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Attorneys for Plaintiff CareFusion 303, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

CareFusion 303, Inc.,

Plaintiff,

v.

B. Braun Medical, Inc.,

Defendant.

Case No. SACV11-01264 CJC (RNBx)

COMPLAINT FOR PATENT INFRINGEMENT OF U.S. PATENT NOS. 5,782,816 AND 5,730,418

DEMAND FOR JURY TRIAL

Plaintiff CareFusion 303, Inc. (hereafter "CareFusion 303" or "Plaintiff"), by its undersigned counsel, hereby brings this action against B. Braun Medical, Inc. (hereafter "B. Braun" or "Defendant") and alleges as follows:

PARTIES

1. CareFusion 303 is a Delaware corporation. It is a wholly owned subsidiary of CareFusion Corporation. CareFusion Corporation is a public Delaware corporation with its headquarters at 3750 Torrey View Court, San Diego, CA 92130. CareFusion 303 also has its principal place of business at 3750 Torrey View Court, San Diego, CA 92130. In 2009, CareFusion Corporation was created from Cardinal Health, Inc.'s clinical and medical products business.

2. CareFusion delivers clinically proven products and services that help measurably improve patient care in the medical field. Its family of products and services are used in more than 120 countries.

3. With fiscal 2010 pro forma revenue of $3.9 billion, CareFusion Corporation is the largest medical-technology company focused on helping the global healthcare industry solve its most challenging patient safety issues.

4. Defendant is a Pennsylvania corporation with its principal place of business in Bethlehem, Pennsylvania.

5. At all material times hereto, Defendant has manufactured, distributed, marketed, offered for sale and sold products, including but not limited to the infringing ULTRASITE® Capless Valve System and CARESITE® Luer Access Device, in this judicial district and elsewhere in the United States.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. The Court has federal question jurisdiction under 28 U.S.C. § 1331 and exclusive original jurisdiction under 28 U.S.C. § 1338(a).

7. This Court has personal jurisdiction over Defendant in this action because Defendant, directly and/or indirectly through its subsidiaries and affiliated companies, has engaged in substantial business within this forum amounting to sufficient minimum contacts, including, but not limited to, distributing, marketing, using, selling, and/or offering to sell products and services in California and this juridical district, and employment of personnel within this judicial district. Defendant has operated a manufacturing facility in Irvine, California, within this judicial district, for over 30 years, presently employing over 1000 people. Defendant also has availed itself of the laws of California and previously submitted itself to the jurisdiction of this Court by filing suit in this Court, and has admitted to having sufficient contacts with this jurisdiction for purposes of litigation. *See,*

e.g., Complaint, Dkt. No. 1, *B. Braun Medical, Inc. v. Westchester Med. Ctr.*, Case No. 8:99-cv-01010 (complaint filed August 6, 1999).

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 5,782,816

9. Plaintiff repeats and realleges the allegations of paragraphs 1 through 8 as if set forth herein.

10. U.S. Patent No. 5,782,816 ("the '816 Patent"), entitled "Bi-Directional Valve and Method of Using Same," was duly and legally issued on July 21, 1998, by the United States Patent and Trademark Office. CareFusion 303 has been assigned the entire right, title and interest in the '816 Patent. A true and correct copy of the '816 Patent is attached hereto as Exhibit A.

11. Defendant has infringed and continues to infringe the '816 Patent by making, using, selling and/or offering to sell within the United States (including within this judicial district) devices that embody the inventions disclosed and claimed in the '816 Patent, and/or importing into the United States devices that embody the inventions disclosed and claimed in the '816 Patent, without authorization from CareFusion 303. At least Defendant's ULTRASITE® Capless Valve System and CARESITE® Luer Access Device directly infringe the claims of the '816 Patent, in violation of 35 U.S.C. § 271. For example and not limitation, Defendant's ULTRASITE® and CARESITE® devices practice each of the limitations of at least independent claim 1 of the '816 Patent.

12. In addition to direct infringement, CareFusion 303 is informed and believes, and on that basis alleges, that Defendant has indirectly infringed and continues to indirectly infringe the '816 Patent by contributing to infringement by others of the '816 Patent, and by knowingly inducing others to infringe the '816 Patent. For example and not limitation, Defendant sells and offers to sell within the United States or imports into the United States devices and/or components of

patented devices knowing the same to be especially made or especially adapted for use in an infringement of the '816 Patent. Such devices and/or components are not staple articles or commodities of commerce, nor are they suitable for substantial noninfringing use. Defendant also actively induces infringement of the '816 Patent by its customers and/or others, including, for example and not limitation, by providing written instructional documents and instructional videos directing customers to use Defendant's ULTRASITE® and CARESITE® devices in a manner that directly infringes the '816 Patent.

13. Further discovery may reveal that Defendant's infringement of the '816 Patent has been and continues to be willful.

14. CareFusion 303 has been and will continue to be damaged by Defendant's infringement of the '816 Patent and will be irreparably harmed unless that infringement is enjoined.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 5,730,418

15. Plaintiff repeats and realleges the allegations of paragraphs 1 through 14 as if set forth herein.

16. U.S. Patent No. 5,730,418 ("the '418 Patent"), entitled "Minimum Fluid Displacement Medical Connector," was duly and legally issued on March 24, 1998, by the United States Patent and Trademark Office. An *ex parte* re-examination certificate was duly and legally issued by the United States Patent and Trademark Office on April 11, 2006. CareFusion 303 has been assigned the entire right, title and interest in the '418 Patent. A true and correct copy of the '418 Patent is attached hereto as Exhibit B.

17. Defendant has infringed and continues to infringe the '418 Patent by making, using, selling and/or offering to sell within the United States (including within this judicial district) devices that embody the inventions disclosed and claimed in the '418 Patent, and/or importing into the United States devices that embody the inventions disclosed and claimed in the '418 Patent, without

authorization from CareFusion 303. At least Defendant's ULTRASITE® Capless Valve System and CARESITE® Luer Access Device directly infringe the claims of the '418 Patent, in violation of 35 U.S.C. § 271. For example and not limitation, Defendant's ULTRASITE® and CARESITE® devices practice each of the limitations of at least independent claim 27 of the '418 Patent.

18. Defendant's infringement of the '418 Patent has been and continues to be willful and carried out with full knowledge of the '418 Patent. Defendant had knowledge of the '418 Patent not later than early 2006, and was notified that its ULTRASITE® device infringes the '418 Patent not later than December 20, 2007.

19. CareFusion 303 has been and will continue to be damaged by Defendant's infringement of the '418 Patent and will be irreparably harmed unless that infringement is enjoined.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

1. A judgment that Defendant has infringed the '816 and '418 Patents;

2. A permanent injunction issued pursuant to 35 U.S.C. § 283, restraining and enjoining Defendant and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from infringement of the '816 and '418 Patents for the full terms thereof;

3. An award of damages to Plaintiff including lost profits and interest thereon, but in any event no less than a reasonable royalty, in an amount adequate to compensate for Defendant's infringement of the '816 and '418 Patents, and, upon a finding of willfulness, that the damages be trebled pursuant to 35 U.S.C. § 284;

4. A declaration that this is an exceptional case and an award of attorney's fees, disbursements, and costs of this action pursuant to 35 U.S.C. § 285; and,

5. Such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

CareFusion 303 demands a trial by jury for all issues so triable pursuant to Federal Rule of Civil Procedure 38(b).

Respectfully submitted,

Dated: August 23, 2011

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By: Amar L. Thakur
AMAR L. THAKUR
Attorneys for Plaintiff CareFusion 303, Inc.

EXHIBIT A

US005782816A

United States Patent [19]

Werschmidt et al.

[11] **Patent Number: 5,782,816**

[45] **Date of Patent: Jul. 21, 1998**

[54] **BI-DIRECTIONAL VALVE AND METHOD OF USING SAME**

[75] Inventors: **Gary S. Werschmidt**, Yorba Linda; **Raymond P. Feith**, Rialto, both of Calif.; **David R. Kipp**, 2371 Edna Way, Upland, Calif. 91784

[73] Assignee: **David R. Kipp**, Upland, Calif.

[21] Appl. No.: **525,837**

[22] Filed: **Sep. 7, 1995**

[51] **Int. Cl.**[6] **A61M 5/00**

[52] **U.S. Cl.** **604/256**; 604/83; 604/283; 137/903; 251/149.6; 251/149.7

[58] **Field of Search** 604/181–3, 202, 604/236, 246, 249, 250, 256–7, 283, 905, 83; 137/903; 251/149.6, 149.7

[56] **References Cited**

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Primary Examiner—Mark Bockelman
Attorney, Agent, or Firm—Richard L. Myers

[57] **ABSTRACT**

A connector adapted to facilitate medicinal access into an intravenous tube includes a housing having a base and a cap defining a channel through the housing. A valve element disposed in the channel includes a plug and elastomeric shaft which biases the plug into sealing engagement with the housing. Operation of the connector by inserting a male Luer fitting in the housing axially compresses the valve element to a canted position thereby permitting medicinal access through the channel and into the intravenous tube. Canting of the valve element can be facilitated by providing a finger along the channel or by providing a predetermined buckling section along the valve element. The shaft of the valve element can be rounded and disposed in an arcuate cavity of the housing to further facilitate canting of the valve element.

24 Claims, 5 Drawing Sheets

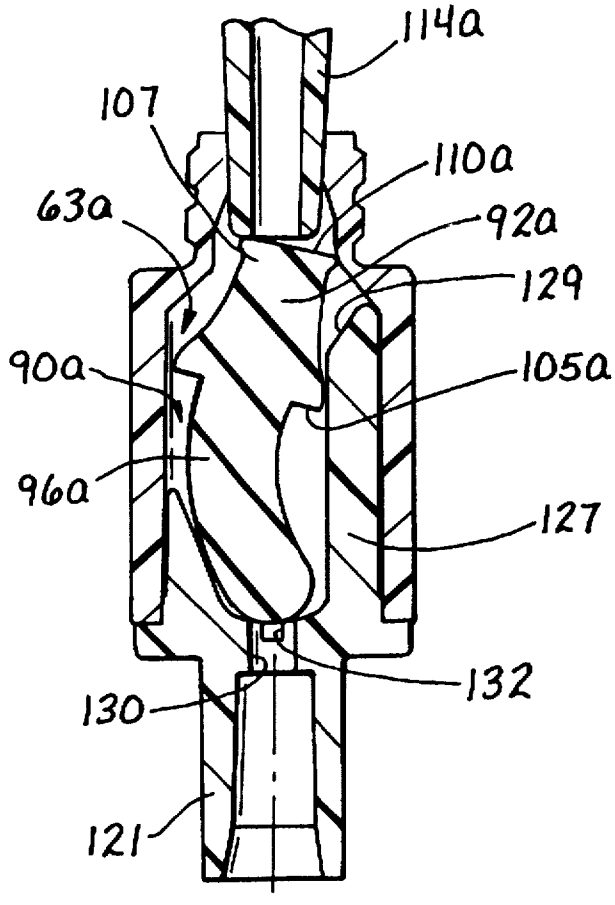

FIG. 1

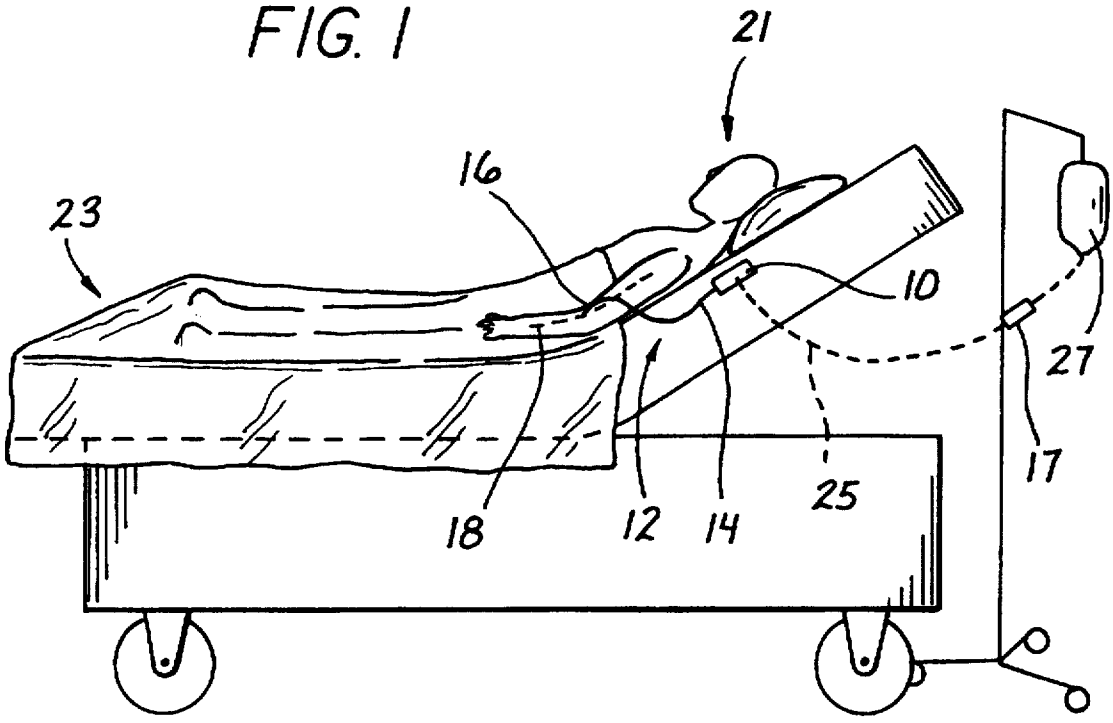
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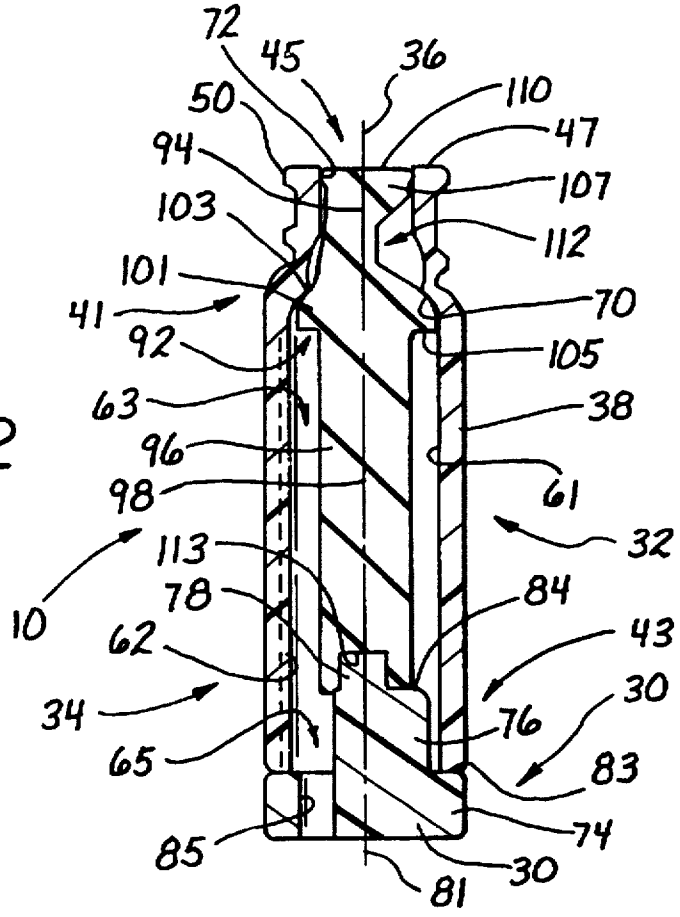
FIG. 2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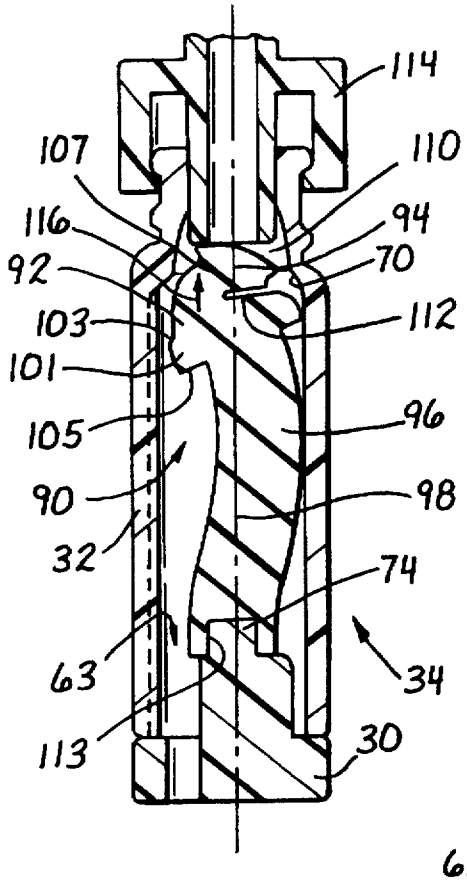
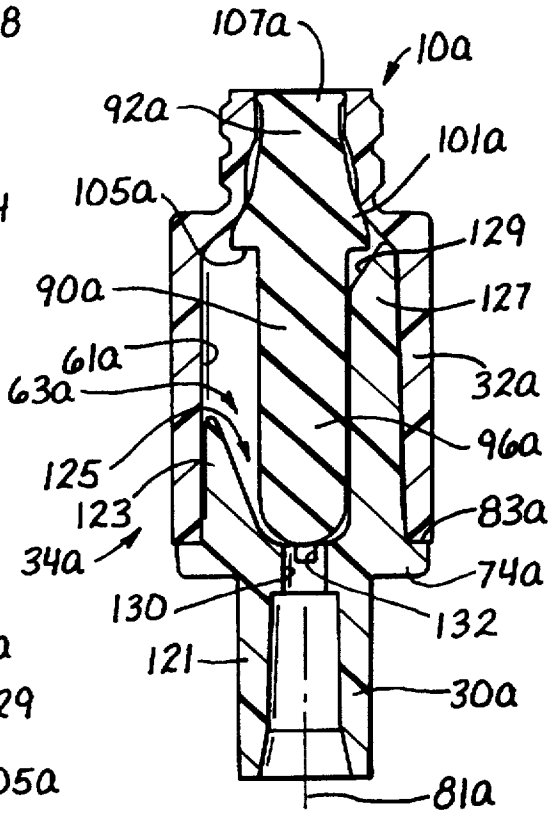


