

Summary of the Invention

According to the present invention, there is provided a catheter assembly comprising:

5 a catheter hub having distal end, a proximal end provided with a female Luer taper and a chamber therein;

a hollow tubular catheter having a proximal end and a distal end, the catheter being connected at its proximal end to the distal end of the catheter hub, the interior of the catheter opening into the chamber within the catheter
10 hub;

a needle having a shaft and a sharpened needle tip;

a valve assembly disposed within the chamber of the catheter hub and comprising a generally tubular first valve portion and a second valve portion, wherein the second valve portion is in the form of a disc, and wherein the
15 valve disc comprises one or a plurality of slits therein, the second valve portion being a two-way valve openable to permit the flow of fluid through the chamber in the catheter hub in both a proximal direction and a distal direction;

a valve opener moveable between a closed position, in which the second valve portion is closed, and an open position, in which the second
20 valve portion is open, the valve opener having a passage extending longitudinally therethrough and/or around for passage of fluid;

a needle guard assembly comprising:

a housing having the needle extending therethrough and having a distal end and a proximal end, the housing being connected at its distal end to
25 the proximal end of the catheter hub;

a needle guard disposed within the housing, the needle guard comprising:

a needle trap moveable between a ready position, in which the needle trap is held to one side of the shaft of the needle extending through the
30 housing; and a protected position, in which the needle trap blocks the

sharpened needle tip of the needle within the housing; the needle trap comprising a first end and a second end;

5 a resilient arm biasing the needle trap into the protected position, the resilient arm bearing against the inner wall of the housing to urge the needle trap into the protected position, wherein the needle trap and the resilient arm are folded to one side of the needle shaft in the ready position;

10 a coupling arm, in the ready position the coupling arm coupling the housing to the proximal end of the catheter hub, movement of the needle trap from the ready position to the protected position causing the coupling arm to release the housing from the catheter hub, wherein the coupling arm is connected to the second end of the needle trap along a line extending perpendicular to the shaft of the needle.

Accordingly, the present disclosure provides a needle guard assembly for a catheter assembly, the needle guard assembly comprising:

5 a housing for receiving a needle extending therethrough and having a distal end and a proximal end, the housing being connectable at its distal end to the proximal end of a catheter hub;

a needle guard disposed within the housing, the needle guard comprising:

10 a needle trap moveable between a ready position, in which the needle trap is held to one side of the shaft of the needle extending through the housing; and a protected position, in which the needle trap blocks the sharpened needle tip of the needle within the housing;

a resilient arm biasing the needle trap into the protected position, the resilient arm bearing against the inner wall of the housing to urge the needle trap into the protected position;

15 a coupling arm, in the ready position the coupling arm coupling the housing to the proximal end of the catheter hub, movement of the needle trap from the ready position to the protected position moving the coupling arm to release the housing from the catheter hub.

20 The needle trap may be connected at one end to the resilient arm. In a preferred embodiment, the needle trap is pivotally attached at a first end thereof to the resilient arm. The resilience of the resilient arm may be provided partly or wholly by resilience in the pivotal connection between the needle trap and the resilient arm. ~~In one embodiment,~~ The needle trap and
 25 the resilient arm are folded together on one side of the needle shaft when in the ready position, such that the needle trap overlies the resilient arm.

In the protected position, the needle trap extends distally across the sharpened needle tip, thereby blocking the needle tip and preventing a needle

30

stick injury. The needle trap may comprise one or more lateral members extending in the proximal direction from each side of the needle trap. The lateral members act to retain the needle trap in position relative to the sharpened needle tip, in particular preventing the needle tip from emerging to one side of the needle trap. In use, the needle trap transitions between the ready position, across the needle tip and into the protected position. Further, the needle trap may comprise a retaining member preventing the needle trap from moving in the reverse direction, that is towards its ready position, relative to the needle.

10

The needle guard further comprises a coupling arm. In the ready position, the coupling arm engages with the catheter hub, to hold the needle guard assembly on the proximal end of the catheter hub. In a preferred embodiment, the coupling arm engages with the outside of the catheter hub, for example with a flange on the proximal end of the catheter hub. The coupling arm is moved by the needle trap transitioning from the ready position to the protected position out of engagement with the catheter hub, thereby releasing the needle guard assembly from the catheter hub. In this way, the needle guard assembly is only released from engagement with the catheter hub once the sharpened needle tip is blocked within the needle guard housing. The coupling arm is preferably connected to the needle trap. In one preferred embodiment particular, the coupling arm is connected to an end of the needle trap, in particular to a second end of the needle trap opposite the first end. The connection between the coupling arm and the needle trap is preferably pivotal and may be a resilient pivotal connection.

