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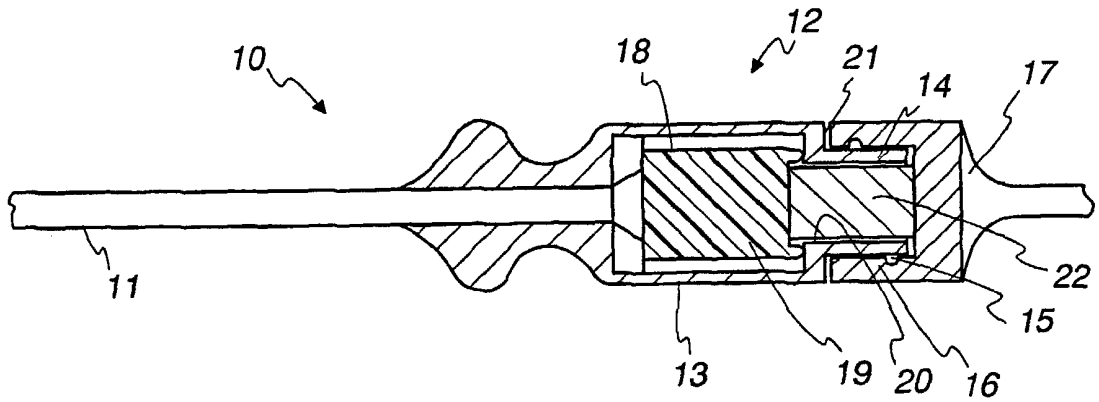
(54) Title: CATHETER WITH CHECK VALVE



(57) Abstract: A catheter (10, 29) and check valve (19) combination is disclosed. In an embodiment, the catheter (10) comprises a PICC line having a first end for introduction into a body and a second end having a valve housing (11). The valve housing (11) includes an end wall (21) defining an opening, and a check valve (19) is disposed within the housing (11) and normally biased against the end wall (21) to seal the opening. The check valve (19) prevents blood loss from the patient when the catheter (10) is introduced into the body of a patient, which is particularly important for lines that connect with the vascular system of the body near the heart. In an embodiment, the catheter comprises an introducer catheter (29) and the check valve (19) prevents blood loss when the introducer catheter is inserted into the patient, as well as preventing the introduction of air or other fluid into the patient through the introducer catheter (29). In other embodiments, the introducer catheter (29) may include a guide wire (31) and/or a needle (33) that are retractable through a check valve (19) disposed in the valve housing (11).

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Catheter With Check Valve

This application claims the benefit of U.S. Provisional Application No. 60/146,045, filed 27 July 1999.

Field of the Invention

This invention relates to peripherally inserted central and/or midline catheters lines and, more specifically, to a catheter device fitted with a simple, very reliable and effective check valves. The check valve prevents hazardous blood spills when a peripherally inserted central catheter line has reached the vascular areas near the heart.

Background of the Invention

Intravenous catheters for the infusion of fluids into the veins of a patient are typically one of two general types. One type is the "through-the-needle" catheter wherein the catheter is threaded through the needle and into the vein of a patient. In the through-the-needle type catheter, the needle is not withdrawn from the patient upon placement of the catheter. The second type of catheters is the "over-the-needle" type. Upon insertion of the introducer catheter into a patient, the insertion needle is withdrawn leaving the catheter in the body.

Traditionally, PICC lines are open-ended, requiring hurried and potentially dangerous manipulations by healthcare workers (HCW) to contain and/or minimize blood spills during their insertion and use. There is no protection from life threatening loss of blood other than the HCW technique during insertion and some devices on the market offer no protection from patient "bleed out" (life threatening loss of blood).

Short peripheral catheters are distinguishable from peripherally inserted central catheter ("PICC") lines in that PICC lines are inserted into the vascular system of the patient whereas short peripheral catheters are inserted into a vein of the patient. Not surprisingly, these different applications require different catheter structures and correspondingly different restrictions to the use of a needle guard on the introducer catheter.

Current PICC lines suffer any of several disadvantages due to the pressure of the peripheral venous system and the time required to place a typical PICC line, which can result in a significant blood spill. Contact with human blood can result in exposure to blood-borne pathogens. The effort to contain the blood flow prior to connection to or changing out an IV bag or other device is difficult and can result in damage to the catheter or the insertion site. Significant blood loss can also occur should the arterial line become accidentally disconnected, and entrapment of air is a problem if the line is left open for a prolonged period of time. The loss of blood can be life threatening for the patient. Finally, the cost associated with the clean-up and disposal of soiled materials can be significant.

In the use of a PICC line, a flexible catheter is introduced into the vascular system of a patient and subsequently manipulated to move the catheter through the vascular system of a patient to a desired location. Because the catheter must be moved upwardly through the vascular system, the catheter must be formed from a soft, biocompatible, pliable, and flexible material which is capable of winding through and extending through substantial lengths of the vascular system. It is not unusual for such catheters to extend from two to thirty inches or more through the vascular system of a

patient. The insertion of the PICC line must also occur without causing trauma to the vascular system.

