Description

This invention relates to I.V. catheters and, in particular, to the prevention of blood backflow and blood leakage which could result in inadvertent contact with blood during the use of such catheters.

United States patent 4,762,516 (Luther et al.), EP-A-0 352 928 and EP-A-0 392 765 describe I.V. catheters with needle guards that are designed to protect medical personnel from inadvertent injury caused by needle sticks subsequent to use of the catheter needle. Such inadvertent needle sticks can result in infection by diseases borne by the blood of the patient from whose vascular system the needle has been previously withdrawn. The catheters described in these patent documents prevent inadvertent needle sticks by covering the needle tip with a needle guard extending from the needle hub as the needle is withdrawn from the patient's body.

It is not only desirable to protect medical personnel from the hazards of inadvertent needle sticks, but it is further desirable to provide protection from any contact with a patient's blood. Even in the use of one of the aforementioned catheters with needle guards, it is possible for medical personnel to come into contact with a patient's blood due to undesired leakage of blood from the catheter. During insertion of the needle into the vascular system of the patient, the clinician administering the catheter will try to locate the tip of the needle in a vein or artery of the patient. When the needle tip is properly located, there will be a small flow or flash of blood through the hollow needle and into the flash chamber at the proximal end of the needle. The clinician will note this presence of blood in the flash chamber as an indication of proper needle placement. The clinician can then advance the catheter into the vascular system and withdraw the needle from the patient, leaving the catheter cannula in place in the blood vessel.

As the needle tip moves to a location proximal the distal end of the catheter, blood will flow under venous or arterial pressure into the catheter and into the hollow needle. As a consequence thereof, blood may also enter the annular space between the outer wall of the needle and the inner wall of the catheter cannula. The flow of blood in this space toward the catheter hub is herein referred to as backflow. Normally, backflow of blood is of little concern, because the catheter hub is usually quickly connected to a tubing set once the needle is withdrawn from the catheter. However, in the aforementioned catheters with needle guards, the distal nose of the needle guard occupies the catheter hub prior to complete withdrawal of the needle. As the needle guard is extended along the length of the needle toward the needle tip, its extention will carry the catheter hub to simultaneously thread the catheter into the vein or artery of the patient. The termination of this motion will eject the catheter hub from the nose of the guard when the guard reaches it full extention. Thus, if blood backflow into the catheter hub occurs prior to ejection of the catheter hub from the nose of the guard, the needle guard will be contaminated with the patient's blood prior to the release of the catheter hub. It would be desirable to prevent this contamination so that contact by medical personnel with blood on the nose of the needle guard will be prevented.

A technique for reducing the possibility of such blood leakage is described in EP-A-0 398 676. As explained in that application, blood leakage between the needle and catheter cannula is retarded by heating and stretching the catheter cannula at a point just distal the distal end of the catheter hub. This process results in the reduction of the inner diameter of the cannula, causing the cannula to hug the needle in the vicinity of this restriction. Blood flow between the needle and cannula will be retarded from reaching the catheter hub as it encounters this restricted section of the catheter cannula. While this technique has been found to effectively retard blood leakage, the technique requires an additional processing step for the catheter cannula after final assembly of the catheter and needle assemblies. It would be desirable, then, to provide this impediment to blood leakage in a manner which obviates the need to perform this additional processing step on the catheter cannula.

In accordance with the principles of the present invention, a catheter is provided which deters the backflow of blood between the insertion needle and the catheter cannula by forming the distal end of the catheter hub so as to restrict the inner diameter of the catheter cannula to a wiping fit with the engaged insertion needle. In a first embodiment the distal end of the catheter hub is pre-formed to its desired final inner dimension. The distal end of the hub is stretched to an oversize condition to facilitate connection of the catheter cannula to the hub. After the catheter and hub have been assembled and engaged by the needle assembly, the distal end of the catheter hub is heated, causing a stress relief of the previously stretched hub. The distal end of the catheter hub will then return to its preformed dimension which will mechanically restrict the diameter of the catheter cannula at that point to form the wiping fit with the engaged needle.

