(12) CERTIFIED INNOVATION PATENT (11) Application No. **AU 2013101567 B4**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
A catheter system

(51) International Patent Classification(s)
A61M 25/14 (2006.01)

(21) Application No: **2013101567** (22) Date of Filing: **2013.11.28**

(30) Priority Data

(31) Number	(32) Date	(33) Country
2013901874	**2013.05.27**	**AU**

(45) Publication Date: **2014.01.09**
(45) Publication Journal Date: **2014.01.09**
(45) Granted Journal Date: **2014.01.09**
(45) Certified Journal Date: **2014.03.13**

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(56) Related Art
US 5098411
US 2005/0165354
US 2010/0249750
EP 0215537
US 2003/0078562

ABSTRACT

A catheter system including a catheter 10 and a stylet 30. The stylet includes an elongate portion 31 and a shaped portion 32. The elongate portion is receivable within the catheter. The elongate portion and the catheter are co-operably configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient. The shaped portion is positioned to be within the patient.

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A CATHETER SYSTEM

FIELD

Various aspects of the invention relate to catheter systems and related methods and components therefor.

BACKGROUND

A catheter is a tube insertable into a patient, so that part of the tube is in the patient and another part is external the patient, to establish fluid communication with one or more sites within the patient. By way of example, nerve block catheters are used to deliver anaesthetic to nerves whereas other catheters are used for withdrawing blood samples, administering medication into the blood stream or measuring pressure.

Some existing catheters take the form of a simple tube being open at both of its ends, whereas others have a closed distal end and a set of side openings.

Nerve block catheters are conventionally inserted by:

1. inserting into the patient a tubular needle;
2. threading the catheter through the tubular needle;
3. withdrawing the tubular needle leaving a free open end of the catheter projecting from the patient; and
4. fitting a connector to the projecting free end of the catheter to connect the catheter to a fluid source (e.g. a syringe loaded with anaesthetic) or a fluid destination (e.g. a vacuum source for drawing a blood sample).

The present inventor has recognised that the proper functioning of catheters is sometimes adversely impacted by the catheter kinking, the buildup of material (e.g. blood clotting) at openings from the catheter, and/or by the catheter inadvertently (partly or wholly) being withdrawn from the patient. Accordingly, the various aspects of the present invention aim to at least partly address one or more of these problems, or at least to provide alternatives for those concerned with catheter systems and their use.

It is not admitted that any of the information in this patent specification is common general knowledge, or that the person skilled in the art could be reasonably expected to ascertain or understand it, regard it as relevant or combine it in any way at the priority date.

SUMMARY

One aspect of the invention provides a catheter system including

a catheter; and

a stylet;

the stylet including an elongate portion and a shaped portion;

the elongate portion being receivable within the catheter;

the elongate portion and the catheter being co-operably configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient;

the shaped portion being positioned to be within the patient.

Preferably the shaped portion is shaped to obstruct the catheter. The shaped portion may be a bulbous portion and is preferably in substance at an end of the stylet.

The catheter may have an open end positionable within the patient in which case the stylet is preferably advanceable within the catheter to move the shaped portion at least to the open end, when the open end is within the patient, to remove build-up at the open end.

It is preferred that at least a rearward portion of an exterior of the shaped portion rearwardly converges.

Another aspect of the invention provides a method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter internally defining a flow path; then

obstructing, at a location within the patient, the flow path.

Preferably the obstructing is at a location along the catheter to establish fluid communication via selected ones of a plurality of side openings along the catheter.

Preferably the inserting into the patient a catheter includes

inserting into the patient a needle externally carrying the catheter; and

withdrawing the needle.

Also disclosed is a catheter system including

a catheter; and

a stylet;

the stylet including an elongate portion;

the elongate portion being receivable within the catheter;

the catheter having an open end positionable within the patient; and

the stylet being long enough to be manipulated external the patient to remove build-up from the open end within the patient.

The system may further include a needle, e.g. a short beveled nerve block needle, for inserting the catheter into the patient, in which case the needle is preferably receivable within the catheter.

