[54]	BLOOD	COLLECTION,	STORAGE	AND	
	ADMINISTERING BAG				
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[63] Continuation-in-part of Ser. No. 243,575, April 13, 1972, abandoned.

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	UNITED STATES PATENTS

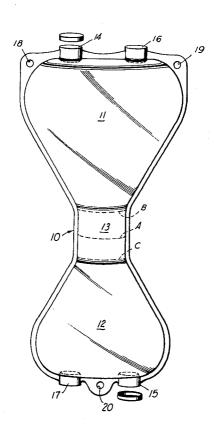
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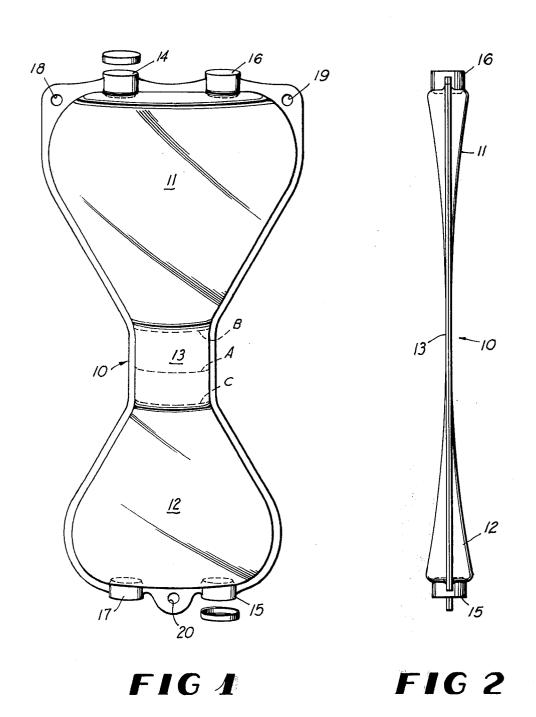
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[57] ABSTRACT

A method and bag or container for storing a viable fluid, such as blood, constructed of an integrally formed flexible plastic material having two storage compartments connected in fluid flow communication by a transfer conduit neck portion. One of the storage compartments is detailed in size to contain approximately 60% of a predetermined quantity of blood with the other storage compartment and the transfer conduit neck portion detailed in size to contain the remainder of the predetermined quantity of blood. The transfer conduit neck portion is constructed of a material which is capable of being sealed so that the container can be divided into a number of separate selfcontained compartments and in another use of the container, the transfer conduit neck portion is sealed adjacent each of the storage compartments to divide the container into three separate self-contained compartments, one compartment containing the liquid plasma portion of a quantity of blood, the transfer conduit neck portion containing the blood platelets and the other storage compartment containing the remaining red blood cells.

5 Claims, 2 Drawing Figures





BLOOD COLLECTION, STORAGE AND ADMINISTERING BAG

CROSS REFERENCE TO RELATED APPLICATION

This is a continuation-in-part of my copending appli- 5 cation, Ser. No. 243,575 filed Apr. 13, 1972 and now abandoned.

BACKGROUND OF THE INVENTION

This invention relates to a flexible plastic bag or con- 10 tainer and is more particularly concerned with a container which is capable of being separated to form a number of individual self-contained storage compartments containing predetermined separated blood portions.

A number of flexible plastic containers have been provided for use in storing blood, with these containers capable of being divided into a number of independent storage compartments. However, the prior art blood storage containers are not detailed in shape and size to 20 contain a predetermined percent of a predetermined quantity of blood, with the predetermined percent being representative to the liquid plasma portion of the blood.

In the collection, storage and administration of whole 25 blood platelets and red blood cells. blood, it is often necessary to separate the cellular components of the whole blood from the liquid plasma portion, so that the liquid plasma portion of the blood can be administered to certain patients, the platelet portion of the whole blood can be administered to certain pa- 30 tients and the remaining red blood cells can be administered to certain patients.

The prior art blood storage containers do not provide a container designed with a specific shape and with specific size storage compartments to automatically sepa- 35 rate the liquid plasma portion, the platelet portion and the remaining red blood cells of a quantity of blood by sedimentation during storage insuitable refrigeration means. Since the prior art blood containers are not designed such that the containers can be sealed and sepa- 40 rated to contain a prescribed portion of the blood, other complex methods are utilized to separate the desired portion to be given to a patient from the remaining portion of the whole blood.

Further, it is often necessary to perform a number of 45 specific laboratory analysis of donar blood in order to determine the donor's state of health. These prior art laboratory methods of analyzing blood to determine the donor's state of health is time consuming and expensive to use.

