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(54) **CATHETER WITH OPEN FACED END PORTION**

**Publication Classification**

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(52) **U.S. Cl.** ..... **604/528**  
(57) **ABSTRACT**

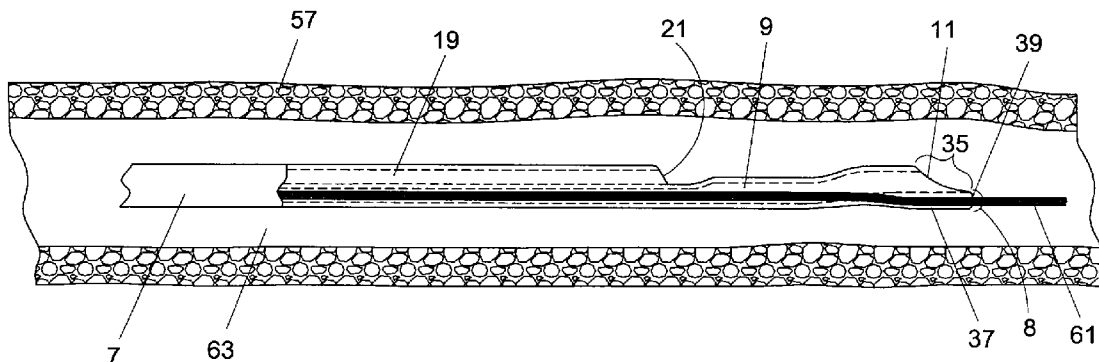
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A vascular access catheter that has a substantially distal end portion that has a distal tip. The distal end portion has a sloped face in the distal portion of the catheter, an outflow lumen aperture, and a second inflow lumen aperture. The outflow lumen aperture is substantially completely open in the sloped face and exits the distal portion adjacent the distal tip. The catheter has a guidewire lumen that is located at least in the region of the distal portion of the catheter and is capable of receiving a guidewire. The guidewire lumen has a proximal aperture and a distal aperture that extends distally of the outflow lumen aperture. The guidewire distal aperture exits at the distal most edge of the distal end portion. The guidewire lumen may extend a partial length of the catheter or substantially the entire length of the catheter. The catheter distal portion may be substantially straight or curved.

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**Related U.S. Application Data**

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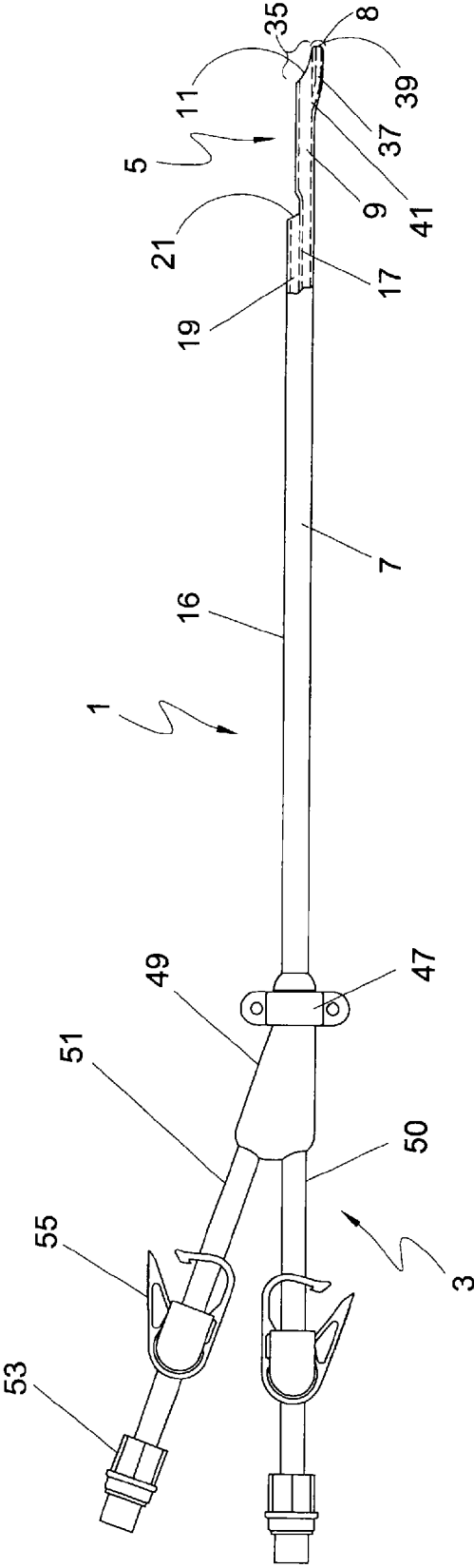