Also disclosed is a catheter system including

a catheter;

a needle; and

a stylet;

the stylet including an elongate portion;

the elongate portion being receivable within the catheter;

the elongate portion and the catheter being co-operably configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient;

the needle being receivable within the catheter to insert the catheter into the patient.

The stylet preferably includes a connector for sealingly engaging an end of the catheter external the patient to fluidly connect the void(s) with at least one of a fluid source or a fluid destination.

Optionally the catheter has one or more side openings positionable within the patient to fluidly connect the void(s) to one or more of the sites within the patient.

The system may be a nerve block catheter system or a blood vessel catheter system.

Also disclosed is a stylet for a catheter system;

the stylet including an elongate portion and a shaped portion;

the elongate portion being receivable within a catheter and configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient;

the shaped portion being positioned to be within the patient.

Preferably the shaped portion has a shape complementary to a cylindrical interior of the catheter to obstruct the catheter.

Also disclosed is a method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter;

inserting into the catheter a stylet.

The method preferably includes manipulating the stylet to position the shaped portion between openings, of the catheter, within the patient. The stylet may be manipulated to

move the shaped portion so as to remove build-up, from the catheter, within the patient, e.g. to remove build-up, from an open end of the catheter, within the patient. Preferably the stylet is manipulated to move the shaped portion beyond an or the open end, of the catheter, within the patient. The method may include at least one of advancing and retracting the stylet to establish fluid communication via selected ones of a plurality of side openings along the catheter.

Also disclosed is a method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter;

inserting into the catheter the stylet;

manipulating the stylet to remove build-up, from an open end of the catheter, within the patient.

The method preferably includes, after inserting the catheter, leaving for a period of time the catheter in place.

Also disclosed is a method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter; and

inserting into the catheter a stylet configured such that, when so inserted, at least a portion of the stylet is spaced from the catheter such that the at least portion and the catheter together define the at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient; then

leaving for a period the stylet in place.

Preferably the period is at least one hour.

Optionally the inserting into the patient a catheter and the inserting into the catheter a stylet are during an attendance to the patient; and

the method further includes leaving the stylet and catheter in place until a subsequent attendance to the patient.

Also disclosed is a method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter;

inserting into the catheter a stylet;

wherein the inserting into the patient a catheter includes

inserting into the patient a needle externally carrying the catheter; and

withdrawing the needle.

Also disclosed is a method of establishing a nerve block including

establishing fluid communication with one or more nerves;

supplying at least one anesthetic to the nerve(s) via the catheter.

Also disclosed is a method of monitoring arterial blood pressure including establishing fluid communication with an artery.

Also disclosed is a method of removing build-up, from a catheter, within a patient,

the method including inserting into the catheter a stylet; and

manipulating the stylet.

BRIEF DESCRIPTION OF DRAWINGS

Figures 1 to 6 are schematic side views illustrating a preferred method of inserting and operating a preferred catheter system;

Figure 7 schematically illustrates another catheter system in use;

Figure 8 is a schematic cross-section view of an arterial catheter system in situ; and

Figure 9 is a transverse cross-section view of a catheter and a stylet.

DESCRIPTION OF EMBODIMENTS

The catheter system of Figures 1 to 6 includes a catheter 10, a needle 20, and a stylet 30.

The catheter 10 includes an elongate thin walled tubular body 11 formed of suitably pliable polymer material. The distal (or forward) end of the body 11 terminates at simple open end 12. The other (or proximal or rearward) end of the body 11 terminates in a rearwardly flared, connector receiving, portion 14. In this example, the connector receiving portion is integrally formed with the body 11.

Preferably, the portion 14 is a female luer connection. To suit nerve blocking applications, the catheter preferably has an outer diameter of 18GA to 22GA. In this example, the catheter has an outer diameter of 20GA (0.902mm, 0.0355in) and is dimensioned to accommodate a 22GA needle. To aid in insertion, the outer diameter may be conically tapered at the tip 12 to define a lead-in.

The needle 20 includes a needle body 21. The body 21 is a straight cylindrical tube of rigid metallic construction. In this example, the needle 20 is a short beveled nerve block needle. The distal end of the body 21 terminates at a penetrating tip 22, which in this example includes a single oblique planar face, the edges of which are sharp.