FIG. 3



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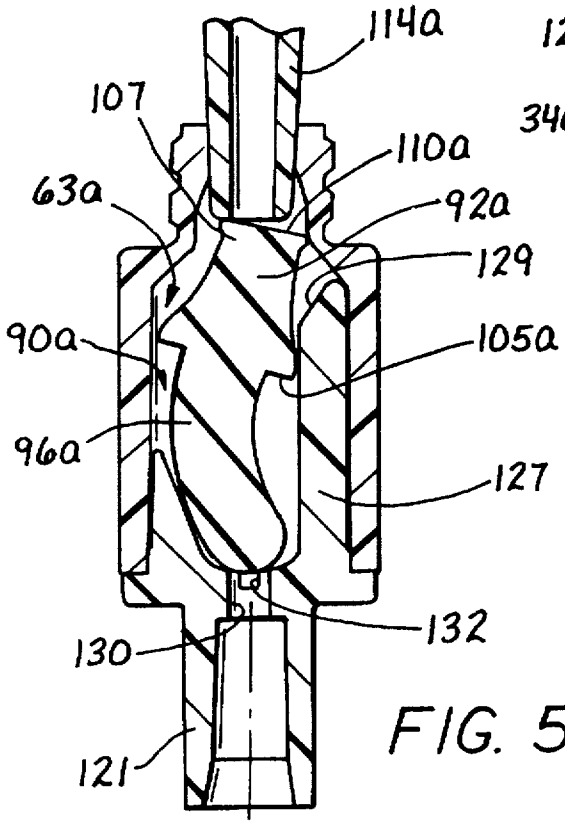

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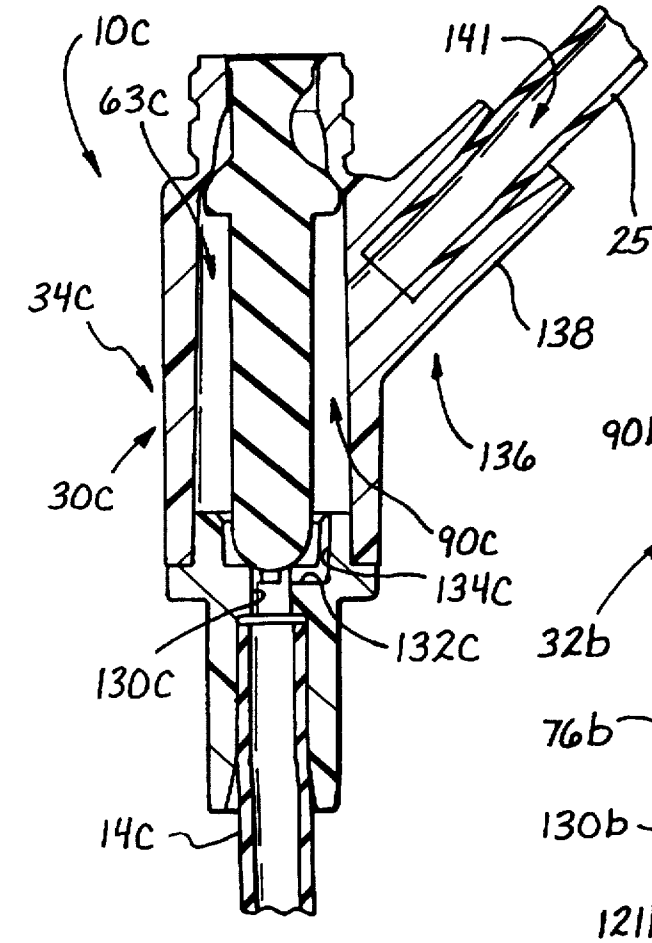

FIG. 7

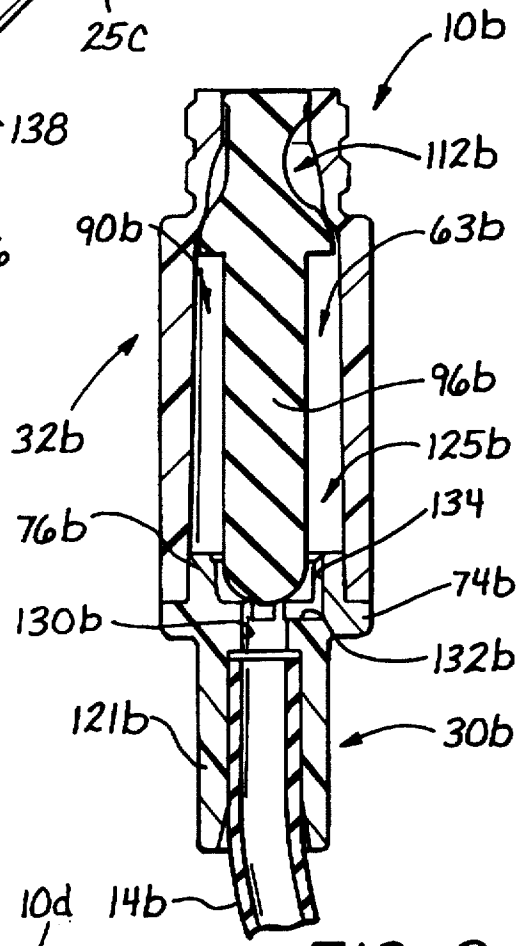

FIG. 6

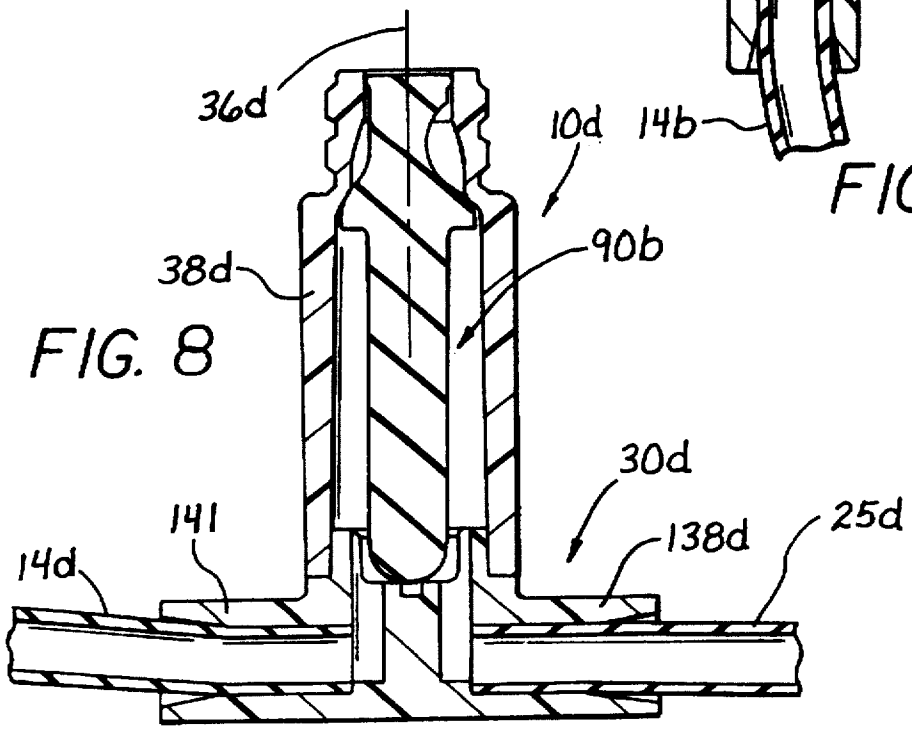

FIG. 8

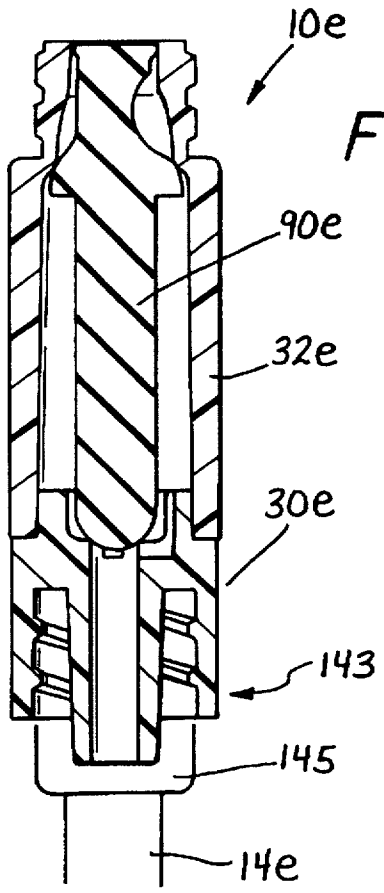

FIG. 9

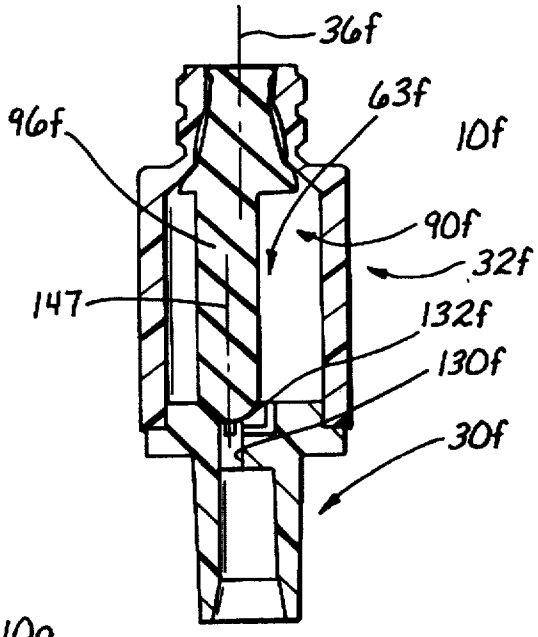

FIG. 10

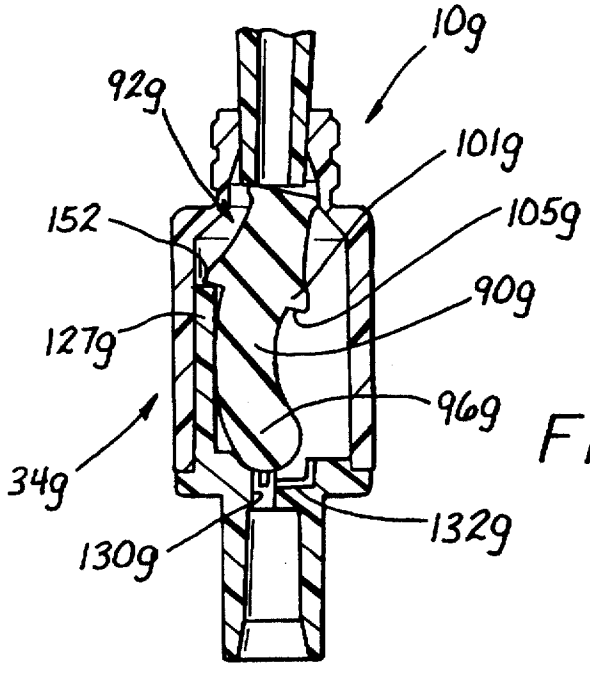

FIG. 11

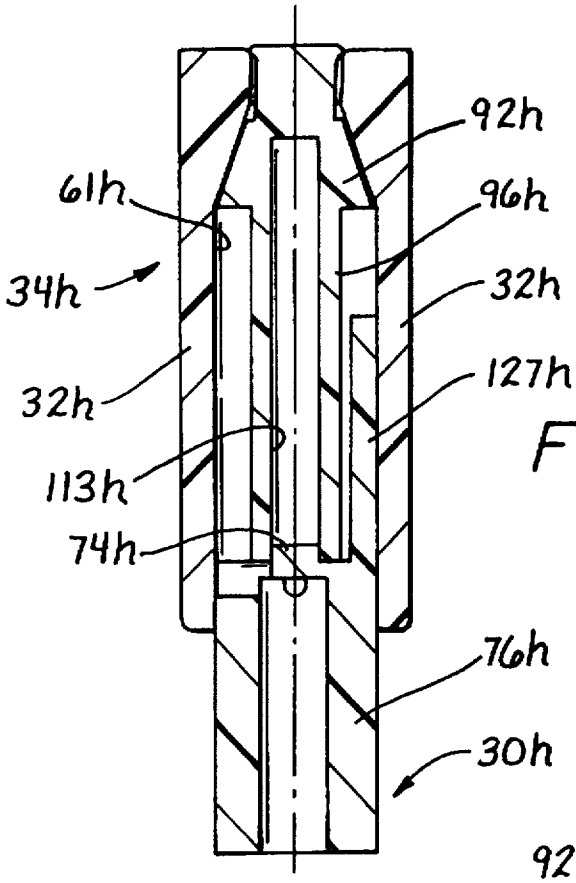

FIG. 12

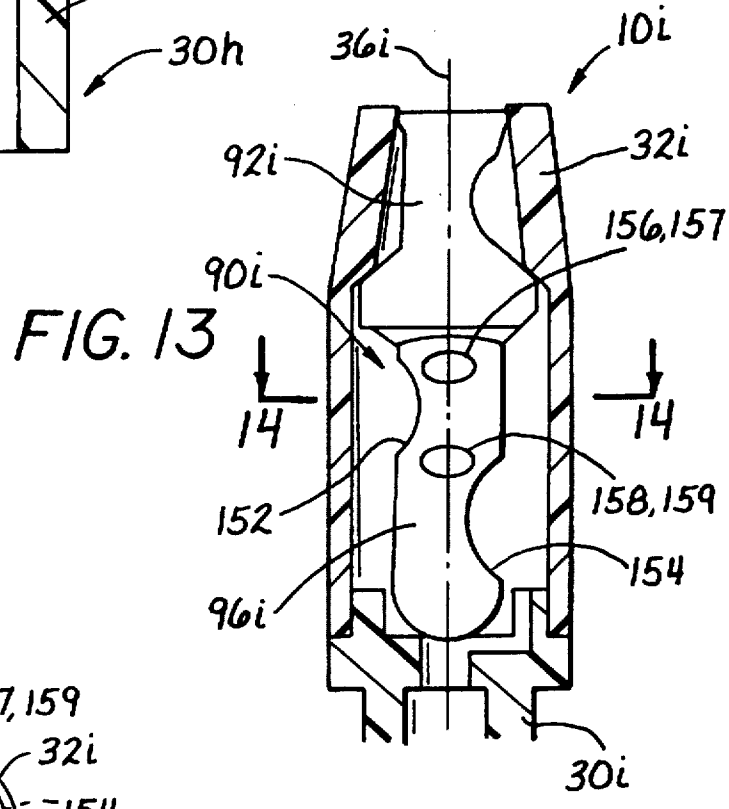

FIG. 13

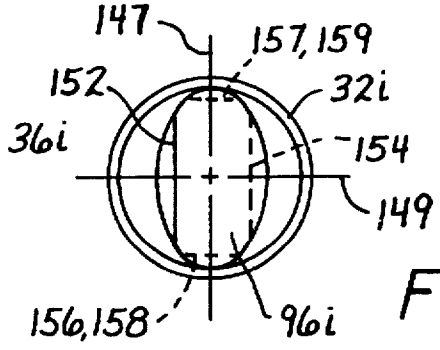

FIG. 14

BI-DIRECTIONAL VALVE AND METHOD OF USING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates generally to fluid delivery devices and more specifically to valves, access parts, and other connectors for use in introducing medication and fluids into a patient and for removing fluids from the patient.

2. Description of the Prior Art

When it is contemplated that a patient will require multiple injections into the vascular system, an intravenous tubing set is commonly used. This set will typically include a primary needle or catheter which provides access to the vascular system, and a connector which is coupled to the needle through tubing. This connector can be repeatedly accessed by a medication delivery apparatus, such as a syringe, having a secondary needle. With this tubing set, the trauma to the patient is reduced to a single puncture of the vascular system by the primary needle. Repeated use of the secondary needle for introducing fluids into the connector does not result in additional trauma to the patient.

In some cases, the connector forms an injection site, a PRN adapter, or PRN extension set in which case the medication is added to a constant flow of nutrients or other intravenous solutions through the connector. In such applications, the intravenous solution flows from an elevated container through the connector and into the primary needle. Medications are typically added to this intravenous solution at the connector.

These types of connectors generally include a sealed entry port which communicates through the tubing and the needle into the vascular system of the patient. This sealed entry port is typically constructed of a latex plug sometimes referred to as a septum. Medication is introduced into the connector by penetrating the septum with the secondary needle. The latex septum is self-sealing such that the needle hole created in the septum automatically closes when the secondary needle is removed.

A major drawback of this conventional practice is associated with use of the secondary needle to puncture the septum. Once this needle is exposed to the patient's body fluids, within a distance of 36" from the insertion site, the injection is considered high risk, and the contaminated needle threatens the health care workers with disease and other life-threatening injuries.

Several devices have been developed which provide for secondary access without the use of the secondary needle. Representative of these devices in the apparatus disclosed is U.S. Pat. No. 5,242,432 issued to DeFrank which discloses a safety valve for introducing medication into a patient. Although such devices may eliminate the risk of secondary needle stick, they present other risks which relate to the pooling of fluid on or around external surfaces. Ideally, a connector or other access device should not promote pooling during the ordinary course of its use due to the potential for bacterial infection. If a reservoir or cavity is created and not cleaned, bacteria may develop in the reservoir. That bacteria could find its way into the patient's bloodstream while either administering fluids to the patient or removing the fluids from the patient.

SUMMARY OF THE INVENTION

These deficiencies of the prior art are overcome with the present invention which comprises a needleless access device which is inexpensive to manufacture, disposable and easily adaptable for use in various medical applications. This device eliminates the need for a secondary needle because it is easily connectable to intravenous administration sets and other standard medical fittings without the need for accessory components such as needles or blunt cannulas. It is simple in design and easy to disinfect, while offering a low cost of manufacture and high reliability.

The connector includes a housing which is typically formed with a base and a cap which define an interior channel that extends through the housing. A valve element, typically including a plug and a shaft is disposed along the channel. In a first natural position, the plug seals the channel. However, the plug is movable to a second position, typically by insertion of a male Luer fitting, in order to create the channel. In the second position, the valve element is canted off axis to open the channel and permit the administration of medication and other liquids into the patient's vascular system. In this canted position, a fluid path occurs along the channel between the top surface of the valve element and the interior of the housing.

The housing of the connector is free of any recesses or external crevices which might promote pooling or otherwise harbor microbes. The valve element and the housing form a substantially flat proximal surface which is easily wipeable, swabable or otherwise cleanable to disinfect the connector. Thus the connector can be decontaminated without requiring a separate cap which would otherwise elevate the cost of the device and complicate its use. The connector is easily activated by insertion of a male Luer fitting which is commonly used in tubing connections associated with intravenous delivery systems.

In one aspect of the invention, a connector is adapted to facilitate bidirectional flow between a male fitting and a receptacle. The connector includes a housing having an axis extending between a proximal end and a distal end which is attached to the intravenous tube. Portions of the housing define a valve seat at its proximal end. A valve element is disposed in the housing and has a second axis. The valve element is movable by insertion of the male Luer fitting into the housing from a first position to a second position. In the first position the valve element forms with a seal with the valve seat of the housing. The valve element in the second position is disposed with the second axis of the valve element displaced from the first axis of the housing to form a fluid channel from the male Luer fitting to the receptacle.

