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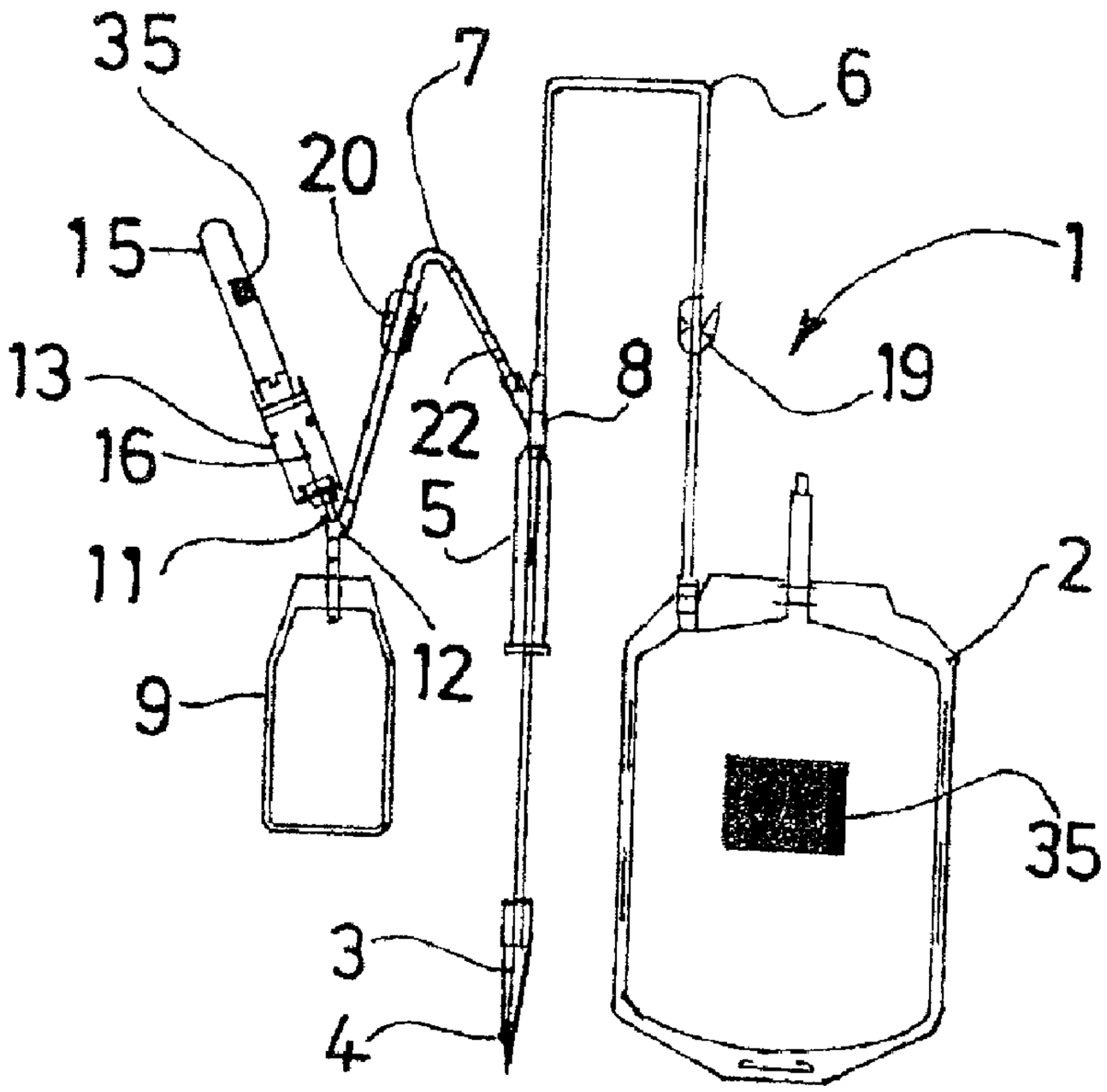

(57) Abrégé/Abstract:
The invention concerns a bag system (1) for taking a biological fluid, in particular blood, the said system comprising a device for taking the fluid which is in fluid communication with at least one fluid collecting bag (2), and a device for sampling the fluid to be collected which comprises at least one sampling receptacle (15), the said sampling device comprising a means (10) of transferring the fluid from the bag system (1) into the sampling receptacle or receptacles (15), in which the transfer means (10) is provided with a means of associating the receptacle or receptacles (15), the said means being arranged to allow the supporting of the receptacle or receptacles (15) in a standby position, the guidance of the receptacle or receptacles (15) to a transfer position and, after transfer, the dissociation of the receptacle or receptacles (15) from the bag system (1).

ABSTRACT

A bag system comprising a means of associating sampling receptacles

The invention concerns a bag system (1) for taking a biological fluid, in particular blood, the said system comprising a device for taking the fluid which is in fluid communication with at least one fluid collecting bag (2), and a device for sampling the fluid to be collected which comprises at least one sampling receptacle (15), the said sampling device comprising a means (10) of transferring the fluid from the bag system (1) into the sampling receptacle or receptacles (15), in which the transfer means (10) is provided with a means of associating the receptacle or receptacles (15), the said means being arranged to allow the supporting of the receptacle or receptacles (15) in a standby position, the guidance of the receptacle or receptacles (15) to a transfer position and, after transfer, the dissociation of the receptacle or receptacles (15) from the bag system (1).

A BAG SYSTEM COMPRISING A MEANS OF ASSOCIATING SAMPLING RECEPTACLES

FIELD OF THE INVENTION

The invention concerns a bag system for collecting a biological fluid in which sampling receptacles are associated.

BACKGROUND OF THE INVENTION

Biological fluids such as whole blood must be collected from a donor in a collection bag. To accomplish this, one normally uses a bag system including in closed circuit, a device for collecting the blood which is in fluid communication with at least one blood collection bag. In addition, the system includes a device for sampling the blood which is intended to receive some of the blood taken. The device normally includes at least one sampling receptacle. The use of such a sampling device makes it possible to obtain, in each receptacle, a sample of blood intended to be analysed, in particular for carrying out serology, virology and a blood count.

In particular, the bag system may be used by collecting the first millilitres of blood in the sampling device, which has a certain number of advantages. Firstly, this reduces the risk of contamination resulting from the presence of bacteria or other foreign substances on the skin of the donor because the first millilitres of blood collected, which are more likely to be affected by this contamination, are sent into the sampling device rather than into the collection bag. Secondly, this makes it possible to take samples before the collection bag is completely filled and consequently does not waste time. Finally, during the collection, the loss of blood volume for the donor may be compensated for the addition of plasma, resulting in a lower haematocrit reading than if the sampling device were filled after the collection bag, and consequently the count would be incorrect.

One problem which is posed is that of the difficulty in handling known bag systems. This is because the user must position several receptacles in order to obtain the samples, which gives rise to a loss of time.

One aim of the invention is in particular to resolve this problem by proposing a bag system in which each sampling receptacle is stored at the device for transferring fluid from the bag system into it, the receptacle then being able to be guided by the operator into the transfer device for collecting a sample.

