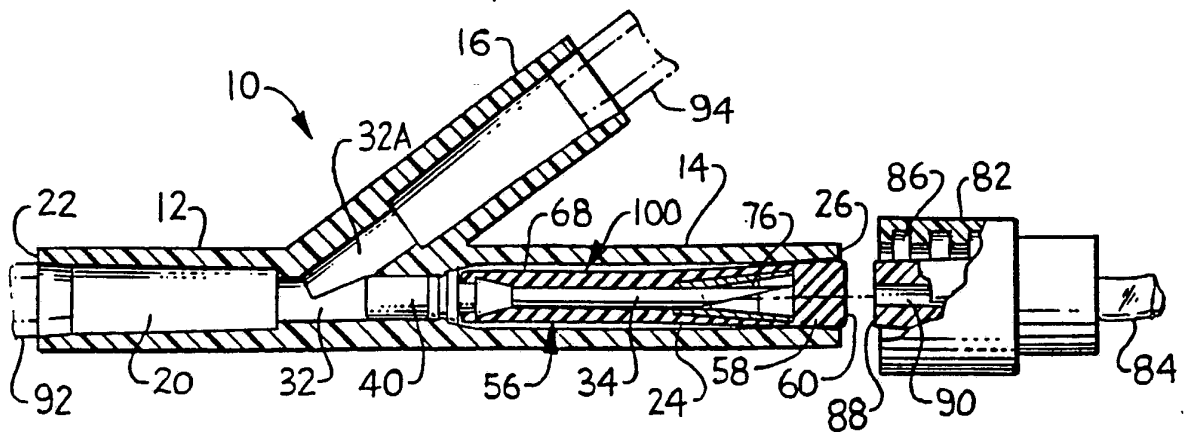




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<p>(21) International Application Number: PCT/US93/02150</p> <p>(22) International Filing Date: 10 March 1993 (10.03.93)</p> <p>(30) Priority data: 07/849,520 11 March 1992 (11.03.92) US</p> <p>(71) Applicant: CARE MEDICAL DEVICES, INC. [US/US]; Vineyard Airport Center, 1440 South Carlos Avenue, Ontario, CA 91761 (US).</p> <p>(72) Inventor: BONALDO, Jean, M. ; 1453 N. Tulare Way, Upland, CA 91786 (US).</p> <p>(74) Agent: ROTH, W., Norman; Roth & Goldman, 523 West 6th Street, Suite 840, Los Angeles, CA 90014 (US).</p>	<p>(81) Designated States: AU, BR, CA, HU, JP, KP, NZ, RU, UA, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).</p> <p>Published <i>With international search report.</i></p>	

(54) Title: MEDICAL VALVE



(57) Abstract

A medical valve has a cannula (40) mounted on a hub (42) fixed in a fluid conduit. The cannula points upstream. An elastomeric valve element (56) is mounted on the valve hub within the conduit so as to enclose the cannula. The valve element has a first solid frustoconical portion (64) upstream of the cannula point, a second hollow frustoconical portion (80) within which the cannula point is disposed, and a third hollow cylindrical portion (68) surrounding the cannula downstream from its point and fixed to the hub. The second portion has a frustoconical interior passageway tapering inwardly from the first portion toward the hub. A supplementary metallic frustoconical sleeve (78) is fixed within the second element interior so as to open outwardly toward the first element and enclose the cannula point.

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MEDICAL VALVE**Background of the Invention****Field of the Invention:**

5 The present invention relates to a valve for medical use in a fluid conduit to prevent the back-flow of blood or other fluid upstream of the valve and is particularly adapted for use in multiple inlet connectors such as Y-side ports.

Description of the Prior Art:

10 U.S. Patent No. 4,512,766, issued April 23, 1985 to Vincent L. Vailancourt, discloses a valve mechanism for catheter use to avoid fluid backflow, including an elastomeric self-sealing valve element which may be pierced by an external needle used to insert a catheter. In an
15 alternate embodiment, the valve element is pre-slit and is opened by an internal insert tube when the valve element is compressed by an external adaptor fitted, for example, on a medication administration set.

