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- (74) Fuldmægtig i Danmark: **Awapatent A/S, Rigsgade 11, 1316 København K, Danmark**
- (54) Benævnelse: **Forbindelsesstykke, beholder med et sådant forbindelsesstykke og fluidklargøringsindretning med et tilsvarende forbindelsesstykke til en sådan beholder**
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DESCRIPTION

[0001] The invention relates to the field of connectors for connecting a container with a fluid preparation device for preparing a fluid. The invention also relates to such containers and fluid preparation devices, in particular to dialysis devices.

[0002] Most hemodialysis devices used for routine treatment prepare the required dialysis fluid themselves by a fluid preparation part which is contained in the device and where the mixing of adequate concentrates with water takes place. These concentrates are commonly distributed in liquid form and filled in canisters. Both the handling and the transportation of such canisters filled with fluid concentrate is posing various problems. Special and rather spatial connectors are necessary on the dialysis device to couple such canisters so that the device can suck the required concentrate. During exchange of a canister fluid may be spilled. Special chambers for accommodating or even rinsing the connector during any periods no canister is connected may be required. As far as the weight is concerned it is primarily only water which is delivered from the manufacturer to the patient. Furthermore, the empty canisters represent an environmental problem as only special material with certain blocking and stability properties should be used.

[0003] It is also known to provide concentrates, for instance in a clinic, from a central preparation unit to various treatment sites by an installed piping network. Though this simplifies the working load at the treatment sites in these clinics it is obvious that such a piping network is expensive, both for installation and maintenance, and not applicable for more flexible conditions.

[0004] It is also known to use at least for some ingredients of the dialysis fluid a powdered or granulated solid concentrate such as bicarbonate. US 5,540,265 describes such a system with a bag containing a concentrate and having a plug component. On the dialysis device there is a complementary plug component by which a flow connection for a first and a second flow path with the interior of the bag may be established. Water is introduced into the bag by the first flow path. Diluted and thus prepared bicarbonate fluid is extracted by the second flow path.

[0005] The plug component has a coaxial design for the two flow paths. The complementary plug component on the dialysis device therefore has a rather sophisticated design which in turn requires elaborate solutions to make routine rinsing and disinfection of this part of the dialysis device possible. Furthermore, as the plug component on the bag has a circular design the manufacturing process of such a bag affords special processes as the plug component is usually welded into a complementary hole in a side wall of the bag. More simple techniques assessing the bag only from the top are hence not applicable.

[0006] It is therefore an object of the invention to provide a connector for a container to be coupled to a mating connector on a fluid preparation device such as a dialysis device which considerably simplifies the handling during the connection procedure, the manufacturing process of the container and the rinsing and disinfection of the mating connector part on the fluid preparation device.

[0007] It is also an object of the invention to provide a corresponding container. Furthermore, it is an object of the invention to provide a fluid preparation device with a corresponding mating connector.

[0008] These objects of the invention are solved by the subject matter as claimed by the independent claim 1. Various embodiments of the invention are subject of the dependent claims.

[0009] The concept of the invention is based on the observation that by separating the mounting means which comprises both fluid line connector parts for the two fluid lines to be connected to two fluid lines of the fluid preparation device, into two laterally spaced-apart mounting means, each incorporating the orifices of one of the two connector parts, it is possible to set up a connector system which significantly simplifies the handling and manufacturing processes. With the aid of the inventive concept it is in particular possible to design a container to be connected to a fluid preparation device, which is mounted in a suspended fashion with the connector parts being used at the same time in a hook-like fashion at the uppermost point of the container to realize an optimum stability of the mounted container.

[0010] These and other advantages of the invention will become more apparent from an embodiment which is now described as an example by the aid of the drawings. In the drawings,

figure 1 shows a perspective view of an embodiment of the connector according to the invention with a boat-like cross-section,

figure 2 shows a first sectional drawing of the connector shown in figure 1,

figure 3 shows a second sectional drawing as defined by figure 2,

figure 4 shows an embodiment for a container according to the invention using the connector shown in figures 1 to 3, and a part of an embodiment of the fluid preparation device according to the invention, which is suitable for mounting the container, a lid of that part being in a first position,

figure 5 shows the same arrangement as figure 4, the container being mounted,

figure 6 shows a first sectional view of that part of the fluid preparation device with the container being mounted, the lid being in a second position,

figure 7 shows a second sectional view of that part of the fluid preparation device without the container being mounted, the lid being in a third position, and

figure 8 shows the container with a single flap-like seal before usage.

