April 26, 1960 C. R. BROMAN 2,934,069

PLASMA ASPIRATING EQUIPMENT

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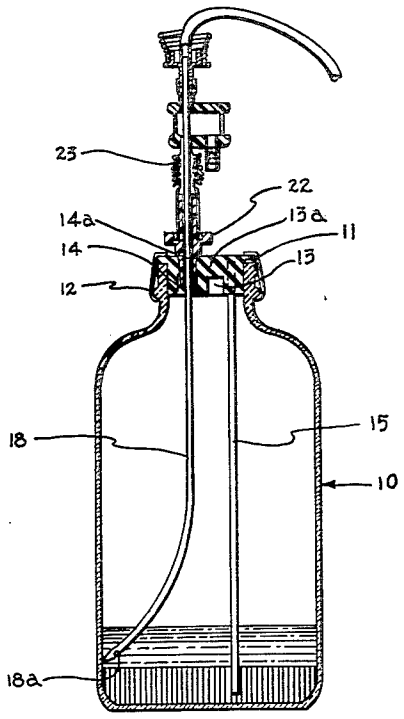
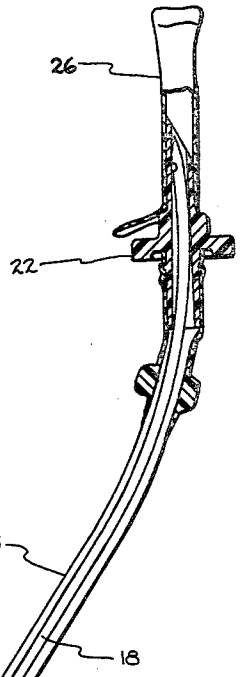


Fig. 1.



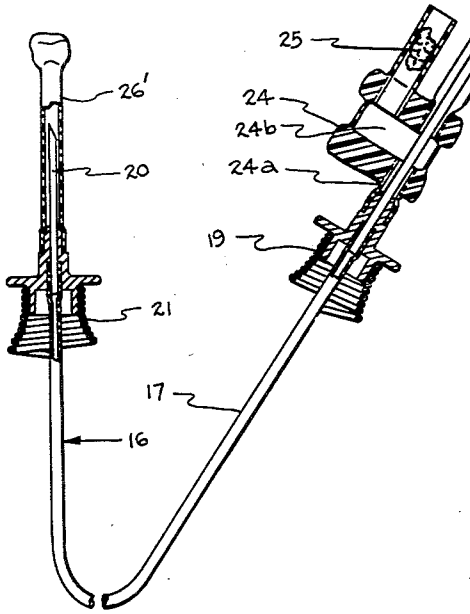


Fig. 2.

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PLASMA ASPIRATING EQUIPMENT

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5 Claims. (Cl. 128—276)

This invention relates to plasma aspirating equipment, and more particularly, to a plasma aspirating needle assembly.

My device can be used in the collection of plasma whether it is derived from freshly-drawn blood or blood that has deteriorated. Plasma is considered useful for administration in cases of shock, loss of blood, and the like. It is not a complete substitute for blood but has the advantage of being administered without the need of having first to ascertaining the blood type and characteristics of the recipient which is necessary in the case of blood. Thus, plasma may be considered to be universal in its application as a temporary expedient to maintain the fluid volume in the human body. This universality of administrability derives, of course, from the fact that plasma does not contain the red blood cells which are responsible for the type and character of blood.

With respect to stored blood it is to be appreciated that whole blood can be stored for only about three weeks, after which the deterioration of the cellular component (i.e., red cells) renders it unsuitable for human administration. This is attributed to the fact that about 40% of the red cells hemolyze in about 21 days, it being necessary to administer blood containing at least 60% live red cells.

When plasma is to be separated from blood, the blood is usually centrifuged to provide stratification, wherein the heavier red cells provide the lower layer and the plasma the upper layer. In the separation of the two layers it is important that aseptic technique be employed.

