"Flow system for medical lines"

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Field of the invention

The subject of the present invention is a flow system for medical lines, in particular for haemodialysis, of the type comprising a flow component having a main duct for a primary fluid and at least one lateral tubular fitting with female luer cone communicating with the main duct through a valve.

Prior art

A flow component of the type defined above is known from the European patent No. EP-B-1661599 filed in the name of the present applicant, in which the valve is a so-called anti-siphon valve, including a diaphragm constituted by the bottom wall of a cup-shaped element made of elastically deformable material, the outer peripheral edge of which is normally kept in fluid-tight contact against an annular valve seat of the lateral tubular fitting. As is also described in the patent No. EP-B-1093828, which is also filed in the name of the present applicant, the sealing edge of this valve can be moved away from the corresponding annular valve seat, to an opening position, following upon insertion of a male luer-cone introducer of fluid within the female luer cone of the lateral tubular fitting. It is hence a two-way valve of the so-called "luer activated" type, opening of which is controlled mechanically, rather than simply by the pressure of the fluid introduced into the lateral tubular fitting.

Mechanical activation is normally obtained in the case of valves of this sort, with the aid of additional components. For example, from the Italian patent No. IT-B-1291508, which is also filed in the name of the present applicant, opening of a diaphragm valve obtained as a result of insertion of the male luer-cone

introducer of fluid within a female luer-cone fitting is obtained with the aid of an auxiliary tubular slider that is axially mobile within the fitting and rests against the diaphragm of the valve. Opening of the valve is thus obtained as a result of the axial thrust applied on the diaphragm by the auxiliary slider, which is in turn moved by the male luer-cone introducer.

A similar solution is described in the document No. US-5,565,938A.

This arrangement, in addition to being relatively complicated, may entail the risk of the valve being opened by the auxiliary slider before the male luer-cone introducer provides the hermetic seal with the female luer cone of the tubular fitting, with consequent problems of contamination and leakage of fluid.

Summary of the invention

The object of the present invention is to overcome the above drawback and to provide a flow system for medical lines of the type defined in the pre-characterizing part of Claim 1 (and generally corresponding to what is described and illustrated in the already cited European patent No. EP-B-1661599), in which opening of the valve upon insertion of the introducer of fluid takes place in a precise and reliable way and without any risk of contamination.

According to the invention, this object is achieved thanks to the fact that the diaphragm of the valve is prearranged for being pushed towards the aforesaid opening position as a result of the direct contact of thrust by the male luer-cone introducer of fluid and to the fact that the lateral tubular fitting is configured in such a way as to couple in a fluid-tight way with the aforesaid introducer before the latter comes into contact of thrust with the aforesaid

diaphragm.

According to a preferred embodiment of the invention, the lateral tubular fitting is made of a relatively yelding elastic material and is conveniently elastically expandable in a radial direction following upon fluid-tight coupling of the aforesaid introducer of fluid to the female luer cone of the lateral tubular fitting.

The radial expansion of the lateral tubular fitting may be conveniently obtained envisaging that its side wall is locally thinned axially.

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:

- Figure 1 is a schematic perspective view of a flow system for medical lines according to the invention;

- Figure 2 is a top plan view at a larger scale of the system of Figure 1;

- Figure 3 is a longitudinal sectional view according to the line III-III of Figure 2;

- Figure 4 is a sectional view according to the line IV-IV of Figure 3;

- Figure 5 is a perspective view of the open/close element of the anti-siphon valve of the flow component;

- Figure 6 is a view in elevation of the lateral tubular fitting of the flow component; and

- Figure 7 is a view in axial section according to the line VII-VII of Figure 6.

Detailed description of the invention

The flow system according to the invention represented in the drawings may be applied in

particular to a medical haemodialysis line.

The flow system basically comprises a flow component 1 having a main duct 2 designed in use to be traversed by the flow of a primary fluid in the direction indicated by the arrow A, and a lateral tubular fitting 3 extending in a direction perpendicular to the duct 2 for introduction of a secondary fluid into the latter.

The lateral tubular fitting 3 is shaped like a female luer-lock connector, the luer-cone internal surface of which is designated by 4, and the internal end of which has an annular flange 5 fixed in a fluid-tight way at an annular collar 6 projecting laterally from the main duct 2.

