

May 1, 1962

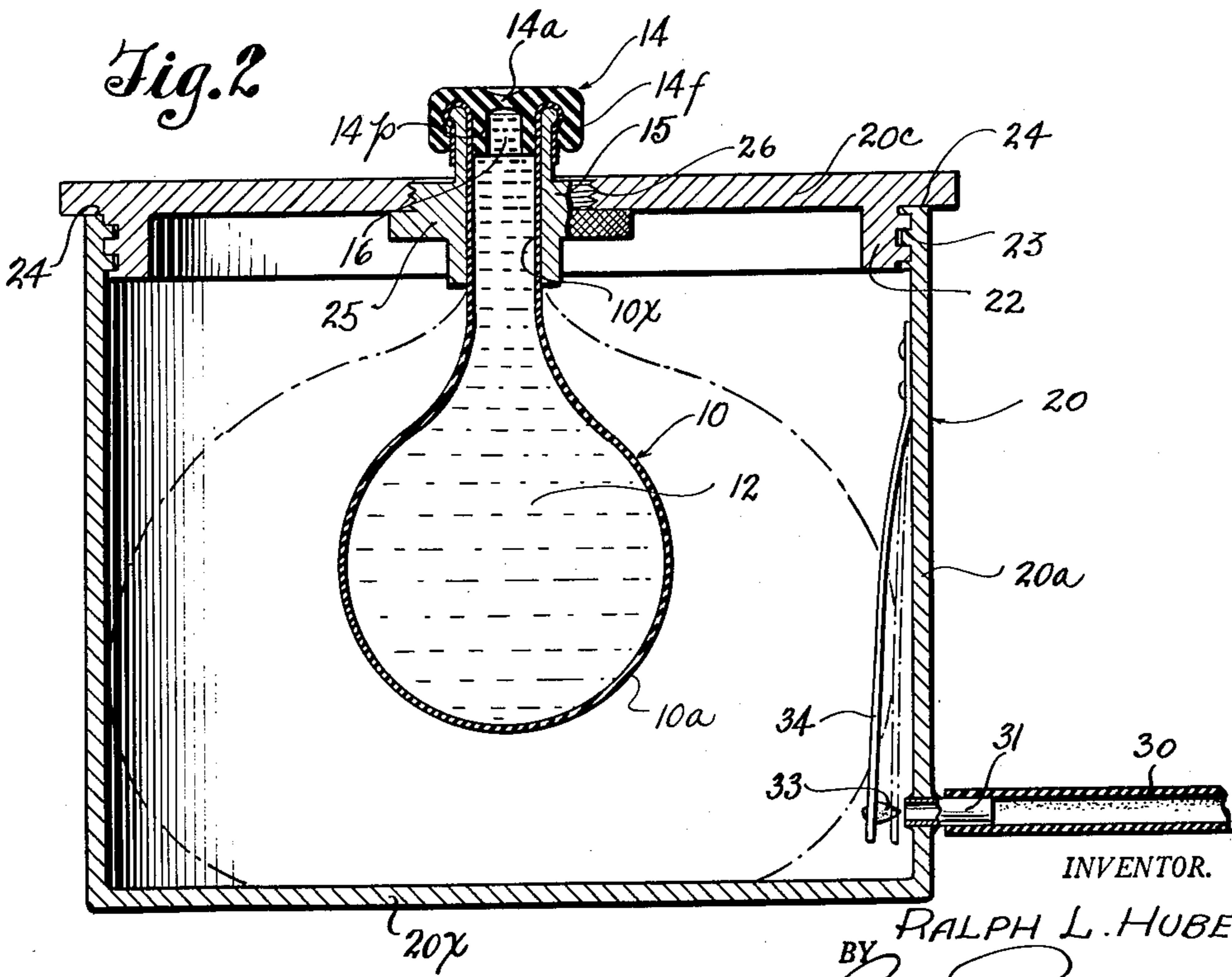
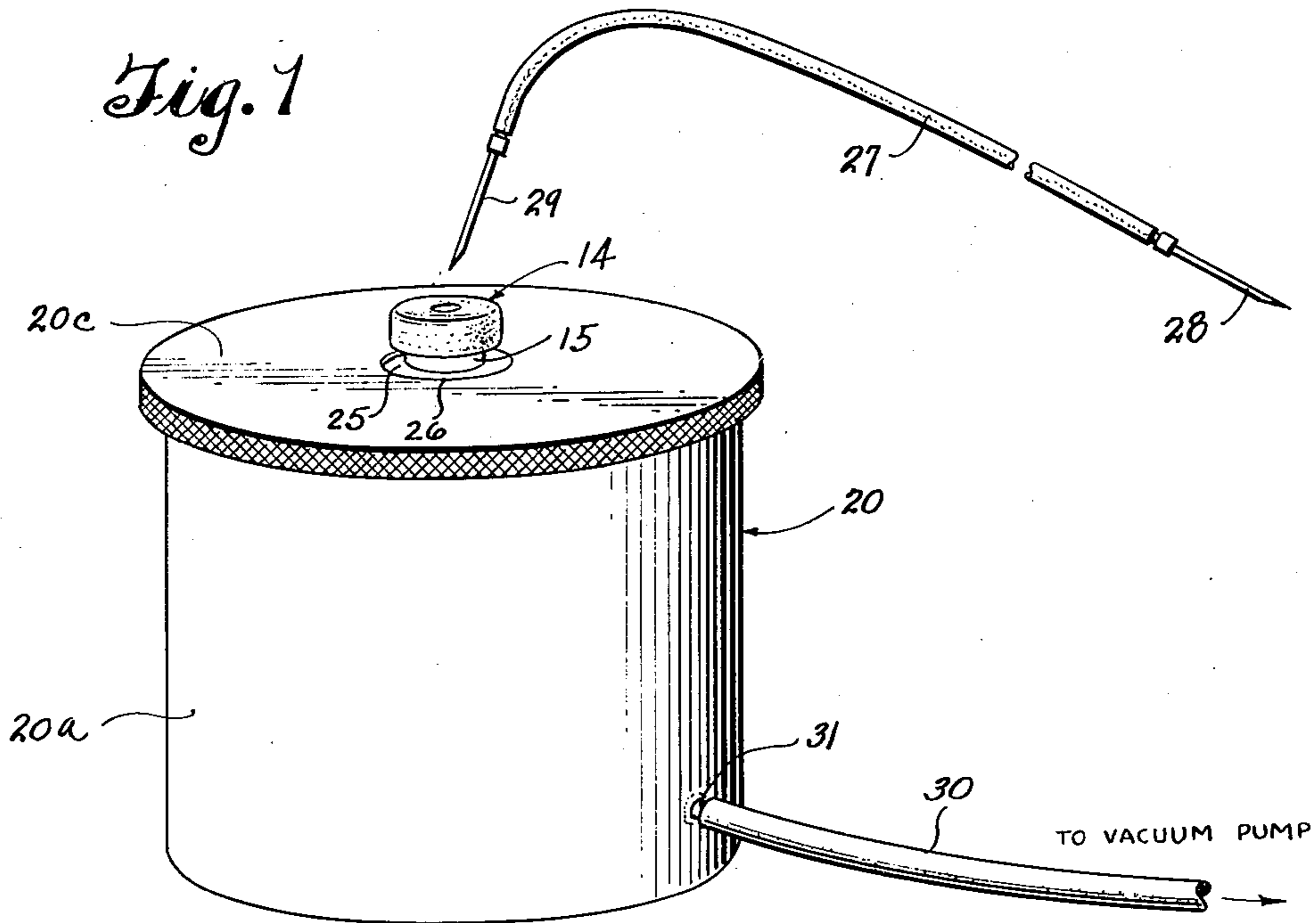
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MEANS FOR THE EXTRACTION AND STORAGE OF BLOOD

