

July 27, 1954

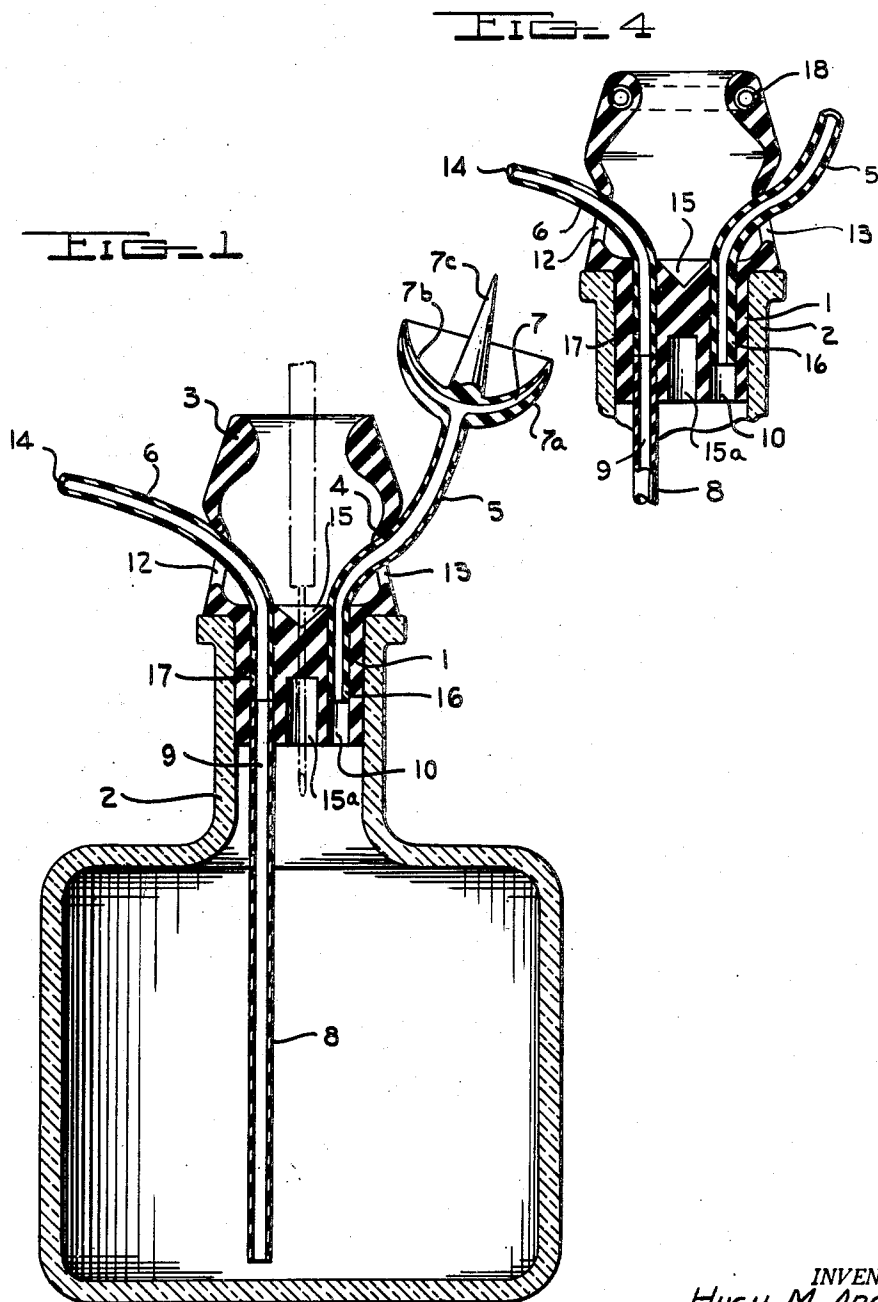
H. M. ARCHER

2,684,674

STOPPER FOR FLUID CONTAINERS

Filed May 28, 1951

2 Sheets-Sheet 1



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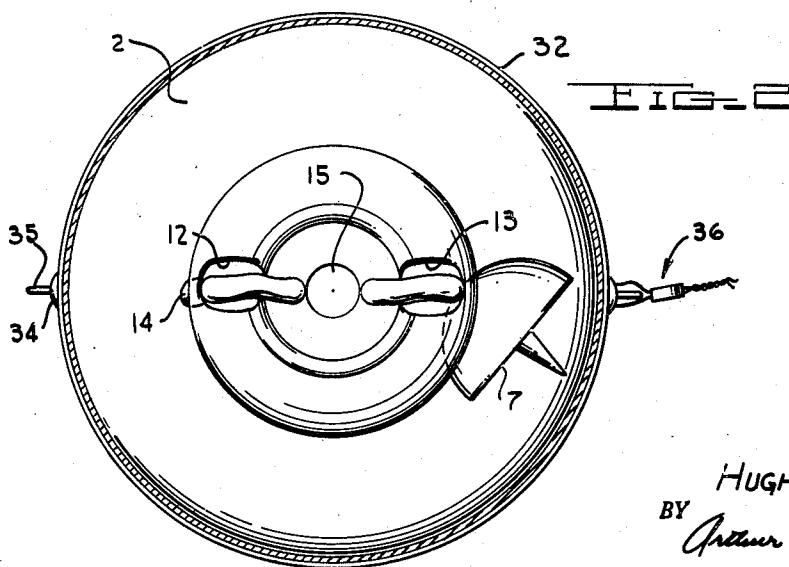
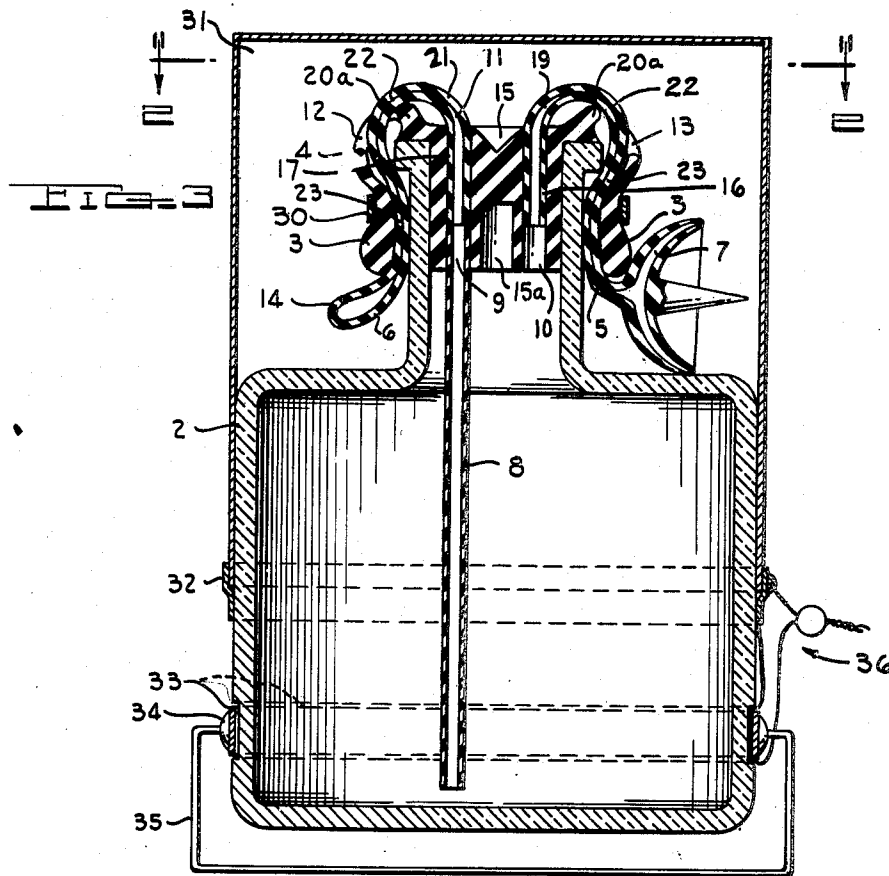
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2 Sheets-Sheet 2



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STOPPER FOR FLUID CONTAINERS

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Application May 28, 1951, Serial No. 228,730

10 Claims. (Cl. 128—214)

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The present invention relates to fluid containers, and particularly to such containers intended for use in operations which involve observance of sterile techniques as, for example, containers used in the collection, handling, processing and storage of blood plasma and whole blood. The present invention is particularly applicable to bottles and bottle closures or stoppers which permit either filling or emptying of such bottles without displacement of the stopper from the mouth thereof. Stoppers embodying the present invention permit a readily controlled access to the contents of the container without violation of sterile procedures, the stoppers also permitting the entry of air or other gases and fluids into the container in accordance with the approved techniques practiced by technicians using such containers in accordance with recognized sterile procedures.