FIG. 1

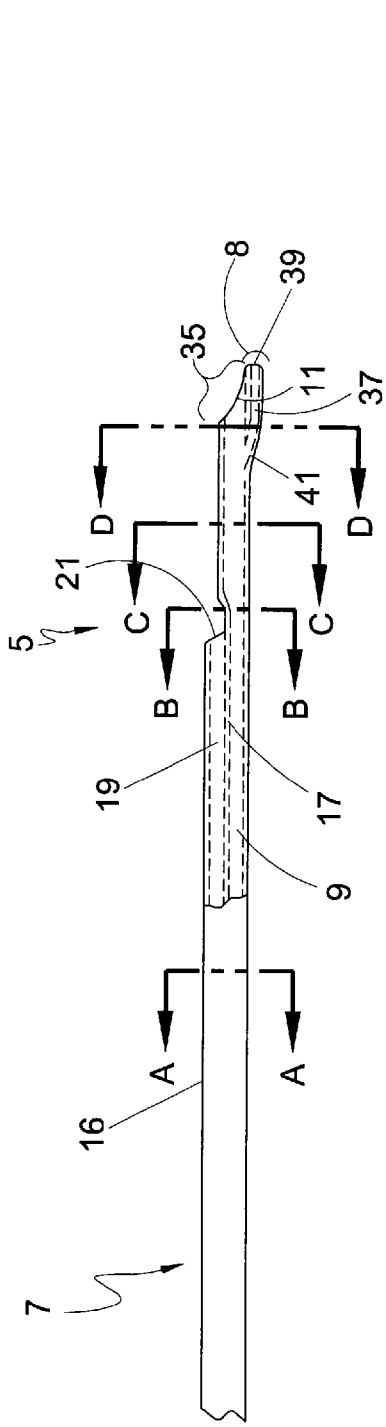


FIG. 2A

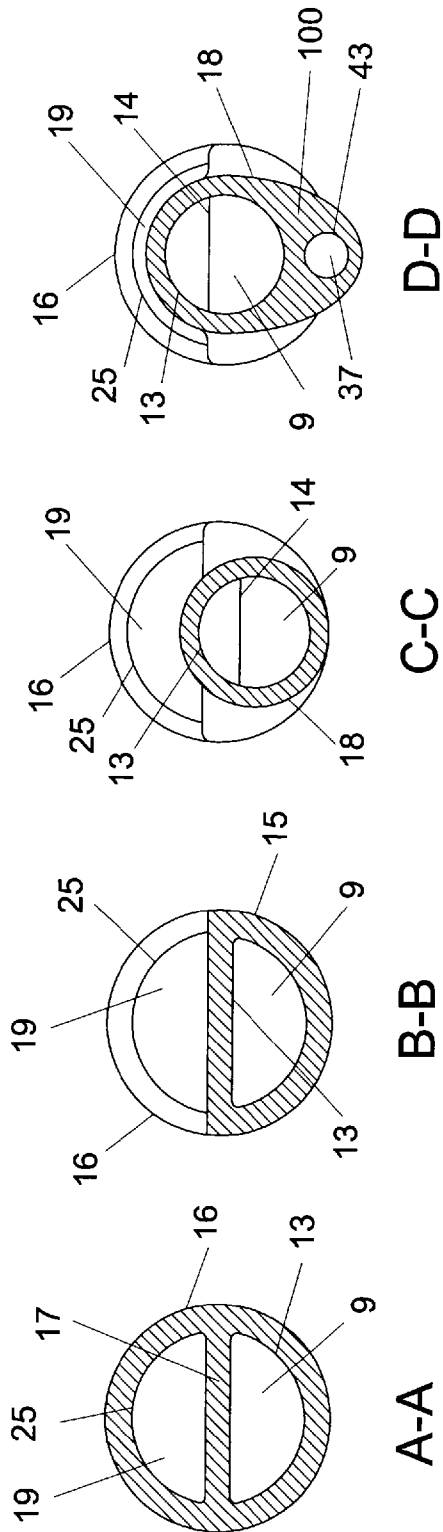


FIG. 2B

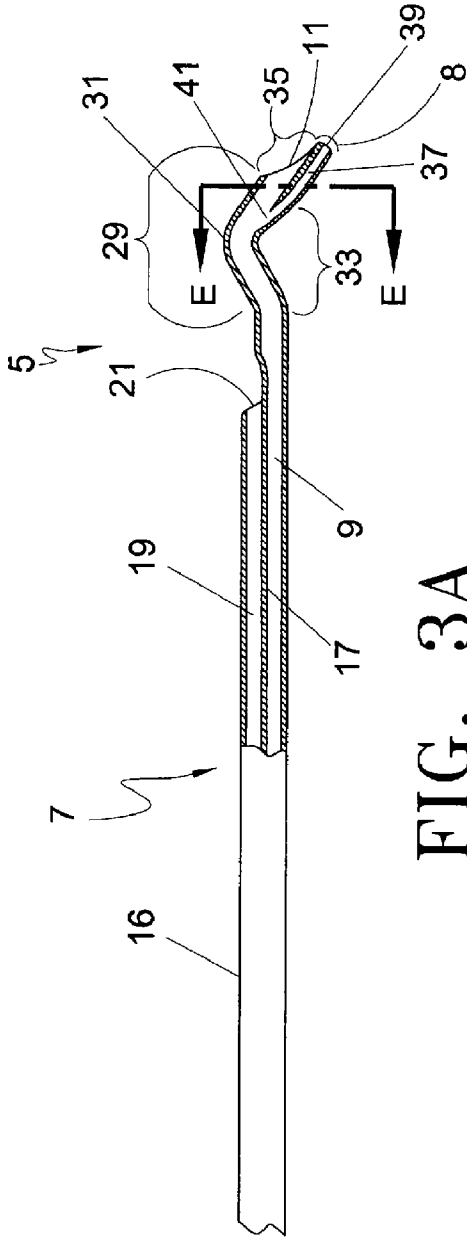


