

[54] MEANS FOR BLOOD ADMINISTRATION
AND THE LIKE

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128/214.2, 272

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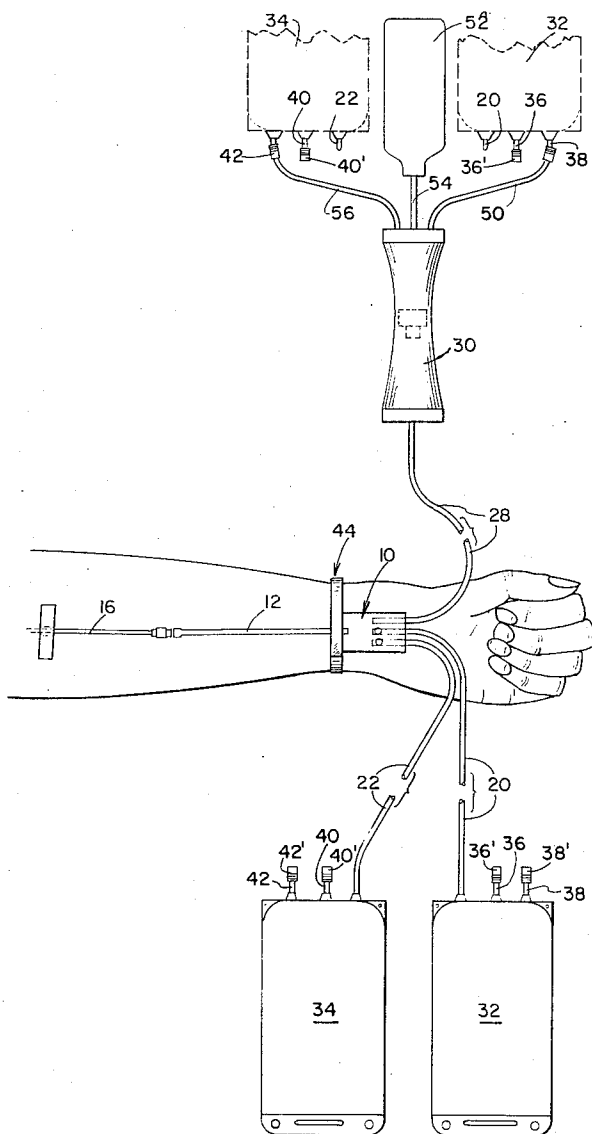
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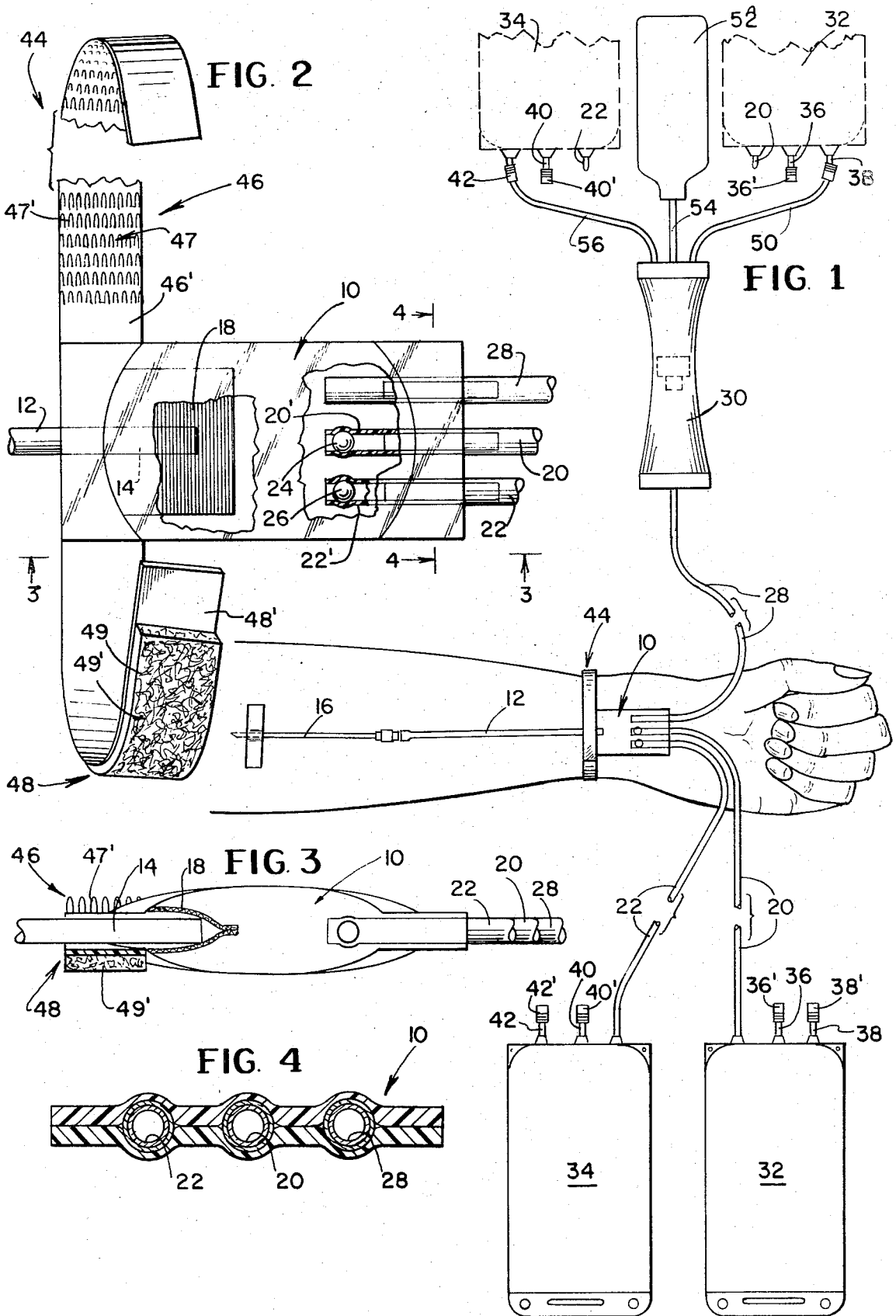
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[57] ABSTRACT

