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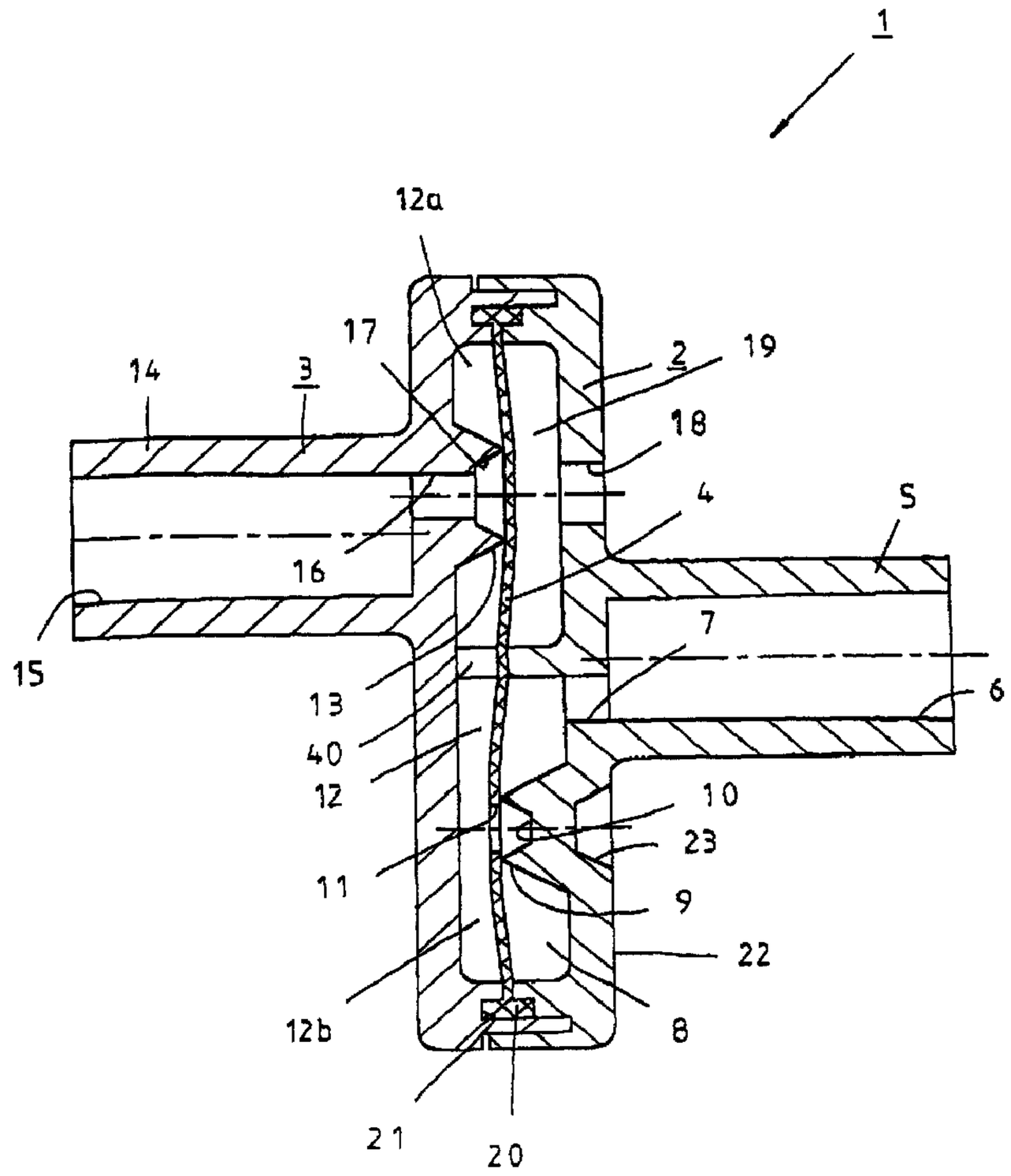

(57) Abrégé/Abstract:
The invention relates to a one-way valve device, especially a low pressure check valve, for use in an infusion set consisting of a housing with one entry tube and one exit tube and with at least one seal positioned in a pressure space. To avoid the ingress of air

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(57) **Abrégé(suite)/Abstract(continued)**:
into the circuit of the infusion liquid according to the invention it is proposed that by means of a static negative pressure at the entry tube and/or the exit tube or an over-pressure at the exit tube an interruption of the flow is occurring. Thereby in a reliable way it is ensured that a flow of the infusion liquid only is occurring at a static over-pressure at the entry tube.

ABSTRACT

The invention relates to a one-way valve device, especially a low pressure check valve, for use in an infusion set consisting of a housing with one entry tube and one exit tube and with at least one seal positioned in a pressure space. To avoid the ingress of air into the circuit of the infusion liquid according to the invention it is proposed that by means of a static negative pressure at the entry tube and/or the exit tube or an over-pressure at the exit tube an interruption of the flow is occurring. Thereby in a reliable way it is ensured that a flow of the infusion liquid only is occurring at a static over-pressure at the entry tube.

One-Way Valve Device

The invention relates to a one-way valve device, especially a low pressure check valve for use in an infusion set, consisting of a housing having an entry tube and an exit tube and at least one seal positioned in a pressure space.

Valve devices of the above-defined species for creating a run-dry stop preferably are used for infusion sets in hospitals, wherein the valve devices are used with the purpose that when a storage container with the infusion liquid is running dry an immediate run-dry stop is occurring to avoid of air entering into the infusion liquid and towards the end of the flow via the existing lines is entering in the venous system of a patient. A valve device for use in an infusion set for example is known from DE-OS 29 19 343 A1 which is provided with a drip chamber and a float valve which with the chamber running dry is preventing the entry of air into the infusion hose, wherein on the exit side in the flexible tube leading to the infusion needle there is positioned a roller clamp. To prevent a filling of the entire line system of the dialyser with air a double seat-float valve with a floating sphere is used. Such floating sphere valves however not always operate reliable such that an admission of air into the infusion hose cannot be prevented in all cases.

A further run-dry safety device is known from German DE-OS 36 32 412 A1 in which in the direction of flow before the drip chamber a run-dry valve is positioned. A floating sphere is contacting with friction the channel wall during the sealing and with a corresponding play cannot prevent an admission of air with absolute safety. Both above-mentioned solutions are not suitable to exclude an admission of air into the human venous system.

From the DE 197 49 562 A1 further an infusion set is known which is consisting of a highly suspended container for the infusion liquid as well as a drip connectable to a throttle container by means of a throttle tube, a roller clamp on a flexible admission line positioned below and an infusion needle provided at the end of the line. To prevent the ingress of air into the infusion liquid, especially towards the end of the admission of the infusion liquid in the direction of flow before the drip chamber or at the entry opening thereof a run-dry stop is included in the flow by means of the valve incorporated therein in dependence from the prevailing static pressure the flow of the infusion liquid can be stopped. The practical use however has shown that a run-dry stop in dependence of the prevailing static pressure of the infusion liquid is not sufficient to prevent the ingress of air. Especially in cases in which the possibility is given that by negligence the connections are changed and therefore the function of the run-dry stop valve is not ensured anymore. This becomes especially dangerous if air enters into the system which could lead to embolism in the patient if the air enters the veins. It is therefore of importance that together with the infusion liquid no air is carried on which is leading to the above-mentioned disadvantage. An especially disadvantage is consisting in the fact that the above-mentioned valve in the case of the existence of a static over-pressure on the exit side cannot prevent the ingress of air into the system.

