

Dec. 17, 1968

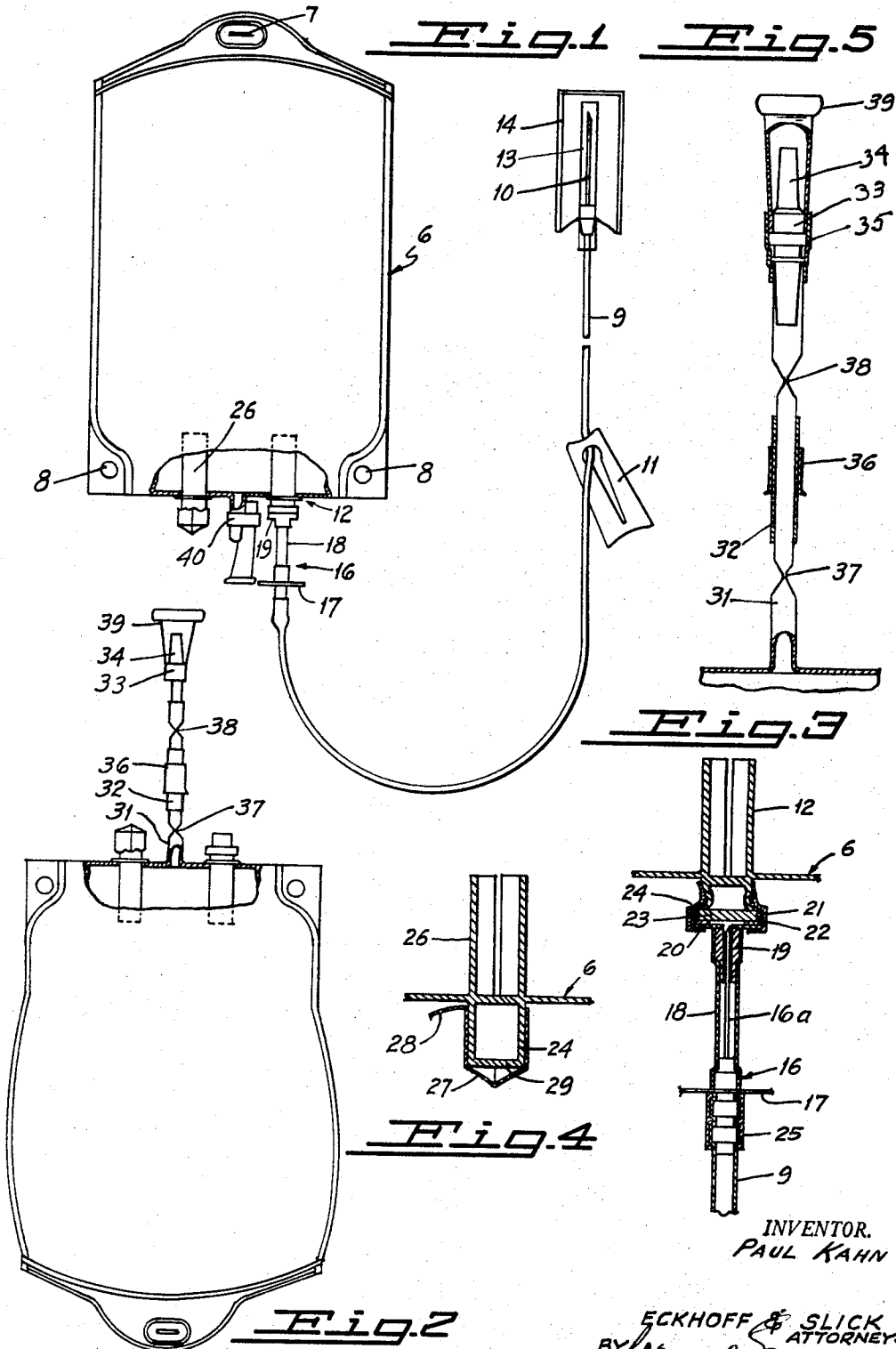
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BLOOD HANDLING EQUIPMENT

