

[54] **HYPODERMIC SYRINGE FOR BLOOD TESTS**

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[51] Int. Cl. **A61b 5/14**

[58] Field of Search **128/2 F, 2 B, 2 G, 128/2 M, 2 R, DIG. 5, 215, 216, 218 R, 218 P, 218 D, 214.4, 221, 276**

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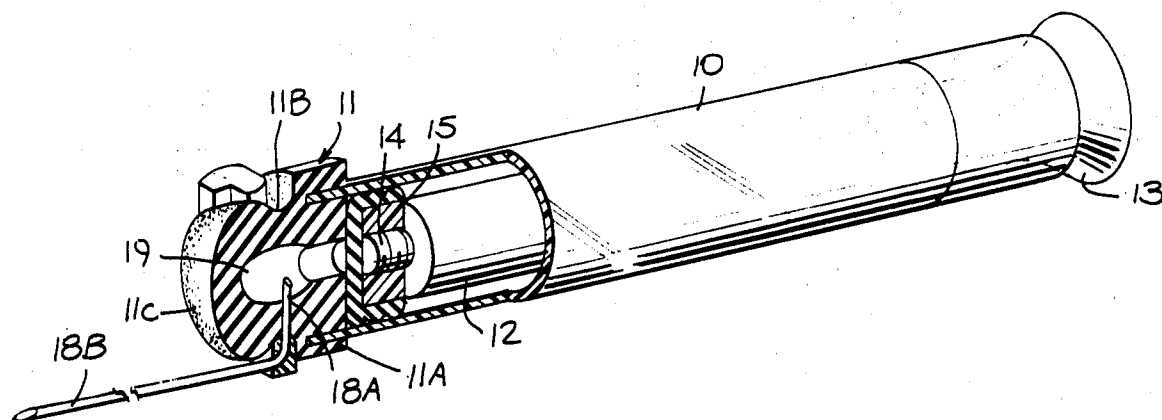
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[57]

ABSTRACT

A syringe assembly for drawing a blood sample into a test tube suitable for blood analysis. The assembly includes an open-ended cylindrical tube secured at one end to a closure provided with a constricted neck of self-sealing elastomeric material and having an internal chamber therein communicating with the tube. Slidably disposed within the tube is a piston which is detachably coupled to a stem terminating in a handle whereby the piston may be shifted from an initial position sealing off said chamber to a final position adjacent the other end of the tube, the withdrawal of the piston creating a suction force. Also provided is an applicator having a yoke adapted to embrace the neck of the closure, and an L-shaped double-pointed needle secured at its junction to the yoke, the lateral arm of the needle penetrating the neck to enter the chamber therein, whereby blood flowing through the longitudinal arm of the needle which is injected in a vein of a patient is conducted into the neck chamber and from there into the tube to a level determined by the piston position. The piston serves as a stopper when the stem is detached therefrom and may be later removed by a puncturing tool which vents the stopper to facilitate its extraction from the tube.

