June 1, 1971 J. C. ILG Re. 27,132

APPARATUS FOR TREATING BLOOD

Original Filed Dec. 13, 1963 8 Sheets-Sheet 1

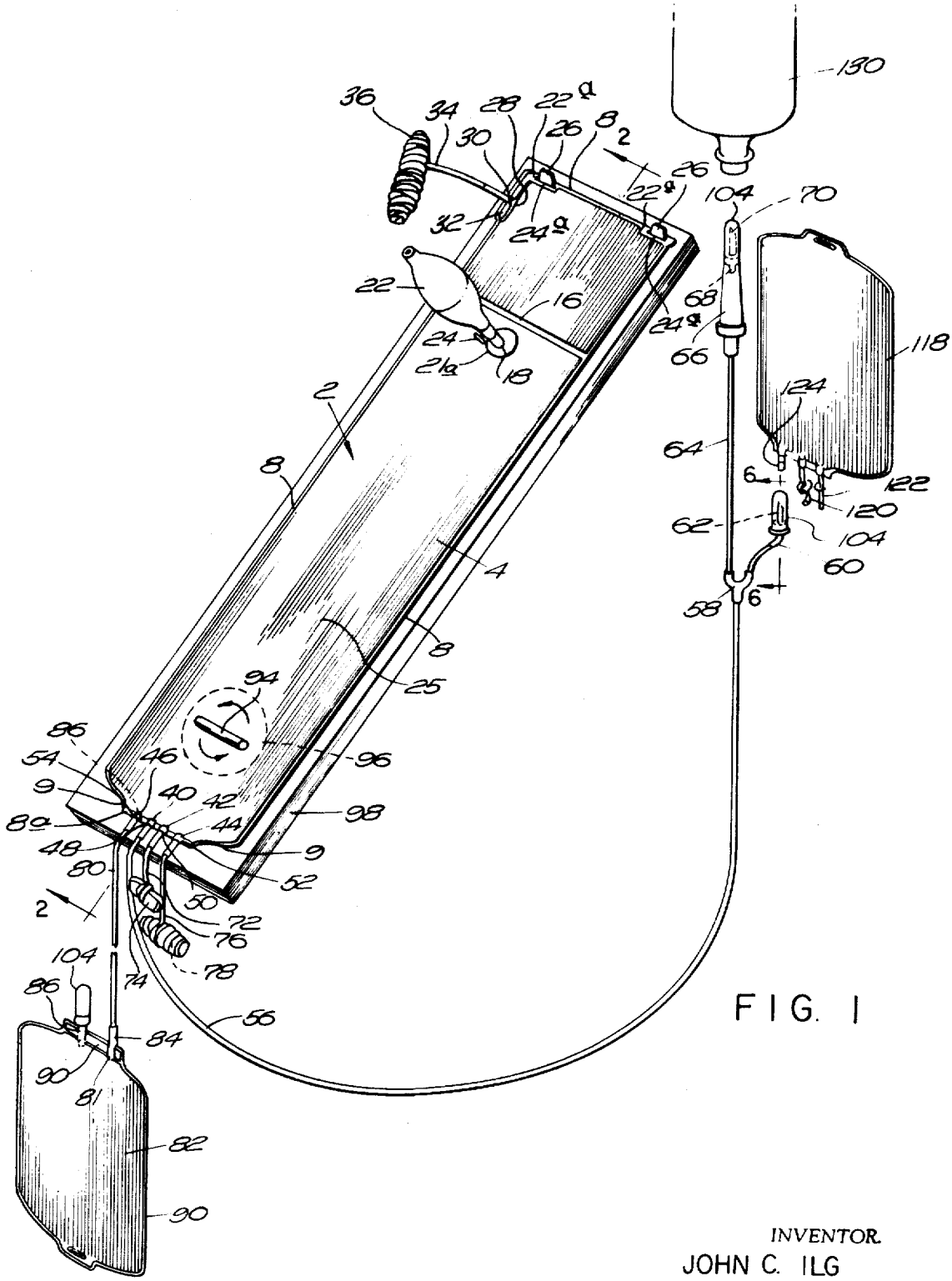



FIG. 1

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

June 1, 1971 J. N. PRATT Re. 27,132

KEYED BURST SEPARATOR

Original Filed Oct. 6, 1966 8 Sheets-Sheet 2

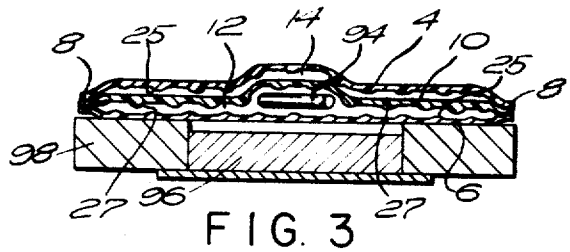



FIG. 3

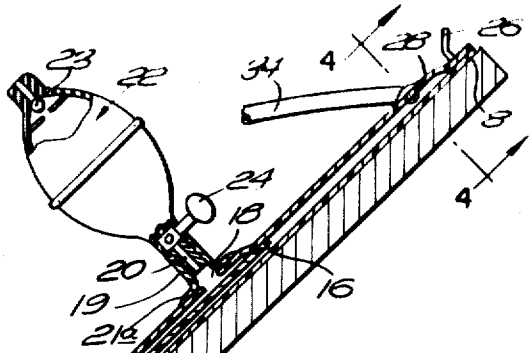
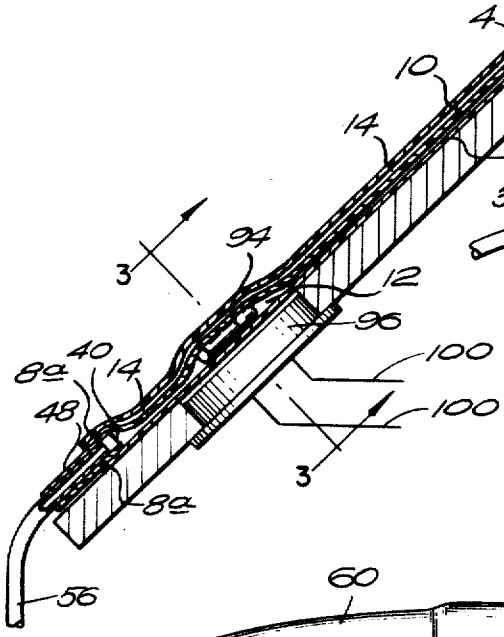



FIG. 2



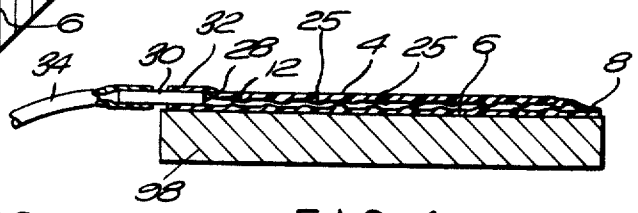




FIG. 4

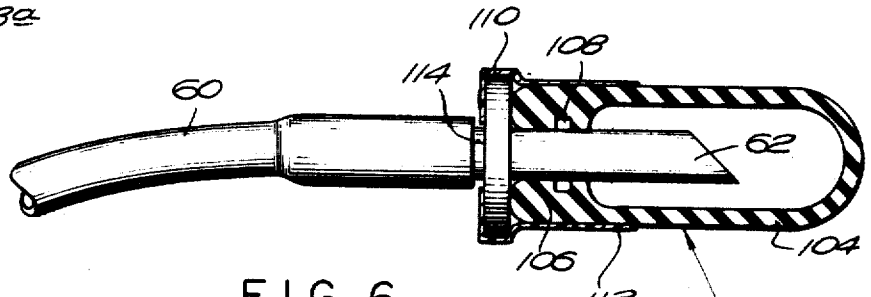



FIG. 6

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

APPARATUS FOR TREATING BLOOD

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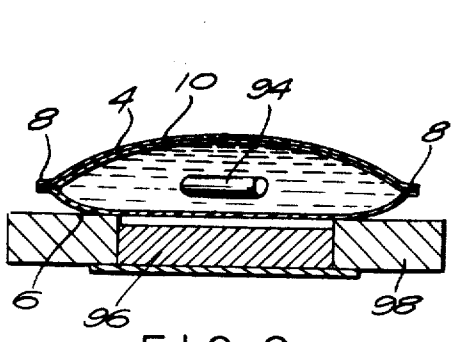



FIG. 9

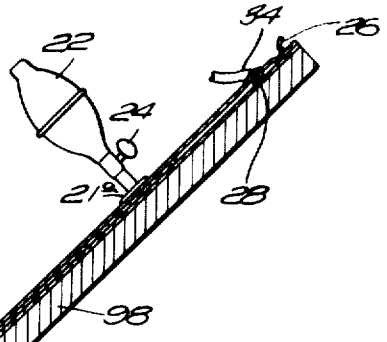



FIG. 8

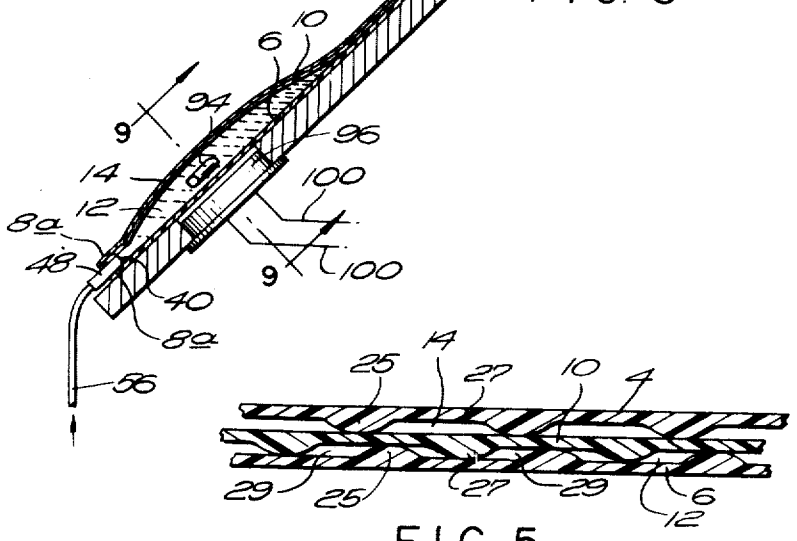






FIG. 5

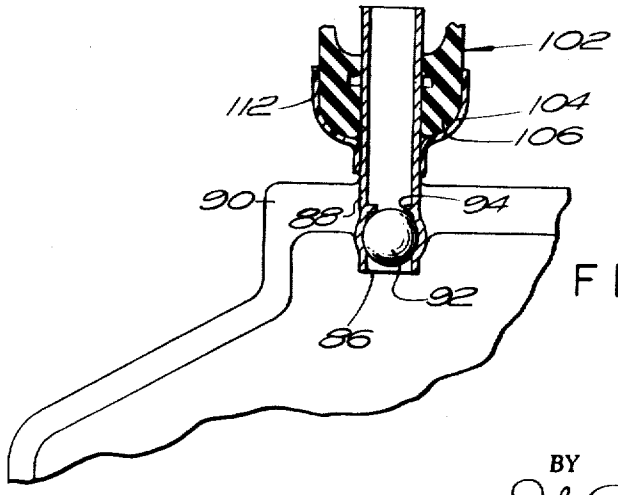



FIG. 7

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

APPARATUS FOR TREATING BLOOD

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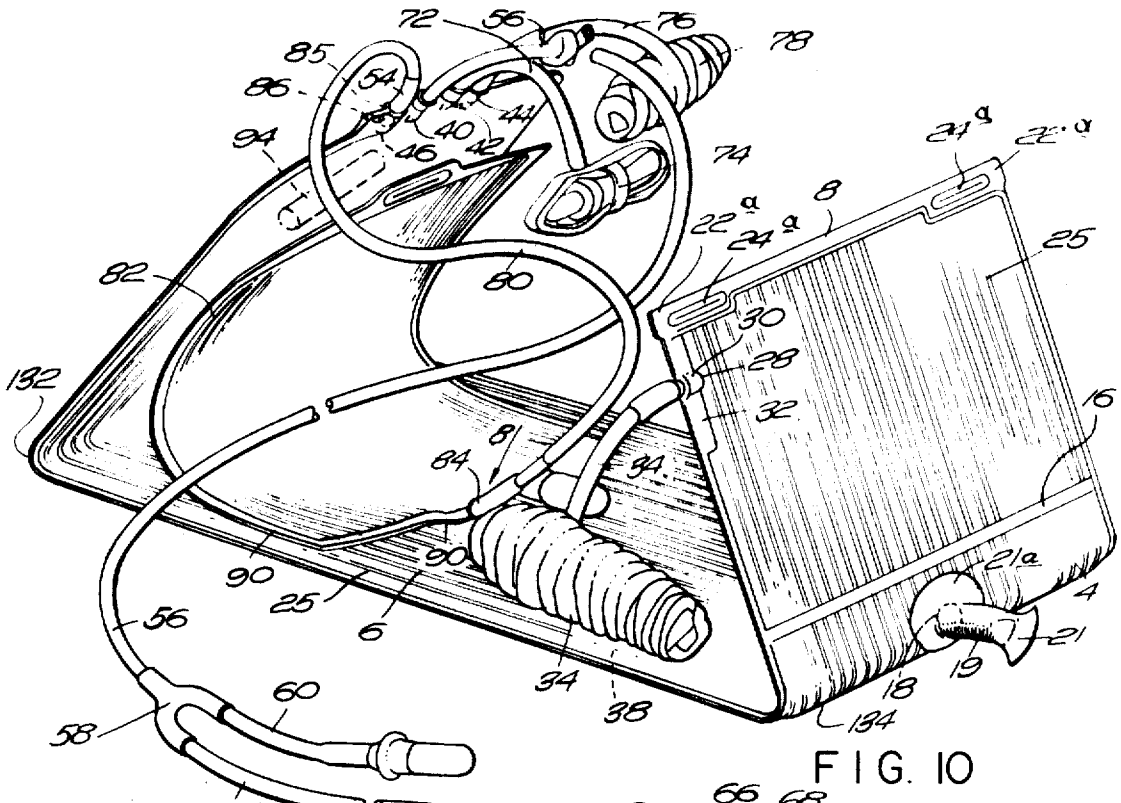



