METHODS AND APPARATUS FOR INHIBITING INTRODUCTION OF AIR INTO THE VASCULATURE DURING A PERCUTANEOUS PROCEDURE

Apparatus and methods for inhibiting the introduction of air into the body during a percutaneous procedure.
METHODS AND APPARATUS FOR INHIBITING INTRODUCTION OF AIR INTO THE VASCULATURE DURING A PERCUTANEOUS PROCEDURE

FIELD OF THE INVENTIONS

The disclosed inventions pertain to methods and apparatus for inhibiting the introduction of air into the vasculature of a patient during percutaneous procedures such as, for example, percutaneous diagnostic, therapeutic and interventional procedures.

BACKGROUND

For many diagnostic, therapeutic, or interventional percutaneous procedures involving the human vasculature, maintaining hemostasis is critical not only to prevent loss of blood, but also to prevent the introduction of air into the patient's vasculature system. Devices such as angioplasty balloon catheters, coronary guidewires, radio frequency (RF) ablation catheters, cryo-therapy catheters, and neurovascular occlusive device delivery catheters are just a sample of what is commonly used percutaneously to treat a wide variety of illnesses. The introduction of air into the blood stream can be quite serious, resulting in a stroke if it is allowed to migrate to the heart or brain (depriving the tissue of oxygenated blood).

Fig. 1 depicts the main components of an exemplary vasculature access device D, including a proximal hub H and a distal shaft F shown extending through an incision made in the patient's skin surface A and a puncture tract extending through the subcutaneous tissue and into a blood vessel BV of the patient's vasculature. With reference also to Figs. 1A-1F, the proximal hub H includes a hemostasis port E that allows for access of a diagnostic, therapeutic or interventional instrument C to pass through the hub H and distal shaft F, respectively, into the blood vessel BV. A fluid-flush port G is also provided on the hub, as is well-known.

The present inventor has determined that introduction of air through the hemostasis valve E into the hub H for possible downstream migration to the vasculature may happen for a number of reasons. With reference to Fig. 1A, air can pass from the external environment through the hemostasis valve E, as indicated by arrows 20, while the instrument C is being passed through the
hemostasis valve E, due to the valve design and a pressure differential i.e.,
when the pressure $P_i$ within the interior of the hub H is less than the ambient
pressure $P_h$. With reference to Fig. 1B, air can pass from the external
environment through the hemostasis valve E, as indicated by arrow 21, when
a pressure differential is created due to the movement of the instrument C,
indicated by arrow 22, resulting from the instrument C acting as an "occlusive
plug" 24 that creates a lower pressure $P_i$ on the proximal side of the
instrument within the hub H. With reference to Fig. 1C, air can pass from the
external environment through the hemostasis valve E when the valve E is
deformed or damaged by the passage of the instrument C, indicated by arrow
23, such as during multiple expansion/contraction cycles caused by
interchanging a catheter and dilator. Air can also pass from the external
environment through the hemostasis valve E while the instrument C is in
place, due vigorous aspiration via the flush-port G, as indicated by arrows 20,
25 and 26, shown amongst the incoming air bubbles B in Fig. 1D. With
reference to Fig. 1E, air can also pass from the external environment through
the hemostasis valve E due to normal aspiration through the flush-port G, as
indicated by arrows 27, when the valve E fails to recover to create a seal after
the instrument C has been removed. With reference to Fig. 1F, it is also worth
noting that air bubbles B drawn into the interior of the hub H, as indicated by
arrows 28, may cling to the instrument C due to surface tension, indicated by
reference number 29, and be drawn into the vasculature along with the
instrument C.

The present inventor has also determined that it would be desirable to
avoid this introduction of air into the interior hub H of the access device D,
since this air can migrate through the distal shaft F and into the patient's
vasculature.

SUMMARY

The present methods and apparatus inhibit the above-described
introduction of air into the vasculature during percutaneous procedures by, in
at least some embodiments, creating a sterile fluid flow (mixing with the
patient's blood) in a proximal portion of the access device or of an adjunct
device coupled to the proximal end of the vascular access device, through
which the various instruments are passed. The present methods and apparatus are suitable for a wide range of percutaneous applications, including ones not involving the vasculature, whenever inhibiting the introduction of air into the body is desired.