In the drawings:

FIGURE 1 is a perspective view of an I.V. catheter assembly with needle guard;

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

FIGURE 3 is an enlarged view of the attachment of the catheter cannula to the catheter hub in

the catheter assembly of FIGURES 1 and 2; and FIGURES 4a-4d illustrate the production and assembly of a catheter cannula and hub in accordance with the principles of the present invention

Referring first to FIGURE 1, an I.V. catheter assembly with a needle guard is shown. The assembly 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.

A catheter 50 and its catheter hub 52, 56 are mounted on the distal end of the needle guard 30 over the needle 24. The point of the needle 24 is seen to extend from the distal tip of the catheter 50, which may be made of Teflon™, for example. 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, shown in FIGURE 2, through which the needle 24 extends. The distal end of the needle 24 is located in a flash chamber 26 which is a part of the needle housing 20.

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

The flash chamber 26 is seen to be located in the center of the needle housing 20, and is mounted on a rail, or base 27. A rectangular aperture 74 is formed in the base of the housing below the flash chamber 26, and extends upward into the base 27 of the flash chamber. As explained in EP-A-0 392 765, the aperture 74 engages the proximal end 92 of the needle guard 30 when the needle guard slides distally to cover the needle, thereby locking the needle guard in its protective position around the needle 24.

Turning now to FIGURE 3, the catheter hub 52 of FIGURES 1 and 2 is shown in greater detail. At the proximal end 56 of the hub is a connecting flange for attachment to a tubing set connector. Passing through the distal end 54 of the hub is a central aperture 51. The catheter cannula 50 is attached inside this aperture by a metal sleeve 16 which is flared at its proximal end. The metal sleeve 16 fits inside the catheter cannula to seal the cannula between the sleeve and the aperture 51. The flared end of the sleeve is in a force fit with the aperture wall proximal the cannula to hold the cannula in place within the catheter hub 52.

It may be seen that in the conventional catheter and hub assembly there is an annular space around the catheter cannula 50 at the distal end 54 of the hub. This space permits the cannula to fit loosely around the needle in this area of the assembly, allowing blood to pass between the outer surface of the needle and the inner surface of the cannula. Blood may then pass into the catheter hub proximal the cannula, where it can contaminate the distal end 60 of the engaging needle guard, as may be seen in FIGURE 2. A purpose of the present invention is to prevent such blood leakage into the catheter hub, which will be explained with reference to FIGURES 4a-4d.

Referring first to FIGURE 4a, a catheter hub 152 is shown. The hub is shown as produced by a molding process which produces a molded hub with a reduced inside diameter at the distal end 154 of the hub. The distal end of the molded hub bears down on the outer wall of the catheter cannula passing through the hub at 156, thereby pressing the cannula against the inner needle in a wiping fit. The hub is molded with the distal end at the size desired for the cannula and needle diameters and wall thicknesses of the final product.

After the catheter hub 152 is molded as shown in FIGURE 4a, it is stretched to the condition shown in FIGURE 4b. The catheter hub is stretched by forcing a tapered pin exhibiting a slightly conical shape into the distal end 154. The hub material, which may be polypropylene, polyurethane, or polyolefin, for instance, is stressed by the stretching forces of the tapered pin, which serve to distend the distal end of the hub from its molded shape to the shape shown in FIGURE 4b. These stresses will be relieved as described below.

After the catheter hub has been stretched, the catheter cannula 14 is inserted into the hub and is secured in place with the metal sleeve 16. With the distal end of the hub having been stretched to eliminate the narrowing of the distal end, this assembly step is essentially the same as that of a conventional catheter hub. The catheter assembly then appears as shown in FIGURE 4c.

After the catheter cannula and hub have been assembled the needle assembly is inserted through the hub 152 and the cannula 14, leaving the catheter hub mounted on the distal end 60 of the needle guard or needle hub, and the needle 24 passing through the hub and cannula 14. At this point the distal end of the catheter hub 152 is heated to a softening temperature. This temperature is chosen in accordance with the material used for the catheter hub and the time of exposure of the hub to the heat, and may be in the range of 300°F to 450°F. It has been found that reciprocal adjustment can be made between the temperature and the time of exposure of the hub to the heat, with an increase in time of exposure resulting in the use of a lower temperature. The effect of the heating step is to relieve the stresses incurred by the catheter hub material during the stretching step. As a result, the stress-relieved hub will assume its originally molded shape, with the distal end 156 of the hub contracted around the catheter cannula. The cannula is thereby pressed against the inner needle 24 in a wiping fit, which prevents blood leakage between the needle and cannula and into the catheter hub. Typically, the diametric change in the distal end of the catheter hub between the stretched shape and the molded shape is less than 20%.