[0011] In figure 1 an embodiment of a connector according to the invention is shown in a perspective view. The connector 1 has two bar-like, laterally spaced-apart mounting means 2 and 4. Such mounting means may easily be mounted to a mating mounting means by insertion in an axial direction. The interior of the mounting means 2 and 4 is hollow thus defining first and second orifices 3 and 5.

[0012] The connector 1 has a boat-like cross-section with a wide middle part 6 and two wing-like projections 7 and 8 on opposing sides of the middle part 6. The boat-like cross-section simplifies the joining of the connector to a containment portion of a container like a flexible tube bag considerably, as is known in the art of manufacturing flexible bags. For welding purposes there may therefore be provided a rip structure 19 at the lower end 16 of the connector 1.

[0013] The middle part 6 of the boat-like cross-section shows a fifth orifice 11 which extends from the upper end 17 to the lower end 16. The orifice 11 may be used for prefilling the containment portion to be joined to the connector during the manufacturing process with a substance.

[0014] The mounting means 2 and 4 protrude from the wing-like projections 7 and 8 by protrusions 28 and 29 in a direction which is perpendicular to the axes of the mounting means 2 and 4 and thus also to the axes of the orifices 3, 5 and 11, which are all parallel. In the embodiment shown in figure 1, the protrusions 28 and 29 are tangential to one side of the wing-like projections 7 and 8.

[0015] Furthermore, a first end 13 of a handle 12 is joined to the first mounting means 2 and a second end 14 of the handle 12 is joined to the second mounting means 4. To ease the use of the handle 12 the ends 13 and 14 may comprise flexible film joints.

[0016] The connector 1 also comprises a ledge 15 which joins the second mounting means 4 with the middle part 6 of the connector 1. This ledge 15, as will be outlined below, serves as a counterpart for a detector means at the mating connectors site for confirming the correct mount of the connector.

[0017] In figure 2 a sectional view of the connector 1 is shown where the middle part 6 and the wing-like projections 7 and 8 are cut along their middle, and the view is from the back as seen in figure 1. The connector 1 extends from the lower end 16 to the upper end 17. In the middle part the continuous orifice 11 for enabling an easy prefilling of the containment portion to be joined to the lower end 16 of the connector is seen.

[0018] In the first wing-like projection 7 there is also a continuous third orifice 9 and in the second wing-like projection 8 a continuous fourth orifice 10. Though the third and fourth orifice 9 and 10 have a varying cross-section along their extensions from the lower end 16 to the upper 17 of the container 1, this has no influence on the fact that a fluid communication is established along these extensions. The third orifice 9 extends to a first distribution chamber 20 and the fourth orifice 10 to a second distribution chamber 21.

[0019] As can be seen in figure 1 the distribution chambers 20 and 21 are in fluid communication with the first and second orifices 3 and 5 by slots 22 and 23, respectively. By mounting the connector 1 in a mating mounting means to be described below, fluid communication is thus established from the first orifice 3 to the third orifice 9 which hence constitutes a first fluid line, and from the second orifice 5 to the fourth orifice 10 which constitutes a second fluid line.

[0020] Figure 3 shows a further sectional view along the line A-A as indicated in figure 2. In this view the protrusions 28 and 29

of the two mounting means 2 and 4 and thus the first and second orifices 3 and 5 in a direction perpendicular to the vertical extension of the wing-like projections 7 and 8 and the middle part 6 of the connector 1 are displayed more clearly.

[0021] In an embodiment of a container according to the invention the connector 1 shown in figures 1 to 3 is representing the connector portion, the lower end 16 to be joined to a containment portion of the container. For this purpose the upper end 17 is sealed along the circumference 26 - which is also encircling and thus sealing the fifth orifice 11 - by a flexible sheet 18 by welding or similar known joining techniques. It is worth noting that due to the design of the connector the flow paths for the first and second fluid lines are not blocked by this seal. The flexible sheet 18 is indicated in figure 2.

