

[54] **PEELABLE SURGICAL PACKAGE**

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[58] Field of Search...206/46 ST, 46 SG, 56 AA, 63.2 R,
206/DIG. 17; 229/51 WB, 51 TS, 85, 87 R,
87 A

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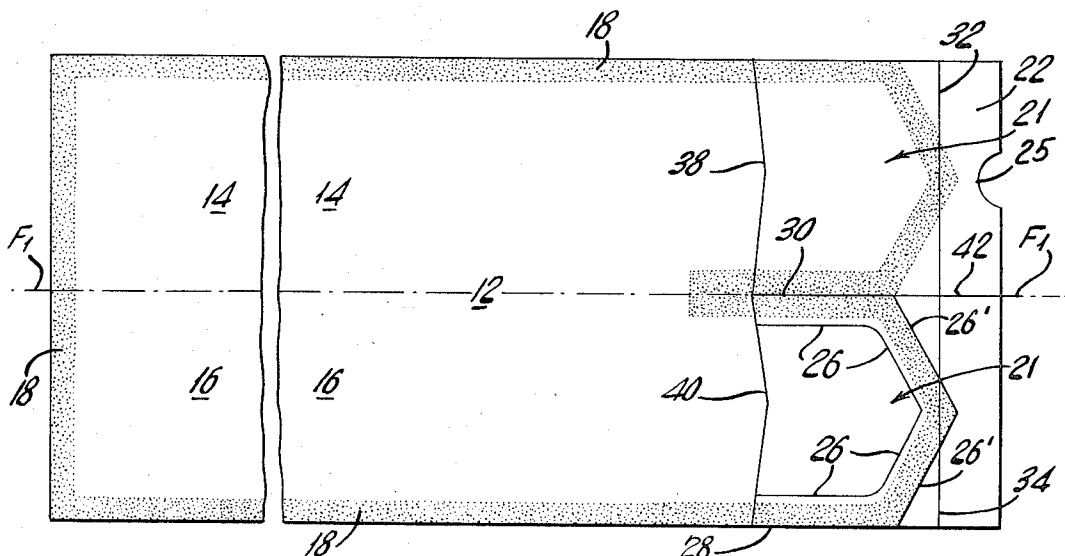