The invention has the task to provide a new check valve with low opening pressure which can be used for an infusion set with gravity pressure and/or pump pressure and which is preventing the ingress of air into the system of the infusion set with an improved safety.

According to the invention for the solution of this task it is provided that by a static negative pressure in the entry tube and/or exit tube or an over-pressure in the exit tube an interruption of the flow is occurring. The entry of air into the system of the infusion set according to the invention

followingly in an advantageous way is avoided with the prevailing of a static negative pressure as well as an over-pressure in the exit tube. A static negative pressure at the entry tube for example can occur if a storage container of the infusion liquid has run-dry, if an infusion pump is operating incorrectly or if air has entered the system. An over-pressure at the exit tube for example can occur with a temporary closure of the veins of a patient, if on the exit side a medicament pump additionally is connected. An over-pressure would lead to pumping the medicament into the gravity infusion set.

By the valve device according to the invention however it is ensured that in the above cases a further transport of the infusion liquid reliably is stopped and therefore the entry of infusion liquid enriched with air into the veins is prevented. Additionally by the one-way valve it is ensured that on the exit side with a prevailing over-pressure by an infusion or medicament pump the valve is closing and therefore the medicament is not reaching the infusion set whereby a short-time over-dosing is prevented. For sealing the entry and exit tube in this connection a seal is provided which within a pressure space on one side is contacting a first sealing lip and on the opposite side alternatingly is contacting a second sealing ring lip each under pretension. Alternatively the possibility is existing that two pressure chambers are provided communicating via a connection channel in which at least one unitary or two separate seals are contacting under pretension a first and a second sealing ring lip, wherein the sealing ring lips again are positioned on both sides of the seals or the connection channel is designed such that it is opening once below and once above the seal. By means of the seals a sealing of the sealing ring lips is achieved which are operatively connected with the entry tube or exit tube, respectively, and in the case of the existence of a negative pressure are enabling a sealing against the sealing ring lips. Because of the alternating sealing of the sealing ring lips by at least one seal it is ensured that in case of an over-pressure at the exit tube only a lifting of

the seal at the sealing ring lip associated with the exit tube is occurring while the seal because of the prevailing over-pressure is pressed against the second sealing ring lip and followingly is closing the entry tube.

According to a further improvement of the invention, it is provided that the entry tube is opening into an antechamber in which the first sealing ring lip with a closed depression is formed which is contacted by a seal limiting the pressure space while the exit tube is opening within the second sealing ring lip into the pressure chamber of the housing which is contacted by a seal limiting the pressure space, wherein opposite to the second sealing ring lip a second antechamber is formed limited by the seal which acted upon with atmospheric pressure through a housing opening. By means of the entry tube, the infusion liquid can flow into the antechamber and can lift the seal contacting the first sealing ring lip which in a further improvement according to the invention in the area of the first sealing ring lip is having an opening which centrically within the first sealing ring lip is provided such that the pressure chamber is sealed against the antechamber. The infusion liquid streaming in is lifting this seal from the sealing ring lip and can flow into the pressure chamber of the housing via the present opening, wherein by the opposite position of the sealing ring lip due to the prevailing over-pressure the present unitary or two-part seal is lifted from the second sealing ring lip such that a connection to the exit tube is formed. This is the normal flow of the infusion liquid in the case that an sufficient static over-pressure is existing at the entry tube. In case at the entry tube a negative pressure should be present a present seal is closing the first sealing ring lip by the suction effect and thereby an interruption of the flow is achieved. The same is true if at the exit tube a negative pressure should be present since the seal due a present housing opening in the area of the first sealing ring lip is acted upon by atmospheric pressure. For the case that at the exit tube an over-pressure should exist this only is reaching the pressure space via the second sealing ring lip and the lifting seal

and therefore is pressing the existing seal due to the existing over-pressure directly onto the first sealing ring lip such that a flow from the entry tube to the exit tube is prevented.

In a further improvement of the invention it is provided that the area enclosed by the first and the second sealing ring lip is smaller than the remaining area of the contacting seal and that by the ratio of the enclosed area within the sealing ring lip to the remaining area of the contacting seal the opening or closing pressure, respectively, can be adjusted. For both provided pressure spaces each a preferably unitary seal is provided. Alternatively the possibility is existing to use a two-part seal which for example is used with two closed pressure spaces, wherein both pressure spaces are connected by a connecting channel.

In a further improvement of the invention it is provided that the seal at the edge thereof is provided with a preferably T-shaped projection which is positioned in a recess of the housing and which is unitary with the seal. By the T-shaped projection a simple possibility of mounting the one or possibly both seals within the housing is created, wherein the T-shaped projection is positioned in a correspondingly designed recess and therefore a sufficient guarantee for a safe mounting of the seals used is present. For improving the seat of the seal it is further provided that the seal in the region of the connection channel is having a reinforcement in the shape of a bar unitarily formed which with respect to the shape is adapted to the edge of the housing half or the pressure spaces, respectively. The housing preferably is in two parts and is held together by means of a clamping tongue and groove connection, wherein by the performed seal and the two-part housing shape a simple possibility of mounting is given. In this connection the entry or exit tubes, respectively, could be positioned normal to the housing, wherein however the possibility is given, too, that these by means of a bend almost are positioned parallel to the housing such forming a suitable end compact shape of the housing.

The special advantage of the present invention is consisting in the fact that in case of the prevailing of a negative pressure at the entry or exit tube or in case of an over-pressure at the exit tube a safe stop of the infusion fluid is guaranteed. The basic concept of the invention is covering among others a simple assembly of the valve seal especially in connection with the T-shaped projection which is positioned in a corresponding recess of the housing halves such that a long-life and safe function of the valve device is ensured.

In the following, the invention is more detailly described with reference to the drawings.

In the drawings show:

Fig. 1 a cross-sectional lateral view of an embodiment of the valve device according to the invention,

Fig. 2 a cross-sectional lateral view of the first housing half,

Fig. 3 a top view of the exterior of the housing half according to Figure 2,

Fig. 4 a top view of the interior of the housing half according to Figure 2,

Fig. 5 a cross-sectional view of the second housing half,

Fig. 6 a top view of the exterior of the housing half according to Figure 5,

Fig. 7 a top view of the interior of the housing half according to Figure 5 and

Fig. 8 a top view and a cross-sectional lateral view of a single seal.

Figure 1 is showing a valve device 1 according to the invention consisting of a first housing half 2 and a second housing half 3 as well as a seal 4 positioned between the housing halves 2, 3 in an assembled state. Here the seal 4 is received between the two housing halves 2, 3 in a clamping manner. The first housing half 2 is having an entry tube 5 with a mouth tube 6 which via an opening 7 is opening into a first antechamber 8 of the housing half 2. The antechamber 8, being for example in a round or elliptical shape, is having a centrally mounted sealing ring lip 9 which monolithically is formed from the housing half 2 and is having a depression 10 positioned in between the sealing ring lip 9. The seal 4 contacting the sealing ring lip 9 is having an opening 11 centrally positioned with respect to the sealing ring lip 9 such that in case of lifting the seal 4 from the sealing ring lip 9 a connection through the opening 11 to the pressure space 12 is possible. Corresponding to the kind of construction, the pressure space 12 can be a pressure space 12 extending over the housing halves 2, 3 or there can be performed two pressure spaces 12a, 12b which are connected by a connecting channel 40 such that an identical static pressure is prevailing. The seal 4 is contacting a second seal ring lip 13 which is assigned to the second housing half 3. The second housing half 3 is having a discharge tube 14 with a mouth tube 15 which via an opening 16 is opening into the depression 17 formed by the sealing ring lip 13 such that in case of lifting the seal 4 an opening to the pressure space 12 is formed. Opposite to the seal ring lip 13 of the second housing half 3 in the first housing half 2 there is an opening which is enabling an acting upon the seal 4 via a second antechamber 19 with atmospheric pressure. The seal 4 is clamped between the two housing halves 2, 3 in such a way that in a pressureless state the seal 4 directly is contacting the sealing ring lips 9, 13. To prevent a slipping of the seal 4 within the housing halves 2, 3 and tc ensure followingly a safe function of the valve device 1 in the exemplary embodiment shown the seal 4 is in one piece and is having a T-shaped projection 20 at the margin thereof which is positioned in a corresponding recess

21 of the first and second housing halves 2, 3. Alternatively the possibility is given to use a two-part seal or to provide a different kind of mounting of the seal 4.

