

Oct. 1, 1963

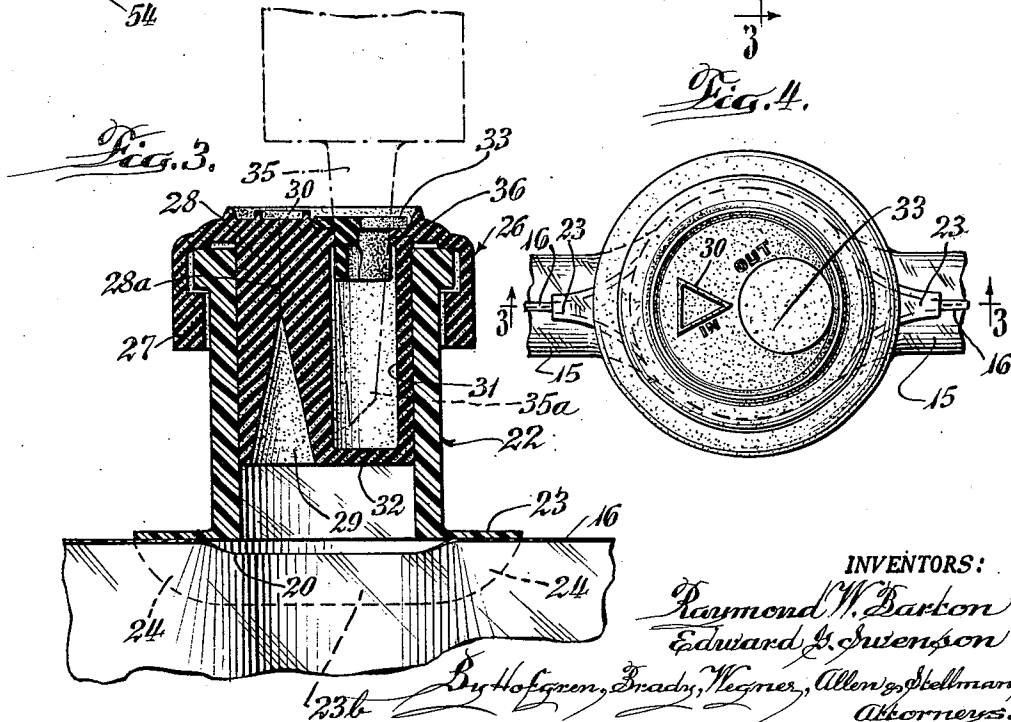
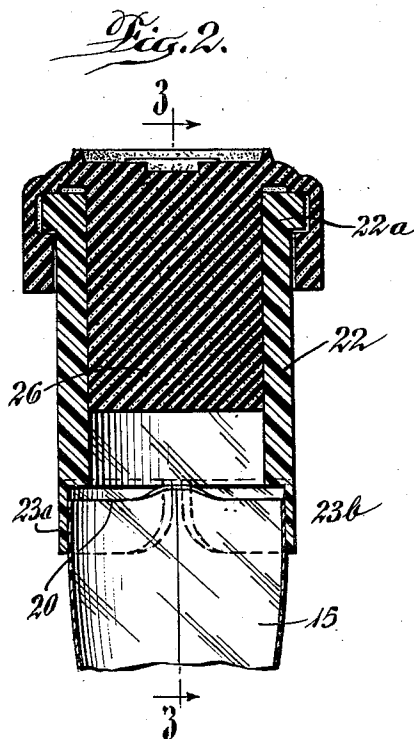
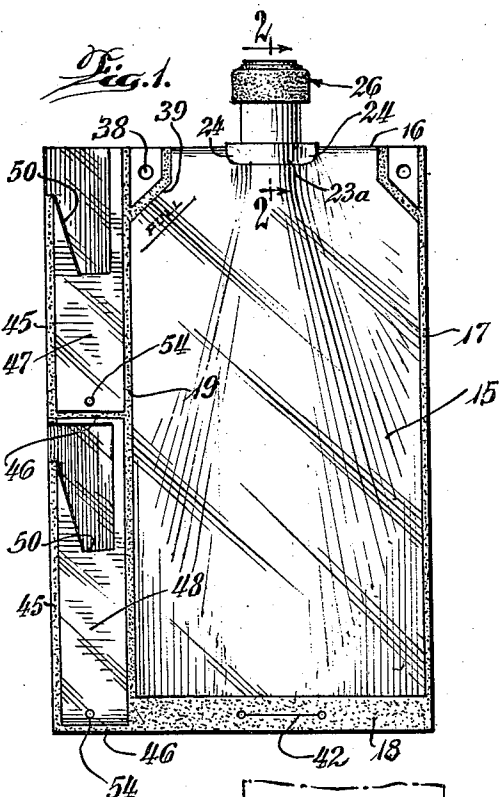
R. W. BARTON ETAL

