Jan. 22, 1963 C. R. BROMAN 3,074,402

BLOOD HANDLING EQUIPMENT

Filed Jan. 4, 1960

Fig. 1.

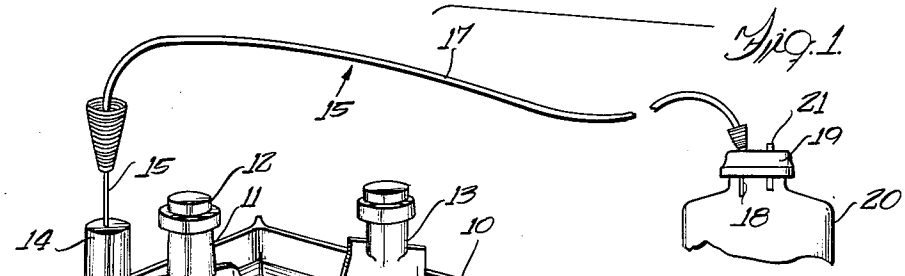
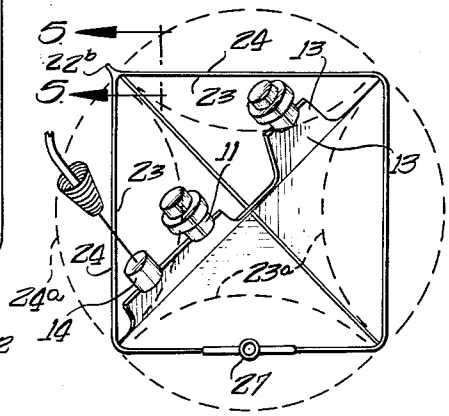


Fig. 2.



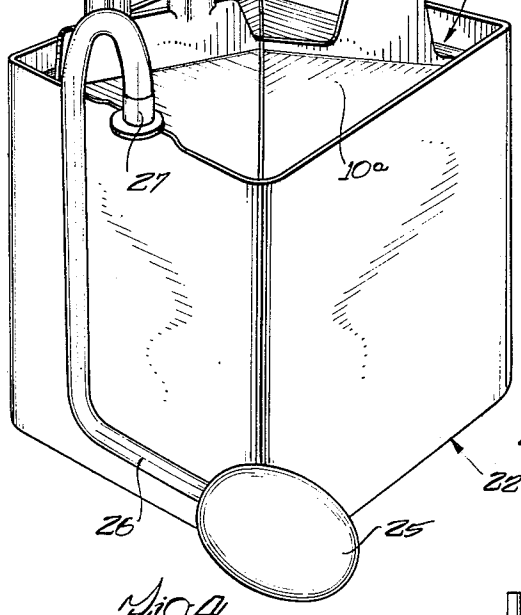


Fig. 4.

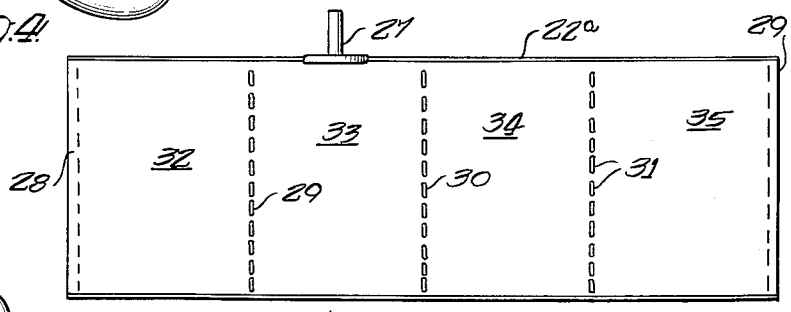


Fig. 3.

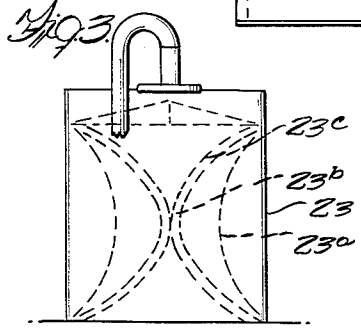
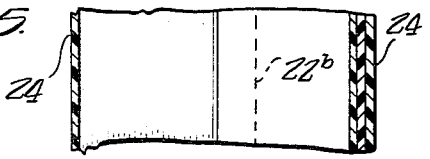


Fig. 5.