In a further aspect of the invention, the housing has a proximal surface at its proximal end. The valve element has a proximal surface which has a substantially planar relationship with the proximal surface of the housing to facilitate antiseptic wiping at the proximal end of the connector.

In a further aspect of the invention, the connector is adapted to facilitate access into an intravenous tube. The connector includes a housing and a valve element disposed in the housing to define with the housing a fluid channel extending between the proximal end and the distal end of the housing. The valve element has a second axis which is movable between a first position wherein the axis of the housing is aligned with the axis of the valve element to close the fluid channel and a second position wherein the axis of the valve element is displaced from the axis of the housing to open the fluid channel.

In still a further aspect of the invention, a connector is adapted to facilitate medicinal access to an intravenous tube. The connector includes a housing having a channel extending therethrough. A base forms a portion of the housing as

does a cap which has a fixed relationship with the base. A valve element disposed in the channel of the housing includes a plug and a shaft having properties for biasing the plug into sealing engagement with the housing to seal the channel in a first position of the valve element, and for being axially compressed to displace the plug from the housing and open the channel.

A method associated with the invention relates to operation of the connector when it is disposed between a male fitting and a receptacle. The method includes the steps of providing a housing having a channel, and an axis extending between a proximal end and a distal end. A valve element is positioned within the channel and biased to close the channel. The receptacle is coupled to the distal end of the housing while the male fitting is positioned to engage the valve element at the proximal end of the housing. In accordance with the method the male fitting is moved generally parallel to the axis of the housing to open the channel between the male fitting and the receptacle.

These and other features and advantages of the invention will become more apparent with a discussion of preferred embodiments and best mode of the invention, and reference to the associated drawings.

DESCRIPTION OF THE DRAWINGS

FIG. **1** is a side elevation view of a patient lying on a bed and connected to an intravenous tubing set including a connector associated with the present invention;

FIG. **2** is an axial cross-section view illustrating a preferred embodiment of the connector disposed in a normal closed state;

FIG. **3** is a side elevation view of the connector illustrated in FIG. **1**, the connector being actuated by a male Luer fitting and being disposed in an activated open state;

FIG. **4** is an axial cross-section view of a further embodiment of the connector providing for a deflection finger and having a spherical base to promote canting of a valve element;

FIG. **5** is an axial cross-section view of the connector illustrated in FIG. **4**, the connector shown in its activated open state;

FIG. **6** is an axial cross-section view illustrating a further embodiment of the connector which is attached through a base to tubing;

FIG. **7** is an axial cross-section view of a further embodiment of the connector providing for a "Y"-site connection;

FIG. **8** is an axial cross-section view of an additional embodiment of the connector, this connector being similar to that of FIG. **6** but providing for a "T"-site connection;

FIG. **9** is an axial cross-section view of a further embodiment of the connector having a base which forms a male Luer fitting;

FIG. **10** is an axial cross-section view of an additional embodiment of the connector including a housing and a valve element with a shaft in a normal state, the shaft being displaced off-axis with respect to the housing of the connector;

FIG. **11** is an axial cross section view of a further embodiment of the connector showing a valve element canted to an open state;

FIG. **12** is an axial cross section view of still a further embodiment of the connector having a valve element with a hollow shaft;

FIG. **13** is an axial cross section view of a further embodiment of the invention wherein the shaft of the valve element is sculpted to facilitate priming and provide a more predictable canting configuration and flow rate; and

FIG. **14** is a radial cross section view taken along lines **14**—**14** of FIG. **13**.

DESCRIPTION OF PREFERRED EMBODIMENTS AND BEST MODE OF THE INVENTION

A connector is illustrated in FIG. **1** and designated generally by the reference numeral **10**. The connector **10** forms part of an intravenous tubing set **12** comprising a length of tubing **14**, and a primary needle **16**. The tubing set **12** is commonly used to facilitate connection to an IV line which may have a Y-site connector **17** for the injection of fluids and medications into a vein **18** of a patient **21**. In FIG. **1**, the patient **21** is illustrated in a generally prone position on a hospital bed **23**.

Repeated injections of medications or other fluids can be administered with multiple needle sticks directly into the vein **18** of the patient **21**. However, each needle stick would be accompanied by trauma to the patient **21**. The tubing set **12** reduces this trauma by requiring only a single stick with the primary needle **16**. Then the remaining secondary needle sticks can be made through the connector **10** which accesses the vein **18** through the tubing **14**. These secondary needle sticks into the connector **10** avoid trauma to the patient **21**.

In some cases, the connector **10** forms a "T"-site or a "Y"-site. In these cases, the connector **10** is also coupled to tubing **25** which communicates with an elevated bottle **27** containing various intravenous solutions. As the solution from the bottle **27** continuously drips into the tubing **25**, it flows through the connector **10**, the tubing **14** and the needle **16** into the vein **18**. Additional medications can be inserted through a secondary channel in the connector **10**. The tubing **25** is dotted in FIG. **1** to indicate that the connector **10** may function as a single access site or as a "T"-site or "Y"-site connector **17**.

A preferred embodiment of the connector **10** is illustrated in FIG. **2** and includes a base **30**, and cap **32** which together form a housing **34** which extends generally along an axis **36**. The cap **32** is elongate in configuration and includes a wall **38** which extends between a proximal end **41** and a distal end **43**. At the proximal end **41**, the wall **38** narrows to form an opening **45** at a proximal surface **47**. The wall **38** can be provided with external threads **50** which form, in a preferred embodiment, a female Luer fitting.

The wall **38** of the cap **32** has an inner surface **61** which defines a channel **63** that extends through the housing **34** to a distal opening **65**. At the proximal end **41**, the inner surface **61** forms an annular shoulder which functions as a primary valve seat **70** best illustrated in FIG. **2**. In proximity to the proximal surface **47**, the inner surface **61** forms a secondary valve seat **72** which has a more cylindrical configuration. One or more longitudinal slots **62** can be formed in the wall **38** to define the channel **63** outwardly of the surface **61**.

The base **30** of the housing **34** can be provided in a variety of forms as described in greater detail below. In the embodiment of FIG. **2**, the base **30** is formed as a plurality of concentric cylinders **74**, **76** and **78** which are stacked along an axis **81** that is concentric with the axis **36** in this embodiment. The bottom cylinder **74** has a diameter which is generally equivalent to the outside diameter of the cap **32**.

A shoulder **83** is formed where the bottom cylinder **74** meets the intermediate cylinder **76**. This intermediate cylinder **76** is preferably provided with an outside diameter substantially equivalent to the inside diameter of the surface

61. This enables the base **30** to be force fit into the distal end **43** of the cap **32**, with the cap **32** resting on the shoulder **83** in abutting relationship with the cylinder **74**.

Interiorly of the channel **63**, the top cylinder **78** forms a post which extends proximally of the intermediate cylinder **76**. A shoulder **84** is formed where the intermediate cylinder **76** meets the top cylinder **78**. The base **30** is suitably apertured, typically by forming a longitudinal hole **85** in the intermediate cylinder **76** and the bottom cylinder **74**, in order to extend the channel **63** through the distal end of the housing **34**.

Of particular interest to the present invention is a valve element **90** which is disposed interiorly of the housing **34** and has a generally elongate configuration in the embodiment of FIG. **2**. This valve element **90** may be formed totally or partially of elastomeric materials to facilitate the deflection and sealing characteristics desired for a particular embodiment of the connector **10**. The valve element **90** in the illustrated embodiment includes a plug **92** which is disposed along an axis **94** and a shaft **96** extending from the plug **92** along an axis **98**. In the illustrated embodiment the valve element **90** is coaxial with the housing **34**. Accordingly, the various axes **36**, **94**, **98** and **81** are collinear in this embodiment.

The plug **92** formed at the proximal end **41** of the valve element **90** includes a flange **101** having a proximal surface **103** and a distal surface **105**. Proximally of the flange **101**, the plug **92** has a generally conical configuration and extends to a nose **107** having a proximal surface **110**. Between the proximal surface **110** and the surface **105** associated with the flange **101**, the plug **92** is provided with a buckling section at a predetermined location laterally of the axis **94**. In the illustrated embodiment this buckling section takes the form of a notch **112**.

The valve element **90** is of particular interest to the present invention as it is the operation of this element **90** which enables the connector **10** to provide for a closed, sealed condition in one operative state, and to provide for an actuated open condition in a second operative state. The closed state is illustrated in FIG. **2** where the proximal surface **110** has a first angle (such as 90 degrees) to the axis **36**; the open state is illustrated in FIG. **3** where the proximal surface **110** has a second angle (less than the first angle) to the axis **36**.

In the closed state, the valve element **90** is generally in a natural condition and is self-biased to substantially its maximum length. In this closed state, the plug **92** associated with the element **90** is biased into sealing engagement with the inner surface **61** of the cap **32**. More specifically, the surface **103** of the flange **101** is pressed into sealing engagement with the primary valve seat **70** to form a primary seal between the cap **32** and the plug **92**. In the closed state, a secondary seal is also formed between the circumferential surface of the nose **107** and the inner surface **61** which defines the opening **45**. For reasons discussed in greater below, the proximal surface **110** of the valve element **90** is in a substantially planar orientation with the proximal surface **47** when the valve element **90** is in the closed state.

In the illustrated embodiment, the valve **90** is provided with an axial bore **113** at its distal end. This bore is sized and configured to receive the post associated with the cylinder **74** of the base **30**. In this embodiment, the distal end of the valve element **90** has a generally fixed relationship with the housing **34**. This is in contradistinction to the proximal end of the valve element **90** which is generally free to move, at least axially, relative to the housing **34**.

As illustrated in FIG. **3**, the open state of the connector **10** is achieved by compressing the valve element **90** generally along its axes **94**, **98**. It will first be noted that this compression is achieved in a preferred embodiment by connecting a common male Luer fitting **114** to the female Luer fitting **52** associated with the cap **32**. By providing the connector **10** with characteristics for being actuated by a common Luer fitting **114**, the possibility of a needle stick with a secondary needle is totally avoided. In FIG. **3**, the valve element **90** is compressed along its axis **94**, **98**. As used herein, the word "compress" and its derivatives refers to any position wherein the two ends of an elongate element are brought closer together. This may occur due to a shortening of the element along its axial length or due to a bending of the element off-axis which may or may not be accompanied with a shortening in the length of the element.

As the male Luer fitting **114** is inserted into the opening **45**, it initially contacts the surface **110** of the valve element **90**. Further insertion of the fitting **114** places an axial load on the valve element **90** which is felt in both the plug **92** and the shaft **96**. In a preferred embodiment, this compressive force operates initially to break the secondary seal between the nose **107** and the housing **34**, and then to compress the plug **92** primarily at the buckling section formed by the notch **112**.

As the plug **92** collapses at the notch **112**, it compresses along that side of the valve element **90** causing the proximal surface **110** to dip in the area of the notch **112**. This effectively moves the area of contact between the Luer fitting **114** and the surface **110** away from the axis **94** and toward the side of the plug **92** opposite the notch **112**. This area of contact is illustrated in FIG. **3** by an arrow **116** which is displaced from the axis **94**.

As the notch **112** collapses, the additional force applied by insertion of the fitting **114** also operates to axially compress the shaft **96**. With the compression of the valve element **90**, the shaft **96** tends to cant, buckle, bow or otherwise bend toward the side of the axis **98** opposite the arrow **116**. This compression of the shaft **96** tends to break the primary seal formed between the surface **103** of the plug **92** and the valve seat **70** of the cap **32**. Having broken both the primary seal associated with the primary valve seat **70**, and the secondary seal associated with the nose **107**, the channel **63** is now opened to receive medication or other liquids through the Luer fitting **114** and the housing **34**. Within the housing **34**, this channel **63** is defined between the surface **61** of the cap and the outer surface of the valve element **90**.

In further embodiments of the invention, elements of structure which are similar to those previously discussed will be designated by the same referenced numeral followed by a lower case letter associated with that embodiment. Accordingly, the embodiment of FIG. **4** includes the cap **32***a* and the base **30***a* which together form the housing **34***a*. The valve element **90***a* includes the plug **92***a* and the shaft **96***a*. This embodiment of the connector **10***a* differs from that previously discussed primarily in the structural configuration of the base **30***a* and the complimentary configuration associated with the distal end of the valve element **90***a*.

In the embodiment of FIG. **4**, the base **30***a* includes the cylinder **74***a* and the associated shoulder **83***a*. Extending distally from the cylinder **74***a*, however, is a cylindrical fitting **121** which is sized and configured to receive the tubing **14** (FIG. **1**). Proximally of the cylinder **74***a*, the base **30***a* is formed with a cylindrical structure **123** which has an outer surface **125** and defines a rounded cavity. The outer surface has an outside diameter which is substantially

equivalent to the inside diameter of the surface **61**. This facilitates sealing engagement between the cap **32***a* and the base **30***a* in the manner previously discussed. Upstanding from the cylindrical structure **123** is a finger or post **127** which extends into proximity with the plug **92***a* of the valve element **90***a*. In this particular embodiment, the finger **127** has a surface **129** which is disposed distally of the surface **105***a* of the flange **101***a* and which is inclined generally toward the plug **92***a*.

The closed state of this connector **110***a* is illustrated in FIG. **4** where the primary seal is formed by the flange **101***a*, and a secondary seal is formed by the nose **107***a*. The valve element **90***a* in this embodiment differs from that previously discussed in that there is no area of predetermined buckling, such as the notch **112** of the FIG. **2** embodiment. Additionally, there is no post **74** associated with the base **30***a*, but rather the valve element **90** is provided with a rounded configuration at the distal end of the shaft **96***a*. This rounded end of the shaft **96***a* seats (with a reduced radius of curvature) within the arcuate spherical recess **125** provided in the base **30***a*.

The channel **63***a* in the embodiment of FIG. **4** also differs from that previously discussed, primarily in the vicinity of the base **30***a*. In the illustrated embodiment, the base **30***a* is apertured along the axis **81***a* to form a hole **130**. This hole **130** communicates with slots **132** and functions primarily to seat the hemispherical end of the shaft **96***a* along the axis **81***a*. The slots **132** provide access to the hole **130** radially outwardly of the shaft **96***a* to provide communication for the channel **63***a* between the cap **32***a* and the base **30***a*.

The connector **10***a* is illustrated in FIG. **4** in its natural closed state, and in FIG. **5** in its activated, open state. Once again, activation of the connector **10***a* is preferably accomplished with the male Luer fitting **114***a*. Insertion of this fitting against the proximal surface **110***a* of the plug **92***a* operates to axially compress the valve element **90***a*. In the absence of the notch **112** however, the fitting **114***a* tends to compress the element **90***a* axially until the distally facing surface **105***a* of the plug **92***a* contacts the surface **129** associated with the finger **127**. At this point further axial compression by the fitting **114***a* forces the plug **92***a* slide along the surface **129** and to cant toward the finger **127**. This causes the shaft **96***a* to cant away from the finger **127**. The resulting portion of the element **90***a* illustrated in FIG. **5**. The hemispherical shape of the shaft **96***a* facilitates rotation of its distal end within the arcuate recess **125** of the base **30***a*. It will be noted that in this embodiment the distal end of the shaft **96***a* is not axially fixed as was the case with the embodiment of FIG. **3**. In general, this provides the advantage of a shorter shaft **96***a* and a commensurately shorter connector **10***a*.

With the valve element canted as illustrated in FIG. **5**, the channel **63***a* extends through the Luer fitting **114***a* and along side the valve element **90***a* interiorly of the housing **34***a*. In the base **30***a*, the channel **63***a* extends into the slots **132** and the hole **130** to exit the connector **10***a* through the fitting **121**.

A further embodiment of the invention is illustrated in FIG. **6** where the connector is designated by the reference numeral **10***b*. This embodiment is similar to that discussed with reference to FIG. **2** in that it includes the notch **112***b*. It is similar to the embodiment of FIG. **4** in that the shaft **96***b* is provided with a hemispherical distal end. The base **30***b* is also similar to that illustrated in of FIG. **4** in that it includes the fitting **121***b* and it provides a recess **125***b* to receive the distal end of the shaft **96***b*. This embodiment of the base **30***b* is similar to that discussed in FIG. **1** in that it includes the cylinder **76***b* in proximity to the cylinder **74***b*. In this particular embodiment, however, the cylinder **76***b* is radially apertured to form a slot **134** outwardly of the shaft **96***b*. This slot **134** communicates with the channel **63***b* interiorly of the cap **32***b* as well as the radial slot **132***b* and hole **130***b* associated with the base **30***b*. Deflection of the valve element **90***b* in response to insertion of the Luer fitting **114** is accomplished generally as described with reference to FIG. **3**. However, the hemispherical distal end of the valve element **90***b* facilitates its canted orientation.

In the embodiment of FIG. **7**, the connector **10***c* is similar to that of FIG. **6** except for the provision of a "Y"-site designated generally by the reference numeral **136**. In this case, the cap **30***c* includes a fitting **138** which is sized and configured to receive the tubing **25***c* previously discussed with reference to FIG. **1**. Thus the connector **10***c* is a "Y"-site connector which includes a primary channel **141** which extends through the tubing **25***c*, the fitting **138**, interiorly of the housing **34***c*, and through the slots **132***c*, **134***c* and the hole **130***c* into the tubing **14***c*. It will be noted that this channel **141** is continuously open and unaffected by the disposition of the valve element **90***c*. When the valve element **90***c* is axially compressed, however, the channel **63***c* communicates with the channel **141** and permits the introduction of medication or other liquids into the tubing **14***c*.

A "T"-site connector **10***d* is illustrated in FIG. **7**. The base **30***d* and valve element **90***d* are similar to those previously discussed but the base **30***d* differs considerably. In this embodiment, the fitting **138***d* which is configured to receive the tubing **25***d* is formed as part of the base **30***d*. A similar fitting **141** is provided to extend generally in the opposite direction from the fitting **138***d* and is sized and configured to receive the tubing **14***d*. With this configuration, the tubing **14***d* and **25***d* are generally collinear, while the axis **36***d* associated with the housing **34***d* is generally perpendicular to the tubing **14***d*, **25***d*.

The connector **10***e* illustrated in FIG. **9** includes a cap **32***e* and valve element **90***e* which can be similar to any of the embodiments previously discussed. In this case however, the base **30***e* is provided in the form of a male Luer fitting **143** making it particularly adapted for connection to tubing, such as the tubing **14***e*, which terminates in a female Luer fitting **145**.