The body 21 is receivable within the catheter 10 such that the catheter 10 is externally carried by the needle 20. The catheter 10 is fitted to the needle 20 in the manner of a sleeve. In particular, the portion 11 forms a closer fitting sleeve about the body 21 and is supported by the body 21 during insertion into the patient.

The proximal end of the body 21 is rigidly mounted within a connector 23. The connector 23 includes a forwardly projecting cylindrical boss 24. The boss 24 is concentric with the body 21 and dimensioned to be snugly received within, and to sealingly engage, the connector receiving portion 14 of the catheter 10 to resist inadvertent separation of the needle 20 from the catheter 10.

A rearward end of the needle 20, or more specifically its connector 23, terminates in a port 25 co-operable with a tube to fluidly connect to the tube with an interior of the needle 21. In an alternate construction, a tube may be directly connected to the needle 21 during manufacture.

The stylet 30 includes an elongate portion in the form of a long cylindrical solid rod 31 formed of incompressible, non-porous, semi-rigid plastic or metal. For the avoidance of doubt, “rigid” and similar terms as used herein refer to material which does not deform appreciably in use, and “semi-rigid” is used in contrast to “freely pliable” to refer to materials which deform, but offer appreciable resistance thereto, in use.

The distal end of the rod 31 terminates in a shaped formation 32. The shaped formation 32 is integrally formed with the rod 31 but is distinct therefrom in that it has an appreciably different shape. The shape formation 32 is a bulbous portion having a cylindrical exterior shaped to closely fit within the cylindrical interior of the catheter 10 (or more specifically its body 11). In this example, the formation 32 has a dome-shaped rounded leading end.

The proximal end of the rod 31 is rigidly mounted within a connector 33. The connector 33 is preferably a female to male luer handle and includes a forwardly projecting, conically tapered cylindrical boss 34 dimensioned to snugly fit within the connector

receiving portion 14 to sealingly engage the catheter 10 and to resist inadvertent separation of the connector 33 and the catheter 10. The catheter 10 has a luer lock or similar mechanism to engage the stylet (i.e. the stylet screws into place with threads). The boss 34 is a male connector end.

The stylet, or more specifically its connector 33, rearwardly terminates in a flow port 35 co-operable with a tube to connect the stylet to a fluid source or fluid destination. In an alternate construction, a tube may be directly connected to the stylet during manufacture. The boss 34 is a tubular boss defining an outlet 36 at its forward end.

Figure 7 schematically illustrates the catheter 10 and stylet 30 inserted into a patient 40 to perform a fascial plane nerve block called a transversus abdominis plane block. As illustrated, the patient 40 includes (in order in an inwards direction) skin layer 41, external oblique layer 42, internal oblique layer 43, fascial plane 44 and transversus abdominis 45. The fascial plane 44 separates the internal oblique and the transversus abdominis and it is within this plane that the nerves lie.

To insert the catheter 10 and stylet 30, first the catheter 10 is inserted. The catheter 10 is fitted to the needle 20 as in Figure 1 and manipulated to drive the piercing tip 22 and to manoeuver the tip 22 and the distal end portions of the catheter 10 and needle 20 into the fascial plane. Positioning of the needle may be guided by electrical stimulation and/or ultrasound. By way of example, a voltage may be applied to the needle body 21 so that when its tip 22 (uninsulated by the catheter 10) acts on the nerves the patient observably twitches.

The configuration of the piercing tip 22 may be application dependent. Needles for arterial puncture are usually sharper (than needles for nerve blocks) having a Quinke tip or other tip more suited to vascular access.

Once the subassembly 10, 20 is appropriately positioned, the needle 20 is withdrawn as suggested by arrow A in Figure 2. The stylet 30 is then inserted into the catheter 10. The

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rounded leading end of the stylet 30 and the tapered interior of the portion 14 guides the stylet into the catheter 10, or more specifically its body 11.

In this example, the shaped formation 32 is dimensioned for a snug receipt within the body 11 so as to substantially occlude the body 11, although obstruction less than substantial occlusion would still be useful.