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BLOOD HANDLING EQUIPMENT

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This invention relates to blood handling equipment and, more particularly, to equipment utilized during the separation of the plasma component of blood.

Plasma constitutes about 45–55% of whole blood, the remainder being the red cells. The red cells carry the identifying characteristics of a particular blood, so that whole blood can only be administered to a patient selectively. On the other hand, plasma is universally acceptable and is widely used to make up blood loss in injury, surgery, etc. Whole blood can only be stored, even under refrigeration, for a period less than about one month because of the deterioration of the red cells—hemolysis. On the other hand, plasma does not so deteriorate, so the available life of plasma is considerably longer. The beneficial use of plasma also offers an excellent salvage for outdated blood.

In the past, blood has been collected for storage in rigid glass bottles. After a time, the heavier red cells separated from the plasma and, if desired, it was possible to cleanly draw off the plasma. In most cases, this was done by aspirating equipment in which an evacuated container was connected to the blood storage bottle through the use of a tube and needle set. The blood bottle was vented to the atmosphere, and the blood bottle needle inserted below the plasma level. The atmospheric pressure operated to force the plasma through the tube and needle set into the low pressure vessel. It was possible to obtain a fairly clean-cut separation between the plasma and red cells because of the stability of the interface made possible through the rigid glass blood storage bottle. However, the transfer was delicate, since inadvertent withdrawal of the blood bottle needle from the plasma would permit air to short-circuit into the plasma collection vessel and "break" the vacuum.

With the advent of flexible blood collection containers, more commonly referred to as blood "bags," there has arisen a problem in the separation of the plasma from the red cells. There is no longer present the stabilized interface between the two components, since the bag walls automatically collapse as some liquid is withdrawn. This may result in an upset of the interface and a wasteful mixing of portions of the red cells and plasma at the interface—resulting in the loss of valuable plasma. Here, it is to be appreciated that the plasma separated from the red cells must be substantially free therefrom to be useful as a blood supplement. Even though the red cells administered as part of plasma may be of the proper character, if unduly hemolyzed, they can prove deleterious to the recipient.

It is a principal object of this invention to provide a novel apparatus for the separation of plasma from whole blood when the blood is stored in flexible containers. Another object is to provide a plasma-handling device that is effective to stabilize the interface developed between layers of plasma and red cells so as to effect a clean-cut separation of plasma from the red cells and in maximum quantity. Still another object is to provide a unique device for pressurizing a flexible blood container. Other objects and advantages of this invention can be seen as this specification proceeds.

The invention, in an illustrative embodiment, will be explained in conjunction with the accompanying drawing, in which—

FIG. 1 is a perspective view of equipment utilized in the separation of plasma from whole blood contained within a flexible storage container and which embodies teachings of this invention;

FIG. 2 is a fragmentary top plan view of a portion of the apparatus seen in FIG. 1, with different operative positions of the apparatus illustrated in dashed line;

FIG. 3 is an elevational view of the apparatus seen in FIG. 2;

FIG. 4 is an elevational view of the pressure-applying member of the apparatus seen in FIG. 1 and in an intermediate stage of fabrication; and

FIG. 5 is an enlarged fragmentary cross-sectional view, taken along the line 5—5 of FIG. 2.

In the illustration given, the numeral 10 designates generally a blood collection and storage container of the flexible-walled type. The container 10 is illustrated and described in greater detail in the copending application of Harrison and Broman, Serial No. 772,951, filed November 10, 1958, and reference may be had to that application for additional details of construction not found herein.

The container 10 is constructed of a thermoplastic material such as polyvinyl chloride, with the various wall portions united by heat-sealing. This material is fairly transparent and is hemorepellent. The shape of the container 10, when liquid-filled, is much like that of a rectangular solid, in that a discrete end wall exists from which side walls upstand. The upper end wall 10*a* is equipped with a series of flow fittings. In the ordinary operation, blood is introduced into the container 10 through the fitting 11 which is equipped with a resilient closure 12 adapted to reseal itself after being pierced by a delivery cannula (not shown). The delivery cannula is provided as part of a donor or collection set and communicates at its other end via a length of tubing with the arm of the donor. In the illustration given, the fitting 11 has already been used for the purpose of filling the container 10 with blood, and the donor set discarded.