[0022] This embodiment of the container is shown in figure 4. The containment portion 31 of the container 30 is made from a tube bag which is sealed at the lower end 32 and joined by welding or similar techniques in a leak-proof manner at the upper end 33 to the lower end 16 of the connector 1. In the embodiment shown in figure 4 the container 30 is furthermore prefilled with a powdered concentrate 34 of a substance to be dissolved for final usage. The substance may be provided in any other condition, solid or fluid, whatever may be useful for the particular purpose.

[0023] For maintaining sterility before usage the lower ends 24 and 25 of the orifices 3 and 5 may be sealed in an appropriate way so that the interior of the container 30 is completely sealed to the exterior. As an example a single flap-like seal 27 is shown in figure 8 which is sealing both orifices 3 and 5. The seal 27 may be removed by a user before usage by peeling off the seal as shown in figure 8.

[0024] Furthermore, not shown tubes and/or filters may be provided in the container 30 which are placed in the first and/or second fluid line in order to filter passing fluid flowing in and/or out the bag and/or extend the lines to a particular site within the containment portion 31. If it is desired to withdraw a saturated solution of a substance to be dissolved it may prove useful to introduce the flushing and hence dissolving fluid like water close to the upper end 33 of the containment portion 31 and to withdraw the saturated solution close to the lower end 32 of the containment portion 30.

[0025] In figure 4 there is also shown a part 50 of an embodiment for a fluid preparation device according to the invention which has mating first and second mounting means 53 and 54 for mounting the connector 1 and thus container 30. These mating first and second mounting means are formed by first and second insertion chambers 53 and 54 which have a complementary cross-section such that the first and second bar-like mounting means 2 and 4 can be mounted by insertion into these chambers. Any cross-section may be used, but a circular cross-section as shown in this embodiment is advantageous in view of improved rinsing and disinfection properties.

[0026] The first insertion chamber 53 is in fluid communication with a third fluid line 51, the flushing fluid line, which is connected to a flushing fluid source (not shown) for the delivery of flushing fluid. This flushing fluid is required during use of the container 30 in order to prepare the prepared fluid from the prefilled substance and the flushing fluid - the latter being in most cases simply water. Correspondingly the second insertion chamber 54 is in fluid communication with a fourth fluid line 52, the prepared fluid line, which enables the delivery of the prepared fluid to a place where it is required. This may still be within the fluid preparation device or by means of a suitable outlet for the delivery to somewhere else.

[0027] The part 50 of the fluid preparation device also comprises a detector means 58 which in this embodiment is a mechanical microswitch. Upon mounting the container 30 and thus the connector 1, the ledge 15 presses the switch 58 which by a not shown electronic evaluation circuit of the fluid preparation device enables the device to confirm the correct mount of the connector 1. It may be possible that this evaluation circuit causes any actuators to block the flow of any flushing fluid into the first insertion chamber 53 until such confirmation has taken place.

[0028] The part 50 of the fluid preparation device further comprises a lid 59. The lid 59 is turnable around a joint 65 from a first, open position which is shown in figure 4, to a third, closed and preferable locked position which will be described below. Between the first and the third position, the lid is arrestable, preferably lockable, in a second position with the container 30 being mounted as will also be explained below. The lid 59 has first and second closure parts 60 and 61 which are suitable to close the first and second insertion chambers 53 and 54, respectively, when the lid 59 is in the third position.

[0029] Figure 5 shows the same view as figure 4 with the connector 1 and thus the container 30 being mounted to the part 50 of the fluid preparation device. The first and second mounting means 2 and 4 are inserted in the first and second insertion chambers 53 and 54. Furthermore, there are two proximity detectors 63 and 64 on the part 50 which detect the presence of the lid 59 in either the second or the third position. These proximity sensors may be non-mechanical sensors like Hall sensors which notice the close position of certain parts of the lid 59. These sensors may as well comprise mechanical switching means which are actuated by movable counterparts (not shown) of the lid which at the time serve to lock the lid 59 in the second or third position.

[0030] Figure 6 shows a first sectional view of the arrangement shown in figure 5 with the lid 59 being in the second position, arresting the connector 1 in its mounted position by pushing with the closure parts 60 and 61 onto the connector 1. The sectional view is taken along the flushing fluid line 51 and the first insertion chamber 53 looking from left to right in figure 5. The prepared fluid line 52 and the second insertion chamber 54 have a symmetric design.