Fluid or blood administration equipment comprising, a plastic manifold, a plurality of flexible conduits connected at one end to said manifold and at their opposite ends each respectively connected to a bag for receiving blood, another flexible conduit connected to said manifold at one end with the opposite end of said flexible conduit adapted to be connected to a blood flow tube, another flexible conduit adapted to be connected at one end to said manifold with the opposite end thereof connected to an intravenous needle, with said pair of conduits leading to said blood bags having at their inner ends within said manifold a removable valve and with said manifold having a filter at the inner end of the conduit from the needle, and a band secured to said manifold whereby said band is strapped around the wrist or arm of the patient to prevent dislodgement of the needle if there should be any pull on the equipment.

8 Claims, 4 Drawing Figures





MEANS FOR BLOOD ADMINISTRATION AND THE LIKE

BRIEF SUMMARY OF THE INVENTION

This invention is an improvement on the equipment shown in U.S. Pat. No. 3,459,182, the inventor of which is one of the inventors herein. The said equipment utilizes a number of Y connectors in the system which had serious objections, as more fully and specifically set forth hereinafter, which could result in a serious consequence to the donor, who in turn would also be the recipient as the blood originally extracted from the donor would be centrifuged and the donor would become the recipient of the red blood cells which are returned to the donor.

In lieu of the Y connectors shown in U.S. Pat. No. 3,459,182 there is provided a plastic manifold made of the same material as the tubes, to which plastic manifold is connected the various tubes leading to the blood bags and to the blood flow tube, with another tube connected at one end to the said manifold and with the opposite end thereof connected to a needle which is intravenously inserted in the patient.