Filed Aug. 17, 1959

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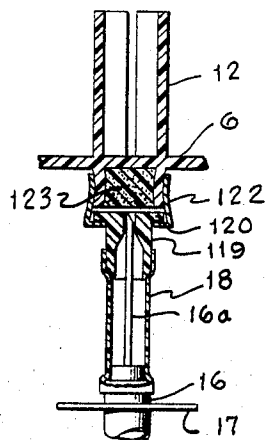


Fig. 6

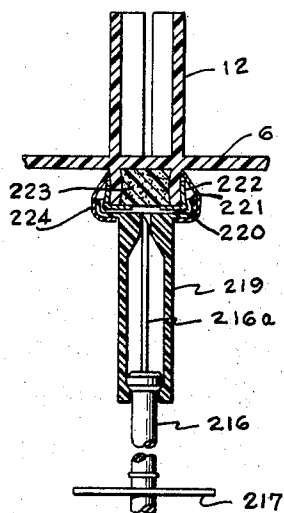


Fig. 7

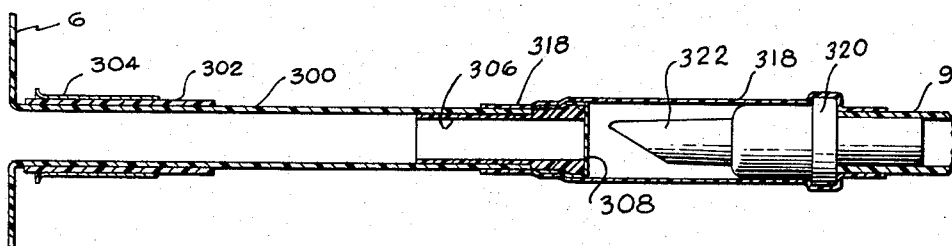


Fig. 8

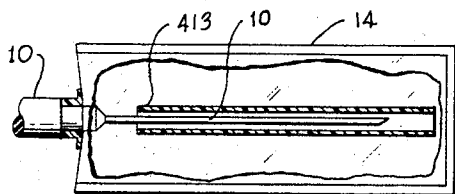


Fig. 9

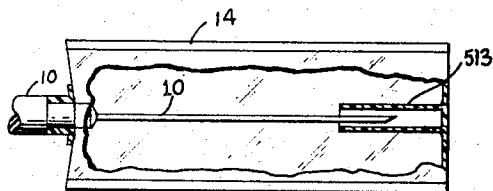


Fig. 10

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3,416,528

BLOOD HANDLING EQUIPMENT

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14 Claims. (Cl. 128—214.2)

This invention relates to a device for the collection, storage and handling of blood and its components.

The device of the present invention includes a container, together with means for collecting blood from a donor, the container usually containing an anti-coagulant so that the blood may be held in storage in the container for some period of time.

The blood donor collection means is attached to the container in such fashion that the assembly is ready for use at all times. This is highly advantageous as the sterility of the entire assembly is thus assured. Further, after use, the blood donor collection means can be disconnected easily from the assembly without compromising the sterility of the container due to the self-sealing feature of the stopper, and used for the collection of pilot blood samples by standard techniques.

Another feature of the blood collection device of the present invention is that the donor needle is covered with a dual cover, the exterior cover being a flexible, essentially air-impermeable envelope which is sealed about the needle hub, and the interior cover being a relatively heavier protective element closely circumscribing the needle itself. The second element serves to prevent the needle from accidentally piercing the exterior sterility envelope. With such protection for the donor needle, the anti-coagulant from the bag can be passed through the tube connected to the needle and to the needle without exposing any portion of the apparatus, thus preserving absolute sterility of the apparatus until immediately prior to insertion of the needle into the vein of the donor.

A further feature of advantage of the device of the present invention is the means enabling portions of fluid to be removed from the bag. This is of advantage for several reasons, one being that it enables the plasma to be drawn off and separated from the red cells without contamination of the contents of the original bag.

The invention includes other objects and features of advantage, some of which, together with the foregoing, will appear hereinafter wherein the preferred form of the device embodying the invention is disclosed.

In the drawings accompanying and forming a part hereof:

FIGURE 1 is a side view, partially in section, showing the present preferred form of the blood collection device of this invention.

