Oct. 31, 1961 E. J. POITRAS 3,006,341

MEDICAL FLUIDS HANDLING AND ADMINISTERING APPARATUS

Filed March 29, 1954 3 Sheets-Sheet 1

Fig. 1.

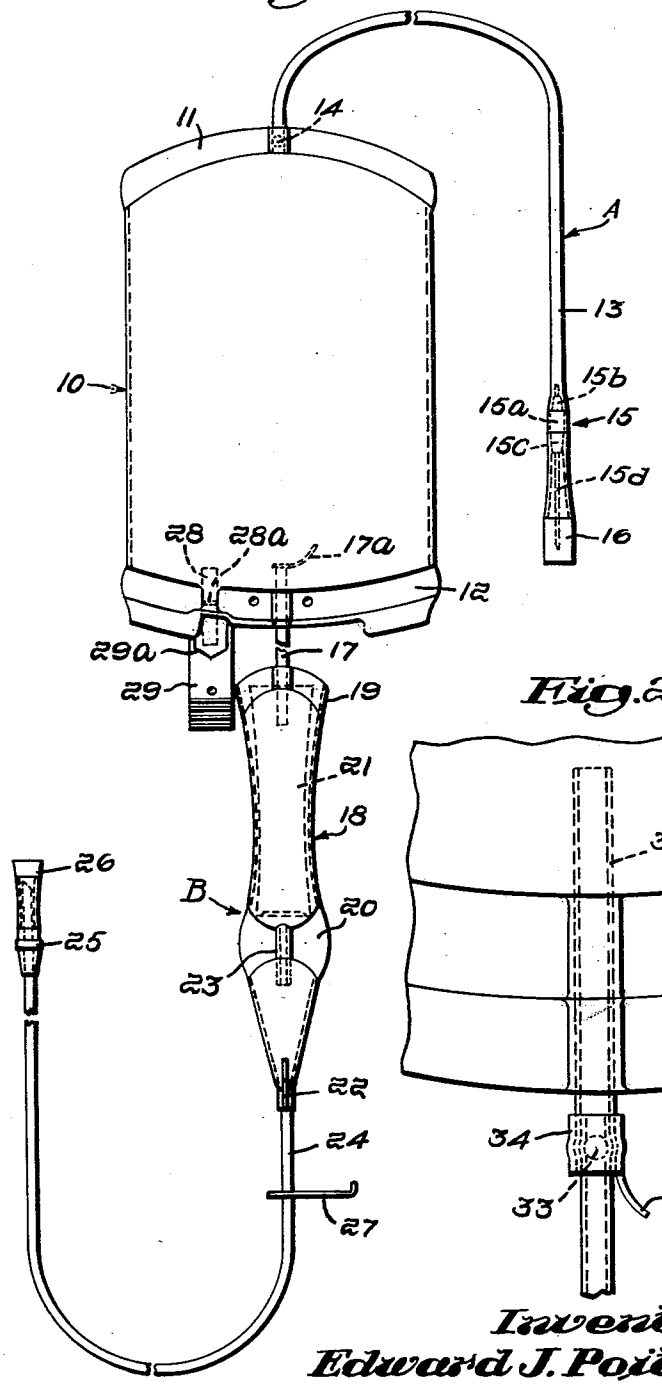


Fig. 2.

