

"One-way valve for medical lines"

5 Field of the invention

 The present invention relates to one-way valves for medical lines, for example, infusion lines and the like, of the type comprising a body formed by a first tubular connector and a second tubular connector that
10 define, respectively, an upstream passage and a downstream passage, which are coaxial and set transversely between which is a diaphragm made of elastically deformable material, which co-operates in a fluid-tight way with an annular valve seat to keep the
15 one-way valve normally closed. A predetermined pressure of fluid in the upstream passage brings about a displacement or an elastic deformation of the diaphragm and consequent opening of the valve, i.e., opening of the communication between the upstream passage and the
20 downstream passage.

 Valves of this sort are used, for example, as check valves, which are purposely designed to open when the pressure in the upstream passage exceeds a predetermined relatively modest threshold value, and
25 then to reclose promptly so as to prevent, with the maximum degree of safety, any reflux from the downstream passage to the upstream passage when the pressure in the latter drops again below the threshold value, or else in the case of an even minimal
30 overpressure within the downstream passage.

Prior art

 From the patent documents Nos. EP-1099457B1, EP-1093828B1 and EP-1946793A1, all of which are filed in the name of the present applicant, there are known one-
35 way valves of the type specified above, in which the

annular valve seat is defined by a wall with conical surface of the first tubular connector, diverging towards the second tubular connector, and the diaphragm is constituted by the bottom wall of a cup-shaped element, the outer peripheral edge of which is normally pressed in fluid-tight contact against the annular valve seat under an axial thrust exerted by the side wall of the cup-shaped element. In operation, when the pressure within the upstream passage reaches the aforesaid predetermined value, an axial displacement of the bottom wall of the cup-shaped element is produced in the direction of the second tubular connector, as a result of which the corresponding outer peripheral edge contracts radially, moving away from the annular valve seat with a high degree of promptness and immediacy of opening of the one-way valve.

In applications on medical infusion lines, a filter is normally provided for filtering any possible impurities contained in the fluid that traverses the valve. Traditionally, the filter consists of an element separate from the valve, set along the line upstream of the first tubular connector, or else a filtering body inserted within the upstream passage defined by the aforesaid first tubular connector.

Both of the solutions prove far from practical and to some extent complicate production of the medical line.

From the document No. WO-2010/107597, a one-way valve is known of the type specified above, in which the filter is integrated within the body and consists of a permeable membrane set transversely and carried by a peripheral ring engaged with interference fit or snap-action fit on an internal annular flange of the body set upstream of the valve seat with respect to the direction of flow through the valve.

The above fit does not ensure the necessary stability of retention of the filter, which can be easily disengaged from the flange of the body, with the consequent risk of opening paths of flow without any
5 filtering.

Summary of the invention

The object of the present invention is to overcome the above drawback, and this object is achieved thanks to the fact that the one-way valve is
10 of the type defined in the pre-characterizing part of Claim 1, the peculiar characteristic of which lies in the fact that the annular element of the filtering membrane is axially clamped and blocked between the first and second tubular connectors.

15 Brief description of the drawings

The invention will now be described in detail with reference to the annexed drawings, which are provided purely by way of non-limiting example and in which:

20 - Figure 1 is a schematic view in axial section of a one-way valve according to a first embodiment of the invention;

- Figure 2 is an exploded view of the valve of Figure 1;

25 - Figure 3 is a view similar to that of Figure 1, which shows a second embodiment of the invention;

- Figure 4 is a view similar to that of Figure 1, which shows a third embodiment of the invention; and

- Figure 5 is an exploded view of the valve of
30 Figure 4.

Detailed description of the invention

With initial reference to Figures 1 and 2, the reference number 1 designates as a whole the body of a tubular connector for tube-to-tube connection of a
35 medical line for infusion, transfusion, and the like.

It should be noted that the connector could be prearranged, in a way in itself known, for luer-to-tube, or else tube-to-luer, or luer-to-luer connections, or other types of connection normally used
5 in medical lines.

The body of the connector 1 comprises, in a way generally in itself known, for example, from the already cited document No. EP-1946793A1, a first tubular connector 2 and a second tubular connector 3,
10 both of which are normally made of a suitable moulded thermoplastic material, axially joined together in a permanent way, with the modalities clarified in what follows.

The first and second tubular connectors 2, 3
15 define, respectively, an upstream passage or inlet passage 4 and a downstream passage or outlet passage 5, which can be connected to respective sections of tubing of the medical line.

