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H. C. BARON
SELF-GENERATING PRESSURE DEVICE FOR
INFUSION ADMINISTRATION SYSTEMS
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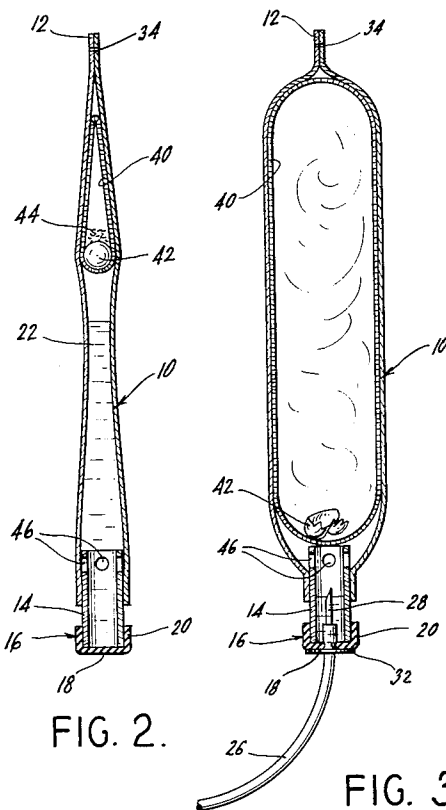
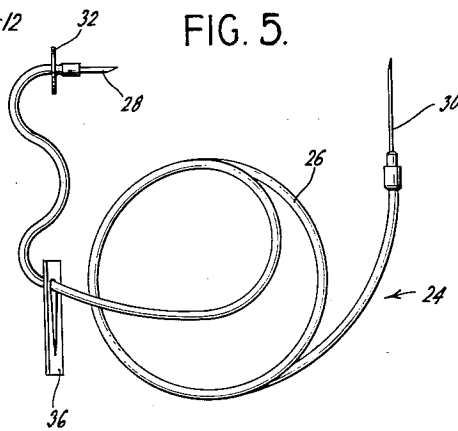
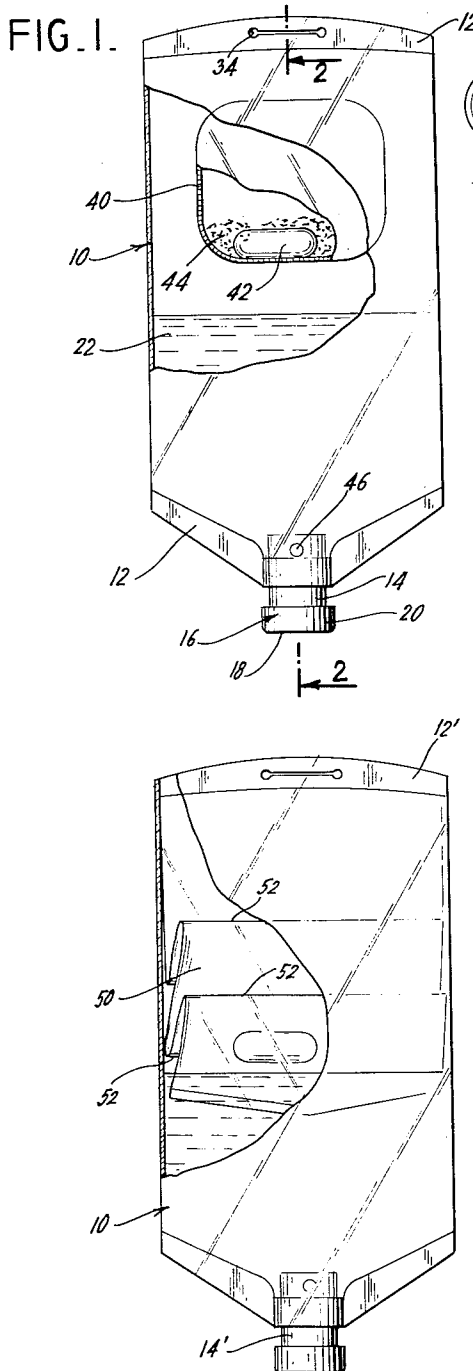


FIG. 4.

