

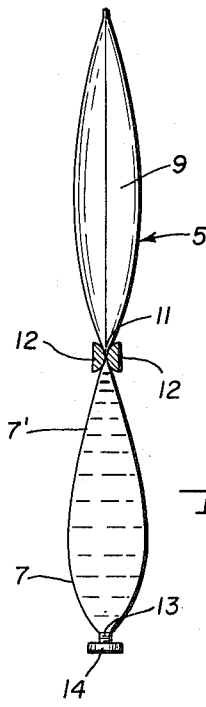
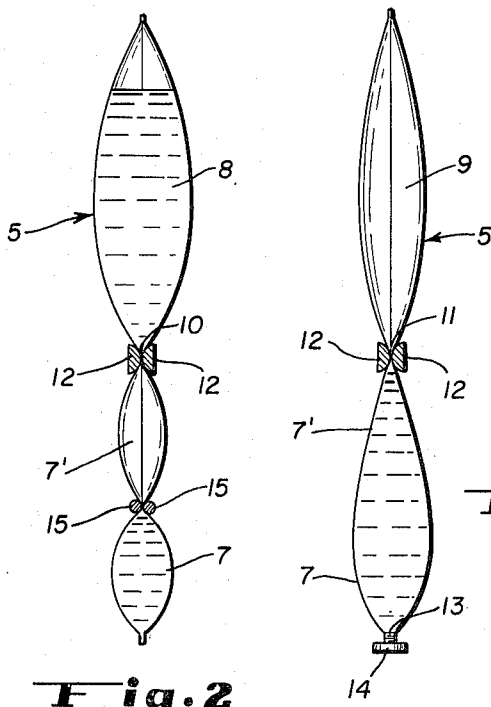
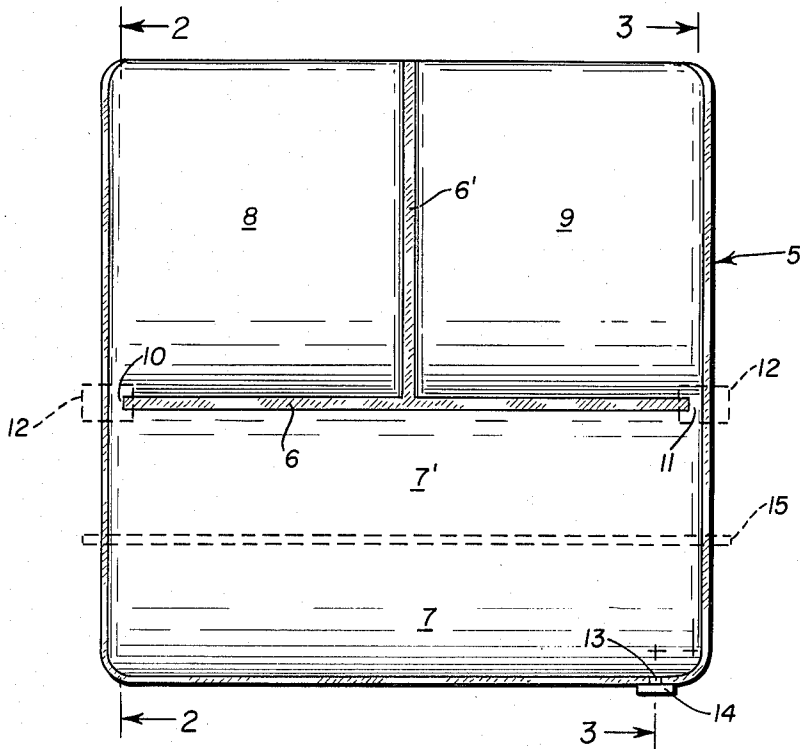
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WHOLE BLOOD STORAGE STRUCTURE

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WHOLE BLOOD STORAGE STRUCTURE

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This invention relates to a method and means for storage of whole blood and has particular application to a novel type of multiple compartment clear container used in blood storage.

Until quite recently the accepted practice for storage and use of whole blood in this country has been to collect whole blood and store it at temperatures of about 38° F. It has been found that the blood cells break down at the rate of about 1 percent per day and by the time 20 percent of the blood cells are hemolyzed, use of the stored blood in the human body may be dangerous. Consequently, a three week limit has been placed on the retention of whole blood under these conditions.

