

"Flow component particularly for haemodialysis medical lines"

Field of the invention

5 The present invention generally refers to liquid
flow lines, particularly but not exclusively
haemodialysis medical lines and more in particular it
regards a flow component for lines thus made of the
type comprising a body defining a duct having a first
10 and a second end tubular connector coaxial to each
other and designed to be connected to the line, and an
intermediate tubular connector arranged orthogonally to
the duct between said end connectors and containing a
valve device.

15 State of the prior art

A flow component of the type defined above is for
example known from document EP-1661599B1 on behalf of
the Applicant, in which the valve device consists in a
hollow elastic element which normally holds said
20 intermediate tubular connector closed and it is
elastically deformable following the coupling of the
intermediate tubular connector with a complementary
male luer connector to enable the introduction of a
secondary liquid in the duct. The hollow elastic
25 element consists in a simple diaphragm housed in a
chamber comprised between the duct and the intermediate
tubular connector of the body, and the chamber is in
communication with a converging and diverging section
of the duct through a pair of radial holes. With this
30 arrangement, the intermediate tubular connector is
difficult to clean before use and can thus be exposed
to risks of contamination from the external
environment.

Various valves of the so-called "swabbable" type,
35 constituted by an elongated elastic body extending into

a female luer lock connector up to the free end thereof, thus the end exposed towards the external of the elastic body can be easily cleaned and disinfected before the coupling of the female connector with a complementary male connector, are known in the prior art. An example of an elastic body thus made is described and illustrated in document US-5,533,708.

It would be desirable to be able to use a similar elastic element in the flow component of the type defined at the beginning, so as to avoid risks of contaminating the intermediate tubular connector and benefiting from the "swabbable" characteristic of the elastic element. However, the axially extended inner cavity of the hollow elastic element according to US-5,533,708 would entail, in particular in application to a haemodialysis medical lines, an extensive stagnation dead area and thus the deterioration of the blood, and this would be unacceptable.

Documents US-2014/207117, US-2015/0190623 and US-2008/086097 disclose a flow component of the type defined at the beginning in which the elastic body consists of a solid block that occupies only the free end area of the intermediate tubular connector. The flow component is configured so that the fluid flow along the duct is diverted towards the intermediate connector, so as to avoid stagnation in the area of the intermediate tubular connector located beneath the solid elastic body. This arrangement is disadvantageous due to the conformation and arrangement of the elastic body which also complicates the traversing thereof by a fluid introducer fitted into the intermediate tubular connector. Additionally, since the entire flow is diverted from the duct into the intermediate connector by a rib or protrusion formed on the bottom part of the duct and projecting therewithin, the dynamic behaviour

of the flow is altered.

Summary of the invention

The object of the invention is to overcome the
aforementioned technical drawback and enable, in a flow
5 component of the type defined at the beginning, the use
- in the relative intermediate tubular connector - of
a hollow elastic element similar to the one mentioned
in document US-5,533,708.

According to the invention, this object is
10 attained thanks to a flow component as defined in claim
1.

Thanks to this solution idea, the flow component
according to the invention is thus provided with an
intermediate tubular connector efficiently protected by
15 the hollow elastic element that can be cleaned from the
external without any risk, in use, of liquid stagnation
therein, in that the swirling flow generated in the
cavity thereof generates a constant fluid change.

Due to this configuration, the swirling motion of
20 the liquid diverted towards the intermediate tubular
connector and introduced along the cavity of said
hollow elastic element, becomes particularly efficient.

Brief description of the drawings

The invention will now be described in detail with
25 reference to the attached drawings, provided purely by
way of non-limiting example, wherein:

- figure 1 is a schematic perspective view of a
flow component for haemodialysis medical lines
according to the invention,
- 30 - figure 2 is a top view of the flow component;
- figure 3 is a longitudinal sectional view
according to line III-III of figure 2,
- figure 4 is a cross-sectional view according to
line IV-IV of figure 3,
- 35 - figure 5 is a cross-sectional view according to

line V-V of figure 3,

- figure 6 is a cross-sectional view according to line VI-VI of figure 3,

- figure 7 is a perspective view of the body of the flow component from which the intermediate tubular connector was removed, and

- figure 8 shows an enlarged scale of a part of figure 7.

Detailed description of the invention

10 The example represented in the drawings refers to the application of the invention to a haemodialysis medical line. However, it should be observed that the invention is equally advantageously applicable to any liquid flow line revealing the same technical drawback.

15 With reference to the drawings, and in particular to figures 1-3, the flow component for haemodialysis medical lines according to the invention essentially comprises a body made of moulded plastic material 1 that forms, in a single piece, a duct 2 having a first end tubular connector 3 and a second end tubular connector 4 coaxial to each other and interconnected by means of a small diameter portion 5 of the duct 2, according to a substantially converging-diverging configuration.

25 The end connectors 3 and 4 are designed to be connected, in use, to ducts respectively connected to a haemodialysis machine and to a patient subjected to haemodialysis.

30 At the small diameter portion 5, the body 1 forms a circular wall 6, represented in larger detail in figures 7 and 8 to be addressed further hereinafter, surrounded by an annular flange 7.

35 An intermediate tubular connector 8, typically of the female luer lock type designed to be coupled with a complementary male luer lock connector, is sealingly

fixed to such annular flange 7.