INVENTOR.
HOWARD C. BARON
BY *Amster & Seif*
ATTORNEYS

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SELF-GENERATING PRESSURE DEVICE FOR INFUSION ADMINISTRATION SYSTEMS

Howard C. Baron, 36 E. 36th St., New York, N.Y.

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6 Claims. (Cl. 128—214)

This invention relates to improvements in apparatus for intravenous infusion or transfusion, and in particular relates to a new and improved pressure-operated assembly for the infusion of blood or plasma to a patient requiring the same.

At the present time several conventional methods are employed for infusing blood or other fluids into the blood stream. The most common method is to hang a glass jar or plastic bag containing blood, blood plasma or the like on an infusion stand and allowing the fluid to flow by gravity to the veins of the patient. It is also known to employ hand pumps which are attached directly to the infusion bottle, these pumps requiring constant or intermittent manual manipulation and consequently an attendant present to operate the same. It is also known to employ mechanical pumps which are attached to the infusion bottle and result in the blood being fed under pressure to the patient. The mechanical pumps also require manual control and in addition must include a power source for the operation thereof. Most recently, the use of flexible plastic infusion containers has become prevalent, such infusion containers being capable of being manually squeezed by an attendant for the feeding of the contents under pressure to the patient.

All of the above conventional methods are subject to inherent disadvantages which limit the use thereof to particular applications. For example, the gravity flow method, which at the present time is in general use, requires a cumbersome infusion stand for purposes of elevating the infusion bottles at least several feet above the level of the patient. The rate of flow is then determined by the diameter of the infusion needle, the height of the infusion bottle, and the intravenous pressure. The intravenous administration of fluid by hand pumps requires the constant or intermittent presence of an attendant to maintain the pressure in the infusion bottle and prevent any possible massive air embolus at the conclusion of the infusion operation. The use of mechanical pumps minimizes the necessity of constant supervision by an attendant, but in this instance, the pumps are bulky and heavy and require a power source for their operation. Thus, they are not usually transportable and are not commercially practical for mass use due to the high cost of each individual unit. The present method of use of flexible plastic infusion containers requires the container to be suspended from an infusion stand for normal gravity flow operation, or in the alternative requires the container to be manually manipulated.

It will be appreciated that in places where mass transfusions are required in large numbers, such as on the battlefield or in disaster areas, it is often essential to provide a controlled flow of blood or plasma expanders in a large number of simultaneous transfusions, but the nature of the situation as such that it is impossible to provide an attendant for each transfusion case. In addition, it is impossible to provide mechanical pumps or the like with each transfusion unit, and even if the provision of such pumps were possible, a power source for said pumps would not be readily available. In addition, it may be mentioned that the gravity flow method of infusion is often impossible to follow under battlefield conditions since the use of upright infusion stands or supports provides a ready target.

In accordance with the present invention, there is provided a self-contained infusion pump for feeding the

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intravenous fluid to a patient under a steady pressure, the infusion pump being in the nature of an expandible bag or envelope contained within the infusion container and having means for filling the expandible bag or envelope with gas in such a manner as to expand the bag within the container and force the intravenous fluid out of the container. In the preferred form of the invention, the expandible bag contains chemical ingredients which, when mixed, generate a gas which fills the bag and causes the latter to expand.

An object of the present invention is the provision of pressure-operated infusion assembly of the character described which will provide a steady flow of intravenous fluid to the patient under a steady pressure and with a minimum of manual attendance, and which can also be used, when desired, in the usual manner for gravity-flow administration.

Another object of the present invention is to provide a pressure-operated infusion assembly of the character described which is of small, compact size, is light in weight, and is inexpensive in manufacture, so that it may be economically provided in quantity for mass use.

