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(54) **MEDICAL CONTAINER.**

(57) A sealed dissolving liquid container (1) and a bottomed cylindrical case (3) having an air vent through bore (8) are connected together via a joint member (4), and a cylindrical drug bottle fixing jig (13) into which a drug vial (2) is inserted with its mouth portion facing downward is movably set in the case (3), a sealed space being thus formed between the drug vial fixing jig (13) and a bottom portion of the case (3). The drug bottle (2) and dissolving liquid container (1) are allowed to communicate with each other quickly by a double ended needle (16) with the sealed condition retained. This medical container enables a drug dissolving operation to be carried out speedily and aseptically during a drip treatment, requires little storage space, and has a smaller number of parts and a smaller total length.

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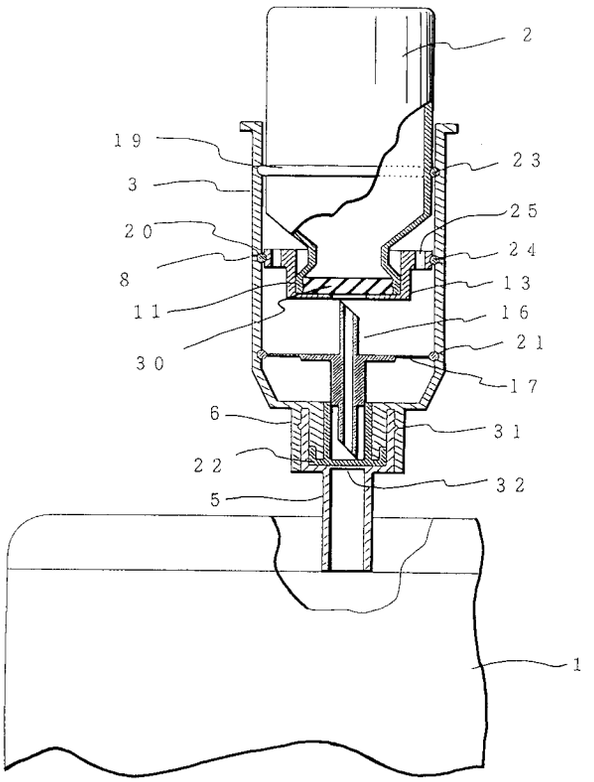
Fig. 6



FIELD OF THE INVENTION

The present invention relates to a medical container which is used for dissolving in the container of sealed system solid drug, such as powder drug or lyophilized drug, in aqueous medium, such as physiological saline or glucose aqueous solution, into injections at the time of use and administering the injections through instillation.

BACKGROUND OF THE INVENTION

From a standpoint of stability of pharmaceutical preparation, some of antibiotics or blood derivatives are used for medical care as solid preparation which is dissolved immediately prior to its use so as to be intravenously administered as injections. In this case, conventionally, dissolving operation of the solid drug is performed by communicating a drug vial with an aqueous medium container, each of which is sealed by a rubber closure, by using, for example, a hollow double ended needle having pointed blades at opposite ends. If this communicating operation is performed under the condition that the rubber closures of the both containers and the double ended needle are exposed to the air, the drug may be contaminated.

Therefore, various medical containers are proposed which enable communication between a drug vial and an aqueous medium container in a sealed system. For example, in a JP,A 61-501129-(PCT WO85/03432), a medical container is disclosed in which a capsule accommodating a drug vial and flexible container for aqueous medium are coupled by a conduit means having communicating means. Furthermore, in a JP,A 2-1277, a medical container is disclosed which enables to perform the communicating operation easily and reliably by improving a communicating mechanism.

The medical container disclosed in JP,A 61-501129 has a problem that the communicating operation is time consuming.

The medical container disclosed in JP,A 2-1277, shows considerable improvements in simplification of communicating operation but does not possess easiness and convenience responsive to urgent medical care requiring rapid drug administration due to the need for performing the communicating operation by turning a cap. Furthermore, since the overall length of this medical container is long, and the number of parts constituting this medical container is large, it is difficult to say that this medical container is suited to medical care for which a storage place for the drug is narrow and, which needs much cost for discarding used medical instruments.

On the other hand, if the medical container is too long, pressure head between the medical container and a portion for administering the injections through instillation becomes small, so that pressure for injecting the injections into a vein becomes low and, in an extreme case, it may become unable to instill the injections due to an inverse flow of blood from a syringe needle held in a vein. Accordingly, in order to smoothly perform instillation based on gravity-drop, it is necessary to minimize overall length of the medical container.

The present invention has, with a view to eliminating such conventional drawbacks, for its objects to provide a medical container by which a communication between a drug vial and an aqueous medium can be performed promptly under a state in which a sealed system is maintained and can be performed a dissolving operation quickly at the time of medical care of instillation under sterile-condition and, which makes it possible to make reduce a storage space and the number of parts and, to shorten the overall length of the medical container.

DISCLOSURE OF THE INVENTION

In order to achieve the aforementioned objects, the present invention is constituted, which comprises a sealed aqueous medium container which has a coupling mouth sealed by a thin film, a cylindrical casing which has a bottom and is sealed by a closure of elastic material and has in the bottom a coupling tube coupled with the coupling mouth by being fitted in the coupling mouth and has a body portion formed with a through-hole for exhaust, a fixing jig which has a flange formed with at least one hole for air vent and a recess in its bottom provided with an opening and the fixing jig being retained so as to be displaced in an axial direction in the casing, a drug vial which is retained in the casing so as to be displaced together with the fixing jig in a state that the coupling mouth sealed by a thin film of elastic material is fitted into the recess, a hollow double ended needle which not only is held in a sealed space defined between the mouth of the drug vial and the bottom so as to be displaced in the axial direction but is formed so as to pierce through the closure of the casing, the closure of the drug vial and the thin film and has a hub for keeping piercing depth of the needle constant, a first shielding member which, before the drug vial is depressed into the casing, closes the through-hole so as to maintain hermetic state of the sealed space and, after the drug vial has been depressed into the casing, is disengaged from the through-hole and, a second shielding member which, before the drug vial is depressed into the casing, maintains together with the first shielding member hermetic state of the sealed space and, after the double ended needle has pierced through

the closure of the casing, the closure of the drug vial and the thin film up to predetermined depth.

According to the present invention, since there are provided the aqueous medium container, the cylindrical casing having a bottom, the drug vial fixing cylindrical jig in which the drug vial directing the mouth downward is mounted, the hollow double ended needle having a hub at middle portion, the through-hole formed at the casing, the shielding members located at the through-hole disengageably from it, it becomes possible to communicate the drug vial with the aqueous medium container promptly under sterile-condition by simple operation and, it becomes possible to perform the operation for dissolving the drug into the aqueous medium quickly.

Further, according to the present invention, since the drug vial is retained in a state that the drug vial is depressed into the casing when the dissolved drug is instilled, the overall length of the medical container is short and, the pressure head between the medical container and a portion for instillation and administration can be made adequately large.

Furthermore, in the medical container of the present invention, the number of its parts is small and the medical container is small in size, thereby resulting in reduction of amount of wastes after use. Especially, in third and fourth embodiments of the present invention, the parts can be separately discarded easily.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view showing a medical container according to first embodiment of the present invention;

Fig. 2 is an exploded perspective view of the medical container of Fig. 1;

Fig. 3 is a longitudinal sectional view of a drug vial fixing jig in the medical container of Fig. 1;

Fig. 4 is a longitudinal sectional view of a double ended needle in the medical container of Fig. 1;

Fig. 5 is a longitudinal sectional view of a casing in the medical container of Fig. 1;

Fig. 6 is a partial sectional front view showing a state of the medical container of Fig. 1 prior to its communicating operation;

Fig. 7 is a partial sectional view showing a state of the medical container of Fig. 1 just after the communicating operation was started;

Fig. 8 is a partial sectional view showing a state of the medical container of Fig. 1 when the communicating operation has been finished;

Fig.9 is a sectional view of the medical container according to a second embodiment of the present invention;

Fig. 10 is a perspective view of the medical container according to a fourth embodiment of the present invention;

Fig. 11 is a partial sectional view of the medical container of Fig. 10;

Fig. 12 is a perspective view of the medical container according to a fifth embodiment of the present invention; and

Fig. 13 is the medical container according to a third embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS

Hereinafter, an embodiment of the present invention is described referring to attached drawings.