FIGURE 2 is a side elevation, partially in section, showing the filled bag in position for separation of the plasma from the red cells.

FIGURE 3 is an enlarged sectional side elevation of that portion of the device which constitutes means for joining the bag and collection equipment.

FIGURE 4 is an enlarged sectional side elevation showing outlet means for connecting the bag to a recipient set.

FIGURE 5 is an enlarged sectional side elevation showing the means provided for withdrawing portions of fluid from the bag.

FIGURE 6 is an enlarged sectional side elevation showing an alternative structure which may be used for joining the bag and collection equipment, the structure being similar to that shown in FIGURE 3.

FIGURE 7 shows a further variation of the structure of FIGURE 3.

FIGURE 8 is an enlarged sectional side elevation of

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an alternative structure which may serve as means for joining the bag and collection equipment.

FIGURES 9 and 10 show variations in the donor needle cover and protective means.

In the drawings (particularly FIGURES 1-5) wherein like characters refer to like parts throughout, there has been indicated a flexible transparent bag 6, made of a suitable plastic material and heat-sealed upon itself about the periphery thereof to provide a closed container. Hanger holes 7 and 8 are provided at opposite ends of the bag to enable it to be supported suitably. A donor set, including tube 9, hollow needle 10 and clamp 11, are attached to the cylindrical inlet on the container, generally indicated at 12, having a slotted upper portion extending into the bag and a lower portion depending therebelow. The cylindrical inlet is sealed in place and thus forms an integral part of the bag. The donor needle 10 is provided with a protective tube 13, preferably secured to the needle hub, and an outer flexible cover 14 in the form of an envelope fabricated from an air impermeable plastic material such as plasticized polyvinyl film, which also fits snugly about the needle hub. The tube 13, conveniently a thermoplastic material of limited flexibility, has relatively thick walls and is conveniently of a cylindrical shape. Another important requirement is that it not be capable of absorbing the citrate solution which is customarily supplied in such bags as an anti-coagulant. The protective tube 13 serves to prevent the needle 10 from accidentally being forced through the sterility cover or envelope 14. The envelope 14 is of sufficient size that when the bag 6 is squeezed so as to force the anti-coagulant customarily supplied, such as a citrate solution, through tube 9, the envelope 14 is capable of receiving any air which may be in tube 9 so as to allow the entire tube to become filled with the citrate up to and including the donor needle 10.

At its other end, flexible tube 9 includes a needle assembly 16 having a large flange 17 thereon. The hollow needle itself 16a, is enclosed by flexible tubular sheath 18, fitting securely about the hub of the needle and secured at the other end to adapter 19 of disc 20. The adapter and disc each have holes therethrough of sufficient size to admit needle 16a. Disc 20 supports a perpendicular flange 21 which telescopes with the exterior of the crimped metal cap 22 for gum rubber sealing element 23. A cylindrical rubber sheath 24 may be used to help hold disc 20 and stopper 23 in a unitary relationship and to maintain internal sterility. However, the flange 21 frictionally engages the cap 22 and largely performs this function. Thus, needle 16a is held in position opposed and perpendicular to the face of pierceable rubber stopper 23 for ready entry therein. At the lower end of the needle, a small tube 25 of rubber serves to secure the polyvinyl tubing 9 tightly over the adapter of the needle assembly 16.

To provide for withdrawal of blood from the bag for administration to a patient, an outlet is provided including tube 26 having a slotted upper portion extending into the bag and a lower portion extending through the bottom of the bag. A removable thermoplastic sterility cover 27 having a tongue 28 thereon is provided. A seal 29 which may be pierced by the needle of an administration set, not shown, forms an integral part of tube 26.

Also mounted upon the bag and integral therewith is outlet tube 31 covered by a length of rubber tubing 32. The outlet tube is telescoped over and snugly engaged with one end of a lower adapter 34. A collapsible metal ring 36 is provided about the rubber tube so that the latter may be sealed off on completion of use thereof.

