

[54] **SERUM/PLASMA SEPARATOR CANNULA
FLUID BY-PASS TYPE CENTRIFUGAL
VALVE CANNULA SEAL**

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210/DIG. 24**

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128/2 F, 214 R, 218 M, 272; 210/83, 84,
131, 359, 514-518, DIG. 23, DIG. 24; 233/1
A, 1 R, 26**

[56] **References Cited**
UNITED STATES PATENTS

2,305,278	12/1942	Smith	128/218 M
2,313,483	3/1943	Smith	128/218 M

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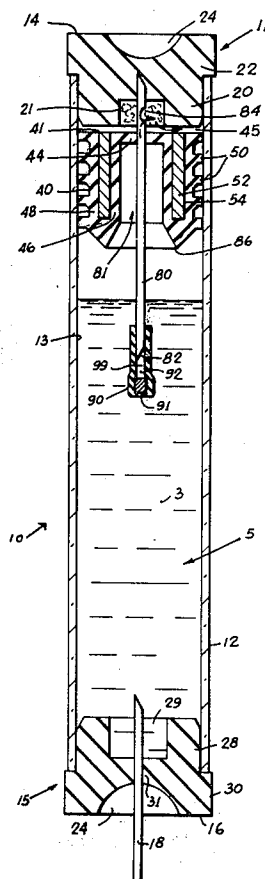
[57] **ABSTRACT**

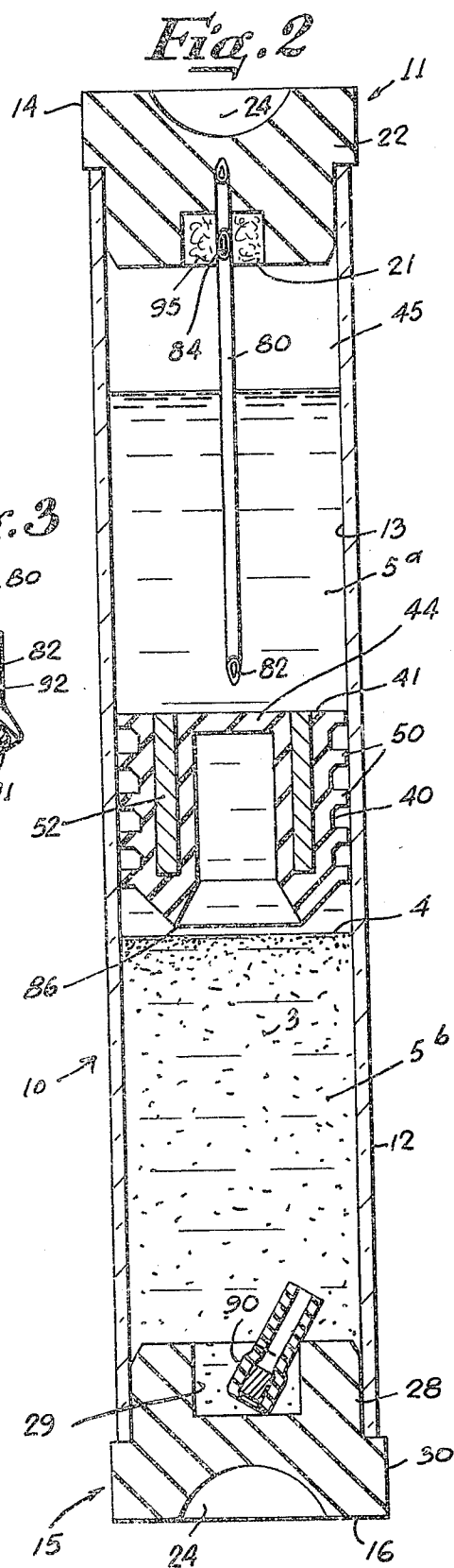
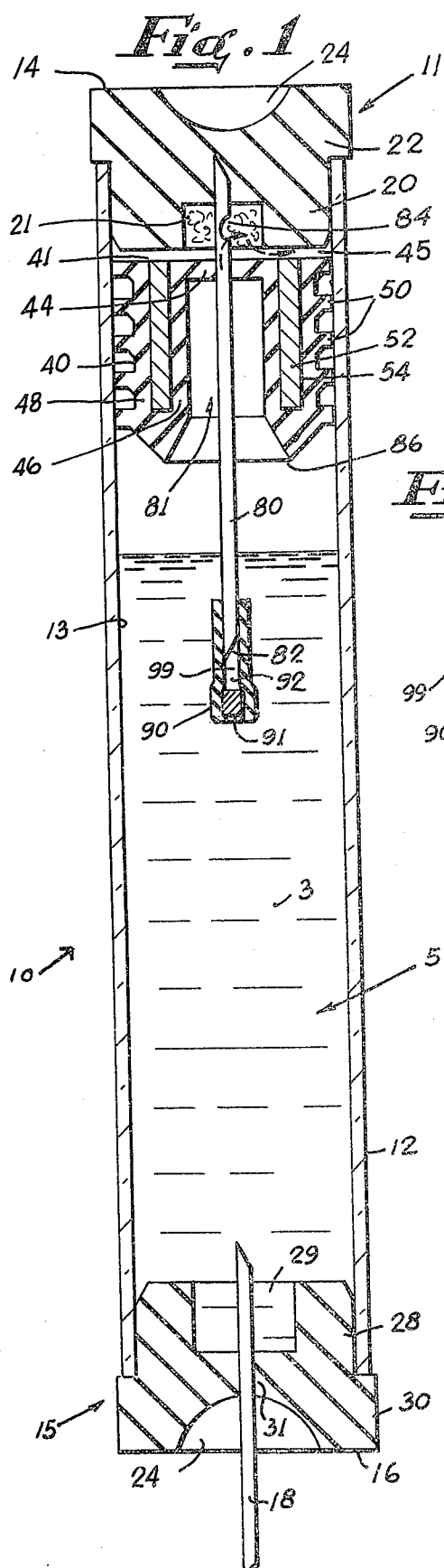
A self-contained fluid separator assembly capable of