FIG. 10

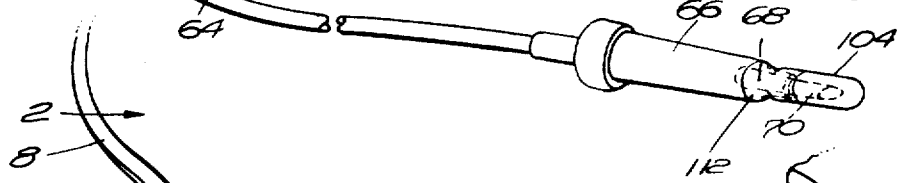






FIG. 17

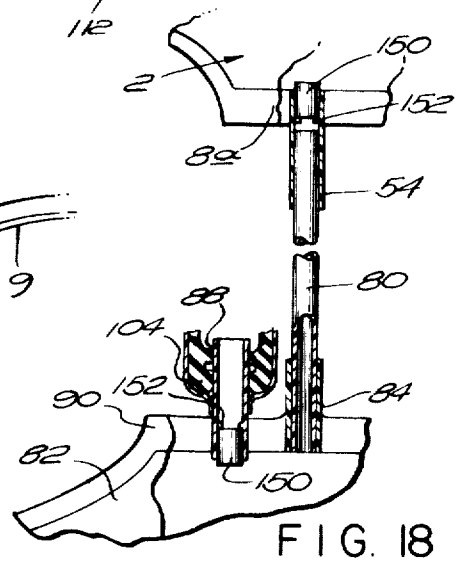



FIG. 18

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

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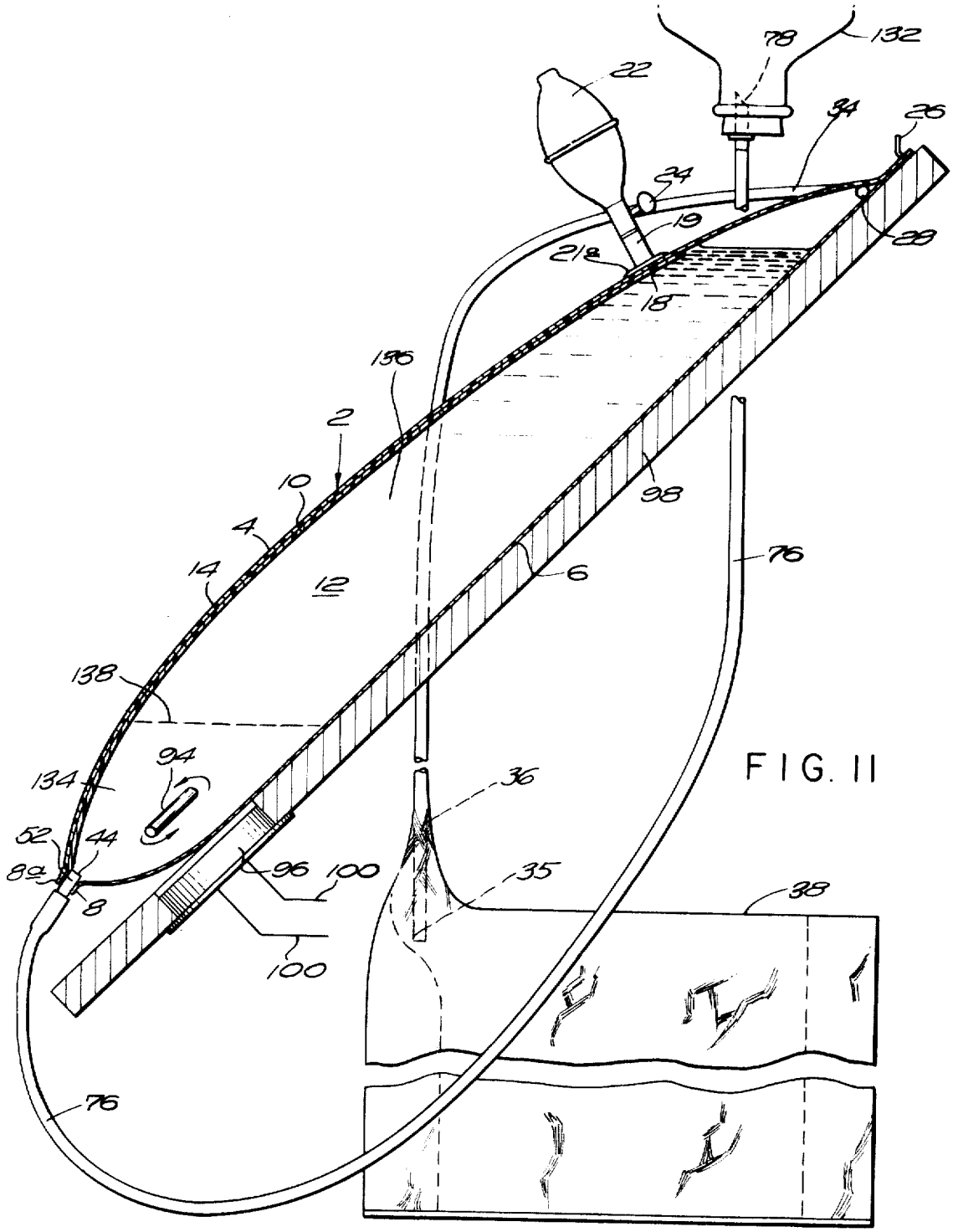



FIG. 11

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

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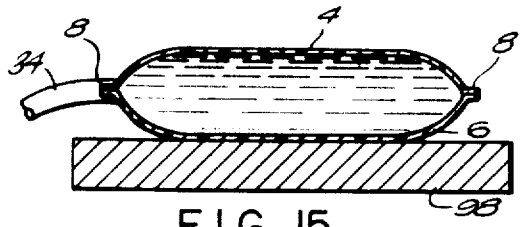



FIG. 15

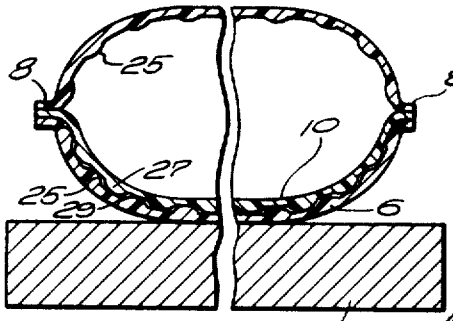



FIG. 14







FIG. 13

FIG. 12

FIG. 16

INVENTOR.
JOHN C. ILG
BY
Dike, Thompson & Bronstein
ATTORNEYS

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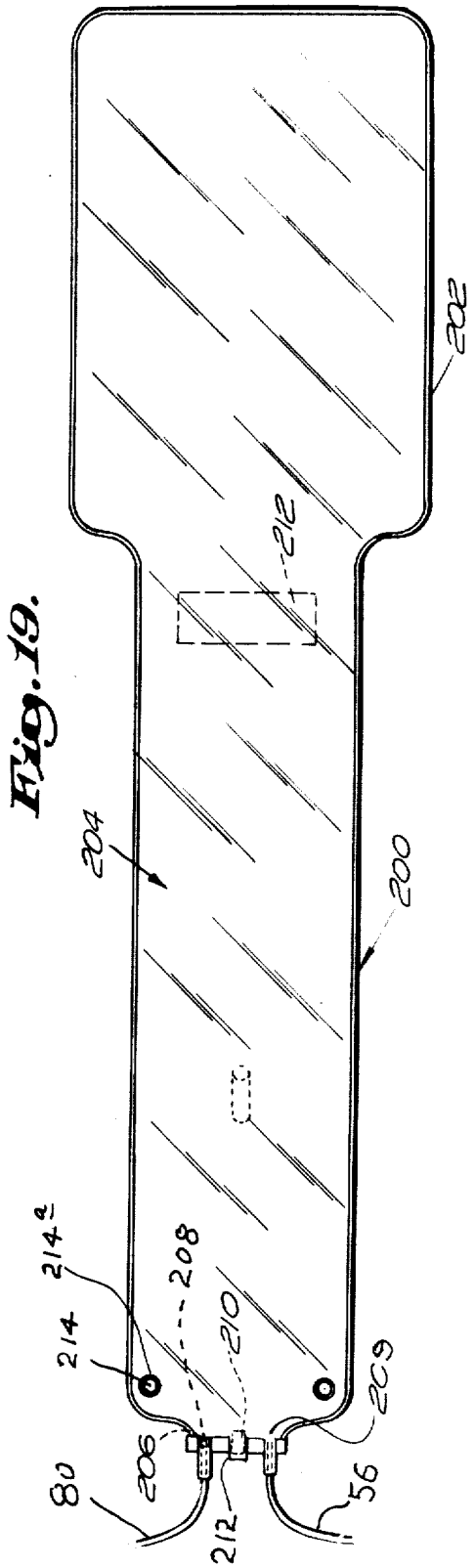



Fig. 19.

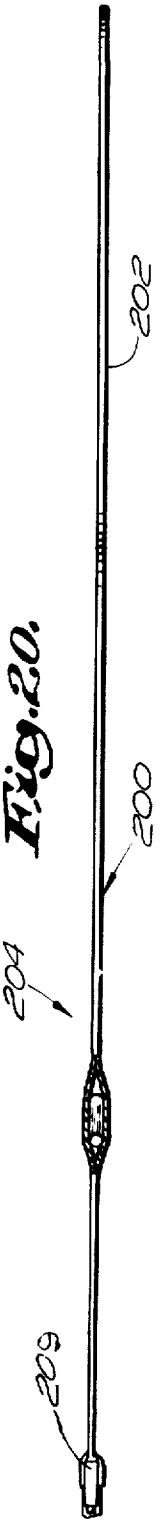



Fig. 20.