Filed June 20, 1958

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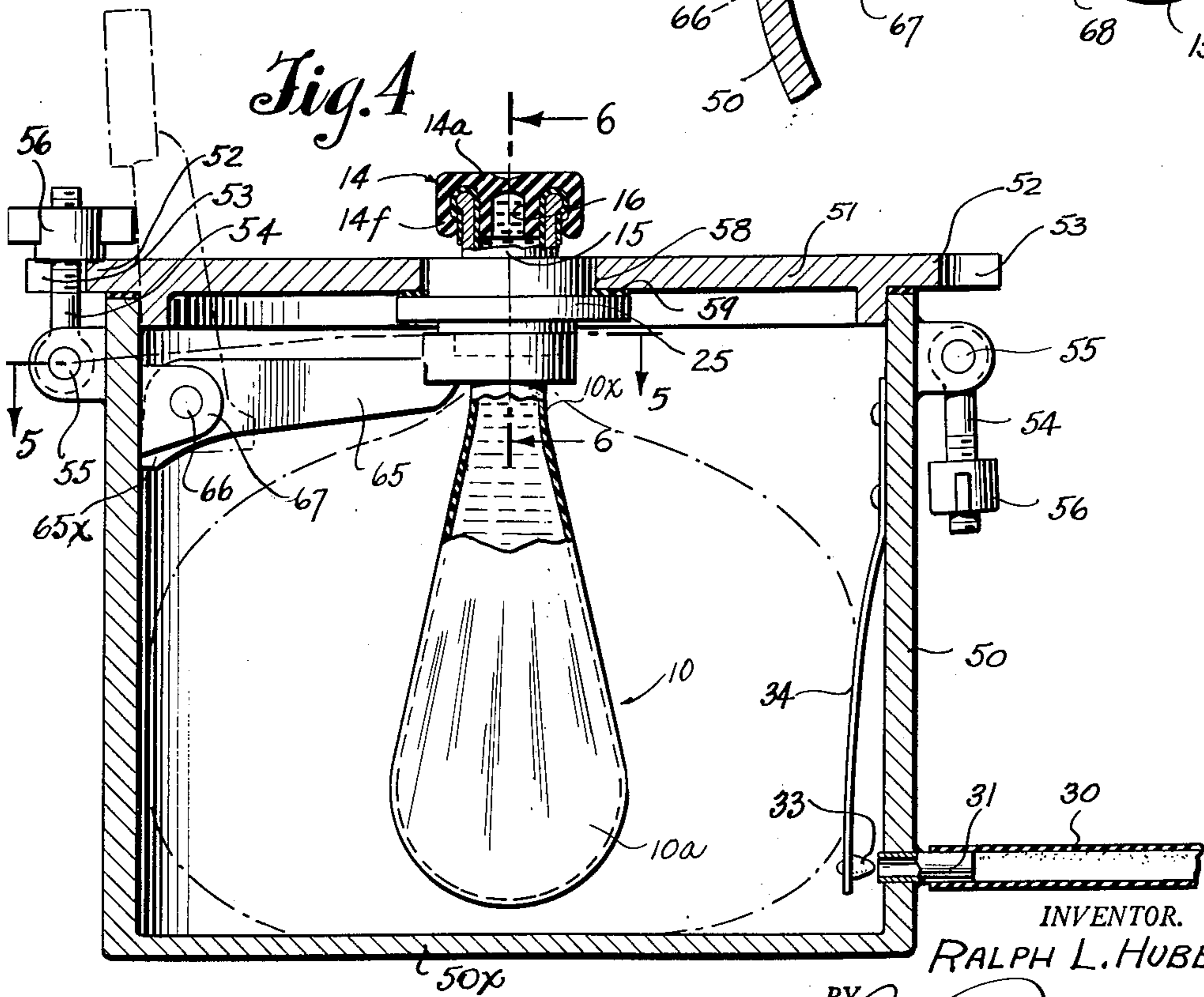
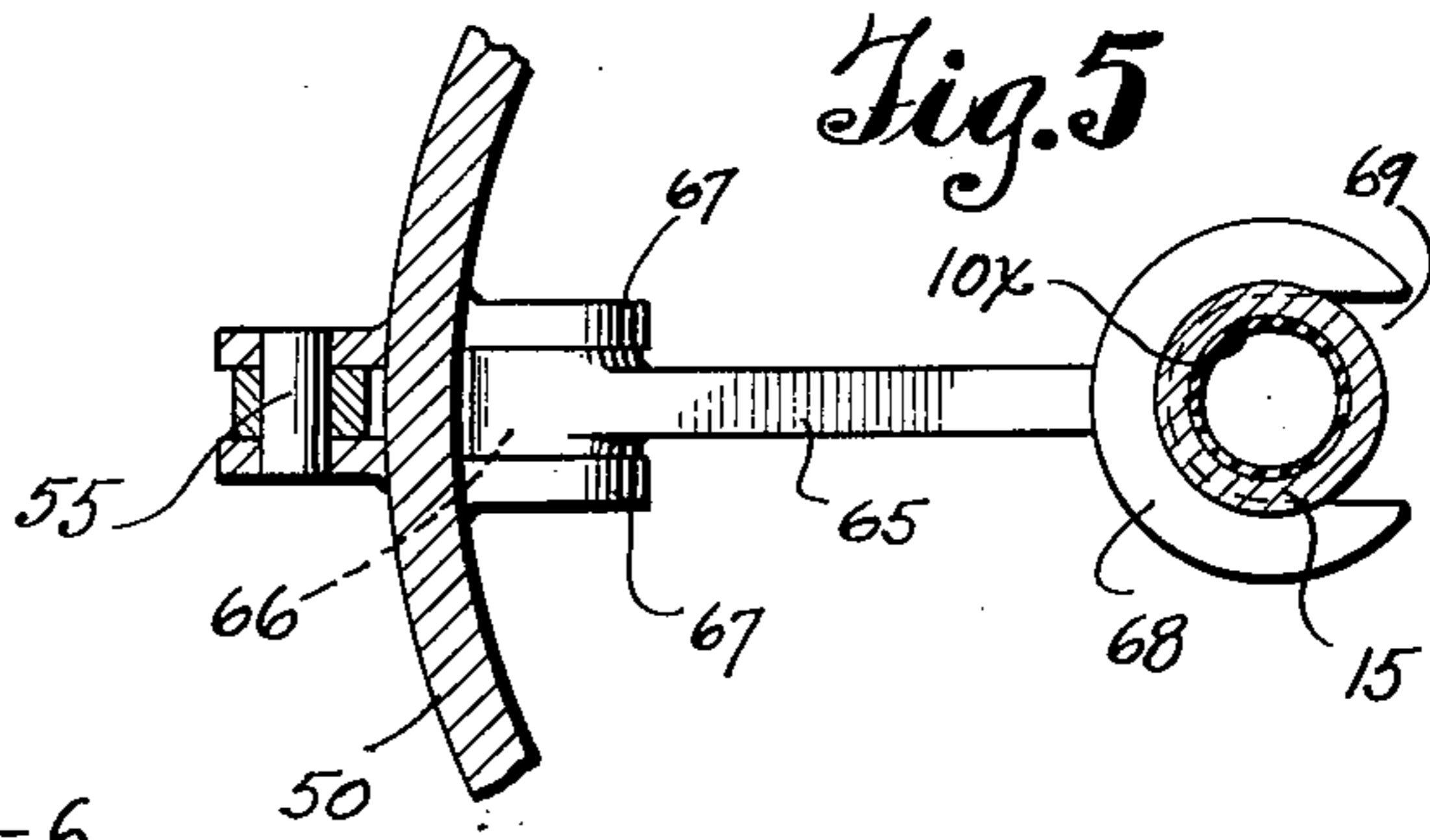
