US012005199B2

(12) **United States Patent**
Trainer et al.

(10) **Patent No.: US 12,005,199 B2**
(45) **Date of Patent: Jun. 11, 2024**

(54) **CATHETER ADAPTER PORT VALVE**

(71) Applicant: **Becton, Dickinson and Company**, Franklin Lakes, NJ (US)

(72) Inventors: **Lawrence J. Trainer**, Murray, UT (US); **S. Ray Isaacson**, Layton, UT (US)

(73) Assignee: **Becton, Dickinson and Company**, Franklin Lakes, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 155 days.

(21) Appl. No.: **17/718,594**

(22) Filed: **Apr. 12, 2022**

(65) **Prior Publication Data**

US 2022/0233817 A1 Jul. 28, 2022

Related U.S. Application Data

(63) Continuation of application No. 15/644,467, filed on Jul. 7, 2017, now Pat. No. 11,324,922, which is a continuation of application No. 13/417,525, filed on Mar. 12, 2012, now Pat. No. 9,737,686.

(51) **Int. Cl.**

A61M 25/00	(2006.01)
A61M 25/06	(2006.01)
A61M 39/02	(2006.01)
A61M 39/06	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 25/0097*** (2013.01); ***A61M 25/0606*** (2013.01); ***A61M 39/06*** (2013.01); ***A61M 39/0693*** (2013.01); *A61M 39/02* (2013.01); *A61M 39/0606* (2013.01); *A61M 2039/062* (2013.01)

(58) **Field of Classification Search**

CPC A61B 17/3498; A61B 2017/3464; A61B 17/3423; A61B 1/018; A61M 25/02; A61M 2025/0266; A61M 5/158; A61M 2025/024; A61M 2025/0253; A61M 2005/1586; A61M 39/26; A61M 39/02; A61M 39/045; A61M 39/0693; A61M 2039/062; A61M 2039/0633

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,063,555	A *	12/1977	Ulinder	A61M 39/02 137/853
4,106,491	A *	8/1978	Guerra	A61B 5/150519 604/167.03
4,432,766	A *	2/1984	Bellotti	A61M 39/16 604/905
4,666,429	A *	5/1987	Stone	A61M 5/1408 604/83
4,944,728	A *	7/1990	Carrell	A61M 25/0606 604/110
5,147,333	A *	9/1992	Raines	A61M 39/02 251/149.6
5,261,895	A *	11/1993	Kablik	A61B 17/3498 604/167.03
5,360,413	A *	11/1994	Leason	A61M 39/26 604/249

(Continued)

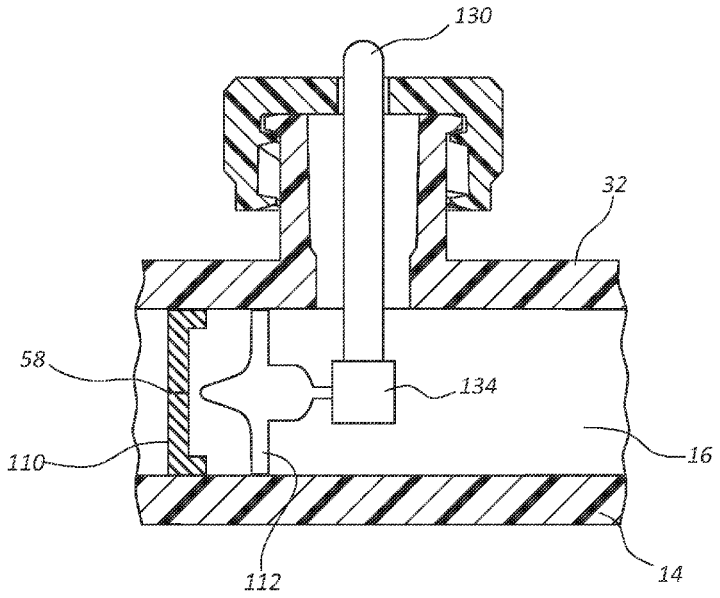
Primary Examiner — Scott J Medway

(74) *Attorney, Agent, or Firm* — Kirton McConkie; Whitney Blair; Kevin Stinger

(57) **ABSTRACT**

A catheter assembly is disclosed that includes a catheter adapter having a port disposed on its sidewall. A valve is coupled to the port to seal the opening in the port.

10 Claims, 7 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

5,512,043	A *	4/1996	Verkaart	A61M 39/02 137/853
5,628,306	A *	5/1997	Kee	A61M 16/0463 128/207.14
5,657,963	A *	8/1997	Hinchliffe	A61M 39/06 604/167.01
5,676,657	A *	10/1997	Yoon	A61B 17/3462 604/167.03
6,077,244	A *	6/2000	Botich	A61M 25/0631 604/110
6,481,462	B2 *	11/2002	Fillmore	A61F 5/4405 251/7
7,326,188	B1 *	2/2008	Russell	A61M 39/24 604/248
7,617,837	B2 *	11/2009	Wilson	A61B 5/0215 137/112
9,597,483	B2 *	3/2017	King	A61M 39/24
9,814,866	B1 *	11/2017	Goswami	A61M 27/00
2004/0068239	A1 *	4/2004	Utterberg	A61M 5/16813 604/533