In an effort to overcome these problems, several devices have been disclosed in the prior art that attempt to provide some means of checking the above-mentioned blood spills and associated problems.

One such prior art system is disclosed in U.S. Patent No. 5,195,980 to Catlin. A Y-connector including a hemostatic valve for enabling the introduction of an elongated member, e.g., a balloon catheter, into the body of a living being while precluding blood from flowing out of the valve. The Y-connector includes a housing having an interior in which a pair of resilient valve elements and a plunger mechanism are located. One valve element, e.g., a disc-like member, has a small diameter opening therein. The other valve element, e.g., a duck-bill valve elements, includes a normally closed, but openable, aperture therein. The plunger mechanism includes a tubular member having an outer diameter, which is smaller than the diameter of the opening in the one valve element. The tubular member is arranged to be moved into and out of the aperture in the other valve element. The tubular member has a central passageway arranged to enable the elongated member to be readily extended therethrough for location at a desired position within the body of the being. The one valve element is arranged for engaging the periphery of the elongated member after the elongated member has been extended through the passageway and after the tubular member is moved out of the opening in the valve member to preclude blood from flowing through the interface between the valve member and the elongated member.

Another prior art system is disclosed in U.S. Patent No. 5,405,323 to Rogers et al. A catheter check valve assembly has a valve housing with a wall defining a generally cylindrical chamber and a transverse wall having an aperture lying on the axis of such chamber. A duckbill valve and an end cap supporting a catheter are positioned on one side of the transverse wall. A separator has a major portion positioned in said cylindrical chamber and an elongated cylindrical probe extending from said major portion. The separator is axially moveable from a retraced position where the probe is out of contact with the duckbill valve to a forward position extending through and opening the duckbill valve. A needle may be extended through the catheter check valve assembly when the separator is in the forward position.

Thomas et al., U.S. Patent No. 5,409,463, discloses an apparatus for introducing a catheter percutaneously into the body of a living being. The apparatus comprises a tubular member having a distal end portion and a proximal end portion. The proximal end portion is in the form of a hollow housing for a hemostatic valve assembly comprising a lubricant reservoir and a valve element. The reservoir is formed of a foam material impregnated with a lubricant liquid, e.g., silicone. The valve element is a disk-like member formed of resilient material, e.g., silicone impregnated with polydimethylsiloxane, located distally of the reservoir and has a openable passageway extending through it for the catheter to pass. The reservoir applies the lubricating fluid in a controlled manner onto the catheter as it is passed through it, to thereby facilitate the passage of the catheter through the openable passageway in the valve element. The hollow housing is arranged to produce peripheral pressure on the valve element to facilitate its closure.

Schmidt, et al., U.S. Patent No. 5,613,663, discloses that in a valve device in a connection piece, it is provided that the valve body is configured as a valve flap (20) with a closed surface, which valve flap is mounted in the connection piece via an elastic radial tongue (21) and rests against an annular supporting surface (26) in the closed position, and that the sliding member pivots the valve flap (20) in opening direction about the radial tongue (21) by pressure against its closed surface.

Wendell, U.S. Patent No. 5,062,836, discloses a placement device for catheter and guide wire comprising, a valve assembly having a proximal end, a distal end for connection to the catheter, an elastic valve member having at least one slit and a slide member begin slidably received in the valve assembly and being movable between a first position spaced from the valve member with the valve member being closed, and a second position engaged against the valve member with the valve member being open, with the slide member having a bore extending therethrough. The device has a valve opener having an elongated stem on an end of the opener with an outer diameter sufficiently small to be received in the bore of the slide member, with the stem having sufficient length to extend through the slide member and open the valve member with the valve opener extending through the valve member, and with the stem having a channel with an inner diameter sufficiently large to receive the guide wire.

Another prior art system is disclosed in U.S. Patent No. 5,156,596 Balbierz, et al. A catheter assembly is provided. An attachment structure has a proximal end portion of an outer cannula attached to it. A needle is insertable through the outer cannula and the attachment structure. An inner cannula is attached to an inner cannula attachment region of the attachment structure. The inner cannula is insertable axially

through the attachment structure. The attachment structure can comprise two, hubs, one for the outer cannula and the other for the inner cannula, the two hubs being attachable to one another to form the overall attachment structure. A valve structure is associated with the attachment structure, suitably with the outer cannula hub. The valve structure normally closes communication between an access passage in the attachment structure, e.g., in the outer cannula hub, and the outer cannula lumen. The valve structure opens sufficiently for the inner cannula to pass through it and to open communication between the access passage and the outer cannula lumen when the inner cannula is inserted through another passage in the attachment structure and through the outer cannula lumen. The assembly allows the removal of the inner cannula and the insertion of a replacement inner cannula, if desired, without removing the outer cannula from the blood vessel. Use of a relatively small diameter needle for a desired diameter outer cannula can also be provided if the material of the outer cannula is such that it will swell in place.

