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APPARATUS FOR BLOOD COLLECTION AND METHOD OF USING THE SAME

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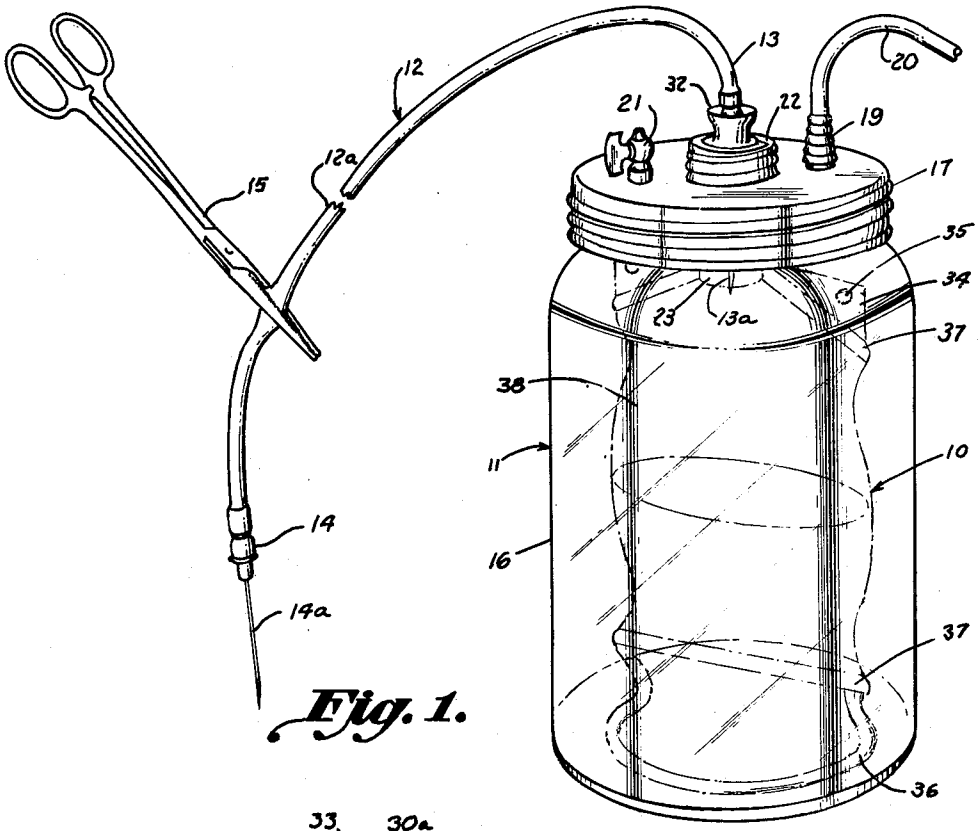

Fig. 1.

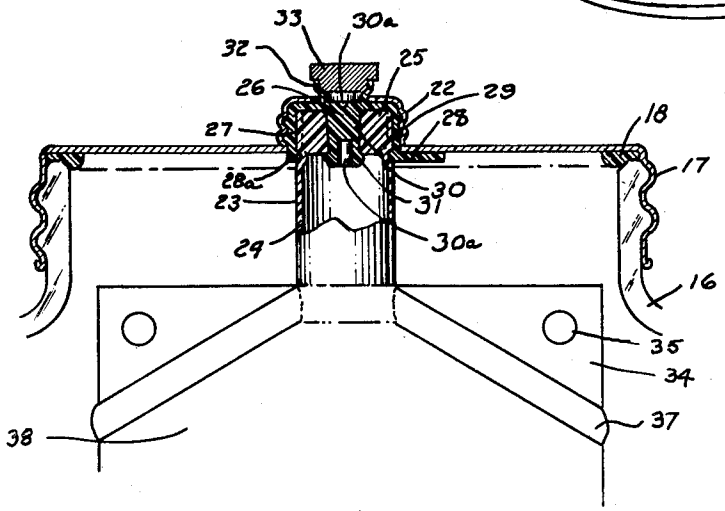

Fig. 2.