Thermoplastic tube 31 is occluded at 37 and 38. This may be accomplished by means of removable obstructions

such as glass beads or outer clamps, but is preferably accomplished by being heat-sealed upon itself entirely across its diameter at these two points. Thus, prior to the time of withdrawal of fluids from the bag, the exit means is well sealed. Sealed about the raised annular neck 33 of the adapter 34 is a sterility cover 39 which may be formed of a single tube of thermoplastic material which has been sealed upon itself along the topmost edge thereof to form an envelope, as seen especially in FIGURE 5.

Conveniently, straps, not shown, are secured to either longitudinal edge of the bag 6. These straps may be coated with a pressure sensitive adhesive so that pilot tubes of conventional shape may be thus secured to the bag to form a conveniently used, unitary assembly for collecting blood in greater or lesser quantities. As in customary practice, pilot tubes are provided having a suitable sealing membrane which may be pierced by needle 16a so that the tubes may serve as receptacles for blood which remains in the tube 9.

A simplified arrangement providing means for joining the bag and collection equipment is shown in FIGURE 6. A gum rubber stopper 123 fills the cylindrical receptacle of inlet element 12. Held adjacent thereto is adapted 119, fabricated from a relatively rigid plastic such as polyethylene or nylon having an integral disc 120 which fits tightly against the gum rubber stopper. The entire assembly is held together by means of metal cap 122. As in the structure of FIGURE 3, tubular sheath 18 telescopes over the polyethylene fitting 119 and over the needle hub 16.

Still another structural variation is seen in FIGURE 7. There is provided a gum rubber stopper 223 which corresponds to that described in FIGURE 6. The adapter 219 is substantially longer than the corresponding adapter previously described for reasons which will be set forth below. The adapter has a suitable disc 220 integral therewith which has a flange 221 which registers with crimped metal cap 222. The cap, in turn, encloses and grips the depending portion of cylindrical inlet element 12. The rubber sheath 224 aids in holding the assembly together. At the lowermost end of adapter 219 there is seen hub 216 for needle 216a. The hub has a relatively long barrel which is so proportioned relative to adapter 219 that the one can telescope into the other when pressure is applied to flange 217 of the needle. A suitable rubber sheath may be placed over the lowermost end of adapter 219 and the uppermost portion of hub 216 so as to provide a better seal, if desired.

Attention is directed to FIGURE 8, wherein still a further alternate structure for joining the bag and collection equipment is shown. This structure is capable of utilizing a piercing element of substantially greater bore than previously described needle 16a. Depending downwardly from bag 6 and integral therewith is a length of plastic tubing 300 having a rubber overlay 302 thereabout, in turn enclosed by metal sleeve 304 which is thin enough to be capable of being collapsed upon itself whereby to seal the tube 300. Telescoped within the free end of the tube is the female receptacle 306 which may be formed of polyethylene or similar semi-rigid, inert material. The female receptacle 306 has a diaphragm 308 covering the mouth thereof. Surrounding the entire structure is one end of flexible tubular sheath 318. The sheath is secured at the other end thereof about the hub 320 of the large-bore piercing element 322. This element, due to the action of the rubber sheath 318, is normally held in position such that its tip is opposed to the face of the diaphragm 308. Finally, tube 9 provides communication with the donor needle 10.

FIGURES 9 and 10 show alternative protected donor needle units. In FIGURE 9, the relatively rigid, non-absorbent tube 413 rides loosely over the needle 10. The tube is of sufficient length that even when forced as far as possible in either direction, the tip of the needle 10 will remain covered and protected. The structure of FIGURE

10 is a further variation having a short, semi-rigid protective element 513 secured to the protective envelope 14 for receipt of the tip of the needle 10.

Initially, the structure appears as it does in FIGURE 1, wherein a length of tape 40 is used to bind together the adjacent folded sections of the outlet assembly, thus to minimize space consumption and eliminate the possibility of damage to the relatively delicate assembly when it is not in use.