3,105,613

BLOOD CONTAINER

Filed May 9, 1960

2 Sheets-Sheet 1



INVENTORS:

Raymond W. Barton  
Edward G. Swenson

By Hofgren, Brady, Wegner, Allen, & Stellman,  
Attorneys.

Oct. 1, 1963

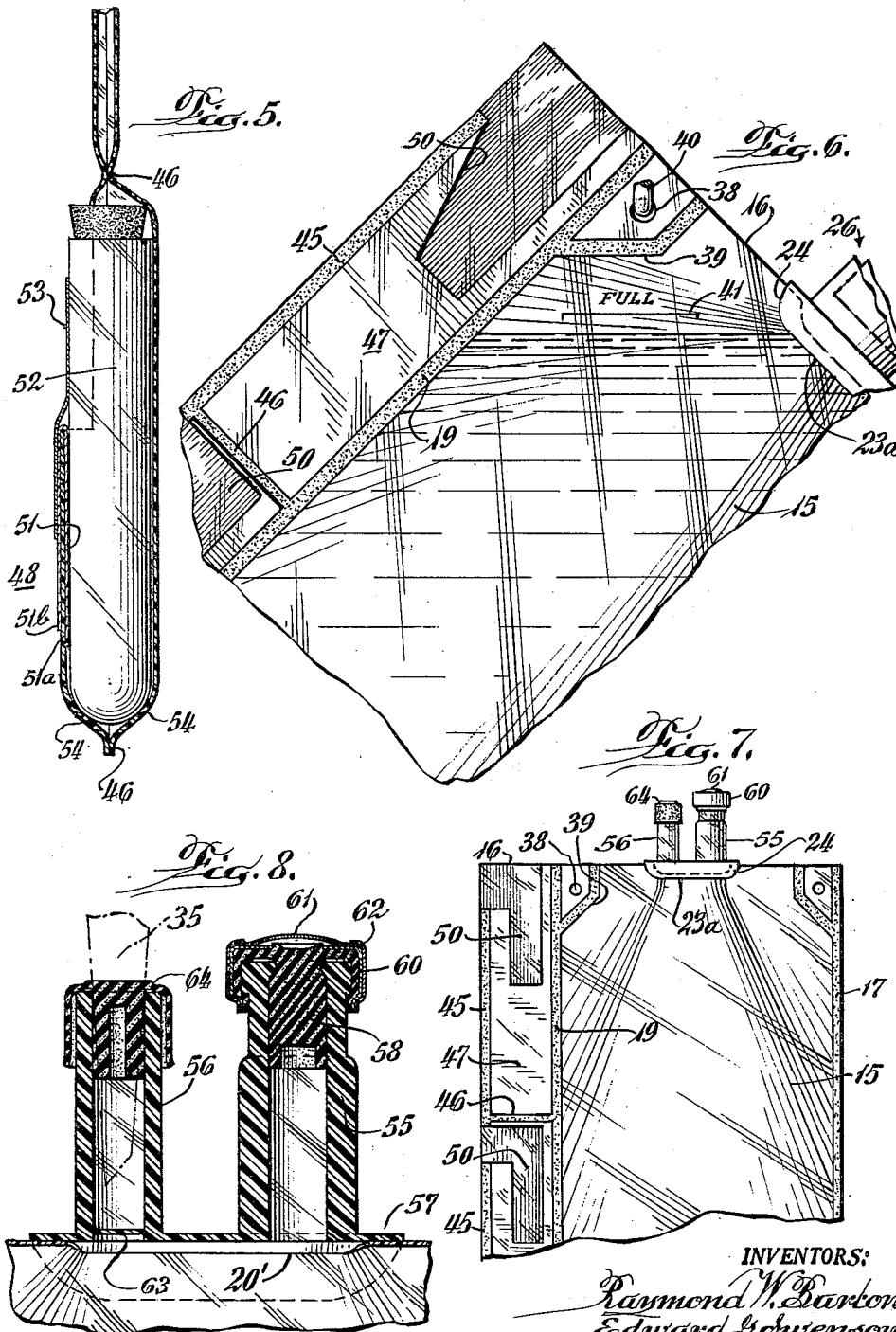
R. W. BARTON ET AL

3,105,613

BLOOD CONTAINER

Filed May 9, 1960

2 Sheets-Sheet 2



INVENTORS:

Raymond W. Barton  
Edward A. Swenson

By Hoffgren, Brady, Hegner, Allen & Hellman  
Attorneys

1

3,105,613

## BLOOD CONTAINER

Raymond W. Barton and Edward G. Swenson, Evansville, Ind., assignors to Don Baxter, Inc., a corporation of Nevada

Filed May 9, 1960, Ser. No. 27,769

7 Claims. (Cl. 222-81)

This invention is concerned with a plastic container for the collection, storage and dispensation or administration of blood, or the like.

The infusion to a patient, of blood which has been collected and stored for a period of time, rather than direct transfusion from a donor, has been known for a long time. In the past, glass containers have been used for the collection, storage and administration of the blood, although in recent years several types of collapsible plastic containers or bags have been developed. This invention is concerned with improvements in such plastic containers, and particularly in the inlet and outlet connector structures and in auxiliary features relating to the filling of the container and to the pilot tubes in which samples are collected for typing and the like.

One feature of the invention is the provision of a liquid storage and dispensing container comprising a flexible plastic container having an outlet structure including means defining an outlet passage closed by a rupturable diaphragm, the passage having a surface which seals with a spike of an outlet connector upon insertion thereof to a depth less than necessary to rupture the diaphragm. This is important to insure that the liquid in the container does not leak out around the connector spike during insertion, particularly as a certain amount of pressure must be exerted on the container when inserting the connector through the diaphragm tending to force the liquid out.

Another feature is that the collapsible plastic bag has an opening in the wall thereof, a neck is connected with the opening and has a skirt overlying and sealed with the plastic bag wall, and a stopper closes the neck. The stopper may have provision for both inlet and outlet passages for filling and emptying the container.

A further feature is the provision of a modified filling and emptying arrangement including an overlay with separate inlet and outlet necks, the overlay having planar sealing surface secured to the wall of the bag, and closure means for each of the inlet and outlet necks. The closure for the outlet is preferably a rupturable diaphragm located at the base of the neck.

Yet another feature is that the bag includes means defining a pocket for receiving a pilot tube, and in particular a pair of pockets are provided in longitudinal spaced relation along one side of the container, in which the pilot tubes are carried. At least one of the tubes is preferably secured in the pocket, as by an adhesive, so that it may not be removed without leaving an indication that this has occurred.

And a further feature is the provision of means for supporting the container during filling in a manner such that an observable meniscus is formed in the blood, as across a corner of a generally rectangular container.

Further features and advantages of the invention will readily be apparent from the following description and from the drawings, in which:

FIGURE 1 is an elevation of a container embodying the invention;

FIGURE 2 is an enlarged sectional view taken generally along line 2-2 of FIGURE 1;

FIGURE 3 is an enlarged sectional view taken generally along the line 3-3 of FIGURES 2 and 4;

2

FIGURE 4 is an enlarged fragmentary top plan view of the container of FIGURE 1;

FIGURE 5 is a fragmentary sectional view taken through the pilot tube receiving pocket;

FIGURE 6 is a fragmentary elevational view illustrating the filling of the container;

FIGURE 7 is a fragmentary elevation view of a modified form of the container; and

FIGURE 8 is an enlarged fragmentary section taken through the inlet and outlet structure of the container of FIGURE 7.

Blood for transfusions is often collected and stored for a period of time, and then used at a future date. The container in which the blood is stored must be sterile and generally contains an anticoagulant material. The previously used glass containers or bottles are assembled or packaged in an evacuated sterile condition so that the reduced pressure within the bottle will cause the blood from the donor to flow into it through a suitable filling apparatus, generally comprising a length of tubing with needles at either end, one of which is inserted in the arm of the donor and the other in or through a resealing stopper on the container. Following filling, a sample of the blood is tested to make sure it does not contain disease-bearing germs and the blood is refrigerated until it is needed. A pilot or sample tube with a small sample of the blood is attached to the container, preferably in a manner such that it cannot be removed without leaving an indication that this has occurred. Immediately prior to administration or transfusion, the blood in the pilot tube is checked for type to insure that it is not administered to a patient with a different blood type.