Palestrant, U.S. Patent No. 5,336,192, discloses a self-sealing valve device for an angiographic catheter includes a housing having a first end adapted to form a luer lock connection with the proximal end of the angiographic catheter. A central bore extends between the first end of the housing and an opposing second end, and a deformable elastomeric slit seal is supported across the central bore to selectively seal the proximal end of the catheter. The slit seal is adapted to permit a guidewire to be passed therethrough and advanced into the catheter while sealingly engaging the walls of the guidewire to prevent blood loss through the catheter. The second end of the housing is provided with a female luer lock connection fitting for receiving the conical tip of a

syringe, stopcock, or the like, and forming a pressure-tight connection therebetween. The insertion of the conical tip of the syringe into the second end of the housing automatically deforms the slit seal for allowing fluid to pass freely therethrough, while again sealing the proximal end of the catheter when the conical tip of the syringe is removed.

Wolbring, U.S. Patent No. 5,456,675, discloses a main cannula arrangement (10) with a metal cannula (12) and a connecting piece (14), featuring a valve (46), which is closed in the disconnected state and open in the connected state.

C.R. Bard also sells a PICC line having a valve type structure in the distal end of the PICC line which is inserted into the patient. This valve at the distal end or tip of the PICC line is known as a Groshong valve.

However, these prior art devices all suffer from one or more disadvantages due to complex design. These include undesirable delicacy in handling and use, undependable operation over time, component wear, difficulty in flushing completely, and difficult, expensive manufacture. The prior art also does not provide a PICC line that provides a positive shut off to the flow of blood out of the body or fluid and/or air into the body.

Summary of the Invention

The present invention provides a catheter and check valve system or combination that advantageously seals the catheter after insertion into the body of a patient. The check valve prevents fluids from flowing out of the patient, which is particularly advantageous when the catheter extends into the vascular system near the heart where there is increased blood pressure. Without the check valve, this increased blood

pressure could cause blood to flow back through the catheter and result in heavy blood loss to the patient. The check valve also prevents the introduction of air, fluids or other contaminants through the catheter into the patient.

In an embodiment, the catheter and check valve combination include a catheter having a distal end for insertion into a body and a proximal end. The combination further includes a valve housing having an internal cavity in fluid communication with the proximal end of the catheter. A check valve is disposed within the internal cavity of the valve housing. The check valve is movable between a first position sealing the proximal end of the catheter to a second position permitting the flow of liquid through the proximal end of the catheter.

In an embodiment, the valve housing has an end wall defining an opening and the check valve is normally biased against the end wall to seal the opening. The check valve is movable to the second position away from the end wall, which opens the opening in the end wall so that liquid can flow through the valve housing to the catheter.

In an embodiment, the proximal end of the catheter includes a connector for securing the catheter to a suitable attachment, such as a drug introduction device, an IV system, or other like systems. The attachment includes a projection adapted for insertion into the proximal end of the catheter in order to move the check valve from the first position to the second position, which permits the flow of liquid through the proximal end of the catheter.

In an embodiment, the catheter comprises a PICC line. The PICC line may be integral with the valve housing or the valve housing may have a fitting for being secured to the PICC line.

In an alternate embodiment, the catheter comprises an introducer catheter having a tube portion for insertion into the body. The valve housing and check valve seal the introducer catheter, but permit fluid communication through the introducer catheter when an attachment is secured to the introducer catheter.

In an embodiment, the introducer catheter includes a connector and a cap is fitted over the connector. A guide wire extends through the introducer catheter and has one end secured to the cap and the other end extending through the tube portion of the catheter to guide placement of the introducer catheter within the body of a patient. The cap and guide wire are removable from the introducer catheter with the guide wire being retractable through the check valve. The check valve is made of a resilient material that reseals itself after retraction of the guide wire through the check valve.

In an embodiment, the introducer catheter further includes a needle extending through the tube portion and having a sharp end that projects outwardly from the tube portion of the introducer catheter. In use, the sharp end or tip of the needle is inserted into the body of a patient and the tube portion of the introducer catheter follows the needle into the patient. After insertion, a needle can be removed from the introducer catheter by withdrawing it with an attached guide wire through the check valve. The guide wire may have one end secured to the needle and the other end secured to a cap on the introducer catheter. When the needle is retracted to the check valve, the check valve automatically reseals itself due to the resilient nature of the check valve that is made of a material such as rubber.

Brief Description of the Drawings

Fig. 1 is a schematic side view shown in partial cross-section of the catheter and check valve combination of the present invention.