Still another object of the present invention is to provide a pressure-operated infusion assembly of the character described which acts automatically to prevent air embolus, and at the same time acts as a check valve at the conclusion of the infusion.

Additional objects and advantages of the present invention will become apparent during the course of the following specification when taken in connection with the accompanying drawings illustrating preferred embodiments thereof, and in which:

FIG. 1 is a plan view of an infusion container shown in inverted position and incorporating a flexible bag in accordance with the invention, portions of the container and bag being broken away to reveal inner constructional details;

FIG. 2 is a section taken along line 2—2 of FIG. 1;

FIG. 3 is a sectional view corresponding to FIG. 2, but showing the flexible bag in an expanded position, and also showing a portion of the administration assembly connected to the container;

FIG. 4 is a plan view of an infusion container incorporating a modified form of the invention; and

FIG. 5 is a perspective view of the administration assembly used with the infusion containers.

While the self-generating pressure system of the instant invention may be applied to any type of infusion container, for purposes of illustration there is shown in the drawings the well-known type of flexible container having walls made of a soft and bendable plastic. This container communicates with a feeding tube which terminates in a hollow needle for injection into the patient's blood stream.

Referring in detail to the drawings, there is shown in FIG. 1, by way of example, an infusion fluid container of the conventional and well-known flexible type in the nature of a pliable plastic bag made of transparent polyvinyl chloride or the like. The container 10 is completely sealed, as by marginal heat sealing 12 at its top and bottom ends, except for an open neck portion formed by a hollow tube 14 which is open at its ends and is sealed in a position extending through the bottom wall of the container 10. The outer end of the tube 14 is closed off by a soft rubber cap 16 having a bottom wall 18 and a peripheral flange 20 which encircles and grasps the lower end of the hollow tube 14.

The container 10 is partially filled with a measured amount of infusion fluid 22 to be administered, the fluid being, for example blood plasma, blood mixed with an anti-coagulant, etc. Prior to the sealing of the con-

tainer 10, the air therein is wholly evacuated, so that a vacuum is created in the space above the fluid 22.

A flexible infusion fluid container such as the container 10 is conventionally provided with an administration assembly which is used to transfer the fluid in the container to the patient requiring such fluid. Such an administration assembly 24 includes a flexible tube 26, normally made of a transparent plastic, to one end of which a hollow needle 28 is affixed, and to the other end of which a longer hollow needle 30 is affixed.

The needle 28 is sized to puncture the bottom wall 18 of the tube cap 16 and to extend upwardly through the tube 14, in the manner shown in FIG. 3, with the hollow interior of the needle 28 in communication with the fluid 22 within the container 10. The fluid thus may flow through the hollow needle 28 and through the flexible tube 26. As is conventional, a metal disc or flange 32 may be affixed at the base of the needle 28 to serve as stop means to prevent the needle 28 from being inserted too far within the tube 14.

The flexible container 10 is conventionally provided with an aperture or slot 34 in the heat-sealed marginal area 12 opposite the neck 14, by means of which the container may be hung in an inverted position from an infusion stand or other support. When the needle 28 is inserted through the cap wall 18 into the hollow tube 14 and the other needle 30 is inserted into a vein of the patient, the fluid 22 within the container 10 is fed by gravity through the tube 26 to the patient. In those cases where the patient requires a pressure feed of the fluid, it is customary to provide an attendant to manually squeeze the flexible container 10 in order to force the fluid from the container. A pinch clamp 36 may also be mounted on the flexible pipe 26 to control the flow of fluid therethrough.

The apparatus thus far described is conventional and well-known, and provides an inexpensive and easily portable assembly for storing and administering blood and other intravenous fluids. The invention herein resides in self-expanding means placed within the container for creating a pressure within the container whereby the fluid therein is forced out and through the flexible tube 26 in a steady, positive flow without relying on gravity, as is usual.

