United States Patent [19]

Bonk

[11] **3,754,700**

[45] **Aug. 28, 1973**

[54] **SURGICAL POUCHES**

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[73] Assignee: **Rollprint Packaging Products, Inc,** Chicago, Ill.

[22] Filed: **Feb. 26, 1971**

[21] Appl. No.: **119,292**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 836,332, June 25, 1969, Pat. No. 3,627,611.

[52] **U.S. Cl.** **229/62,** 206/63.2

[51] **Int. Cl.** **B65d 31/00**

[58] **Field of Search** ..... 206/63.2 R, 56 AA; 229/62, 66

[56] **References Cited**

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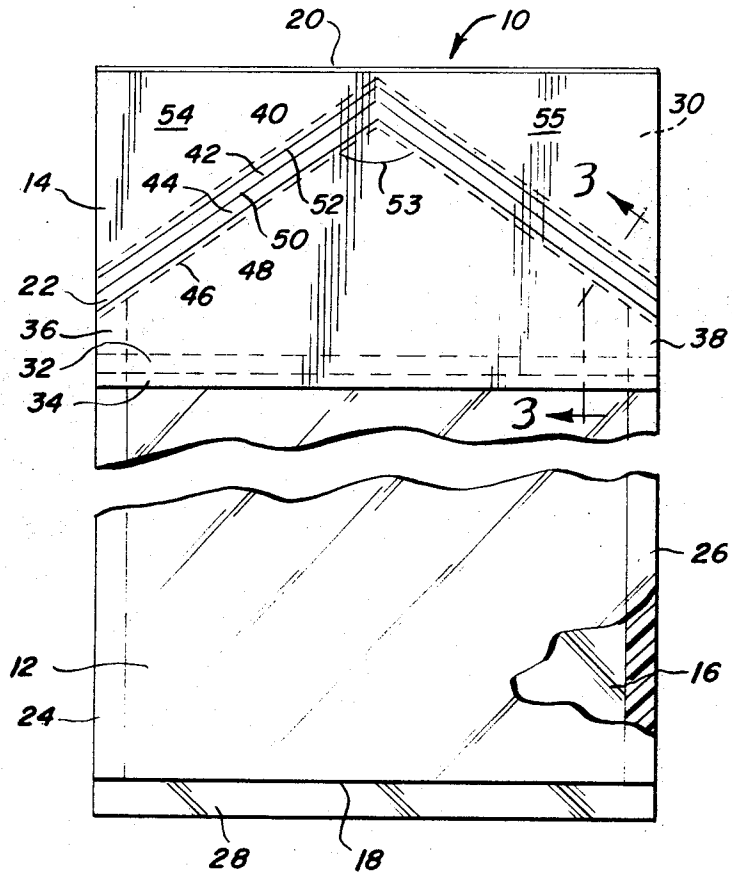
Primary Examiner—Donald F. Norton

Attorney—Pendleton, Neuman, Williams & Anderson

[57] **ABSTRACT**

Surgical pouches having a back wall of sheet polyethylene and a front wall of sheet polyethylene with a header piece of sterilizable, surgical kraft paper or other gas permeable, sheet material having bacteria holdout properties are disclosed wherein the instrument contained within the pouch may be sterilized after the pouch is sealed.