* cited by examiner

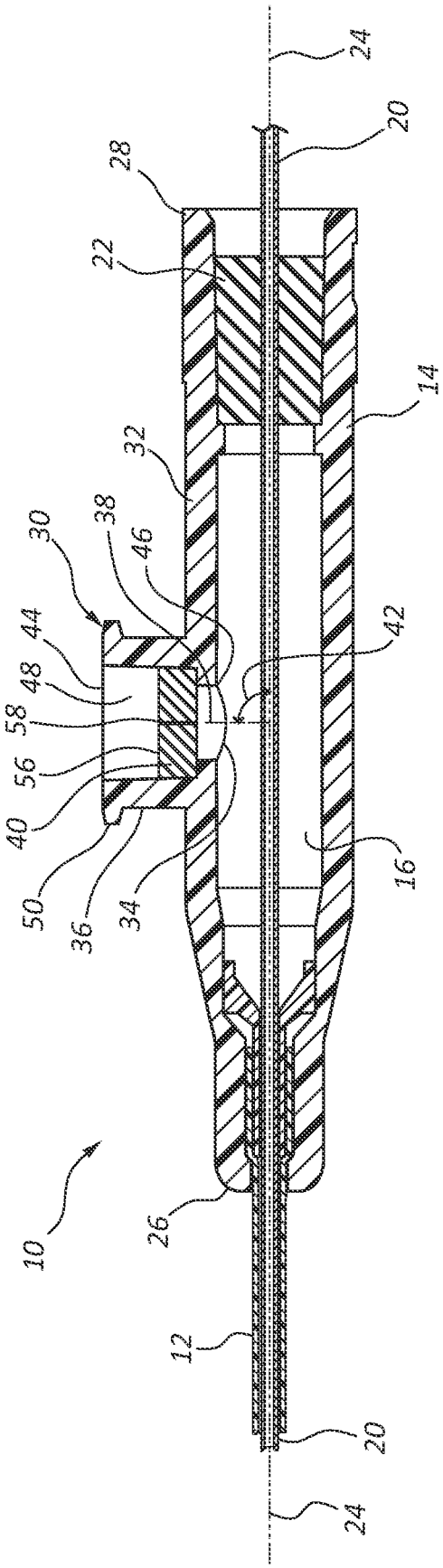

24
20
28
22
14
32
30
38
46
44
42
48
58
56
40
50
36
34
16
10
26
12
20
24

FIG. 1

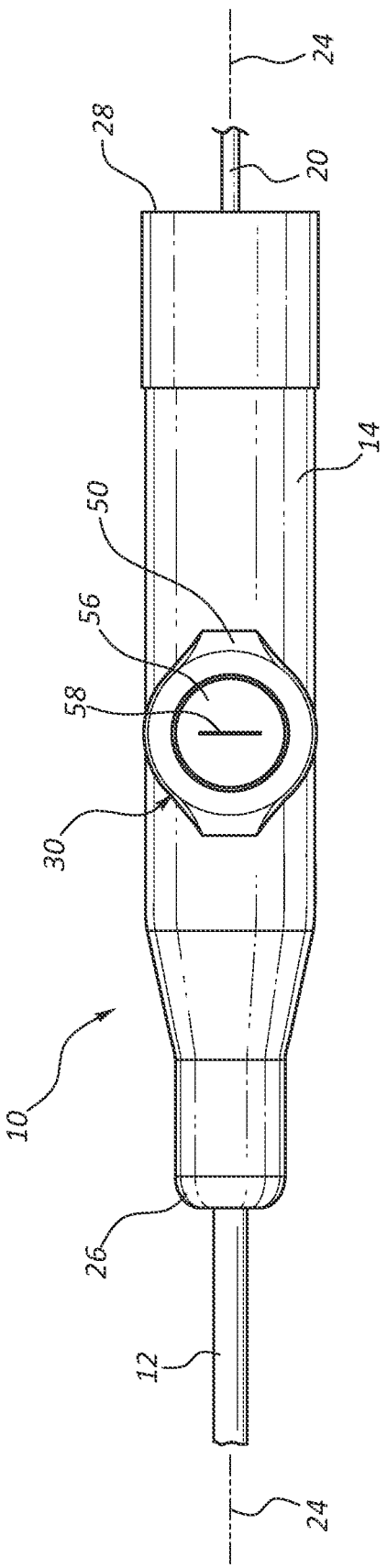

24
28
20
14
50
56
58
30
10
26
12
24

FIG. 2

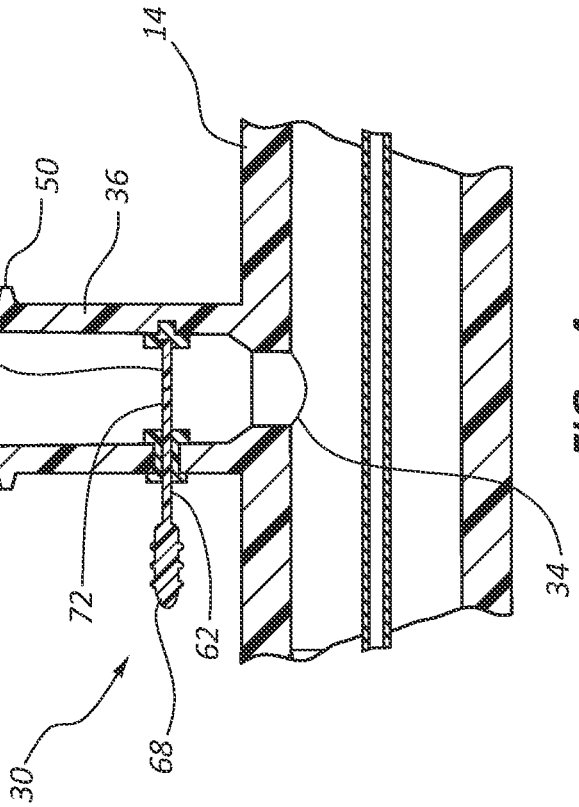


