"VALVE CONNECTOR FOR MEDICAL LINES"

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Field of the invention

The present invention relates in general to connectors for medical lines, for example for haemodialysis.

More in particular, the invention relates to a valve connector of the type comprising a tubular body having a male inlet fitting with external luer cone, which can be coupled axially by friction within a female fitting with internal luer cone that is to be connected to a first section of the line (for example, a tubing connected to a patient undergoing dialysis). The tubular body has an outlet fitting designed to be connected to a second section of the line (for example, the tubing of a dialyser), and valve means for controlling the passage of flow between the inlet and outlet fittings.

State of the prior art

A valve connector of the above sort is described and illustrated in the European patent application No. EP-1747796A1 filed in the name of the present applicant. In said connector, the male inlet fitting of the tubular body comprises an internally threaded external tubular element to be engaged by screwing to the female fitting, and an internal tubular element that can be displaced axially with respect to the tubular body. The valve means are constituted by a transverse diaphragm of a hollow body made of elastic material, equipped with a pre-cut that can be opened elastically by said internal tubular element when this is moved, via the female fitting, from a retracted position of closing to an advanced position of opening of the passage of flow through the tubular body in such a way as to open the communication between the two

sections of the medical line. Set between the tubular body and the internal tubular element of the inlet fitting are slidable sealing means, and elastic means are moreover provided that tend to keep the internal tubular element in the retracted closing position, in which the communication between the two sections of the line is interrupted.

In the valve connector according to the document No. EP-1747796, the externally threaded tubular element of the male inlet fitting is fixed with respect to the tubular body and is in fact formed integrally therewith. Opening of the passage of flow through the valve connector is obtained following upon axial engagement of the female fitting with internal luer cone on the male inlet fitting with external luer cone as a result of screwing of the female fitting with respect to the internally threaded external tubular element of the male inlet fitting. Screwing causes axial displacement of the internal tubular element of the male inlet fitting in the direction of the outlet fitting, through the pre-cut diaphragm of the elastic body of the valve means, and consequent opening of the passage of flow.

In the eventuality where, during use of the connector, there accidentally occurs unscrewing between the female fitting and the male inlet fitting of the tubular body, the section of the medical line connected to said female fitting (which, as has been said, in the case of a haemodialysis line, is the section connected to the patient) is subject to the risk of uncontrolled opening. In fact, in this eventuality, whilst the communication between the inlet fitting and the outlet fitting of the tubular body is interrupted as a result of the closing of the valve means following upon return of the internal tubular element of the inlet fitting

into the retracted position, the female fitting can disengage completely from the male inlet fitting of the tubular body, thus freeing the flow towards the outside of the corresponding first section of the medical line, with the dramatic consequences that can result therefrom.

Summary of the invention

The present invention represents an improvement of the one according to the document No. EP-1747796A1 and has the object of overcoming the drawbacks described above in the case of accidental unscrewing of the female fitting from the male inlet fitting of the tubular body.

According to the invention, the above object is achieved thanks to the fact that the internally threaded external tubular element of the male inlet fitting of the tubular body is free to turn with respect to the internal tubular element, and to the fact that the rotatable external tubular element and the internal tubular element are configured in such a way that, when the external luer cone is axially coupled within the internal luer cone of the female fitting, screwed engagement between the rotatable external tubular element and the female fitting is obtained only following upon an initial axial displacement of the female fitting, which produces a consequent axial displacement of the internal tubular element of the male inlet fitting from the position of closing to the advanced position of opening of the passage of flow against the action of the aforesaid elastic means. Furthermore, the configuration is such that, when the rotatable external tubular element of the male inlet fitting is screwed off the female fitting and the elastic means bring the internal tubular element back from the advanced position of

opening into the retracted position of closing of the passage of flow, the aforesaid external luer cone remains axially coupled by friction within the internal luer cone of the female fitting.

Thanks to this arrangement, important advantages are obtained.

In the first place, in the case where during use of the connector there occurs an accidental unscrewing between the female fitting and the male inlet fitting of the tubular body, the risk of uncontrolled opening of the section of the line connected to the female fitting (typically the tubing connected to a patient undergoing haemodialysis) is ruled out. In fact, in this eventuality, closing of the passage of flow through the tubular body, resulting from retraction of the internal tubular element of the male inlet fitting, and the continuance of the axial coupling by friction between the internal luer cone of the female fitting and the external luer cone of the male inlet fitting of the tubular body keep said section of the line in a condition of controlled closing.