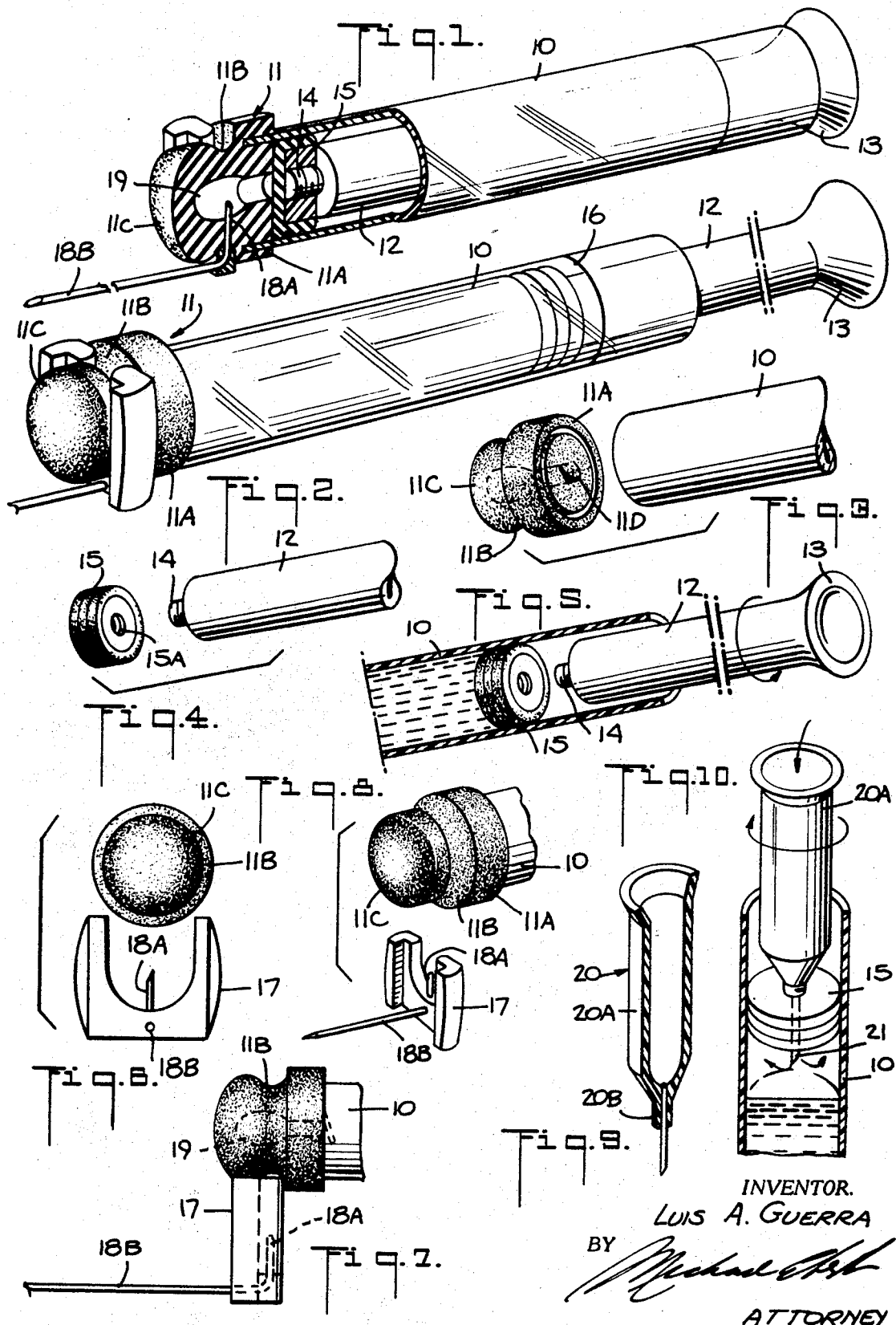
5 Claims, 17 Drawing Figures



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PRIOR ART

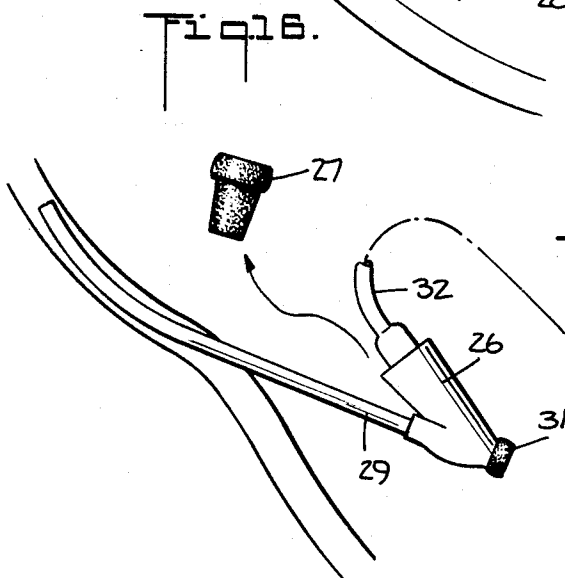
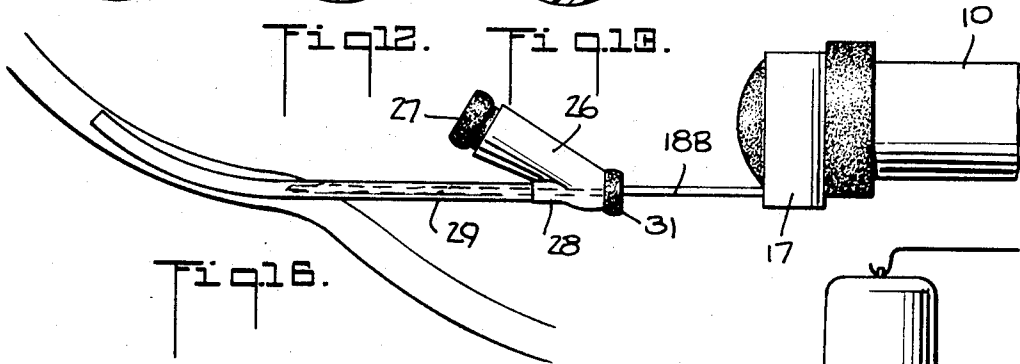
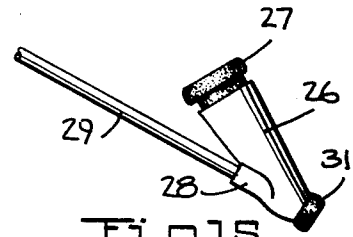
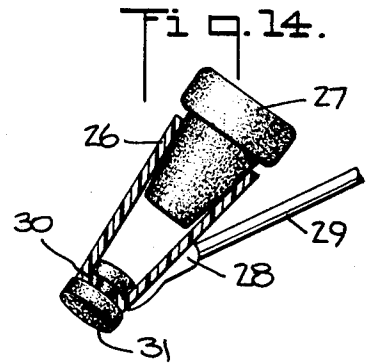
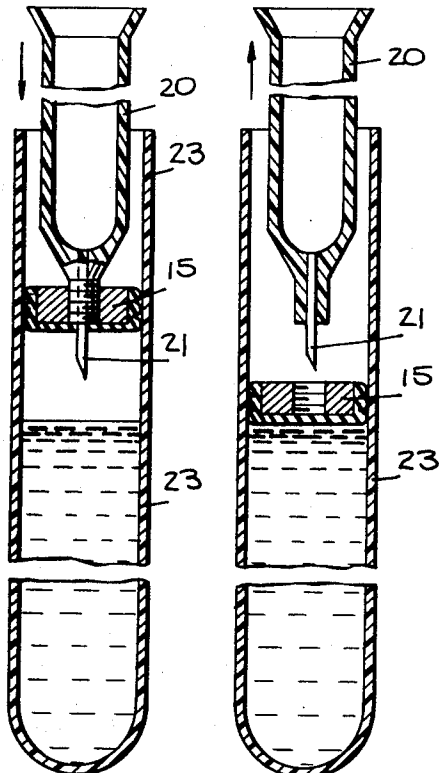
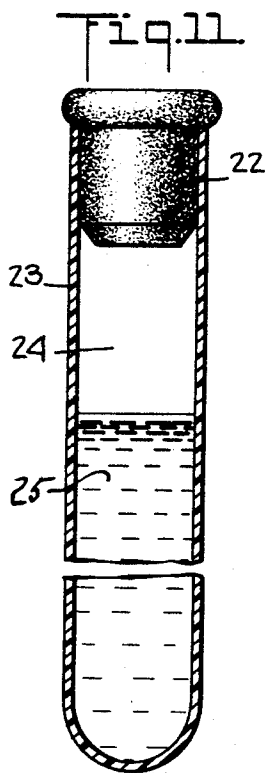
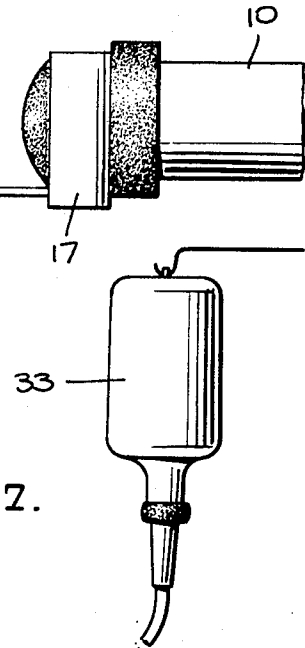


Fig. 17.



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HYPODERMIC SYRINGE FOR BLOOD TESTS

BACKGROUND OF THE INVENTION

This invention relates generally to hypodermic techniques for obtaining blood samples, and more particularly to a hypodermic syringe assembly adapted to draw blood from a patient and to feed it directly into a test tube.

Medical procedures carried out in a hospital, which entail some degree of care and skill, are time-consuming and may contribute significantly to the expenses of medical care. With present-day shortages of doctors, nurses, and trained hospital personnel, the time factor involved in any procedure reduces the working time available for carrying out other essential functions, so that it is not only the cost of a procedure in terms of labor and material which must be taken into account, but also the loss of valuable professional time.