SUMMARY OF THE INVENTION

The invention provides a bag system for taking a biological fluid, the system comprising a fluid taking device in fluid communication with at least one fluid collecting bag and a sampling device for the fluid to be collected having at least one sampling receptacle and a means for transferring the fluid from the bag system into the at least one sampling receptacle; the transfer means having a hollow guide to enable introduction of one sampling receptacle therein, means for associating the at least one sampling receptacle, and a hollow needle in fluid communication with the bag system; wherein the transfer means and the association means are adapted to enable the support of the at least one sampling receptacle in a standby position away from the hollow needle; wherein the transfer means is adapted to position by translation the at least one sampling receptacle in a transfer position wherein a downstream end of the hollow needle is in fluid communication with an inside of the sampling receptacle; and wherein, after the transfer, the transfer means and the association means are adapted to enable detachment of the at least one sampling receptacle from the bag system.

BRIEF DESCRIPTION OF THE DRAWINGS

Other objects and advantages of the invention will emerge during the following description given with reference to the accompanying drawings, in which:

Figure 1A depicts schematically a bag system for collecting blood which includes a sampling device according to a first embodiment;

Figure 1B depicts schematically a bag system for collecting blood and separating the blood components which includes a sampling device according to a second embodiment;

Figure 2 depicts schematically the transfer device of the sampling device depicted in Figure 1A;

Figure 3A and 3B depict schematically the transfer device of Figure 2 in which a sampling receptacle is disposed respectively in a position at a distance and in a transfer position; Figure 3C is a representation similar to Figure 3B showing a variant embodiment of the transfer device;

Figure 4 depicts schematically a bag system for collecting blood which includes a sampling device provided with several transfer devices according to Figure 2;

Figure 5A to 5E depict schematically the transfer device of the sampling device of Figure 2, respectively front on, in perspective, in profile, in plan view and in transverse section, the sampling receptacles being in the standby position;

Figure 6A and 6B depict schematically the transfer device of Figure 5 according to a variant embodiment, respectively front on and in profile, the receptacles being in the standby position; Figure 6C is a view similar to Figure 6B in which a receptacle is in the transfer position.

DETAILED DESCRIPTION OF THE EMBODIMENTS

Figures 1A and 1B depict bag system 1 including a collection device for collecting fluid from a donor and at least one collection bag 2 intended to receive the fluid collected, in particular blood.

The collection device may consist in particular of needle 3 allowing access to the vein of the donor and cap 4 protecting needle 3. In addition, needle protector 5 may be placed slidably on first tube 6. First tube 6 places collection bag 2 in fluid communication with the collection device.

Bag system 1 also includes a sampling device, which is in fluid communication with collection bag 2 by way of first 6 and second 7 tubes connected at first connector 8 in the form of a three-way junction.

In the embodiments depicted, the sampling device includes sampling bag 9 which is connected to the downstream end of second tube 7. The terms downstream and upstream are defined with respect to the direction of flow of the blood, from the collection device to the bags and sampling device.

The sampling device also includes fluid transfer device 10 which is in fluid communication with collection bag 2 by way of first 6 and second 7 tubes, and possibly third tube 11 connected to second tube 7 at second connector 12 in the form of a three-way junction.

As depicted in Figure 2, transfer device 10 includes hollow guide 13, open at front part 14 to allow the insertion of sampling receptacle 15, and hollow needle 16 passing through rear part 17 of the guide, so that a

downstream part of the said needle extends inside the guide and an upstream part of the said needle 16 extends outside the guide. The downstream segment of the hollow needle 16 is enclosed in an elastic sheath 18. The upstream segment of the hollow needle 16 allows the connection of the transfer means with the bag system 1. A fluid communication means or tube is then connected to the said upstream segment.

First 19 and second 20 clamps can be situated respectively on the first tube 6, downstream of the connector 8, and on the second tube 7. The clamps 19, 20 make it possible to orient the flow of fluid taken off, either to the sampling bag 9, when the first clamp 19 is closed whilst the second clamp 20 is open, or to the collecting bag 2, when the second clamp 20 is closed whilst the first clamp 19 is open.

The sampling receptacle 15 is filled with the taken-off blood contained in the sampling bag 9, when the said receptacle 15 is placed in the transfer position, namely when the downstream end of the needle 16 is in fluid communication with the inside of the receptacle 15, by perforation of a closure element 21 of the receptacle 15.

Circuit openers can be provided within the bag system 1. In particular a circuit opener 22 can be situated on the second tube 7 close to the first connector 8.

As depicted in Figure 1b, in order to perform filtration and separation steps as well as the removal of the leukocytes from the various constituents of the blood, the collecting bag 2 can be in fluid communication, by means of a fourth tube 23, with satellite bags 24a-c. A filter 25 for removing leukocytes is situated between the collecting bag 2 and a satellite bag 24a. The satellite bag 24a can be in fluid communication with one or more other satellite bags,

for example the satellite bag 24a can be in fluid communication with two other satellite bags 24b, c. A clamp 26 can be provided on the fourth tube 23 between the collecting bag 2 and the filter 25 for removing leukocytes. According to one embodiment, the satellite bags 24a-c can be provided with an identification means 35.

According to a first embodiment, the transfer means 10 is provided with a means of associating the sampling receptacle 15, as depicted in Figure 2. The association means comprises first 27 and second 28 sets of projections distributed longitudinally on the internal surface of the guide 13, respectively close to the needle 16 of the guide and close to the front part 14 of the guide 13. The projections are arranged so as to be deformable by sliding of the receptacle 15 within the guide 13 so as to allow a reversible association of the receptacle 15 inside the guide 13, and a sliding of the receptacle 15 inside the guide 13 between a standby position (Figure 3a), at a distance from the needle 16, and the transfer position (Figure 3b).

As depicted in Figures 2, 3a and 3b, the projections are flexible, in particular elastic, and are reversibly deformable from a forward inclined position to a rearward inclined position by contact of the receptacle 15 when it slides inside the guide 13 in the front to rear direction. When the receptacle 15 is withdrawn from the guide 13, the projections incline from rear to front so that the receptacle is not dissociated from its closure element 21.

In the embodiment depicted, the sampling receptacle 15 comprises a closure element 21 whose diameter is greater than that of the body of the receptacle 15, it is during the passage of the closure element 21 that the projections incline in one direction or the other.

According to a variant, depicted in Figure 3c, the projections of the first set 27 situated close to the needle 16 are breakable under the effect of the sliding of the receptacle 15 placed in the transfer position. The perforation of the closure element 21 is thus visible, and the user can check that the perforation has not taken place prior to the taking of samples.

As depicted in Figure 4, several transfer means 10, in each of which a sampling receptacle 15 is associated in a dissociable fashion, can be connected to the bag system 1 by means of the second tube 7 or the third tube 11, connected to the second tube 7 by the second connector 12. Associating several receptacles 15 in a dissociable fashion with several transfer means 10 has advantages, firstly a saving in time for the person responsible for taking the fluid since he does not need to place the receptacle 15 in the transfer means 10, and secondly a reduction in the risk of error in traceability of the donations, since this makes it possible to fix traceability labels prior to the taking of samples, in particular at the time of manufacture.

According to a second embodiment, the association means is arranged to enable the supporting of several receptacles 15 at a distance from the guide 13 in a standby position and their sequential guidance in the guide 13, as depicted in Figures 1b and 5a to 5e.

The association means and the transfer means 10 are associated by clipping on or welding, or can be moulded in one and the same piece.

The association means comprises a housing 29 associated with the guide 13. The said housing 29 is provided with a skirt 30 in which the closure element 21 of the receptacles 15 is introduced to allow the longitudinal sliding of the

receptacles 15 in the housing 29 towards the guide 13. The internal wall of the said skirt 30 is provided with a projection 31 intended, by interaction with the closure elements 21, to prevent the transverse withdrawal of the receptacles 15 from the housing 29.