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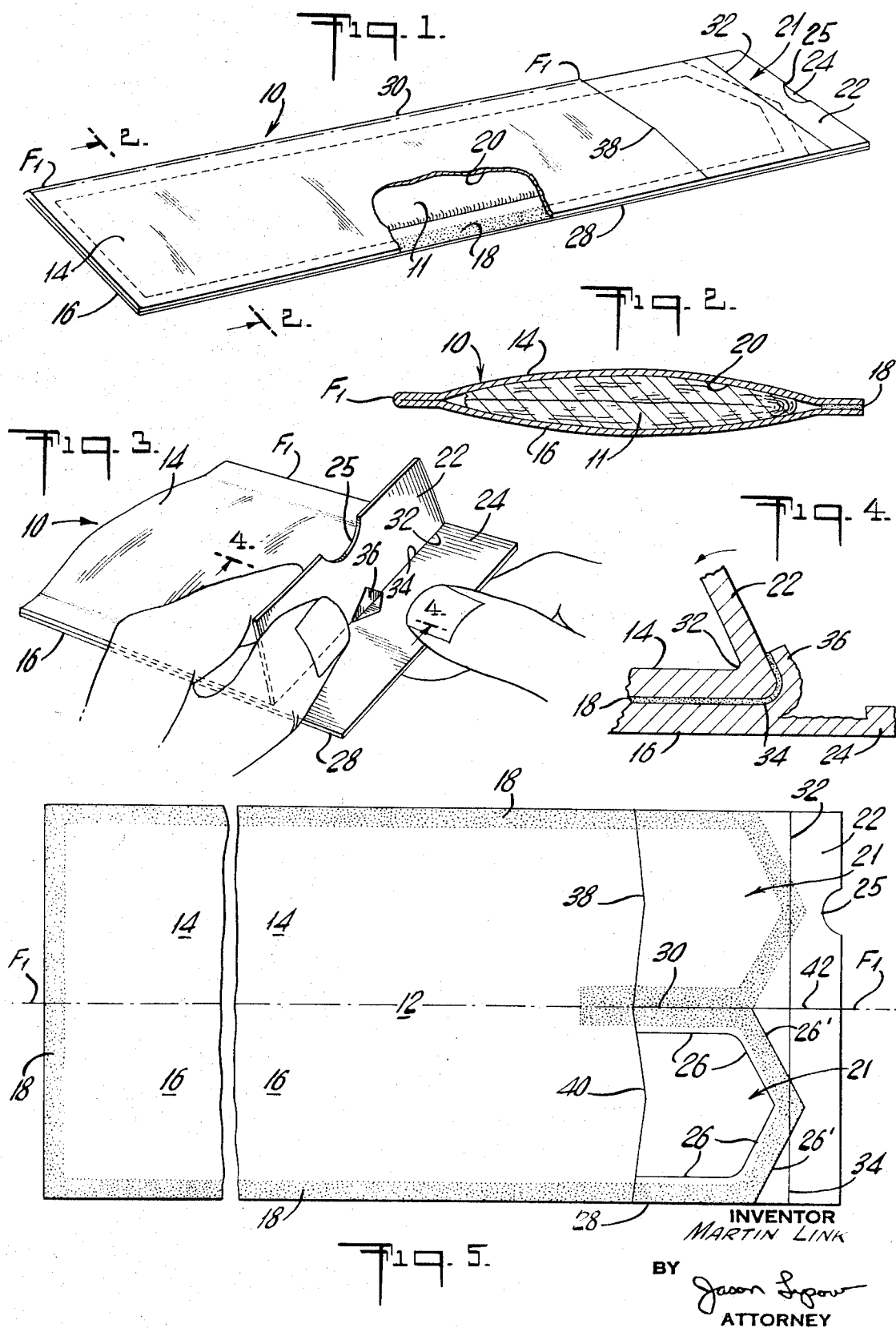
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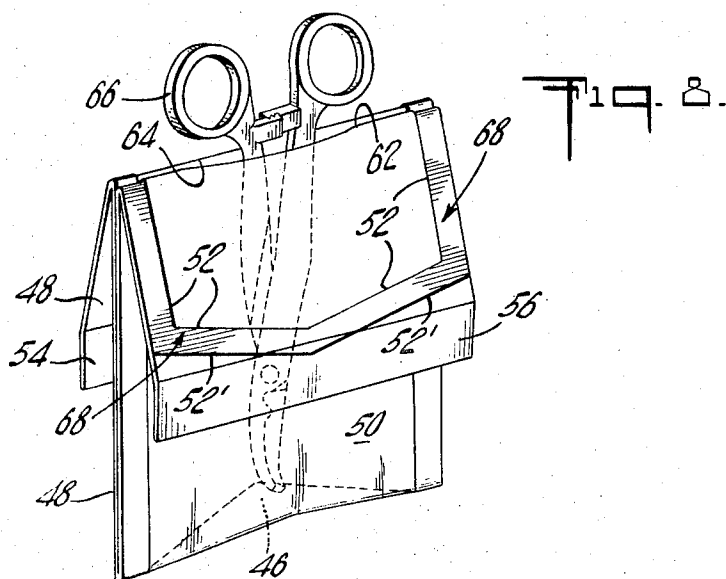
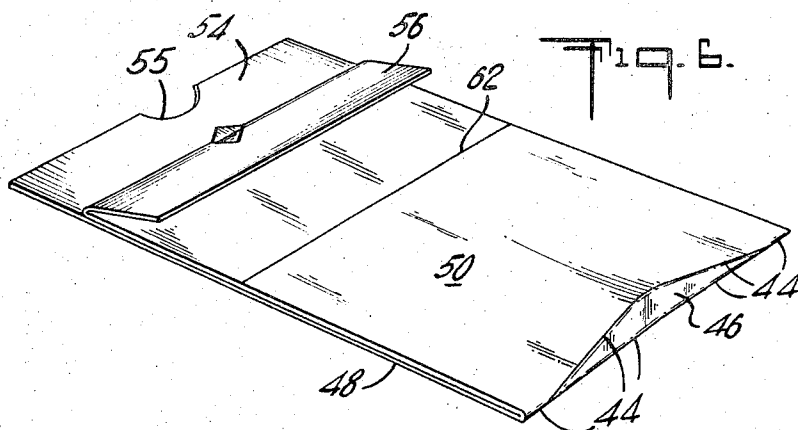
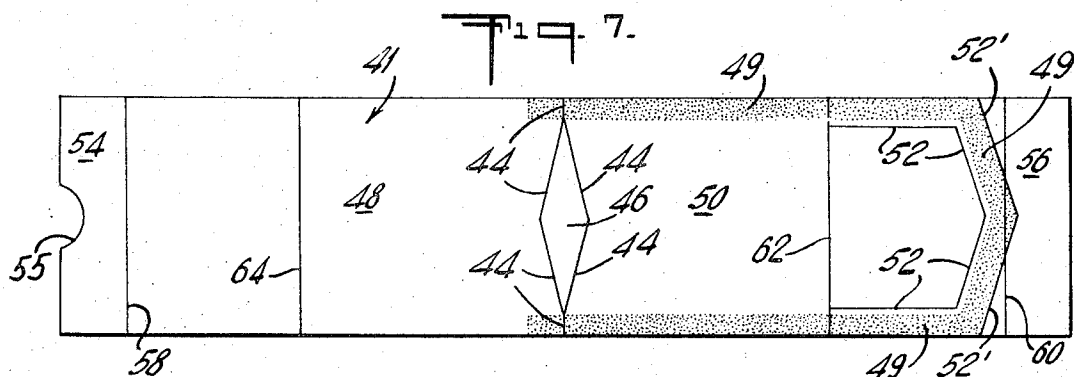
[57] **ABSTRACT**

