Description

This invention relates to I.V. catheters and, in particular, to catheters with valves which open when the catheter is connected to a tubing set.

During use of an I.V. catheter assembly the catheter cannula and its insertion needle are inserted into the body of a patient. When the cannula is properly located in a blood vessel, as evidenced by the appearance of a small amount of blood in the flash chamber of the needle assembly, the needle is withdrawn from the patient and removed from the catheter. A tubing set is then connected to the catheter to deliver fluids to the patient. Throughout this procedure it is desirable to minimize, and preferably eliminate entirely, any blood leakage from the assembly so as to reduce the risk of transmitting blood-borne diseases to medical personnel. In particular, as the needle is withdrawn from the catheter, it would be desirable for a valve mechanism to automatically seal the catheter cannula to prevent blood leakage from the catheter. The cannula should preferably remain sealed until the tubing set is connected to the catheter for delivery of fluids to the patient. Once the tubing set is connected to the catheter, the assembly is in a fluid-tight condition and subsequent blood leakage is unlikely.

DE-C-3809127 which is considered to represent the closest prior art with respect to the present invention discloses a catheter hub for attachment of a catheter thereto, comprising a valve having a membrane disposed within said hub to seal said hub from said catheter, said hub further comprising a membrane opener.

US-A-4311137 discloses a catheter assembly comprising a tubular needle housing, a hollow needle extending from the distal end of said needle housing, a flash chamber located within said housing, wherein said hollow needle extends from said flash chamber and the passageway of said hollow needle is in fluid communication with the interior of said flash chamber, a catheter hub mountable upon said needle housing, and a catheter attached to said catheter hub and into which is insertable said needle, wherein said hub further comprises a valve having a membrane disposed between said flash chamber and said catheter.

United State patent number 3,585,996 describes an arterial catheter placement unit which includes a needle assembly having a needle connected to a needle hub. Located within the needle hub is a self-sealing disc valve made of a relatively thick piece of rubber with several fine slits. The needle hub is designed to connect with a catheter and sheath provided with a sheath hub. Extending from the distal nose of the sheath hub is a hollow pilot tube, through which the catheter is advanced during insertion and threading. When the needle hub is not connected with the sheath hub, the disc valve is in its normally closed condition, preventing blood leakage from the hub. When the sheath hub is connected to the needle hub, the pilot tube on the sheath hub nose extends through the valve disc to hold the valve open and allow the catheter to be threaded through the valve. After the sheath hub is removed from the needle hub, the valve automatically closes and prevents flow of blood from the artery through the needle.

It would be desirable to apply the valve principle of the '996 patent to a catheter assembly to enable the catheter to automatically open when an insertion needle is passed through the catheter, then automatically close when the needle is withdrawn from the catheter, then automatically open when a tubing set is connected to the catheter. The assembly must thus be capable of these specific modes of operation with the various ancillary components listed in order to prevent blood leakage from the catheter prior to connection of the catheter to a tubing set.

In accordance with the principles of the present invention, a catheter assembly is provided, including a catheter cannula connected to a catheter hub. Located within the catheter hub is a normally closed valve membrane which is adapted to be punctured by a catheter needle. The valve membrane is opposed by a moveable valve membrane opener. When the catheter and hub are connected to an insertion needle assembly the insertion needle passes through the membrane opener and the valve membrane. When the needle is withdrawn from the membrane opener and membrane the membrane automatically seals the passageway of the catheter hub. When a tubing set is connected to the catheter hub, the tubing set connector actuates the valve membrane opener to open the valve membrane so that fluids may be delivered through the catheter to a patient.

In the drawings:

FIGURE 1 is a perspective view of a catheter assembly to be used with a catheter hub constructed in accordance with the principles of the present invention;

FIGURE 2 is a cross-sectional view of the catheter assembly of FIGURE 1;

FIGURE 3 is a detailed cross-sectional view of the catheter hub of the present invention; and

FIGURES 4a-4c illustrate a catheter and catheter hub of the present invention during various stages of use.

Referring first to FIGURE 1, a catheter assembly is shown in perspective.