[0031] Within the first insertion chamber 53 there is first male connector element 55 which terminates the flushing fluid line 51 within the first insertion chamber 53. The first male connector element 55 is joined to the housing of part 50 with a flexible sealing and compensation element 57 which may be made of any suitable material, e.g. rubber. The sealing and compensation element 57 enables movements of the first male connector element 55 relative to the housing in order to compensate tolerances which may exist for the relevant counterparts of the connector 1.

[0032] In the arrangement displayed in figure 6 the first orifice 3 and hence the first fluid line of the connector 1 and container 30 are now in fluid communication with the flushing fluid line 51. The orifice 3 is limited by first sealing lips 66 at the lower circumference of the first mounting means 2. The sealing lips 66 may easily be created by injection molding. The lips 66 assure a leak-proofed connection to the first male connector element 55 which they encompass at its outer circumference.

[0033] The first mounting means 2 is inserted into the first insertion chamber 53 as far until a first step-like projection 69 of the first mounting means 2 is touching the housing of the part 50 of the fluid preparation device.

[0034] From the first insertion chamber 53 there also branches off a fifth fluid line 62. When the connector 1 is mounted this fifth fluid line 62 will be sealed by the first sealing lips 66, i.e. there is no fluid communication to the connected first and third fluid lines, that latter being the flushing fluid line 51.

[0035] For the connection of the second and fourth fluid lines there are corresponding elements, i.e. a second male connector element, a second sealing and compensation element, second sealing lips, a second step-like projection and a branching sixth fluid line.

[0036] The purpose of the fifth and sixth fluid lines becomes apparent from figure 7. This figure shows a second sectional view of the part 50 of the fluid preparation device. It differs from figure 6 by the fact that no connector 1 is mounted and that the lid 59 is in the closed, third position. The first insertion chamber 53 is now closed by the first closure part 60 which is a part of the lid 59. The closure is sealed by sealing means 67 on the outer circumference of the first closure part 60, which here is accomplished by an o-ring gasket. On the inner side of the first closure part 60 there is a first opening 68 which has a larger diameter than the outer diameter of the first male connector element 55.

[0037] In this configuration the fluid lines of the part 50 of the fluid preparation device may easily be rinsed with any fluid like water or disinfection fluid. As the second closure part 61 is sealing the second insertion chamber 54 in a similar way, the rinsing fluid may be provided by the third fluid line, i.e. the flushing fluid line 51. The flushing fluid then enters the first insertion chamber 53 and leaves it via the fifth line 62. In this embodiment the fifth and sixth lines are joined (not shown). The rinsing fluid hence enters the second insertion chamber 54 by the sixth fluid line and leaves it by the fourth fluid line, i.e. the prepared fluid line 52. By this configuration an easy and effective rinsing and/or disinfection of all relevant parts of the fluid preparation device in the mating connector area is accomplished. Any parts which are above the gasket 67 are not reached by the rinsing fluid, but these parts will not be part of the fluid path if a connector 1 is connected either.

[0038] The connector 1 or container 30, respectively, may be designed as a disposable article for single-use purposes. Hence special solutions for their disinfection have not to be found. In this case a sensitive part like the sealing lips 66 is automatically exchanged from one use to another without affording any extra parts or expensive maintenance procedures.

[0039] The detector means 63 and 64 sense the lid 59 in the second or the third position. The electronic evaluation circuitry of the fluid preparation device is monitoring the signals provided by these detector means in order to confirm an expected position of the lid 59 during specific modes of the fluid preparation device like disinfection or online fluid preparation.

[0040] It is worth noting that the boat-like cross section of the connector 1 represents a preferred embodiment. Any other shape of the connector which still meets the concept of the invention as outlined by the claims would nevertheless enable an easy handling of the connector system during use. As is apparent from figures 4 to 7 the shape of this part of the connector hardly has any influence on the connection steps themselves.

[0041] The invention is hence providing easy to handle and reliable components for a fluid preparation system consisting of a container with a special connector and a fluid preparation device. The container may be prefilled with a substance, but also applications are possible where an initially empty container is used which will be filled and/or emptied during use. The container can be of any type, rigid or flexible. A flexible bag represents however a preferred embodiment.