Figs. 1 to 8 show a medical container according to a first embodiment of the present invention, in which reference numeral 1 shows an aqueous medium container, 2 shows a drug vial, 3 shows a cylindrical casing having a bottom portion and, 4 shows a coupling portion.

The aqueous medium container 1 is a flexible container made of material, such as thermoplastic polyolefin resin, flexible vinyl chloride resin, ethylene-vinyl acetate copolymer or the like and is provided, at its upper portion, with a coupling mouth 5 sealed by a thin film 32 (See Fig. 6) and is provided, at its lower portion, with medicinal solution outlet 9 sealed by a rubber closure and is filled with aqueous medium.

The drug vial 2 is a container, in which drug is contained and, a mouth of which is sealed by a rubber closure.

A bottom portion of the casing 3 includes a hollow coupling tube 6 formed integrally with the casing 3. Furthermore, the casing 3 includes a flange portion at its upper end portion and, a suspender 7 and a suspender supporting portion 10 at upper portion of its outer wall and, through-holes 8 at four positions in nearly central portion of the outer wall. The suspender 7 is supported by the suspender supporting portion 10 provided at the outer wall of the casing 3.

The coupling portion 4 comprises the above-mentioned coupling tube 6 and the coupling mouth 5, both of which are hermetically fitted and engaged.

Hereinafter, a structure of the medical container according to the above-mentioned embodiment is described in detail with reference to Figs 2 to 6. As shown in Fig. 2, the drug vial 2 is disposed such that its mouth 11 is directed downwardly. The mouth 11 is fitted into a recess 14 of a drug vial fixing jig 13. An annular packing 23 is mounted around an annular groove 12 formed on a body portion of the drug vial 2. An annular packing 24 is mounted around an annular groove 15 formed on a flange portion of the drug vial fixing jig 13. As

described above, the drug vial 2 and the drug vial fixing jig 13 are hermetically mounted in the casing 3 via the annular packings 23 and 24 so as to be displaced. Between the drug vial fixing jig 13 and the bottom portion of the casing 3, a sealed space is formed, in which a double ended needle 16 is located.

As shown in Fig. 3, a bottom portion of the recess 14 of the drug vial fixing jig 13 has an opening 26 for passing a blade face of the double ended needle 16 therethrough. Moreover, a flange portion of the drug vial fixing jig 13 is formed with at least one hole 25 for air vent extending vertically therethrough. Hard plastic, rubber and the like are preferable as material of the drug vial fixing jig 13. The annular packing 24 can be formed integrally with the drug vial fixing jig 13. Soft plastic such as polyethylene and the like, silicone rubber, butadiene rubber, isoprene rubber and the like are preferable as material of the annular packing 24.

As shown in Fig. 4, the double ended needle 16 has a hub 27 for keeping the piercing depth constant when the double ended needle 16 pierces through the rubber closure 30 of the mouth of the drug vial (See Fig. 6), an engagement portion 17 at the middle portion for retaining the double ended needle 16 by engaging with an annular groove 20 formed on an inner wall of the casing 3 and, liquid-tight portion 18. Metal needle of stainless steel, hard plastic resin and the like are preferable as material of the double ended needle 16.

As shown in Fig. 5, in the casing 3, three annular grooves 19, 20 and 21 are formed on the inner wall. At the part of the annular groove 20, through-holes 8 are formed. The coupling tube 6 located at the bottom portion of the casing 3 has a through-hole 29 in which a coupling rubber closure 22 is fitted (See Fig. 2) and, an engagement groove 28 in which a projection 31 for engaging with the coupling portion of the aqueous medium container 1 is fitted (See Fig. 6).

As shown in Fig. 6, the drug vial 2 and the drug vial fixing jig 13 are mounted in the casing 3 in a state that the annular packing 23 is brought into close contact with the annular groove 19 and the annular packing 24 is brought into close contact with the annular groove 20.

As mentioned above, a sealed space is formed between the drug vial fixing jig 13 and the bottom portion of the casing 3 by mounting the drug vial fixing jig 13 in the casing 3. Incursion of air into the sealed space from outside is avoided and, sterility in the sealed space is guaranteed by the annular packing 23. Since the two annular packings 23, 24 are fitted into the annular grooves 19, 20, respectively, fluctuations of position of the drug vial fixing jig 13 in the casing 3 due to vibration, etc. produced during transport are avoided. On the through-hole 8, the annular packing 24 is located, which is disengaged from the through-hole 8 by depressing the bottom portion of the drug vial 2.

Hereinafter, referring to Figs. 7 and 8, method of use of the above-described medical container is described.

Fig. 7 shows a state just after an operation for communicating the drug vial 2 with the aqueous medium container 1 was started and, Fig. 8 shows a state after the operation has been finished. At first, the bottom portion of the drug vial 2 is pushed downwardly so as to communicate the drug vial 2 with the aqueous medium container 1. More concretely, the drug vial fixing jig 13 is descended toward the aqueous medium container 1 by depressing the bottom face of the drug vial 2 with a finger. By this operation, two annular packings 23, 24 are disengaged from the annular grooves 19, 20. Concurrently with disengagement of the annular packing 24 from the annular groove 20, the through-hole 8 closed by the annular packing 24 is opened.

Furthermore, air in the sealed space in the casing 3, which space is reduced upon descent of the drug vial fixing jig 13, is discharged to outside of the casing 3 from the through-hole 8 through the holes 25 for air vent. By this discharge of the air, the drug vial fixing jig 13 retaining the drug vial 2 can descend easily without being pushed back by the air in the reduced sealed space. Still more, the drug vial fixing jig 13 is depressed, end portions of the engagement portion 17 of the double ended needle 16 is disengaged from the annular groove 21 and, the double ended needle 16 descends toward the aqueous medium container 1. Thus, as shown in Fig. 8, the coupling rubber closure 22 of the coupling portion 40 and the thin film 32 and the rubber closure 30 of the mouth 11 of the drug vial 2 in opposite side are pierced through instantaneously. At this time, the annular packing 23 is fitted into the annular groove 20, so that the through-hole 8 is closed again. Moreover, the annular packings 23 and 24 are, respectively, fitted into the annular grooves 20 and 21 so as to prevent ascent of the drug vial fixing jig 13.

After the drug vial 2 and the aqueous medium container 1 are communicated, they are laid horizontally or laid in a state that the aqueous medium container 1 is raised higher than the drug vial 2 and, the aqueous medium is transferred into the drug vial 2 by depressing a surface of the aqueous medium container 1, so that the drug is dissolved. After the drug is dissolved completely, a solution is returned to the aqueous medium container 1, thereafter the suspender 7 is suspended to a hook of a stand for fluid therapy and, a fluid therapy unit is attached to the outlet 9 of the aqueous medium container 1 and, the solution is intravenously ad-

ministered through instillation to a patient.

Fig. 9 shows a medical container according to a second embodiment of the present invention. As shown, in this embodiment, an outer wall of the drug vial fixing jig 13 extends to a body portion of the drug vial 2. Furthermore, the medical container of this embodiment is different from that of Figs 1 to 8 in that, in this embodiment, the body portion of the drug vial 2 is not provided with the annular groove 12 and the annular packing 23. In this embodiment, the drug vial 2 is hermetically mounted in the drug vial fixing jig 13 such that the mouth portion of the drug vial 2 is directed downwardly. An annular packing 33 is mounted around an annular groove which is formed on an outer wall of the drug vial fixing jig 13.