FIG. 4

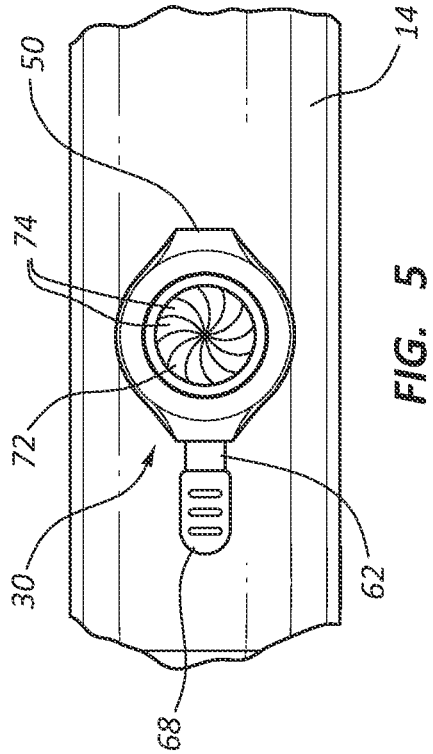


FIG. 5

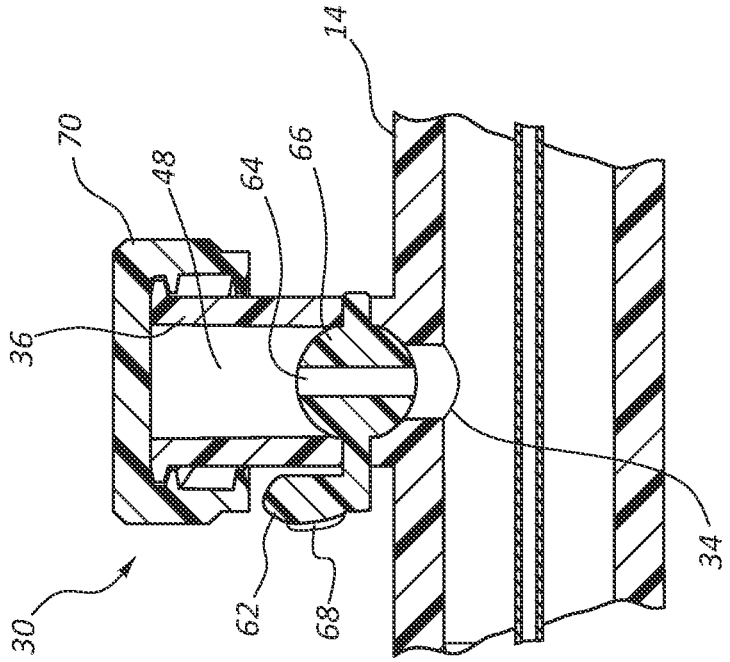


FIG. 3

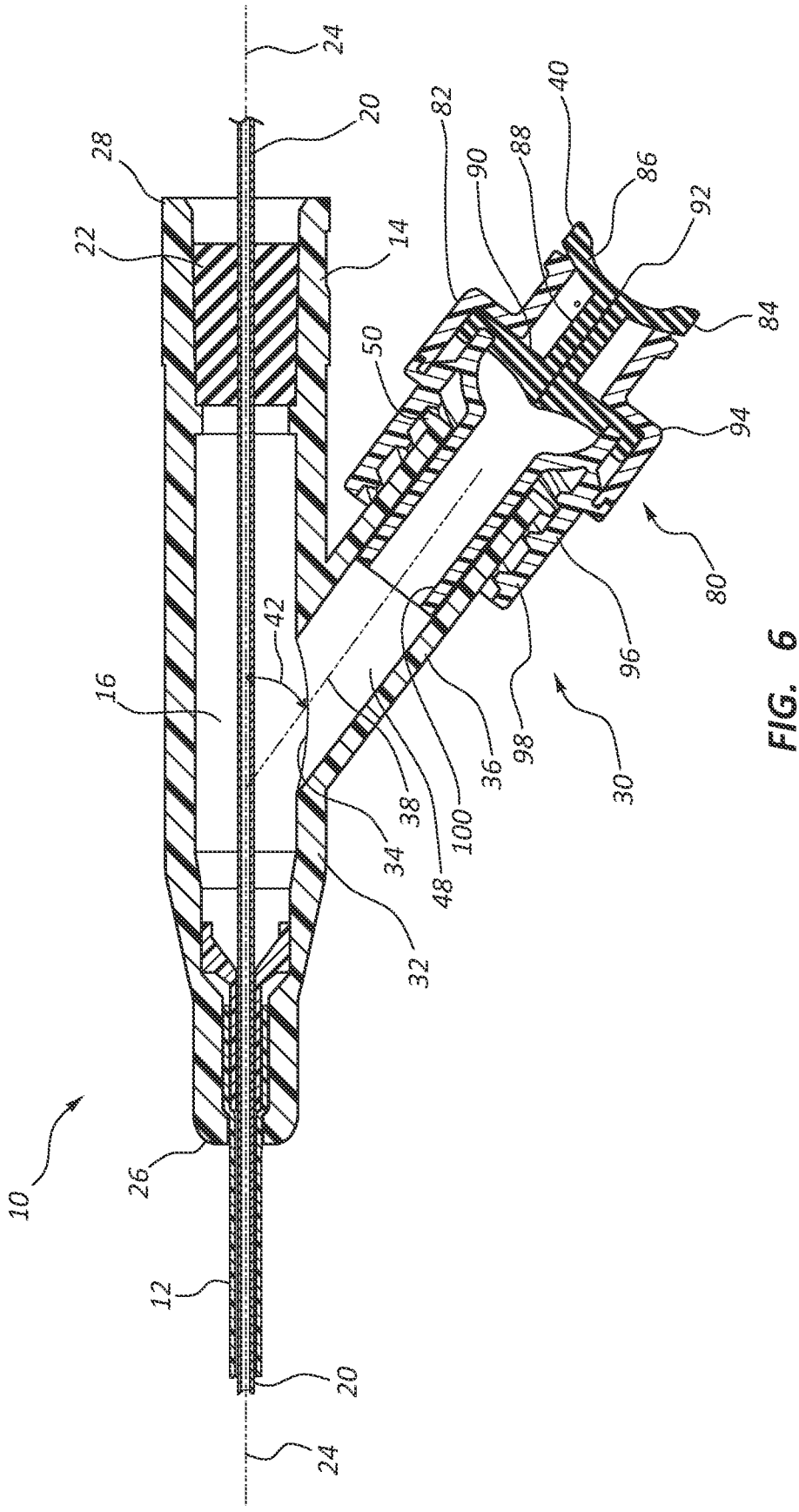

24
20
28
22
14
82
90
88
40
86
92
84
50
94
80
96
42
16
98
30
36
38
100
34
48
32
10
26
12
20
24