In one embodiment, a "degassing section" is located in a proximal end portion of the vascular access device, for example just distally of the hemostasis valve through which the various instruments may be introduced. The degassing section may be part of a system for inhibiting the introduction of air into the body during a percutaneous procedure that also includes a container supplied with sterile fluid (e.g., a plastic bag of hepanized saline). The system may also include a supply line, which has a first end in fluid communication with the sterile fluid container and a second end in fluid communication with the degassing section, and a return line, which has a first end in fluid communication with the degassing section and a second end in fluid communication with the sterile fluid container. A closed-loop fluid circulation system may be formed by the degassing section of the access device, the container, and the supply and return lines. A pump, such as a peristaltic pump, may be provided along the supply line to cause circulation of the sterilized fluid through the degassing section, for example in a distal-to-proximal direction, i.e., with the supply line in fluid communication with a more distal portion of the degassing section than the return line. In particular, air bubbles that may be introduced into the access device through the proximal end hemostasis valve are collected by the circulating flow of sterile fluid in the degassing section and pushed through the return line into the sterile fluid container.

In one embodiment, the degassing section is incorporated into a proximal handle of a vascular access sheath. The sheath may be of a type introduced "bareback" into the vasculature (as is well-known), and has an interior working lumen passing through the handle through which various elongate instruments (e.g., stylet/dilator sets, guidewires and catheters) are introduced into the vasculature through a hemostasis valve located in a proximal end of the handle. The respective supply and return lines are coupled to the handle, with the supply line placed in fluid communication with the interior working lumen of the sheath in a distal portion of the handle, and
the return line placed in fluid communication with the interior working lumen in a proximal portion of the handle, the section of the working lumen between the respective supply and return lines defines the degassing section.

In another embodiment, the degassing section is incorporated into an adjunct device that is coupled to a distal end of a standard vascular access device (or sheath). The adjunction device has a distal end opening that is coupled in a fluidly-sealed manner to the proximal hemostasis valve of the vascular access device (or sheath). The adjunct device comprises its own proximal end hemostasis valve through which the various elongate instruments are introduced, passing through the adjunction device degassing section, which may be defined by a lumen within the device, then through the access device hemostasis valve and into the vasculature. The respective supply and return lines may be coupled to the adjunction device with the supply line in fluid communication with a distal end portion of the interior degassing section and the return line in fluid communication with a proximal end portion of the interior degassing section.

In variations of the above embodiments, the respective supply and return lines may be provided in a co-axial arrangement to reduce the number of individual fluid flow lines coupled to the vascular access device. Alternatively, the fluid supply line may be gravity fed into the degassing section of the vascular access device or adjunct device (with no pump needed), and instead of a return line to the sterile fluid container, the fluid outflow from the degassing section may be gravity expelled to a drain line.

The above described and many other features of the present inventions will become apparent as the inventions become better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Detailed descriptions of exemplary embodiments will be made with reference to the accompanying drawings. The systems and apparatus shown in the drawings are not necessarily drawn to scale, with emphasis instead being placed on illustrating the various aspects and features of the depicted embodiments.
**Fig.** 1 is a partially cut-away side view showing a conventional vascular access device inserted percutaneously into a patient's blood vessel.

**Figs. 1A-1F** are partially cut-away side views of the proximal hub portion of the vascular access device shown in Fig. 1, illustrating various scenarios in which air can enter into the access device and patient's vasculature through a proximally located hemostasis valve.

Fig. 2 is a schematic illustration of a system in accordance with one embodiment of a present invention.

Fig. 2A is a side, partially cut-away view of a portion of the system illustrated in Fig. 2.

Fig. 3 is a side, partially cut-away view of an apparatus in accordance with one embodiment of a present invention.

Fig. 3A is a section view take along line 3A-3A in Fig. 3.

Fig. 3B is a section view take along line 3B-3B in Fig. 3A.

Fig. 4 is a side, partially cut-away view of an apparatus in accordance with one embodiment of a present invention.

Fig. 5 is a side, partially cut-away view of an apparatus in accordance with one embodiment of a present invention.