One embodiment of the present invention provides a container of the type customarily used by the medical profession in handling, storage and processing of whole blood and other fluids such as plasma, vaccines, serums and the like, which are intended for use in the treatment of various diseases, ills or ailments.

In the disclosure of the invention hereinafter set forth, such applications of the invention are particularly discussed but it is to be specifically understood that the improvements in containers and manipulatable stoppers therefor as taught in the present disclosure may be applied to other types of containers and stoppers therefor. Such disclosures shall not be construed as limiting the scope of the present invention except as required by the pertinent provisions of the patent laws.

The closure or stopper for such containers when used, for example, in handling and processing whole blood must serve multiple purposes.

(1) It must provide a barrier against the unintended escape of blood from the bottle and must also provide a barrier to prevent the entry of unwanted materials into the container. (2) It must provide a means for the ready insertion of a hollow needle through which whole blood may be readily introduced directly into the sterile container during the bleeding of the donor. (3) It must provide a means for readily inserting a hollow needle for the removal of the blood directly from the sterile container into the infusion apparatus at the time of infusion of the blood into a recipient. (4) It must permit controlled entry of air into the container at the time of recipient infusion to assure a regular flow of blood from the bottle through the infusion apparatus. (5)

The air entry port must be maintained in a closed condition until the container is to be used either to supply or to receive blood. In the case of an empty container it sometimes is customary to evacuate the container prior to its use to facilitate the flow of blood into the container during bleeding. In this instance, entry of air into the container during the storage period and prior to use of the container must be prevented.

One of the features of the present invention is the provision of a stopper which combines a plug and valving mechanism in an integral device, thus providing for closure of the access port of the container and permitting controlled communication with the interior of the container through flexible tubular members extending through the plug element of the stopper. Heretofore it has been a common practice to provide plug type stoppers and separate clamping devices for each tube which extends through such a stopper. Such conventionally used clamping devices usually are formed of metal. Corrosion of such devices and the difficulties in securing proper sterilization of such devices make it desirable to eliminate such clamping devices. Conventional types of mechanical clamps make it difficult to maintain sterile conditions because the chances of contamination are increased because of the difficulty in securing positive sterilization of all parts of such devices. Since such clamps are separable devices, they frequently become lost or misplaced.

Using the conventional types of separate mechanical clamps, it is difficult for the operator to be sure that the clamps are properly adjusted to effect complete closure of the tubes. As distinguished from the prior clamping devices the present invention affords a clamping element in which the force applied on the tubes is a direct function of the materials employed, thus eliminating the possibility of operational error in the use of the device. The device of the present invention also assures that the efficiency of the clamping action will be readily observed by casual visual inspections.

The device of the present invention also provides a positive clamping action at a plurality of points along the length of each tube, thus eliminating variance in the clamping action which may occur when using conventional clamps in which the clamping pressure is applied in but single localized areas on the tubes.

It is therefore an object of the present invention to provide a fluid container in which a novel plug and valving element is formed as an integral

part of a stopper or closure which permits access to the interior of the container through a flexible tube inserted through the plug element, the valving element providing means for selectively opening or closing the entry to the container through said tube.

Another object of the present invention is to provide a novel plug type stopper or closure for fluid containers which utilizes an integral valving element to control inlet to the container and which also provides a supplemental storage unit affixed thereto which may be used to provide a sample of the fluid within the container without danger of contamination of the contents thereof, or to supply materials to be added to the fluid in the container.

Another object of the present invention is to provide a simple and efficient closure or stopper for fluid containers wherein a guide means is provided to facilitate the ready insertion of a hollow needle therethrough to establish communication with the interior of the container under sterile conditions.

A further object of the present invention is to provide a container having a closure thereon which particularly adapts it for use in the handling, storage and treatment of blood, plasma, serums, vaccines and the like under prescribed sterile conditions and in which provision is made to permit filling the container, sampling and testing of the contents thereof or the emptying of the container without affecting the sterile conditions obtaining therein and in which provision is made to assure a positive closure of the ingress or egress passages when desired.