FIG. 3A

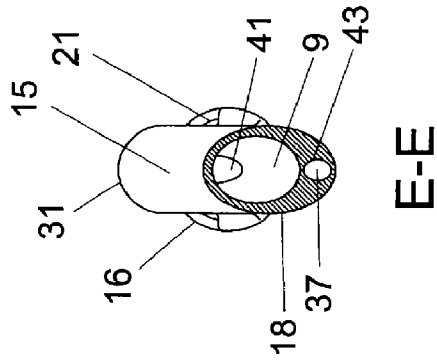


FIG. 3B

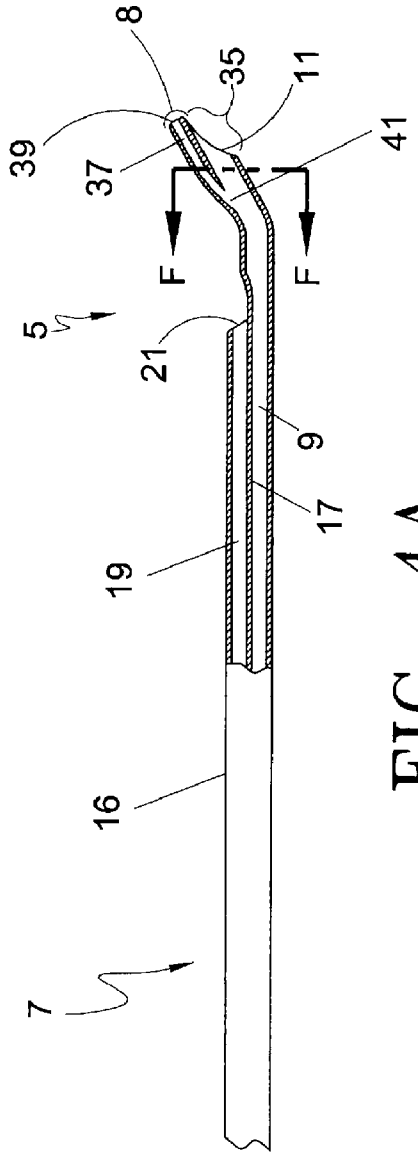
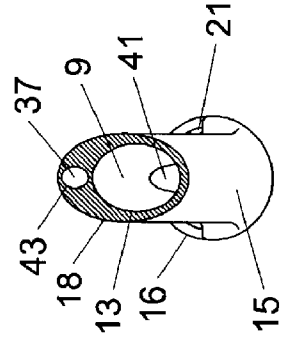