[0042] The components of the inventive system are particularly useful in the medical field where the handling is especially sensitive to sterility conditions. At the same time the invention provides inexpensive solutions which is not of lesser interest. The invention has proven particularly useful in the field of dialysis where the fluid preparation device is part of the dialysis device. The prepared fluid may represent only a part of the complete dialysis fluid like bicarbonate, or the complete dialysis fluid. It may be applied to any type of dialysis like hemodialysis or peritoneal dialysis.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US5540265A [0004]

P A T E N T K R A V

1. Kombination af en beholder og en fluidklargøringsindretning (50) med en skyllefluidkilde, som er forbundet til en skyllefluidledning (51) og med en færdigfluidledning (52) til fluidet, som skal klargøres,

5 hvor beholderen omfatter et indeslutningsafsnit (31) og et forbindelsesafsnit (1), hvor forbindelsesafsnittet omfatter et forbindelsesstykke (1) til at forbinde fluidledninger med en første forbindelsesdel (2), som tilvejebringer en første åbning (3) til at forbinde en første fluidledning til en tredje fluidledning, en anden forbindelsesdel (4), som tilvejebringer en anden åbning (5) til at

10 forbinde en anden fluidledning til en fjerde fluidledning, og et monteringsorgan (2, 4), som gør det muligt at forbinde den første (2) og den anden (4) forbindelsesdel til de tilsvarende dele af en tilsvarende forbindelsesstykke, hvor monteringsorganet omfatter to monteringsorganer (2, 4), som er placeret med sideværts afstand og som muliggør forbindelse til to

15 tilsvarende monteringsorganer, som er placeret med samme sideværts afstand, af den tilsvarende forbindelsesdel, hvor hvert af de to monteringsorganer (2, 4) inkorporerer én af de to åbninger (3, 5), hvor fluidklargøringsindretningen omfatter en monteringsforbindelsesdel (53, 54)

20 egnet til montering og forbindelse af beholderen, således at skyllefluidledningen (51) og færdigfluidledningen (52) er i fluidforbindelse med det indre af beholderen (30), hvor monteringsforbindelsesdelen omfatter det første (53) og det andet (54) monteringsorgan, hvor skyllefluidledningen (51) er den tredje fluidledning og

25 færdigfluidledningen (52) er den fjerde fluidledning, og hvor det første (53) og det andet (54) tilsvarende monteringsorgan er et første (53) og et andet (54) indføringskammer, i hvilket det første (2) og det andet (4) monteringsorgan af forbindelsesstykket (1) er indsat for at skabe forbindelse, og som omfatter et første hanforbindelseselement (55), som

30 afslutter skyllefluidledningen (51) og et andet hanforbindelseselement, som afslutter færdigfluidledningen (52).
2. Kombination ifølge krav 1, hvor et tætnings- og compensationselement (57) er indsat i hver af det første (53) og det andet (54) indføringskammer for at tætn

og kompensere for bevægelser af det første (55) og det andet hanforbindelseselement.

35
3. Kombination ifølge et hvilket som helst af kravene 1 og 2, hvor det første (53) og

det andet (54) indføringskammer har parallelle orienteringer.

4. Kombination ifølge et hvilket som helst af kravene 1 til 3, hvor fluidklargøringsindretningen (50) yderligere omfatter et detektororgan (58) til detektering af tilstedeværelsen af forbindelsesstykket (1).
5. Kombination ifølge et hvilket som helst af kravene 1 til 4, hvor fluidklargøringsindretningen yderligere omfatter et låg (59) til at dække monteringsforbindelsesdelen.
6. Kombination ifølge krav 5, hvor låget (59) omfatter en første lukkedel (60) til at lukke det første indføringskammer (53) og en anden lukkedel (61) til at lukke det andet indføringskammer (54).
7. Kombination ifølge krav 6, hvor fluidklargøringsindretningen yderligere omfatter en femte fluidledning (62), som er i fluidforbindelse med det første indføringskammer (53) og således skyllefluidledningen (51), når den første lukkedel (60) lukker det første indføringskammer (53), og en sjette fluidledning, som er i fluidforbindelse med færdigfluidledningen (52), når den anden lukkedel (61) lukker det andet indføringskammer (54).
8. Kombination ifølge krav 7, hvor den femte (62) og sjette fluidledning er sammenføjet.
9. Kombination ifølge et hvilket som helst af kravene 5 til 8, hvor låget (59) er bevægeligt mellem en første position, som muliggør montering og/eller fjernelse af forbindelsesstykket (1), en anden position, hvor det monterede forbindelsesstykke (1) holdes på plads af låget (59), og en tredje position, hvor det første (53) og det andet (54) indføringskammer er lukkede og intet forbindelsesstykke (1) er monteret.
10. Kombination ifølge krav 9, hvor fluidklargøringsindretningen yderligere omfatter et lågpositionsdetektororgan (63, 64) til at detektere én, nogle eller alle tre positioner af låget.
11. Kombination ifølge et hvilket som helst af kravene 1 til 10, hvor fluidklargøringsindretningen er en del af en dialysefluidklargøringsindretning og den klargjorte fluid er, eller er en del af, dialysefluiden.

