(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 2 399 565 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
28.12.2011 Bulletin 2011/52

(51) Int Cl.:
A61J 1/20 *(2006.01)* ***A61J 1/10*** *(2006.01)*

(21) Application number: **11170981.2**

(22) Date of filing: **22.06.2011**

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR
Designated Extension States:
BA ME

(30) Priority: **25.06.2010 IT MI20101154**

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(54) Device for dosed reconstitution and administration of liquid solutions containing active substances available in separate form, in particular in powder or gel form

(57) A device is disclosed for dosed reconstitution and administration of liquid solutions containing active substances available in a separate form, in particular in powder or gel. The device comprises a bag (1) containing a basic liquid solution, a tube (3) closed by a hermetic cap (4) for administering the liquid solution, a tube (5) connecting said bag (1) to an terminal (7) for hooking and perforating a closing cap (16) of a bottle (9) of active substance, a breakable cap (17) housed inside said connecting tube (5) near said hooking and perforating end (7), and a flow deviator (18) inserted in said connecting tube (5) between said bag (1) and said breakable cap (17). The flow deviator (18) enables communication to be established selectively between the bag (1) and the hooking and perforating terminal (7) or between either said bag (1) and said hooking and perforating terminal (7) and a connecting mouth (20) of a dosing syringe (31) for dosing the quantity of active substance to be inserted into said basic liquid solution. (Fig. 1)

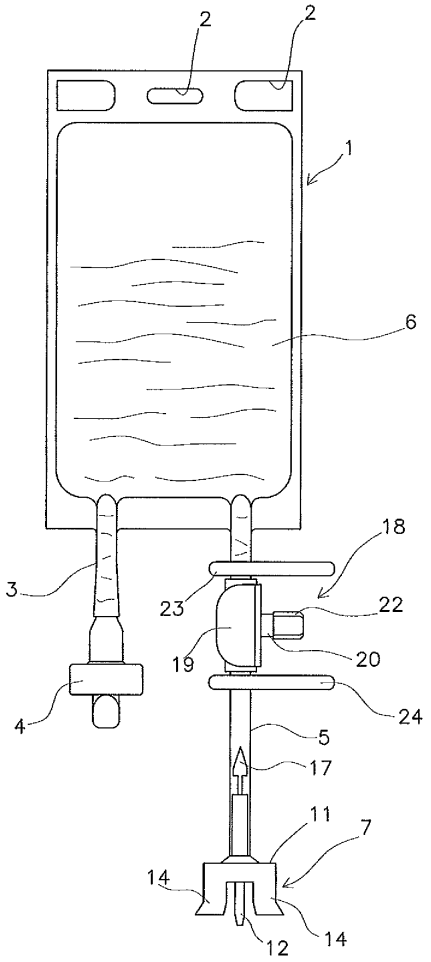

FIG. 1

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Description

[0001] The present invention relates to a device for dosed reconstitution and administration of liquid solutions containing active substances available in a separate form, in particular in powder or gel form.

[0002] In hospital environments there is often a need to administer active substances of various kinds, in particular drugs or nutritional substances, which are made available in a separate form, in particular in powder or gel form, inside suitable sealed bottles.

[0003] In order to make the active substances suitable for administration (infusion or other method) it is necessary to form a liquid mixture that comprises, in addition to the active substance, a basic liquid solution that operates as a solvent.

[0004] It is extremely important that the formation of this mixture and the delivery thereof into a bag intended for infusion or another administration method (for example for washing wounds) occurs in a closed-circuit environment in such a manner as to avoid both contamination of the active substance and harm to the medical and nursing staff that may arise from possible toxicity of the active substance if it is in drug form.

[0005] It is also important that the drug or food to be administered can be reconstituted in a dosed manner, i.e. that the final liquid solution contains a variable dose of active substance to meet the variable treatment needs.

[0006] US-A-5899877 discloses a device for administrating medicines in accordance with the preamble to claim 1.

[0007] The object of the present invention is thus to make a device for dosed reconstitution and administration of liquid solutions containing active substances available in a separate form, in particular in powder or gel form, that meets the dual need of forming the mixture in a closed circuit and variable dosing of the quantity of active substance contained in the final solution to be administered to the patient.

[0008] According to the present invention, this object is achieved with a device comprising the further features defined in the characterising part of claim 1.

[0009] The device according to the invention constitutes a closed circuit that does not allow contact of the active substance with the exterior and at the same time enables suitable dosing by the syringe of the quantity of active substance to be mixed with the basic liquid solution and thus pharmacological or nutritional loading of the mixture to be administered to the patient.

[0010] The constructional features and the operating procedures of the device according to the invention will be made clear by the following detailed description of possible embodiments shown by way of non-limiting example in the attached drawings, in which:

figure 1 shows a device according to the present invention in a nonoperative condition;
figure 2 shows the device in figure 1 after hooking and perforation of a bottle with active substance in powder form;
figure 3 shows a plan view of an opening and closing clamp of the connecting tube between the bag and the hooking and perforating means for hooking and perforating a bottle with a drug in powder form;
figure 4 shows an enlarged section view of the three-way passage of the flow deviator of the device in figure 1;
figure 5 shows the attaching and perforating means 1 in a cross section according to the line V-V in figure 2;
figure 6 shows the device in figure 2 during the step of transferring a quantity of basic solution from the bag to the bottle for transformation of the active substance in powder form into a liquid mixture;
figure 7 shows the same device in an upturned position for transferring said liquid mixture from the bottle to the bag;
figure 8 shows the same device positioned as in figure 6 after the application of a dosing syringe for removing a dosed quantity of basic liquid solution;
figure 9 shows the same device in a subsequent step of transferring said dosed quantity of basic solution from the syringe to the bottle for mixing thereof with the active substance contained in the bottle;
figure 10 shows the same device in a subsequent step of removing a dosed quantity of liquid mixture from the bottle;
figure 11 shows the same device in a subsequent step of transferring said dosed quantity of liquid mixture from the syringe to the bag;
figure 12 shows in a non-operating condition a possible variation of the invention device disclosed above;
figure 13 shows in a non-operating condition a further version of the invention device disclosed above;
figure 14 shows an enlarged section view of the flow deviator comprised in the device in figure 13;
figure 15 shows the device in figure 13 during the step of transferring a quantity of basic solution from the bag to the bottle for transforming the active substance in powder form into a liquid mixture;
figure 16 shows the device in figure 15 after the application of a dosing syringe to remove a dosed quantity of basic solution from the bag;
figure 17 shows the same device in a subsequent step of transferring said dosed quantity of basic solution from the syringe to the bottle to form a liquid mixture of active substance and basic solution,
figure 18 shows the same device in figure 17 in an upturned position for transferring said liquid mixture from the bottle to the bag.

[0011] According to the embodiment shown in figure 1, the device according to the present invention comprises a transparent flexible bag 1 that is provided with hooking windows 2, with a flexible administering tube 3 closed

by a hermetic cap 4, for example of the perforable type, and with a flexible mixing tube 5. The bag 1 is supplied to the medical facility filled with a basic solution or solvent 6.

[0012] The mixing tube 5 connects the bag 1 to a terminal 7 that is usable for hooking and perforating the perforable cap 8 of a bottle 9 that contains an active substance 10 in powder for (or gel form or other material) to be mixed with the basic solution 6 contained in the bag 1 (figure 2). As also shown in figure 5, the end 7 comprises a top plane 11, from which extend a perforating needle 12 with an axial hole 13 communicating with the internal passage of the tube 5 and two pairs of elastically deformable jaws 14 provided with an undercut 15 that is suitable for grasping and supporting the sealing collar 16 of the bottle 9.

[0013] Near the end 7, the tube 5 provides internally a breakable closing cap 17 that can be broken and opened by manual action exerted on the outside of the tube 5.