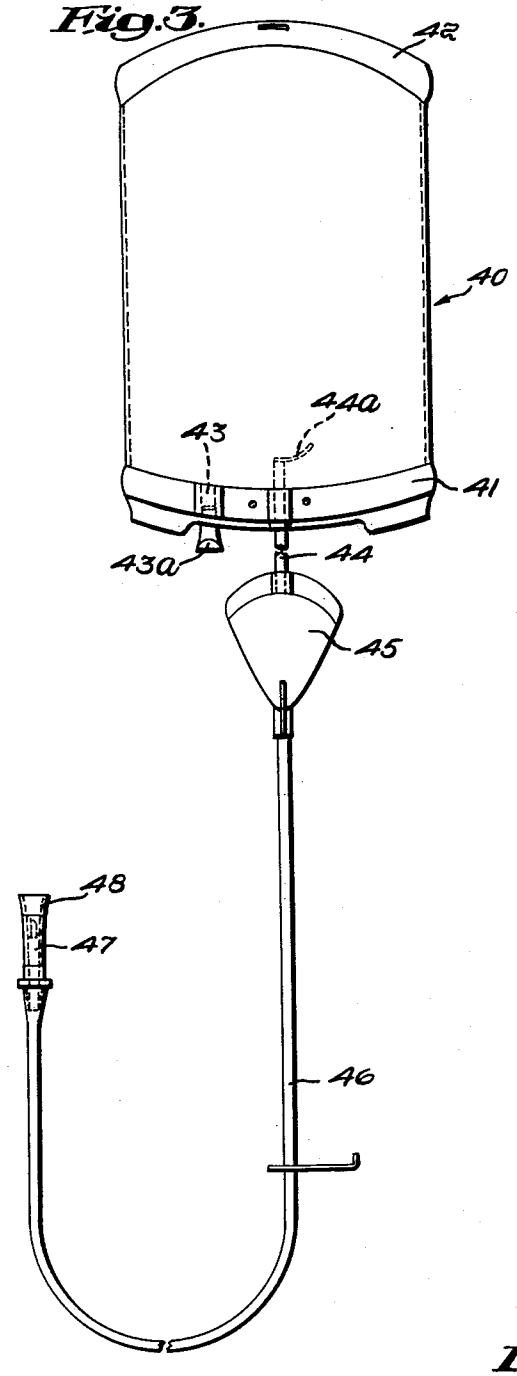
Inventor:
Edward J. Poitras,
By Emery, Booth, Townsend, Miller & Weidner
Attys

Oct. 31, 1961 E. J. POITRAS 3,006,341

MEDICAL FLUIDS HANDLING AND ADMINISTERING APPARATUS

Filed March 29, 1954 3 Sheets-Sheet 2

Fig. 3.



Inventor:
Edward J. Poitras,
by Emery, Booth, Townsend, Miller & Weidner
Attys

Oct. 31, 1961 E. J. POITRAS 3,006,341

MEDICAL FLUIDS HANDLING AND ADMINISTERING APPARATUS

Filed March 29, 1954 3 Sheets-Sheet 3

Fig. 4.

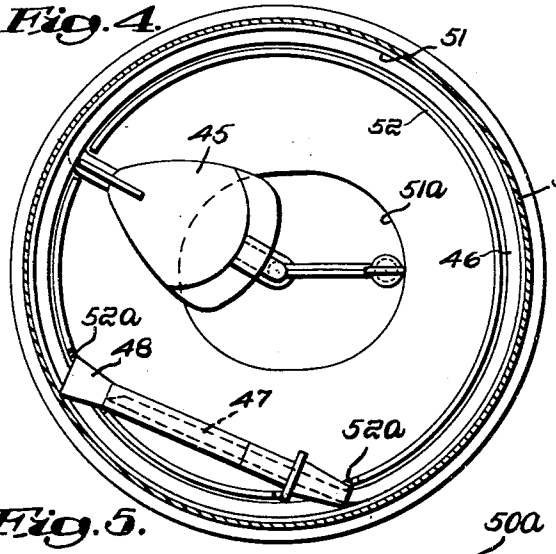
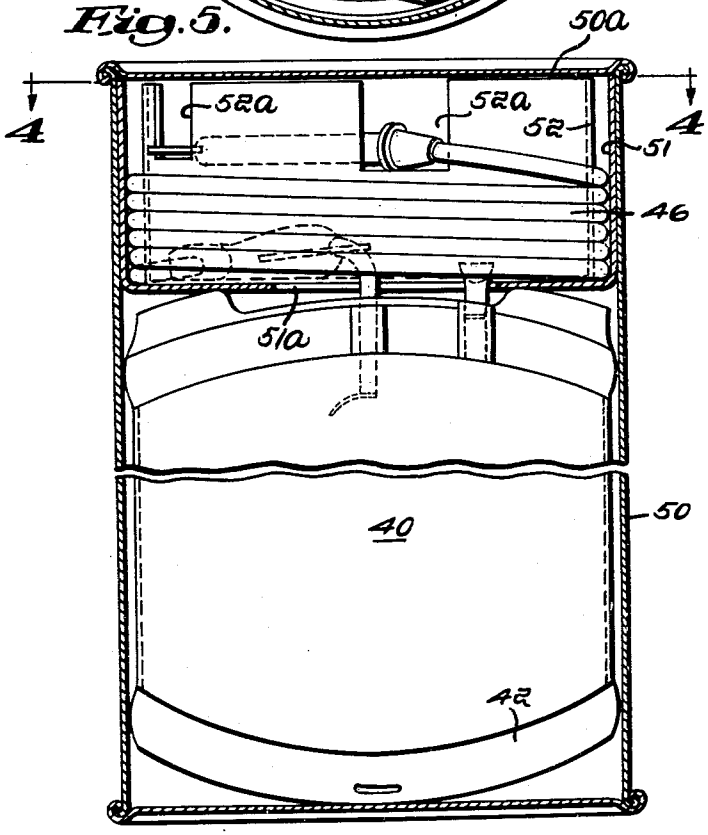