The connector **10***f* illustrated in FIG. **10** includes a cap **32***f* which is generally symmetrical about an axis **36***f*. However, in this embodiment the valve element **90***f* is generally asymmetrical. Although the plug **92***f* in this embodiment can be coaxial with the housing **32***f*, the shaft **96***f* is preferably disposed along an axis **147** which is non-aligned with the axis **36***f* of the housing **32***f*. This configuration for the valve element **90***f* is advantageous in that a force applied along the axis **36***f* is not applied along the axis **147** associated with the shaft **96***f*. This tends to cause the shaft **96***f* to cant or buckle in the manner previously disclosed in order to open the channel **63***f* and facilitate the introduction of medication. In order to accommodate the off-axis orientation of the shaft **96***a*, a base **30***f* is formed with a hole **130***f* and slots **132***f* which are similarly to those described in FIG. **6**. However in this embodiment, the hole **130***f* and slots **132***f* are similarly offset for disposition relative to the axis **147**. Thus, even though the shaft **96***f* is offset from the axis **36***f*, it is nevertheless symmetrically disposed with reference to the hole **130***f* and slots **132***f* in the manner previously described with reference to FIG. **6**.

The connector **10***g* illustrated in FIG. **11** is similar to the connector **10***a* illustrated in FIGS. **4** and **5** in that it also

includes a finger **127***g*. However, in the earlier embodiment, the finger **127** was provided with the surface **129** which faced proximally and radially toward the valve element **90**. In FIG. **11**, the finger **127***g* includes a surface **152** which faces proximally, but in this embodiment the surface **152** does not face toward the valve element **90***g*. As a consequence, the distally facing surface **105***g* associated with the plug **92***g* tends to engage and pivot on the surface **152** associated with the finger **127***g*. Rather than permitting these two surfaces to slide against each other, as was the case with the FIG. **4** embodiment, their engagement in the embodiment of FIG. **11** causes the valve element **90***g* to cant in the opposite direction. Thus, the plug **90***g* tilts away from the finger **127***g* while the shaft **96***g* bends toward the finger **127***g*. With this distinction, both of the embodiments of FIGS. **4** and **11** function to open and close the respective connectors **10***a* and **10***g* when the valve element **90** is axially compressed within the housing **34**.

In still a further embodiment of the connector **10***h* illustrated in FIG. **12**, the cap **32***h* fits directly over the base **30***h*. In this embodiment, the base **30***h* does not include the enlarged cylinder **74** (FIG. **2**) but only the intermediate cylinder **76***h* which has substantially the same diameter as the inner surface **61***h* of the cap **32***h*. This embodiment of the connector **10***h* is of further interest due to its elongation of the bore **113***h* which is sized to fit on the post **74***h*. In this case, the bore **113***h* extends along the entire length of the shaft **96***h* and into the plug **92***h*. The post **74***h* will typically have an axial length significantly shorter than that of the bore **113***h*. As a consequence, those regions of the bore **113***h* which extend beyond the bore **74***h* provide the shaft **96***h* with a generally hollow structure. This configuration adds considerable flexibility to the shaft **96***h* and facilitates its canting or bending relationship with the housing **34***h*.

In still a further embodiment of the connector **10***i* illustrated in FIG. **13**, the base **30***i* and cap **32***i* can be provided with any of the configurations previously disclosed. Similarly, the plug **92***i* can be formed as previously disclosed. This embodiment of FIG. **13** differs primarily in the structural formation of the shaft **96***i* which is provided with a generally sculpted configuration. As opposed to the previous embodiment where the shaft **96** has been formed substantially as a cylinder with a circular cross section, the shaft **96***i* of FIG. **13** can have generally any cross sectional shape such as the shape of an ellipse. This shape is best illustrated in FIG. **14** where the ellipse is characterized by a major axis **147** and a minor axis **149**. Notches can be formed at various positions to provide a variety of advantages to the connector **10***i*. In the illustrated embodiment, these notches include a pair of relatively large notches **152** and **154** and a pair of relatively smaller notches **156** and **158**. Opposing smaller notches **157** and **159**, shown separately in FIG. **14**, may be provided on the opposite side of the shaft **96***i*.

In the illustrated embodiment, the major notches **152** and **154** are formed on opposing sides of the elliptical shaft **96***i*. They are similar in shape but offset from each other along the axis **36***i* of the connector **10***i*. These notches **152** and **154** preferably extend parallel to the major axis **147** and inwardly toward the axis **36***i* a distance less than half of the dimension of the shaft **96***i* along the minor axis **149**. In this embodiment, the smaller notches **156–159** are formed along the major axis **147**.

The notches **152–159** are representative of any structural deviation in an otherwise smooth surface of the shaft **96***i*. The larger notches **152** and **154** will affect the canting or bending of the shaft **96***a* as it moves toward its compressed state. Where these notches **152** and **154** are formed at positions displaced along the axis **36***i*, the shaft **96***i* will tend to form a different bend at each of the notches **152** and **154**. Where these notches **152**, **154** are diametrically opposed, the bend of the shaft **96***a* will have an "s" shape as illustrated in FIG. **13**. Thus the larger notches **152**, **154** provide for more predictable bending of the shaft **96***i* in the compressed state. When the shaft **96***i* forms more than one bend, its axial length can generally be shorter. This advantage is particularly appreciated when a shorter connector **10***i* is desired.

The smaller notches **156–159** create flow channels around the valve element **90***i*. The smaller notches **156–159** also facilitate priming the connector **10***i* by preventing dead spots in the flow channel which might otherwise trap air bubbles.

In the illustrated embodiments, when the valve element **90** is in the natural closed state, its proximal surface **110** is in a substantially planar orientation with respect to the surface **47** of the cap **32**. This orientation is preferred in order to avoid reservoirs and crevices which might otherwise result in pooling and bacterial contamination. With the substantially planar orientation of the surfaces **110** and **47**, the proximal end of the connector **10** can be easily wiped in order to disinfect this region of the connector **10**. This enables the connector **10** to be formed without the additional cost and inconvenience associated with a proximal end cap common to prior devices.

In each of the foregoing embodiments, the connector **10** functions to open and close the channel **63** by operation of the male Luer fitting **114**. This type of fitting is commonly available and offers no risk of needle stick to the health care workers. The connector **10** can be constructed of only three elements including the cap **32** and base **30** which form the housing **34** and the elastomeric valve element **90**. Both elongate and compact configurations can be provided depending on design considerations associated with the base **30** and the distal end of the shaft **96**. The canting or bending of the valve element **90** can be facilitated by providing for an predetermined buckling section such as the notch **112** or by providing the finger **127** having an interfering relationship with the plug **92** as in the connector **10***f*. Both primary and secondary seals can be formed between the valve element **90** and the inner surface **61** of the cap **32**. These seals can be non-simultaneously activated or deactivated to close or open the channel **63** of the connector **10**.

In the foregoing embodiments, the connector **10** has been disclosed for use with intravenous tubing which is used to access the vascular system of a patient. The advantages provided by the connector would be equally appreciated if it were used to access other body conduits such as those associated with the urinary system. In general, the connector **10** will be operable by the male Luer fitting **114** to provide controlled access to the tubing set **12** or any other receptacle. Such other receptacles may include for example a catheter, a fluid reservoir or an injection manifold of the type commonly used for the administration of anesthesia. In this context, the connector **10** can be used to generally control the flow of any fluid, either gas or liquid, where it functions automatically to provide self-sealing with controlled access for either unidirectional or bidirectional flow.

Given these wide variations, which are all within the scope of this concept, one is cautioned not to restrict the invention to the embodiments which have been specifically disclosed and illustrated, but rather encouraged to determine the scope of the invention only with reference to the following claims.

We claim:

1. A connector adapted to facilitate bi-directional flow between a male Luer fitting and a receptacle tube, comprising:

a housing having an axis extending between a proximal end and a distal end, the housing having its distal end attached to the intravenous tube and portions defining a valve seat at its proximal end;

a valve element disposed in the housing and having a second axis, the valve element being movable by insertion of the male Luer fitting into the proximal end of the housing from a first position to a second position, the valve element in the first position forming with the valve seat of the housing a seal; and

the valve element in the second position being disposed with the second axis of the valve element displaced from the first axis of the housing to form a fluid channel from the male Luer fitting to the receptacle tube.

2. The connector recited in claim **1** wherein:

the housing at its proximal end is defined by a first wipable surface; and

the valve element has a second wipable surface which in the first position has a substantial planar relationship with the first wipable surface of the housing.

3. The connector recited in claim **1** wherein the fluid channel through the housing is disposed between the housing and the valve element.

4. The connector recited in claim **1** wherein the valve element is asymmetrical about the second axis so that a force directed against the valve element along the first axis of the housing causes the valve element to cant from the first position to the second position.

5. The connector recited in claim **4** wherein the second axis of the valve element is aligned with the first axis of the housing when the valve element is in the first position.

6. A connector adapted to facilitate bi-directional flow between a male Luer fitting and an intravenous tube, comprising:

a housing having an axis extending between a proximal end and a distal end, the housing having a proximal surface and a valve seat at its proximal end, and being adapted at its distal end for connection to the intravenous tube;

a valve element disposed in the housing and having a proximal surface, the valve element being movable by insertion of the male Luer fitting into the housing from a first position to a second position;

the valve element in the first position forming a seal with the valve seat of the housing;

the valve element in the second position being displaced off-axis from the first position to form a fluid channel from the male Luer fitting to the intravenous tube the fluid channel being non-concentric with the axis of the housing; and

the proximal surface of the valve element having a substantially planar relationship with the proximal surface of the housing to facilitate antiseptic wiping at the proximal end of the connector.

7. The connector recited in claim **6** wherein:

the housing having a first axis;

the valve element has a second axis; and

the valve element in the second position is disposed with the second axis in a displaced relationship with the first axis of the housing.

8. A connector adapted to facilitate access into a receptacle comprising:

a housing having a first axis extending between a proximal end and a distal end, the housing having its distal end attached to the receptacle; and

a valve element disposed in the housing and defining with the housing a fluid channel extending between the proximal end and the distal end of the housing, the valve element having a second axis and being movable between a first position wherein the first axis is aligned with the second axis to close the fluid channel, and a second position wherein the second axis is displaced from the first axis to open the fluid channel.

9. The connector recited in claim **8** further comprising:

portions of the housing forming a valve seat; and

the valve element being disposed in sealing engagement with the valve seat of the housing when the valve element is in the first position.

10. The connector recited in claim **9** further comprising:

portions of the valve element forming a predetermined area of buckling on one side of the second axis; whereby

axial compression of the valve element collapses the valve element portions resulting in displacement of the second axis of the valve element from the first axis of the housing.

11. The connector recited in claim **10** wherein the valve element further comprises:

a plug;

a shaft disposed at the distal end of the housing and supporting the plug in proximity to the proximal end of the housing; and

the portions of the valve element being included in the plug of the valve element.

12. The connector recited in claim **10** wherein the housing further comprises:

a base supporting the valve within the housing; and

a cap coupled to the base and including the portions defining the valve seat.

13. The connector recited in claim **12** wherein the valve element further comprises:

a plug disposed along the second axis; and

a shaft supporting the plug within the housing and disposed along a third axis different than the second axis.

14. The connector recited in claim **12** wherein the housing further comprises:

portions of the cap defining at least one longitudinal slot forming the channel in juxtaposition to the valve element.

15. A connector adapted to facilitate bi-directional flow with an intravenous tube, comprising:

a housing having an axis and a channel extending through the housing;

a base forming a portion of the housing;

a cap forming a portion of the housing and having a fixed relationship with the base;

a valve element disposed in the channel of the housing and defining with the housing a fluid flow path;

a plug included in the valve element;

a shaft included in the valve element and having properties for biasing the plug into sealing engagement with the housing to seal the channel in a first position of the valve element, and for being axially compressed to displace the plug from the housing and open the channel in a second position of the valve element; wherein

the fluid flow path is concentric with the axis of the housing when the valve element is in the first position and the fluid flow path is displaced from the axis of the housing when the valve element is in the second position.

16. The connector recited in claim 15 further comprising:

portions of the base forming an arcuate cavity facing toward the cap of the housing; and

portions of the shaft of the valve element having an arcuate configuration and being seated in the cavity of the base.

17. A method for operating a connector disposed between a male fitting and a receptacle, including the steps of:

providing a housing having a channel and an axis, the axis extending between a proximal end of the housing and a distal end of the housing;

positioning a valve element in the channel of the housing;

biasing the valve element to close the channel of the housing;

coupling the receptacle to the distal end of the housing;

engaging the valve element at the proximal end of the housing with a male fitting; and

moving the male fitting generally parallel to the axis of the housing to open the channel substantially along only one side of the housing between the male fitting and the receptacle.

18. The method recited in claim 17 wherein the moving step includes the step of moving the male fitting generally along the axis of the housing.

19. The method recited in claim 17 wherein the method step includes the step of:

compressing the valve element to open the channel of the housing.

20. The method recited in claim 19 wherein:

the positioning step includes the step of providing a valve element with a length;

the biasing step includes the step of positioning the valve element with its length extending along the axis of the housing to close the channel; and

the compressing step includes the step of compressing the valve element off-axis to open the channel of the housing between the male fitting and the receptacle.

21. A connector adapted to facilitate access into a receptacle, comprising:

a housing having an axis extending between a proximal end and a distal end, the housing having its distal end attached to the receptacle; and

a valve element disposed in the housing and having a proximal surface, the valve element being movable between a first position wherein the proximal surface has a first acute angle with the axis of the housing and a second position wherein the proximal surface has a second angle with the axis of the housing; and

the first angle being greater than the second angle.

22. The connector recited in claim 21 wherein:

the housing includes portions defining a channel extending through the housing;

the valve element being disposed within the channel of the housing;

the valve element in the first position forming a seal with the housing to close the channel; and

the valve element in the second position being compressed off-axis to open the channel through the housing.

23. The connector recited in claim 21 wherein the valve element includes:

a plug disposed in proximity to the proximal end of the housing;

a shaft formed integral with the plug and extending into proximity with the distal end of the housing;

portions of the plug forming a first buckling section with characteristics for being axially compressed to move the proximal surface from the first position toward the second position; and

portions of the shaft defining a second buckling section with characteristics for being compressed to move the proximal surface to the second position.

24. A connector adapted to facilitate access into a receptacle, comprising:

a housing having a first axis extending between a proximal end and a distal end, the housing having its distal end attached to the receptacle;

a valve element disposed in the housing and defining with the housing a fluid channel extending between the proximal end and the distal end of the housing, the valve element having a second axis and being movable between a first position wherein the first axis is aligned with the second axis to close the fluid channel, and a second position wherein the second axis is displaced from the first axis to open the fluid channel;

portions of the housing defining a valve seat, the valve element being disposed in sealing engagement with the valve seat of the housing when the valve element is in the first position;

portions of the valve element forming a predetermined area of buckling on one side of the second axis such that axial compression of the valve element collapses the valve element portions resulting in displacement of the second axis of the valve element from the first axis of the housing;

a base included in the housing and supporting the valve element within the housing;

a cap included in the housing and coupled to the base, the cap including the portions defining the valve seat; and

a finger included in the base of the housing and extending longitudinally within the cap to engage the valve element between the first position of the valve element and the second position of the valve element in order to displace the second axis from the first axis.

* * * * *

EXHIBIT B

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Feith et al.

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[54] **MINIMUM FLUID DISPLACEMENT MEDICAL CONNECTOR**

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[51] **Int. Cl.**^{6} **F16L 37/28**

[52] **U.S. Cl.** **251/149.6**; 251/149.1; 604/256; 604/905

[58] **Field of Search** 251/149.1, 149.6; 604/905, 256

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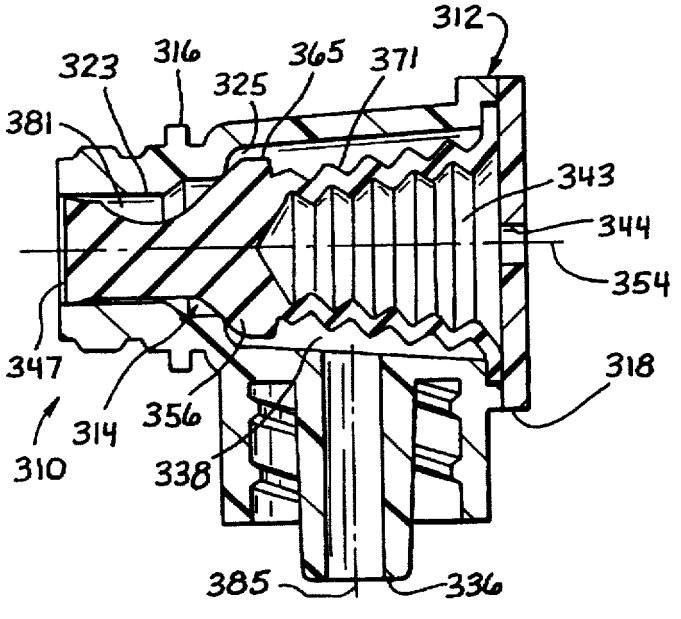
[57] **ABSTRACT**

A device for transferring fluid with minimum fluid displacement includes a valve internal chamber adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber. A biased member abuts against either a compressible gas or an ambient atmosphere, and is adapted for being moved by the actuator. Movement of the biased member results in displacement of either the compressible gas or the ambient atmosphere to thereby offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber. A valve outlet port is adapted for outputting fluid from the valve internal chamber. The valve outlet port is configured in fluid communication with the valve internal chamber at all times, and is adapted for allowing fluid to freely flow between the valve internal chamber and the valve outlet port.