[0014] Between the breakable cap 17 and the bag 1 the tube 5 has a flow deviator 18, shown in an enlarged section in figure 4, which comprises a three-way passage 19 with a first way in communication with the bag 1, a second way in communication (via the breakable cap 17) with the terminal 7 and a third way in communication with a lateral mouth 20 with a valve device 21, that is normally closed by a screw cap 22. The flow deviator 18 is completed by two clamps 23 and 24 of the type shown in a plan view in figure 3, having a narrow part 25 that is suitable for tightening and closing the section of the tube 5 to which the opening and closing clamp is applied and a wide part 26 that is suitable for enabling the liquid to circulate freely inside the tube 5.

[0015] The device illustrated in figures 1-5 is usable as follows.

[0016] With the bag 1 filled with a basic liquid solution 6 that is suitable for acting as a solvent and the clamps 23 and 24 in the opening position of figures 1 and 2, a bottle 9 containing an active substance 10 in powder form is applied to the terminal 7 in such a manner that the needle 12 perforates the cap 8 of the bottle and the jaws 14 with undercuts 15 hook and support the sealing collar 16 of the bottle.

[0017] Subsequently, the breakable cap 17 is broken, so the basic liquid solution, assisted by manual compression of the bag 1, starts to flow from the bag 1 to the bottle 9, where it mixes with the active substance in powder form, forming a liquid mixture composed of the active substance and of the basic solution (fig. 6).

[0018] By overturning the device as shown in figure 7, the mixture that is thus formed flows into the bag 1, after which at least one of the clamps 23 and 24 is moved to a closing position and the bag is thus ready for the infusion, which is performed by connecting the tube 3 to the patient by means of an intravenous tube with simultaneous or subsequent opening of the cap 4.

[0019] The device in figures 1-5 also enables the active substance to be delivered in a dosed quantity in the basic solution 6. In order to obtain this, with the clamps 23 and 24 shut, the cap 22 is unscrewed and the nozzle 30 of a syringe 31 is inserted into the side mouth 20 of the three-way passage 19 of the flow deviator 18 by pushing forwards and thus opening the valve device 21. By opening the clamp 23 and pulling back the piston 32 of the syringe (fig. 8), a dosable quantity of the basic liquid solution present in the bag 1 is sucked into the internal chamber 33 of the syringe. After closing the clamp 23 and opening the clamp 24, the subsequent advance of the piston 32 enables the dosed quantity of basic solution previously sucked by the syringe 31 to be transferred to the bottle 9, where it mixes with the active substance in powder form contained in the bottle (figure 9).

[0020] A dosable quantity of the liquid mixture that is thus formed is subsequently sucked into the syringe 31 (fig. 10) and, once the clamp 24 is closed and the clamp 23 is opened, is delivered to the bag 1 (fig. 11).

[0021] By separating the syringe 31 from the mouth 20, the valve device 21 recloses automatically because of the pressure difference between the ends thereof.

[0022] Figure 12 shows a possible version of the device in figures 1-5, which is completely similar to the previously disclosed one and also operates in a similar manner. The only difference is that the administering tube 3 is located at one end of the bag 1 that is opposite the one from which the mixing tube 5 extends.

[0023] Figures 13-18 in turn show a further variant of the device, which is distinguished from that of figures 1-5 by the fact that the flow deviator 18 consists of a three-way cock 40, in which three radial arms 41, 42, 43 provided with an indicating arrow are usable for rotating an internal valve 44 (figure 14) and to alerting the user to the communications made each time.

[0024] In this case, with the cap 22 closed and the cock 40 in the position in figure 13 the basic solution 6 can flow into the bottle 9 and form a mixture with the active substance in powder form contained in the bottle 9 and then, by overturning the device, the mixture can be made to flow into the bag 1 in the manner disclosed with reference to figures 6 and 7.

[0025] In order to obtain a dosed quantity of mixture and deliver the dosed quantity of mixture to the bag 1, the cock 40 is rotated to the position in figure 16 and the nozzle of a syringe 31 is inserted into the mouth 20 by removal of the cap 22. By retracting the piston 32, a dosed quantity of basic solution is sucked from the bag 1 to the syringe 31.

[0026] The cock 40 is then rotated to the position in figure 17 and the piston 32 is advanced to transfer the dosed quantity of basic solution previously sucked by the syringe 31 to the bottle 9, where a mixture in a dosed quantity is formed that then, after the cock 40 is rotated to the position in figure 18, after the cap 22 is retightened and the device is overturned, flows into the bag 1.

[0027] It is also possible, once the mixture has been obtained, to take a dosed sample thereof by means of the syringe 31 and deliver such dosed quantity of mixture

to the bag 1 with the same methods as those disclosed with reference to figures 10 and 11.

Claims

1. Device for dosed reconstitution and administration of liquid solutions containing active substances available in a separate form, in particular in powder or gel form, comprising a bag (1) containing a basic liquid solution, a first tube (3) made as a single piece with said bag (1) and closed by a hermetic cap (4) to administer the liquid solution, a second tube (5) made as a single piece with said bag (1) for connecting said bag (1) to a terminal (7) for hooking and perforating a closing cap (16) of a bottle (9) of active substance, a breakable cap (17) housed inside said connecting tube (5) near said hooking and perforating end (7), and a flow deviator (18) comprising a three-way passage (19) made of a single piece in said second tube (5) to enable communication between said bag (1), said hooking and perforating terminal (7) and a mouth (20) provided with a closing cap (22) that is penetratable by the dispensing nozzle (30) of a syringe (31) comprising a piston (32) that is movable backwards and forwards to vary the volume of an internal chamber (33) of the syringe (31), **characterised in that** with said second tube (5) there are associated a first openable and closable clamp (23) positioned between the three-way passage (19) and the bag (1) and a second openable and closable clamp (24) positioned between the three-way passage (19) and the breakable cap (17), and said internal chamber (33) of the syringe (31) is normally empty to enable a dosed quantity of active substance to be delivered inside said basic liquid solution inside said bag (1) by the following sequence of operating steps:

   a) opening said first clamp (23) with said second clamp (24) closed and retraction of the piston (32) of the syringe (31) to transfer a dosed quantity of basic liquid solution from said bag (1) to said internal chamber (33) of the syringe (31);
   b) closing said first clamp (23), opening said second clamp (24) and advancing of the piston (32) of the syringe (31) to transfer said dosed quantity of basic liquid solution from said internal chamber (33) of the syringe (31) to said bottle (9) of active substance to form a mixture of basic liquid solution and of said active substance;
   c) retraction of the piston (32) of the syringe (31) with said second clamp (24) open and said first clamp (23) closed to transfer a dosed quantity of said mixture of basic liquid solution and said active substance from said bottle (9) to said internal chamber (33) of the syringe (31);
   d) closure of said second clamp (24), opening said first clamp (23) and advancing the piston (32) of the syringe (31) to transfer said closure of said second clamp (24) dosed quantity of said mixture of basic liquid solution and of said active substance from said internal chamber (33) of the syringe (31) to said bag (1).

2. Device according to claim 1, **characterised in that** said closing cap (22) is automatically reclosable by extracting said nozzle (30) of the syringe (31).