separating blood into its component parts of plasma or serum, the light phase, and cellular portion, the heavy phase, is disclosed. The assembly comprises a container having a first open end for receiving blood for subsequent separation and a second open end for removing separated light phase; and elastomeric closures sealing the open ends of the container. A piston responsive to centrifugal force is slidably disposed within the container, having its lateral surface in sealing contact with the inner surface of the container. The piston divides the chamber defined by the container into upper and lower compartments. In its initial position within the container, the piston is in cooperation with a conduit means closed by a valve means which is responsive to centrifugal force.

The assembly is operated by first filling the lower chamber with blood to be separated. Separation is carried out at relatively low centrifugal speeds. Following separation the centrifugal speed is increased, opening the conduit valve to establish communication between upper and lower compartments. Pressure of the descending piston forces the light phase blood component through the conduit and into the upper chamber where it is isolated. When the piston reaches a predetermined position, continued cooperation between piston and conduit terminates, closing the communication between upper and lower chambers.

4 Claims, 3 Drawing Figures





SERUM/PLASMA SEPARATOR CANNULA FLUID BY-PASS TYPE CENTRIFUGAL VALVE CANNULA SEAL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The invention concerns an assembly for the separation and isolation of blood plasma and blood serum from the cellular material of blood.

2. Brief Description of the Prior Art

Previously it was known to separate blood into its component parts by centrifugation, particularly employing a seal container such as is disclosed in U.S. Pat. No. 2,460,641. This patent discloses a container having a closure at its open end which is capable of being penetrated by a cannula through which blood passes into the container. Clinical laboratories have heretofore used this device to collect a blood sample for subsequent separation into a light phase, i.e. the serum or plasma and the heavy phase, i.e. the cellular portion. The light phase is then decanted from the cellular portion by any conventional means, for example, by the use of a syringe fitted with a cannula, or a pipette, or the like.

An apparatus also heretofore employed for the separation of blood is disclosed in U.S. Pat. No. 3,508,653. This patent discloses a self-contained assembly for separation of body fluids such as blood in which a deformable piston is disposed in the container and is positioned initially adjacent the stopper for closing the container. After the blood to be separated is in the container, the assembly is centrifuged. After the blood is separated, increased centrifugal force is applied to the container, the seal between the inner surface of the container and piston is broken and the piston is deformed, moving through the light phase with the light phase passing solely around the lateral surfaces of the piston and the inner surfaces of the container. When the piston reaches the interface between the light phase and the heavy phase, the piston movement is stopped, the force is terminated, and the seal is re-established between the inner surface of the container and the resilient piston to present a barrier between the two phases.

