(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) Publication number: **0 076 062**
B2

(12) # NEW EUROPEAN PATENT SPECIFICATION

(45) Date of publication of the new patent specification: **27.12.89**

(51) Int. Cl.⁴: **A 61 J 1/00**

(21) Application number: **82304876.4**

(22) Date of filling: **16.09.82**

(54) **Blood product storage bag.**

(30) Priority: **25.09.81 US 305490**

(43) Date of publication of application: **06.04.83 Bulletin 83/14**

(45) Publication of the grant of the patent: **23.07.86 Bulletin 86/30**

(45) Mention of the opposition decision: **27.12.89 Bulletin 89/52**

(84) Designated Contracting States: **AT CH DE FR GB IT LI NL SE**

(56) References cited:
BE-A-533 018
DE-A-2 023 419
DE-B-1 815 288
DE-U-1 896 046
DE-U-1 943 336
DE-U-7 204 922
DE-U-7 407 072
DE-U-7 505 523
DE-U-7 531 981
DE-U-7 834 426
FR-A-2 495 583
GB-A-387 271
GB-A-690 614
GB-A-2 044 220
GB-A-2 133 383
US-A-3 051 368
US-A-3 259 235
US-A-3 412 918
US-A-3 516 537

(73) Proprietor: **HAEMONETICS CORPORATION(a Massachusetts Corporation), 400 Wood Road, Braintree Massachusetts 02184 (US)**

(72) Inventor: **Lueptow, Richard M., 1359 Commonwealth Avenue, Allston Massachusetts 02134 (US)**

(74) Representative: **Harvey, David Gareth, Graham Watt & Co. Riverhead, Sevenoaks Kent TN13 2BN (GB)**

(56) References cited: (continuation)
US-A-3 604 616
US-A-3 615 711
US-A-3 913 789

The Lancet, April 17, 1982, pages 909 and 910, "Contamination of plasma for fractionation: a design solution"
Collins English Dectionary, page 1315
Oxford Shorter English Dictionary, page 1920
Websters 3rd New International Dictionary, page 2047

EP 0 076 062 B2

Description

This invention relates generally to the field of blood component therapy and more particularly relates to containers for apparatus for the collecting, storing and dispensing of blood plasma to be processed into blood components such as albumin, globulins and so on.

A relatively modern medical technology known as blood component therapy involves administering to a patient just that part of the blood that he actually needs. Rather than whole blood, the physician decides what portion or component of blood is necessary for the patient and administers only that component to him. He, thus, avoids many of the hazards which are inherent in whole blood usage. Not only is the practice better for the patient in that certain risks involving transfusing whole blood are reduced, but it permits one unit of donated blood to be used for more than one patient. For example, from one unit of whole blood, which subsequently is fractionated, there may be derived red blood cells, platelets, fresh plasma, frozen or stored plasma, albumin, globulins and so on.

Furthermore, in the most modern techniques, cell separators permit the separation of blood into its components while the donor is in the process of making a donation. Through modern technology it is possible for a blood bank to take from the donor specific components which are needed by a patient while other components are returned simultaneously to the donor.

In the technique known as plasmapheresis, the plasma is separated from the cellular elements of the blood and the cells returned to the donor. The plasma is then subsequently used for blood volume expansion or blood augmentation in the form of stored plasma or fresh frozen plasma. The plasma can also be processed into a number of useful products such as albumin, globulins and antihemophiliac factor. It is to this purpose that the present invention is directed.

Blood is collected from the donor in a connected, sealed collection system and then centrifuged to separate the cells and the plasma. The cells are returned to the donor and the plasma is subsequently frozen in a collection bag. In the frozen state the plasma may be stored for a number of months before being removed for plasma component manufacturing. Subsequently, large quantities of plasma are batch processed, i. e. plasma from many donors.

During this batch processing contamination is an obvious risk. The whole blood is initially collected in a sealed system which is followed by centrifuging and freezing while still sealed. However, the bags must ultimately be cut open and the plasma removed either manually or automatically. It is possible that during the opening and removing operation the plasma can become contaminated.

The system just described is the subject of GB-A-2 044 220. The blood product collection bag of that system is made of flexible material and has a body with front and rear faces and there is a closure seam at or adjacent an end of the body. As noted above, this bag has to be cut open to free the frozen plasma, which is then ejected from the bag by squeezing the bag.

The present practice involves receiving blood from the donor in a collection system and centrifuging it so that the plasma is collected in one of the bags of the system. The plasma containing bag is then separated from the rest of the collection system and is stored after freezing its contents, all prior to processing weeks or months later. Subsequently, many bags are opened, and the plasma put in a container for batch processing. The present invention is directed to an "easy-open" plasma bag which need not be cut to remove the plasma.