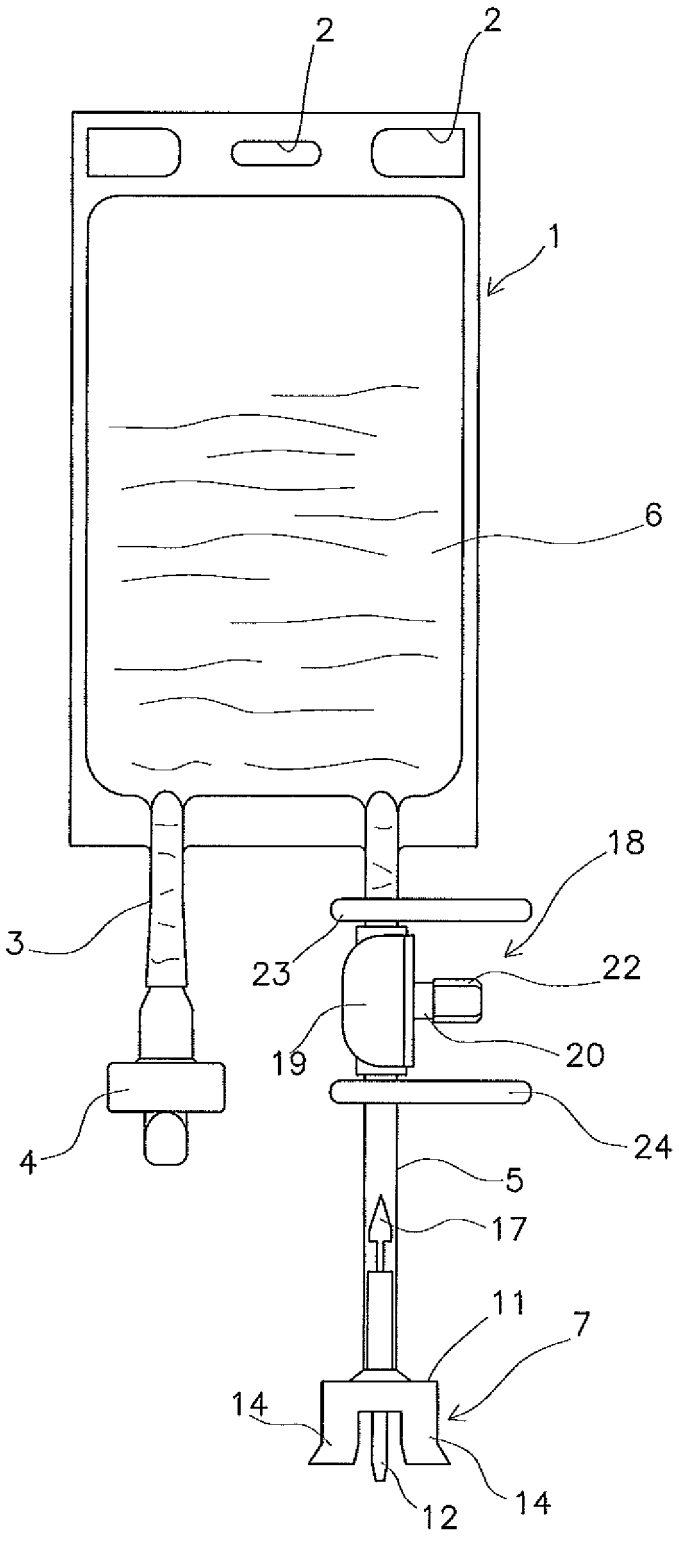


FIG. 1

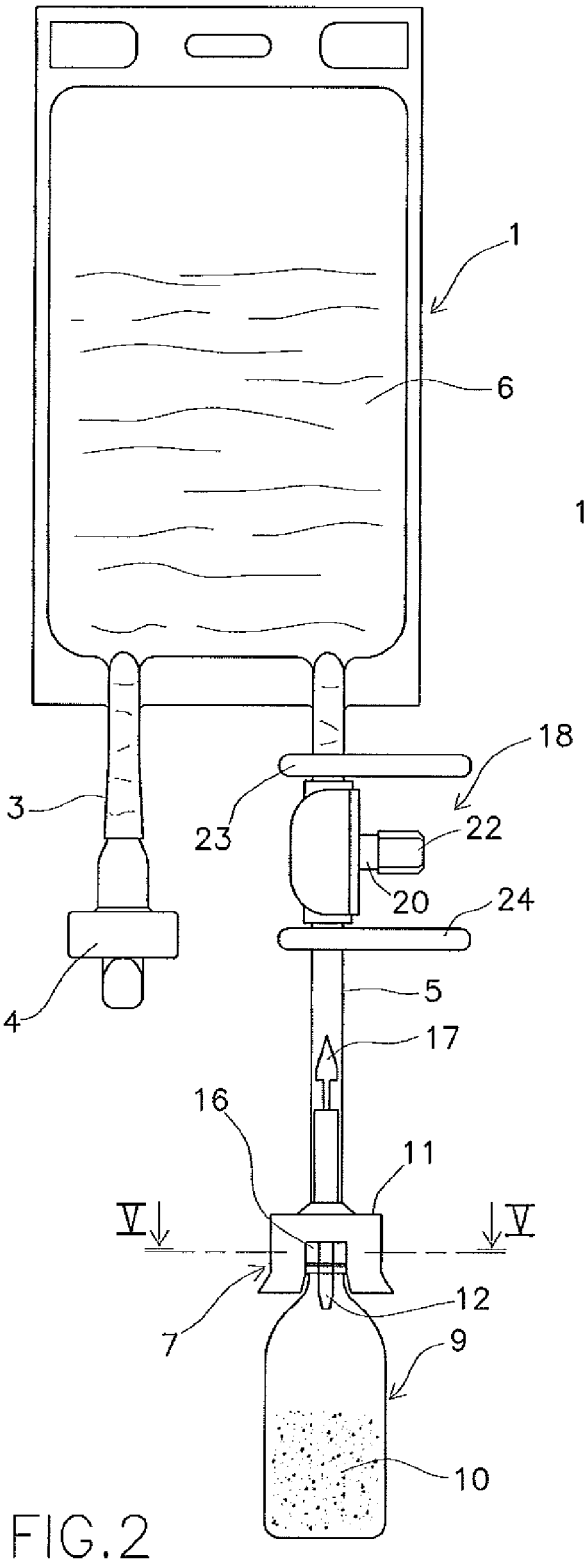


FIG.2

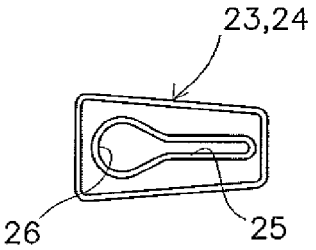