Set between the upstream passage 4 and the
20 downstream passage 5 is a one-way valve, the open/close element of which, set within a widened portion 9 of the tubular connector 3 coaxially with the latter, consists of a cup-shaped element 6, which comprises a circular bottom wall 7 and a skirt or side wall 8 and is
25 conveniently made of a single piece of soft elastomeric material, for example, silicone rubber.

The free edge 8a of the skirt 8 rests on a radial array of transverse projections 10 formed at the base of the widened portion 9 and delimiting respective
30 radial channels that communicate on one side with a restricted central passage 11, which is in turn in communication with the downstream passage 5, and on the other with peripheral axial passages 12 designed to be set in communication, in the condition of opening of
35 the open/close element 6, with the upstream passage 4.

Preferably, the resting surface between the free edge 8a of the skirt 8 and the sectors 10 is provided, according to what is envisaged in the already cited document No. EP-1946793A1, only in angular portions
5 separated by portions that do not provide a rest.

The edge of the open/close element 6 comprised between the bottom wall 7 and the skirt 8, which is designated by 13, constitutes the sealing element of the open/close element 6, which co-operates with an
10 annular valve seat 14 with conical surface. In the condition of closing of the valve (represented in Figure 1), the skirt 8 is subjected to a predetermined axial elastic preload and presses the edge 13 in fluid-tight contact against the valve seat 14 so as to
15 interrupt communication between the axial passages 12, and hence the downstream passage 5, and the upstream passage 4. When an overpressure of higher degree than a pre-set threshold value is produced within the upstream passage 4, the axial displacement of the bottom wall 7
20 of the open/close element 6 in the direction of the tubular connector 3 causes separation between the edge 13 and the valve seat 14, setting the upstream passage 4 in communication with the downstream passage 5.

According to the peculiar characteristic of the
25 invention, the connector 1 incorporates, in an integrated way, a filter set through the line of flow between the upstream passage 4 and the downstream passage 5, which is axially blocked between the first tubular connector 2 and the second tubular connector 3,
30 upstream of the open/close element 6 of the valve with respect to the flow through the body 1 of the valve.

In the embodiment represented in Figures 1 and 2, the filter consists of a transverse membrane 15, made of an appropriate permeable filtering material, the
35 outer peripheral edge of which is fixed on a radially

inner flange 17 of an annular element 18 set between the tubular connectors 2 and 3. The surface of the flange 17 opposite to the filtering membrane 15 defines the annular valve seat 14.

5 On the side opposite to the flange 17, the membrane 15 frontally bears upon an annular projection 16 of the tubular connector 2, projecting axially towards the tubular connector 3. The annular element 18 has a peripheral flange 19 for front coupling to a
10 radially outer flange 20 of the tubular connector 2, and a stepped side wall 21 for coupling to a complementary stepped internal surface 22 of the widened portion 9 of the tubular connector 3. Fixing
15 between the flanges 19 and 20 on one side and the stepped walls 21 and 22 on the other can be obtained by ultrasound welding, gluing, or any other suitable system.

 The central part of the membrane filter 15 moreover rests against an inner axial annular
20 projection 23 of the tubular connector 2 and faces a restricted terminal portion 24 of the inlet passage 4.

 The variant of the valve connector according to the invention illustrated in Figure 3, is generally similar to the embodiment described previously, and
25 here only the differences will be described in detail, using the same reference numbers for parts that are identical or similar.

 In the above variant, the annular element of the filtering membrane 15, designated by 25, is axially
30 blocked in an annular seat 26 formed between the annular flange 20 of the tubular connector 2 and a complementary annular flange 27 of the tubular connector 3, which in this case are directly fixed to one another. The annular element 25 is conveniently
35 welded inside the flange 27, which is in turn welded to

the flange 20.

The filtering membrane 15 is, also in this case, inserted peripherally between the flange 17 of the annular element 25 and the annular projection 16 of the tubular connector 2, and the valve seat 14 for the open/close element 6 is also formed by the surface of the flange 17 of the annular element 25 opposite to the one on which the peripheral edge of the membrane 15 is fixed.

10 In the variant represented in Figures 4 and 5, where likewise the same reference numbers are used to designate parts that are identical or similar to the ones already described with reference to the previous embodiments, the filter is formed by a body made of moulded plastic material 35 having a perforated wall 36 and made of a single piece with an intermediate annular element 37 axially blocked between the radially outer annular flange 20 of the first tubular connector 2 and the second tubular connector 3.

20 The perforated wall 36 is formed with a series of micro-slits 38 separated by intermediate septa 39. Alternatively, the aforesaid perforated wall 36 could present a micro-grid conformation.