It has been found through experimentation that direct contact heating is the preferred technique for stress-relieving the hub. In a constructed embodiment the distal end of the hub was inserted into an aperture in a block of Teflon™ heated to the desired temperature. The distal end of the hub was heated and stress-relieved by contact with the surrounding heated Teflon™ of the block.

Claims

1. A catheter device comprising:

   a needle assembly including a pointed needle (24) extending from the distal end of said assembly; and

   a catheter assembly including a catheter hub (52, 56) having an aperture (51) extending through said hub and a catheter cannula (50) affixed to extend from the distal end of said hub aperture (51), said catheter assembly adapted to engage said needle assembly with said needle (24) extending through said distal end (54) of said catheter hub and said catheter cannula,

   characterized in that said aperture (51) of said hub exhibits circumferential protrusion means (156) extending toward the center of said aperture from the inner wall of said aperture for pressing said catheter cannula (50) against said engaged needle (24) in a wiping fit.

2. The catheter device of claim 1, wherein said catheter cannula (50) is affixed within said aperture (51) at a point proximally located from the distal end (54) of said catheter hub (52, 56), and said circumferential protrusion means (156) is located near the distal end (54) of said catheter hub (52, 56).

3. The catheter device of claim 2, where said catheter cannula (50) is affixed within said aperture (51) by a metal eyelet which engages the proximal end of said catheter cannula (50) and the inner wall of said aperture (51).

4. The catheter device of claim 2, wherein said circumferential protrusion means (156) is formed during molding of said catheter hub (52, 56).

5. The catheter device of claim 2, wherein said circumferential protrusion means (156) is formed by swaging the distal end (54) of said catheter hub (52, 56).

6. A method of producing a catheter assembly for use with a needle assembly in which a catheter cannula is in a wiping fit with a needle extending therethrough comprising the steps of:

   a) forming a catheter hub (52, 56) with an aperture (51) extending therethrough and having a circumferential protrusion (156) extending inward from the inner wall of said aperture (51) near the distal end (54) of said hub (52, 56);

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After the catheter hub 152 is molded as shown in FIGURE 4a, it is stretched to the condition shown in FIGURE 4b. The catheter hub is stretched by forcing a tapered pin exhibiting a slightly conical shape into the distal end 154. The hub material, which may be polypropylene, polyurethane, or polyolefin, for instance, is stressed by the stretching forces of the tapered pin, which serve to distend the distal end of the hub from its molded shape to the shape shown in FIGURE 4b. These stresses will be relieved as described below.

After the catheter hub has been stretched, the catheter cannula 14 is inserted into the hub and is secured in place with the metal sleeve 16. With the distal end of the hub having been stretched to eliminate the narrowing of the distal end, this assembly step is essentially the same as that of a conventional catheter hub. The catheter assembly then appears as shown in FIGURE 4c.

After the catheter cannula and hub have been assembled the needle assembly is inserted through the hub 152 and the cannula 14, leaving the catheter hub mounted on the distal end 60 of the needle guard or needle hub, and the needle 24 passing through the hub and cannula 14. At this point the distal end of the catheter hub 152 is heated to a softening temperature. This temperature is chosen in accordance with the material used for the catheter hub and the time of exposure of the hub to the heat, and may be in the range of 300°F to 450°F. It has been found that reciprocal adjustment can be made between the temperature and the time of exposure of the hub to the heat, with an increase in time of exposure resulting in the use of a lower temperature. The effect of the heating step is to relieve the stresses incurred by the catheter hub material during the stretching step. As a result, the stress-relieved hub will assume its originally molded shape, with the distal end 156 of the hub contracted around the catheter cannula. The cannula is thereby pressed against the inner needle 24 in a wiping fit, which prevents blood leakage between the needle and cannula and into the catheter hub. Typically, the diametric change in the distal end of the catheter hub between the stretched shape and the molded shape is less than 20%.