FIG. 6

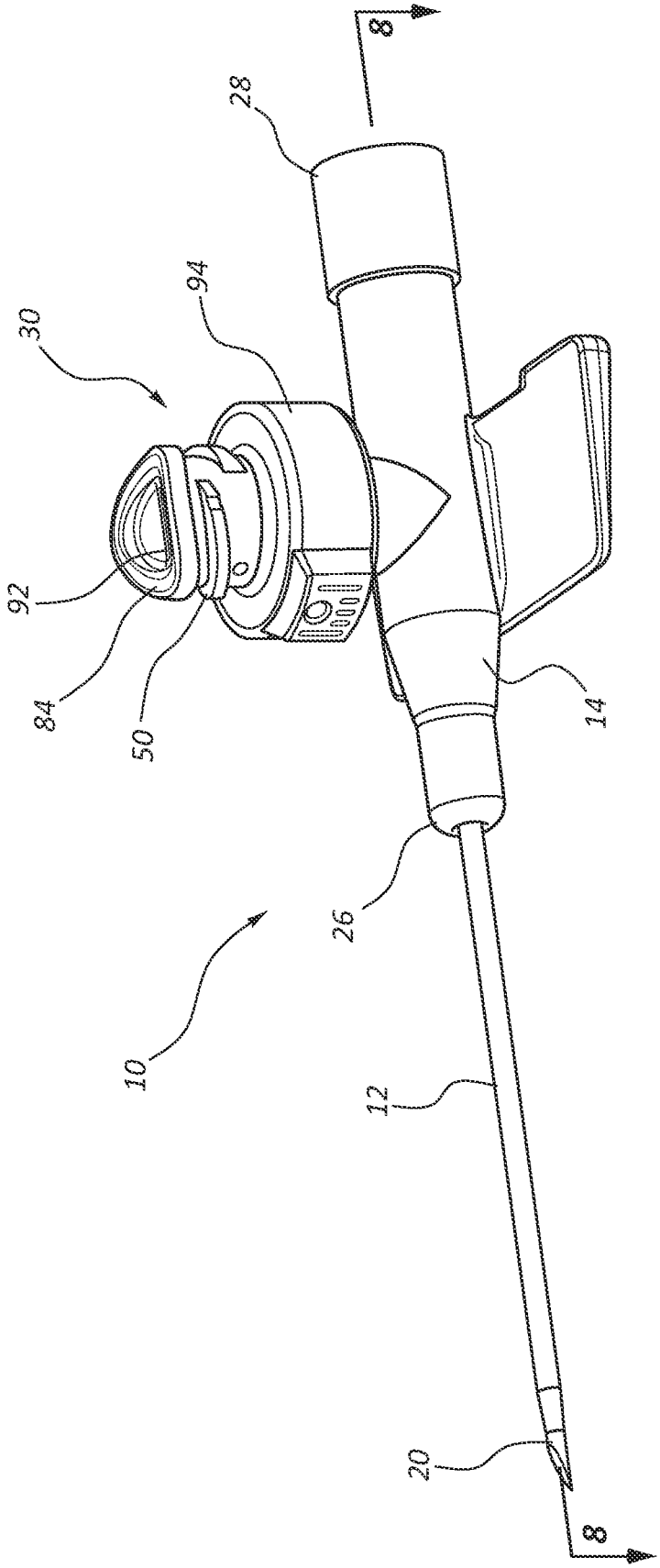


FIG. 7

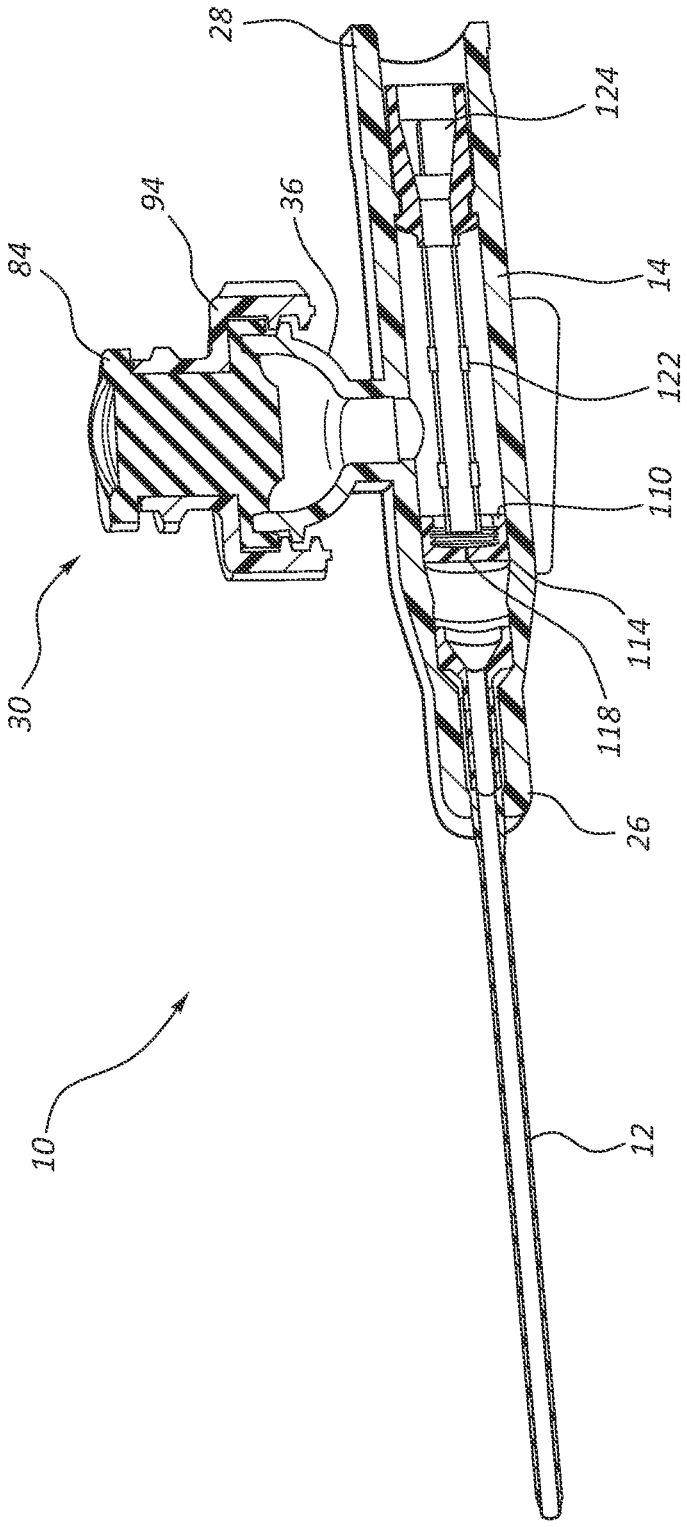


FIG. 8

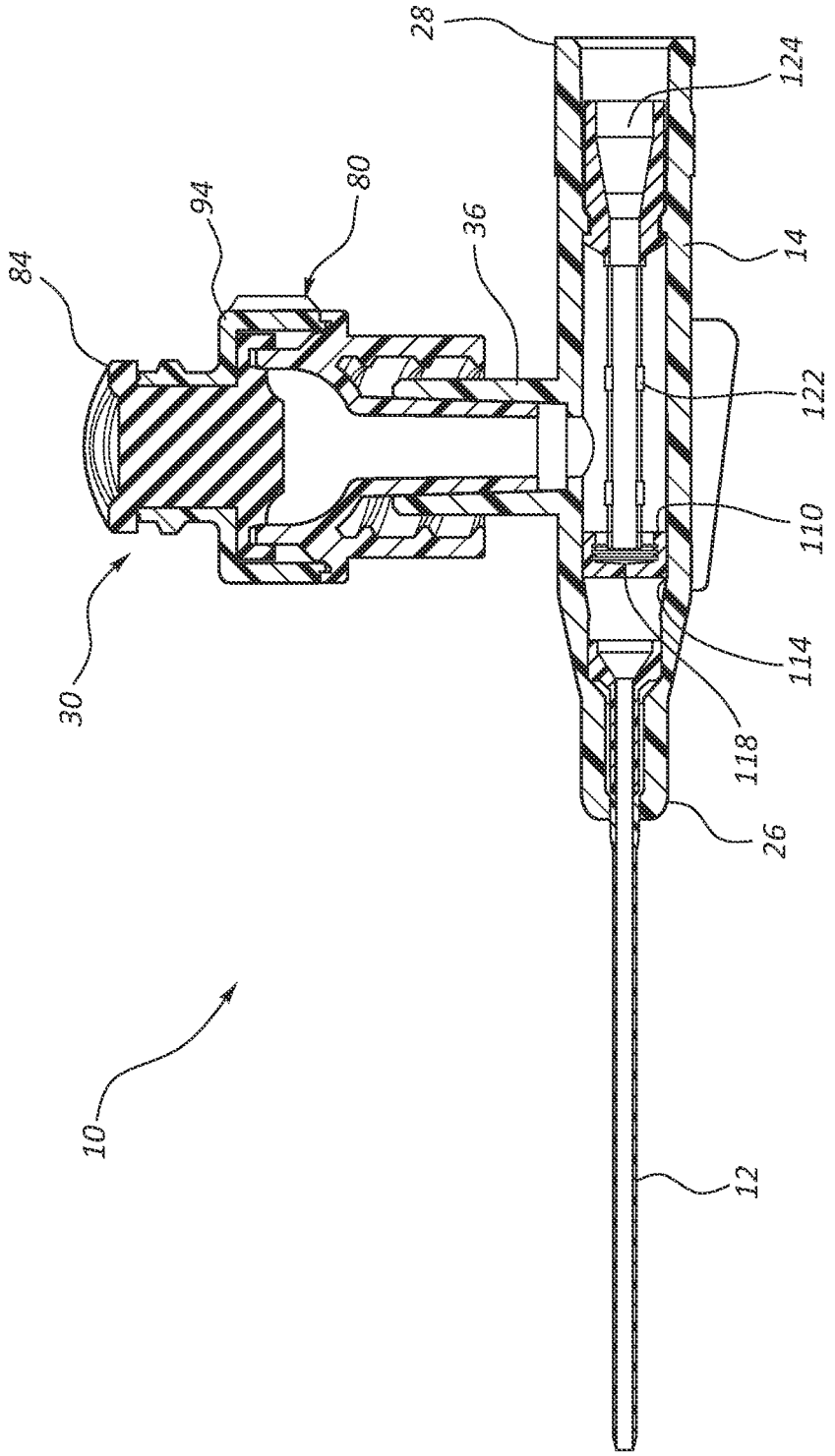


FIG. 9

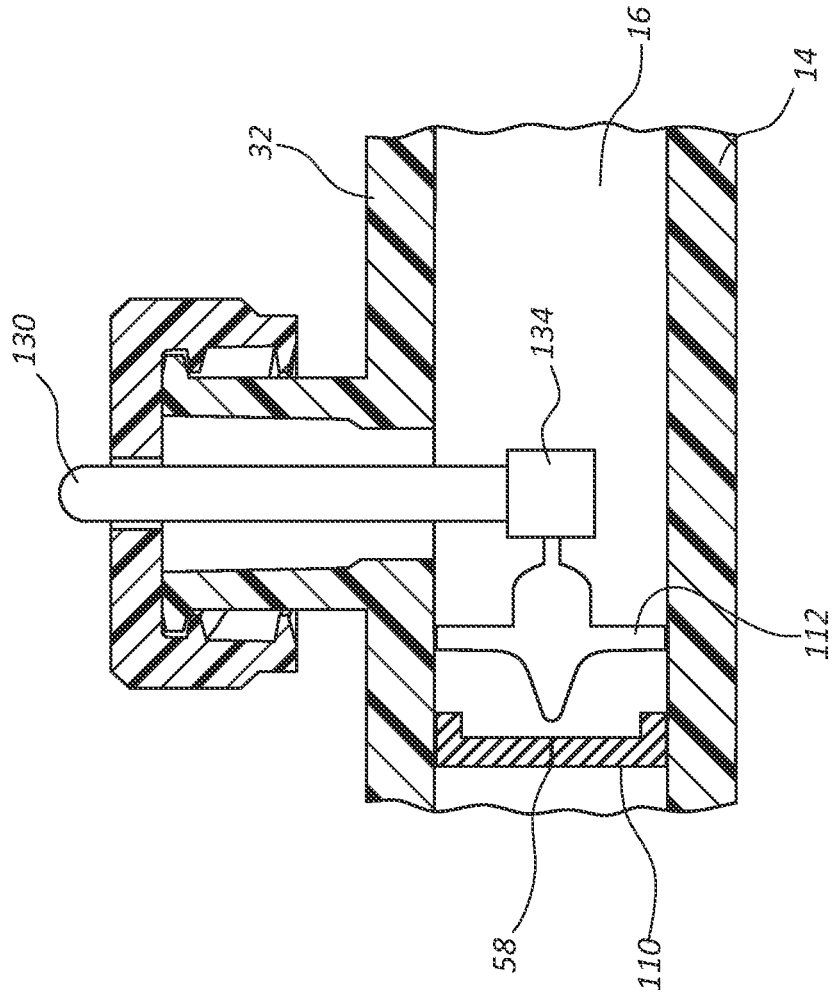


FIG. 10

CATHETER ADAPTER PORT VALVE

RELATED APPLICATION

This application is a continuation of U.S. patent application Ser. No. 15/644,467, filed on Jul. 7, 2017, entitled CATHETER ADAPTER PORT VALVE, which is a continuation of U.S. patent application Ser. No. 13/417,525, filed on Mar. 12, 2012, entitled CATHETER ADAPTER PORT VALVE, which are incorporated herein in their entirety.

BACKGROUND OF THE INVENTION

The present invention relates to port valves used in catheter assemblies. In medicine, catheter assemblies are used to place a catheter properly into the vascular system of a patient. Once in place, catheters such as intravenous (or "IV") catheters may be used to infuse fluids including normal saline, medicinal compounds, and/or nutritional compositions into a patient in need of such treatment. Catheters additionally enable the removal of fluids from the circulatory system and monitoring of conditions within the vascular system of the patient.

One type of commonly used catheter is a peripheral intravenous catheter. These short, indwelling intravenous catheters are often used to provide an entry route for medications, fluid for hydration, and in some cases, for parenteral feeding, into a patient. Such catheters are generally short in length, ranging from about one-half to about three inches in length, and are generally made of flexible biocompatible materials. Peripheral intravenous catheters are often provided as "over-the-needle" catheters mounted over an introducer needle with a sharp distal tip. A portion of the catheter including at least the distal tip of the catheter securely grips the outside of the needle to prevent catheter peelback during insertion of the catheter into the circulatory system of the patient. Although several techniques for placing such catheters are practiced in the art, many generally include the step of inserting at least a portion of the needle into the target vessel and then sliding the catheter over the needle into place.

Once placement of the needle has been confirmed, the medical personnel may remove the needle, leaving the catheter in place. A septum within the catheter adapter can prevent the outflow of fluid during and following removal of the introducer needle. These septum structures are generally elastomeric and are designed to closely conform to the shape of a needle during storage and use to prevent leaking, then to seal upon removal of the needle. However, if the needle is left within the septum for long periods, the septum may not completely seal after the needle is removed, having conformed, in part, to the shape of the withdrawn needle. An incompletely sealed septum can increase the risk of blood exposure to medical personnel, since blood may flow through the small opening in the slit of the septum. It would thus be an improvement in the art to provide a catheter assembly with more reliable sealing functionality. Such a catheter assembly is disclosed herein.