Blood is usually handled in what is called the "closed system." In the closed system, all components are sterile and the only air contacting the blood between the time it leaves the donor and enters the recipient being air that has passed through a filter capable of stripping the air of any macromolecular contaminants, especially microbes. Such can be achieved by a relatively simple plug of cotton batting. It is deemed just as important to handle plasma aseptically, hence the same precautions against contamination are applied.

The technique for the collection of plasma is essentially the same whether the blood has been collected for this purpose or whether it was collected primarily for direct administration but was not used in the effective storage period. When it is decided to separate the plasma, the stored blood is centrifuged and a hospital attendant or technician makes use of the equipment of my invention. This includes a rather elongated needle connected to one end of a length of flexible tubing, the other end of the tubing being provided with a conventional type of hypodermic needle. The plasma is aspirated from the storage container into another container of similar design and which is under high vacuum. To achieve this transfer, it is necessary that the blood storage container be vented so as to permit entry of air to replace the withdrawn plasma.

In the past, the simple three-element aspirating set described above was employed in conjunction with a separate filter venting needle that was thrust through the resilient stopper closing the blood storage bottle. Not only was this technique time-consuming, but resulted in a rather cumbersome arrangement of fittings that had to be carried by the resilient closure of the blood storage bottle.

It is to be appreciated that virtually every closure for blood bottles now used in the United States employs a hardened-rubber stopper having at least three passageways extending only partway through the stopper. Two of these passageways are closed by thin, rather easily-rupturable integral diaphragms, while the third passageway is closed by a rather thick diaphragm capable of resealing itself after puncture by a hypodermic needle. Such a stopper structure is described in U.S. Patent No. 2,457,120.

In the use of a blood storage bottle equipped with the above-described stopper or closure, the blood is introduced into the container from the vein of a donor by thrusting the flask needle of a donor set through the thick or self-sealing diaphragm. The flask needle is connected to a length of tubing the other end of which is provided with a similar needle which is inserted in the vein of the donor. After the requisite amount of blood has been collected, the needles are withdrawn from the donor and the stopper whereby the container is automatically sealed. The containers are usually provided under vacuum, which facilitates the withdrawal of blood from the donor.

In the event blood from the filled container is desired to be administered as such, the plug-in connector end of a conventional blood administration set is thrust through one of the rupturable diaphragms of the stopper. The other rupturable diaphragm closes a passage which carries an air tube, hence cannot be used for withdrawal of blood from the blood storage bottle. This second, or air tube diaphragm, is also ruptured as by inserting a hypodermic needle through it. This air diaphragm hypodermic needle is not connected to a length of tubing, but rather is equipped with a filter housing through which air must pass to be filtered before entering the blood storage bottle. The assembly thus achieved is then inverted; that is, mounted in mouth-downward fashion, and blood is caused to flow through the administration set, it being replaced by air entering the container through the air tube.

If, however, the blood is not administered within the indicated storage life, the plasma is aspirated from the bottle, the bottle then being in an upright position. The transfer of blood is caused by a lower pressure condition within the plasma receiving container than in the blood storage container. To achieve the higher pressure in the blood storage container, that is, atmospheric pressure, it is necessary that a vent be provided through the hard-rubber stopper. The usual location for this vent is through the thick self-sealing diaphragm since the rupturable diaphragm communicating directly with the interior of the blood storage bottle is utilized by the aspirating needle assembly, and the other rupturable diaphragm is not useful for this purpose since the air would then have to travel down through the air tube in order to enter the main interior of the blood storage bottle. It is to be appreciated that the stopper is rather small in diameter, being less than 1¼ inches in diameter. The positioning of two needle assemblies in this small closure, especially where one must be thrust through a resisting thickness of hard rubber, is a difficult operation. The difficulty of the operation becomes apparent when it is realized that ordinarily a nurse or other female attendant performs this work and that the puncture of the thick diaphragm requires considerable force. Notwithstanding the laborious-

ness and difficulty of this technique, it has been used uniformly for over a decade without change.

By the improved aspirating needle assembly of my invention, I eliminate the need for the difficult puncture through the self-sealing diaphragm which makes the entire technique of plasma aspirating much simpler and more easily performable without the exercise of considerable manual strength.