By a static pressure for example of the infusion liquid streaming in from an elevated supply container into the mouth tube 6 through the opening 7 into the first antechamber 8 the seal 4 is lifted from the first seal ring lip 9 such that the infusion fluid can flow under the seal 4 through the opening 11 into the pressure space 9. Due to the increasing pressure in the pressure chamber 12 the seal 4 slightly is lifted in the region of the second sealing ring lip 13, too, such that the infusion fluid via the depression 17 and the opening 16 can flow into the mouth tube 15. With a decreasing of the static pressure by the infusion fluid, for example a run-dry of the supply container, the seal 4 directly again comes into contact with the sealing ring lip 9 such that a stop of the infusion fluid is ensured. For the case of a negative pressure at the mouth tube 6 additionally the seal 4 is sucked onto the sealing ring lip 9 and leads to a stop of the flow, too. In case a negative pressure should be existing with respect to the exit tube 14 or the mouth tube 15, respectively, the seal 4 in the same way is sucked on and is pressed onto the second sealing ring lip 13 such that a further flow is stopped. In case that an over-pressure is prevailing at the exit tube 14 or the mouth tube 15, respectively, it is true that the seal 4 can be lifted from the second sealing ring lip 13 but the seal 4 in the region of the first sealing ring lip 9 is pressed on due to the over-pressure and the present pretension and followingly is preventing a flow of the infusion liquid into the mouth tube 6. The valve device 1 followingly enables a stop of the infusion fluid for the case that a negative pressure is present at the entry tube 5 or a negative pressure or over-pressure is prevailing at the exit tube 14 such that an ingress of air into the system of the infusion set can be excluded. Only for the case that the static over-pressure is existing at the entry tube 5 or the mouth tube 6, respectively, a predefined direction of flow of the infusion agent is possible.

Figure 2 is showing the first housing half 2 with its entry tube 5 and the mouth tube 6 as well as the monolithically formed sealing ring lip 9 with its depression 10 in a cross-sectional lateral view as this can be learnt especially from Figures 3 and 4. The housing half 2 is having a oval basic shape from which the entry tube 5 is projecting in a normal direction. The entire housing half 2 is monolithically formed and is having a depression 23 on the exterior surface 22 in the region of the first sealing ring lip 9 as well as further triangular depressions 24 laterally off-set to the mouth tube 6. For receiving the T-shaped projection 20 of the seal 4 a recess 21a is present which is merging in a stepped shape into a further recess 25. The recess 25 is limited by a circumferential collar 26 and is provided for receiving a corresponding ring-shaped projection of the second housing half 3.

Figure 3 and 4 are showing the first housing half 2 in a exterior and inner top view. Here the antechamber 8 or 19, respectively, are formed by an annular recess 28, 29.

Figure 5 in a lateral cross-sectional view is showing the second housing half 3 with its exit tube 14 or mouth tube 15, respectively, and the second sealing ring lip 13 with its depression 17 into which the mouth tube 15 is opening by an opening 16. For receiving the T-shaped projection 20 of the seal 4 a recess 21b is provided which together with the recess 21a of the first housing half 2 is receiving the T-shaped projection 20. The basic shape of the second housing half 3 is corresponding generally to the first housing half 2 as this can be learnt especially from Figures 6 and 7. For the clamping connection with the first housing half 2 the second housing half 3 is having a circumferential collar 30 which is engaging the present recess 25 of the first housing half 2. The collar 30 is formed by a recess 31 with respect to the radial surface 32.

Figure 6 and 7 are showing the inner or outer surface, respectively, of the second housing half 3 in a top view. In the outer housing half 3 there are formed generally triangular recesses 33 while on the interior side the pressure space 12 is formed by two annular recesses 34, 35 and the two recesses 34, 35 are connected with each other by an opening 36.

Figure 8 is showing in a top view and a cross-sectional lateral view a seal 4 which is monolithic with a circumferential T-shaped projection 20. The projection 20 after the assembly is resting in a recess of the two housing halves. The present opening 11 after the assembly is positioned centrally within the sealing ring lip 9. To avoid a pretension or a deformation of the seal 4, there are provided monolithically formed segment-shaped bars 41, 42 which are adapted to the shape of the pressure spaces of the two housing halves and are provided to facilitate the assembly or to ensure an additional sealing with respect to the housing halves 2, 3 such that the infusion fluid cannot reach another pressure space or an antechamber passing the seal.

LIST OF REFERENCE NUMERALS

5

1 = valve device
2 = housing half
3 = housing half
4 = seal
5 = entry tube
6 = mouth tube
7 = opening
8 = antechamber
9 = sealing ring lip
10 = depression
11 = opening
12 = pressure space
13 = sealing ring lip
14 = discharge tube
15 = mouth tube
16 = opening
17 = depression
18 = opening
19 = antechamber
20 = projection
21 = recess
22 = exterior surface
23 = depression
24 = depression
25 = recess
26 = collar
27 = annular projection
28 = recess
29 = recess
30 = collar
31 = recess
32 = radial surface

33 = recess

34 = recess

35 = recess

36 = opening

40 = connection channel

41 = bar

42 = bar

CLAIMS:

1. A low pressure check valve for use in an infusion set having infusion fluid comprising:

(a) a first housing half having an inlet and first lipped sealing ring, the exterior of the first lipped sealing ring in communication with the inlet;

(b) a second housing half having an outlet and second lipped sealing ring, the interior of the second lipped sealing ring in communication with the outlet;

(c) a gasket with a first portion overlying the first lipped sealing ring and having at least one opening communicating with the interior of the first lipped sealing ring, and another portion overlying the second lipped sealing ring;

(d) means for sealing the first and second housing halves together and clamping the gasket portions therebetween; and

(e) means for tensioning the gasket portions over the first lipped sealing ring and the second lipped sealing ring, thereby forming a pressure chamber in communication with the second lipped sealing ring exterior and the first lipped sealing ring interior via the at least one gasket openings;

whereby infusion fluid flow in the pressure chamber is interrupted by one of the gasket portion engaging the first lipped sealing ring when the fluid pressure at the inlet is less than the fluid pressure of the pressure chamber, and the gasket portion engaging the second lipped sealing ring when the fluid pressure at the outlet is less than the fluid pressure of the pressure chamber, and the gasket portion engaging the first lipped sealing ring when there is a higher

pressure at the outlet and pressure chamber as compared to the pressure at the inlet.