Summary of the Invention

20 According to the present invention, a valve for medical usage within a rigid fluid conduit has, as a first component, a hub fixed within the conduit so as to hold a cannula so that the cannula lumen opens onto a point which points away from the hub and, as a second component, an
25 elongated flexible valve element having a first solid frustoconical portion which tapers from a base which forms an internal seal at the conduit to a top, a second hollow valve portion element which is at least in part frustoconical with its base formed on a first element top
30 so as to continue the frustoconical taper, and a third portion which is cylindrical and connected to the second portion so as to extend away from said second portion and

terminate in a valve outlet, the first, second, and third portions being axially aligned with one another, and in which the third portion has a longitudinal passage extending therethrough so as to be in direct communication with and axially aligned with the interior of the second portion, the second portion interior being generally frustoconical so as to open outwardly between the third portion and the first portion, and within which a rigid supplementary frustoconical sleeve is disposed so as also to open outwardly between the third portion and the first portion, and in which the third portion is attached to the hub so that the valve first and second portions normally enclose the cannula and the valve third portion forms an internal seal of the conduit at the conduit inlet by extending slightly beyond the conduit inlet.

Brief Description of the Drawing

The medical valve of the present invention is illustrated in the accompanying drawing, in which like numerals indicate like parts, and in which:

Fig. 1 is a isometric view of the Y-side port for use with a medical valve according to the present invention;

Fig. 2 is a cross-sectional view of a port body for the connector as shown in Fig. 1;

Fig. 3 is a cross-sectional view of a needle and hub assembly for use in the medical valve of the present invention;

Fig. 4 is a cross-sectional view of a valve element for use in the medical valve of the present invention;

Fig. 5 is a cross-sectional view of the components illustrated in Figs. 3,4, and 5 assembled in the body of Fig. 2 and ready to receive a medical device having a female Luer fitting; and

Fig. 6 is a cross-sectional view of the device of Fig. 5 with a female Luer fitting attached to; open the

valve; and

Fig. 7 is a cross-sectional view of the device shown in Fig.5 illustrating its configuration in use for receiving an external cannula.

5 **Detailed Description of the Preferred Embodiment**

Referring now to Fig. 1, there is shown, in perspective, a Y-side port type connector 10 for use with a medical valve according to the present invention. The port 10 has a body 11 from which extended an outlet arm 12, a first inlet arm 14, and a second inlet arm 16. Luer-type lock lugs 18 (only one of which is shown in Fig.1) extended outwardly from the first arm 14 for use in attaching other medical devices to the arm 14. If desired, the lugs 18 may be omitted, or similar lugs may be added to the other arms 12, 16. As is seen in Figure 1, the first arm 14 and second arm 16 intersect one another at an acute angle and the arm 14 is generally longitudinally aligned with the out let arm 12. Any other configuration may be equally used with respect to the present invention, or the arm 16 omitted if multiple inlets are not desired.

Referring now to Fig. 2, there is shown, in section the body portion 11 of the port 10 shown in Fig. 1. As is seen in Fig. 2, the outlet arm 12 is hollow and generally cylindrical in cross-section with a passage 20 extending from an outlet 22 formed on the outlet arm 12 inwardly toward the inlet arms 14, 16. the inlet arm 14 has a passage 24 which extends from a first arm inlet 26 toward the outlet arm passage 20. The second inlet arm 16 has a second arm inlet 28, from which a second inlet passage 30 extend toward the outlet passage 20. The outlet passage 20 and inlet passages 24, 30 meet in a central chamber 32. For the particular embodiment shown in Fig. 2, the central chamber 32 is axially aligned with first inlet arm passage 24 and the outlet arm passage 20. The second inlet arm passage 30 communicated with the central chamber 32 through a chamber extension 32A. Obviously, it is not necessary

that the outlet arm 12 be aligned with either of the inlet passages 24, 30, so long as the three passages 20, 24 and 30 communicate directly with one another, such as by the central chamber 32 and chamber extension 32A shown in Fig. 2.

