(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 June 2010 (17.06.2010)

PCT

(10) International Publication Number
WO 2010/067062 A1

(51) International Patent Classification:
A61M 25/00 (2006.01)

(21) International Application Number:
PCT/GB2009/002843

(22) International Filing Date:
8 December 2009 (08.12.2009)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
0822357.0 8 December 2008 (08.12.2008) GB

(71) Applicant *(for all designated States except US)*: **IMPERIAL INNOVATIONS LIMITED**; Level 12, Electrical and Electronic Engineering Building, Exhibition Road, London SW7 2AZ (GB).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **COPPOLA, Gianfilippo** [IT/GB]; 145 Holland Road, London W14 8AS (GB).

(74) Agent: **DEHNS**; St. Bride's House, 10 Salisbury Square, London EC4Y 8JD (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: CATHETERS

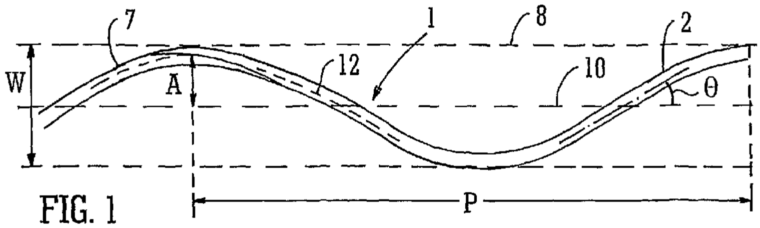

FIG. 1

(57) Abstract: A catheter for insertion in a vessel of the human or animal body, the catheter comprising tubing defining a flow lumen, the tubing having an outer surface portion which extends longitudinally and helically so as to induce swirl flow in a vessel externally of the tubing when in use in the vessel.

WO 2010/067062 A1

CATHETERS

The invention relates to catheters.

Patients suffering from renal disease may be treated by blood dialysis. Haemodialysis involves removing blood from the patient, passing it through a dialyser where toxins and water are removed by membrane diffusion, and then returning the processed blood back to the patient. This treatment requires vascular access and a preferred way of achieving such access is to surgically modify the patient's blood vessels to create an arteriovenous fistula. This involves joining an artery and a vein to form the fistula and then waiting a period of time, typically a small number of months, for the fistula to mature. After maturation has taken place, the fistula is available for dialysis and this is accomplished by inserting two needles through the skin and into the fistula, one for withdrawing blood and the other for returning the dialysed blood to the patient.

The use of a fistula for vascular access is a widely preferred choice for doctors. However the requirement to wait for the fistula to mature means that another vascular access method is needed in the meantime. Further, successful fistula maturation is not possible in some patients and for these patients alternative vascular access methods have to be used. A common form of vascular access involves the use of percutaneous catheter assemblies. A catheter is inserted through the skin and into a major vein, such as the femoral, subclavian or jugular vein. The distal end of the catheter is passed along the vein to a suitable site such as the superior vena cava. The catheter usually is in the form of a single assembly having a suction or aspiration line with an inlet and a return line with an outlet. The assembly is left in the body after its surgical deployment, ready to be used in a haemodialysis session.

A problem with the use of percutaneous catheter assemblies is that they are subject to infection and stenosis problems. One response to the stenosis (blockage of the vessel into which the catheter is inserted) is to remove the catheter assembly and start again. However, at that point the tissue which has formed around the catheter assembly can inhibit removal.

According to the invention there is provided a catheter for insertion in a vessel of the human or animal body, the catheter comprising tubing defining a flow lumen, the tubing having an outer surface portion which extends longitudinally and helically so as to induce swirl flow in a vessel externally of the tubing when in use in the vessel.

When such a catheter is in use in a vessel it can induce or enhance swirling flow in the vessel, externally (shell side) of the tubing, and so inhibit the occurrence of thrombosis. This may be of benefit when the catheter is in place for long periods of time. One use of such a catheter is in a line used for dialysis, for example for end stage renal failure patients in whom it is not feasible to construct arteriovenous fistulae, or for patients awaiting maturation of a fistula. Other illustrations would be in the treatment of patients requiring intravenous drips and patients with temporary renal shutdown.