Whilst easy-open packaging such as bags and other containers are known for containing various products, see for example US-3 259, 235, US-A-3 516 537 and US-A-3 604, 616, so far as we know no-one hitherto has devised an easy-open arrangement suiting the requirements of a blood product storage bag.

The "easy-open" bag which holds the plasma is a sealable container of flexible material. It comprises a body so constructed that a manually applied opening force exerted thereon causes the body to rupture at predetermined locations and to tear open along frangible seams, thus affording separation of the body from the frozen plasma without any necessity for the bag being cut by a knife or any other instrument, or for the plasma to be contacted by the hands.

According to the present invention, there is provided a blood product storage bag made of flexible material and having a body with front and rear faces and a closure seam at or adjacent an end of the body, characterised by the body having an easy-open frangible construction provided by opposed frangible seams, one in each of the said faces, which extend to the closure seam and are aligned with one another thereat, and stress-concentrating means which concentrate an applied opening force at the juncture of the seam and said frangible seams for causing the body to rupture at the juncture and be torn open along the frangible seams to separate the bag from its contents.

The closure seam can be of V-shape configuration, the point of which intersects the juncture, the said closure seam defining a V-shape removable portion of body material on the side of the closure seam which is opposite the frangible seams whereby the closure seam may be ruptured at the juncture and the body torn open along the frangible seams to separate it from its contents after the V-shape body material is removed.

Preferably, the bag is provided with means which may be gripped by hand to facilitate the application of the rupturing force. Moreover, the bag is preferably formed of a material which is capable of remaining flexible at temperatures of -25 to -80°C, e. g. of polyolefinic type.

The present invention will now be more particularly described with reference to the accompanying drawings in which containers embodying the invention are shown by way of exemplary illustration only. The principles of this invention may be employed in other embodiments without departing from the scope of the appended claims. In the drawings:

Fig. 1 is a perspective view of an "easy-open" sealable container or bag of flexible material embodying the invention;

Figs. 2 and 3 are views of the bag shown in Fig. 1 being opened;

Figs. 4 and 5 are views of alternative bag constructions according to the invention; and

Figs. 6 and 7 are views of another alternative bag construction according to the invention.

Fig. 1 shows a transfer bag embodying the present invention. The bag was used as part of multiple bag collection system and is now in an inverted position and containing frozen plasma ready for opening. The body 10 of the bag communicated with a donor bag (not shown) by means of a flexible tube 12, the tube now being closed by a conventional seal 14. The bag includes hanger holes 16 which may be employed when the donor bag is being filled. The bag comprises a sealable container of flexible plastics material such as polyolefin of 6 mils thickness (0.15 mm) which is capable of remaining flexible at temperatures of -25 to -80°C, i. e. the range of temperatures in which plasma is frozen and stored.

Depending on its method of manufacture, the body 10 of the container includes a pair of frangible seams 20 or similar running from the top to the bottom of the body (as oriented in Fig. 1). The seams join one another at a juncture 22.

As viewed in Figs. 2 and 3 (which is a view only slightly in perspective of the openable end of the bag), the frangible seams 20 will be seen to be located at opposite sides of the body 10 and in a plane bisecting the body. Transversely intersecting the juncture 22 of the frangible seams 20 is a closure seam 24 which is of greater width than the width of the frangible seams. In the construction shown in Figs. 1, 2 and 3 a pair of ears 26 lie laterally of the juncture 22 to one side of (in this instance above) the closure seam 24, opposite the frangible seams 20. The edges of the ears 26 are rounded and converge toward the juncture 22. The closure seam 24 is essentially along a straight line, sealing the top of the bag and separating the interior of the body from the ears 26.

Also as seen in Figs. 1 and 2 (but hidden in Fig. 3) ribs 28 are formed in the body and extend from the closure seam 24 in diverging directions away from the juncture 22 to the edges of the body 10. The ribs 28 define portions 30 of the body lying laterally of the juncture which are sealed from the interior of the body and accordingly contain no plasma.

To open the body, the ears 26 alone or together with the closure seam 24 and/or the portions 30 are gripped and pulled apart either as shown in Fig. 2 or in Fig. 3, thereby directing or concentrating force at the juncture 22. The bag ruptures at the juncture 22 permitting the body 10 to be torn apart along the frangible seams 20 whereby the flexible plastics film may be peeled away from the frozen plasma within the bag and the plasma allowed to fall into a collection container without being touched by a knife or other opening instrument, or by the hands. The bag of course would be inverted from the positions shown in Figs. 1, 2 and 3 for releasing its contents. While Figs. 2 and 3 show the flexible container being torn apart by bare hands, some may prefer to wear gloves as insulation from the cold contents.