Defined between the annular flange 5 and the annular collar 6 is a chamber 7 for a two-way valve, the general conformation of which is known from the already cited European patents Nos. EP-B-1093828 and EP-B-1661599. In detail, and as is more clearly visible also in Figure 5, the valve comprises an element 8 shaped like a cup turned upside down made of elastic material, for example, silicone, the side wall 9 of which rests on the bottom of the chamber 7 and the bottom wall of which, designated by 10, defines an elastically deformable transverse diaphragm, the perimetral edge 11 of which is normally set in hermetic contact against an annular valve seat 12 with conical surface formed inside the annular flange 5 of the lateral tubular fitting 3. The hermetic contact is obtained thanks to the axial thrust applied by the side wall 9 of the cup-shaped element 8 on the diaphragm 10.

The diaphragm 10 is formed with a ring of axial projections 13 (in the example illustrated, four in number), which radially face the base of the female luer cone 4 of the lateral tubular fitting 3 and the

function of which will be clarified in what follows.

The lateral tubular fitting 3 advantageously has two peculiar characteristics: in the first place, it is made of a relatively yelding i.e. compliant elastic material (for example, polybutylene-terephthalate and analogues), and preferably its side wall is locally thinned axially, for example, in the way represented in Figure 7, with two diametrally opposite portions 14 thinner than the remaining portions 15, which are thicker.

In the second place, the female luer-cone internal surface 4 is obtained with the minimum tolerance possible in proportion to the size of a normal male luer-cone introducer of fluid, partially represented schematically with a dashed line and designated by H in Figures 3 and 4.

These characteristics contribute to achieving the functional effect that will be discussed in what follows.

In the case of the example illustrated, the main duct 2 has, in a region axially corresponding to the chamber 8, a portion 16 with an internal wall having a convergent-divergent profile. This profile is defined by a localized narrowing of rounded shape 17 of the internal wall of the portion 16, upstream of which (with respect to the direction of flow A of the primary fluid) the convergent part is defined, in communication with the chamber 7 through a first radial passage 18, and downstream of which the divergent part is defined, in turn in communication with the chamber 7 through a second radial passage 19. This conformation, which however is not strictly necessary in relation to operation of the valve, corresponds to the one described and illustrated in the already cited patent No. EP-B-1661599, with the functional effect that will

also be described in what follows.

In operation, as explained previously, the valve defined by the cup-shaped element 8 is normally set in the closing position, with the peripheral edge 11 of the diaphragm 10 kept in fluid-tight contact against the annular valve seat 12 as a result of the axial thrust exerted by the side wall 9.

For introduction of a secondary fluid within the main duct 2 (or else for extraction of fluid from the main duct 2), the male luer-cone introducer H is introduced axially into the lateral tubular fitting 4 and pushed therein. Considering the minimal tolerance referred to above, the hermetic seal between the male luer cone of the introducer H and the female luer cone 4 of the lateral tubular fitting 3 is obtained already at a certain distance from the axial projections 13 of the diaphragm 10, i.e., approximately in the area represented in Figures 3 and 4. The further axial advance of the introducer H, made possible by the radially yelding and possibly locally thinned conformation of the lateral tubular fitting 3 referred to above, produces interaction thereof with the axial projections 13 of the diaphragm 10 and separation of the perimetral edge 11 of the latter from the valve seat 12, against the action of thrust applied by the side wall 9. In this way, there is allowed flow of the secondary fluid from the introducer H to the chamber 7 and thus into the main duct 2, or vice versa. In this step, the cross section with a convergent-divergent profile 16 defines a Venturi tube designed to prevent the stagnation of the secondary fluid within the chamber 7. Part of the flow of the primary liquid penetrates into the chamber 7 through the first passage 18 and comes out of this through the second passage 19, entrained thanks to the ejecting effect obtained by the

aforesaid flow of the primary fluid in the area of the divergent profile. In this way, the primary fluid in the main duct 2 achieves not only an effect of emptying of the chamber 7, but also an effective action of continuous flushing thereof.

When the introducer H is taken out of the lateral tubular fitting 3, the latter is brought back again into its undeformed condition, and the side wall 9 of the cup-shaped element 8 brings the diaphragm 10 back into the closing position, pushing the perimetral edge 11 again into fluid-tight contact with the annular valve seat 12.