Inventor:
John C. Ilg,
By Dike, Thompson & Bronstein Attorneys

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APPARATUS FOR TREATING BLOOD

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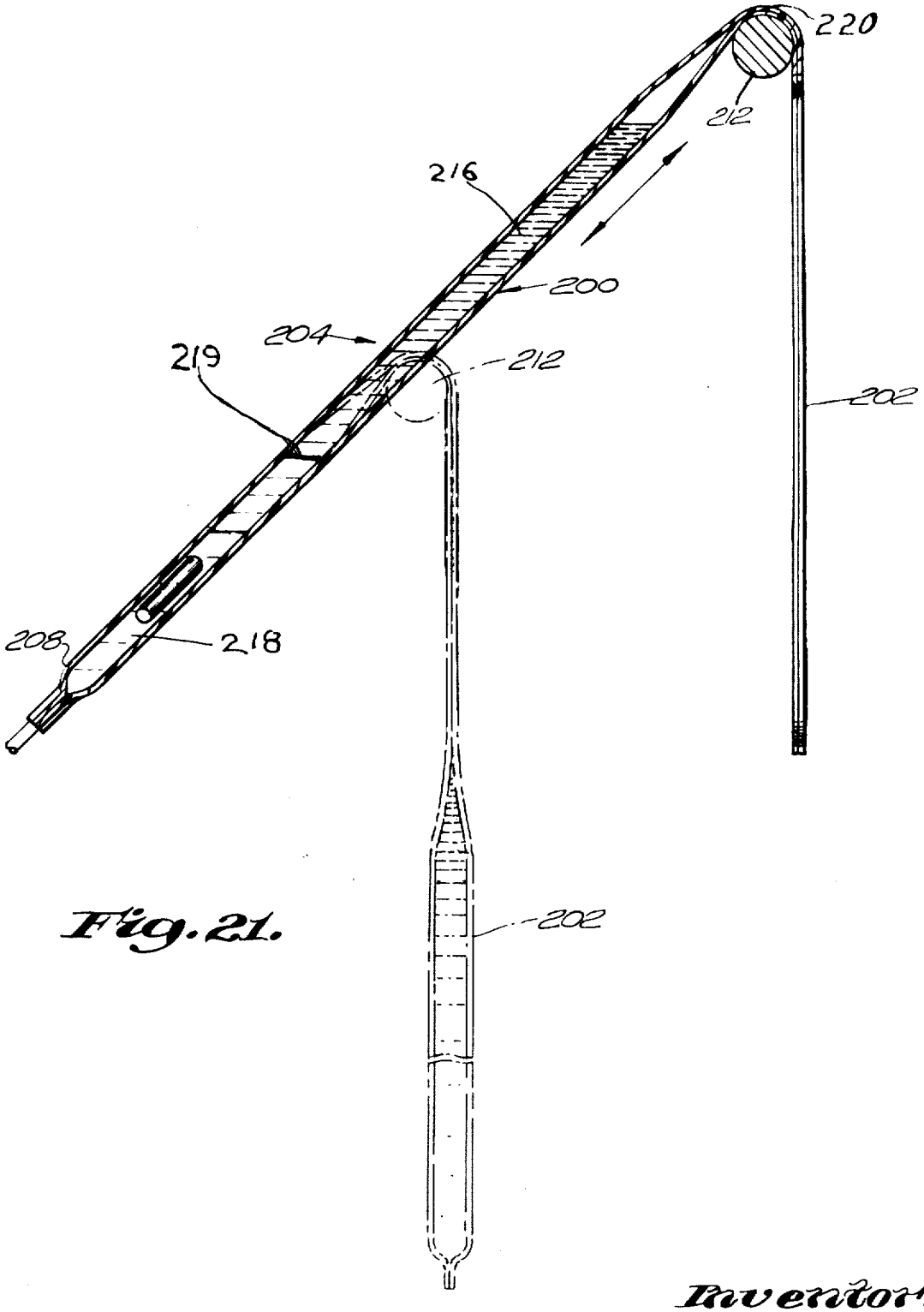



Fig. 21.

Inventor:
John C. Ilg,

By Dike, Thompson & Bronstein Attorneys

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Re. 27,132
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27,132

# APPARATUS FOR TREATING BLOOD

John C. Ilg, Fitzwilliam, N.H., assignor to Elliot Laboratories, Inc., Fitzwilliam, N.H.

Original No. 3,399,040, dated Aug. 27, 1968, Ser. No. 598,443, Dec. 1, 1966, which is a division of Ser. No. 331,342, Dec. 13, 1963, now Patent No. 3,328,255, dated June 27, 1967, which in turn is a continuation-in-part of Ser. No. 297,854, July 26, 1963. Application for reissue Dec. 1, 1969, Ser. No. 888,172

Int. Cl. A61m *1/03*

U.S. Cl. 23—258.5

41 Claims

**Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue.**

*ABSTRACT OF THE DISCLOSURE*

A disposable, sterile closed system, including an elongated plastic blood bag, for freezing blood cells, washing the thawed blood cells to agglomerate the cells to form a lower agglomerated cell layer and an upper spent washant layer containing undesired materials removed from the cells.

The blood bag is sealed and is provided with a magnetic stirrer. Preferably, it comprises a pair of flat, transparent or translucent plastic panels normally collapsed against each other, has a wide portion and a narrower portion with the wider portion having at least twice the capacity of the narrower portion and the internal surfaces of the plastic bag panels are provided with longitudinal ribs to provide flow passages when the panels are squeezed together.

The bag is provided with an outlet and a satellite bag connected therewith for collecting washed blood cells.

One or more of the bags has a fitting or cannula connected to an inlet or outlet thereof over which is located a protective cap sealed to the fitting or cannula by a plastic band shrunk therearound and is also provided with an inlet or outlet sealed by a cylindrical plug located therein and adapted to be forced out of the inlet or outlet into the bag by insertion of a cannula.

This is a division of my application Ser. No. 331,342, filed Dec. 13, 1963, now Patent No. 3,328,255 which in turn is a continuation-in-part of my application Ser. No. 297,854, filed July 26, 1963, and now abandoned.

The present invention relates to a method and disposable apparatus for washing blood cells and recovering the washed cells in a closed system. It also relates to a novel method and disposable apparatus for freezing blood cells, washing from the thawed frozen cells additives added prior to freezing to prevent cell damage and recovering the washed cells for reconstitution to whole blood all in a closed system in which the danger of contamination is reduced to a minimum.

In the past, blood banks have had to rely on refrigeration. By keeping the blood cool it has been possible to store it up to a maximum of twenty one days. After that, by Federal Regulation, refrigerated blood must be disposed of. This not only results in a considerable waste but also means that more blood cannot be kept on hand for emergencies. Thus, for many years there has been an urgent need for some way of storing blood for long periods without spoilage.

It has been attempted in the past to fulfill this need by freezing blood. The method and apparatus involved are elaborate and so expensive as to be impractical for civilian hospitals. One of the problems involved was that freezing of the blood damaged the blood cells. It was discovered that such damage could be prevented by adding an additive such as glycerine to the blood before freezing. However, it is essential to remove the additive from the thawed blood before it can be used. This was attempted by elaborate, expensive and bulky centrifuge equipment which is not entirely practical from a civilian hospital standpoint. One of the problems involved was to ensure against contamination during the rather extensive handling of the blood required.



It is an object of the present invention to provide a simple, inexpensive, safe and practical method and disposable apparatus for freezing blood and treating the thawed blood to make it safe for use. In this way, blood can be stored for long periods of time with no harmful effects.

It is yet another object of the present invention to provide a simple, inexpensive, safe and practical method and disposable system for removing from the frozen blood, additives added to it prior to freezing to prevent cell damage, hereinafter referred to as additives, without the necessity of complicated centrifuges. The invention is not limited however, to the removal of such additives from the blood but is also useful for removing any other type of undesired soluble materials from the blood and also to separate red blood cells from other blood constituents without the necessity of centrifuging.

The present invention is based on the discovery that by reducing the electrolyte concentration of blood below about 0.1% (0.02 M) by the addition of a large volume of washant, such as wash water, the red blood cells are precipitated out, the additive remaining in the washant. The precipitated red blood cells and the spent washant form well defined strata, the heavier red blood cells forming the lower strata. By removing the upper spent washant strata, the red blood cells, free from additive, are left with no necessity of complicated centrifuges or other equipment. Upon addition of plasma and other blood constituents to the precipitated, washed red blood cells to form reconstituted whole blood the electrolyte concentration is increased substantially above 0.1%, i.e., to normal whole blood concentration, and the red cells become again suspended as in whole blood. The washant preferably contains a non-electrolyte, such as a sugar or an amino acid, and preferably the washing step is carried out at an acid pH, i.e. a pH below 7.0, preferably below 6.5. It is believed that the gamma globulin in the blood is instrumental in the precipitation. See Science, Feb. 8, 1963, Vol. 139, No. 3554, pages 504–505.

By removing most of the plasma by centrifuging prior to freezing and adding it to the thawed, washed red blood cells, the amount of washant required to reduce the electrolyte concentration to a concentration at which the red cells are precipitated, is reduced. Also, the washant would wash the plasma away if it was present with the red cells during washing.

The present invention provides a simple, inexpensive, safe, disposable closed system, for carrying out the above techniques with minimum risk of contamination.

In accordance with the present invention, the washing and removal of the spent washant strata from the red blood cell strata are carried out in a container or bag having a flexible wall, such removal being provided by flexing of the flexible wall to force the upper spent washant strata out of the container leaving the washed red cell strata.

More specifically, the thawed red blood cells are washed and precipitated and the spent wash water strata is removed from the red blood cell strata in a novel, inexpensive, disposable, flexible and collapsible washing bag made of a flexible, transparent or translucent plastic of the type conventionally used to make blood bags. In a preferred embodiment, the bag is elongated and has a pair of opposed outer flexible and collapsible walls and an

intermediate wall dividing the bag into a gas chamber and a liquid chamber sealed from each other. By introducing gas into the gas chamber its volume is increased and the volume of the liquid chamber is decreased by flexing of the flexible intermediate wall common to both chambers, whereby the level of the stratified liquid in the liquid chamber is forced upwardly without disturbing the strata until the upper spent washant strata flows out of an outlet at the top of the liquid chamber, such flow continuing with resulting rising of the interface of the two strata until the spent washant upper strata has completely flowed out of the bag after which the gas pressure in the gas chamber is released and the washed red cells from which the additive has been removed fall back to the bottom of the bag.

The precipitation of the red cells to form such strata coupled with the extreme simplicity of the above mentioned manner of removing the upper spent wash water strata provides an extremely simple disposable and inexpensive technique for removing the additive from the red blood cells and recovering the washed cells without the neceessity of centrifuges.

Preferably, the liquid chamber is longer than and extends upwardly beyond the upper end of the gas chamber, e.g. by making the intermediate wall shorter than the two outer walls, and the spent washant outlet is located at the upper end of the liquid chamber above the gas chamber.

Another feature of the invention is the provision of stirring means within the sealed liquid chamber operated by means outside the bag to achieve stirring in the closed system. The stirring means is a magnetic stirring rod rotated by a rotating magnetic field created by a mechanism outside the bag. Accordingly, it is another object of the present invention to provide a novel stirring mechanism for stirring blood (e.g. the red blood cells and washant), blood components and parenteral fluids in closed systems by means of a magnetic stirring rod inside the system and actuated by a mechanism outside the system which creates a rotating magnetic field which rotates the rod.

Preferably, the washant inlet to the liquid chamber of the bag is at the bottom of the bag although this is not essential. The washant inlet comprises flexible plastic tubing integral and disposable with the bag.

Also, in a preferred embodiment, the outlet for the spent washant at the top of the bag comprises flexible plastic tubing integrally connected at one end to the wash bag and at the other to a sealed plastic bag having very thins walls and in the which the spent washant is collected whereby the washant collection bag and wash bag form a closed system disposable together.

Also, in a preferred embodiment, the washed red blood cells are reconstituted into whole blood in the wash bag by adding plasma and other blood constituents, the electrolyte in the plasma and other constituents raising the electrolyte concentration to that of whole blood and above 0.1% so that the red blood cells again become suspended. To provide for this a plasma inlet is provided, preferably at the bottom of the bag, comprising a flexible plastic tube integral and disposable with the bag and having a cannula at its end.

Also, in a preferred embodiment, the wash bag is also a freezing bag in which the blood is frozen and stored and in which the additive is added to the red cells with stirring by the magnetic stirrer referred to above. In such case, red blood cells and additive inlet are provided at the bottom of and integral with the bag. In a preferred embodiment, these inlets comprise tubing integral with the bag and having a cannula for connection with a container containing the red blood cells and a drip chamber and cannula for connection with a container containing the additive, the drip chamber being for the purpose of measuring the amount of additive. After the red cells and additive are added the tubing is tied and cut off followed by freezing of the red cells in the wash bag.



Whole blood is drawn from the donor into a blood storage container, e.g. plastic blood bag, containing anticoagulant and the red cells are separated from the plasma in the blood bag by centrifuging, the plasma being drawn off leaving the red cells. It is these red cells which are introduced into the wash and freeze bag followed by adding the additive.

In a preferred embodiment, the bottom of the blood bag, i.e. the liquid chamber, has a washed blood outlet comprising flexible plastic tubing integral with the wash bag at one end and integral with a flexible, plastic and collapsible blood bag at the other end. The washed blood outlet has a closure normally closing the outlet during addition of red blood cells and additive to the wash bag and during freezing, washing, removal of spent washant and reconstitution of the blood but which is manipulable from outside the bag to open the outlet after the blood cells are reconstituted, whereby the reconstituted blood flows into the blood bag. After the blood bag is full the tube is tied off and cut and the blood in the blood bag is ready to be administered, the blood bag having a sealed outlet for administration. The integral connection between wash bag and blood bag provides a closed system.

All of the cannulae and the outlets of the blood bag are covered and sealed by a unique type of cap and seal. The cap is made of a resilient flexible material, e.g. rubber, having an opening for receiving the cannula tip which is normally smaller in diameter than the tip so that the cap resiliently grips the tip. The open end portion of the cap and the part of the cannula adjacent thereto have a band of shrinkable plastic material shrunk tightly around them to provide a seal. Accordingly, it is another object of the invention to provide a unique but simple and inexpensive protective sealed covering for cannulae and other openings in a closed system for handling blood, blood constituents and parenteral solutions, which covering prevents against contamination but is simple to remove.