In certain preferred embodiments, the tubing and the flow lumen defined thereby extend longitudinally and helically. Thus the locus of centroids of the tubing is a line which follows a helical path in the longitudinal direction (the centroid being the centre point of the cross-section of the tubing at any location along its length). This helical path is referred to in this specification as the "helical centreline". By virtue of the tubing extending longitudinally and helically in these preferred embodiments, its outer surface forms the outer surface portion which will induce the desired swirl flow.

The geometry of the helical centreline may be defined in terms of its amplitude and its helix angle. In this specification the amplitude of the helix refers to the extent of displacement from a mean position to a lateral extreme. So, in the case of the tubing having a helical centreline, the amplitude is one half of the full lateral width of the helical centreline.

The helical tubing can be regarded as occupying an imaginary envelope which extends longitudinally and has a width equal to the swept width of the helical tubing. Thus in preferred embodiments, the tubing and the flow lumen defined thereby extend longitudinally and helically and the helical tubing forms an imaginary envelope which extends longitudinally and has a width equal to the swept width of the helical tubing. The envelope may be regarded as having a central longitudinal axis, referred to also as an axis of helical rotation. Where the axis of helical rotation is straight then the envelope occupied by the helical tubing will be generally cylindrical.

Catheter tubing typically has an external diameter smaller than the internal diameter of the vessel into which it is to be inserted. The external diameter of the helical tubing of the present invention is preferably smaller than the internal diameter of the vessel for which it is intended. This ensures that the flow external of the tubing in the vessel is not blocked.

It is desirable that the preferred helical tubing when in a vessel engages with the inner wall of the vessel. In these circumstances the helical tubing effectively forms a helical rib projecting radially inwardly from the vessel wall and tending to promote swirl flow in the region of the vessel wall at least.

The engagement of the helical tubing with the inner wall of the vessel can be achieved by over sizing the helical tubing relative to the inner diameter of the vessel. In other words, when the tubing is *ex vivo* the envelope which it occupies has a width greater than that of the internal diameter of the vessel. Thus, for any given use, a catheter having a helical tubing with an envelope having a diameter greater than the internal diameter of the vessel may be selected. A range of different catheters may be provided for appropriate uses.

By making the tubing from a resilient material, such as plastics, the tubing can adopt the required smaller envelope width *in vivo* as compared to its width *ex vivo*. The resilience of the tubing can ensure the engagement between the tubing and the vessel wall, so that the tubing is centred in the vessel.

It is generally desirable that the external surface area of the tubing should not be too large as a larger external surface area creates more opportunity for thrombosis to develop. Tubing of larger cross sectional areas will also tend to reduce the cross section of the vessel available for flow externally of the tubing, and so may lead to an undesirable level of pressure drop caused by the presence of the catheter. In certain preferred embodiments of helical tubing which occupies an imaginary envelope which extends longitudinally and has a width equal to the swept width of the helical tubing, the external diameter of the tubing (as measured in a direction radially of the envelope) is less than or equal to half of the width of the envelope.

For a given width of the envelope, a smaller external diameter of the helical tubing means that it will have a greater helical amplitude. In certain preferred embodiments, the amplitude of the helical centreline of the tubing is greater than one quarter of the width of the envelope defined by the swept width of the tubing. This means, in most cases, and in the case of a tubing and a vessel with circular cross-sections, that there is a "line of sight" along the centre of the vessel, unimpeded by the tubing. In other words the helical tubing rotates around a "virtual" core. This is like the configuration of a corkscrew. It is desirable for there to be a core where flow in the lumen of the vessel can take place externally of the tubing. This reduces the extent to which the tubing blocks the flow externally thereof and so reduces the amount of any pressure drop along the vessel caused by the presence of the catheter. Flow local to the vessel inner wall will be influenced by the helical configuration of the tubing, tending to swirl and thus inhibiting thrombosis.

Since in certain instances it is desired that the helical tubing before the placement in a vessel has a swept width which is greater than the internal diameter of the vessel for which it is intended, once the catheter is installed the amplitude will be reduced. In certain preferred embodiments, therefore, the amplitude is greater than 0.3 of the width swept by the helical tubing (the width of the envelope) when *ex vivo*. Thus, the ratio of the amplitude of the helical tubing to the width of the envelope *ex vivo* is greater than 0.3. In other preferred embodiments, the ratio may be greater than 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, 1, 1.1, 1.2, 1.3, 1.4, 1.5, 1.6, 1.7, 1.8, 1.9, 2.0, 2.1, 2.2, 2.3, 2.4, 2.5, 2.6, 2.7, 2.8, 2.9 or 3.0. For the larger ratios flow in the lumen of the vessel at its centre will tend not to be significantly influenced by the helical tubing at the radial periphery of the vessel lumen. The flow will be most influenced, however, in the important region near to the inner wall of the vessel where it is expected that the promotion of swirl flow will reduce any tendency to flow stagnation.