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APPARATUS FOR BLOOD COLLECTION AND METHOD OF USING THE SAME

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4 Claims. (Cl. 128—214)

This invention relates to an apparatus for blood collection and method of using same, and more particularly, to a collapsible container mounted in an evacuable housing and the method of using the same for blood collection.

In the past, blood collection apparatus has usually included a glass bottle as the storage vessel. Blood is removed from the body of the donor through a hypodermic needle inserted into a vein, the needle being connected to the storage bottle by means of flexible tubing. An outstanding advantage of a glass type container is that it may be evacuated prior to blood collection. Vacuum extraction of blood permits the use of a smaller puncture needle and tubing than that used in extraction at atmospheric pressure because the additional frictional losses resulting from the use of smaller tubing are compensated for by the vacuum. Vena-puncture of the donor with a small needle is such less painful than puncture with a large needle.

Notwithstanding the advantage of possibility of evacuation, glass containers are undesirable from the standpoint that they are easily breakable and are not adapted to fit into small or irregular spaces. In particular, the use of glass storage bottles is distinctly limited for military purposes. Transporting and storing them for battlefield use without breakage has brought about extensive investigation for a satisfactory substitute not subject to the aforementioned disadvantages. An expedient struck upon in the past to solve this problem is the use of a collapsible container for the storage of blood. The most commonly used type of collapsible container is manufactured from a plastic material. However, collapsible containers by their very nature are incapable of being previously evacuated so that the one advantage is offset by the corresponding disadvantage of reduced flow rates and larger puncture needle sizes.

This expedient has proved unsatisfactory for another reason, namely that the plastic materials used thus far have not proved impervious to the transmission of the vapor formed from the anti-coagulant solution contained in the blood storage container which is essential to properly preserve the blood. As a result, the plastic container is not capable of storage for any extended period of time and still maintain the anti-coagulant solution contained therein in suitable liquid form.

The presence of an anti-coagulant solution in the plastic bag has brought about other difficult problems. Since it is necessary to ascertain whether the anti-coagulant solution is in a proper liquid state prior to introduction of blood into the storage container, the container must be of a transparent nature. This necessarily limits the number of plastic materials which are available for use in the fabrication of such collapsible blood container. Still another problem brought about by the use of a plastic material in the fabrication of the storage container is that when the anti-coagulant solution is incorporated therein, the container must be sterilized by steam rather than any of the gas sterilization procedures now known to the art. Steam sterilization by necessity must be carried out at elevated temperatures generally in the range of from 230 to 250° F., so that the choice of plastic materials is further limited to those capable of withstanding temperatures in that range without being adversely affected.

By the apparatus and method of our invention, it is possible to use a collapsible container which is not subject to any of the foregoing disadvantages. Essentially the apparatus of our invention includes a collapsible container for blood collection and storage removably mounted in a housing capable of being evacuated when the container is mounted therein. Incorporated into the aforementioned container is a passage communicating to the atmosphere in which is mounted a self-sealing closure permitting introduction of anti-coagulant material into the container just prior to blood collection, the anti-coagulant material being derived from a separate but associated source. The method of our invention involves the utilization of the above apparatus in combination with the separate but associated source of anti-coagulant material in the collection and storage of blood.

It is, therefore, an object of our invention to provide an apparatus combining the foregoing advantages in the collection and storing of blood. A corollary object is to provide a method therefor. Other objects and advantages of our invention will be seen as the specification proceeds.

Our invention will be explained in conjunction with the following drawing, in which Fig. 1 is a perspective view of a blood collection system equipped with the apparatus of our invention; and Fig. 2 is an enlarged elevational view, partially in section, of the blood collection apparatus of our invention.