Fig. 5.



Inventor:
Edward J. Poitras,
by Emery, Booth & Townsend, Miller & Weidner
Attys

United States Patent Office 3,006,341
Patented Oct. 31, 1961

3,006,341

MEDICAL FLUIDS HANDLING AND ADMINISTERING APPARATUS

Edward J. Poitras, 198 Highland St., Holliston, Mass.

Filed Mar. 29, 1954, Ser. No. 419,496
9 Claims. (Cl. 128—214)

My present invention relates to medical equipment and techniques, and more particularly to an improved method and apparatus for handling medical fluids. It aims to provide an integral, unitary, closed, sealed system for such handling and with minimum chance for the contamination of the fluids. In one embodiment here concerned it affects more particularly the sterile, anti-coagulant collecting, storing and infusing of blood.

The invention will be better understood from the following description taken in conjunction with the accompanying drawing in which:

FIG. 1 is an assembly view of the embodiment of the invention adapted to handling and administering blood;

FIG. 2 shows an alternative form of one of the features of FIG. 1;

FIG. 3 is a plan of another embodiment of the medical fluids handling equipment; and

FIGS. 4 and 5 show the embodiment of FIG. 3 as fitted for shipping and storage.

A primary objective in the design and construction of apparatus for handling medical fluids is reducing and holding to a minimum the possibility of contamination of the fluids. Ideally the apparatus should be of unitary or one piece construction, thus providing an integral passage sealing the fluids against any exposure to atmosphere or contaminating influence throughout the handling and administering of the same. In the case of blood, for example, a completely sealed apparatus and a sterile technique is required for the necessary preservation of shed blood against coagulation and degradation. It has been established also that medical fluids handling equipment should be non-toxic, non-reactive, and susceptible of sterilization under medically acceptable conditions. My present invention provides new and improved means and methods which meet these requirements and specifications.

Generally considered, the apparatus of the invention comprises a unitary hermetic-sealed fluid handling system. It incorporates centrally a closed collapsible container defining a storage means or reservoir for the fluid. Integrally associated therewith are sterile sealed assemblies for supplying and administering the fluids to and from the reservoir. Further, the unitary fluid container and conduits and associated fluid contacting elements of the invention system are fashioned of a flexible lightweight material which is non-reactive to the fluids, particularly blood, and which provides a compact, inexpensive and durable apparatus.

In its embodiments adapted specially to the handling of blood, the apparatus of the invention comprises more particularly integrally associated means for the sterile collection, anti-coagulant storage, and filtered infusion of the blood. Such means are predeterminedly and importantly hemo-repellant, by which is meant that the surfaces which they present for contact with the blood are chemically inert or non-reactive, and exert repulsive forces to fend off the formed elements and proteins concerned in the blood-clotting mechanism.