In the modern hospital, blood tests are carried out on a large scale and the price of equipment used for this purpose and the time involved in the procedure are important operating cost factors. Existing blood-sampling procedures are deficient in many respects and give rise not only to a loss in time but also to trauma and defective blood analysis.

Since in a hospital most patients are confined to bed, in order to analyze a patient's blood, a sample must be taken at bedside and conveyed to the hospital laboratory. In a typical multi-story hospital structure and logistics of collecting and transporting blood samples from the hospital rooms to the laboratory are fairly complicated.

It is for this reason that some hospitals are equipped with a network of pneumatic conduits, making it possible to convey test tubes from the rooms directly to the laboratory under pneumatic pressure at high speed. The pneumatic conveyor makes use of multi-cell cartridges designed to accommodate test tubes and to pass through the conduits. But, as will later be explained, present blood-sampling techniques do not lend themselves to pneumatic conveyance; hence it becomes necessary to hand-carry the blood samples, with an attendant loss in time.

The traditional means for taking a blood sample is the hypodermic syringe which can be used not only to draw blood from a patient, but also to inject medication. The standard syringe includes a cylindrical tube having a piston therein which, when pulled by an operator, creates a suction force drawing blood into the tube through a nozzle coupled to a hypodermic needle. The amount of blood drawn into the tube is determined by the extent to which the piston is withdrawn. A syringe has many practical advantages, for it gives the operator the feeling of being inside the vein, and blood may be drawn at a gentle or fast rate, as desired, in the amount needed or available and with little trauma.

However, in order to carry out blood tests, the blood in the syringe must be transferred to a test tube that can be centrifuged and is therefore suitable for blood analysis. Thus, in order to use a standard syringe for blood tests, a sample must be drawn from the patient and the blood contained in the syringe transferred to a test tube which is then sent to the testing laboratory. Since it is not possible to include an anti-coagulating agent in the syringe, this agent must be later introduced in the sample, and if a delay occurs, as is sometimes the case, co-

agulation may result and the sample rendered defective.

In an attempt to overcome the drawbacks of standard syringes, a vacuum container has been developed, making it possible to obtain a blood sample in a test tube and to obviate the need to transfer the sample.

In a vacuum chamber an evacuated test tube having a removable, self-sealing rubber stopper, operates in conjunction with a multi-sample needle, one end of which is injected into the stopper whereby blood from the patient is sucked into the tube, which may then be sent to the laboratory where it is centrifuged. Not only does the vacuum container do away with the need for blood transfer, but it has another important advantage in that an anti-coagulant may be stored in the evacuated tube to intermingle with the blood at the moment the sample is taken, thereby avoiding the delayed contact.

Nevertheless, the vacuum container has a number of serious drawbacks. To begin with, the operator has no feeling of being inside the vein and when switching tubes on the multisample needle, he may lose the vein. Also, in coupling the vacuum container to the needle, the pressure must be applied along the needle axis to penetrate the stopper. This pressure is transmitted to the patient and may be traumatic. Another difficulty with the vacuum container is that the vacuum may collapse the vein, and it then becomes impossible to draw blood. In the event the needle associated with the Vacutainer does not penetrate the vein but instead makes contact with tissue, the suction force may traumatize this tissue. Also, the operator has no control over the rate at which the blood is drawn.

In addition to the above drawbacks, with the vacuum container, one has no control over the amount of blood drawn into the tube, for this is determined by a predetermined vacuum pressure. Since to minimize the possibility of vein collapse, the vacuum must be moderate, the amount of blood drawn into the tube is generally such as to only partially fill the tube. Because of the free air space in a vacuum container containing a blood sample, the sample is subject to a mixing action and cannot, therefore, be sent to the laboratory by way of a pneumatic system. The reason for this is that the agitation of the sample within the free air space produces air bubbles in the blood which promote the destruction of red blood cells and therefore interferes with test procedures.

Since the traditional syringe provides better control in extracting blood samples, whereas the vacuum container is useful in that it provides a pre-closed test tube which may be quickly filled and may contain an anticoagulant for immediate contact with the blood, the present practice is to use the syringe to draw the sample and to inject the blood into a Vacutainer.