FIG.3

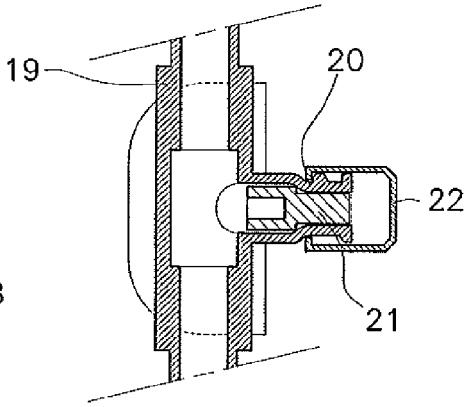


FIG.4

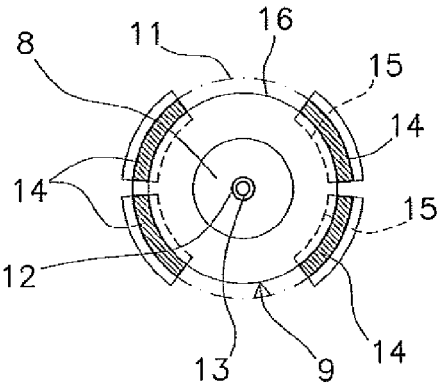


FIG.5

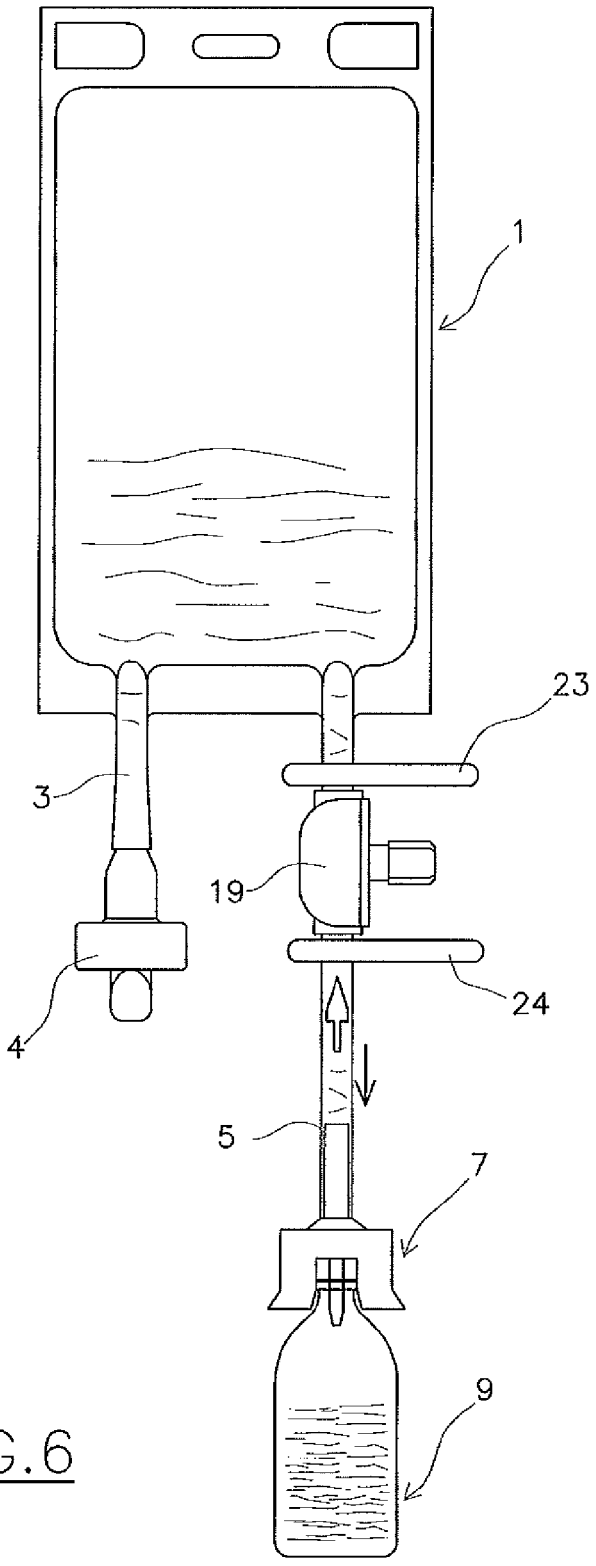