In some prior plasma bag constructions, opening required the bag to be cut open with a knife to expose the plasma as well as thawing of its contents slightly from the outside inwardly to release the frozen plasma from the inner surface of the bag. Because of the construction of the present invention, the bag need not be cut. Since the bag is essentially peeled back away from the frozen plasma, there is no skin thawing necessary preparatory to opening the bag.

Fig. 4 shows an alternative construction of the openable portion of the bag. The closure seam 24, as in the Fig. 1 construction, is essentially a straight line running across top of the bag intersecting the juncture with the frangible seams 20. The closure seam 24 has a notch 34 aligned with the juncture 22 to concentrate rupturing force at the juncture 22. There are no ears 26 on the body and it would be optional to provide ribs 28 defining the sealed portions 30 containing no plasma.

Another alternative construction of the body is shown in Fig. 5. In this alternative the closure seam 24 is of V-shape configuration comprising portions 24a and 24b converging toward the juncture 22. Ribs 28 define areas 30 equivalent to the portions 30 in the Fig. 1 construction. Again, the ribs 28 and unfilled areas 30 are optional. However, since there are no ears, it would be the closure seam portions 24a and 24b (with the portions 30 if provided) that would be gripped and pulled apart. The V-shape configuration of the seam 24 concentrates the applied force at the juncture 22 to initiate tearing of the frangible seams 20.

Figs. 6 and 7 show another alternative construction. The closure seam 24 as in the Fig. 5 construction is of V-shape configuration converging at the juncture with the frangible seams 20. The ribs 28a and 28b also converge at the juncture and as described above define unfilled areas 30.

For ease of construction, the ribs 28a and 28b converge at the juncture. The closure seam portions 24a and the rib 28a are aligned linear extensions of each other as are the seam portion 24b and the rib 28b. By this configuration, there is a substantially triangular portion 40 on the side of

the closure seam 24a - 24b opposite the areas 30 which is made up of the folded overlapping corners of the bag material designated 42. These are secured together by a combining seam 44.

The triangular portion 40 remains attached to the bag until it is ready to be opened. It will be noted in Fig. 6 that a line of serrations 46 extend along the closure seam portions 24a and 24b. The provision of the triangular portion 40 lends additional strength to the bag to guarantee against premature rupture at the juncture 22.

When the bag is ready to be opened, the portion 40 is torn from the bag along the lines of serration 46 rendering the bag as it appears in Fig. 7. Thereafter, the portions 30 and/or the closure seam portions 24a and 24b may be gripped and pulled apart to develop and concentrate rupturing force at the juncture 22 as in above described constructions.

The various constructions may be fabricated in various ways. They may be made by cutting off blanks from a continuous tube of polyolefin material and forming the frangible seams 20, the bottom 36, the closure seam 24, and the ribs 28 by heat sealing. Another method of fabrication would be to start with sheet material folded upon itself with the various ribs, seams and lines also formed by heat sealing.

Another method would be by forming the entire bag by blow molding. The various ribs and seams would be formed in the mold cavity and imparted to the bag in the blow molding process.

Claims

1. A blood product storage bag made of flexible material and having a body (10) with front and rear faces and a closure seam (24) at or adjacent an end of the body, characterised by the body (10) having an easy-open frangible construction provided by opposed, frangible seams (20), one in each of the said faces, which extend to the closure seam (24) and are aligned with one another thereat, and stress-concentrating means (e. g. 34) which concentrate an applied opening force at the juncture (22) of the seam (24) and said frangible seams (20) for causing the body to rupture at the juncture (22) and be torn open along the frangible seams (20) to separate the bag from its contents.

2. A bag according to claim 1, characterised by portions (26 or 30) of the body (10) being located laterally of the juncture (22) and providing means to be gripped for applying the opening force which is concentrated at the juncture (22).

3. A bag according to claim 1 or claim 2, characterised by ribs (28) extending from the closure seam (24) and diverging away from the juncture (22) to define unfilled areas (30) of the body (10) which may be gripped to apply the opening force which is concentrated at the juncture (22).

4. A bag according to claim 3, characterised in that the ribs (28a, 28b) are aligned linear extensions of a V-shape closure seam (24).

5. A bag according to claim 1, 2, 3 or 4, characterised in that portions (26) of the flexible material lie laterally of the juncture (22) on the side of the closure seam (24) opposite the frangible seams (20) and are formed to concentrate the opening force at the juncture when the lateral portions (26) are pulled apart.

6. A bag according to any of claims 1 to 3 or 5 characterised in that the closure seam (24) is essentially along a straight line.

