

- [54] **PLASMA SEPARATOR ASSEMBLY**
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- [52] **U.S. Cl.**..... 128/272, 128/2 F, 128/DIG. 5, 215/47, 23/230 B, 23/258.5
 [51] **Int. Cl.**..... **A61b 5/14**
 [58] **Field of Search**..... 128/276, DIG. 5, 272, 2 F; 23/258.5, 259, 230 B, 292; 233/26; 215/47

[56] **References Cited**
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[57] **ABSTRACT**

An assembly adapted to receive blood for separation into a light liquid phase of serum or plasma and a heavy phase is disclosed. The assembly includes a self-sealing, pierceable, elastomeric stopper-piston member which is capable of acting as a slidable piston as well as a closure for holding a vacuum in an evacuated container for collecting blood. Means is provided which is capable of pushing the piston member downwardly in the container; the means having a pointed tubular member associated therewith which is capable of piercing the piston so as to provide a passage for conducting the separated light liquid phase from one side of the stopper-piston to the other side thereof.

12 Claims, 8 Drawing Figures

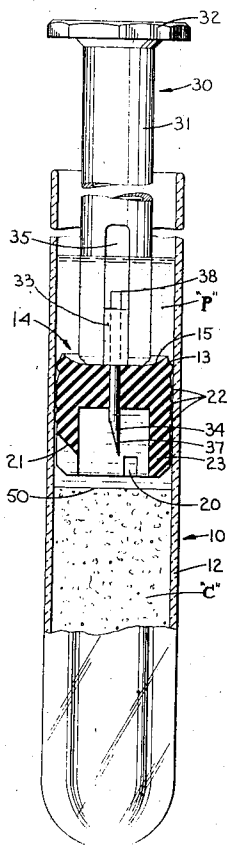


Fig. 1

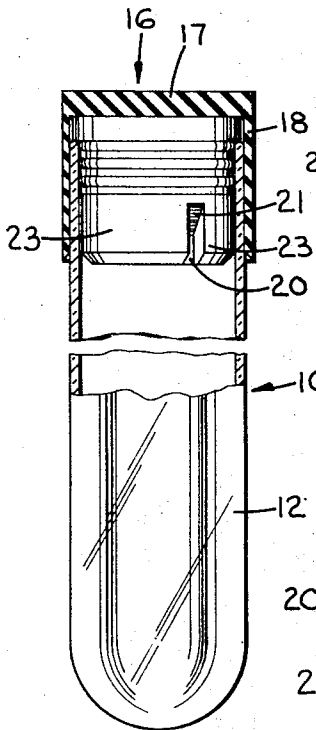


Fig. 2

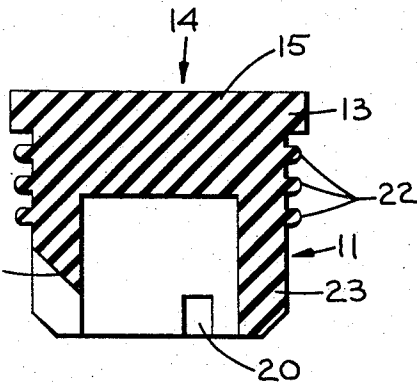


Fig. 3

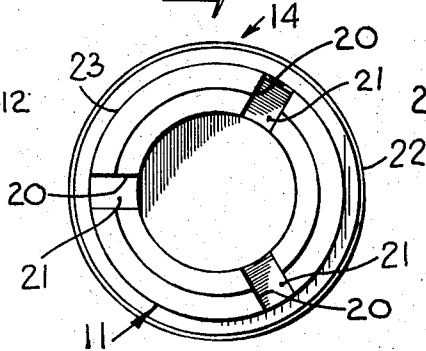


Fig. 5

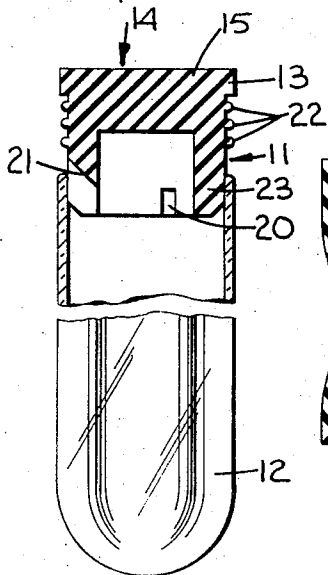


Fig. 4

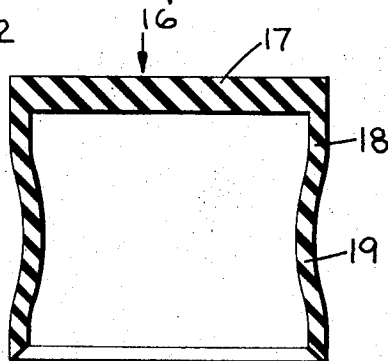
