United States Patent

Wilson et al.

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[54] BLOOD COLLECTION ASSEMBLY

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[52] **U.S. Cl.** ..... **128/214 D**, 128/272

[51] **Int. Cl.** **A61m 05/14**

[58] **Field of Search** ..... 128/214, 214.2, 272, 276, 278, 128/214 D; 23/258.5; 285/2–4, 235

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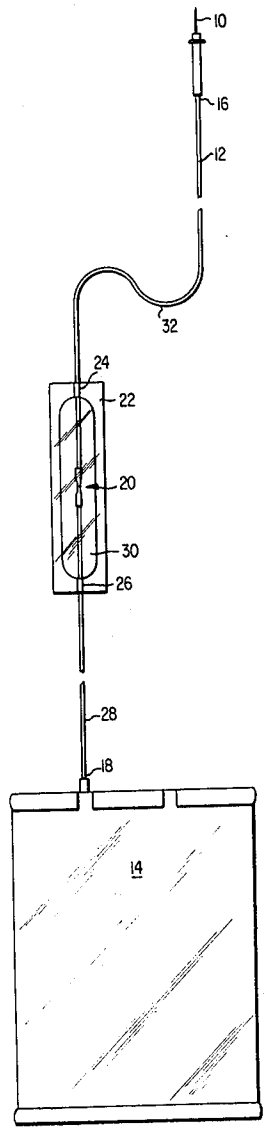
[57] **ABSTRACT**

Disclosed herein is a blood collection assembly including an auxiliary sample pouch with a pass-through tube for filling the blood bag. The pass-through tube is the same diameter as the remaining tubing of the assembly and is frangible within the pouch so that the tubing can be placed in communication with the pouch.