Fig. 3 is a cross-sectional view of a cannula 34 and hub 36 for use in the port body 11 by being fixed in the first outlet arm passage 24. As will be seen in Fig. 2, the first inlet arm passage 24 communicated with the central chamber 32 through a connecting passage 36 which tapers inwardly from the first inlet arm passage 24 to the central chamber 32. An annular lip 38 is formed in the connecting passage 36. The cannula 34 is mounted on a hub 40 which has a body portion 42 formed on the cannula opposite the cannula's point 44. The cannula has a lumen 46 which extends through the cannula from the point 44 to a cannula end 48 opposite the point 44. The hub 40 has a body portion 50 which is mounted about the cannula end 48. The body portion 50 tapers outwardly to a shoulder 52, on which an peripheral ring 54 is formed. As will be seen with respect to Fig. 5, the peripheral ring 54 engages the annular lip 38 on the body 11 so; as to lock the hub end 40 and so the cannula 34 within the first inlet arm passage 24.

Referring now to Fig. 4, there is shown an elongated valve element 56 for use in the present invention. The valve element 56 may typically be constructed of an elastomeric material such as latex commonly used in medical application. As is seen in Fig. 4, the valve element 56 has a first portion 58 which is generally frustoconical in shape so as to taper from a base 60 forming a first end of the valve element 56 to a top 62. The valve element 56 has a second portion 64 which is generally frustoconical in exterior configuration over the majority of its length and tapers from the top 62, which forms the base of the second portion 64, to a second portion top 66, shown in dotted lines in Fig. 4. The valve element 56 has a third portion

68 which is generally cylindrical in configuration and extends from the second portion top 66 to a second end 70 of the valve element 56.

As will be seen in Figure 4, the third portion 68 has a cylindrical passageway 74 extending therethrough from the valve element second end 70 to the second portion top 66. The second portion 64 has an interior passageway 76 which is generally frustoconical in shape over most of its length so as to taper outwardly between a shoulder 72 formed adjacent the second portion top 66 and the first portion top 62. In the particular embodiment shown, the cylindrical passage from the third portion passage 74 extends onward into the interior of the second portion 64 a short distance before opening onto the should 72 in the second portion interior passageway 76. The valve portions 58, 64, 68 are axially aligned with one another and provide a central passageway consisting of the passageways 74, and 76, within which the hub 40 and cannula 34 are disposed, as shown in Fig. 5

Seated within the cylindrical passageway 76 against the shoulder 72 is a frustoconical sleeve 76 which preferably is made of stainless steel. The frustoconical sleeve 78 has an exterior surface which conforms with the interior surface 80 of the passageway 76.

Referring now to Fig. 5, there is shown a side elevational view of the port 10 adapted for use with respect to the attachment to the inlet arm 12 of a Luer-type fitting 82 from which a surgical tube 84 of conventional construction extends so as to selectively apply fluid to the fitting 82. The fitting 82 has a female Luer thread 86 which engages the lug 18 on the port 10 shown in Fig. 1. The Luer-type fitting 82 has a nose 88 of conventional construction, *i.e.*, slightly tapered, through which a passageway 90 extends in communication with the surgical tubing 84. The port 10 has a surgical-type outlet tube 92 extending through the outlet 22 of the outlet arm 12 so as to be in communication with the outlet bore 20.

A surgical type inlet tube 94 is similarly connected to the second inlet arm 16 so as to provide a source of fluid to the central chamber 32.

5 A valve 100 according to the present invention is shown disposed within the first inlet arm bore 24. The valve 100 is seen to consist of the cannula 34 and hub 40 shown in Fig. 3 disposed within the valve element 56 shown in Fig. 4. As will be seen in Fig; 5, the valve element first portion 58 at its base 60 is at lease even with and should extend slightly beyond the inlet 26 of the inlet arm 14. By slightly extending beyond the inlet 26, rather than being recessed therein as is the case in the prior ar, the base 60 can be readily swabbed with disinfectant prior to use to insure sterility during the utilization of the valve 100, as described with respect to Fig. 6.

10 Referring now to Fig. 6, the port 10 shown in Fig. 5 is shown with the Luer fitting 82 attached to the first inlet arm 14. In the attachment process, the Luer fitting nose 88 presses against the base 60 of the valve element first portion 58 so as to compress the valve element third portion 68 against the hub 40 and the interior surface of the first inlet arm bore 24 at the connecting passage 36. This compression of the valve element third portion 68 permits the Luer fitting nose 88 to force the valve element first portion 58 onto the point 44 of the cannula 34 and , after the point 44 pierces the first portion 58, the first portion 58 is forced inwardly along the cannula 34 so as to open a path for fluid communication from the surgical tubing 84 through the passageway 90 formed in the Luer fitting 82 and the cannula lumen 46.