It has been found through experimentation that direct contact heating is the preferred technique for stress-relieving the hub. In a constructed embodiment the distal end of the hub was inserted into an aperture in a block of Teflon™ heated to the desired temperature. The distal end of the hub was heated and stress-relieved by contact with the surrounding heated Teflon™ of the block.

Claims

1. A catheter device comprising:

   a needle assembly including a pointed needle (24) extending from the distal end of said assembly; and

   a catheter assembly including a catheter hub (52, 56) having an aperture (51) extending through said hub and a catheter cannula (50) affixed to extend from the distal end of said hub aperture (51), said catheter assembly adapted to engage said needle assembly with said needle (24) extending through said distal end (54) of said catheter hub and said catheter cannula,

   characterized in that said aperture (51) of said hub exhibits circumferential protrusion means (156) extending toward the center of said aperture from the inner wall of said aperture for pressing said catheter cannula (50) against said engaged needle (24) in a wiping fit.

2. The catheter device of claim 1, wherein said catheter cannula (50) is affixed within said aperture (51) at a point proximally located from the distal end (54) of said catheter hub (52, 56), and said circumferential protrusion means (156) is located near the distal end (54) of said catheter hub (52, 56).

3. The catheter device of claim 2, where said catheter cannula (50) is affixed within said aperture (51) by a metal eyelet which engages the proximal end of said catheter cannula (50) and the inner wall of said aperture (51).

4. The catheter device of claim 2, wherein said circumferential protrusion means (156) is formed during molding of said catheter hub (52, 56).

5. The catheter device of claim 2, wherein said circumferential protrusion means (156) is formed by swaging the distal end (54) of said catheter hub (52, 56).

6. A method of producing a catheter assembly for use with a needle assembly in which a catheter cannula is in a wiping fit with a needle extending therethrough comprising the steps of:

   a) forming a catheter hub (52, 56) with an aperture (51) extending therethrough and having a circumferential protrusion (156) extending inward from the inner wall of said aperture (51) near the distal end (54) of said hub (52, 56);

b) stretching the distal end (54) of said catheter hub (52, 56) in a radially outward direction to substantially reduce the inward extension of said protrusion (156);
c) attaching a catheter cannula (50) within said aperture (51) at a location proximal the location of said protrusion (156); and
d) heating the distal end (54) of said catheter hub (52, 56) to cause said protrusion (156) to extend inwardly against said catheter cannula (50).

Patentansprüche

1. Katheteeinrichtung mit
einer Nadelanordnung, die eine von dem distalen Ende der Anordnung abstehende spitze Nadel (24) umfaßt; und
einer Katheteranordnung, die eine Katheternabe (52, 56) mit einem sich durch die Nabe erstreckenden Durchlaß (51) und eine Katheterkanüle (50) umfaßt, die so befestigt ist, daß sie vom distalen Ende des Nabendurchlasses (51) absteht und die Katheteranordnung für den Eingriff mit der Nadelanordnung ausgebildet ist, wobei sich die Nadel (24) durch das distale Ende (54) der Katheternabe und durch die Katheterkanüle erstreckt,
dadurch gekennzeichnet, daß die Öffnung (51) der Nabe einen Umfangsvorsprung (156) aufweist, der von der Innenwand des Durchlasses in Richtung der Durchlaßmitte vorsteht, um die Katheterkanüle (50) in gleitendem Kontakt gegen die erfaßte Nadel (24) zu drücken.

2. Katheteranordnung nach Anspruch 1, wobei die Katheterkanüle (50) im Inneren des Durchlasses (51) an einem proximal vom distalen Ende (54) der Katheternabe (52, 56) angeordneten Punkt befestigt ist und der Umfangsvorsprung (156) in der Nähe des distalen Endes (54) der Katheternabe (52, 56) angeordnet ist.

3. Katheteranordnung nach Anspruch 2, wobei die Katheterkanüle (50) im Durchlaß (51) mittels einer metallischen Öse befestigt ist, die mit dem proximalen Ende der Katheterkanüle (50) und der Innenwand des Durchlasses (51) im Eingriff steht.

4. Katheteranordnung nach Anspruch 2, wobei der Umfangsvorsprung (156) bei der Formung der Katheternabe (52, 56) gebildet ist.

5. Katheteranordnung nach Anspruch 2, wobei der Umfangsvorsprung (156) durch Stauchen des distalen Endes (54) der Katheternabe (52, 56) geformt ist.