It is preferred that the helix angle should not be too large as this may create an obstruction to flow near the vessel inner wall and have the opposite of the desired effect. The helix angle is preferably less than or equal to 65° (measured with respect to the axis of helical rotation), more preferably less than or equal to 55°, 45°, 35°, 25°, 20°, 15°, 10° or 5°. Higher helix angles correspond to smaller helix pitches. In certain embodiments the helix angle is less than 20° or less than 15°.

If the swept width of the helical tubing *ex vivo* is greater than its swept width when *in vivo*, as discussed above, then there will be a reduction in the helix angle when the tubing is placed in a vessel as the tubing tends to be straightened out when it is laterally constrained. Thus the helix angle *ex vivo* will be chosen to be slightly larger than the requirement when *in vivo*.

In those embodiments in which helical tubing forms an imaginary envelope which extends longitudinally and has a width equal to the swept width of the helical tubing, the helical tubing may have a distal end portion which is positioned radially inwardly of the imaginary envelope. As discussed it is desirable that in use the helical tubing engages with the inner wall of the vessel. Then, if the distal end portion is positioned radially inwardly of the imaginary envelope, it will tend to be positioned at a radial spacing from the inner wall. This has the advantage of avoiding problems with clogging with the end region of the tubing, where it typically has an opening communicating the flow lumen of the tubing with the vessel. If the distal end portion of the tubing does not lie on the vessel wall, there is a reduced risk of flow stagnation around the opening or of clotting or tissue in-growth in the opening. This may lead to an increased useful life of the catheter. The radial spacing of the distal end portion of the catheter from the inner wall of the vessel may also facilitate removal of the catheter when required, as this end portion will normally not be adhered to the vessel inner surface by tissue, clotting or other material.

According to some preferred embodiments, the helical amplitude of the tubing decreases towards the distal end thereof. When the helical tubing is in use and engages with the inner wall of the vessel, if the helical amplitude decreases towards the distal end, that end will tend to be positioned at a radial spacing from the inner wall. If the helical amplitude decreases towards zero, the end of the tubing will tend to adopt a generally central position in the vessel. Thus a reducing helical amplitude is one way of achieving a position of the catheter distal end portion at a radially inward spacing from the vessel inner wall.

There can be a problem with catheters in that when it is time to remove them they may have adhered to the vessel wall and become very difficult to pull out. According to preferred embodiments of the present invention, this problem can be mitigated. Preferably, the side portion of the tubing which when inserted in the vessel faces radially outwardly with respect to the vessel is fenestrated or porous. Such holes or pores can provide a flow through the radially outer part of the tubing and this may inhibit the development of an adherent coating on this side portion which would otherwise cause the tubing to stick to the vessel wall. Thus, such a catheter is easier to remove. Preferably, the tubing is arranged so that a flow lumen feeding flow to the vessel, rather than a flow lumen for aspiration, has the radially outwardly facing portion which is fenestrated or porous. In these embodiments, the flow will be outward, from the flow lumen of the tubing to the vessel, via the pores or holes, and so benefit the aim of reducing a tendency for the tubing to stick to the vessel wall.

The tubing may be made from non-porous material with holes formed in the radially outwardly facing side portion. It may be made from a combination of a porous material and a non-porous material. In certain preferred embodiments, the tubing is made from a porous material and has a non-porous layer on a side which when in use in the vessel faces radially inwardly with respect to the vessel.

It will be appreciated that because the preferred tubing is formed to extend longitudinally and helically, it will be known in advance of insertion in a vessel which portions will face radially outwardly with respect to the vessel, and which portions will face radially inwardly.

The tubing may have a single flow lumen, for example if it is to be used as an intravenous drip, or it may define a plurality of flow lumens. Typically, catheters used for dialysis treatment have two flow lumens, one for suction from the vessel and one for return to the vessel. In certain preferred embodiments of the invention, the tubing has a plurality of flow lumens, for example two flow lumens. Preferably each flow lumen has an opening for communication with the vessel and the openings of the respective lumens are axially separated. At least in the case of a catheter used for dialysis, axial separation is generally desirable to avoid blood which has been dialysed being immediately returned to the dialyser unit.

