ABSTRACT OF THE DISCLOSURE

A blood collecting set having one or more vessels each containing a quantity of anti-coagulant in association with a flexible needle-equipped tubing system which is adapted for the collection of blood from a donor into one or more empty blood collecting vessels following introduction of the anti-coagulant into the empty vessel, as well as for plasmapheresis procedures, all of which may be effected by a single entry of a needle into the blood collecting vessel.

This invention relates to an apparatus for and method of receiving blood from a donor for collection in a hermetically sealed container and more particularly to improvements in blood collecting sets adapted for single and double plasmapheresis through single insertion into the blood collecting vessel of a needle in communication with the phlebotomy needle inserted into the vein of the blood donor.

It is well known that the container in which blood from a donor is collected and which contains an indicated quantity of anti-coagulant should be entered steriley by a needle or otherwise a minimal number of times (preferably only once) during the process of collecting the blood, since repeated entry into the blood container increases the risk of contamination of the blood and poses a serious problem. In addition, an empty container is preferable for the collection of blood provided that the anti-coagulant can be added at the time of the blood collection without necessitating repeated entry of a needle into the container. This increases greatly the versatility in use of the container and makes possible when collecting the blood to use any suitable anti-coagulant as needed.

In order to condition an empty container for acceptable collection of blood therein it has been necessary heretofore to make at least two needle entries into the container, one for introducing therein the indicated amount of anti-coagulant and the second for introducing the blood received from the donor. To avoid this double entry into the blood collecting vessel, the customary recognized procedure has been to initially include in the container a sealed-in quantity of the anti-coagulant.

It is among the principal objects of the present invention to provide an apparatus and a method by which blood collection may be performed with use of a completely empty container requiring but a single entry of a needle for introducing into the container not only the blood received from the donor but also the anti-coagulant required to prevent clotting of the collected blood.

A further object of the invention is to provide a means for and method of using an empty satellite container such as is provided with currently available multiple bag closed systems for collection of whole blood, whenever such satellite container is not required to be utilized for the separation or collection of specific components of the blood, as, for example, plasma, platelets, etc.

Still other objects, advantages and aspects of the present invention will appear more fully hereinafter, it being understood that the invention consists in the combination, location and relative arrangement of parts as described in the following specification, as shown in the accompanying drawings and as finally pointed out in the appended claims.

In the accompanying drawings:

FIGURE 1 is an elevational view of a blood collecting set constructed in accordance with and embodying the principles of the present invention;

FIGURE 2 is an elevational view of the set in conjunction with a blood collecting vessel showing the set conditioned for introduction of the anti-coagulant or other liquid into the blood collecting vessel preliminary to introducing into said vessel the blood collected from a donor;

FIGURE 3 is an elevational view showing the set conditioned for receiving blood from the donor and entering it into the blood collecting vessel;

FIGURES 4, 5 and 6 are views respectively corresponding to FIGURES 1, 2 and 3 but showing a modified construction of the blood collecting set;

FIGURE 7 is an elevational view of a further modification of the blood collecting set constructed in accordance with and embodying the principles of the present invention and designed particularly for use in carrying out a double plasmapheresis procedure by which a second donation of blood may be given safely by a blood donor without removing from his vein the needle which was inserted for obtaining the first donation of blood, the two donations of blood being respectively collected in one empty container and in another already containing anti-coagulant; and

FIGURE 8 is an elevational view showing a modification of the blood collecting set for obtaining two donations of blood from a donor while the needle is still inserted into the vein of the donor, the two collections in this instance being respectively made in two empty containers.

Referring now to the drawings and more particularly to FIGURES 1 to 3, it will be noted that the blood collecting set of the present invention essentially comprises a sterile vessel 10 having connected thereto a sterile system of flexible tubing consisting of a branch 11 terminating in a phlebotomy needle 12 for insertion into the vein of a blood donor, a branch 13 terminating in a needle 14 adapted for insertion into a completely empty blood collecting vessel 15 and a branch 16 having one end commonly in communication with the branches 11 and 15 of the tubing system, as by a T-connection 17, and its opposite end connected to the vessel 10, as at 18. All of the tubing branches 11, 13 and 16 are preferably formed of a compressible material, such as rubber or plastic, and the branches 11 and 16 each have a suitable closure clamp 19, of any approved form, for opening or closing the branch with which it is associated to control the flow of fluid therethrough. The inner end of the branch 16 of tubing is interiorly fitted with a ball 20 which is normally frictionally retained in position within the end of the tube as shown to serve as a closure for sealing the vessel 10 against undesired flow therefrom of its liquid content, which ball is adapted to be dislodged from its sealing position by expressing it out of the open end of the tube branch 16 and into the vessel 10 when it is desired to effect flow of fluid 10 from the vessel into and through the tubing system.