The following patents exemplify the prior art: U.S. Pat. Nos. 3,692,493, 3,554,256, 3,545,671, 3,520,471, 3,375,824, 3,257,072, 3,187,750, 2,848,995.

SUMMARY OF THE INVENTION

The above disadvantages have been overcome by the present invention which basically includes an integrally formed flexible plastic container having two storage compartments connected in fluid flow communication by a narrow transfer conduit portion, with the transfer conduit portion capable of being sealed so that the container can be divided into a number of self-contained storage compartments.

One important feature of the present invention is that 65 the storage compartments are detailed in size whereby one storage compartment has a capacity representative of the plasma portion of whole blood, the other storage

compartment has the capacity representative of the red blood cells and wherein the transfer neck portion has a capacity representative of the platelet portion of whole blood.

Another important feature of the present invention resides in the shape and size of the storage compartments with the interconnecting transfer conduit neck portions so that the transfer conduit neck portion will trap separated blood platelets, and wherein the transfer conduit neck portion is adapted to be sealed adjacent each of the storage compartments whereby the container can be separated into three separate selfcontained compartments, one compartment containing the liquid plasma portion of a quantity of blood, the 15 other storage compartment containing the red blood cells and the transfer conduit neck portion containing the blood platelets.

It is therefore a primary object of the present invention to provide a container capable of storing and separating the components of blood into a number of predescribed compartments which can be individually separated into self-contained storage means.

A further object of the present invention is to provide a method of separating donor blood into liquid plasma,

Another object of the present invention is to provide a container capable of providing a ready reference to a donor's state of health.

An additional object of the present invention is to provide a blood collection, storage and administering container which is simple in construction and use, economical to manufacture and reliable in performance.

These and other objects and advantages of the details of construction will become apparent after reading the following description of the illustrative embodiment with reference to the attached drawing wherein like reference numerals have been used to refer to like parts throughout the several figures, and wherein:

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a front elevational perspective view of a container embodying the principles of the present invention, shown in a partially filled stage so as to give it a bulbous appearance; and,

FIG. 2 is a side elevational view of FIG. 1 in the deflated state.

DESCRIPTION OF THE ILLUSTRATIVE **EMBODIMENTS**

Referring now to the drawing, a storage container embodying the principles of the present invention is shown and generally represented by the reference numeral 10. Storage container 10 is integrally formed and constructed of flexible plastic material having a large storage compartment 11 and a smaller storage compartment 12. The storage compartments 11 and 12 are connected by a relatively small transfer conduit neck portion 13. The storage compartments 11 and 12 tapers toward the transfer conduit neck portion 13 which is substantially narrower and smaller than storage compartments 11 and 12 so as to give the container an overall appearance of an hourglass. Thus compartments 11 and 12 provide progressively narrowing compartments as they approach neck 13 from opposite ends. Each of the storage compartments 11, 12 is provided at their outer ends, i.e., their upper and lower ends with port means 14, 15, respectively, which have

removable caps C and are operable for receiving spike means (not shown) utilized to drain the storage compartments in administering the blood portions to a patient. Each of the compartments 11, 12 is provided with an opening having a stopper element 16, 17, respec- 5 tively, which is operable for receiving a drainage needle

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In more detail, the container 10 depicted in the drawing, is formed of a pair of opposed complimentary plastic sheets 21 and 22, each of which is an integral elasto- 10 meric web member. Sheets 21 and 22 are respectively provided with flat contiguous endless perimeters or border flanges 23 and 24.

Within and defined by the perimeter flange 23 are the upper, intermediate, and lower compartment defin- 15 ing walls 25, 26 and 27. The upper wall 25 integrally merges with the flange 23 while the lower wall edge 31 integrally merges with the upper edge of intermediate wall 26.

together and, as viewed in FIG. 1, provide an upper edge or flange portion 30 which is essentially straight, extending laterally or horizontally across the top of the bag. The ends of the upper flange portion 30 merge with the ends of downwardly extending side edges or 25 flange portions 28 and 29. From the ends of upper edge 30, the edges 28 and 29 curve outwardly and downwardly and then inwardly about radii within the upper wall 25. Thence, the intermediate and lower portions of the side edges or flanges 28 and 29 are straight and 30 taper downwardly, converging toward the narrowed upper throat at the lower end portion of compartment 11, i.e., at the junction of compartment 11 and conduit neck portion 13.

At the upper throat, the edges 28 and 29 respectively 35 merge with the spaced opposed edges approximately parallel to intermediate edges or flange portions 32 and 33 of the intermediate wall 26, which forms conduit neck portion 13.