There has been a recent development of a clinically acceptable system for whole blood storage which permits the blood to be stored for relatively long periods without breakdown of the cells and which may be reconstituted at any time for safe use in the human body. This system involves introducing the whole blood into a container and centrifuging it for about 3 minutes. This serves to separate the red cells from plasma and they are then moved to separate storage areas. An isotonic saline citrated glucose solution is next added to the red cells to result in a 15 percent glucose solution. The separated plasma and the glucose-red cells mixture are then frozen separately and stored at liquid nitrogen temperature.

When it is desired to take the frozen blood for use in the human body, the plasma and the glucose-red cells mixture are thawed in a 37° C. water bath. After thawing, the major portion of the glucose is separated from the red cells by spinning in a centrifuge for three minutes and then decanting. The original whole blood is then reconstituted by adding its thawed plasma and is ready for use in the human body.

One of the chief difficulties in the new storage system is the care that must be exercised to prevent contamination of the red cells or the plasma while separated and to insure the same red cell-plasma mixture being brought together in the reconstituting procedure.

The present invention provides the requisite safeguards in the use of such a system and also provides convenience in handling and storage, including advantages not specified in the standards established for the use of such a system.

Accordingly, it is an object of this invention to provide a storage container for whole blood which permits minimum handling to maintain sterility and keep out pyrogens, which is capable of being sterilized, which provides proper heat transfer during freezing and thawing operations, which has adequate mechanical strength to withstand the centrifuging operations, which is compatible with blood and liquid nitrogen and which confines the blood from the time of initial introduction until withdrawal after reconstituting for use in the human body while permitting the specified separations within its hermetically sealed interior.

Another object of my invention is to provide a simple, durable and sterile container for storage and processing of whole blood which is transparent or translucent and permits visual inspection of its contents at all times, and which is of such low cost as to be treated as a disposable item.

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A further object of the invention is to provide a multiple compartment container for whole blood storage and processing which is sterile and permits transfer of whole blood components and compatible solution as required for cryogenic storage and for later reconstituting, and which is formed of clear material permitting visual inspection of its contents at all times to and including introduction of the reconstituted blood into a patent.

Still another object of the invention is to provide a system of using a multiple compartment sterile container in the cryogenic storage and subsequent reconstituting of whole blood which prevents any accidental mixing of separated plasma and red cells from different blood in the reconstituting procedure.

Other objects reside in novel details of construction and novel combinations and arrangements of parts, all of which will be set forth in detail in the course of the following description.

The practice of my invention will be described with reference to the drawings illustrating one form of container embodying features of the invention. In the drawings, in the several views of which like parts bear similar reference numerals,

FIG. 1 is a front elevation of a container being used in the processing and storage of whole blood with passage-sealing members shown in dash lines;

FIG. 2 is a section taken approximately on the line 2-2, FIG. 1, with clamping members shown in operating relation to other structure; and

FIG. 3 is a developed section taken approximately along the line 3-3, FIG. 1, and showing the position of contents at a different stage of the processing than depicted in FIG. 2.

As shown in FIG. 1, the container 5 is formed as a circumferentially closed bag-like member of a clear material, such as "Teflon FEP" fluorinated ethylene propylene, which will permit heat sealing and is clear for visual inspection, possesses the desired mechanical strength, clinically acceptable, and is flexible at liquid nitrogen temperature. The interior of the bag is partitioned as shown at 6 and 6' by heat sealing, forming a larger blood storage chamber 7 and smaller storage containers 8 and 9, the functioning of which will be described subsequently.

A passage 10 is provided in partition 6 to permit exchange of stored material between compartments 7 and 8 and a similar passage 11 permits interchange of stored material between compartments 7 and 9. Each of the passages 10 and 11 may be selectively closed and secured against interchange of material by a pinch-type device indicated by the dash lines 12. A headed passage 13 into compartment 7 permits introduction into and withdrawal of material from container 5 and a valve 14 which may be a clamping device is accessible from the outside of the container and effectively seals the entrance passage 13 except during introduction and withdrawal of material.

At the beginning of a given operation, a measured quantity of isotonic saline glucose solution is introduced through opening 13 with passage 11 open and the bag disposed with the opening 13 at its top. The charge to chamber 7 is directed through passage 11 into compartment 9 and when the complete charge is disposed therein, the clamp 12 is applied to close passage 11 and prevent interchange of material between compartments 7 and 9.