2. The check valve of claim 1, wherein the pressure chamber defined by the housing halves comprises two sub-chambers and a junction opening therebetween, and the first lipped sealing ring and second lipped sealing ring are not coaxial.

3. The check valve of claim 2, further comprising the first housing half defining an antechamber intermediate the inlet and first lipped sealing ring and in communication with the inlet, whereby the antechamber is sealed from the pressure chamber when the gasket engages the first lipped sealing ring.

4. The check valve of claim 3, further comprising the first housing half defining an antechamber in communication with ambient and not in communication with the inlet, wherein the gasket portion is intermediate the antechamber and the second lipped sealing ring, whereby the antechamber remains at ambient pressure during operation of the check valve.

5. The check valve of claim 4, wherein the gasket portion area adjacent the first lipped sealing ring interior is less than the gasket portion area adjacent the first lipped sealing ring exterior, and gasket portion area adjacent the second lipped sealing ring interior is less than the gasket portion area adjacent the second lipped sealing ring exterior.

6. The check valve of claim 5, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

7. The check valve of claim 6, at least one gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

8. The check valve of claim 1, further comprising the first housing half defining an antechamber in communication with ambient and not in communication with the inlet, wherein the gasket portion is intermediate the antechamber and the second lipped sealing ring, whereby the antechamber remains at ambient pressure during operation of the check valve.

9. The check valve of claim 8, wherein the gasket portion area adjacent the first lipped sealing ring interior is less than the gasket portion area adjacent the first lipped sealing ring exterior, and gasket portion area adjacent the second lipped sealing ring interior is less than the gasket portion area adjacent the second lipped sealing ring exterior.

10. The check valve of claim 9, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

11. The check valve of claim 10, at least one gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

12. The check valve of claim 8, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

13. The check valve of claim 12, at least one gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

14. The check valve of claim 8, the gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

15. The check valve of claim 1, wherein the gasket portion area adjacent the first lipped sealing ring interior is less than the gasket portion area adjacent the first lipped sealing ring exterior, and gasket portion area adjacent the second lipped sealing ring interior is less than the gasket portion area adjacent the second lipped sealing ring exterior.

16. The check valve of claim 15, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

17. The check valve of claim 16, at least one gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

18. The check valve of claim 1, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

19. The check valve of claim 18, the gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

20. The check valve of claim 1, the gasket portion further comprising at least one reinforcement rib adapted to engage one of the first housing half and the second housing half, whereby placement of the gasket portion overlying one of the adjacent first and second sealing ring is assured.

21. The check valve of claim 20, wherein the gasket includes an attachment portion, and at least one of the housing halves include a recess that accommodates the attachment portion.