In its every form, the invention system may be placed and preserved in completely sterile condition, and effectively seals the blood or other medical fluid against contamination from any source.

Referring now more particularly to the drawing, one embodiment of the blood handling form is shown in

FIG. 1, with the means for the anti-coagulant storage of the blood indicated generally at **10**. Integrally associated therewith in the unitary donor-recipient set of FIG. 1 are a collecting assembly indicated generally at A and a filtering and infusing assembly identified generally at B. In accordance with the invention, in the manufacture of the central storage means **10** and also the integrally associated donor-recipient assemblies A B, a flexible, lightweight material providing inert, impermeable, glossy and non-toxic surfaces and chaarcterized also and importantly by the above defined quality of hemo-repellence is employed. Other characteristics desired for and provided in the appaartus of the invention include tensile and flexural strength, or a general toughness, together with stability to sterilizing temperatures of at least 120° C. and capacity for hermetic sealing by heat. I prefer to use materials selected from the elastomeric thermoplastic resins class and more particularly from the polyvinyl chloride group as best exemplifying these qualities and characteristics.

The blood storing means **10** comprises a deformable, collapsible contanier, vessel, or bag formed from a tubular envelope or sleeve which is closed and more particularly dielectrically heat-sealed or fused at its ends along the bands or margins **11**, **12**. The bag **10** is manufactured from thin, manually manipulable stock in the tough flexible plastic material above mentioned and with a suitable volume, which may be that accommodating an adult donation together with the appropriate quantity of anti-coagulant. In one comemrcial embodiment, for example, the bag is sized for a donation of 500 cc. collected into 75 cc. of acid citrate dextrose. The described bag construction is seen to be one which is completely collapsible flatwise, and thus adapted to evacuation prior to use as desired for minimum liquid gas interface. And in use it provides a compact, lightweight and relatively indestructible blood storing means which lends itself to quick and certain handling both in the hospital and in the field.

Integrally associated with the bag **10** in my novel system is a collecting tube **13**, one end of which is passed through the end wall or flatted closure **11** before it is heat sealed, or fused together and about the said tube end. The said one or inner end of the tube **13** may be stoppered or closed for a reason hereinafter apparent by a slightly oversized hemo-repellent bead **14**, lodged in the same in the region of the closure **11**. The free end of the tube **13** is seized over a phlebotomy needle **15** of a type adapted specially for use with the invention apparatus and shown to comprise handling and manipulating means including a central gripping portion **15***a*, conical hubs **15***b*, **15***c* extending oppositely thereof; and a blood letting tube or cannula **15***d* extending longitudinally from the hub **15***c*. The cannula **15***d* may project within the manipulating portion **15***a,b,c*, for the full length of the needle and may be coated interiorly with a hemo-repellent film or liner in accordance with known practice. Surrounding the said cannula **15***d* and tightly drawn over the proximate hub **15***c* is a sealing sheath **16**, the outer end of which has been flatted and fused about the tip of the cannula, thereby effecting desired sterile, hermetic sealing of the needle tip and also of the entire system in unitary association therewith.

Integrally connected also to the central blood bag **10** is the outlet or infusing assembly indicated generally at B and shown more particularly to comprise outlet tube **17**, which is passed through and similarly fused to the bag wall at the end seal **12**. This integral outlet tube **17** is provided with a novel closure or seal located within the bag **10** but manipulated, disengaged, or removed from without the bag, and without requiring the opening of the

same or the destroying or disturbing of the hermetic seal obtaining throughout the system. Such novel outlet seal is shown as a fragment of the bag material formed as a tear tab **17***a* supported across and detachably fused to the tube end projecting within the bag.