12 Claims, 4 Drawing Figures



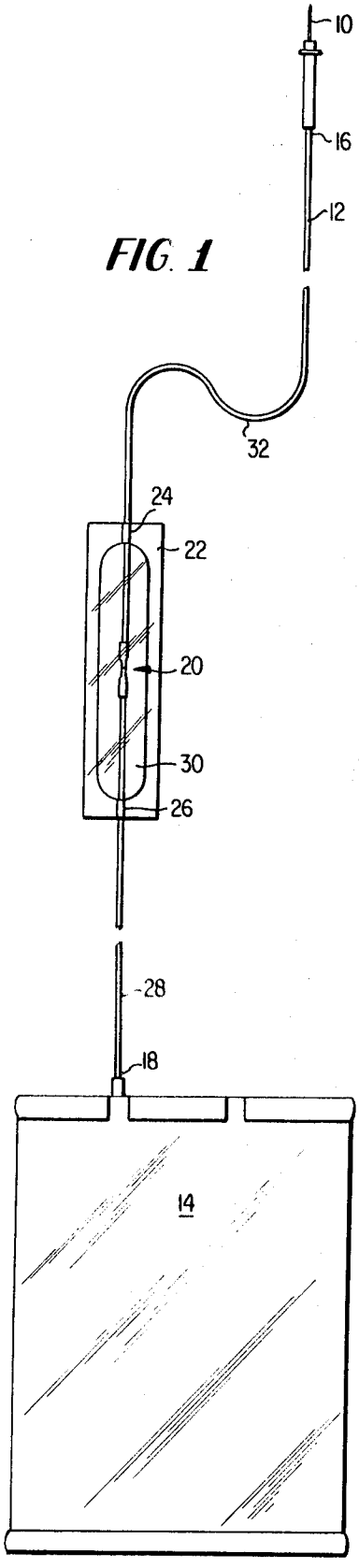


FIG. 1

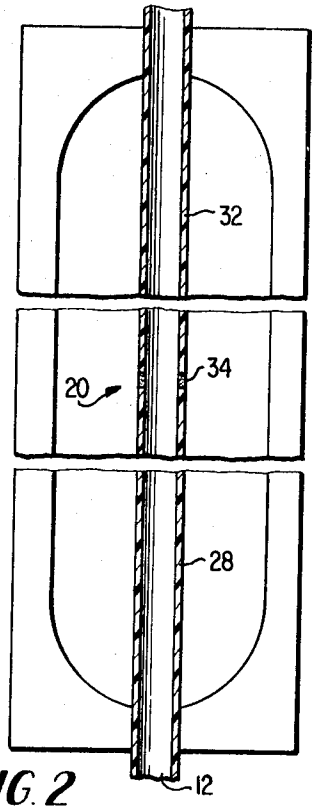


FIG. 2

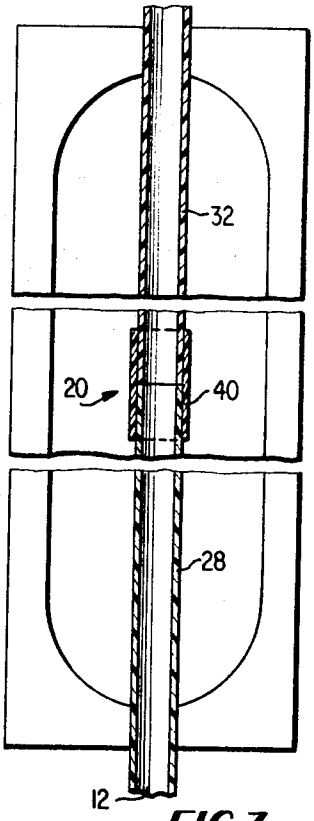


FIG. 3

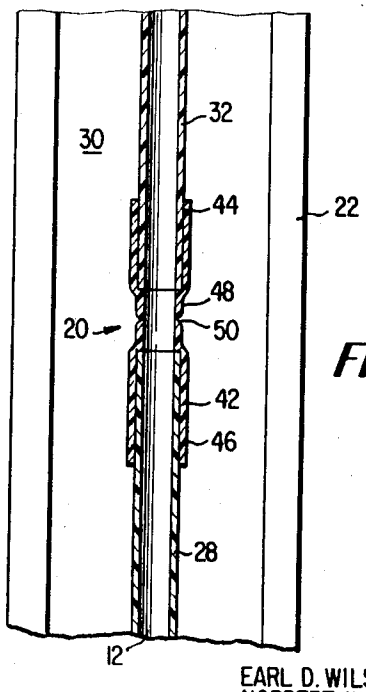


FIG. 4

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BLOOD COLLECTION ASSEMBLY

This invention relates to a blood collection assembly and particularly to an assembly that includes a blood bag and tubing connected to the blood bag with an auxiliary sample pouch in line with the tubing.

A number of devices are presently available to deal with the problem of collecting, handling and storage of whole blood or other fluid donations. And while several such devices have considered the generic idea of a primary storage bag to contain the bulk of the donation with an auxiliary sample pouch for segregating a sample of the donation for tests, etc.; the prior art devices designed as a solution to the generic problem have not been totally acceptable or free from problems.

The most common of these prior art devices includes a phlebotomy needle connected through tubing to one end of a sample pouch. The tubing is connected to the opposite end of the sample pouch and communicates the sample pouch with a blood bag. With this device, blood from the donor passes through the first tubing, the sample pouch and then through the second tubing into the blood bag. When the blood bag is full, the tubing closest to the bag is clamped off. At this point, the sample pouch is allowed to fill with blood and then the tubing closest to the donor is clamped off and the needle is withdrawn from the patient. At this point, the sealed sample pouch is then removed by cutting the tubing on either side thereof and a sample of the blood just collected is thus provided for testing purposes.

