

## Summary of the Invention

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

5 a catheter hub having distal end, a proximal end and a chamber therein, ~~the catheter hub having a distal end and a proximal end, the catheter hub being connectable at its proximal end to a device for the infusion or withdrawal of fluids to or from the chamber within the catheter hub;~~

10 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;

15 a needle having a shaft and a sharpened needle tip, ~~in a ready position the needle extending through the chamber in the catheter hub and the catheter with the needle tip extending beyond the distal end of the catheter;~~

20 ~~a hollow extension tube having a distal end and a proximal end, the extension tube being connected at its distal end to the catheter hub between the proximal and distal ends thereof, the extension tube opening at its distal end into the chamber within the catheter hub, the extension tube connectable at its proximal end to a device for infusing fluid into the chamber within the catheter hub;~~

25 a valve assembly disposed within the chamber of the catheter hub, the valve assembly 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;

30 ~~a first valve member closing the distal end of the extension tube and openable under the action of a pressurised fluid within the extension tube; and~~

~~a second valve member preventing the flow of fluid through the chamber to or from the proximal end of the catheter hub, the second valve member being a two-way valve and openable to permit the flow of fluid through the chamber in the catheter hub in both a proximal 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 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 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 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;

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.

The device of the present ~~disclosure~~invention comprises a catheter hub. The catheter hub is hollow and has an internal chamber therein, the internal chamber being open at both the proximal and distal ends of the catheter hub. The catheter hub may be formed as a single piece.

- 5 Alternatively, the catheter hub may be formed as two or more separate pieces connected together.

- 10 The catheter hub is formed at its proximal end to be connectable to a device for infusing fluid into the patient or removing fluid from the patient, such as a syringe. Such devices are known in the art and will be familiar to the person skilled in the art. In particular, the inner wall of the proximal end of the catheter hub defining the chamber is provided with an internal Luer taper, that is a female Luer taper, allowing standard fittings having a standard male Luer taper to be connected to the proximal end of the catheter hub. The person  
15 skilled in the art will be familiar with the Luer taper standard and its requirements.

- 20 In one embodiment, the catheter hub comprises a distal hub portion and a proximal hub portion. The proximal hub portion is as hereinbefore described and is connectable to a device for infusing fluid into or removing fluid from the patient. The distal hub portion may have any suitable form. In one embodiment, the distal hub portion has a generally flattened form, such that the catheter hub lies flatter against the skin of the patient and protrudes less from the patient's skin in use. More preferably the distal hub portion  
25 comprises wing members extending from opposing sides of the distal hub portion. The wing members increase the stability of the catheter assembly, in particular when the catheter has been inserted into the vein of the patient, and may be used to secure the catheter hub to the skin of a patient, for example by way of adhesive tape. In this way, movement of the catheter hub and the  
30 catheter is restricted, in turn reducing the occurrence of phlebitis of the vein of the patient.

the slot and into the catheter around the needle shaft. The blood can then flow from the catheter into the catheter hub, to provide a flashback to the user.

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The catheter assembly of the present disclosure invention may further  
5 comprises a hollow extension tube having a distal end and a proximal end.  
The extension tube is flexible. The extension tube is connected at its distal  
end to the catheter hub between the proximal and distal ends thereof.  
Preferably, the distal end of the extension tube is connected to the distal  
portion of the catheter hub. The extension tube opens at its distal end into the  
10 chamber within the catheter hub, to allow fluid to flow between the extension  
tube and the internal chamber. The extension tube is connectable at its  
proximal end to a device, such as a syringe, for infusing fluid into the chamber  
within the catheter hub. For example, the extension tube may be provided at  
its proximal end with a connection hub, preferably a hub having a female Luer  
15 taper.

In use, fluid may be introduced into the catheter hub and the catheter  
by way of the extension tube. By having the device for introducing fluid  
connected at the proximal end of the extension tube, it may be located away  
20 from the catheter hub and the catheter located in the vein of the patient. By  
having the extension tube flexible, movement of the catheter hub and the  
catheter as a result of the action of connecting or disconnecting the fluid  
delivery device at the proximal end of the extension tube is reduced or  
eliminated. This in turn reduces the occurrence of phlebitis of the vein in the  
25 region of the catheter.

The catheter assembly comprises a valve assembly disposed within  
the internal chamber of the catheter hub. The valve assembly, when closed,  
prevents the flow of fluid between the extension tube and the internal chamber  
30 of the catheter hub and the flow of fluid in either the proximal or distal direction  
through the internal chamber. The valve assembly comprises a first valve

chamber of the catheter hub to and from the proximal end thereof. The second valve member is disposed in the internal chamber of the catheter hub in a position proximal to the distal opening of the extension tube and the first valve member. In one embodiment, the second valve member comprises a flexible, resilient valve disc extending laterally across the internal chamber of the catheter hub. The disc is provided with one or more closable openings, such as slits, therein, in particular one or more radially extending slits.