It is a further object of the present invention to provide a container adapted for use in procedures performed under sterile conditions and in which the closure or stopper provides ingress or egress passages which may be opened or closed by clamping means formed as an integral part of said closure or stopper without removing the closure or stopper from the container.

Other objects of this invention will appear in the following description and appended claims, reference being had to the accompanying drawings forming a part of this specification wherein like reference characters designate corresponding parts in the several views.

In the drawings:

Figure 1 is a mid-sectional view of a container in the form of a typical blood collecting bottle embodying the present invention and in which the plug and valving mechanism which forms the stopper or closure of the bottle is shown mounted in the mouth of the bottle;

Fig. 2 is a top plan view of the container as shown in Fig. 3 with the enclosing cap shown in section taken substantially on the line 2—2 in the direction of the arrows, Fig. 3;

Fig. 3 is a mid-sectional view similar to Fig. 1 but showing the closure or stopper manipulated to seal the container and showing an enclosing cap or cover overlying the said closure or stopper and secured to the body of the bottle; and

Fig. 4 is a fragmentary view in mid-section of a portion of a neck of a blood collecting bottle having a closure or stopper therein which is a modified embodiment of the present invention.

Before explaining the present invention in detail it is to be understood that the invention is not limited in its application to the details of construction and arrangement of parts illustrated in the accompanying drawings, since the invention is capable of other embodiments and of being practiced or carried out in various ways.

Also, it is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation.

Referring to Figs. 1 and 2 of the drawings, the body 1 of the closure or stopper is shown inserted in the mouth of a conventional blood bottle 2. A cylindrical sealing member 3 and a web 4 are attached to the body 1 of the said stopper. In a preferred construction, the closure or stopper is formed of vulcanized rubber or a similar resilient material.

As shown in the drawings, the sealing member preferably consists of an enlarged bead or torus ring 3 carried by the web 4 and is shown in Fig. 1 in the position which it occupies when the flexible access tubes 5 and 6 are in their unfolded and unclamped positions. The bead or torus ring 3 acts to reinforce the upper edge of the web 4 and reduces the danger of tearing the web. It also increases the pressures exerted to effect the resilient clamping action on the tubes 5 and 6 when the bead or torus ring 3 is stretched and rolled downwardly over the neck of the bottle 2. This movement turns the bead or torus ring 3 inside out as it is moved into the position shown in Fig. 3. When in the position shown in Fig. 3, the bead or torus ring 3 of the sealing member exerts a resilient clamping action on the flexible tubes which are folded downwardly over the neck of the bottle 2 and presses the tubes against the outside of the neck of the bottle 2. The flexible tubes are collapsed and held in the closed position by said stretched bead or torus ring 3.

This construction of the bead or torus ring 3 is a preferred embodiment of the present invention and has many desirable features which recommend it for use in all instances where sterile conditions are to be maintained within the container. Other forms of web and bead may be employed, however, as long as the rim and web possess sufficient strength to withstand the strains imposed upon it and to exert the desired clamping effect on the flexible tube members when moved into clamping position.

As shown in the drawings, the web 4 is provided with apertures 12 and 13 in its side walls. A flexible tube 6 extends from the interior of the container through the body 1 of the stopper and then continues through the aperture 12 in the web 4. A flexible tube 5 extends from the interior of the container through the body 1 of the stopper and thence through the aperture 13. It will be noted by reference to Fig. 1 that when the tubes 5 and 6 are not engaged by the bead or torus ring 3 of the sealing member they extend upwardly through the said apertures 12 and 13 and thus are open throughout their exposed lengths for communication with the interior of the bottle. The apertures 12 and 13 formed in the web 4 are located at points adjacent a thickened upwardly extending portion 20A formed on the body of the stopper 1. While I have shown the use of two flexible tubes and two apertures, it is to be understood that any desired number of tubes may be used and that sufficient apertures will be provided in the web 4 to accommodate the number of tubes to be employed.

The action of the bead or torus ring 3 of the sealing member and the web 4 when moved to the position shown in Fig. 3 is to effectively shut off and seal the tubes 5 and 6. When the tubes 5 and 6 are in the position shown in Fig. 1 they are out of contact with the thickened upwardly extending portion 20A. When, however, the tubes 5 and 6 are folded by the action of the bead or

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torus ring 3 of the sealing member as shown in Fig. 3, the portion 20A provides a reaction point bearing on the tubes 5 and 6 which permits resiliently applied pressures to be exerted on the said tubes 5 and 6 to assure their collapse and effective closure and sealing.