Referring to the drawing, Fig. 1 shows a blood collection apparatus including collapsible blood storage container **10**, evacuable housing **11**, and administration set **12**, interconnected and arranged for blood collection. In particular, one end **13** of flexible tubing **12***a* of collection set **12** is removably inserted into container **10**, the other end **14** being adapted to be inserted into a vein of a donor (not shown). To facilitate these insertions, the ends **13** and **14** of collection set **12** are provided with needles, **13***a* and **14***a*, respectively. Mounted on tubing **12***a* intermediate the ends thereof is some form of clamping means such as hemostat **15**, useful in controlling the flow of blood. Thus, a conduit is established between the donor and container **10** which is intended to store the transfused blood.

Container **10** is removably mounted in housing **11**, the arrangement of mounting being adapted to permit evacuation of housing **11** while permitting connection of set **12** to container **10**. Housing **11** is of a rigid nature, and may include, as in the embodiment pictured, a glass container **16** closed in airtight fashion with screw cap **17**. It is to be noted that housing **11** may take many forms, but it is desirable that at least a portion of housing **11** be transparent so that the rate of blood collection can be visually ascertained.

In the event the inexpensive and simple form of housing **11** shown in the drawing is used, the seal of container **16** by threadable mounting thereon of cap **17** is improved by the interposition therebetween of gasket **18**.

To permit evacuation of housing **11**, screw cap is provided with outlet fitting **19** to which is connected vacuum tubing **20** leading to a vacuum pump (not shown). Valved inlet **21** is also provided in cap **17** to permit destruction of the vacuum in housing **11** by venting.

As mentioned above, container **10** is removably mounted in housing **11** in a manner permitting evacuation of the housing yet permitting connection of set **12** to container **10**. This arrangement permits introduction of blood into container **10** while its walls are distended under

the influence of the vacuum inside housing **11**. For this purpose, an airtight seal must be established between housing **11** and that portion of container **10** external to housing **11** and through which blood is introduced.

Many expedients capable of achieving such a seal will be apparent to those skilled in the art. One such structure would include an integral peripheral flange about the outlet portion of the collapsible container, and means associated with the housing adapted to clamp such flange in an airtight fashion to the housing. However, we prefer a seal achieved by the simple expedient of threading.

For this purpose, cap **17** is provided with integral collar **22**. Collar **22** is internally threaded; thereby being adapted to removably receive externally threaded neck **23** of container **10**, and seal all but inlet passage **24** in neck **23** in an airtight fashion to housing **11**. To provide a more effective seal, neck **23** is of a semi-rigid nature permitting it to be tightly threaded into collar **22**. Thus, a vacuum condition may be maintained within housing **11** when container **10** is mounted therein, yet fluid from a source external to housing **11** can be introduced into container **10**.

In order to adapt container **10** to the collection of blood, passage **24** is provided with self-sealing means which permits the removal after transfusion of needle **13***a* which was inserted therein prior to blood transfusion while still preventing the introduction of foreign contaminants. In view of the fact that a needle if improperly inserted may puncture the plastic container, neck **23** is of substantial length, providing thereby a protective sleeve for needle **13***a*. In this connection it is desirable to have collar **22** of cap **17** offset upwardly from the surface of cap **17** so as to accommodate the length of neck **23** without the need of lengthening housing **11** to adequately house container **10** when the same is in an expanded condition.

To achieve the aforementioned design advantages, the structure shown in Fig. 2 is preferred. Referring specifically to Fig. 2, thermoplastic plug **25** is mounted in passage **24** of neck **23**. Plug **25** is adapted to fit snugly within neck **23**, and, in the preferred embodiment is immovably secured in its mounting by solvent sealing. Plug **25** is provided with axial passage **26** extending therethrough, permitting introduction of blood into container **10**. By solvent sealing, we refer to the use of liquid plasticizer materials adapted to dissolve adjacent portions of two assembled plastic elements, and upon drying, creating a tight union therebetween. In the embodiment shown, plug **25** is of a substantially stiff nature, thereby contributing to the stiffness of neck **23** especially desirable for achieving a firm member for threadable engagement with collar **22**.