The catheter 10 and the stylet 30 are co-operably configured whereby when the stylet 30 is fully advanced the shaped portion 32 is brought into register with the open end 12 and the boss 34 sealingly engages the connector receiving portion 14. The cylindrical exterior of the rod 31 is of lesser diameter than the nominally cylindrical interior of the body 11 whereby a nominally annular void is defined between the exterior of the rod 31 and the interior of the body 11. Of course, given that the body 11 is flexible, this nominally annular void would in fact vary in shape along its length, and of course the portions of the void defined within the flared connector receiving portion 14 are larger than the void portions defined within the body 11.

The connector 33 defines one or more flow paths communicating the port 35 with the outlet 36 to fluidly communicate the port 35 with the nominally annular void.

Once the subassembly 10, 30 is in situ as in Figure 7, the flexible tube of a fluid source comprising the tube and a syringe containing anaesthetic is fitted to the port 35. By advancing the plunger of the syringe, fluid is driven through the connector 33 as suggested by arrow C to emerge from the connector 33 via the outlets 36 into the nominally annular void as suggested by arrows D. The fluid is in turn conveyed along the voids to the side openings 13 to emerge therefrom at respective sites within the fascial plane 44 or next to a nerve as suggested by arrows E.

The shaped formation 32 obstructs the open free end 12 of the catheter 10 and so promotes fluid flow through the side openings 13. In this example, the shaped formation 32 substantially occludes the open free end at 12 and causes outward flow through the side openings 13.

The described catheter over needle mode of insertion has been found to lead to more secure embedding of the catheter 10 within the patient (i.e. to have higher resistance to inadvertent withdrawal of the catheter) than conventional catheter through needle techniques.

The use of a stylet as described serves to not only reinforce the catheter 10 against kinking but also gives the anaesthetist a degree of control over the delivery pattern of anaesthetic within the patient. By way of example, the catheter 10 once inserted may be used without a stylet, i.e. a fluid source may be directly connected to the connector receiving portion 14. By operating the catheter 10 without the stylet 30, a high proportion of the supplied anaesthetic would be delivered to the patient via the open free end 12 of the catheter thus appreciably varying the delivery pattern. In other variants of the disclosed system and method, the delivery pattern may be varied by varying the location of the shaped portion 32 relative to the openings 12, 13. For example, in the illustrated variant, when the shaped portion 32 is inserted as illustrated, the side openings 13 are selected for fluid delivery and the open end 12 is deselected for fluid delivery. By more proximally positioning the shaped portion 32, distal ones of the openings 13 can be deselected. By way of example, if the shaped portion 32 were positioned half way along the group of four openings 13, only the proximal two of the openings 13 would be selected to convey fluid.

To so vary the position of the shaped portion 32, a set of stylets of varying length may be provided. Alternatively, the rod 31 may be mounted to slide through the connector 33 so that the spacing of the portion 32 from the connector 33 may be varied.

Alternatively the portion 32 may be advanced beyond the open end 12 to open the end 12 to flow.

Figure 8 schematically illustrates a catheter 110 and stylet 130, both parts of an arterial catheter system, in situ in an artery 146. The stylet 130 includes a connector (not shown) akin to the connector 33 to seal the arterial catheter 110 and allow fluid to flow

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up and down the arterial catheter. By way of example, the catheter may be used to deliver medicament, draw a blood sample, or simply to monitor blood pressure. When blood pressure is monitored in this way, a flow of saline may be very slowly delivered to the artery 46 via the catheter 110 to resist clotting within the catheter. Nonetheless build-up in the form of clotting can occur about the catheter tip 112. For this purpose the stylet 130 includes a distinct shaped portion 132 and is configured for that shaped portion to extend beyond the open end 112. The stylet 130 is longer than the catheter 110, long enough (relative to the catheter 110) to so clean the open end of the catheter whilst a portion of the stylet remains external the patient to be manipulated by hand. By periodically withdrawing the stylet 130, the shaped portion 132 is moved to act upon any such build-up causing it to break up and safely move away along the artery before it occludes the catheter 110 or grows to a dangerous size. Optionally, the stylet 130 may be fully withdrawn and replaced by another stylet.