Referring first to FIGURE 1, a catheter assembly 10 is shown. The assembly 10 includes a needle housing 20 which is semi-tubular in shape

and open at the top. Molded on the sides of the needle housing 20 are opposing contoured finger grips 22, one of which is visible in FIGURE 1. Located inside the semi-tubular needle housing and extending proximally therefrom is a tubular needle guard 30. On the upper surface of the needle guard are a number of small projections 32 which provide surfaces against which a user may press to fully extend the needle guard. These projections permit a user to extend the needle guard with the index or other finger while holding the catheter assembly with one hand. Extending distally from the needle housing 20 is a protective sheath not shown which covers the distally extending needle and catheter.

FIGURE 2 illustrates the assembly of FIGURE 1 after removal of the protective sheath. This drawing shows the catheter 50 and its catheter hub 52 mounted on the distal end of the needle guard 30. The point of the needle 24 is seen to extend from the distal tip of the catheter 50. A push-off tab 34 is seen projecting upward from the needle guard proximal the catheter hub 52. Located on the distal end of the needle guard is a needle guard tip 60, through which the needle 24 extends.

FIGURE 2 also serves as a cross-sectional view of the catheter assembly 10. The catheter 50 is seen to extend from the distal end 54 of the catheter hub 52 and is concentric therewith. The catheter may be attached to its hub by any means known in the art, including adhesively or mechanically by means of a metal eyelet. The larger diameter proximal portion 56 of the catheter hub 52 is flanged at its proximal end for connection to an infusion set, and the inner diameter of the proximal portion of the hub is sized to fit over the distal portion of the needle guard tip 60.

The needle 24 is attached to the distal end of the flash chamber 26 of the needle housing with the proximal end of the needle 24 terminating within the chamber. The needle 24 is affixed in place by adhesive 28. The needle extends through the needle guard tip 60, the needle hub 52, and the catheter 50, with the point of the needle extending from the distal end of the catheter. The rear of the flash chamber 26 is plugged by a microporous plug 70. The needle guard is seen to extend proximal the rear of the needle housing with the needle guard tip 60 affixed to the distal end of the needle guard at the location of the push-off tab 34. The tubular needle guard surrounds the flash chamber 26, with the base 27 of the flash chamber being located in a longitudinal slot 36 at the bottom of the needle guard. As the needle guard slides in the distal direction to cover the needle it is maintained concentric with the needle housing by the concentric tubular construction of the needle housing and needle guard and by the tracking of the base 27 of the flash chamber in the needle guard slot 36.

A flange 72 is formed at the distal end of the housing. The flash chamber 26 is seen to be centrally located in the housing. Needle guard 30 and housing 20 slide together until the narrowed proximal end 92 of needle guard slot 36 engages the aperture 74 of the housing, causing the two components to lock together. An instrument is inserted into the aperture 74 and into slot 36 to spread the narrowed portion 92 of the slot and thereby permit the needle guard to proceed fully into the needle housing.

The concentric tubular construction of the needle guard and housing also permits the needle guard to slide into the housing from the proximal end of the housing. Thus, the catheter device can then be assembled without causing the needle guard 30 to pass through its locking position, thereby obviating the need to unlock the narrowed portion 92 of the guard slot during assembly of the device.

The catheter assembly of FIGURE 2 may be used in the conventional manner by inserting the concentric catheter and needle through the skin of a patient and into a blood vessel. When the point of the needle 24 is properly located in the vessel, a small amount of blood will flow through the needle and into the flash chamber 26. Since the needle housing and guard are made of transparent or translucent polymeric materials, the flow of blood will be readily apparent in the flash chamber. The needle is then retracted from the vessel and the catheter 50 threaded into the vessel by grasping the finger grips 22 of the housing with the thumb and fingers and pushing the push-off tab 34 in the distal direction with one finger. This motion will push the catheter hub 52 off of the needle guard tip 60 to advance the catheter. As the needle guard begins to extend out from the distal end of the needle housing such that the push-off tab 34 is beyond the reach of the finger of the user, the user may engage the projections 32 with the finger to continue the distal motion of the needle guard.