FIG. 4A



F-F

FIG. 4B

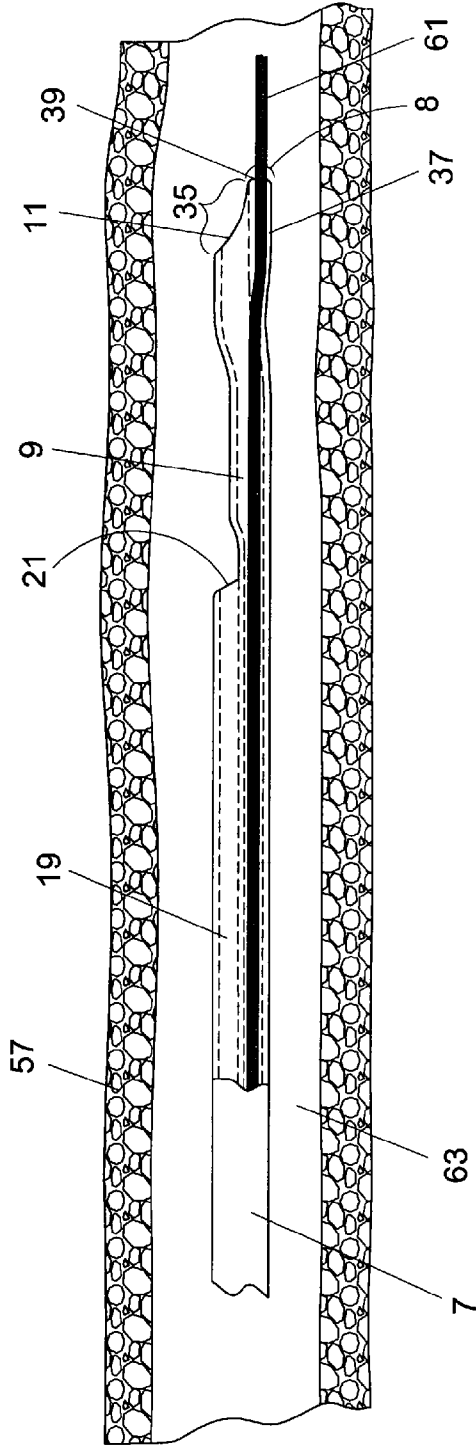


FIG. 5A

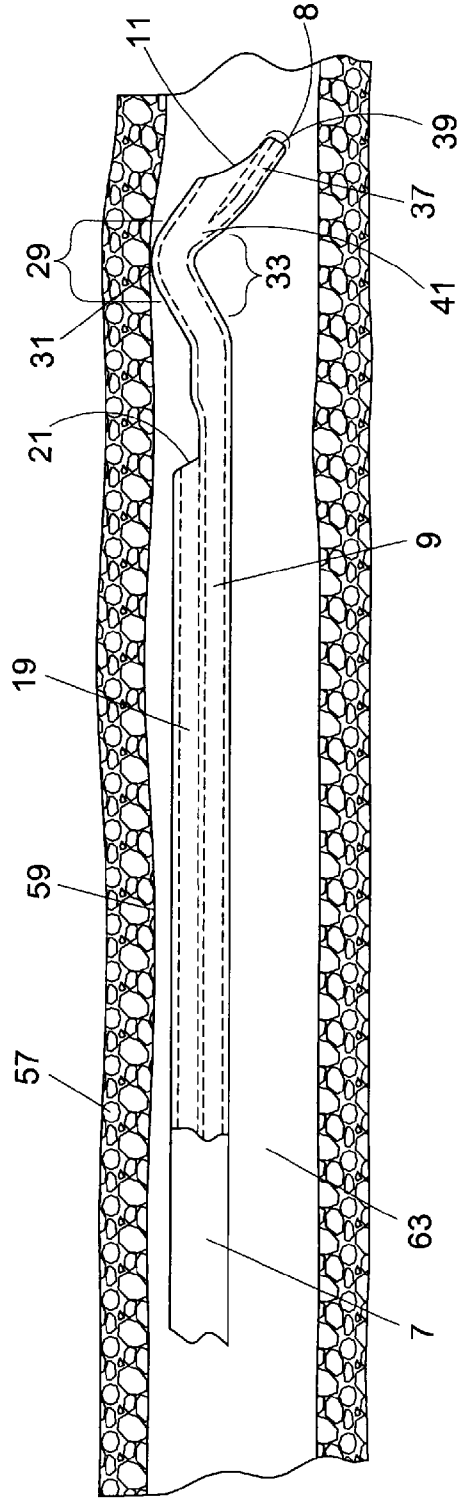
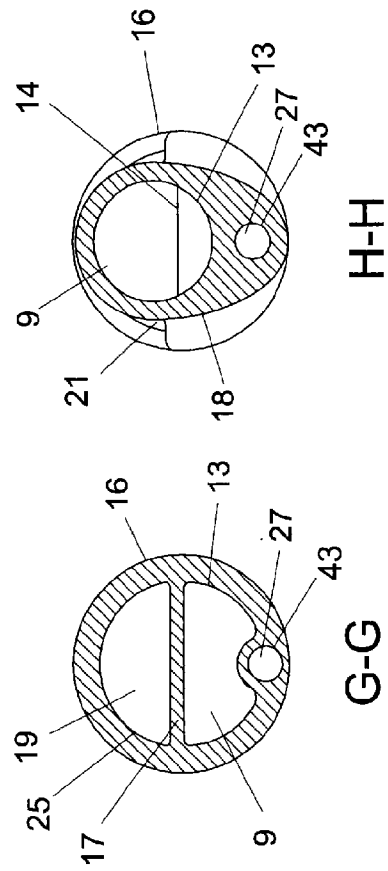
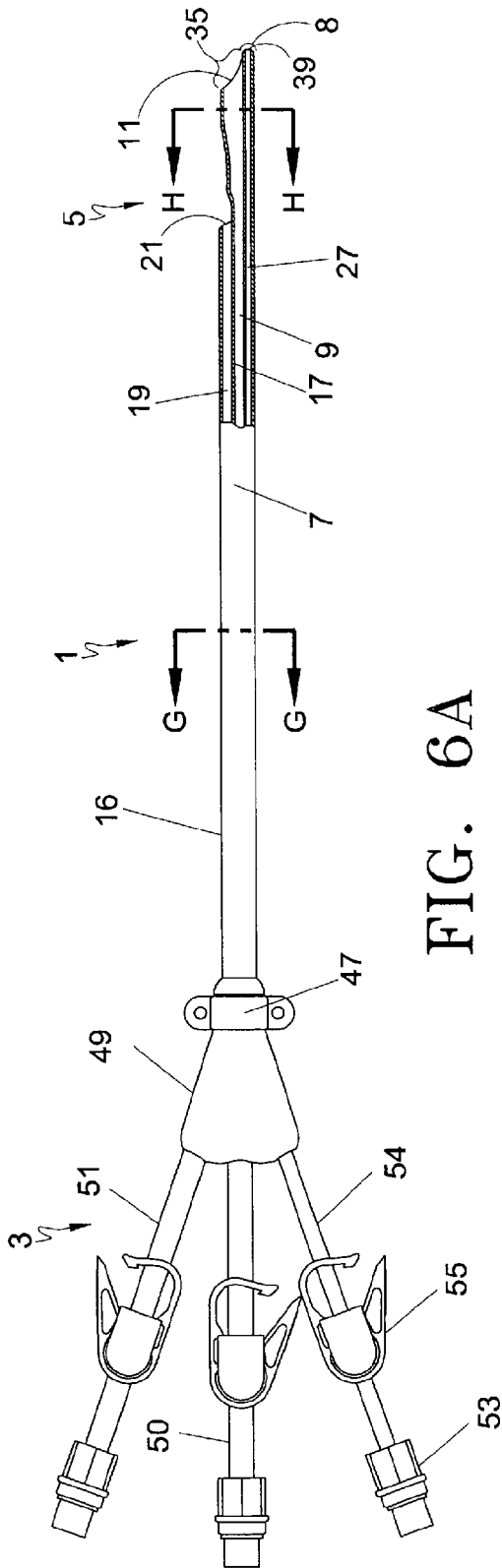