The skirt 30 comprises an open end disposed opposite a scallop formed in the guide, and an opposite closed end. In the other axis, a first open end is disposed opposite the other end which is open so that the body of the receptacle or receptacles 15 extends beyond the housing 29.

At the time of manufacture, the sampling receptacles 15 are introduced into the guide 13 through its open front part 14 so that the closure element 21 is situated level with the groove 32 in the housing 29 so that it can be slid therein.

A cap 33 is then placed on the guide 13 making it possible to hold the receptacles 15 in the housing 29 until the samples are taken by the user of the system 1.

The housing can be of variable size so as to contain from two to ten receptacles 15. The number of receptacles 15 used varies according to the legislation, in France in particular five receptacles 15 are used for carrying out normal analyses.

When samples are taken, the person responsible for taking off removes the cap 33 from the guide 13, makes the receptacles 15 slide as far as the guide 13, and then introduces them so that, by perforation of a closure element 21 of the receptacle 15, the downstream end of the needle 16 is in fluid communication with the inside of the receptacle 15. After a receptacle 15 has been filled, the user withdraws it from the guide 13. In one example embodiment, the cap 33 can be provided with a tamper-evident element,

such as a tongue which is broken on first opening, so as to be able to identify the first handling of the plug 33.

According to a variant, depicted in Figures 6a to 6c, the transfer means 10 can slide on the association means, so that it can be placed level with each receptacle 15. When the transfer means 10 is placed level with a receptacle 15, the user can then move the said transfer means 10 transversely so that the closure element 21 is perforated by the needle 16. So that the transfer means 10 can slide on the association means, two opposite scallops are then formed in the guide 13.

As depicted in Figure 1b, the transfer means 10 associating several sampling receptacles 15 can be connected to a bag system 1 by means of the second tube 7 and possibly the third tube 11.

With the known bag systems for taking off blood, the person responsible for taking off must identify, by means of a marking, the collecting bag 2 and the sample receptacle or receptacles 15 corresponding to one and the same donation.

According to the invention, the possibility of error in traceability of these donations is considerably reduced since the sampling receptacle or receptacles 15 and the collecting bag 2 are associated at the time of manufacture in a dissociable fashion. In addition, as from manufacture, the collecting bag 2 and the sampling receptacle or receptacles 15, as well as any satellite bags 24a-c, are each provided with an identification means 35, for example by means of a self-adhesive label with bar codes, which comprises information making it possible, after dissociation of the receptacle from the bag system 1, to unequivocally establish that the sampling receptacle 15 and the collecting bag 2, as well as any satellite bags 24a-c, come from the

same bag system 1.

CLAIMS:

1. A bag system (1) for taking a biological fluid, comprising:

a first device for taking the biological fluid which is in fluid communication with at least one fluid collecting bag (2); and

a second device for sampling the biological fluid to be collected, the second device being in fluid communication with the first device and comprising

at least one sampling receptacle (15), and

at least one transfer means (10) for transferring the biological fluid from the bag system (1) into the at least one sampling receptacle (15), the at least one transfer means (10) comprising a hollow guide (13) for introducing therein the at least one sampling receptacle (15), the hollow guide (13) being provided with

a hollow needle (16) in fluid communication with the bag system (1), and

an association means for removably associating the at least one sampling receptacle (15) thereto, the association means being shaped for removably supporting the at least one sampling receptacle (15) in at least a standby position in which the at least one sampling receptacle is away from the hollow needle (16), thereby preventing the biological fluid from flowing into the at least one sampling receptacle (15), and a transfer position in which a downstream end of the hollow needle (16) is in fluid communication with an inside of the at least one sampling receptacle (15), thereby allowing the biological fluid to flow into the given one of the at least one sampling receptacle (15), and for guiding the given one of the at least one sampling receptacle (15) between the standby and transfer positions.

2. A bag system according to Claim 1, characterised in that the at least one fluid collecting bag (2) is in fluid communication with the first device by means of a first tube (6) to which the second device is connected by means of a second tube (7).

3. A bag system according to Claim 2, characterised in that the second device comprises a sampling bag (9) which is connected to a downstream end of the second tube (7).

4. A bag system according to any one of Claims 1 to 3, characterised in that the at least one sampling receptacle (15) comprises a closure element (21) having a diameter that is greater than a diameter of a body of the at least one sampling receptacle (15).

5. A bag system according to Claim 4, characterised in that the hollow guide (13) is open at a front part (14) to allow the introduction of a given one of the at least one sampling receptacle (15), and the hollow needle (16) passes through a rear part (17) of the hollow guide (13) so that a downstream part of the hollow needle (16) extends inside the hollow guide (13) and an upstream part of the hollow needle (16) extends outside the hollow guide (13), the hollow needle (16) being in fluid communication with the bag system (1), in order, by translation, to allow an arrangement of the given one of the at least one sampling receptacle (15) in the transfer position in which, by perforation of the closure element (21) of the given one of the at least one sampling receptacle (15), the downstream part of the hollow needle (16) is in fluid communication with the inside of the given one of the at least one sampling receptacle (15).

6. A bag system according to Claim 5, characterised in that the association means comprises a first (27) and a second (28) set of projections distributed longitudinally on an internal face of the hollow guide (13), the projections being arranged so as to be deformable by sliding of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) so as to permit a reversible association of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) and a sliding of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) between the standby position at a distance from the hollow needle (16) and the transfer position.

7. A bag system according to Claim 6, characterised in that at least some of the projections are flexible and are reversibly deformable from a position inclined towards a rear towards a position inclined towards a front by contact of the given one of the at least one sampling receptacle (15) during the sliding inside the hollow guide (13) in a rear to front direction, or respectively front to rear.

8. A bag system according to Claim 7, characterized in that the at least some of the projections are elastic.

9. A bag system according to any one of Claims 6 to 8, characterised in that the projections in the first set (27) which is situated close to the hollow needle (16) are breakable under an effect of a deformation.

10. A bag system according to any one of Claims 5 to 9, characterised in that the at least one sampling receptacle (15) comprises a plurality of sampling receptacles (15) and the at least one transfer means (10) comprises a plurality of transfer means (10) in each of which a respective one of the plurality of sampling receptacles (15) is associated in a dissociable fashion, the plurality of transfer means (10) being connected to the bag system (1) by means of a connection tube.

11. A bag system according to Claim 5, characterised in that the at least one sampling receptacle (15) comprises a plurality of sampling receptacles (15) and the association means is arranged so as to allow the supporting of the plurality of sampling receptacles (15) at a distance from the hollow guide (13) in the standby position and a sequential guidance thereof in the hollow guide (13).

12. A bag system according to Claim 4, characterised in that the at least one sampling receptacle (15) comprises a plurality of sampling receptacles (15) and the association means is arranged so as to allow the supporting of the plurality of sampling receptacles (15) at a distance from the hollow guide (13) in the standby position and a sequential guidance thereof in the hollow guide (13), the association means comprising a housing (29) associated with the hollow guide (13), the housing (29) being provided with a skirt (30) in which closed ends of the plurality of sampling receptacles (15) are introduced in order to allow a longitudinal

sliding of the plurality of sampling receptacles (15) in the housing (29) towards the hollow guide (13), an internal wall of the skirt (30) being provided with a skirt projection (31) intended, by interaction with the closure element (21), to prevent a transverse withdrawal of the plurality of sampling receptacles (15) from the housing (29).