A measured quantity of whole blood is next introduced through passage 13 and when the entire charge is confined, the clamping member 14 is secured to complete the hermetic circumferential seal of container 5. Container 5 is next disposed in the position shown in FIG. 1 and is centrifuged for 3 minutes. After removal from

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the centrifuging operation, the red cells are collected in the bottom in a distinct layer separated from the plasma which stands above such cells. A clamping member 15 is then applied to the exterior of bag 5 along the lines of such separation and exerts sufficient force to completely separate blood cells from the plasma. The clamping member securing passage 10 is then removed and the plasma is directed to flow through passage 10 and fill compartment 8. When all of the plasma has been removed in this manner, the clamping member is again actuated to seal passage 10, after which clamping member 15 is removed and the clamping member 12 securing passage 11 also is removed to permit outflow of the solution from compartment 9 into compartment 7 where it mixes with the red cells confined therein. The container 5 is then frozen in liquid nitrogen or cold nitrogen gas, and the portion of the bag containing the red cells will be restrained into a physical shape to have a thickness of 2½ centimeters more or less for proper freezing. In this same action, the stored plasma in compartment 8 also is frozen to liquid nitrogen temperature and the plasma and red cells glucose solution may be stored at such temperatures for long periods without deterioration.

After such a storage period when it is desired to use the stored contents, the entire unit will be thawed in a warm water bath accompanied by agitation until the contents resume the liquid form. At this time, the unit is centrifuged again for 3 minutes to separate the glucose layer from the red cells. Clamping member 15 is affixed along the line of separation and passage 11 is opened to permit outflow of the solution into compartment 9. When the entire solution charge is confined therein, clamp 12 is applied to close passage 11 and the other clamp 12 is removed to open passage 10, permitting the plasma to descend into the compartment 7 and reconstitute the whole blood. At this stage, the blood is ready for use and the container 5 may be transported to the site of use and hung in the usual manner for withdrawal of the blood in treating a patient. Because of its relatively low cost, container 5 may be treated as a disposable item and disposed of when the whole blood charge is withdrawn.

Use of the container 5 as described above affords several advantages. The blood is collected and processed in one hermetically sealed unit and the red cells of the blood are never separated from its own plasma except within the confines of the container, thus avoiding any possible mixing of cells from one source with plasma from another source. The provision of a clear container permits visual observation of contents at all stages of the processing and during the final withdrawal of the reconstituted blood from the container, as during a transfusion.

The utilization of the "Teflon" material in forming the bag meets all required criteria including the maintenance of sterile conditions, hermetical sealing after blood is placed in the container and adequate heat transfer during the freezing and thawing procedures. It possesses the requisite mechanical strength to withstand the centrifuging procedure and is compatible with blood and liquid nitrogen. "Teflon" is resistant to heat and can be sterilized. Two forms of "Teflon" are available commercially and suited for use in the practice of my invention. "Teflon TFE" is polytetrafluoroethylene, also sold as "Halon TFE." The other sold under the name "Teflon FEP" is fluorinated ethylene propylene, a copolymer of TFE and hexafluoropropylene.

By utilizing such a container in conjunction with the newly developed blood storage system, it is possible to safely store whole blood for long indefinite periods and to reconstitute it with original qualities and characteristics when it is to be used. The mixing of the red cells and glucose solution has been adequately tested and is an accepted method for preparing red cells for long period storage at liquid nitrogen temperatures.

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While I have shown a partitioning arrangement providing a three compartment bag, it will be understood that the partitioning arrangement may be modified to provide any plurality of compartments required in such procedures and to maintain the contents of such compartments under sterile hermetically sealed condition as required. I have also indicated a preferred material for use in forming the container of the present invention, but it will be understood that any material possessing equivalent properties and characteristics may be used for this purpose.

I claim:

1. A container for the treatment and storage of whole blood, comprising a flexible bag of translucent composition sterilized after fabrication and having a circumferential enclosure providing a hermetic seal for the contents of the container, valve-controlled means for selective introduction and withdrawal of fluent material including a measured quantity of blood at the beginning and end of a storage period, at least one liquid-sealing partition dividing the interior of the bag into a plurality of treatment compartments, a passage in said partition for selective exchange of stored material between compartments, and means exteriorly of the bag for closing said passage by forcing opposite sides of the bag into sealing engagement in said passage, and said bag being characterized by:

- (a) its ability to withstand centrifugal forces of centrifuging,
- (b) maintaining sterility of its contents,
- (c) providing proper heat transfer in freezing and thawing operations,
- (d) being compatible with blood and liquid nitrogen, and
- (e) being flexible at all temperatures in a range from ambient to the temperature of liquid nitrogen.