Finally this motion will result in proper threading of the catheter into the vessel and the complete withdrawal of the needle from the patient's body. The needle guard 30 is then advanced to its fullest extension. As it does so, the tapered proximal section of the flash chamber 26 will spread the narrowed proximal portion 92 of the needle guard slot 36 until the narrowed portion 92 engages aperture 74. At the fullest extension of the needle guard from the housing the engagement of the narrowed portion 92 in the aperture 74 will lock the needle guard 30. The needle 24, housing 20 and guard 30 may then be set aside without concern for inadvertent injury to the user or others.

As better seen in FIGURES 3, 4a, 4b and 4c, there is shown the catheter 50 and catheter hub 52 assembly incorporated with the membrane assembly 100 of the invention. This membrane assembly 100 is spaced within catheter hub 52 and comprises a one-directional valve membrane 110. This valve membrane is originally sealed before the needle 24 is inserted into the catheter 50. This valve membrane 110 comprises essentially a malleable gasket material, such as known plastics, rubber, or any other one-directional valve material. Upon insertion of the plastic hub introducer needle 24 into the catheter 50 assembly, the membrane 110 is punctured, as is better seen in FIGURE 4a. Accordingly, the remainder of the introduction of needle 24 into the patient remains according to currently preferred procedures.

As is better seen in FIGURE 4b, the needle 24 is removed from the catheter 50 and catheter hub 52 assembly. Upon removal from the catheter hub 52, the valve membrane 110 closes. It is to be noted that upon removal of the needle 24 two significant improvements to operation of the catheter assembly 10 are realized. First, unlike in other systems, the present catheter assembly 10 prevents leakage of blood through catheter 50 into flash chamber 26. Normally, blood flowing out of the body has an approximate pressure of about 13,3 kPa (2 psi). The valve membrane 110 is configured so that it withstands outwardly directional flow of blood greater than about 20 kPa (3 psi) or well above the normal human limit, through catheter 50 into flash chamber 26. Also, even though valve membrane 110 is inserted into the catheter assembly 10, the valve membrane 110 is configured so that there is no frictional drag on needle 24 during its retraction from the catheter 50. This is so because valve membrane 110 is generally configured as a "duck-bill" valve or a valve of similar configuration and smoothly allows removal of the needle 24 from the catheter. Upon removal of the needle 24 from the catheter 50, the valve membrane unidirectionally closes so that blood will not flow into flash chamber 26.

As is further seen in FIGURES 3 and 4c, hub 52 also contains membrane opener 120. Membrane opener 120 is generally cylindrical in shape and contains nose-shaped opening means . These nose shaped opening means fit comfortably within valve membrane 110 when so inserted. Also attached to cathether hub 52 is collar mechanism 160. This collar mechanism 160 holds membrane opener 120 in place when liner assembly 150 is attached to catheter hub 52. Upon attachment of liner assembly 150 to catheter hub 52 at flanges 58, intravenous fluids are connected with the catheter 50 so that they may be diffused into the body.

As luer assembly 150 is being attached to catheter hub 52, collar mechanism 160 holds membrane opener 120 in place so that the nose-shaped opening means of membrane opener 120 proceed to open valve membrane 110. This is best seen in FIGURE 4c. Thus, when the valve membrane 110 is open, nutritional fluids are able to be disposed into the body.

Importantly, even though liner assembly 150 now forces open membrane opener 120, there is no significant increase in the force necessary to attach liner assembly 150 to catheter hub 52, or to open valve membrane 110. Accordingly, practicing the catheter control valve assembly of this invention causes no additional steps or exertion by the user. In addition, the opening means is created so that it opens valve membrane 110 as wide as is necessary to maintain flow rates within catheter 50. Accordingly, the same flow rates within catheter 50 are realized. In this way, performance is not compromised during practice of this invention.

Thus, a valved catheter hub assembly is disclosed as above described. It is to be realized that the invention described by this control valve assembly is to be seen in the following claims and equivalents.

Claims

1. A catheter hub (52) for attachment of a catheter (50) thereto, wherein a valve having a membrane (110) is disposed within a passageway of said hub to seal said passageway from said catheter, and wherein said hub further comprises a membrane opener (120),

   characterized in that said membrane (110) is adapted to be punctured by a catheter needle (24) inserted into said catheter (50), and in that said membrane opener (120) is adapted to be actuated by connection of a tubing set to said catheter hub.