7. A bag according to any of claims 1 to 5, characterised in that the closure seam (24) is of V-shape converging at the juncture (22) to concentrate the said force thereat.

8. A bag according to any of claims 1 to 7, characterised in that the closure seam (24) is notched (at 34) to concentrate the opening force at the juncture (22).

9. A bag according to any of claims 1 to 8 characterised in that the body (10) is formed from sheet and seams forming the frangible seams (20) and closure seam (24) are formed by heat sealing.

10. A bag according to any of claims 1 to 8, characterised in that the body (10) is formed by blow molding.

11. A bag according to any of claims 1 to 10, made from plastics material which is capable of remaining flexible at temperatures of -25°C to -80°C.

12. A bag according to any of claims 1 to 11, characterised by having removable material (40, 42) to one side of the closure seam (24) opposite the frangible seams (20) to strengthen the container and render the closure seam (24) unlikely to be ruptured prematurely.

13. A bag according to any of claims 1 to 11, characterised by the closure seam (24) being of V-shape configuration the point of which V intersects the juncture (22), the said closure seam defining a V-shape removable portion (40) of body material on the side of the closure seam which, is opposite the frangible seams (20) whereby the closure seam (24) may be ruptured at the juncture (22) and the body (10) torn open along the frangible seams (20) to separate it from its contents after the " V-shape body material is removed.

14. A bag according to claim 13, characterised by lines of weakness (46) separating the removable portion (40) from the remainder of the body (10).

Patentansprüche

1. Beutel zur Speicherung von Blutkomponenten aus flexiblem Material mit einem Aufnahmeteil (10) mit einer Vorder- und einer Rückseite sowie einer Verschlußnaht (24) am oder nahe dem Ende des Aufnahmeteils, dadurch gekennzeichnet, daß der Aufnahmeteil (10) eine leicht zu öffnene aufreißbare Konstruktion aufgrund von einander gegenüberliegenden aufreißbaren Nähten (20) aufweist, von denen eine in jeder der Beutelseiten vorgesehen ist und die zur Verschlußnaht (24) hinlaufen und dort miteinander in Übereinstimmung gebracht sind, und daß Spannungskonzentrationsmittel (z. B. 34) vorgesehen sind, die eine aufgebrachte Öffnungskraft an der Verbindungsstelle (22) der Verschlußnaht (24) und der aufreißbaren Nähte (20) für ein Aufreißen des Aufnahmeteils an der Verbindungsstelle (22) und ein Auftrennen entlang den aufreißbaren Nähten (20) zur Trennung des Beutels von seinem Inhalt konzentrieren.

2. Beutel nach Anspruch 1, gekennzeichnet, durch Bereiche (26; 30) des Aufnahmeteils (10), die seitlich der Verbindungsstelle (22) angeordnet sind und Handhabungsmittel zum Aufbringen der Öffnungskraft bilden, die an der Verbindungsstelle (22) konzentriert ist.

3. Beutel nach Anspruch 1 oder 2, gekennzeichnet durch Rippen (28), die von der Verschlußnaht (24) ausgehen, von der Verbindungsstelle (22) fort divergieren und unbefüllte Bereiche (30) des Aufnahmeteils (10) begrenzen, die ergriffen werden können, um die Öffnungskraft aufzubringen, die in der Verbindungsstelle (22) konzentriert ist.

4. Beutel nach Anspruch 3, dadurch gekennzeichnet, daß die Rippen (28a, 28b) fluchtende lineare Verlängerungen einer V-förmigen Verschlußnaht (24) sind.

5. Beutel nach Anspruch 1, 2, 3 oder 4, dadurch gekennzeichnet, daß seitlich der Verbindungsstelle (22) auf der Seite der Verschlußnaht (24) gegenüber den aufreißbaren Nähten (20) Bereiche (26) des flexiblen Materials liegen und derart geformt sind, daß sich die Öffnungskraft an der Verbindungsstelle bei einem Auseinanderziehen der seitlichen Bereiche (26) konzentriert.

6. Beutel nach einem der Ansprüche 1 bis 3 oder 5, dadurch gekennzeichnet, daß die Verschlußnaht (24) im wesentlichen entlang einer geraden Linie verläuft.

7. Beutel nach einem der Ansprüche 1 bis 5, dadurch gekennzeichnet, daß die Verschlußnaht (24) eine V-Form besitzt, die an der Verbindungsstelle (22) zum Konzentrieren der Öffnungskraft an dieser Stele zusammenläuft.

8. Beutel nach einem der Ansprüche 1 bis 7, dadurch gekennzeichnet, daß die Verschlußnaht (24) zum Konzentrieren der Öffnungskraft an der Verbindungsstelle (22) eingekerbt ist (bei 34).