The outlet of the blood bag is provided with a novel type of closure in the form of a plug located in a piece of resilient, flexible plastic tubing sealed between the sealed peripheries of the walls of the blood bag with a portion extending out of the bag over which the aforesaid protective cap is placed. The plug is larger in diameter than the normal diameter of the tube so that it is gripped by the tube to form a seal. The plug seats on a seat (slight shoulder) in the tube located outwardly from the plug. When the cannula of a blood administration set is inserted into the tubing it forces the plug out of the tubing into the blood bag to provide communication between the cannula and bag. The diameter of the cannula is slightly larger than the tubing so that when it is inserted in the tubing the fit is a snug one. Accordingly, it is yet another object of the invention to provide a unique but simple closure for outlets of plastic blood bags, which closure is manipulable from outside the bag and outlet to open the closure.

Preferably, the wash bag and associated tubing and blood bag are made of a transparent plastic which can be easily packaged in a relatively small compact package.

Other objects and advantages will be apparent from the following description and the accompanying drawings which describe and show for illustrative purposes only an embodiment of the invention and in which drawings:

FIG. 1 is a view in perspective of an embodiment of the present invention;

FIG. 2 is a vertical section taken along the line 2—2 of FIG. 1;

FIG. 3 is a horizontal section taken along the line 3—3 of FIG. 2;

FIG. 4 is a horizontal section taken along the line 4—4 of FIG. 2;

FIG. 5 is an enlarged view of part of a horizontal section taken along the line **5**—**5** of FIG. 2 to show the parallel longitudinal ribs on the walls of the wash bag;

FIG. 6 is a section taken along the line **6**—**6** of FIG. 1;

FIG. 7 is an enlarged view in vertical section showing the outlet of the blood bag for collection of the thawed, washed and reconstituted blood from the wash bag;

FIG. 8 is a vertical section like FIG. 2 but after the red blood cells and additive have been added before freezing;

FIG. 9 is a horizontal section taken along the line **9**—**9** of FIG. 8 with the parallel longitudinal ribs on the walls of the wash bag omitted for simplification;

FIG. 10 is a view in perspective of the wash bag showing how it is folded for storage and freezing after the red blood cells and additive are added and after the inlet tubing for inletting such cells and additive is tied and cut off, the cut off tubing also being shown in the figure;

FIG. 11 is a view like FIG. 2 showing the bag with the washant added to the unthawed blood cells and additive with stirring by the magnetic stirrer to precipitate the red blood cells and wash out the additive, the interface between the red blood cell strata and spent washant strata after cessation of stirring being shown in broken lines;

FIG. 12 is a view like FIG. 2 showing the various stages of expansion of the gas chamber and contraction of the liquid chamber to force the upper spent washant strata containing the extracted additive out of the top of the wash bag, leaving the precipitated, washed red blood cells in the bag, the final stage of expansion being shown in full lines and the intermediate stages in broken lines;

FIG. 13 is a view taken along the line **13**—**13** of FIG. 12 with the parallel longitudinal ribs on the walls of the wash bag omitted for simplification;

FIG. 14 is a view taken along the line **14**—**14** of FIG. 12;

FIG. 15 is a view taken along the line **15**—**15** of FIG. 12 with the parallel longitudinal ribs on the walls of the wash bag omitted for simplification;

FIG. 16 is a view taken along the line **16**—**16** of FIG. 12;

FIG. 17 is an enlargement of the bottom part of the wash bag of FIG. 1;

FIG. 18 shows the use of a plug other than a ball for the reconstituted blood outlet from the wash bag and the outlet from the blood bag;

FIG. 19 is a view of another embodiment of the wash bag of the present invention;

FIG. 20 is a side view partially in section of the bag of FIG. 19;

FIG. 21 is a view showing another way of separating the spent washant strata from the precipitated blood cell strata in the blood bag of FIG. 19, the position of the parts after stratification but before separation being shown in full lines and the position of the parts during separation being shown in broken lines.

With reference to the figures, **2** represents a flexible walled, collapsible and disposable wash bag embodying the present invention. The walls of the bag and its associated tubing are made of a flexible, tough, transparent or translucent plastic of the type used in conventional plastic disposable blood bags, such as polyvinyl chloride resins, e.g. polyvinyl chloride acetate copolymers, trichlorofluoroethylene, polyethylene, etc., which can withstand sterilization conditions (gas or autoclaving), which are chemically inert, hemorepellant, non reactive, impermeable and non-wettable, which have a glossy surface as delays the coagulation and degradation of blood and which can withstand the extremes of heat and cold in storage including freezing conditions for long periods of time. The relatively thin wall sizes employed for the tubing and bag are flexible and elastic, i.e. self restoring. The thin wall thicknesses of the bags are flexible and collapsible so that they are capable of lying flat.

The bag is elongated, as shown, and comprises a pair of opposed flexible, transparent plastic outer walls **4** and **6**, which are sealed together along their outer peripheries at **8**, and an intermediate, flexible, transparent plastic inner wall **10** which divides the bag into a liquid chamber **12** and an air or gas chamber **14**. Intermediate wall **10** is of the same width but is not as long as the two outer walls **4** and **6**. It is sealed along its lower and side edges to the lower and side edges of the two outer walls at **8**. However, its upper edge does not extend to the upper edge of the two outer walls and such upper edge is sealed to the outer wall **4** along the seam **16** but not to outer wall **6**. Thus, the liquid chamber **12** and air chamber **14** are sealed from each other and the liquid chamber is longer than, and extends upwardly beyond, the gas or air chamber.

The portion of seam **8** at the lower edge of the bag is slightly wider at **8a** than the rest of the seam **8**.

The gas chamber is formed by the lower part of outer wall **4** and intermediate wall **10** and the liquid chamber is formed by outer wall **6**, intermediate wall **10** and the portion of outer wall **4** above the sealed seam **16**.

The air chamber **14** has an air inlet **18** which extends into a short length of tubing **19** which is sealed to the wall **4** by flange **21a** and which is adapted to receive the metal shank **20** (FIG. 2) of a conventional flexible rubber pressure bulb assembly **22** by which air can be pumped into the air chamber **14** to expand it. The pressure bulb assembly has a conventional valve **24** which is shut when air is pumped into the air chamber by squeezing the bulb. By opening the valve **24**, the air pressure in the air chamber is released. The pressure bulb is also provided in a conventional manner with a one way valve **23** which is closed when the bulb is squeezed so that the air in the bulb is forced into chamber **14**, and opened when the squeezing force is released so that the air in the bulb is replenished. Pressure bulb assembly **22** is of the conventional type used in equipment for measuring blood pressure.

In the wash bag **2**, as manufactured and sold, the end of tube **19** is sealed at **21** (FIG. 10) and remains sealed during freezing and storage. When the thawed blood is to be washed the sealed end **21** of the tube is cut off by a scissors or knife and the shank **20** of the pressure bulb assembly is attached, as shown, by insertion into the open end of tube **19**.

The inner surfaces of outer walls **4** and **6** are provided with parallel, longitudinally extending ribs **25** (see FIG. 5). The surface of intermediate wall **10** facing wall **6** is also provided with such parallel, longitudinally extending ribs **27**. The ribs extend along the entire length of the walls and are evenly spaced along the entire width thereof. The ribs **25** are staggered with respect to the ribs **27** and provide longitudinally extending passages **29** between the outer wall **6** and intermediate wall **10** when the two walls are forced together, as described in detail hereinafter. The ribs **25** of each of the outer walls **4** and **6** are also staggered with respect to each other.

The sealed seam **8** at the top of the bag is slightly wider at its ends **22a**. Horizontal slits **24a** are provided in those widened portions **22a** for supporting or hanging the bag on hooks **26**.

The upper portion of the liquid chamber **12** is provided with an outlet **28** for outletting spent washant as described hereinafter. Outlet **28** extends through a widened upper portion **32** of a sealed side edge **8** of the bag and is located close to the top of the liquid chamber **12** well above the seam **16**. Outlet **28** comprises a short piece of plastic, transparent tubing **30** extending through the upper widened portion **32** of the sealed side edge **8**, such upper portion **32** being slightly wider than the rest of the sealed seam **8**, as aforesaid. The sealed side edge portions **32** of the outer walls **4** and **6** are sealed around and to the periphery of tubing **30**, as shown. The outer end of the tubing **30**, which outer end extends outwardly beyond the side edge of the bag, is sealed by cement or otherwise (FIGS. 1 and 4) within the end of a long length of larger diameter, transparent plastic tubing **34**, the other

end 35 (FIGS. 11 and 12) of which is received within an opening 36 in the top of a disposable spent washant collection bag 38 made of very thin, flexible, transparent plastic like that used for garment bags, e.g. polyethylene. The portion of the bag 38 around the opening 36 is gathered and wrapped around the end 35 of tube 34 and is sealed thereto so that wash bag 2, tubing 34 and bag 38 form a closed system with the end 35 of the tubing extending into the bag 38, as shown. Bag 38 is otherwise sealed at its edges and the side portions thereof are provided with expansion folds 40 (FIG. 16) so as to reduce the dimension of the unfilled bag. When the bag 38 is filled the folds expand to increase the capacity of the bag. The wash bag assembly is packaged and the blood is introduced into, and frozen in, the wash bag 2 with the spent washant collection bag 38 rolled up tightly and with the length of tubing 34 wrapped tightly around the rolled bag 38 as shown in FIGS. 1 and 10. An elastic band is placed around the rolled bag 38 and tube 34 to prevent them from unrolling. They are unrolled just prior to contracting the liquid chamber to expel the spent washant strata through tube 34 and into bag 38. They are shown unrolled in FIGS. 11 and 12. The thinness of the material of bag 38 permits it to be rolled into a small package while at the same time having a sufficient capacity to hold a large total volume of washant used, for example, when the red blood cells are washed a number of times. When the bag 38 and tube 34 are rolled as shown in FIG. 1, the rolled tubing is flattened to thereby close the tubing and prevent the flow of liquid from the wash bag 2 into the bag 38 and most of the tubing 34.

The lower end of the liquid chamber 12 of the wash bag is provided with a red blood cell and additive inlet 40 for inletting the red blood cells and additives prior to freezing, a plasma inlet 42 for inletting plasma and other blood constituents to reconstitute the washed thawed red blood cells after freezing a washant inlet 44 for inletting washant to precipitate the thawed red cells and wash the additive out of the thawed cells, and a reconstituted blood outlet 46 for outletting the reconstituted, washed and thawed blood. In each case the outlet or inlets comprises a short length of flexible plastic transparent tubing 48, 50, 52 and 54 respectively, extending through the lower sealed edge 8a of the wash bag 2 between the sealed lower edge portions 8a of the outer wall 6 and intermediate wall 10, such lower edge portions being sealed around and to the outside of the short-lengths of tubing. These lengths of tubing protrude downwardly a short distance beyond the lower edge of the bag 2 for attachment to larger lengths of plastic tubing as described hereinafter. The lengths of tubing 50 and 52 are slightly larger in diameter than 48 and 54.

It is noted that the lower side edges 8 of bag 2 are tapered inwardly at 9 to the lower edge 8a of the bag.

Sealed within the protruding portion of tubing 48 (the red blood cell and additive inlet) is the end of a relatively long length (.116 I.D.) of flexible, transparent, plastic tubing 56 (FIGS. 1 and 2) which branches at 58 into a red blood cell branch 60, having a cannula 62 sealed thereto at its end, and an additive branch 64 having a transparent drip chamber 66 sealed thereto at its end, the drip tube 68 of which drip chamber extends upwardly into cannula 70. Tubing 56 is of smaller diameter than tubing 48 so that the end thereof is receivable within the protruding end of tubing 48, as shown.

The protruding end of tubing 50 (plasma inlet) is sealed within the end of a length of larger diameter flexible, transparent plastic tubing 72 (.234 I.D.), the other end of which tubing 72 is provided with a cannula 74 sealed thereto. The bag 2 is packaged with the tubing 72 rolled tightly around the longitudinal length of the cannula 74 and tubing 72, as shown in FIGS. 1 and 10, remains so rolled during addition of the red cells and additive to the wash bag and during freezing, washing and removal of the spent washant. This arrangement prevents the escape of liquid from the bag through this tubing because rolling the tubing around the cannula in this manner pinches it together to thereby block the passage of liquid. The tubing is unrolled, as shown in FIG. 17, just prior to the introduction of plasma into the bag.

The protruding end of tubing 52 (wash solution inlet) is sealed in an end of a relatively long length of larger diameter (.234 I.D.) flexible, transparent plastic tubing 76, the other end of which is provided with a cannula 78 sealed thereto (see FIGS. 1 and 11). The wash bag 2 is packaged with the tubing 76 wrapped or rolled tightly around the longitudinal length of the cannula 78 and such tubing remains so rolled when the red cells and additive are added to bag 2 and during freezing. This arrangement prevents the escape of liquid from the bag through tubing 76 since rolling the tubing in this manner pinches the tubing shut. The tubing 76 is unrolled when it is desired to add washant to the bag, as shown in FIG. 11.