15

20

25

In one preferred embodiment, the resilient arm, the needle trap and the coupling arm are formed as a single component, with resilient pivotal connections between the resilient arm and the needle trap and between the needle trap and the coupling arm, the resilient connections biasing the needle

30

provided with a hollow connecting hub 64 having a proximal opening and provided with an internal taper, in particular a standard female Luer taper, for accepting a fitting, such as a syringe and the like, in known manner. A vented plug 66 may be provided at the proximal end of the connecting hub 64, as shown in Figure 1, to maintain sterility. The connecting hub 64 may be used to introduce fluid into the extension tube 62 and the catheter assembly 2, for example by way of a syringe 68, shown in Figure 3.

The distal portion 42 of the catheter hub 4 is further provided with a valve assembly 70 therein. The valve assembly 70 is disposed within the internal chamber 12 of the catheter hub and comprises a firstsecond valve portion 72, disposed in the internal chamber 12 distal of the valve opener, and a secondfirst valve portion 74, distal of the firstsecond valve portion.

The function of the firstsecond valve portion 72 is to seal the internal chamber 12 within the catheter hub 4, to prevent the flow of fluids in either the proximal or distal direction when the firstsecond valve portion is closed. The firstsecond valve portion 72 comprises a flexible valve disc 76 extending laterally across the internal chamber 12 of the catheter hub 4. The valve disc 76 is of a flexible, resilient material. The valve disc 76 is provided with one or more radial slits therein. In this way, the shaft 34 of the needle 30 extends through the valve disc 76 in the ready position, shown in Figures 1 and 2. Details of embodiments of the valve assembly are shown in Figures 7a to 7c and described hereinbelow.

With the needle in the ready position, the valve disc 76 closes around the outer surface of the needle shaft 34. With the needle 30 in the ready position, the slits are held open a sufficient distance to allow air to vent through the valve disc in the proximal direction, while being sufficiently closed so as to prevent the flow of blood through the valve disc in the proximal direction. By allowing air to vent through the valve disc 76 in this manner, the

flow of blood from the slot 38 in the needle shaft 34 within the catheter 10 along the outside of the needle is possible, or without the slot 38 in the needle, as the needle tip is withdrawn into the hollow catheter tubing, thereby providing the secondary flashback.

5

The ~~first~~second valve portion 72 is a two-way valve. With the needle 30 retracted and the valve disc 76 closed, the flow of fluid in either the distal or the proximal direction within the catheter hub 4 is prevented. When there is no valve opener 50, then the valve disc 76 opens under the action of a
10 reduced fluid pressure on the proximal side of the valve disc 76, for example by applying a vacuum to the proximal end of the catheter hub with a syringe engaged with the proximal end of the catheter hub 4. In this way, fluid may be withdrawn in the proximal direction through the catheter hub from the catheter 10 to the proximal end 8 of the catheter hub 4. Applying an increased fluid
15 pressure to the proximal side of the disc valve 76, for example by way of a syringe engaged with the proximal end of the catheter hub 4, opens the valve and allows the passage of fluid in the distal direction through the catheter hub. In this way, fluid may be infused to the patient through the catheter hub 4 and catheter 10.

20

Engaging a fitting to the proximal end 8 of the catheter hub 4, such as a syringe or the like having a male taper, in particular a standard male Luer taper, urges the valve opener 50 in the distal direction. Movement of the valve opener 50 in the distal direction causes the head 54 of the valve opener
25 to contact the valve disc 76 and open the slits in the disc. Fluid may be withdrawn from or infused to the patient with the valve open in this manner. The valve disc 76 is formed from a resilient material. As the male fitting is removed from engagement with the proximal end 8 of the catheter hub 4, the valve opener 50 is urged in the proximal direction by the valve disc 76 until the
30 slits in the valve disc close. As noted above, further movement of the valve

opener 50 in the proximal direction is prevented by the protrusion 46 in the proximal portion of the catheter hub 4.

The ~~second~~first valve portion 74 is disposed within the internal
 5 chamber 12 of the catheter hub 4 distal of the ~~first~~second valve portion 72.
 The function of the ~~second~~first valve portion 74 is to seal the opening in the
 distal end of the extension tube 62. The ~~second~~first valve portion 74 is in the
 form of a tube 80 of flexible, resilient material extending around the
 circumference of the internal chamber 12 of the catheter hub 4. The tube 80
 10 conforms to the inner surface of the distal portion 42 of the catheter hub and
 provides a fluid-tight seal against the inner surface. The internal chamber 12
 within the distal portion 42 of the catheter hub 4 may be generally cylindrical,
 in which case the tube 80 is generally cylindrical. Alternatively, the internal
 chamber 12 within the distal portion 42 of the catheter hub 4 may be elliptical
 15 in cross-section. The tube 80 for such an arrangement is also elliptical in
 cross-section. Embodiments of the valve assembly are shown in Figures 7a
 to 7c and described in more detail below.