9. Beutel nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß der Aufnahmeteil (10) von Folie gebildet ist und die aufreißbaren Nähte (20) und die Verschlußnaht (24) bildende Nähte durch Heißsiegeln gebildet sind.

10. Beutel nach einem der Ansprüche 1 bis 8, dadurch gekennzeichnet, daß der Aufnahmeteil (10) durch Blasformen gebildet ist.

11. Beutel nach einem der Ansprüche 1 bis 10, dadurch gekennzeichnet, daß er aus Kunststoffmaterial besteht, das bei einer Temperatur von -25°C bis -80°C flexibel bleibt.

12. Beutel nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß wegnehmbares Material (40, 42) auf einer Seite der Verschlußnaht (24) gegenüber den aufreißbaren Nähten (20) vorgesehen ist, um die Festigkeit des Behälters zu erhöhen und es unwahrscheinlich zu machen, daß die Verschlußnaht (24) vorzeitig aufgerissen wird.

13. Beutel nach einem der Ansprüche 1 bis 11, dadurch gekennzeichnet, daß die Verschlußnaht (24) eine V-förmige Gestalt aufweist, die Spitze des V die Verbindungsstelle (22) schneidet und die Verschlußnaht einen V-förmigen wegnehmbaren Bereich (40) des Aufnahmteilmaterials auf der Seite der Verschlußnaht begrenzt, die den aufreißbaren Nähten (20) gegenüberliegt, wodurch die Verschlußnaht (24) an der Verbindungsstelle (22) aufgerissen und der Aufnahmeteil (10) entlang den aufreißbaren Nähten (20) offengetrennt werden kann, um ihn von seinem Inhalt nach dem Entfernen des V-förmigen Aufnahmeteilmaterials zu trennen.

14. Beutel nach Anspruch 13, gekennzeichnet durch Schwächungslinien (46), die den wegnehmbaren Bereich (40) vom verbleibenden Bereich des Aufnahmeteils (10) trennen.

Revendications

1. Sachet de stockage pour un produit sanguin, ledit sachet étant fait en une matière flexible et comprenant un corps (10) à face frontale et arrière et une ligne de fermeture (24) à une extrémité du corps ou adjacente à celle-ci, caractérisé en ce que le corps (10) est d'une construction fragile pouvant être facilement ouverte due par des jonctions frangibles (20) opposées une dans chacune desdites faces, qui s'étendent vers la ligne de fermeture (24) et sont alignés l'un avec l'autre sur celle-ci, et des moyens de concentration de contrainte (p. ex. 34) qui concentrent une force d'ouverture appliquée sur l'intersection (22) de la ligne (24) et les jonctions frangibles (20) pour provoquer la rupture du corps à l'intersection (22) et

son ouverture par déchirement le long des jonction frangibles (20) pour séparer le sachet de son contenu.

2. Sachet selon la revendication 1, caractérisé par des parties (26 ou 30) du corps (10) qui se trouvent latéralement de l'intersection (22) et qui fournissent un moyen destiné à être saisi pour appliquer la force d'ouverture qui est concentrée sur l'intersection (22).

3. Sachet selon la revendication 1 ou 2, caractérisé par des nervures (28) s'étendant à partir de la ligne de fermeture (24) et divergeant à partir de l'intersection (22) pour définir des zones (30) non remplies du corps (10) qui peuvent être saisies pour appliquer la force d'ouverture qui est concentrée sur l'intersection (22).

4. Sachet selon la revendication 3, caractérisé en ce que les nervures (28a, 28b) sont des extensions linéaires alignées d'une ligne de fermeture (24) en forme de V.

5. Sachet selon la revendication 1, 2, 3 ou 4, caractérisé en ce que les parties (26) de la matière flexible se trouvent latéralement de l'intersection (22) sur le côté de la ligne de fermeture (24) opposé à jonctions frangibles (20) et sont formées pour concentrer la force d'ouverture sur l'intersection, quand les parties latérales (26) sont tirées à part.

6. Sachet selon l'une quelconque des revendications 1 à 3 ou 5, caractérisé en ce que la ligne de fermeture (24) se trouve essentiellement le long d'une ligne droite.

7. Sachet selon l'une quelconque des revendications 1 à 5, caractérisé en ce que la ligne de fermeture (24) a la forme de V convergeant à l'intersection (22) pour concentrer ladite force sur celle-ci.

8. Sachet selon l'une quelconque des revendications 1 à 7, caractérisé en ce que la ligne de fermeture (24) est pourvue d'une entaille (à 34) pour concentrer la force d'ouverture sur l'intersection (22).