SUMMARY OF THE INVENTION

The present invention has been developed in response to problems and needs in the art that have not yet been fully resolved by currently available catheter assemblies. Thus, these catheter assemblies are developed to include a valve that is located on a port of a catheter adapter. Placing the valve on the port can avoid the problems involved when a valve is in the path of an introducer needle. This valve can further provide the ability to infuse and withdraw fluids through the port.

Accordingly, in some aspects of the invention, a catheter assembly is provided that includes a catheter adapter having an inner lumen. A port in the catheter adapter can form an opening into the inner lumen. A valve can be coupled to the port and which selectively seal the opening of the port. The catheter assembly can also have a catheter tube and a septum within the inner lumen that seals the proximal end of the inner lumen.

Various types of valves can be incorporated into the port to provide medical personnel with the ability to infuse and withdraw fluids through the port. Non-limiting examples of valves include an elastomeric septum, a ball valve, and an iris valve. The valve can be a one-way valve or a two-way valve. The valve can be located on a removable luer access connector that can be connected and disconnected from the port. Alternatively, the valve can be located on a luer access connector that is fixedly connected to the port. The valve can be a luer access valve that accommodates the insertion of a luer device, such as those commonly used in the medical industry. Moreover, a body portion of the port can include luer threads that can secure a luer device to the catheter adapter. In some configurations, the port can be disposed at an angle relative to the longitudinal axis of the catheter in order to modify the direction at which fluids are infused into the inner lumen. This angle can be between about 15° to about 90°.

Additionally, the valve on a port can provide a number of benefits when used with blood control-type catheter assemblies. Blood control-type catheter assemblies can have an internal blood control valve that may remain permanently open after it is activated by the insertion of a luer. In these instances, the valve can provide medical personnel with an additional point of connection that has a limited risk of blood exposure. Accordingly, in some implementations of the invention, the valve on the port is utilized with a catheter assembly having an internal blood control valve. The blood control valve may include a blood control septum located within the inner lumen of the catheter adapter. A septum activator may also be located within the inner lumen at a location that is behind the blood control septum. When a separate luer device is inserted into the proximal end of the catheter adapter, the septum activator is advanced forward through the blood control septum, activating the blood control septum.