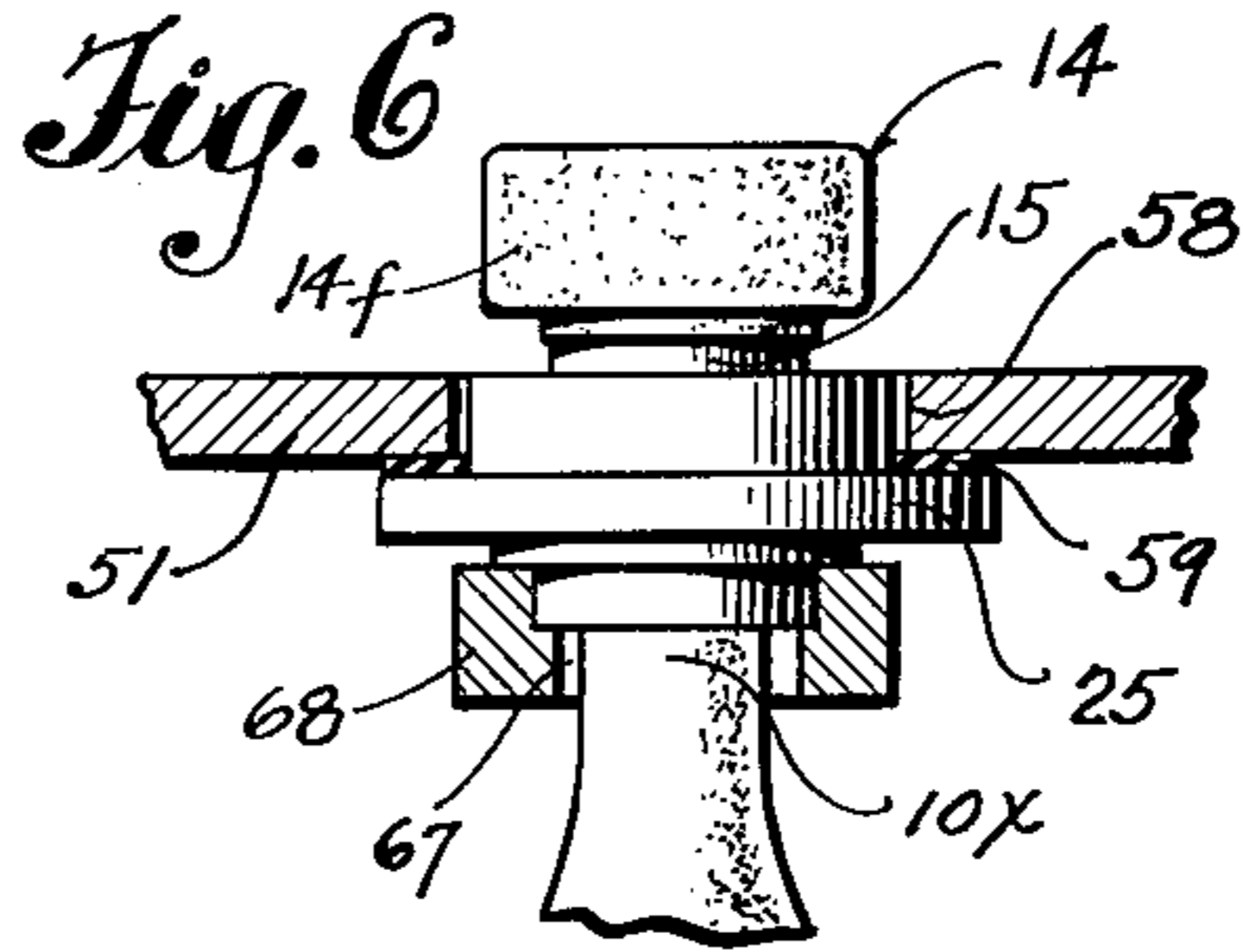
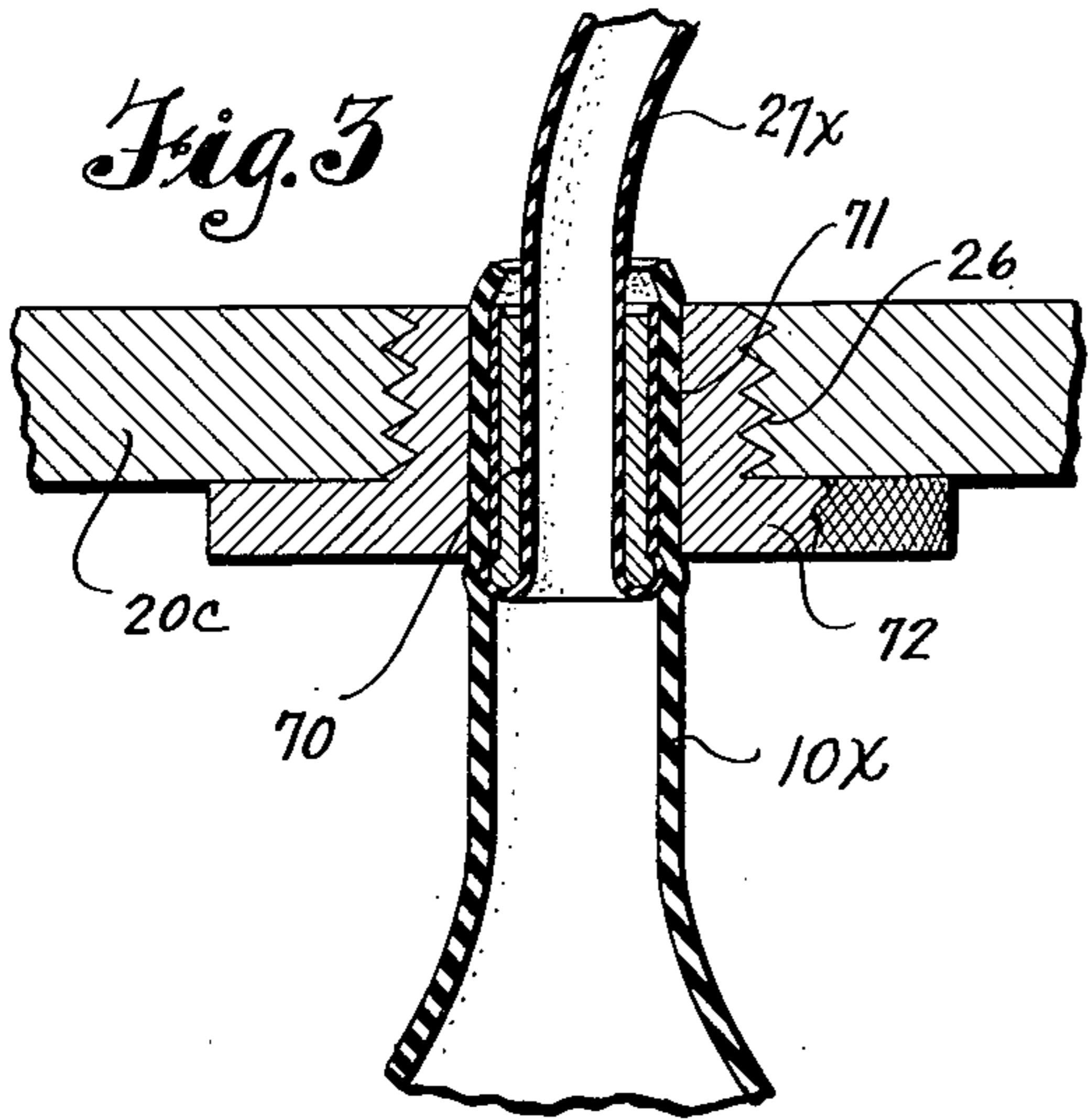
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MEANS FOR THE EXTRACTION AND STORAGE OF BLOOD