The rearward portion 137 of the shaped formation 132 rearwardly converges to define a lead-in surface to guide the shaped formation 132 into the catheter 110 so that the stylet 130 may be fully retracted from the catheter 110. In this example, the bulbous end formation 132 has a continuous, smoothly curved exterior to minimise build-up on the formation 132.

The described catheter systems may be installed and removed from the patient during a single attendance to the patient, although it is preferred that the catheter remain in place for ongoing use during a lengthy surgery, or even during the patient's entire hospital stay. By way of example, the described arterial catheter 110 and its stylet 130 may be left in place to provide continuous monitoring of arterial blood pressure over a period of days, or if ongoing monitoring is not required the connection arrangement (not shown) external the patient may simply be capped.

The installed components 110, 130 of the disclosed catheter system may advantageously be left in place well beyond their initial installation. By way of example, the catheter may be left in place and then removed during a subsequent attendance to

the patient prior to leaving hospital, or even removed by the patient after leaving the hospital.

The stylet may be produced separately, e.g. to suit existing catheters.

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CLAIMS

1. A catheter system including

a catheter; and

a stylet;

the stylet including an elongate portion and a shaped portion;

the elongate portion being receivable within the catheter;

the elongate portion and the catheter being co-operably configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient;

the shaped portion being positioned to be within the patient and shaped to obstruct flow through the catheter.

2. The system of claim 1 wherein the catheter has an open end positionable within the patient; and

the stylet is advanceable within the catheter to move the shaped portion at least to the open end, when the open end is within the patient, to remove build-up at the open end.

3. The system of claim 1 or 2 further including a needle, receivable within the catheter, for inserting the catheter into the patient.

4. The system of any one of claims 1 to 3 wherein the catheter has one or more side openings positionable within the patient to fluidly connect the void(s) to one or more of the sites within the patient.

5. A method, of establishing fluid communication with one or more sites within a patient, including

inserting into the patient a catheter internally defining a flow path; and

inserting, into the catheter, a stylet;

the stylet including an elongate portion and a shaped portion;

the elongate portion being receivable within the catheter;

the elongate portion and the catheter being co-operably configured such that, when the elongate portion is so received, at least a portion of the elongate portion is spaced from the catheter such that the at least portion and the catheter together define at least one elongate void for conveying fluid along the catheter at least one of to or from one or more sites within a patient; and

the shaped portion being positioned to be within the patient and shaped to obstruct flow through the catheter.