FIG. 5B



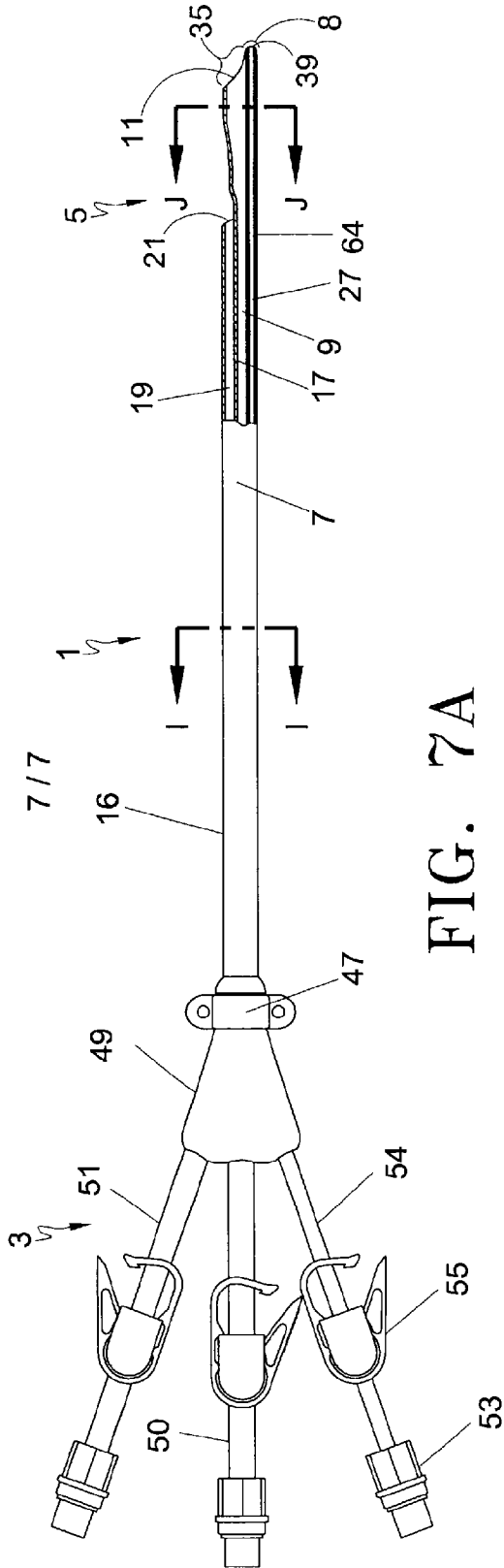


FIG. 7A

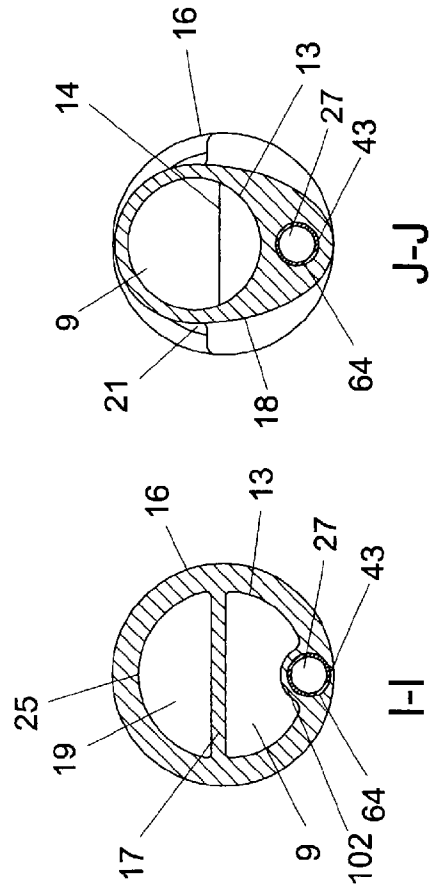


FIG. 7B



**CATHETER WITH OPEN FACED END PORTION**

**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] Not Applicable

**STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH**

[0002] Not Applicable

**THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT**

[0003] Not Applicable

**INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC**

[0004] Not Applicable

**BACKGROUND OF THE INVENTION**

[0005] 1. Field of the Invention

[0006] The present invention pertains to the field of medical devices. More particularly, the present invention relates to blood treatment catheters and a method of using such catheters.

[0007] 2. Description of the Related Art Including Information Disclosed Under 37 CFR 1.97 and 1.98

[0008] Hemodialysis is a method for removing waste products such as potassium and urea from the blood, such as in the case of renal failure. During hemodialysis, waste products that have accumulated in the blood because of kidney failure are transferred via mass transfer from the blood across a semi permeable dialysis membrane to a balanced salt solution. The efficiency of a hemodialysis procedure depends on the amount of blood brought into contact with the dialysis membrane. A flow of 250 milliliters of blood per minute under a pressure gradient of 100 millimeters of mercury is considered a minimum requirement for adequate dialysis. Over the past several years, flow rates between 350 milliliters per minute and 400 milliliters per minute have become common.

[0009] The long hours and the frequency of the dialysis treatment in patients with renal failure require reliable, continued access to the venous system for blood exchange. Long-term venous access mechanisms commonly used for hemodialysis treatment include vascular access ports, dialysis grafts, and hemodialysis catheters. One type of blood treatment catheter that is well-known in the art is a dual or triple-lumen hemodialysis catheter. These catheters are designed to provide long-term access to the venous system for dialysis. The dual-lumen catheter typically has an inflow lumen for withdrawing blood to be treated from a blood vessel and an outflow lumen for returning cleansed blood to the vessel. The distal segment of the catheter is preferably positioned at the junction of the superior vena cava and right atrium to obtain a blood flow of sufficient volume to accommodate dialysis treatment requirements. This allows blood to be simultaneously withdrawn from one lumen, to flow into the dialysis circuit, and be returned via the other lumen. Triple lumen catheters function in a similar manner but have an additional smaller lumen which may be used for guidewire insertion,

administration and withdrawal of fluids such as drugs or blood sampling, and for injection of contrast media required for imaging procedures.

[0010] To optimize blood flow rates during dialysis and reduce treatment times, catheters have been designed to maximize the cross-sectional lumen area of the inflow and outflow lumens. It is well known in the art that blood flow rates are negatively impacted if the cross-sectional area of the lumens does not remain essentially consistent and as large as possible throughout the entire length of the catheter from the proximal portion of the catheter to the distal portion of the catheter. Catheters with large, consistent luminal space typically have exit ports with blunt or flat-faced open tips, so as not to compromise the luminal area. Typically the exit port at the distal end of the catheter is cut at a 90 degree angle to the axis of the catheter.