20 Because the valve element 56 is formed of a flexible and resilient material, such as latex or some similar elastomeric material, removal of the Luer fitting 82 from the first inlet arm 12 decompresses the valve element third portion 68 so that the valve element first portion 58 moves outwardly away from the hub 40 to its original position as shown in Fig. 5. The first portion 58 is made of a self-

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sealing material, so that the movement of the first portion 58 off of cannula 34 and beyond the cannula point 44 then seals, once more, the fluid passageway which existed through the cannula lumen 46 in the utilization shown in Fig. 6.

5 For certain requirement, such as an emergency procedure utilizing a hypodermic syringe with an attached cannula to rapidly inject a fluid into the central chamber 32, it may be inappropriate to attempt to use the Luer-type fitting 82. The valve of the present invention permits the alternate use of an external cannula to provide a fluid passage through the valve element first portion 58 to the 10 cannula lumen 46. It is desirable to be able to insert such an external cannula within the cannula lumen 46. It is desirable to be able to insert such an external cannula 15 within the cannula lumen 46. However, the valve of the present invention obviates such a necessity while, at the same time, assisting in such an alignment if desired. In this regard, referring now to Fig. 7, there is shown a partial sectional view of the inlet arm 14 and valve 56. 20 In Fig. 7. and external cannula 102 which may be attached, for example, to a hypodermic syringe, is shown as having been inserted into the frustoconical passageway 76 formed within the valve element second portion 64. The frustoconical sleeve 78 guides the external cannula 102 to 25 a position adjacent the valve cannula 34. In an instance, such as in illustrated in Fig.7, whether, because of the emergency nature of the procedure being performed or otherwise, the cannula 102 is not centered in the valve element first portion 58, the piercing of the valve element second portion inner surface 80 is avoided by the sleeve 78 30 guiding the cannula point 104 along its inner surface to the lumen 46 of the valve cannula 34. The contents of the syringe may then be expelled through the external cannula 102 into the second element passageway 76 even if the user 35 fails to properly align the external cannula 102 with the valve cannula lumen 46 so as to be able to directly insert

the external cannula 102 into the lumen 46. The user simply need insert the external cannula 102 until resistance is felt by reason of the external cannula 102 reaching the valve cannula 34 or the frustoconical sleeve 78, and then proceed to expel the contents of the hypodermic syringe, confident that the contents will pass through the valve cannula 34 into the central chamber 32 and then out the outlet arm 20 into the outlet tube 92.

The valve assembly 100 has been described heretofore in a particular embodiment specifically adapted for use in a Y-side port. However the valve assembly 100 and accompanying components, may be generally used in the medical field for various fluid transfer applications. Consequently, the present invention, in its broadest implementation, is not limited to use in a Y-side port. The various components of the port are molded from conventional medical grade plastics. For example, valve element 56 may be molded of medical grade latex, such as 7377-30 gum formulated to 80 Shore A durometer hardness, formulated and molded by West Company of Philadelphia, Pennsylvania. the port body 11 may be injection molded from medical grade polypropylene, such as grade PD-626 Pro-fax polypropylene distributed by Himont U.S.A., Inc. of Wilmington Delaware. The sleeve 78 and cannula 34 may be made of #304 Stainless steel. The needle hum 26 may be injection molded from medical grade polypropylene or from medical grade polycarbonate, such as from Calibre® 200-15 polycarbonate resin manufactured by Dow Chemical Company of Midland, Michigan. The foregoing materials are described by way of example only, and are not intended to constitute limitations upon the practice of the present invention, as defined in the following claims.