Plastic containers mentioned above have many advantages over glass bottles. The initial cost is less, they take a great deal less storage space when empty, and somewhat less space even after filling. They are much lighter, facilitating handling. They are not subject to breakage when dropped and they may readily be disposed of following use as by incinerating them.

Turning now to the drawings, the novel features of the present invention will be described in detail. In FIGURE 1, a plastic container 15 is illustrated. The container is preferably formed of a single sheet of suitable plastic material, as a polyvinyl chloride sheet material of the order of 0.015 inch thickness. The sheet is doubled on itself along fold line 16 and the contiguous surfaces sealed at 17, 18 and 19 to provide the closed blood receiving container. Seal 17 extends along one longitudinal edge of the container, seal 18 along the bottom (opposite fold 16), and seal 19, which forms the other longitudinal boundary of the container is spaced inwardly from the edge of the sheet. An opening 20 (FIGURES 2 and 3) is provided in the plastic material and has a generally oval shape centered on and extending along fold line 16. A neck structure 22 communicates with opening 20 in the wall of the container and provides for the inlet and outlet connections utilized in filling and emptying the container. The neck itself is of a suitable plastic material, as a polyvinyl plastic, and is generally cylindrical in cross section. At the lower end of the neck a skirt 23 is formed which has a reduced thickness and comprises two generally semicircular or arcuate portions 23a and 23b provided with extensions 24 which project beyond the wall of the neck proper. The skirt 23 overlays and is sealed with the wall of the container surrounding opening 20, the semicircular form and the extensions of the skirt conforming with and avoiding excessive deformation of the wall of the bag. The skirt 23 is secured to the plastic sheet before edge seals 17, 18 and 19 are made, so that an electrode or mandrel may be placed on the inner surface at the seal area.

A stopper 26 closes neck 22 and is provided with a

3

sleeve 27 which overlaps the outer surface of the neck and locks with an outwardly extending rib 22a at the upper end of the neck. Stopper 26 provides for the connection of both filling and emptying apparatus with the container. The filling apparatus, or blood donor set (not shown), normally includes a length of tubing having a needle at one end adapted for insertion in the vein of the donor and a second needle which is inserted through a resealing portion 23 of stopper 26 communicating with an inlet passage 29 extending partially therethrough. This area of the stopper is preferably indicated on the upper surface of the stopper, as by the triangular raised ring 30. During collection of the blood, the bag is placed below the donor and blood flows, as a result of venous pressure and gravity through the donor set by the bag. After the container is filled, the needle is withdrawn and the rubber stopper reseals as shown at 28a to prevent contamination of the blood or leakage.

An outlet passage 31 extends almost all the way through the body of the stopper and is closed at its lower or inner end by an integral, thin rupturable diaphragm 32. A small rubber plug 33 closes the upper end of inlet outlet passage 31 to prevent contamination prior to use. Blood administration equipment normally includes a connector device having a spike or pointed end portion as indicated in dashed lines at 35. The connector is in turn part of suitable flow measuring, regulating, and filtering apparatus, as may be desired. The spike end of the connector is pointed and tapered, and in most apparatus has a slot formed therein as indicated at 35a. While inserting the spike through rupturable diaphragm 32, it is necessary that a certain amount of pressure be applied to the container itself tending to cause a portion of the contents to be ejected through outlet passage 31 as the point of the connector ruptures the diaphragm. In order to avoid this occurrence, the outlet passage 31 is of such a diameter and length that the spike 35 of the connector sealingly engages the wall of the passage upon insertion thereof to a depth less than that necessary to rupture the diaphragm. This relation is effected in the disclosed embodiment of the invention by an inwardly extending rib 36 around the outer end of the outlet passage.