13. A bag system according to Claim 12, characterised in that the skirt (30) comprises an open end disposed opposite a scallop formed in the hollow guide (13), and an opposite closed end.

14. A bag system according to any one of Claims 11 to 13, characterised in that the hollow guide (13) is provided with a cap (33) which is provided with a tamper-evident element.

15. A bag system according to any one of Claims 11 to 14, characterised in that the at least one transfer means (10) is shaped for associating the plurality of sampling receptacles (15), the at least one transfer means (10) being connected to the bag system (1) by means of a connection tube (11).

16. A bag system according to any one of Claims 1 to 15, characterised in that the at least one fluid collecting bag (2) and the at least one sampling receptacle (15) are each provided with a first identification means (35) which comprises information making it possible, after dissociation of the at least one sampling receptacle (15) from the bag system (1), to unequivocally establish that the at least one sampling receptacle (15) and the at least one fluid collecting bag (2) come from the bag system (1).

17. A bag system according to any one of Claims 1 to 16, characterised in that the at least one fluid collecting bag (2) is in fluid communication, by means of a fluid tube (23), with satellite bags (24a-c), the said satellite bags being provided with a second identification means (35).

18. A bag system according to any one of claims 1 to 16, characterised in that the biological fluid comprises blood.

19. A bag system according to any one of Claims 1 to 3, characterised in that the hollow guide (13) is open at a front part (14) to allow the introduction of a given one of the at least one sampling receptacle (15), and the hollow needle (16) passes through a rear part (17) of the hollow guide (13) so that a downstream part of the hollow needle (16) extends inside the hollow guide (13) and an upstream part of the hollow needle (16) extends outside the hollow guide (13), the hollow needle (16) being in fluid communication with the bag system (1), in order, by translation, to allow an arrangement of the given one of the at least one sampling receptacle (15) in the transfer position in which, by perforation of a closure element (21) of the given one of the at least one sampling receptacle (15), the downstream part of the hollow needle (16) is in fluid communication with the inside of the given one of the at least one sampling receptacle (15).

20. A bag system according to Claim 19, characterised in that the association means comprises a first (27) and a second (28) set of projections distributed longitudinally on an internal face of the hollow guide (13), the projections being arranged so as to be deformable by sliding of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) so as to permit a reversible association of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) and a sliding of the given one of the at least one sampling receptacle (15) inside the hollow guide (13) between the standby position at a distance from the hollow needle (16) and the transfer position.

21. A bag system according to Claim 20, characterised in that at least some of the projections are flexible and are reversibly deformable from a position inclined towards a rear towards a position inclined towards a front by contact of the given one of the at least one sampling receptacle (15) during the sliding inside the hollow guide (13) in a rear to front direction, or respectively front to rear.

22. A bag system according to Claim 21, characterized in that the at least some of the projections are elastic.

23. A bag system according to any one of Claims 20 to 22, characterised in that the projections in the first set (27) which is situated close to the hollow needle (16) are breakable under an effect of a deformation.

24. A bag system according to any one of Claims 19 to 23, characterised in that the at least one sampling receptacle (15) comprises a plurality of sampling receptacles (15) and the at least one transfer means (10) comprises a plurality of transfer means (10) in each of which a respective one of the plurality of sampling receptacles (15) is associated in a dissociable fashion, the plurality of transfer means (10) being connected to the bag system (1) by means of a connection tube.

25. A bag system according to Claim 19, characterised in that the at least one sampling receptacle (15) comprises a plurality of sampling receptacles (15) and the association means is arranged so as to allow the supporting of the plurality of sampling receptacles (15) at a distance from the hollow guide (13) in the standby position and a sequential guidance thereof in the hollow guide (13).