9. Sachet selon l'une quelconque des revendications 1 à 8, caractérisé en ce que le corps (10) est formé d'une feuille et que les lignes formant les jonctions frangibles (20) et la ligne de fermeture (24) sont formées par thermosoudage.

10. Sachet selon l'une quelconque des revendications 1 à 8, caractérisé en ce que le corps (10) est formé par soufflage.

11. Sachet selon l'une quelconque des revendications 1 à 10, réalisé en une matière plastique qui est capable de rester flexible à des températures de -25°C à -80°C.

12. Sachet selon l'une quelconque des revendications 1 à 11, caractérisé par une matière amovible (40, 42) sur un côté de la ligne de fermeture (24) opposé aux jonctions frangibles (20) pour renforcer le sachet et faire que la ligne de fermeture (24) ne peut se rompre prématurément.

13. Sachet selon l'une quelconque des revendications 1 à 11, caractérisé en ce que la ligne de fermeture (24) a la forme d'un V dont la pointe intersecte l'intersection (22), la ligne de fermeture définissant une partie en forme de V (40) amovible de la matière du corps sur un côté de la ligne de fermeture qui est opposé aux jonctions frangibles (20), de sorte que la ligne de fermeture (24) peut être rompue à l'intersection (22) et le corps (10) peut être ouvert par déchirement le long des jonctions frangibles (20) pour le séparer de son contenu après avoir enlever la matière du corps en forme de V.

14. Sachet selon la revendication 13, caractérisé par des lignes affaiblies (46) séparant la partie amovible (40) du restant du corps (10).

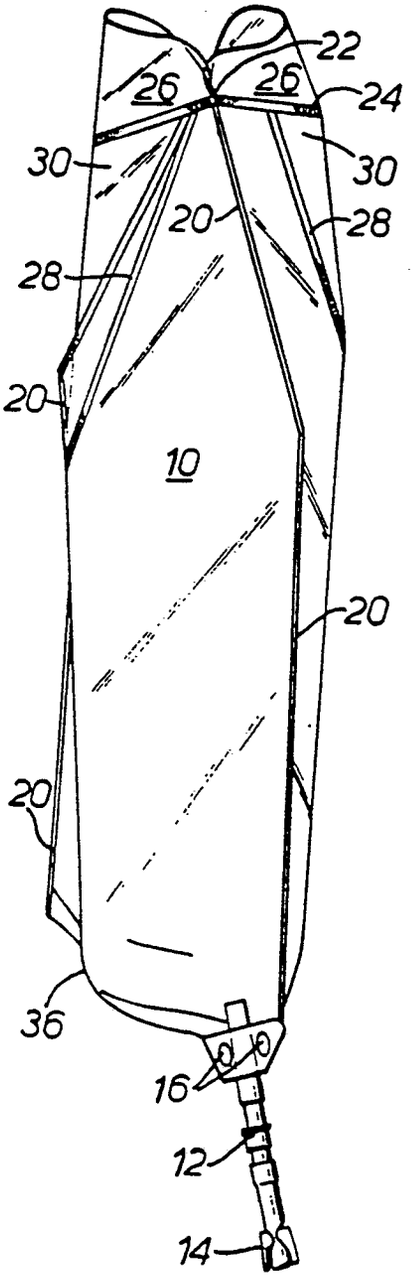

FIG. 1.