During filling of the container it is desirable that the quantity of blood extracted from the donor be accurately determined. With a flexible plastic container, this is rather difficult, as graduations may not be accurate and it is difficult to obtain an accurate view of the level of the blood in the container. It has been found, however, that if the extent of the surface of the liquid or blood is relatively small, a readily observable meniscus is formed which provides an accurate volume indication, if the container is hanging free so that its shape is not distorted. Accordingly, an aperture or hole 38 is provided in the wall of the container adjacent one of the corners thereof and spaced from the interior of the container by a sealed area 39. When the container is supported from this single hole, as by hanging the container over a hook 40, FIGURE 6, the container assumes a canted position and the surface of the blood occupies the relatively small dimension between seal 19 and fold 16, across the corner of the container, forming a suitable meniscus for observation. A graduation mark 41 may be provided to facilitate accurate filling of the container, and extends transversely across the corner thereof.

During administration, the container is preferably inverted and hung from a suitable support inserted through a slit 42 in the seal 18 in the bottom of the container. If desired, the administration of the blood may be accelerated by applying pressure to the container to force the blood through the outlet and administration apparatus.

As pointed out above, in the handling of blood collected and stored for future use, it is the usual practice that samples be provided to permit testing the blood for contamination and to allow typing immediately before use to insure that the blood is not improperly transfused into

4

a patient with a different blood type. For this purpose two pilot tubes may be provided with the blood collection container, and a sample of the blood is placed in each of the tubes at the time of collection. One is readily removable from the container and is checked shortly following the collection. The other is preferably securely fastened to the container in such a manner that it cannot be removed without leaving an indication, and remains with the container until the time of administration. With glass bottles it is a relatively simple matter to secure the pilot tube or tubes to the bottle as with a piece of adhesive tape. This cannot practically be done with a plastic container; and if the pilot tube is affixed to the outside of the bag it might, if broken, puncture the bag.

In accordance with the present invention, the plastic sheet material of which the container is formed is somewhat wider than required to provide the capacity for the blood collection itself and the edge seal 19 is formed inwardly of the edge of the plastic material, leaving a portion of the doubled material extending therebeyond. The two plastic sheets which make up this extending portion are sealed together at spaced areas 45, along the edge thereof and at 46, transversely to the seals 45 forming a pair of longitudinally spaced pockets 47 and 48 which are designed to receive the pilot tubes, as shown in FIGURE 5. One of the plastic panels which make up the pockets 47 and 48 is cut away as shown at 50 to facilitate insertion and removal of the pilot tubes.

The blood bags may be supplied by the manufacturer without pilot tubes, which are then inserted later by the user. In this situation it is necessary to provide some means for preventing the walls of the pockets 47 and 48 from sticking together during autoclaving. In FIGURE 5, a strip of paper or slip sheet 51 is shown inserted in the pocket 48. The surface 51a of the slip of paper is preferably coated with an adhesive and adheres to the inner wall of the pocket. The paper strip is preferably of sufficient length that its upper end 51b may be folded down over the outside of the pocket, below opening 50 and adhered to the outer surface of the plastic. Pilot tube 52 is provided with a label 53 which extends downwardly over the flap 51b and may be secured thereto so that the pilot tube may not be removed without tearing the label. Insertion of the adhesive tape into the pocket may be facilitated by moistening it with alcohol which temporarily inhibits the adhesive action and lubricates the paper slip. The paper 51 is preferably moisture resistant in order to prevent damage during autoclaving and should be somewhat smaller than the pocket in width to compensate for shrinkage of the plastic during autoclaving.

Holes 54 are provided in the pockets adjacent the lower seals thereof to permit drainage of accumulated water following the autoclaving process. These holes may be provided in one or both of the pocket walls.

A modified inlet and outlet connector structure is illustrated in FIGURES 7 and 8. In this arrangement, separate necks 55 and 56, of plastic material, are molded integrally with an overlay sealing surface or skirt 57 which extends generally transversely of the two necks. The surface 57, which is preferably planar, is heat sealed to the wall of the bag with the inlet and outlet necks in communication with the opening 20 therein. Inlet neck 55 is provided with a plug stopper 58 of resealing resilient material, as rubber, which has a sleeve portion extending around the outside of the upper portion of the neck and secured thereto by a clamping ring 60. A metal disc 61 protects the upper surface of stopper 58, which is usually sterile, and is held in place by tear-away ring 62 which is removed at the time of filling to permit insertion of the filling needle through the stopper.