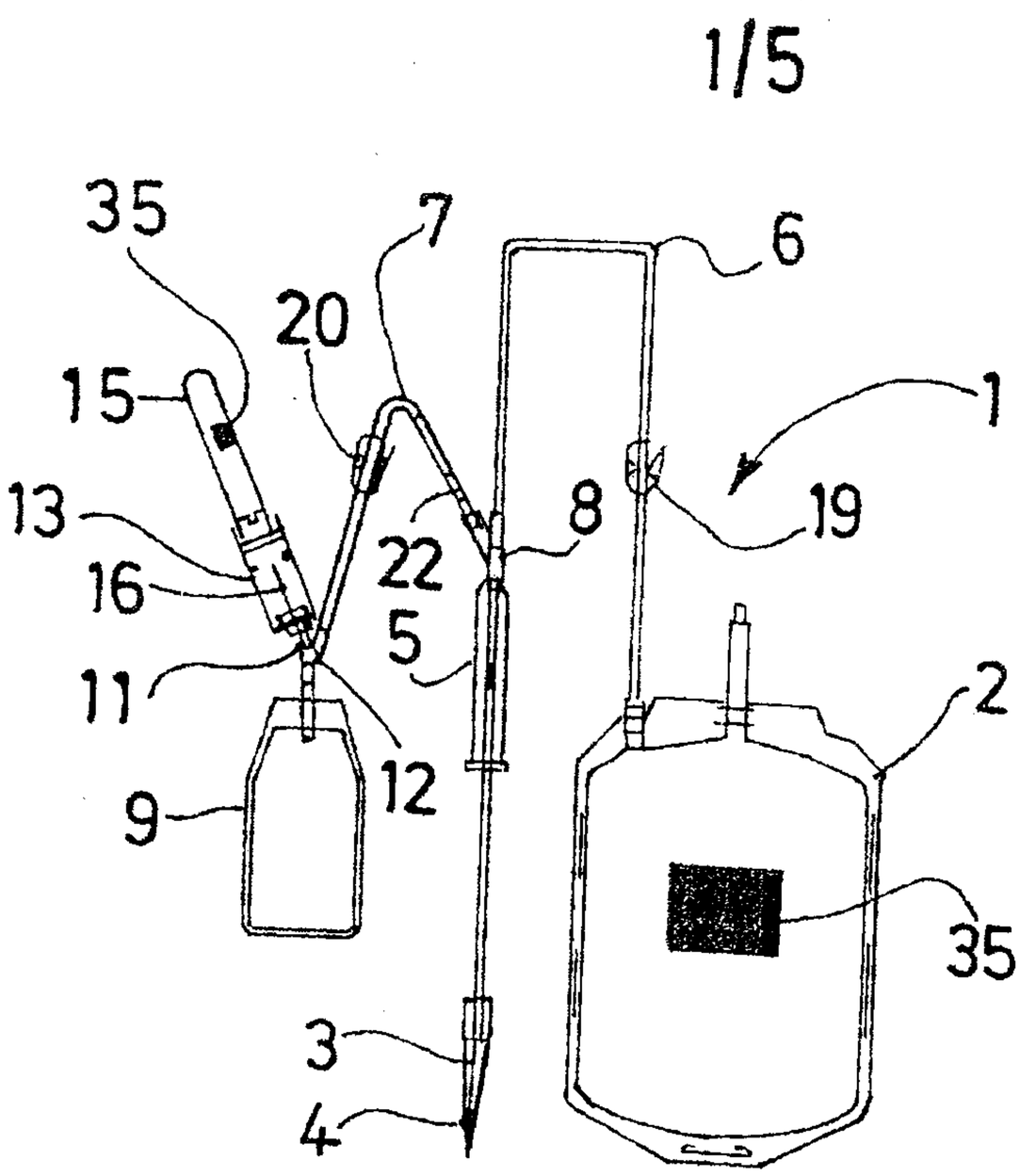
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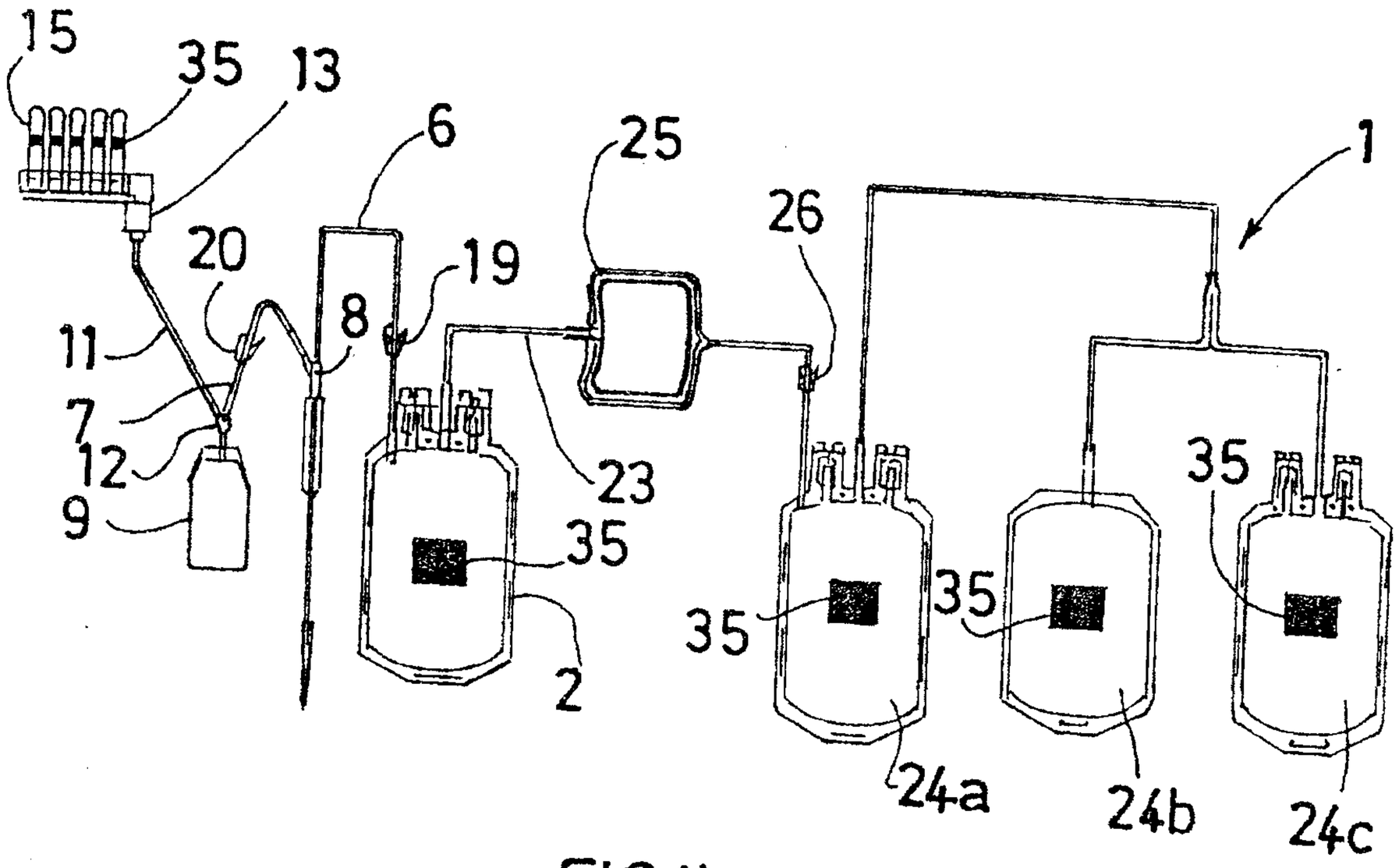
FIG.1a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24a
24b
24c