[0011] While blunt, open ended catheters maintain optimal flow rates, they are difficult to insert into the patient because of their blunt leading ends. An introducer sheath will often be used to facilitate insertion. The introducer sheath has a dilating tip which is easily advanced through the track and into the vessel. The sheath has a large lumen into which the blunt-tipped catheter is inserted and advanced into the vessel. Although an introducer sheath may facilitate catheter placement, use of a sheath has several disadvantages. A sheath increases the risk of air embolism due to the presence of air gaps between the sheath and catheter. In addition, procedures that use an introducer sheath result in an enlarged insertion track due to the larger diameter of the sheath relative to the catheter. The use of a sheath also increases procedure time and costs.

[0012] A guidewire insertion technique is therefore often the preferred insertion technique for dialysis catheter placement. A guidewire is a thin, flexible wire that is usually made of stainless steel and has an atraumatic tip. A guidewire is typically inserted into a lumen of a dual or triple lumen catheter and then the catheter is advanced over the guidewire through the tissue track and into the vessel. The guidewire also provides additional stiffness or reinforcement in the wall of a catheter, to prevent kinking or accordioning of the catheter shaft as it is advanced through a tissue track and into a vessel.

[0013] If a guidewire is used for insertion of a blunt-end catheter with a large distal end opening, excess space will exist between the outer diameter of the guidewire and the inner diameter of the catheter lumen. A close fit between the lumen and the inserted guidewire is not dimensionally possible, thus leaving an annular gap between the guidewire and the distal opening of the catheter lumen. The excess annular space causes the leading distal edge of the catheter to accordion proximally over the guidewire during insertion, resulting in difficulties in advancing the catheter into the vessel. The distal portion of the catheter may grab or snare tissue as the practitioner attempts to advance the catheter into and through the vessel. This can increase procedure time, prevent the practitioner from reaching the intended target site within a patient vessel, or potentially cause other complications.

[0014] To overcome insertion difficulties common with inserting blunt tipped catheters, dialysis catheters have been designed with conical tapered distal portions that are narrower compared to the proximal portion of the catheter. The conical tip acts as a dilator to facilitate advancement of the catheter through the tissue track and into the vessel. These conical tip designs may include a guidewire lumen that exits

from the distal tip of the catheter through a guidewire opening of reduced diameter, typically 0.037 inches.

**[0015]** While conical, tapered tip designs address the problems associated with inserting blunt tip full lumen distal end designs, they are disadvantageous in that they do not allow for optimum flow rates due to the reduced lumen diameter at the distal tip. To overcome reduced flow rates, conical, tapered tip catheters have been designed with distal side facing ports or apertures cut through the catheter sidewall. The ports are located proximal to the conical tapered section and accordingly provide an exit channel from the lumen at a location where the cross-sectional area of the lumen has not been reduced.

**[0016]** Using side holes or apertures eliminates the problems of reduced flow rates but side-facing apertures are more likely to occlude than distally facing apertures. Those side holes located adjacent to the vessel wall are more likely to become blocked by the vessel wall, and are thus prone to clot-formation. In addition, the presence of side holes compromises the effectiveness of a fluid lock. A fluid lock, as known in the art, is used to prevent clot formation within the catheter between dialysis sessions. Typically, a heparin-saline fluid solution is infused into the full length of the catheter lumens. The fluid lock will only be effective up to the first proximal side hole, where the fluid will exit from the catheter and be replaced by blood. In the absence of the heparin-saline fluid solution, a portion of the lumen distal of the first side hole will become occluded by clot formation, complicating future dialysis sessions.

**[0017]** Another common complication of dialysis catheters is occlusion of the inflow and outflow apertures due to contact between the catheter and the vessel wall at the location of the apertures. During dialysis, negative pressure is generated within the inflow lumen in order to draw blood from the vessel through the lumen and into the dialysis machine. The suction created by the negative pressure may cause the catheter to move away from the center of the vessel and into contact with the vessel wall. The vessel wall essentially blocks the aperture, preventing further blood from being drawn into the inflow lumen. Although not as common, the outflow apertures may also come to rest up against the vessel wall, resulting in occlusion.

**[0018]** Thus, there exists a need in the art for a dual or triple lumen hemodialysis catheter that has a dilating distal tip that is not reduced in lumen cross-sectional area compared to the rest of the lumen. Such a lumen would be able to maintain consistent and optimal blood flow rates throughout the entire length of the catheter, eliminating the need for side hole ports. The catheter would have one lumen capable of receiving a guidewire that can provide enhanced guidewire tracking along various lengths of the catheter, thereby eliminating the need for an introducer sheath. The catheter would be designed to prevent occlusion of the blood lumen apertures by having a distal end shape that creates a barrier between the blood lumens and vessel wall.

**[0019]** A hemodialysis catheter has not yet been proposed that solves all of the above-mentioned problems. The present invention addresses problems with prior art catheters by providing a hemodialysis catheter that has at least two lumens, each with at least one aperture, and a distal portion that has one lumen with a substantially open sloped face distal end portion with a distal tip and consistent cross-sectional area compared to the rest of the lumen of the catheter, which allows for maximum blood flow. The catheter also has a third

lumen located adjacent the distal tip that is capable of receiving a guidewire. The guidewire aperture and the sloped face of the distal end portion facilitate insertion, without the use of an introducer sheath. The luminal cross-section area is maintained for the entire length of the catheter, eliminating the need for side holes, and thereby avoiding problems associated with compromised fluid lock and resulting side hole occlusion. The catheter **1** may optionally include a curved or bent distal end shape to prevent contact between the lumen apertures and the vessel wall.

**[0020]** Accordingly, it is a purpose of the present invention to provide a hemodialysis catheter that may have two or three lumens and a sloped open-faced distal end portion that provides for optimal blood flow rates by maintaining a uniform cross-sectional area throughout the lumen, eliminating the need for attachments or additional steps, thereby minimizing procedure time and improving patient treatment outcomes.