A number of problems are associated with this type of system. First of all, the blood bag provided in the system normally contains an anti-coagulant which helps to preserve the collected blood during storage. This anti-coagulant, before the bag is used to collect blood is free to flow through the tubing and into the sample pouch. Although the anti-coagulant is necessary to preserve the collected blood, it can be considered a contaminate of the sample of blood which is collected in the pouch for testing. Another problem associated with these prior art type devices is the large change in diameter of the passage for the blood when the blood travels through the small diameter tubing into the large diameter sample pouch and then back into the small diameter tubing before entering the blood bag. The varying diameter between the tubing and the sample pouch causes a turbulent flow path for the blood which increases the chance that some of the blood will coagulate within the pouch.

The present invention is designed to obviate these and other problems associated with the prior art devices and includes in its most elementary form a sample pouch sealed about a continuous tubing passing from the phlebotomy needle to the blood bag with a frangible section provided in the tubing interior of the encapulating sample pouch. With a device of this type, it is thus possible to prevent the anti-coagulant from entering the sample pouch prior to use of the collection assembly and moreover, during use of the collection assembly of the present invention, the blood from the donor flows through a constant diameter tubing to the blood bag so as to avoid turbulent flow and the resultant detrimental coagulation within the sample pouch.

In use, the blood collection assembly of this invention is first removed from its shipment package and the phlebotomy needle is inserted in the donor's vein. The blood then flows through the tubing of the assembly into the blood bag and when the flood bag is filled, it is isolated from the system by a clamp or tying of the tubing. Next, the frangible section of the tubing interior of the encapulating sample pouch is broken so that the blood will flow into the pouch. Once the pouch is filled, the tubing between the pouch and the phlebotomy needle is clamped off and a sample of the donation is thus provided.

From this brief description of the prior art and summary of the invention, it would be apparent that one of the primary objects of this invention is to provide a blood collection assembly which insures a constant diameter flow path of the blood from the donor to the blood bag and which assembly further permits the collection of a sample of the donation after the blood bag is filled.

Still another primary object of this invention is to provide an assembly of the type just described with a frangible section in the tubing encapulated by the sample pouch so that the sample pouch may be placed in communication with the feed tube after the blood bag is filled.

Some of the primary objects of the invention having been stated, other objects attending this invention will become apparent to those of skill in the art when consideration is given to the following detailed description of an exemplary embodiment. This description is made in conjunction with the accompanying drawings wherein:

Fig. **1** is a schematic perspective of the basic system,

FIG. **2** is a blow-up partially in cross-section of the portion of the system including the sample pouch,

FIG. **3** is a blow-up partially in cross-section of a second embodiment of the invention including the portion of the system having the sample pouch, and

FIG. **4** is a yet another embodiment of the invention showing features comparable to those features shown in FIGS. **2** and **3**.

Referring now to FIG. **1**, the system can be seen to include a phlebotomy needle **10** for insertion into a vein of the donor. Connected to the hub of the needle **10** is the feed tube **12**. Connected to the opposite end of the feed tube **12** is the blood bag **14**. Intermediate the initial end **16** and the terminal end **18** of the tube **12** is a frangible portion indicated generally at **20**.

Encapsulating the segment of the feed tube **12** including the frangible portion **20** is the sample pouch **22** which is sealed at end walls about the outside diameter of the feed tube **12** at **24** where the tube enters the pouch and at **26** where the tube exits from the pouch.

The first step in the use of the blood collection assembly of the present invention would be to remove the assembly from its shipment package (not shown) and mount the blood bag on a suitable standard. The phlebotomy needle is then inserted in the donor's vein and passage of the blood will proceed immediately through the feed tube **12** and directly into the blood bag **14**.

It should be noted here that the packaged assembly will normally include a standard anti-coagulant in the blood bag and that during shipment, some of the anti-coagulant will possibly drain into the feed tube **12**. However, with the initial in rush of blood through the tube **12**, the anti-coagulant will be swept back into the blood bag **14** where it operates in its desired capacity to prevent coagulation of the donation during storage and shipment.