As shown in Fig. 3 the improved closure or stopper of the present invention assures a complete clamping of the tubes at at least three major points along their lengths as indicated generally by the numerals 21, 22 and 23. The point 21 is located adjacent the top of the body 1 of the stopper. The point 22 is located adjacent the point of contact between the wall of the tubes and the portion 20A. The point 23 is located between the outer surface of the neck of the bottle 2 and the inner surface of the inverted torus or bead 3 on the sealing member.

It is contemplated that there will be instances where certain of these pressure exerting points may be safely eliminated but the use of the three pressure exerting points as here shown provides an adequate margin of safety to assure a positive sealing of the tubes 5 and 6 under all normally anticipated conditions. It is to be understood therefore that the number of such points of pressure application may be reduced or enlarged as may be required to meet the particular operational conditions under which the container is likely to be used.

As shown in Fig. 1, the end of tube 6 is preferably sealed as at 14. Attached to the end of tube 5 is a pump sac 7 which is the subject of my copending application, Serial No. 264,023, filed December 29, 1951. The size and shape of the pump sac 7 preferably are so designed and constructed with relation to the top shoulder portion of the bottle 2 that it will lie on the upper surface of the top shoulder of the bottle and be retained entirely within the circumference of the body portion of the bottle. This facilitates encasing the entire stopper and neck portion of the bottle in a suitable enclosure such as the removable cover 31.

The ends 16 and 17 of the tubes 5 and 6 are inserted through holes in the body 1 of the stopper as indicated at 9 and 10. The depression indicated at 15 serves as a guide point to aid the technician when inserting the hollow needle shown in phantom, Fig. 1, to cause the needle to emerge in the portion indicated at 15a, thus making it possible to insert the needle readily through the relatively thin portion of the body 1 provided between the guide depression 15 and the portion 15a.

The bleeding process for the collection of whole blood when using a container and stopper embodying the present invention is carried out as follows:

With the body 1 of the stopper inserted as shown in Fig. 1 and with the tubes 5 and 6 in place with their endings as shown at 14 and 7, the technician inserts the hollow needle shown in phantom, Fig. 1, through the body 1 of the stopper using the depression 15 as a guide. Attached to the hollow needle is any desired type of conventional apparatus (not shown) to accomplish the bleeding of the blood from the donor. The bottle is inverted from the position shown so that the air vent tube 8 will vent the air from the bottle without permitting the blood to flow from it as an outlet from the bottle. If the technician wishes to collect the blood by the so-called "gravity" process, the end 14 of tube 6 is either snipped off as with a pair of scissors, or the end

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14 is pierced with a hollow needle to permit the escape of the air displaced by the incoming blood.

On the other hand, if the process preferred by the technician is the so-called "vacuum" process, the closed end 14 of tube 6 is left intact. In this process the bottle is usually evacuated prior to use and as supplied is sealed against the admission of air. The less than barometric pressure maintained in the bottle exerts a suction which draws the blood from the donor and into the bottle and tends to effect a faster bleeding rate.

When sufficient blood has been drawn into the bottle, the hollow needle is withdrawn from the stopper. The resilient body of the stopper immediately seals the puncture therein when the needle is withdrawn.

The use of the herein disclosed container and stopper during the infusion process is as follows:

The hollow needle (shown in phantom, Fig. 1) used to gain access to the contents of the bottle is inserted through the body of the stopper at 15 or for larger blunt needles, access can be obtained by snipping the tube 6 as at 19, Fig. 3, and inserting the hollow needle through the aperture 10 provided in the stopper. This aperture can be made in any desired size, thus it may be made large enough to accommodate any conventional type of gross clot filter either incorporated as a part of the hollow extraction needle, or as a part of the stopper, so that clots in the contents of the bottle are not permitted to enter the infusion apparatus and clog the flow of blood into the veins of the recipient. The bottle is then inverted and supported by any suitable conventional means at the desired height above the recipient according to the wishes of the technician administering the blood. The last step necessary before the blood can flow freely from the bottle is the provision of air access to the bottle. This is easily accomplished by the present invention by either opening the tube 6 at, for example, point 11, Fig. 3, or by inserting into the tube 6 at 11 a hollow needle through which the air may enter the bottle. At the discretion of the technician any conventional type of air filter may be inserted into the tube or attached to the hollow needle through which the air is entering to prevent gross contamination of the contents of the bottle.