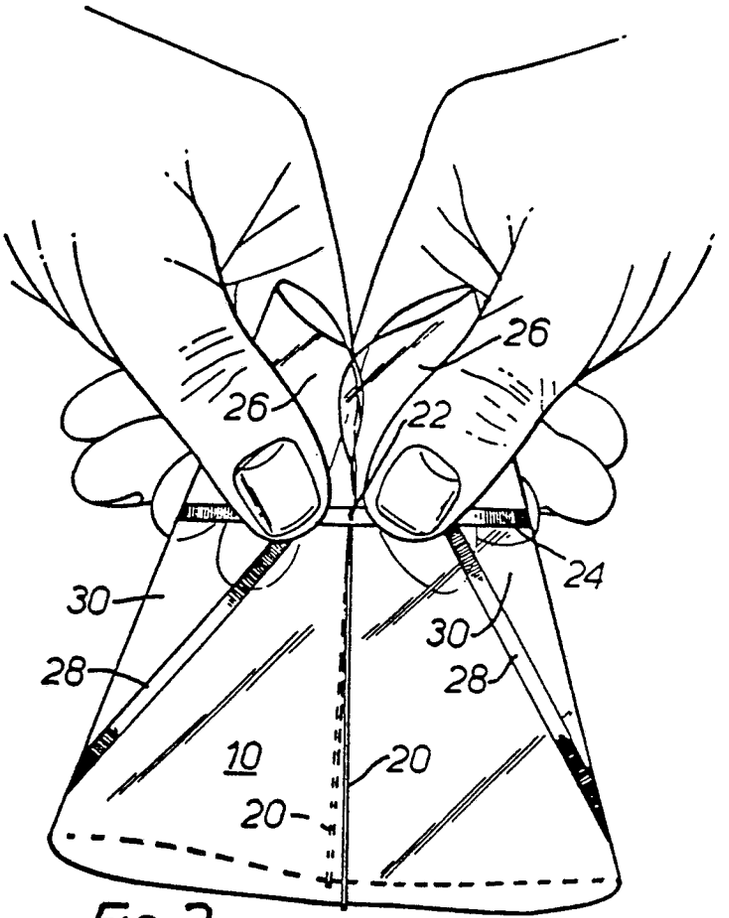

FIG. 2.

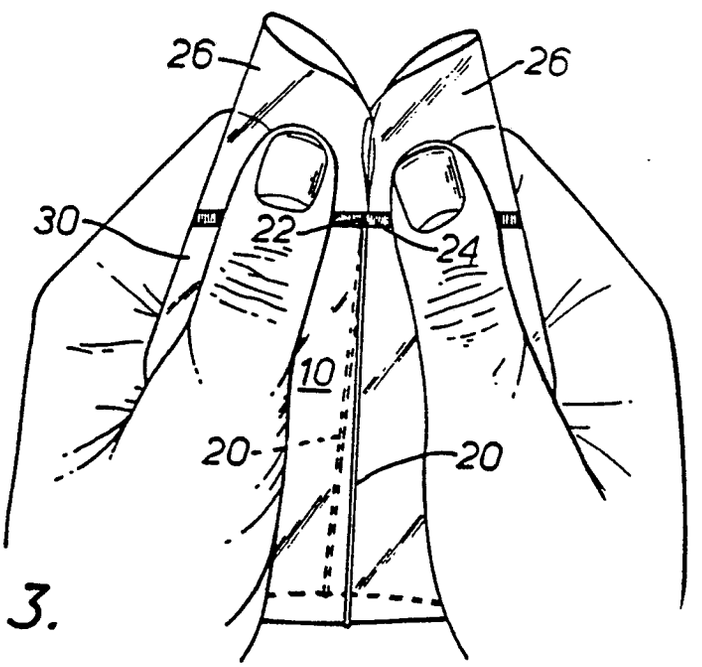

FIG. 3.

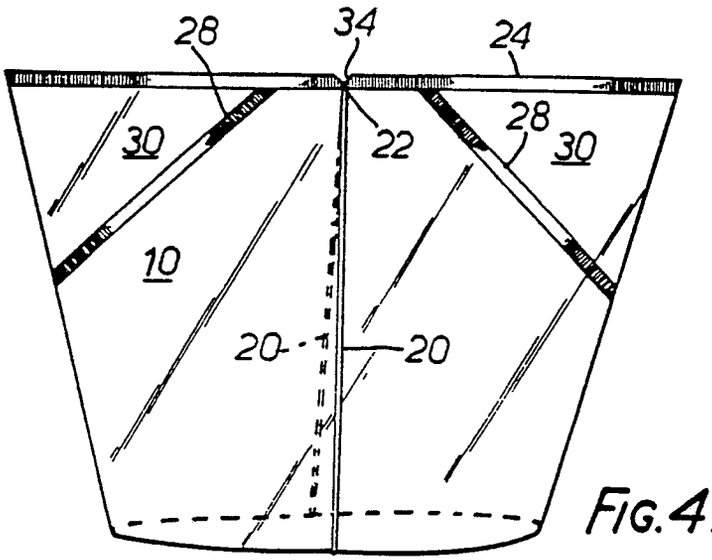

FIG. 4.

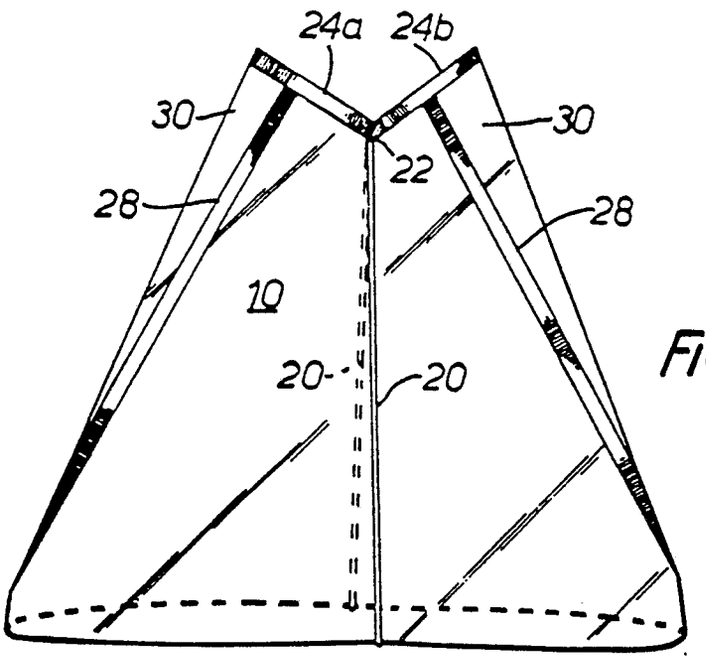

FIG. 5.