32 Claims, 3 Drawing Sheets



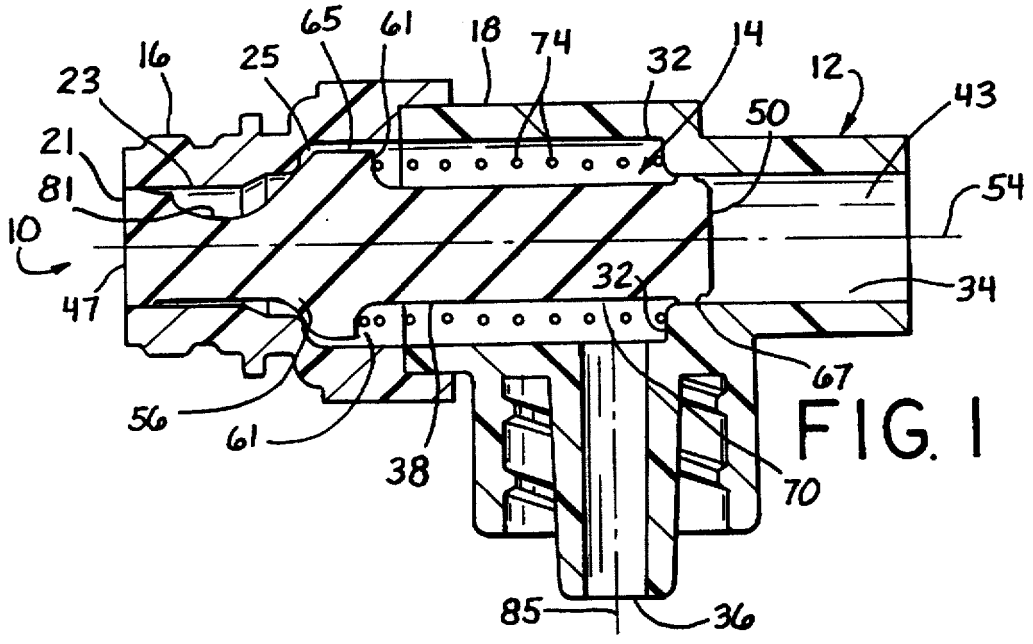


FIG. 1

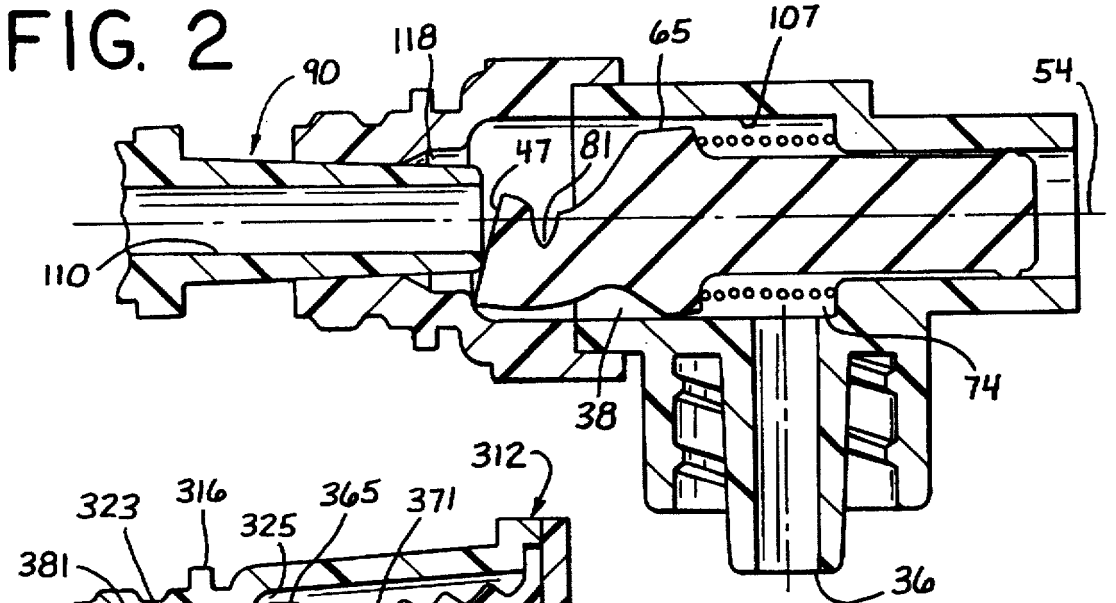


FIG. 2

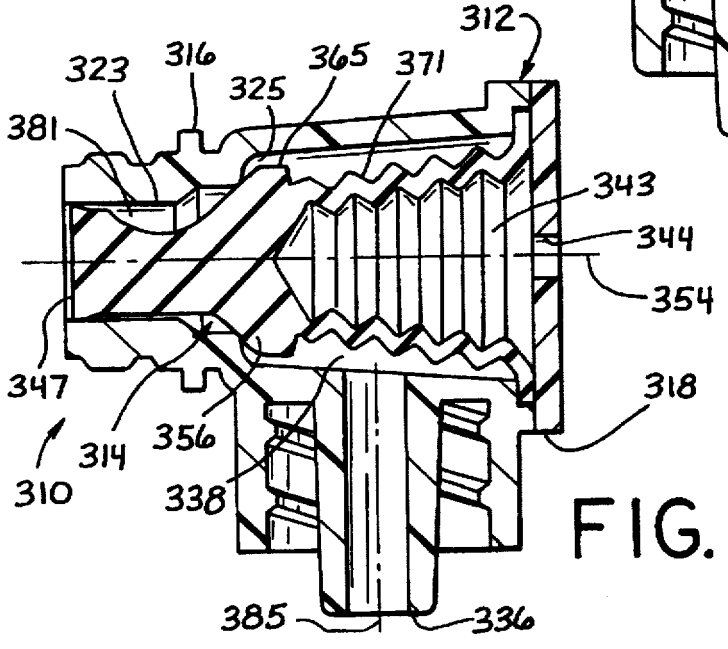


FIG. 3

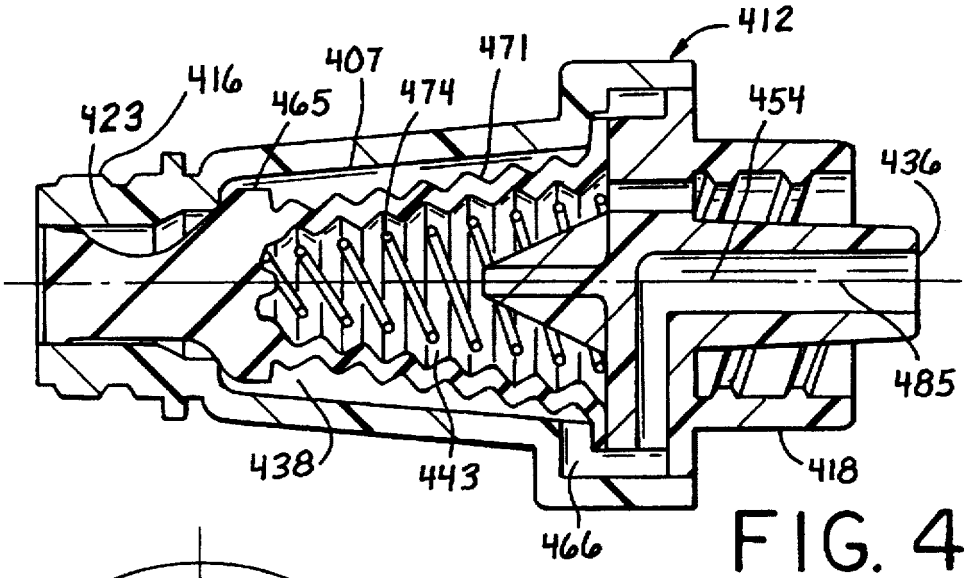


FIG. 4

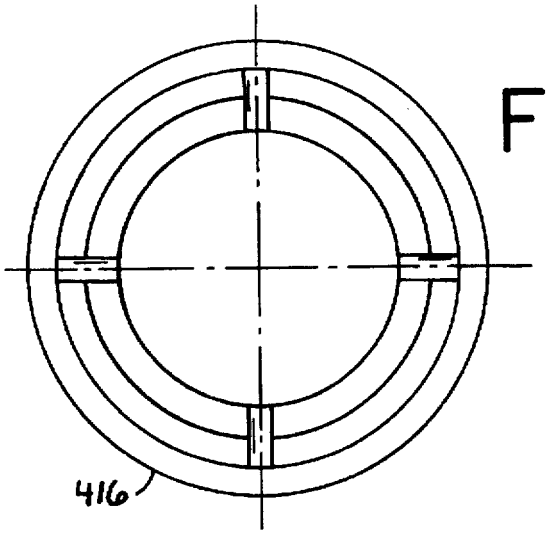


FIG. 5

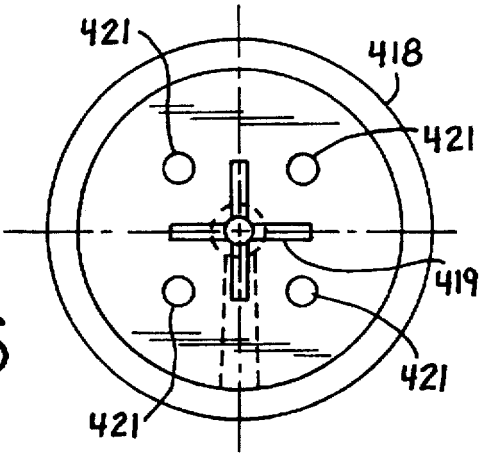


FIG. 6

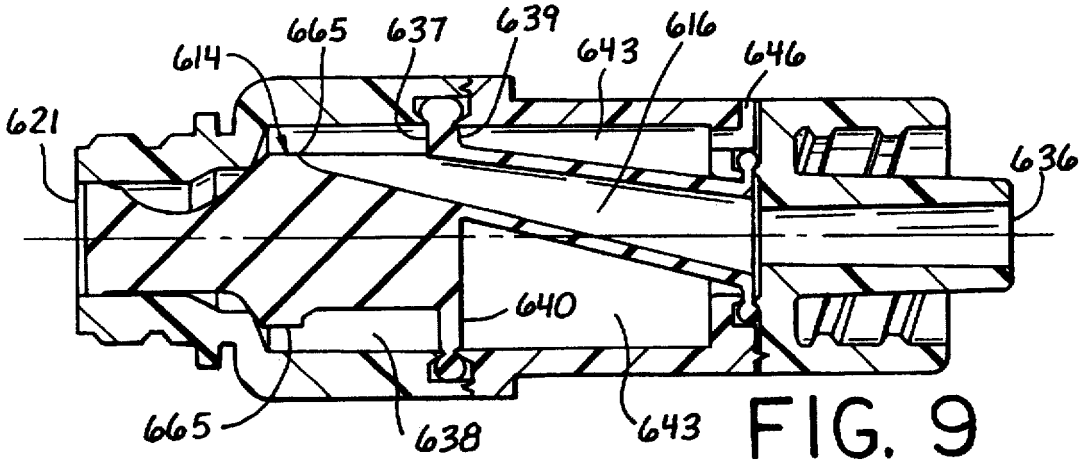


FIG. 9

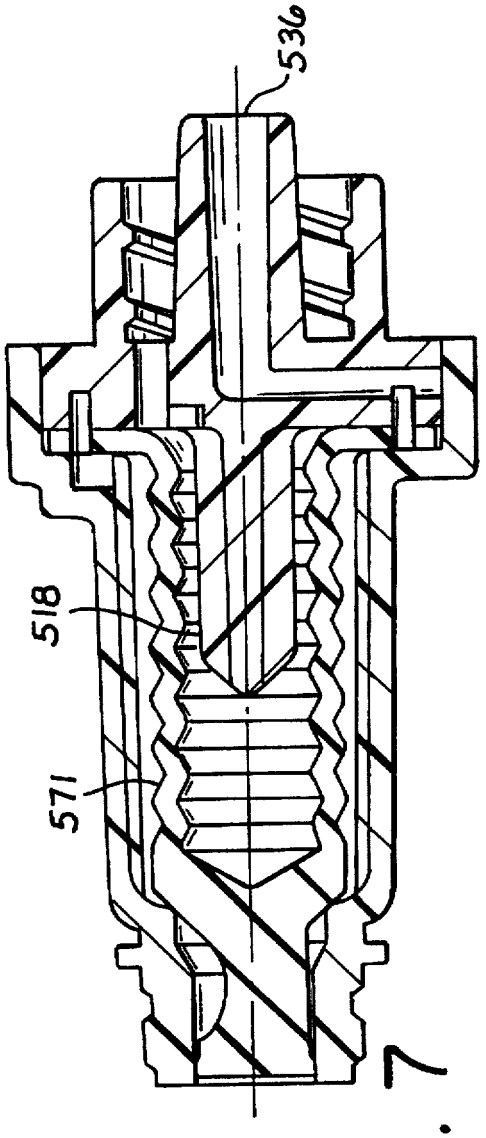


FIG. 7

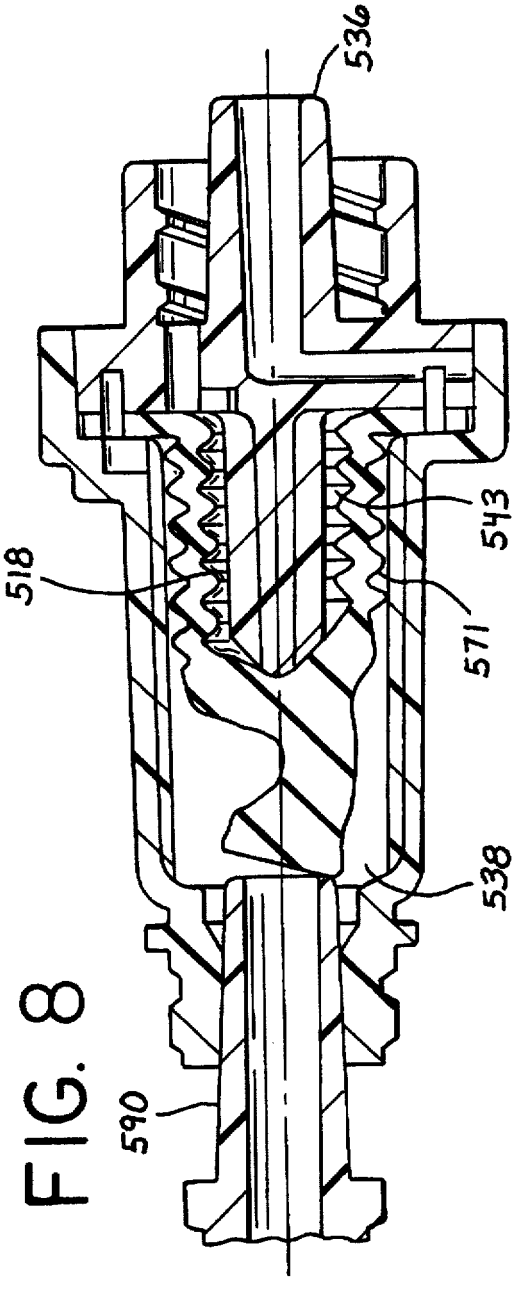


FIG. 8

MINIMUM FLUID DISPLACEMENT MEDICAL CONNECTOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to devices for establishing connections in closed fluid systems where fluid displacement due to the connection process must be controlled and, more particularly, to devices for establishing connections to medical intravenous fluid lines for the purposes of adding fluids to or removing fluids from a patient's venus or arterial blood system, and for sampling or removing fluids from such fluid lines.

2. Description of Related Art

Aseptic medical connections have been widely used in the prior art in connection with intravenous fluid lines, blood access, hemodialysis, peritoneal dialysis, enteral feeding, drug vial access, etc. The general standard for many such aseptic medical connections has been to puncture an elastomeric diaphragm or septum, which has one side in contact with the fluid, with a sharpened hollow hypodermic needle. The use of such hypodermic needles has been gradually decreasing in the prior art, as a result of both safety and cost considerations associated with infectious disease acquired from needle sticks.

A phenomenon referred to as fluid displacement can occur whenever a connection is made between two closed fluid systems. When a hypodermic needle is inserted into an intravenous fluid tubing through a rubber (latex) injection site, fluid displacement occurs. Because the intravenous fluid is incompressible, a volume of fluid equal to the needle volume is displaced out of the intravenous tubing and into the patient's blood vessel, when the hypodermic needle is inserted into the injection site. This displacement of fluid from the intravenous tubing into the patient's blood vessel is referred to as antegrade flow. Similarly, when the hypodermic needle is withdrawn, an equivalent volume of blood will be drawn back, usually through the catheter, into the intravenous tubing. This retrograde flow can be harmful when the blood drawn into the end of the catheter remains stagnant for a long period of time. The stagnant blood tends to settle, and may begin to clot, thereby restricting flow through the catheter and possibly requiring insertion of a new intravenous catheter into the patient.

The phenomenon of retrograde flow is known to sophisticated medical practitioners, who may deliberately attempt to balance the retrograde flow and displacement by using a syringe to squeeze a last bit of fluid through the needle as the needle is being withdrawn from the latex septum. The success of this method, however, is highly variable and technique-dependent and, in any event, can only be employed when the device being disconnected is a needle. Many connections are from male Luers on ends of other intravenous tubing sets. The fluid displacement phenomenon described above can also occur in any closed fluid system, medical or not, where part of one of the connectors displaces volume into the system as the connector is actuated during coupling.

In addition to fluid displacement problems associated with hypodermic needle access intravenous connectors, many medical needle-free access devices create fluid displacement during actuation. Needle-free access devices employing blunt cannula "actuators," which penetrate a pre-slit rubber septum, and needle-free access devices activated by insertion of standard male Luer nozzles, often suffer from fluid displacement during actuation. In each of these cases, the actuator typically displaces fluid as it is inserted into the connector, creating antegrade flow. Also, when the actuator is removed from the connector, a volume within the connector must then be replaced by fluid within the intravenous tubing. If there is no other source (such as from an infusion container via a Y-connector), the replacement fluid will likely be the patient's blood, which will flow into the intravenous catheter.

The volume of fluid displaced during actuation in a case where a male Luer nozzle is used as the actuator, will often be approximately equal to the volume of the male Luer nozzle penetrating into the connector when coupled. This volume can vary substantially, based upon device design, materials, and the tolerances allowed for both male and female Luers. Displacement volumes can be 100 microliters or higher. A fluid displacement on the order of 50 microliters, for example, may seem very small but, in fact, can be significant. For instance, the fluid volume inside a one inch long 22 gauge intravenous catheter is only 6 microliters, and the volume of a one and a quarter inch 18 gauge catheter is 23 microliters. The volume displaced by inserting a 20 gauge needle to a depth of one inch is 24 microliters. Based upon the above dimensions, a catheter may be filled with blood by simply withdrawing a needle from an injection site. A displacement-free medical connector, or a minimum fluid displacement medical connector, or a self-flushing medical connector would attenuate or completely alleviate many of the problems associated with these prior art medical connectors.

SUMMARY OF THE INVENTION

The minimum displacement connector of the present invention includes an actuator and an internal chamber that is vented to the atmosphere. The present invention further includes a biased member that can be moved by the actuator to displace air out of the internal chamber while significant fluid is not displaced during actuation.

According to one feature of the present invention, a device for transferring fluid with minimum fluid displacement includes a valve internal chamber adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber. A biased member abuts against either a compressible gas or an ambient atmosphere, and is adapted for being moved by the actuator. Movement of the biased member results in displacement of either the compressible gas or the ambient atmosphere to thereby offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber. A valve outlet port is adapted for outputting fluid from the valve internal chamber. The valve outlet port is configured in fluid communication with the valve internal chamber at all times, and is adapted for allowing fluid to freely flow between the valve internal chamber and the valve outlet port.

According to another aspect of the present invention, a valve for transferring fluid includes an internal chamber that is in fluid communication with an outlet port. The internal chamber is adapted for accommodating an actuator therein. Insertion of the actuator into the internal chamber results in a positive fluid displacement within the internal chamber and, further, removal of the actuator from the internal chamber results in a negative fluid displacement within the internal chamber. The valve further includes an air chamber, and a biased member adapted for being moved into a portion of the air chamber upon insertion of the actuator and for being removed out of a portion of the air chamber upon

removal of the actuator. Movement of the biased member into a portion of the air chamber results in a negative fluid displacement within the internal chamber which substantially compensates for the positive fluid displacement, and movement of the biased member out of a portion of the air chamber results in a positive fluid displacement within the internal chamber which substantially compensates for the negative fluid displacement, for a zero displacement within the internal chamber.