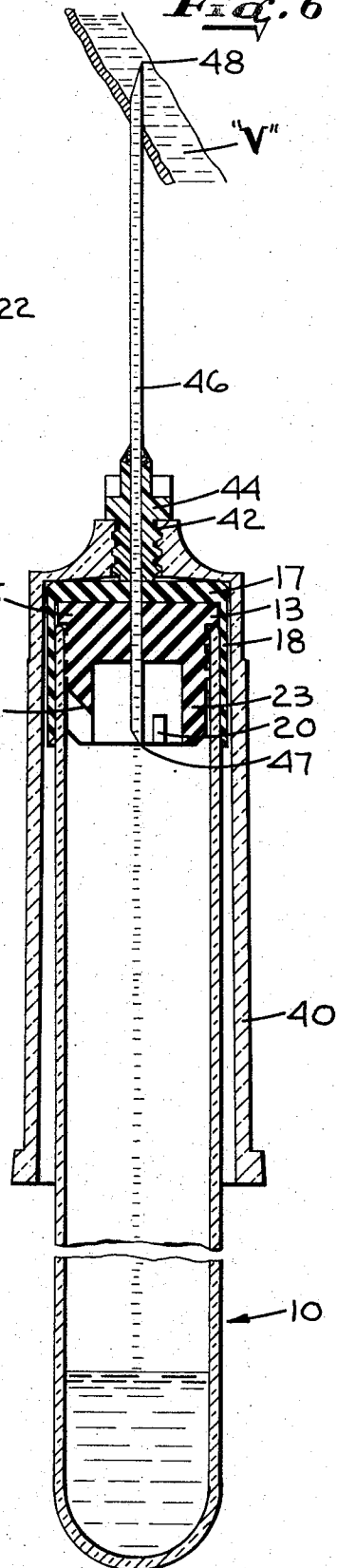
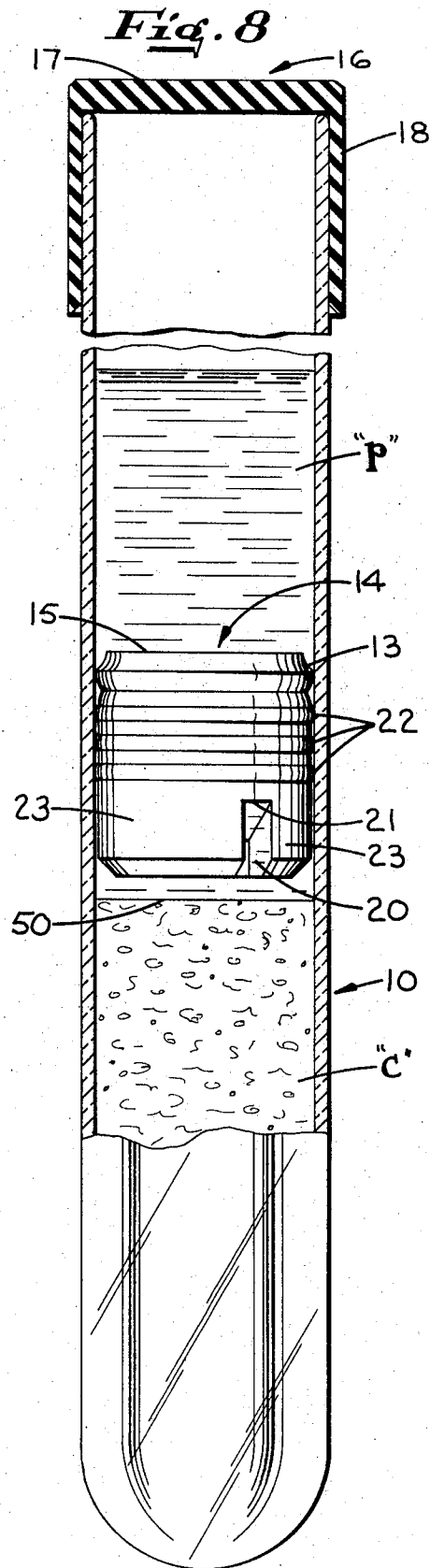
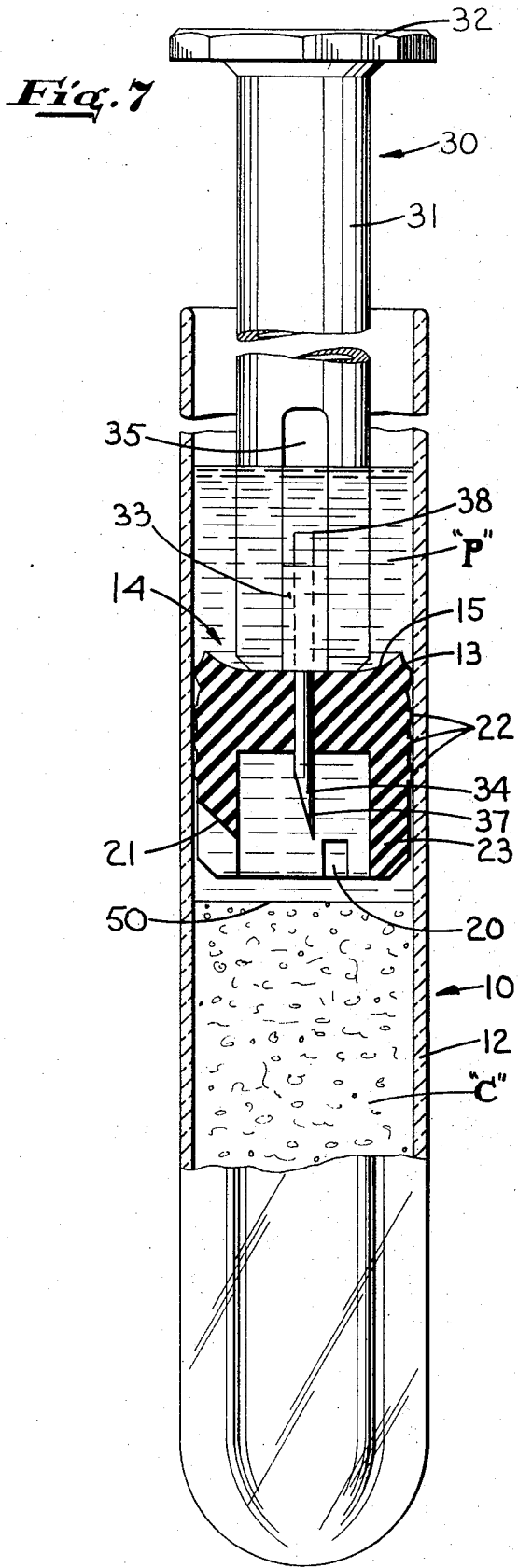


Fig. 6





PLASMA SEPARATOR ASSEMBLY

BACKGROUND OF THE INVENTION

The present invention relates to an assembly for the separation of blood into its component phases of serum or plasma and cellular or solid phase. Various devices are known and are used for separating blood into its component phases. It is clinically desirable to isolate the liquid phase from the solid phase of blood to prevent chemical interaction between the separated cellular portion and the plasma or serum. Several of the devices presently used are disclosed in U.S. Pat. Nos. 3,355,089; 3,481,477; 3,508,653 and 3,512,940.