A hollow elastic element 9, typically made of elastomeric material, whose longitudinal axis is indicated with Z in figure 3 is arranged in the intermediate tubular connector 8. The hollow elastic element 9 has a distal end 10 normally arranged substantially flushed with respect to the free end of the intermediate tubular connector 8, and a proximal end 11 that forms a support base on the circular wall 6 of the body 1. The condition shown in the drawings (figures 3-6) corresponds to the non-deformed configuration of the hollow elastic element 9 in which the intermediate tubular connector 8 is sealingly closed in proximity of the distal end 10, which is immediately accessible from outside so as to be cleaned and disinfected. Should the complementary male luer lock connector be used with the intermediate connector 8, the hollow elastic element 9 is partly deformed and compressed ("luer activated") so as to open the communication between the intermediate connector 8 and the duct 2.

The hollow elastic element 9 delimits, therein, an axially extended cavity 12, closed at the distal end 10 and in which, in use, a portion of blood flow flowing through the duct 2 between the end connectors 3 and 4 thereof can enter and exit through a pair of by-pass apertures 13, 14, addressed below, formed through the flat wall 6.

The by-pass apertures 13 and 14, represented further in detail in figures 7 and 8, are arranged one upstream and the other downstream of the axis Z with respect to the direction of blood flow into the duct 2 and they are configured so that, in use, the blood flow that traverses the duct 2 and which - as mentioned - partly penetrates into the cavity 12 of the hollow

elastic element 9, is diverted in a unique manner and subjected to a swirling motion along such cavity 12. This effect is attained thanks to the fact that the apertures 13 and 14 have a generally juxtaposed semi-circular shape and they are separated from each other by a baffle or diverter fin 15 projecting from the wall 6 towards the internal of the cavity 12. As clearly observable in figure 8, a plane or diametrical axis Y of the two apertures 13, 14 passing through the diverter fin 15 is arranged obliquely with respect to the longitudinal axis X of the duct 2. More precisely, the angle formed between the axis Y and the axis X is comprised between 10° and 50° and it is preferably in the order of about 45° .

The diverter fin 15 is also arranged obliquely with respect to the axis X of the duct 2 according to an angle comprised between 10° and 50° and preferably of the order of about 45° .

Thanks to this arrangement, the flow component according to the invention operates as follows.

Assuming that the blood flow traversing the duct 2 is directed by the end connector 3 towards the end connector 4, i.e. from left to right with reference to figure 3, during its path, part of the blood intercepts the upstream aperture 13, whose semi-circular and obliquely arranged shape widens towards one side with respect to such part of flow. Then, this part of the blood flow begins to be channelled into the smaller area of the aperture, and finds an increasingly wider aperture 13 as the flow advances progressively. Thus, the part of the blood flow is diverted and pushed with a spiral motion towards the internal of the cavity 12, in which it meets a depression due to the presence of the aperture 14 downstream. The blood cannot move directly towards the aperture 14, due to the presence

of the diverter fin 15, but it is introduced along the cavity 12 with a generally helical swirling movement, before returning into the duct 2 through the aperture 14. Thus, the combination between the shape and
5 orientation of the openings 13, 14 as well as the presence of the diverter fin 15 enables obtaining a spiral-like swirling flow that keeps the blood penetrated into the cavity 12 in motion, thus preventing stagnation and the ensuing deterioration
10 thereof.

Obviously, the construction details and the embodiments may widely vary with respect to what has been described and illustrated, without departing from the scope of protection of the present invention as
15 defined in the claims that follow.

CLAIMS

1. A flow component, particularly for haemodialysis medical lines, comprising a body (1) defining a duct (2) having a first and a second end tubular fitting (3, 4) coaxial to each other and designed to be connected to the line, and an intermediate tubular connector (8) of the female luer type arranged orthogonally to the duct (2) between said end connectors (3, 4) and containing a valve device, wherein said valve device is formed by an elastic hollow element (9) which normally keeps said intermediate tubular connector (8) closed and it is elastically deformable following the coupling of the intermediate tubular connector (8) with a complementary male luer connector, wherein the hollow elastic element (9) substantially extends over the entire intermediate tubular connector (8) and has an axially extended cavity (12), characterised in that said intermediate tubular connector (8) is delimited, on the side of said duct (2), by a wall (6) supporting the elastic hollow element (9), said wall (6) being formed with two juxtaposed by-pass apertures (13, 14) located respectively upstream and downstream of the elastic hollow element (9) with respect to the flow within the duct (2), said apertures (13, 14) being separated by an intermediate baffle (15) projecting into the cavity (12) of said elastic hollow element (9) whereby said body (1) is internally configured so that, in use, the flow along said duct (2) is partially diverted towards the intermediate tubular connector (8) and introduced with a swirling motion along the cavity (12) of said elastic hollow element (9).

2. Flow component according to claim 2, characterised in that said apertures (13, 14) have a

substantially juxtaposed semi-circular shape and are oriented obliquely with respect to the axis (X) of the duct (2).

5 **3.** Flow component according to claim 2, characterised in that an axis (Y) containing radiuses of said two apertures (13, 14) passing through said intermediate baffle (15) forms an angle comprised between 10° and 50° and preferably of about 45° with respect to the axis (X) of the duct (2).

10 **4.** Flow component according to claim 3, characterised in that said baffle (15) forms an angle comprised between 10° and 50° and preferably of about 45° with respect to the axis (X) of the duct (2).