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3 Sheets-Sheet 2



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MEANS FOR THE EXTRACTION AND STORAGE OF BLOOD

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Fig. 7

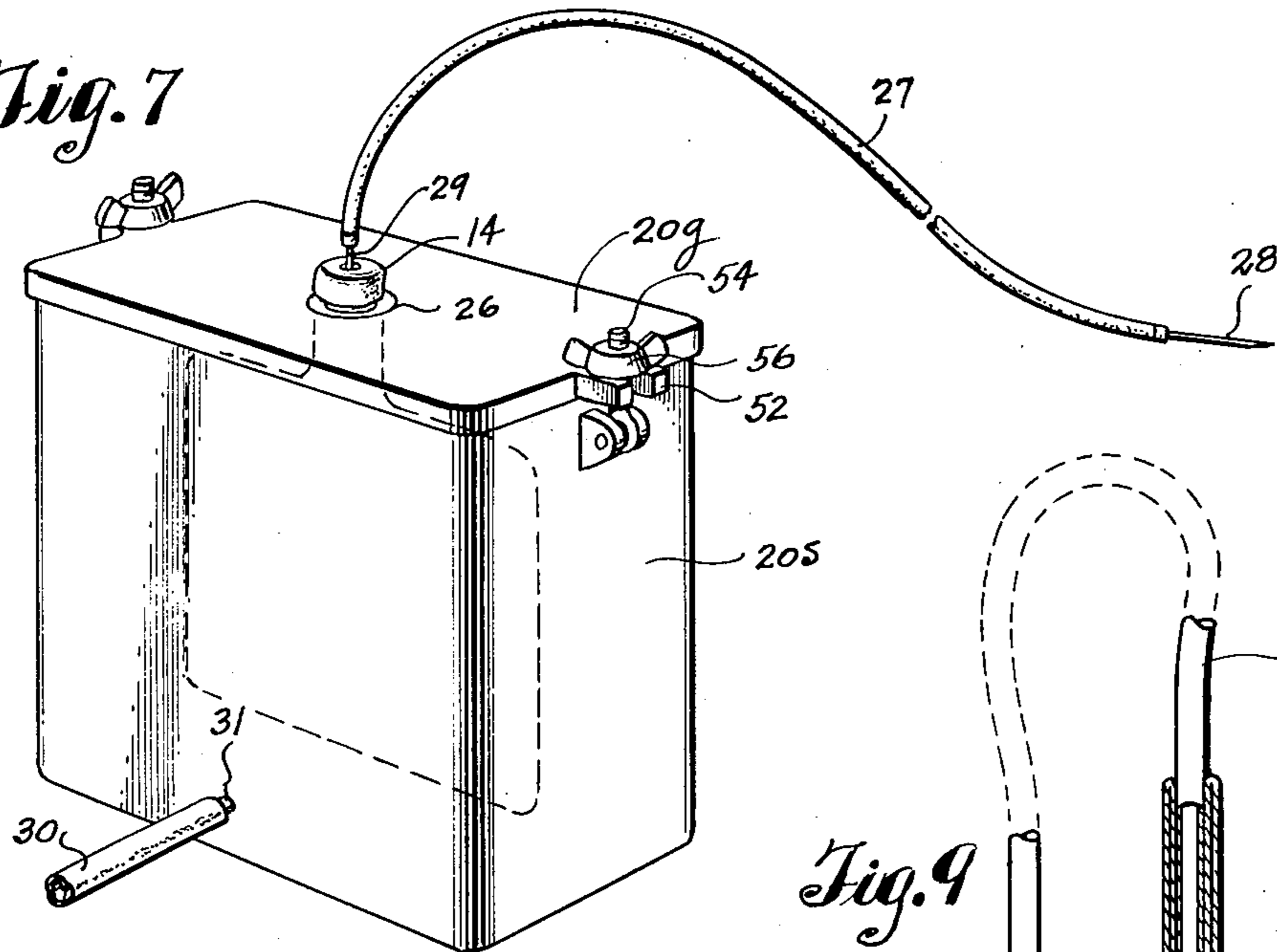


Fig. 9

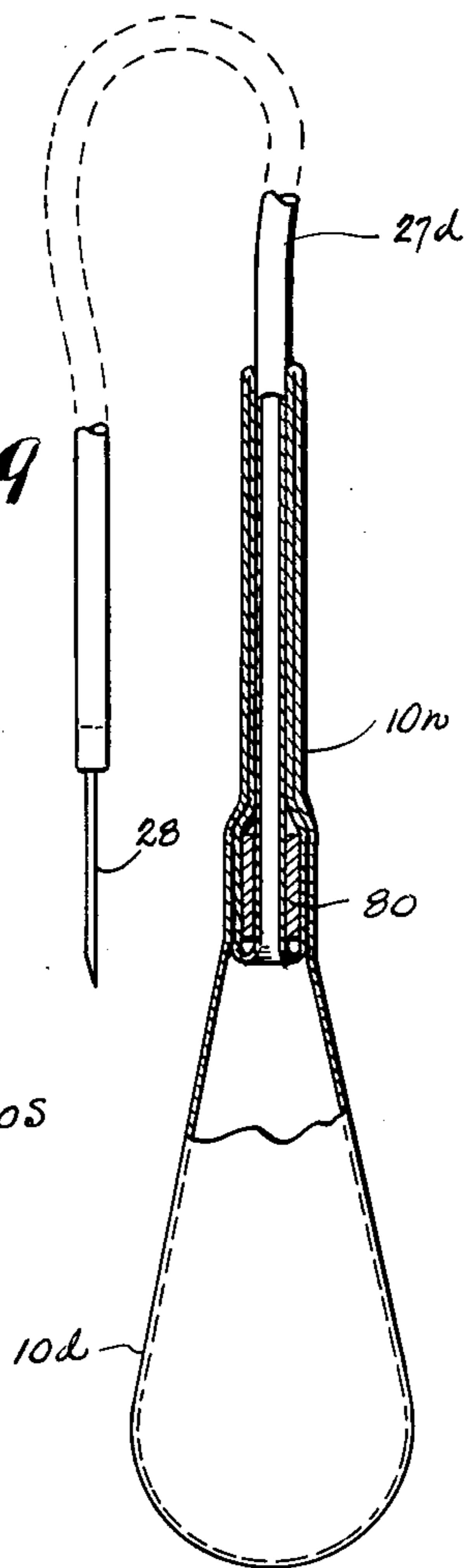
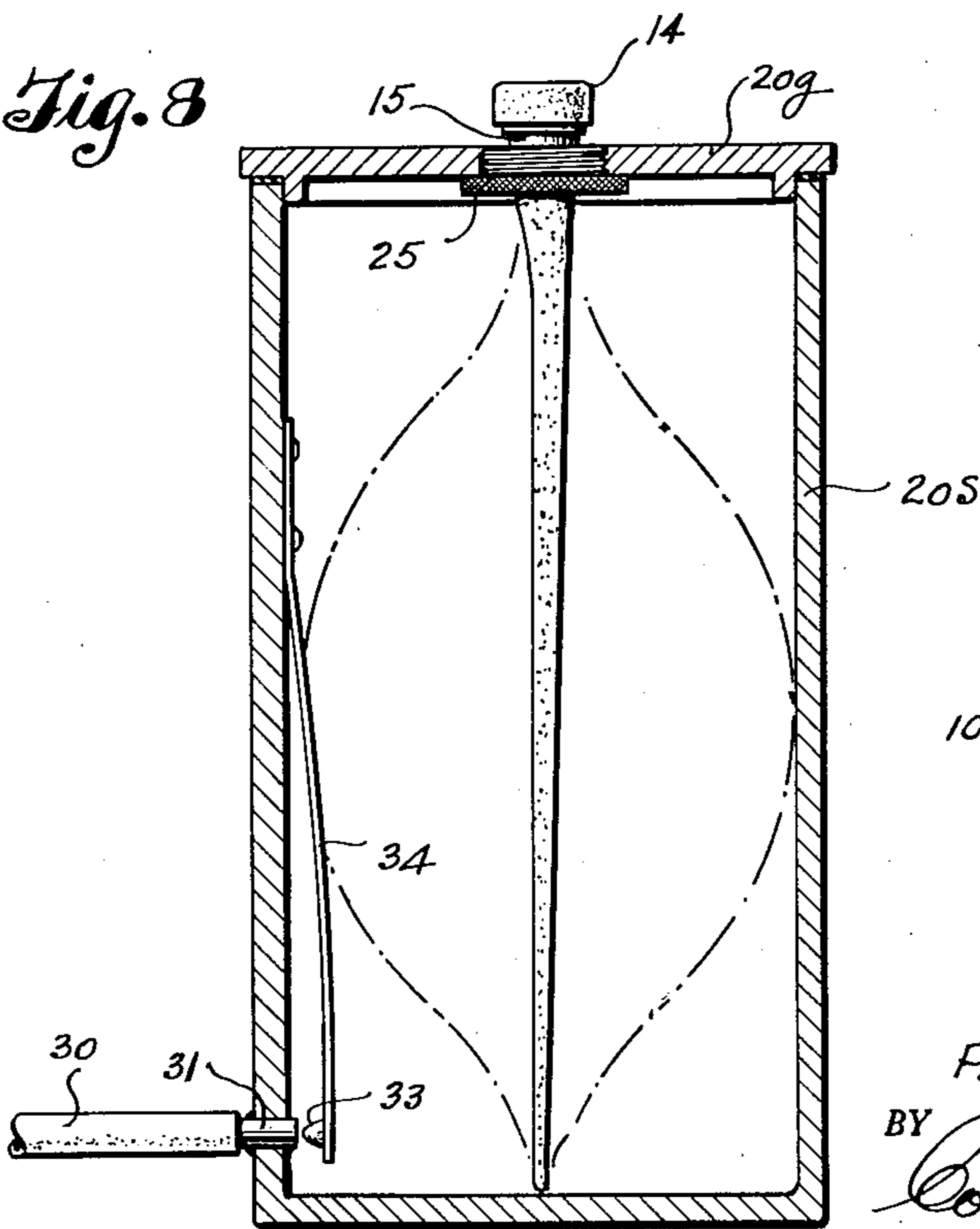


Fig. 8



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3,032,037

## MEANS FOR THE EXTRACTION AND STORAGE OF BLOOD

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13 Claims. (Cl. 128—276)

This invention relates to a method of and means for the extraction and the storage of blood in sterile condition. More particularly, it has to do with a method of and means for the drawing of blood from a donor by aid of vacuum, and in the storing of the blood in a sterile container and free from contacts with air; the invention having to do primarily with the provision of novel blood extracting equipment, including a vacuum chamber with means for drawing low vacuum therein during the extracting operation and a sealed, collapsible and expandable receptacle of bottle form, designed to be enclosed in the chamber and to be filled with blood from the donor through the usual form of tubing and under the influence of the vacuum as applied externally to the receptacle.