25 In the case of the example illustrated, the perforated wall 36 has a generally conical shape converging towards the inlet passage 4 and faces a wall 40 having a complementary conical shape of the first tubular connector 2. Its apex projects towards the restricted terminal portion 24 of the inlet passage 4.

30 Also in this case, the intermediate annular element 37 forms the annular valve seat 14 for the diaphragm 6 and has a peripheral flange 41 for front coupling with the radially outer annular flange 20 of the first tubular connector 2. Its side wall is also formed with steps 42 for coupling to the stepped

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internal surface 22 of the second tubular connector 3.

It should be noted that the perforated wall 36 of the filter body 35 could present a surface geometrically different from the one illustrated; for
5 example, it could be spherical.

Of course, the details of construction and the embodiments may vary widely with respect to what has been described and illustrated herein, without thereby departing from the scope of the present invention as
10 defined in the ensuing claims.

CLAIMS

1. A one-way valve for medical infusion lines and the like, comprising a body (1) having a first tubular
5 connector (2) and a second tubular connector (3), which define, respectively, an upstream passage (4) and a downstream passage (5) coaxial with each other and set transversely between which is a diaphragm (6) made of elastically deformable material co-operating in a
10 fluid-tight way with an annular valve seat (14) to keep said valve normally closed, wherein a predetermined pressure of fluid in said upstream passage (4) brings about a displacement or an elastic deformation of said diaphragm (6) and consequent opening of said valve,
15 said valve being provided with a filter integrated within the body (1) and including a permeable membrane (15; 35) carried by an annular element (18; 25; 37) and set between said first tubular connector (2) and said diaphragm (6), said valve being characterized in that
20 said annular element (18; 25; 37) is axially clamped and blocked between said first and second tubular connectors (2, 3).

2. The valve according to Claim 1, characterized in that said annular element (18; 25; 37) is axially
25 blocked between a radially outer annular flange (20) of said first tubular connector (2) and the second tubular connector (3).

3. The valve according to Claim 2, characterized in that said membrane (15) is peripherally clamped
30 between a radially inner annular projection (16) of said first tubular connector (2) and a radially inner flange (17) of said annular element (18; 25).

4. The valve according to Claim 3, characterized in that said annular element (18; 25) is formed with
35 said annular valve seat (14).

5. The valve according to Claim 3 or Claim 4, characterized in that said annular element (18) has a peripheral flange (19) for front coupling with said radially outer annular flange (20) of said first tubular connector (2), and a stepped side wall (21) for fixing to a complementary stepped internal surface (22) of said second tubular connector (3).

6. The valve according to any one of Claims 2 to 4, characterized in that said annular element (25) is blocked within an annular seat (26) formed between a radially outer annular flange (20) of said first tubular connector (2) and a complementary annular flange (27) of said second tubular connector (3), which are directly fixed to one another.

7. The valve according to Claim 1, characterized in that said filter is formed by a body made of moulded plastic material (35) having a perforated wall (36) and made of a single piece with an intermediate annular element (37) axially blocked between a radially outer annular flange (20) of said first tubular connector (2) and the second tubular connector (3).

8. The valve according to Claim 7, characterized in that said perforated wall (36) is formed with a series of micro-slits (38) separated by intermediate septa (39).

9. The valve according to Claim 7 or Claim 8, characterized in that said perforated wall (36) has a generally conical shape converging towards said inlet passage (4).

10. The valve according to Claim 9, characterized in that said perforated wall (36) faces a wall (40) having a complementary conical shape of said first tubular connector (2) and projects towards a restricted terminal portion (24) of said inlet passage (4).

11. The valve according to Claim 7, characterized

in that said intermediate annular element (37) forms said annular valve seat (14).

5 **12.** The valve according to Claim 7 or Claim 11, characterized in that said intermediate annular element (37) has a peripheral flange (41) for front coupling with a radially outer annular flange (20) of said first tubular connector (2), and a stepped side wall (42) for coupling to a complementary stepped internal surface (22) of said second tubular connector (3).

10 **13.** The valve according to one or more of the preceding claims, characterized in that said diaphragm (6) is constituted by the bottom wall (7) of a cup-shaped element (6), the outer peripheral edge (13) of which is normally pressed in fluid-tight contact
15 against said annular valve seat (14) under the action of an axial thrust exerted by the side wall (8) of said cup-shaped element (6).

20 **14.** The valve according to Claim 13, characterized in that the side wall (8) of said cup-shaped element (6) has a free edge (8a) set resting against a grooved transverse surface of said second tubular connector (3) defined by a plurality of radial projections (10) angularly separated by angular portions that do not provide a rest.