As mentioned above it is desirable to close passage **24** with self-sealing means. For this purpose we prefer to close that portion of passage **24** located in plug **25** and designated **26** by means of a removable cap **27**.

Cup-shaped rubber cap, designated generally **27**, is removably mounted on neck **23** which is rendered substantially stiffer by the mounting of plug **25** therein. Cap **27** is provided with integral tab **28** extending from the lip portion of the cup-shaped body **29**. The lip portion of cup-shaped body **29** is provided with an inwardly extending annular flange **28***a* adapted to permit cap **27** to be mounted securely but removably on neck **23**, as can be seen from the indented portion of neck **23**. Integral with and in axial relation to the cup-shaped body **29** is inwardly extending stopper portion **30**. Stopper portion **30** of cap **27** is adapted to be removably inserted into passage **26**, providing an airtight closure therefor. The airtight closure is not only provided by the close fit between rubber stopper portion **30** and the wall of passage **26** in thermoplastic plug **25**, but also by annular lip portion **31** of stopper portion **30**. Lip portion **31** also cooperates with flange **28***a* to act as a guard against inadvertent displacement of cap **27**. The length of stopper portion **30** is sufficient to permit self-sealing of the puncture created when needle **13***a* of administration set **12** is inserted.

Inasmuch as the entire depth of stopper portion **30** is not required to provide the aforementioned self-sealing feature, recessed portions **30***a* are provided therein. The smaller thickness of stopper that has to be punctured as a result of recessed portions **30***a*, permits easier insertion and removal of needle **13***a* without detracting from the ability of stopper portion **30** to re-seal itself.

External to cup-shaped body portion **29** and in axial relation thereto is integral tubular portion **32**. Tubular portion **32** provides a receptacle for removably receiving flanged closure member **33** so as to keep the portion of top surface of cap **27** relatively sterile prior to needle puncture for blood collection.

Operation

The mode of using our operation can be best understood from the following description relating to the embodiment pictured in the drawing. In the usual course of using our invention, it is expected that plastic container **10** will be supplied to the user in a collapsed form. For example, a large number of these plastic bags can be shipped overseas for military use in a relatively small cardboard carton. An additional advantage of this type of container over a glass bottle lies in its lighter weight. It is also contemplated that in the same carton and associated with plastic container **10** will be source of anti-coagulant liquid (not shown in the drawing). This source of anti-coagulant liquid may take many forms known to the art, but the primary problem that has to be overcome in this respect is the provision of it in some kind of container which does not permit evaporation of the liquid therefrom. Therefore, it is expected that the most convenient form for providing the necessary elements for blood collection would be a package containing (1) plastic container **10**, (2) blood collection set **12** including some kind of clamping means, and (3) a tube or vial of anti-coagulant liquid equipped with outlet means adapted to permit extraction of the anti-coagulant liquid therefrom under substantially sterile conditions.

It is to be noted that the structure of our invention is not restricted to uses wherein the anti-coagulant solution is provided separately from the collapsible container, only that, up to this time, no suitable container has been found that is capable of containing the anti-coagulant liquid for a substantial period without some kind of degradation such as crystallization resulting from evaporation of liquid.

At the site of blood collection, the aforementioned package would be opened and container **10** threadably mounted in housing **11**. The contents of the anti-coagulant-containing vial are then transferred to container **10** by removing closure member **33**, inserting plug-in needle **13***a* of collection set **12** into stopper portion **30** of cap **27**, inserting hypodermic needle **14***a* into the anti-coagulant-containing vial and causing the contents thereof to flow through set **12** into container **10** by gravity.

Collection set **12** is then clamped, as by hemostat **15**, and a vacuum drawn on housing **11**. It is not essential to the method of our invention that container **10** be mounted in housing **11** before the anti-coagulant material is introduced into container **10**. It is desirable, however, to leave needle **13***a* inserted into stopper portion **30** after the initial insertion and until the blood collection process is finished in order to minimize the possibility of contamination. It would therefore be necessary to thread set **12** through collar **22** before neck **23** could be threadably mounted therein.

