(57) Abstract: A valve arrangement for controlling the flow of a liquid through a line is provided, a flow set comprising the valve arrangement, use of the valve arrangement in providing nutrition to an individual and a method of treatment of an individual that comprises administering an effective amount of a nutritional composition through the valve arrangement.
Declarations under Rule 4.17:

— as to applicant’s entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, IK, LR, IS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MD, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— as to the applicant’s entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, IK, LR, IS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZM, ZW, ARIPO patent (GH, GM, KE, LS, MW, MD, SD, SI, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

— of inventorship (Rule 4.17(iv)) for US only

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the “Guidance Notes on Codes and Abbreviations” appearing at the beginning of each regular issue of the PCT Gazette.
Anti free-flow valve

The present invention relates to an anti free-flow valve arrangement for controlling the flow of a liquid through a line, a flow set comprising the valve arrangement, use of the valve arrangement for providing liquid or nutrition to an individual and a method of treatment of an individual that comprises administering an effective amount of a nutritional composition through the valve arrangement.

Hospital patients are routinely provided fluids for maintaining a good state of hydration. Furthermore, fluid can act as a carrier for nutrients in order to provide an individual with adequate nutrition, e.g. following surgery.

Systems for administering fluids to an individual are widely known. In order to propel the fluid to an individual these systems make use of gravitation, of a pressure applied on a deformable container, or of a pump. In pump-operated administration systems, the pump must be capable of administering the fluid in a controlled, generally continuous manner.

In practical use pumps are employed to meet the need for a high degree of accuracy in the administration of fluids, to protect the patient and to maximise the effectiveness of medication.

An example of a pump presently used for pumping fluid along a tube to an individual is a rotary peristaltic pump. However, this type of pump suffers from the problem that if a flow set is not properly connected or disconnected from the pump, free-flow may occur. A free flow generally indicates a flow of fluid which occurs passively by gravity, generally without the intervention of a mechanical device, such
as a pump. Free-flow may be quite harmful to patients as it can lead to aspiration of fluid into lungs.

In general, this type of pump does not have anti free-flow protection, which puts the individual to danger, in case un-inhibited free flow of fluid to the individual occurs - it may eventually lead to drowning.

Another example of a pump presently used is a linear peristaltic pump. This type of pump exhibits the shortcoming that if a flow set is not properly connected, it is subject to (pumped) back-flow of liquid in a direction opposite to the intended direction of flow to a patient. It is clear that if free-flow or back-flow proceeds unchecked, it may be dangerous for a patient.

In order to solve the problem of free-flow, a device known as an "occluder" has been employed. This piece of medical device operates by folding a length of a resilient tubing, thereby pinching the tubing and causing its internal diameter to be reduced, whereby flow through it is inhibited. This arrangement has been found to work to a certain extent, yet it still suffers from the problem that, if an elastic part of the occluder (for keeping a resilient tube folded) is over-stretched, it may be easily broken. Therefore, if an operator disconnects the pump, but fails to close the tubing, for example with a roller clamp, free-flow may occur.

Accordingly, an objective of the present invention resides in overcoming the drawbacks of the prior art, and to provide a device that allows a good flow through it but prevents un-inhibited free-flow.

This problem has been solved by providing a valve arrangement, which comprises a chamber 1 having at least one inlet opening 2, 2a, 2b and at least one outlet opening 3, a body 4 arranged within the chamber 1 between the inlet 2, 2a, 2b and the outlet openings 3, and a member 5, the periphery thereof contacting the walls of the
chamber 1 in a sealing manner, and which has an aperture 6, the inner diameter of which corresponding to an outer diameter of at least a section of the body 4 and being slidably arranged on at least the said body 4, such that upon a flow of fluid into the chamber 1 in the direction from the inlet 2 to the outlet opening 3, the pressure of the fluid moves the member 5 from a closed position, where the inner diameter of the aperture 6 contacts a segment of the body 4, to an open position, where the aperture 6 of the member 5 is wider than the outer diameter of the body 4, such that flow of liquid may pass through the valve.

In the figures,

Fig. 1 shows a section of a valve arrangement according to the present invention;

Fig. 2 shows an assembly of a valve arrangement according to the present invention;

Fig. 3 shows a an embodiment of a valve arrangement according to the present invention, wherein the member is pre-compressed on the body;

Fig. 4 shows an embodiment of a member with an central aperture;

Fig. 5 shows an embodiment of a valve arrangement, with a tapering body;

Fig. 6 shows an embodiment of a valve arrangement with the member being pre-compressed on the tapering body;

Fig. 7 shows the embodiment of Fig. 6 in an opened position.