2. A catheter hub according to claim 1, said hub (52) having a circular cross-section with said membrane (110) placed across said cross-section, said opener (120) slideably engaged within said hub and engageable with said membrane, said membrane placed between said opener and said catheter (50).

3. A catheter hub according to claim 1 or claim 2, said valve permitting flow of fluid from said opener (110) side to said catheter (50) side, and rejecting fluid flow from said catheter side to said opener side.

4. A catheter hub according to any preceding claim, further comprising a needle (24) con-

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As better seen in FIGURES 3, 4a, 4b and 4c, there is shown the catheter 50 and catheter hub 52 assembly incorporated with the membrane assembly 100 of the invention. This membrane assembly 100 is spaced within catheter hub 52 and comprises a one-directional valve membrane 110. This valve membrane is originally sealed before the needle 24 is inserted into the catheter 50. This valve membrane 110 comprises essentially a malleable gasket material, such as known plastics, rubber, or any other one-directional valve material. Upon insertion of the plastic hub introducer needle 24 into the catheter 50 assembly, the membrane 110 is punctured, as is better seen in FIGURE 4a. Accordingly, the remainder of the introduction of needle 24 into the patient remains according to currently preferred procedures.

As is better seen in FIGURE 4b, the needle 24 is removed from the catheter 50 and catheter hub 52 assembly. Upon removal from the catheter hub 52, the valve membrane 110 closes. It is to be noted that upon removal of the needle 24 two significant improvements to operation of the catheter assembly 10 are realized. First, unlike in other systems, the present catheter assembly 10 prevents leakage of blood through catheter 50 into flash chamber 26. Normally, blood flowing out of the body has an approximate pressure of about 13,3 kPa (2 psi). The valve membrane 110 is configured so that it withstands outwardly directional flow of blood greater than about 20 kPa (3 psi) or well above the normal human limit, through catheter 50 into flash chamber 26. Also, even though valve membrane 110 is inserted into the catheter assembly 10, the valve membrane 110 is configured so that there is no frictional drag on needle 24 during its retraction from the catheter 50. This is so because valve membrane 110 is generally configured as a "duck-bill" valve or a valve of similar configuration and smoothly allows removal of the needle 24 from the catheter. Upon removal of the needle 24 from the catheter 50, the valve membrane unidirectionally closes so that blood will not flow into flash chamber 26.

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As luer assembly 150 is being attached to catheter hub 52, collar mechanism 160 holds membrane opener 120 in place so that the nose-shaped opening means of membrane opener 120 proceed to open valve membrane 110. This is best seen in FIGURE 4c. Thus, when the valve membrane 110 is open, nutritional fluids are able to be disposed into the body.

Importantly, even though liner assembly 150 now forces open membrane opener 120, there is no significant increase in the force necessary to attach liner assembly 150 to catheter hub 52, or to open valve membrane 110. Accordingly, practicing the catheter control valve assembly of this invention causes no additional steps or exertion by the user. In addition, the opening means is created so that it opens valve membrane 110 as wide as is necessary to maintain flow rates within catheter 50. Accordingly, the same flow rates within catheter 50 are realized. In this way, performance is not compromised during practice of this invention.

Thus, a valved catheter hub assembly is disclosed as above described. It is to be realized that the invention described by this control valve assembly is to be seen in the following claims and equivalents.

Claims

1. A catheter hub (52) for attachment of a catheter (50) thereto, wherein a valve having a membrane (110) is disposed within a passageway of said hub to seal said passageway from said catheter, and wherein said hub further comprises a membrane opener (120),

   characterized in that said membrane (110) is adapted to be punctured by a catheter needle (24) inserted into said catheter (50), and in that said membrane opener (120) is adapted to be actuated by connection of a tubing set to said catheter hub.

2. A catheter hub according to claim 1, said hub (52) having a circular cross-section with said membrane (110) placed across said cross-section, said opener (120) slideably engaged within said hub and engageable with said membrane, said membrane placed between said opener and said catheter (50).