My invention essentially includes a rigid puncturing tubular member slidingly mounted over the plasma aspirating needle, the unpointed end of the puncturing member being provided with means for admitting air into the puncturing member.

My invention will be explained in conjunction with the accompanying drawing in which Fig. 1 is an elevational view partially in section of a portion of the aspirating device of my invention shown inserted into a blood collection and storage bottle, and Fig. 2 is an elevational view partially in section of the device of my invention as it is constituted for sale.

Referring to the drawing, and in particular to Fig. 1, the numeral **10** generally indicates a blood collection and storage bottle. Conventionally these bottles are constructed of glass and have a characteristic bell shape. The mouth of the bottle is closed by a rubber stopper **11**, which has an annular flange overlying the lip of the neck of bottle **10**. Maintaining stopper **11** in position in the neck of bottle **10** is a channel shaped metal clamping ring **12** which overlies the top surface of stopper **11** and underlies an annular head **10***a* on the neck of bottle **10**.

Stopper **11** is provided with three passageways extending partway therethrough. One passageway is provided with a substantially thicker diaphragm integral with the main body of the closure than the diaphragms provided for the other two passageways. This passageway is indicated **13** and its associated diaphragm **13***a*. As pointed out above, it is through this diaphragm that the needle delivering blood to the bottle is inserted. A second passageway is designated **14** and is closed by a thick, easily-rupturable diaphragm designated **14***a*. Yet a third passageway (not shown) receives the end of air tube **15** which extends almost to the bottom of bottle **10**.

Shown extending through diaphragm **14***a* is the needle assembly of my invention which is a portion of a plasma aspirating set generally designated **16**. The entire set can be seen in Fig. 2, wherein one end of tubing **17** is provided with a needle substantially longer than those encountered in ordinary parenteral therapy and designated **18** in both views. Needle **18** is secured to tubing **17** by means of a conventional hub assembly designated **19** wherein the tubing is telescoped over the needle and held in place thereon by means of staking an internal collar provided in hub **19**. The same type of mounting for the plasma collection bottle needle designated **20** is employed in the form of hub **21**.

Slidingly mounted on needle **18** is tubular piercing member **22**. Secured to the unpointed end of member **22** and concentric to needle **18** is a length of flexible plastic tubing **23**. Tubing **23** at its unmounted end is heat-sealed to a flat sleeve portion **24** which is tightly secured to a portion of hub **19** as at **24***a*. At **24***a*, portion **24** is ensleeved over a portion of hub **19**. Collar **24** is provided with a C-shaped internal air passageway **24***b* partially obstructed by a cotton ball plug **25**. Thus air can only enter bottle **10** by flowing through cotton ball plug **25**, thence through collar member passage **24***b*, through tubing **23**, and puncture member **22**.

Needle **18** is provided with a pointed end achieved by staking. Spaced from that end, the needle wall is interrupted to provide an entryway **18***a* into the hollow interior of needle **18**. It has been found that this type of needle opening is superior to the end opening achieved by a conventional bevel cut in that it permits positioning of the needle opening **18***a* right at the interface of the red cell stratum and the plasma stratum so as to aspirate the maximum possible quantity of plasma.

It is significant to note that in the needle aspirating device of my invention, needle **18** is provided in an arcuate form. This permits the needle point to be positioned near the wall of bottle **10** so as to give visual evidence that the needle opening **18***a* is at the interface.

Referring now to Fig. 2 it is to be noted that when the set is in condition for marketing sleeve **23** is in extended form, at which time puncture member **22** extends beyond aspirating needle **18**. Thus, the first penetration of stopper **11** is by the pointed end of puncture member **22**. Any air entering bottle **10** must pass through cotton filter **25**. This effectively prevents entry of any injurious microbial material.

For storage prior to use, I provide a flexible plastic protector **26** to seal and protect the end of puncture member **22**. A similar type protector **26'** is mounted on hub **21** and covers plasma collection bottle needle **20**.