Outlet neck 56 is closed at its inner end by an integral rupturable diaphragm 63 and the outer end of the neck is closed by an easily removable sleeve stopper 64. The dimensions of outlet neck 56 in length and diameter, are

5

such that the spike portion 35 of the administration set connector seals with neck 56, upon insertion thereof to a depth less than that necessary for the pointed end of the connector to rupture diaphragm 63, as discussed above.

While we have shown and described certain embodiments of our invention, it is to be understood that it is capable of many modifications. Changes therefore, in the construction and arrangement may be made without departing from the spirit and scope of the invention as disclosed in the appended claims.

We claim:

1. A blood collection, storage, and dispensing container, comprising: two sheet portions of flexible plastic material sealed together to form a collapsible plastic bag having an inlet for filling and an outlet for emptying the bag; a first sealed surface of the container spaced inwardly from the edge of the sheet portions so as to form extensions on each of the two sheet portions outwardly of said first sealed surface; a second sealed surface generally parallel to the first sealed surface, spaced therefrom and sealing the two extensions together; a pocket defined by the extensions between the first and second sealed surfaces; a portion of one of the extensions being cut away to provide an opening; a strip of adhesive coated moisture resistant paper a portion of which is inserted in said pocket with the adhesive adhering to the inner wall surface of said extension; a further portion of the paper strip extending out through the pocket opening and folded over the outside of the pocket with the adhesive adhering to the outer wall surface of said extension; a pilot tube in the pocket, one end of said tube projecting through said opening; and a label extending along the length of said tube, part of which is attached to the pilot tube and part of which is secured to the portion of the paper strip on the outside of the pocket, whereby the pilot tube is held in the pocket and cannot be removed therefrom without tearing the label.

2. A blood collection, storage, and dispensing container, comprising: a collapsible plastic bag having two opposed walls of flexible plastic sheet sealed to each other around the major portion of the periphery of the bag, an inlet for filling the bag and an outlet for emptying the bag; extensions of the two walls projecting outwardly of at least one sealed surface; a second sealed surface generally parallel to said one sealed surface, spaced therefrom, and sealing the two extensions together to form a pocket having an opening at one end; a strip of adhesive coated moisture resistant paper a portion of which is inserted in said pocket with the adhesive adhering to an inner surface of one of the extensions; a further portion of the strip of paper extending out through the pocket opening and folded over the outside of the pocket; a pilot tube in the pocket, one end of said tube projecting through said opening; and a label extending longitudinally of said tube, part of which is attached to the pilot tube and part of which is secured to the portion of the paper strip on the outside of the pocket, whereby the pilot tube is held in the pocket and cannot be removed therefrom without tearing the label.

3. A blood collection, storage, and dispensing container for use with a pilot tube and adhesive label comprising: two sheet portions of flexible plastic material sealed together to form a collapsible plastic bag having an inlet for filling and an outlet for emptying the bag; a first sealed surface of the container spaced inwardly from the edge of the sheet portions; extensions on each of the two sheet portions outwardly of said first sealed surface; a second sealed surface generally parallel to the first sealed surface, spaced therefrom and sealing the two extensions together; a pocket defined by the extensions between the first and second sealed surfaces; a portion of one of the extensions being cut away to provide an opening; a strip of adhesive coated moisture resistant, paper a portion of which is inserted in said pocket with the adhesive adhering to the inner wall surface of said exten-

6

sion; a further portion of the paper strip extending out through the pocket opening and folded over the outside of the pocket with the adhesive adhering to the outer wall surface of said extension whereby a pilot tube may be inserted in said pocket with one end projecting through said opening and a label may be secured along the length of said tube with part of the same attached to the pilot tube and part secured to the portion of said paper strip outside said pocket, and the pilot tube cannot be removed from said pocket without tearing the label.

4. The structure as set forth in claim 3 wherein said bag includes an opening in which a neck is connected, an elastic stopper in said neck, said stopper including said inlet and outlet, said stopper being of substantial depth with an inner end located in said neck, said stopper outlet comprising a passage through said stopper and including a rupturable diaphragm closing said passage at a location adjacent the inner end of said stopper, said stopper having an annular, inwardly extending, elastic rib projecting radially into and partially closing the outer end of said passage; and a tapered, tubular spike of an outlet connector telescoped into said passage, said spike having an intermediate outer surface sealingly engaged with the elastic rib when a pointed end of said spike located in the stopper passage is at a depth less than that necessary to pierce the stopper diaphragm, said spike being movable axially in said outlet passage in sealed relation with said elastic rib for rupturing said diaphragm.

