Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).
The use of the tear away sheath is also potentially problematic. The tear away sheath has lines of weakness to separate it as it is pulled apart by the pull弱 away sheath. The tear away sheath is also potentially problematic. The tear away sheath has lines of weakness to separate it as it is pulled apart by the pull weak away sheath.
as it is being pulled apart and can cause infection. Moreover, pulling the sheath laterally can enlarge the incision, thereby increasing the difficulty of closing the incision at the end of the procedure. Also, since the sheath is pulled in the proximal direction for removal, it could pull the catheter proximally as well, thereby pulling it away from the desired site, and requiring repositioning. The edges of the tear away can also lacerate the surgeon’s glove and finger. Over dilation by the sheath can cause blood leakage.

[0009] An additional potential risk with utilizing tear away sheaths is that air embolism can occur. During the time the surgeon withdraws the dilator from the sheath and inserts the catheter, a passageway through the sheath to the vessel is open. If the patient inhales during this catheter exchange, an air bubble can enter the vascular system and obstruct the vessel, potentially causing stroke or even death.

[0010] It would therefore be advantageous if a dialysis catheter insertion method could be provided which reduces some of the foregoing procedural steps, thereby decreasing the complexity of the procedure and decreasing the hospital and surgeon costs. It would also be advantageous if such dialysis catheter insertion method could be provided which would be less traumatic and avoid the foregoing problems associated with the use of a tear-away sheath, such as increased risk of air embolism, trauma to the vessel wall, incision enlargement and dislodgement of the catheter.

[0011] Another area of dialysis catheter insertion, which needs improvement, is guiding the catheter to the target site. Dialysis catheters are composed of flexible tubing to minimize damage to the vessel wall during insertion and use. This flexibility, however, oftentimes results in kinking of the catheter since the catheter must navigate curves to reach the target vessel. This kinking can adversely affect blood flow. Also, the catheter needs to have some degree of stiffness to enable directing the catheter around the curves of the vessels. The stiffness, however provides its own risks since if the catheter is not properly directed, the catheter can inadvertently be forced against the vessel wall, thereby puncturing or damaging the vessel. Several different approaches have been discussed in the prior art to increase stiffness of catheters such as providing a distal tip of stiffer material to guide the catheter as in U.S. Patent No. 5,957,893, using materials of different durometers in various portions of the catheter (U.S. Patent No. 5,348,536), placing an additional concentration of material in the tip as in U.S. Patent No. 4,583,968, or providing reinforcing strips, obturators or tubes within the catheter body to increase the rigidity (e.g. U.S. Patent Nos. 4,619,643, 4,950,259, 5,221,255, 5,221,256, and 5,246,430). The need however exists to improve the balance between flexibility and stiffness. Thus it would be advantageous to provide a catheter with sufficient flexibility to accommodate anatomical curves of the patient while still having sufficient stiffness to enable guiding the flexible catheter tubingatraumatically through the length of the vessels.

[0012] In navigating vessels to access the target site, such as the right atrium, it is desirable to provide the smallest catheter profile, i.e. the smallest outer diameter catheter body. This profile facilitates insertion through smaller vessels as it reduces the likelihood of the catheter engaging the wall of the vessel and reduces trauma to the vessel by minimizing frictional contact with the vessel wall. However, the desire for smaller diameter catheters must be balanced against the need for providing sufficient sized lumens to enable proper blood flow. If the lumens are too small, sufficient blood flow may not be able to be maintained and the blood can be damaged during transport. Also, a sufficient relationship must be maintained between the size of the lumens and the overall diameter of the catheter to maintain the structural integrity of the catheter.

[0013] Numerous attempts have been made in the prior art to optimize the multi-lumen configuration. In some approaches, such as disclosed in U.S. Patent Nos. 4,568,329 and 5,053,023, inflow and outflow lumen are provided side by side in D-shaped form. In other approaches, such as those disclosed in U.S. Patent Nos. 4,493,696, 5,167,623 and 5,380,276 the inflow and outflow tubes are placed in concentric relation. Other examples of different lumen configurations are disclosed in U.S. Patent Nos. 5,221,256, 5,364,344, and 5,451,206. The lumen configuration must accommodate two competing factors: keeping the catheter as small as possible to facilitate insertion while keeping the lumens as large as possible for blood flow. This balance must be achieved while maintaining the structural integrity of the catheter. It would therefore be advantageous to provide a catheter which reaches an optimum compromise between these two competing factors.

[0014] Another important feature of dialysis catheters is the suction openings to withdraw blood. Keeping the suction openings clear of thrombolytic material and away from the vessel wall is clearly essential to dialysis function since an adequate supply of blood must be removed from the patient to be dialyzed. However, a problem with prior dialysis catheters is that during blood withdrawal, as suction is being applied through the catheter openings and lumen, the suction can cause the catheter to be forced against the side wall of the vessel, known as "side port occlusion", which can block the opening and adversely affect the function of the catheter by enabling only intermittent suction. In fact, the opening can become completely blocked, thereby preventing necessary intake of blood, i.e. venous flow. Fibrin sheath growth around the outside of the catheter can occur since dialysis catheters are oftentimes implanted for several months or even years. This fibrin growth, caused by the body’s attempt to reject the catheter as a foreign body, could result in blocking of the suction holes.

[0015] The need therefore exists for an improved dialysis catheter which facilitates the surgical dialysis procedure. Such catheter would advantageously reduce the
The intake lumens may each terminate distally to the return lumen via the connector member. A connector member may be positioned over the connector member and may have a lumen formed therethrough to provide fluid communication with the return lumen, and the venous extension tube may be provided centrally of the catheter and at least three intake lumen catheters may transition to a substantially circular cross-section at the flared portion. A proximal flared portion of the catheter may include a stiffening insert embedded in a wall of the catheter at the distal portion. A proximal portion of the stiffening member may have a series of threads for mounting the stiffening member to the catheter.

**SUMMARY**

According to the present invention there is provided a catheter for delivering and withdrawing blood from a patient's body, the catheter comprising a catheter body having an outer wall, a distal portion, a return lumen extending from a proximal portion of the catheter body to the distal portion to allow blood passage therethrough, a longitudinally extending intake lumen independent of the return lumen, and means for enabling fluid flow to the intake lumen to be cut off, wherein the return lumen is provided centrally of the catheter and at least three intake lumens are radially displaced with respect to the central return lumen, and wherein the means for enabling fluid flow to the intake lumen to be cut off enables substantial simultaneous cut off of fluid flow to the at least three intake lumens.

The means for enabling substantial simultaneous cut off of fluid flow to the at least three longitudinally extending lumens may comprise at least three arterial extension tubes each having a lumen, each of the extension tube lumens communicating with one of the intake lumens, and a sleeve retaining a least a portion of the arterial extension tubes, the sleeve dimensioned to receive a clamping member, wherein clamping of the clamping member closes each of the lumens of the arterial extension tube.

Each of the intake extension tubes may be inserted into the respective intake lumen of the catheter body. A connector insert may be interposed between at least one of the intake extension tubes and the respective intake lumen.

The intake extension tubes may have a funneled proximal region to facilitate wire insertion. An independent venous extension tube may be provided communicating with the return lumen.

A connector member may be positioned within the return lumen, and the venous extension tube may be positioned over the connector member and may have a lumen formed therethrough to provide fluid communication to the return lumen via the connector member.

The intake lumens may each terminate distally in a longitudinally directed opening. The intake lumens may be disposed in a spoke-like fashion substantially equidistant from the central return lumen. The catheter body may include a first portion having a first diameter, the distal portion of the catheter body having a second diameter smaller than the first diameter and a transition region which tapers toward the distal portion.

At least a portion of the wall thickness of the catheter in the distal portion may taper toward a distal most end, the cross-sectional area of the central lumen remaining substantially constant throughout its length in the distal portion.

The catheter may have a proximal flared portion and each of the intake lumens may transition to a substantially circular cross-section at the flared portion. The distal portion of the catheter may include a stiffening insert embedded in a wall of the catheter at the distal portion.

A stiffening member may be removably positionable within the catheter to temporarily increase stiffness of the catheter to facilitate insertion.

A proximal portion of the stiffening member may have a series of threads for mounting the stiffening member to the catheter.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Preferred embodiment(s) of the present disclosure are described herein with reference to the drawings wherein:

Figure 1 is a plan view of a first embodiment of the multi-lumen catheter of the present invention being inserted through the right internal jugular vein and superior vena cava into the right atrium of a patient's body;

Figure 2 is a plan view illustrating the multi-lumen catheter of Figure 1 being inserted through the left internal jugular vein and superior vena cava into the right atrium;

Figure 3 is an isometric view of the first embodiment of the multi-lumen catheter of the present invention and showing the direction of insertion of the stiffening rod;

Figure 4A is a side view of a first embodiment of a stiffening rod of the present invention insertable through the catheter of Figure 3 to facilitate catheter insertion;

Figure 4B is a side view of an alternate embodiment of the stiffening rod of the present invention having a series of mounting threads at its distal end;

Figure 5 is a perspective view of the distal portion of the multi-lumen catheter of Fig. 3 and showing a guidewire extending through the central lumen;

Figure 6A is a longitudinal cross-sectional view taken along lines 6A-6A of Fig. 5;
Figure 6B is a longitudinal cross-sectional view similar to Figure 6A except showing an alternate embodiment of the catheter having internal threads for securing the stiffening rod of Figure 4B;

Figure 7 is a transverse cross sectional view taken along lines 7-7 of Figure 6A;