The cost of this procedure therefore includes the cost of both syringes and vacuum container. Moreover, because vacuum container cannot be conveyed pneumatically, the sample must be transported to the laboratory by hospital personnel. In some instances the delay encountered in obtaining a blood analysis may jeopardize the life of a patient.

SUMMARY OF THE INVENTION

In view of the foregoing, it is the main object of this invention to provide a hypodermic syringe assembly adapted to draw blood from a patient directly into a

test tube, which tube has no free air space, and may be transmitted pneumatically to a laboratory without rendering the blood unsuitable for analysis.

More specifically, an object of the invention is to provide a syringe assembly wherein the piston is manipulated by a detachable stem, and also serves as the removable stopper of the test tube, the piston being caused to assume a position in the tube avoiding an air space therein.

Still another object of the invention is to provide a removable piston of the above type which may be used to replace the existing stopper in a vacuum container to avoid a free space in the test tube thereof and to permit pneumatic conveyance of the vacuum container tube.

Yet another object of the invention is to provide an improved catheter adapted to cooperate with a syringe assembly in accordance with the invention.

Also an object of the invention is to provide a disposable hypodermic syringe assembly which may be manufactured and assembled at low cost.

Briefly stated, in a syringe assembly in accordance with the invention, an open-ended cylindrical tube is secured at one end to a closure including a constricted neck having an internal chamber, the closure being formed of self-sealing elastomeric material which may be penetrated by a hypodermic needle. Slidably disposed within the tube is a piston also formed in part of similar elastomeric material, the piston being manipulated by a detachable stem terminating in a handle, whereby the piston position in the tube is initially such as to seal off the neck chamber.

Also provided is an applicator having a U-shaped yoke adapted to embrace the neck of the closure, the applicator including an L-shaped, double-pointed needle whose junction is embedded in the yoke, the needle having a lateral arm which penetrates the neck to enter the chamber, and a longitudinal arm for vein injection, whereby blood flows from the patient into the neck chamber and from there into the tube.

The amount of blood drawn into the tube is controlled by the piston position, no air space being created between the piston and the sample. To convey the sample to the laboratory, the tube is detached from the applicator and the stem is detached from the piston, which now functions as a stopper. This stopper may be later removed by a puncturing tool attachable to the stopper and including a hollow puncturing needle to vent the stopper and thereby facilitate its removal from the tube.

OUTLINE OF THE DRAWING

For a better understanding of the invention, as well as other objects and further features thereof, reference is made to the following detailed description to be read in conjunction with the accompanying drawing, in which:

FIG. 1 is a perspective view, partly in section, of a hypodermic syringe assembly in accordance with the invention, the syringe being shown in its initial state;

FIG. 2 shows the same syringe assembly after a blood sample has been taken;

FIG. 3 separately shows the tube and closure of the syringe assembly;

FIG. 4 separately shows the detachable stem and piston of the syringe;

FIG. 5 shows the manner in which the stem is de-

tached from the piston after a sample has been taken; FIG. 6 is a front view of the applicator and its relationship to the closure of the syringe;

FIG. 7 is a side view of the same applicator;

FIG. 8 is a perspective view showing the manner in which the applicator is coupled to the syringe closure;

FIG. 9 is a section of the puncturing tool for removing the piston;

FIG. 10 illustrates the manner in which the puncturing tool is used;

FIG. 11 shows a conventional vacuum container containing a blood sample;

FIG. 12 shows how the puncturing tool is used to replace the vacuum container stopper with a piston in accordance with the invention;

FIG. 13 illustrates the position of the piston in the Vacutainer;

FIG. 14 is a sectional view of a catheter in accordance with the invention;

FIG. 15 is a lateral view of the catheter;

FIG. 16 shows the catheter in cooperation with a syringe assembly in accordance with the invention; and

FIG. 17 shows the catheter used for the transfusion of fluid.

DESCRIPTION OF THE INVENTION

Referring now to FIGS. 1 to 8, there is shown a syringe assembly in accordance with the invention, comprising an open-ended cylindrical tube 10 which may be fabricated of glass or of a suitable transparent, disposable plastic material. The lower end of the tube is attached to a closure generally designated by numeral 11, formed of self-sealing elastomeric material, such as neoprene rubber. The closure is constituted by a coupling shoulder 11A having an annular groove therein which frictionally receives the end of the syringe tube, the shoulder being integral with a constricted neck 11B and a bulbous head 11C. Neck 11B is provided with an internal chamber 19 which communicates with tube 10.