Further in accordance with the invention, means are provided intermediate the infusing or recipient assembly B for filtering and detecting or observing the flow of the blood. Referring still to FIG. 1, such means are seen as the drip chamber and filter assembly indicated generally at **18**. My novel drip chamber and filter comprises a sleeve or larger tube flatted and fused at one end margin **19** and at an intermediate lateral band **20**. The end closure **19** is sealed about the outlet tube **17**, the free end of which is seen to project within the sleeve **18**. A nylon mesh screen **21** of appropriate gauge is received in the chamber defined between the end and the intermediate seals **19, 20**. The lower or outermost portion of this assembly or sleeve **18** is formed as a relatively rigid chamber by collapsing and fusing the lower sleeve end or margin **22** in a plane at right angles to that of the upper and intermediate lateral margins or bands **19, 20**. Fluid passage between the filter and drip chambers is afforded by a tube **23** fused in and extending through the intermediate seal **20**.

Outward of the described filter drip chamber in the recipient assembly is an infusing tube **24** having one end integrally received within the drip chamber and seized at the other to a suitable infusing needle **25**, which latter has drawn over it a sealing sheath **26** similarly as with the collecting tube **13**. The flow of the blood through the infusing or recipient tube **24** may be regulated by any suitable means, such as the control clamp or clip **27**.

The collapsible blood storing and preserving means central to the described blood handling form may be provided with additional or alternative means for the outlet or discharge of the blood or blood fraction. Such means may comprise for example a relatively short tube **28**, entering and fused to the bag in the same manner as and adjacent the outlet tube **17**, and closed off in the region of said bag by a puncturable diaphragm **28***a*. The exposed, outwardly projecting portion of the tube **28** is encased with a removable sealing sheath or pouch **29** such as originally shown and described in the co-pending application of David Bellamy, S.N. 412,549, filed February 25, 1954, now Patent No. 2,894,510 and comprising duplicate strips of the bag material received and fused between the opposed walls defining the lower bag margin **12** and fused together also about said projecting tube portion so as to define a sterile sealed region or pocket **29***a*.

It may here be noted that for the diaphragm closures **17***a*, **28***a* there may be substituted a manually displaceable, hemo-repellent bead such as already described for the collecting assembly. In FIG. 2 the blood storing bag **30** has an outlet tube **32**, into which is seized an oversized bead **33**, positioned outwardly of the bag margin **31**, and additionally retained by an elastic ring or clamping band **34** proportioned normally to compress the tube **32** and to contract the same about the bead **33**. The band **34** incorporates a manipulating tab **34***a* whereby the same is conveniently withdrawn from the indicated clamping position and the bead freed for manual ejection from the tube **32** into the blood pack **30**.

The integral blood handling or donor recipient set of FIG. 1 is prepared for use by evacuating it and charging the bag **10** and donor tube **13** with the indicated quantity of anti-coagulant solution, commonly acid citrate dextrose solution A, U.S.P. The apparatus is fully assembled or sealed and then sterilized according to medically accepted practice. Finally, it is folded or rolled into a compact lightweight and relatively indestructible package or kit.

In use and for collection of the blood, the bag is hung inverted, so that the blood will flow into the ACD solution. A loose knot is formed in the donor tube **13**, the sheath **16** is removed, and the needle applied for phlebotomy at a site prepared in known manner. Influx of air into the system and also efflux of the ACD solution is prevented by the bead **14**, which is manually worked or milked out of the tube and into the bag **10** to permit the blood flow. The blood bag having been filled by gravity, the knot in the collecting tube **13** is pulled tight before the needle **15** is removed, thereby sealing the bag and contents against contamination. For storage of the blood, the donor tube is conveniently dielectrically sealed off near the bag. The bag is then suspended or hung up in any convenient manner for storage, refrigerated at 4° C. ± 1°. It will be appreciated that by the method and with the apparatus just described, safe storage of whole blood is had for the maximum period, or for up to 25 days.

It should here be noted also that one may alternatively employ for the sterile anti-coagulant collection of the blood a blood pack equipped with an ion exchange column, such as shown and described in the co-pending application of Carl W. Walter, S.N. 174,891, filed July 20, 1950, now Patent No. 2,702,034, dated February 15, 1955.