DRAWINGS

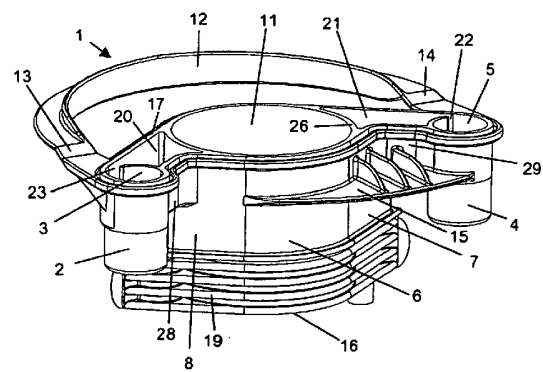


Fig. 1

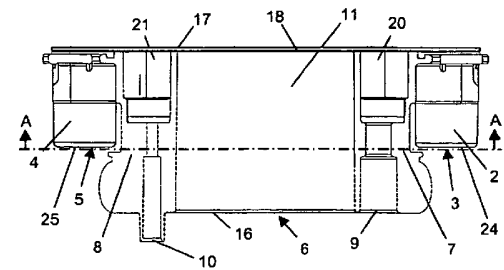


Fig. 2

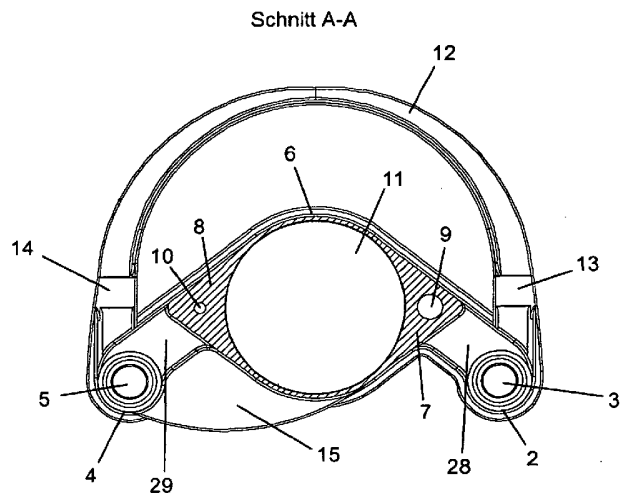


Fig. 3

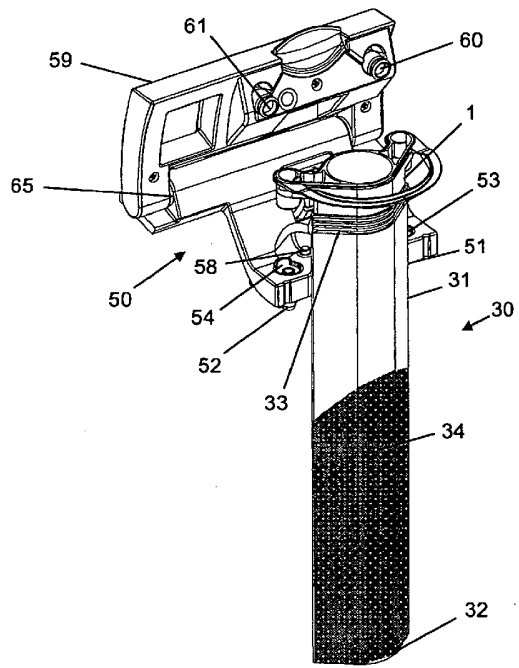