The vessel 10 contains steriley sealed therewithin an anti-coagulant solution, such as acid citrate dextrose solution A, U.S.P., heparin or any suitable anti-coagulant solution, in an amount sufficient to prevent coagulation of the blood given at any one time by the donor for introduction into the blood collecting vessel 15. Normally about 500 cc. of blood is so collected from the donor at any one time.
In use of the set as shown in FIGURES 1 to 3, with all of its tube clamps 19 closed and the ball valve 20 in its sealing position as shown in FIGURE 1, the needle 14 is inserted into and through the blood-collecting vessel 15 preferably through a self-sealing port. Then, with the clamp 19 of the tube branch 16 released or opened and the ball 20 expressed from its seat to permit the free flow of the anti-coagulant from its container 10 into the blood-collecting vessel 15 by way of the interconnecting tubes 11 and 13. Having thus introduced the anti-coagulant into the empty blood-collecting vessel, the clamp 19 on the tube branch 16 is re-closed, the clamp 19 on the tube branch 11 is opened and the phlebotomy needle 12 is inserted into the vein of the blood donor, whereupon blood from the donor may flow into the blood-collecting vessel 15 through the branches 11 and 13 of the tubing system for admixture with the anti-coagulant previously introduced into the vessel 15.

It will be noted that by use of the blood collecting set as above described, only one entry of a needle into a completely empty blood collecting vessel is required for introducing thereto the blood collected from the donor and the requisite quantity of anti-coagulant for preventing coagulation of the collected blood, thereby reducing the risk of contamination of the blood as might result from multiple insertions of a needle or needles into the collecting vessel.

By the procedure described with use of the blood collecting set of the present invention for collecting blood in a hermetically sealed, completely empty vessel, the same sterile conditions which normally prevail when blood is collected in a blood bag already having sealed therein the requisite quantity of anti-coagulant are maintained and thus the present procedure diminishes the risks of contamination of the collected blood. In addition, the use of empty bags for collecting blood in a hermetically sealed container reduces the need for cross-contamination of the collection set when blood is collected from different donors.

FIGURE 4 to 6 illustrate a modified form of the blood collecting set wherein the tubing system connected to the anti-coagulant container 10 consists of two flexible tubes 28 and 29 which are adapted to be interconnected interiorly of the container 10a, which in this instance is in the form of a flexible walled bag made of suitable plastic material. Thus, the tube 21 fitted at its outer free end with a phlebotomy needle 12a extends into the interior of the container with its inner end being fitted with a tapered sleeve 23 having frictionally seated therein a ball 24 which normally maintains the inner end of the tube sealed against flow of fluid therethrough. The tube 21, is, of course, sealed at 25 to the bag 10a at the point of its entry into the bag. The container-enclosed portion of the tube is of a length such that by manipulation of the tube within the flexible bag 10a its tapered sleeve may be seated in the complementally shaped fitting 22 fitted upon the inner end of the second tube 22. This fitting 26, which is sealed into the end of the bag opposite that through which the tube 21 enters the bag, is also provided with a ball 27 which normally maintains the tube sealed against flow of the anti-coagulant out of its container interiorly and through the tube 21, which latter is provided at its outer free end with a needle 14a for insertion into the empty blood-collecting vessel 15. As in the previously described form of the blood-collecting set, the tube 21 fitted with the phlebotomy needle 12a is provided with a suitable closure clamp 19a.

The modified set as shown in FIGURES 4 to 6, with the clamp 19a closed and the inner ends of the tubes 21 and 22 disconnected as in FIGURES 4 and 5, the needle of the tube 22 is first inserted into the empty blood-collecting vessel 15 and then the valve ball 27 is unseated by expressing it into the anti-coagulant container 10a, whereupon the anti-coagulant contained in the flexible bag 10a is introduced into the empty blood-collecting vessel 15 and then the valve ball 27 having expressed the anti-coagulant from its container into the blood-collecting vessel, the ball valve 24 is freed of the tube 21 and the two inner ends of the tubes 21 and 22 are then coupled together so that they provide in effect a continuous length of tubing leading from the phlebotomy needle 12a to the set shown in the blood-collecting vessel. The phlebotomy needle 12a is then inserted into the vein of the blood donor and upon releasing the clamp 19a, the blood collected from the donor is passed through the coupled tubes 21 and 22 directly into the vessel 15 for admixture with the anti-coagulant previously introduced thereto. Thus, as in the first described form of the blood-collecting out of the present invention, both the anti-coagulant and the collected blood are introduced into an empty blood-collecting vessel or bag by way of a single needle inserted only once into said vessel or bag.