By the above-described constitutions, it becomes unnecessary to form an annular groove 12 on the body portion of the drug vial 2 and, glass vial usually used is utilized as a drug vial

Constitutions other than the above-described constitutions are substantially the same as those of the embodiment of Figs. 1 to 8.

Fig. 13 shows a medical container according to third embodiment of the present invention, which is substantially the same as that shown in Figs. 1 to 8 except for that the engagement portion 17 of the double ended needle 16 acts, in place of the annular packing 24, as a shielding member for shielding the through-hole 8.

Figs. 10 and 11 show a medical container according to a fourth embodiment of the present invention.

As shown in Fig. 11, an outer wall of the drug vial fixing jig 13 of this embodiment extends to a bottom portion of the drug vial 2. The drug vial fixing jig 13 has a flange portion at the lower portion and, a flange portion 34 comprising an outward flange portion 37 and an inward flange portion 38 at the upper end portion (See Fig. 10). Further, in the drug vial fixing jig 13 of this embodiment, projections 35 on the side wall of the body portion and at least two cut portions 36 are provided. Furthermore, in the drug vial fixing jig 13 of this embodiment, on the inner wall thereof, an annular packing 39, which is brought into close contact with the drug vial 2, is provided.

In the medical container of this embodiment, ascent of the drug vial 2, which occurs when the rubber closure 30 of the mouth portion of the drug vial 2, thin film 32 and, the rubber closure 22 of the coupling portion are pierced through by the double ended needle 16, is prevented by the inward flange portion 38 provided on the drug vial drug vial fixing jig 13 and, by the projections 35 each of which has a wedgy form at lower portion thereof. When the drug vial fixing jig 13 descends by communicating operation which is performed by depressing the bottom portion of the drug vial 2, the projection 35 is brought into contact with the inner wall of the casing 3 resulting in a side wall of upper portion of the drug vial fixing jig 13 being deformed inwardly toward a center of an axis and, the bottom portion of the drug vial 2 is depressed by the inward flange portion 38 with the deformation of the side wall, whereby the ascent of the drug vial 2 is prevented.

Moreover, the medical container of this embodiment has a feature that discarding separately after use is performed easily. After the medical container of the this embodiment has been used, the outward flange portion 37 provided at the upper end portion of the drug vial fixing jig 13 is pulled upwardly, whereby the drug vial fixing jig 13 can be taken out from the casing. After the drug vial fixing jig 13 has been taken outwardly, the drug vial 2 mounted in the drug vial fixing jig 13 can be taken outwardly by holding and pulling upwardly with fingers a side wall of the drug vial 2 exposed by the cut portions 36.

The annular packing 39 provided at the inner wall of the body portion of the drug vial fixing jig 13 prevents hermetic state in the casing 3 from being spoiled by dispersion of diameter size of the body portion of the drug vial 2 which occurs due to mass production. Meanwhile, although three annular packings 24, 33 and 39 on the drug vial fixing jig 13 may be mounted around the annular grooves which are made around the drug vial fixing jig 13, they may be made integrally with the drug vial fixing jig 13

Fig. 12 shows a medical container according to fifth embodiment of the present invention.

As shown, the through-hole 8 is formed in the annular groove 21 with which the double ended needle 16 is engaged, thereby an engagement portion 17 of the double ended needle 16 becomes a shielding member closing and opening the through-hole 8.

The other constitutions are substantially identical with those of the medical container of Figs. 10 and 11.

Claims

1. Medical container comprising:

a sealed aqueous medium container which has a coupling mouth sealed by a thin film;

a cylindrical casing which has a bottom portion and is sealed by a closure of elastic material and has in said bottom portion a coupling tube coupled with said coupling mouth by being fitted in said coupling mouth and has a body portion formed with a through-hole for exhaust;

a fixing jig which has a flange formed with at least one hole for air vent and a recess at its

bottom provided with an opening and, said fixing jig being retained so as to be displaced in an axial direction in said casing;

a drug vial which is retained in said casing so as to be displaced together with said fixing jig in a state that said coupling mouth sealed by a thin film of elastic material is fitted in said recess;

a hollow double ended needle which not only is held in a sealed space defined between said mouth of said drug vial and said bottom portion so as to be displaced in the axial direction but is formed so as to pierce through said closure of said casing, said closure of said drug vial and said thin film and has a hub for keeping piercing depth of said needle constant;

a first shielding member which, before said drug vial is depressed into said casing, closes said through-hole so as to maintain hermetic state of said sealed space and, after said drug vial has been depressed into said casing, is disengaged from said through-hole; and

a second shielding member which, before said drug vial is depressed into said casing, maintains together with said first shielding member hermetic state of said sealed space and, after said double ended needle has pierced through said closure of said casing, said closure of said drug vial and said thin film up to predetermined depth.

2. Medical container as claimed in Claim 1 wherein said first shield member is provided on outside portion of said fixing jig and said shielding member is provided around outside portion of said drug vial.

3. Medical container as claimed in Claim 1 wherein said first and second shielding members are provided around outside portion of said fixing jig, respectively.

4. Medical container as claimed in Claim 1 wherein said first shielding member is provided around periphery portion of said hub of said double ended needle.

5. Medical container as claimed in Claim 3 or 4 wherein said fixing jig is provided with an outward flange portion and an inward flange portion for retaining said drug vial and a cut portion on an end portion of said fixing jig opposite to said recess.

6. Medical container as claimed in Claim 5 wherein said fixing jig is provided with outward projections, each lower portion of which has wedgy form and engages with an end portion of said casing when said drug vial is depressed into said casing.