Fig. 4

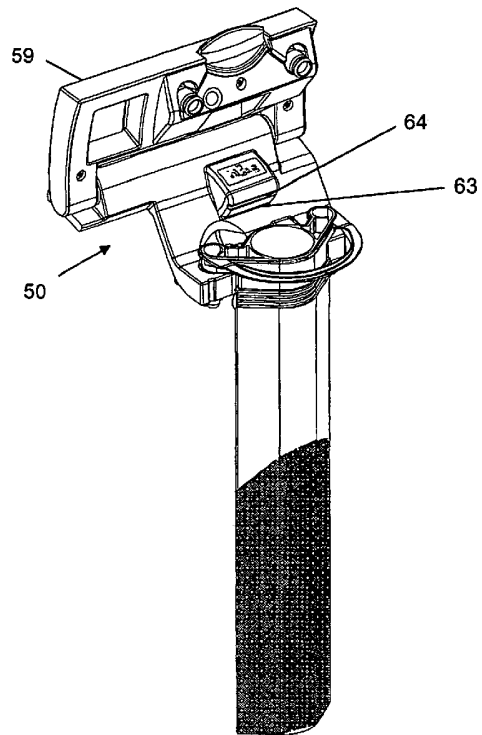


Fig. 5

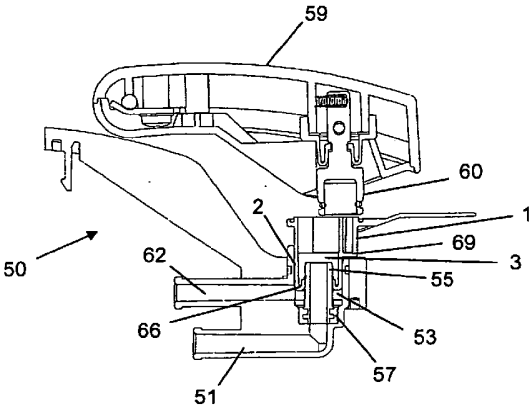


Fig. 6

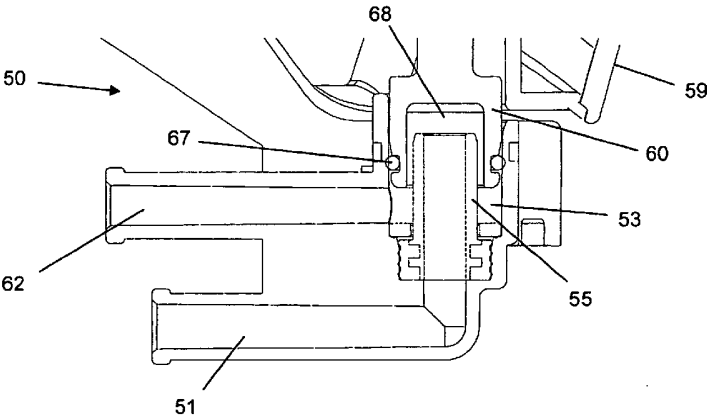


Fig. 7

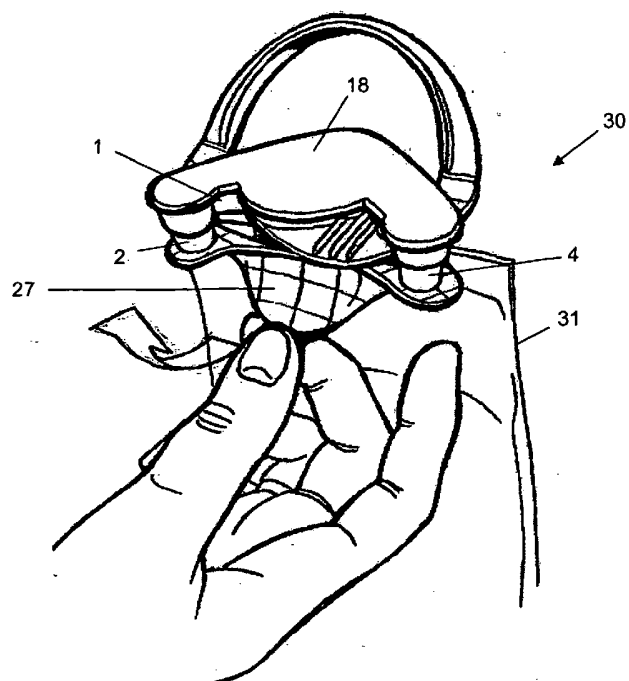


Fig. 8