The biased member has a generally cylindrical shape and, according to one aspect of the present invention, includes a hollow, collapsible skirt which surrounds and defines the air chamber. Movement of the actuator into the internal chamber collapses the collapsible skirt and moves the biased member into a portion of the air chamber. According to another aspect of the present invention, a biasing member such as a spring can be disposed within the collapsible skirt, and movement of the actuator out of the internal chamber uncollapses the collapsible skirt and moves the biased member out of a portion of the air chamber under forces exerted by the spring. In one configuration of the present invention, an axis of the internal chamber is substantially perpendicular to an axis of the outlet port, and in another configuration of the present invention the axis of the internal chamber is substantially parallel to the axis of the outlet port. The valve may include an internal strut disposed within the collapsible skirt, where movement of the actuator into the internal chamber collapses the collapsible skirt for a predetermined distance until a portion of the biased member contacts the internal strut.

According to another aspect of the present invention, the biased member includes a hollow passage connecting the internal chamber to the outlet port. The hollow passage is surrounded by the air chamber, and is adapted to expand into a portion of the air chamber when the actuator is inserted into the internal chamber. The hollow passage is further adapted to contract and move out of a portion of the air chamber when the actuator is removed from the internal chamber. The air chamber is configured in fluid communication with an ambient atmosphere, and movement of the biased member into a portion of the air chamber results in displacement of air within the air chamber out of the air chamber and into the ambient atmosphere. The biased member further includes an annular member adapted for being secured to a wall of the internal chamber. The annular member serves as a biasing means for contracting the hollow passage and moving the hollow passage out of the air chamber when the actuator is removed from the internal chamber.

According to yet another feature of the present invention, a minimum fluid displacement self-flushing connector includes a valve internal member, and a valve inlet port adapted for receiving an actuator. The actuator includes a lumen for introducing fluid through the valve inlet port and into the valve internal chamber. The minimum fluid displacement self-flushing connector further includes a valve outlet port, which is adapted for outputting fluid from the valve internal chamber. The valve outlet port is in fluid communication with the valve internal chamber at all times, and is adapted for allowing fluid to freely flow into and out of the valve internal chamber. The minimum fluid displacement self-flushing connector further includes an air chamber and a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve internal chamber. Movement of the plug into the air chamber results in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve internal chamber. A displacement of air within the air chamber, resulting from movement of the plug into a portion of the air chamber, is approximately equal to a displacement of fluid within the valve internal chamber, resulting from movement of the actuator into the valve internal chamber. The valve inlet port includes an inlet port axis, and the air chamber is centered about the inlet port axis. The plug has a generally cylindrical shape which is also generally centered about the inlet port axis, and the plug is adapted for being moved from an inlet port closed position to an inlet port open position.

The actuator is adapted for moving the plug into the inlet port open position, where a distal portion of the plug is moved into a portion of the air chamber. The proximal portion of the plug is adapted for being pushed by the actuator from the inlet port closed position out of the valve inlet port and into the inlet port open position where the distal portion of the plug is positioned within a portion of the air chamber. The minimum fluid displacement connector may also include a spring, and the plug is adapted for being pushed by the spring from the inlet port open position to the inlet port closed position. Movement of the actuator into the valve internal chamber roughly corresponds to movement of the distal portion of the plug into a portion of the air chamber. Movement of the actuator into the valve internal chamber results in a displacement of fluid within the valve internal chamber that is compensated by movement of portions of the plug out of the valve internal chamber to thereby generate an approximately zero displacement within the valve internal chamber. The plug includes a primary shoulder seal adapted for contacting a valve seal of the minimum fluid displacement connector when the plug is in the inlet port closed position.

The primary shoulder seal is removed from contact with the valve seat when the plug is moved from the inlet port closed position to the inlet port open position. A first portion of the primary shoulder seal contacts an inner surface of the valve internal chamber when the plug is in the inlet port open position, and a second portion of the primary shoulder seal does not contact the inner surface of the valve internal chamber when the plug is in the inlet port open position. The inlet port open position of the plug facilitates a flow of fluid from the valve inlet port into the valve internal chamber, and between the second portion of the primary shoulder seal and the inner surface of the valve internal chamber into the valve outlet port.

The present invention, together with additional features and advantages thereof, may best be understood by reference to the following description taken in connection with the accompanying illustrative drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** illustrates a cross-sectional view of the minimum fluid displacement connector of the presently preferred embodiment in an unactuated configuration;

FIG. **2** illustrates a cross-sectional view of the minimum fluid displacement connector of the presently preferred embodiment in an actuated configuration;

FIG. **3** illustrates a minimum fluid displacement connector according to a first alternative embodiment;

FIGS. **4** illustrates a minimum fluid displacement connector according to a second alternative embodiment;

FIGS. **5** and **6** illustrate cross-sectional views of the minimum fluid displacement connector shown in FIG. **4**;

FIGS. **7** and **8** illustrate cross-sectional views of a minimum fluid displacement connector according a third alternative embodiment; and

FIG. **9** illustrates a cross-sectional view of a minimum fluid displacement connector according to a fourth alternative embodiment of the present invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

Turning to FIG. **1**, a minimum fluid displacement connector **10** is illustrated in cross-sectional view. The minimum fluid displacement self-flushing connector **10** comprises a valve housing **12** and a rubber valve plug **14** disposed within the valve housing **12**. As presently embodied, the valve housing **12** comprises a valve cap **16** and a valve base **18**. The valve cap **16** is secured to the valve base **18** using conventional means, such as solvent bonding, ultrasonics, spin welding, etc, and comprises a valve inlet port **21**, a valve throat **23**, and a valve seat **25**. The valve base **18** comprises spring bases **32**, a valve distal cylinder **34**, and a valve outlet port **36**. A valve internal chamber **38** is formed between the valve base **18** and the valve cap **16**, and a vented air chamber **43** is formed within the valve distal cylinder **34**. The valve base **18** and the valve cap **16** may comprise either metal or plastic, for example.

The rubber valve plug **14** comprises a generally cylindrical shape for slidably fitting within the valve internal chamber **38** and the vented air chamber **43** of the valve housing **12**. The rubber valve plug **14** comprises a plug proximal portion **47** and a plug distal portion **50**. The positioning of the plug proximal portion **47** may be flush or, may be sub-flush requiring use of a cap. An axis of the rubber valve plug **14** is generally aligned with an axis **54** of the valve throat **23** and the valve distal cylinder **34**. The rubber valve plug **14** comprises a plug primary shoulder seal **56** adapted for abutting against the valve seat **25** of the valve cap **16**. The rubber valve plug **14** further comprises plug spring bases **61**, which in combination with the plug primary shoulder seal **56** form an enlarged diameter portion **65** of the rubber valve plug **14**. Located near the plug distal portion **50** is a plug biased member **67** for sealingly sliding within the valve distal cylinder **34**. A plug cylindrical portion **70** is disposed between the plug spring base **61** and the plug biased member **67**. A metal or plastic spring **74** fits between the spring base **32** of the valve housing **12** and the plug spring base **61**. Other biasing means may be employed in addition to, or as an alternative to, the metal spring **74**.

A reduced diameter portion **81** of the rubber valve plug **14** is not centered about the axis **54**. The reduced diameter portion **81** is presently configured to facilitate a clockwise pivoting action of the plug proximal portion **47** about the reduced diameter portion **81**, when a force is applied to the plug proximal portion **47** in a direction toward the plug distal portion **50**. (See FIG. **2**.) An outlet port **36** of the valve housing **12** comprises an outlet port axis **85** that can be generally perpendicular or in line (parallel) to the axis **54**.

Broadly speaking, the general concept of the minimum fluid displacement or self-flushing connector **10** of the presently preferred embodiment is to transfer fluid between the valve inlet port **21** and the valve outlet port **36**. The plug primary shoulder **56** of the rubber valve plug **14** prevents fluid flow between the valve inlet port **21** and the valve outlet port **36**, in the inlet port closed configuration. Further, in this inlet port closed configuration, the valve inlet port **21** is sealed from the valve internal chamber **38**, but the valve internal chamber **38** is not sealed from fluid communication with the valve outlet port **36**.

Turning to FIG. **2**, an actuator **90** can be inserted into the valve inlet port **21** to thereby push the plug proximal portion **47** in the direction of the plug distal portion **50**. The actuator **90** comprises a male Luer nozzle in the presently preferred embodiment. The actuator **90** pushes the plug proximal portion **47** out of the valve throat **23** and, simultaneously, causes the plug proximal portion **47** to slightly rotate relative to the reduced diameter portion **81** in the clockwise direction, as presently embodied. This slight rotation of the plug proximal portion **47**, coupled with a general migration of both the plug proximal portion **47** and the reduced diameter portion **81** away from the axis **54** in a direction toward the valve outlet port **36**, results in a portion of the enlarged diameter portion **65** located generally opposite the valve outlet port **36** moving away from an internal wall **107** of the valve internal chamber **38**. Fluid can then be introduced through the lumen **110** of the actuator **90** and into the internal valve chamber **38**. Further, fluid is able to move between the enlarged diameter portion **65** of the rubber valve plug **14** and the wall **107** of the valve internal chamber **38** and, subsequently, into the valve outlet port **36**. Thus, introduction of the actuator **90** through the valve inlet port **21** results in the establishment of a fluid flow path between the valve inlet port **21** and the valve outlet port **36**.

The actuator **90** is inserted through both the valve inlet port **21** and the valve throat **23** against a bias of the metal or plastic spring **74**. When the actuator **90** is removed from the valve inlet port **21**, the spring **74** biases the elastomeric valve plug **14** back through the valve throat **23** and into the valve inlet **21**. Curved guiding surfaces **118** help to facilitate this process of generally realigning the plug proximal portion **47** about the axis **54**.

Introduction of the actuator **90** through the valve throat **23** and into the valve internal chamber **38** introduces a positive fluid displacement, which, if not compensated, results in an antegrade flow of fluid out of the valve outlet port **36**. The slidable elastomeric valve plug **14** of the present invention is adapted for introducing a negative fluid displacement within the valve internal chamber **38**, to thereby compensate for the positive fluid displacement introduced by the insertion of the male Luer nozzle **90**. More particularly, as the elastomeric valve plug **14** is pushed in the direction of the plug distal portion **50** by the actuator **90**, the plug cylindrical distal portion **70** is moved out of the valve internal chamber **38**, to thereby generate a negative fluid displacement within the valve internal chamber **38**. The plug cylindrical distal portion **70** is moved into the vented air chamber **43** to thereby effectively transfer the fluid displacement introduced by the actuator **90** into the ambient atmosphere.

Although the vented air chamber **43** is provided in fluid communication with the ambient atmosphere in the presently preferred embodiment, the air chamber **43** may, alternatively, be sealed. If the air chamber **43** is sealed, movement of the plug cylindrical distal portion **70** into a portion of the air chamber **43** results in compression of the gases within the air chamber **43** to thereby yield similar results.

Similarly, as the actuator **90** is removed from the valve inlet port **21**, a negative fluid displacement is generated within the valve internal chamber **38** and the valve throat **23**. The spring **74**, however, biases the elastomeric valve plug **14** back into the valve inlet port **21** to thereby generate a positive or neutral fluid displacement within the valve internal chamber **38**. The positive/neutral fluid displacement generated by movement of a portion of the elastomeric valve plug **14** back into the valve internal chamber **38** compensates for the negative fluid displacement generated by removal of the actuator **90** from the valve internal chamber **38**. In the presently preferred embodiment, the diameter of

the plug cylindrical distal portion **70** is configured to be approximately equal (or proportional) to the diameter of the actuator **90**, to thereby yield very close compensating displacements between the two devices. If the diameters are changed, flushing can be achieved.

If the volume of the plug cylindrical distal portion **70** is slightly greater than the volume of the actuator **90**, a small amount of retrograde flow will be created during insertion of the actuator **90** and, subsequently, antegrade (self-flushing) flow will be produced during removal of the actuator **90**. This antegrade flow (self-flushing) produced during removal of the actuator **90** can be considered a desirable feature.

A first alternative embodiment of the present invention is illustrated in FIG. **3**, where similar elements are numbered as in FIGS. **1** and **2**, but preceded by a 3. In the alternative embodiment illustrated in FIG. **3**, both the spring **74** and the plug cylindrical distal portion **70** are eliminated. The biasing force and valve return force of this embodiment are facilitated by a plug collapsible skirt **371**, which is preferably integrally formed with the plug **314**. The vented air chamber **343** is formed within the plug collapsible skirt **371** and the valve base **318**. As the plug proximal portion **347** is pushed out of the valve throat **323** by an actuator (not shown), the plug collapsible skirt **371** is collapsed somewhat in a direction toward the valve base **318**. As the plug collapsible skirt **371** is collapsed, air is displaced out of the vent aperture **344**. This displacement of air through the vent aperture **344** compensates for displacement resulting from introduction of the actuator into the valve internal chamber **338**. The configuration of FIG. **3** eliminates any potential problems which may be associated with the plug biased member **67** of FIG. **1**.

A second alternative embodiment is illustrated in FIGS. **4–6**, where a spring **474** is provided within the plug collapsible skirt **471**. Operation of this second alternative embodiment is similar to the operation of the embodiment of FIG. **3**, with the exception of an additional biasing force facilitated by the spring **474**. Another feature of the second alternative embodiment, which may be provided in any of the other embodiments of the present invention as well, is a distally located valve outlet port **436**. An outlet port axis **485** of the valve outlet port **436** is substantially aligned with an axis **454** of the valve housing **412**. The spring **474** of this embodiment may act as a rib cage to thereby limit the collapse of the plug collapsible skirt **471** under high fluid pressure.

The fluid path of this second alternative embodiment, when the system is actuated, is from the valve inlet port **421**, through the valve throat **423**, between the enlarged diameter portion **465** and the wall **407** of the valve internal chamber **438**, through the U-shaped passage **466**, and out of the valve outlet port **436**. Air within the air chamber **443** may simply be compressed or, alternatively, may be vented to the ambient atmosphere upon actuation of the system. FIG. **5** illustrates a bottom view of the valve cap **416**, and FIG. **6** illustrates a top view of the valve base **418**. In the top view of the valve base **418**, an internal strut **419** comprises an "X" configuration, and four vent ports **421** are provided for venting air from the air chamber **443** into the ambient atmosphere.

FIGS. **7** and **8** illustrate a third alternative embodiment of the present invention, which is similar to the embodiment of FIGS. **1** and **2**. The third alternative embodiment of the present invention, however, comprises a plug collapsible skirt **571**, an internal strut **518**, and a distally located valve outlet port **536**. As shown in FIG. **8**, the internal strut **518** limits the collapse of the plug collapsible skirt **571** under high pressure. When the actuator **590** is inserted into the valve internal chamber **538** a positive fluid displacement is generated within the valve internal chamber **538**. The plug collapsible skirt **571** collapses in a direction toward the valve outlet port **536** to thereby generate a compensating negative fluid displacement within the valve internal chamber **538**. As the plug collapsible skirt **571** collapses and decreases the size of the air chamber **543**, the air within the air chamber **543** is either compressed or vented to the ambient atmosphere.

A fourth alternative embodiment of the present invention is illustrated in FIG. **9**, where the rubber valve plug **614** comprises a plug hollow passage **616**. The plug hollow passage **616** connects the valve outlet port **636** to the valve internal chamber **638**. A valve vented air chamber **643** generally surrounds the plug hollow passage **616** of the rubber valve plug **614**. When the device is actuated by insertion of an actuator (not shown) through the valve inlet port **621**, the enlarged diameter portion **665** of the rubber valve plug **614** is moved generally in the direction of the valve outlet port **636**. A plug annular member **637**, however, resists this movement and provides return biasing action to the rubber valve plug **614** when the actuator is removed from the valve inlet port **621**. The plug annular member **637** comprises thicker portions **639** and thinner portions **640**. The thicker portions **639** provide stronger biasing effects than the thinner portions **640**. As the actuator is inserted into the valve inlet port **621**, the valve vented air chamber **643** contracts, as a result of the first and second portions **639** and **640** of the plug annular member **637**, and the movement of the rubber valve plug **614** toward the valve outlet port **636**. The positive fluid displacement introduced by insertion of the actuator through the valve inlet port **621** is thus countered by venting of air from the valve vented air chamber **643** through the vent aperture **646**. The rubber valve plug **614** of this embodiment thus contains a plug hollow passage **616**, which is somewhat centrally located and sealed from the valve vented air chamber **643** by assembled elements of the housing. These assembled elements of the housing may be joined by solvent bonding, ultrasonic welding, snap-fitting etc. As an alternative to using air in the valve vented air chamber **643**, other gases may also be used. These other gases may be vented or compressible, as long as they facilitate compensating movement of the rubber valve plug **614** in response to insertion of the actuator into the device.

Although the above embodiments have been described in the context of medical devices, the principles of the present invention apply to any other valve connectors where it is desired to minimize fluid displacement as a result of valve actuation. Although exemplary embodiments of the invention have been shown and described, many other changes, modifications and substitutions, in addition to those set forth in the above paragraphs, may be made by one having ordinary skill in the art without necessarily departing from the spirit and scope of this invention.

We claim:

1. A minimum fluid displacement connector, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the

valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the distal chamber end of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

2. The minimum fluid displacement connector as recited in claim **1**, the air chamber being in fluid communication with an ambient atmosphere, and movement of the plug into the air chamber resulting in movement of air out of the air chamber and into the ambient atmosphere.

3. The minimum fluid displacement connector as recited in claim **1**, a displacement of air within the air chamber, resulting from movement of the plug into a portion of the air chamber, being approximately equal to or greater than a displacement of fluid within the valve internal chamber, resulting from movement of the actuator into the valve internal chamber.

4. The minimum fluid displacement connector as recited in claim **3**, the valve inlet port having an inlet port axis, the air chamber being centered about the inlet port axis, the plug having a generally cylindrical shape which is also generally centered about the inlet port axis, and the plug being adapted for being moved from an inlet-port-closed position to an inlet-port-open position.

5. The minimum fluid displacement connector as recited in claim **4**, the plug being adapted for being moved by the actuator from the inlet-port-closed position to the inlet-port-open position.

6. The minimum fluid displacement connector as recited in claim **5**, the inlet-port-open position orienting a distal portion of the plug within a portion of the air chamber.

7. The minimum fluid displacement connector as recited in claim **6**, the proximal portion of the plug being adapted for being pushed by the actuator from the inlet-port-closed position out of the valve inlet port and into the inlet-port-open position where the distal portion of the plug is positioned within a portion of the air chamber.

8. The minimum fluid displacement connector as recited in claim **7**, further comprising a spring, the plug being adapted for being pushed by the spring from the inlet-port-open position back to the inlet-port-closed position.

9. The minimum fluid displacement connector as recited in claim **7**, movement of the actuator into the valve internal chamber roughly corresponding to movement of the distal portion of the plug into a portion of the air chamber, the movement of the actuator into the valve internal chamber resulting in a displacement of fluid within the valve internal chamber that is compensated by movement of portions of the plug out of the valve internal chamber to thereby generate an approximately zero displacement within the valve internal chamber.