As noted above, the tube 80 seals the distal end of the extension tube
 20 62 at its opening into the internal chamber 12 in the catheter hub 4. An
 interference fit between the tube 80 and the catheter hub 4 urges the outer
 surface of tube 80 into contact with the inner surface of the distal portion 42 of
 the catheter hub, forming a fluid-tight seal. Increased fluid pressure within the
 extension tube 62 urges a portion of the tube 80 away from the inner surface
 25 of the internal chamber 12, allowing fluid to flow from the extension tube 62
 into the internal chamber 12 and in a distal direction to the catheter 10. In this
 way, fluid may be introduced into the catheter 10 by way of the extension tube
 62, for example from a syringe 68 connected to the connecting hub 64, as
 shown in Figure 3.

30

CLAIMS

1. A catheter assembly comprising:

5 a catheter hub having a distal end, a proximal end provided with a female Luer taper and a chamber therein;

a hollow tubular catheter having a proximal end and a distal end, the catheter being connected at its proximal end to the distal end of the catheter hub, the interior of the catheter opening into the chamber within the catheter hub;

10 a needle having a shaft and a sharpened needle tip;

a valve assembly disposed within the chamber of the catheter hub and comprising a generally tubular first valve portion and a second valve portion, wherein the second valve portion is in the form of a disc, and wherein the valve disc comprises one or a plurality of slits therein, the second valve portion being a two-way valve openable to permit the flow of fluid through the chamber in the catheter hub in both a proximal direction and a distal direction;

15 a valve opener moveable between a closed position, in which the second valve portion is closed, and an open position, in which the second valve portion is open, the valve opener having a passage extending longitudinally therethrough and/or around for passage of fluid;

20 a needle guard assembly comprising:

a housing having the needle extending therethrough and having a distal end and a proximal end, the housing being connected at its distal end to the proximal end of the catheter hub;

25 a needle guard disposed within the housing, the needle guard comprising:

a needle trap moveable between a ready position, in which the needle trap is held to one side of the shaft of the needle extending through the housing; and a protected position, in which the needle trap blocks the sharpened needle tip of the needle within the housing; the needle trap comprising a first end and a second end;

30

a resilient arm biasing the needle trap into the protected position, the resilient arm bearing against the inner wall of the housing to urge the needle trap into the protected position, wherein the needle trap and the resilient arm are folded together to one side of the needle shaft in the ready position;

5 a coupling arm, in the ready position the coupling arm coupling the housing to the proximal end of the catheter hub, movement of the needle trap from the ready position to the protected position causing the coupling arm to release the housing from the catheter hub, wherein the coupling arm is connected to the second end of the needle trap along a line extending
 10 perpendicular to the shaft of the needle.

2. The catheter assembly according to claim 1, wherein the needle guard housing has a portion for extending into the proximal end of the catheter hub in the ready position.

3. The catheter assembly according to either of claims 1 or 2, wherein the needle trap is pivotally attached at a first end to the resilient arm.

~~4. The catheter assembly according to any of claims 1 to 3, wherein the needle trap and the resilient arm are folded together to one side of the needle shaft in the ready position.~~

~~45.~~ The catheter assembly according to any preceding claim, wherein the needle trap comprises one or more lateral members extending in a proximal direction from each side of the needle trap.

~~56.~~ The catheter assembly according to any preceding claim, wherein the needle trap comprises a retaining member preventing movement of the needle trap from the protected position to the ready position.

67. The catheter assembly according to any preceding claim, wherein the coupling arm engages with an exterior portion of the proximal end of the catheter hub.

5 ~~8. The catheter assembly according to any preceding claim, wherein the coupling arm is connected to a second end of the needle trap.~~

79. The catheter assembly according to any preceding claim-8, wherein the coupling arm is pivotally connected to the needle trap.

10

~~840. The catheter assembly according to any preceding claim, wherein the coupling arm comprises an opening therein, the needle extending through the opening in the ready position.~~

15 944. The catheter assembly according to any preceding claim, further comprising means for limiting movement of the needle in the proximal direction relative to the needle guard assembly.

20 1042. The catheter assembly according to claim 944, wherein the needle guard housing comprises a proximal wall having an opening therein, the needle shaft extending through the opening in the proximal wall, the opening for engaging with a bulge in the needle shaft having a radial dimension that is greater than that of the opening in the proximal wall.

25 1143. The catheter assembly according to claim 1042, wherein the region of the proximal wall adjacent the opening is reinforced.

30

23 08 19