Telescoping within tube 10 is a stem 12, one end of which is flanged to define a handle 13, the other end having a hollow screw 14 extending axially therefrom, the screw being threadably received within the central socket 15A of a piston 15. Piston 15 is in the form of a ring, which may be made of high-strength, rigid plastic material, the ring fitting within a cup formed of self-sealing resilient elastomeric material or rubber. The cup is provided with peripheral corrugations to effect a fluid-tight seal with the inner wall of tube 10. By pulling handle 13, one may slide piston 15 up the tube to create a suction force to draw blood therein to a maximum level indicated by stop-mark 16.

The syringe cooperates with a hypodermic applicator constituted by a U-shaped yoke member 17 preferably made of plastic material such as polypropylene, adapted to frictionally embrace neck 11B of closure 11, and an L-shaped, double-pointed hypodermic needle 18, the junction of whose arms is embedded in yoke 17. The short or lateral arm 18A of the needle lies at right angles to the longer longitudinal arm 18B, whereby when neck 11B is laterally pressed onto yoke 17, the short arm penetrates the neck and enters internal chamber 19 therein, which communicates with tube 10. Because of this lateral coupling arrangement, no axial pressure is produced which is transmitted to the patient, and no trauma is caused thereby.

Chamber 19 is filled with a suitable anti-coagulant agent and is initially sealed by piston 15. However, when the hypodermic needle arm 18B pierces a vein or artery and the piston is pulled away from the closure by handle 13 to create a suction force, blood flows into chamber 19 by way of short arm 18A where it intermingles with the anti-coagulant agent therein.

After the desired amount of blood has been drawn into tube 10, the closed syringe tube is disconnected from applicator 17 and, as shown in FIG. 5, stem 12 is disconnected from piston 15, this being accomplished simply by rotating the stem to unscrew it from the piston. The detached syringe tube 10 is therefore now a sealed test tube, and because there is no air space therein and the piston 15 now functions as a stopper, it may be transmitted pneumatically to the hospital laboratory. At this point, another syringe tube may be coupled to the applicator, which is still in place, and another blood sample may be taken.

In the laboratory, the piston 15 must be removed so that the blood can be analyzed. Extraction of the piston 15 from tube 10 is effected by a puncturing tool 20, as shown in FIGS. 9 and 10, which includes a hollow shank 20A provided with an externally-threaded hollow screw 20B and a puncturing needle 21 projecting axially therefrom. When screw 20B is threaded into the socket 15A of piston 15, as shown in FIG. 10, the needle 21 penetrates the piston to vent the tube, making it then possible to pull out the piston which otherwise, by reason of air pressure, resists displacement.

The puncturing tool 20 also makes it possible to replace the stopper 22 in a conventional vacuum container tube 23, as shown in FIGS. 11, 12 and 13, with a piston 15 serving as a stopper in a manner whereby the new stopper may be brought into direct contact with the blood to preclude free air space.

Thus as shown in FIG. 11, with the conventional vacuum container, there is an air space 24 between stopper 22 and the blood sample 25, whereas when this stopper is replaced by piston 15, which is forced down the vacuum container tube until it makes contact with the blood, the air space is totally eliminated. The same puncturing tool is used to insert the piston and to later remove it; in both cases the puncturing needle vents the piston to facilitate its passage up or down the tube.

By replacing the standard stopper of the vacuum container with a piston, as described herein, it then becomes possible to pneumatically convey the vacuum container to the laboratory, thereby effecting major economies in transit time, so that a rapid blood analysis may be made.

Referring now to FIGS. 14 to 17, there is shown an improved form of catheter which may be used in conjunction with a syringe assembly of the type previously disclosed, to take blood samples or for purposes of blood or fluid transfusion.

The catheter is constituted by a short funnel 26 of a suitable plastic material, which may be transparent, the mouth of the funnel being closed by a removable stopper 27. Adjacent the lower end of the funnel there is formed a small outlet port 28 which is inclined relative to the longitudinal axis of the funnel and is coupled to a flexible catheter tube 29 of a suitable high-grade, inert plastic material, such as polyvinyl chloride or Teflon.