FIG.6

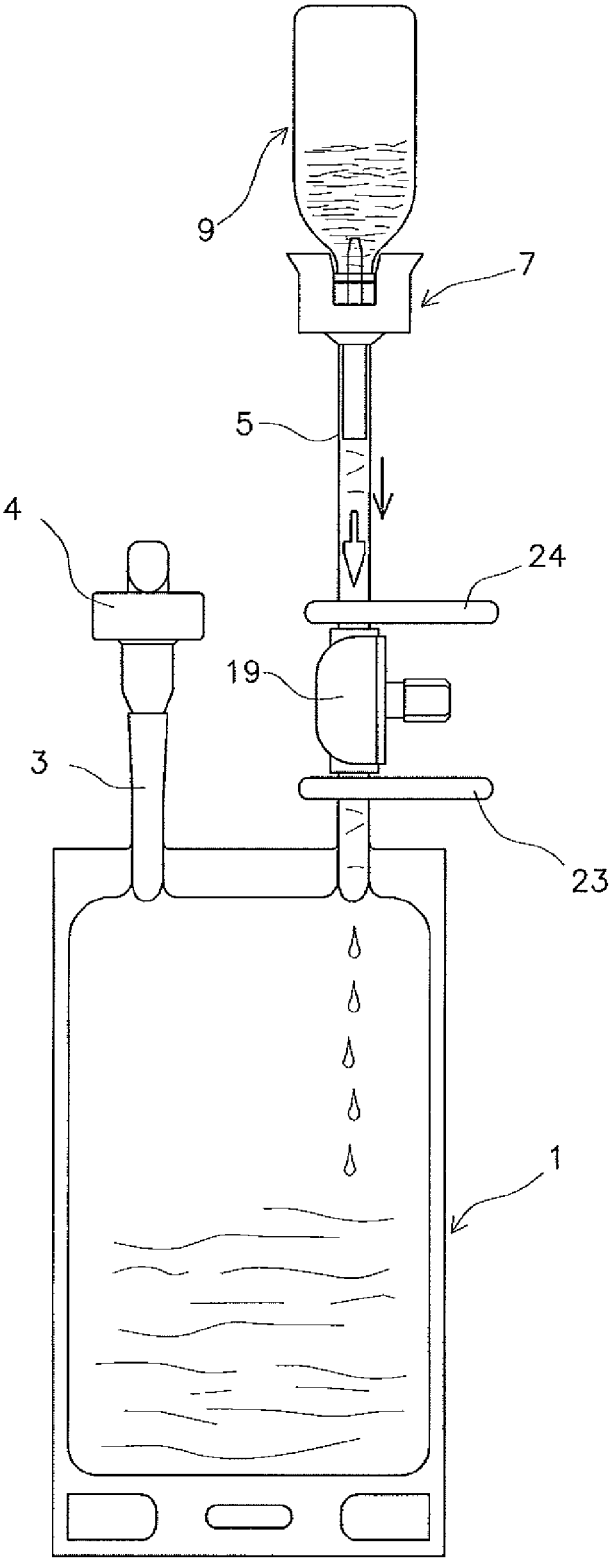


FIG.7

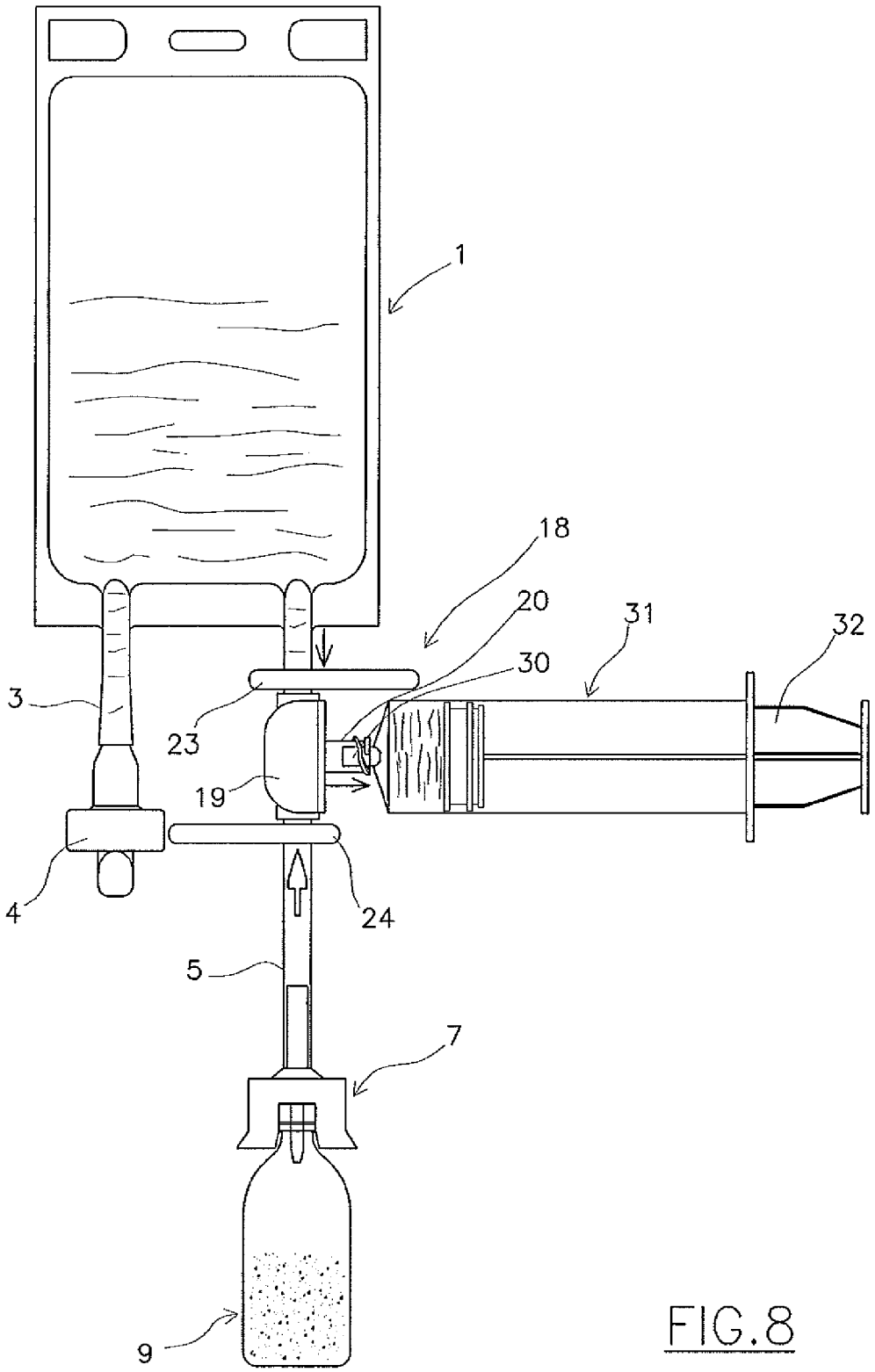


FIG.8

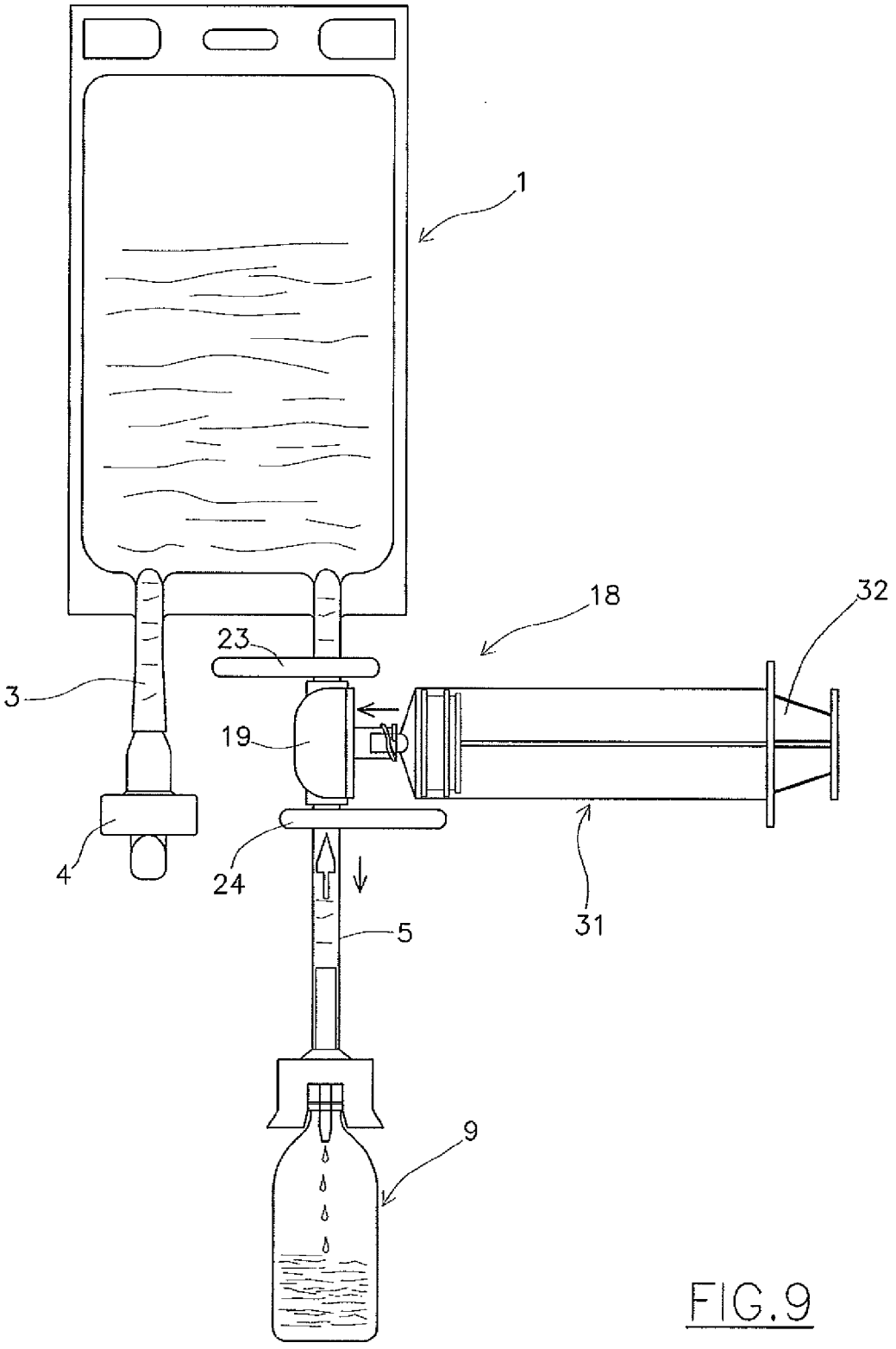