The valve arrangement of the present invention essentially comprises three main constituents, a housing or chamber 1, providing a through flow channel, and exhibiting at least one inlet 2, 2a, 2b and at least one outlet opening 3, a body 4,
which is arranged within the chamber 1 and which may extend longitudinally therein, and a member 5.

The housing or chamber 1 has at least one inlet opening 2 or port that opens into the chamber 1, e.g. through lines 2a, 2b, and at least an outlet opening or port 3, for introducing and discharging a liquid. The chamber 1 may be manufactured in two or more pieces for easy assembly and comprises conventional materials, conveying sufficient rigidity to the arrangement.

Within the chamber 1 a body 4 is arranged that may be manufactured integrally with the chamber 1 or a part thereof, or implemented therein as a separately produced entity introduced into the chamber 1 upon assembly and fixed therein. It may in principle have any suitable form but has preferably the form of a circle, an ellipse or a rectangle. The body 4 may be manufactured of the same material as the chamber 1, but may likewise be made of a different material.

The member 5 is essentially adapted to the form of the chamber 1 and that of the body 4 arranged therein. The circumference of the member 5 will essentially be sized to be easily accommodated in the chamber 1, into which it will be arranged, and has preferably an outer diameter of from about 5 to 20 mm. Likewise, the form and the size an location of the aperture 6 in the member 5 will essentially be dictated by the form of the body 4 and its arrangement within the chamber 1. Consequently, according to a preferred embodiment also the aperture has the form of a ring, an ellipse or a rectangle and has an inner diameter of between about 1 to about 5 mm.

The thickness of the member ranges from about 0.2 to about 2 mm, preferably from about 0.4 to about 1 mm, and is more preferably 0.6 mm. The member 5 may be made of any suitable material normally utilized in valve arrangements, such as plastics, or polyurethane or silicone. The only requirement resides in that the material is sufficiently flexible to allow movement and/or expansion, i.e. essentially a widening of the aperture 6, upon exerting pressure thereon.
When fluid enters the valve arrangement at the inlet opening 2, the fluid flows up to the member 5 which initially prevents a further flow of the fluid through the valve and fills the space limited by the part of the chamber 1 adjacent to the inlet opening 2, the body 4 and the member 5. With more fluid advancing into the valve the pressure in the said space and eventually on the member 5 increases. The member as the most flexible material in the valve arrangement tends to be displaced in the direction towards the outlet opening 3. Since the periphery of the member 5 is fixed at the walls of the chamber 1 primarily the section of the member 5 adjacent to the body 4, in particular the aperture 6, will move towards the outlet opening 3, when a certain pressure has been arrived at, the cracking pressure of the valve arrangement. A "cracking pressure" designates the threshold pressure at which flow is allowed to occur. At this point the diameter of the aperture 6 increases in response to the cracking pressure. If the pressure of fluid across a valve is below this threshold, flow is not permitted. This movement/displacement eventually creates an open space between the outer diameter of the body 4 and the inner diameter of the aperture 6 with the effect that the valve is opened.

Likewise, if the fluid pressure is reduced below the cracking pressure, the member 5 will return to its original position, at which the inner diameter of the aperture 6 corresponds to the outer diameter of the body 4 and contacts it in a sealing manner, thus closing the valve. The member 5 may be arranged on the body 4 as it is but may likewise be pre-compressed thereon.

In order to avoid movement of the member 5 in a direction towards the inlet opening 2 the member may be supported by an element 7, positioned on the side of the member 5 facing the inlet opening 2 and which essentially extends from the wall of the chamber 1 in the direction to the body 4. This element 7 may be part of the chamber and may support the member 5 on its periphery. Hence, according to a preferred embodiment said element may be constituted by a plate or disc having
openings formed therein, such as in form of a sieve, but may likewise be constituted by bars extending from the walls of the chamber 1 to the body 4. It will be appreciated that the form and position of the plate or disc having openings therein or the form and position of the bars may be chosen by the skilled person based on e.g. the mode of manufacture of the valve arrangement or other desired characteristic of the valve arrangement, such as the cracking pressure.