Fig. 1

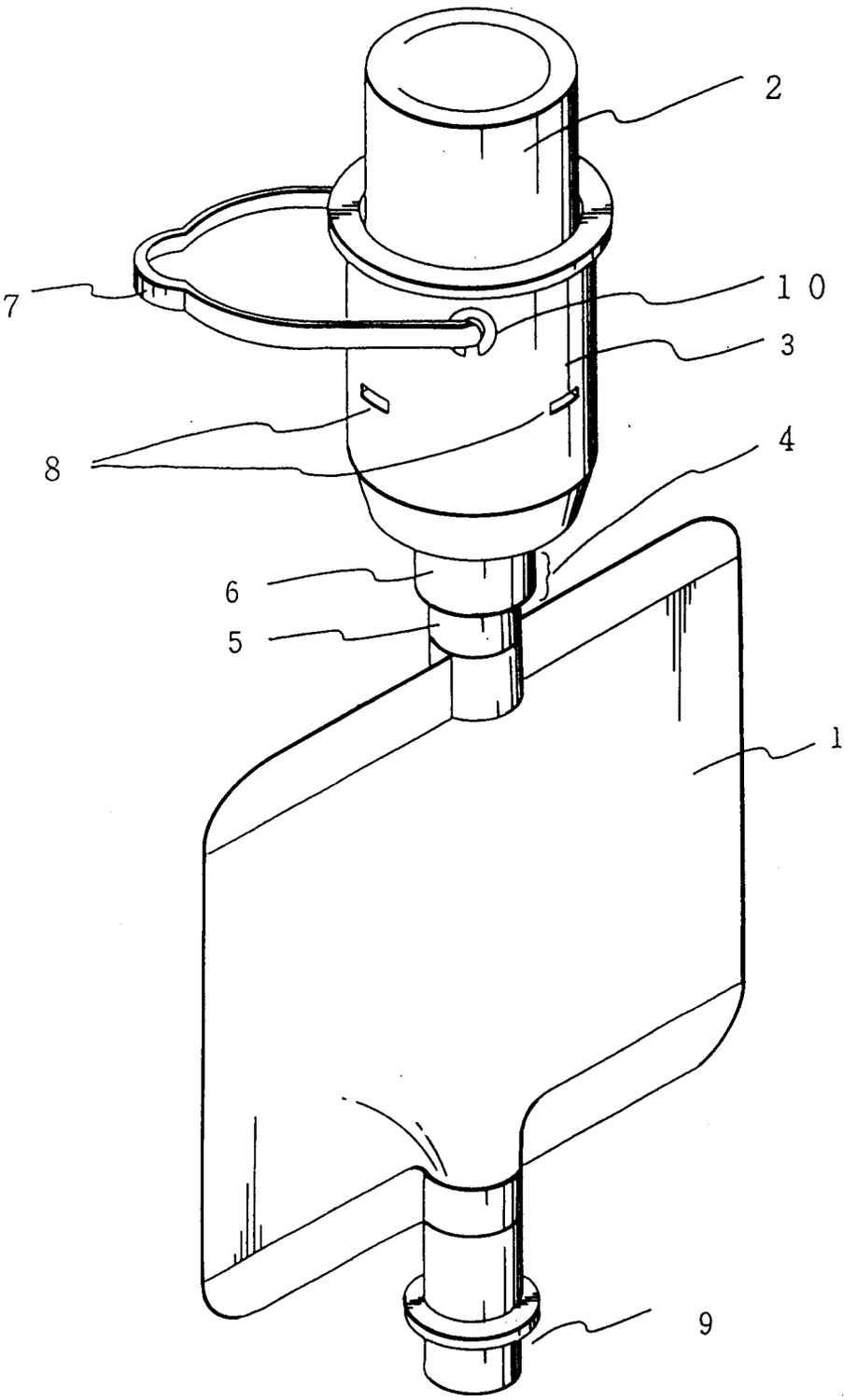


Fig. 2

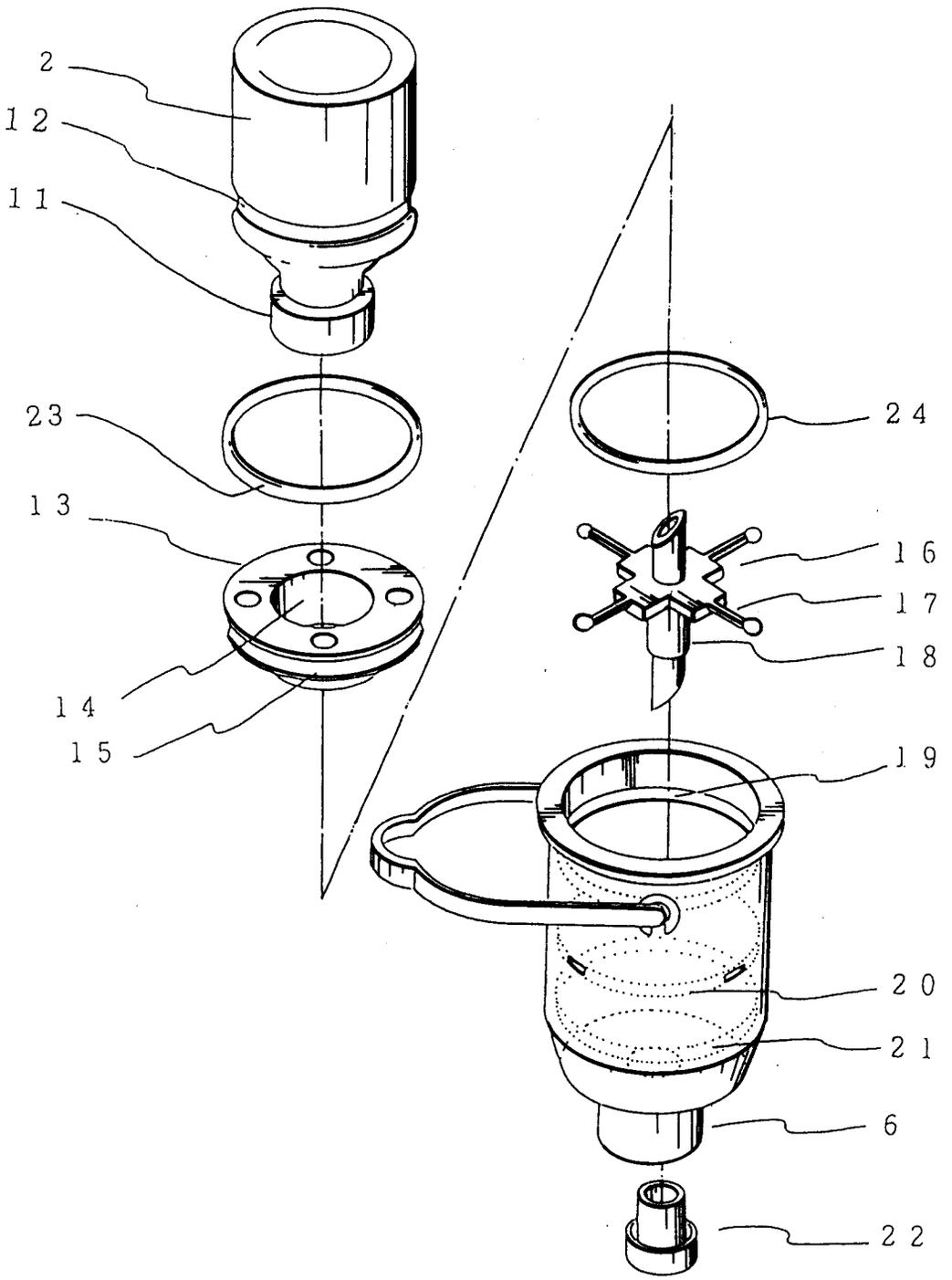


Fig. 3

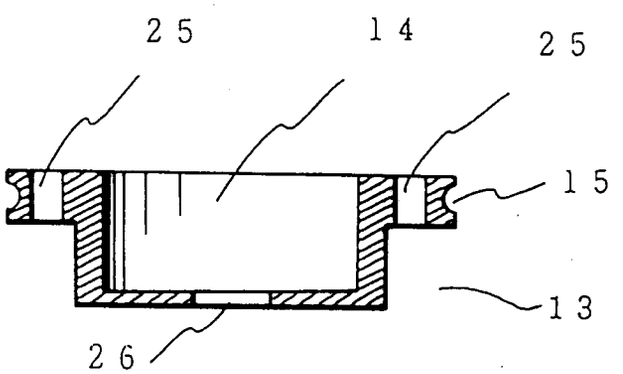


Fig. 4

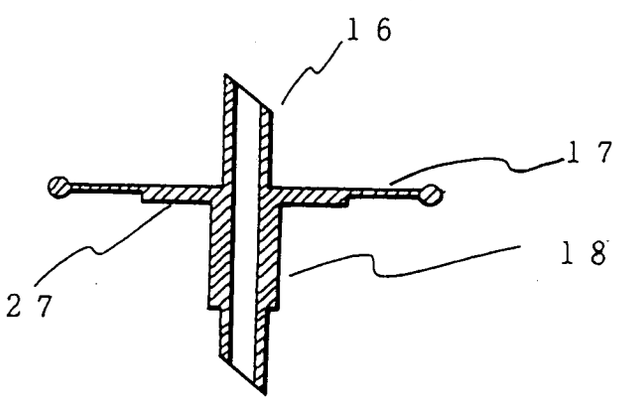


Fig. 5

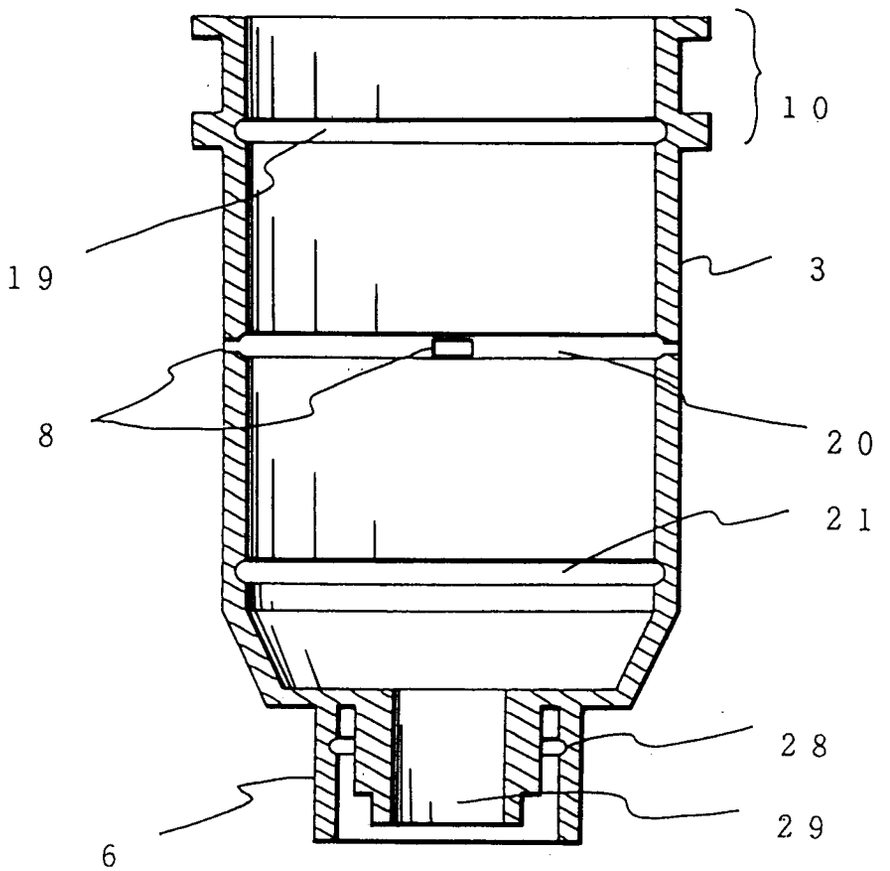


Fig. 6