The valve assembly may be retained within the internal chamber of the catheter hub by any suitable means. In one embodiment, the valve assembly is retained by friction between the valve members and the inner surface of the catheter hub. Alternatively, the valve assembly may engage with one or more recesses or protrusions formed in the inner surface of the catheter hub.

In the ready position, the needle shaft extends through the valve assembly. The second valve member preferably seals around the shaft of the needle in the ready position, more preferably in a manner that allows gas to vent through the second valve member in the proximal direction, but prevents blood from passing the second valve member. In embodiments in which the second valve member comprises a disc having one or more slits therein, this can be achieved by appropriate arrangement of the or each slit, such that, in the ready position, the or each slit is held open by the needle shaft a sufficient amount to allow the passage of gas but prevent the passage of blood therethrough.

The second valve member may open under the action of a difference in fluid pressure across the valve member. In particular, the second valve member may open under the action of an increased fluid pressure on the proximal side of the valve, to allow fluid to be infused into the catheter and vein of the patient. Similarly, the second valve member may open under the

action of a reduced pressure on the proximal side of the valve, to allow fluid to be withdrawn from the catheter and the vein.

~~In one embodiment,~~ The catheter assembly further comprises a valve opener disposed within the chamber in the catheter hub. The valve opener is disposed within the internal chamber of the catheter hub proximally of the valve assembly. The valve opener is moveable between a closed position, in which the second valve member is closed, and an open position in which the second valve member is open. The valve opener is moved in the proximal distal direction to the open position by the insertion of a device into the proximal end of the catheter hub, such as a syringe or other male fitting. The valve opener is urged into the closed position by the action of the second valve member closing, for example by the resilience of the valve disc. The valve opener preferably has a passage extending longitudinally therethrough and/or around for the passage of fluid.

Movement of the valve opener in the distal direction is limited by the valve assembly. Preferably, means are provided to limit the movement of the valve opener in the proximal direction. In one embodiment, the inner surface of the catheter hub is provided with one or more protrusions to engage with the valve opener.

In the ready position, the needle shaft extends through the valve opener. One preferred form of valve opener comprises a stem, having a passage therethrough, and a head portion at the distal end of the stem, having a passage therethrough. In use, a device inserted into the proximal end of the catheter hub contacts the stem of the valve opener, urging the valve opener from the closed position into the open position. As the valve opener is moved ~~proximally~~ distally into the open position, the head portion is urged into contact with the second valve member, opening the valve assembly.

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

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:

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;

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.

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 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

needle shaft being inadvertently pulled through the proximal wall of the housing. This is particularly advantageous when the needle guard housing is formed from a relatively soft material, such as plastic. In the ready position, the bulge in the needle shaft preferably lies within the hollow catheter. When  
5 the bulge is non-circular it has the advantage of allowing blood to flow between the inside of the catheter and the outside of the needle, to provide the secondary blood flashback.

10 In a further aspect, the present ~~invention~~ disclosure provides an IV catheter assembly comprising a needle guard assembly as hereinbefore described.

#### Brief Description of the Drawings

15 Embodiments of the present invention will be described, by way of example only, having reference to the accompanying drawings, in which:

20 Figure 1 is a cross-sectional view of a device according to a first embodiment of the present disclosure in a ready position;

Figure 2 is a cross-sectional view of the device of Figure 1 in the direction II;

25 Figure 3 is a cross-sectional view of the device of Figure 1 in a retracted position;

Figure 4 is a cross-sectional view of a needle guard assembly according to the present invention in a catheter assembly in a ready position;

30 Figure 4a is an enlarged cross-sectional view of the needle guard assembly of the device of Figure 4;



Figure 5 is a cross-sectional view of the device of Figure 4 in a protected position;

5 Figure 5a is an enlarged cross-sectional view of the needle guard assembly of the device of Figure 5a;

10 Figure 6 is a cross-sectional view of a device according to a needle guard assembly of a further embodiment of the present invention in a ready position;

Figure 7a is a cross-sectional view of a valve assembly for use in the devices of any of Figures 1 to 6;

15 Figure 7b is a proximal end view of one embodiment of the valve assembly of Figure 7a; and

20 Figure 7c is a proximal end of a second embodiment of the valve assembly of Figure 7a.

Referring to Figures 1 and 2, there is shown a device according to a first embodiment of the present disclosure, generally indicated as 2. The device 2 is shown in Figures 1 and 2 in a ready position. The device is shown 25 in Figure 3 in a retracted position, that is with the needle withdrawn in the proximal direction.