It is also not necessary to flow the anti-coagulant material from its vial into container **10** by gravity, but the same can be achieved if housing **11** is evacuated prior

to such transfer. In that event, collection set **12** must be clamped prior to evacuating housing **11** to prevent drawing of air into container **10**.

The container which previously contained the anticoagulant liquid is then removed from donor needle **14***a*, and donor needle **14***a* is then inserted into a vein of the donor. The clamping means is then removed from the collection set and the course of blood collection begun. When sufficient blood has been collected, as determined by visual examination of container **10**, collection set **12** is once again clamped, and set **12** is disconnected first from the body of the donor and secondly from stopper portion associated with container **10**. Inasmuch as inlet **23** of container **10** is provided with a stopper of a self-sealing nature, which may be of the form shown in the pictured embodiment, the collected blood is available for storing in a condition free from contact with the atmosphere.

For ease in storing, integral ear portions **34** are provided on container **10**, and holes **35** are provided in integral ear portions **32**. Thus, a plurality of filled containers can be stored along a pair of parallel rods extending through holes **35**. When the stored blood is to be used for transfusion purposes, container **10** may be inverted and suspended by bail member **36**, which may be a plastic band solvent-sealed to the base of container **10**.

There are many methods available in the art for fabricating container **10** into the embodiment shown herein. A method we consider especially suitable involves the application of dielectric heating through the use of high frequency electricity to heat seal the edges **37** of the body portion **38** of container **10**. Body portion **38** may be either an extruded tube or two lengths of plastic heat-sealed along opposite edges thereof to form a tubular body. In addition, we prefer to use the method of heat sealing to attach neck **23** to body **38**.

When it is desired to remove the stored blood from container **10** either for transfusion or extraction of plasma, cap **27** is removed by grasping tab **28** and exerting a pulling pressure thereon. This exposes the top portion of plug **25** with passage **26** extending therethrough. Inasmuch as passage **26** is substantially larger than plug-in needles conventionally used in extracting blood from stored containers, the possibility of blockage of the extracting apparatus by coagulated elements in the blood is materially lessened. In the usual process of extraction of blood from the storage container, some form of conduit is used, with means affixed to one end suitable for inserting into passage **26**.

An additional advantage accrues through the use of a container of the type pictured in that only one passage is necessary for both collecting and extracting blood since there is no need for an additional passage necessary for the introduction of air to take the place of the blood extracted from the collapsible container.

The foregoing detailed description has been set forth for clearness of understanding only, and no unnecessary limitations are to be inferred therefrom, as modifications will be obvious to those skilled in the art.

We claim:

1. A blood collection apparatus comprising a collapsible container provided with a threaded inlet portion, and an evacuable housing provided with a threaded collar element, said threaded inlet portion being threadably mounted in said threaded collar element to form a unitary device, whereby said container is adapted to be removably mounted in airtight fashion in said housing.

2. A blood collection apparatus comprising a collapsed plastic bag provided with an externally threaded inlet portion, a self-sealing stopper removably mounted in said inlet portion, and an evacuable housing provided with a window and with an internally threaded collar element, said threaded inlet portion being threadably received in said threaded collar element to form a unitary device, whereby all of said container except said self-sealing stopper is releasably sealed within said housing.

3. A blood collection apparatus comprising a collapsible plastic container equipped with an integral, substantially rigid neck having an external threaded portion, self-sealing means removably mounted in said neck, said neck being of such length to prevent puncture of said container when a hollow needle is inserted into said self-sealing means; and a housing having a transparent portion in a side wall thereof and adapted to be evacuated, said housing being provided with a removable end closure, and in said closure an internally threaded collar in which is threadably received said threaded neck, whereby all of said container except said self-sealing means is releasably sealed within said housing.

4. A blood collection apparatus of the character set forth in claim 3 wherein the said housing is a glass bottle and the said end closure is threadably attached thereto.

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