In accordance with the invention, there is provided a small expandable bag within the container 10, the bag containing a supply of gas or containing means for generating gas. The bag thus continually expands during use of the infusion apparatus, forcing the liquid under pressure out of the container. The gas generating means may be in the form of a small container of compressed gas which can be ruptured or otherwise opened to release the gas within the expandable bag. Preferably, however, the gas generating means is in the form of two or more chemical agents which may be mixed or dissolved in a liquid to generate the gas.

FIGS. 1 and 2 illustrate one example of the preferred gas generating means. In these views, a small flexible and resilient bag 40 is located within the container 10. The bag 40 may be made of soft rubber or a plastic which is capable of stretching, and is in the form of a hollow envelope which is completely sealed around all of its edges.

The bag 40 contains a capsule or ampule 42 which is capable of being crushed or ruptured from the exterior of the container 10. For this purpose, the member 42 may be a thin-walled glass ampule or may be a conventional medicinal capsule, both of which may be crushed by squeezing through the flexible walls of the container 10 and of the bag 40. The capsule or ampule 40 may contain a liquid or chemical, while an additional chemical (in FIG. 1 being shown as a powder 44), is contained within the bag 40 outside the ampule or capsule 42. The chemical agents are such that upon mix-

ing they will generate gas to cause the bag 40 to expand in size.

The aforementioned chemical agents may be any suitable ingredients which will generate gas when mixed or when dissolved in water; there being a large number of well-known materials suitable for this purpose. For example, the powdered chemical 44 within the bag 40 may be a measured amount of dry baking soda, while the capsule 42 may contain water. When the capsule 42 is broken, the water will mix the baking soda, generating carbon dioxide gas. As another example, the chemical ingredient 44 in the bag 40 may be calcium carbonate and the capsule 42 may contain dilute hydrochloric acid.

The bag 40 may be secured within the container 10 or may be loosely contained therein. When the capsule or ampule 42 is ruptured or crushed, the material therein will mix with the chemical agent 44, generating gas which will cause the walls of the bag 40 to stretch and the bag 40 to expand until it fills the interior of the container 10 above the infusion fluid 22. When the bag 40 expands sufficiently to press downwardly upon the infusion fluid 22, it exerts a positive pressure upon the fluid, forcing the fluid out through the tube 14, the hollow needle 28 and the flexible tube 26, to the vein of the patient.

The use of the expandable bag 40 eliminates the danger of an air embolus almost completely. In the final stages of the infusion, the bag 40 expands until it completely fills the interior of the container 10, as shown in FIG. 3. The outlet tube 14 is therefore completely sealed off when the last of the infusion fluid 22 leaves the container 10, and there is no possibility for air within the system to be fed to the veins of the patient. At the same time, the fully-expanded bag 40 acts as a check valve in sealing off the outlet tube 14, preventing the return of blood or infusion fluid to the container.

In conventional transfusion arrangements of the type shown herein, the outlet tube 14 is open at its top to permit the passage of infusion fluid therethrough. An examination of FIG. 3 will reveal that when the bag 40 is almost fully expanded, it will engage and seal off the open top of the outlet tube 14, with the result that the container 10 will be sealed off from the outlet flow of fluid before all of the intravenous fluid has been fed to the patient. As a result there is provided in the side walls of the outlet tube 14, a series of apertures 46, the bottom edges of which register with the bottom wall of the container 10, as is best seen in FIG. 3. The apertures 46 insure that all of the contained infusion fluid 22 is discharged from the container 10. At the same time the apertures 46, are sealed off by the fully-expanded flexible bag 40 at the completion of the transfusion operation, to prevent air embolus.

FIG. 4 illustrates an alternate manner of constructing the expandable bag. In this view, the bag 50 is made of the same material as the container 10', that is to say of a flexible plastic sheet material which need not be stretchable. The bag 50 is in the form of a completely sealed envelope which is of slightly larger size than the container 10'. The bag 50 is sealed at its top end to the top heat-sealed edge portion 12' of the container 10'. The free lower portion of the bag 50 is folded up in a number of staggered folds 52, so that in the unexpanded condition, the lower folded portion of the bag 50 is located above the level of the intravenous fluid 22. The bag 50 contains chemicals for the rapid generation of gas, as was previously described, or contains a small cylinder of compressed gas. When gas is generated or released therein, the bag 50 will expand and unfold, forcing the intravenous liquid from the container 10', until the bag 50 entirely fills the interior of the container and its bottom end seals off the outlet tube 14'.