The manifold of this invention has the following advantages over the Y connectors shown in the aforementioned patent.

1. The manifold reduces the incidence of clotting as compared with the Y connectors.

2. The manifold provides means for observing the progress of plasmapheresis at a central location, which is not the case with the separate and several Y connectors.

3. The manifold constitutes a substantial savings by replacing the several Y connectors.

4. The Y connectors by their very construction cause the presence of dead ends, i.e., residual blood enters the dead end of one leg of the Y where it is trapped in the bleeding process and where it often clots and the clots may be reincorporated in the infusion stage when saline and/or the centrifuged blood cells are returned to the patient. This is a potential hazard with every Y connector in the present plasmapheresis art. This hazard is prevented by the use of the manifold and the valved construction shown in this application which permits no residual blood to remain in the tubing and thereby eliminates dead ends.

The donor and the recipient will for the purpose of this description be referred to as the "patient" since in one capacity he serves as the donor and in the other capacity he is the recipient of the blood cells.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. 1 is a diagrammatic view of the blood collection and administration apparatus, with the collection components shown in full lines and the administration components in phantom lines.

FIG. 2 is an enlarged plan view partly in section of the manifold and the means for attaching same to the wrist or arm of the patient.

FIG. 3 is a view taken on line 3—3 of FIG. 2, and

FIG. 4 is an enlarged sectional view taken on line 4—4 of FIG. 2.

Since the apparatus herein is an improvement of the apparatus of U.S. Pat. No. 3,459,182, certain of the components referred to in said patent will not be de-

scribed in detail but will be referred to generally, sufficiently to understand the invention herein.

The apparatus is to be used in plasmapheresis, which involves the withdrawal of whole blood from the patient, followed by removal of the plasma which in turn is followed by a return to said patient of the red blood cell content of the withdrawn blood.

The apparatus embodied in this invention includes a manifold generally designated by the numeral 10 which, as shown, is of generally rectangular shape and is made of a plastic transparent material which is pliable, which is inert, nontoxic and of medical grade quality, such as polyethylene, vinyl plastic, or polyvinyl chloride. Connected to one end of the manifold is a flexible transparent plastic tube 12, the inner end of which tube extends into the manifold, as indicated by the numeral 14. Attached to the opposite end of said conduit is an intravenous needle 16 which is adapted to be inserted in the vein of the patient. When not in use the needle may be covered by a removable shield. Positioned inside the manifold 10 and surrounding the end 14 of the tube 12 in the manifold is a filter 18 which is a nylon mesh monofilament filter, which serves to filter out any possible clots that may form between the first and second bleeding.

Connected to the opposite end of the manifold is a pair of flexible tubes or conduits 20 and 22, the inner ends 20' and 22' of which extend into the manifold 10. Positioned within each of the inner ends of each of said tubes is a single small metallic bead or metallic ball 24 and 26 respectively. These beads are made preferably of a metal and serve as valves when positioned inside their respective tube ends, however, each of said beads may be ejected from their respective tube ends by pressing against the manifold adjacent thereto and against the tube end and thus are expelled from the tube end into the manifold so that the inner end of said respective tube is unblocked. This is done in connection with the operation of the unit, as will be more fully explained.

Also connected to the same end of the manifold is a flexible tube 28, the inner end of which extends into the manifold, similar to that previously described. Said tube 28 has no valve means therewithin. The opposite end of tube 28 is adapted to be connected to the blood flow tube designated generally by the numeral 30. The blood flow tube 30 is of the character illustrated and described in U.S. Pat. No. 3,459,182 and therein also designated by the numeral 30.

All of the tubes referred to herein are made of the same transparent plastic material as is the manifold, such as polyethylene, vinyl plastics, etc.