This present invention utilizes certain different principles and construction as compared with my U.S. Pat. No. 3,779,383 covering a serum/plasma separator. The piston component of U.S. Pat. No. 3,779,383 is disclosed as having a diaphragm type of valve means in association with the piston. Light phase blood component is permitted to flow through the diaphragm type of aperture valves during piston descent by centrifugation. The apparatus of my previously disclosed invention required a specialized container in that it had to have a constriction built into the container wall to stop the sliding piston from descending into the heavier phase of blood component. The separator assembly of my present invention operates without the previously specialized requirement for a container constriction and is therefore more economical to manufacture.

Other devices known to the art are generally the filtration devices which separate blood into its component phases such as those disclosed in U.S. Pat. Nos. 3,481,477 and 3,512,940.

SUMMARY OF THE INVENTION

The invention comprises: a self-contained fluid separator assembly capable of separating blood into its parts of light phase, plasma or serum, and heavy phase cellular material, said assembly comprising (a) a container having a first open end which is adapted to receive blood for subsequent separation into a light phase and a heavy phase and a second open end for removing the separated light phase; (b) closures sealing the open ends of the container, the closures being formed of a self-sealing elastomeric material which is penetrable by a cannula; (c) a piston slidably mounted in said container, having a specific gravity greater than the cellular portion of the blood and having means on an outer surface in sealing engagement with an inner surface of the container, said piston being disposed in said container so as to separate said chamber into upper and lower compartments; said piston being initially mounted in said container at a position adjacent to said second end and being movable by centrifugal force to a second position within said container, whereby said upper chamber is expanded in volume and said lower chamber is reduced in volume; (d) a tube having one end fixed to the closure for said second end and one end free, terminating within the chamber defined by said container said tube having an opening into said chamber at the terminal free end and an opening into said chamber at the fixed end; (e) valve means normally closing said opening at the terminal, free end of said tube, said valve means being adapted to open when subjected to substantial centrifugal force, said piston in its initial position cooperating with said tube, whereby said tube forms a conduit through said piston communicating with said upper and lower compartments; said piston in its second position being removed from cooperation with said tube, whereby said conduit is terminated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional side elevational view of a separator assembly of the invention illustrating a cannula penetrating one of the closures through which blood is introduced into the container prior to separation.

FIG. 2 is a view similar to FIG. 1 illustrating the separation of the blood into the light phase and heavy phase with the piston separating the two phases.

FIG. 3 is a fragmentary cross-sectional view of the valve means employed in the illustrated embodiment, showing the valve in an open position.

DETAILED DESCRIPTION OF THE INVENTION

For a better understanding of the invention a description of the drawings of the illustrative embodiments is had, particularly with respect to the embodiments shown in FIGS. 1 through 3.

Referring to FIG. 1 it is seen that the separator assembly 10 includes a tubular member or container 12 having mounted in each open end 11, 15 closures 14 and 16. Closures 14 and 16 are made of a self-sealing elastomeric material such as rubber which is capable of receiving cannula 18 penetrated therethrough as illustrated in FIG. 1, for conducting blood 5 into the container. When the cannula is removed the closure is resealed with no loss of blood 5 passing through the penetration portion 31 as illustrated in FIG. 2.

Closure 14 is formed having a depending cylindrical body portion 20 and a flanged head portion 22 integrally formed therewith. Body portion 20 has a diameter slightly greater than the internal diameter of the container 12 so that closure 14 when mounted into end 11 provides a pressure fit to seal the end. Head portion 22 is preferably shaped in the form of a hexagon and is slightly greater in diameter than body portion 20 which permits the assembly to be positioned on its side without danger of rolling. A lower annular recess 21 is provided in the bottom surface 19 of closure 14 for receiving an initial flow of separated blood plasma or serum as hereinafter described in greater detail. The annular recess 21 is in open communication with upper compartment 45 defined by the container walls 13, upper closure 14 and the upper surface 41 of piston 40.