A peelable package is provided for containing surgical articles and devices which may be sealed and sterilized within the package and subsequently removed therefrom with a minimum probability of contamination by the unsterile outer surfaces of the package. The package comprises two panels sealed together at their marginal portions to form a chamber therebetween having a sealed mouth and adjacent sealed edges. A section of the sealed marginal portions of one panel, extending across the mouth and along the adjacent edges of the package, is weakened, as by scoring, so that upon the package, the weakened section of the panel will delaminate to the depth of the scoring in preference to yielding at the seal. The package is additionally provided with tabs extending beyond the sealed mouth. The tabs include bending scores which allow them to be folded away from the sterile portions of the package and additionally initiate the delamination of the panel when opening the package.

15 Claims, 8 Drawing Figures







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PEELABLE SURGICAL PACKAGE

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention concerns bacteria-impervious packages for surgical, obstetrical or other medical articles as, for example, surgical drapes, surgical instruments and surgical sponges. Often, such packages are designed so as to be at least partially pervious to gases, thereby allowing the article to be packaged and then sterilized within the package.

In surgical procedures, a great deal of care is taken to prevent the contamination of the articles used during the course of an operation. An operating team includes an unsterile nurse, whose function is to open packages containing such articles and present them to a sterile nurse in a manner whereby the sterile nurse may remove the contents without contacting them with the unsterile outer surfaces of the package. The present invention therefore concerns a package which will allow for rapid opening by the unsterile nurse and presentation of the opened package to the sterile nurse so as to allow her to remove the contents without contacting them with the unsterile surfaces of the package.

While the present invention is described herein with reference to the packaging of surgical devices, it should be clearly understood that the invention is not to be limited thereto. Instead, the invention may be embodied in any packaging requirement wherein the features of rapid opening and easy removal of the package's contents, as described herein as appertaining to this invention, are desirable.

2. Description of the Prior Art

Various means are available for opening sterile packages as, for example, the simple tear-off opening. Generally, this is used for opening sterile packages in the form of envelopes, which are color-marked to indicate the area which may be torn off to provide an access opening to the contents without affecting the sterility of the contents. Alternatively, a tear string is provided to sever the envelope at the appropriate place. The contents are then removed from the package by means of a forceps or otherwise, exercising great care to avoid contacting the contents with the outward-facing surface areas surrounding the access opening, as these surfaces are unsterile. It has been found difficult to so remove the contents with the rapidity desired, while simultaneously maintaining sterility.

Sterile packages have also been provided with integral tear strips which, when removed, not only sever the packages but, additionally, provide delaminated margins on the outward-facing surfaces of the packages adjacent to the severed edges. It has been found that care must be taken in the removal of the tear strip to avoid failure of the strip before the delamination is completed and the package is completely open. While an area of sterile surface adjacent to the access area is provided by this method, the sterile area is limited in width to the delaminated margin which, of necessity, must be narrow to prevent failure of the tear strip. Accordingly, the degree of care required in removing the contents of the package without contacting the unsterile surface surrounding the access area, while lessened, is still inconveniently great.