The lower wall 27 is congruent in shape to the upper 40 wall 25, but is smaller. The side edges or flange portions 34 and 35 of wall 27 therefore are straight, being reversely tapered or diverging and then curving arcuately inwardly to merge with the lower edge or bottom portion 36, which is essentially straight and parallel to 45 upper edge 30. The throat line 37 of wall 27 integrally merges with the lower edge of wall 26 in the same manner as the merger of throat line 31.

The sheet 22 has a complimentary structure to that of sheet 21 having upper wall 45, intermediate wall 46 and lower wall 47 encompassed by border 24.

As seen in FIG. 2, the opposed upper walls 25 and 45 are spaced from each other and converge downwardly defining a progressively narrowing compartment as it approaches the throat lines 31. Also, the opposed lower walls 27 and 47 converge upwardly, defining an upwardly narrowing compartment as throat line 37 is approached. The intermediate walls, such as wall 26, form the straight tubular cylindrical or eliptical junction or neck 13.

It is understood that the sheets 23 and 24 can be readily and easily vacuum formed and the flanges glued together. The bag 10 can also be readily blow molded as an entirely integral member.

In the embodiment shown in FIGS. 1 and 2, the port means 14, 15, 16 and 17 are formed integrally in or between the opposed flanges 23 and 24.

As shown in FIG. 1, container 10 is provided with a pair of holes or openings 17, 18 adjacent an upper portion of storage compartment 11. Openings 17, 18 are provided for use in suspending container 10 during storage and for use in suspending the container while administering blood to a patient. Container 10 is also provided with a single opening 19 adjacent a bottom edge of storage compartment 12 which is operable for use in suspending the container in a blood administering operation.

The above described flexible plastic blood storage container is referred to as a "hemocrit" since it is operable for determining the ratio of the volume of red blood cells to the volume of whole blood as will be described in more detail below.

Container 10 can be constructed of a number of sizes for accommodating various quantities of whole blood. However, the bag is normally constructed in three sizes, namely: the large size having a capacity of 512 The upper portions of flanges 23 and 24 are secured 20 ml., the intermediate size having a capacity of 256 ml., and a small size having a capacity of 128 ml. The storage compartments 11 and 12 and the transfer conduit portion 13 are constructed to make a blood collection, storage and administering container which is easy to use, versatile and scientifically efficient. Storage compartment 11 is detailed in size to have a capacity representing approximately 60% of the entire capacity of the container, since the human whole blood includes approximately 60% plasma. The smaller storage compartment 12 is detailed in size to have a capacity of approximately 40% of the capacity of the entire container and will be operable for containing the remaining cellular components of whole blood, including the white cells, the lymphocytes, the platelets, and the red blood cells. In use, the smaller storage compartment 12 will be used to store the red blood cells and the larger compartment 11 will be used to contain the liquid plasma portion of the blood. The transfer conduit portion 13 will be utilized for storing the white cells and platelet portions of whole blood.

In using container 10, the donor blood is introduced into the container through one of the port openings in a conventional manner. After the container 10 has been filled with blood, the container is properly sealed and immediately placed in a suitable refrigeration storage means. Container 10 is stored with the larger compartment 12 in an elevated position so that during storage, the red blood cells, being heavier, will settle to the smaller compartment 12. When the heavier blood cells settle to the smaller storage compartment 12, the liquid plasma will remain in the upper or larger storage compartment 11. After sedimentation, the white cells and platelets are trapped in the narrow transfer conduit portion 13. Storage container 10 can also be utilized in a conventional centrifuging process so that the red blood cells can be more quickly separated from the liquid plasma portion of the whole blood. A centrifuging process for separating blood is desirable in a plasmapheresis technique, wherein the red blood cells have been separated from the plasma portion, and are transfused back into the blood donor. The donor's plasma is kept for use as liquid plasma, or it can be used for blood testing and blood typing since it contains desirable antibodies, such as specific agglutinins.

After the blood contained in container 10 has been separated either by sedimentation or in a centrifuging process, these containers can be sealed along an intermediate portion of the transfer conduit portion represented by letter A. The transfer conduit neck portion is sealed by utilizing a conventional heat sealing process. Container 10 is separated into two self-contained storage compartments by making a cut along line A 5 after a heat sealing operation has been performed. When container 10 is separated into two self-contained storage compartments 11, 12, storage compartment 11 will contain the blood plasma and storage compartment 12 will contain the red blood cells. The red cells con- 10 tained in storage compartment 12 are administered to certain anemic patients who need the red blood cells but who do not need whole blood. For example, a geriatric patient may need two units of red blood cells. However, if two units of whole blood were adminis- 15 tered, his circulatory system might well be overloaded and this might produce injurious effects to the patient.

