Claim No. HP-2018-000021

IN THE HIGH COURT OF JUSTICE
BUSINESS AND PROPERTY COURTS
OF ENGLAND AND WALES
INTELLECTUAL PROPERTY LIST (ChD)
PATENTS COURT

B E T W E E N:

BECTON, DICKINSON & COMPANY
(a company incorporated under the laws of the State of New Jersey, USA)

Claimant

- and -

B. BRAUN MELSUNGEN AG
(a company incorporated in the Federal Republic of Germany)

Defendant

ANNEX TO STATEMENT OF GROUNDS FOR AMENDMENT

Description

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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 ~~first~~ second valve portion 72, disposed in the internal chamber 12 distal of the valve opener, and a ~~second~~ first valve portion 74, distal of the ~~first~~ second valve portion.

The function of the ~~first~~ second 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 ~~first~~ second valve portion is closed. The ~~first~~ second 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 herein below.

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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 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 In this way, fluid may be withdrawn in the proximal direction through the catheter hub from the catheter 10 to the proximal end 8 of the catheter hub 4.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 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.

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The ~~second~~ first valve portion 74 is disposed within the internal 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 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 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.

Claims

1. A catheter assembly comprising:

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;

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 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; the needle trap comprising a first end and a second end;

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;

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.

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.~~

~~5~~4. 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.

~~6~~5. 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.

~~7~~6. 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.

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

~~9~~7. The catheter assembly according to any preceding claim ~~8~~, wherein the coupling arm is pivotally connected to the needle trap.

~~10~~8. 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.

~~11~~9. 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.

~~12~~10. The catheter assembly according to claim ~~11~~9, 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~~11. The catheter assembly according to claim ~~12~~10, wherein the region of the proximal wall adjacent the opening is reinforced.

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