10. The minimum fluid displacement connector as recited in claim **9**, the plug comprising a primary shoulder seal adapted for contacting a valve seat of the minimum fluid displacement connector when the plug is in the inlet-port-closed position, the primary shoulder seal being removed from contact with the valve seat when the plug is moved from the inlet-port-closed position to the inlet-port-open position.

11. The minimum fluid displacement connector as recited in claim **10**, a first portion of the primary shoulder seal contacting an inner surface of the valve internal chamber when the plug is in the inlet-port-open position, and a second portion of the primary shoulder seal not contacting the inner surface of the valve internal chamber when the plug is in the inlet-port-open position.

12. The minimum fluid displacement connector as recited in claim **11**, the inlet-port-open position of the plug facilitating a flow of fluid from the valve inlet port into the valve internal chamber, and between the second portion of the primary shoulder seal and the inner surface of the valve internal chamber into the valve outlet port, and out of the valve outlet port.

13. The minimum fluid displacement connector as recited in claim **9**, a portion of the plug no longer being centered about the inlet port axis when the plug is in the inlet-port-open position, whereby fluid can pass from the valve inlet port, around a portion of the plug, and into the valve outlet port, when the plug is in the inlet-port-closed position.

14. The minimum fluid displacement connector as recited in claim **13**, the valve outlet port having an outlet port axis that is substantially perpendicular to the inlet port axis.

15. The minimum fluid displacement connector as recited in claim **13**, the valve outlet port having an outlet port axis that is substantially parallel to the inlet port axis.

16. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end, and adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow between the distal chamber end of valve internal chamber and the valve outlet port.

17. A valve for transferring fluid, comprising:

an internal chamber that is in fluid communication with an outlet port, the internal chamber being adapted for accommodating an actuator therein, insertion of the actuator into the internal chamber placing the actuator into fluid communication with both the outlet port and substantially all of the internal chamber and resulting in a positive fluid displacement within the internal chamber and removal of the actuator from the internal chamber resulting in a negative fluid displacement within the internal chamber;

an air chamber; and

a biased member adapted for being moved into a portion of the air chamber upon insertion of the actuator and for being moved out of a portion of the air chamber upon removal of the actuator, movement of the biased member into a portion of the air chamber resulting in a negative fluid displacement within the internal chamber which substantially compensates for the positive fluid displacement, and movement of the biased member out of a portion of the air chamber resulting in a positive

fluid displacement within the internal chamber which substantially compensates for the negative fluid displacement, for a zero displacement within the internal chamber.

18. The valve as recited in claim **17**, the biased member comprising a generally cylindrical member.

19. The valve as recited in claim **18**, the generally cylindrical member comprising a hollow, collapsible skirt which surrounds and defines the air chamber, movement of the actuator into the internal chamber collapsing the collapsible skirt and moving the biased member into a portion of the air chamber.

20. The valve as recited in claim **19**, further comprising a spring disposed within the collapsible skirt, movement of the actuator out of the internal chamber uncollapsing the collapsible skirt and moving the biased member out of a portion of the air chamber under forces exerted by the spring.

21. The valve as recited in claim **20**, an axis of the internal chamber being substantially perpendicular to an axis of the outlet port.

22. The valve as recited in claim **20**, an axis of the internal chamber being substantially parallel to an axis of the outlet port.

23. The valve as recited in claim **19**, further comprising an internal strut disposed within the collapsible skirt, movement of the actuator into the internal chamber collapsing the collapsible skirt for a predetermined distance until a portion of the biased member contacts the internal strut.

24. The valve as recited in claim **17**, the biased member comprising a hollow passage connecting the internal chamber to the outlet port, the hollow passage being surrounded by the air chamber and expanding into a portion of the air chamber when the actuator is inserted into the internal chamber, the hollow passage further contracting and moving out of a portion of the air chamber when the actuator is removed from the internal chamber.

25. The valve as recited in claim **17**, the air chamber being in fluid communication with an ambient atmosphere, and movement of the biased member into a portion of the air chamber resulting in displacement of air within the air chamber out of the air chamber and into the ambient atmosphere.

26. The valve as recited in claim **17**, the biased member further comprising an annular member adapted for being secured to a wall of the internal chamber, the annular member serving as a biasing means for contracting the hollow passage and moving the hollow passage out of the air chamber when the actuator is removed from the internal chamber.

27. A self-flushing connector, comprising:

a valve internal chamber;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port at all times;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve internal chamber and for being moved out of a portion of the air chamber when the actuator is removed from the valve internal chamber, movement of the actuator into the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and into the valve internal chamber, and movement of the plug out of the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and out of the valve internal chamber.

28. A self-flushing connector, comprising:

a valve inlet port adapted for receiving an actuator in an inward direction into the valve inlet port, the actuator having a lumen for introducing fluid through the valve inlet port in the inward direction;

a valve outlet port adapted for transferring fluid in one of a first direction out of the self-flushing connector and a second direction into the self-flushing connector; and

displacing means adapted for providing displacements of fluid within the self-flushing connector, the displacing means effecting a relatively small movement of fluid through the valve outlet port in the second direction in response to movement of the actuator in the inward direction, and the displacing means effecting a relatively small movement of fluid through the valve outlet port in the first direction in response to movement of the actuator in an outward direction opposite to the inward direction.

29. A minimum fluid displacement connector, comprising:

a valve internal chamber;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in an unobstructed fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

30. A minimum fluid displacement connector, comprising:

a valve internal chamber having a volume;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with substantially all of the volume of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of substantially all of the volume of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug adapted for being moved into a portion of substantially all of the volume of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

31. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve internal chamber having a volume and adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with substantially all of the volume of the valve internal chamber at all times and being adapted for allowing fluid to freely flow between substantially all of the volume of the valve internal chamber and the valve outlet port.

32. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve internal chamber adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in an unobstructed fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow between the valve internal chamber and the valve outlet port at all times.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

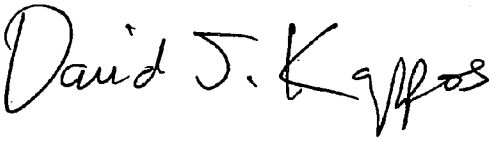
PATENT NO. : 5,730,418 C1
APPLICATION NO. : 90/006177
DATED : April 11, 2006
INVENTOR(S) : Feith et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 8, line 27, remove the "," between "A self-flushing connector" and "comprising"
Column 10, line 11, insert the word --out-- between "valve outlet port" and "of the self-flushing connector"
Column 10, line 48, insert the word --the-- between "is removed from" and "valve inlet port"

Signed and Sealed this

Twenty-fourth Day of August, 2010



David J. Kappos
Director of the United States Patent and Trademark Office

US005730418C1

(12) EX PARTE REEXAMINATION CERTIFICATE (5331st)

United States Patent
Feith et al.

(10) **Number: US 5,730,418 C1**
(45) **Certificate Issued: Apr. 11, 2006**

(54) **MINIMUM FLUID DISPLACEMENT MEDICAL CONNECTOR**

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(73) Assignee: **Porex Medical Products, Inc.**, Ontario, CA (US)

Reexamination Request:
No. 90/006,177, Dec. 27, 2001

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Patent No.: **5,730,418**
Issued: **Mar. 24, 1998**
Appl. No.: **08/724,180**
Filed: **Sep. 30, 1996**

(51) **Int. Cl.**
F16L 37/28 (2006.01)

(52) **U.S. Cl.** **251/149.6**; 251/149.1; 604/256; 604/905

(58) **Field of Classification Search** 251/149.6, 251/149.1; 604/256, 905
See application file for complete search history.

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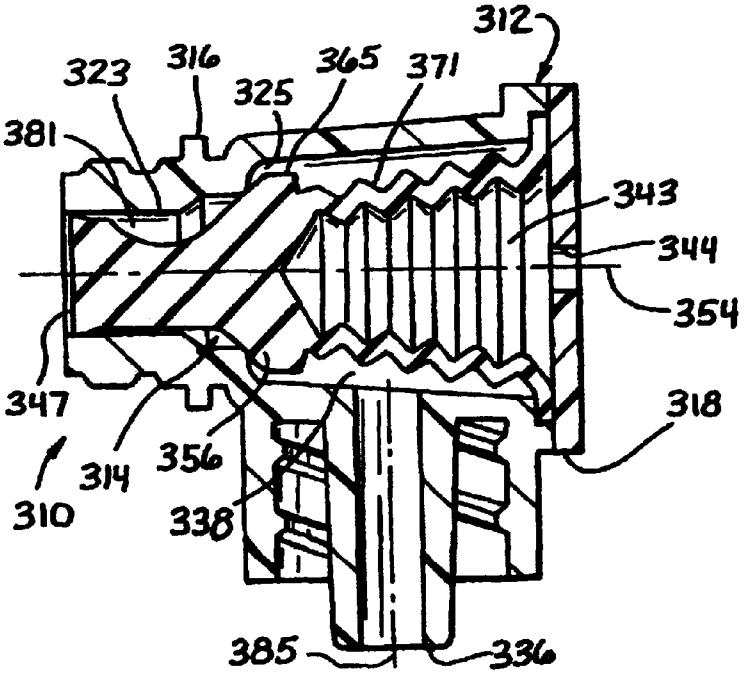
Primary Examiner—John Bastianelli

(57) **ABSTRACT**

A device for transferring fluid with minimum fluid displacement includes a valve internal chamber adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber. A biased member abuts against either a compressible gas or an ambient atmosphere, and is adapted for being moved by the actuator. Movement of the biased member results in displacement of either the compressible gas or the ambient atmosphere to thereby offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber. A valve outlet port is adapted for outputting fluid from the valve internal chamber. The valve outlet port is configured in fluid communication with the valve internal chamber at all times, and is adapted for allowing fluid to freely flow between the valve internal chamber and the valve outlet port.



EX PARTE REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

ONLY THOSE PARAGRAPHS OF THE SPECIFICATION AFFECTED BY AMENDMENT ARE PRINTED HEREIN.

Column 5, line 66 to column 6, line 22:

Turning to FIG. **2**, an actuator **90** can be inserted into the valve inlet port **21** to thereby push the plug proximal portion **47** in the direction of the plug distal portion **50**. *As shown in FIGS. 1 and 2, plug proximal portion 47 is not slitted, in contrast to prior art connectors having a slit septum. Accordingly, when actuator 90 is inserted, it enters the connector by displacing the plug proximal portion rather than by passing through a slit in the plug.* The actuator **90** comprises a male Luer nozzle in the presently preferred embodiment. The actuator **90** pushes the plug proximal portion **47** out of the valve throat **23** and, simultaneously, causes the plug proximal portion **47** to slightly rotate relative to the reduced diameter portion **81** in the clockwise direction, as presently embodied. This slight rotation of the plug proximal portion **47**, coupled with a general migration of both the plug proximal portion **47** and the reduced diameter portion **81** away from the axis **54** in a direction toward the valve outlet port **36**, results in a portion of the enlarged diameter portion **65** located generally opposite the valve outlet port **36** moving away from an internal wall **107** of the valve internal chamber **38**. Fluid can then be introduced through the lumen **110** of the actuator **90** and into the internal valve chamber **38**. Further, fluid is able to move between the enlarged diameter portion **65** of the rubber valve plug **14** and the wall **107** of the valve internal chamber **38** and, subsequently, into the valve outlet port **36**. Thus, introduction of the actuator **90** through the valve inlet port **21** results in the establishment of a fluid flow path between the valve inlet port **21** and the valve outlet port **36**.

Column 6, lines 31–47:

Introduction of the actuator **90** through the valve throat **23** and into the valve internal chamber **38** introduces a positive fluid displacement, which, if not compensated, results in an antegrade flow of fluid out of the valve outlet port **36**. The slidable elastomeric valve plug **14** of the present invention is adapted for introducing a negative fluid displacement within the valve internal chamber **38**, to thereby compensate for the positive fluid displacement introduced by the insertion of the male Luer nozzle **90**. More particularly, as the elastomeric valve plug **14** is pushed in the direction of the plug distal portion **50** by the actuator **90**, the plug cylindrical distal portion **70** is moved out of the valve internal chamber **38**, to thereby generate a negative fluid displacement within the valve internal chamber **38**. The plug cylindrical distal portion **70** is moved into the vented air chamber **43** to thereby effectively transfer the fluid displacement introduced by the actuator **90** into the ambient atmosphere. *As shown in FIGS. 1 and 2, plug 14 comprises a side surface that is exposed to fluid introduced into the valve internal chamber by actuator 90 and a distal portion 50 comprising a surface that is not exposed to fluid introduced into the valve internal chamber but is exposed to air chamber 43.*

Column 7, lines 13–32:

A first alternative embodiment of the present invention is illustrated in FIG. **3**, where similar elements are numbered as in FIGS. **1** and **2**, but preceded by a **3**. In *contrast to the embodiment illustrated in FIGS. 1 and 2, where the biasing force and valve return force are provided by spring 74 and plug cylindrical distal portion 70 is not collapsible and moves into vented air chamber 43 to compensate for fluid displacement caused by introduction of the actuator into the valve internal chamber 38, in* the alternative embodiment illustrated in FIG. **3**, both the spring **74** and the plug cylindrical distal portion **70** are eliminated. The biasing force and valve return force of this embodiment are facilitated by a plug collapsible skirt **371**, which is preferably integrally formed with the plug **314**. The vented air chamber **343** is formed within the plug collapsible skirt **371** and the valve base **318**. As the plug proximal portion **347** is pushed out of the valve throat **323** by an actuator (not shown), the plug collapsible skirt **371** is collapsed somewhat in a direction toward the valve base **318**. As the plug collapsible skirt **371** is collapsed, air is displaced out of the vent aperture **344**. This displacement of air through the vent aperture **344** compensates for displacement resulting from introduction of the actuator into the valve internal chamber **338**. The configuration of FIG. **3** eliminates any potential problems which may be associated with the plug biased member **67** of FIG. **1**.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

The patentability of claim **28** is confirmed.

Claims **1**–**3**, **5**, **6**, **16**–**27** and **29**–**32** are determined to be patentable as amended.

Claims **4** and **7**–**15**, dependent on an amended claim, are determined to be patentable.

New claims **33**–**77** are added and determined to be patentable.

1. A minimum fluid displacement connector, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the distal chamber end of the valve internal chamber through the valve outlet port;

a valve housing with an inner surface that defines at least in part an air chamber; and

a plug *with a proximal portion and a distal portion, the distal portion of the plug being non-collapsible, the*

plug forming a slidable seal with the inner surface of the valve housing and being adapted for [being moved into a portion of] *movement relative to* the air chamber when the actuator is moved into the valve inlet port, *the* movement of the plug [into a portion of] *relative to* the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

2. The minimum fluid displacement connector as recited in claim **1**, the air chamber being in fluid communication with an ambient atmosphere, and *the* movement of the *distal portion of the* plug into the air chamber resulting in movement of air out of the air chamber and into the ambient atmosphere.

3. The minimum fluid displacement connector as recited in claim **1**, a displacement of air within the air chamber, resulting from *the* movement of the *distal portion of the* plug into a portion of the air chamber, being approximately equal to or greater than a displacement of fluid within the valve internal chamber, resulting from movement of the actuator into the valve internal chamber.

5. The minimum fluid displacement connector as recited in claim **4**, the plug being adapted for being moved by the actuator from the inlet-port-closed position to the inlet-port-open position, *the proximal portion of the plug comprising a generally planar surface that is disposed in a non-perpendicular relationship with the inlet port axis when the plug is in the inlet-port-open position*.

6. The minimum fluid displacement connector as recited in claim **5**, the inlet-port-open position orienting [a] *the* distal portion of the plug within a portion of the air chamber.

16. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve housing having an inner surface;

a valve internal chamber *defined within the valve housing and* having a proximal chamber end and a distal chamber end, and adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, *the biased member comprising a non-slitted biased member proximal portion,* movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber, *the biased member comprising a distal sealing member that slidably engages the inner surface of the valve housing*; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow between the distal chamber end of valve internal chamber and the valve outlet port.

17. A valve for transferring fluid, comprising:

an inlet port defining an axis;

an internal chamber that is in fluid communication with an outlet port, the internal chamber being adapted for accommodating an actuator therein, insertion of the actuator into the internal chamber placing the actuator into fluid communication with both the outlet port and substantially all of the internal chamber and resulting in a positive fluid displacement within the internal chamber and removal of the actuator from the internal chamber resulting in a negative fluid displacement within the internal chamber;

an air chamber; and

a biased member adapted for being moved *from a first position* into a portion of the air chamber *to a second position* upon insertion of the actuator and for being moved *from the second position* out of a portion of the air chamber *to the first position* upon removal of the actuator, movement of the biased member [into a portion of the air chamber] *from the first position to the second position* resulting in a negative fluid displacement within the internal chamber which substantially compensates for the positive fluid displacement, and movement of the biased member [out of a portion of the air chamber] *from the second position to the first position* resulting in a positive fluid displacement within the internal chamber which substantially compensates for the negative fluid displacement, for a zero displacement within the internal chamber*;*

wherein the biased member comprises a biased member proximal portion with a generally planar surface that is disposed in a non-perpendicular relationship with the axis when the biased member is in the second position.

18. The valve as recited in claim **17**, the biased member comprising *a biased member distal portion having* a generally cylindrical member.

21. The valve as recited in claim **20**, [an] *the* axis of the [internal chamber] *inlet port* being substantially perpendicular to an axis of the outlet port.

22. The valve as recited in claim **20**, [an] *the* axis of the [internal chamber] *inlet port* being substantially parallel to an axis of the outlet port.

24. The valve as recited in claim **17**, the biased member [comprising] *defining in part* a hollow passage connecting the internal chamber to the outlet port, the hollow passage being surrounded by the air chamber and expanding into a portion of the air chamber when the actuator is inserted into the internal chamber, the hollow passage further contracting and moving out of a portion of the air chamber when the actuator is removed from the internal chamber.

26. The valve as recited in claim [**17**, the biased member] *24,* further comprising an annular member adapted for being secured to a wall of the internal chamber, the annular member serving as a biasing means for contracting the hollow passage and moving the hollow passage out of the air chamber when the actuator is removed from the internal chamber.

27. A self-flushing connector, comprising:

a valve internal chamber;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port at all times;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve internal chamber and for being moved out of a portion of the air chamber when the actuator is removed from

the valve internal chamber, movement of the actuator into the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and into the valve internal chamber, and movement of the [plug] *actuator* out of the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and out of the valve internal chamber.