This application is a continuation-in-part of application Serial No. 277,979, filed March 22, 1952, entitled Method of and Means for the Extraction and Storage of Blood and now abandoned.

It is the primary object of this invention to provide a practical and economical means for blood extraction. It is characterized by the use of a constant and relatively low vacuum, and the reception and storage of the blood in a collapsible, elastic container for subsequent injection without the blood coming into contact with air either in collecting or giving it.

It is also an object of the invention to provide a collapsible and expandable receptacle for receiving the blood, and to equip it with a closure member of novel form through which a tubular cannula or needle can be projected for the filling or emptying of the receptacle.

Another object of the invention is to provide the vacuum chamber with a removable cover member, fitted thereto in an air tight joint and equipped to receive the neck portion of the blood receiving receptacle there-through in an air sealed connection.

It is also an object of the invention to provide improved closure means for sealing the present type of blood receptacle.

Still further objects and advantages of the invention reside in the details of construction of the various parts of the apparatus in its various forms; in the method of use of the apparatus for filling the receptacle with blood from a donor, and in the method of and means for dispensing the blood from the receptacle to a patient.

In accomplishing the above mentioned and other objects of the present invention, I have provided equipment having improved details of construction, the preferred forms of which are illustrated in the accompanying drawings, wherein:

FIG. 1 is a perspective view of one form of vacuum chamber, comprising a part of the present blood drawing equipment; showing the exposed closure member, the blood receptacle and the needle equipped tube through which blood is drawn from the donor into the receptacle.

FIG. 2 is a vertical, cross-sectional view of the vacuum chamber, showing the expandable blood receptacle as supported from the cover member thereof for filling.

FIG. 3 is an enlarged, cross-sectional view of the neck portion of a blood receptacle, showing an alternative means for making a connection between the receptacle and the extracting tube.

FIG. 4 is a central, cross-sectional view of a vacuum

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chamber as equipped with another form of closure and including an arm form of support for the blood receptacle.

FIG. 5 is a sectional detail taken on the line 5—5 in FIG. 4, particularly illustrating the supporting arm for the blood receptacle.

FIG. 6 is a sectional detail, taken substantially on line 6—6 in FIG. 4.

FIG. 7 is a perspective view of a vacuum chamber of an alternative form.

FIG. 8 is a cross-sectional view of the vacuum chamber of FIG. 7, and the expandable receptacle as supported therein for receiving blood.

FIG. 9 is a view, partly in section, of a collapsible blood receptacle and filling tube made as a part thereof.

It is present day practice to store extracted human blood in glass bottles. To prepare these bottles for the reception of blood from a donor, first they are sterilized and sealed under high vacuum. The sealing is effected by means of a pharmaceutical closure member in the form of a stopper or cap made of a material, such as rubber, that can be pierced by a tubular needle or cannula. The filling of the bottle is generally by direct flow of blood from the donor, through a flexible tube of small diameter; one end of the tube being equipped with a hypodermic needle that is projected into a blood vessel of the donor, and the other end being equipped with a similar needle that is projected through the pierceable stopper of the bottle. After such a connection has been made, flow of blood from the donor into the bottle is induced by reason of its vacuumized condition and will continue until pressure in the bottle balances that at the entrance to the extracting tube.

In order that such bottles can be filled substantially full in this manner, they must be rather highly vacuumized. Usually approximately a 20 to 25 inch vacuum is drawn therein. The drawing of such vacuum has disadvantages, one of which is that it causes the rupturing of certain blood cells when subjected thereto, as will be understood by those familiar with this art.

A disadvantage in use of glass bottles or other breakable receptacles resides in the high percentage of loss by breakage in their use, for example, in filling, shipping and storage. Also, much space is required to store them prior to use; and many precautions are necessary to prevent breakage in shipment of blood. Also, in consideration of shipment by air, their weight and bulk is an important item.

The present invention is predicated upon the inherent advantages residing in use of an elastic, non-breakable, expandable and collapsible receptacle for blood storage and shipment, and the present forms of apparatus have been developed as practical means for filling such receptacles. The claims which terminate this specification are based upon the equipment, including the receptacle, and the method employed, for filling the receptacle.

Referring now more in detail to the drawings, and particularly to FIG. 2; reference numeral 10 designates a practical and the present preferred form of blood storage receptacle. For convenience in the following specification, this receptacle will be referred to as a "bottle." It consists of a thin walled rubber bag 10a, resembling the well known toy balloon of rubber, and is formed with a rather elongated, tubular neck portion 10x. The bottle may be made of a tough, flexible elastic material, such as rubber or plastic of a character that can be subjected without damage to sterilizing treatment by heat or otherwise. Such bottles are usually designed to contain from one to two pints of blood for their present intended uses.

Prior to their being used, the bottles 10 are rendered sterile, by heat treatment or otherwise, and are then sealed

under vacuum. Either prior to, or after being sealed, it is generally the case that the bottles receive measured amounts of a liquid anti-coagulant; such as the liquid designated by numeral 12 in FIG. 2.

The sealing of the sterile bottle is generally effected by the application of a special form of pharmaceutical closure or stopper 14 to the entrance of the neck portion 10x. In the use of a closure of the kind shown in FIG. 2, the neck portion 10x of the bottle is first passed upwardly through a tubular bushing 15 of metal or plastic, and somewhat beyond the upper end of the latter. Then the upper end portion of the neck is folded back and drawn downwardly over the beaded upper end of the bushing and along the outside of the bushing; then the closure 14 is applied thereto.

The closure 14 is made of rubber, or a like material, and it comprises a flat cap-like body portion 14a with downwardly extended peripheral flange 14f and a centrally located plug portion 14p coaxially of the cap and projecting downwardly from its underside. This plug portion is of such diameter that it can be fitted snugly in the end of the bottle neck, as the flange 14f of the cap is fitted over and about the downturned portion of the neck. The plug 14p is formed with a central recess 16 leading upwardly thereinto from its lower end, to provide a relatively thin wall through which the needle at one end of a blood drawing tube can be easily projected as presently explained.

For the reception of blood, the bottle 10 is suspended in a vacuum chamber. One of the present preferred forms of chambers is that which has been shown in FIGS. 1 and 2 and designated in its entirety by numeral 20. The chamber, which has a cylindrical body 20a, closed at its lower end by a wall 20x, is equipped with an easily removable lid or cover 20c. This has an exteriorly threaded concentric and depending flange 22 on its underside adapted to be secured by inter-engaging threads, 23, within the upper end of the cylindrical body. The closure is adapted to be tightened in an air tight joint, 24, against the top edge of the body.

The bushing 15, through which the neck portion of the bottle extends, is formed with an encircling flange 25, the upper part of which is somewhat reduced in diameter and is threaded upwardly into an opening 26 formed centrally of and through the closure, in an air tight joint.