At this point, while in a sense the blood passing through the system has passed through the sample pouch, none of the blood is actually entered the pouch but rather it has flowed through the tubing **12** directly into the blood bag **14**. The tubing **12** from its initial end to its terminal end is of a substantially constant diameter and it is essential that no abrupt changes in the diameter of the tubing be present. The substantially constant diameter of the tube **12** throughout its entire length insures a laminae flow of the blood from the donor to the bag **14** and avoids any turbulence in the flow which would tend to result in coagulation. This is particularly true when the blood is passing through the pouch **22** since in the initial use of the system, the pouch **22** acts merely to encapsulate the tubing **12** and the smooth flow of the blood through the pouch is uninterrupted during the period in which the donation is collected.

It should be noted that when the system is initially taken out of its shipment package, the bag, pouch and possibly the tubing will be collapsed and air will have been expelled from at least a major portion of the system. This condition of the system may be insured by either the construction of the bag and pouch to have basically a flat or sandwich type construction so that a minor amount of interior space will initially be presented, or, on the other hand, the system may be connected to a vacuum source and completely collapsed with a clamp placed on the feed tube **12** adjacent the initial end **16** and which clamp is removed only after the phlebotomy needle **16** has been inserted in the donor's vein. The purpose of insur-

ing that air is expelled from the system initially is to avoid the need for a vent port or the like to which air may escape when a volume of air that would otherwise be within the bag or pouch is displaced by the inrushing blood. If the bag is collapsed initially so as to avoid having any air in the chamber thereof, the flexible bag or pouch will deform in response to the incoming blood in order to provide a sufficient volume within its chamber to accomodate the donation and/or sample.

Once the donation has been collected, the blood bag **14** is isolated from the system by either providing a clamp on the segment of tube **28** or tying off the tube at the section **28** in any convenient manner. Next, the frangible portion **20** within the flexible pouch **22** is broken so as to place the passage of the tube **12** in communication with the chamber **30** formed interior of the sample pouch **22**. Since the pouch **22** is sealed to the outside diameter of the tube **12** at points **24** and **26**, the interior side walls of the pouch form a collection chamber surrounding the tubing in which may be collected a sample of the donation being offered. After the chamber **30** is filled, the section **32** of the tubing **12** is clamped or sealed off in any desired manner and the needle **10** is removed from the donor. The sealed sample pouch is then removed from the system by cutting the tubing and a sample of the blood just collected is thus provided for testing purposes. This sample is exactly representative of the donation just collected and is obtained with a minimum of coagulation and at the same time "contamination" of the sample by any of the anti-coagulate in the system is prevented.

Referring now to FIGS. **2**, **3** and **4**, details of the frangible portion **20** are illustrated. In FIG. **2**, the frangible portion **20** is shown as either a hardened or weakened segment **34** in the line of the tube **12** between the sections **32** and **28**. Since the pouch **22** is of a flexible and preferably transparent material, once the blood bag **14** has been filled, it will merely be necessary to grasp the sections **28** and **32** and break the tube **12** at the point **34** in order to place the passage of the tube **12** in communication with the chamber **30**.

Referring now to FIG. **3**, the frangible portion **20** of this embodiment is shown to include a sleeve **40** connecting the two sections **28** and **32** of the tube **12**. In this embodiment, when the bag **14** is filled, and after the section **28** has been clamped or sealed off to isolate the bag **14** from the system, it is merely necessary to flex the pouch so as to create some slack and then grasp the sections **28** and **32** and pull them axially, taking up the slack that had been created and thus freeing sections **28** and **32** of the sleeve **40**. When either of the sections **28** and **32** are freed from the sleeve **40**, the passage of the tube **12** is placed in communication with the chamber **30** and the sample of the donation may be collected.