Fig. 6 is a schematic illustration of a system in accordance with one embodiment of a present invention.

Fig. 6A is a section view take along line 6A-6A in Fig. 6.

Fig. 6B is a section view take along line 6B-6B in Fig. 6.

Fig. 6C is a perspective view of a portion of the system illustrated in Fig. 6.

Fig. 6D is front, partially cut-away view of a portion of a system in accordance with one embodiment of a present invention.

**DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENTS**

The following is a detailed description of the best presently known modes of carrying out the inventions. This description is not to be taken in a limiting sense, but is made merely for the purpose of illustrating the general principles of the inventions.

**Figs. 2 and 2A** depict a system 40 for inhibiting the introduction of air into a vascular access device and a patient's vasculature according to one
embodiment of at least one of the present inventions. The system 40 generally includes a container 50, e.g., a standard plastic "iv" bag, filled or partially filled with sterile fluid 52, e.g., hepanized saline. A supply line 53 has a first end 51 in fluid communication with the sterile fluid container 50 and a second end 62 in fluid communication with a degassing section 66 located in a device 58 (e.g. by way of a port). The device 58 may, for example, be the proximal end portion of a vascular access device or may be an adjunct device that is coupled to a proximal end of a vascular access device. The exemplary device 58 includes distal and proximal end hemostasis valves 59 and 69, through which various elongate working instruments may be introduced. The degassing section 66 in the illustrated implementation extends from a point just proximal of the distal end hemostasis valve 59 to a point just distal of the proximal end hemostasis valve 69. For purposes of illustration, an exemplary instrument 68 is shown placed through the proximal hemostasis valve 69, extending through the degassing section 66, through the distal hemostasis valve 59, and heading towards the vasculature, as indicated by arrow 60, in Figs. 2 and 2A.

A return line 56 has a first end 64 in fluid communication with the degassing section 66 of the device 58 (e.g. by way of a port) and a second end 61 in fluid communication with the sterile fluid container 50. A closed-loop fluid circulation system is defined by the fluid container 50, the supply and return lines 53 and 56, and the degassing section 66. A peristaltic pump 54, or other suitable pump, is provided along the supply line 56 to cause circulation of sterilized fluid 52 through the degassing section 66 in a distal-to-proximal direction that is the same direction as blood flow from the patient (i.e. is antegrade), as indicated by arrows 55 and 57. In particular, air bubbles B that may be introduced into the access device through the proximal end hemostasis valve 69 are collected by the circulating flow of sterile fluid 52 in the degassing section 66 and pushed through the return line 53 into the sterile fluid container 50. The locations of the junctions 51 and 61 of the respective supply and return lines 53 and 56 may be spaced apart on the container 50, as shown, to prevent the air bubbles B pushed into the container 50 through the return line 56 from re-entering the degassing section 66 through the supply line 53.
The return line 56 and container 50 may be formed from a clear plastic material to allow for visual confirmation that air bubbles B are being removed from the degassing section 66 and pushed through the return line 56 into the container 50. It should also be appreciated that many variations of the exemplary embodiment illustrated in Figs. 2 and 2A are possible. By way of non-limiting example, the respective supply and return lines 53 and 56 may be provided in a co-axial arrangement to reduce the number of individual fluid flow lines coupled to the vascular access device (one such embodiment is described below in conjunction with Fig. 6). Also, the fluid supply line 53 may be gravity fed into the degassing section of the vascular access device or adjunct device (i.e., with no pump 54 needed), wherein instead of the return line to the sterile fluid container 50, the fluid outflow from the degassing section may be gravity expelled to a drain line.

Referring to Figs. 3-3B, a degassing section 66a may be incorporated into the proximal handle 75 of a device that also includes a vascular access sheath 82. The handle 75, which may be in the form of a housing that defines distal and proximal ends 77 and 85, may be connected to the container 50 and to the supply and return lines 53 and 56 to form a system in the manner described above with reference to Figs. 2 and 2A. The sheath 82 may be of a type introduced "bareback" into the vasculature (as is well-known), and has an interior working lumen 70, through which various elongate instruments (e.g., stylet/dilator sets, guidewires, and catheters; collectively represented by reference numeral 68 in Figs. 3 and 3A) may be introduced into the vasculature through a hemostasis valve 84 located at the proximal end 85 of the handle 75. The supply and return lines 53 and 56 are physically secured (either permanently or temporarily) to the handle 75, and are fluidically connected to the degassing section 66a, by connectors (or ports) 30 and 39.