Sealed within the protruding end of tubing 54 (outlet for reconstituted blood) is the end of a smaller diameter flexible, transparent, plastic tubing 80, the other end of which is sealed within the inlet 81 of a flexible, transparent, plastic blood bag 82 comprising two opposed flexible transparent plastic walls sealed along their peripheral edges at 90, the above mentioned inlet 81 to the blood bag comprising a short length of plastic tubing 84 extending through and sealed in a sealed edge 90 of the bag 82 and protruding outwardly from such edge, as shown in FIGS. 1 and 10. The end of tubing 80 is sealed in tubing 84 so that the wash bag 2, blood bag 82 and tubing 80 form a closed system.

Within the portion of outlet tubing 54 located in the seam 8a is a hard plastic ball 86 (FIGS. 1, 10 and 17) which functions as a closure normally shutting off communication between washbag 2 and blood bag 82. Ball 86 is larger in diameter than the normal diameter of the flexible and resilient tubing 54 so that it is gripped tightly by the tubing to form a seal preventing passage of fluid from wash bag 2 to blood bag 82. Ball 86 seats on a seat 85 (FIGS. 10 and 17) in tubing 54 to prevent the ball from moving outwardly too far. The ball can be forced out of the tubing 54 into bag 2 by manipulation of tubing 54 from outside the bag and tubing to thereby provide communication between wash bag 2 and blood bag 82. The ball normally closes such communication during addition of the red cells and additive to the wash bag and during freezing, washing, removal of the spent washant and addition of the plasma to reconstitute the blood cells. Thereafter, it is manipulated out of tubing 54 into the washbag 2 to transfer the reconstituted blood to the blood bag 82.

Blood bag 82 has an outlet 86 (FIGS. 1 and 7) comprising a short length of flexible, transparent, plastic tubing 88 extending through a sealed edge 90 of the blood bag, the sealed edges of the walls of the bag being sealed around and to the tubing 88. Tubing 88 extends slightly into the blood bag and also protrudes outwardly of the sealed edge 90 as shown. A ball 92 is located in tubing 88, as shown, and functions as a closure normally closing tubing 88 and hence outlet 86. The diameter of the ball 92 is larger than the normal diameter of the flexible, resilient tubing 88 so that the ball is gripped tightly by the tube to form a seal therebetween. The horizontal diameter of the ball is located slightly below the seal strip 90, i.e., it is located within the portion of tubing 88 protruding into the bag. The ball seats against a seat 94 within tubing 88 to prevent it from being forced outwardly out of the tubing. As aforesaid, normally ball 92 seals the tube 88. However, when it is desired to administer the reconstituted blood from the blood bag 82,

movement of the cannula of the blood administration set into the tubing **88** forces the ball **92** out of the tubing **88** into the bag **82** so that communication is provided between the cannula and blood bag interior. The normal diameter of the tubing **88** is smaller than that of the cannula so that the tubing grips the cannula to ensure against leakage.

Located within the liquid chamber **12** of wash bag **2** is a magnetic stirring rod **94** which is rotated end over end about an axis perpendicular to the longitudinal axis of the rod **94** and perpendicular to the plane of the bag **2** from outside the bag **2** by a rotating magnetic field which is created by a rotating magnetic field creating device **96** of conventional design.

The stirrer is operated during addition of the red blood cells and additive to mix them thoroughly and during the washing operation to mix the washant with the red cells and additive. During these operations and also during removal of the spent washant strata by contracting the liquid chamber, as will be described hereinafter, the bag is supported on a board **98** at an inclination to horizontal, e.g. at an inclination of about 45° to horizontal, by means of a pair of hooks **26** on the board **98** and the slits **24a** This aids in preventing the stirring rod **94** from falling to the bottom of the bag. However, the rotating magnetic field also holds the rod **94** from falling to the bottom of the bag during operation. The inclination of the bag may vary widely.

The rotating magnetic field creating device **96** is located in a recess in board **98** and is provided with electrical leads **100**.

This magnetic stirring device permits stirring in the closed system.

All of the cannulae and the tubing **88** forming the outlet **86** of the blood bag **82** are provided with a unique protective covering **102** (FIGS. 6 and 7) to protect against contamination. The covering comprises a resilient, flexible rubber cap **104** placed over the cannula tip **62**, as shown in FIG. 6, and over the protruding portion of tubing **88**, as shown in FIG. 7, and having a reduced diameter portion **106** at its open end which receives the cannula tip **62**. The reduced diameter **106** is normally less than the diameter of the cannula tip **62** so that the portion **106** resiliently grips the cannula tip to form a seal. The bore of the reduced diameter portion **106** has an annula groove **108** therein closer to the inner end of the reduced portion than the outer end, as shown, to provide a better seal. The portion of **106** inwardly of the groove **108** is slightly smaller in diameter than the portion of **106** outwardly of the groove **108** for better gripping and sealing. The cap **104** is moved over the cannula tip **62** until the open end engages the cannula flange **110**, as shown. A thin annular band **112** of a shrinkable plastic such as cellulose resin, sold by Du Pont de Nemours under the trade name Cell-O-Seal, is shrunk tightly around the open end portion **106** of the cap **104** and the flange **110**, as shown, to provide an excellent seal and to hold the cap on the cannula. Shrinkage of the plastic band **112** around portion **106** of the rubber cap squeezes such portion tightly against the outer periphery of the cannula tip to increase the sealing effect. Shrinkage of the band **112** around the flange **110** causes the end portion of the band to move against the flange surface **114**, as shown, to hold the cap **104** firmly on the cannula. These cellulose bands, having an inside diameter sufficient to be placed over the cap and cannula, are purchased wet and after being placed in the proper position over the cap and cannula they are dried. Drying shrinks them tightly around the cap and cannula as shown. However, heat shrinkable plastics can be used also. In the case of the tubing **88** of blood bag **82** (FIG. 7), the band **112** is shrunk around portion **106** of the cap and a part of tubing **88**, as shown. In the case of the cannula **70** at the end of the drip chamber **66**, the band **112** is shrunk around portion **106** of the cap **104** and the upper portion of the drip chamber adjacent the cannula. In all cases the cap is held firmly over the cannula and tubing **88** by the band **112** but it can be removed by pulling it off or by breaking the band **112**.

The tip of cannula **74** (plasma inlet) has a flexible, plastic sleeve **114** (See FIG. 17) located over it with a light friction fit and extending outwardly beyond the pointed end of the cannula **74**, the outer end of the sleeve **114** having a plug of cotton **116** therein. Sleeve **114** is received with the cannula tip **74** within the protective cap **104** and is pulled off the cannula tip with the cap. The purpose of the sleeve **114** and cotton plug **116** is for gas sterilization of the unit. That is, after the entire unit has been assembled with all the protective caps in place except for the cap for the plasma inlet cannula **74** and with sleeve **114** and cotton plug **116** in place, the entire unit is gas sterilized, the sterilizing gas entering the interior of the unit through the cotton plug in the sleeve. After sterilization the sterilized cap **104** for the plasma cannula **74** is placed over the canula and sleeve **114**. The sleeve **114** protects the cannula tip from contact with the cap or the hands which might not be sterile. Since the sleeve comes off with the cap, the cap never touches the cannula tip.

The entire system is a closed one, the only openings being the plasma, washant, red blood cell and additive cannulae inlets but these are protected by the protective caps **104** and band **112** until ready for use.

The entire apparatus is disposable and with it the additive can be added to the red cells and the red cells frozen, thawed, washed free of additive, reconstituted and transferred to the blood bag in which it is ready for use all in a safe, disposable, inexpensive, closed system with minimum danger of contamination.

The bag assembly is packaged as shown in FIG. 10 except that the tubing **56** and its branches, cannulae and protective coverings for the cannulae are not cut off, as in FIG. 10, but are intact as per FIG. 1, the rolled tubing **34**, **72**, and **76**, as well as the tube **56** and its branches, being folded in the wash bag **2** and the wash bag, as shown in FIG. 10, being again folded the middle to provide a compact unit which is packaged in a plastic bag (not shown) which holds it in its folded condition.

The method of using the above apparatus will now be described.

First the blood is taken from the donor in a conventional plastic blood bag **118** (FIG. 1) containing an anticoagulant in a conventional manner through the tubing **120** after which the tubing is tied and cut. Thereafter, the red blood cells are separated from the plasma by centrifuging in bag **118** in conventional manner, the plasma being removed from the bag through the plastic tubing **122**, leaving the red cells and some white cells unless they too are separated out by centrifuging. After plasma removal tubing **122** is tied and cut as shown. The amount of red cells left in bag **118** may be about 300 cc. of which about 80% is packed red (and white) blood cells and 20% is plasma, the plasma having an electrolyte (e.g. sodium chloride) concentration equivalent about 0.85% NaCl.

Thereafter, the wash bag unit is removed from the plastic bag (not shown) in which it is packaged and is placed on board **98** at an angle of about 45°. the wash bag being supported by hooks **26**, as shown. The stirrer **94** is manipulated from outside the bag a substantial distance above the bottom of the wash bag as shown.

Thereafter, cap **104** is removed from the cannula **62** (FIG. 1) and the conventional protective cap (not shown) over the outlet **124** of blood bag **118** is also removed. Cannula **62** is then inserted in the outlet **124** through a conventional pierceable sealing diaphragm therein to provide communication between the cannula and the interior of the blood bag. The outlet **124** may be provided with a plug which is forced out of the outlet **124** into the blood

bag by insertion of the cannula. The blood bag **118** is elevated above the bottom of the wash bag, as shown, to permit the red cells to flow from the blood bag into the liquid chamber **12** of wash bag **2** through tube **60**, **56** and inlet **40**. At the same time, the magnetic stirrer **94** is actuated by energizing the leads **100**, e.g. by a switch, so that the blood cells are stirred as they flow into the bag.

Thereafter, the cap **104** of cannula **70** is removed and the cannula inserted in a hole in the sterilized stopper of a sterilized bottle **130** of the additive, after which the bottle is inverted above the wash bag to permit a measured flow of additive through the drip chamber **66**, branch **64**, tubing **56** and inlet **40** into the liquid chamber **12** of the bag **2** while the stirrer **94** is operated, whereby the additive is thoroughly mixed with the red blood cells. The wash bag with the red cells and additive added is shown in FIG. 8.

A preferred additive is dimethyl sulfoxide in the form of an 8.6 molar solution in a 6% glucose-1% fructose aqueous solution, about 300 cc. of such solution being added to and admixed with the red cells.

The purpose of the additive is to prevent damage to the red blood cells during the freezing and thawing steps.

The purpose of the glucose and fructose is to equalize the concentration of solute inside and outside the blood cells when the additive is added to the cells. Without the glucose and/or fructose or some other non-electrolyte, upon addition of the additive the solute concentration outside the cells would be much less than that inside the cells and the resulting migration of water from inside the cell to outside the cell by osmosis caused by the difference in solute concentration might cause cell rupture.

The addition of the additive reduces the electrolyte concentration of the resulting mix to about 0.17% at which the red blood cells remain suspended in the water and plasma.

After the additive has been added the tubing **56** is tied tightly close to the bag and then is cut, as shown in FIG. 10.

The bag **2** is then removed from board **98** and laid flat so that the contents are spread out in the bag after which the bag is folded as shown in FIG. 10 with the rolled tubing folded within the bag, as shown. The folds **132** and **134** when the bag is folded flat form seals so that the blood cells remain distributed throughout the liquid chamber.

The unit is then placed in a freezer and the blood cells frozen. They can remain frozen for long periods of time.

When it is desired to use the blood cells the unit is removed from the freezer and the blood cells permitted to thaw. Thereafter, the bag is placed on board **98**, as shown, at an angle of about 45° and the stirrer **94** manipulated from outside the bag a short distance, about a fourth or less of the bag length, above the bottom of the bag. Then the tubing **76** is unrolled or unwrapped from around its cannula **78**, the cap **104** removed from cannula **78** and the cannula inserted into the sterilized stopper of a sterilized bottle **132** (FIG. 11) of washant preferably comprising a 6% aqueous solution of dextrose and 1% fructose. The stirrer **94** is then actuated and the bottle **132** is raised about the wash bag **2**, as shown, so that the wash water flows through tubing **76** and inlet **44** into the liquid chamber **12** of bag **2** where it is thoroughly admixed with the red blood cells and additive by the stirrer **94**. About 1500 to 2000 cc. of wash water are added with stirring. Stirring is continued until thorough mixing is achieved. It is usually best to stir the thawed cells and additive a short time before addition of the wash water. FIG. 11 shows the bag after the wash water has been added.

Because of the large volume of wash water, which contains no electrolyte, the electrolyte concentration in the liquid chamber is reduced below about 0.1% (0.02 M) and consequently the red blood cells are precipitated out leaving the additive in the wash water. The blood cells are thoroughly washed by the wash water to remove the additive and also some or all of the residual plasma, which remain in the wash water.