On the other side of the funnel, in a position in registration with the outlet, is a small inlet port 30, within

which is inserted a plug 31 of rubber or other self-sealing material. The common axis of the inlet and outlet ports lies at an oblique angle relative to the longitudinal axis of the funnel.

When, as shown in FIG. 16, the needle arm 18B of the syringe assembly is injected into plug 31, the needle passes through outlet port 28 and coaxially into catheter tube 29.

Once the catheter is in place, and one then desires to transfuse blood or any other fluid into the patient, stopper 27 is removed as shown in FIG. 17, and the fluid line 32 from a fluid supply 33 is coupled to the mouth of funnel 26. At this point one removes the needle and the syringe, and fluid from the supply then flows into the vein.

Because of its configuration, the catheter disclosed herein does not require a long needle in order to enter a vein, and it is therefore possible to use a regular sampling needle as a tutor. Multi-samples of blood may be taken directly into test tubes without having to use standard syringes as intermediaries. Because no plug is pulled out when taking samples, no loss of blood is encountered when using the catheter.

The syringe tube acts as a view chamber for the catheter, thereby eliminating the need for a special view chamber to indicate whether the catheter is in place, and there is no need to remove the end of an intravenous device already set in place, in order to take blood samples.

It is to be noted that after blood has been drawn into a syringe of the type shown in FIGS. 1 to 7, the danger exists that through inadvertence or carelessness, one may then push the stem of the piston toward the wrong end - that is, toward closure 11. This action will produce a positive pressure causing a flow of blood mixed with anti-coagulant back into the vein of the patient. Should the anti-coagulant be toxic in nature, its injection into the patient may have adverse effects.

This drawback is avoided by installing a simple one-way security valve at the outlet of chamber 19. This valve is adapted to admit the flow of blood and anti-coagulant from chamber 19 into tube 10, but to prevent countercurrent flow. In practice, the valve may take the form of a flap 11D of elastomeric material, secured to closure 11 at the outlet chamber 19, as shown in FIGS. 3 and 7. This flap is caused to open when stem 12 is pulled out to create a suction force whereby blood is free to flow from chamber 19 into tube 10. But when stem 12 is pushed in to produce positive pressure, valve 11D closes to block the chamber passage.

The security valve is only necessary when an anti-coagulant is employed, but not otherwise. When the syringe is used for injection purposes, the valve is omitted.

While there have been shown and described, preferred embodiments of a hypodermic syringe for blood tests, in accordance with the invention, it will be appreciated that many changes and modifications may be made therein, without, however, departing from the essential spirit of the invention.

I claim:

1. A syringe assembly for drawing blood samples, said assembly comprising:

A. an open-ended cylindrical tube of transparent material,

B. a needle-pierceable closure secured to one end of said tube, said closure being formed of self-sealing

material and having a coupling shoulder attached to said end of said tube, a constricted neck extending from said shoulder and having an internal chamber communicating through a passage in said shoulder with said tube and a bulbous head extending from the neck,

C. a piston slidable in said tube from an initial position abutting said coupling shoulder and blocking the passage therein to seal said chamber to a final position adjacent the other end of said tube,

D. a stem telescoping in said tube and terminating in a handle outside of said tube at said other end of said tube, said stem being coupled to said piston and being detachable therefrom whereby after said piston is pulled by said handle to said final position drawing a desired amount of blood in said tube, said stem may be detached from said piston which then serves as a stopper, and

E. an applicator frictionally engaging said closure for filling said tube with a blood sample and being removable therefrom when the filled tube is to be transmitted, said applicator having a U-shaped yoke engaging said neck of said closure laterally,

said applicator being provided with an L-shaped, double-pointed needle whose junction is secured to said yoke, said needle having a lateral arm which penetrates said neck to enter said chamber and a longitudinal arm for injection.

2. An assembly as set forth in claim 1, wherein said closure is formed of rubber.

3. An assembly as set forth in claim 1, wherein said piston is formed in part of needle-puncturable self-sealing material.

4. An assembly as set forth in claim 1, wherein said tube is made of a disposable transparent plastic material.

5. A catheter cooperating with the longitudinal arm of the applicator in the syringe assembly as set forth in claim 1, said catheter comprising a funnel adjacent whose lower end is an outlet port coupled to a catheter tube and an inlet port in registration with said outlet port, said inlet port having a self-sealing needle-penetrable plug receiving the longitudinal arm of said applicator, the upper end of said funnel being provided with a removable stopper.

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