Operation

In the use of my aspirating device, a bottle of centrifuged stored blood, out-dated or otherwise, and an empty, evacuated plasma collection bottle are provided. An example of the latter type bottle is the bottle designated "Plasma Vac" and marketed by Baxter Laboratories, Inc., Morton Grove, Illinois. Conventionally, such a receiving container may have a slight quantity of anti-coagulant material and has its contents under a vacuum of the order of about 20" Hg. The degree of vacuum present in the blood storage bottle is considerably less—of the order of a few inches of mercury despite the fact that before collection that bottle also was under a substantial vacuum. The introduction of whole blood into the blood storage bottle limits the volume occupied by any remaining air so the pressure of that air is increased.

A set such as pictured in Fig. 2 is also provided which has a sterile interior, being heat sterilized before use and provided with protectors **26'** and **26** over its ends to maintain the interior in sterile condition. The set is clamped closed at one or more intermediate positions, either by a hemostat or by inserting tubing **17** between the convolutions of spring hubs **19** and **21** and "cinching" the tubing between the spring convolutions to clamp it tightly. After removing the two protectors, the now-exposed needle **20** is inserted into a blood storage bottle.

After plasma aspirating needle **18** is positioned within the plasma stratum in the blood storage bottle **10**, the tubing **17** is unclamped and plasma is aspirated from blood storage bottle **10** to a plasma collection bottle (not shown but of same general design). Air enters bottle **10** by passing through the annular passage provided by the loose fit of puncture member **22** on needle **18**. Flexible sleeve **23** permits positioning of the end of needle in various spaced relationships to the end of puncture member **22** while still restricting air entry to a passage through the set rather than around it. This not only permits positioning the needle tip at any point within bottle **10** but also permits the set to be used with different sized bottles.

The foregoing detailed description has been given for clearness of understanding only, and no unnecessary limitations are to be inferred therefrom.

I claim:

1. A plasma aspirating needle assembly comprising an elongated, arcuate needle, hub means associated with the unpointed end of said needle, a rigid puncturing tubular member slidingly mounted on said needle, flexible sleeve means secured at one end to the unpointed end of said tubular member and at the other end thereof to said hub means, said sleeve means being provided with a filter-equipped air entry.

2. A plasma aspirating needle assembly, comprising an elongated needle having hub and conduit means secured to the unpointed end thereof, a rigid puncturing tubular member slidingly mounted on said needle, air

flow passage means associated with the bore of said tubular member, and air filter means associated with said flow passage means, the said needle being provided with an arcuate portion intermediate its ends whereby the sharpened point of said needle can be positioned adjacent the wall of a container so as to render the said point visible when said container contains an opaque substance.

3. A plasma aspirating needle assembly, comprising an elongated needle, hub means associated with the unpointed end of said needle, a rigid puncturing tubular member slidably mounted on said needle, flexible sleeve means secured at one end to the unpointed end of said tubular member and at the other end thereof to said hub means, said sleeve means being provided with a filter-equipped air entry.

4. In a plasma aspirating set adapted to be inserted through the closure of a rigid blood bottle, a needle having a hub and a flow conduit secured to the unpointed end thereof, said needle being sufficiently long to have its pointed end positioned adjacent the inner bottom of the bottle when said hub is positioned outwardly of the bottle closure, a rigid tubular puncturing member slidingly mounted on said needle with the pointed end thereof adjacent the pointed end of said needle, flexible sleeve means secured at one end to the unpointed end of said tubular member and at the other end thereof to said hub, said sleeve means being provided with an entry for air, said sleeve means having a length sufficiently

long so as to position said puncturing member about the pointed end of said needle, and protector means over said puncturing member closing the pointed end thereof.

5. In plasma aspirating equipment, an elongated needle connected to flexible tubing at one end, said tubing being connected to a delivery needle, said elongated needle having a length sufficient to extend substantially over the depth of a glass blood collection bottle, a tubular puncturing member on said elongated needle mounted for movement thereon substantially over the length of said elongated needle, said puncturing member having a pointed end oriented in the direction of the unconnected end of said elongated needle, and a flexible connector between the unpointed end of said member and the connected end of said elongated needle, said connector being equipped with air entry means.

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