While in the form of the set as shown in FIGURES 4 to 6 the anti-coagulant container 10a is preferably in the form of a flexible walled bag to facilitate effective coupling together of the tubes 21 and 22 by manual manipulation thereof from outside of the bag, in the form of the set as shown in FIGURES 4 to 6 the anti-coagulant container 10a may be made of any suitable rigid or flexible material, such as glass, rubber, plastic or the like.

FIGURE 7 shows a blood-collecting set embodying the principles of the present invention adapted for double plasmapheresis use whereby two collections of blood are maintained from the same donor for introduction into two separate blood-collecting bags, one of which is completely empty and receives the anti-coagulant required for the first donation of blood as a part of the phlebotomy procedure and the other of which contains the requisite quantity of anti-coagulant for the second donation of blood. By this plasmapheresis procedure employing the blood collecting set of FIGURE 7, the first donation of blood may be centrifuged to separate out therefrom its red cell fraction for return of the same to the blood donor.

Thus, as shown in FIGURE 7, the blood-collecting set includes a vessel 10b containing an amount of anti-coagulant for a single donation of blood, which vessel is provided, as in the case of FIGURES 4 to 6, with two flexible tubes 28 and 29 respectively fitted at their free outer ends with needles 12b and 14b. These tubes 28 and 29 are adapted to be coupled together and uncoupled internally of the vessel 10b as previously described in connection with the tubes 21 and 22 of FIGURES 4 to 6.

In addition to these tubes 28 and 29, the tubing system of the plasmapheresis set of FIGURE 7 includes a tube branch 30 leading from the tube 28 through a Y-connection 31 to a pair of tube branches 32 and 33, the latter of which is end-fitted with a needle 34. The outer end of the tube branch 32 is in turn connected by a Y-connection 35 to a pair of tube branches 36 and 37. Both of the tubes 28 and 29 and all of the branch tubes leading from the tube 28 are each provided with a suitable clamp 38 for closing and opening each individual section of the tubing system.

For use of this set shown in FIGURE 7, two hermetically sealed blood-collecting bags are employed as shown in phantom. One of these bags, designated 39, is completely empty, while the other bag, designated 40, contains anti-coagulant in the amount necessary to prevent coagulation of blood entered into said bag.

The step in use of this set is to insert the needle 14b into the empty bag 39 after which upon opening only the clamp 38 of the tube 29 and with the tubes 28 and 29 uncoupled as shown, the anti-coagulant is expressed from its container 10b into the bag 39. Follow-
ing this, the tubes 28 and 29 are coupled together internally of the container 10b to thereby provide a continuous length of tubing leading from the phlebotomy needle 12b to the needle 14b inserted in the blood collecting bag 39. The phlebotomy needle 12b is then inserted in the vein of the blood donor, the clamps 29 on the tube 28 are released, and the first supply of the donor’s blood is then allowed to pass through the blood bag and tube branch 30 is now reclosed or occluded by its clamp 38, following which there is attached to the free end of either one of the tube branches 36 and 37 a conventional saline infusion set (shown in phantom and designated 41) for supplying a saline solution to the blood donor by way of the tube branches 36 (or 37), 35, 34, 30, and the needle 12b which has remained inserted in the vein of the blood donor. Of course, for this purpose, those clamps which are associated with the several tube branches used for administering the saline solution to the donor will have been released or opened, while maintaining closed the clamps on the tube branches not so in use.

Following conventional centrifugation and separation of the red cells and plasma of the first donation of blood contained in the blood collecting bag 39 and injection of the saline solution into the vein of the blood donor, the red cells from that bag are returned to the donor by way of the needle-fitted tube portion of the infusion set in communication with that one of the tube branches 36 and 37 of the blood collecting set used for supplying the saline solution to the blood donor. Of course, for this purpose, the needle of the infusion set is projected into that section of the bag 39 which contains the red cells and upon withdrawal of said red cells, only the plasma fraction of the blood originally taken from the donor will be contained in the bag 39.