Another opening technique used is to form a package by sealing panels together with adhesive which, while forming a strong seal, is readily separable so that the package is peelable within the confines of the adhesive layer. The package is opened by peeling apart the panels and bending them back so as to provide a large access area, surrounded by large sterile surfaces. Drawbacks encountered in using this technique are, firstly, the peeling is essentially uncontrolled and if the forces applied to the package in pulling the panels apart are uneven or too rapid, the panels will tear or otherwise fail, thereby exposing the contents to the unsterile portions of the package. Secondly, encapsulation of the package contents frequently occurs. "Encapsulation," as used herein, denotes the phenomenon whereby a portion of the inner surface of one panel of the package, upon opening, delaminates while still adhered to the opposite panel, thereby bridging across the access area and impeding the removal of the package contents or imperiling the sterility of the contents by contact with unsterile bridging portions. Encapsulation occurs primarily because the materials used for packages of this type often have surface areas which are less cohesive than the adhesion of the sealing material and, therefore, rather than peeling, the panel will tend to delaminate in an uncontrolled manner. When encapsulation occurs, the bridging, delaminated portion must be removed to allow access to the package contents and frequently this is either impossible or at least difficult without affecting the sterility of the contents. It should be noted, in this connection, that even if encapsulation is not complete (i.e., the delaminated portion is not even partially adhered to the opposite panel), the presence of the delaminated portion across the access area makes it difficult to remove the contents of the package without affecting sterility.

SUMMARY OF THE INVENTION

In accordance with this invention, a surgical package is provided from which the contents can be rapidly removed without imperiling their sterility by peelably opening the package in a controlled manner whereby the phenomenon of encapsulation is obviated. More specifically, a package is provided which comprises two panels sealed together at their corresponding marginal portions, thereby forming a sealed chamber therebetween; the chamber having a sealed mouth and adjacent sealed edges, the seal extending continuously along the edges and across the mouth. The seal is provided by coating the marginal portions of at least one panel with an adhesive which is preferably heat sealable. It should be noted that other sealing methods may be used such as pressure sealing or hot melt sealing.

A section of the marginal portions of one panel is weakened, the weakened section extending at least as far inward, with respect to the chamber, as the seal, and continuously extending across the mouth and along at least a portion of the adjacent edges of the chamber. The weakening is accomplished by score lines cut on the surface of the panel which penetrate into the surface to a portion of the thickness of the panel, thereby weakening the cohesiveness of the panel material at a planar depth corresponding to the depth of the score. The adhesive used forms a seal having an internal cohesive strength and an adhesive strength to the panel

material greater than the cohesion of the weakened section to the bulk of the panel material.

The weakened section of panel material is continuous so that it will not tear before delamination is completed to the end of the weakened section. The score lines, however, will not be completely continuous. Substantially continuous score lines in the form of a series of cuts along a line, separated by very short spaces, as in the form known as a "dotted line," may be used, if desired, provided that the spacing depth of the cuts strongly favor tearing along the line of the cuts over tearing elsewhere.

The novel package of this invention is peelably opened by delaminating the weakened section from the bulk of one panel while it remains adhered to the opposite panel, in contrast to prior packages wherein the peeling occurs by a separation within the adhesive mass. The peeling of this invention is controlled by weakening the delaminating section of one panel in a predetermined manner as, for example, by a predetermined pattern of score lines cut to a predetermined depth in the panel in the delaminating section thereof heretofore described.

In a specific embodiment of the invention the package is in envelope form having side panels and a mouth at one end. On at least one panel, the marginal portions (i.e., those portions extending around the periphery of the envelope) are coated with an adhesive and are adhered one to the other, thereby providing a seal for the panels and the mouth and forming a sealed chamber. A portion of each panel extends beyond the sealed chamber and provides a tab which may be gripped and pulled to facilitate the peeling operation. A section of the marginal portions on one panel is weakened, preferably by outlining the section with score lines cut into the panel to a portion of its thickness, the weakening extending across the mouth and continuously along the longitudinal edges of the envelope adjacent the mouth, to the extent necessary to provide adequate access to the contents of the envelope. In opening, the tabs are gripped and gradually pulled apart, thereby causing the weakened section of the panel containing the same to delaminate, the delamination propagating across the mouth of the envelope and down the longitudinal edges to present a wide access area surrounded by advantageously large sterile surfaces, these comprising the interior surfaces of the package and the delaminated marginal portions. Only the portions of the panels which form the tabs are unsterile. To minimize the chance of contact between the contents and these unsterile tabs, in a preferred embodiment of this invention, the portions of the panels which form the tabs are diverted from the remaining portion of the panel by bending scores which run transverse to the longitudinal direction of the envelope. As used herein, the term "bending scores" is used to describe creases formed in the surface of the panel to facilitate bending the panel along the creases. By folding these tabs outwardly along the bending scores and away from the mouth of the envelope before beginning the peeling operation, the chance of contact between the contents of the package and the unsterile tabs is greatly reduced.