CLAIMS

1. A medical valve for use in a conduit comprising:
a hub;

means for fixing said hub within the conduit so
5 as to hold a cannula with a point within the conduit with
its point pointing in a first direction;

an elongated flexible valve element having:

a first portion which is solid and is
generally frustoconical along at least a major part of its
10 length and tapers from a base forming a first end of the
element to a top;

a second portion which is hollow and is
generally frustoconical along at least a major part of its
length and is axially aligned with the first portion so as
15 to taper from a second portion base coincident with the
first portion top to a second portion top; and

a third portion which is hollow and is
generally cylindrical along at least a major part of its
length and is axially aligned with the second portion and
20 extending from said second portion top away from said first
portion to a valve element second end opposite said first
end, the third portion having a longitudinal passageway
extending between the second end and the second portion and
in which said second portion has a longitudinal passageway
25 extending therethrough in direct communication with and
axially aligned with said third portion passageway, said
second portion passageway being generally frustoconical
over at least a substantial part of its length so as to
open outwardly from the third portion toward the first
30 portion and contain said cannula point; and

means for attaching the valve to the hub so that
the valve element is disposed in the conduit and the third
valve portion normally closes the conduit.

2. A medical valve according to Claim 1, and
35 including a supplementary frustoconical sleeve disposed
within the frustoconical interior of the second valve

portion passageway so as to open outwardly away from the third valve portion toward the first valve portion.

5 3. A medical valve according to Claim 2, and in which the valve is attached to the hub adjacent the third valve element second end.

4. A medical valve according to Claim 3, and in which the valve element is attached to the hub by the engagement of the valve element second end with an annular recess formed on the hub.

10 5. In a medical connector having a connector body with an outlet arm having an outlet and at least one inlet arm having an inlet, and in which the inlet arm and the outlet arm each have a passage extending therethrough in communication with one another to provide a fluid
15 passageway between the inlet and the outlet, the combination of:

a hub fixed within the inlet arm passage so as to hold a cannula within the inlet arm so that the cannula is aligned to point away from the outlet;

20 an elongated flexible valve element having:
a first portion which is solid and generally frustoconical in shape over at least the majority of its length so as to taper from a base of a first diameter to a top of a second diameter, smaller than said
25 first diameter,

a second portion which is hollow and generally frustoconical over at least the majority of its length and having a base of said second diameter formed at said first portion top and axially aligned with said first
30 portion so as to taper away from said first portion base to a second portion top of a third diameter, smaller than said second diameter; and

a third portion which is generally cylindrical along at least the majority of its length and is connected to said second portion top so as to extend
35 away from said second portion to a valve outlet end, said first, second, and third portions being axially aligned

with on another;

and in which the third portion has a longitudinal passage extending therethrough of a fourth diameter and said second portion has a longitudinal passage extending therethrough so as to be in direct communication with and axially aligned with said third portion passage, said second portion passage being generally frustoconical over a substantial part of its length so as to open outwardly between said third portion passage and the top of the first portion in axial alignment with said third portion passage;

a rigid frustoconical sleeve disposed within the second portion passageway so as to open outwardly between the third portion and the first portion and enclose one end of the cannula; and

means for attaching the valve to the hub so that the valve normally seals the inlet.

6. A connector according to Claim, and in which the means for attaching the valve element to the hub includes the outlet end.

7. A connector according to Claim 6, and in which the outlet end engages an annular recess formed on the hub.

8. A connector according to any of Claim 5, 6, or 7, and in which the first valve portion extends at least to the inlet arm inlet.

9. A connector according to Claim 8, and including a second inlet arm attached to the connector body and having a passageway therethrough which joins the fluid passageway downstream of the hub.

10. In a Y-side port type medical connector having a connector body with at least one inlet arm with an inlet passage terminating in an inlet and an outlet arm with an outlet passage terminating in an outlet, and in which the inlet arm passage is of generally circular cross-section over the majority of its length and extends from the inlet through the inlet arm so as to be in fluid communication with the outlet passage, the combination of:

a hub fixed within the inlet arm passage so

as to hold a cannula within the inlet arm, the cannula thereby being axially aligned with the inlet arm, the cannula having a lumen which opens onto a point which points away from the outlet arm;

5 an elongated valve element having:

a first portion which is generally frustoconical in shape and tapers from a base which is solid and of a first diameter to a top which is solid and of a second diameter, smaller than said first diameter,

10 a second portion which is generally frustoconical in shape over the majority of its length and tapers from a base at the top of the first portion of said second diameter to a second portion top of a third diameter, smaller than said second diameter; and