Having so returned the red cells of the original blood donation to the donor, he is now ready to give a second donation of blood through use of the blood collecting set 28 without excluding the phlebotomy needle 12b from his vein. For this second donation blood, all of the clamps 38 of the tube system are closed except for those providing direct communication between the phlebotomy needle 12b in the vein of the blood donor and the needle 34 inserted in the blood collecting bag 39, as originally made, had sealed therein a predetermined quantity of anti-coagulant. There will now be collected in the second bag 40 the second donation of blood which will be processed as was the first donation and the red cells then will be returned to the donor using the same infusion set 41.

FIGURE 8 shows a modified blood collecting set for use in carrying out a double plasmapheresis, which differs from that shown in FIGURE 7 only in that it includes a second vessel 10c containing anti-coagulant so that the two donations of blood successively obtained from a donor through the single insertion of a needle into his vein may each be collected in a completely empty bag which the anti-coagulant is introduced preliminarily to collection of blood in each bag. This second anti-coagulant vessel 10c is connected in the tube line leading from the Y-connection 31 to the needle 34, which line includes a pair of tubes 35c and 33b and an unclamped vessel 10c in the same manner as are the tubes 28 and 29 associated with the anti-coagulant vessel 10b.

It will be apparent that the tubing system of FIGURES 1 to 3, in lieu of and as distinguished from that shown in the modified arrangement of FIGURES 4 to 6, may be employed in the double plasmapheresis set of either FIGURE 7 or FIGURE 8 and that other modifications and changes may be made from time to time without departing from the general principles or real spirit of the present invention. Accordingly, it will be understood that it is intended to claim the invention broadly, as well as specifically, as indicated in the appended claims.

What is claimed as new and useful is:

1. A blood collecting bag set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system connected to said vessel, said system having one section directly communicable with the interior of said vessel and other sections fitted at their terminal ends with holes and adapted to be inserted into the vein of a blood donor and into an empty hermetically sealed blood collecting container, and means for selectively opening and closing said sections for sequentially delivering into said empty blood collecting container first the anti-coagulant contained in said vessel and then the blood taken from the donor while said needles are respectively inserted in the vein of the blood donor and in the blood collecting container.

2. A blood collection set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system permanently connected to said vessel, said tubing system including a plurality of branches respectively leading into the interior of said anti-coagulant-containing vessel and to hollow needles insertable into the vein of a blood donor and into an empty hermetically sealed bag in which the donor’s blood is collected, means effecting direct communication between the interior of said anti-coagulant-containing vessel and the hollow needle insertable into the blood collecting bag while maintaining occluded the tubing branch leading to the needle insertable into the donor’s blood supplying vein, and means effecting direct communication between the two needles for direct delivery of blood from the donor into said blood collecting bag without any possible accumulation of blood in said anti-coagulant vessel.

3. A blood collection set of the character described comprising a hermetically sealed vessel containing therein a liquid consisting of an anti-coagulant solution and a flexible tubing system connected to said vessel, said system including a plurality of branches each having a freely extending terminal end fitting with a hollow needle, said needles being respectively insertable into the vein of the blood donor and into a hermetically sealed empty blood collecting container, means for normally maintaining the blood collecting container within said vessel containing the anti-coagulant, means for occluding the conduit branch connected to the vein-insertable needle and for opening the anti-coagulant vessel only to flow of the anti-coagulant solution therefrom into the blood-collecting container by way of the conduit branch connected to the needle insertable into said blood collecting container, said means being further operative to render said needle-connected branches effective as a direct conduit for the flow of blood from the donor to the blood collecting bag following transfer of the anti-coagulant solution from its vessel into the blood collecting bag.

4. In a blood collection set as defined in claim 3 where in said needle-fitted conduit branches extend in by-passing relation to said anti-coagulant containing vessel and are commonly connected to the latter by auxiliary conduit branch having one end in communication with said needle-fitted conduit branch and at the opposite end connected to said vessel for communication with the interior thereof.

5. In a blood collection set as defined in claim 4 wherein in the valve means for maintaining said anti-coagulant containing vessel hermetically sealed consists of a spherical element frictionally seated in the said end of said auxiliary conduit branch which is connected to said vessel,
said element being expressible out of its seat into the interior of said vessel to open the same to discharge of the anti-coagulant solution therefrom.