3. A catheter hub according to claim 1 or claim 2, said valve permitting flow of fluid from said opener (110) side to said catheter (50) side, and rejecting fluid flow from said catheter side to said opener side.

4. A catheter hub according to any preceding claim, further comprising a needle (24) con-

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nected to said hub (52) and insertable through said membrane (110) into said catheter (50), said membrane remaining sealed to fluid flow from said catheter side to said opener (120) side.

5. A catheter assembly comprising:
a tubular needle housing;
a hollow needle (24) extending from the distal end of said needle housing;
a flash chamber (26) located within said housing, wherein said hollow needle extends from said flash chamber and the passageway of said hollow needle is in fluid communication with the interior of said flash chamber; and
a catheter hub according to any preceding claim mountable on said needle housing.

6. A catheter assembly comprising:
a semi-tubular needle housing having an open top;
a flash chamber (26) located in the interior of said needle housing and having a hollow needle (24) extending from the distal end thereof;
a tubular needle guard slideably located within said needle housing and including an aperture at its distal end for passage of said hollow needle therethrough and containing said flash chamber;
a catheter and a catheter hub assembly according to any of claims 1 to 4 suitable for mounting on the distal end of said needle guard.

7. The assembly of claim 6 wherein said opener (120) is slideably engaged in said hub (52) and said hub is attachable to a luer assembly such that with said luer assembly attached to said hub, said valve opener slides to open said valve.

Patentansprüche

1. Katheteransatzstück (52) zum Anbringen eines Katheters (50) daran, wobei ein eine Membran (110) aufweisendes Ventil im Durchgang des Ansatzstückes angebracht ist, um den Durchgang des Katheters zu verschließen und wobei das Ansatzstück weiterhin einen Membranöffner (120) aufweist, dadurch gekennzeichnet, daß die Membran (110) daran angepaßt ist, mit einer in den Katheter (50) eingeführten Katheternadel (24) durchlöchert zu werden und daß der Membranöffner (120) daran angepaßt ist, durch die Verbindung eines Satzes von Röhren mit dem Katheteransatzstück betätigt zu werden.

2. Katheteransatzstück nach Anspruch 1, bei dem das Ansatzstück (52) einen kreisförmigen Querschnitt mit der Membran (110) im Durchmesser des Querschnitts gelegen aufweist, wobei der Öffner (120) innerhalb des Ansatzstükkes gleitend erfaßt und mit der Membran in Eingriff bringbar ist, und wobei die Membran zwischen dem Öffner und dem Katheter (50) gelegen ist.

3. Katheteransatzstück nach Anspruch 1 oder Anspruch 2, bei dem das Ventil den Durchfluß von Flüssigkeit von der Seite des Öffners (110) zur Seite des Katheters (50) hin zuläßt, dagegen den Durchfluß von Flüssigkeit von der Seite des Katheters zur Seite des Öffners verhindert.

4. Katheteransatzstück nach einem der vorstehenden Ansprüche, das weiterhin eine mit dem Ansatzstück (52) verbundene, durch die Membran (110) in den Katheter einführbare Nadel (24) aufweist, wobei die Membran für den Durchfluß von Flüssigkeit von der Seite des Katheters zur Seite des Öffners (120) verschlossen bleibt.

5. Katheteranordnung mit
einem röhrenförmigen Nadelgehäuse;
einer sich vom distalen Ende des Nadelgehäuses erstreckenden Hohlnadel (24);
einer in dem Gehäuse gelegenen Entspannungskammer (26), wobei die Hohlnadel sich von der Entspannungskammer erstreckt und der Durchlaß der Hohlnadel in Durchflußverbindung mit dem Inneren der Entspannungskammer steht; und einem auf dem Nadelgehäuse anbringbaren Katheteransatzstück in Übereinstimmung mit einem der vorhergehenden Ansprüche.

6. Katheteranordnung mit
einem halb röhrenförmigem Nadelgehäuse mit einer offenen Oberseite,
einer Entspannungskammer (26), die sich im Inneren des Nadelgehäuses befindet und eine Hohlnadel (24) aufweist, die sich von dessen distalem Ende erstreckt;
einem röhrenförmigen, gleitend innerhalb des Nadelgehäuses gelegenen Nadelschutz, der an seinem distalen Ende eine Öffnung zur Passage der Hohlnadel durch ihn hindurch einschließt und die Entspannungskammer enthält;
einem Katheter und einem Katheteransatzstück nach einem der Ansprüche 1 bis 4, geeignet zum Anbringen an dem distalen Ende des Nadelschutzes.