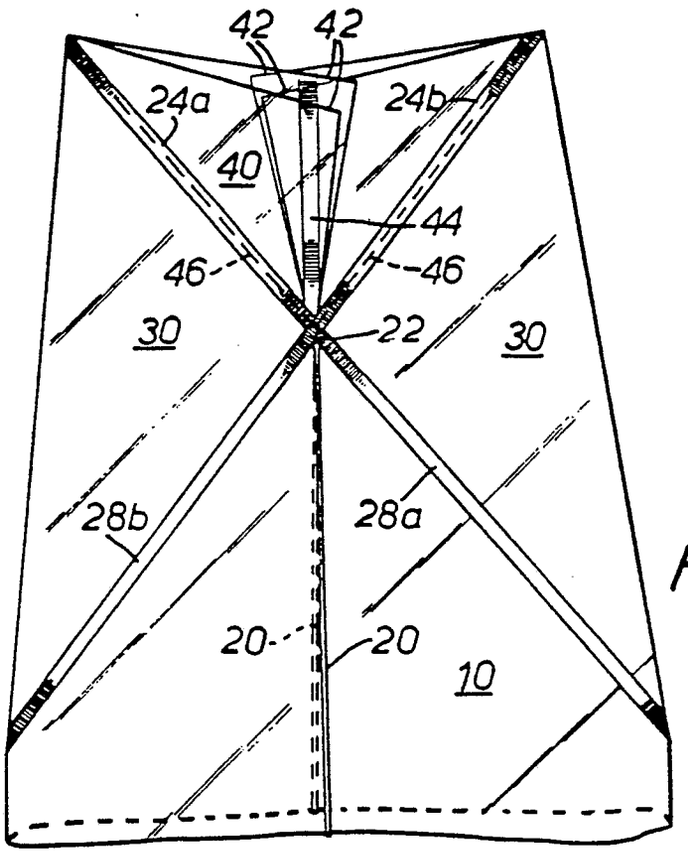
42
42
24a
24b
40
44
46
46
30
22
30
28b
28a
20
20
10

FIG. 6.

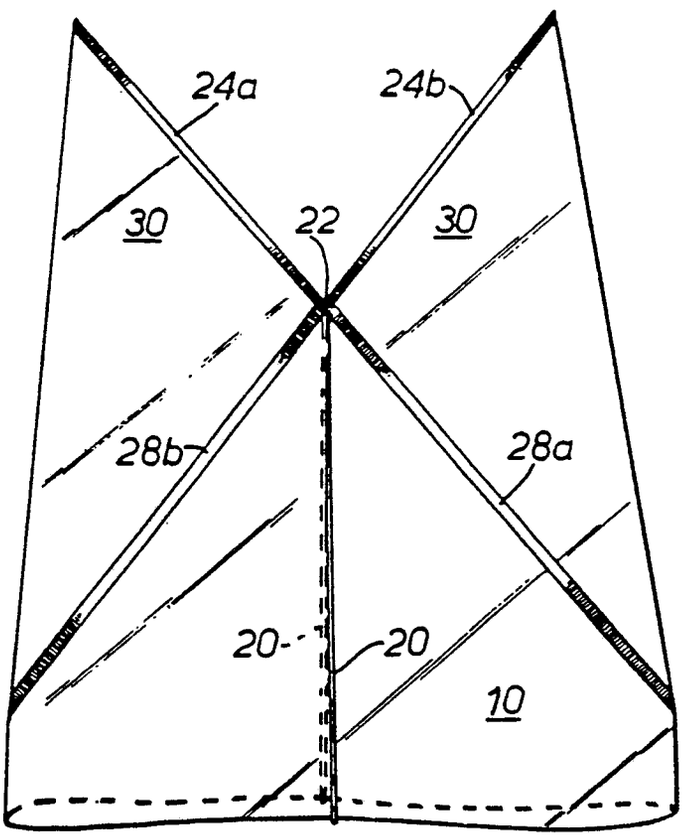
24a
24b
30
22
30
28b
28a
20
20
10

FIG. 7.