Figure 8 is a transverse cross sectional view taken along lines 8-8 of Figure 6A:

Figure 9A is a transverse cross-sectional view similar to Figure 8 except showing a second alternate embodiment of the lumen configuration of the catheter of the present invention;

Figure 9B is a transverse cross-sectional view similar to Figure 8 except showing a third embodiment of the lumen configuration of the catheter of the present invention;

Figure 9C is a transverse cross-sectional view similar to Figure 8 except showing a fourth embodiment of the lumen configuration of the catheter of the present invention;

Figure 10 is a transverse cross-sectional view similar to Figure 8 except showing a fifth embodiment of the lumen configuration of the catheter of the present invention;

Figure 11 is a longitudinal cross sectional view of the distal end portion of the catheter of Figure 3 illustrating the stiffening rod of Figure 4A being inserted through the central lumen of the catheter;

Figure 12 is a longitudinal cross sectional view similar to Figure 11 except showing the stiffening rod fully positioned within the central lumen, in abutment with the stop in the distal tip;

Figures 13-15 illustrate an alternate embodiment of the distal tip of the catheter of the present invention and the method steps for forming the tip wherein:

Figures 13A and 13B are perspective and cross-sectional views, respectively, of the tip before formation shown receiving a stiffening insert;

Figures 14A and 14B are perspective and cross-sectional views, respectively, of the tip once the stiffening inserted has been placed therein;

Figures 15A and 15B are perspective and cross-sectional views, respectively, of the distal tip formed into a bullet nose configuration and showing side holes formed therein;

Figure 16A is a perspective view of a distal portion of another alternate embodiment of the multi-lumen catheter of the present invention having a series of spacer wires and showing a guidewire extending therethrough;

Figure 16B is a longitudinal cross-sectional view of the distal portion catheter of FIG. 16A showing the spacer wires in the extended position;

Figure 16C is a longitudinal cross-sectional view similar to FIG. 16A except showing the profile of the spacing wires and catheter body reduced as the stiffening rod of Figure 4A is inserted into the central lumen over the guidewire to stretch the catheter during insertion;

Figure 17A is a perspective view of a distal portion of yet another alternate embodiment of the catheter having a series of integral spacer ribs;

Figure 17B is a longitudinal cross-sectional view of the distal portion of catheter of FIG. 17 showing the spacer ribs in the extended position;

Figure 17C is a longitudinal cross-sectional view similar to FIG. 17A except showing the profile of the spacer ribs and catheter body reduced as the stiffening rod of Figure 4A is inserted into the central lumen to stretch the catheter during insertion;

Figure 18 is a perspective view of a distal portion of another alternate embodiment of the multi-lumen catheter of the present invention having a tapered tip;

Figure 19 is a longitudinal cross-sectional view of the distal portion of the catheter of Figure 18 showing the stiffening rod positioned through the central lumen of the catheter over the guidewire;

Figure 20 is a perspective view of a distal portion of yet another alternate embodiment of multi-lumen catheter of the present invention;

Figure 21A is a perspective view of a first embodiment of a trocar of the present invention having a barbed proximal end for attachment to the catheter for creating a subcutaneous tissue tunnel and for pulling the catheter through the tissue tunnel;

Figure 21B is a perspective exploded view of an alternate embodiment of the trocar of Figure 21A having a removable handle;

Figure 21C is a close up view of the connecting structure of the trocar of FIG. 21B;

Figure 21D is a close up view of an alternate embodiment of the trocar having a threaded connecting structure;

Figure 21E is a perspective view of the trocar of FIG. 21B being inserted through a subcutaneous tissue tunnel;

Figure 21F is a transverse cross-sectional view taken along lines 4-4 of FIG. 21E showing the latch for releasably connecting the trocar of FIG. 21B to the handle;

Figure 21G is a cross-sectional view showing the threaded connection of the trocar of FIG. 21D to the handle;

Figure 21H is a perspective view of another alternate embodiment of the trocar having a series of threads distal of the barbed fitting;

Figure 22 illustrates an alternate embodiment of the trocar of the present invention having a lumen for receiving a guidewire;

Figure 23 illustrates the trocar of Figure 22 being withdrawn after a subcutaneous tissue tunnel has been created;

Figure 24A is a bottom view of another alternate embodiment of the trocar of the present invention having a lumen for receiving a guidewire;

Figure 24B is a longitudinal cross-sectional view of
the distal end portion of the trocar of Figure 24A; Figures 25-28 illustrate the surgical method steps for inserting the multi-lumen catheter of Figure 3 through the right internal jugular vein and superior vena cava into the right atrium wherein: Figure 25 shows the introducer needle being inserted through the right jugular vein and the guidewire being inserted through the right jugular vein, through the superior vena cava and into the right atrium; Figure 26 illustrates the needle introducer removed leaving the guidewire in place in the right internal jugular vein, superior vena cava and right atrium; Figure 27 illustrates the trocar of Figure 22 being inserted through a first incision site and exiting a second incision site to create a subcutaneous tissue tunnel adjacent the incision site for the introducer needle; Figure 28A illustrates the guidewire being threaded through the lumen of the trocar of Figure 22; Figure 28B illustrates the trocar being removed, leaving the guidewire in place extending through the tissue tunnel; and Figure 28C illustrates the multi-lumen catheter of Figure 3 inserted over the guidewire through the tissue tunnel, and curved down into the right internal jugular vein, superior vena cava and right atrium; Figures 29A-29G illustrate the steps for an alternate method of inserting the multi-lumen catheter of Figure 3 through the right internal jugular vein and superior vena cava into the right atrium wherein the trocar creates a tissue tunnel with an exit opening at the incision site where the needle and guidewire are introduced, wherein: Figure 29A illustrates the trocar of Figure 22 inserted over the guidewire through a first incision site, creating a subcutaneous tissue tunnel, and exiting the incision site created for insertion of the introducer needle and guidewire; Figure 29B illustrates the trocar being removed, leaving the guidewire in place extending through the tissue tunnel and forming a loop adjacent the needle incision site; and Figure 29C illustrates the multi-lumen catheter of Figure 3 being inserted over the guidewire for passage through the tissue tunnel; Figure 29D illustrates the catheter inserted through the subcutaneous tissue tunnel and forming a loop corresponding to the loop formed in the guidewire, Figure 29E illustrates the catheter extending through the subcutaneous tissue tunnel and being inserted further along the guidewire down into the right internal jugular vein; Figure 29F is a view similar to Figure 29E except showing the guidewire being removed; and Figure 29G illustrates the catheter in place extending through the subcutaneous tissue tunnel and advanced into the right internal jugular vein, superior vena cava and right atrium; Figure 30 illustrates an alternate method of retracting the guidewire through the subcutaneous tissue tunnel formed by the trocar; Figures 31-37 illustrate a method for manufacturing a first embodiment of the hub of the multi-lumen catheter of Figure 3 wherein: Figure 31 illustrates a slit formed in the outer wall of the catheter; Figure 32 is a view similar to Figure 31 except showing the central arterial lumen of the catheter; Figure 33 is a transverse cross-sectional view taken along lines 33-33 of Figure 32; Figure 34 illustrates a pin inserted through the slit in the outer wall of the catheter; Figure 35 illustrates the tubing inserted over the pin; Figure 36 illustrates the injection of soft material over the pin and catheter tube to form the catheter hub which retains the lumen connector tubes in position; Figure 37 illustrates the hub resulting from the injection molding process enabling one connector to communicate with the inflow (arterial) lumen and the other connector to communicate with the multiple outflow (venous) lumens; Figures 38-40 illustrate an alternate embodiment of the hub of the multi-lumen catheter of Figure 3 wherein: Figure 38 illustrates a perspective view of the proximal end of the catheter body split into five segments to accommodate the separate connector tubes; Figure 39 is a perspective view illustrating the connector tubes inserted into the respective lumens of the catheter body; and Figure 40 is a transverse cross-sectional view illustrating the cuts made in the catheter wall to form the separate segments. Figure 41 is a perspective view of another alternate embodiment of the hub of the catheter of the present invention having the lumen configuration of Figure 9C; Figure 42 is an exploded view of the hub and tube structure of Figure 41; Figure 43 is an enlarged perspective view showing the transition of the venous holes from a substantially oval to a substantially round configuration at the flared proximal portion of the catheter; and Figure 44 is an enlarged perspective view showing the multi-lumen extension tube tapering proximally and transitioning from substantially circular venous holes to substantially triangular holes; Figures 45-54 illustrate an alternate preferred embodiment of the dialysis catheter of the present invention, wherein Figure 45 is a perspective view of the catheter; Figure 46 is a perspective view similar to Figure 45 except showing the stiffener rod positioned therein; Figure 47 is an enlarged perspective view of the catheter tip showing the return and intake lumen open-
ments; Figure 48 is a side view of the catheter tip; Figures 48A, 48B and 48C are transverse cross-sectional views taken along lines A-A, B-B and C-C, respectively, of Figure 48; Figure 49A is a longitudinal cross-sectional view of a distal portion of the catheter showing the stiffener rod extending through the catheter; Figure 49B is a side view of the stiffener rod of Fig. 49A; Figure 50 is a perspective view showing the arterial extension tubes extending from the proximal flared portion of the catheter, the venous extension tube is removed for clarity; Figure 51 is a side view of the proximal end of the catheter, with one of the hub halves removed, showing the extension tubing connections to the catheter lumens; Figure 52 is a perspective view of a proximal portion of the arterial extension tubing illustrating the funnelled surfaces for wire insertion; Figure 53 is a transverse cross-sectional view taken along lines D-D of Fig. 46 showing the lead in for the cleaning wire insertion; and Figure 54 is a transverse cross-sectional view taken along lines E-E of Fig. 50 showing the arterial extension tubes within the sheath; Figure 55 is a side view of the proximal end of the catheter, with one of the hub halves removed, showing an alternate embodiment of the extension tubing connections to the catheter lumens; Figure 56 is a perspective view of another alternate embodiment of the extension tubing connections illustrating the arterial extension tube prior to connection to the catheter; Figures 57A, 57B and 57C are cross-sectional views of alternate embodiments of the lumen configurations of the arterial extension tube; and Figures 58-60 illustrate side views of another embodiment for connecting the extension tubings to the catheter and showing the manufacturing steps wherein Figure 58 shows placement of the pins prior to the injection molding process, Figure 59 shows the injection molded hub section over the pins, and Figure 60 shows the catheter and hub after completion of the injection molding process and removal of the pins.

**DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS**

[0033] Referring now in detail to the drawings where like reference numerals identify similar or like components throughout the several views, the first embodiment of the catheter of the present invention is designated generally by reference numeral 10. The catheter 10 is typically inserted into an area of high velocity blood flow to ensure sufficient blood can be transported from the body for dialysis. Figure 1 illustrates the catheter 10 inserted through the right internal jugular vein "a", into the superior vena cava "b", and into the right atrium "c"; Figure 2 illustrates the catheter 10 inserted into the left internal jugular vein "d", into the superior vena cava "b" and into the right atrium "c". Insertion into the right atrium, from either the right or left side provides the necessary high blood flow to the dialysis machine. Note that the catheter body (catheter tube) 11 is sufficiently flexible to enable it to bend to accommodate the anatomical curves as shown.

[0034] Catheter 10 has a catheter body or catheter tube 11 having a distal end portion 31, a proximal end portion 33, and an intermediate portion 35. Distal portion 31 terminates in nose 32 which is illustratively substantially conical in shape. Proximal end portion 33 includes hub 12, where the lumens formed within catheter tube 11 are connected, i.e. transition, to the respective inflow and outflow tubes, 16, 18, respectively, to enable return and withdrawal of blood for dialysis. Conventional tube clamps 17 and 19 cut off blood flow through inflow and outflow tubes 16, 18 as desired. As used herein, the terms "inflow" and "outflow" refer to the direction of blood flow with respect to the catheter such that "return", "delivery" or "venous flow" refers to flow from the dialysis machine and delivered to the body while "intake", "withdrawal" or "arterial flow" refers to flow withdrawn from the body and transported to the dialysis machine.

[0035] As shown, intermediate portion of catheter 10 extends through subcutaneous tissue tunnel "t", and curves downwardly toward the target site, e.g. the right atrium. This tunnel "t" secures the catheter in place for dialysis for a period of weeks, or even months, with fibrous cuff 36 (Figure 3) enabling tissue ingrowth. The formation of the tunnel "t" and the insertion of the catheter 10 therethrough will be discussed below in conjunction with the discussion of the catheter insertion method.

[0036] It should be appreciated that although the catheter is shown emerging from the tissue tunnel "t" at a second incision site, preferably, the tissue tunnel would not have an exit opening at a second site but instead would exit through the same incision through which initial access is made by the needle and dilator into the internal jugular vein "a". This is described in more detail below.

[0037] A series of lumens are formed in catheter tube 11 for transporting blood to and from a dialysis machine. As is well known in the art, a dialysis machine essentially functions as a kidney for patients suffering from kidney failure. Blood is removed from the patient and transported to the dialysis machine where toxins are removed by diffusion through a semi-permeable membrane into a dialysis fluid. The filtered blood is then returned through the catheter body to the patient.

[0038] More specifically, and with reference to Figures 5, 6A, 7 and 8, details of the catheter lumens will now be described. Central longitudinal lumen 40 is formed within catheter tube 11, extends the entire length and is designed to transport filtered blood to the patient. Lumen 40 is also configured to receive a guidewire 20 to direct
the catheter to the desired position. Lumen 40 extends to nose 42, and terminates in region 37 where it aligns with central longitudinal lumen 41 of nose 42. Central lumen 41 of nose 42 communicates with narrowed lumen 45, terminating in distal opening 47 to communicate with the patient’s body so blood can be delivered through distal opening 47. Lumens 41 and 45 also receive guidewire 20. Thus, lumen 40, lumen 41 and narrowed lumen 45 together form a central lumen enabling blood to be delivered from the dialysis machine to the patient. The transition from lumen 41 into narrowed lumen 45, forms a stop or shoulder 43, the function of which will be described below.

[0039] Nose 42 also includes side venous (delivery) openings 46 formed through the outer wall 44 wall in fluid communication with lumen 41, also functioning to return blood to the patient’s body. Side openings or ports 46 are preferably angled outwardly as shown to facilitate delivery of blood in the direction of blood flow and lessen mechanical hemolysis. These additional openings help maintain the desired flow volume by distributing the blood through multiple holes. Although only four openings are shown, it is contemplated that additional or fewer openings can be provided and the openings can be axially displaced with respect to each other. Additional set(s) of openings can also be provided spaced proximally or distally from side openings 46.

[0040] In this embodiment, nose 42 forms the distal tip portion and is composed of a different material than the other portions of the catheter body 11 and is welded or attached by other means to the catheter body 11. The tip (nose) in this embodiment is composed of a stiffer material to facilitate tunneling and blunt dissection through tissue. The nose could alternatively be composed of a softer material, thereby being less traumatic upon contact with the vessel wall. However, in a preferred embodiment, the nose is composed of the same material as the catheter body, having a small stiffener member embedded therein. This configuration is described in detail below in conjunction with Figures 13-15.

[0041] Catheter 10 also has a series of arterial (withdrawal) lumens 34a-34e, extending longitudinally along the length of the catheter body 11, each terminating at surface 48 of nose 42. In the preferred embodiment, shown in the cross-sectional view of Figure 8, the lumens 34 are oval-like in configuration, with opposite curved walls 37a, 37b and opposite substantially flat walls 39a, 39b. These spaced apart lumens have solid material between them therefore increasing the structural integrity of the catheter body 11. The lumens 34a-e are independent from one another through the distal, intermediate and proximal portions 33, 35, 31 of the catheter body 11, until the hub 12 where the lumens 34a-34e connect to a common connector tube. This is described in more detail below. Lumens 34a-34e, as shown, are symmetrically positioned and radially displaced from the central return lumen 40.

[0042] With continued reference to Figures 5 and 6A, a series of side openings or ports 50 are provided in the outer wall 14 of catheter body 10. These openings 50a, 50b, 50c, 50d, and 50e are each in fluid communication with a respective intake lumen 34a-34e and are designed and configured to withdraw blood from the patient’s body for delivery to the dialysis machine. A second set of openings 52a-52e, spaced proximally from openings 50a-50e, is also in communication with a respective lumen 34a-34e. Only three of the side openings 50, 52 are shown in Fig. 5, it being understood that the other three openings are positioned on the other side of the catheter, preferably symmetrically placed to accommodate the circumferential arrangement of the intake lumens 34a-34e.

[0043] Although lumens 34a-34e are isolated along a substantial length of the catheter, they preferably have a common flow source at the proximal portion 33 of the catheter 10. This is described in more detail below.

[0044] In the embodiment of Figure 8, the venous (return) lumen size preferably ranges from about 3.87 mm² to about 5.16 mm² (about .006 inches² to about .008 inches²) in cross-sectional area, and is more preferably 4.52 mm² (.007 inches²). The cross-sectional area of each of the arterial (intake) lumens 34 preferably ranges from about 1.29 mm² to about 2.58 mm² (about .002 inches² to about .004 inches²), and more preferably about 1.94 mm² (about .003 inches²), bringing the total cross-sectional area of the intake lumens to about 6.45 mm² to about 12.90 mm² (about .01 inches² to about .02 inches²), and more preferably about 9.68 mm² (about .015 inches²). This means that the ratio of total cross sectional area of the return lumen to the intake lumens is about 1 to about 2.1. Other dimensions are also contemplated.

[0045] It should be appreciated that although five separate lumens 34 are shown, a fewer or greater number can be provided. Also, although two sets of side openings are shown (set 50 and set 52), a fewer or greater number of sets can be provided, and a fewer or greater number of openings in each set could be provided.

[0046] Alternative lumen configurations spaced circumferentially are illustrated in Figures 9A, 9B, 9C and 10. In Figure 9B, three arc-shaped lumens 60a, 60b, 60c are positioned around the arterial central lumen 40. These larger sized lumens provide for additional arterial (intake) flow but result in the reduction of the strength of the catheter wall due to the less wall material as compared to the lumen configuration of Figure 8. In Figure 9A, five lumens 66a, 66b and 66c are provided. These lumens have more of a rectangular (or trapezoidal) shape with one pair of opposing walls having a straighter configuration than the lumen configuration of Figure 8. As shown, the other pair of opposing walls has a slight curvature. In Figure 9C, four oval-like intake lumens 76a, 76b, 76c and 76d are positioned around a substantially square central lumen 78. This lumen configuration provides for a substantially sized central lumen and sufficient room between the central lumen 78 and each of the intake lumens 76a-76d for the catheter walls to flex. In Figure
10, five lumens 70a-70e of circular cross-section are provided around the central lumen 40°, adding to the stability of the catheter by increasing the wall material, but reducing the overall venous lumen size as compared to the embodiment of Figure 8. Preferably, the intake (arterial) lumens in each of these embodiments are independent from one another along the substantial length of the catheter.