Fig. 1

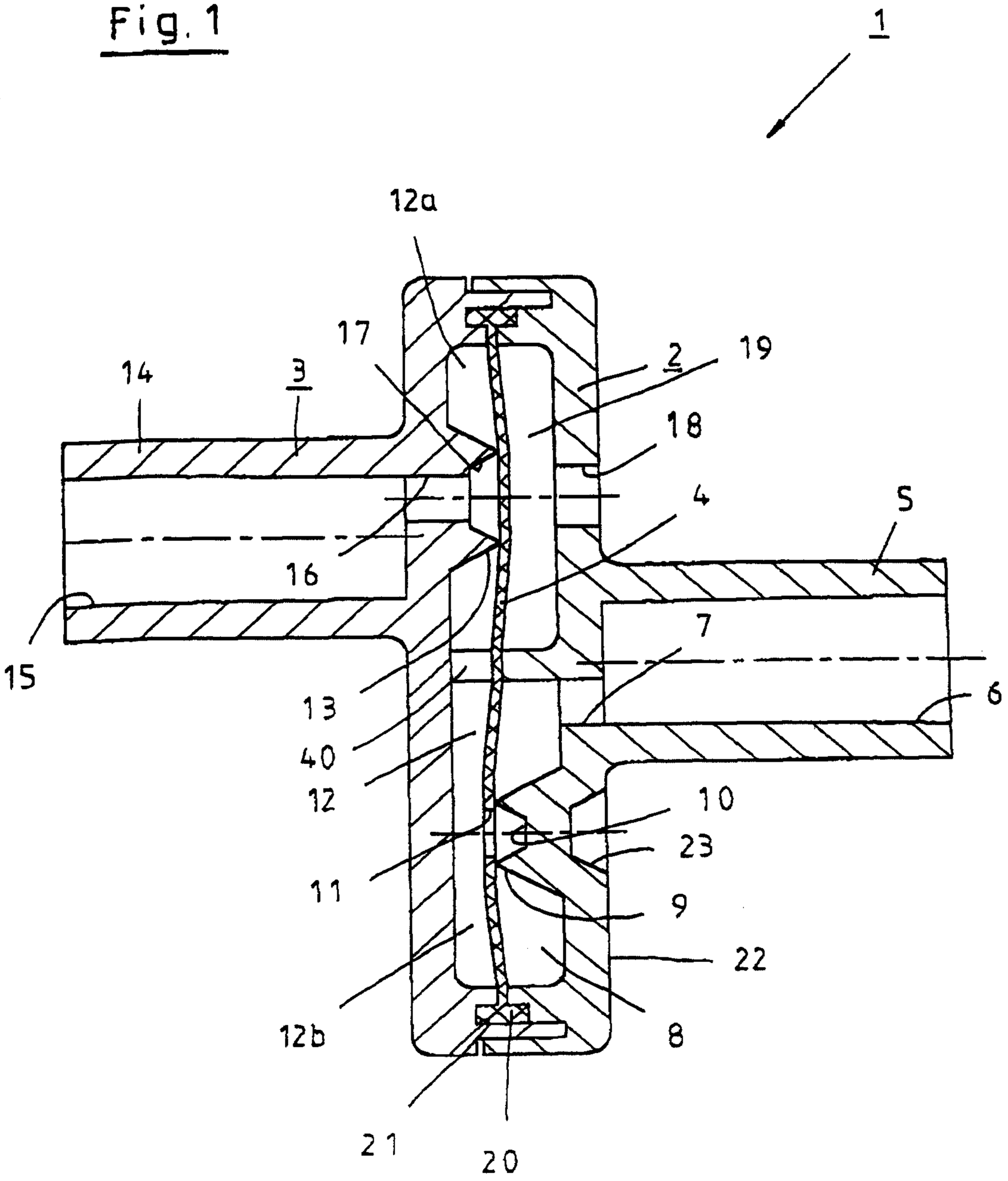


Fig. 2

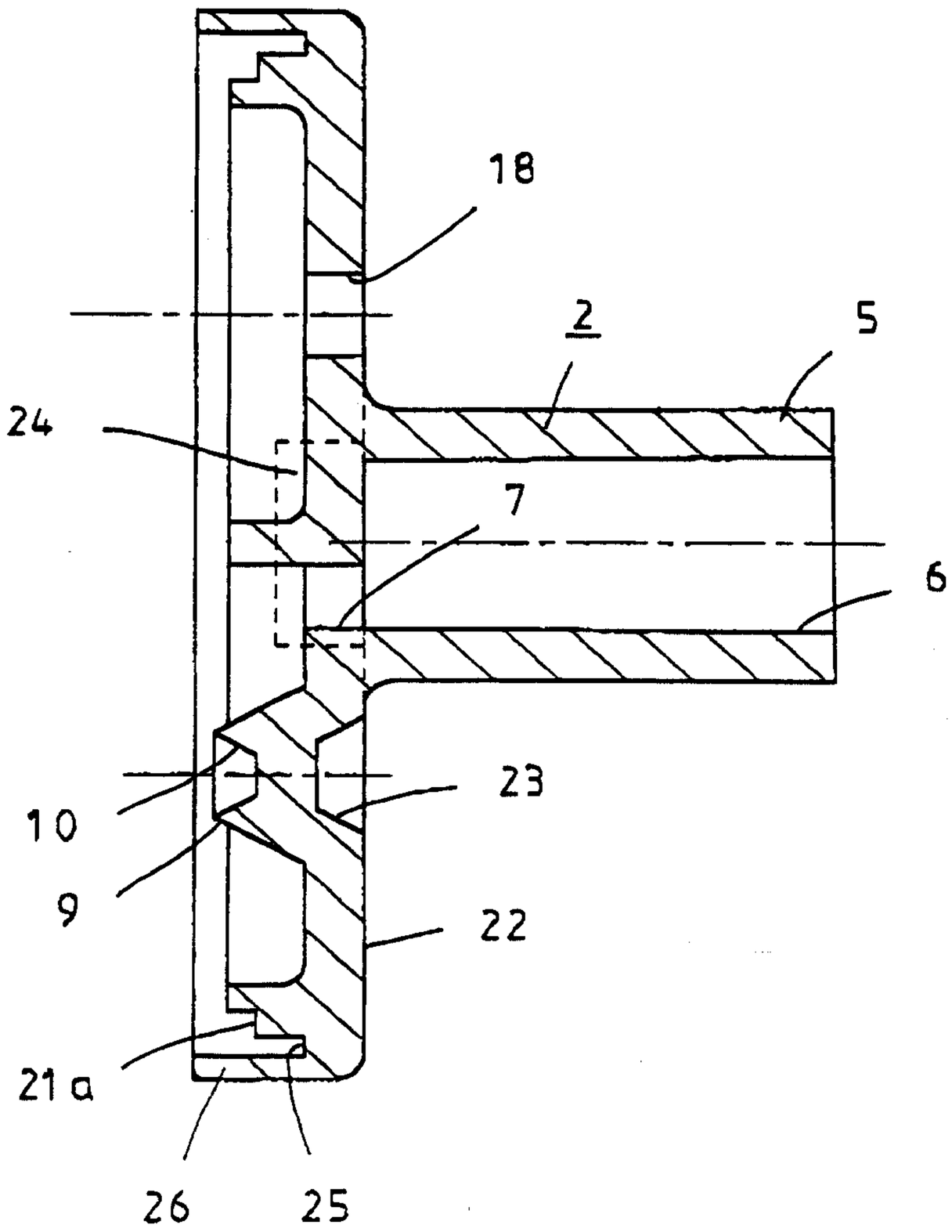


Fig. 3