According to a preferred embodiment the body 4 does not exhibit a constant diameter along its length, but tapers in the direction towards the outlet opening 3, preferably at a total angle of from 1 to 75°, more preferably of from 10 to 20°, most preferred at about 14°. According to this embodiment the tapering form of the body 4 assists in a quick and reliable opening of the valve, when the slidable member 5 with the aperture 6 leaves the closed position.

A valve arrangement according to this embodiment may essentially function in two ways. In the closed position the inner diameter of the aperture 6 coincides with a diameter of a section of the circumference of the tapering body 4. When fluid enters the valve at the inlet opening, the fluid flows into the space limited by the member 5, the tapering body 4 and the walls of the chamber 1. When a selected pressure, the cracking pressure of the valve, has been arrived at, the said pressure of the fluid moves the ring in the direction of a decreasing diameter of the tapering body. The inner diameter of the member 5 encounters on the tapering body 4 a decreasing diameter, with the effect that at a certain position fluid flow between the outer diameter of the tapering body 4 and the inner diameter of the aperture 6 will be allowed.

According to an embodiment the member 5 as such may be arranged within the chamber 1 in a slidable manner. Consequently, when the pressure exceeds the forward cracking pressure, the entire member 5 will travel a way in the chamber 1 along the tapering body 4 and along the walls of the chamber 1 in the direction
towards the outlet opening 3. Due to the decreasing diameter of the tapering body 4 the distance between the tapering body 4 and the inner diameter 6 of the member 5 will increase as the member travels its way along the chamber 1. In this embodiment the member 5 may be selected to exhibit relatively limited flexibility only, since the opening of the valve will be achieved primarily by the travel of the entire member 5.

According to another mode of action, the member 5 may be fixed at the walls of the chamber 1. Also, in this embodiment, when fluid enters the chamber 1 it exerts a pressure on the member 5, which will, when a predetermined pressure (the cracking pressure) has been achieved, move essentially only the section of the member 5 around the aperture 6 in the direction of a decreasing diameter of the tapering body 4, thus opening the valve and allowing for a flow of liquid through the chamber. In case the fluid pressure decreases below a threshold value (i.e. below the cracking pressure) the aperture 6 (the member 5) will return to its original position.

According to an alternative preferred embodiment the member 5 may also be pre-compressed on the body 4 (whether it tapers or not) such that either the concave or the convex surface thereof faces the inlet opening 2. In case of the concave surface facing the inlet opening 2 the fluid entering the valve at the inlet side exerts a pressure on the member 5 which will - at the cracking pressure - eventually expand to allow a flow of fluid through the valve. Alternatively, in case of a tapering body 4 also the convex surface of the member 5 may face the inlet opening 2, wherein, at the cracking pressure, a switch of the member's aperture 6 in a flip-flop manner in the direction of a decreasing diameter of the tapering body 4 takes place, thus allowing fluid flow through the valve.

The forward cracking pressure of the valve arrangement according to the present invention should be in a range of between 0.2 - 0.6 bars, preferably 0.3 bars, which provides protection of at least 2 m height of water (i.e. 0.2 bars).
In principle, the forward cracking pressure of the present valve arrangement may be essentially controlled by a variety of different parameters. First, in the embodiment, where the entire member 5 moves in the direction of the outlet opening 3, said member may be biased against the tapering body 4, which may be achieved by means well known in the art, such as e.g. spring means attached on the walls of the chamber 1. Alternatively, the selected hardness (shore) of the member 5 may be used for determining the level of the cracking pressure. It will be appreciated that the less flexible the material chosen and/or the thicker the member 5, the higher the resulting cracking pressure. Alternatively, the inner diameter of the aperture 6 of the member, occasionally the outer diameter of the member 5 (in case it is fixed at the walls), the outer diameter of the tapering body 4 may be considered for adjusting the cracking pressure. Also, the angle of the tapering body 4 (in case the body 4 tapers in the direction of the outlet opening 3) is an important characteristic influencing the cracking pressure. It will be appreciated that the steeper the angle, the larger the volume of fluid that will pass the valve upon a small movement of the member 5 from its closing position. Furthermore, the location of attachment of the member 5 to the chamber 1 and therefore the level of pre-compression of the inner diameter of the aperture 6 of the member 5 in the radial direction is also an feature influencing the cracking pressure.