[0047] Fewer or greater number of lumens could be provided and lumens of other configurations are also contemplated. This positioning of the intake lumens in a circle-like array around the catheter, i.e. radially displaced from the center of the catheter, more evenly distributes the vacuum, as compared to a side by side venous/arterial lumen configuration, and ensures constant return flow since if one of the lumens becomes stuck against the vessel wall or otherwise clogged, the remaining lumens will maintain adequate flow. The openings in the side-walls communicating with the lumens can also be elongated instead of circular, creating a series of longitudinally extending openings for entry of suctioned blood. This version of elongated openings is shown for example in Figures 18 and 20 described in detail below.

[0048] To facilitate insertion, the catheter is configured to receive a stiffening member in the form of a stiffening rod which stretches the catheter to reduce its profile to aid in over the wire insertion and better navigate through small vessels. That is, the stiffening rod is inserted into central lumen 40 of catheter 10 and torqued to stiffen the flexible catheter for ease in over the wire insertion and navigation through the small vessels, and to reduce the outer diameter of the catheter body by stretching it during insertion. After placement of the catheter 10, the stiffening rod is removed, allowing the catheter to return to its higher profile position with the lumens of the necessary size for blood transport to and from the body. Two embodiments of the stiffening rods are illustrated in Figures 4A and 4B and are shown prior to insertion into the catheter 10 in Figure 3. A third embodiment of the stiffening rod is illustrated in Figure 49.

[0049] Turning to the first embodiment of the stiffening rod illustrated in Figure 4A, the stiffening rod is designated generally by reference numeral 80. Stiffening rod 80 has a distal tip 82, a proximal end portion 85 and an internal lumen 87 extending therethrough (see Fig. 11). Stiffening rod 80 is inserted through the proximal end of inflow tube 16, in the direction of the arrow of Figure 11, over the guidewire 20 (which extends through lumen 87 and through central lumen 40) until distal tip 82 abuts shoulder or stop 43 as shown in Figure 12. The proximal end portion 85 of stiffening rod 80 has a threaded portion 81 which is screwed onto screw thread 15 of inflow tube 16. This temporarily secures the stiffening rod 80 within the catheter 10 during insertion. This threaded mounting requires the stiffening rod 80 to be manually twisted, thereby torquing rod 80 as it presses forwardly and applies a force against shoulder (abutment surface) 43 to stretch the catheter body 11 to reduce its outer diameter.

It is contemplated in one embodiment, for example, that the catheter body 11 can be reduced in diameter from about 215 millimeters to about 207 millimeters by the stiffening rod 80. (Other size reductions are also contemplated. This reduction in catheter body diameter or profile is represented by the arrows D1 and D2 in Figures 11 and 12, respectively, which show the change in dimension effected by the stiffener rod 80.

[0050] After the catheter 10 is positioned at the desired site, the stiffening rod 80 is unthreaded from the proximal thread 15 of venous (return) tube 16 and removed from the central lumen 40 of the catheter 10 and from the venous (return) tube 16, thereby allowing the catheter to return to its normal profile of Figure 11.

[0051] It should be appreciated that stiffening rod 80 can alternatively be temporarily attached at its proximal end to the tube 16 by other means such as a bayonet lock, snap fit, etc. The rod could first be manually twisted and then mounted by these various means for retention in its torqued position.

[0052] An alternate embodiment of the stiffening rod is illustrated in Figure 4B and designated generally by reference numeral 90. Stiffening rod 90 has a threaded distal end 92 which is threaded onto internal threads 251 of catheter 200 shown in Figure 6B. A series of proximal threads 91 are screwed onto the threads 15 of the inflow tube 16 in the same manner as described above for stiffener rod 80. The stiffening rod 90 functions in the same manner as stiffening rod 80, i.e. to stretch the catheter during insertion to reduce its profile to stiffen it to facilitate insertion, the only difference being the mechanical threaded attachment of the distal end of the stiffening rod 90 to the catheter 200 instead of the abutting relation of stiffening rod 80 with shoulder 43 of catheter 10. Preferably, the distal threads 92 are first threaded onto internal thread 251, followed by attachment of the proximal threads 91 as the stiffening rod 90 is torqued. Stiffening rod 90, like stiffening rod 80, is preferably circular in cross-section, although other configurations are also contemplated.

[0053] Catheter 200 of Figure 6B is identical to catheter 200 in all respects except for the threads 251 instead of shoulder 43 and lumen 241 which is uniform in diameter. Similar to catheter 10, catheter 200 has distal return opening 247 and side openings 246 in outer wall 244 communicating with lumen 241 in distal tip portion 242, which communicates with central lumen 40. Arterial intake lumens 234a-234e terminate at wall 248 and have respective side openings 252a-252e and 250a-250e formed in the outer wall 214. Only one of the side openings 250a, 252a are shown in the longitudinal cross-sectional view of Figure 6B.

[0054] As noted above, distal tip (nose) can be composed of a different stiffer material than the catheter body 11 or can be composed of a material having a higher durometer than the catheter body. This stiffer material will facilitate both tunneling through and dilating tissue. In an alternate preferred embodiment, however, the distal...
tip is composed of the same material as the catheter body but has a stiffening insert.

[0055] More specifically, the alternative nose (tip) configuration is illustrated in Figure 15, with the method of manufacturing the tip shown in Figures 13 and 14. This nose or distal tip 104, is composed of the same material as the catheter body 108 and has a stiffening insert 110 inserted through central lumen 106 of nose 104. Central lumen 106 extends through the catheter body. The stiffening insert 110 is preferably composed of the same material as the catheter body 11 and nose 104, except it is made of a harder durometer material such as 72 shoreD vs. 85 shoreA for the catheter body 11. The material utilized can be, by way of example, urethane. For convenience, only the distal tip is shown, the remaining portions of the catheter 100 being identical to catheter 10.

[0056] The stiffening insert 110, preferably cylindrical as shown, has a hole 112 for receipt of the guidewire and for communication with central lumen 106. Insert 110 engages the inner wall surface 114 of central lumen 106. Lumen 106, proximal of side openings 119, will include either a stepped portion to provide an abutment surface (shoulder) for stiffening rod 80 or internal threads to mount stiffening rod 90 as described above.

[0057] The method of manufacturing this bullet shaped nose 104 will now be described in conjunction with Figures 13-15. Once cylindrical tube is formed, preferably by injection molding techniques, with central return lumen 106 and intake lumens 109a-109e, stiffening insert 110 is placed within central lumen 106 at the distalmost end and substantially flush with the distalmost edge 102 of the cylindrical tube.

[0058] Once the stiffening insert or slug 110 is placed within central lumen 106, the tube is formed into the bullet nose shape of Figures 15A and 15B, by a conventional radiofrequency or other heating process which allows the tip material to flow and form around the harder insert 110. After heating of the die and formation into this configuration, the material is cooled and thereby hardens to the configuration of Figure 15 as the material fuses to the insert 110. A conventional core pin (not shown) can be inserted through the hole 112 and central lumen 106 during the forming process. When the material hardens, the pin is withdrawn to maintain these openings. After the forming process, side holes 114 are either cut or drilled through the wall 108 of catheter 100 to communicate with lumen 106 in the same manner as side holes 46 communicate with central lumen 40 of Figures 1-6.

[0059] Figures 16A-17C illustrate two alternate embodiments of the catheter of the present invention having spacers to minimize contact of the catheter body with the vessel wall. Provision of these spacers is optional. In the embodiment of Figures 16A-16C, catheter 150, similar to catheter 10, has a distal portion having a nose 154, a central return lumen 156 which also receives a guidewire 20, and a series (e.g. 5) of intake lumens 160 - 160. Venous return lumen 156 communicates with lumen 151 and narrowed lumen 153 of the nose 154, terminating in open distal end 158. A plurality of side openings 159 communicate with lumen 151 and function in the same manner as side openings 46 of catheter 10. Arterial intake lumens 160 each terminate at side openings 161, similar to side openings 52 of intake lumens 34 of catheter 10. Although only one series of side openings 161 are shown, clearly additional arrays of side openings, positioned distally or proximally of side openings 161 could be provided. The arterial lumen configuration can also vary in a similar manner as described above with respect to catheter 10. Thus, except for the spacers, catheter 150 is identical to catheter 10.

[0060] A plurality of spacer wires 164 are embedded in the wall 169 of the catheter 150 and are secured at region 158 by adhesive or other suitable means. In the normal configuration, spacer wires 164 bow slightly outwardly with respect to the outer wall 169 of the catheter 150 to reduce the likelihood of contact with the vessel wall. When the stiffening rod 80 is inserted over guidewire 20 and through central lumen 156, as shown in Figure 16C, and edge 170 is forced against the abutment surface or stop 159, the catheter body is stretched and the spacer wires 164 stretch to a straightened position, substantially flush with the outer surface of wall 169. This reduces the profile of the catheter and ensures the spacer wires do not interfere with catheter insertion. When the stiffener rod 80 is withdrawn, the catheter returns to its normal position, and the spacer wires 164 bow outwardly as in Figures 16A and 16B. It should be appreciated that stiffening rod 90 can also be used with catheter 150 and would function to reduce the profile in the same manner as rod 80. Catheter 150 would then be provided with internal threads for mounting stiffening rod 90 as described above.