6. Verfahren zur Herstellung einer Katheteranordnung für die Verwendung mit einer Nadelanordnung, bei der sich eine Katheterkanüle in gleitendem Kontakt mit einer sich durch diese erstreckenden Nadel befindet, mit folgenden Schritten:
a) Bilden einer Katheternabe (52, 56) mit einem sich durch diese erstreckenden Durchlaß (51) und mit einem Umfangsvorsprung (156), der im Bereich des distalen Endes (54) der Nabe (52, 56) von der Innenwand des Durchlasses (51) nach innen vorsteht;
b) Dehnen des distalen Endes (54) der Katheternabe (52, 56) nach radial außen, um die nach innen gerichtete Erstreckung des Vorsprungs (156) wesentlich zu reduzieren;
c) Befestigen einer Katheterkanüle (50) in dem Durchlaß (51) an einer Stelle, die proximal zur Position des Vorsprungs (156) liegt; und
d) Erwärmen des distalen Endes (54) der Katheternabe (52, 56), damit sich der Vorsprung (156) nach radial innen gegen die Katheterkanüle (50) erstreckt.

Revendications

1. Dispositif de cathéter comprenant :
un ensemble aiguille qui comprend une aiguille pointue (24) s'étendant à partir de l'extrémité distale dudit ensemble ; et
un ensemble cathéter comprenant un embout de cathéter (52, 56) ayant une lumière (51) qui traverse ledit embout et une canule de cathéter (50) fixée de manière à s'étendre à partir de ladite extrémité distale de ladite lumière (51) de l'embout, ledit ensemble cathéter étant adapté pour être en contact avec ledit ensemble aiguille dans une position dans laquelle ladite aiguille (24) s'étend à travers ladite extrémité distale (54) dudit embout de cathéter et à travers ladite canule du cathéter,
caractérisé en ce que ladite lumière (51) dudit embout présente une protubérance circonférentielle (156) qui fait saillie sur la paroi intérieure de ladite lumière vers le centre de ladite lumière pour presser ladite canule (50) du cathéter contre ladite aiguille (24) à ajustement glissant.

2. Dispositif de cathéter selon la revendication 1, dans lequel ladite canule (50) du cathéter est fixée dans ladite lumière (51) en un point situé à proximité de l'extrémité distale (54) dudit embout (52, 56) du cathéter, et ladite protubérance circonférentielle (156) est placée à proximité de l'extrémité distale (54) dudit embout

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(52, 56) du cathéter.

3. Dispositif de cathéter selon la revendication 2, dans lequel ladite canule (50) du cathéter est fixée dans ladite lumière (51) par un oeillet métallique qui attaque l'extrémité proximale de ladite canule (50) du cathéter et la paroi intérieure de ladite lumière (51).

4. Dispositif de cathéter selon la revendication 2, dans lequel ladite protubérance circonférentielle (156) est formée pendant le moulage dudit embout (52, 56) du cathéter.

5. Dispositif de cathéter selon la revendication 2, dans lequel ladite protubérance circonférentielle (156) est formée par refoulement de l'extrémité distale (54) dudit embout (52, 56) du cathéter.

6. Procédé de fabrication d'un ensemble de cathéter destiné à être utilisé avec un ensemble d'aiguille dans lequel une canule de cathéter est à ajustement glissant par rapport à une aiguille qui le traverse, comprenant les phases consistant à :

a) former un embout (52, 56) de cathéter présentant une lumière (51) qui le traverse et ayant une protubérance circonférentielle (156) qui fait saillie vers l'intérieur sur la paroi intérieure de ladite lumière (51) à proximité de l'extrémité distale (54) dudit embout (52, 56) ;

b) dilater l'extrémité distale (54) dudit embout (52, 56) du cathéter radialement vers l'extérieur pour réduire sensiblement la saillie de ladite protubérance (156) vers l'intérieur ;

c) fixer une canule (50) de cathéter dans ladite lumière (51) en un emplacement proche de ladite protubérance (156) ; et

d) chauffer l'extrémité distale (54) dudit embout (52, 56) du cathéter pour amener ladite protubérance (156) à faire saillie vers l'intérieur en s'appliquant contre ladite canule (50) du cathéter.