To place the structure in use, the needle 16a is forced through the gum rubber stopper in the inlet 12, the rubber sleeve 18 collapsing to permit this to occur and the rubber stopper 23 then holding the needle in place. The bag 6 is then squeezed gently to fill the donor set with the anti-coagulant. As indicated, anti-coagulant fills the entire tube 9 and the hollow donor needle 10. Small amounts of the anti-coagulant may issue from the end of the donor needle 10; hence the necessity for a non-absorbent protective element 13. The provision of a unitary structure of the type described here makes it possible for one or more of the units to be readied for receipt of blood well in advance of the time of expected use. This makes the structure particularly convenient for use in mobile units or prior to collecting blood on a mass scale. When the tube and needle have been filled with anti-coagulant, clamp 11 is moved into place. Envelope 14 is not removed until immediately prior to the venipuncture. The bag is then suspended in proper relation to the donor, the needle protectors are removed and the needle inserted in the vein of the donor. The clamp is then opened and the collection started. At the conclusion of the collection, the needle 16a is withdrawn and the entire needle assembly may be separated from the gum rubber sealing member 23 and the bag 6 by simply rolling down rubber sleeve 24 so as to allow the flanged disc to be pulled free. On withdrawal of the needle, the entry site of the needle 16a is automatically sealed by the action of the resilient stopper. A cap, not shown, may also be placed over the top of the gum rubber sealing element to provide tamperproofing.

The structural variations shown in FIGURES 6-8 permit substantially the same manipulative steps. In the preferred structural modification of FIGURE 8 wherein the gum (or other relatively thick) rubber stopper is eliminated entirely, a thin sealing membrane is necessitated by the fact that the male element 322 is of sufficiently large size that the gum rubber stopper would effectively prevent entry thereof. The use of the pierceable diaphragm necessitates the use of a metal sleeve 304 which may be crushed with pliers whereby to perform the function of the self-sealing rubber stopper shown in FIGURES 3, 6 and 7. However, it is seen that the structure of FIGURE 8 is functionally equivalent to the structure of FIGURES 3, 6 and 7 except that separate resealing means are required where the larger bore piercing element is used.

If pilot tubes are available, the blood remaining in flexible tube 9 may be collected for testing purposes. Pilot blood samples, which are required for blood testing and typing, can be collected by standard techniques in standard tubes which may be affixed to the bag in a tamperproof manner. The attachment consists of a self-adhesive paper strip partly overlaid on a plastic strip, heat-sealed to the bag. The self-adhesive paper is rolled around the tube and onto itself in such a manner that the tube cannot be removed without tearing the paper strip. The tube can be readily removed for laboratory use by cutting the plastic connecting strip.

If it is desired to separate the red blood cells, this may be done by gravity or centrifuging with the fixture end of the bag uppermost (FIGURE 2). The bag is then placed or hung in a plasma expressor in the same orientation and external pressure is applied to the bag. The tube of a suitable transfer set is then secured to the adapter 34. Next, the pinched tubing is opened at 37 and then at 38 by rolling firmly between the thumb and fore-

finger, or by use of forceps. The pressure which has been applied to the bag causes the plasma to flow from the bag. The rate of flow may then be adjusted by kinking the tubing or by application of a hemostat to the tubing. After separation or transfer has been completed, flow may be stopped entirely by pinching the metal sleeve 36 with pliers. Similarly, if it is desired to separate red cells from plasma in such a manner as to retain the plasma in the original container, the same sequence of operations is performed as described above, except that the bag is hung or centrifuged with the fixture end of the bag lowermost and is placed or hung in the plasma express or in the same orientation. The contents of the tubing used in conjunction with the apparatus may be used as a plasma sample.

In the preferred embodiment of this invention, a structure having separate ingress and egress means on the bag is employed. However, the invention is not to be limited to a structure embodying both of these features, since it is possible to use the single means shown in FIGURES 3 and 6-8 for both filling and emptying the bag. A structure of this type displays many of the advantages set forth above in that the contents of the bag are maintained in a sterile condition until immediately prior to use and only at that time is puncture made in the sealing element, whether a diaphragm or a gum rubber stopper. If the donor needle protective envelope 14 is utilized, sterility of the contents of the unit is assured and the assembly can be prepared in advance for subsequent use, the anti-coagulant being forced out of the bag into the tubing and donor needle. The blood collected is sealed in the bag and thereafter the stopper element or the bag itself is punctured to allow for withdrawal of the blood or one of its components.