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 defined in the ensuing claims.

CLAIMS

1. A flow system for medical lines comprising a flow component (1) having a main duct (2) for a primary fluid and at least one lateral tubular fitting (3) with female luer cone (4) communicating with the main duct (2) through a valve (8) including a transverse diaphragm (10) constituted by the bottom wall of a cup-shaped element (8) made of elastically deformable material, the outer peripheral edge (11) of which is normally kept in fluid-tight contact against an annular valve seat (12) of said lateral tubular fitting (3), and a male luer-cone introducer of secondary fluid (H), which can be inserted into said lateral tubular fitting (3) with female luer cone (4) to displace said transverse diaphragm (10) into an opening position, said flow system being characterized in that said diaphragm (10) is prearranged for being pushed into said opening position as a result of the direct contact of thrust by said introducer (H), and in that said lateral tubular fitting (3) is configured in such a way as to couple in a fluid-tight way with said introducer (H) before the latter comes into contact of thrust with said diaphragm (10).

2. The flow system according to Claim 1, characterized in that said lateral tubular fitting (3) is made of a relatively yelding elastic material and can expand elastically in a radial direction following upon fluid-tight coupling with said introducer (H).

3. The flow system according to Claim 2, characterized in that said lateral tubular fitting (3) has a wall locally thinned axially (15).

4. The flow system according to one or more of the preceding claims, characterized in that said diaphragm (10) has a ring of axial projections (13)

radially facing said female luer cone (4).

5. The flow system according to Claim 4, characterized in that the outer peripheral edge (11) of said diaphragm (10) is normally kept in fluid-tight contact against said annular valve seat (12) under the action of an axial thrust applied by the side wall (9) of said cup-shaped element (8); the deflection of said diaphragm (10) produced in use following upon the interaction between said introducer (H) and said axial projections (13) bringing about radial contraction of said peripheral edge (11) and its consequent separation from said annular valve seat (12).

6. The flow system according to one or more of the preceding claims, characterized in that said main duct (2) has, in a position corresponding to said anti-siphon valve (8), an axial section (16, 17) with a convergent-divergent profile.

"Flow system for medical lines"

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Field of the invention

The subject of the present invention is a flow system for medical lines, in particular for haemodialysis, of the type comprising a flow component having a main duct for a primary fluid and at least one lateral tubular fitting with female luer cone communicating with the main duct through a valve.

Prior art

A flow component of the type defined above is known from the European patent No. EP-B-1661599 filed in the name of the present applicant, in which the valve is a so-called anti-siphon valve, including a diaphragm constituted by the bottom wall of a cup-shaped element made of elastically deformable material, the outer peripheral edge of which is normally kept in fluid-tight contact against an annular valve seat of the lateral tubular fitting. As is also described in the patent No. EP-B-1093828, which is also filed in the name of the present applicant, the sealing edge of this valve can be moved away from the corresponding annular valve seat, to an opening position, following upon insertion of a male luer-cone introducer of fluid within the female luer cone of the lateral tubular fitting. It is hence a two-way valve of the so-called "luer activated" type, opening of which is controlled mechanically, rather than simply by the pressure of the fluid introduced into the lateral tubular fitting.

Mechanical activation is normally obtained in the case of valves of this sort, with the aid of additional components. For example, from the Italian patent No. IT-B-1291508, which is also filed in the name of the present applicant, opening of a diaphragm valve obtained as a result of insertion of the male luer-cone

introducer of fluid within a female luer-cone fitting is obtained with the aid of an auxiliary tubular slider that is axially mobile within the fitting and rests against the diaphragm of the valve. Opening of the valve is thus obtained as a result of the axial thrust applied on the diaphragm by the auxiliary slider, which is in turn moved by the male luer-cone introducer.

A similar solution is described in the document No. US-5,465,938A.

This arrangement, in addition to being relatively complicated, may entail the risk of the valve being opened by the auxiliary slider before the male luer-cone introducer provides the hermetic seal with the female luer cone of the tubular fitting, with consequent problems of contamination and leakage of fluid.