[0061] An alternative to spacer wires is illustrated in Figures 17A-17C. Catheter 180 is identical to catheter 150, except it is provided with integral ribs 194 proximal of nose 184. That is, similar to catheter 150, catheter 180 has a central return lumen 186 configured to receive guidewire 20 and stiffening rod 80 or 90. Lumen 186 communicates with lumen 181 and narrowed lumen 183 of the nose 184 which terminates in open distal end 188. Side openings 189 of nose 184 communicate with lumen 181. A series of independent intake lumens 190 are provided, terminating in side openings 192, similar to side openings 161 of catheter 150. Although only one series of side openings 192 are shown, clearly additional arrays, positioned proximally or distally of side openings could be provided.

[0062] Spacer ribs 194 are formed by cutout portions in the wall 193 of the catheter 150. Figure 17B illustrates the spacer ribs 194 in their normal position, outwardly bowed from the outer surface of the wall 193 of the catheter body. Figure 17C illustrates the straightened or retracted position of the spacer ribs 194, where the ribs 194 are substantially flush with the outer surface of wall 193, after stiffener rod 80 of Figure 4A (or rod 90 of Figure 4B) is inserted through central lumen 186 to stretch the
catheter 150 for insertion in the manner described above.

Figures 18 and 19 illustrate another alternative embodiment of the catheter of the present invention. Catheter 500 has a distal tip 502 with a tapered region 510 transitioning to a reduced diameter region 504. The central lumen terminates in distal opening 506 for fluid delivery. Unlike the previously described embodiments, the distal opening 506 is the sole fluid delivery passageway into the body. However, it is also contemplated that additional side holes could be provided in the tip to provide additional venous ports for blood delivery to the patient.

A series of intake (arterial) openings 508 (only two are shown in the view of Figure 18) are provided in the transition or tapered region 510 of the tip 502. These openings are elongated to provide additional area for suctioning. Each of the openings 508 communicates with a respective arterial lumen 510 formed in the catheter. The venous lumen configuration (and arterial lumen configuration) can be in the form of those illustrated in Figures 7-10, or other variations, as described above.

Stiffening rod 520 is shown positioned in the central lumen of the catheter 500. Rod 520 is similar to the rods 80 and 90 described above except it extends distally of the distal tip 502 of catheter 500, has a tapered distal end 524 to facilitate tunneling and dilating tissue, and has a stepped portion to abut the internal structure of the catheter 500. More specifically, guidewire 20 is shown extending through the central lumen of stiffening rod 520. The stiffening rod 520 is inserted through the central lumen of the catheter 500. More specifically, guidewire 20 and catheter 600 are inserted over the guidewire 20, with the tapered tip 524 facilitating passage of the catheter as it dilates tissue.

Catheter 500 has a cylindrical insert 514 positioned in the distal tip, similar to insert 110 of Figure 13A. The insert 514 is composed of a stiffer material to stiffen the tip of the catheter 500 to facilitate insertion. Insert 514 has an opening to receive stiffening rod 520 as shown. Shoulder 526 formed by stepped portion 524 abuts the insert 514, thereby functioning as a stop in a similar manner that shoulder 43 acts as a stop for stiffening rod 80 shown in Figure 11, the difference being the shoulder is formed in the internal wall of the catheter rather than on the stiffening rod. Stiffening rod 520 thus acts in the manner as the aforementioned rods 80, 90, i.e. pressing against the catheter tip portion to stretch the catheter for insertion, in addition to providing a tissue tunneling and dilation function.

Figure 20 illustrates an alternative tip design of the catheter of the present invention. Catheter tip 602 has a bullet nose configuration, somewhat similar to the nose of Figure 15, except having more of a progressive taper. Catheter tip 602 also has a series of elongated intake holes 608 (only two are shown in the view of Figure 20). In all other respects, e.g. stiffening insert, stiffening rod, distal blood delivery opening 606, etc, catheter 600 is identical to catheter 500 of Figure 18.

Figures 45-54 illustrate another alternate embodiment of the catheter of the present invention, designated generally by reference numeral 800. Catheter 800 has a catheter body or catheter tube 810 having a distal portion 812 and a transition portion 814 between the distal portion 812 and an intermediate portion 816 of the catheter. The proximal portion 818 of catheter body 810 has a flared region as will be described below.

With reference to Figures 45 and 47, the distal portion 812 of catheter 800 is elongated and has a diameter less than the diameter of the intermediate portion 816. By way of example, in one embodiment, the diameter of the distal portion 812 can be about 3.00 mm (about .118 inches) and the diameter of the intermediate portion 816 can be about 5.54 mm (about .218 inches). Clearly other dimensions are contemplated.

The transition portion 814 provides a smooth transition between the intermediate portion 816 and the distal portion 812 as it tapers in a distal direction. Formed in the transition portion 814 are four widened somewhat trapezoidal open areas, separated by ribs 849, each extending longitudinally to communicate with the intake openings. Thus, the intake openings terminate in longitudinally aligned openings at the transition portion 814.

The distal portion 812 has a non-uniform wall thickness with two tapered regions, best shown in Figure 49. The wall thickness remains substantially constant until slightly proximal of the transition region 814 where it increases in thickness over a portion of the length, beginning at portion 819. The wall thickness of distal portion 812 then decreases towards the distal end at region 817 forming a first taper. A second taper 813 is formed at the distalmost end. In one embodiment the first taper at region 817 is about 2 degrees and the distalmost end taper at region 813 is about 5 degrees, although clearly other tapers are contemplated. These tapered regions provide for easier insertion of the catheter 800. Since the tapers are created by a change in wall thickness, the cross-sectional area of the central return lumen remains constant and the venous pressure is unaffected.

Embedded in the distal portion 812 is a stiffening insert 820 similar to the cylindrical stiffening insert 110 described in conjunction with Figures 13A-15B, except it is located proximal of the distalmost tip. The stiffening insert 820 is placed during formation of the catheter tube by melting the catheter material around the insert during formation in a similar fashion as insert 110.

Figure 48 illustrates the lumen configuration of the catheter 800 which is similar to the lumen configurations of Figure 9C. A central return (venous) lumen 830 is encircled by a series of intake lumens 840a-840d in a spoke-like fashion. The central return lumen 830 is substantially square in cross-section with rounded corners as shown in Figure 48A. The four intake lumens 840a-840d are oval-like in cross section with a substantially planar edge 842a-842d and opposing inwardly angled side walls. The central lumen 830 terminates in opening 832 at the distalmost end of the catheter tube 810. The
intake lumens are independent and each terminates in an open area 844a-844d in the transition region 814 as described above.

[0074] In a preferred embodiment, the central return lumen 830 is of substantially constant cross-sectional area throughout its length. At the distal portion 812 the lumen 830 transitions to a more circular shape (Fig. 49B), but the cross-sectional area preferably remains the same. In a preferred embodiment, the cross-sectional area of the central lumen is about 4.52 mm² (about .007 inches²), although other dimensions are contemplated. At the flared portion 821 (Fig. 50) the return lumen 830 transitions to a more circular configuration.

[0075] In the preferred embodiment, the intake lumens 840a-840d remain constant throughout their length until the proximal flared portion 821 where they are substantially circular (Fig. 50) and of greater cross-sectional area to receive the arterial extension tubes described below. The intake lumens 840a-840d transition to a more arcuate shape, as shown in Figure 48B, just proximal of the transition region 814, but the cross-sectional area preferably remains the same. (This lumen configuration is similar to that of Figure 9A in that it is more of a trapezoidal than oval shape with curved walls and inwardly angled substantially straight side walls). The cross-sectional area of each intake lumen 840 is preferably about 1.94 mm² (about .003 inches²) so that the total intake cross-sectional area is preferably about 7.74 mm² (about .012 inches²), but other dimensions for the intake lumens are contemplated.

[0076] Turning now to the hub and tubing design for connecting the catheter 810 to the dialysis machine tubing, and with reference to Figs 50 and 51, four arterial extension tubes 850a-850d are each placed in a respective intake lumen 840a-840d at the flared portion 821 to provide fluid communication. A sleeve 852 is attached during a thermal forming process to blend with the individual tubes 850a-850d to retain the four arterial extension tubes 850a-850d together. A connector tube or insert 854, preferably of stainless steel, is inserted into the central lumen 830 and a tapered venous extension tube 856 is placed over the tube 854 to provide fluid communication between extension tube 856 and central lumen 830. The two hub halves 860, 862 of hub 861 are snapped fitted over the region containing flared portion 821, connector tube 854, and a portion of extension tubes 850a-850d, 856 and sleeve 852 as shown in Fig. 51. Conventional arterial and venous clamps C1, C2, respectively, are illustrated in Figure 45. In the preferred embodiment, a single arterial clamp C1 would clamp on the sleeve 852 to cut off flow simultaneously through all the arterial extension tubes 850a-850d. Thus separate arterial clamps would not be required. A luer lock 858 on venous extension tube 856 is for mounting the stiffener rod, and subsequent to insertion and after removal of the stiffener rod, for mounting tubing for connection to the dialysis machine. The luer lock for the arterial tubing mounts dialysis machine tubing.

[0077] A conventional suture ring 870 (Fig. 45), having suture holes for attaching the catheter, is fitted in an annular groove in the hub 861. A conventional fibrous cuff 872 for tissue ingrowth is shown at an intermediate section of the catheter 810 for tissue ingrowth as described above.

[0078] In an alternate embodiment shown in Figure 55, a connector tube or insert 857 composed of stainless steel or other materials, similar to connector insert 854 of Fig. 51, is provided in each of the catheter arterial intake lumens to provide fluid communication between the intake lumens and the respective arterial extension tube 850a'-850d' (only two of which are shown) placed over the insert 857. A sleeve 852', like sleeve 852, for retaining the arterial extension tubes 850a'-850d' is preferably provided and a single clamp would stanch blood flow in all the arterial extension tubes 850a-850d when clamped on sleeve 852'. In this embodiment, the catheter optionally could be provided without a flared proximal portion as the connector inserts would stretch the arterial lumens and catheter when inserted.