In accordance with this invention, a surgical package may be peelably opened in a controlled manner so as to

substantially lessen the problems of encapsulation associated with prior packages of this type. However, in extreme cases, there is a possibility of shearing the delaminating section of the marginal portion before the delamination has fully propagated across the mouth and then along the longitudinal edges of the envelope. This shearing may occur, for example, when the tabs are gripped in such a manner as to impose a substantial torque on the delaminating section. In particular, the delaminating section is most susceptible to shear when the first small area is being delaminated because at that stage even small torque forces are sufficient to shear the initially small delaminated section.

Accordingly, the novel package of this invention has been provided with means whereby the problem of imposing a substantial shearing torque upon the initial delaminated section may be obviated. As aforementioned, the specific package embodiment of this invention is provided with tabs for gripping and peeling apart the panels during the opening operation and, to prevent contaminating the contents of the package by contact with these unsterile tabs, bending scores are provided whereby the tabs may be folded away from the mouth of the envelope. In one aspect of this invention, it has been discovered that if the bending scores are oriented so as to, at least partially, pass through the weakened marginal portion, the aforementioned shearing problem is avoided. To understand this, reference is made to the above-described procedure for opening the package of this invention. Prior to pulling the package apart, the tabs are folded outwardly along the bending scores. By orienting the bending scores through the weakened section of the marginal portion, the folding operation, in addition to removing the tabs from a contaminating position with respect to the mouth of the envelope, simultaneously initiates the delamination of the weakened section. The stresses imposed on the weakened section by the folding of the tabs are all in planes which are transverse to the plane of the marginal portion, i.e., the folding motion of the tabs precludes the imposition of a torque on the initial delaminating section.

The invention may be more clearly understood by reference to the appended drawings which are described in detail below.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a first embodiment of a peelable package of this invention, with a portion of the upper surface layer broken away;

FIG. 2 is an enlarged cross-sectional view of the package illustrated in FIG. 1, taken along line 2—2;

FIG. 3 is a perspective view of a portion at the peelable end of the package of FIG. 1, illustrating the method of opening same;

FIG. 4 is an enlarged cross-sectional view of a portion of the package illustrated in FIG. 3, taken along line 4—4;

FIG. 5 is a plan view of a blank from which the package of FIG. 1 may be constructed;

FIG. 6 is a perspective view of a second embodiment of a peelable package of this invention;

FIG. 7 is a plan view of a blank from which the package of FIG. 6 may be constructed; and

FIG. 8 is a perspective view of the package of FIG. 6 opened and ready for the removal of its contents.

DETAILS OF SPECIFIC EMBODIMENTS

Referring to FIGS. 1 through 5, the package 10 consists of a bacteria-impervious air-permeable paperboard blank 12 folded longitudinally along its centerline F1 so as to form two side walls 14 and 16. An adhesive coating 18 is applied along the marginal portions of the paperboard blank 12 so that when folded along the centerline F1, the two side walls 14 and 16 may be sealed along their peripheries to form therebetween a sealed chamber 20 for containing, for example, a folded surgical drape 12. The side walls are extended beyond the seal at the mouth end 21 of the package so as to form tabs 22 and 24, which may be gripped as shown in FIG. 3, to facilitate opening the package. An arcuate cutout 25 in the tab 22 facilitates the separation of the tabs from each other.

In accordance with the teachings of this invention and as best illustrated in FIG. 5, score lines 26 and 26' are cut into one side wall 16 of the package to outline and weaken a section of the marginal portions thereof. The score lines extend across the mouth of the package and then continuously along the longitudinal edges 28 and 30 to an extent determined by the access area requirements of the contents. In depth, score lines 26 and 26' are cut into, but not through, the thickness of side wall 16.