FIG.9

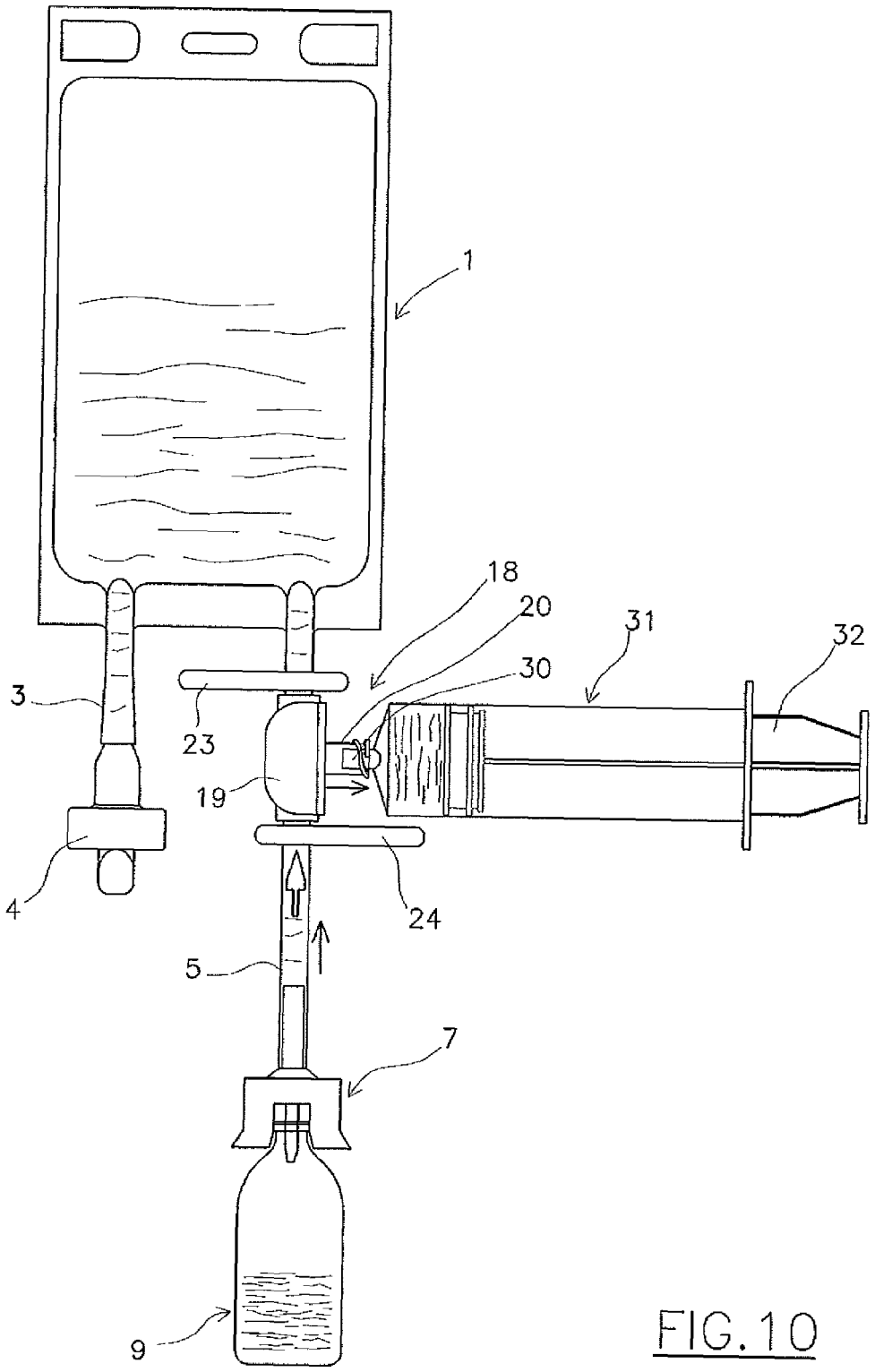


FIG. 10

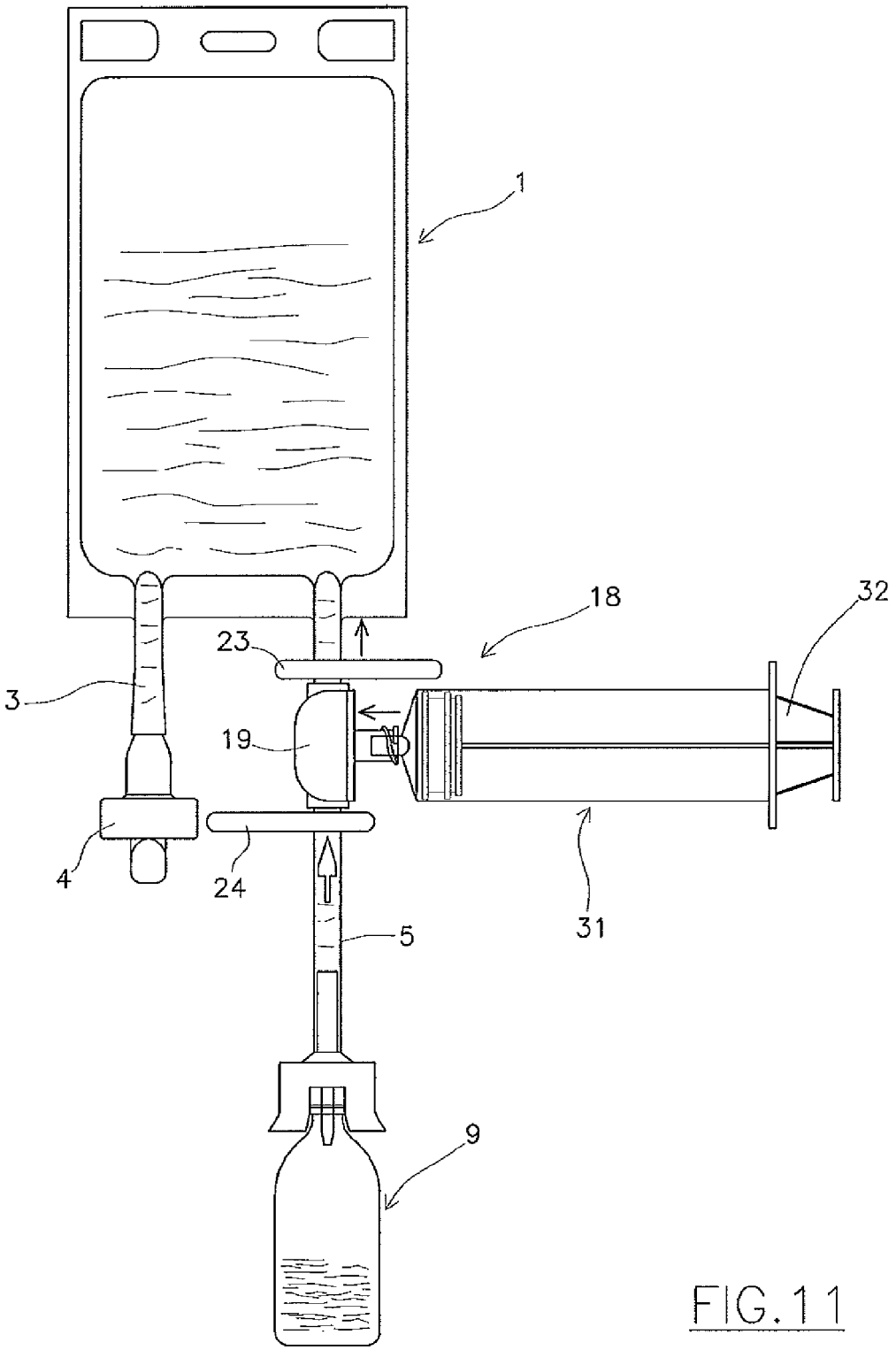
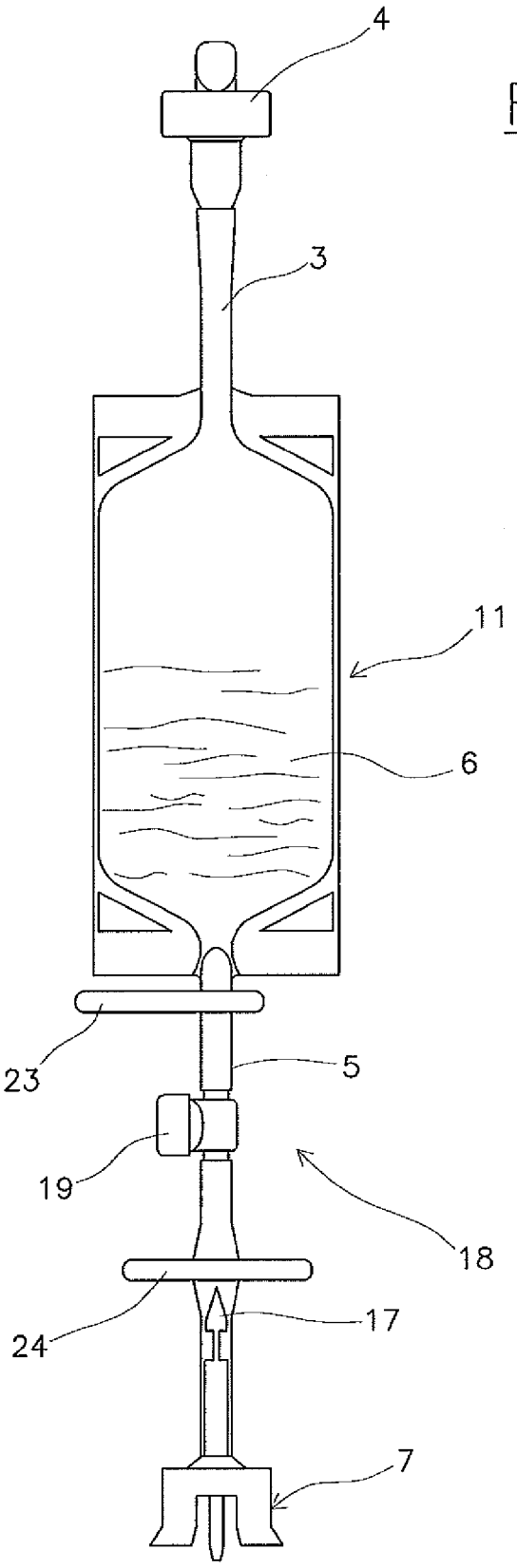