It is to be understood that the expandable bag may also be used within a container of the glass bottle type also commonly used for blood infusion. In this instance, the

expandible bag could be pre-filled with sufficient compressed air or other gas to permit the bag to expand to an extent to fill the interior of the bottle after the intravenous fluid has been fed to the patient. In the event that an expandible bag containing a capsule or ampule is used within a glass bottle, the capsule or ampule can be broken by means of a needle puncture through a rubber stopper, to permit mixing of the chemical agents.

The use of an expandible bag within the infusion container, as described above, presents the advantages of providing a readily transportable pressure system in which constant attendance is unnecessary. In operation, all that is necessary is to attach the administration assembly 24, inject the patient, and release or generate the gas. The system is entirely independent of gravity and the infusion bottle or container, can be placed at body level or below. For example, the container can be suspended between the legs of a patient on a litter, suspended from the patient's belt, hung from the neck of a transported patient, etc. In hospitals it may be placed on a bed stand next to the patient or on the anesthesia machine at the head of the operating table. No cumbersome infusion stands are required as in gravity administration. Sufficient pressure may be generated to overcome the venous pressure of the patient, and, if necessary, the systolic blood pressure of the patient where intra-arterial transfusions are required. With the assembly of the invention, as many transfusions may be given as are needed without depleting the available manpower in a mass emergency or even in routine hospital work.

While preferred embodiments of the invention have been shown and described herein, it is obvious that numerous omissions, changes, and additions may be made in such embodiments without departing from the spirit and scope of the invention.

What I claim is:

1. Infusion apparatus comprising a flexible-walled container for storing a supply of fluid to be fed intravenously and having a fluid outlet opening, an expandible bag within said container, said bag being completely sealed and having a normal collapsed position in which it occupies a portion of the container, and means within said bag for generating a supply of gas therein in sufficient volume to cause said bag to expand to an extended position in which it substantially fills the interior of said container, said gas-generating means comprising a plurality of chemical ingredients capable of generating gas when mixed, and a frangible member normally separating said chemical ingredients, said frangible member being accessible from the exterior of said container through the flexible walls of the latter, whereby the frangible member may be selectively and manually ruptured to mix said chemical ingredients.

2. Infusion apparatus according to claim 1 in which said frangible member comprises a capsule containing one of said chemical ingredients.

3. Infusion apparatus according to claim 1 in which said expandible bag comprises an envelope having stretchable walls.

4. Infusion apparatus according to claim 1 in which said expandible bag comprises an envelope of an expanded size at least equal to the internal volume of said container said envelope being normally folded to occupy only a portion of said container.

5. Infusion apparatus comprising a flexible container having a fluid outlet opening, a completely sealed expandible bag within said container, and chemical means within said bag for generating a supply of gas to expand said bag to substantially fill said container, said chemical means comprising a plurality of chemical ingredients capable of generating gas when mixed, and a frangible member normally separating said chemical ingredients, said frangible member being selectively and manually ruptured to mix said chemical ingredients.

6. Infusion apparatus comprising a flexible container for storing a supply of fluid to be fed intravenously and having a fluid outlet opening, an expandible bag contained within said container, said bag being completely sealed and having a normal collapsed position in which it occupies a portion of the container, and means including a frangible member within said bag for generating a supply of gas therein in sufficient volume to cause said bag to expand to an extended position in which it substantially fills the interior of said container so that said bag in expanding acts to exert pressure upon said fluid to force the latter out of the container, said frangible member being selectively and manually ruptured through said flexible container and through said expandible bag manually from outwardly of said container.

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