In infusing practice, the red cells and plasma are first thoroughly mixed. The outlet closure **17***a* is then removed by appropriate manipulation of the bag **10** and the filter chamber squeezed and then released to establish a halfway blood level therein. The infusion needle sheath **26** may then be removed and the blood flowed to thoroughly expel the air from the recipient tube **24**. When the venipuncture is made the blood is flowed by gravity, being filtered as at the screen **21**, observed as at the drip chamber **20, 23**, and regulated as by the control clip **27**.

When the blood is outdated, or for extraction of plasma from the bag **10**, the outlet tube **28** may be employed. In this the opposing strips of the tab **29** are pulled apart to expose the end of the tube and a coupler needle is inserted and seized in the same with its tip piercing the diaphragm **28***a*, all as shown and described in the abovementioned co-pending application of Bellamy. It will be understood that where desired such tab-sealed tube **28** may also be employed as an inlet. The same or additional blood or other fluid solutions might be desired to be introduced into the pack during or after emptying or administering the fluid originally filled. The present system permits, of course, the administering of more than one solution without removing the recipient needle from the patient. The filling of the pack through the tube **28**, identical with that just described requires but the pulling apart of the opposing strips of the tab **29** to expose the ends of hte tube and the insertion of a coupler needle so as to seize in the tube and pierce the diaphragm **28***a*.

Another form of the compact, lightweight, sterile sealed medical fluids handling equipment of the invention, and more particularly a unitary parenteral solution pack and intravenous set is illustrated in FIGS. 3, 4 and 5. In the embodiment therein shown the pack comprises a sleeve designated generally at **40** and formed as a collapsible bag by sealing its ends **41, 42** similarly as with the blood pack **10** already described. The opposing walls of the bag **40** are seen to be fused together at one end **41** about an inlet tube **43** and also about an outlet tube **44** forming part of a unitary infusing assembly. Said assembly further comprises a drip chamber **45** integrally coupled to the tube **44** and defined like the drip chamber of FIG. 1 by a relatively short length of larger tubing flatted and sealed at its ends in longitudinal planes which are predeterminedly normal, one to the other. Integrally coupled to the outer end of said chamber is an infusing tube **46**, mounting a needle **47**, the latter encased in a sealing sheath **48**.

The parenteral solution pack and intravenous set of FIG. 3, is prepared for use in the same manner as the blood pack of FIG. 1, namely, by first evacuating and filling it with the desired solution and then sterilizing it in ac-

cordance with known practice. The bag **40** is filled through the inlet **43**, which is shown as sealed off as at **43***a* after filling. With respect to the embodiments of FIGS. 1 and 3 it will be understood that the elements and appendages of the one may be employed interchangeably with those of the other, without departing from the invention. For example, and as will be obvious, the FIG. 3 form may be provided with fluid inlet-outlet means additional to the inlet and outlet **43**, **44** there shown, as for example the upper end inlet such as illustrated at A, FIG. 1.

My present invention further comprises means for storing and preserving my novel parenteral pack without solution vapor loss and without kinking of the infusing tube prior to use. As illustrated in FIGS. 4 and 5, such means comprise a can or container **50** of desired proportions and in which the bag **40** is deposited, upper end **42** first. In accordance with the invention the container **50** provides in combination with the bag **40** a humid atmosphere or vapor barrier preventing the undesired drying out of the pack in storage. A protective spacer or cup **51** is next inserted in the can. The cup **51** is seen to have a bottom opening **51***a* such that it may be slipped down over the infusing assembly to engage, and to be of a height to confine the bag **40** in the position shown in FIG. 5. An incomplete or parti-cylindrical ring or form **52** having a radius slightly smaller than the cup **51** is next inserted in the can and positioned with its vertical wall opening opposite the drip chamber **45**, FIG. 4. Kinking of the infusing tube **46** is prevented in accordance with the invention by confining it to the periphery of the can **50** and more particularly by coiling it to lay flat about and between the concentric form **52** and cup **51**, FIGS. 4 and 5. The storage assembly of the parenteral pack is completed by seating the needle **47** in the complementary recesses **52***a* in the upper rim of the holder **52** and then applying the can cover **50***a*, FIG. 5. The parenteral pack is thus ordered for shipping and storage is desired vapor sealed and confined conditions and in uniquely compact lightweight assembly.