Stopper 16 is formed preferably of the same material as stopper 14. Stopper 16 has a cylindrical body portion 28 and an integrally formed head portion 30. Stopper 16 has an outer axial recess 34, a body portion 28 having an inner annular recess 29 to provide a self-sealing penetrable zone 31 to facilitate insertion of the cannula 18 with minimum force while maintaining a seal closure. As noted above, stopper or closure 14 as well as 16 is inserted into ends 11 and 15 respectively in compression to maintain ends 11 and 15 of container 12 in sealed engagement.

Tubular member or container 12 is formed preferably of glass but a suitable plastic material may be employed. Intermediate ends 11 and 15 of tubular member 12 is piston 40 which moves from the initial starting position illustrated in FIG. 1 under centrifugal force to the terminal position after the separation of the light phase from the heavy phase as shown in FIG. 2. The piston comes to rest near the interface 4 between separated lighter phase 5a and heavier phase 5b of the separated blood 5 as will be hereinafter described. It is necessary that the piston 40 have a specific gravity exceeding the specific gravity of the blood. Further, the piston 40 component of the invention herein does not deform; that is, the seal of the piston 40 with respect to the inner surface 13 of the container 12 is constant throughout its travel from its initial position at FIG. 1 to its terminal position at FIG. 2.

Piston 40 includes a tubular metal insert 52 which is mounted in annular recess 54 of piston 40. Metal insert 52 is preferably made of stainless steel or other rigid, chemically inert material having a specific gravity greater than blood. Piston 40 is formed of elastomeric material and is provided with annular recess 54 which is dimensioned to receive tubular member 52 in an interference fit so that no air space remains in annular recess 54.

The elastomeric portion of piston 40 comprises an outer wall 48 and spaced therefrom is inner wall 46 which defines annular recess 54. Formed integrally with wall 48 are a plurality of axially spaced sealing rings 50 which contact the inner wall surface 13 of container 12 in sealing engagement. Piston 40 when mounted in container 12 will maintain sealing contact with inner surface 13 of container 12 throughout its path of travel within container 12. During the higher speed centrifuging operation hereinafter described, piston 40 is subjected to centrifugal forces which tend to move it downwardly and when the centrifugal valve 90 is open, light phase liquid 5a is forced up through tube

80 and out port 84 and into chamber 48, passing through filter 95.

Piercing the top wall 44 of piston 40 from lower end 86 to upper end 41 is tube 80 having openings 82 and 84. Tube 80 is rigidly fixed to closure member 14 on the end adjacent to opening 84. Upper opening 84 communicates with recess 21 and opening 82 at the lower end of tube 80 would communicate with compartment 3 of container 12 if it were not normally sealed with centrifugal valve 90 as shown in FIG. 1.

To operate the separator assembly of the invention, it is preferred that the assembly 10 be first evacuated of air so that when cannula 18 penetrates closure 16, blood will fill the lower chamber 3 of container 12. After cannula 18 is withdrawn and chamber 3 of container 12 is filled with blood 5 the assembly 10 is placed in a centrifuge and the blood is separated employing relatively low centrifugal forces at first which do not cause valve member 90 to open as hereinafter described nor will piston 40 move downward substantially. At this low speed centrifugation the light phase is separated from the heavier phase of the blood 5 as shown to have occurred in FIG. 2. Thereafter, the rotational speed of the centrifuge is increased to a higher speed to cause a substantial downward thrust on the piston 40. Piston 40 will descend to a point in the light phase 5a wherein piston 40 is supported by the incompressible fluid 5a beneath it. Simultaneously with the beginning of piston 40 descent, the increased centrifugal force opens centrifugal valve 90. Referring to FIG. 3 a cross-sectional fragmentary view of centrifugal valve 90 it is seen that centrifugal valve 90 comprises a closed tube-like structure defining a chamber 92 which is in communication with opening 82 of tube 80. In the lower end of the structure there is seen a weight 91. A cut or slit in the side wall of the valve structure forms a valve opening which is opened when centrifugal force causes weight 91 to respond by moving diagonally downward. Thus, the increased centrifugal force opens valve slit 99 to permit ingress of the light phase 5a. Piston 40 is now free to displace light phase 5a through the valve means 90 and into tube 80 where it flows upward and exits through opening 84 and into recess 21. Recess 21 being in open communication with upper compartment 45 permits the light fluid phase 5a to flow from its position beneath piston 40 to the upper compartment. As shown in FIGS. 1 and 2, recess 21 is fitted with a filter element 95 as an optional structure to filter fluid phase 5a prior to its entry into compartment 45.