In some aspects of the invention, a button that extends outwardly from a sidewall of the catheter adapter can activate and deactivate the blood control septum. The button can be connected to the septum activator and configured to move the septum activator distally through the septum when the button is pressed. In some implementations, the button is configured to be pressed inwardly towards the inner lumen, and a translating mechanism translates the inward movement of the button to a distal movement of the septum activator.

These and other features and advantages of the present invention may be incorporated into certain embodiments of the invention and will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter. The present invention does not require that all the advantageous features and all the advantages described herein be incorporated into every embodiment of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

In order that the manner in which the above-recited and other features and advantages of the invention are obtained will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. These drawings depict only typical embodiments of the invention and are not therefore to be considered to limit the scope of the invention.

FIG. **1** illustrates a cross-sectioned, side view of a representative catheter assembly having a port and a valve.

FIG. **2** illustrates a perspective, top view of the catheter assembly of FIG. **1**.

FIG. **3** illustrates a partial cross-sectioned view of a representative ball valve on a port.

FIG. **4** illustrates a partial cross-sectioned view of a representative iris valve on a port.

FIG. **5** illustrates a top view of the iris valve of FIG. **4**.

FIG. **6** illustrates a cross-sectioned view of a representative removable valve on a port.

FIG. **7** illustrates a perspective view of another representative catheter assembly having a valve on a port and a needle extending through the catheter assembly.

FIG. **8** illustrates a cross-sectioned view of the catheter assembly of FIG. **7** taken along line **8-8** of FIG. **7** with the needle removed.

FIG. **9** illustrates a cross-section view of yet another representative catheter assembly having a removable valve on a port.

FIG. **10** illustrates a partial cross-sectioned view of a representative push-button mechanism for actuating a blood control septum within a catheter assembly.

DETAILED DESCRIPTION OF THE INVENTION

The presently preferred embodiments of the present invention can be understood by reference to the drawings, wherein like reference numbers indicate identical or functionally similar elements. It will be readily understood that the components of the present invention, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description, as represented in the figures, is not intended to limit the scope of the invention as claimed, but is merely representative of presently preferred embodiments of the invention.

As used herein, the term "proximal", "behind", "top", "up", or "upwardly" refers to a location on the device that is closest to the clinician using the device and farthest from the patient in connection with whom the device is used when the device is used in its normal operation. Conversely, the term "distal", "forward", "bottom", "down", or "downwardly" refers to a location on the device that is farthest from the clinician using the device and closest to the patient in connection with whom the device is used when the device is used in its normal operation.

As used herein, the term "in" or "inwardly" refers to a location with respect to the device that, during normal use, is toward the inside of the device. Conversely, as used herein, the term "out" or "outwardly" refers to a location with respect to the device that, during normal use, is toward the outside of the device.

FIG. **1** illustrates a cross-sectioned view of one embodiment of a catheter assembly **10**. As shown, the catheter assembly **10** generally includes a catheter **12** coupled to the distal end **26** of a catheter adapter **14**. The catheter **12** and the catheter adapter **14** are integrally coupled such that an inner lumen **16** of the catheter adapter **14** extends into the catheter **12**. The catheter **12** generally includes a biocompatible material that is made of a flexible or a semi-flexible polymer. The catheter **12** may be used in combination with a rigid introducer needle **20**, as shown, to enable insertion of the catheter **12** into a patient. It is contemplated that other types of implantable catheter assemblies may also be used in combination with the present invention.

After the introducer needle **20** is removed from the catheter **12** and catheter adapter **14**, fluids may be infused into the patient. These fluids can include normal saline, medicinal compounds, and/or nutritional compositions (including total parenteral nutrition, or "TPN"). Fluids, such as blood samples, can also be removed from the circulatory system of the patient through the catheter **12** for monitoring of conditions within the vascular system of the patient.

In some embodiments, a needle septum **22** is disposed within the catheter adapter **14** to prevent the outflow of fluid during and following removal of the introducer needle **20**. The needle septum **22** can be elastomeric and be designed to closely conform to the shape of an introducer needle **20** to prevent leaking. The needle septum **22** can also seal upon removal of the needle due to axial compression forces on the needle septum **22** that induces it to close.

In some instances, fluids may be infused and withdrawn from the catheter **12** through a port **30** in a sidewall **32** of the catheter adapter **14**. The port **30** can form an opening **34** extending through a sidewall **32** of the catheter adapter **14**. The sidewall **32** can be any wall of the catheter adapter **14** that extends substantially longitudinally (in relation to the longitudinal axis **24**) along the catheter adapter **14**. A port **30** can be a side port or a top port. The port **30** can form a fluid path from the external environment into the inner lumen **16** of the catheter adapter **14**.

To prevent contamination from entering the catheter adapter **14** through the port **30**, a valve **40** can be coupled to the port **30** that provides selective access through the port **30**. In some embodiments, the valve **40** can be a two-way valve. A two-way valve is a valve **40** that permits fluid flow in two directions through the valve **40** when the valve **40** is open. Non-limiting examples of a two-way valve include a split septum, a ball valve, and an iris valve. Thus, a two-way valve can permit fluid to be introduced into the catheter adapter **14** (a first way) and to be withdrawn from the catheter adapter **14** (a second way). In other embodiments, the valve **40** is a one-way valve, which is a valve **40** that only permits substantial fluid flow in a single direction when the valve **40** is open. A non-limiting example of a one-way valve is a check valve. In some embodiments, no other valves are used to regulate fluid flow through the port **30** other than the valve **40**. By thus positioning the valve **40** on a port **30** of a catheter adapter **14**, the valve **40** can avoid problems caused when an introducer needle **20** is left within an in-line valve for an extended time.

In some configurations, the port **30** can be disposed at an angle **42** relative to the longitudinal axis **24** of the catheter adapter **14**. The angle **42** can be measured between the portion of the longitudinal axis **24** extending to the proximal end of the catheter adapter **14** and the central axis **38** of the port **40**. For example, the angle **42** of the port **30** of FIG. **1** is about 90° and the angle **42** of the port **30** of FIG. **6** is about 45°. The angle **42** can at least partially control to the direction at which fluids are infused though the port **30**. Thus, the angle **42** of the port **30** can be modified to facilitate

use, optimize performance, and/or optimize fluid flow within the inner lumen **16**. In some embodiments, the angle **42** is between about 15° to about 30°. In other embodiments, the angle **42** is between about 30° to about 45°. In still other embodiments, this angle **42** is between about 45° to about 60°. In yet other embodiments, the angle **42** is between about 60° to about 90°. Accordingly, in some embodiments, the angle **42** is between about 15° to about 90°.

The port **30** can include a port body **36** having one or more integrated body portions, which extend outwardly from the sidewall **32** of the catheter adapter **14**. Typical plastic materials such as, for example, polycarbonate, polyethylene, polypropylene and co-polyesters could be used to form the port body **36**. The port body **36** can define an inlet **44** and a bore **48** extending between the inlet **44** and the opening **34** of the inner lumen **18**. The inlet **44** and at least a portion of bore **48** can be shaped and sized in conformity with at least some of the International Standards Organization (ISO) standards for a female luer connection. This will allow a male luer slip or male luer lock to be connected to port **30**.