Where a plurality of flow lumens is defined by the tubing, various constructions may be used. Plural flow lumens may be defined by respective tubes. Such tubes may be joined together by a longitudinally extending seam and/or they may be contained in a sheath. In one example, a pair of flow lumens of generally circular cross-section are arranged side by side, whereby the tubing has a figure of "8" cross-sectional shape. This arrangement may be formed by a pair of tubes joined along a longitudinally extending seam, or by two tubes held together in a sheath.

An alternative construction may involve a pair of generally "D" shaped flow lumens which, in cross section, are joined along the straight portions of the "D". Thus, the tubing may have a generally circular cross-sectional shape, with the circle being divided into two generally semi-circular flow lumens.

In the embodiments in which the tubing has plural flow lumens, the respective flow lumens may have distal end parts which extend bundled together. Thus the distal end parts do not separate or diverge from each other. The distal end parts may form the distal end portion of the helical tubing which is positioned radially inwardly of the imaginary envelope. For example, the distal end parts of the respective flow lumens may extend bundled together as the helical amplitude of the tubing decreases towards the distal end thereof.

The flow lumens formed by respective tubes or the "D" shaped flow lumens discussed above are examples of how the flow lumens may be bundled together.

As discussed above, in the preferred embodiments in which the tubing and the flow lumen defined thereby extend longitudinally and helically, the tubing has a helical centreline. In the case of tubing consisting of a single flow lumen, then the helical centreline of the tubing will correspond to the helical centreline of the flow lumen. In the case of tubing having plural flow lumens, then the helical centreline will normally follow a different path from the helical centrelines of the respective flow lumens (unless the flow lumens are formed co-axially, i.e. with a central inner tube concentric with an outer tube). The path of the helical centreline will be determined by the locus of the centroids of the tubing as a whole, rather than by the centroids of individual flow lumens.

The feature of the outer surface portion of the tubing extending longitudinally and helically so as to induce swirl flow in a vessel may be achieved by the helical outer surface portion protruding radially outwardly from circumferentially adjacent portions of the tubing. For example the tubing may comprise one or more helically extending ribs. The tubing itself may for example be cylindrical (rather than helical) with at least one external helical rib. However this arrangement leads to a larger external surface area of the tubing, with a possible increased risk of thrombosis. It is therefore preferred that the tubing as a whole (and the flow lumen defined internally thereof) extends longitudinally and helically, i.e. so as to form helical tubing.

The catheter may comprise conventional non-helical tubing in addition to the tubing which induces swirl flow. It may for example have helical tubing at a downstream location and non-helical tubing upstream thereof. For example where the tubing is expected to pass through a patient's skin it may be non-helical, whilst where it is expected to lie in a vessel then it may be helical.

The tubing may be made from material typically used to manufacture the tubing of catheters, for example plastics or metals. Helical tubing may be manufactured by winding the tubing around a mandrel. In the case of tubing made of plastics, the tubing may be heat set in the helical condition when on a mandrel and then the mandrel removed. It may be desirable to use a member internally of the tubing so as to prevent the flow lumen from being flattened when the tubing is deformed into the helical configuration.

A preferred embodiment of the catheter may be inserted in a patient as follows. A vessel such as a blood vessel is punctured by a needle, a guide wire is inserted into the vessel via the bore of the needle, the needle is withdrawn, and the helical tubing is placed over the guide wire and advanced so that its front end extends into the vessel and its rear end is external of the patient. After the catheter has been introduced into the vessel in this way the guide wire is withdrawn leaving the catheter in place. In the case of helical tubing, it will tend to be straightened out by the guide wire, with a reduction in helical amplitude and an increase in pitch, but the tubing material will be such that it returns to a helical shape after the guide wire is withdrawn. The use of conventional biocompatible plastics material with resilient elastic properties can achieve the desired effect.

Other methods of deployment of the catheter may of course be used.

Certain preferred embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, in which:

Figure 1 is a side view of helical tubing forming part of a catheter.