15 a third portion disposed on said second portion top so as to extend away from said second portion and which is generally cylindrical with an outer diameter which is not substantially greater than the third diameter, said first, second and third portion being axially aligned with one another;

20 and in which the third portion has a longitudinal passage extending therethrough and said second portion has a longitudinal passage formed therein which is at least in part frustoconical in shape and is in direct communication and axially aligned with said third portion passage so that
25 said frustoconical part opens outwardly between said third portion and the top of the first portion;

30 a frustoconical metallic sleeve disposed within the frustoconical part of the second portion passage in axial alignment therewith so as to open outwardly between the third portion and the first portion, said metallic sleeve having an outer surface generally continuously in shape to the frustoconical part of the second portion passage; and

35 means for attaching the valve to the hub so that the valve element third portion normally seals the inlet arm passage at the inlet.

11. A connector according to Claim 10, and in which

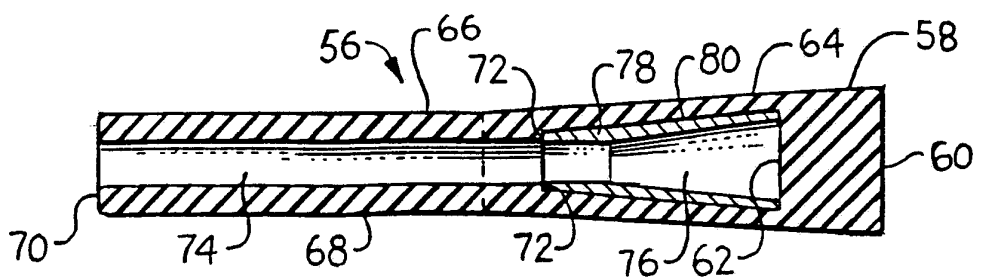
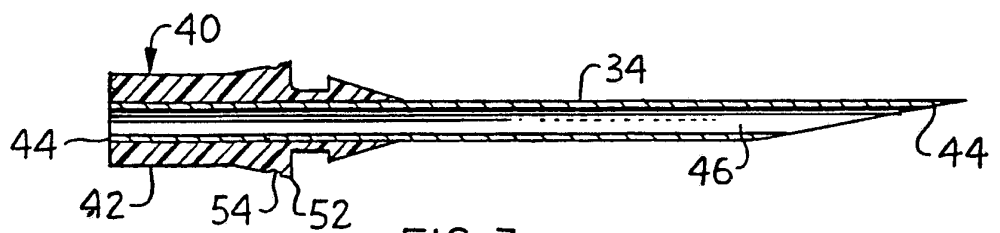
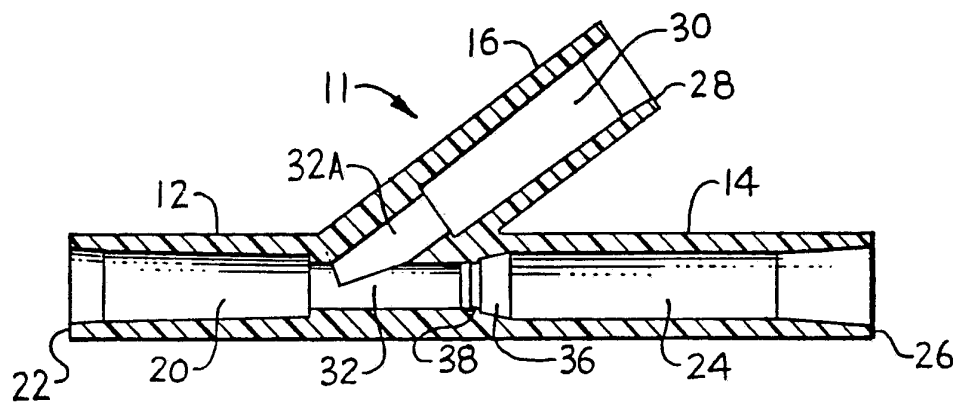
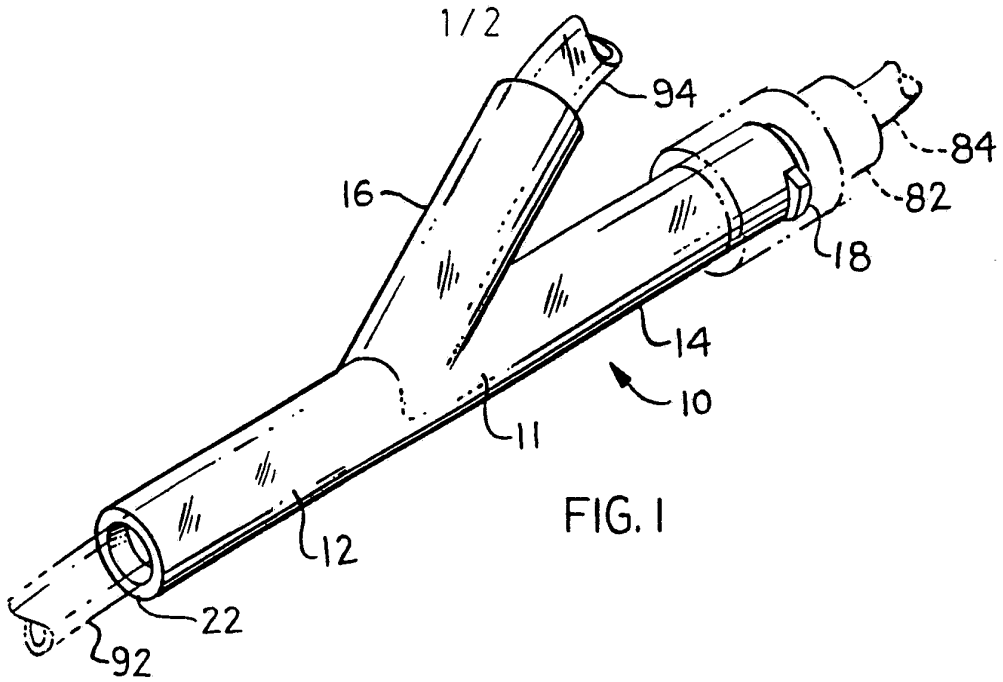
the valve element second portion frustoconical passage terminates in a shoulder adjacent said valve element third portion, against which shoulder the sleeve is seated.