The plasma portion of the blood contained in storage compartment 11 can be administered to those patients who are best helped by receiving blood plasma. For example, plasma is administered to patients in shock.

As indicated above, after the blood has been allowed to separate either by sedimentation or centrifuging, the transfer conduit portion 13 will contain the white cells and platelets. It is often desirable to administer only the white cells and platelets to certain patients. If only the white cells and platelets are to be administered to a patient, a sealing operation is made along line B transversely across the transfer conduit portion 13 adjacent 30 ends of said container. compartment 11 and is made along line C transversely across conduit neck portion adjacent compartment 12. By making a heat seal along lines B and C, a cut can be made along lines B and C to separate the container 10 into three self-contained storage compartments, with 35 storage compartment 11 including the blood plasma portion, storage compartment 12 including the red blood cells and with blood storage compartment 13 containing the white cells and platelets.

In administering white cells or platelets, they are 40 withdrawn from the transfer conduit neck portion 13 by a hypodermic syringe under aseptic conditions. This concentrated dose of platelets can be administered to those patients who are deficient in platelets. Also, by separating the white cells and platelets from the plasma 45 and red blood cells, the plasma and red cells can be administered to a small percentage of patients who are hypersensitive or allergic to white cells.

The above described container 10 is useful in determining the donor's state of health. If the donor is anemic, not having a normal quantity of red blood cells, this will be quickly reflected as the bottom or smaller storage compartment 12 will not be filled with red blood cells. Further, those patients with polycythemia can be readily detected, since those patients will have too many red blood cells, and the red blood cells will extend up into the upper storage compartment 11. Since polycythemia is a disease syndrome, such blood would not be used for administering to other patients.

It now becomes obvious that the above described blood collection, storage and administering container is capable of obtaining the above stated objects and advatages. It is obvious that those skilled in the art may make modifications in the details of construction without departing from the spirit of the invention which is to be limited only by the scope of the appended claims.

What is claimed is:

1. A plastic bag for storing viable fluid comprising a pair of generally flat, flexible, face-to-face, opposed and peripherally joined side walls defining:

a. a relatively large upper storage compartment;

- a relatively large lower storage compartment spaced a predetermined distance from said upper storage compartment;
- c. a means for selectively defining an intermediate third compartment comprising a relatively narrow transfer conduit neck formed by a pair of rupturable seals, one at the bottom of said upper compartment and another at the top of said lower compartment, said intermediate third compartment providing fluid flow communication between the two compartments while potentially defining a third storage compartment;

 d. said upper compartment tapering downwardly toward said neck to provide a progressively narrowing upper compartment approaching said conduit neck; and,

e. said side walls being normally in a collapsed condition and being deformable outwardly by receipt of the viable fluid.

2. A container as defined in claim 1 further characterized in that said upper compartment is of a size to contain approximately 60% of a predetermined amount and wherein said lower storage compartment and said transfer conduit neck is detailed in size to contain approximately 40% of said predetermined amount.

3. A container as defined in claim 1 further characterized in that each of said storage compartments includes fluid entrance and fluid discharge means at the ends of said container.

4. A container as defined in claim 5 further characterized in that said predetermined capacity of said third compartment is approximately 50 cc.

5. A bag for the storage and gravity separation of viable fluids comprising a pair of opposed complimentary elastomeric sheets respectively provided with flat border flanges, each of said flanges confining within its border a relatively wide upper wall, a relatively wide lower wall and a relatively narrow intermediate wall joining the upper wall and lower wall at their central portions, said flanges being joined in contiguous abutting relationship; the flanges, adjacent said upper walls of said sheets, forming an upper, essentially straight, laterally extending, flange portion and a pair of opposed downwardly extending upper side flange portions, said upper side flange portions converging downwardly; said flanges, adjacent said intermediate walls, having a pair of intermediate flange portions in spaced relationship to each other and joined to said downwardly converging portions; said flanges, adjacent said lower walls, forming a pair of opposed downwardly diverging lower side flange portions and an essentially straight, lower flange portion joining the lower ends of said lower side flange portions, said upper walls defining a relatively large upper compartment tapering downwardly toward said intermediate walls, said lower walls defining a relatively large lower compartment tapering upwardly toward said intermediate walls, said intermediate walls defining a relatively small intermediate compartment providing communication between the upper and the lower compartments, said upper flanges being provided with hole means which permit the container to be supported, said flanges being provided with port means through which said viable fluid can be introduced into the compartments and removed therefrom, said intermediate walls being collapsible and having transverse spaced portions selectively sealable to each other and severable so that the upper and lower portions of said bag can be separated from each other and from said small intermediate compartment.