In various embodiments, the exterior of the port body **36** can include one or more luer threads **50** in any number of thread configurations available to provide and interlock between mating devices. The luer threads **50** can allow another medical device having a male luer lock to be connected to and interlocked with the port **30**. Alternatively, as shown in FIG. **9**, the port body **36** can also have no luer threads to accommodate luer slip and luer lock connections.

FIGS. **1** through **9** illustrate various types of valves **40** that can be used in accordance with various embodiments of the port **30**. These valve types are not presented as an exhaustive set of valve types, and thus it will be understood that other suitable valves **40** can be utilized in port **30**. Reference will first be made to the valve **40** of FIG. **1**. The valve **40** can include an elastomeric septum **56** that can form a fluid barrier until it deforms to allow fluid flow therethrough. The septum **56** can be located on the inlet **44**, within the inlet **44**, or within the bore **48** of the port body **36**. Materials such as silicone, silicone rubber, or polyisoprene can be used to form septum **56**. The septum **56** can be formed as a single piece of elastomeric material that is formed to having various shapes and features. Alternatively, the septum **56** can be a two-piece configuration having a flexible inner material, such as silicon or silicone rubber, and a more rigid outer portion, such as an outer ring. The outer ring can be formed of a plastic or metal or other suitable material. The septum **56** can also include a slit **58**. In some configurations, at least a portion of the septum **56** is glued to the port body **36** using one or more adhesives. Additionally or alternatively, in some configurations, at least a portion of the septum **56** is held in place between two or more portions of the port body **36**.

FIG. **2** illustrates a perspective top view of the catheter assembly **10** of FIG. **1**. As shown, the port **30** can be accessed, with a male luer device (such as the luer access connector **80** of FIG. **6**) that is inserted through the slit **58** of the septum **56**. The male luer device can be interlocked with the luer threads **50** if the male luer device includes a luer lock. In this manner, a separate access device can be coupled to the catheter adapter **14** through the port **30** to establish fluid communication therethrough. Additionally, a syringe, needle, or other such device can be inserted through the slit **58** of the septum **58** to withdraw fluids therethrough.

FIGS. **3** to **5** will now be referenced. These figures illustrate the use of manually activated valves **40** that can control the flow of fluid through the port **30**. Reference will first be made to FIG. **3**, which illustrates a ball valve **60** that includes a spherical member **66** disposed within the bore **48** of the port **30**. The spherical member **66** can have a hole **64** through the middle so that when the hole **64** is in line with a central axis **38** of the port **30**, the ball valve **60** is open. By turning the spherical member **66**, such as with an actuator **62**, the hole **64** becomes perpendicular to the central axis **38** of the port body **36** and the ball valve **60** is closed. An actuator **62** can be coupled to the spherical member **66** such that as the actuator **62** is turned, the spherical member **66** is moved between the open and the closed positions. In some configuration, as shown, the actuator **62** includes the gripping portion **68** that is shaped and sized to accommodate the fingers of a medical personnel and to provide leverage for turning the actuator **62**.

Some embodiments of the ball valve **60** are configure so that the hole **64** through the spherical member **66** is in conformity with at least some of the ISO standards for a female luer connection, as described above. This configuration can permit the insertion of a male luer into the hole **64** of the spherical member **66** as the male luer is inserted into the port **30**. Additionally, as shown, a cap **70** can be removably coupled to the inlet **44** of the port **30**. The cap **70** can cover the inlet **44** and prevent contamination from entering therein.

FIGS. **4** and **5** illustrate another manually activated valve **40**, an iris valve. FIG. **4** illustrates a cross-sectioned view of the iris valve **72**. The iris valve **72** can generally includes a series of plates **74** that can fold in on each other and expand out to open and close the port **30**. When actuated, this series of plates **74** can open by degrees to provide a variable sized opening through the iris valve **72**. FIG. **5** illustrates a top perspective view of the iris valve **72**. As shown, the iris valve **72** is in a closed position with the series of plates **72** forming a barrier across the port **30** that seals the opening **34** into the inner lumen **16** of the catheter adapter **14**. An actuator **62** can be coupled to the iris valve **72** such that as the actuator **62** is moved, the iris valve **72** is moved between the open and the closed positions. In some configuration, as shown, the actuator **62** includes the gripping portion **68** that is shaped and sized to accommodate the fingers of a medical personnel and to provide leverage for turning the actuator **62**.

Reference will now be made to FIG. **6**, which illustrates a port **30** with a central axis **38** disposed at an angle **42** of approximately 45° relative to the longitudinal axis **24** of the catheter adapter **14**. As shown, in some embodiments, the port **30** can be coupled to a removable valve **40**. The removable valve **40** can be selectively coupled to the port body **36**, such as, via the luer threads **50**. For instance, the removable valve **40** can be coupled to a removable luer access connector **80**. A non-limiting example of such a luer access connector **80** is described in United States Published Patent Application No. 2003/0109853, filed on Dec. 7, 2001, entitled, "Needleless luer access connector," which is herein incorporated by reference in its entirety. Other such luer access connectors **80** can also be used. As shown, some embodiments of a luer access connector **80** can include a housing **82** having a top housing portion **94** and bottom housing portion **96**. A septum **84** can be located in top housing portion **94** of the luer access connector **80** to control fluid flow therethrough. The septum **84** can have a top portion **86**, a medial portion **88**, and a bottom portion **90**. The bottom portion **21** of the septum **84** can be disposed and/or held in tension between the top housing portion **94** and bottom housing portion **96**. Additionally, a slit **92** can be formed in septum **84** which extends longitudinally through proximal portion **86**, medial portion **88**, and distal portion **90** of the septum **84**.

The bottom housing portion **96** of the luer access connector **80** can have an outlet **100** that is sized and configured as a male luer taper that complies with the ISO standards for a male luer taper and which thus can be inserted into the bore **48** of the port **30**. Moreover, the bottom housing portion **96** can include a luer lock collar **98** formed about the outlet **100** to selectively lock the luer access connector **80** to the luer threads **50** of the port body **36**.

Turning now to FIG. **7**, in some embodiments, the top housing portion **94** of the luer access connector **80** is connected directly and/or fixedly to the port body **36**. This configuration can reduce the overall port size and number of require parts included in the port **30**.

FIG. **8** depicts a cross-sectioned view of the catheter assembly of FIG. **7** taken along line **8-8** of FIG. **7**. As shown, in embodiments where top housing portion **94** of a valve housing **82** is directly connected to the port body **36**, the bottom portion **90** of the septum **84** can be held in tension between the top housing portion **94** and the port body **36**. Moreover, to secure this connection, the top housing portion **94** and the port body **36** can be bonded together to prevent contamination of the port **30**. Any standard bonding technique, such as chemical adhesive or ultrasonic welding can be used to bond top housing portion **94** of the housing to port body **36**. In addition, as shown, the shape and size of the port body **36** can be configured to accommodate the movement of the septum **84**.

As further shown in FIG. **8**, in some embodiments, a port **30** and the valve **40** are used with a blood control-type catheter assembly **10**. Blood control-type catheter assemblies **10** generally includes a blood control septum **110** disposed within the inner lumen **16** of the catheter assembly **10**. The blood control septum **110** can open by a septum activator **112** when a luer device (not shown) is inserted into the proximal end **28** of the catheter adapter **14**. The luer device can advance the septum activator **112** distally through the blood control septum **110** to form an open fluid path therethrough. A representative blood control-type catheter assembly is disclosed in United States Published Patent Application No. 2011/0046570, entitled "Systems and methods for providing a flushable catheter assembly," filed Aug. 20, 2009, which is herein incorporated by reference in its entirety.