The tube 20 is connected at its opposite end to a first blood bag 32. Tube 22 is connected to a second blood bag 34. Said blood bags are made of the material described in the aforementioned patent, or of any other suitable material well-known in the art, and each blood bag is provided at the top thereof with outlet ports for allowing separate removal of the blood plasma and the red blood cells respectively, as will be more fully explained. Removable caps are provided for closing each of said outlet ends. The first blood bag 32 has outlet ports 36 and 38 which are closed by removable caps 36' and 38' respectively. The second blood bag 34 has outlet ports 40 and 42 which are closed by removable caps 40' and 42' respectively.

Secured to the manifold adjacent one end thereof is a wrist or arm band generally designated by the numeral 44 which is made of two cooperating hooking sections 46 and 48, with the inner ends of each of said sections permanently secured and affixed to the manifold. The sections 46 and 48 extend in opposite directions from the manifold, as shown in FIG. 2, but when positioned around the wrist or arm of the patient cooperatively hook to each other to form a band around the wrist or arm, as shown in FIG. 1.

The section 46 includes a flexible strip 46' to which is adhesively or otherwise secured a strip of flexible material 47 which has on the face side thereof a hooking surface 47'. The inner end of the strip 46' is permanently affixed to the manifold 10.

The oppositely extending section 48 includes a flexible strip 48' to which is adhesively or otherwise secured an attaching strip of flexible material 49 which has a facing surface 49' which when in engagement with the hooking surface 47' will hold it attached thereto. The hooking strip and the cooperating attaching strip are components of a trademarked product VELCRO which, as far as is known to applicants, is manufactured and distributed by John Dritz & Sons of New York City, N. Y.

As best seen in FIG. 1, the two sections 46 and 48 forming the band 44 are positioned preferably around the wrist of the patient, with the outer ends of the sections interlocked so that the band in its locked position surrounds the wrist of the patient at a point removed from where the needle 16 enters the arm. Therefore, any pull or outward pressure that might be applied accidentally or otherwise against the manifold or the flexible tubes connected thereto will not be transmitted to the needle 16. With the band 44 wrapped around the patient's wrist or arm no amount of pull will have any effect on the tube 12 carrying the needle so that the needle will not be dislodged from the patient.

Referring to FIG. 1, the blood from the patient will be allowed to flow into the first blood bag 32 and then subsequently into the second blood bag 34 in the following manner. As the blood flows through the needle 16 and tube 12 into the manifold 10, it cannot pass into either tube 20 or tube 22 unless the inner ends of the tubes are unblocked by their respective ball valves. Thus, for example, to fill the first blood bag 32 the ball valve 24 is manually pressed out of the end of tube 20' so that the ball valve passes into the interior of the manifold and unblocks the end 20' of the tube 20 to open the inlet into the tube. At this point the ball valve 26 is still retained in the end 22' of tube 22 and blocks entrance into tube 22. The blood will flow first through tube 20 to the first blood bag 32.

When the first blood bag is filled, the tube 20 is heat-sealed and the bag is placed in a conventional blood bag centrifuge in order to force the red blood cells to the bottom of the bag. After the blood is centrifuged the plasma is removed by conventional plasma extraction techniques. The red cells remaining in the first blood bag 32 are then returned to the patient in the manner as generally described in U.S. Pat. No. 3,459,182. Briefly, blood bag 32 is connected through its outlet 38 to the flexible tube 50 which connects to the blood flow tube 30 which is described in detail in said patent, and the outlet end of the flow tube 30 is connected to the tube 28, previously described, from the manifold.

After the phlebotomy and during the period of time that blood is not being collected from the patient, it is common practice to allow a small amount of saline solution to flow into the vein in order to prevent clotting at the needle and to help replace a portion of the blood volume given by the donor. The bottle 52 containing the saline solution flows to the patient through tube 54, blood flow tube 30, tube 28, through the manifold 10, through the filter 18, through the tube 12 and the needle 16 to the patient.