FIG 1b

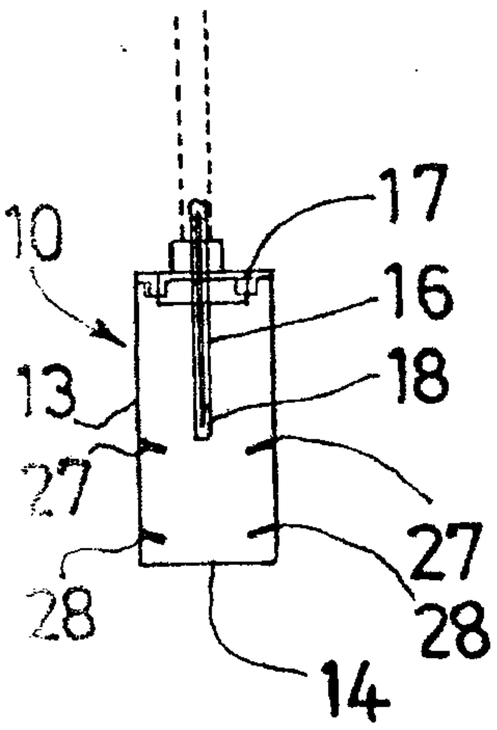


FIG.2

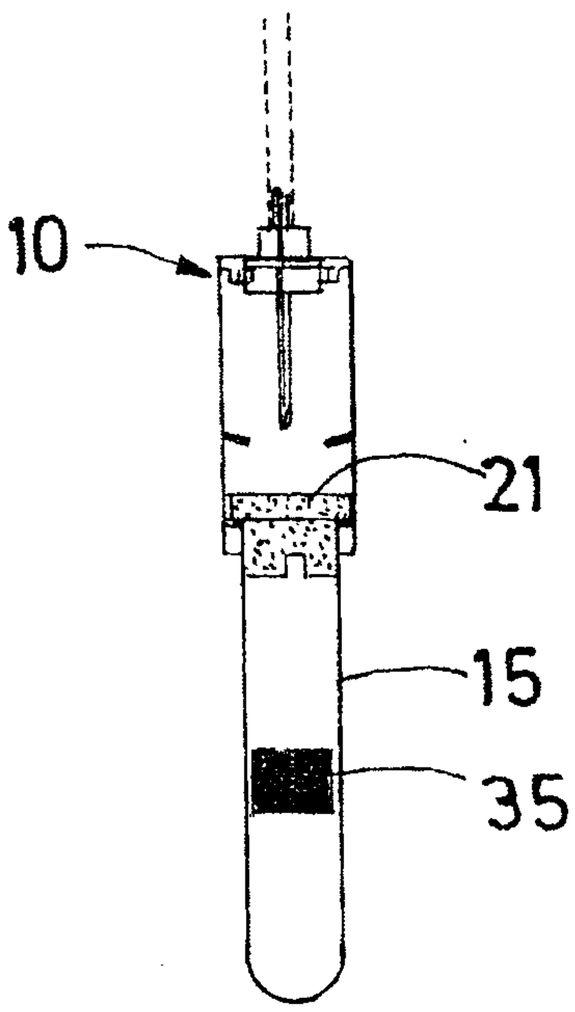


FIG.3a

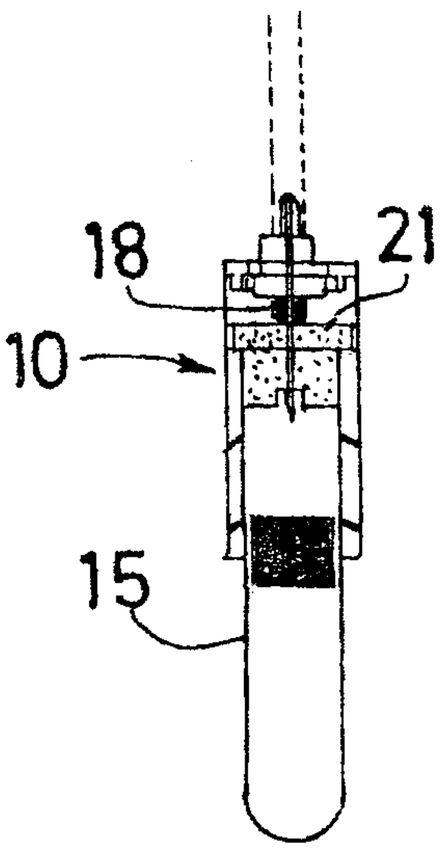


FIG.3b

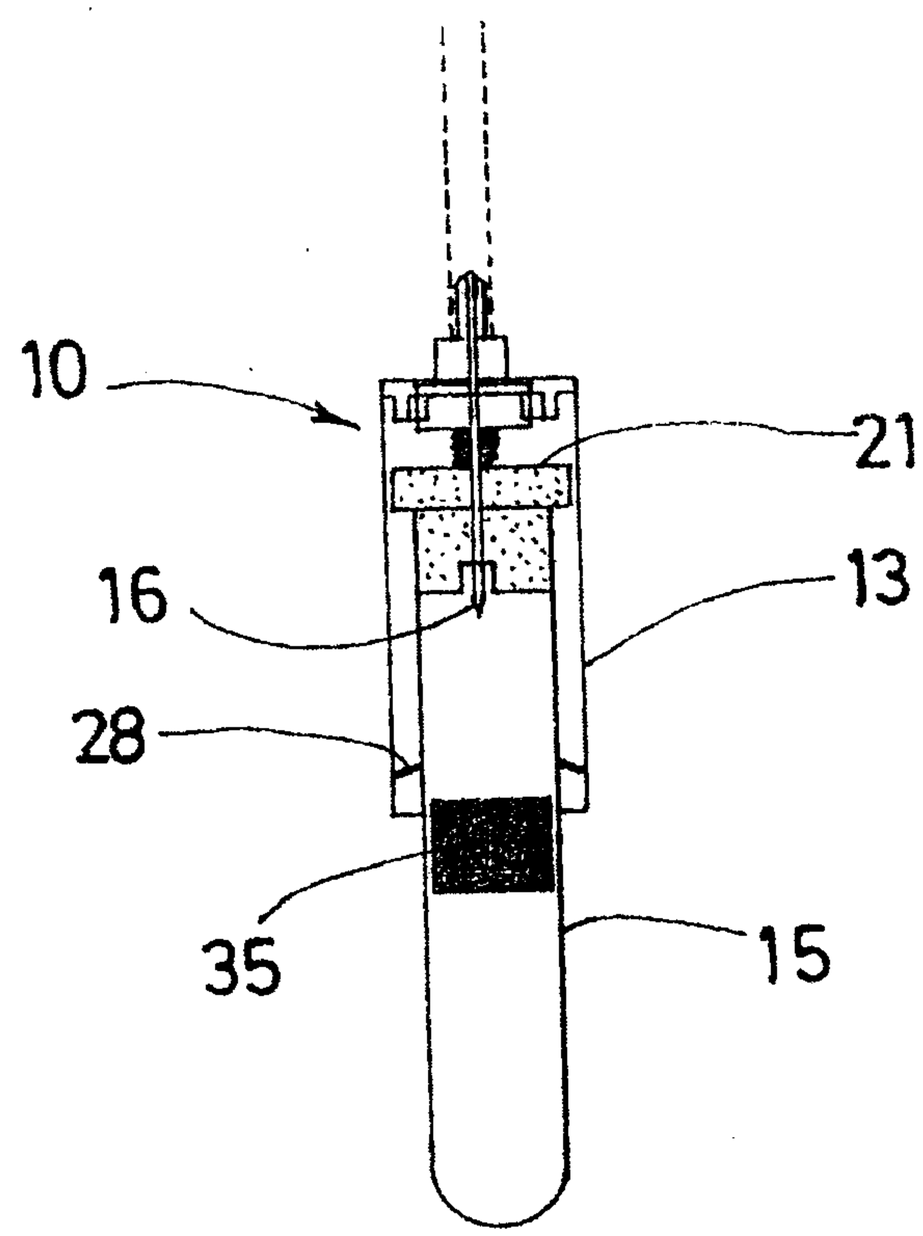


FIG.3c

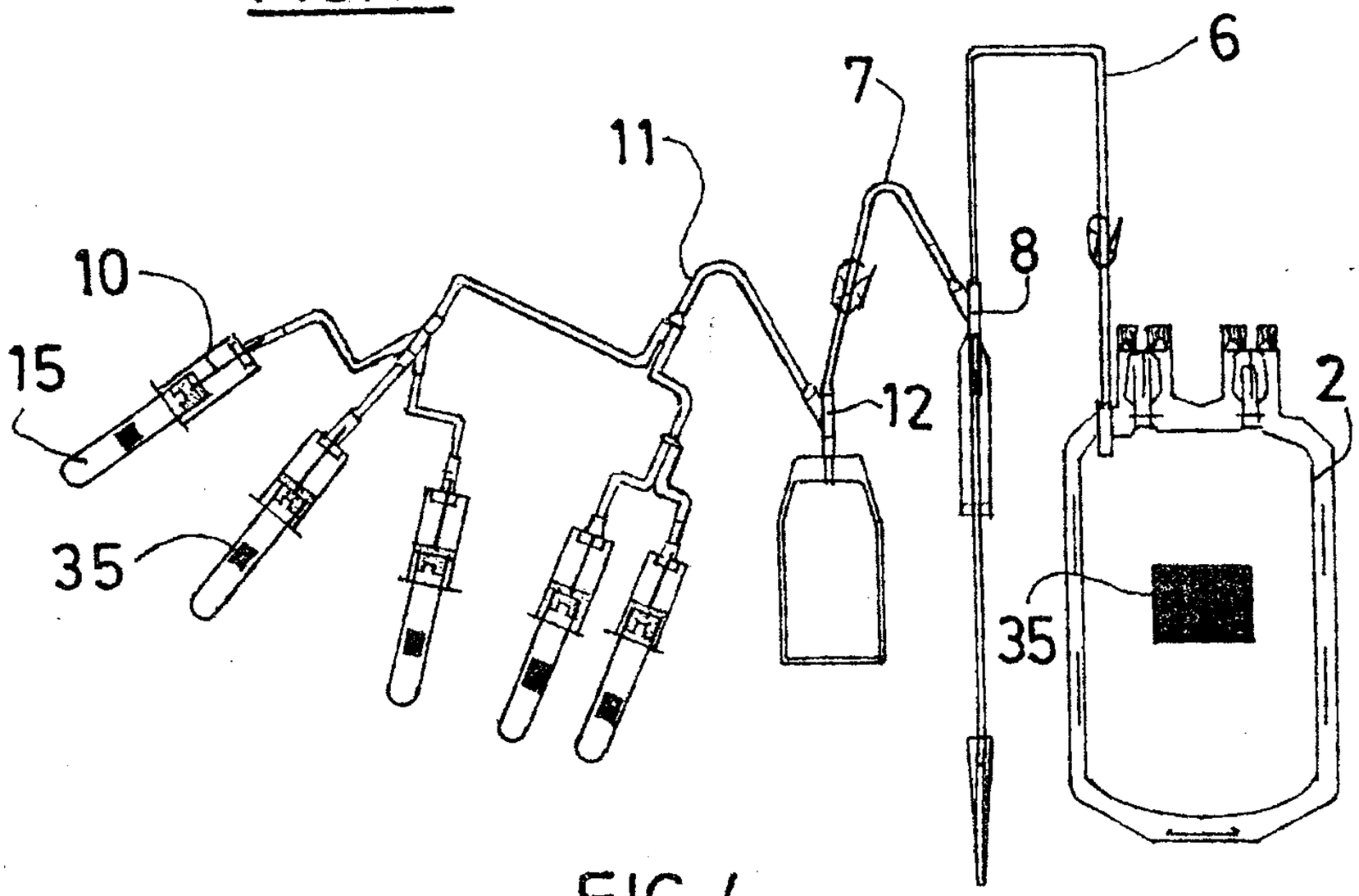