When stirring is discontinued, the precipitated washed red blood cells collect at the bottom of the wash bag with the spent wash water, containing the removed additive and plasma, at the top of the bag above the red blood cells. The cells and spent wash water form well defined strata **134** and **136** respectively with an interface **138**, as shown in FIG. 11.

Thereafter, the spent wash water collection bag **38** and tubing **34** are unrolled as in FIG. 12 and a clamp **140** is applied to the tubing **76** close to the wash bag to shut off the tubing **76**.

Then the sealed end **21** of the air tubing **19** is cut off by a scissors and the pressure bulb **22** connected to such tubing as shown. Air is then pumped into the air chamber **14** by continously squeezing and releasing the pressure bulb to expand the air chamber **14** and reduce the volume of the liquid chamber **12**, as shown in FIG. 12, the expansion of chamber **14** commencing at the top of the air chamber at the air inlet and working down from **10a** to **10e** to increasingly reduce the volume of the liquid chamber. The air pressure in the air chamber **14** forces the intermediate wall **10** toward the opposite outer wall **6**, as shown in FIG. 12.

Expansion of the air chamber expands the intermediate wall **10** against the opposite outer wall **6**, as shown in FIG. 12, the area of contact between wall **10** and wall **6** working down and increasing as the air pressure is increased in the air chamber. The ribs **25** and **27** form channels **29** (FIG. 14) between the two walls **10** and **6** at the area of contact therebetween to permit the flow of liquid upwardly from below the contact area to above the contact area.

As the air chamber **14** is increased in volume and the liquid chamber is correspondingly decreased in volume the upper wash water strata is forced or squeezed upwardly in the liquid chamber out of outlet **28** and tube **34** into collection bag **38** without destroying or disturbing the well defined blood cell and spent wash water strata. Since all the other inlets and outlets to and from bag **2** are closed, the liquid in chamber **12** has no place else to go.

As the liquid chamber volume continues to be decreased and more of the upper spent wash water strata is squeezed or forced out of the top of the liquid chamber, the interface **138** rises until it is located in the passages **29** with the lower precipitated red blood cell strata **134** below the contact area and the spent wash water strata **136** above the contact area, position **10e** of the flexible intermediate wall **10** in FIG. 12. Thereafter, the flow of the spent wash water out of the liquid chamber continues by siphen action, the interface **138** continuing to rise, until all of the spent wash water strata is removed and red blood cells commence to flow out of outlet **28**. The operator can observe this because of the transparency of the wash bag and the tube **34** and at this point he releases the pressure in the pressure chamber **14** by opening valve **24** of the pressure bulb, i.e. after all the spent wash water phase has flowed out of the wash bag but before any substantial amount of red blood cells flow out of the bag. Upon release of the air pressure, the air chamber contracts i.e. the flexible walls thereof collapse, and the washed red cells fall back to the bottom of the liquid chamber. At this stage the wash bag appears as shown in FIG. 8. The lower end **35** of the tube **34** should be below the level of the wash bag to ensure the above mentioned siphon action. Also, preferably no part of tube **34** should be above outlet **28**. Otherwise, it is necessary for the red cells to pass the highest point of the tube **34** in order to insure against wash water in the upper part of the tubing falling back into the bag when the pressure is released in the air chamber.

Preferably, this washant removal step is followed by at least two other identical washing and removal steps, i.e.

the clamp **140** is released and another 1000 or 1500 or 2000 cc. of wash water is admitted to the wash bag through tubing **76** with stirring followed by another wash water removal step. After the last washing step the red cells at the bottom of the wash bag are free from additive.

Thereafter, the tubing **34** and **76** are tied tightly in a knot close to the bag and are cut, the plasma tubing **72** is unrolled and the protective cap **104** and sleeve **114** removed from the cannula **74** at the end thereof and the cannula is inserted into the sterilized outlet of a sterilized bag or bottle (not shown) of plasma and other blood constituents to be added to the red cells to reconstitute them into whole blood. The magnetic stirrer is actuated and the bottle or bag of plasma is raised above the wash bag to cause plasma to flow through tube **72** into the liquid chamber where it is thoroughly admixed with the red cells by the stirrer. The addition of the plasma (which contains about 0.85% electrolyte) increases the electrolyte concentration in the liquid chamber of the bag above 0.1% so that the red blood cells again become suspended in the plasma and other blood liquids as in whole blood. After addition of the plasma, the plasma tube **72** is tied and cut close to the bag.

Thereafter, the ball **86** is manipulated by the fingers from outside the system, out of the tubing **54** of the outlet **46** into the liquid chamber of wash bag **2**. This is achieved by manipulating the tubing **54** to force the ball out of the inner end thereof into the wash bag. Upon forcing the ball out of the tubing the reconstituted blood flows into the blood bag **82** through tube **80**. Thereafter, tubing **80** is tied in a knot and cut off close to the bag **82** and the reconstituted blood in bag **82** is ready to be administered. The rest of the unit can be thrown away.

The blood in bag **82** is administered by removing the protective cap **104** from the tubing **88** (FIG. 7) and inserting the cannula of the blood administration set into tubing **88**. The cannula forces the ball **92** out of the tubing **88** into the blood bag and the blood flows through the cannula and other parts of the administration set to the patient.

In the particular embodiment shown in the drawings the wash bag is about 19½ inches long and about 5½ inches wide and the sealed seam **16** is about 5 inches below the top of the bag. However, these dimensions are not critical.

The particular volume of red cells and additive and wash water added to the wash bag are not critical. It is enough to say that an amount of additive is added sufficient to prevent red cell damage during freezing and thawing and an amount of wash water is added sufficient to reduce the electrolyte concentration in the liquid chamber to a concentration at which the red cells will precipitate, i.e. below about 0.1%, and to wash the additive out of the red cells. A lesser volume of wash water can be used per wash step with a greater number of wash steps.

The wash water contains the non-electrolyte glucose and/or fructose for the same reason as the additive, namely to make the concentration of solute outside the red cells after addition of the wash water about the same as it is inside the cells to thereby prevent rapid migration of water through the cell walls from inside the cells to outside the cells by osmosis at a rate which is apt to cause damage to (bursting of) the cell walls. Without the non-electrolyte, the addition of the large volume of wash water to the cells will resut in a very low solute concentration outside the cells as compared to inside the cells with resulting rapid migration of water through the cell walls from inside the cells to outside the cells (water flows through a membrane from a more concentrated to a less concentrated solution), which might result in bursting of the cell walls. The greater the difference in concentration the more rapid the flow of water through the cell walls. The amount of electrolyte in the wash water need not be such as to make the solute concentration outside the cells exactly the same as that inside the cells so long as it is enough to reduce the difference in concentrations inside



and outside the cells to an amount which will prevent cell damage. The amount may range from slightly hypotonic (about 200 milliosmols per kilogram) to about two and one half times normal osmotic strengtht, or approximately 750 milliosmols per kilogram.

In place of glucose and/or fructose in the additive and wash water, any suitable non-electrolyte can be used such as dextrose, sucrose and other types of sugars as well as amino acids such as glycine. It is obvious that an electrolyte cannot be used since one of the functions of the wash water is to reduce the electrolyte content in the bag so as to precipitate the red cells.

The plasma is removed from the red cells prior to freezing for two reasons, (1) if the plasma was not removed too much wash water would be required to lower the electrolyte concentration sufficiently to precipitate the red blood cells and (2) the plasma would be washed away with the wash water.

If desired, the removed plasma can be frozen separately but with the red cells and added to the cells after they have been thawed and washed or other plasma can be added to the thawed, washed cells. Plasma can be kept for relatively long times, even without freezing. Preferably, if the plasma of the donor is used it is treated to remove any danger of hepatitis.

During washing, some of the white cells are removed with the washant. This is an advantage and the white cells removed are manufactured rapidly by the body of the recipient of the blood. As a matter of fact, the present apparatus and method can be used to separate red cells from white cells. This is achieved by washing the red and white cells as described a number of times whereby the red cells are precipitated out and the white cells are removed with the wash water from which they can be recovered by other means if desired.

Although dimethyl sulfoxide is the preferred additive to prevent cell damage during freezing and thawing, others can be used such as glycerine, ethylene glycol and other glycols and glycerols.

The pH during the washing step should preferably be acidic, i.e. below 7.0, preferably below about 6.5, to achieve good precipitation. Above about pH 6.1, i.e. between about 6.1 and 6.5, settling of the precipitated or clumped or agglomerated red cells is somewhat retarded. The pH optimum for settling is between about 5.2 and 6.1. Human red blood cells in ACD anticoagulant (acid citrate dextrose), which is the standard anticoagulant, fortunately fall within this optimum pH range. Consequently no pH control is normally necessary. Since the washant does not contain any electrolyte it does not affect the pH.

A preferred magnetic stirrer is one sold under the trade name Magmix by Precision Scientific Corporation. The iron stirring rod is coated with Teflon. This manner of stirring by a magnetic stirrer actuated by a rotating field created outside the bag is an important feature of the invention. To my knowledge, it has never been used before in handling blood or parenteral fluids. It is useful not only in the wash bag shown and described but can also be used in conventional disposable and non-disposable blood bags such as **118** and bags for handling parenteral fluids where mixing is desired in a sealed or closed system without rendering the blood or other fluid unsterile. Such use comes within the present invention. For example, in conventional plastic blood bags, the bag in which the blood is collected contains an anticoagulant. By use of the magnetic stirrer of the present invention, good mixing of the anticoagulant and blood is achieved. In any case where such stirrer is used, it is advantageous to hold the bag at an inclination to vertical during stirring as shown in the drawings.

The stirring rod in operation should be held a sufficient distance above the bottom of the bag so that it can turn freely without hitting the bottom and so that it creates an even swirling of the fluid.

Although the wash bag and method described and shown is used for freezing, washing and reconstituting the blood cells, it can be used to wash the blood cells without freezing. For example, the thawed frozen blood cells containing the additive and frozen in another container can be introduced into the wash bag and washed as set forth above. Furthermore, the red cells can be removed from the wash bag before being reconstituted in which case the plasma inlet can be eliminated. Also it is not necessary to have the blood bag **82** integrally connected with the wash bag, in which case the blood outlet would comprise merely tubing with a cannula at the end. In fact the reconstituted blood can be administered directly from the wash bag.

Also, if desired, the washant inlet tubing and/or the additive branch **64** can be integrally connected with a supply of sterilized washant or additive, e.g. a sealed plastic bag full of washant or additive and having a ball closure at its outlet which can be manipulated out of the outlet to provide flow to the wash bag.

Not only can the wash bag be used for washing frozen red blood cells to remove the additive but also to wash any blood cells, frozen or not, to remove any undesired constituents and to isolate the blood cells. For example, it can be used as aforesaid to separate the white cells from the red cells. By precipitation of the red cells they can be isolated from other normal blood constituents or from any kind of additive or undesirable material which is not a normal blood constituent.

Although the walls of the bag shown have ribs, grooves can be provided.

The liquid chamber is made longer than the gas chamber and the spent wash water outlet is located above the upper end of the gas chamber to insure against the outlet being closed by the expanding intermediate wall **10**.

It is preferred that the air inlet to the gas or air chamber be located at the upper end of the chamber so that expansion thereof and contact of the wall **10** with the wall **6** works downwardly as air pressure is increased.

The use of the three wall construction, two outer walls and an intermediate wall, can be used for blood bags for collecting and storing blood of the type shown as **118**. In such case the intermediate wall may be of the same size as the outer walls, i.e., extend across the width and length of the bag to provide a liquid and air chamber, the liquid chamber having either conventional inlet and outlet constructions as in bag **118** or an outlet of the type shown in FIGS. 7 and 18.

Although the use of a ball **86** and **92** has been shown and described for closing the outlet **46** of the wash bag and the outlet **86** of the blood bag **82**, a cylindrical shaped solid plug **150** (FIG. 18) made for example of Teflon or Kel–F or other compatible material can be used, which is plugged tightly into the inner end of the tubing **54** in the case of the wash bag and tubing **88** in the case of bag **82**. The diameter of the plug is larger than the normal diameter of the tubing into which it is plugged so that it is gripped tightly by the tubing to form an excellent seal. In the case of the wash bag, the plug can be forced out of the tubing **54** into the wash bag by manipulation of the tubing from outside the system and in the case of the blood bag **82** the plug is forced into the blood bag by insertion of the cannula of the blood administration set into the tubing **88**. A slight seat **152** is provided as in the case of the ball to prevent movement of the plug in the wrong direction. The advantage of such a plug over a ball is that it provides an annular contact and sealing area between its periphery and the inside of the tubing rather than a circular sealing line of contact to thereby provide a better seal. Also, in the case of the blood bag the cannula strikes the flat bottom of the plug to force it out of its tubing. With a ball, the point of the cannula is apt to be wedged between the ball and tubing which interferes with movement of the ball out of the tubing. The plug may be tapered slightly at one end to facilitate plugging into the tubing.