By gripping the tabs 22 and 24 as shown in FIG. 3 and pulling them apart, the weakened section of the marginal portion of the side wall 16 will delaminate from the remaining bulk thereof in a pattern controlled and contained within the outline of the score lines 26 and 26'. To aid in propagating the delamination across the mouth 21 of the package and to prevent a sudden change in the direction of forces applied to the delaminating section of the marginal portion as the delamination proceeds from the mouth to the longitudinal edges 28 and 30, the pattern of coating and the associated outlining score cuts across the mouth end are in the form of two legs of a triangle whose apex, the included angle, is directed outward from the mouth end of the package.

As illustrated in FIG. 5, terminating bending scores 38 and 40 are provided to limit the delamination when the package has been opened to the extent necessary to render the contents accessible. The centerline F1 of blank 12 has been provided with a through cut 42 which extends from the edge of the mouth end of the package to the terminating bending scores to allow the package to be opened. As used herein, the term "through cut" is used to describe a line cut completely through the thickness of the blank.

To reduce to a minimum the chances of contaminating the contents of the package by contact with the unsterile tabs 22 and 24, panels 14 and 16 are provided with bending scores 32 and 34, respectively. As illustrated in FIGS. 3 and 4, the tabs are folded outwardly along these bending scores during the opening operation so as to be inaccessible to contact with the contents of the package when such contents are removed. That is to say, the tabs may be gripped by the fingers and rotated away from the mouth of the package.

In accordance with the further teachings of this invention, it has been discovered that if care is used in delaminating a small initial area of the weakened section of panel 16, delamination thereafter continues before shearing forces can be developed, precluding the

possibility of shearing the weakened section when rapidly opening the package. Accordingly, bending score 34 is oriented so as to pass through a small area of the weakened section of the marginal portion sealing the mouth of the package. The simple initial opening operation of folding back the tab, deemed advantageous to insure sterility, simultaneously initiates the delamination of the weakened section. This is best illustrated in FIG. 4. Having delaminated an initial area 36, the remaining section may be rapidly delaminated without fear of shearing. It should be noted in this regard that the bending scores 32 and 34 provide a directional constraint to the manner in which the tabs may be folded, thereby imposing delaminating stresses on the initial delaminating area 36 which are in planes substantially perpendicular to the plane of the side wall from which the area is delaminating. Stated in other words, in the critical initial delaminating stage, a means has been provided to assure that only perpendicular shearing stresses will be applied.

FIGS. 6 and 7 show another embodiment illustrative of a package in accordance with the present invention. Unlike the flat package or envelope illustrated in FIGS. 1 through 5, the envelope of the embodiment shown in FIGS. 6 and 7 has a larger defined volume and thus is especially useful in packaging such rigid, three-dimensional objects as forceps, clamps or scalpels.

The package of FIGS. 6 and 7 is made from a bacteria-impervious, air permeable paperboard blank 41 provided with bending scores generally transverse to the longitudinal direction of the blank and substantially centrally thereof, arranged in a pattern to provide a base for the package of substantial dimensions. The bending scores may take any suitable form, rectangular, circular, oval, etc., but, preferably, are arranged to provide a generally diamond shape, the longitudinal dimension of which extends generally transverse to the longitudinal direction of the blank and substantially centrally thereof, as the four bending scores 44 shown in FIG. 7.

The blank is folded along these bending scores to provide the side walls 48 and 50 and the bottom wall or the floor 46 of the package. The side walls merge upwards from the floor area to the mouth of the package, thus providing the enlarged volume referred to.

An adhesive coating may be applied, as in the embodiment shown in FIGS. 1 through 5, to the marginal portions of both side walls. As shown in FIG. 7, however, an adhesive coating 49 is applied only to the marginal portions of the side wall 50. When the blank is folded along the bending scores 44, the adhesive layer comes into contact with the marginal portion of the opposite side wall 48 and the marginal portions are sealed together forming a sealed package having sealed edges and a sealed mouth.

As in the embodiment of FIGS. 1 through 5, the portion of the adhesive layer defining the sealed mouth of the package is located inward of the end of the panel 50, providing a tab 56, extending beyond the mouth. The panel 48 is of substantially the same length as the panel 50, thereby providing its own tab 54. Arcuate cutout 55 in tab 54 is similar to cutout 25 in the embodiment of FIGS. 1 through 5.