It is desirable to provide a member 30 which preferably is in the form either of a tape or of a rigid or resilient band which is placed on the outside surfaces of the web 4 at a point immediately above the bead 3 as shown in Fig. 3. This serves the two-fold purpose of assuring that the clamping action of the bead 3 has not been impaired and of warning the user in the event that there has been a tampering with the stopper. It also is desirable in certain instances to assure the integrity of the contents of the container to provide a cap 31 for covering the entire stopper and neck portion of the bottle. This is preferably formed of a transparent material but may, if desired, be formed of a non-corrosive metal of suitable thickness. The cap 31 may be held in place on the bottle 2 in any desired manner, such for example as an attaching adhesive tape 32 which may be sealed in any desired manner to prevent displacement of the cap 31. The attaching tape 32 and cap 31 may be further sealed to reveal by visual inspection any tampering with the container and its contents by providing a conventional type of metal seal 36 which may be attached between an encircling band 33 and

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the cap 31. Bands 33 are usually provided on such bottles and are provided with bail sockets to which is attached the bail 35 which permits hanging of the bottle in an inverted position during the infusion process.

It is desirable when using such containers for blood to provide a small sample of the blood from the container for typing and reaction tests. For this purpose I have provided the tube 5 through which such samples may be readily drawn into the flexible pump sac shown at 7. Such sample may be taken at the time of filling the container or it may be taken just prior to the use of the filled container. In either instance, the sample is taken without impairing the sterile condition of the contents of the container. After the sampling has been completed, the blood may be retained in the pump sac and not returned to the container. Thus the sampling is completed without impairing the sterile condition of the contents of the container. The blood in the pump sac may be withdrawn by puncture of the pump sac diaphragm in any desired manner. In some instances a supplementary material such as a dextrose solution may be added to the contents just prior to its infusion in a patient. Where this is desired, the pump sac 7 is filled with such supplementary material before the container is filled with blood and is emptied into the container just prior to its use. This is readily accomplished by releasing the clamping pressure on the tube 5 and collapsing the filled pump sac 7.

When the entire bleeding and sampling operation is complete the flexible tubes 5 and 6 are clamped shut by forcing the cylindrical sealing member 3 down over the neck of the bottle 2. In doing this it will be seen that the flexible tubes 5 and 6 are folded and compressed as previously described to effectively shut the said tubes, without the necessity of using separate auxiliary clamping devices.

In those instances in which the sample of the contents of the bottle has been placed in the pump sac 7 prior to the closure of the tube 5, the member 30 probably will be left in position to hold the tubes closed so as to prevent any return flow of the contents of the pump sac 7 through the tube 5 and into the bottle 2. In this instance, access to the contents of the bottle can be had through the exposed top portions of the tubes as, for example, at the points 11 and 19.

Although the clamping action in the present embodiment of the stopper is obtained through the use of a resilient material such as rubber, a similar action can be obtained when using flexible but relatively non-resilient materials. This is accomplished by the modified embodiment of the present invention as shown in Fig. 4, in which a spring 18 is incorporated in the enlarged bead portion of the web 4. The spring 18 preferably is in the form of an endless coiled spring as shown or any other form which will accomplish the same result. Except for the addition of the spring 18 to the bead portion as shown, the structure and operation of the parts is the same as previously described in connection with the embodiment shown in Figs. 1-3 inclusive. The use of the spring 18 is particularly recommended if the resilient forces developed by the materials used in forming the bead are not sufficient to provide the required clamping action on the tubes 5 and 6.

It is apparent from the foregoing that I have made it possible through the invention of the

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container as described herein to provide a container for the collection of whole blood which is completely sealed to maintain sterile conditions within the container and to permit evacuation of the container to lower the pressures therein. Thus the same container may be adapted to either the "gravity" or "vacuum" process of bleeding at the option of the technician. The flexible access tubes which comprise a part of the stopper make it possible to have a readily controllable access to the contents of the container at all times without impairment of the sterile condition of the container.