Figure 2 is a cross-section of the helical tubing of Figure 1, to an enlarged scale;

Figure 3 shows the downstream end of a catheter in a vessel;

Figure 4 shows an end elevation of the downstream end of the catheter of Figure 3, viewed in the direction of arrow IV of Figure 3;

Figure 5 is an enlarged view of the tip of the catheter of Figure 3;

Figure 6 is a cross-section on the lines VI - VI of Figure 3; and

Figure 7 is a cross-section similar to that of Figure 2 but showing helical tubing of another embodiment in a vessel.

The helical tubing 2 shown in Figures 1 and 2 has a pair of tubes 4 and 5, one located inside the other. In this embodiment an inner tube 4 is located inside an outer tube 5. The outer surface 7 of the tubing is therefore formed by the outer surface of the outer tube 5.

The tubing 2 is coiled into a helix of constant amplitude A (as measured from mean to extreme), constant pitch P, constant helix angle θ and swept width W. The tubing 2 is contained in an imaginary envelope 8 which extends longitudinally and has a width equal to the swept width W of the tubing 2. The envelope 8 may be regarded as having a central longitudinal axis 10, which may also be referred to as an axis of helical rotation. The illustrated helical tubing has a straight longitudinal axis 10, but it will be appreciated that in alternative designs the longitudinal axis may be curved. The helical tubing has a centreline 12 which follows a helical path about the central longitudinal axis 10.

Figures 3, 4 and 6 show the catheter 1 in a blood vessel 14. The blood vessel has an inner wall 18 which defines the vessel flow lumen 19. The inner wall 18 is engaged by an engagement portion 20 of the outer surface 7 of the tubing 2 along a helical engagement region. The outer surface engagement portion 20 is that part of the surface of the tubing which faces radially outwardly with respect to the vessel. Alternatively, it can be considered as facing radially outwardly with respect to the central longitudinal axis 10, i.e. the axis of helical rotation. In effect, the tubing forms a helical rib following the inside surface of the vessel 14 so as to create rotating flow in the region of the vessel inner wall 18. The direction of blood flow is shown by an arrow 24.

Figure 6 is a cross-sectional view of the catheter in a vessel. The inner tube 4 can be seen inside the outer tube 5 where the section is taken, and the outer surface 7 of the tubing 2 is then seen in elevation. The engagement portion 20 of the outer surface 7 of the tubing 2 engages the vessel inner wall 18 along the helical engagement region.

The tube 4 of the tubing 2 is intended as an aspirating tube, for aspirating blood from the patient and passing it to a dialyser unit (not shown). The tube 4 has an inlet opening 26. Tube 5 is intended as a return tube, to return dialysed blood to the vessel and has an outlet opening 28. The outlet opening 28 is downstream of the inlet opening 26 in order to avoid or minimise recirculation of dialysed blood back to the dialyser unit. This arrangement is shown in Figure 3 and further details are shown in the enlarged view of Figure 5. Inner tube 4 passes through an opening 11 in the wall of outer tube 5 in a sealed manner.

In alternative embodiments, the outer tube 5 could be the aspirating tube and the inner tube 4 the return tube, and in these arrangements the inner tube would preferably extend so that its opening communicating to the vessel lumen 19 is downstream of the opening of the outer tube with respect to the flow in the vessel. Alternative tubing configurations are of course possible within the scope of the invention. For example the aspirating tube and the return tube may be two tubes placed side by side, so that the cross-section is generally that of the number "8". Another example may have tubing of a generally circular cross-sectional shape, with the circle being partitioned into two generally "D" shaped flow passages. More than two flow lumens may be provided in certain embodiments. Tubing which comprises only a single flow lumen may be provided as part of a catheter for uses other than haemodialysis.

The helical tubing has a downstream end portion 3 where its helical amplitude A reduces. This is shown in the right hand part of Figure 3 and in Figure 4. The amplitude A1 identified at the left of Figure 3 is equal to the full amplitude A of the tubing in the vessel. Amplitude A2, which is closer to the distal tip, is smaller than amplitude A. This ensures that the inlet 26 and outlet 28 are radially inwardly spaced from the inner wall 18 of the vessel. This arrangement advantageously avoids these openings becoming blocked by clots or just through contact with the inner wall. Thus the helical nature of the tubing 2 enables it to adopt a predetermined position in the vessel, in the sense that it engages the vessel inner wall along a helical engagement region, whilst permitting the inlet and outlet openings to be radially inwardly spaced from the wall.

The engagement portion 20 of the outer surface 7 of the tubing 2 may be fenestrated or porous so that a flow may pass through the tubing wall. By the wall being fenestrated or porous in this region, where it engages with the inner wall 18 of the vessel, the flow can reduce a tendency for thrombosis at the contact area.