The present invention proposes to improve upon these devices which are used for the separation of blood into its component phases.

SUMMARY OF THE INVENTION

The invention generally contemplates the provision of an assembly adapted to receive blood for separation into a light liquid phase of serum or plasma and a heavy phase. The assembly includes a self-sealing pierceable, elastomeric stopper-piston member which is capable of acting as a slidable piston as well as a closure for holding a vacuum in an evacuated container for collecting blood.

Means is provided which is capable of pushing the stopper-piston downwardly into the container while at the same time a pointed tubular member associated with the means penetrates the stopper-piston to form a passageway therethrough to permit the plasma-serum to be conducted through the passageway thereby enabling the stopper-piston to be moved downwardly through the light phase to just above the heavy phase of blood. After the downward movement of the stopper-piston is completed the pointed tubular member is removed from the self-sealing pierceable stopper-piston to form an impermeable barrier between the light phase and the heavy phase of blood.

It is an object of the invention to provide a stopper-piston which is capable of closing the open end of a blood collection container and seals the container to maintain a vacuum therein.

Another object of the invention is to provide a serum-plasma separator assembly having a self-contained slidable member which will act as a closure element prior to use and a piston when in use.

Another object of the invention is to provide an assembly for separating the serum-plasma phase from the cellular phase said assembly including a blood container, a stopper-piston and a sealing cap, whereby the serum plasma is contained in a first chamber including the blood container, the stopper-piston and the sealing cap, and the cellular phase being contained in a second and separate chamber including the blood container and the stopper-piston so that the container can be inverted, handled roughly or shipped without spilling any of the contents or without remixing the serum-plasma and cellular phases.

DESCRIPTION OF THE DRAWINGS

FIG. 1 is a compressed elevational and partially sectional view of the blood collection assembly fitted with the stopper piston of the invention herein and a cap for sealing the tube prior to use.

FIG. 2 is a sectional elevational view of the stopper piston.

FIG. 3 is a bottom view of the stopper piston as shown in FIG. 1.

FIG. 4 is a sectional elevational view of a cap for enclosing the stopper piston as in FIG. 1 and for closing the open end of the collection container as illustrated in FIG. 8. FIG. 5 is a sectional elevational view of the blood collection assembly illustrated in FIG. 1 prior to inserting the piston-closure all the way into the open end of the container.

FIG. 6 is an elevational sectional view which illustrates the collection of blood using the device of FIG. 1.

FIG. 7 is an elevational sectional view of the assembly of FIG. 1 in which the stopper-piston has been moved downwardly through the separated liquid phase.

FIG. 8 is an elevational sectional view of the blood collection container after the serum or plasma has been separated from the cellular phase and the means for pushing the piston to the interface has been removed and the cap (of FIG. 4) has been placed over the upper end of the blood container tube to seal in the light phase of the blood.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For a better understanding of the invention reference is had to the drawings which illustrate the various elements of the blood collection and separator assembly. In FIG. 1 a blood collection assembly 10 includes a blood collection container 12 generally made of a transparent material such as glass or a transparent plastic material which is inert to blood or any of its components, anticoagulants or other chemicals used in connection with the collection, storage or analysis of blood.

Stopper-piston 14 is removably mounted in the open end of container 12 and provides an interference fit capable of maintaining a vacuum until the blood sample is collected. A cap 16 which is designed to enclose the stopper-piston end of the collection container is provided to maintain sterility of the exposed outer surface 15 of stopper-piston 14 until the device is used. Cap 16 is molded as a unitary structure and is preferably formed of a material which is capable of being pierced by a pointed tubular member and is sufficiently elastic to provide a compression fit when mounted in position as seen in FIG. 1. Cap 16 may be made of an elastomeric material, such as rubber, natural or synthetic. Attached to the closed end 17 of cap 16 is skirt 18. Skirt 18 is formed having a concave surface 19 and is sufficiently deformable to provide a compression fit to hold cap 16 in place as seen in FIG. 1.