Fig. 2 is a schematic side view shown in partial cross-section of the catheter and check valve combination of the present invention.

Fig. 3 is a schematic side view shown in cross-section of the check valve disposed within the valve housing of the combination of the present invention.

Fig. 4 is a schematic side view shown in cross-section of the check valve disposed within the valve housing of the combination of the present invention.

Fig. 5 is a schematic side view shown in partial cross-section of an embodiment of a catheter and check valve combination of the present invention.

Fig. 6 is a schematic side view shown in partial cross-section of an embodiment of a catheter and check valve combination of the present invention.

Fig. 7 is a schematic side view shown in partial cross-section of an embodiment of a catheter and check valve combination of the present invention.

Fig. 8 is a schematic side view shown in partial cross-section of an embodiment of a catheter and check valve combination of the present invention.

Detailed Description of the Preferred Embodiments

Referring to Figs. 1 and 2, the numeral 10 designates a PICC line having a first end 11 and a second proximal end 12. The proximal end 12 includes a valve housing 13 and a fitting or connector 14 so that various attachments can be connected to the PICC line 10. In the embodiment show is the drawings, the connector 14 takes the form of a male luer 15 for connection to a female luer 16 on an attachment 17. However, other suitable connectors or fittings may be used. It will also be understood that PICC line 10

is shown for purposes of representation, and that the check value of the present invention could be used with other similar catheter devices. The attachment 17 is also shown as a generic attachment, which will be understood to represent any one of a number of various attachments that are commonly connected to PICC lines or other similar catheters.

The valve housing 13 defines an internal cavity 18 in fluid communication with the proximal end 12 of PICC line 10. In particular, fluids that are introduced into or withdrawn from the proximal end 12 of PICC line 10 flow through the internal cavity 18 to or from the PICC line 10. The check valve 18 can thus be used to control fluid flow to or from the PICC line 10

A check valve 19 is positioned within the internal cavity 18 for sealing or opening the PICC line 10. In particular, the check valve 19 is designed to seal an opening 20 in an internal wall 21 of value housing 11. In the normal position, the check valve 19 is biased against internal wall 21 and seals the opening 20, as shown in Fig. 1. In this position, the check valve 19 seals the valve housing 11 to prevent, for example, blood from flowing out of the PICC line 10 and to prevent air or fluids from entering the PICC line 10. This check valve 19 and PICC line combination 10 is particularly advantageous when the line is connected to the vascular system near the heart where the blood is highly pressurized and the blood could otherwise flow back through the PICC line 10 and cause significant blood loss to the patient.

In order to secure an attachment 17 to PICC line 10 and open the check valve 19, the connector 16 on attachment 17 includes a projection 22 that is inserted through the

second end 12 and into the internal cavity 18 to displace the check valve 19 away from the internal wall 21. When the check valve 19 is displaced, fluid can flow through the internal cavity 18 and into or from the PICC line 10. The check valve 19 may take the form of a variety of different check valves. In preferred embodiments, the check valve 19 would take the form of one of the check valves disclosed in U.S. Patent Nos. 5,954,698 or 5,967,490, which are commonly owned by the assignee of this application, Vadus, Inc., and which references are hereby incorporated by reference.

To illustrate the operation of the check valve 19, a representative embodiment is illustrated in Figs. 3 and 4. As shown in Figs. 3 and 4, the check valve 19 normally seals against wall 21, and projection 22 is used to push check valve 19 inward to unseal opening 20. The passageway 23 at the other end of the valve housing 13 is always open due to a valve seat 24 that includes a number of fluid passageways (not shown) that connect passageway 23 to valve cavity 18. While one particular embodiment has been shown in Figs. 3 and 4, it will be understood that a wide variety of check valves 19 could be incorporated into the PICC line and check valve combination of the present invention, including the various check valves disclosed in U.S. Patent Nos. 5,967,490 and 5,954,698, which are hereby incorporated by reference.

Referring to Figure 5, the PICC line 10 and the valve housing 13 may be separate components that are secured together. As shown in that embodiment, the valve housing 13 includes a fitting 25 and lock member 26 that are inserted into the PICC line 10 to secure it to the valve housing 13. This embodiment is advantageous because the PICC line 10 can be introduced into the patient's body in a variety of well known

mechanisms, and then the valve housing 13 can be used to cap the open end of the PICC line 10. The valve housing 13 and check valve 18 thus seal the PICC line 10, while still permitting various attachments to be easily connected to the PICC line 10.