[0079] In Figure 56, instead of separate arterial extension tubes held by a sleeve as in the embodiments of Figs 51 and 55, a single arterial extension tube 901 having four separate lumens 902a-902d is provided. The extension tube 901 is separated into four segments (branches) 904a-904d at the distal end, and each segment 904a-904d is placed within a respective intake lumen 840a-840d in flared portion 821 of the catheter. A single arterial clamp could be used to substantially simultaneously cut off flow to all arterial lumens 840a-840d by clamping on tube 901 proximal of the separated segments. A venous extension tube 906 is connected to the venous central lumen 830. In this embodiment the tubes can be inserted directly into the respective lumens or alternatively a connector insert can be provided for the venous lumen and/or for one or more of the intake lumens.

[0080] Figures 57A-57D are exemplary embodiments of the cross-sectional lumen configuration of the extension tube 901. In Figure 57A, each of the lumens 913a-913d are substantially circular in configuration; in Figure 57B the lumens 915a-915d are wedge or pie-shaped; and in Figure 57C the lumens 917a-917d are triangular in configuration within a rectangular tubing. Other cross-sectional lumen configurations are also contemplated. Also the cross-sectional configuration of the tubing branches could also vary from that shown in Fig. 56.

[0081] In the embodiment of Figures 58-60, a different approach for forming the tubing connections is disclosed in which the hub forms the communication lines for the extension tubing as the hub 920 is injection molded around a series of connector pins. More specifically, prior to formation, an arterial extension tube 922 is provided with four separate pins 924a-924d extending the length of tube 922 and extending into the respective intake lumens of the catheter. Preferably the pins are identical in cross-sectional configuration and dimension to corre-
spond to the preferred embodiment of the catheter having four identically dimensioned arterial (intake) lumens.

Another pin 932 extends along the length of venous extension tube 930 and into the central venous lumen of the catheter, bent as shown to create an arcuate path. The injection molding process forms the hub around the pins 924a-924d, 932 (Fig. 59) and when the pins are removed, four separate lumens 929a-929d are formed through the arterial extension tube 922 and hub 920 and a separate lumen 936 is formed through the venous extension tube 930 and through hub 920. These lumens are shown in phantom in the hub 920 in Fig. 60. In this manner fluid communication is maintained through the lumens in the extension tubes 922, 930, the lumens (channels) in the hub 920 and the catheter arterial and venous lumens. A single tubing clamp (not shown) can be provided for the venous tube 930 and a single clamp D can be provided for the arterial tube 922, with the arterial clamp substantially simultaneously closing off all lumens in the tube 922.

As described above, the catheters of the present invention provide a way to secure the catheter as described below. Guidewire 20 is inserted through the needle into the right internal jugular vein “a” and into the superior vena cava “b” as shown in Figure 25. The guidewire 20 is further advanced into the right atrium “c”, and preferably into the inferior vena cava. The needle “N” is then withdrawn, leaving the guidewire 20 in place, extending out of the patient’s body at the proximal portion 21. Next, trocar 300 is inserted through a first incision “s” in the patient, bluntly dissecting and tunneling under the skin, and forced out of the tissue at a second incision or site “u”, creating a subcutaneous tunnel “t” under the tissue as shown in Figure 27. This provides a way to secure the catheter as described below. Guidewire 20 is then threaded through lumen 304 of the trocar, with proximal portion 21 first inserted through trocar distal opening 310 so it emerges out of proximal opening 306 as shown in Figure 28A. Trocar 300 is then withdrawn from the body in the direction of the arrow of Figure 28B, leaving the guidewire 20 in place as shown. Thus, guidewire 20 extends from the right atrium and superior vena cava, out through the right internal jugular vein and through the tissue tunnel “t”.

Catheter 10 is then threaded over the guidewire with the proximal portion 21 of the guidewire inserted through the distal tip lumen of the catheter, through the length of the central lumen, and through the hub 12 into the inflow tube 116 and out through fitting 15. The catheter 10 is thus threaded over the wire, through the tissue tunnel “t” where cuff 36 (not shown in Fig. 28C) is positioned in the tissue tunnel “t” to aid in securement of the catheter by enabling tissue ingrowth over a period of time. The catheter is further advanced over guidewire 20 down into the right internal jugular vein, into the superior vena cava, and into the right atrium. The guidewire 20 is with-
drawn in the direction of the arrow, leaving the catheter 10 in place for use as shown in Fig. 28C. Note the stiffening member 80 or 90 (not shown in Fig. 28C for clarity) is preferably utilized, i.e. inserted over the guidewire 20 through the fitting 15, infow tube 16, hub 12, and central lumen 40 to help guide the catheter 10 as described above. Thus, the guidewire 20 would extend through the central lumen of catheter by extending through the central lumen of the stiffening member which is positioned within the central lumen of the catheter.

[0091] As can be appreciated, the catheter will be inserted in a similar fashion through the left internal jugular vein to be positioned as depicted in Fig. 2. In this method, the subcutaneous tissue tunnel will be formed on the left side as shown in Fig. 2, by the trocar 300, and the catheter inserted over the guidewire through the tissue tunnel and through the left internal jugular vein or subclavian vein and into the superior vena cava and right atrium in the same way as described for right side insertion. It should be understood that any of the aforedescribed catheters of the present invention can be inserted in this fashion.

[0092] An alternative method of insertion is illustrated in Figures 29A-29G. In this method instead of forming a second incision site adjacent the incision site through which the needle and guidewire are introduced into the internal jugular vein as in Figure 27, the trocar 300 emerges from the needle/guidewire insertion site. Although catheter 10 is shown, any of the foregoing catheters can be inserted in the same manner.

[0093] In this method, the needle and guidewire are inserted in an identical manner as illustrated in Figures 25 and 26. After removal of the needle, the guidewire 20 is left in place extending outwardly from the incision site, designated by "w". Next, as shown in Figure 29A, trocar 300 is inserted through a first incision "s" (as in Figure 27) to create a subcutaneous tissue tunnel; however, unlike Figure 27, trocar 300 does not emerge at a second incision site "u". Instead, trocar 300 is advanced subcutaneously to the needle incision site "w", and emerges through the site "w" as shown. Thus, as shown in Figure 29A, the distal end of trocar 300 exits incision site "w" alongside the guidewire 20.

[0094] Guidewire 20 is then inserted (threaded) through the opening in trocar 300 as described above and then the trocar is withdrawn through the tissue tunnel "t" and out through the first incision "s", pulling the guidewire 20 through the tunnel. After the guidewire 20 is pulled through the tunnel "t" and out through incision "s", the trocar 300 is removed as shown in Figure 29B, leaving the guidewire 20 in place. Note the guidewire 20 is positioned to form a guidewire loop 22 to facilitate insertion of the catheter as will be described below.

[0095] The catheter 10 is then advanced over the guidewire 20 (Fig. 29C), through the tissue tunnel, and exiting incision site "w" into the internal jugular vein "a" (Fig. 29D). The catheter 10, as shown, is formed into a loop 13, tracking the loop 22 of guidewire 20, and then advanced downwardly through the internal jugular vein, the superior vena cava and into the right atrium (Fig. 29E). The guidewire 20 is then withdrawn as shown in Fig. 29F, and the catheter is pushed downwardly and/or pulled back to straighten the loop to position the catheter as shown in Fig. 29G. If the catheter is inserted with a stiffening member, the guidewire would extend through the lumen of the stiffening member.

[0096] It should be appreciated that formation of the loop in the guidewire and the catheter is optional and the procedure can be performed without the loop.

[0097] Figure 30 shows an alternate embodiment of a trocar utilized to retrieve the suture and retract it through the subcutaneous tissue tunnel. Trocar 300' is similar to trocar 300 of Figure 29 except for the provision of eyelet 312. The suture is threaded through the eyelet (shown as two small opposing holes in the wall at the distal end of the trocar 300') and the trocar is pulled proximally through the tissue tunnel to pull the suture out through incision "s". As shown, the trocar extends through incision "w", the same incision created for insertion of the needle and guidewire.

[0098] Instead of an eyelet, a hook or other means can be provided on the trocar for holding the guidewire to enable pulling the guidewire through the tissue tunnel. That is, in these versions, the guidewire is not threaded through the trocar lumen, but rather the trocar is utilized to pull (retract) the guidewire through the tissue tunnel.

[0099] Figure 21A illustrates an alternative trocar used for a different approach to catheter insertion. This trocar, designated by reference numeral 350, does not provide for an entire over the wire system, however it is used with an approach providing a partial over the wire system which eliminates the need for a tear way introducer sheath. As discussed in the Background Section of this application, tear away introducer sheaths are currently being utilized to guide the dialysis catheter through the vessels into the right atrium. To avoid the problems associated with the tear away sheath, the catheter in this alternate method can be advanced over a guidewire which can be placed in the manner illustrated in Figs 25 and 26.

[0100] In this method, trocar 350 is attached to the distal end of the catheter by insertion of barbed end 352 into a mating fitting. Other means for temporarily attaching the trocar are also contemplated. Trocar 350 has a blunt distal tip 354 and is advanced through a first tissue incision and out through a second tissue incision, bluntly dissecting tissue and forming a subcutaneous tissue tunnel in a similar manner as described above, except without the guidewire. Since trocar 350 is attached to the catheter, it pulls the catheter through the tissue tunnel, so it emerges out through the second incision. The trocar 350 is then detached from the catheter. The catheter is then bent as necessary and threaded over the guidewire into jugular vein, superior vena cava, and right atrium.