6. In a blood collection set as defined in claim 4 wherein said needle-fitted conduit branch insertable into the donor's vein and said auxiliary conduit branch are respectively fitted with clamp means operative to selectively open and close said branches to passage of fluid therethrough.

7. In a blood collection set as defined in claim 3 wherein said needle-fitted conduit branches are adapted to be connected together internally of the vessel containing the anti-coagulant to effectively provide a continuous conduit extending through said vessel, the connectable ends of said branches being each fitted with closure means for individually sealing said branches against flow of fluid therethrough, said being sequentially openable to permit sequential delivery into the blood collecting container of the anti-coagulant solution from said vessel and of the blood from the donor through said conduit, both flows being by way of the same needle inserted into the blood-collecting container.

8. In a blood collection set as defined in claim 3 wherein said anti-coagulant containing vessel is formed of a substantially rigid, inflexible material.

9. In a blood collection set as defined in claim 3 wherein said anti-coagulant containing vessel as formed of flexible material and is provided with walls which may be pressed together to express therewith the contained anti-coagulant solution.

10. In a blood collection set as defined in claim 3 wherein said tubing system is provided with an auxiliary conduit system for collecting a second donation of blood from the donor through a single insertion of a needle into the vein of the donor, said auxiliary conduit system having a branch connected at one end to said needle-fitted conduit branch insertable into the donor's vein and at its opposite end to a pair of freely extending branches one of which terminates in a hollow needle adapted for insertion into a second hermetically sealed blood collecting container and the other of which is adapted for connection to an infusion set for supplying an indicated solution into the vein of the blood donor.

11. In a blood collection set as defined in claim 10 wherein the needle-fitted branch of said auxiliary conduit system is connected to a second vessel containing an anti-coagulant solution and wherein means are provided for sequentially delivering into the second blood collecting container first the anti-coagulant contained in said second vessel and then the second donation of blood taken from the vein of the blood donor.

12. In a blood collection set as defined in claim 10 wherein each conduit branch of said auxiliary conduit system is provided with means for selectively opening and closing the same to flow of fluid therethrough.

13. A method of collecting blood from a donor for introduction into a hermetically sealed empty blood collecting container which consists in delivery of an anti-coagulant solution from a vessel in which said solution was initially sealed into the blood collecting container by way of a flexible delivery tube extending from said vessel to a hollow needle fitted on the end of said tube and inserted into said container, in then re-sealing the anticoagulating vesel by occluding the solution deliver.

14. A method of conducting plasmapheresis which consists of hermetically sealing a predetermined quantity of anti-coagulant solution in a vessel having a tube extending therefrom and terminating in a hollow needle, in inserting said needle into a hermetically sealed empty blood collecting container, in opening said vessel to free flow of the anti-coagulant solution therefrom into said container by way of the needle inserted into said container, in then closing off the interior of said vessel from said container, in then inserting into the vein of a blood donor a phlebotomy needle having direct tubular communication with the needle inserted in the blood collecting container for free flow of a first donation of blood from the donor into said container, in then removing the blood collecting container from its inserted needle and centrifuging the same to separate the red cell and plasma components of the collected blood while introducing into the donor's vein a saline solution by way of the phlebotomy needle initially inserted therein, in then returning to the donor's vein also by way of said phlebotomy needle the red cells recovered by said centrifugation of the first donation of blood, and thereafter delivering a second donation of blood through said phlebotomy needle in the vein of the donor to and into a second blood collecting container.

15. A method of conducting plasmapheresis as defined in claim 14 wherein the second blood collecting container has already sealed therein a predetermined quantity of anti-coagulant solution.

16. A method of conducting plasmapheresis as defined in claim 14 wherein prior to introduction of the second donation of blood into said second container anti-coagulant solution from an external source of supply is introduced into said second container with both the anti-coagulant solution and the second donation of blood being successively introduced into said second container by way of a single entry of a needle into said second container.

References Cited

UNITED STATES PATENTS

1,517,849 12/1924 McLellan 128—214.2
1,610,622 12/1926 Shawker 128—214.2
2,950,716 8/1960 Bellamy et al. 128—214
3,078,847 2/1963 Gendall et al. 23—258.5
3,064,647 11/1962 Earl 23—258.5

FOREIGN PATENTS

865,661 3/1941 France.
1,082,035 6/1954 France.

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23—258.5