**[0021]** A further purpose of this invention is to provide a catheter that maintains the cross-sectional area of the blood lumen of the catheter without increasing the outer diameter of the catheter.

**[0022]** A further purpose of this invention is to provide a transitional guidewire lumen that is positioned at the distal most edge of the sloped distal end portion of the catheter that does not cause the overall outer diameter of the catheter to be increased.

**[0023]** A further purpose of this invention is to provide a catheter that is capable of receiving a guidewire in a third lumen that is designed for optimal guidewire tracking without requiring the use of an introducer sheath. The lumen may extend a partial length of the catheter, where it may be joined to another lumen, or it may extend substantially all the way through to the proximal end of the catheter, which may be useful for injections or infusion of drug treatments.

**[0024]** A further purpose of this invention is to provide a catheter that minimizes occlusion of the lumen apertures of the catheter by providing a substantially curved distal portion that abuts against the vessel wall while the catheter is deployed in a vessel. The abutting curved distal portion acts to guard one of the lumen apertures of the catheter from being occluded, which in turn, maintains maximum blood flow.

**[0025]** A further purpose of this invention is to provide a catheter that has a distal portion that allows for increased ease of insertion of the catheter into a vessel. The insertion is facilitated by straightening or flattening the distal portion of the catheter from a substantially curved to a straight configuration, which causes less resistance upon insertion. The distal portion of the catheter is more flexible, compared to the rest of the catheter, which helps to facilitate straightening of the distal portion. The flexibility of the distal portion of the catheter allows the distal portion to return to its original configuration after the guidewire is removed.

**[0026]** It is a further purpose of this invention to provide a catheter that maximizes flow rates without requiring side hole ports.

**[0027]** It is yet another purpose of this invention to provide a non-conical distal end portion catheter that may be placed without the use of an introducer sheath.

**[0028]** Various other objectives and advantages of the present invention will become apparent to those skilled in the art as more detailed description is set forth below. Without limiting the scope of the invention, a brief summary of some of the claimed embodiments of the invention is set forth below. Additional details of the summarized embodiments of

the invention and/or additional embodiments of the invention may be found in the Detailed Description of the Invention.

#### BRIEF SUMMARY OF THE INVENTION

**[0029]** The present invention is advantageous over the prior art because it provides a dual or triple lumen catheter with a substantially open lumen aperture at the distal portion of the catheter that allows for optimal blood flow by maintaining the lumen cross-sectional area throughout the entire catheter without increasing the outer diameter of the catheter. The need for supplemental side holes is eliminated because the cross-sectional area of the blood flow lumens is maintained.

**[0030]** The vascular access catheter of the present invention has a proximal portion and a distal portion. The distal portion of the catheter has a distal tip and a distal end portion, which is substantially sloped with a sloped face. The catheter includes at least two lumens, each lumen having at least one aperture that communicates between the lumen and the exterior of the lumen. The catheter has a first lumen aperture, which is substantially completely open in the sloped face and exits the distal portion adjacent the distal tip. A third lumen is located at least in the region of the distal portion of the catheter. The third lumen is capable of receiving a guidewire and has a proximal aperture and a distal aperture which exits the distal portion distally of the first lumen aperture.

**[0031]** The first lumen may function as an outflow lumen, and the second lumen may function as an inflow lumen, but these functionalities may be interchanged between the first lumen and the second lumen. The inflow lumen aperture of the catheter is spaced proximally of the outflow aperture to minimize re-circulation. The cross-sectional area of each lumen is substantially uniform throughout the entire length of the catheter. The catheter optionally provides a substantially curved distal portion which serves as a guard against occlusion of the catheter lumens.

**[0032]** The third guidewire lumen extends distally adjacent the substantially open outflow lumen aperture, either partially or substantially completely throughout the entire catheter, thereby providing enhanced guidewire tracking capabilities and eliminating the need for an introducer sheath. The guidewire lumen also allows the curved distal portion of the catheter to be straightened for easier insertion. The distal end portion of the catheter has a forward-facing sloped surface profile, instead of a blunt face, to facilitate catheter insertion and advancement, as well as to assist in orienting the catheter end portion once in a vessel.

#### BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

**[0033]** The foregoing advantages and features, as well as other advantages and features, will become apparent with reference to the description and accompanying figures below, which are included to provide an understanding of the invention and constitute a part of the specification, in which like numerals represent like elements, and in which:

**[0034]** FIG. 1 is a plan view of the catheter and a partial cross-sectional view of the distal portion of the catheter, in accordance with the present invention.

**[0035]** FIG. 2A is an enlarged partial cross-sectional view of the distal portion of the catheter of FIG. 1, in accordance with the present invention.

**[0036]** FIG. 2B illustrates three different cross-sectional views of the catheter shaft and one cross-sectional end view of

the catheter of FIG. 2A along lines A-A, B-B, C-C, and D-D, respectively, in accordance with the present invention.

**[0037]** FIG. 3A is an enlarged partial cross-sectional view of an additional embodiment of the catheter with a curved distal portion, in accordance with the present invention.

**[0038]** FIG. 3B is a cross-sectional end view of the curved distal portion of the catheter of FIG. 3A, in accordance with the present invention.

**[0039]** FIG. 4A is a partial cross-sectional view of an additional embodiment of the catheter with a curved distal portion, in accordance with the present invention.

**[0040]** FIG. 4B is a cross-sectional end view of the curved distal portion of the catheter of FIG. 4A, in accordance with the present invention.

**[0041]** FIG. 5A is a partial cross-sectional side view of the catheter of FIGS. 3A and 3B, while deployed inside a vessel with a guidewire inserted into the catheter, in accordance with the present invention.