[0101] Figures 21B-21H illustrate alternate embodiments of a trocar adapted to create a subcutaneous tissue tunnel and to subsequently be attached to a catheter.
Trocar 900 and 920 each has a removable handle which is grasped by the user and then inserted into the body to create the subcutaneous tissue tunnel. The handle provides additional leverage for facilitating trocar insertion/passage. Once inserted through the tunnel, the handle is detached and the trocar is attached to the dialysis catheter as described above, for example, with reference to trocar 350 of Figure 21A. The distal end has a dilating distal tip as described above.

Turning now to one method of manufacturing the hub of the catheter, and with particular reference to Figs 31-37, a method is disclosed which enables connection of the central venous return (delivery) lumen of the catheter with an inflow tube and fluid connection of the five independent arterial intake (withdrawal) lumens with a single outflow tube to provide fluid connection through the connectors.

Turning first to Figure 31, a longitudinal slit 201 is formed at a proximal portion of catheter tube 203. Figure 32 shows the relationship of the slit 201 and the central venous lumen 205 as the slit is formed to communicate with the central lumen 205. As can be appreciated from the cross-sectional view of Figure 33, the slit 201 is formed in the wall 206 of the catheter tube 203 between adjacent arterial lumens 209a-209e. Next, a metal pin 207 is inserted through the slit 201 for the molding process. Outer plastic venous tubing 210 is placed over the metal pin 207 as shown in Figure 35 to ultimately communicate with the central lumen 205. Outer plastic arterial tubing 211 is also shown positioned over the catheter tube 203 which will communicate with the arterial lumens 209.

Next, conventional injection molding techniques are utilized so the soft plastic material flows around the catheter tube 203 and the metal pin 207 as shown in Figure 36. Then, the material is cooled to harden, forming a hub 208, with the metal pin 207 removed to form lumen 204. Lumen 204 has a narrowed region 202. As shown in Figure 37, lumen 204 fluidly connects lumen 207 of venous tube 210 with the central lumen 205 of the catheter. Lumen 212 of arterial tubing 211 communicates with the five independent arterial lumens 209.

Figs. 38-39 illustrate another method for manufacturing the catheter connections. In this method, catheter body 402 of catheter 400 is separated into five segments 401a-401e at its proximalmost end, corresponding to each of the arterial (intake) lumens 403a-403e. Figure 40 illustrates the five cuts 406 made in the catheter wall 407 between the adjacent arterial lumens 403 to form the five segments 401.

A separate arterial connector tube 412a-412e is positioned within a respective arterial lumen 403a-403e and is connected to a respective segment 401a-401e by solvent bonding or pressure fit. The proximal end of each connector tube 412 is positioned within arterial tube 414 which transports blood to the dialysis machine. Thus, blood flows through the arterial lumens 403, through each arterial connector tube 401 and into a single arterial (intake) tube 414. It should be understood, that if fewer or larger number of arterial lumens are provided, then an equal amount of arterial tubes would be utilized as the arterial lumens would be cut into the corresponding number of segments.

Venous (return) tubing 416 is connected to central venous lumen by venous connector tube 410 which is attached inside the venous lumen by solvent bonding, glue application or compression fit. Note that venous connector tube 410 is positioned between the segments 401. Figures 41-43 illustrate another alternate method for
manufacturing the hub of the catheter of the present invention. This hub and associated tubing is illustrated for use with a catheter having the lumen configuration of Figure 9C, although it can be utilized with other lumen configurations as well.

[0111] A central lumen connector (intermediate) tube 702 is joined with central lumen 78 of catheter 700. Four arterial connecting (intermediate) tubes 704 are connect- ed to a respective arterial lumen 76a. These tubes each have a lumen that is substantially circular in cross-section along its length. The substantially circular lumens corres- pond to the cross-sectional shape of the arterial lu- mens within catheter 10 which transition from a substan- tially oval cross-sectional configuration to a substantially circular cross-sectional configuration at the flared proximal portion shown in Figure 43. Note that venous lumen 78 also transitions to a substantially circular cross- sectional configuration.

[0112] Each of the connector tubes 704 is connected to multi-lumen extension (arterial) tube 708 which provides flow of blood to the dialysis machine. Extension tube 708 has a flared distal portion 711 with four lumens 710, each configured for communicating with one of the connector tubes 704. As shown, each of the lumens 710 has a substantially circular cross-sectional configuration that transitions to a substantially triangular cross-sectional configuration towards the proximal portion.

[0113] Single lumen extension (venous) tube 712, which provides return of blood to the patient, connects to connector tube 702. Tube 712 has a tapered distal end 718 and its lumen 719 transitions from a substantially circular cross-sectional configuration to a substantially square configuration toward the proximal end. Molding of housing 716 with the foregoing tubes forms the cath- eter hub. Conventional tube clamps, such as clamps 17, 19 of Fig. 1, are placed around extension tubes 708, 712 for cutting off blood flow.

[0114] A rotatable suture ring 720 is placed around the catheter hub and preferably has a planar surface 722 to sit substantially flush with the patient’s skin. Suture holes 724 are configured to receive sutures for attaching the ring (and thus the catheter) to the patient.

[0115] The catheters described above can optionally include a surface treatment on the exterior and/or the interior. The surface treatments can include for example, an hydrophilic coating to increase lubricity and facilitate insertion, a drug coating such as heparin or containing IIb IIIa inhibitors, inert coating substances such as Sorins carbon coating, and/or active coatings such as a silver ion coating.

[0116] It should be appreciated that although the cath- eter is described herein as a dialysis catheter for hemodialysis, the catheter disclosed herein could have other surgical applications, such as drug delivery or blood sampling. Moreover, features of the catheter, tip configura- tions and lumen configurations can be utilized on other catheters.

Claims

1. A catheter for delivering and withdrawing blood from a patient’s body, the catheter comprising a catheter body (108, 810) having an outer wall (14, 214), a distal portion (31, 812), a return lumen (40, 40', 40", 78, 106, 156, 241, 830, 936) extending from a proximal portion (818) of the catheter body to the distal portion to allow blood passage therethrough, a longitudinally extending intake lumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) independent of the return lumen, and means (850a-d, 850a'-d, 901, 922) for enabling fluid flow to the intake lumen to be cut off, characterized in that the return lumen is provided centrally of the catheter and at least three intake lumens are radially displaced with respect to the central return lumen, and in that the means for enabling fluid flow to the intake lumen to be cut off enables substantial simultaneous cut off of fluid flow to the at least three intake lumens.

2. A catheter as claimed in claim 1, characterized in that the means for enabling substantial simultaneous cut off of fluid flow to the at least three longitudinally extending lumens (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) comprises at least three arterial extension tubes (850a-d, 850a'-d, 901, 922) each having a lumen, each of the extension tube lumens communicating with one of the intake tubes, and a sleeve (852, 852') retaining a clamping member (19, C1, D), wherein clamping of the clamping member closes each of the lumens of the arterial extension tube.

3. A catheter as claimed in claim 2, characterized in that each of the intake extension tubes (850a-d, 850a'-d, 901, 922) is inserted into the respective intake lumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) of the catheter body (11, 108, 810).

4. A catheter as claimed in claim 2, characterized in that a connector insert (857) is interposed between at least one of the intake extension tubes (850a-d, 850a'-d, 901, 922) and the respective intake lumen (840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d).

5. A catheter as claimed in any one of claims 2 to 4, characterized in that the intake extension tubes (850a-d, 850a'-d, 901, 922) have a flanged proximal region (892a-d) to facilitate wire insertion.

6. A catheter as claimed in any preceding claim, char-
A catheter as claimed in any preceding claim, characterized in that an independent venous extension tube (856) is provided communicating with the return lumen (40, 40', 40", 78, 106, 156, 186, 241, 830, 936).

7. A catheter as claimed in claim 6, characterized in that a connector member (854) is positioned within the return lumen (40, 40', 40", 78, 106, 156, 186, 241, 830, 936), and in that the venous extension tube (856) is positioned over the connector member and has a lumen formed therethrough to provide fluid communication to the return lumen via the connector member.

8. A catheter as claimed in any preceding claim, characterized in that the intake lumens (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) each terminate distally in a longitudinally directed opening.

9. A catheter as claimed in any preceding claim, characterized in that the intake lumens (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) are disposed in a spoke-like fashion substantially equidistant from the central return lumen (40, 40', 40", 78, 106,156, 186, 241, 830, 936).

10. A catheter as claimed in any preceding claim, characterized in that the catheter body (11, 108, 810) includes a first portion (816) having a first diameter, and in that the distal portion (31, 812) of the catheter body has a second diameter smaller than the first diameter and a transition region (814) which tapers toward the distal portion.

11. A catheter as claimed in any preceding claim, characterized in that at least a portion of the wall thickness of the catheter in the distal portion (31, 812) tapers toward a distalmost end, the cross-sectional area of the central lumen (40, 40', 40", 78, 106, 156, 186, 241, 830, 936) remaining substantially constant throughout its length in the distal portion.

12. A catheter as claimed in any preceding claim, characterized in that the catheter has a proximal flared portion (821) and each of the intake lumens (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) transitions to a substantially circular cross-section at the flared portion.

13. A catheter as claimed in any preceding claim, characterized in that the distal portion (31, 812) of the catheter includes a stiffening insert (110, 514, 820) embedded in a wall of the catheter at the distal portion.