With the bottle so mounted by the bushing 15 in the vacuum chamber cover member, 20c, and the latter applied to the chamber, as in FIG. 2, in an air sealed manner, the blood drawing tube can then be applied.

A blood drawing tube of common form has been designated by numeral 27 in FIG. 1, and it is shown to be a flexible tube of predetermined length and small diameter, equipped at its opposite ends with tubular needles 28 and 29 of hypodermic type. The needle 28 is then projected into the blood vessel of the donor, and the needle 29 is projected through the cap or closure 14 to make connection with the inside of the bottle. Vacuum is then drawn in the chamber 20. The means for drawing vacuum in the chamber may consist of any suitable device, such as a vacuum pump or a connection with another source of vacuum. In FIGS. 1, 2 and 3, a tube 30 leading from a constant source of vacuum is shown to be attached to the chamber 20 through a wall fitting 31. It is of significance that in the present operation a constant low vacuum, of from 2 to 4 inches only is employed, such as that drawn by a small motor driven pump.

As the vacuum is applied to the chamber 20, the bottle 10 contained therein is caused to be expanded and blood from the donor will be drawn thereinto through the tube. The bottle can receive blood until it fills the chamber if so desired, but usually extraction is stopped when it has been expanded to the dotted line size shown in FIG. 2. When the bottle has received the amount desired, the vacuum is cut off. Then the top or cover is removed from the chamber and the bottle lifted from the chamber

therewith. The bushing 15 is then unscrewed from the cover but is left in place about the bottle neck.

It will be readily understood that the bottle, as thus filled, will contain no air and is sealed in a sterile condition. Furthermore, since a vacuum of constant and low amount was used to fill the bottle, the damage to blood cells, by reason of high vacuum was avoided.

In the present use of the vacuum chamber, 20, provision has been made for an automatic closing of the vacuum connection with pipe 30 after the receptacle 10 has been filled to a certain volume. This is accomplished by means of a conical stopper 33 that is fixed to one end of a leaf spring 34 that is attached at its other end to a side wall of the chamber, as shown in FIG. 2. The spring normally holds the stopper away from the open inner end of fitting 31. However, when the bottle 10 has been filled to a predetermined volume, it bears outwardly against the spring and causes it to press the valve or stopper 33 to a position seated in the end of the tubular fitting 31 to prevent drawing a further vacuum in the chamber. When the container is lifted from the chamber, the spring returns the stopper to its open position.

For the dispensing of the blood to a patient, the bottle is suspended from its lower end, with the neck portion depending downwardly. Then a tube, like that for filling, is applied to make a blood connection, one needle being projected into the vein of the patient and the other being projected through the stopper. Since the bottle is collapsible, the blood will flow therefrom as fast as it can be received by the patient. At no time, either in filling or emptying the bottle, can outside air contact the stored blood.

In lieu of the vacuum chamber of FIG. 2, a chamber like that of FIG. 4 may be employed. This chamber comprises a cylindrical body, 50, closed at its lower end by a wall 50x and equipped with a removable closure or lid 51. The lid has projecting ears 52—52 at opposite sides, formed with open slots 53 designed to receive clamp bolts 54.

The bolts 54 have lower ends thereof pivotally hinged to the chamber body, as at 55, permitting them to be swung to and from positions within or free of the slots, 53, and they are equipped at their upper ends with wing units 56 adapted to be tightened against the ears 52 to clamp the cover against the top edge of the chamber wall in an air sealed joint.

Centrally of the lid is a circular opening 58 through which the mounting bushing for the bottle can be extended, and the flange 25 of the bushing seated against the under side of the lid about the opening. A gasket 59 is applied between flange 25 and the cover or lid to insure an air tight seal between cover and bushing.

The bushing here used to suspend the bottle may be like, or substantially like that previously described. It is not necessary, however, that it be threaded for application to the lid. It is desirable that the reduced upper portion of the flange 25 be loosely received in the cover opening 58 as indicated in FIG. 4.

To suspend the bottle in the chamber of FIG. 4, I employ a horizontal arm 65 that is mounted in the chamber, near its upper end. The arm is disposed radially of the chamber and has its outer end pivotally supported by a pivot pin 66 between spaced lugs 67—67 on the chamber wall. A shoulder 65x, directed downwardly from the pivoted end of the arm, engages with the chamber wall to limit the downward movement of the arm and to support it rigidly in the horizontal position shown. At its inner end the arm has a bifurcated head 68 forming a recess 69 in which the lower end portion of the bushing is received, as in FIG. 5, for support. When so disposed in the arm support, the cover 51 can be applied over the chamber and sealed by tightening the nuts of the clamp bolts against the ears 52—52. Incident to such placing and clamping of the cover, the cover closes

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in on air sealed joint against the gasket 59 about the bushing thus to seal the opening 58.

Filling of the bottle with blood is carried on in this chamber in the same manner as previously described in connection with the device of FIGS. 1 and 2, by the same chamber vacuumizing means. To remove the filled bottle from the chamber, the clamp nuts 56 are released and the bolts 54 disengaged from the ears 52. Then the cover 51 is lifted off. Then the arm 65 is swung upwardly from the chamber and the bushing 15, supporting the filled bottle, is slipped from the recess of the head portion of the arm 65.

In FIG. 3, I have shown an alternative means for and method of attaching the blood extracting tube to the blood receiving bottle. It is the intent, in making this connection, that the tube shall be permanently attached to the bottle and after being used for blood extraction, shall later be used to give the blood to a patient. In making this connection, the end of the blood drawing tube 27x is passed downwardly through and beyond a tubular bushing 70 and is then folded back thereover. Then the bottle neck is applied over the backturned end of the tube and the bushing, and the end of the neck and enclosed bushing pushed upwardly into and through a bore 71 in a nut 72 that is threaded upwardly into the opening 26 of the chamber lid 20c. By so applying the tube 27x to the bushing 70, there is no metal exposed to the blood contained in the bottle.

In FIGS. 7 and 8, I have shown a vacuum chamber of rectangular or box-like form. This particular shape is intended to accommodate a bottle of the rectangular form indicated in the dotted line showing of FIG. 7. The method of use of the chamber, and method of filling the bottle is as previously described.

In these views, the chamber is designated by numeral 20s, and the cover member by numeral 20g. The cover is held in place by clamp bolts 54 equipped with wing nuts 56 to engage with slotted ears 52 extended from the cover. The rectangular receptacle is designated by numeral 10h, and the other parts bear reference numerals corresponding to those previously used.