The presently described valve arrangements, in particular the embodiments illustrated above, have the advantage that they also reliably work with enteral feeding containing large fibers and particles with a scale of up to about 300 μm. With these solutions/compositions the situation often occurs that fibers and particles are trapped between the inner diameter of the aperture 6 of the member 5 and the (tapering) body 4 during closing of the valve arrangement, thus normally preventing a secure and reliable closing of a valve-system with the danger of free-flow or back flow arising. Yet, in the present valve arrangement these fibers and/or particles are crushed by the radial inward force of the member 5 (in case due to pre-compression), such that a proper closing of the valve is ensured. The material contained in the
solution does, therefore, not interfere with the correct functioning of the valve in either forward or reverse direction.

The present valve arrangement also prevents free-flow or back-flow, respectively.

In case of a flow in the reverse direction, i.e. in the direction towards the inlet opening 2, the fluid flows through the "outlet" 3 towards the member 5 and forces the aperture 6 on the body 4. In order to prevent a switch of the member 5 in the direction towards the inlet opening the member is supported by an element 7 as described above. Alternatively, in case of the body 4 tapering towards the outlet 3, the fluid forces the member 5, or the aperture 6, respectively, towards the increasing diameter of the tapering body 4 thus closing the valve. According to this embodiment the increasing diameter itself prevents a switch of the member 5.

According to the embodiment(s), wherein the member 5 is pre-compressed on the tapering body 4, the valve will close, when the pressure of the fluid in the direction of a decreasing diameter of the tapering body 4 decreases below a threshold level, i.e. the cracking pressure. In case of a tapering body 4, the inner diameter of the aperture 6 of the member, pre-compressed radially on the tapering body 4, encounters an increasing diameter of the tapering body 4, with the effect that no fluid may pass the valve in the reverse direction. In consequence no back-flow is allowed.

According to another embodiment the invention provides a flow set for the administration of at least one fluid to a patient which comprises a valve arrangement as described above, an inlet tube for connecting a container to an inlet opening of the valve, and an outlet tube for connecting to an outlet of the valve for the delivery of a fluid to an individual.

The valve arrangement may be used for supplying a liquid to an individual in need thereof. Liquids to be supplied comprise e.g. glucose, salts, nutritional components
etc. and are e.g. Sondalis HP Fibres, Salvimulsin, Salvi peptide, Salviplus, Nutren (Nestlé Clinical Nutrition France). The present valve arrangement may likewise be utilized for supplying enteral nutrition to an individual, e.g. after surgery. As described above the present valve arrangement also enables a correct closing in case the enteral nutrition contains larger particles, which normally tend to accumulate in the valve mechanism and prevent closing thereof.

According to another embodiment the present invention also provides for a method of treatment of a patient that comprises administering an effective amount of a fluid via a valve arrangement according to an embodiment of the invention.

The present valve arrangement provides the advantage of permitting simple and safe administration of a fluid from a container to a patient. If the pressure of fluid across the valve assembly exceeds a predetermined cracking pressure, flow is permitted, but unless the cracking pressure is exceeded, for example by a pump, flow of fluid is not permitted through the valve arrangement.

As mentioned above, no leakage is allowed with this valve. During normal use, the height of the container may never be such so as to generate a static pressure that exceeds the cracking pressure of the valve. If, in addition, the set has been disconnected from the pump, flow of fluid through the valve assembly is restricted, i.e. free-flow is totally inhibited so that the arrangement presents no risk for a patient. In contrast thereto, known valve arrangements have suffered from the problem that they have allowed a high flow rate of free flow to occur from a container to a patient if the set is misloaded or unloaded from the associated pump. It has also been found that the above mentioned cracking pressures provide the advantage that they do not alter a pump's operation.

Another advantage provided by the present invention is that the volume of programmed flow by the pump is not affected by the valve arrangement. This is a
result of the pump being able to overcome the impedance of the valve arrangement.

Another advantage of the present invention is that no disconnection of tubing, no manual adjustment of valves or use of other equipment for blocking flow is required. Therefore, the flow of fluid from the valve arrangement can be accurately controlled. Furthermore, in view of the fact that no disconnection of tubing is required during use, the risk of contamination is lowered. In addition, no special software or mechanical modification of a known pump is required.

Yet, another advantage of the present invention is that it provides an arrangement that is easy and inexpensive to manufacture. A simple construction method can be carried out comprising a simple housing and piston or membrane and this increased simplicity adds to the speed at which production can be achieved. Furthermore, if a valve arrangement according to the invention is employed, fewer pieces of commercially available apparatus (such as a pinch-clip occluder or roller clamp) are required.