The exemplary connector 30 includes a tubular portion 31 with a lumen 32, which may be connected to the supply line 53, and an annular portion 33, which delivers fluid to the sheath lumen 70. Referring more specifically to Figs. 3A and 3B, the annular portion 33 delivers fluid, as indicated by arrows 72, to various points around the perimeter the instrument 68. Delivering fluid around the perimeter of the instrument 68 as it exits the supply line 53, as opposed to merely delivering fluid to the side of the instrument that faces...
tubular portion 31, insures that all air bubbles near the distal end of the
degassing section 66a will be driven proximally away from the vasculature.
There are a variety of ways to connect the annular portion 33 of the connector
31 to the lumen 70 within the access sheath 82. In the illustrated embodiment,
the annular portion 33 includes an annular lumen 34 that is connected to the
tubular portion lumen 31, an abutment 35, and a plurality of openings 78 that
are connected to the annular lumen. The sheath 82 is a two-part structure that
includes first and second sheath portions 82a and 82b which abut opposite
sides of the abutment 35 and are connected to the annular portion 33 by
adhesive or some other suitable instrumentality. In another exemplary
implementation, the abutment may be omitted and the sheath may be a
unitary structure with fluid openings that are aligned with the connector
openings 78. The connector 39 includes a lumen 32a that is in fluid
communication with the sheath lumen 70. The portion of the sheath lumen 70
between the connectors 30 and 39 defines the degassing section 66a.

It should be noted that the connectors 30 and 39 are located at the
distal and proximal ends 77 and 85 of the handle 75 and define the distal and
proximal ends of the degassing section 66a. As such, all fluid flow though the
degassing section 66a is distal-to-proximal, i.e. away from the vasculature. As
such, air bubbles B that may be introduced into the sheath lumen 70 through
the proximal end hemostasis valve 84 are collected by the circulating flow of
sterile fluid in the degassing section 66a, as indicated by flow arrows 72, 74
and 76, and are pushed into the return line 56. A variety of modifications may
be made to this embodiment. By way of non-limiting example, the fluid
connection between the supply line 53 and the sheath lumen 70 may be
accomplished by means other than the openings 78, for example, by using a
convention "Y" connector or other type of inlet port. It should also be noted
that the exemplary embodiment illustrated in Figs. 3-3B does not include a
distal end hemostasis valve and that fluid is delivered to the sheath lumen 70
at a pressure equal to blood pressure in order to insure that the fluid does not
travel distally from the connector 30. In other implementations that are
otherwise identical to that illustrated in Figs. 3-3B, a hemostasis valve may be
provided distal of the connector 30.
The exemplary handle 75a illustrated in Fig. 4 is substantially similar to the handle 75 illustrated in Figs. 3-3B and may be employed in the system illustrated in Fig. 2. Here, however, the supply and return lines 53 and 56 used for circulating the sterile fluid that removes air bubbles B from the portion of the sheath lumen 70 that defines the degassing section 66a may be tethered or otherwise connected (e.g., using a "figure 8" style tubing set) and physically coupled near one longitudinal end of the sheath handle 75a in order to reduce the possibility of entanglement during a procedure. The tubular portion 31a of the connector 30a includes a lumen (not shown) that bends at a 90 degree angle to accommodate the redirection of the supply line to the proximal end 85. The exemplary handle 75a also includes a distal end hemostasis valve 84d may be interposed across the sheath lumen 70 at the distal end 77 of the handle 75a to further isolate the degassing section 66a.

