of the panel to facilitate dispensing of the surgical product when the opening flap is folded upwardly.

10. A surgical package according to claim 7, wherein means is provided for securing said opening flap to said sleeve when the sleeve is in position over said panel and said package is adapted to be opened by tearing a portion of said opening flap.

11. A surgical package according to claim 10, wherein said opening flap presents a detent at its inner end and a slot is defined in one side of said sleeve for cooperating with said detent for locking the sleeve on said panel when the detent is inserted in said slot.

12. A surgical package according to claim 11, wherein the detent has an inclined leading edge and a trailing latching portion and the cooperating slot is inclined away from its ends toward the end of the sleeve, said slot being wider across its ends than said detent but the latching portion of said detent being adapted to catch on one edge of the slot when withdrawal of the detent from the slot is attempted.

13. A surgical package according to claim 7, which further comprises a hermetically sealed outer envelope enclosing said heat-sterilizable envelope, and wherein the interior and contents of said outer envelope are sterile.

No references cited.