One particularly advantageous feature of the structure is that by the provision of a unitary collection bag, tubing and sterile donor needle, it is possible to insure sterility for the contents of the bag at all times. At no time may a contaminated needle be inserted into the bag since the needle which eventually is forced through the pierceable sealing member is maintained out of contact with air and in an aseptic condition until used.

The use of the integral withdrawal tube also insures that the remaining contents of the bag, even after withdrawal of selected components of the blood, remains completely sterile as no foreign element need be inserted into the bag at any time. Contamination of the bag interior is rendered even more unlikely by the dual seals 37 and 38 which are broken in an order such that the possibility of contamination is minimized.

Obviously, many modifications and variations of this invention may be made without departing from the spirit and scope thereof, and therefore only such limitations should be imposed as are indicated in the appended claims.

I claim:

1. In an apparatus for obtaining separate main donation and pilot sample blood volumes in sterile manner, a flexible plastic collecting tube, a flexible plastic blood container connected to an end of said collecting tube, a donor needle mounted at the other end of the tube, and a stopper piercing cannula received in said tube and pointed at one end for applying to a stoppered pilot tube, said tube being conditioned for movement to expose the pointed end of the stopper piercing cannula, said collecting tube providing a substantially uninterrupted path for the flow of blood from the donor needle to the flexible blood container.

2. In an apparatus for obtaining separate main donation and pilot sample blood volumes in sterile manner, a flexible plastic blood container, blood collection means for transferring blood from a donor to said container, said means including a flexible plastic collecting tube having a donor needle mounted at one end thereof, said tube being connected to said container to deliver blood

from a donor to said container, and a stopper piercing cannula received in said tube and providing a portion of the flow path to said container, said collecting tube being detachably mounted on said container to permit blood in said tube to be discharged through said cannula into a pilot tube.

3. In a device for the collection and storage of blood, a flexible storage container for blood having an inlet, said inlet having a tube attached thereto and extending outwardly from said container, a pierceable sealing member mounted in the said inlet tube, a first needle having a sharpened tip at one end thereof, a length of flexible tubing, the other end of said first needle being secured to said tubing, said tubing further having a donor needle secured to the second end thereof, means secured to said other end of said first needle and to said inlet tube for yieldably maintaining the sharpened tip of said first needle in an orientation wherein said tip is opposed to said pierceable member, said pierceable member being resealable after having been pierced by said first needle.

4. In an apparatus for the sterile collection of separate blood donation and sample volumes, an integral collecting tube conditioned for separating into two lengths, a cannula received and entirely enclosed within said tube and arranged with its one end secured in one length and with its pointed end slidable in the other of said lengths, a donor needle mounted at the free end of said one tube length, a flexible blood container integrally joined to said other tube length, and means initially closing said other tubing length at an intermediate point normally spaced from that cannula end, said other tube length in the portion slidable on said cannula being axially collapsible whereby said cannula may be advanced relative to and to engage and open said means initially closing that other tube length while remaining sealed therewithin.

5. The apparatus of claim 4 wherein said tube closing means is self-sealing, and wherein the separating of said tube occasions the retraction of said cannula past the tube closing means.

6. In a blood handling apparatus, a plastic blood container, a collecting tube integrally joined and inletting to the container, a needle mounted at the free end of said collecting tube and for application to a donor, an integral-separable coupling in said tube intermediate said container and needle, a pointed cannula in said coupling, and means closing said tube between said container and cannula, said cannula being manipulable to remove said means without disturbing said integral-separable coupling.

7. In a blood handling apparatus, a plastic blood storing container, a collecting tube integrally joined and inletting to the container, a needle mounted at the free end of said collecting tube and for application to a donor, an integral-separable coupling in said tube intermediate said container and needle, a pointed cannula in said coupling, and means closing said tube between said container and cannula, said coupling manipulable from without the apparatus to open said tubing to flow between the container and cannula.