In use my novel parenteral pack is manipulated similarly as the blood pack according to a simple, sure and thorough technique. The apparatus is first arranged with the pack **40** supported for gravity or pressure flow to the patient or recipient. The sheath **48** is then removed and venipuncture effected at a prepared site. Flow of the parenteral fluid is initiated by removing the infusing column closure, which may comprise for example a tear tab **44***a* sealing the bag outlet **44**. The flow of the parenteral solution will be observed at the chamber **45**, and may additionally be controlled in known manner.

From the foregoing it will be appreciated that my present invention provides a simple sure method and compact lightweight and durable apparatus for the handling and administering of medical fluids. Further, the collection, storage and infusion of blood has been shown to be conducted under the invention in a closed, hemo-repellent, sterile sealed system, wherein air-blood interface, platelet aggregation, and contamination of the blood is eliminated or retarded throughout its passage from donor to storage reservoir to recipient. The invention apparatus will be understood additionally to comprise apparatus for the storage and transport of the medical fluid handling equipment in desired sterile-preserving and substantially indestructible condition.

It will be understood that my invention either as to means or method is not limited to the exemplary embodiments or steps here illustrated or described, and I set forth its scope in the following claims:

I claim:

1. Apparatus for handling and administering medical fluids, comprising a collapsible bag, a fluid outlet on the bag, a fluid administering set permanently sealingly connected at said outlet and incorporating therein a drip chamber, means removably sealing the administration set at the end remote from the bag, and a closure element positioned within the apparatus at said outlet and maintaining said bag closed when said sealing means is removed to open said administration set, said closure element manipulable from without and through the walls of the apparatus to remove it from its outlet closing position and thereby to open said bag to said administration set.

2. The apparatus of claim 1 wherein said closure element is an oversized bead lodged in the outlet and which is removed by manually working it out into the bag.

3. Apparatus for the collection, storage and infusion of blood comprising storing means including a collapsible container; collecting means including a tube adapted at one end for connection to a blood supply and at the other end sealingly affixed and admitting into the container; infusing means including a tube sealingly affixed to and communicating with the container and means integrally associated therewith for drip-ordering, observing and regulating the flow of the blood; means removably sealing the outer ends of said collecting and infusing means and whereby said storing container and collecting and infusing means are integrally connected in a closed, sterile sealed system presenting a continuous donor-to-recipient passage for the blood; and closure means positioned within said system and for sealing said collecting and infusing tubes in the region of said container, said closure means manipulable from without and through the walls of said system for removal from the sealing position and to open said collecting and infusing tubes to said container.

4. Apparatus for the collection, storage and infusion of blood comprising storing means including a collapsible container; collecting means including a tube adapted at one end for connection to a blood supply and at the other end sealingly affixed and admitting into the container; infusing means including a tube sealingly affixed to and communicating with the container and means integrally associated therewith for drip-ordering, observing and regulating the flow of the blood; means removably sealing the outer ends of said collecting and infusing means and whereby said storing container and collecting and infusing tubes are integrally connected in a closed, sterile sealed system presenting a continuous donor-to-recipient passage for the blood; and closure means positioned within said system and for sealing said collecting and infusing tubes in the region of said container, said closure means manipulable from without and through the walls of said system for removal from the sealing position and to open said collecting and infusing tubes to said container, and at least one said closure means comprising an over-sized hemorepellent bead lodged in the associated tube.