Referring now to FIG. **4**, another embodiment of the invention is shown in which the frangible portion **20** includes the relatively rigid sleeve **42**. The sleeve **42** is counterbored at **44** and **46** for receiving the sections **32** and **28**, respectively, of the tubing **12**. The central portion **48** of the sleeve **42** is of the same inside diameter as the tube **12** and the counterbores **44** and **46** are of the same outside diameter as the tube **12** so that a substantially constant diameter passage is provided for the blood flowing from the donor to the bag **14** and laminae flow of the blood is insured. This laminae flow is also insured in the embodiment shown in FIGS. **2** and **3** due to the substantially constant inside diameter of the tubing as is apparent from the drawings.

The central portion **48** of the sleeve **42** is weakened at **50**, and once the bag **14** has been filled and isolated from the system by the clamping procedure previously described, it is merely necessary to grasp the two ends of the sleeve **42** on either side of the central portion **48** and snap the frangible member at the point **50**. This rupture of the sleeve **42** places the passage of the tube **12** in communication with the chamber **30** of the pouch **22** so that the sample may be collected.

The exemplary embodiments of the invention having been described, the true nature and scope of what is desired to be insured by letters patent is defined in the appended claims.

I claim:

1. In a blood collection assembly including a needle for inserting in a donor's vein, a bag for collection of the donation, and tubing having an initial end and a terminal end, said tubing connected to said needle at said initial end and to said bag at said terminal end, the improvement comprising: said tubing having a passageway therethrough of substantially constant inside diameter from said initial end to said terminal end to insure laminar flow of blood through said tubing and avoid turbulent flow at any point along said passageway, said tubing having a frangible portion intermediate said initial and terminal ends, and a closed sample pouch encapsulating said frangible portion and having end walls sealed to said tubing on either side of said frangible portion, said pouch including an empty chamber formed about the continuous length of said tubing including said frangible portion, said frangible portion being disposed intermediate, but spaced from, said end walls.

2. The assembly as defined in claim **1** wherein said frangible portion is a hardened segment of said tubing.

3. The assembly as defined in claim **1** wherein said frangible portion is a weakened section of said tubing.

4. The assembly as defined in claim **1** wherein said tubing includes a first section communicating with said initial end and a second section communicating with said terminal end, and said frangible portion includes a sleeve holding said first and second sections of said tubing in abutting engagement.

5. The assembly as defined in claim **4** wherein said sleeve is flexible.

6. The assembly as defined in claim **4** wherein said sleeve is rigid.

7. The assembly as defined in claim **1** wherein said tubing includes a first section communicating with said initial end and a second section communication with said terminal end, said frangible portion includes a hardened sleeve having a weakened central section, counterbored end sections and shoulders interconnecting said central sections and said end sections, the inside diameter of the central section being substantially constant and equal to the inside diameter of said tubing, the inside diameter of said end sections being substantially equal to the outside diameter of said tubing and said first and second sections of said tubing fitted within said end sections and abutting said shoulders.

8. The assembly as defined in claim **1** wherein said bag contains an amount of anti-coagulant and said frangible portion is unbroken.

9. A method of collecting blood from a donor which includes placing tubing in communication with a donor source, passing blood through said tubing in a laminar flow pattern from said cource to a collection point, collecting a donation of blood at said collection point, interrupting said laminar flow pattern intermediate said source and said collection point, and collecting a sample of blood in a pouch having a first end wall sealed to the tubing upstream of the point of interruption of said flow pattern and a second end wall sealed to the tubing downstream of the point of interruption of said flow pattern said pouch having side walls surrounding said tubing to define a chamber for collecting the sample of blood.

10. The method as defined in claim **9** further including providing an anti-coagulant at said collection point prior to passing blood thereto.

11. The method as defined in claim **10** further including maintaining said chamber free from anti-coagulant solution.

12. The method as defined in claim **9** further including insuring said laminar flow pattern by providing the tubing with a substantially constant inside diameter between said source and said collection point and interrupting said flow pattern by breaking the tubing at a frangible portion thereof.

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