A further functional advantage lies in the fact that, when the female fitting is engaged by screwing within the rotatable external tubular element of the male inlet fitting of the tubular body, following upon initial axial displacement of the female fitting, the passage of flow through the valve connector is already open. Subsequent screwing between the rotatable external tubular element of the male inlet fitting and the female fitting produces a further displacement of overtravel of the internal tubular element beyond the aforesaid advanced position of opening of the passage of flow so that the flowrate of the fluid that flows through the connector is the same during the entire step of connection between the male fitting of the

tubular body and the female fitting.

Furthermore, the voluntary operation of coupling or uncoupling between the female fitting and the tubular body is facilitated by the rotation of the external tubular element of the male fitting of the tubular body, which prevents any torsion of one and/or other section of the medical line to which the connector is associated in use.

Brief descriptions 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 view in longitudinal section of a valve connector according to the invention, represented in the deactivated condition, i.e., where it is closed to the flow of fluid;

- Figure 2 is a view similar to that of Figure 1, which shows the valve connector in the activated condition, i.e., where it is open to the flow of fluid; and

- Figure 3 is a view similar to those of Figures 1 and 2, which shows the valve connector in an intermediate condition between the deactivated condition illustrated in Figure 1 and the activated condition of Figure 2.

Detailed description of the invention

With initial reference to Figure 1, designated as a whole by 1 is a valve connector according to the invention, basically comprising a tubular body 2 provided coaxially at its opposite ends with an inlet fitting 3 and an outlet fitting 4, and a tubular fitting 5. The components listed above of the medical connector 1 can all be made of moulded plastic material.

The tubular fitting 5 has a portion 6 designed to

be connected to a first section of a medical line (for example, the tubing connected to a patient undergoing haemodialysis), and a second portion designated by 7, which can be coupled, in the way clarified in what follows, to the inlet fitting 3 of the tubular body 2.

The outlet fitting 4 of the tubular body 2 can in turn be connected to a second section of the medical line (for example, to the tubing of a dialyser).

The portion 7 of the tubular fitting 5 is shaped like a female luer-lock: it has, in a generally conventional way, an internal luer cone 8 and an external end thread 9.

The inlet fitting 3 of the tubular body 2 is of the male luer-lock type, comprising an external tubular element 10 formed with an internal thread 11 complementary to the thread 9 of the female tubular fitting 5, and an internal tubular element 12. Said internal tubular element 12 is mounted axially slidable, with respect to the tubular body 2, between a retracted position, represented in Figure 1, and an advanced position in the direction of the outlet fitting 4, represented in Figure 2, passing through the partially advanced position illustrated in Figure 3.

The internal tubular element 12 has a portion 13 projecting on the outside of the tubular body 2, through, and for a substantial stretch beyond, the internally threaded element 10 shaped like an external luer cone 14, complementary to the internal luer cone 8 of the female tubular fitting 5. Said internal tubular element 12 moreover has an axially internal portion 15 radiused to the axially external portion 13 through an annular flange 16, for example with a polygonal or star shape, coupled in a slidable but non-rotatable way to corresponding internal longitudinal grooves of the body 2 (not visible in the drawings). The flange 16, in the

retracted position illustrated in Figure 1, rests against an internal annular arrest collar 17 of the tubular body 2, and said position is maintained thanks to the action of a hollow element made of elastic material 18 that is interposed substantially in a fluid-tight way within the tubular body 2, between the inlet fitting 3 and the outlet fitting 4 thereof.

This element made of elastic material 18 performs substantially three functions: a first function, as has been said, of elastic thrust of the internal tubular element 12 towards the retracted position; a second function of slidable seal of the portion 15 of the tubular element 12; and a third function consisting in defining a valved passage of flow between the inlet fitting 3 and the outlet fitting 4 of the tubular body 2.

In the embodiment described, the hollow element made of elastic material 18 has, at one end, an enlarged part 19 blocked between the tubular body and the outlet fitting 4 and formed internally with one or more integral seal rings (not visible) in sliding contact with the external surface of the portion 15 of the internal tubular element 12, and an opposite end 20 resting against the annular flange 16 of the internal tubular element 12. An intermediate part 21 of the element 18 has a wall elastically more compliant in an axial direction, conveniently shaped with alternating helical ribbings and grooves, for example, in the way described in detail in the already cited document No. EP-1747796A1.

Furthermore, the elastic tubular body 18 has, in a position corresponding to its end facing the outlet fitting 4, a transverse diaphragm 22 formed with a central cut 23 that is normally kept hermetically closed as a result of an appropriate radial pre-loading

between the enlarged part 19 and the tubular body 2.