17 Claims, 7 Drawing Figures



Patented Aug. 28, 1973 3,754,700

2 Sheets-Sheet 1

FIG. 1

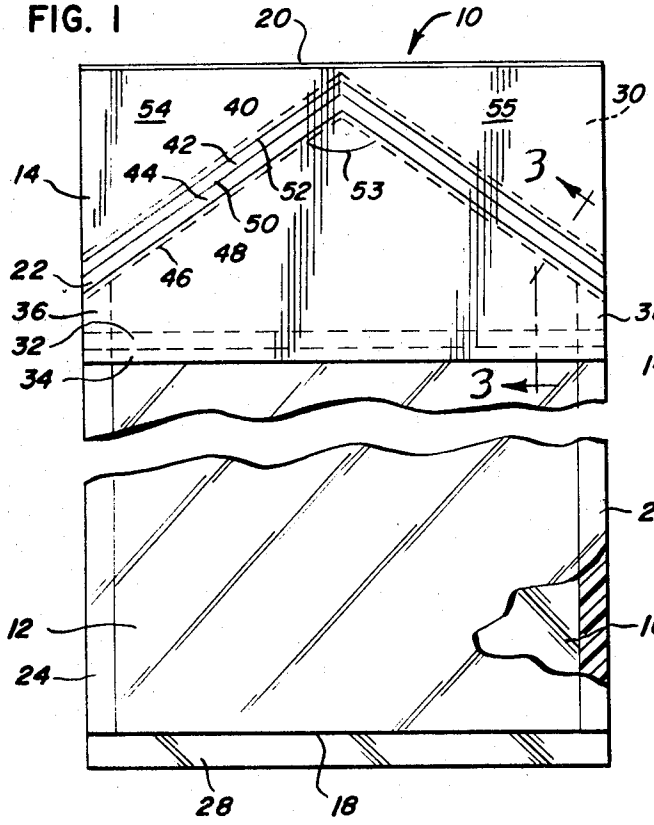


FIG. 2

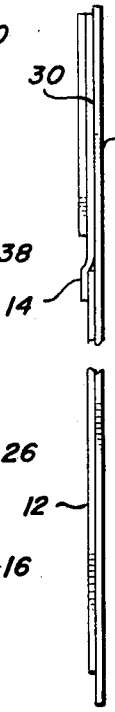


FIG. 3

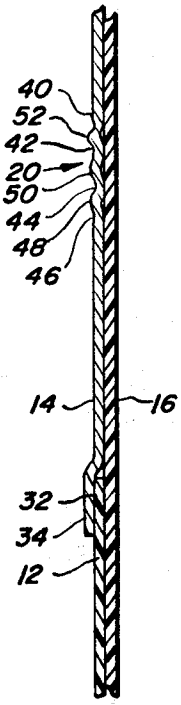


FIG. 4