Referring to Figs. 6 and 7, an alternate embodiment of the present invention is shown in which an introducer catheter 27 includes a valve housing 28 and a check valve 29. The check valve 29 is disposed in an internal cavity 30 within valve housing 28 and works in substantially the same way as check valve 19. The introducer catheter 27 includes a tube portion 27a formed of soft, pliable and biocompatible material and is adapted for insertion into the body of a patient. When the introducer catheter 27 is inserted into the body of a patient, the check valve 29 and valve housing 28 prevent the escape of blood from the patient and also prevents the introduction of fluid or air into the patient through the introducer catheter 27. When it is desired to connect an attachment 17 (Fig. 2) to the introducer of catheter 27, the attachment 17 can be connected to the connector 30 on the introducer catheter in the same fashion as it would be connected to the PICC line 10 in the embodiment in Figs. 1 and 2, wherein the projection 22 on the attachment 17 engages the check valve 29 in order to permit fluid flow through the valve housing 28.

In some instances, it is desirable to have a guide wire 31 that passes through an introducer catheter, PICC line or other similar catheter device in order to guide placement of the line within the body of a patient. In the embodiment shown in Figs. 6 and 7, such a guide wire 31 extends through the tube portion 27a of the introducer catheter 27 and also through the valve housing 28. The guide wire 31 has an end 31a connected to a cap 32. The cap 32 can be connected to connector 30 with the shown

male and female luer connectors 30a and 32a or other suitable connecting mechanisms. After the introducer catheter 27 is inserted into the patient, the cap 32 can be disconnected from the introducer catheter 27 and the guide wire 31 can be retracted from the introducer catheter 27 by pulling on the cap 32 as shown in Fig. 7.

In embodiment shown in Fig. 8, the introducer catheter 27 is used in combination with a needle 33 that is disposed in a tube portion 27a of the introducer catheter 27. The needle 33 has a sharp end or tip 33a that projects outwardly beyond the end of the tube portion 27a. In use, the sharp tip or end 33a of the needle 33 is first inserted into the body, and then the tube portion 27a of introducer catheter 27 follows the needle 33 into the body of the patient. The needle 33 is attached by guide wire 31 to the cap 32, which has been previously described. The check valve 29 is made of a resilient resealable material such as rubber, thus the needle 33 and guide wire 31 can easily be passed through check valve 29, and then check valve 29 automatically reseals the opening due the resiliency of the material. Thus, after introduction of the introducer catheter 27 with the needle 33 into a patient, the cap 32 can be removed with the guide wire 31 and needle 33 being retracted through check valve 29 in a bloodless fashion so that check valve 39 seals the end of the catheter. Thereafter, the introducer catheter 27 remains in the patient and is sealed against blood loss or introduction of fluids or air into the patient until it is desired to attach a suitable attachment device to the introducer catheter 27.

The introducer catheter 27 may also be connected to a needle guard assembly (not shown). The needle guard assembly may take the form of the needle guard

assembly disclosed in U.S. Patent No. 5,954,698, which is hereby incorporated by reference.

The catheter and check valve combination of the present invention provides a rugged, dependable system for preventing blood loss and for preventing the introduction of fluid or air into the catheter. Among other advantages, the check valve eliminates the various slits, multiple elements, and other complex configurations disclosed in the PICC prior art.

While this invention has been described with specific embodiments, many alternatives, modifications and variations will be apparent to those skilled in the art in light of the foregoing description. Accordingly, it is intended to include all such alternatives, modifications and variations set forth within the spirit and scope of the description.

We claim:

1. A catheter and check valve combination comprising:

a catheter having a distal end for insertion into a body and a proximal end;

a valve housing having an internal cavity in fluid communication with the proximal end of the catheter; and

a check valve disposed in the internal cavity, the check valve being movable between a first position sealing the proximal end of the catheter to a second position permitting the flow of liquid through the proximal end of the catheter.

2. The combination of claim 1 wherein the valve housing has an end wall defining an opening, and the check valve is normally biased against the end wall to seal the opening.

3. The combination of claim 2 wherein the check valve is movable to a second position away from the end wall and the opening of the valve housing so that the opening is unsealed and liquid can flow through the valve housing to the catheter.

4. The combination of claim 1 in which the proximal end of the catheter includes a connector.

5. The combination of claim 1 further including an attachment for connection to the proximal end of the catheter, the attached including a projection adapted for an insertion into the proximal end of the catheter in order to move the check valve from the first position to the second position, which permits the flow of liquid through the proximal end of the catheter.

6. The combination of claim 1 wherein the catheter comprises of PICC line.

7. The combination of claim 1 wherein the catheter comprises a PICC line, and the valve housing is a separate piece have a fitting that is secured to the PICC line.

8. The combination of claim 1 in which the catheter comprises an introducer catheter having a tube portion for insertion into the body of a patient.

9. The combination of claim 8 in which the introducer catheter has a connector, a cap fitted over the connector and a guide wire connected to the cap and extending through the valve housing, check valve, and tube portion of the introducer catheter, the cap and guide wire being removable from the introducer catheter with the guide wire being retracted through the check valve such that the check valve reseals itself after retraction of the guide wire from the check valve.