29. A minimum fluid displacement connector, comprising:

a valve internal chamber;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in an unobstructed fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port;

a valve housing having an inner surface that defines an air chamber; and

a plug *with a plug proximal portion and a non-collapsible plug distal portion, the non-collapsible plug distal portion having a slidable seal that engages the inner surface of the valve housing, the non-collapsible plug distal portion* adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port, movement of the *non-collapsible* plug *distal portion* into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

30. A minimum fluid displacement connector, comprising:

a valve internal chamber having a volume;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with substantially all of the volume of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of substantially all of the volume of the valve internal chamber through the valve outlet port;

an air chamber *defined at least in part by a distal cylinder of a valve housing*; and

a *non-slitted* plug adapted for being moved into a portion of substantially all of the volume of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

31. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve internal chamber having a volume and adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to [offset] *overcompensate* a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with substantially all of the volume of the valve internal chamber at all times and being adapted for allowing fluid to freely flow between substantially all of the volume of the valve internal chamber and the valve outlet port.

32. A valve for transferring fluid with minimum fluid displacement, comprising:

a valve internal chamber adapted for receiving an actuator therethrough for facilitating introduction of fluid into the valve internal chamber;

a biased member abutting against one of a compressible gas and an ambient atmosphere, and adapted for being moved by the actuator, movement of the biased member resulting in displacement of one of the compressible gas and the ambient atmosphere to offset a displacement of fluid in the valve internal chamber that was introduced by insertion of the actuator into the valve internal chamber, *the biased member having a generally planar surface adapted for being abutted by the actuator, the generally planar surface being oriented in a slanted relationship with respect to an end surface of the actuator when the actuator is inserted into the valve internal chamber*; and

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in an unobstructed fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow between the valve internal chamber and the valve outlet port at all times.

33. The minimum fluid displacement connector as recited in claim 4, the valve outlet port having an outlet port axis that is substantially perpendicular to the inlet port axis.

34. The valve as recited in claim 16, the biased member comprising a biased member proximal portion and a biased member distal portion.

35. The valve as recited in claim 34, the biased member proximal portion comprising a reduced diameter portion, the biased member proximal portion being pivotable about the reduced diameter portion.

36. The valve as recited in claim 35, the biased member distal portion being non-collapsible.

37. The valve as recited in claim 17, the biased member proximal portion facilitating a seal of the internal chamber when the biased member proximal portion is in the first position.

38. The valve as recited in claim 17, the planar surface being in a perpendicular relationship with the axis when the biased member proximal portion is in the first position.

39. The self-flushing connector as recited in claim 27, the plug comprising a planar surface adapted for being abutted by the actuator.

40. The self-flushing connector as recited in claim 39, wherein:

the valve inlet port defines an axis; and

when the actuator is moved into the valve internal chamber, the planar surface is disposed in a non-perpendicular relationship with the axis.

41. The self-flushing connector as recited in claim 39, wherein:

the valve inlet port defines an inlet port axis; and

the valve outlet port defines an outlet port axis that is substantially perpendicular to the valve inlet port axis.

42. The self-flushing connector as recited in claim 28, wherein:

the valve inlet port defines an inlet port axis; and

the valve outlet port defines an outlet port axis that is substantially perpendicular to the valve inlet port axis.

43. The minimum fluid displacement connector as recited in claim 29, wherein:

the valve inlet port defines an inlet port axis; and

the valve outlet port defines an outlet port axis that is substantially perpendicular to the valve inlet port axis.

44. The minimum fluid displacement connector as recited in claim 29, the valve outlet port being substantially parallel to the valve inlet port.

45. The minimum fluid displacement connector as recited in claim 30, wherein:

the valve inlet port defines an inlet port axis; and

the valve outlet port defines an outlet port axis that is substantially perpendicular to the valve inlet port axis.

46. The minimum fluid displacement connector as recited in claim 30, the plug comprising a distal sealing member that slidably seals the air chamber from the valve internal chamber.

47. The valve as recited in claim 31, the biased member comprising a biased member distal portion that translates into one of the compressible gas and the ambient atmosphere when the actuator is inserted into the valve internal chamber.

48. A minimum fluid displacement connector, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber, the valve inlet port defining an axis;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the distal chamber end of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug having a plug proximal portion and a non-collapsible plug distal portion, the plug proximal portion being adapted for movement between a first position, when the actuator is not inserted in the inlet port, and a second position, when the actuator is inserted into the inlet port, the non-collapsible plug distal portion being adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port,

wherein the plug proximal portion comprises a generally planar surface adapted for being abutted by the actuator, the generally planar surface being disposed in a non-perpendicular relationship with the axis when the plug proximal portion is in the second position, and

wherein movement of the non-collapsible plug distal portion into a portion of the air chamber results in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port.

49. The connector as recited in claim 48, the plug distal portion comprising an annular sealing member.

50. The connector as recited in claim 48, the outlet port being substantially perpendicular to the inlet port.

51. The connector as recited in claim 48, the outlet port being substantially parallel to the inlet port.

52. A minimum fluid displacement connector, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the distal chamber end of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port when the actuator is moved into the valve inlet port;

the plug comprising a side surface that is exposed to fluid introduced into the valve internal chamber by the actuator and a non-collapsible distal portion comprising a surface that is not exposed to fluid introduced into the valve internal chamber by the actuator but is exposed to the air chamber.

53. A self-flushing connector, comprising:

a valve internal chamber;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the valve internal chamber through the valve outlet port at all times;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve internal chamber and for being moved out of a portion of the air chamber when the actuator is removed from the valve internal chamber, movement of the actuator into the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and into the valve internal chamber, and movement of the plug out of the valve internal chamber resulting in a relatively small movement of fluid through the valve outlet port and out of the valve internal chamber;

the plug comprising a side surface that is exposed to fluid introduced into the valve internal chamber by the actuator and a non-collapsible distal portion comprising a surface that is not exposed to fluid introduced into the valve internal chamber by the actuator but is exposed to the air chamber.

54. The self-flushing connector as recited in claim 28 wherein the displacing means includes a non-slitted plug.

55. The self-flushing connector as recited in claim 28 wherein the displacing means includes a plug separating an air chamber from a valve internal chamber in fluid communication with the valve outlet port.

56. The self-flushing connector as recited in claim 55 wherein the plug includes a collapsible skirt defining the air chamber within the collapsible skirt.

57. The self-flushing connector as recited in claim 56 further comprising a spring, the plug adapted for being

pushed by the spring from an inlet-port-open position back to an inlet-port-closed position.

58. The self-flushing connector as recited in claim 56 wherein the air chamber generally surrounds a plug hollow passage forming a part of the valve internal passage.

59. The self-flushing connector as recited in claim 28 wherein the displacing means includes an air chamber and a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port.

60. The self-flushing connector as recited in claim 28 wherein the self-flushing connector includes a valve internal chamber in fluid connection with the valve inlet port and the displacing means includes a plug having a collapsible skirt defining an air chamber, the plug being moved into a portion of the air chamber when the actuator is moved into the valve inlet port.

61. The self-flushing connector as recited in claim 27, a displacement of air within the air chamber, resulting from movement of the plug into a portion of the air chamber, being approximately equal to or greater than a displacement of fluid within the valve internal chamber, resulting from movement of the actuator into the valve internal chamber.

62. The self-flushing connector as recited in claim 27, the valve inlet port having an inlet port axis, the air chamber being centered about the inlet port axis, the plug having a generally cylindrical shape which is also generally centered about the inlet port axis, and the plug being adapted for being moved from an inlet-port-closed position to an inlet-port-open position.

63. The self-flushing connector as recited in claim 62, further comprising a spring, the plug being adapted for being pushed by the spring from the inlet-port-open position back to the inlet-port-closed position.

64. The self-flushing connector as recited in claim 27, the plug comprising a primary shoulder seal adapted for contacting a valve seat of the self-flushing connector when the plug is in the inlet-port-closed position, the primary shoulder seal being removed from contact with the valve seat when the plug is moved from an inlet-port-closed position to an inlet-port-open position.

65. The self-flushing connector as recited in claim 27, the plug including a hollow, collapsible skirt which surrounds and defines the air chamber, movement of the actuator into the internal chamber collapsing the collapsible skirt.

66. The self-flushing connector as recited in claim 27, the plug including a hollow passage connecting the internal chamber to the outlet port, the hollow passage being surrounded by the air chamber and expanding into a portion of the air chamber when the actuator is moved into the internal chamber, the hollow passage further contracting and moving out of a portion of the air chamber when the actuator is removed from the internal chamber.

67. The self-flushing connector as recited in claim 27, wherein the plug has a proximal portion adapted for being pushed by the actuator from the inlet-port-closed position into the inlet-port-open position and the plug further has an enlarged diameter portion located in the valve internal chamber when the plug is in the inlet-port-closed position.

68. A self-flushing connector, comprising:

a valve internal chamber having a proximal chamber end and a distal chamber end;

a valve inlet port adapted for receiving an actuator, the actuator having a lumen for introducing fluid through the valve inlet port and into the valve internal chamber;

a valve outlet port adapted for outputting fluid from the valve internal chamber, the valve outlet port being in fluid communication with the distal chamber end of the valve internal chamber at all times and being adapted for allowing fluid to freely flow into and out of the distal chamber end of the valve internal chamber through the valve outlet port;

an air chamber; and

a plug adapted for being moved into a portion of the air chamber when the actuator is moved into the valve inlet port, movement of the plug into a portion of the air chamber resulting in a minimum displacement of fluid through the valve outlet port into the self-flushing connector when the actuator is moved into the valve inlet port and a minimum displacement of fluid through the valve outlet port of the self-flushing connector when an actuator is moved out of the valve inlet port.

69. The self-flushing connector as recited in claim 68, a displacement of air within the air chamber, resulting from movement of the plug into a portion of the air chamber, being approximately equal to a displacement of fluid within the valve internal chamber, resulting from movement of the actuator into the valve inlet port.

70. The self-flushing connector as recited in claim 68, the valve inlet port having an inlet port axis, the air chamber being centered about the inlet port axis, the plug having a generally cylindrical shape which is also generally centered about the inlet port axis, and the plug being adapted for being moved from an inlet-port-closed position to an inlet-port-open position.

71. The self-flushing connector as recited in claim 70, further comprising a spring, the plug being adapted for being pushed by the spring from the inlet-port-open position back to the inlet-port-closed position.

72. The self-flushing connector as recited in claim 68, the plug comprising a primary shoulder seal adapted for contacting a valve seat of the self-flushing connector when the plug is in the inlet-port-closed position, the primary shoulder seal being removed from contact with the valve seat when the plug is moved from an inlet-port-closed position to an inlet-port-open position.

73. The self-flushing connector as recited in claim 68, the plug including a hollow, collapsible skirt which surrounds and defines the air chamber, movement of the actuator into the internal chamber collapsing the collapsible skirt.

74. The self-flushing connector as recited in claim 68, the plug including a hollow passage connecting the internal chamber to the valve outlet port, the hollow passage being surrounded by the air chamber and expanding into a portion of the air chamber when the actuator is inserted into the valve inlet port, the hollow passage further contracting and moving out of a portion of the air chamber when the actuator is removed from valve inlet port.

75. The self-flushing connector as recited in claim 68, wherein the plug has a proximal portion adapted for being pushed by the actuator from the inlet-port-closed position into the inlet-port-open position and the plug further has an enlarged diameter portion located in the valve internal chamber when the plug is in the inlet-port-closed position.

76. The self-flushing connector as recited in claim 70, the plug comprising a primary shoulder seal adapted for contacting a valve seat of the self-flushing connector when the plug is in the inlet-port-closed position, the primary shoulder seal being removed from contact with the valve seat when the plug is moved from an inlet-port-closed position to an inlet-port-open position.

77. The self-flushing connector as recited in claim 76, wherein the plug has a proximal portion adapted for being pushed by the actuator from the inlet-port-closed position into the inlet-port-open position and the plug further has an enlarged diameter portion located in the valve internal chamber when the plug is in the inlet-port-closed position.

* * * * *

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES MAGISTRATE JUDGE FOR DISCOVERY

This case has been assigned to District Judge Cormac J. Carney and the assigned discovery Magistrate Judge is Robert N. Block.

The case number on all documents filed with the Court should read as follows:

SACV11- 1264 CJC (RNBx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge

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NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

[ ] **Western Division**
312 N. Spring St., Rm. G-8
Los Angeles, CA 90012

[X] **Southern Division**
411 West Fourth St., Rm. 1-053
Santa Ana, CA 92701-4516

[ ] **Eastern Division**
3470 Twelfth St., Rm. 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

ORIGINAL

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3579 VALLEY CENTRE DR., SUITE 300
SAN DIEGO, CA 92130-3302
Phone: 858.847.6700, FAX 858.792.6773

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CareFusion 303, Inc.,
PLAINTIFF(S)
V.
B. Braun Medical, Inc.,
DEFENDANT(S).

CASE NUMBER

FAXED

SACV11-01264CJC(RNBx)

SUMMONS

TO:DEFENDANT(S): B. Braun Medical, Inc.

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it), you must serve on the plaintiff an answer to the attached ☒ complaint ☐ _____ amended complaint ☐ counterclaim ☐ cross-claim or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff's attorney, Foley & Lardner LLP, whose address is 3579 Valley Centre Dr., Suite 300, San Diego, CA 92130-3302. If you fail to do so, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

Clerk, U.S. District Court

Dated: August 23, 2011

By: _____
Deputy Clerk

(Seal of the Court)

[Use 60 days if the defendant is the United States or a United States agency, or is an officer or employee of the United States. Allowed 60 days by Rule 12(a)(3)].

FAXED

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself ☐)
CareFusion 303, Inc.

DEFENDANTS
B. Braun Medical, Inc.

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)
Amar L. Thakur, CA Bar No. 194025 (see attachment)
FOLEY & LARDNER LLP, Attorneys at Law
3579 VALLEY CENTRE DR., SUITE 300
SAN DIEGO, CA 92130-3302
Phone: 858.847.6700, FAX 858.792.6773

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an X in one box only.)

☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant.)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify): ☐ 6 Multi-District Litigation ☐ 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check 'Yes' only if demanded in complaint.)
CLASS ACTION under F.R.C.P. 23: ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT: $** _____

VI. CAUSE OF ACTION (Cite the U. S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

VII. NATURE OF SUIT (Place an X in one box only.)

OTHER STATUTES
☐ 400 State Reapportionment
☐ 410 Antitrust
☐ 430 Banks and Banking
☐ 450 Commerce/ICC Rates/etc.
☐ 460 Deportation
☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 480 Consumer Credit
☐ 490 Cable/Sat TV
☐ 810 Selective Service
☐ 850 Securities/Commodities/ Exchange
☐ 875 Customer Challenge 12 USC 3410
☐ 890 Other Statutory Actions
☐ 891 Agricultural Act
☐ 892 Economic Stabilization Act
☐ 893 Environmental Matters
☐ 894 Energy Allocation Act
☐ 895 Freedom of Info. Act
☐ 900 Appeal of Fee Determination Under Equal Access to Justice
☐ 950 Constitutionality of State Statutes

CONTRACT
☐ 110 Insurance
☐ 120 Marine
☐ 130 Miller Act
☐ 140 Negotiable Instrument
☐ 150 Recovery of Overpayment & Enforcement of Judgment
☐ 151 Medicare Act
☐ 152 Recovery of Defaulted Student Loan (Excl. Veterans)
☐ 153 Recovery of Overpayment of Veteran's Benefits
☐ 160 Stockholders' Suits
☐ 190 Other Contract
☐ 195 Contract Product Liability
☐ 196 Franchise

REAL PROPERTY
☐ 210 Land Condemnation
☐ 220 Foreclosure
☐ 230 Rent Lease & Ejectment
☐ 240 Torts to Land
☐ 245 Tort Product Liability
☐ 290 All Other Real Property

TORTS PERSONAL INJURY
☐ 310 Airplane
☐ 315 Airplane Product Liability
☐ 320 Assault, Libel & Slander
☐ 330 Fed. Employers' Liability
☐ 340 Marine
☐ 345 Marine Product Liability
☐ 350 Motor Vehicle
☐ 355 Motor Vehicle Product Liability
☐ 360 Other Personal Injury
☐ 362 Personal Injury-Med Malpractice
☐ 365 Personal Injury-Product Liability
☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
☐ 462 Naturalization Application
☐ 463 Habeas Corpus-Alien Detainee
☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
☐ 370 Other Fraud
☐ 371 Truth in Lending
☐ 380 Other Personal Property Damage
☐ 385 Property Damage Product Liability

BANKRUPTCY
☐ 22 Appeal 28 USC 158
☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
☐ 441 Voting
☐ 442 Employment
☐ 443 Housing/Accommodations
☐ 444 Welfare
☐ 445 American with Disabilities – Employment
☐ 446 American with Disabilities – Other
☐ 440 Other Civil Rights

PRISONER PETITIONS
☐ 510 Motions to Vacate Sentence Habeas Corpus
☐ 530 General
☐ 535 Death Penalty
☐ 540 Mandamus/ Other
☐ 550 Civil Rights
☐ 555 Prison Condition

FORFEITURE / PENALTY
☐ 610 Agriculture
☐ 620 Other Food & Drug
☐ 625 Drug Related Seizure of Property 21 USC 881
☐ 630 Liquor Laws
☐ 640 R.R.& Truck
☐ 650 Airline Regs
☐ 660 Occupational Safety /Health
☐ 690 Other

LABOR
☐ 710 Fair Labor Standards Act
☐ 720 Labor/Mgmt. Relations
☐ 730 Labor/Mgmt. Reporting & Disclosure Act
☐ 740 Railway Labor Act
☐ 790 Other Labor Litigation
☐ 791 Empl. Ret. Inc. Security Act

PROPERTY RIGHTS
☐ 820 Copyrights
☒ 830 Patent
☐ 840 Trademark

SOCIAL SECURITY
☐ 61 HIA(1395ff)
☐ 862 Black Lung (923)
☐ 863 DIWC/DIWW 405(g))
☐ 864 SSID Title XVI
☐ 865 RSI (405(g))

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS-Third Party 26 USC 7609

SACV11-01264

FOR OFFICE USE ONLY: Case Number: _____

AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? ☒ No ☐ Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? ☐ No ☒ Yes
If yes, list case number(s): 8-06-cv-00619 (CACD Southern Division - Santa Ana)

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)
- ☐ A. Arise from the same or closely related transactions, happenings, or events; or
- ☐ B. Call for determination of the same or substantially related or similar questions of law and fact; or
- ☒ C. For other reasons would entail substantial duplication of labor if heard by different judges; or
- ☒ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

(a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named plaintiff resides.
☐ Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	San Diego County

(b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** named defendant resides.
☐ Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
	Pennsylvania

(c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which **EACH** claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Orange County	

*** Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties**
Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): Amar L. Thakur **Date** August 23, 2011
Amar L. Thakur, Foley & Lardner LLP

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3 -1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

ATTACHMENT TO CIVIL COVER SHEET

CareFusion 303, Inc. v. B. Braun Medical, Inc.

United States District Court for the Central District of California

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