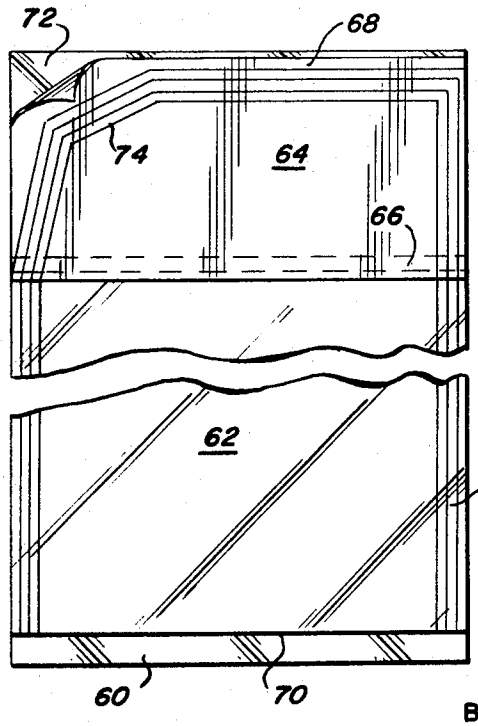


FIG. 7

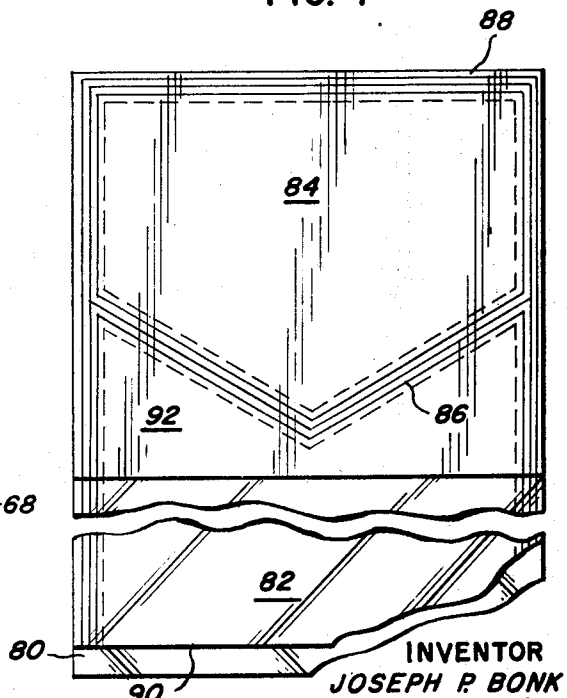


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FIG. 5

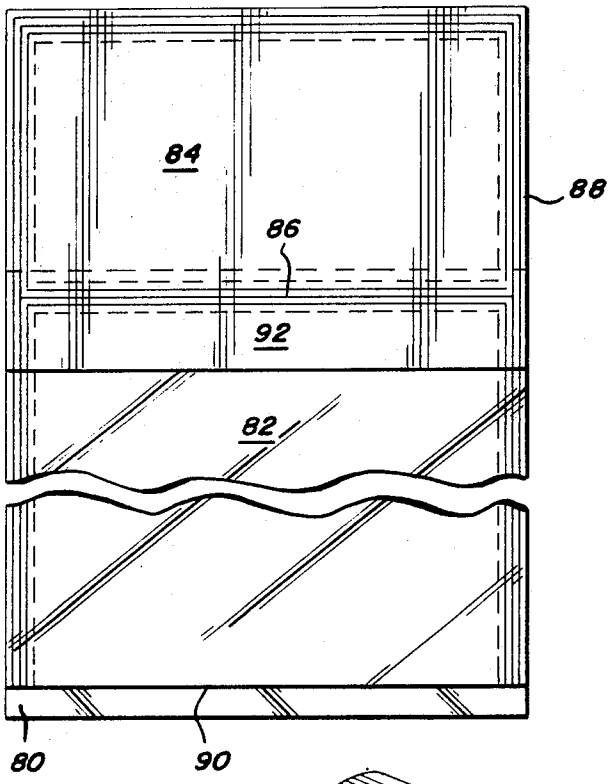
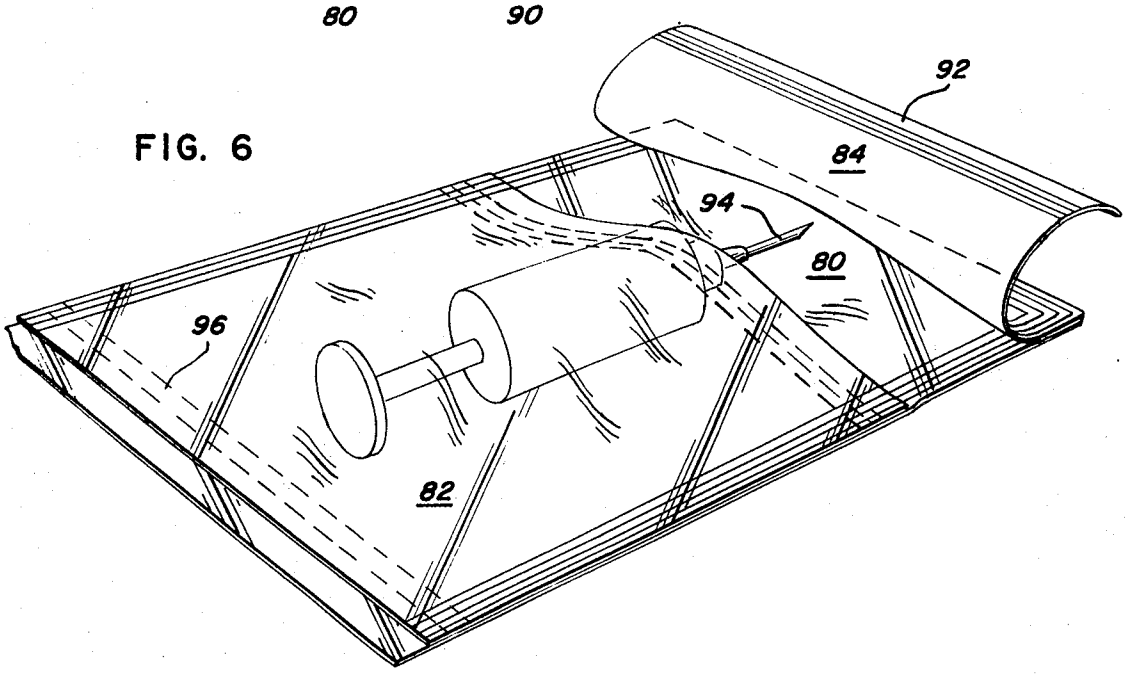