Although in the embodiment shown in the drawings, the wash bag is made from flat panels sealed along their peripheries, it can be made from a length of flattened plastic tubing of the proper inner diameter to give the bag dimension desired, and sealed at its ends. A third wall may be sealed to the outside of the flattened tubing to form the gas chamber. Also, smaller diameter tubing may be sealed within larger diameter tubing, the annular space between the tubing forming the gas chamber.

Although the use of a three-wall, flexible plastic bag provides an excellent way of carrying out the step of removing the spent plasma strata from the wash bag in the method of the present invention, a two wall plastic flexible bag can be used, e.g. the wash bag shown and described without the intermediate wall **10**, in which case the upper washant strata is removed by applying a controlled compressive force to the outside of the bag to compress the bag and squeeze the washant strata out of the bag without disturbing the stratified condition of the two strata. However, this requires great care and control in applying the compressing force not only to prevent mixing of the two strata but also to prevent loss of red cells due to overcompression, and is quite difficult to do correctly by hand.

Such a bag and method are shown in FIGS. 19 to 21 in which transparent, flexible, plastic bag **200** is made like that of FIG. 1 except that the shorter intermediate wall is omitted and the upper end thereof has a widened extension portion at **202**, the lower narrower elongated part **204** being about the same length (between 19 and 26 inches but preferably 25 or 26 inches) and width (between 5 and 7 inches but preferably 6 or 7 inches) as the entire bag of FIG. 1. The widened extension portion **202** may be between about 10 and 11 inches wide and about fifteen inches long and takes the place of the spent washant outlet **28**, tube **34** and bag **38** of the FIG. 1 embodiment in that it functions as a spent washant collection bag, as will be described more fully hereinafter. The lower end of the bag has only three ports, one being the balled outlet **206** corresponding to **46** in FIG. 1 communicating with the blood collection bag **82** through tubing **80** as in the FIG. 1 embodiment and containing a ball valve **208** like ball **86** of the FIG. 1 embodiment. Another of the three ports is a blood cell and additive inlet **209** corresponding to **40** in FIG. 1 and communicating with tubing **56** and cannulae **62** and **70** attached thereto exactly like the FIG. 1 embodiment for inflow of blood cells and additive. The third port is formed by a short length of plastic tubing **212** sealed into the lower sealed seam of the bag and having a cylindrical nylon seal plug **210** fitted tightly in the opening at the inner end thereof to seal the port, such tubing and plug having the construction shown in FIG. 18.

The protruding end portion of the tubing **212 has a** protective covering (not shown) exactly like **102** (with cap **104**) shown in FIG. 18.

The washant is added to the bag through a separate feed tubing (not shown) having a cannula at an end thereof which is inserted into the tubing **212 (after removal** of protective covering **102**) to force the plug **210** into the bag (the cannula is gripped tightly by the tubing **212** to form a seal) whereby the feed tubing is placed in communication with the interior of the bag. The plasma and other materials added to reconstitute the blood are added through the same feed tubing after completion of washing, such materials being added to the feed tubing through a branch having a cannula at the end thereof with a protective covering like **102**. This branch may also be provided with a flexible plastic drip chamber or other measuring device. The washant is added through another pair of branches beyond the plasma adding branch, such washant being flowed simultaneously from two bottles or containers through the two branches into the feed tubing. The ends of the two branches are provided with cannulae with protective coverings like **102** and the internal diameters of the two branches are greater than that of the rest of the feed tubing. Clamps are provided to close off the

feed tubing from the bag during strata separation, to close off the washant branches during addition of the plasma through the plasma branch to reconstitute the blood and to close off the plasma branch when the washant is being added through the washant branches.

The upper end of the bag has no openings in it.

The inner surfaces of the bags have longitudinal ribs as in the FIG. 1 embodiment.

The lower narrow elongated portion **204** of the bag has a capacity of at least 1200 cc. and preferably 2500 cc. to 3000 cc. but it may be as large as 4000 cc. or 5000 cc. whereas the enlarged end **202** has a capacity of from 4000 or 5000 cc. to 10,000 cc. or more. In a preferred embodiment the capacity of **202** is about 9000 cc. The capacity of enlarged portion **202** should be at least twice, and preferably three times, that of the narrow portion **204**.

Washing of the blood cells is carried out in the lower narrow portion of the bag while it is supported in an inclined position, as shown in FIG. 2, the upper part of the narrow portion being folded over a steel support roller **212**, as shown, with the wide portion **202** hanging downwardly on the side of the roller opposite the inclined narrower portion. Most of the narrow portion of the bag in which washing is done lies on the other side of the roller at an incline, as shown. The opposed walls of the bag along the top of the supporting roller are squeezed into contact with each other by the roller due to the weight of the bag. The holes **214** at the bottom of the bag are located in small circular seal area **214a** where the walls are sealed together, and are adapted to receive pins for holding the bottom of the bag on the support, as shown.

After washing the blood cells in the narrow inclined portion of the bag, as already described, the top spent washant strata **216** is separated from the bottom precipitated blood cell strata **218** (interface shown as **219**) by moving the roll downwardly relative to the bag in the direction shown by the arrow in FIG. 21 to move the squeeze area **220** downwardly and thereby decrease the size of the liquid chamber between the roller **212** (the squeeze area **220**) and the bottom of the bag. As the squeeze area is moved downwardly to decrease the size of such chamber, the spent washant is forced past the squeeze area (over and past the roller) and then falls downwardly by force of gravity into the enlarged portion **202** of the bag on the other side of the roller. The ribs on the inner bag surfaces permit flow of the liquid past the squeeze area. Also the roll **212** is not as wide as the narrow portion **204** of the bag at the squeeze area so the liquid can flow in the bag along the sides of the squeeze area past the roller. Because of the nature of the bag (the walls thereof are normally flat and collapsed against each other) and the ribs, once the liquid starts to flow upwardly past the squeeze area and then downwardly into the enlarged end of the bag, a siphon action occurs. The roller is continued to be moved downwardly to thereby move the squeeze area toward the lower bag end until substantially all of the upper spent washant strata is removed after which it must be moved upwardly rapidly to break the siphon action. The roll may be mounted on screw jacks on a frame to provide the above mentioned movement, such screw jacks preferably being driven by means of an electric motor.

It is apparent that the action is the same as the FIG. 1 embodiment except that instead of applying a squeezing force and moving the squeeze area downwardly toward the lower bag end to decrease the size of the liquid chamber between such squeeze area and the bottom of the bag and thereby force the spent washant upper strata to move upwardly past the squeeze area, by means of pneumatic pressure (air chamber), as in FIG. 1, it is done mechanically by means of roller **212**. In both, the liquid emerging from the squeeze area is removed from such area by flowing it downwardly by gravity. In both, there is a siphon action. However, instead of an additional washant collection bag **38** located below the squeeze area so that spent washant emerging from the squeeze area will flow downwardly away from the squeeze area through a tube **34** between such collection bag and the blood bag, the upper part of the blood bag is made bigger and by folding the bag over the roller, such upper portion is located below the squeeze area and acts as a collection bag.

The capacity of the enlarged part of the bag should be at least two times, and preferably three times that of the narrow portion so that it can hold the washants from at least two, and preferably three, washings, the roller **212** being returned to its full line position after each separation followed by the succeeding wash and then by separation of the spent washant strata from the blood cell strata as aforesaid.

The height of the narrow, blood washing bag portion in all embodiments should preferably be at least two, and preferably, three times its width in order to provide proper control during separation of the strata.

The three-wall bag permits the required carefully controlled and incremental compression of the liquid chamber, to minimize mixing of the strata and loss of red cells due to overcompression. The use of the roll **212** also provides such controlled and incremental compression.

Although in the preferred embodiment of the method of the present invention the spent washant strata is removed from the red cell strata by use of a container for the stratified liquid column having a flexible wall which is flexed to apply pressure to the stratified liquid column to force the washant strata out of the container, pressure may be applied to the stratified column of liquid to force the spent washant strata out of the container in which the stratified column is located by means other than a flexible wall of the container.

Instead of integrally attaching long lengths of tubing to the short tubing lengths extending through the edges of the bag, as shown in the drawings, such short tubing lengths can be provided with cannula pierceable sealing membranes or with sealing plugs, the various liquids being inletted and outletted by inserting cannulae at the ends of such long lengths of tubing through such membranes or against such plugs to force them into the wash bag.

Human blood, which has been frozen, thawed, washed and reconstituted in accordance with the method described above and in the above described apparatus, has been successfully administered to a number of patients with no harmful effects.

It will be understood that the present invention is not limited to the particular embodiments thereof illustrated and described herein and I set forth its scope in the following claims.

I claim:

**1.** A container for washing blood cells and separating the spent wash water from the cells, said container having a flexible inner wall dividing the container into a gas chamber and a liquid chamber sealed from each other, the gas chamber being shorter than said liquid chamber whereby the liquid chamber extends beyond an end of said gas chamber, an outlet for said liquid chamber located at a portion of said liquid chamber located beyond the gas chamber and means for introducing gas into said gas chamber to increase the volume thereof and decrease the volume of said liquid chamber to thereby force liquid in said liquid chamber out of said outlet.

**2.** A flexible and collapsible sealed wash bag for washing blood cells comprising a pair of opposed flexible and collapsible outer walls and a flexible and collapsible intermediate wall between said opposed walls dividing said bag into a sealed gas chamber, formed by one of said outer walls and said intermediate wall, and a sealed liquid chamber formed by the other of said outer walls and the intermediate wall, said chambers being sealed from each other, one of said intermediate wall and said one opposed wall being shorter than the other, the end of the shorter being sealed to an intermediate portion of the longer to

form an end of said gas chamber and to provide a gas chamber which is shorter than said liquid chamber, said longer wall extending beyond said gas chamber and being sealed at its extened end to the corresponding end of said other opposed outer wall, which is also longer than and extends beyond said shorter wall, to form an end of said liquid chamber, said liquid chamber having an outlet at said end portion thereof beyond said end of said gas chamber.

3. A bag according to claim 2 having an outlet for outletting washed blood cells from said wash bag, said outlet comprising a conduit integral at one end with said liquid chamber, a flexible and collapsible blood bag integral with the other end of said outlet conduit whereby said wash bag and blood bag form a closed system, a plug in said outlet normally closing off communication between said wash bag and said blood bag, said plug being manipulable from outside said system to open communication between said wash bag and said blood bag.

4. A bag according to claim 2, including means for introducing gas into said gas chamber to expand the volume of said gas chamber and decrease the volume of said liquid chamber to thereby force liquid in said liquid chamber out of said outlet, said intermediate wall being forced by the introduction of said gas toward said other outer wall.

5. A bag according to claim 4, whereby when said liquid chamber contains stratified liquid layers and gas is introduced into said gas chamber, said intermediate wall is forced into contact with said opposite other outer wall to decrease the volume of said liquid chamber without disturbing the liquid strata until the strata located adjacent said outlet is forced through said outlet out of said bag leaving only the other strata of said stratified liquid, and means for releasing the gas pressure in said gas chamber after the strata forced through said outlet has flowed out of said bag thereby leaving only the desired other strata, whereby said strata are separated from each other in a closed system.

6. A bag according to claim 5, at least one of said intermediate wall and said other outer wall where they come in contact with each other being provided with means forming passages for flow of liquid therethrough when said walls are forced into contact with each other by the gas pressure in said gas chamber.

7. A cannula having a protective cap of flexible, elastic material located over the tip portion thereof, the opening in said cap having a portion of reduced diameter normally smaller than said tip portion whereby the cap tightly but yieldably grips said tip portion, a band of shrinkable plastic shrunk tightly around the open end portion of said cap and the portion of the cannula adjacent said cap to tighten the grip of said cap on said cannula and to form an easily broken seal between the cannula and cap.

8. A sealed flexible, collapsible plastic blood bag having an inlet and an outlet, said outlet comprising flexible tubing located between and sealed to sealed peripheral portions of said bag, said tubing having a plug located therein, said plug being larger in diameter than the normal diameter of said tubing whereby it is resiliently gripped by said tubing to form with the inner wall of said tubing a seal, said plug being adapted to be forced out of said tubing into said bag by insertion of a cannula into said tubing whereby communication is established between said bag and cannula, said tubing extending out of said bag, the outward extension of said tubing being received in a flexible and resilient protective cap, the opening in said cap being normally smaller than the size of said outward extension of said tubing whereby said extension is gripped by said cap, the open end portion of said cap and the portion of said outward extension of said tube adjacent said open end of said cap having located thereover a band of shrinkable plastic shrunk tightly therearound to form an easily broken seal therebetween.