Summary of the invention

The object of the present invention is to overcome the above drawback and to provide a flow system for medical lines of the type generally corresponding to what is described and illustrated in the already cited European patent No. EP-B-1661599, in which opening of the valve upon insertion of the introducer of fluid takes place in a precise and reliable way and without any risk of contamination.

According to one aspect of the present invention, there is provided a flow system for medical lines comprising a flow component having a main duct for a primary fluid and at least one lateral tubular fitting with female luer cone communicating with the main duct through a valve including a transverse diaphragm constituted by the bottom wall of a cup-shaped element made of elastically deformable material, the outer peripheral edge of which is normally kept in fluid-tight contact against an annular valve seat of said

lateral tubular fitting, and a male luer-cone introducer of secondary fluid, which can be inserted into said lateral tubular fitting with female luer cone to displace said transverse diaphragm into an opening position. The diaphragm is prearranged for being pushed into the opening position as a result of the direct contact with and thrust by the introducer. The lateral tubular fitting is made of a relatively yielding elastic material and can expand elastically in a radial direction following upon coupling with said introducer in such a way as to couple in a fluid-tight way with the introducer before the latter comes into contact with and applies a thrust to the diaphragm.

The radial expansion of the lateral tubular fitting may be conveniently obtained envisaging that its side wall is locally thinned axially.

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:

- Figure 1 is a schematic perspective view of a flow system for medical lines according to the invention;

- Figure 2 is a top plan view at a larger scale of the system of Figure 1;

- Figure 3 is a longitudinal sectional view according to the line III-III of Figure 2;

- Figure 4 is a sectional view according to the line IV-IV of Figure 3;

- Figure 5 is a perspective view of the open/close element of the anti-siphon valve of the flow component;

- Figure 6 is a view in elevation of the lateral tubular fitting of the flow component; and

- Figure 7 is a view in axial section according to the line VII-VII of Figure 6.

Detailed description of the invention

The flow system according to the invention represented in the drawings may be applied in particular to a medical haemodialysis line.

The flow system basically comprises a flow component 1 having a main duct 2 designed in use to be traversed by the flow of a primary fluid in the direction indicated by the arrow A, and a lateral tubular fitting 3 extending in a direction perpendicular to the duct 2 for introduction of a secondary fluid into the latter.

The lateral tubular fitting 3 is shaped like a female luer-lock connector, the luer-cone internal surface of which is designated by 4, and the internal end of which has an annular flange 5 fixed in a fluid-tight way at an annular collar 6 projecting laterally from the main duct 2.

Defined between the annular flange 5 and the annular collar 6 is a chamber 7 for a two-way valve, the general conformation of which is known from the already cited European patents Nos. EP-B-1093828 and EP-B-1661599. In detail, and as is more clearly visible also in Figure 5, the valve comprises an element 8 shaped like a cup turned upside down made of elastic material, for example, silicone, the side wall 9 of which rests on the bottom of the chamber 7 and the bottom wall of which, designated by 10, defines an elastically deformable transverse diaphragm, the perimetral edge 11 of which is normally set in hermetic contact against an annular valve seat 12 with conical surface formed inside the annular flange 5 of the lateral tubular fitting 3. The hermetic contact is obtained thanks to the axial thrust applied by the side

wall 9 of the cup-shaped element 8 on the diaphragm 10.

The diaphragm 10 is formed with a ring of axial projections 13 (in the example illustrated, four in number), which radially face the base of the female luer cone 4 of the lateral tubular fitting 3 and the function of which will be clarified in what follows.

The lateral tubular fitting 3 advantageously has two peculiar characteristics: in the first place, it is made of a relatively yielding i.e. compliant elastic material (for example, polybutylene-terephthalate and analogues), and preferably its side wall is locally thinned axially, for example, in the way represented in Figure 7, with two diametrally opposite portions 14 thinner than the remaining portions 15, which are thicker.

In the second place, the female luer-cone internal surface 4 is obtained with the minimum tolerance possible in proportion to the size of a normal male luer-cone introducer of fluid, partially represented schematically with a dashed line and designated by H in Figures 3 and 4.

These characteristics contribute to achieving the functional effect that will be discussed in what follows.