The end wall 10*a* is also equipped with a delivery fitting 13 which, when whole blood is to be administered, provies the place for connection of an administration set (not shown). The conventional administration set also includes a flexible tube equipped with needles at the ends thereof for the purpose of establishing communication between the interior of container 10 and the vascular system of the intended recipient.

Where, however, it is desired to separate plasma from the whole blood, either for the purpose of salvaging outdated whole blood or for the purpose of securing plasma from still useful blood, a third fitting 14 is employed. This fitting, like fitting 11, is equipped with a self-sealing closure through which the needle 15 of a plasma aspiration set generally designated 16 is inserted.

The set 16, at the other end of the flexible tubing 17, includes a flask needle 18 which is inserted through the stopper 19 of a plasma collection vessel 20. The stopper 19 of the vessel 20 is vented by means of an airway cannula 21 so that atmospheric pressure exists within the vessel 20. The stopper closure 19, where pierced by the needle 18 and the cannula 20 is of a character adapted to reseal itself, so that the plasma in container 20 can be stored without possibility of contamination by contact with air-borne microorganisms, or the like.

Still referring to FIG. 1, it is to be seen that the generally box-shaped container 10 is encircled by a perimetric body generally designated by the numeral 22 and which provides the means for pressurizing the container 10 so as to force the plasma therefrom and into the vessel 20.

Now referring to FIG. 2, it is seen that the body 22 includes an inner wall 23 and an outer wall 24 on each

of the four sides of the container 10, these walls shown also in dotted line to indicate their positions when the body 22 is distended. When a pressurized fluid such as air is introduced between these walls, the walls are urged apart and into the configurations designated 23*a* and 24*a* in FIG. 2. The elevational aspect of the inner wall 23 can be appreciated from a consideration of FIG. 3, wherein the dashed lines designated 23*a*, 23*b* and 23*c* represent successive inflated positions of wall 23.

For the purpose of inflating the member 22, a check valve-equipped squeeze bulb 25 may be provided which is coupled by means of a tube 26 to a flow port 27. The flow port 27 is installed in an edge portion of the member 22 and communicates between the inner and outer walls 23 and 24, respectively. In the preferred construction, the member 22 utilizes a heat-sealable plastic material such as polyvinyl chloride, and the fitting 27 is constructed of like material so that a rigid, air-tight assembly is readily achieved.

In the fabrication of the member 22, two or more sheets of thermoplastic material, each having a generally rectangular configuration, are assembled in face-to-face, superposed relation to provide a blank of the general outline seen in FIG. 4 and which is designated 22*a*. The wall-forming sheets are then perimetrically united to form a closed envelope, one of the edges being interrupted in its union to provide a place for the insertion of the fitting 27. The shorter edge portions of the edge 22*a*, as illustrated, are brought together and united to form a seam 22*b*—see FIG. 2. Intermediate the edges 28 and 29 so brought together and united, the walls 23 and 24 making up the blank or envelope 22*a* are united together along a series of spaced lines 29, 30 and 31 (see FIG. 4). The structure thus developed provides a box-like, open-ended configuration which serves as an inflatable cuff for the container 10. The unions, along the lines 29, 30 and 31 are interrupted so as to provide communication between the four chambers 32, 33, 34 and 35 and thereby equalize the pressure in each of these chambers, each chamber abutting against a side wall of the generally rectangular container 10. I have found that additional advantages accrue from employing three or more sheets in making up the walls 23 and 24, the outer center wall 24 comprising at least two sheets. This results in a stiffer outer wall 24 so that distention produced by internally pressurizing the body preferentially occurs in the wall 23 and thus inwardly of the body 22 rather than outwardly.

The walls 23 and 24 have a height approximately that of the container 10, and when expanded to the condition shown in dotted line in FIG. 3, serve to divide the internal volume of the container 10 into two approximately equal parts. Thus, the inwardly-distended walls of the container restrict the interface and permit the achievement of a clean-cut separation of the plasma and red cells.

Thus, the inflatable cuff provides an effective device for the separation of the red cells and plasma, ordinary blood comprising about 55% red cells and 45% plasma. The inward distention of the walls of the cuff at about the center of the height of the container means that there is an effective separation between the cells and plasma.