8. A container adapted for use in the handling of blood, said container having an inlet, said inlet having a tube integral therewith extending downwardly from the said container, a pierceable sealing element in the said inlet tube, a first needle having a tip and a hub, said hub being secured to flexible tubing at a first end of said tubing, said tubing having secured at a second end thereof a donor needle, said first needle having means secured to the hub thereof and to the said inlet tube for yieldably maintaining the tip of the said first needle in an orientation wherein said tip is opposed to the said pierceable member, and means in the said inlet tube for resealing the said inlet tube after the said pierceable member is pierced by the said needle and the said needle returned to the said orientation wherein said tip is opposed to the said pierceable member.

9. The structure of claim 8 wherein the said pierceable

sealing member and the said re-sealing means comprise a single gum rubber stopper which is capable of resealing itself after having been pierced by said first needle, said gum rubber stopper being positioned in the said inlet tube.

10. A container adapted for use in the handling of blood, said container having an inlet and having secured thereto at the said inlet a length of flexible tubing having a donor needle at one end thereof and juncture-providing means for said tubing and said inlet at the second end thereof, said means comprising a second needle having a tip and a hub, said hub being secured to the said flexible tubing, said inlet comprising a pierceable container-sealing member, and means secured to the hub of said second needle at one end thereof and secured to said inlet adjacent said pierceable sealing member yieldably maintaining the tip of said second needle in an orientation wherein its tip is opposed to the said pierceable member, said means for yieldably maintaining the tip of said second needle in the said orientation comprising a resilient rubber sheath secured at one end thereof about the hub of the said needle and at the second end thereof to the said inlet of the said container, said pierceable sealing element comprising a rubber diaphragm, and means adjacent said rubber diaphragm for sealing the said tube after the said diaphragm is pierced and the said needle returned to the said orientation wherein its tip is opposed to the said pierceable member.

11. A flexible container adapted for use in the handling of blood, said container having a first means thereon for use in the collection of blood and a second means thereon for use in withdrawing at least a portion of the said blood after collection, the second means comprising a length of flexible plastic tubing integral with the bottom of the said flexible container, the said tubing having concentrically thereabout at a point intermediate the ends thereof a length of rubber tubing, the said rubber tubing having a collapsible metal sleeve concentric therewith and mounted thereabout, the said flexible tubing being of a thermoplastic material and being occluded across the entire diameter thereof at points along its length on either side of said rubber tubing, the said flexible thermoplastic tubing having sealed at the free end thereof an adapter for use with an additional length of flexible plastic tubing, the said adapter having sealed to the neck thereof and about the free end thereof an envelope of air-impermeable material.

12. The structure of claim 11 wherein the first means comprises a resilient sealing member mounted in an orifice at the base of the said flexible container and depending slightly therebelow, a first needle secured to one end of a length of flexible plastic tubing and having a donor needle on the opposite end thereof, the said first needle having a length of hollow flexible tubing secured about the hub thereof and extending the entire length of the said first needle, the said hollow flexible tubing having means in association therewith securing said tubing

to the said resilient sealing member and in sealing engagement therewith, whereby to maintain the said needle normally in a position adjacent and opposed to the said sealing member.

13. A flexible container adapted for use in the handling of blood, said container having a first means thereon for use in the collection of blood and a second means thereon for use in withdrawing at least a portion of the said blood after collection, the second means comprising a length of flexible plastic tubing integral with the bottom of said flexible container, the said tubing having concentrically thereabout at a point intermediate the ends thereof a collapsible metal sleeve, said flexible tubing being of a thermoplastic material and being occluded across the entire diameter thereof at points along its length on either side of the said metal sleeve, the said flexible tubing having sealed at the free end thereof an adapter for use with an additional length of flexible tubing.

14. A container adapted for use in the handling of blood, said container having means thereon for use in the collection of blood, said means comprising a length of flexible tubing secured to a donor needle at one end thereof and secured to said container at the second end thereof, said donor needle being provided with a flexible, air-impermeable sterility envelope, said envelope being secured about the hub of said needle and surrounding the entirety of said needle, said needle being immediately surrounded by a tube of sufficient rigidity and thickness to prevent said needle from piercing said tube in normal handling, said tube extending beyond the end of said needle and being entirely encased by the said sterility envelope.

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