5 12. A connector according to Claims 10 or 11, and in which the valve element first portion extends at least slightly externally at the inlet arm inlet.

10 13. A connector according to Claim 12, and in which the means for attaching the valve element to the hub includes an end of the valve element third portion remote from the valve element second portion.

14. A connector according to Claim 13, and in which the valve element third portion remote end engages an annular recess formed on the hub.

15 15. A connector according to Claim 14, and including at least one additional inlet arm attached to the connector body and having an inlet passage which joins the outlet passage upstream of the outlet and downstream of the hub.



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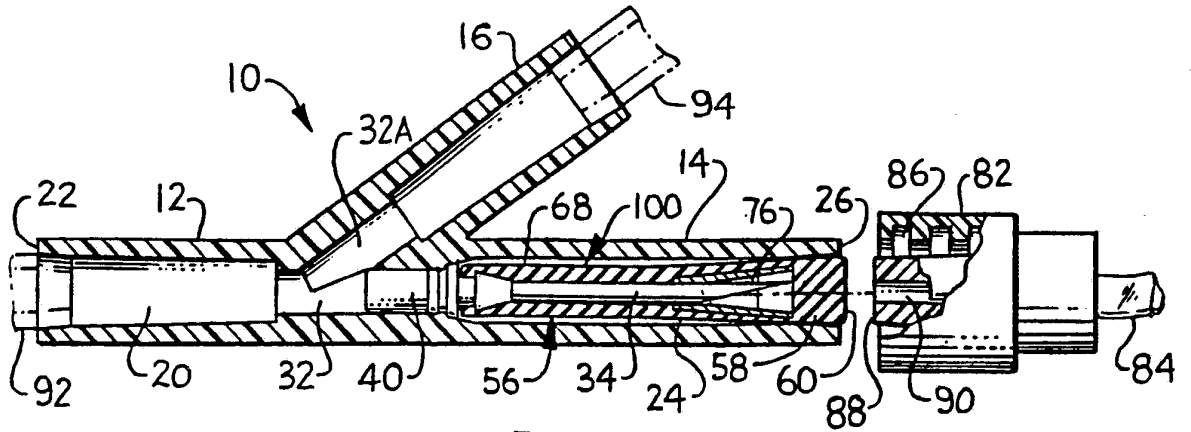