Stopper-piston 14 is made of a self-sealing, pierceable, elastomeric material inert to and unaffected by blood or other parenteral fluids and chemicals associated with the collection thereof. Examples of such a material may be natural or synthetic rubber. Stopper piston 14 includes a tubular body portion 11 having a diameter slightly smaller than the internal diameter of container 12. A plurality of sealing rings 22 is integrally formed with body portion 11, the sealing rings having a diameter slightly greater than the internal diameter of container 12 so that when body portion 11 is inserted into container 12 the sealing rings exert compressive

forces against the inner wall of container 12 sufficient to hold and maintain a vacuum prior to the collection of blood.

Stopper-piston 14 is formed having an enlarged solid top rim portion 13 integrally formed with the upper end of a tubular body portion 11. The diameter of top rim portion 13 is greater than body portion 11 and substantially equal to the external diameter of container 12. Rim portion 13 is resilient and is capable of flexing when a sufficient force is applied to stopper-piston 14 as illustrated in FIG. 7. Body portion 11 of stopper-piston 14 is trilobal and each lobe 23 is separated by a venting channel 20. Base 21 of each channel is beveled inwardly to provide additional elastomeric material to support and reinforce lowest seal ring 22. The base 21 of channel 20 is preferably pitched at about 45° with the lobes 23 preferably spaced about 120° apart. When container 12 is being evacuated channels 20 provide air passages to permit air to escape while stopper-piston 14 has been inserted part way into container 12, as shown in FIG. 5. Also, since stopper-piston 14 is trilobal rather than bilobal, stopper-piston 14 has less tendency to become tilted or cocked as it is being moved into container 12 to engage sealing rings 22. Since stopper-piston 14 remains in substantial axial alignment with container 12 maximum contact is achieved between seal rings 22, the top rim 18 and the inner wall surfaces of container 12. This prevents any loss of vacuum or later any remixing of light phase liquid and heavy phase around stopper-piston 14. When stopper-piston 14 is at its initial position, as in FIGS. 1 and 6, rim portion 18 prevents stopper-piston 14 from sliding into container 12 as tubular member 46 is inserted, even though container 12 has been evacuated. In this connection, rim 18 rests on the top edge surface of container 12 and helps prevent stopper-piston 14 from sliding prematurely into container 12.

FIG. 4 illustrates a form of a closure cap 16 designed and employed to maintain the top surface portion 15 of stopper-piston 14 in aseptic condition prior to the filling of blood in collection container 12. Cap 16 is made of a resilient material which is capable of being penetrated by a pointed tubular member 34 as illustrated in FIG. 6. During the blood collection step, cap 16 is either removed or is not removed from the assembly as preferred. If not removed, during this procedure, the pointed tubular member pierces cap 16 and then stopper-piston 14, the force of the needle penetration being insufficient added force to cause stopper-piston 14 to be pushed into container 12. After the blood is collected the collection assembly is ready for processing.

FIG. 7 illustrates blood collection assembly 10 with stopper-piston 14 moved toward the blood cell and plasma interface by employing a pusher element or member 30. Pusher 30 is elongated and has a shaft 31 and a finger engaging head portion 32 at its upper or outer end. A pointed tubular member 34 is mounted at the lower or inner end of shaft 31. The lower end of shaft 31 is formed having a longitudinally extending slot 35 having a diameter sufficient to mount tubular element 34 therein. Tubular element 34 is fitted into a hub 33 and is rigidly mounted within slot 35. The pointed end 37 of tubular member 34 is capable of piercing stopper-piston 14. As illustrated in FIG. 7, tubular member 34 has pierced stopperpiston 14 to form a passage therethrough so as to conduct plasma "P"

through stopper-piston 14 through its exit opening 38 at the other end of tubular member 34 so that plasma "P" becomes separated from the cellular portion "C" in container 12. After pusher member 30 has moved stopper-piston 14 to a location adjacent the blood cell-plasma/serum interface 50, pusher 30 is removed and piston 14 seals itself and a permanent barrier is thereby formed between cells "C" and plasma "P," as illustrated in FIG. 8.