5. The structure of claim 3 in which said bag includes an opening in the periphery of said bag formed by folded wall portions and including said inlet and outlet, a relatively rigid, cylindrical neck sealed in communication with said opening by rigid skirts, said skirts being substantially semi-circular and integrally formed at the base of said neck and having narrow, converging terminal, rigid end portions projecting radially and transversely outward from opposite sides at the base of said neck, each of said terminal end portions being sealed to a portion of the bag edge adjacent the opening and maintaining said bag edge substantially rigid at said neck, said skirts including opposed, depending, arcuate skirt portions projecting axially beyond the base of said rigid neck and substantially parallel thereto, each of said arcuate skirt portions overlying and being sealed to a portion of one of the opposed bag walls adjacent said opening, and the respective end portions of each arcuate skirt portion extending radially beyond the neck and being integrally attached to one side of the converging terminal end portions, said skirts and neck maintaining said flexible bag walls in spaced relation to form a free drainage funnel at said bag opening.

6. A blood collection, storage, and dispensing container for use with a pilot tube and including a collapsible plastic bag of flexible material having an inlet for filling and an outlet for emptying said bag, and wherein said bag includes an opening in which a neck is connected, an elastic stopper in said neck, said stopper including said inlet and outlet, said stopper being of substantial depth with an inner end located in said neck, said stopper outlet comprising a passage through said stopper and including a rupturable diaphragm closing said passage at a location adjacent the inner end of said stopper, said stopper having an annular, inwardly extending, elastic rib projecting radially into and partially closing the outer end of said passage; and a tapered, tubular spike of an outlet connector telescoped into said passage, said spike having an intermediate outer surface sealingly engaged with the elastic rib when a pointed end of said spike located in the stopper passage is at a depth less than that necessary to pierce the stopper diaphragm, said spike being movable axially in said outlet passage in sealed relation with said elastic rib for rupturing said diaphragm.

7. A blood collection, storage, and dispensing container for use with a pilot tube and including a collapsible plastic bag of flexible material having an inlet for filling and an

7

outlet for emptying said bag, and in which said bag includes an opening in the periphery of said bag formed by folded wall portions and including said inlet and outlet, a relatively rigid, cylindrical neck sealed in communication with said opening by rigid skirts, said skirts being substantially semi-circular and integrally formed at the base of said neck and having narrow, converging terminal, rigid end portions projecting radially and transversely outward from opposite sides at the base of said neck, each of said terminal end portions being sealed to a portion of the bag edge adjacent the opening and maintaining said bag edge substantially rigid at said neck, said skirts including opposed, depending, arcuate skirt portions projecting axially beyond the base of said rigid neck and substantially parallel thereto, each of said arcuate skirt portions overlying and being sealed to a portion of one of the opposed bag walls adjacent said opening, and the respective end portions of each arcuate skirt portion extending radially beyond the neck and being integrally attached to one side

8

of the converging terminal end portions, said skirts and neck maintaining said flexible bag walls in spaced relation to form a free drainage funnel at said bag opening.

#### References Cited in the file of this patent

#### UNITED STATES PATENTS

|            |                     |               |
|------------|---------------------|---------------|
| Re. 24,251 | Kaplan et al. ....  | Dec. 4, 1956  |
| 723,606    | Jacobs .....        | Mar. 24, 1903 |
| 1,303,696  | McGregor .....      | May 13, 1919  |
| 1,702,974  | MacDonald .....     | Feb. 19, 1929 |
| 1,789,959  | Fedeler .....       | Jan. 27, 1931 |
| 2,524,365  | Smith .....         | Oct. 3, 1950  |
| 2,667,986  | Perelson .....      | Feb. 2, 1954  |
| 2,684,789  | Marchant .....      | July 27, 1954 |
| 2,780,225  | Barr et al. ....    | Feb. 5, 1957  |
| 2,784,716  | Broman .....        | Mar. 12, 1957 |
| 2,851,201  | Poitras et al. .... | Sept. 9, 1958 |
| 2,894,510  | Bellamy .....       | July 14, 1959 |