One example of an adjunct device that may be coupled to the distal end of standard vascular access device, and employed in the system illustrated in Fig. 2, is generally represented by reference numeral 100 in Fig. 5. The exemplary adjunct device 100 includes a degassing section 66b within a housing 115 that is coupled, e.g., by a clip-on or clamshell manner, to the proximal hemostasis valve 124A of a standard vascular access device (or sheath) 82. The degassing section 66b is defined by the internal lumen 102 of a tube 104. The distal end of the lumen 102 is connected to the supply line 53 by the above-described connector 30 with fluid openings 78 (Figs. 3A and 3B), while the proximal end of the lumen 102 is connected to the return line 56 by the above-described connector 39. As such, fluid is received at the distal end 116 of the degassing section 66b and is removed at the proximal end 98 of the degassing section. The access device hemostasis valve 124A may be directly connected to the connector annular portion 33, connected to the connector annular portion 33 by a short tube 105 (as shown), or connected to the tube 104 in those instances where the tube 104 is provided with holes that are aligned with the connector fluid openings 78 (Figs. 3A and 3B). The adjunct device 100 also includes a proximal end hemostasis valve 124B, through which the various elongate instruments are introduced, passing through the degassing section 66b, and then through the access device hemostasis valve 124A and into the vasculature. As with the above-described
embodiments, air bubbles B that may be introduced into the lumen 102 (and degassing section 66b) through the proximal end hemostasis valve 124B are collected by the circulating flow of sterile fluid in the degassing section 66b and pushed into the return line 56, as indicated by arrows 112, 101 and 128.

The exemplary adjunct device 100 illustrated in Fig. 5 also includes one or more brushes 117 positioned within the degassing section 66b, for example on the interior wall of tube 104, to facilitate moving of air bubbles B away from the wall and/or instrument 68 and into the fluid flow stream without substantially impeding fluid flow. The exemplary implementation includes a plurality of brushes 117 which are longitudinally and circumferentially offset from one another along a length of the degassing section 66b to minimize any resulting flow impedance. The brushes 117 may also be employed in any of the other implementations described herein.

Another exemplary system for inhibiting the introduction of air into a vascular access device and a patient’s vasculature is generally represented by reference numeral 180 in Fig. 6. Similar to system 40 (Fig. 2), fluid is used to remove air and, to that end, the system 180 generally includes a sterile fluid container 200, e.g., a standard plastic "iv" bag, filled or partially filled with sterile fluid 202, e.g., hepanized saline. The exemplary system also includes a handle 75b that is a portion of a device that also includes a vascular access sheath 82, although other embodiments may include an adjunct device coupled to a proximal end of a vascular access device. The handle 75b is substantially similar to the handle 75 illustrated in Figs. 3-3B and similar elements are represented by similar reference numerals. The system 180 also includes a supply line 210 with a first end in fluid communication with the sterile fluid container 200 (and fluid 202) and a second end connected to and in fluid communication with the distal end of the degassing section 66a by a connector 30a in the manner described above. The system 180 also includes a return line 225 with a first end connected to and in fluid communication with the proximal end of the degassing section 66a by way of a connector 39a and a second end in fluid communication with the sterile fluid container 200 (and fluid 202). As such, a closed-loop fluid circulation system that includes the degassing section 66a is provided.
In contrast to the exemplary system 40 illustrated in Fig. 2, the supply and return lines 210 and 225 in system 180 are in a coaxial arrangement (note Figs. 6 and 6A). The return line 225 extends out of the open end of the supply line 210 within the interior of the fluid container 200. Arrows 228 in Fig. 6 show the fluid outflow with air bubbles B from return line 225, and arrows 222 show the fluid intake into the supply line 210. Within the handle 75b, the supply line 210 separates from the return line 225 and feeds the degassing passage 66a through the plurality of openings 78 (Figs. 3A and 3B) in the connector 30a. As with the previously described embodiments, the fluid connection between the supply line 210 and the degassing passage 66a may be accomplished by instrumentalities other than the openings 78 of the connector 30a. For example, a "Y" connector or some other conventional inlet port may be used.