5. Apparatus for the collection, storage and infusing of blood comprising storing means including a collapsible container; collecting means including a tube adapted at one end for connection to a blood supply and at the other end sealingly affixed and admitting into the container; infusing means including a tube sealingly affixed to and communicating with the container and means integrally associated therewith for drip-ordering, observing and regulating the flow of the blood; means removably sealing the outer ends of said collecting and infusing means and whereby said storing container and collecting and infusing tubes are integrally connected in a closed, sterile sealed system presenting a continuous donor-to-recipient passage for the blood; and closure means positioned within said system and for sealing said collecting and infusing tubes in the region of said container, said closure means manipulable from without and through the walls of said system for removal from the sealing position and to open said collecting and infusing tubes to said container, and at least one said closure means comprising a hemorepellent bead lodged in the associated tube, a clamping ring expanded over said bead and tube, and a manipulating tab on said ring.

6. Apparatus for the collection, storage and infusion

of blood comprising a collapsible bag evacuated and partially filled with an anticoagulant solution, an inlet and a plurality of outet tubes having integral connection to and defining passages opening into said bag, means removably sealing the outer ends of said inlet and outlet tubes, and means positioned within the apparatus and removably closing said inlet and outlet tube passages in the region of said bag, said closing means being engageable to open said passages without disturbing the integral connection of said tubes to said bag.

7. Apparatus for the collection, storage and infusion of blood comprising a collapsible bag evacuated and partially filled with an anticoagulant solution, an inlet and a plurality of outlet tubes having integral connection to and defining passages opening into said bag, means removably sealing the outer ends of said inlet and outlet tubes, and means positioned within the apparatus and removably closing said inlet and outlet tube passages in the region of said bag, said closing means being engageable to open said passages without disturbing the integral connection of said tubes to said bag, the means closing the inlet tube being an oversized hemorepellent bead lodged in the tube and which may be manually worked out of the tube and into the bag, and the means closing one said outlet tube being a puncturable diaphragm.

8. Apparatus for the collection, storage and infusion of blood comprising a collapsible bag evacuated and partially filled with an anticoagulant solution, an inlet and a plurality of outlet tubes having integral connection to and defining passages opening into said bag, means removably sealing the outer ends of said inlet and outlet tubes, and means positioned within the apparatus and removably closing said inlet and outlet tube passages in the region of said bag, said closing means being engageable to open said passages without disturbing the integral connection of said tubes to said bag, the means closing the inlet tube being an oversized hemorepellent bead lodged in the tube and which may be manually worked out of the tube and into the bag, and the means closing one said outlet tube being a tear tab detachably sealed across its end and manipulable for removal from without the apparatus.

9. Apparatus for collecting and storing blood comprising a collapsible storage bag, a flexible collecting tube permanently sealingly joined and communicating to said bag, a needle at the free end of the collecting tube, a sealing sheath removably installed on said needle, fluid delivery means permanently sealingly joined and communicating to said bag, means positioned within the apparatus and removably closing said collecting tube and said delivery means in the region of said bag, and means closing said delivery means outside said bag, said outside closing means having projecting portions adapted to be grasped between the fingers and pulled apart to open said delivery means.

References Cited in the file of this patent

UNITED STATES PATENTS

714,544	Wertz	Nov. 25, 1902
920,225	Van Denburgh et al.	May 4, 1909
2,452,644	Fields	Nov. 2, 1948
2,625,264	Edwards	Jan. 13, 1953
2,663,298	Rose	Dec. 22, 1953
2,702,034	Walter	Feb. 15, 1955
2,848,995	Ryan	Aug. 26, 1958
2,894,510	Bellamy	July 14, 1959
2,949,712	Bieberdorf et al.	Aug. 23, 1960

FOREIGN PATENTS

383,204	Germany	Oct. 11, 1923

OTHER REFERENCES

Baxter: "Intravenous Solutions, Transfusion Equipment, Plasma and Serum, and Preparation Equipment," Apr. 27, 1942, 7 pages, page 3 relied upon. (Copy Div. 55, 128–214.)

Walter et al.: "A Closed Gravity Technique for the Preservation of Whole Blood in Acid Solution Utilizing Plastic Equipment," Surgery, Gynecology, and Obstetrics, volume 94, No. 6, June 1952, pages 687–692, pages 687–692 relied upon. (Copy in Scientific Library.)