10. The combination of claim 9 in which the introducer catheter further includes a needle extending through the tube portion and having a sharp end that projects outwardly from the tube portion of the introducer catheter, the needle being connected to the guide wire and being retractable with the cap and guide wire from the introducer catheter.

11. A method of placing a catheter in intravenous connection with a living being, the method comprising the steps of:

providing a catheter having a first end for insertion into the body and a second end having a valve housing, the valve housing including a check valve normally biased against an opening in an end wall of the valve housing to seal the proximal end of the catheter;

inserting the first end of the catheter into the body of a patient;

providing an attachment having a connector adapted to connect to a connector on the proximal end of the catheter, the attachment further including a projection shaped to project into the opening in the end wall of the valve housing and push the check valve away from the opening;

connecting the connector on the attachment to the connector on the catheter so that the check valve is pushed away from the opening in the housing so that fluid communication is established between the catheter and the attachment.

12. The method of claim 11 wherein the catheter comprises a PICC line.

13. The method of claim 11 wherein the catheter comprises an introducer catheter.

14. The method of claim 11 wherein the check valve is comprised of a resealable material.

15. The method of claim 11 wherein, prior to insertion of the catheter into the patient, the catheter further includes an end cap secured to a connector on the catheter and connected to a guide wire, the guide wire extending through the valve housing, check valve, and tube portion of the catheter.

16. The method of claim 15 further including the step of, prior to securing the attachment to the catheter, removing the end cap and guide wire from the catheter.

17. The method of claim 11 wherein the catheter comprises an introducer catheter and a needle is positioned within the tubular portion of the catheter and has a sharp end projecting outward from the tube portion of the catheter.

18. The method of claim 17 wherein the step of inserting the catheter into the patient includes first inserting the sharp end of the needle into the patient, and then having the tube portion of the catheter follow the needle into the patient.