FIG. 6



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SURGICAL POUCHES

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of my application entitled "Method and Apparatus for the Manufacture of Surgical Pouches", Ser. No. 836,332, filed on June 25, 1969 which issued as U.S. Pat. No. 3,627,611 on Dec. 14, 1971.

BACKGROUND OF THE INVENTION

This invention relates to pouches or containers for packaging of surgical or pharmaceutical instruments. More particularly, this invention relates to surgical pouches or packages which permit the pouch interior and the instrument contained therein to be conveniently sterilized after the pouch is sealed and the instrument to be aseptically removed therefrom when the instrument is to be used.

It has been found desirable in the past to pack surgical instruments in packages or pouches which may be easily opened during the course of an operation and from which the instrument may be removed without contamination. Specifically, at a central instrument supply station a pouch is provided in which a surgical instrument is placed and the pouch sealed. The instrument is sterilized while it is in the pouch so that the interior of the pouch is sterilized simultaneously. The pouch and instrument are then transported to the operating room. When it is desired to use the instrument during the course of an operation, the pouch is opened and the instrument removed. Preferably, the pouch should be capable of being opened in such a way that the instrument may be removed without contacting any exterior, perhaps non-sterile, surface of the pouch.

It has further been found desirable to use surgical pouches which permit packaging of the instrument and subsequent sterilization thereof with sufficient ease that, at the conclusion of a surgical operation and in the actual operating room, the used instruments may be sealed into a new pouch, sterilized, and thereby made ready for use again. A convenient sterilizing method used in the past, commonly referred to as the gas sterilization process, has required the use of paper pouches. There, the pouch with the instrument sealed therein is placed in a pressure chamber and ethyloxide is introduced into the chamber under pressure so that it penetrates the paper and sterlizes the instrument. The chamber is then partially evacuated to withdraw the ethyloxide from the pouch. The pouch is then removed from the chamber, and the contained instrument is sterilized and ready for use. This gas sterilization process is relatively quick and does not require high temperatures.

Various surgical pouches have heretofore been proposed but they have had many weaknesses associated therewith. Many did not permit use of the described gas sterilization method. The pouches of the prior art were often either relatively difficult to open or had seals which did not adequately protect the contained instruments from contamination. They were often of complex design or made of expensive material. Further, some of the prior art pouches were of insufficient strength to withstand repeated handling without rupturing and resultant contamination of the contents, or did not allow for easy identification of the instrument within the pouch.

SUMMARY OF THE INVENTION

Surgical pouches of transparent plastic sheeting and gas permeable sheet material are provided by this invention. Polyethylene front and back pieces form the pouch walls and a header of paper or other gas permeable, sheet material having bacteria holdout properties is supplied to form a portion of the pouch front wall. The pouch components are heat sealed together and the pouch configured so that the header may easily be torn away to permit aseptic removal of the instrument.

Accordingly, it is an object of this invention to provide a surgical pouch which permits gas sterilization of the pouch interior and its contents which is both durable and allows easy identification of the contained instrument.