For a better understanding of practicing the invention herein reference is had to FIGS. 6, 7 and 8. When a blood sample is to be collected in the blood collection assembly of FIG. 1 a blood collecting apparatus such as is disclosed in U.S. Pat. No. 2,460,641 may be employed.

As shown in FIG. 6, the apparatus includes a holder 40 open at one end and closed at the other end. The closed end is formed having a threaded passageway 42 for receiving a threaded hub 44 supporting tubular member 46. The tubular member 46 is mounted in hub 44 intermediate its ends 47 and 48. Ends 47 and 48 are pointed and are capable of piercing a vein "V" and stopper-piston 14 and cap 16 as depicted in FIG. 6. After pointed end 48 has punctured vein "V," blood collection assembly 10 is pierced by pointed end 47 of tubular member 46 so that a blood sample is sucked into evacuated tube 12. After the blood sample is collected assembly 10 is removed from holder 40 and is then processed for chemical testing in the usual manner, such as by centrifuging to separate the serum or plasma from the cellular phase.

Then pointed tubular member 34 mounted on pusher 30 is pushed downwardly until it pierces stopper-piston 14. With tubular member 34 in position a passage from the lower side of stopper-piston 14 to the upper side is provided. Then by exerting downward pressure on pusher 30 and by moving the stopperpiston 14 downwardly the plasma or serum is conducted through the plasma or serum is conducted through tubular element 34 and is stored on the upper surface 15 of stopper-piston 14. When pointed end 37 of tubular member 34 and the stopper-piston 14 approach the blood interface 50 the downward force is stopped and pusher 30 is pulled out of stopper-piston 14 so that a permanent barrier is formed between the plasma on one side of stopper-piston 14 and the cells on the other. The plasma is then ready for testing in the usual manner.

In FIG. 8, blood collection assembly 10 is illustrated with stopper-piston 14 adjacent the blood interface 50. Cap 16 is mounted over the open end of blood collection container 12. The blood collection assembly 10 can then be stored, transported or can be used to obtain samples of plasma or serum to perform various tests. Further, the blood collection assembly in the form illustrated in FIG. 8 can be shipped for subsequent testing at a different laboratory or facility.

It is apparent that the several objects of the invention as set forth herebefore have been accomplished and it is obvious that numerous changes in structures or the steps required for practicing the invention can be employed without departing from the invention as defined in the claims.

What is claimed:

1. An assembly for collecting blood and anti-coagulant treated blood and for separating said blood into its light liquid phase and its heavy, substantially cellular phase which comprises;

a blood collection container having at least one open end;

a stopper-piston slidably mounted in said open end made of a self-sealing, elastomeric, pierceable material which functions as a stopper to seal said open end of said blood collection container when emplaced therein and which functions as a piston when moving from its position at the open end of said container to a position within said container which is intermediate to the ends thereof;

said stopper-piston having;

- i. a lower tubular body portion having slidingsealing means positioned around the outer periphery thereof and integrally formed therewith, said tubular body portion with sealing means being of a dimension such that when inserted in said container, a sliding seal is made with the inner walls of said container; and
- ii. an upper solid body portion having integrally formed means on the outer periphery thereof for (a) engaging the rim of the open end of said container when the stopper-piston functions as a stopper and for (b) forming a seal with the inner walls of said container when the stopper-piston functions as a piston; and

means for sliding said stopper-piston downwardly into said collection chamber when it contains blood separated into its light and heavy phases, so as to establish an impermeable barrier separating the light liquid phase from the heavy phase of blood which comprises a pusher having,

- A. a blunt end for pressing against the upper surface of said stopper-piston; and
- B. a tubular member mounted at said blunt end and being capable of piercing said stopper-piston to form a passage therethrough, said tubular member having open ends so that upon piercing said stopper-piston there is fluid communication via said member between the upper and lower surfaces of the stopper-piston and whereby an axial force exerted against said pusher will cause the light phase to be conducted through the tubular member, enabling the stopper-piston to move downwardly.