To obtain the flow of red blood cells from the bag 32 back to the patient, the outlet port 38 of said bag is connected through tube 50 to blood flow tube 30 so that the blood will flow together with the saline solution through the filter in the blood flow tube 30 and the tubing to the patient's vein. Suitable clamps are connected to the tubing at certain locations in order to control the flow within the respective tube.

After the red blood cells have been returned to the patient another unit of blood can be collected in the second blood bag 34 in the same manner as in the first blood bag. The process is repeated and after the blood is collected in the second blood bag and centrifuged, the plasma is extracted from the second bag and the red blood cells remaining in the second bag are returned to the patient. The outlet port 42 of the second bag 34 is connected by flexible tube 56 to blood flow tube 30 so that the red blood cells can flow back to the patient through tube 28, manifold 10, tube 12 and needle 16. It will also be seen that the manifold is secured to the wrist or arm of the patient so that it cannot be yanked or jerked away therefrom.

The apparatus herein is not limited to plasmapheresis techniques but is also useful in connection with the administration of blood, serums, biological or pharmaceutical fluids whenever desired. The apparatus is used preferably as a disposable single use apparatus.

While the invention is shown in connection with two blood bags, namely, a first and a second blood bag, it will be understood that it can be utilized with a single blood bag or with any number of blood bags, and instead of a pair of tubes leading from the manifold to separate blood bags there could be a single tube leading to a single blood bag or the number can be increased as desired.

What is claimed is:

1. Means for blood administration and the like which comprises, a manifold formed of a bag made of a transparent material which is generally pliable and which is inert and nontoxic, an inlet tube connected at one end to said manifold and a needle for insertion into the vein connected to the opposite end of the inlet tube, a blood receiving bag and a first tube connecting said manifold to said blood receiving bag, a blood flow tube and a second tube connecting said manifold to said blood flow tube, said first and second tubes being connected to said manifold at the end opposite said inlet tube connection, and filter means located within said manifold on said inlet tube, said manifold being of a size so as to be attached directly to the patient's limb.

2. Means as set forth in claim 1 in which the end of the tube connecting the manifold to the blood receiving bag extends into the manifold with a ball valve inside said end of the tube for blocking the flow of blood into said tube, which ball valve may by manual pressure applied against the manifold and the end of the tube eject

5

the ball valve from the tube into the manifold to unblock said tube.

3. Means as set forth in claim 1 in which there is a pair of blood receiving bags each connected by a tube to said manifold, which tubes have a ball valve inside the end of the tube within the manifold for blocking the flow of blood into said tube, which ball valve may by manual pressure applied against the manifold and the end of the tube eject the ball valve from the tube into the manifold to unblock said tube.

4. Means as set forth in claim 3 in which a band is adapted to encompass the hand or wrist of a patient so that accidental withdrawal of the needle from the patient is prevented.

5. Means for blood administration and the like which comprises, a manifold formed of a bag made of a transparent material which is generally pliable and which is inert and nontoxic, an inlet tube connected to one end of said manifold and a needle for insertion into the vein connected to the opposite end of the inlet tube, a blood receiving bag and a first tube connecting said manifold to said blood receiving bag, a blood flow tube and a

6

second tube connecting said manifold to said blood flow tube, means connected to said manifold adapted to engage around the arm or wrist of a patient to prevent accidental removal of the needle from the patient.

6. Means as set forth in claim 5 in which the means adapted to engage around the arm or wrist comprises a band formed of flexible material having hooking means and cooperating attaching means.

7. Means as set forth in claim 5 in which the end of the tube connecting the manifold to the blood receiving bag extends into the manifold with a ball valve inside said end of the tube for blocking the flow of blood into said tube, which ball valve may by manual pressure applied against the manifold and the end of the tube eject the ball valve from the tube into the manifold to unblock said tube.

8. Means as set forth in claim 5 in which the means adapted to engage around the arm or wrist of a patient comprises a band of attaching members formed of Velcro material whereby the opposite ends of the band are readily attachable and detachable from each other.

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