It is an object of this invention to provide a surgical pouch which may be easily opened and the contents aseptically removed therefrom.

It is an object of this invention to provide a surgical pouch which may be sealed shut once the contents have been placed therein in a relatively simple manner using relatively economical equipment.

It is an object of this invention to provide a surgical pouch which is of simple design and construction which can be made from inexpensive materials.

Further and additional objects will appear from the description, accompanying drawings and appended claims.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a partial top plan view of a surgical pouch of a first embodiment of this invention;

FIG. 2 is a partial side view of the surgical pouch of FIG. 1;

FIG. 3 is a partial cross section of the surgical pouch of FIG. 1 taken along the line 3—3 of FIG. 1;

FIG. 4 is a partial top plan ivew of a surgical pouch of a second embodiment of this invention;

FIG. 5 is a partial top plan view of a surgical pouch of a third embodiment of this invention;

FIG. 6 is a perspective view showing the use of the surgical pouch of FIG. 5; and

FIG. 7 is a partial top plan view of a surgical pouch of a fourth embodiment of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, and more particularly to FIGS. 1, 2 and 3, a surgical pouch or package 10 of one of the preferred embodiments of the present invention is there disclosed. The pouch 10 is comprised generally of a front piece 12, a header 14, and a back piece 16, and has an insertion opening 18 at one end and a removal opening 20 at the other end. The front piece, header, and back piece are so disposed that the pouch rear wall is formed by the back piece and the pouch front wall is formed by the front piece and header. In the finished pouch, the removal opening area 20 is closed by a tortuous, corrugated chevron seal 22, which will be described in greater detail hereinafter. The instrument to be packaged may be inserted into the pouch through insertion opening 18 which would then be heat-sealed shut. When it is desired to use the instrument, the pouch is opened at removal opening 20 and the instrument removed.

Front piece 12 and back piece 16 are preferably of transparent polyethylene sheet and in one application a thickness of 0.004 inch has been found to be desirable. Header 14 should be made of sheet material which is gas permeable, yet will not permit the reintroduction of bacteria or other contaminating agents through the header into the pouch after the contents have been sterilized by the above-described gas sterilization process. Paper headers have been used with this invention and in one application 42-pound sterilizable, surgical kraft has been found useful. This paper is gas penetrable allowing proper performance of gas sterilization processes. However, header 14 is preferably made of a spun bonded polyolefin material commercially available from the E. I. du Pont de Nemours & Company, designated by that company with the number 1073B, and sold under the trade name Tyvek. A conventional heat seal coating, such as a polyvinyl acetate, must be applied to the side of that material which is sealed to the remainder of the pouch before the pouch is assembled. The coated, spun bonded polyolefin material has been found to have greater resistance to recontamination of the pouch interior than paper, especially if the pouch should accidentally become damp. The desired overall dimensions of the illustrated pouch are 7 inches wide by 13 inches long.

Back piece 16 underlies the entire area of the pouch. Front piece 12 partially overlies back 16 and is coextensive therewith and heat-sealed thereto by two side seals 24 and 26. Front 12 is preferably disposed on back 16 so that the back extends beyond the front a short distance, perhaps ½ inch, at one end of the pouch to form a lip 28 and a greater distance, perhaps 4 inches, at the other end of the pouch to expose a header mating area 30 where the header 14 and back 16 may be sealed at removal opening 20. Header 14 partially overlies both front 12 and back 16. It is coextensive with front 12 and back 16 along the sides of the pouch.

Header 14 is heat-sealed to front 12 at seal 32 along their area of overlap leaving a loose flap of header 34. Header 14 is additionally sealed to back 16 at chevron seal 22 and side seals 36 and 38. Chevron seal 22 must be such that the pouch is sufficiently sealed to maintain required sterility, yet is still capable of being easily opened for removal of the enclosed sterilized instrument. In the preferred embodiment shown, the chevron seal 22 consists of four parallel V-shaped seal strips 40, 42, 44 and 46, separated by three parallel nonseal strips or ridges 48, 50 and 52. The header 14 and back 16 are heat-sealed together at the V-shaped strips, but are not sealed at the ridges. As may best be seen in FIG. 3, header 14 may separate from back 16 in the area of ridges 48, 50 and 52.