FIG.11

FIG.12



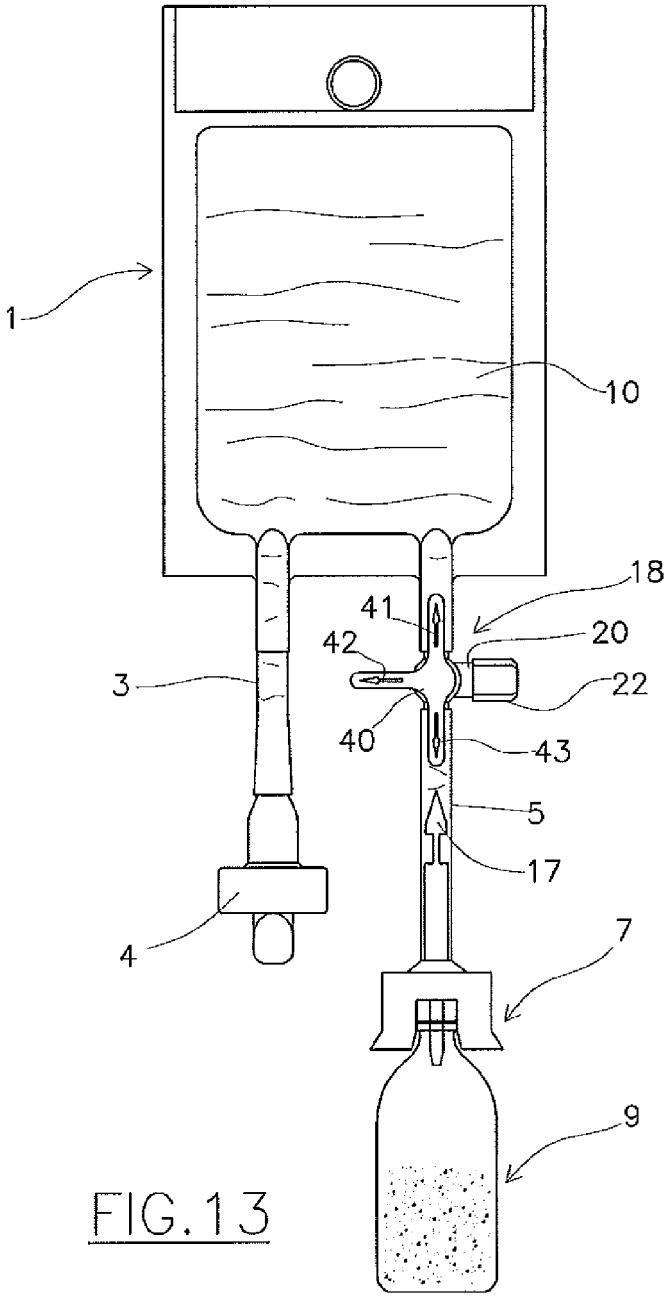


FIG.13

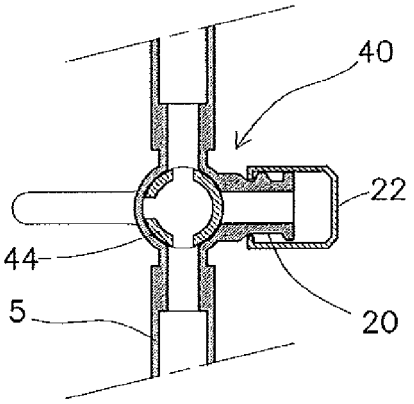


FIG.14

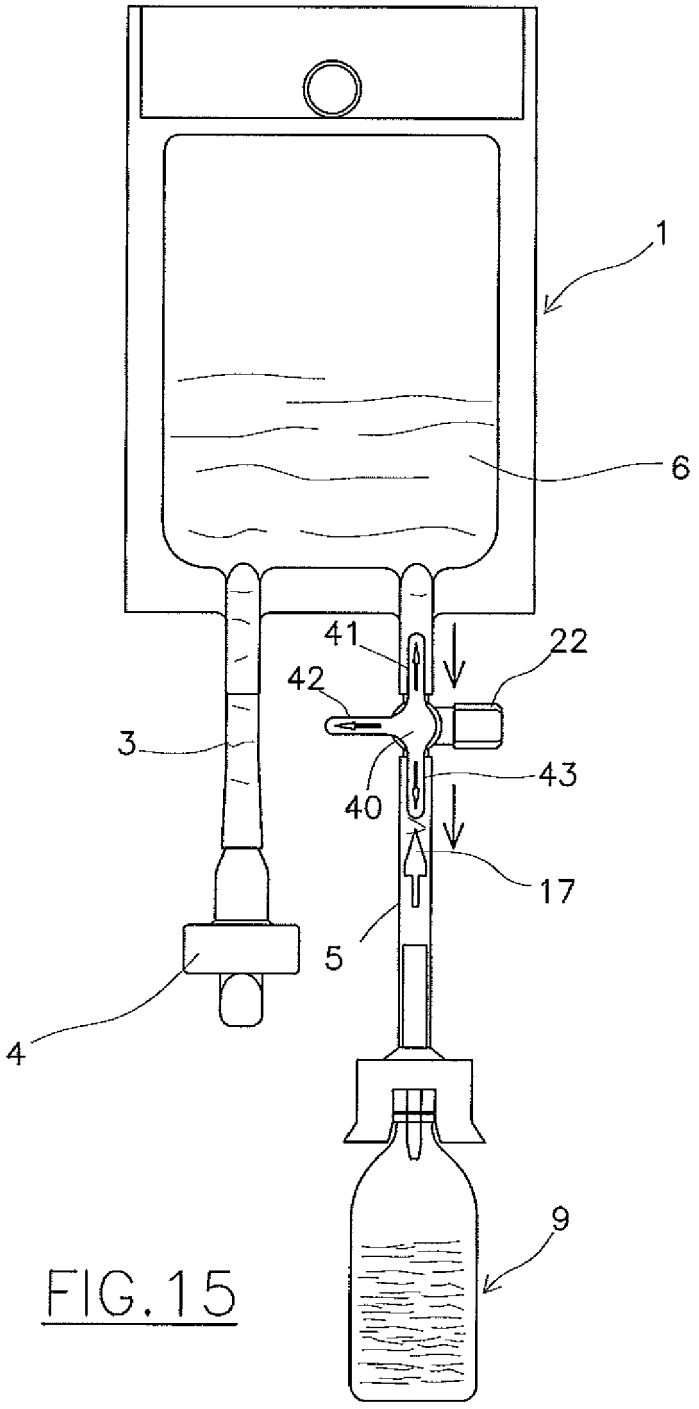


FIG.15

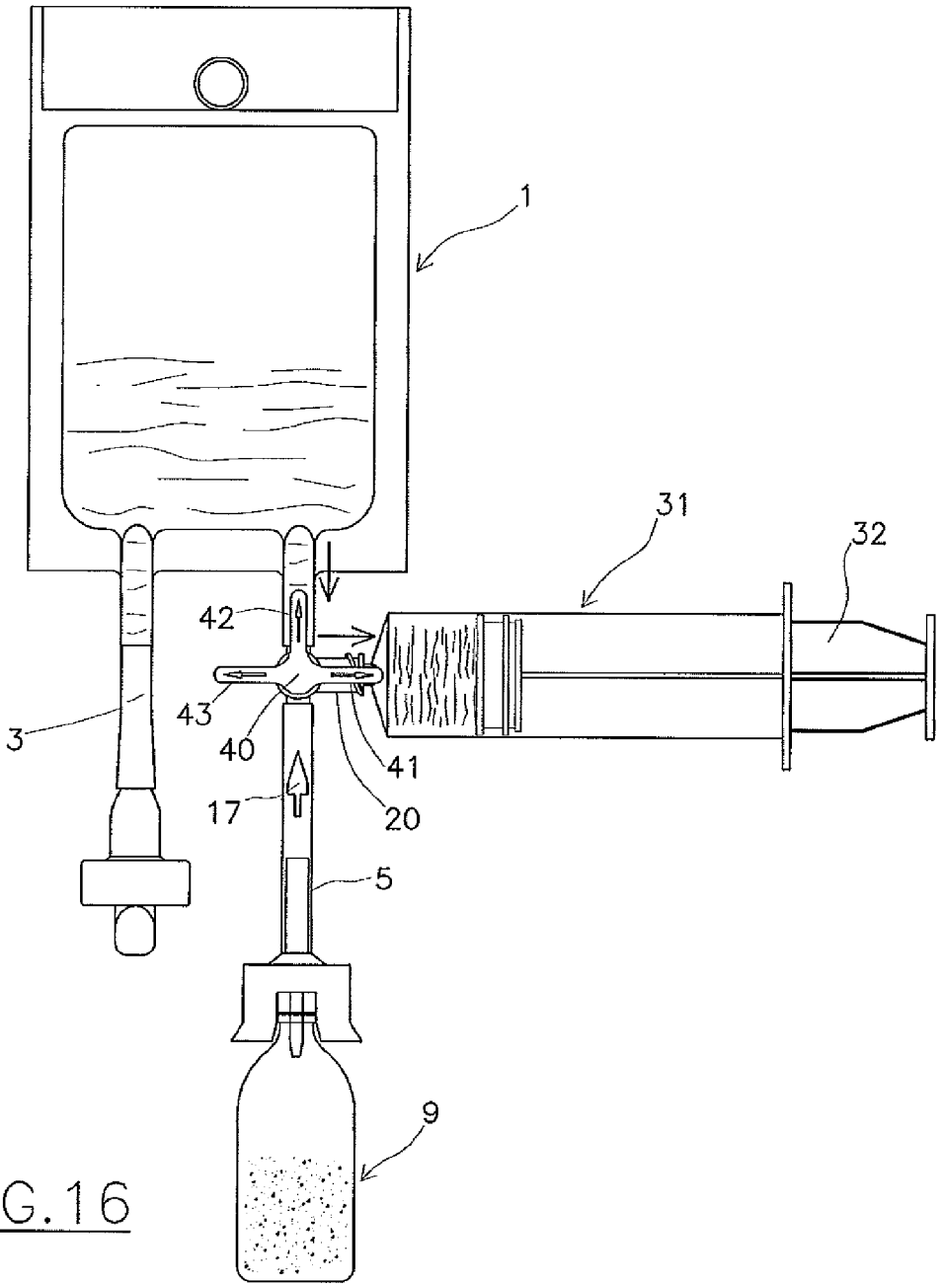


FIG.16

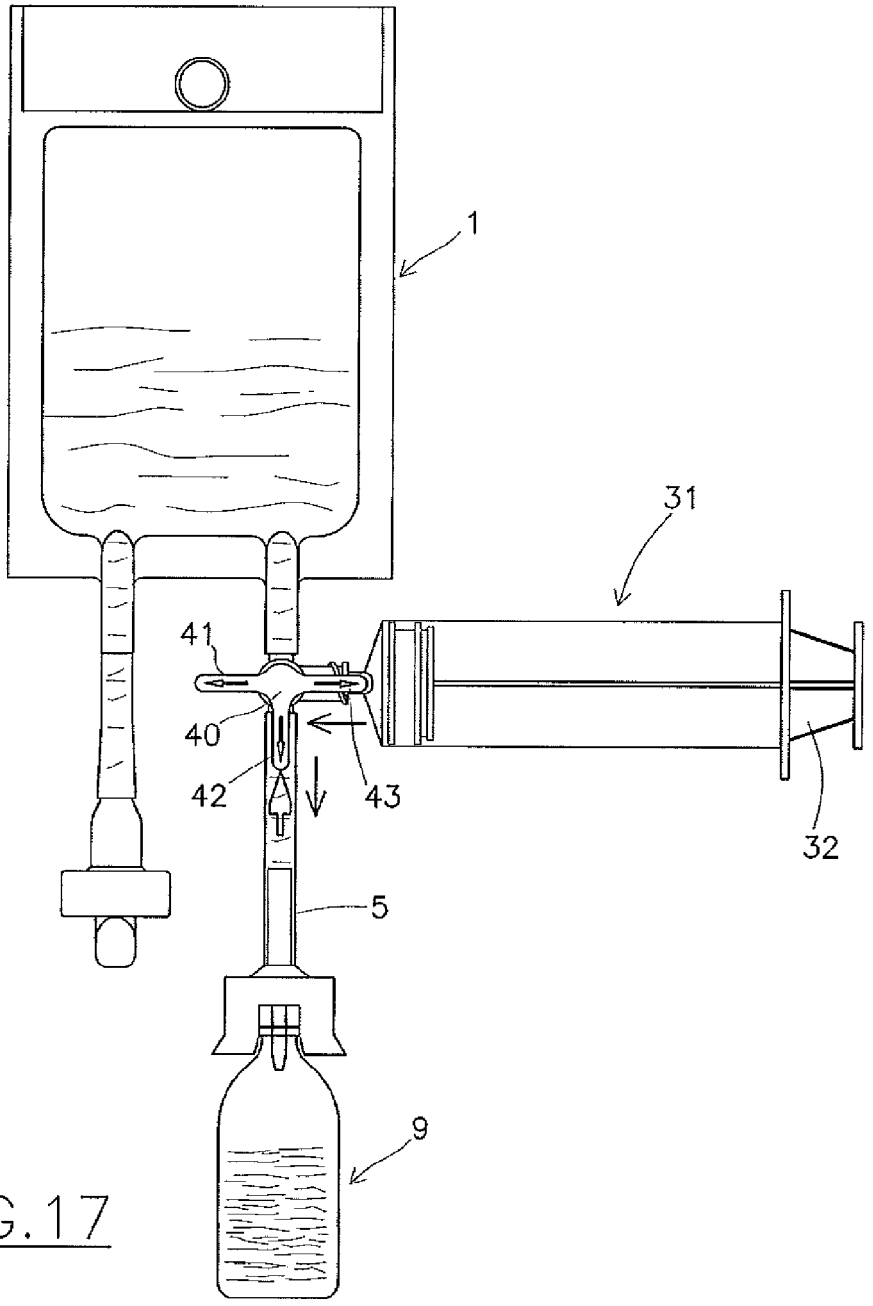


FIG.17

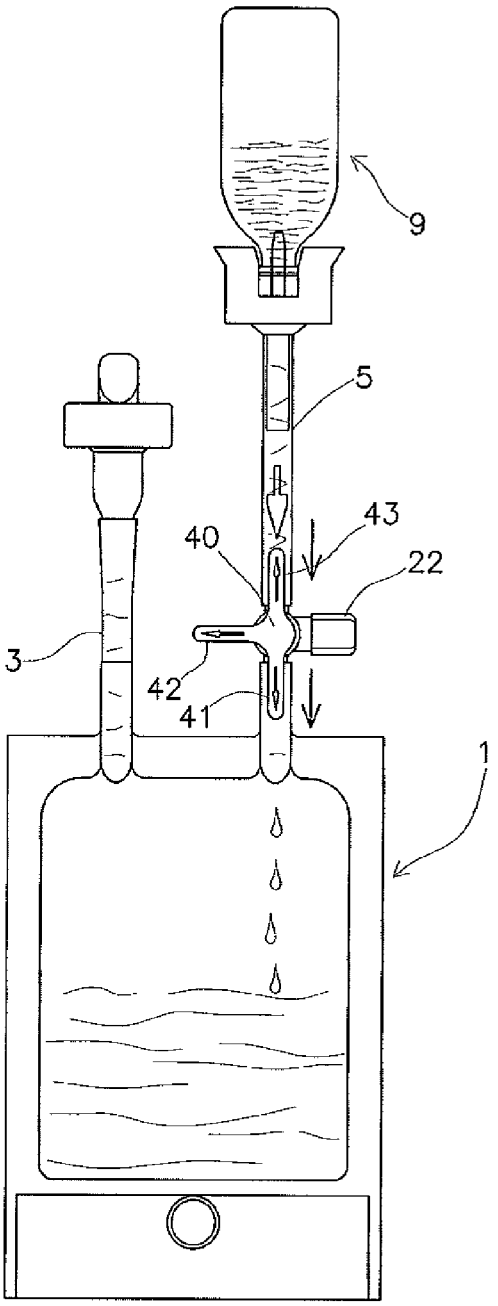


FIG.18

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EUROPEAN SEARCH REPORT

Application Number
EP 11 17 0981

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A	WO 03/079956 A1 (CARMEL PHARMA AB [SE]) 2 October 2003 (2003-10-02) * figures 1,4,5 * * page 8, line 7 - page 9, line 6 * -----	1	
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TECHNICAL FIELDS SEARCHED (IPC)

A61J

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	29 September 2011	Mammeri, Damya

CATEGORY OF CITED DOCUMENTS

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