In Figure 7 an embodiment of helical tubing 2 is shown where the outer tube 5 is entirely formed of porous material which is then provided with a non-porous coating 32 over part of its periphery, thereby creating a porous engagement portion 20 at its radially outer region. In this embodiment it is the tube functioning as the return tube which is in the radially outermost position, although the aspiration tube may alternatively be in the radially outermost position. Of course, in embodiments where there is no fenestrated or porous region, it is not important whether one lumen or the other is in a radially outermost position compared to the other.

CLAIMS

1. A catheter for insertion in a vessel of the human or animal body, the catheter comprising tubing defining a flow lumen, the tubing having an outer surface portion which extends longitudinally and helically so as to induce swirl flow in a vessel externally of the tubing when in use in the vessel.

2. A catheter as claimed in claim 1, wherein the tubing and the flow lumen defined thereby extend longitudinally and helically.

3. A catheter as claimed in claim 2, wherein the helical tubing occupies an imaginary envelope which extends longitudinally and has a width equal to the swept width of the helical tubing, and wherein the helical tubing has a distal end portion which is positioned radially inwardly of the imaginary envelope.

4. A catheter as claimed in claim 2 or 3, wherein the helical amplitude of the tubing decreases towards the distal end thereof.

5. A catheter as claimed in any preceding claim, wherein the tubing has a plurality of flow lumens.

6. A catheter as claimed in claim 5, wherein the respective flow lumens have distal end parts which extend bundled together.

7. A catheter as claimed in any preceding claim, wherein a side portion of the tubing which when inserted in the vessel faces radially outwardly with respect to the vessel is fenestrated or porous.

8. A catheter as claimed in claim 7, wherein the tubing is made from a porous material and has a non-porous layer on a side which when in use in the vessel faces radially inwardly with respect to the vessel.

9. A catheter as claimed in claim 1, wherein the helical outer surface portion protrudes radially outwardly from circumferentially adjacent portions of the tubing.