FIG.4

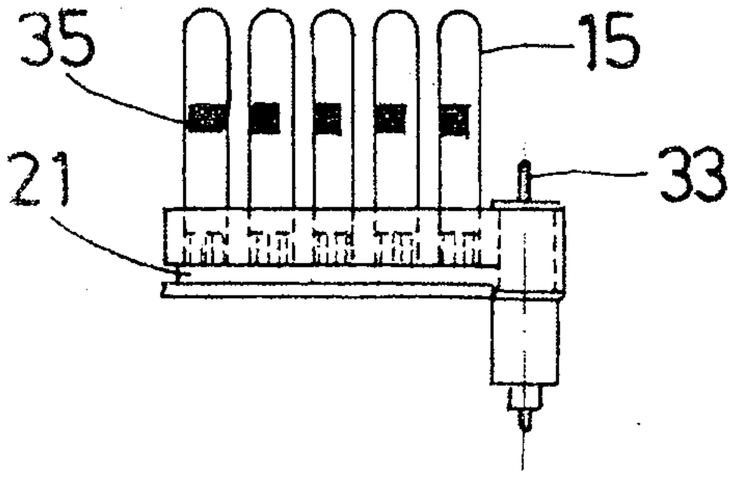


FIG.5a

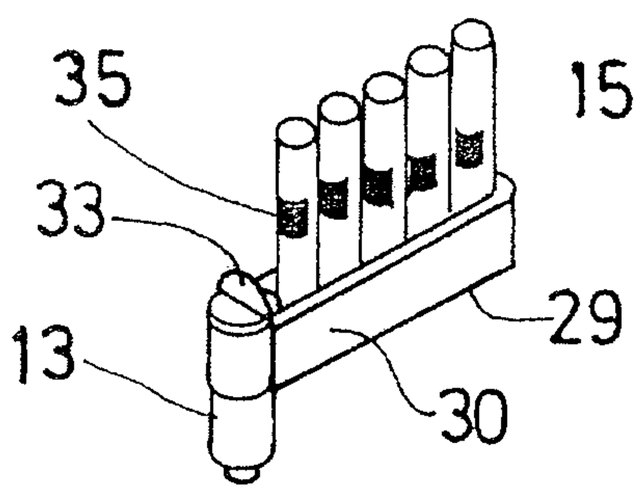


FIG.5b

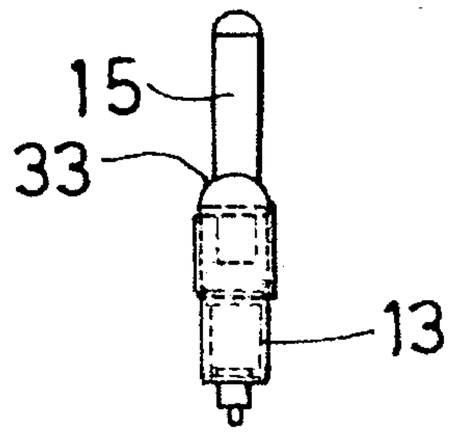


FIG.5c

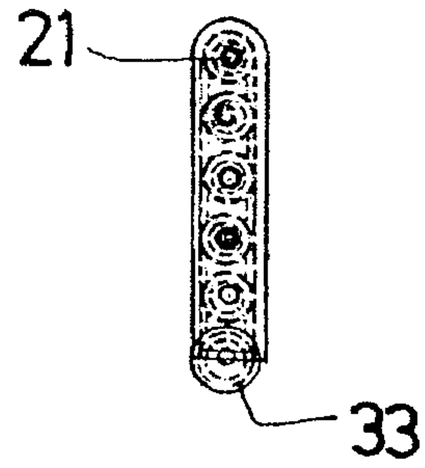


FIG.5d

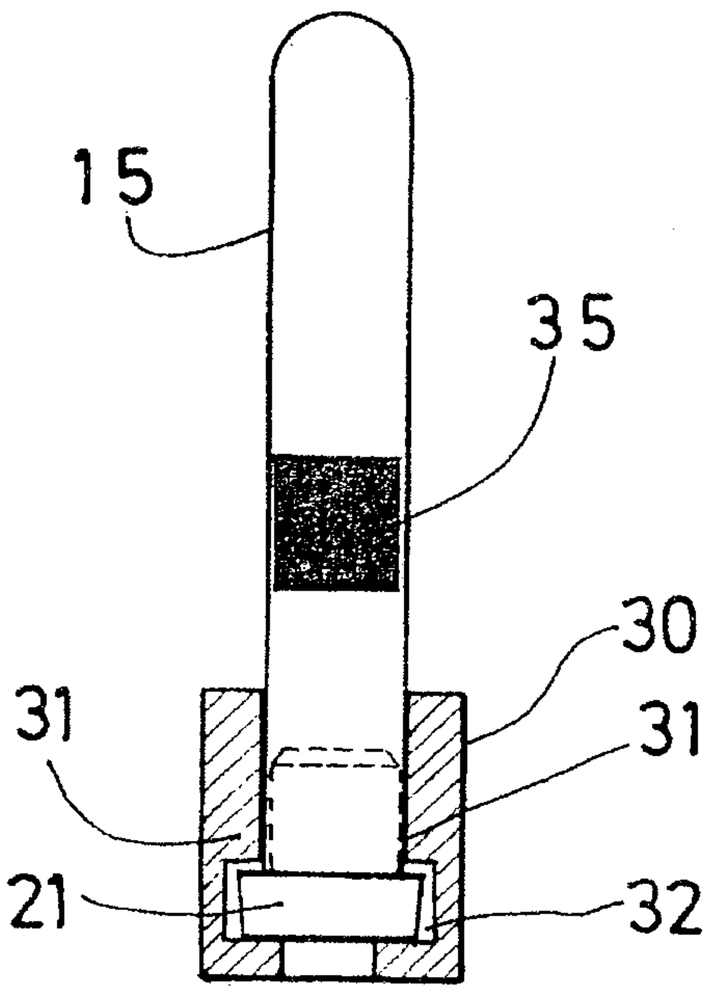