Referring to FIG. 2 which is a cross-sectional view of the assembly of the invention as seen in FIG. 1 but rotated 90° about its long axis to show more clearly the openings 84 and 82 in tube 80. As also shown in FIG. 2 piston 40 has descended to the free end of tube 80 where in its greater weight has pushed valve member 90 off the end of tube 80, causing valve 90 to descend to the bottom of the lower compartment 3. After passing beyond the terminal end of rod 80 piston 40 is freed of further cooperation with tube 80. Since the upper diaphragm 44 of piston 40 is a resilient elastomeric material it is self-sealing and closes the pierced aperture made by entry of tube 80 through diaphragm 44. This action interrupts communication between upper chamber 45 and lower chamber 3. Piston 40 comes to rest, as shown in FIG. 2, slightly above the interface 4 between phases because the fluids below piston 40 are

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incompressible and there is no longer any way the fluid can flow by piston 40. It will be obvious to one skilled in the art that by proper determination of the length of tube 80 one can readily predetermine the position for stopping further descent of piston 40. In general, since the concentrated red cells of the blood comprise about from 55 to 60 percent of the blood by volume, one can readily calculate for a given specimen of blood the position where the interface is likely to occur. Therefore, for any given container one can select an appropriate length for tube 80 and thereby assure that the piston 40 will come to rest just above the interface of the separated blood phases. In its terminal position as illustrated in FIG. 2, piston 40 forms an impervious barrier between the separated phases. During its descent, piston 40 maintains sealing engagement with the inner wall 13 of container 12. This superior seal insures that the now separate and isolated blood phases will not remix or react chemically with each other. Following termination of piston 40 descent, centrifugal forces are terminated and the separated blood samples are ready for use.

What is claimed is:

1. A self-contained fluid separator assembly capable of separating blood into its component phases of plasma and serum, the light phase, and cellular material, the heavy phase, comprising:

a container having a first open end which is adapted to receive blood for subsequent separation into a light phase and a heavy phase and a second open end for removing the separated light phase;

closures sealing the open ends of the container, the closures being formed of a self-sealing elastomeric material which is penetrable by a cannula;

a piston slidably mounted in said container, having a specific gravity greater than the specific gravity of the blood and having means on an outer surface in sealing engagement with an inner surface of the container, said piston having a diaphragm portion forming partial upper and lower surfaces of said piston, said diaphragm portion being of a self-sealing elastomeric material penetrable by a cannula; said piston being disposed in said container so as to separate the chamber defined by said con-

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tainer with said closures, into upper and lower compartments;

said piston being initially mounted in said container at a position adjacent to said second end and being constructed and arranged to move at a predetermined centrifugal force to a second position within said container, whereby said upper compartment is expanded in volume and said lower compartment is reduced in volume;

a tube of pre-determined length having one end fixed to the closure for said second end and one end free, terminating within said chamber, said tube having an opening into said chamber at the terminal free end and an opening into said upper compartment at the fixed end;

centrifugal valve means normally closing said opening at the terminal, free end of said tube and constructed and arranged to open under said predetermined centrifugal force; and

said piston in its initial position cooperating with said tube, so that said tube pierces the diaphragm portion of said piston, whereby said tube together with said valve means forms a closed conduit through said piston, and whereby upon opening of said valve means by centrifugal force, communication between said upper and lower compartments is established, said piston in its second position being removed from cooperation with said tube, whereby said conduit is terminated and the diaphragm portion of said piston previously pierced by said tube is self-sealed.

2. The self-contained fluid separator of claim 1 wherein the piston includes a rigid tubular sleeve mounted in a generally tubular outer body portion formed of an elastomer and having at least one sealing ring on its outer portion for sealing engagement with the inner surface of the container.

3. The self-contained fluid separator of claim 1 wherein at least one sealing ring is formed on the periphery of the piston and in sealing engagement with the interior of the container.

4. The self-contained fluid separator of claim 1 wherein said container is fabricated from glass.

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