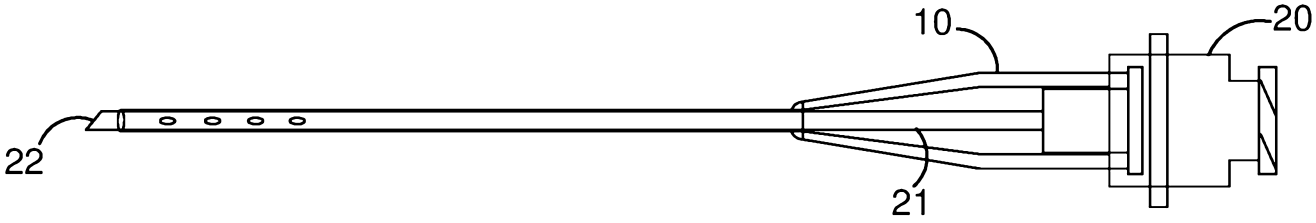

Fig 1

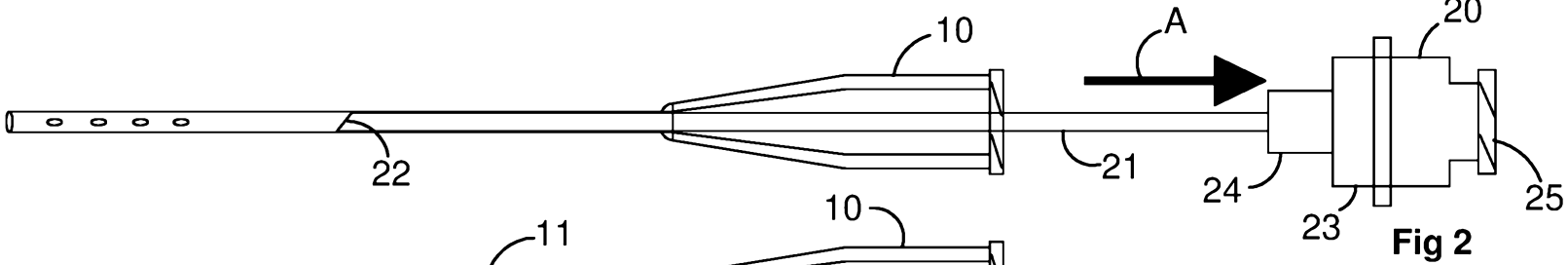

Fig 2

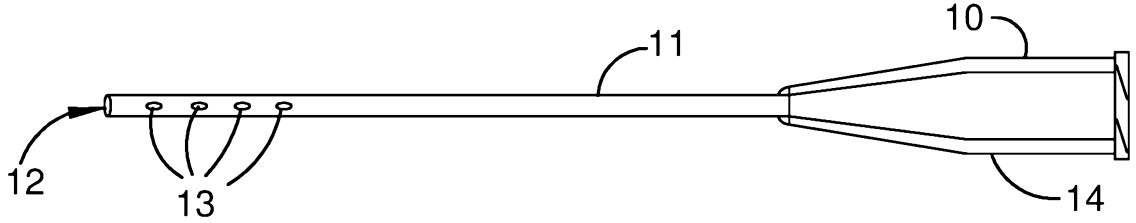

Fig 3

Fig 4

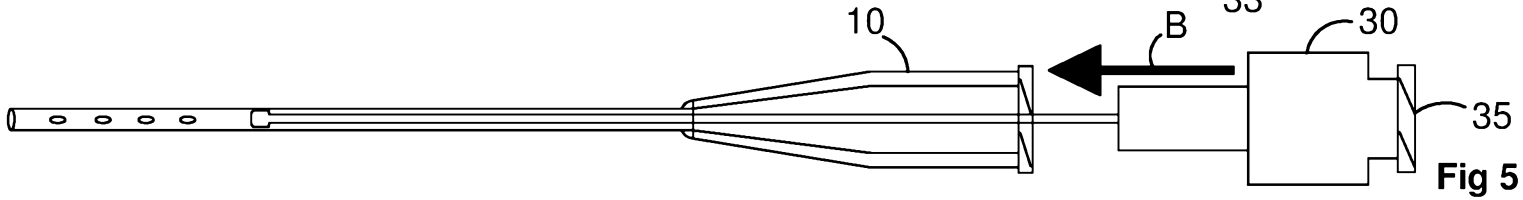

Fig 5