The free end of the portion 15 of the internal tubular element 12, designated by 24, has a chamfered configuration provided for co-operating, in the way clarified in what follows, with the transverse diaphragm 22 and the corresponding cut 23 of the hollow elastic element 18.

According to the primary characteristic of the invention, the external tubular element 10 with the internal thread 11 of the inlet fitting 3 is constituted by a ring nut that is free to turn on the tubular body 2. Said rotatable ring nut 10 has a rotatably engaged attachment part 25, for example, following upon an axial snap-action coupling, on an axial appendage 26 of the tubular body 2.

According to a further peculiar characteristic of the invention, said rotatable ring nut 10 with the corresponding internal thread 11 and the projecting portion 13 of the internal tubular element 12 formed with the external luer cone 14 are configured in such a way that, when said external luer cone 14 is axially coupled within the internal luer cone 8 of the female fitting 5, screwed engagement between the internal thread 11 of the rotatable ring nut 10 and the external thread 9 of the female fitting 5 is obtained only after engagement by friction between the cones 14 and 8, and following upon an initial axial displacement of the female fitting 5 that produces a consequent axial displacement of the internal tubular element 12 in the direction of the outlet fitting 4, i.e., from the position of closing to the advanced position of opening of the passage of flow through the valve connector 1, compressing the axially more compliant portion 21 of the elastic element 18. The arrangement is moreover such that, when the rotatable ring nut 10 is screwed

off the female fitting 5 and consequently the internal tubular element 12 returns into the retracted position for closing the passage through the connector 1 as a result of the elastic return of the portion 21 of the body 18, the cones 14 and 8 remain axially coupled to one another by friction and can be separated from one another only following upon a positive action tending to move them away from one another.

The foregoing will now be explained in greater detail with reference to operation of the valve connector.

In the absence of coupling between the female fitting 5 and the tubular body 2, the internal tubular element 12 is kept by the hollow elastic element 18 in the retracted position represented in Figure 1. In said condition, the end 24 of the internal tubular element 12 is axially retracted with respect to the transverse diaphragm 22 of the hollow elastic element 18 so that the cut 23 remains hermetically closed and the passage of flow between the inlet fitting 3 and the outlet fitting 4 is interrupted.

When the female tubular fitting 5 is coupled to the tubular body 2, initially the luer cones 8 and 13 are axially engaged to one another by friction, in the way represented in Figure 1.

At the end of said axial coupling, between the external thread 9 of the female fitting 5 and start of the internal thread 11 of the rotatable ring nut 10 there remains an axial distance between them, designated by A in Figure 1, which prevents their mutual engagement and screwing as long as the female fitting 5 and the tubular body 2 are not pushed axially towards one another so as to move the internal tubular element 12 from the retracted position of Figure 1 into the partially advanced position represented in Figure

3, where fitting between the threads 9 and 11 is made possible. As is illustrated in Figure 3, in this condition the end 24 of the internal tubular element 12 has already interacted with the transverse diaphragm 22 of the hollow elastic element 18, expanding elastically and traversing the cut 23 so as to form an initial opening for flow of the fluid through the connector 1.

Starting from said position, a manual rotation of screwing imparted on the rotatable ring nut 10 produces screwing between the threads 9 and 11 and consequently further advance of the female fitting 5 and of the internal tubular element 12 in the direction of the outlet fitting 4 up to the final condition represented in Figure 2. In said condition, the passage of flow through the connector 1, already opened previously, continues to remain open as a result of the further displacement of overtravel of the end 24 of the internal tubular element 12 through the cut 23 of the diaphragm 22 of the hollow elastic element 18.

The manoeuvre of disengagement between the female tubular fitting 5 and the tubular body 2 obviously involves unscrewing of the rotatable ring nut 10 to obtain disengagement between the threads 9 and 11 and consequent return of the internal tubular element 12 from the condition of Figure 2 to that of Figure 1 as a result of the thrust exerted by the hollow elastic element 18, which causes consequent re-closing of the cut 23 and hence of the passage of flow through the connector 1. At the end of said step, to separate the female fitting 5 physically from the tubular body 2 it is necessary to release further the axial coupling by friction between the cones 8 and 14 so as to obtain separation thereof.

The configuration according to the invention described above, with particular reference to the

rotatable ring nut 10, to the axial projection of the portion 13 of the internal tubular element 12, and to the reciprocal arrangement of the threads 9 and 11, not only renders more convenient and secure the operations of coupling and uncoupling between the fitting 5 and the tubular body 2, but also ensures a high degree of safety against risks of any accidental opening of the medical line to which the valve connector 1 is applied, in the eventuality in which the threads 9 and 11, in the condition of use of the connector with the passage of flow open, accidentally unscrew and disengage.