FIG.5e

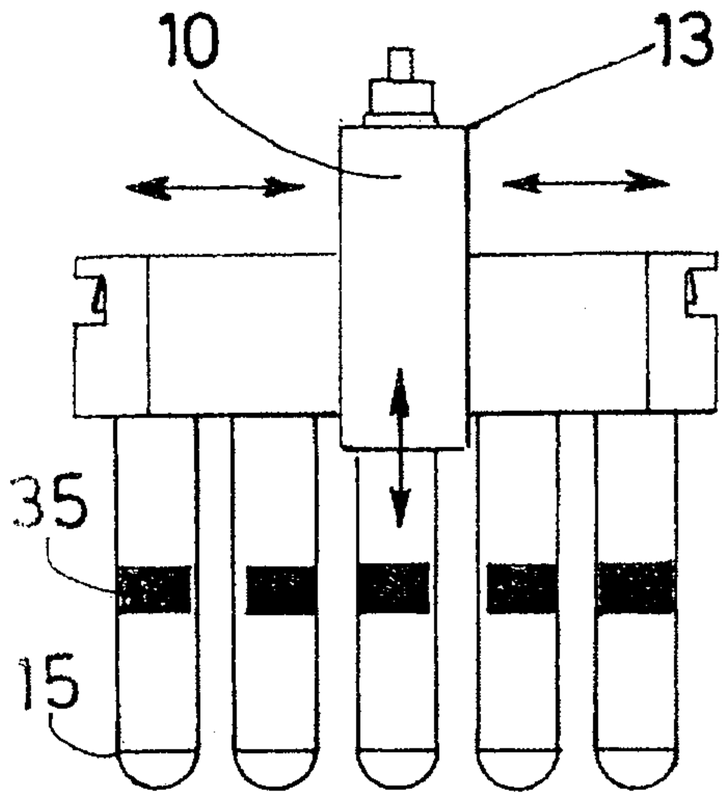


FIG.6a

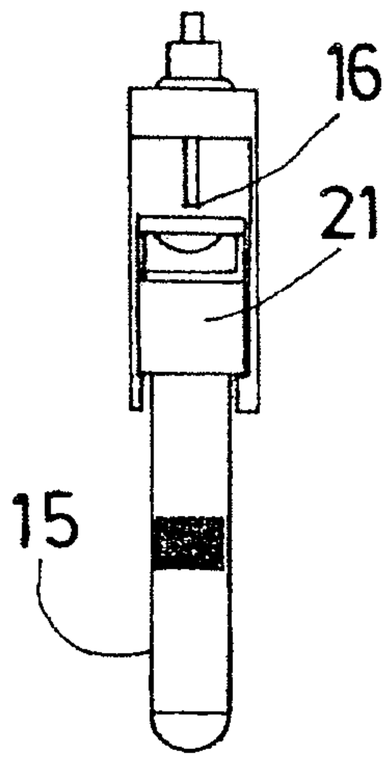


FIG.6b

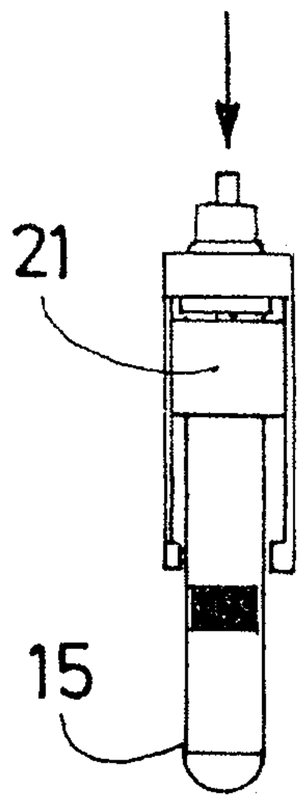
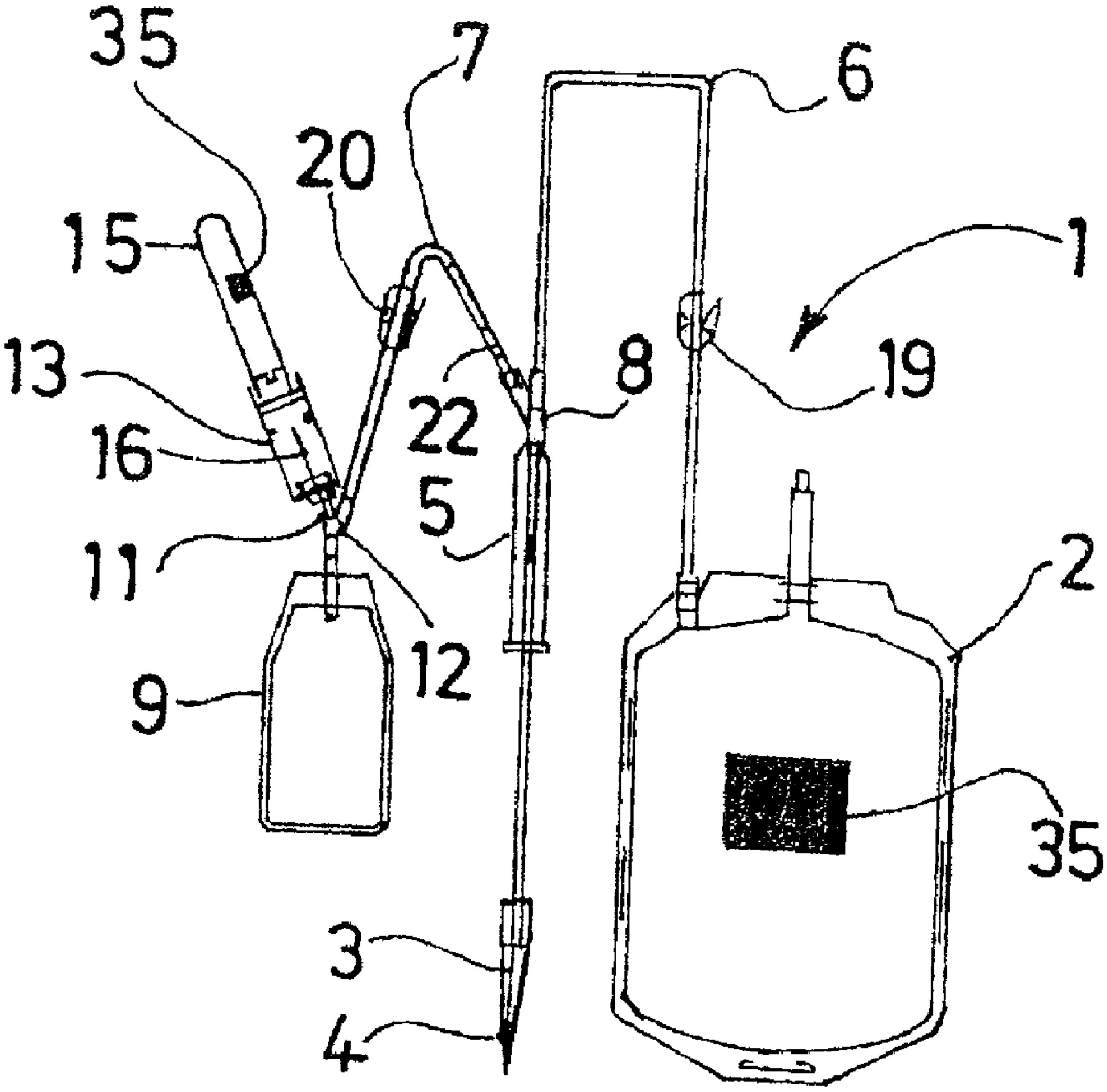


FIG.6c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