2. The assembly of claim 1 wherein said stopper-piston includes a tubular body portion having a diameter less than the inner diameter of said blood collection container and a plurality of circumferentially spaced rings integrally formed around the outer periphery thereof; said spaced rings comprising the sliding-sealing means.

3. The assembly of claim 1 wherein said tubular body portion is formed having three spaced lobes so that when said stopper-piston is mounted in the open end of said blood collection container, said lobes will compress inwardly toward the axis of the stopper-piston to provide three supporting contact areas to maintain the stopper-piston in axial alignment when an axial force is exerted against the piston to move the piston downwardly into the container.

4. The assembly of claim 3 wherein said three lobes are separated 120° each lobe being separated by a venting channel the sides of which are defined by the end surfaces of the adjacent lobes, the base of said venting channel being inclined with respect to the longitudinal axis of said tubular body portion.

5. The assembly of claim 4 wherein the base of the venting channel is inclined 45°; the upper and outer edge portion of which terminates adjacent said sealing ring formed on said tubular body portion.

6. The assembly of claim 1 wherein a cap is removably mounted over the end of the blood collection container containing the stopper-piston so as to maintain the assembly in aseptic condition.

7. The assembly of claim 6 wherein the cap is made of elastomeric and pierceable material, said cap having a deformable skirt portion capable of forming a compressive fit over the open outer end of said container.

8. For collection, separation and storage of blood plasma and blood serum, an assembly comprising:

- A. an evacuated tubular container having one end open and the other end closed;
- B. a stopper-piston slidably mounted in said open end; said stopper-piston being adapted to both maintain a vacuum within said assembly prior to being filled with blood and being adapted to slide downwardly into the container upon application of axial pressure so as to establish an impermeable barrier substantially between the separated serum or plasma and cellular phases of blood; said stopper-piston comprising a self-sealing, elastomeric, pierceable material having (i) a lower tubular body portion having sliding-sealing means positioned around the periphery thereof and integrally formed therewith, said tubular body portion with sealing means being of a dimension such that when inserted in said container, a sliding seal is made with the inner walls of said container; and (ii) an upper solid body portion having integrally formed means on the outer periphery thereof for engaging the rim of the open end of said container so as to maintain a vacuum within said assembly prior to being filled with blood; and
- C. means for sliding said stopper-piston downwardly into said collection chamber when it contains blood separated into its light and heavy phases, so as to establish an impermeable barrier separating the light liquid phase from the heavy phase of blood which comprises a pusher having,
 - i. a blunt end for pressing against the upper surface of said stopper-piston, and
 - ii. a tubular member mounted at said blunt end and being capable of piercing said stopper-piston to form a passage therethrough, said tubular member having open ends so that upon piercing said stopper-piston the tubular member provides fluid communication between the upper and lower sides of the stopper-piston and whereby an axial force exerted against said pusher will cause the light phase to be conducted through the tubular member, enabling the stopper-piston to move downwardly.

9. The assembly of claim 8 including a sealing cap member adapted to close said tubular container to contain the serum or plasma within the tube and between the stopper-piston and the cap member.

10. The assembly of claim 8 wherein said stopperpiston has at least one air channel for use during manufacture of the assembly whereby the stopper-piston may be partially inserted in the tubular container and the assembly be placed within a chamber, subsequently evacuated, said air channel enabling the air within the

container to flow out, with the stopper-piston later being pushed farther into the container thereby sealing off the air channel and thereafter maintaining the vacuum until the assembly is used.

11. The assembly of claim 10 wherein said stopper-piston has three air channels located substantially 120°

apart.

12. The assembly of claim 9 wherein said sealing cap member has a portion of its skirt with a smaller diameter than the skirt opening.

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