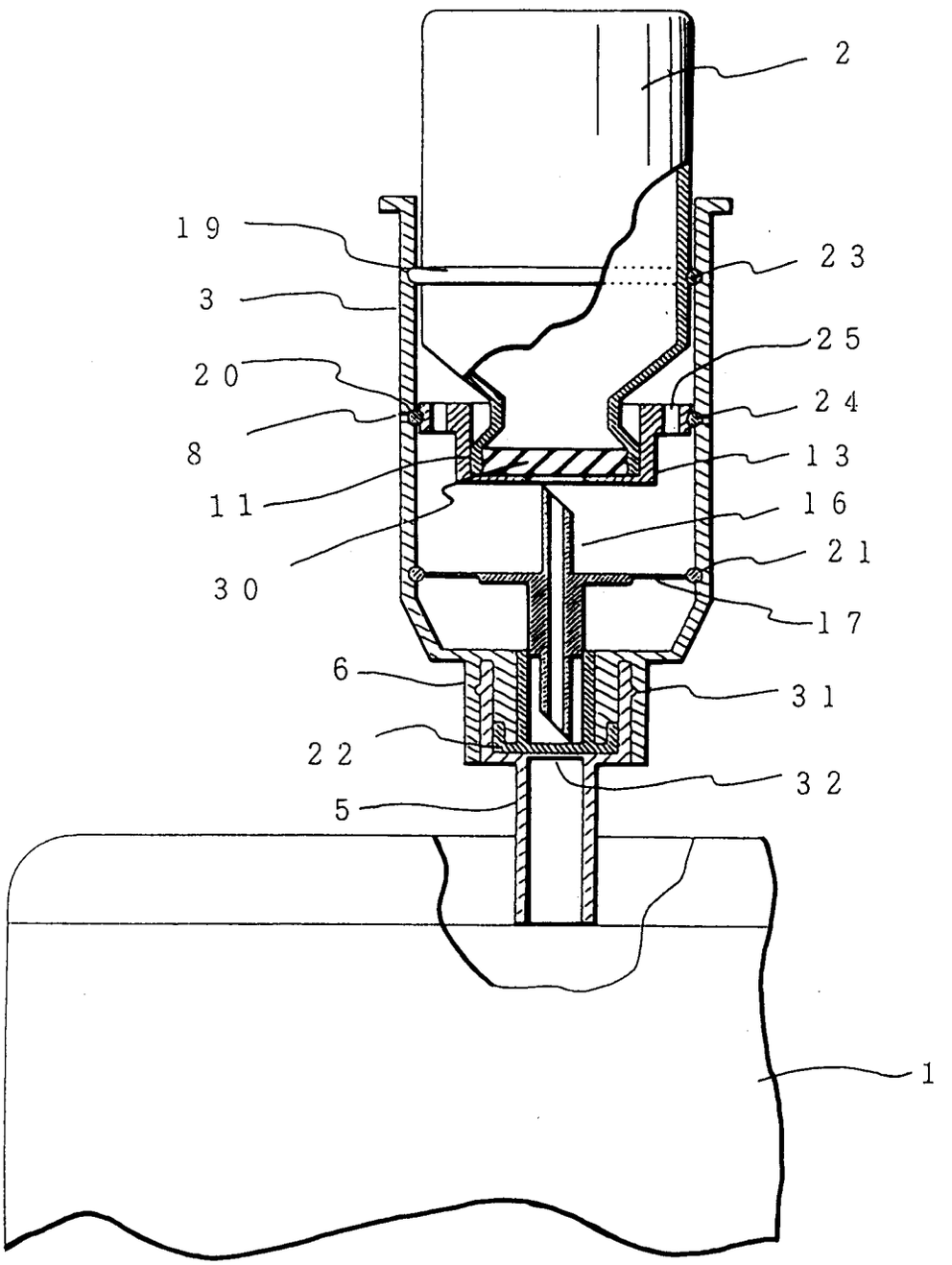


Fig. 7

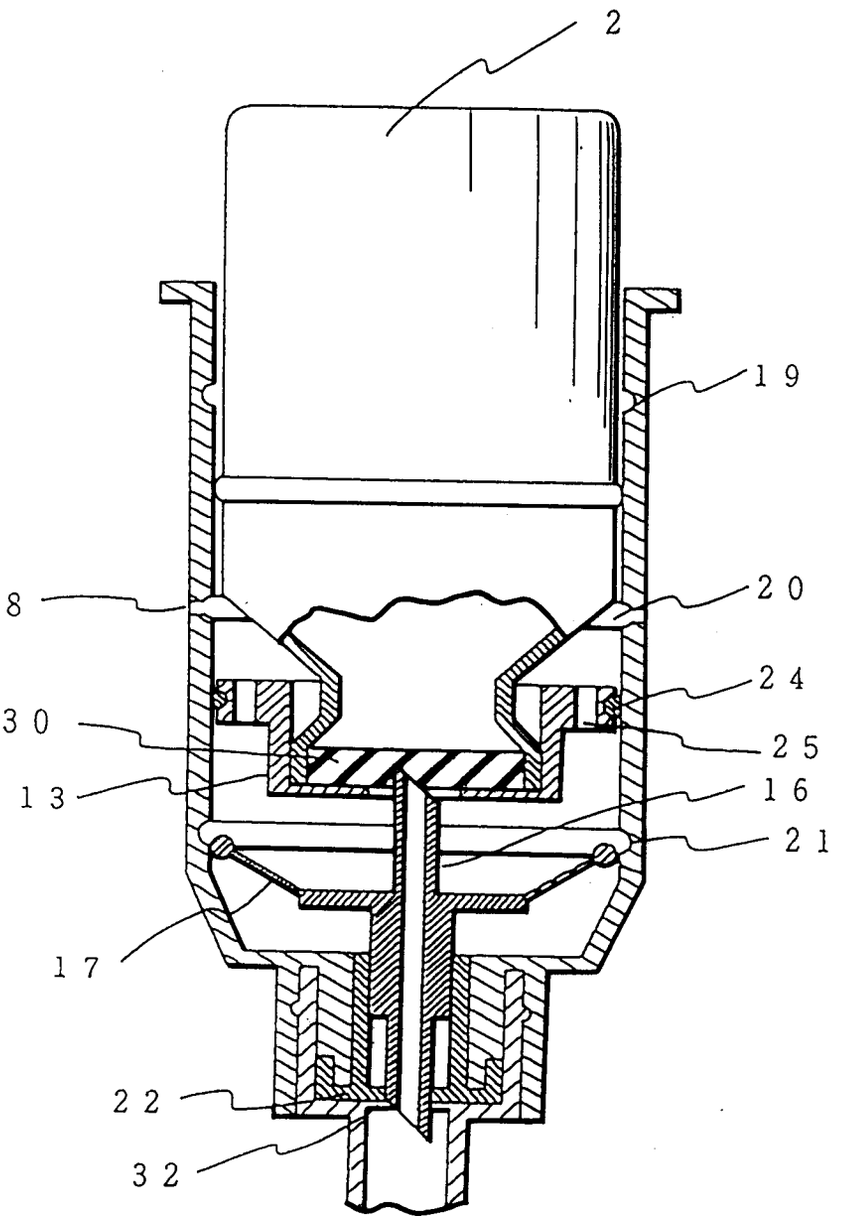


Fig. 8

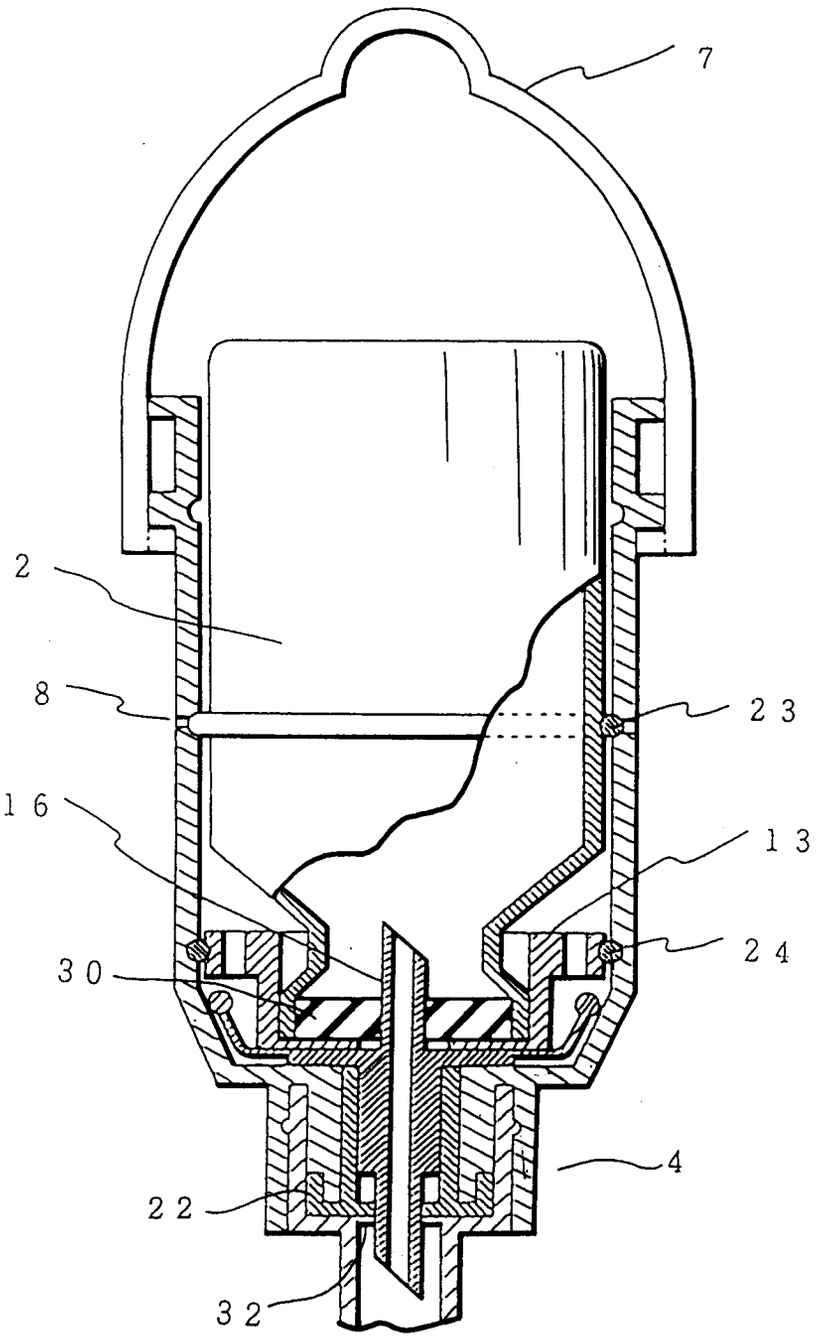


Fig. 9

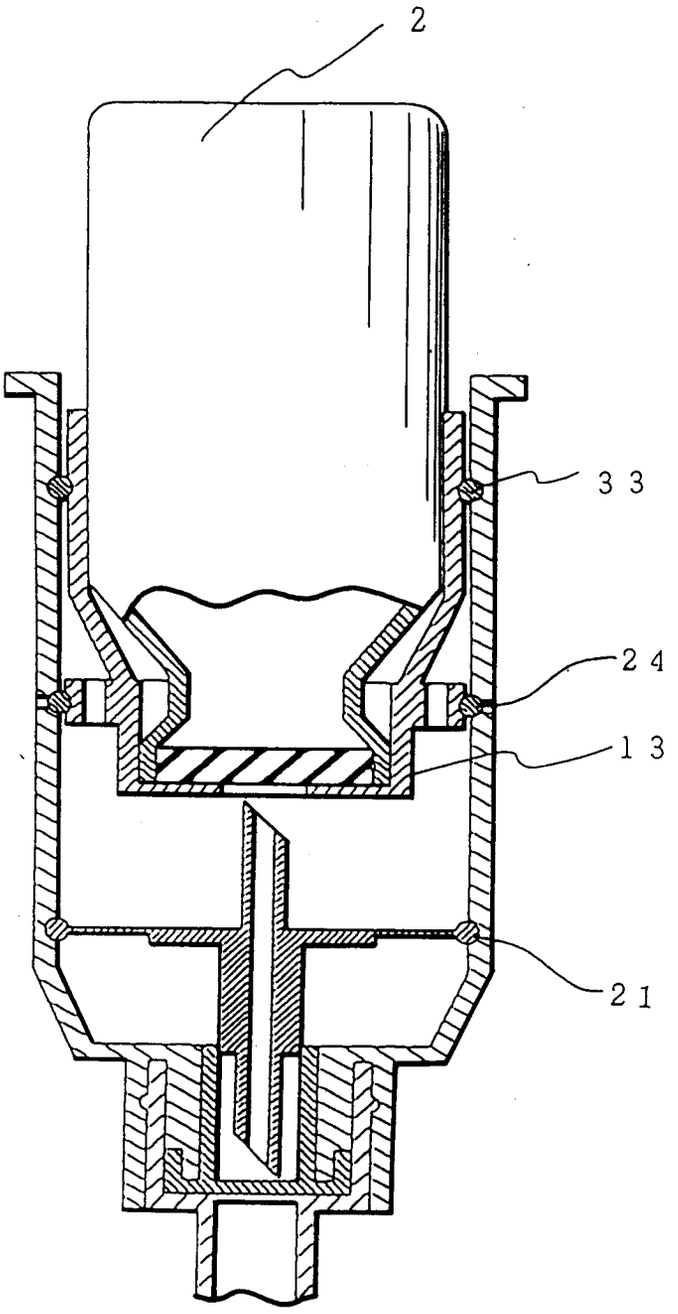


Fig. 10

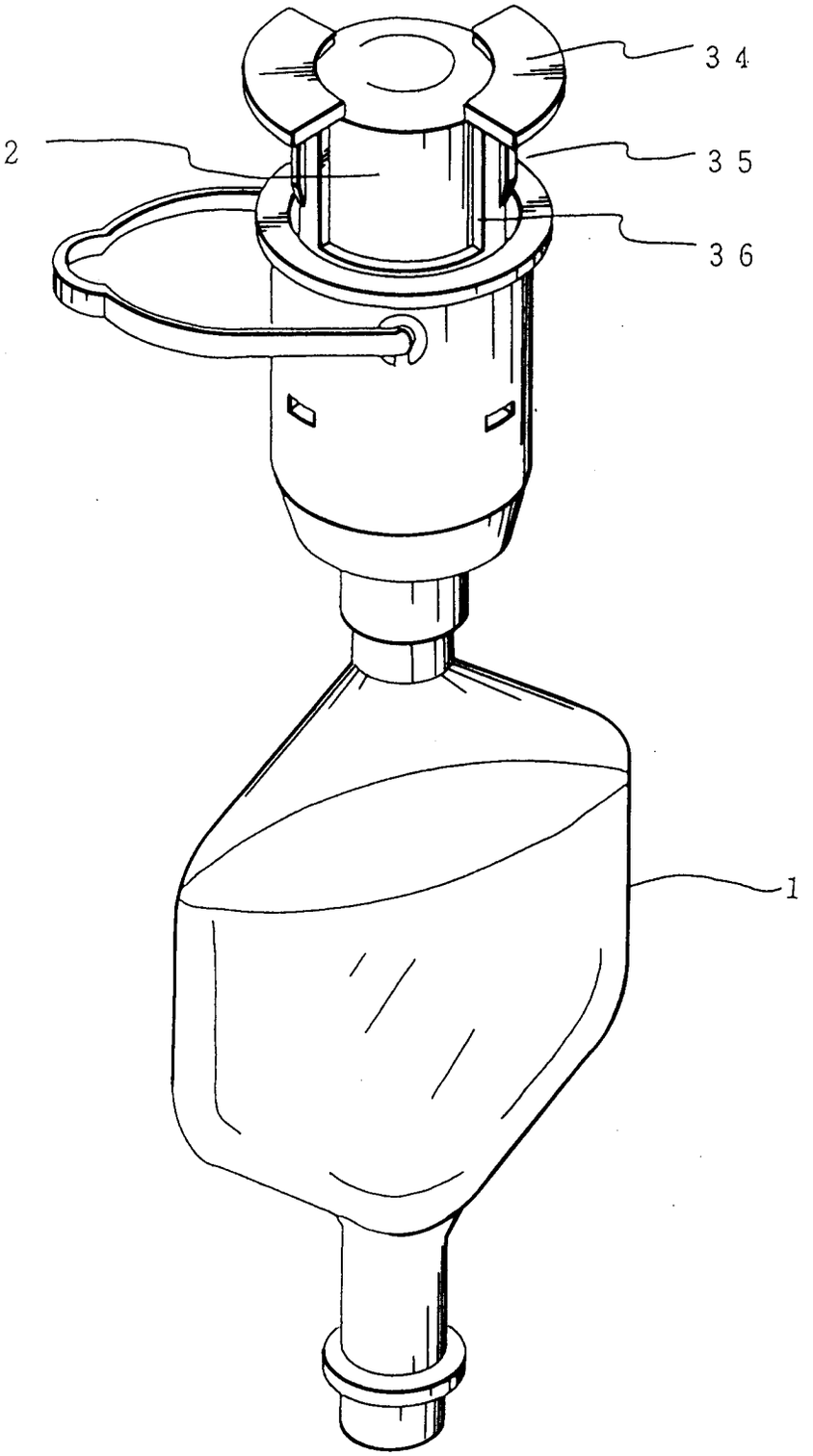


Fig. 11

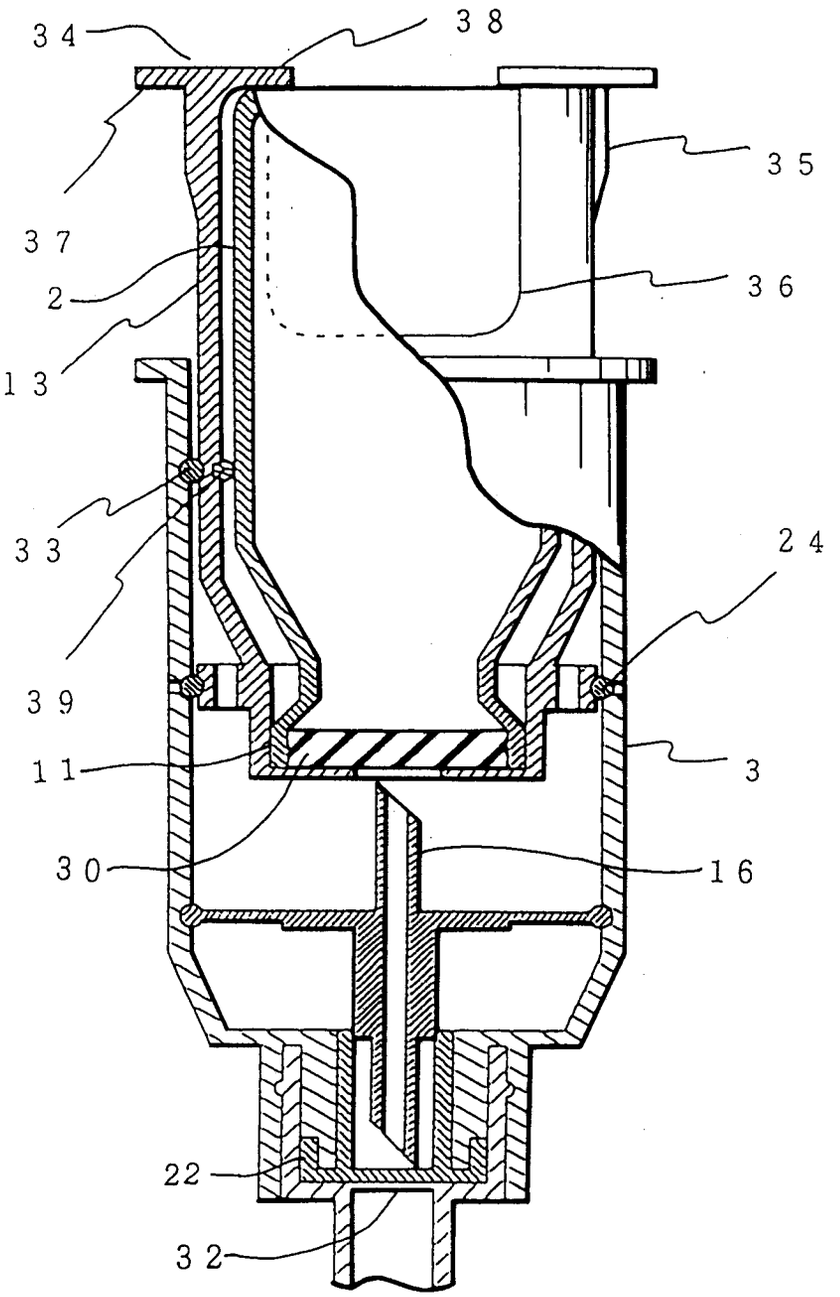


Fig. 12