It has been found that the angle included within the chevron, indicated at 53, is critical and should be within a certain range in order to insure both proper sealing and the desired ease of opening. In the described embodiment, angle 53 should be in the range of 110°–120° and is preferably 114°. The chevron-shaped seal additionally provides two triangular-shaped gripping portions 54 and 55. At these portions, header 14 and back 16 are separately exposed so that they may be gripped and torn apart to open the pouch. Once the chevron seal 22 is broken, the bag is normally disposed of.

A second embodiment of this invention is disclosed in FIG. 4. In general configuration, the pouch of FIG. 4 is similar to that of FIGS. 1–3; it is comprised of a back piece 60 with a front piece 62 partially overlying it and a gas permeable header 64 overlying the remainder of the back piece and in overlapping relationship with the front piece. The header and front piece are sealed together in their area of overlap at seal 66 to form the pouch front wall. A corrugated, tortuous seal 68, similar to that used in the embodiment of FIGS. 1–3, is used to seal the front wall to the rear wall. Seal 68 extends generally about three sides of the pouch so as to leave an insertion opening 70 at the end of the pouch removed from the header. Seal 68 is brought inward from the sides of the pouch in the area of the upper left-hand corner of the pouch shown to form a gripping portion 72 where the back 60 and header 64 are separately exposed so that they may be gripped and torn apart to open the pouch. Seal 68 may advantageously have an outwardly pointing, chevron seal area 74 similar to that described in relation to the embodiment of FIG. 1.

A third embodiment of this invention is disclosed in FIGS. 5 and 6. This embodiment also has a general configuration similar to that of the embodiment of FIGS. 1–3 in that it includes a back piece 80 with a front piece 82 partially overlying it and a gas permeable header 84 overlying the remainder of the back piece and in overlapping relationship with the front piece. The header and front piece are sealed together in their area of overlap at seal 86 to form the pouch front wall. A corrugated, tortuous seal 88, similar to that used in the embodiment of FIGS. 1–3, is used to seal the front wall to the rear wall. Seal 88, extends generally about three sides of the pouch so as to leave an insertion opening 90 at the end of the pouch removed from the header. In this embodiment, seal 86 is also a corrugated, tortuous seal similar to that used in the embodiment of FIGS. 1–3. The embodiment of FIGS. 5 and 6 is also characterized by the presence of a flap 92 of header material overlying front piece 82 and extending substantially beyond seal 86. Flap 92 is then used as a gripping portion and the pouch is opened by pulling flap 92 in an upward direction.

FIG. 6 shows how the embodiment of this invention disclosed in FIG. 5 is used. There a syringe 94 has previously been placed in the pouch, the insertion opening 90 closed by a seal 96, and the pouch interior and the syringe sterilized. To remove the syringe, flap 92 is grasped and pulled upwards peeling the header off the front piece 82 and the back piece 80 in turn. The syringe may then be removed from the opening thus formed. In the embodiments of FIGS. 1–4, the instrument contained in the pouch may accidentally come in contact with the external, non-sterile areas of the pouch, particularly those portions of the back piece which form gripping portions 54 and 55 in the embodiment of FIGS. 1–3, and gripping portion 72 in the embodiment of FIG. 4, as the instrument is being removed therefrom. In the embodiments of FIGS. 5 and 6, however, only sterile surfaces are presented for contact with the instrument, the interior surface of back piece 80 and the interior surface of header 84. Header 84 may also be completely removed from the pouch, leaving only the sterile, interior surface of back piece 80 for contact with the instrument. The instrument may thus be removed from the pouch completely aseptically with

no danger from contamination by contact with non-sterile surfaces of the pouch.