A specialized peristaltic pump 240 is provided along the coaxial supply/return line 210/225, to cause circulation of the sterilized fluid 202 through the degassing section 66a a distal-to-proximal direction, as indicated by the flow arrows 207 and 217. Air bubbles B that may be introduced into the access device through the proximal end hemostasis valve 84 are collected by the circulating flow of sterile fluid 202 in the degassing section 66a (arrow 207) and pushed through the return line 225 into the sterile fluid container 200 (arrows 228). With reference also to Figs. 6B and 6C, the specialized peristaltic pump 240 may be provided with rotating wheels 244 that have central grooves to receive the coaxial tubing and compress the outer tubing (supply line 210) sufficiently to circulate the sterile fluid 202 therethrough, while not compressing the inner return tubing 225 to an extent which would impede fluid circulation. The outer tubing 210 may be compressed part way to the inner return tubing 225 (as shown), or all the way to the inner return tubing. In the illustrated embodiment, the wheels 244 compress the coaxial tubing against a station set of round surfaces 242 that have corresponding central grooves for receiving the tubing 210.

The respective ends of the supply and return lines 210 and 225 may be spaced apart sufficiently within the container 200 to prevent the air bubbles B being pushed out the return line 225 from re-entering the degassing section 66a through the supply line 210. This may be accomplished in a variety of
ways. For example, as illustrated in Fig. 6, the ends of the supply and return lines 210 and 225 within the container 200 are longitudinally spaced. Referring to Fig. 6D, in another embodiment, the ends of the supply and return lines 210 and 225 may be coupled to the container 200 in the same manner that supply/return lines 53 and 56 are coupled to the fluid container 50 (Fig. 2) and a "Y" connector 230 may be employed to couple the lines in a coaxial relationship. Here too, the return line 225 and container 200 may be formed from a clear plastic material to allow for visual confirmation that air bubbles B are being removed from the degassing section 66a and pushed through the return line 225 into the container 200.

It will be apparent to those skilled in the art that the inventions may be embodied in other specific forms besides and beyond those described herein. The foregoing embodiments are therefore to be considered in all respects illustrative rather than limiting.
What is claimed is:

1. A system, comprising:
   a device defining a distal end and a proximal end and including
   a distal hemostasis valve associated with the distal end, a proximal
   hemostasis valve associated with the proximal end, an instrument passage
   lumen located between the hemostasis valves and defining a degassing
   region with a distal end and a proximal end, an inlet port in fluid
   communication with degassing region distal end and an outlet port in fluid
   communication with degassing region proximal end;
   a source of fluid; and
   a supply line having a first end in fluid communication with the
   fluid source and a second end in fluid communication with the inlet port.

2. A system as claimed in claim 1, wherein
   the fluid source comprise a container at least partially filled with
   fluid; and
   the system further comprises a return line having a first end in fluid
   communication with the outlet port and a second end in fluid
   communication with the container such that fluid flowing through the outlet
   port is discharged into the container.

3. A system as claimed in claim 2, wherein the return line is at
   least partially disposed coaxially within the supply line.

4. A system as claimed in claim 1, further comprising:
   a circulation pump along the supply line.

5. A system as claimed in claim 1, wherein
   the device comprises an introducer sheath including a proximal
   handle and a guide sheath that defines the instrument passage lumen; and
   the inlet and outlet ports are associated with the handle.

6. A system as claimed in claim 1, wherein
the degassing region distal end abuts the distal hemostasis valve; and
the degassing region proximal end abuts the proximal hemostasis valve.

7. A system, comprising:
   a device defining a distal end and a proximal end and including
   a proximal hemostasis valve associated with the proximal end, an instrument
   passage lumen extending through the device and defining a perimeter and a
degassing region with a distal end and a proximal end, an inlet port that
delivers fluid into degassing region from a plurality of locations around the
perimeter of the instrument passage lumen and an outlet port in fluid
communication with degassing region proximal end
   a container at least partially filled with a fluid;
   a supply line having a first end in fluid communication with the
fluid container and a second end in fluid communication with inlet port; and
   a return line having a first end in fluid communication with the
instrument passage lumen and a second in fluid communication with the fluid
container.

8. A system as claimed in claim 7, further comprising:
   a circulation pump operatively coupled to the supply line.

9. A system as claimed in claim 7, wherein
   the device comprises an introducer sheath including a proximal
   handle and a guide sheath that defines the instrument passage lumen; and
   the inlet and outlet ports are associated with the handle.