In fact, in such an eventuality, the connector 1 sets itself, following upon accidental or in any case undesired unscrewing of the rotatable ring nut 10, in the condition represented in Figure 1, where retraction of the internal tubular element 12 obtained by the thrust of the hollow elastic element 18 following upon disengagement of the threads 9 and 11 produces closing of the passage of flow as a result of hermetic re-closing of the cut 23 of the diaphragm 22, thus isolating the inlet fitting 3 from the outlet fitting 4. In said condition, the cone 8 of the female fitting 5 remains, however, axially coupled by friction on the cone 14 of the internal tubular element 12 so that the section of the medical line connected to the female fitting 5 is kept closed, in a controlled way, by the valve system of the tubular body 2.

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

CLAIMS

1. A valve connector (1) for medical lines, comprising:

- a female tubular fitting (5) with internal luer cone (8);

- a tubular body (2) having a male inlet fitting (3) with external luer cone (14), which can be coupled axially by friction within said female fitting (5); an outlet fitting (4); and valve means for controlling the passage of flow between said inlet and outlet fittings (3, 4),

wherein said male inlet fitting (3) comprises an external tubular element (10) internally threaded for screwed engagement with said female fitting (5), and an internal tubular element (12) that can be displaced axially with respect to said tubular body (2) from a retracted position of closing to an advanced position of opening of said passage of flow, slidable sealing means (18) of said internal tubular element (12), and elastic means (18) tending to keep said internal tubular element (12) in said retracted closing position,

said connector being characterized in that:

- said internally threaded external tubular element (10) of the male inlet fitting (3) of the tubular body (2) is free to turn with respect to said internal tubular element (12); and

- said rotatable external tubular element (10) and said internal tubular element (12) are configured in such a way that:

- when said external luer cone (14) is axially fitted within said internal luer cone (8) of the female fitting (4), screwed engagement between said rotatable external tubular element (10) and said

female fitting (5) is obtained only following upon an initial axial displacement of said female fitting (5), which produces a consequent axial displacement of said internal tubular element (12) from the retracted position of closing towards said advanced position of opening of said passage of flow, against the action of said elastic means (18); and

- when said rotatable external tubular element (10) is screwed off said female fitting (5) and said elastic means (18) bring back said entire tubular element (12) into said retracted position of closing of said passage of flow, said external luer cone (14) remains axially coupled by friction within said internal luer cone (8) of the female fitting.

2. The valve connector according to Claim 1, characterized in that said valve means, said slidable sealing means, and said elastic means are integrated in a hollow element made of elastic material (18) interposed axially in a fluid-tight way within said tubular body (2) between said inlet and outlet fittings (3, 4).

3. A method for controlling the flow through a medical line via a valve connector (1) including a female fitting (5) with internal luer cone (8) and a tubular body (2) having a male inlet fitting (3) with external luer cone (14), which can be coupled axially by friction within said female fitting (5), an outlet fitting (4), and valve means for controlling the passage of flow between said inlet and outlet fittings (3, 4), wherein said male inlet fitting (3) comprises an internally threaded external tubular element for screwed engagement with said female fitting (5), and an internal tubular element (12) that can be displaced axially with respect to said external tubular element (10) from a retracted position of closing to an

advanced position of opening of said passage of flow, and provided in which are elastic means (18) tending to keep said internal tubular element (12) in said retracted position,

said method being characterized in that said internally threaded external tubular element (10) is free to turn with respect to said internal tubular element (12) and in that:

- when said external luer cone (14) is axially coupled within said internal luer cone (8) of the female fitting (5), screwed engagement between said rotatable external tubular element (10) and said female fitting (5) is obtained only following upon an initial axial displacement of said female fitting (5) that produces a consequent axial displacement of said internal tubular element (12) from the position of closing to the advanced position of opening of said passage of flow, against the action of said elastic means (18);

- when said rotatable external tubular element (10) screwed off said female fitting (5), and said elastic means (18) bring back said internal tubular element (12) into said retracted position of closing of said passage of flow, said external luer cone (14) and said internal luer cone (8) remain axially coupled to one another by friction.

4. The method according to Claim 3, characterized in that screwed engagement between said rotatable external tubular element (10) and said female fitting (5) brings about an axial displacement of overtravel of said entire tubular element (12) beyond said advanced position of opening of said passage of flow.

5. The method according to Claim 3 or Claim 4, characterized in that said valve means, said slidable sealing means, and said elastic means are provided

integrally in a hollow element made of elastic material (18) set, within said tubular body (2), between said inlet and outlet fittings (3, 4).