30 The device 2 comprises a catheter hub 4 having a distal end 6 and a proximal end 8. An elongate, hollow, tubular catheter 10 is connected to the catheter hub 4 and extends from the distal end 6 of the catheter hub, in known manner. The catheter hub 4 comprises an internal chamber 12. The internal

76 or a flange can be extended from disc 76 that is held in a groove in the inside surface of the catheter hub.

Turning to Figures 4 and 5, there is shown an embodiment of the device of the present invention. The device of this embodiment, generally indicated as 102, comprises a catheter hub, catheter, needle hub and needle, valve assembly and valve opener, and extension tube of the same general configuration as the embodiment of Figures 1 and 2 and described above. Features of the embodiment of Figures 3 and 4 common to the embodiment of Figures 1 and 2 are indicated using the same reference numerals.

The embodiment of Figures 4 and 5 comprises a needle guard assembly disposed between the distal end of the needle hub 20 and the proximal end of the catheter hub 4, when the device is in the ready position, as shown in Figure 3. The needle guard assembly, generally indicated as 120, is shown in the ready position in greater detail in Figure 4a.

There can be some overlapping of the proximal end of the needle guard and the distal end of the needle hub and/or overlapping of the distal end of the needle guard and the proximal end of the catheter hub.

Referring to Figure 4a, the needle guard assembly 102-120 comprises a generally cylindrical needle guard housing 122 having a proximal end 124 and a distal end 126. Alternative shapes for the needle guard housing include a generally rectangular cross-section. The distal end portion is conical in form and provided with a standard taper, in particular a standard male Luer taper. In the ready position shown in Figure 3, the conical distal end 126 of the needle guard housing 122 extends within the female Luer taper in the proximal end 8 of the catheter hub 4.

The needle guard housing 122 comprises an internal chamber 128 open at the distal end 126 and closed at the proximal end 124 by a proximal wall 130. In the ready position, the needle shaft 34 extends through the internal chamber 128 of the needle guard housing 122 and the proximal wall 130, as shown in Figures 4 and 4a.

A needle guard 140 is disposed within the needle guard housing 122 and comprises a needle trap 142 having lateral or side members 144 extending proximally from the needle trap 142. The needle trap further comprises a retaining member 146. When the needle 30 is retracted to the protected position shown in Figure 5, the side members 144 and retaining member 146 prevent the needle trap 142 moving laterally relative to the needle and exposing the needle tip.

The needle guard 140 further comprises a resilient arm 150 pivotally connected at a first end 152 to the needle trap and bearing on the inner surface of the needle guard housing 122 at a second end 154.

The needle guard 140 further comprises a coupling arm 160 pivotally connected at a first end to the needle trap 142 at a position opposite to the connection between the needle trap and the resilient arm 150. The coupling arm 160 extends from the needle trap 142 across the internal chamber 128 and through an opening 162 in the needle guard housing 122. The coupling arm 160 is provided with a hook 164 at its free end outside the needle guard housing 122, which engages with a flange 166 on the exterior of the proximal end 8 of the catheter hub 4, as shown in Figure 4. An opening 168 is provided in the coupling arm 150, through which the needle shaft 34 extends in the ready position, as shown in Figure 4a.

In the ready position shown in Figures 4 and 4a, the needle trap 142 is held to one side of the needle shaft 34 in a folded position overlying the

## CLAIMS

1. A catheter assembly comprising:

a catheter hub having a distal end, a proximal end 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;

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;

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 the passage of fluid;

a needle guard assembly for a catheter assembly, the needle guard  
assembly comprising:

a housing for receiving a 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 a 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  
housing; and a protected position, in which the needle trap blocks the  
sharpened needle tip of the needle within the housing;

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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;

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.

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

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

20 4. The catheter ~~needle-guard-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.

5. The catheter ~~needle-guard-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.

25 6. The catheter ~~needle-guard-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.

30 7. The catheter ~~needle-guard-assembly~~ according to any preceding claim, wherein the coupling arm engages with an exterior portion of the proximal end of the catheter hub.

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

9. The catheter ~~needle-guard-assembly~~ according to claim 8, wherein the coupling arm is pivotally connected to the needle trap.

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

11. The catheter ~~needle-guard-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.

12. The catheter ~~needle-guard-assembly~~ according to claim 11, 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.

13. The catheter ~~needle-guard-assembly~~ according to claim 12, wherein the region of the proximal wall adjacent the opening is reinforced.

14. ~~A catheter assembly comprising a needle guard assembly according to any preceding claim.~~