2. A container for the treatment and storage of whole blood, comprising a flexible bag of a translucent composition selected from the group consisting of polytetrafluoroethylene and fluorinated ethylene propylene, said composition being sterilized after fabrication and having a circumferential enclosure providing a hermetic seal for the contents of the container, valve-controlled means for selective introduction and withdrawal of fluent material including a measured quantity of blood at the beginning and end of a storage period, at least one horizontal partition dividing the interior of the bag into at least one upper and one lower treatment compartment, a passage in said compartment for selective exchange of stored material between adjoining upper and lower compartments, and means exteriorly of the bag for closing said passage by forcing opposite sides of the bag into sealing engagement in said passage, and said bag being characterized by:

- (a) its ability to withstand centrifugal forces of centrifuging,
- (b) maintaining sterility of its contents,
- (c) providing proper heat transfer in freezing and thawing operations,
- (d) being compatible with blood and liquid nitrogen, and
- (e) being flexible at all temperatures in a range from ambient to the temperature of liquid nitrogen.

3. A container for the treatment and storage of whole blood, comprising a flexible bag of a translucent composition selected from the group consisting of polytetrafluoroethylene and fluorinated ethylene propylene, said composition being sterilized after fabrication and having a circumferential enclosure providing a hermetic seal for the contents of the container, valve-controlled means for selective introduction and withdrawal of fluent material including a measured quantity of blood at the beginning and end of a storage period, at least one vertical partition dividing the interior of the bag into adjoining treatment compartments, a passage in one wall of each compartment for selective exchange of stored material between said compartments and an adjoining interior portion of the

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bag, and means exteriorly of the bag for closing said passage by forcing opposite sides of the bag into sealing engagement in said passage, and said bag being characterized by:

- (a) its ability to withstand centrifugal forces of centrifuging,
- (b) maintaining sterility of its contents,
- (c) providing proper heat transfer in freezing and thawing operations,
- (d) being compatible with blood and liquid nitrogen, and
- (e) being flexible at all temperatures in a range from ambient to the temperature of liquid nitrogen.

4. A container for the treatment and storage of whole blood, comprising a flexible bag of a translucent composition selected from the group consisting of polytetrafluoroethylene and fluorinated ethylene propylene, said composition being sterilized after fabrication and having a circumferential enclosure providing a hermetic seal for the contents of the container, valve-controlled means for selective introduction and withdrawal of fluent material including a measured quantity of blood at the beginning and end of a storage period, at least one horizontal partition between opposed sides of the bag, a vertical partition extending from the horizontal partition to an outer edge of the bag, said partitions dividing the interior of the bag into an elongated material receiving compartment and two smaller exchange compartments, a passage at each end of the horizontal partition for selective exchange of stored material between the receiving compartment and an adjoining exchange compartment, and means exteriorly of the bag for closing said passage by forcing opposite sides of the bag into sealing engagement in said passage, and said bag being characterized by:

- (a) its ability to withstand centrifugal forces of centrifuging,
- (b) maintaining sterility of its contents,
- (c) providing proper heat transfer in freezing and thawing operations,
- (d) being compatible with blood and liquid nitrogen, and
- (e) being flexible at all temperatures in a range from ambient to the temperature of liquid nitrogen.

5. A container for the treatment and storage of whole blood, comprising a flexible bag of a translucent composition selected from the group consisting of polytetrafluoroethylene and fluorinated ethylene propylene, said composition being sterilized after fabrication and having a cir-

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cumferential enclosure providing a hermetic seal for the contents of the container, valve-controlled means on the outside of the bag for selective introduction and withdrawal of fluent material including a measured quantity of blood at the beginning and end of a storage period, at least one horizontal partition between opposed sides of the bag, a vertical partition extending from the horizontal partition to an outer edge of the bag, said partitions dividing the interior of the bag into an elongated material receiving compartment and two smaller exchange compartments, a passage at each end of the horizontal partition for selective exchange of stored material between the receiving compartment and an adjoining exchange compartment, means exteriorly of the bag for closing said passages by forcing opposite sides of the bag into sealing engagement in each said passage, pinch-type clamping means disposed on the exterior of the receiving compartment throughout its lengthwise extent for selective segregation of its contents according to composition, and said bag being characterized by:

- (a) its ability to withstand centrifugal forces of centrifuging,
- (b) maintaining sterility of its contents,
- (c) providing proper heat transfer in freezing and thawing operations,
- (d) being compatible with blood and liquid nitrogen, and
- (e) being flexible at all temperatures in range from ambient to the temperature of liquid nitrogen.

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