The stopper may be readily sealed to warn of any tampering with the container and may be fully protected by the removable cap element here shown. The use of the pump sac 7 assures the continued attachment of the sample to the container in which the sampled material is held. Thus confusion as to sample identity is eliminated. The pump sac 7 also permits sampling of the contents of the container without impairment of the sterile conditions obtaining therein and likewise may be used if desired as a reservoir of supplemental materials which may be readily added to the contents of the container without affecting the sterile conditions therein.

Having thus described my invention, I claim:

1. A fluid container comprising a bottle having a body portion, a shoulder, a neck extending upwardly from said shoulder and terminating in an open mouth, a stopper comprising a body portion inserted into the said open mouth and having an upwardly extending flexible web secured thereto, a plurality of flexible tubes each extending through the said body portion of said stopper to establish communication with the interior of the bottle, each tube also extending through an aperture in said web, one of said tubes terminating in a closed pump sac lying outside the neck of said bottle, said pump sac being so proportioned with relation to the dimensions of the shoulder of said bottle that the said pump sac may be retained on said shoulder inside the circumference of the body portion of said bottle and a clamp carried by said web and adapted, upon folding of said web, to engage the neck of said bottle and simultaneously fold and close said flexible tubes.

2. A fluid container as claimed in claim 1 further characterized in that a removable enclosing cap is secured to said bottle and overlies the neck, stopper and shoulder of said bottle to thereby enclose said stopper, flexible tubes and pump sac.

3. A stopper for bottles comprising a plug portion, a web depending upwardly from the periphery of said plug portion, a plurality of flexible tubes extending through said plug portion and through apertures in said web, a clamping member comprising an endless coil spring carried by said web, said web and clamping member being adapted to fold downwardly over a neck on said bottle for clamping and shutting said tubes between the neck of said bottle and said clamping member.

4. A container adapted for handling, storing and processing fluids in accordance with sterile techniques and comprising a fluid receptacle having an entry port closed by a resilient stopper having a body portion tightly fitted in the said port, a flexible web secured at one edge to the upper periphery of said body portion and having a resilient bead forming the terminal edge thereof, an aperture in said web adjacent its point of

attachment to the body of said stopper, a flexible tube extending into said receptacle through the body portion of said stopper at a point lying inside the line of attachment of said flexible web to the body portion of said stopper and extending through the said aperture in the wall of said flexible web to a point beyond the outer circumference of said resilient bead, thereby permitting flexing and clamping of said tube between the outside surface of said receptacle and said resilient bead upon folding of said web and movement of said resilient bead into engagement with the surface of said receptacle adjacent said entry port.

5. A container as claimed in claim 4 further characterized in that a cap is detachably secured to the outside surfaces of the fluid receptacle and overlies and encloses said stoppered entry port, stopper and flexible tube.

6. A container as claimed in claim 4 further characterized in that a second flexible tube is provided and extends through said flexible web and said stopper to provide communication with the interior of said container and a flexible pump sac is secured to the end thereof outside of said container.

7. A container as claimed in claim 6 further characterized in that the entry port, flexible tubes and pump sac are covered by a removable cap secured to the container.

8. A blood container stopper comprising a body member having a pair of holes therein, a first flexible tube having one open end and one closed end and extending through one of said holes and out of said stopper with the closed end of said first tube extending out of said stopper, a second tube extending through the other of said holes and out of said stopper and having an open end in communication with the inside of said container and a combination blood collection and storage member affixed to the other end thereof outside of said container, and a guiding means provided in the body member of said stopper to guide and aid in the insertion of a needle through said stopper.

9. A bottle stopper having an apertured upwardly projecting lip adapted to be folded downwardly over the neck of a bottle, a flexible conduit extending through said stopper providing fluid communication between the upper and lower sides thereof, one end of said flexible conduit extending through an aperture in said lip so that when said lip is folded downwardly over the neck of a bottle said flexible conduit will be constricted under said lip preventing fluid communication through said conduit.

10. The combination of a plug for insertion into an open mouth, a flexible tube extending through said plug, an expandable hollow cylindrical extension attached to the accessible end of said plug, an aperture in said extension to permit passage of said flexible tube through the wall of said extension at a point adjacent the confluence of said plug and said cylinder, said expandable hollow cylindrical extension being proportioned to permit the inversion of said hollow cylinder over the outside of a wall defining said open mouth thereby to subject said flexible tube to a compressive, compressive bending, and folding pressure to effect its collapse and shut said tube against flow therethrough.

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