14. A catheter as claimed in any preceding claim, characterized in that a stiffening member (80, 90, 520, 880) is removably positionable within the catheter to temporarily increase stiffness of the catheter to facilitate insertion.

15. A catheter as claimed in any preceding claim, characterized in that a proximal portion of the stiffening member (80, 90, 520, 880) has a series of threads for mounting the stiffening member to the catheter.

**Patentansprüche**

1. Katheter zur Abgabe und Abnahme von Blut vom Körper eines Patienten, wobei der Katheter einen Katheterkörpers (108, 810) mit einem Außenwand (14, 214), einen distalen Teil (31, 812), ein Rückflusslumen (40, 40', 40", 78, 106, 156, 186, 241, 830, 936), das sich von einem proximalen Teil (818) des Katheterkörpers zum distalen Teil erstreckt, um Blutfluss dort hindurch zu ermöglichen, ein sich längs erstreckendes Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d), das vom Rückflusslumen unabhängig ist, und ein Mittel (850a-d, 850a'-d, 901, 922) zum Ermöglichen, den Flüssigkeitsfluss zu den Zuflusslumen zu stoppen, umfasst, dadurch gekennzeichnet, dass das Rückflusslumen zentral im Katheter vorgesehen ist und mindestens drei Zuflusslumen in Bezug auf das zentrale Rückflusslumen radial versetzt sind und dass das Mittel zum Ermöglichen, den Flüssigkeitsfluss zum Zuflusslumen zu stoppen, einen im Wesentlichen gleichzeitigen Stop des Flüssigkeitsflusses zu den mindestens drei Zuflusslumen ermöglicht.

2. Katheter nach Anspruch 1, dadurch gekennzeichnet, dass das Mittel zum Ermöglichen eines im Wesentlichen gleichzeitigen Stopps des Flüssigkeitsflusses zu den mindestens drei sich längs erstreckenden Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) mindestens drei arterielle Verlängerungslackäue (850a-d, 850a`-d, 901, 922), die jeweils ein Lumen aufweisen, wobei jedes der Verlängerungslackäue mit einem der Zuflusslumen in Verbindung steht, und eine Hülle (852, 852'), die mindestens einen Teil der arteriellen Verlängerungslackäue hält, umfasst, wobei die Hülle so bemessen ist, dass sie ein Klemmement (19, C1, D) aufnimmt, wobei ein Klemmement des Klemmementen jedes der Lumen der arteriellen Verlängerungslackäue verschließt.

3. Katheter nach Anspruch 1, dadurch gekennzeichnet, dass jeder der Zuflussverlängerungslackäue...
(850a-d, 850a-‘d’, 901, 922) in das jeweilige Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) des Katheterkörpers (11, 108, 810) eingeführt ist.

4. Katheter nach Anspruch 2, dadurch gekennzeichnet, dass ein Verbindungseinsatz (857) zwischen mindestens einem der Zuflussverlängerungsschläuche (850a-d, 850a-‘d’, 901, 922) und dem jeweiligen Zuflusslumen (840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) eingeschoben ist.

5. Katheter nach einem der Ansprüche 2 bis 4, dadurch gekennzeichnet, dass die Zuflussverlängerungsschläuche (850a-d, 850a-‘d’, 901, 922) einen trichterförmigen proximalen Bereich (892a-d) zum Erleichtern der Drahtführung aufweisen.


8. Katheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) jeweils distal in einer längs gerichteten Öffnung enden.

9. Katheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass die Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) speichenartig, im Wesentlichen gleich weit entfernt vom zentralen Rückflusslumen (40, 40’, 40”, 78, 106, 156, 186, 241, 830, 936) angeordnet sind.


12. Katheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass der Katheter einen proximalen konisch erweiterten Teil (821) aufweist und jedes der Zuflusslumen (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) in einem im Wesentlichen kreisförmigen Querschnitt am konisch erweiterten Teil übergeht.


14. Katheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass ein Versteifungselement (80, 90, 520, 880) herausnehmbar in dem Katheter angeordnet werden kann, um vorübergehend die Steifheit des Katheters zu erhöhen, um die Einführung zu erleichtern.

15. Katheter nach einem der vorhergehenden Ansprüche, dadurch gekennzeichnet, dass ein proximaler Teil des Versteifungselementes (80, 90, 520, 880) eine Reihe Drähte zum Befestigen des Versteifungselements an dem Katheter aufweist.

Revendications

1. Cathéter pour fournir et prélever du sang du corps d’un patient, le cathéter comprenant un corps de cathéter (108, 810) ayant une paroi externe (14, 214), une portion distale (31, 812), une lumière de renvoi (40, 40’, 40”, 78, 106, 156, 186, 241, 830, 936) s’étendant depuis une portion proximale (818) du corps de cathéter vers la portion distale pour permettre le passage de sang à travers elle, une lumière d’aménée s’étendant longitudinalement (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902ad, 913a-d, 915a-d, 917a-d, 929a-d) indépendante de la lumière de renvoi, et des moyens (850a-d, 850a-‘d’, 901, 922) pour permettre à l’écoulement de fluide vers la lumière d’aménée d’être cou-
Cathéter selon la revendication 6,
cathéter selon l’une quelconque des revendications précédentes,
cathéter selon l’une quelconque des revendications précé-
dentes,
cathéter selon la revendication 2,
cathéter selon la revendication 1,
cathéter selon l’une quelconque des revendications précé-
dentes,
cathéter selon l’une quelconque des revendications précé-
dentes,
cathéter selon l’une quelconque des revendications précé-
dentes.

2. Cathéter selon la revendication 1, **caractérisé en ce que** les moyens pour permettre la coupure simultanée importante de l’écoulement de fluide vers la lumière d’aménée d’être coupé permettent une coupure simultanée importante de l’écoulement de fluide vers les au moins trois lumières d’aménée.

3. Cathéter selon la revendication 2, **caractérisé en ce que** chacun des tubes de prolongement artériels (850a-d, 850a'-d', 901, 922) est inséré dans la lumière d’aménée respective (34a-e, 60a-c, 66a-c, 76ad, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) se terminant chacun de manière distale dans une ouverture dirigée longitudinalement.

4. Cathéter selon la revendication 2, **caractérisé en ce qu’**un insert connecteur (857) est interposé entre au moins un des tubes de prolongement d’aménée (850ad, 850a'-d', 901, 922) et la lumière d’aménée respective (840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) du corps du cathéter (11, 108, 810).

5. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que** les tubes de prolongement d’aménée (850a-d, 850a'-d', 901, 922) se terminent chacun de manière distale dans une ouverture dirigée longitudinalement.

6. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce qu’un** tube de prolongement veineux (856) est positionné au sein de la lumière de renvoi (40, 40', 40", 78, 106, 156, 186, 241, 830, 936), et **en ce que** le tube de

7. Cathéter selon la revendication 6, **caractérisé en ce qu’un** élément connecteur (854) est positionné au sein de la lumière de renvoi (40, 40', 40", 78, 106, 156, 186, 241, 830, 936), et **en ce que** le tube de prolongement veineux (856) est positionné sur l’élément connecteur et a une lumière formée à travers celui-ci pour fournir une communication fluidique vers la lumière de renvoi par le biais de l’élément connecteur.

8. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que** les lumières d’aménée (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) se terminent chacun de manière distale dans une ouverture dirigée longitudinalement.

9. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que** les lumières d’aménée (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) sont disposées à la manière d’un rayon essentiellement à équidistance de la lumière de renvoi centrale (40, 40', 40", 78, 106, 156, 186, 241, 830, 936).

10. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que** le corps du cathéter (11, 108, 810) comprend une première portion (816) ayant un premier diamètre, et **en ce que** la portion distale (31, 812) du corps du cathéter possède un second diamètre inférieur au premier diamètre et une région de transition (814) qui s’amincit vers la portion distale.

11. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce qu’au moins une** portion de l’épaisseur de paroi du cathéter dans la portion distale (31, 812) s’amincit vers une extrémité la plus distale, la zone en section transversale de la lumière centrale (40, 40', 40", 78, 106, 156, 186, 241, 830, 936) restant essentiellement constante sur toute sa longueur dans la portion distale.

12. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que le cathéter possède une** portion proximale évasée (821) et chacune des lumières d’aménée (34a-e, 60a-c, 66a-c, 76a-d, 70a-e, 109a-e, 160, 190, 234a-e, 840a-d, 902a-d, 913a-d, 915a-d, 917a-d, 929a-d) se transforme en une section transversale essentiellement circulaire au niveau de la portion évasée.

13. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce que la** portion distale (31, 812) du cathéter comprend un insert de raideissement (110, 514, 820) encastré dans une paroi du cathéter au niveau de la portion distale.

14. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce qu’un** élément de
raidissement (80, 90, 520, 880) peut être positionné de manière amovible au sein du cathéter pour augmenter temporairement la raideur du cathéter afin de faciliter l’insertion.

15. Cathéter selon l’une quelconque des revendications précédentes, **caractérisé en ce qu’une portion proximale de l’élément de raidissement (80, 90, 520, 880) possède une série de filetages pour monter l’élément de raidissement sur le cathéter.**
REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader’s convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 5797869 A [0001]
- US 5221256 A [0011] [0013]
- US 4568329 A [0013]
- US 5053023 A [0013]
- US 4493696 A [0013]
- US 5167623 A [0013]
- US 5380276 A [0013]
- US 5364344 A [0013]
- US 5451206 A [0013]