FIG. 5

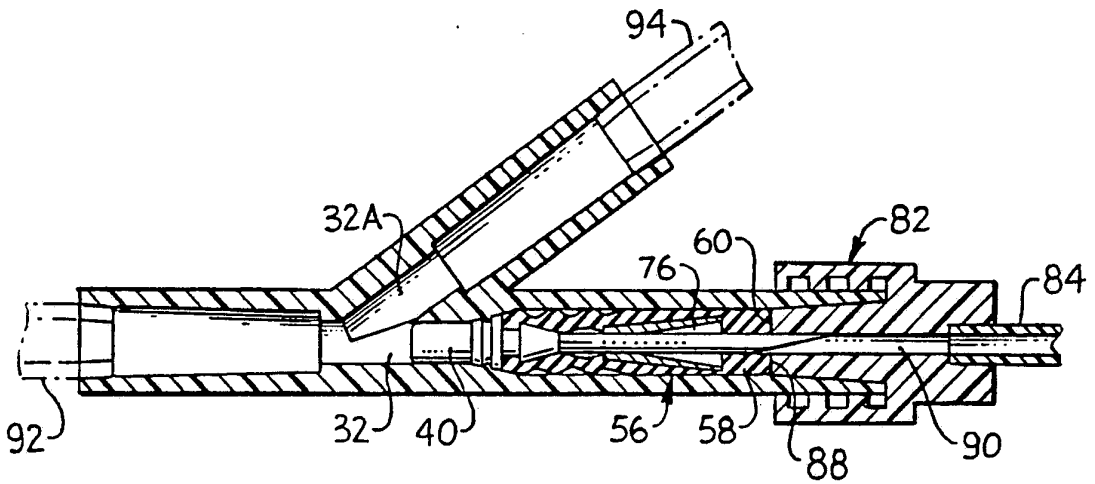


FIG. 6

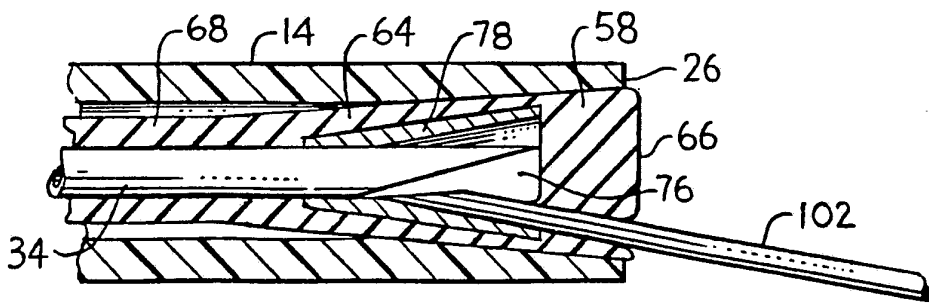


FIG. 7

INTERNATIONAL SEARCH REPORT

 Internauonal application No.
 PCT/US93/02150

A. CLASSIFICATION OF SUBJECT MATTER		
IPC(5) :A61M 5/32 US CL :604/83 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED		
Minimum documentation searched (classification system followed by classification symbols) U.S. : 604/83,86-88,167,224,246,256,283,905; 251/149.7; 137/68.1		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) N/A		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US,A, 5,122,123 (VAILLENCOURT) 16 JUNE 1992 See figures 6 and 7	1-15
A	US,A, 4,121,585 (BECKER, JR.) 24 OCTOBER 1978 See figures 3-5	9,15
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
* "A"	Special categories of cited documents: document defining the general state of the art which is not considered to be part of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search 31 MAY 1993	Date of mailing of the international search report 24 JUN 1993	
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. NOT APPLICABLE	Authorized officer <i>Mary Beth Jones</i> MARY BETH JONES NGUYEN NGOC-HO INTERNATIONAL DIVISION Telephone No. (703) 308-0858	