7. Anordnung nach Anspruch 6, bei der der Öffner (120) im Ansatzstück (52) gleitend erfaßt ist und bei der das Ansatzstück an eine Lueranordnung so angebracht werden kann, daß der Ventilöffner so gleitet, daß sich das Ventil öffnet, wenn die Lueranordnung an das Ansatzstück angebracht ist.

Revendications

1. Flasque de cathéter (52) pour y fixer un cathéter (50), dans laquelle une soupape ayant une membrane (110) est placée dans un passage de ladite flasque pour fermer hermétiquement ledit passage depuis ledit cathéter, et dans laquelle ladite flasque comprend un dispositif (120) d'ouverture de membrane, caractérisée en ce que ladite membrane (110) est adaptée pour être percée par une aiguille de cathéter (24) insérée dans ledit cathéter (50), et en ce que ledit dispositif d'ouverture de membrane (120) est adapté pour être actionné par la connexion d'une ligne de tubes fixée à ladite flasque de cathéter.

2. Flasque de cathéter selon la revendication 1, ladite flasque (52) ayant une section transversale circulaire avec ladite membrane (100) placée sur ladite section transversale, ledit dispositif d'ouverture (120) s'engageant de manière coulissante à l'intérieur de ladite flasque et pouvant s'engager avec ladite membrane, ladite membrane étant placée entre ledit dispositif d'ouverture et ledit cathéter (50).

3. Flasque de cathéter selon la revendication 1 ou 2, ladite soupape permettant l'écoulement de fluide dans le sens côté dudit dispositif d'ouverture (110) vers le côté dudit cathéter (50), et empêchant un écoulement de fluide dans le sens côté du cathéter vers le côté dudit dispositif d'ouverture (120).

4. Flasque de cathéter selon l'une quelconque des revendications précédentes, comprenant de plus une aiguille (24) connectée à ladite flasque (52) et pouvant s'insérer à travers ladite membrane (110) dans ledit cathéter (50), ladite membrane étant fermée de manière étanche à un écoulement fluide depuis le côté dudit cathéter vers le côté dudit dispositif d'ouverture (120).

5. Ensemble à cathéter, comprenant :
   - un boîtier d'aiguille tubulaire ;
   - une aiguille creuse (24) s'étendant depuis l'extrémité distale dudit boîtier d'aiguille ;
   - une chambre de détente (26) située à l'intérieur dudit boîtier, dans laquelle ladite aiguille creuse dépasse de ladite chambre de détente et le passage de ladite aiguille creuse est en communication de fluide avec l'intérieur de ladite chambre de détente ; et
   - une flasque de cathéter selon l'une quelconque des revendications précédentes, se montant sur ledit boîtier d'aiguille.

6. Ensemble à cathéter, comprenant :
   - un boîtier d'aiguille semi-tubulaire ayant un dessus ouvert ;
   - une chambre de détente (26) située à l'intérieur dudit boîtier d'aiguille et ayant une aiguille creuse (24) dépassant depuis l'extrémité distale de celui-ci ;
   - un protège-aiguille tubulaire placé en glissement à l'intérieur dudit boîtier d'aiguille et comprenant une ouverture à son extrémité distale pour le passage de ladite aiguille creuse à travers, et contenant ladite chambre de détente ;
   - un cathéter et une flasque de cathéter selon l'une quelconque des revendications 1 à 4, adapté pour se monter sur l'extrémité distale dudit protège-aiguille.

7. Ensemble selon la revendication 6, dans lequel, ledit dispositif d'ouverture (120) est engagé en glissement dans ladite flasque (52) et ladite flasque peut se fixer sur un ensemble de Luer, de sorte qu'avec ledit ensemble de Luer fixé à ladite flasque, ledit dispositif d'ouverture glisse pour ouvrir ladite soupape.