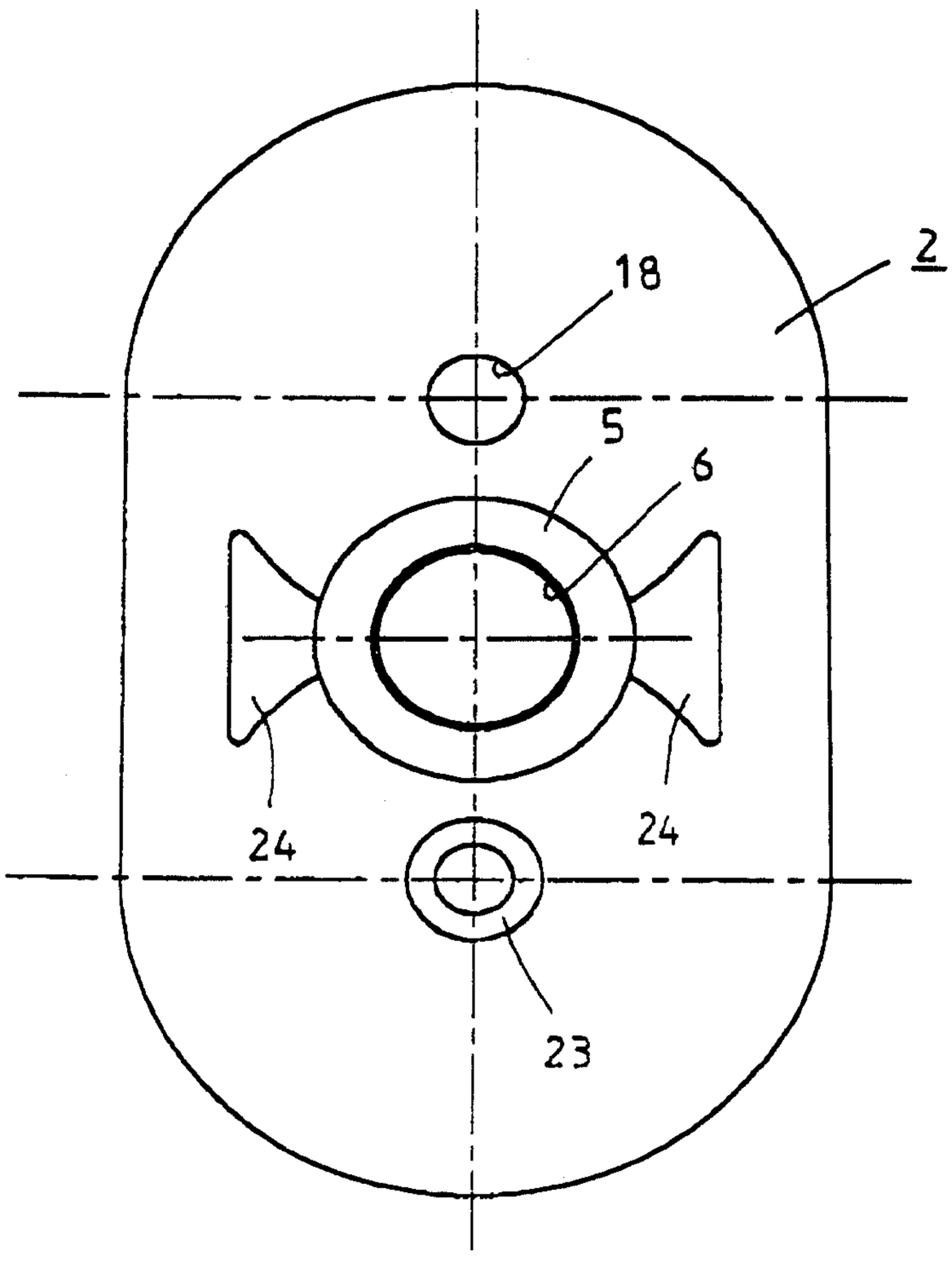


Fig. 4

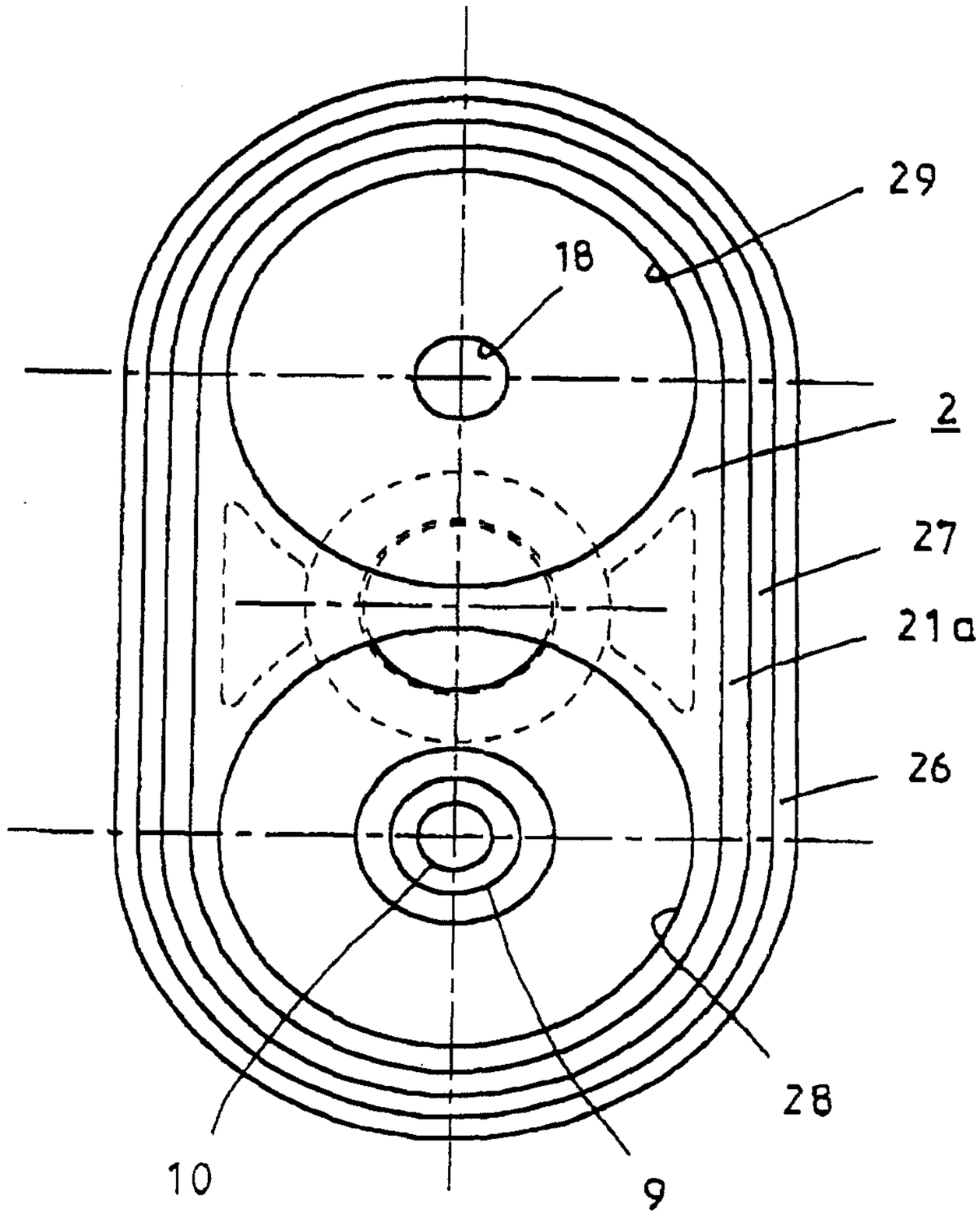


Fig.5