In FIG. 9 I have shown a collapsible and expandable blood receptacle 10d of the character of that already described, but having the filling and dispensing tube 27d formed as a part thereof, that is, the filling tube is a continuation of the neck portion of the bottle-like receptacle reduced to usual tube diameter. The neck portion 10n, in this instance is doubled back upon and within itself to the extent necessary to reduce its normal length a substantial extent, and a cylindrical band 80 is enclosed as shown between the base end of the tube and adjacent back folded portion of the bottle neck, so that the neck portion of the bottle can be fitted and secured in the central opening of the nut 25 after the fashion of securing the bottle neck in the bushing 73 in FIG. 3. A needle 28 is applied to the outer end of tube 27d as in the device of FIG. 1 and filling the bottle is as previously explained in connection with the device of FIG. 1.

In using a container or bottle of the type shown in FIG. 9, for giving blood therefrom to a patient, the back folded neck portion of the bottle can be extracted from the opening in the vacuum chamber closure and then drawn out to produce substantial additional effective length to the tube and thus provide easier use of the device.

In this kind of receptacle also, no outside air can contact the blood at any time.

Having thus described my invention, what I claim as new therein, and desire to secure by Letters Patent, is:

1. Apparatus of the character described comprising in combination, a closed chamber equipped for the extraction of air therefrom, a collapsible and expandable bottle of air and liquid tight material disposed in the chamber for expansion under influence of vacuum as produced by extraction of air from the chamber, and a filling connection interconnected to the bottle and extending there-

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from to the exterior of the chamber and through which connection blood drawing suction will be produced by the expanding of the bottle and means operable by the expansion of the bottle whereby the extraction of air from the chamber is regulated.

2. Apparatus of the character described comprising in combination, a vacuum chamber equipped with means for extraction of air therefrom and with a removable closure member applied to said vacuum chamber and having an opening therethrough, an elastic expandable bottle of air and liquid tight material secured to the closure member and movable into and from the chamber with the application to and removal of the closure member from the vacuum chamber, and a filling tube leading from the bottle to the exterior of the chamber, through the said opening of the closure member in an air sealed joint, and equipped at its outer end with a tubular needle for effecting a blood drawing connection with a blood donor and means operable by the expansion of the bottle whereby the extraction of air from the chamber is regulated.

3. Apparatus as recited in claim 2 wherein the bottle neck is sealed at its outer end with a penetratable rubber stopper and said filling tube is equipped at its inner end with a tubular needle adapted to be projected through the stopper to complete the bottle filling connection.

4. Apparatus as recited in claim 2 wherein the neck portion of the bottle is fitted with and secured to a tubular bushing and said bushing is applied to the opening of the closure member in an air tight connection for sealing the opening and for the support of the bottle from the closure member.

5. Apparatus as recited in claim 2 wherein the neck portion of the bottle is fitted exteriorly with and secured to a tubular bushing that is removably applied to the opening of the closure member in an air tight connection to suspend the bottle in the chamber from the closure member, and is removable from the closure member to disconnect the bottle therefrom.

6. Apparatus of the character described comprising in combination, a vacuum chamber equipped with means for the extraction of air therefrom, a closure member secured to said vacuum chamber and formed with an opening therethrough, a collapsible and expandable bottle of an elastic, liquid and air tight material, disposed in said chamber, a tubular bushing applied to the said opening of the closure member, to seal the same and extending beyond the closure member; said bottle having the neck portion thereof extended outwardly through and beyond the tubular bushing and turned back over and about the extended outer end portion thereof in an air tight seal, a rubber cap fitted over the outer end of the bottle neck and bushing to secure and seal the bottle; and a blood drawing tube equipped for connection at its outer end with a donor to receive blood and fitted at its inner end with a tubular needle adapted to be projected through the cap to effect a blood drawing connection between bottle and donor.

7. A device as recited in claim 6 wherein the said vacuum chamber has a lever arm supported therein and said bushing is supported by said lever arm in an air sealed joint, against the said closure member, about the said opening therein when the closure member is applied to the chamber, and is removable from the lever and chamber when the closure is removed from the latter.

8. A device as recited in claim 6 wherein the said vacuum chamber has a lever arm mounted therein for support of the said bushing in an air sealed joint against the said closure member about the said opening therein and said closure member is removable from the chamber and bushing, and said bushing is removable from the lever upon such removal of the closure member.

9. Apparatus of the character described comprising a vacuum chamber, a removable cover member for the chamber applied thereto, means for securing the cover member to the chamber in an air tight joint; said cover

member having an opening therethrough, a lever arm, within the chamber, and pivotally supported at one end from a sidewall thereof for swinging movement from within to above the chamber when the closure is removed therefrom, a tubular bushing removably applied to the swinging end of the supporting lever arm, in position to engage in an air sealing joint against the cover member, about the opening therein, an expandible blood receiving bottle disposed in the chamber and having its neck portion extended outwardly through the tubular bushing to the top side of the closure in an air tight connection, a rubber cap sealing the bottle neck at its upper end, a blood drawing tube connected with the bottle through the cap, and a means for drawing vacuum in the chamber to effect expansion of the bottle.

10. Apparatus as in claim 9 wherein the vacuum drawing means includes an open passage through a chamber wall, a valve member in the chamber, and a yieldable supporting member for the valve member disposed in position to be engaged by the bottle when expanded to seat the said valve member in the open passage to close the vacuum drawing connection.

11. The combination with a vacuum chamber having a wall opening; of a collapsible and expandable bottle adapted to be contained in the chamber for expansion and filling incident to its expansion in the chamber; a tubular bushing secured to the vacuum chamber in an air tight connection and projected through said wall opening of the chamber and extended outwardly beyond the wall, and said bottle having a neck portion extended from the chamber through the bushing and folded back over the outer portion of the tubular bushing, and a bottle sealing, rubber cap fitted over and about the back turned portion of the bottle neck in an air sealed joint and having a central portion that is pierceable by a tubular needle in making a blood drawing or giving connection.

12. A fluid receptacle including a rigid, open ended outer container, a sealed inner container positioned within and operatively joined to said outer container and

adapted for storing fluid, said inner container being normally substantially smaller than said outer container, said inner container including a stretchable, elastic section and a rubber-like self-sealing section puncturable by a sharp instrument and providing means for charging or discharging fluid therefrom, means for sealing the open end of said outer container and for mounting said inner container in operative position within said outer container with said rubberlike section positioned in an exposed, readily accessible position, and an aperture in a wall of said outer container permitting communication with the interior of said outer container when the inner container is mounted therein and the open end is sealed.

13. A fluid receptacle including a rigid, open ended outer container, an internally aseptic and hermetically sealed inner container joined to and forming a removable liner for said outer container and adapted for storing fluid, said inner container being normally substantially smaller than said outer container, said inner container including a stretchable elastic section and a rubber-like self-sealing section adapted to be punctured by a sharp instrument for charging said inner container with fluid and discharging fluid therefrom, means for sealing the open end of said outer container and for mounting said inner container in operative position within said outer container with said rubber-like section positioned in an exposed readily accessible position, said outer container being provided with an aperture in the peripheral wall thereof for permitting communication with the interior of said outer container when the inner container is mounted therein and the open end is sealed.

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