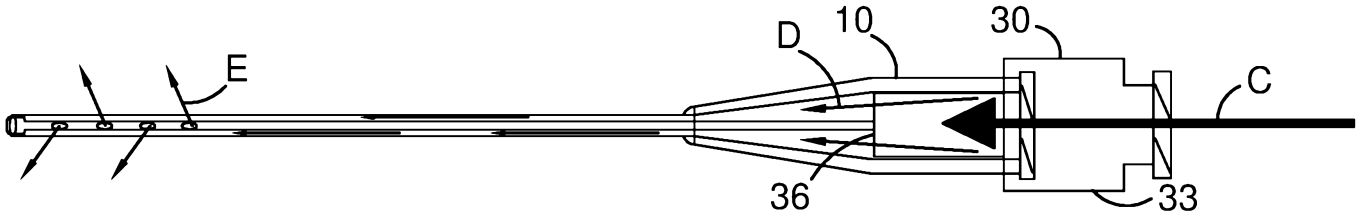

Fig 6

1/2

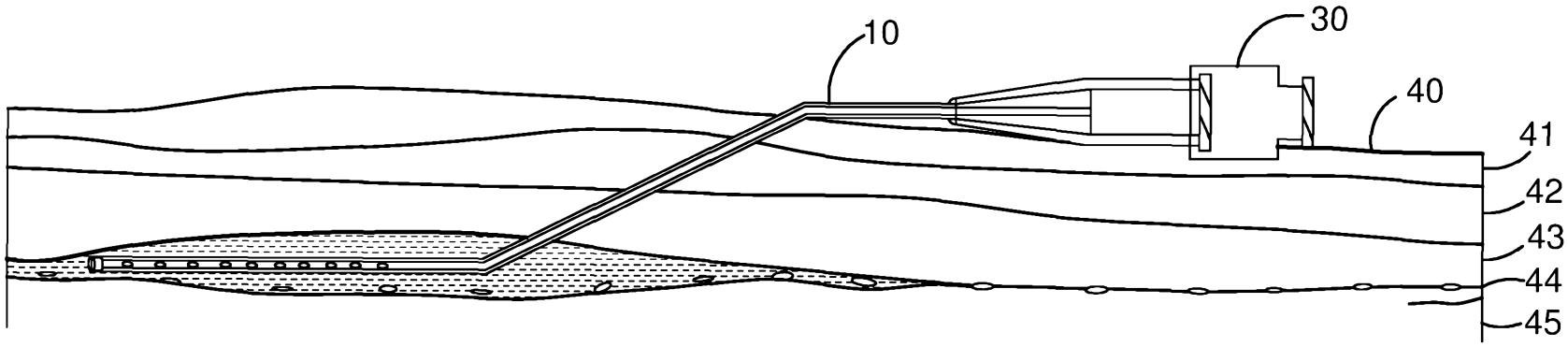

Fig 7

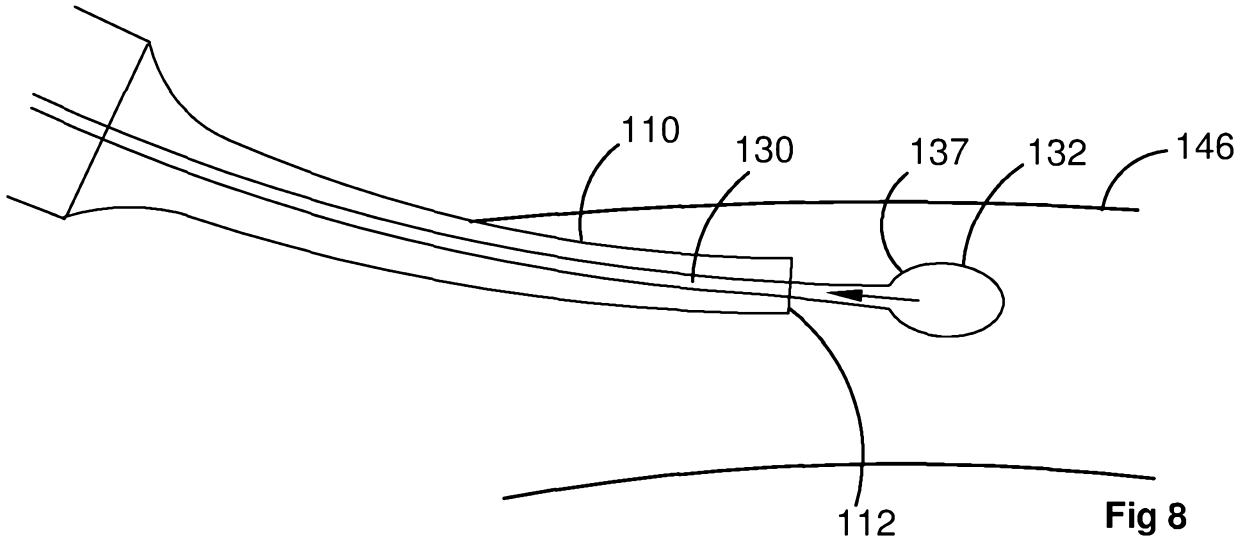

Fig 8

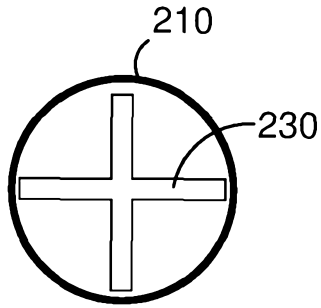

Fig 9