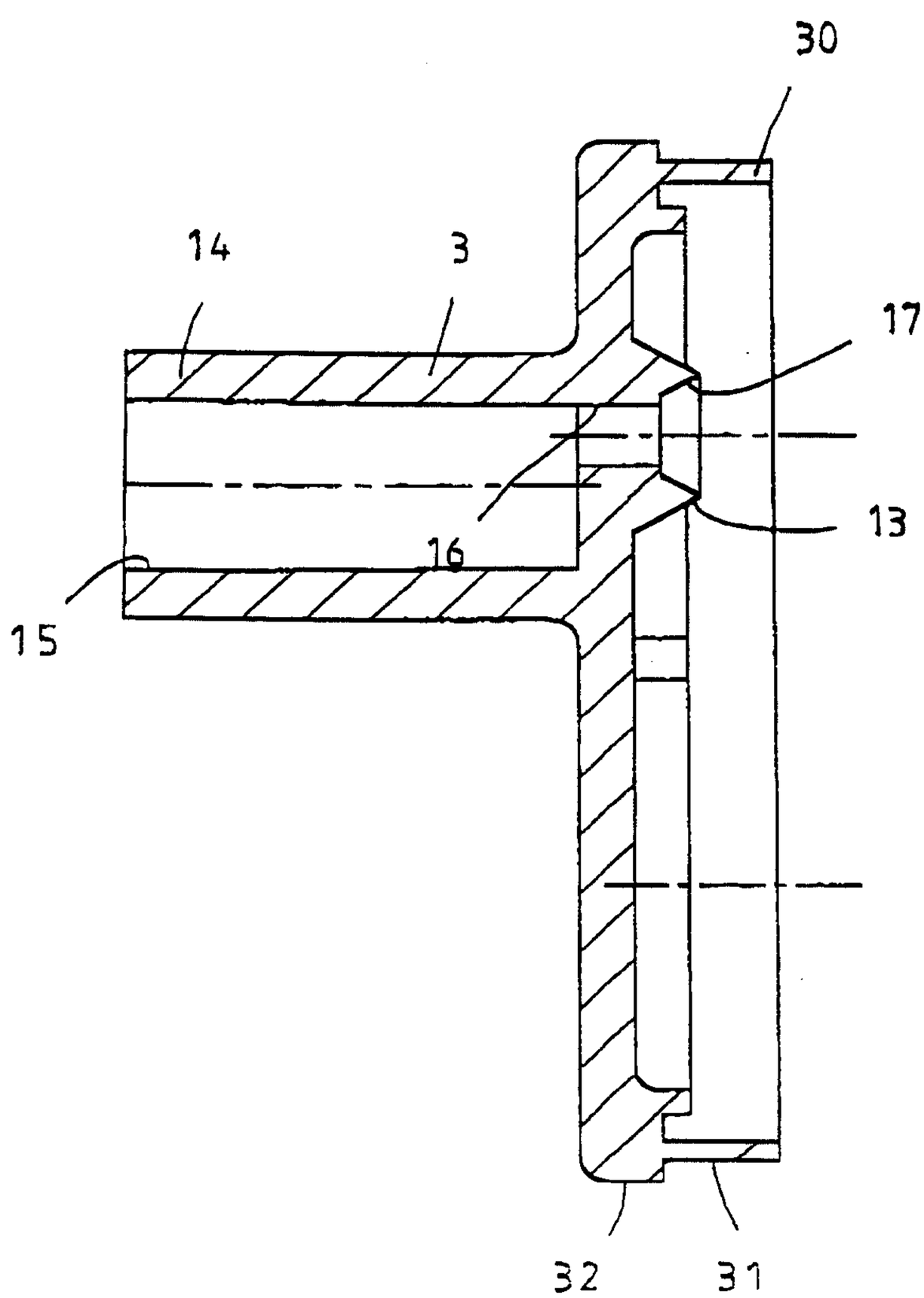


Fig. 6

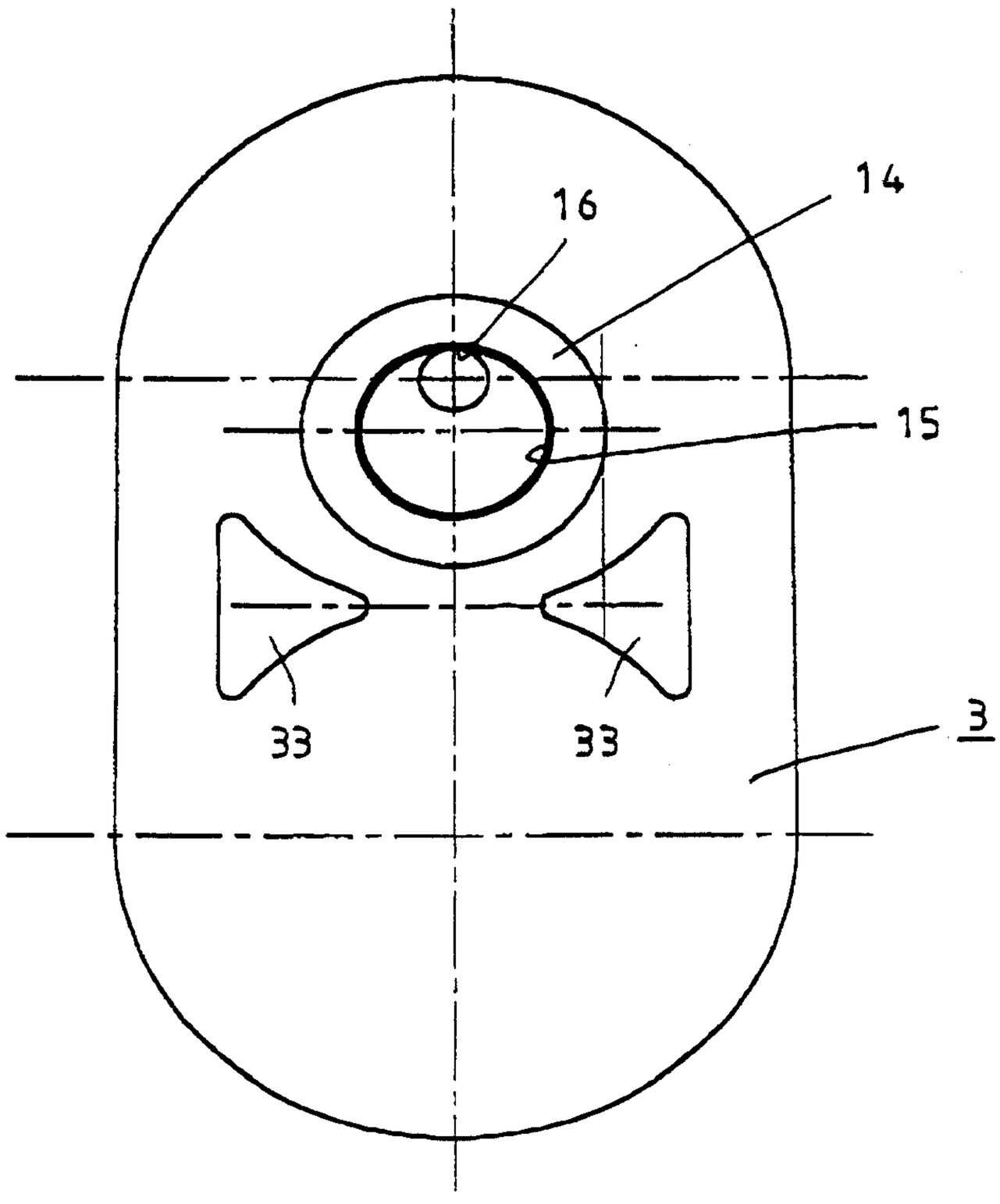
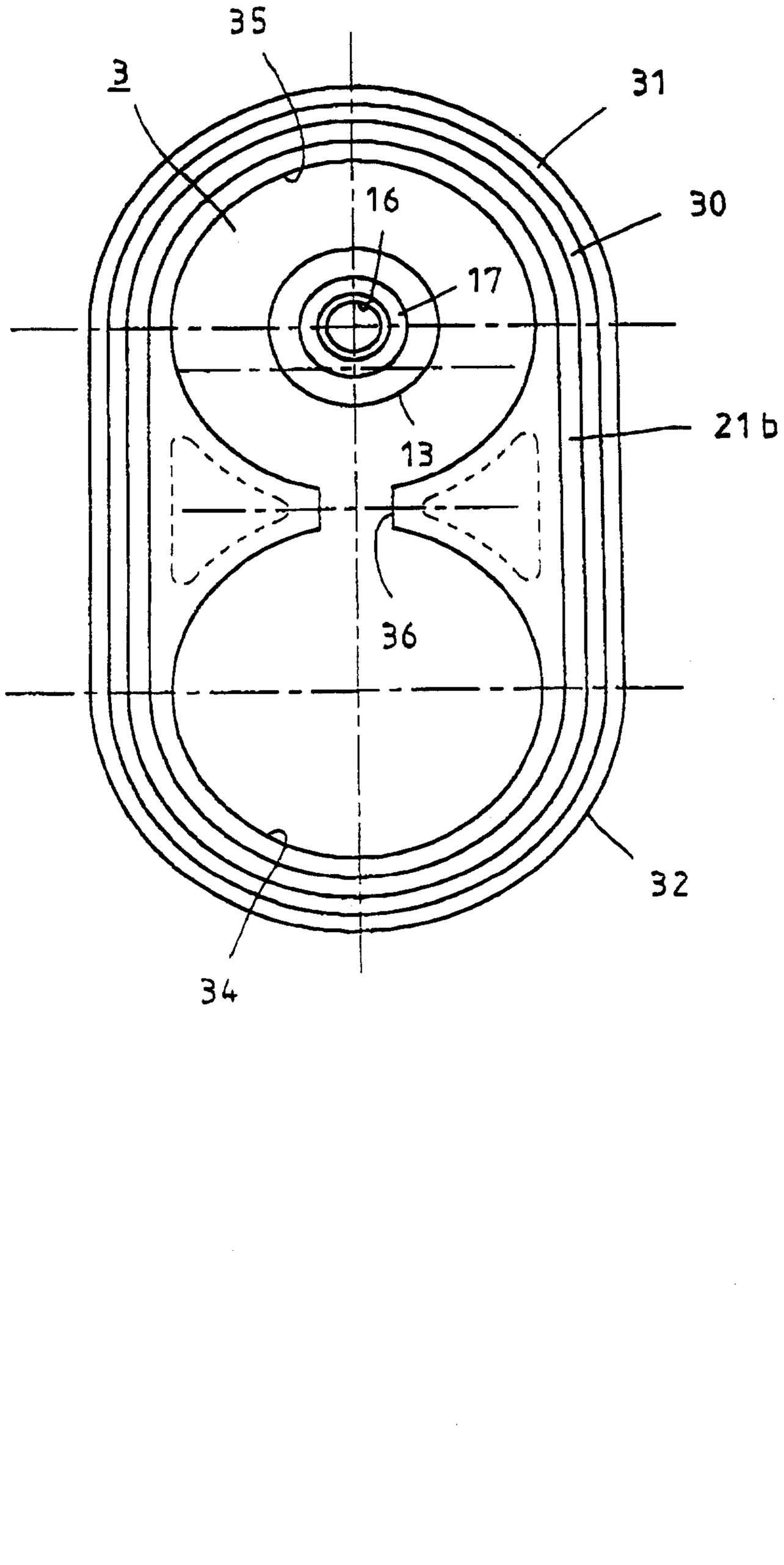