9. A sealed flexible, collapsible plastic blood bag having an inlet and an outlet, at least one of said inlet and outlet comprising a flexible and resilient tubing located between and sealed to sealed peripheral portions of said bag, said tubing having a plug located tightly in the inner end thereof, said plug being larger in diameter than the normal diameter of said tubing whereby it is resiliently gripped by said tubing to form with the inner wall of said tubing a seal along an annular surface, said plug normally closing said tube, said plug being adapted to be forced out of said tubing into said bag by insertion of a cannula into said tubing whereby communication is established between said bag and cannula, said plug being cylindrical in shape to thereby provide sealing contact with said tubing along an annular area.

10. A disposable, sealed, flexible, collapsible blood bag for handling blood and parenteral fluids having an inlet and an outlet and containing therein a magnetic stirring rod and means located outside said bag for creating a rotating magnetic field to rotate said stirring rod thereby to provide stirring of the contents from outside the bag.

11. A bag according to claim 10, said bag being a collapsible, flexible, sterile, pyrogen free plastic bag through which the bag contents are visible, said outlet being integrally connected to a satellite blood collection bag in a closed system for flow of liquid from said first mentioned bag to said satellite bag, said satellite bag being a flexible, collapsible plastic bag through which the bag contents are visible and which is substantially smaller than said first mentioned bag.

12. A bag according to claim 11, said outlet connected to said satellite bag having a plug therein adapted to seal said outlet but movable out of said outlet into said elongated bag by manipulation from outside said closed system, said satellite bag having a sealed outlet.

13. A flexible and collapsible sealed wash bag for washing blood cells, said bag being of substantially greater length than width and comprising a pair of opposed and elongated flexible and collapsible walls, said bag having an inlet and an outlet, the inner surface of at least one of said walls having means thereon for cooperating with the inner surface of the other wall to provide at least one longitudinally extending passage for flow of fluid therethrough when said surfaces are brought into contact with each other.

14. A bag according to claim 13, said bag being a collapsible, flexible, sterile, pyrogen free plastic bag through which the bag contents are visible, said outlet being integrally connected to a satellite blood collection bag in a closed system for flow of liquid from said first mentioned bag to said satellite bag, said satellite bag being a flexible, collapsible plastic bag through which the bag contents are visible and which is substantially smaller than said first mentioned bag.

15. A bag according to claim 14, said outlet connected to said satellite bag having a plug therein adapted to seal said outlet but movable out of said outlet into said elongated bag by manipulation from outside said closed system, said satellite bag having a sealed outlet.

16. An apparatus for washing blood cells by adding thereto a sufficient volume of water to precipitate said blood cells to form a precipitated red cell strata and a spent washant strata and thereafter separating said strata, said apparatus comprising a container in which said blood cells are adapted to be washed and having at least one flexible wall, means for squeezing said flexible wall toward an opposed container wall and for moving the squeeze area toward an end of said container to decrease the size of the chamber between said end of said container and the squeeze area to force liquid in said chamber to flow from said chamber past said squeeze area in a direction reverse from the direction of movement of the squeeze area.

17. A bag according to claim 16, said chamber containing stirring means operable from outside said bag whereby the contents within said liquid chamber can be stirred.

18. An apparatus according to claim 16, said squeezing means squeezing said flexible wall into contact with said opposed wall, said means for moving said squeezing area moving the contact area toward said end of the container, said liquid being forced to flow past said contact area through at least one passage formed between said walls adjacent the contact area, said opposed wall also being flexible, said container comprising a sealed flexible plastic bag.

19. An apparatus according to claim 16, said end of said bag being the lower end, said bag being sealed against the escape of liquid below said squeeze area at least during said squeezing, said red cell strata being the lower strata and said spent washant strata being the upper strata, said squeeze area being moved downwardly, said upper strata being forced to flow upwardly past said squeeze area by movement of said squeeze area downwardly, means for removing said upper strata from adjacent the outlet side of said squeeze area after it has flowed past said squeeze area by flowing it in a downward direction below said squeeze area.

20. An apparatus according to claim 19, said means for removing said upper strata comprising siphoning means.

21. An elongated sealed flexible bag having a pair of flat, opposed flexible walls, said bag having an elongated narrow lower portion at least two times as long as it is wide and a wider upper portion, the capacity of said upper portion being at least twice as great as the capacity of the lower portion, the lower end of said bag having a sealed inlet port and a sealed outlet port.

22. A bag according to claim 21, folded over a support with the large end portion hanging at one side of said support and the narrow portion supported at an inclination to horizontal at the other side of said support, said support and bag being movable with respect to each other along the narrow length of said bag.

23. A bag according to claim 21, said bag being a collapsible, flexible, sterile, pyrogen free plastic bag through which the bag contents are visible, said outlet port being integrally connected to a satellite blood collection bag in a closed system for flow of liquid from said first mentioned bag to said satellite bag, said satellite bag being a flexible, collapsible plastic bag through which the bag contents are visible and which is substantially smaller than said first mentioned bag.

24. A bag according to claim 23, said outlet port connected to said satellite bag having a plug therein adapted to seal said outlet port but movable out of said outlet port into said elongated bag by manipulation from outside said closed system, said satellite bag having a sealed outlet.

25. A closed system for freezing and washing blood cells comprising a sealed flexible, collapsible plastic blood bag having at one end a sealed inlet for flowing unwashed blood thereinto, a sealed inlet for flow of washant thereinto to agglomerate said blood cells to form an agglomerated blood cell layer and a spent washant layer, and an outlet for flowing the washed blood cells therefrom, said washed blood cell outlet being integrally connected with a flexible, collapsible, plastic satellite bag for collecting the washed blood cells in a closed system and having a sealed outlet, said blood bag forming a blood washing chamber which is at least about three times as long as it is wide and which is substantially larger than said satellite bag, said blood bag having an integral chamber at the end thereof opposite from said inlets and outlet for collecting in a closed system said spent washant layer removed from said agglomerated blood cell layer and from said blood washing chamber after a washing step, said outlet of said blood bag connected to said satellite bag having a plug therein sealing said outlet and movable from said outlet into blood bag by manipulation from outside said closed system to provide communication between said blood bag and said satellite bag, each of said bags comprising flat plastic panels normally collapsed against each other and sealed along their peripheries and through which the bag contents are visible, said bags being sterile and pyrogen free.

*26. A blood bag according to claim 10, also including a support for supporting said bag in an inclined position to vertical during operation of said stirring rod.*

*27. A blood bag according to claim 10, said bag forming part of a closed sterile and disposable system for freezing and washing blood cells, said inlet comprising at least part of sealed inlet means for flow of unwashed blood cells into said bag and for flow for washant thereinto to agglomerate said blood cells to form an agglomerated blood cell layer and a spent washant layer, said outlet being an outlet for flow of the washed blood cells from the bag and being located at the lower end of said bag, said washed blood cell outlet being connected in a closed, sterile manner with a disposable, sterile, flexible, collapsible, plastic satellite bag for collecting the washed blood cell layer in a closed, sterile manner and having a sealed outlet, said blood bag forming a blood washing chamber which is substantially longer than it is wide and which is substantially larger than said satellite bag, said blood bag having a spent washant outlet which is spaced a substantial distance longitudinally along said bag and upwardly from said end of said bag and from said washed blood cell outlet and which is connected in a closed, sterile manner with a disposable, sealed, flexible, sterile and collapsible plastic spent washant collection bag for collecting in a closed, sterile manner said spent washant layer removed from said agglomerated blood cell layer, said blood bag and satellite bag each comprising flat, plastic panels normally collapsed against each other and sealed along their peripheries and through which the contents thereof are visible.*

*28. A bag according to claim 27, said satellite bag being integrally and sealably connected to said washed blood cell outlet and said washed blood cell outlet having means for closing the same but manipulable from outside said closed system to open the same.*

*29. A bag according to claim 28, said spent washant collection bag being integrally and sealably connected to said spent washant outlet.*

*30. A bag according to claim 27, said spent washant outlet being spaced downwardly from the upper end of said blood washing chamber and being connected with said spent washant collection bag by a tube extending laterally from a side of said blood bag, said tube being of sufficient length to permit said spent washant collection bag to be located below the level of said spent washant outlet and below the level of the interface of said blood cell and spent washant layers.*

*31. A bag according to the claim 30, said means for creating said rotating magnetic field being located at a level between said washed blood cell outlet and said spent washant outlet during operation thereof.*

*32. A blood bag according to claim 10, said bag forming part of a closed system for freezing and washing blood cells, said inlet comprising an inlet for flowing unwashed blood cells into said bag, said bag also having an inlet for flow of washant thereinto to agglomerate said blood cells to form a lower agglomerated blood cell layer and an upper spent washant layer, said outlet being located at the lower end of said bag and being an outlet for flowing the washed blood cells therefrom, said washed blood cell outlet being connected in a closed and sterile manner with a flexible, collapsible, plastic satellite bag for collecting the washed blood cells in a closed and sterile system, said blood bag forming a blood washing chamber in which said stirring rod is located, which is more than two times as long as it is wide and which is substantially larger than said satellite bag, said blood bag having a spent washant outlet which is spaced longitudinally and upwardly along said bag from said washed blood cell outlet and which is connected in a closed and sterile manner with a flexible and collapsible plastic bag*

*for collecting in a closed and sterile system said spent washant layer removed from said agglomerated blood cell layer and from said blood washing chamber after washing step, each of said blood and satellite bags comprising flat plastic panels normally collapsed against each other and sealed along their peripheries and through which the bag contents are visible, said bags being sterile and pyrogen free.*

*33. A bag according to claim 32, said inlets also being located at the lower end of said bag.*

*34. A bag according to claim 32, said means for creating said magnetic field and said stirring rod being located at a level substantially above said lower end of the blood bag but below said spent washant outlet during operation thereof.*

*35. A bag according to claim 32 also including a support for supporting said bag in an inclined position to vertical during operation of said stirring rod.*

*36. A bag according to claim 32, said spent washant outlet being spaced below the upper end of said blood bag.*

*37. A bag according to claim 36, said spent washant outlet being connected to said spent washant collection bag by a tube extending laterally from the side of said blood bag, said tube being of sufficient length to permit the spent washant collection bag to be located at a level below the level of said spent washant outlet and below the level of the interface between said blood cell layer and the spent washant layer.*

*38. A bag according to claim 37, said satellite bag being integrally and sealably connected to said washed blood cell outlet and means for closing said washed blood cell outlet but manipulable from outside the closed system to open it.*

*39. A bag according to claim 37, said spent washant outlet being integrally and sealably connected to said spent washant collection bag through said tube.*

*40. A closed system for freezing and washing blood cells, comprising a sealed flexible, collapsible plastic blood bag having a sealed inlet for flowing unwashed blood cells thereinto, a sealed inlet for flow of washant thereinto to agglomerate said blood cells to form a lower agglomerated blood cell layer and an upper spent washant layer, and an outlet located at the lower end of said bag for flowing the washed blood cells from said bag, said washed blood cell outlet being connected in a closed and*



*sterile manner with a flexible, collapsible, plastic satellite bag for connecting the washed blood cells in a closed sterile system and having a sealed outlet, said blood bag forming a blood washing chamber which is more than two times as long as it is wide and which is substantially larger than said satellite bag, said blood bag having a spent washant outlet spaced a substantial distance above the lower end of said bag and above said outlet and also spaced below the upper end of said bag and connected in a closed and sterile manner with a disposable, flexible, collapsible, plastic spent washant collection bag for collecting the spent washant layer removed from said blood cell layer through a flexible tube extending laterally from said blood bag and of sufficient length to permit said spent washant collection bag to be located below said spent washant layer and below the interface between said spent washant and blood cell layers, said blood bag and satellite bag each comprising flat plastic panels normally collapsed against each other and sealed along their peripheries and through which the contents thereof are visible and being sterile and pyrogen free.*

*41. A bag according to claim 40, said inlets being located at the lower end of said bag.*


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MORRIS O. WOLK, Primary Examiner

B. S. RICHMAN, Assistant Examiner

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# UNITED STATES PATENT OFFICE
# CERTIFICATE OF CORRECTION

Patent No. Re. 27,132 Dated June 1, 1971

Inventor(s) John C. Ilg

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

In the drawings, sheet 2, the heading should read:

--J. C. ILG
APPARATUS FOR TREATING BLOOD
Original Filed Dec. 13, 1963--

Signed and sealed this 2nd day of November 1971.

(SEAL)
Attest:

EDWARD M.FLETCHER,JR.
Attesting Officer

ROBERT GOTTSCHALK
Acting Commissioner of Patents

# UNITED STATES PATENT OFFICE
# CERTIFICATE OF CORRECTION

Patent No. Re. 27,132 Dated June 1, 1971

Inventor(s) John C. Ilg

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

In the specification:

Column 5, line 20 should read:

--washant added to the thawed blood cells and additive--

Column 11, line 63 should read:

--bottle 132 is raised above the wash bag 2, as shown, so--

Signed and sealed this 13th day of June 1972.

(SEAL)
Attest:

EDWARD M.FLETCHER, JR.
Attesting Officer

ROBERT GOTTSCHALK
Commissioner of Patents

FORM PO-1050 (10-69)

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