10. A catheter as claimed in any preceding claim, wherein the helix angle of the outer surface portion is less than 65°.

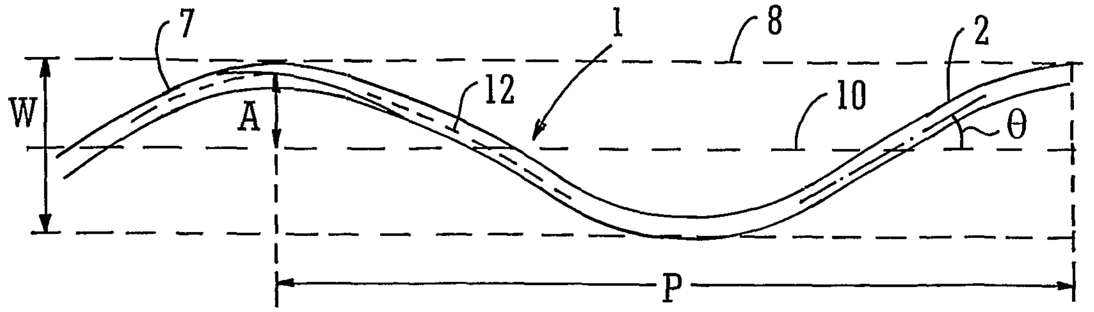

FIG. 1

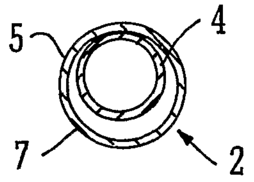

FIG. 2

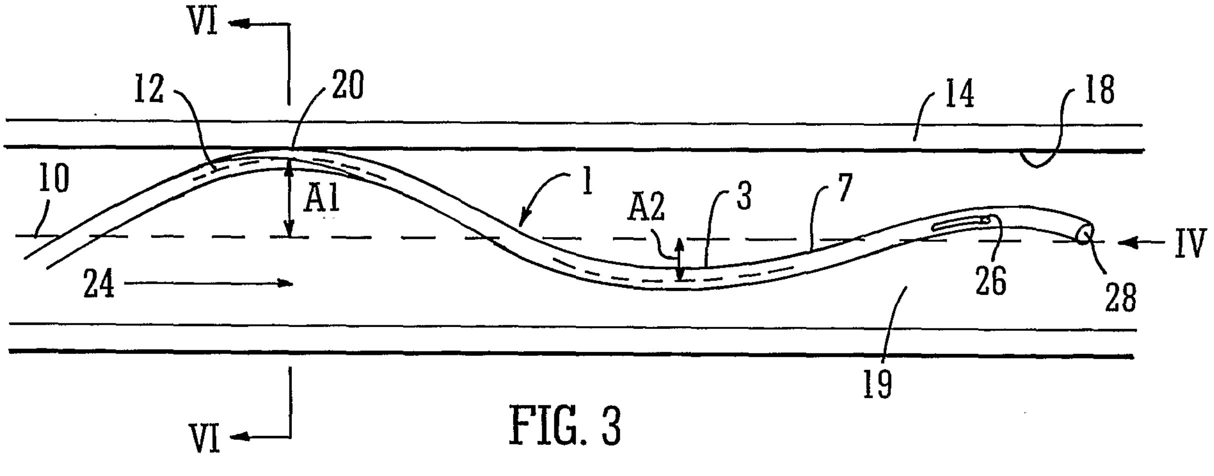

FIG. 3

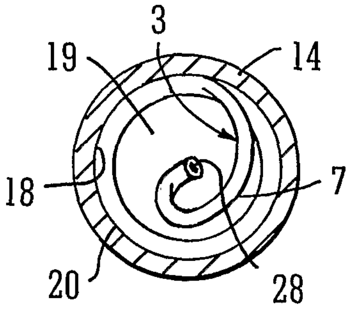

FIG. 4

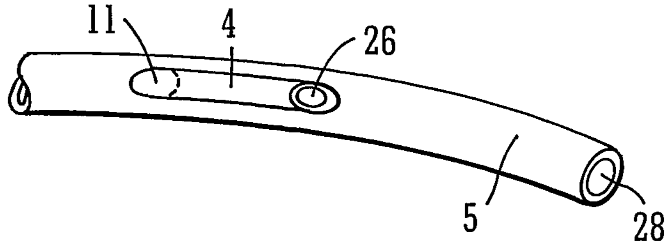

FIG. 5

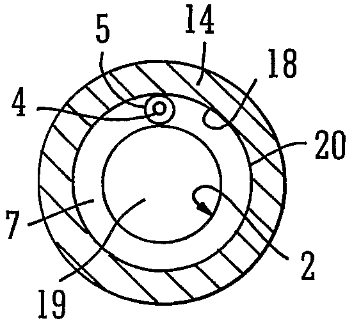

FIG. 6

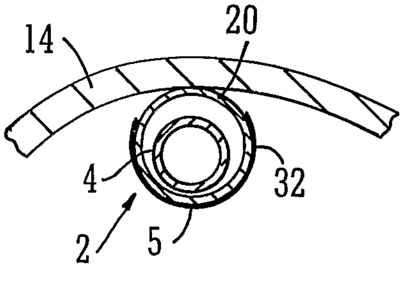

FIG. 7

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2009/002843

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/00

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

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, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/13295 A1 (MICRO THERAPEUTICS INC [US]) 9 May 1996 (1996-05-09) page 14, line 22 - page 15, line 15; figure 8	1-3,7-9
X	US 5 873 865 A (HORZEWSKI MICHAEL [US] ET AL) 23 February 1999 (1999-02-23) abstract page 6, line 62 - page 7, line 27; figure 1	1-7,9-10
X	EP 0 386 408 A1 (BRAUN MELSUNGEN AG [DE]) 12 September 1990 (1990-09-12) column 5, line 58 - column 6, line 49; figure 7	1-7,9-10
X	US 2003/144623 A1 (HEATH KEVIN R [US] ET AL) 31 July 2003 (2003-07-31) paragraph [0035]; figures 6a,6b	1-7,9-10

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search 9 March 2010	Date of mailing of the international search report 18/03/2010
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Kousouretas, Ioannis

5

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/GB2009/002843

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9613295 A1	09-05-1996	CA 2160847 A1 EP 0787018 A1 JP 10509350 T US 5554114 A	21-04-1996 06-08-1997 14-09-1998 10-09-1996
US 5873865 A	23-02-1999	NONE	
EP 0386408 A1	12-09-1990	DE 3907618 A1	20-09-1990
US 2003144623 A1	31-07-2003	WO 03063941 A1	07-08-2003