Although a valve arrangement in accordance with the present invention is primarily suitable for use with a linear peristaltic pump, it is not limited to use with only this type of pump or any particular type of flow set.

Preferably, an embodiment of a valve arrangement according to the present invention is obtained by modification of known apparatus. Suitable starting materials are for example: a housing/chamber 1 manufactured of metal or plastics material, preferably rigid plastics material including ABS, polycarbonate, PVC, acrylic or MABS; and a valve membrane manufactured of a resilient/flexible material including polyurethane, silicone or rubber.

A pump of a pump unit is coupled to valve arrangement via tubings. The pump is preferably a peristaltic pump but any pump which is able to pump fluid at controlled
flow rates and which is suitable for clinical applications may be used. The pump unit may include a control unit. The control unit typically comprises a control panel which has a display and a key pad. The key pad may be used for manual control of the pump, data entry, and the like. The control unit may include a microprocessor for controlling and activating the pump. A memory may be associated with, or be incorporated in, the microprocessor. If desired, the control unit may include an audio, visual or dual alarm signaling means.

A flow set comprising the valve arrangement is typically mounted on a stand with a container for fluid being held by an arm at the top of the stand. Drip chambers may be provided adjacent the outlet of the valve arrangement or between the container and the inlet of the valve arrangement. The system provides a safe and rapid means of administering a fluid to a patient which is extremely simple to operate.

Additional features and advantages of the present invention are described in, and will be apparent from the description of a presently preferred embodiment which are set out below with reference to Fig. 6 and 7.

A valve arrangement according to an embodiment of the invention comprises a chamber or housing 1, respectively. The chamber 1 has an inlet opening 2 that opens into the chamber 1 through lines 2a, 2b, and an outlet port 3, for introducing and discharging a liquid. Within the chamber 1 a conus-like section 4 is arranged, with the inlet openings 2a, 2b being manufactured within the conus-like section 4.

The position of the conus-like section 4 in the chamber 1 is such that the body 4 having a larger outer circumference 4a being adjacent to the inlet lines 2a, 2b and the body 4 having a reduced diameter 4b being directed to the outlet port 3. It will be appreciated that the body 4 of the conus-like section 4 adjacent to the inlet opening 2 (in case the inlet opening is not manufactured in the tapering body 4) or harbouring the inlet lines 2a, 2b (as is shown in the figures) may be formed without a reducing
circumference, i.e. with parallel walls, while a constantly reducing circumference will prevail at locations more distant from the inlet lines 2a, 2b. It will likewise be appreciated that more than one inlet opening may be provided to ensure a rapid filling of the chamber 1.

A ring 5 with a hole 6 in the central body 4 thereof is fixed at a position of the walls of the chamber 1a, 1b, such that the ring 5 is pre-compressed on the conus-like section 4 and forms a somewhat concave surface 5a facing the inlet lines 2a, 2b.

When fluid enters the chamber through the inlet opening 2 and inlet lines 2a, 2b it fills the body 4 of the chamber 1 being defined by the walls of the chamber, the conus-like section 4 and the concave surface 5a of the ring 5. When a predetermined pressure has been reached that exceeds the force exerted by the ring 5 on the conus-like section due to its pre-compression, the ring 5 will lift to a position, wherein the concave surface 5a will increase its level of concavity. In this position the inner diameter of the ring 5 is larger than the circumference of the conus-like section opposite to it, thus allowing a way for liquid passing into the body 4 of the chamber adjacent to the outlet port 3 and out of the port 3.

In case the pressure exerted by the fluid flow ceases to sustain, such as when the pump is switched off, the ring 5, due to its pre-compression, will move back to its original position, thus closing the valve.

It will be appreciated that numerous modifications may be made to the preferred embodiments without departing from the spirit and scope of the invention as set out in the claims.
Claims

1. A valve arrangement, comprising
   (i) a chamber (1) having at least one inlet opening (2, 2a, 2b) and at least
       one outlet opening (3),
   (ii) a body (4) arranged within the chamber (1) between the inlet (2, 2a, 2b)
       and the outlet opening (3), and
   (iii) a member (5), the periphery thereof contacting the walls of the chamber
       (1) in a sealing manner, and which has an aperture (6), the inner diameter of
       which corresponding to an outer diameter of at least a section of the body (4)
       and being slidably arranged on the said body (4),
   such that upon a flow of fluid into the chamber (1) in the direction from the inlet
   (2) to the outlet opening (3), the pressure of the fluid moves the member (5)
   from a closed position, where the inner diameter of the aperture (6) contacts a
   segment of the body (4), to an open position, where the aperture (6) of the
   member (5) is wider than the outer diameter of the body (4), such that flow of
   liquid may pass through the valve.