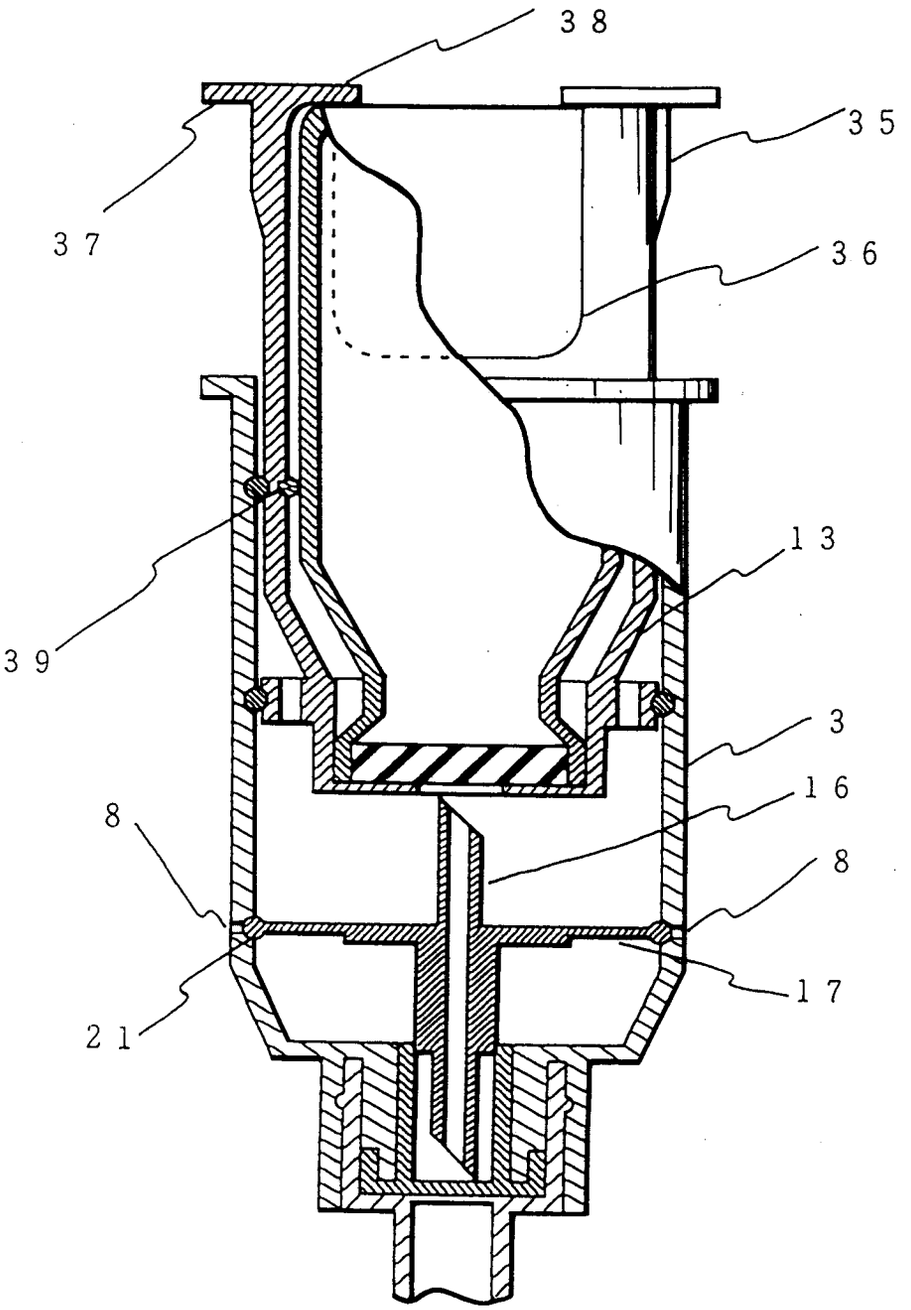
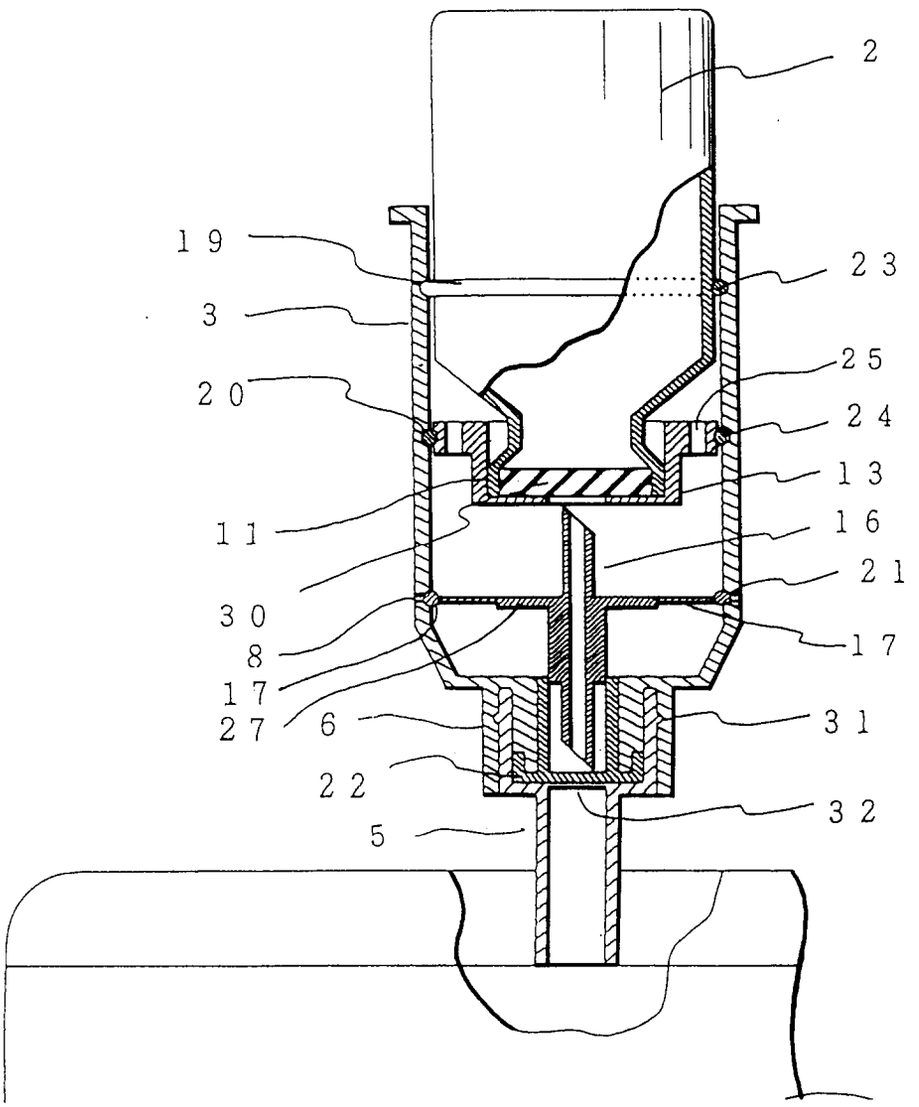


Fig. 13



INTERNATIONAL SEARCH REPORT

International application No.
PCT/JP93/00789

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl^5 A61J1/00, 3/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Int. Cl^5 A61J1/00, 3/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Jitsuyo Shinan Koho 1926 - 1993
Kokai Jitsuyo Shinan Koho 1971 - 1993

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JP, A, 3-37067 (Hishiyama Seiyaku K.K.), February 18, 1991 (18. 02. 91), (Family: none)	1-6

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
August 24, 1993 (24. 08. 93)	October 12, 1993 (12. 10. 93)
Name and mailing address of the ISA/ Japanese Patent Office	Authorized officer
Facsimile No.	Telephone No.

Form PCT/ISA/210 (second sheet) (July 1992)