A valve in the port **30** can provide a number of benefits to the blood control-type catheter assemblies **10**. For instance, a blood control septum **110** may remain open after the septum activator **112** is inserted through the blood control septum **110**. This blood control septum **110** may remain open, even after the male luer that advanced the septum activator **122** is removed. In this open state, fluids can flow out the catheter adapter **14** and be exposed to medical personnel. However, using the valve on the port **30**, medical personnel can access the inner lumen **16** of the catheter adapter **14** without being exposed to the patient's blood.

Specific reference will now be made to the components of the blood control-type catheter assembly **10** depicted in FIG. **8**. As shown, a catheter assembly **14** can have a blood control septum **110** located within the inner lumen **16** of the catheter adapter **14**. A septum activator **112** can be located within the inner lumen **16** at a location that is behind the blood control septum **110**. The blood control septum **110** can generally comprises a flexible or semi-flexible polymer plug. The blood control septum **110** can have an outer diameter that is configured to compatibly seat within a groove or channel **114** formed on an inner surface **116** of the catheter adapter **14**. Alternatively, a groove or channel can be formed in the outer surface of the blood control septum **110**, which interlocks with one or more features on the inner surface **116** of the catheter adapter **14**. In some embodiments, the blood control septum **110** is barrel shaped, while in other configurations, the blood control septum **110** is substantially cylindrical or disk shaped. The blood control septum **110** can be elastomeric and include one or more slits **118** through which the septum activator **112** can be inserted.

The septum activator **112** can be a probe-like structure that is primarily housed behind the septum **110** within the inner lumen **16** of the catheter adapter **14**. The septum activator **112** generally comprises a tubular body **122** that is rigid or semi-rigid. The tubular body **122** further comprises an inner lumen **124** for facilitating flow of a fluid and/or liquid through the septum activator **112**. The distal end of the tubular body **122** can be shaped and sized to compatibly enter within the one or more slits **118** of the septum **110**.

Referring now to FIG. **9**, in some instances, as shown, the exterior of the port body **36** may have no luer threads. This can allow for a luer access connector **80** or another separate luer device having a male luer slip to be connected to the port body **36**. This type of port **30** can thus enable a wide variety of devices to be connected therein. Furthermore, in some instances, a septum **56**, such as that shown in FIG. **1**, can be included within the port **30** to avoid blood exposure when the separate luer device is removed from the port **30**.

Turning now to FIG. **10**, in some embodiments, the septum activator **112** of a blood control-type catheter assembly **10** can be activated and/or deactivated by pressing a button **130** on a port **30**. The button **130** can enable medical personnel to manually activate and deactivate the septum **110** as needed. In operation, the septum activator **112** can be advanced distally through the septum **110** when the button **130** is pressed a first time, and withdrawn from the septum **110** when the button **130** is pressed a second time. In some configurations, the button **130** is coupled to the sidewall **32** and extends outwardly from the catheter adapter **14**. Moreover, the button **130** can be coupled directly to the septum activator **112** or be indirectly coupled thereto via one or more connecting members. For example, the button **130** can be coupled to one or more translating mechanisms **134** that translate the inward movement of the button **130** to distal or proximal movements of the septum activator **112**.

From the foregoing it will be understood, that a catheter assembly of the present invention can include a valve that is located on a port of a catheter adapter rather than in-line with the needle path of an introducer needle. This valve on a port can avoid problems caused when a needle is left within septum for an extended period and further provide the ability to infuse and withdraw fluids through the port. This valve can be a two-way valve that facilitates the infusion and withdrawal of fluids to and from the catheter assembly. When used with blood control-type catheter assemblies, the valve can reduce the likelihood of blood contamination when connecting and disconnecting various components to the catheter assembly. Some configurations also include a push-button septum activator that can provide medical personnel with the ability to manually activate and deactivate the blood control valve as needed.

The present invention may be embodied in other specific forms without departing from its structures, methods, or other essential characteristics as broadly described herein and claimed hereinafter. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing

description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

The invention claimed is:

1. A method, comprising:

pressing a button of an intravenous catheter assembly a first time, wherein the intravenous catheter assembly comprises:

a catheter adapter having a sidewall extending between a distal end of the catheter adapter and a proximal end of the catheter adapter, wherein the catheter adapter further comprises an inner lumen extending within the sidewall between the distal end and the proximal end;

an intravenous catheter coupled to the distal end of the catheter adapter, the intravenous catheter having an inner lumen in fluid communication with the inner lumen of the catheter adapter;

a port disposed on the sidewall of the catheter adapter, the port forming an opening between the inner lumen and an external environment such that the port provides direct access to the inner lumen of the catheter adapter;

a septum positioned within the inner lumen of the catheter adapter;

a septum activator positioned within the inner lumen of the catheter adapter, the septum activator configured to be forced through the septum to open a fluid pathway through the inner lumen; and

the button that extends through the port, wherein when the button is pressed the first time the septum activator is forced through the septum, wherein the button is configured to be pressed inwardly towards the inner lumen of the catheter adapter.

2. The method of claim **1**, further comprising pressing the button a second time, wherein when the button is pressed the second time, the septum activator is withdrawn from the septum.

3. The method of claim of claim **1**, wherein the button is coupled with one or more translator elements that translate inward movement of the button to a distal movement of the septum activator.

4. The method of claim of claim **3**, wherein the one or more translator elements are disposed in the inner lumen of the catheter adapter.

5. The method of claim **1**, wherein the button extends through the opening.

6. The method of claim **1**, wherein the button extends through the port perpendicular to a longitudinal axis of the inner lumen of the catheter adapter.

7. The method of claim **1**, wherein the button protrudes from the port to allow a user to press the button.

8. The method of claim **1**, wherein the port includes a first end coupled with the side wall and a second end opposite the first end, wherein the button protrudes from the second end to allow a user to press the button.

9. A method, comprising:

pressing a button of an intravenous catheter assembly a first time, wherein the intravenous catheter assembly comprises:

a catheter adapter having a sidewall extending between a distal end and a proximal end and an inner lumen extending within the sidewall between the distal end and the proximal end;

an intravenous catheter coupled to the distal end of the catheter adapter, the intravenous catheter having an inner lumen in fluid communication with the inner lumen of the catheter adapter;

a port disposed on the sidewall of the catheter adapter, the port forming an opening between the inner lumen and an external environment such that the port provides direct access to the inner lumen of the catheter adapter;

a septum positioned within the inner lumen of the catheter adapter;

a septum activator positioned within the inner lumen of the catheter adapter, the septum activator configured to be forced through the septum to open a fluid pathway through the inner lumen; and

the button that extends through the port, wherein when the button is pressed the first time the septum activator is forced through the septum, wherein the button is coupled with one or more translator elements that translate the inward movement of the button to a distal movement of the septum activator.

10. The method of claim of **9**, wherein the one or more translator elements are disposed in the inner lumen of the catheter adapter.

* * * * *