Fig. 7



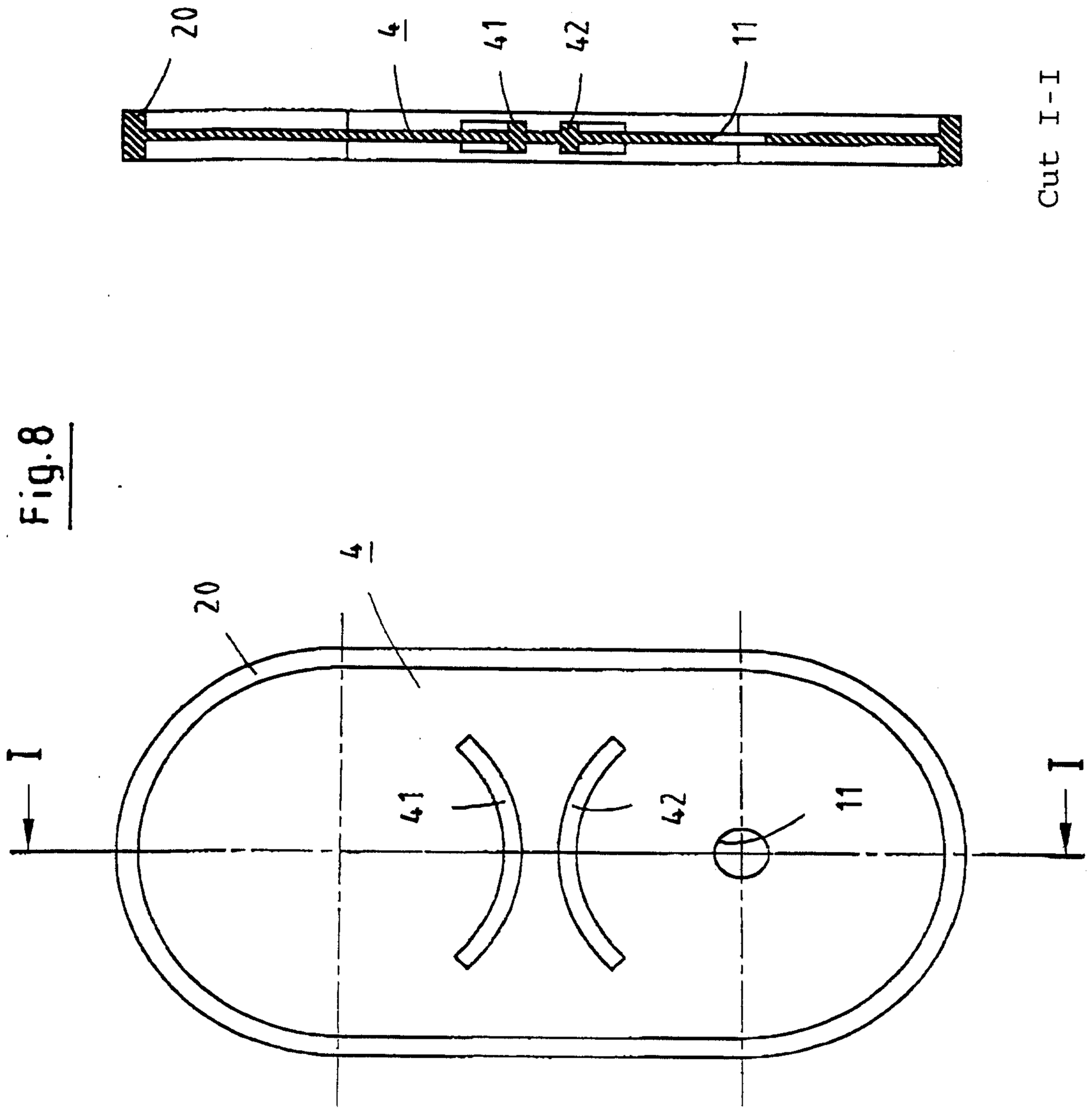
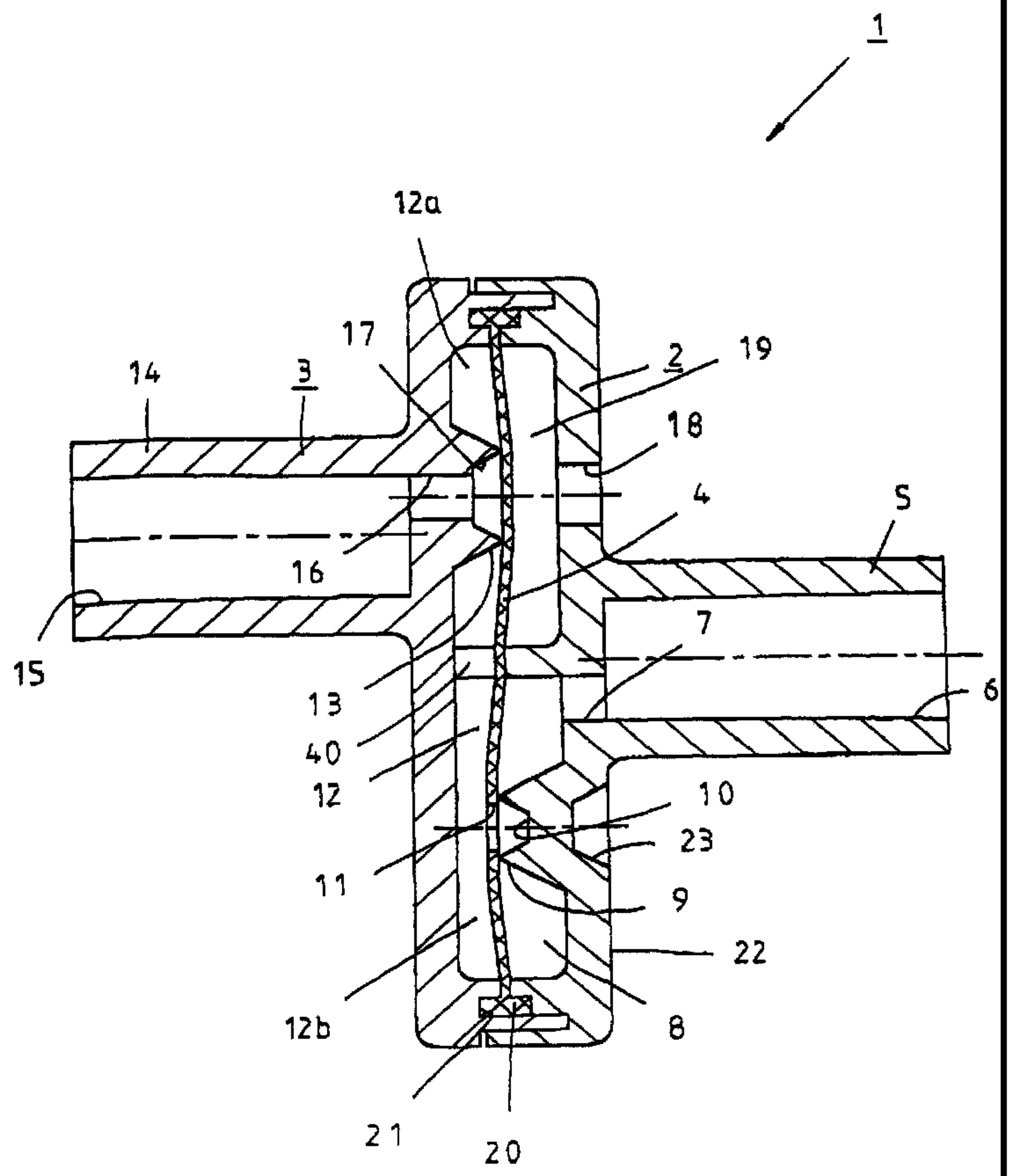


Fig.8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