10. A system as claimed in claim 7, wherein the return line is at
    least partially disposed coaxially within the supply line.

11. A system as claimed in claim 7, wherein the inlet port includes
    an annular lumen that extends around the perimeter of the instrument
passage and a plurality of spaced openings that are connected to the annular lumen.

12. A system as claimed in claim 11, wherein the inlet port is associated with the distal end of the degassing region.

13. A system as claimed in claim 12, further comprising:
   a distal hemostasis valve associated with the distal end of the device.

14. A method for inhibiting the introduction of air into a body passage during a percutaneous procedure, the method comprising the step of:
   pushing air bubbles out of a vascular access device by circulating a fluid in only an antegrade direction in a proximal portion of the vascular access device to an outlet port.

15. A method as claimed in claim 14, further comprising the steps of:
   supply fluid from a container to the vascular access device; and returning fluid from the outlet port to the container.

16. A device for use in a vascular access procedure, the device comprising:
   a housing defining a distal end and a proximal end and having an instrument passage lumen extending from the distal end to the proximal end;
   a distal hemostasis valve associated with the distal end of the housing;
   a proximal hemostasis valve associated with the proximal end of the housing;
   an inlet port associated with the housing distal end, proximal of the distal hemostasis valve and in fluid communication with the instrument passage lumen; and
an outlet port proximal of the inlet port and in fluid communication with the instrument passage lumen.

17. A device as claimed in claim 16, wherein
the instrument passage lumen defines a longitudinal axis and a perimeter that extends around the longitudinal axis; and
the inlet port delivers fluid from a plurality of locations around the perimeter of the instrument passage lumen.

18. A device as claimed in claim 17, wherein the inlet port includes an annular lumen that extends around the perimeter of the instrument passage lumen and a plurality of spaced openings that are connected to the annular lumen.

19. A device as claimed in claim 18, wherein the inlet port is associated with the distal end of the instrument passage lumen.

20. A device as claimed in claim 16, further comprising:
at least one brush located within the instrument passage lumen.

21. A device as claimed in claim 16, wherein
the housing comprises a vascular access device handle; and
the instrument passage lumen is defined by a sheath having a portion thereof within the vascular access device handle.

22. A device as claimed in claim 16, wherein the housing is configured to be secured to a vascular access device.
**INTERNATIONAL SEARCH REPORT**

**International application No**
PCT/US2009/037026

**A. CLASSIFICATION OF SUBJECT MATTER**

INV. A61M39/06 BO1D19/00

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

A61M BO1D A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and where practical search terms used)

EPO-Internal, WFI Data

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

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<td>WO 2007/089309 A (UNIV CALIFORNIA [US]; SHIVKUMAR KALYANAM [US]; CESARIA DAVID A [US]) 9 August 2007 (2007-08-09) page 1, paragraph 1 page 1, paragraph 3 - page 7, paragraph 15 page 10, paragraph 41 - page 24, paragraph 71; claims 1-33; figures 5-13</td>
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<td>US 2004/220519 A1 (WULFMAN EDWARD I [US]; ET AL) 4 November 2004 (2004-11-04) page 1, paragraph 11 - page 2, paragraph 13 page 6, paragraph 52 - page 7, paragraph 58; figures 5-6B</td>
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 xcb Further documents are listed in the continuation of Box C

 xcb See patent family annex

**Date of the actual completion of the international search**

30 April 2009

**Date of mailing of the international search report**

11/05/2009

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### DOCUMENTS CONSIDERED TO BE RELEVANT

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<td>US 5 542 931 A (GRAVENER ROY D [US] ET AL) 6 August 1996 (1996-08-06)</td>
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**INTERNATIONAL SEARCH REPORT**

**Box No. II** Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [x] Claims Nos.: 14 15
   
   because they relate to subject matter not required to be searched by this Authority, namely:

   Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos:-
   
   because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos:
   
   because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III** Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable inventions.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:  

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims: it is covered by claimsNos.:  

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant’s protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant’s protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.
## INTERNATIONAL SEARCH REPORT

### Information on patent family members

**International application No**

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<th>Patent family member(s)</th>
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<td>Wo 2007089309 A</td>
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