In the case of the example illustrated, the main duct 2 has, in a region axially corresponding to the chamber 8, a portion 16 with an internal wall having a convergent-divergent profile. This profile is defined by a localized narrowing of rounded shape 17 of the internal wall of the portion 16, upstream of which (with respect to the direction of flow A of the primary fluid) the convergent part is defined, in communication with the chamber 7 through a first radial passage 18, and downstream of which the divergent part is defined, in turn in communication with the chamber 7 through a

second radial passage 19. This conformation, which however is not strictly necessary in relation to operation of the valve, corresponds to the one described and illustrated in the already cited patent No. EP-B-1661599, with the functional effect that will also be described in what follows.

In operation, as explained previously, the valve defined by the cup-shaped element 8 is normally set in the closing position, with the peripheral edge 11 of the diaphragm 10 kept in fluid-tight contact against the annular valve seat 12 as a result of the axial thrust exerted by the side wall 9.

For introduction of a secondary fluid within the main duct 2 (or else for extraction of fluid from the main duct 2), the male luer-cone introducer H is introduced axially into the lateral tubular fitting 4 and pushed therein. Considering the minimal tolerance referred to above, the hermetic seal between the male luer cone of the introducer H and the female luer cone 4 of the lateral tubular fitting 3 is obtained already at a certain distance from the axial projections 13 of the diaphragm 10, i.e., approximately in the area represented in Figures 3 and 4. The further axial advance of the introducer H, made possible by the radially yielding and possibly locally thinned conformation of the lateral tubular fitting 3 referred to above, produces interaction thereof with the axial projections 13 of the diaphragm 10 and separation of the perimetral edge 11 of the latter from the valve seat 12, against the action of thrust applied by the side wall 9. In this way, there is allowed flow of the secondary fluid from the introducer H to the chamber 7 and thus into the main duct 2, or vice versa. In this step, the cross section with a convergent-divergent profile 16 defines a Venturi tube designed to prevent

the stagnation of the secondary fluid within the chamber 7. Part of the flow of the primary liquid penetrates into the chamber 7 through the first passage 18 and comes out of this through the second passage 19, entrained thanks to the ejecting effect obtained by the aforesaid flow of the primary fluid in the area of the divergent profile. In this way, the primary fluid in the main duct 2 achieves not only an effect of emptying of the chamber 7, but also an effective action of continuous flushing thereof.

When the introducer H is taken out of the lateral tubular fitting 3, the latter is brought back again into its undeformed condition, and the side wall 9 of the cup-shaped element 8 brings the diaphragm 10 back into the closing position, pushing the perimetral edge 11 again into fluid-tight contact with the annular valve seat 12.

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 defined in the ensuing claims.

CLAIMS

1. A flow system for medical lines comprising a flow component having a main duct for a primary fluid and at least one lateral tubular fitting with female luer cone communicating with the main duct through a valve including a transverse diaphragm constituted by the bottom wall of a cup-shaped element made of elastically deformable material, the outer peripheral edge of which is normally kept in fluid-tight contact against an annular valve seat of said lateral tubular fitting, and a male luer-cone introducer of secondary fluid, which can be inserted into said lateral tubular fitting with female luer cone to displace said transverse diaphragm into an opening position, wherein said diaphragm is prearranged for being pushed into said opening position as a result of the direct contact with and thrust by said introducer, and wherein said lateral tubular fitting is made of a relatively yielding elastic material and can expand elastically in a radial direction following upon coupling with said introducer in such a way as to couple in a fluid-tight way with said introducer before the latter comes into contact with and applies a thrust to said diaphragm.

2. The flow system according to Claim 1, wherein said lateral tubular fitting has a wall locally thinned axially.

3. The flow system according to Claim 1 or Claim 2, wherein said diaphragm has a ring of axial projections radially facing said female luer cone.

4. The flow system according to Claim 3, wherein the outer peripheral edge of said diaphragm is normally

kept in fluid-tight contact against said annular valve seat under the action of an axial thrust applied by the side wall of said cup-shaped element; the deflection of said diaphragm produced in use following upon the interaction between said introducer and said axial projections bringing about radial contraction of said peripheral edge and its consequent separation from said annular valve seat.

5. The flow system according to any one of the preceding Claims, wherein said main duct has, in a position corresponding to said valve, an axial section with a convergent-divergent profile.