Fig. 1

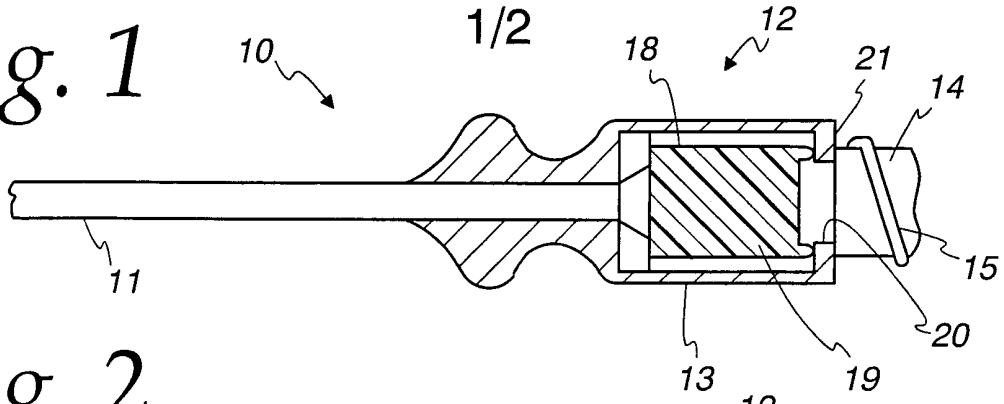


Fig. 2

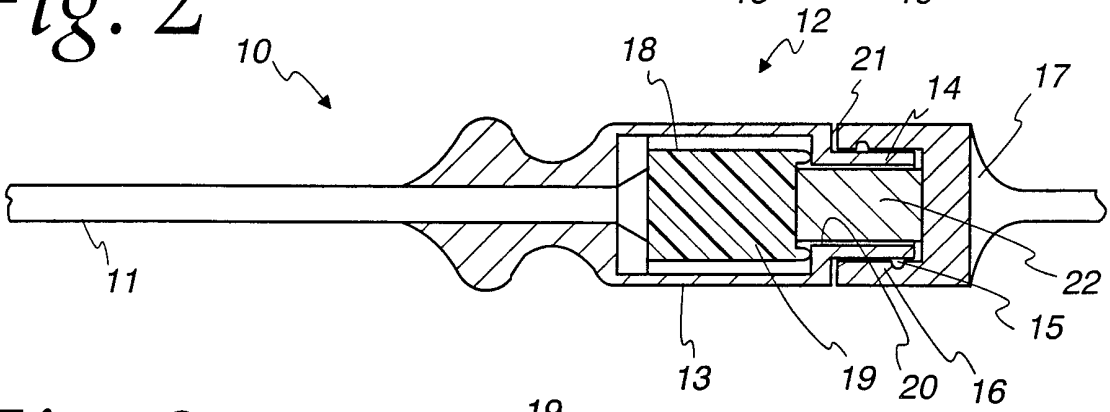


Fig. 3

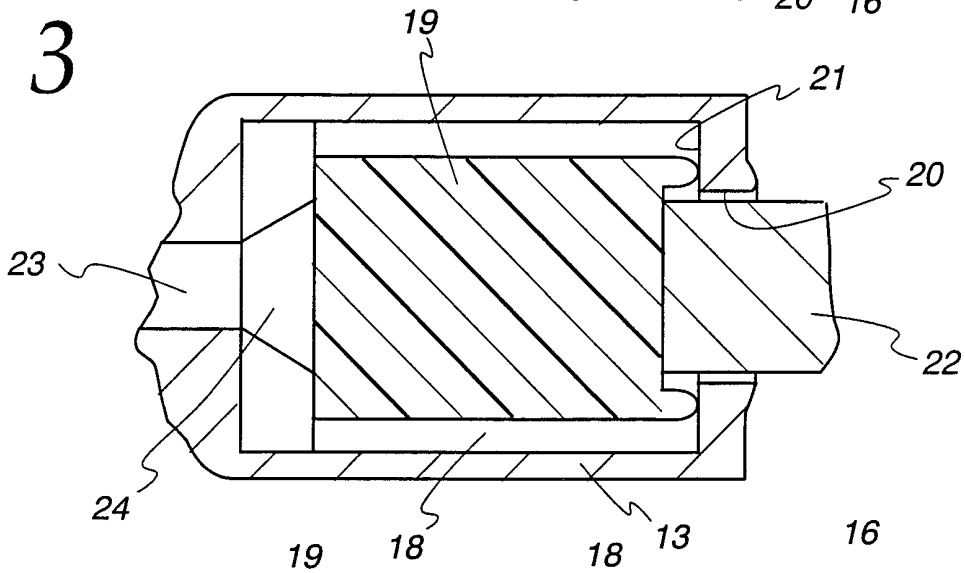


Fig. 4

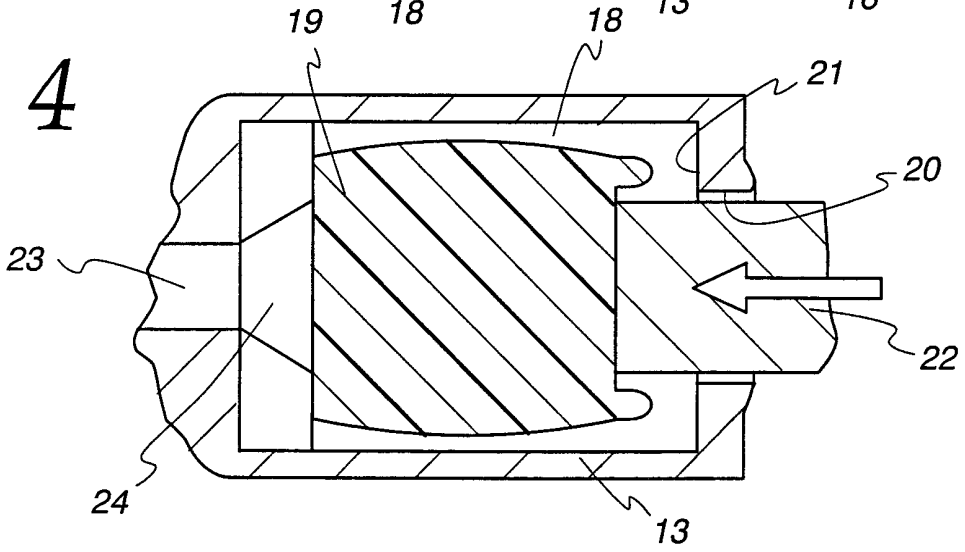


Fig. 5

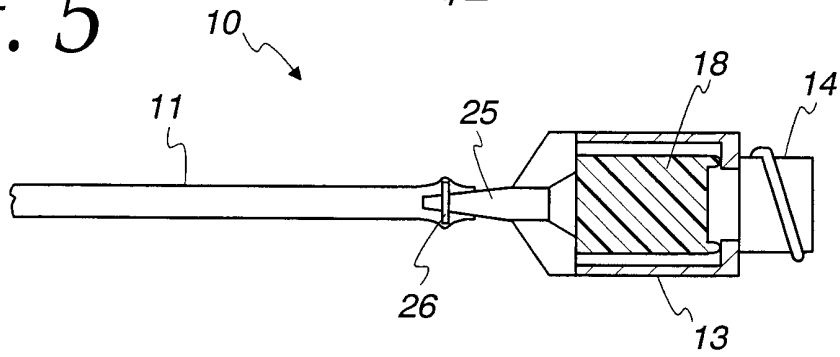


Fig. 6

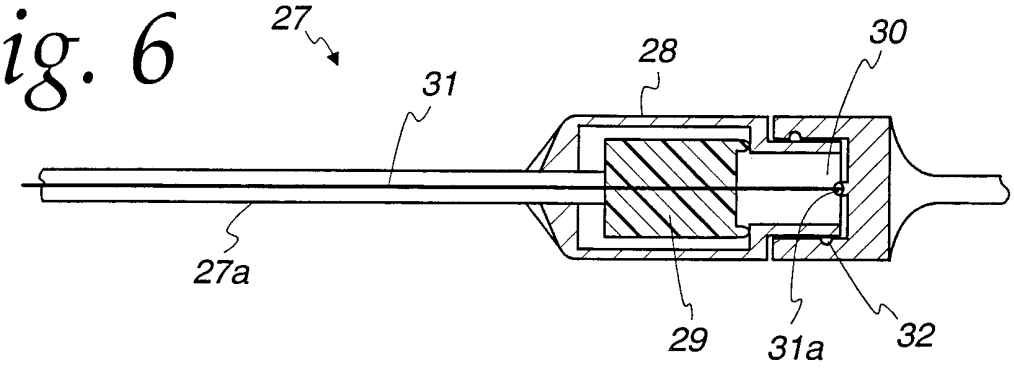


Fig. 7

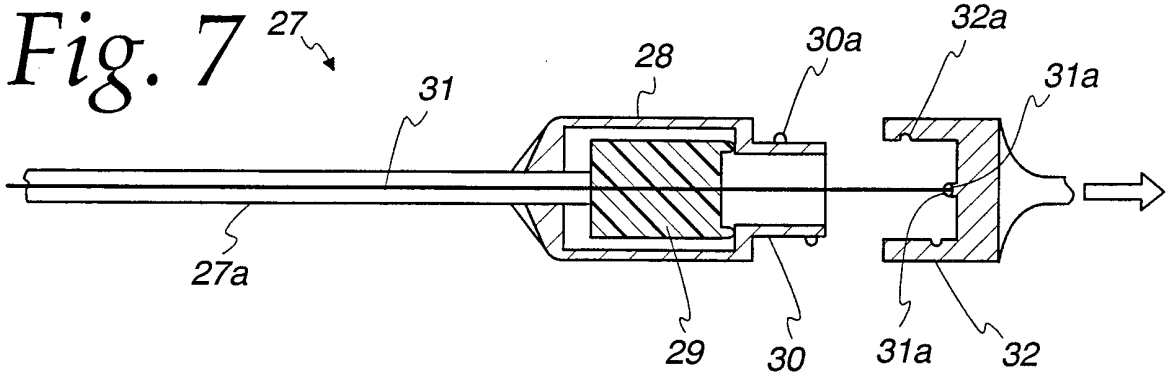
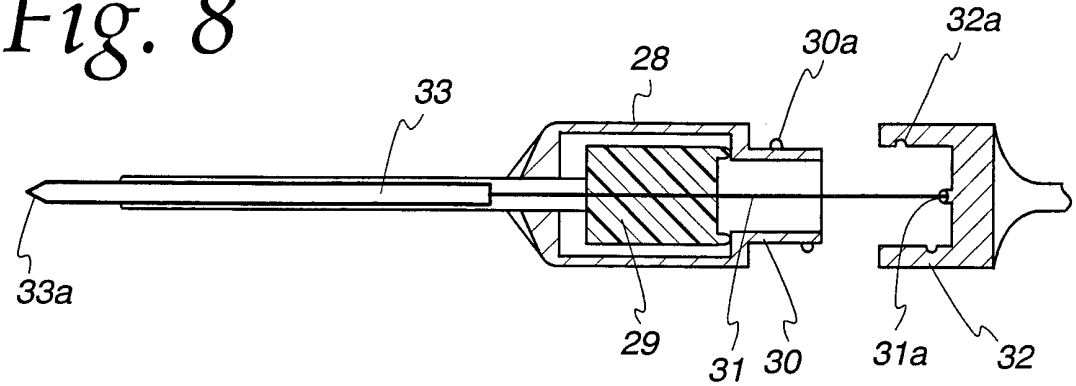


Fig. 8



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/20369

A. CLASSIFICATION OF SUBJECT MATTER
IPC(7) :A61M 5/00
US CL :604/246
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/246,249

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,613,663 A (SCHMIDT et al.) 25 MARCH 1997, Figs. 1-5 and related text.	1-5,8,10 11,13,14, 17,18 --- 6,7,12,
X	US 5,749,861 A (GUALA et al.) 12 MAY 1998, Figs 2,4,5 and related text.	1-5,8,11, 14
Y	US 5,357,961 A (FIELDS et al.) 25 OCTOBER 1994, See Figs. 1,2 and related text.	6-9,12,15
A,P	US 5,967,490 A (PIKE) 19 OCTOBER 1999, See entire patent.	1-18

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 OCTOBER 2000	Date of mailing of the international search report 03 NOV 2000
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Form PCT/ISA/210 (second sheet) (July 1998) ★