FIG. 7 discloses a fourth embodiment of this invention similar to that of FIGS. 5 and 6. In this embodiment, however, the corrugated, tortuous seal 86 is made in the shape of a downward pointing chevron. Such a seal provides increased ease in opening over the embodiment of FIGS. 5 and 6.

All four of the embodiments described above include an opening, shown at 18 in FIG. 1, 70 in FIG. 4, and 90 in FIGS. 5 and 7, for insertion of an instrument into the pouch. That opening may conveniently be sealed shut using presently available heat sealers. Alternatively, the insertion opening may be sealed shut using conventional autoclave tape. It should be observed that if the front and back polyethylene pieces are transparent, the contents of the pouches may be easily identified and there will be no need to label them.

It will thus be seen that a plurality of surgical pouches have been provided which are of relatively simple design and construction, permit gas sterilization of the pouch interior and contents, are very durable, allow for easy identification of the contained instrument, and which may be easily opened and the contents aseptically removed therefrom. It will be obvious that certain modifications of the specific embodiments shown may be made without departing from the spirit and scope of this invention. Different materials might be used for the front, back and header pieces, different methods of sealing might be used, and many different configurations for the pouch could be devised.

While several particular embodiments of this invention are disclosed above, it will be understood, of course, that the invention is not to be limited thereto since many modifications may be made. It is contemplated, therefore, by the appended claims, to cover any such modifications as fall within the true spirit and scope of this invention.

I claim:

1. A surgical package comprising:
a first wall of plastic sheet material;
a second wall comprising a piece of flexible plastic sheet material and a header, said header forming a gas penetrable wall area and being in partial overlapping relationship with said piece of flexible plastic sheet material and sealed thereto in the area of overlap; and
means for securing said second wall to said first wall comprising a corrugated, tortuous seal between the plastic sheet material of said first wall and the header of said second wall.

2. The surgical package of claim 1 wherein the plastic sheet material and the header of said second wall are sealed together with a corrugated, tortuous seal.

3. The surgical package of claim 2 wherein a portion of said second seal has the shape of a chevron.

4. The surgical package of claim 2 wherein said header is of spun bonded polyolefin material.

5. The surgical package of claim 1 wherein said header is of spun bonded polyolefin material.

6. The surgical package of claim 1 wherein a portion of said seal has the shape of a chevron.

7. The surgical package of claim 1 wherein said header is of paper.

8. A surgical pouch comprising:
a first layer of plastic sheeting;
a gas permeable header in overlapping relationship with a portion of said first layer;
a first area of seal between said header and said first layer forming a front wall of said package;
a second layer of plastic sheeting underlying said front wall forming a back wall of said package; and
means for sealing said front wall to said back wall comprising a tortuous, corrugated seal between said header and said second layer of plastic sheeting.

9. The surgical pouch of claim 8 wherein said first area of seal is a second tortuous, corrugated seal.

10. The surgical pouch of claim 9 wherein a portion of said second tortuous, corrugated seal is in the shape of a chevron.

12. The surgical pouch of claim 11 wherein said header is of spun bonded polyolefin.

13. The surgical pouch of claim 9 wherein said header is of spun bonded polyolefin.

14. The surgical pouch of claim 8 wherein a portion of said tortuous, corrugated seal is in the shape of a chevron.

15. The surgical pouch of claim 14 wherein said first and second layers of plastic sheeting are of polyethylene.

16. The surgical pouch of claim 8 wherein said header is of paper.

17. The surgical pouch of claim 8 wherein said header is of spun bonded polyolefin.

* * * * *

UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,754,700 Dated August 28, 1973

Inventor(s) JOSEPH PAUL BONK

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

Column 2, line 39, "ivew" should be -- view --;

Column 4, line 35, delete the comma after "88"; and

Column 6, line 34, insert claim 11 as follows:

-- 11. The surgical pouch of claim 9 wherein said first and second layers of plastic sheeting are of polyethylene. --

Signed and sealed this 18th day of December 1973.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

RENE D. TEGTMEYER
Acting Commissioner of Patents