In the employment of containers such as that designated by the numeral 10 in the drawing, there is also a worthwhile application of the cuff for the purpose of accelerating the outflow of whole blood during the course of administration thereof to a human patient. In this environment, the cuff is especially desirable since it permits the application of a gentle but steady pressure on the whole blood, which has been found effective in eliminating undesirable hemolysis. It is to be appreciated that the delicate red cells may hemolyze under harsh application of pumping pressures—this being characteristic of many previously-employed expedients for this purpose.

While, in the foregoing specification, I have set forth a detailed description of an embodiment of the invention for the purpose of explanation thereof, many variations in the details herein given may be seen by those skilled in the art without departing from the spirit and scope of the invention.

I claim:

1. In combination, a flexible blood storage container which attains the shape of a rectangular solid when liquid-filled, said solid having a discrete end wall as well as side walls upstanding therefrom, discharge conduit means connected to said container, an inflatable cuff for said container comprising inner and outer walls united together along opposite parallel edges, and a flow fitting in said cuff for introducing pressurized fluid between said walls, said cuff being disposed about said side walls and when inflated to compress a central portion of said container to divide the interior container volume into volumes containing plasma and red cells, respectively.

2. The apparatus of claim 1 in which a plasma collection vessel is connected to said conduit means, said vessel being equipped with vent means establishing atmospheric pressure therein.

3. In combination, a flexible blood collection and storage container having discrete end walls as well as side walls extending therebetween, said container adapted to be substantially collapsed when empty of liquid and to assume the shape generally of a rectangular solid when liquid-filled, port means in one of said end walls of said container, a pressure member effective to partially collapse said container to selectively remove plasma from blood contained therein, said member comprising a flexible perimetric body for the side walls of said container, a chamber in said body for each of said container side walls, means in said body for equalizing the pressure in each chamber, and means for supplying pressurized fluid to said chambers.

4. The structure of claim 3 in which said body comprises inner and outer walls arranged in face-to-face relation, the pressurized fluid being effective to urge said walls apart and thereby partially collapse said container.

5. The structure of claim 4 in which said inner and outer walls are united together along spaced lines to provide said chambers, some of the unions between walls being interrupted to provide said equalizing means.

6. The structure of claim 3 in which said body comprises a plurality of generally rectangular sheets arranged in face-to-face, superposed relation and perimetrically united together, said sheets being additionally united together along spaced interrupted lines parallel to a pair of opposite edges of said superposed sheets, said pair of opposite edges being united together to provide an open ended box-like structure, and a flow port communicating with the space between said sheets and being positioned in one of the edges of said superposed sheets other than said pair of opposite edges.

7. In combination with a flexible blood storage container adapted to be compressed intermediate its length to divide the interior space into approximately equal volumes, said container being equipped with an end wall, a plurality of side walls upstanding therefrom with the side walls extending generally lengthwise of the container, a liquid exit fitting in said end wall, means connecting said fitting to a plasma collection vessel, a hollow open-ended member disposed perimetrically about said container and in contact with each of said side walls, said member having flexible inner and outer walls united together along spaced lines to provide an inflation chamber effective to provide intermediate compression of said container, and means for internally pressurizing said chamber.

8. The improvement in the separation of the plasma phase from the blood cells phase of whole blood contained in a rectangular when liquid-filled flexible container which comprises placing said container within a perimetric pressure member, said member comprising a

perimertic body constructed of a plurality of sheets of heat-sealable thermoplastic material, each of said sheets being united together along he edges thereof with a pair of opposite edges united together to provide the perimetric shape, said sheets being additionally united together along interrupted lines to provide a generally box shaped member with a plurality of communicating chambers, and means for internally pressurizing said body to inflate the same, internally pressurizing said body to inflate the same and distend the walls of the rectangular container inwardly thus resulting in a reduction in the cross-sectional area of the container at the interface point of the plasma and blood cell phases so as to facilitate the removal of the maximum amount of plasma without removal of blood cells.

9. A pressure device for facilitating the separation of plasma from blood in a flexible blood container, comprising a perimetric body constructed of an outer and an inner member of heat-sealable thermoplastic material, each of said members being rectangular and arranged in face-to-face superposed relation, said members being united together along the edges thereof with a pair of opposite edges united together to provide a perimetric

shape, said members being additionally united together along interrupted lines to provide a generally box-shaped device with a plurality of communicating chambers, said outer member which forms the outer wall of said device being of a stiffer nature than said inner member, whereby the distention produced by internally pressurizing said device preferentially occurs inwardly rather than outwardly.

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