A section of the marginal portions of the side wall 50 is weakened by providing score lines 52 and 52' outlin-

ing this section in the same manner as the weakened section of panel 16 is outlined by the score lines 26 and 26' in the embodiment of FIGS. 1 through 5.

Bending scores 58 and 60 are provided to allow the tabs to be folded outwardly from the mouth of the complete package to preclude contact between these unsterile tabs and the package contents. Bending score 60 passes through a small portion of the weakened section of side wall 50 to provide means, as discussed in connection with the embodiment of FIGS. 1 through 5, for insuring that the initial delamination will proceed without shearing the delaminating section.

Terminating bending scores 62 and 64 are provided to limit the delamination of the marginal portions when the package has been opened to the extent necessary to render the contents accessible. It should be noted in this connection that when it is advantageous to completely open the package of FIGS. 6 and 7, score lines 52 and 52' may be extended to meet bending scores 44 and terminating bending scores 62 and 64 are eliminated.

FIG. 8 illustrates the package of FIGS. 6 and 7 opened and with its contents 66 ready for removal. Area 68 is an inner plane of wall 50 which is now exposed as a result of the delamination of the weakened section of the coated marginal portions from the side wall 50, said section now adhering to the other side wall 48.

The materials used to construct the sterile packages specifically described herein are generally paperboard panels having a density which is such as to render the panels pervious to gas but impervious to airborne bacteria. A paperboard sheet having a porosity of from 40 to 300 seconds per 100 cc. of air per square inch, measured by a procedure described in the test manual of The Technical Association of Pulp and Paper Industry (T460-M49), is satisfactory. Such paperboards of the type known as cylinder board or solid bleached sulfate are particularly useful in practicing the teachings of this invention in that, because of the higher density of fibers on their surface as compared to the internal fiber density, these paperboard types lend themselves advantageously to the delaminating methods of this invention.

As to the adhesives used, a suitable adhesive is one which forms a seal having an internal cohesive strength and an adhesive strength to the panel material greater than the cohesion of the weakened section to the bulk of the panel. Preferably, the adhesive is a thermoplastic one which is heat sealable, such as, for example, polyvinyl acetate.

It should be understood by those skilled in the art that, while the invention has been described and illustrated above in connection with certain specific embodiments, many variations and modifications may be employed without departing from the scope of the invention.

What is claimed is:

1. A one-piece blank for constructing a package having two ends and a centerline substantially parallel to and midway between said ends, comprising:
 - two side walls defined by the centerline;
 - an adhesive coating continuously extending along the outer marginal portions of at least one of said side walls, said adhesive coating partially defining

a completely enclosed area within the coated side wall bounded by the coated marginal portions and the centerline so that when the blank is folded along the centerline, corresponding marginal portions of the two side walls may be sealed together by the adhesive coating to form a completely sealed chamber therebetween having a sealed mouth corresponding to the meeting of the two blank ends; and

score lines cut into a portion of the thickness of at least one of said side walls to weaken a section of the corresponding marginal portions thereof provided for sealing the mouth end of the chamber.

2. The one-piece blank of claim 1 wherein the side walls are extended at the ends to provide tabs, said tabs being provided with bending scores whereby the tabs may be folded outwardly from the sealed mouth along said bending scores when the package is constructed.

3. The one-piece blank of claim 2 wherein the bending score provided on the tab of the weakened side wall passes through an area of the weakened section, whereby the delamination of the weakened section may be initiated by folding the tab outwardly from the sealed mouth after the package is constructed.

4. The one-piece blank of claim 1 wherein the adhesive coating extending across the end of the coated side wall is in the form of two legs of a triangle whose apex is the included angle, said apex pointing outward from the sealed chamber when said package is constructed.

5. A one-piece blank for constructing a package having a base end, a mouth end and a centerline transverse to said base and mouth ends, comprising:

two side walls defined by the centerline;

a through-cut partially severing the blank at the mouth end and collinear to at least a portion of the centerline;

an adhesive coating extending along the outer marginal portions of at least one side wall and along at least a portion of the through-cut, said adhesive coating partially defining a completely enclosed area within the coated side wall, said area bounded by the coated marginal portions and the centerline so that when the blank is folded along the centerline, corresponding marginal portions of the two side walls may be sealed together by the adhesive coating to form a completely sealed chamber therebetween; and

score lines cut into a portion of the thickness of one side wall to weaken that section of the corresponding marginal portions thereof provided for sealing the mouth end of the chamber.