2. The valve arrangement according to claim 1, wherein the member (5) has a
   thickness of 0.2 to 2 mm, preferably 0.4 to 1 mm.

3. The valve arrangement according to any of the preceding claims, wherein the
   member (5) has an aperture (6) with an inner diameter of between 1 - 5 mm, and
   an outer diameter of between 5 - 20 mm.

4. The valve arrangement according to any of the preceding claims, wherein the
   aperture (6) has the form of a ring, an ellipse or a rectangle having a thickness of
   about 0.2 to 2 mm.

5. The valve arrangement according to any of the preceding claims, wherein the
member (5) having an aperture (6) is made of plastics or silicone.

6. The valve arrangement according to any of the preceding claims, wherein the member (5) is biased against the body (4).

7. The valve arrangement according to any of the preceding claims, wherein the member is supported by an element (7), located on the side of the member (5) facing the inlet opening (2) and essentially extending from the wall of the chamber (1) to the body (4) such that a movement of the member (5) towards the inlet opening (2) is prevented.

8. The valve arrangement according to claim 7, wherein the element (7) is an integral part of the chamber or a plate containing holes or at least two bars (7a, 7b).

9. The valve arrangement according to claim 1, wherein the body (4) tapers in the direction of the outlet opening (3).

10. The valve arrangement according to claim 9, wherein the tapering body (4) tapers at a total included angle of from 5° to 75°, preferably 10° to 20°.

11. The valve arrangement according to any of the claims 9 or 10, wherein the member (5) is slidably arranged within the chamber (1), such that when a pressure is exerted by a fluid entering the chamber from the inlet opening (2) the member (5), slides at the walls of the chamber and at the circumference of the tapering body (4) in the direction to the outlet opening (3).

12. The valve arrangement according to any of the claims 1 to 9, wherein member (5) is fixed at the circumference at the walls of the chamber.
13. The valve arrangement according to claim 12, wherein the member (5) is pre-compressed on the tapering body (4).

14. The valve arrangement according to any of the claims 9 to 13, wherein the tapering part has the form of a cone, an ellipse or a rectangle.

15. The valve arrangement according to any of the preceding claims, wherein the cracking pressure is between 0.2 - 0.6 bar, preferably 0.3 bar.

16. A flow set for the administration of at least one fluid to a patient which comprises a valve arrangement according to any preceding claims, an inlet tube for connecting a container to an inlet opening of the valve arrangement, and an outlet tube for connecting to an outlet of the valve arrangement for the delivery of a fluid to a patient.

17. Use of a valve arrangement according to any of the claims 1 to 15 or a flow set according to claim 16 for providing enteral nutrition to an individual.

18. A method of treatment of an individual that comprises administering an effective amount of a fluid via a valve arrangement according to any one of claims 1 to 15 or a flow set according to claim 16.

19. A method according to claim 18, which includes the steps of administering a fluid from a container to an individual using a pump to propel the fluid via a valve arrangement according to any one of claims 1 to 15 or a flow set according to claim 16.
Fig. 6  Valve in equilibrium position; membrane in pre-compressed state
Fig. 7  Valve in opened position
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
   IPC 7 A61M39/24

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)
   IPC 7 A61M F16K

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

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)
   EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication where appropriate of the relevant passages</th>
<th>Relevant to claim No.</th>
</tr>
</thead>
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<tr>
<td>X</td>
<td>EP 0 388 828 A (ICA SPA; SANTAGIULIANA EVANS &amp; C TAPLAS (IT)) 26 September 1990 (1990-09-26) column 3, line 26-49; claim 1; figures 1-4</td>
<td>1-16</td>
</tr>
<tr>
<td>A</td>
<td>US 4 919 167 A (MANSKA WAYNE E) 24 April 1990 (1990-04-24) the whole document</td>
<td>1-16</td>
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</tbody>
</table>

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

Date of the actual completion of the international search
   9 December 2002

Date of mailing of the international search report
   18/12/2002

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Form PCT/ISA/10 (second sheet) (July 1992)
INTERNATIONAL SEARCH REPORT

Box I  Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. X Claims Nos.: 17-19 because they relate to subject matter not required to be searched by this Authority, namely:
   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.

2. ☐ Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II  Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

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