6. The one-piece blank of claim 5 wherein the side walls are extended at the mouth end to provide tabs, said tabs being provided with bending scores whereby the tabs may be folded outwardly from the sealed mouth along said bending scores when the package is constructed.

7. The one-piece blank of claim 6 wherein the bending score, provided on the tab of the weakened side wall, passes through an area of the weakened section, whereby the delamination of the weakened section may be initiated by folding the tab outwardly from the sealed mouth when the package is constructed.

8. The one-piece blank of claim 5 wherein the adhesive coating extending across the mouth end of the

blank is in the form of two legs of a triangle whose apex is the included angle, said apex pointing outward from the sealed chamber when said package is constructed.

9. The one-piece blank of claim 5 wherein terminating bending scores are provided on the weakened side wall, said further bending scores passing transversely through the weakened section of the marginal portions at a position on the weakened section corresponding approximately to the terminus of the through-cut.

10. A package comprising:

two panels sealed together by a continuous seal and forming therebetween a sealed chamber; said seal defining a portion of the periphery of said sealed chamber including continuously a sealed mouth and adjacent sealed edges;

score lines cut into a portion of the thickness of one panel to weaken a continuous section of the marginal portions thereof, said weakened section extending at least as far inward, with respect to said chamber, as the seal and extending continuously across said mouth and along at least a portion of the adjacent edges of the sealed chamber;

the seal between said panels having an internal cohesive strength and an adhesive strength to the panel material greater than the cohesive strength of the weakened section to the bulk of the weakened panel, whereby said package may be peelably opened by delaminating the panel material in the weakened section.

11. The package of claim 1 wherein said panels are extended beyond the sealed mouth of the sealed chamber to form tabs, and said tabs are provided with bending scores, whereby the tabs may be folded outwardly from the sealed mouth along the bending scores and pulled to peelably open the package in a controlled manner.

12. The package of claim 1 wherein the panel having the weakened section is extended beyond the sealed mouth of the sealed chamber to form a tab provided with a bending score passing through a part of the weakened section extending across the sealed mouth, whereby the delamination of the weakened section may be initiated by folding the tab along the bending score outwardly from the sealed mouth.

13. The package of claim 12 wherein the sealed mouth of the sealed chamber is in the form of two legs

of a triangle whose apex is the included angle, said apex pointing outward from the sealed chamber.

14. The package of claim 1 wherein terminating bending scores are provided on the weakened panel, said terminating bending scores passing transversely through the portion of weakened section extending along the adjacent edges of the sealed chamber, whereby delamination of the weakened section may be terminated.

15. A package comprising:

two panels;

an adhesive coating on the marginal portions of at least one of the panels sealing the two panels together and forming therebetween a sealed chamber; said sealing adhesive coating defining a portion of the periphery of said sealed chamber including continuously a sealed mouth and adjacent sealed edges, said sealed mouth being in the form of two legs of a triangle whose apex is the included angle, said apex pointing outward from the sealed chamber;

score lines cut into a portion of the thickness of one panel to weaken a continuous section of the marginal portions thereof, said weakened section extending at least as far inward with respect to the chamber, as the seal and extending across the mouth of said sealed chamber and along at least a portion of the adjacent edges of the sealed chamber;

the seal between said panels having an internal cohesive strength and an adhesive strength to the panel material greater than the cohesive strength of the weakened section to the bulk of the weakened panel;

two tabs, formed by extending the panels beyond the sealed mouth, said tabs each provided with a bending score passing transverse to the longitudinal direction of the panels, whereby the tabs may be folded outwardly from the sealed mouth, the bending score on the tab of the weakened panel also passing through an area of the weakened section extending across the sealed mouth; and

terminating bending scores passing transversely through a part of the weakened section extending along the adjacent edges of the sealed chamber.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,724,651 Dated April 3, 1973

Inventor(s) Martin Link

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

In the Abstract, line 12, "upon the package" should read
--- upon opening the package ---.

In Column 5, line 12, "surgical drape 12" should read
--- surgical drape 11 ---.

Signed and sealed this 13th day of November 1973.

(SEAL)
Attest:

EDWARD M. FLETCHER, JR.
Attesting Officer

RENE D. TEGTMEYER
Acting Commissioner of Patents