**[0042]** FIG. 5B is a partial cross-sectional side view of the catheter of FIG. 5A after the guidewire has been removed from the catheter, in accordance with the present invention.

**[0043]** FIG. 6A is a plan view of a triple lumen catheter and a partial cross-sectional view of the distal portion, in accordance with the present invention.

**[0044]** FIG. 6B illustrates two different cross-sectional views of the catheter shaft of FIG. 6A, along lines G-G and H-H, respectively, in accordance with the present invention.

**[0045]** FIG. 7A is a plan view of an additional embodiment of a triple lumen catheter and a partial cross-sectional view of the distal portion, in accordance with the present invention.

**[0046]** FIG. 7B illustrates two different cross-sectional views of the catheter of FIG. 7A at the catheter shaft, along lines I-I and J-J, respectively, in accordance with the present invention.

#### DETAILED DESCRIPTION

**[0047]** The following detailed description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict selected preferred embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention.

**[0048]** The present invention pertains to a hemodialysis catheter and a method of inserting the catheter in the body of a patient. The hemodialysis catheter of the present invention is illustrated in FIGS. 1-7.

**[0049]** FIG. 1 illustrates one embodiment of the hemodialysis catheter of the present invention. The unitary catheter 1 has a proximal portion 3 and a distal portion 5. In this embodiment, the distal portion 5 of the catheter 1 is substantially straight. The proximal portion 3 of the catheter 1 is comprised of a bifurcate 49, a suture ring 47 coaxially arranged around the distal portion of the bifurcate 49, a pair of extension tubes 50, 51, extension tube clamps 55, catheter hub connectors 53 for connection to a dialysis machine, and a catheter shaft 7 which extends from the bifurcate 49 to the distal tip 8 at the distal portion 5 of the catheter 1.

**[0050]** Catheter shaft 7 is a tubular structure comprised of an outer wall 16 and two longitudinal lumens 19 and 9 extending substantially the entire length of the catheter shaft 7. Lumen 19 is in fluid communication with extension tube 51, and lumen 9 is in fluid communication with extension tube

**50.** Both extension tubes **50**, **51** communicate through bifurcate **49**. Blood is typically withdrawn from the vessel into lumen **19** where it is passed through the extension tube **51** into the dialysis machine. Blood is returned to the patient through extension tube **50** into lumen **9** which exits through the distal aperture **11** into the vessel.

**[0051]** The outer diameter of the catheter **1** is approximately 0.203 inches, although other diameter catheters are within the scope of this invention. The usable length of the catheter **1**, as measured from the distal end of bifurcate **49** to the distal tip **8**, is between approximately 20 cm to 55 cm, depending on the patient's anatomy and physician preference. Preferably, the catheter **1** usable length is between approximately 32 and 36 cm.

**[0052]** The catheter **1** of the present invention is a unitary catheter composed of carbothane, but any suitable material may be used, such as, but not limited to, polyurethane or silicone. The catheter **1** of the present invention may also contain a radiopaque material to enhance visibility under fluoroscopy. The catheter shaft **7** is preferably more flexible at its distal portion **5** than its proximal portion **3** because the distal portion **5** is of a reduced diameter and is formed with less material, compared to the proximal portion **3**. The catheter shaft **7** may optionally be comprised of materials of different durometers to produce a shaft **7** with enhanced flexibility at the distal portion **5**. It is preferable that the catheter shaft **7** be stiffer at the proximal portion **3** outside of the patient's body for durability and more flexible at the distal portion **5** to facilitate insertion of the catheter **1** and to provide a catheter **1** with an atraumatic tip, when placed within a vessel.

**[0053]** The catheter **1** has an inflow lumen **19** that exits the distal portion **5** of the catheter **1** through an inflow aperture **21**. The inflow lumen **19** is typically used for withdrawal of blood from the patient. The inflow aperture **21** is forward-facing, as defined by an angle greater than about 90 degrees proximally from the axis of the catheter **1**. The catheter **1** also has an outflow lumen **9** which is typically used for delivering cleansed blood back into the patient's circulatory system. Blood exits the distal portion **5** of the catheter **1** through outflow aperture **11**, located distally of the inflow aperture **21**. The two lumens **9** and **19** are separated along their longitudinal length by dividing wall **17**. Although designated herein as inflow and outflow lumens, dialysis may be performed by reversing the blood flow through the lumens. Hence, the terms first lumen and second lumen may also be used herein to designate the interchangeability of the outflow and inflow lumens, respectively.

**[0054]** The catheter **1** has a third guidewire lumen **37** that is located at least in the region of the distal portion **5**. The guidewire lumen **37** extends proximally from guidewire exit aperture **39** to proximal guidewire aperture **41** where lumen **37** terminates within outflow lumen **9**. The guidewire lumen **37** is capable of slidably receiving a guidewire (not shown). The guidewire lumen **37** provides a guidewire track for the guidewire to facilitate insertion of the catheter **1** through tissue into the target vessel. In this embodiment, the guidewire lumen **37** extends a partial length of the catheter **1**. For instance, the length of the guidewire lumen **37** may be between approximately 3 mm and 10 mm, and preferably between approximately 6 mm and 7 mm in length. The inner diameter of guidewire lumen **37** may be approximately 0.037 inches so as to accommodate a guidewire with an outer diameter of approximately 0.035 inches.

**[0055]** The distal tip **8**, outflow aperture **11**, and the guidewire exit aperture **39** define the sloped distal end portion **35** of the distal portion **5** of the catheter **1**. Sloped, as it pertains to the description herein, means that distal end portion **35** has an edge that is not at a perpendicular angle to the axis of the catheter **1**, and could include end portions **35** defined by flat, arcuate, or extended arcuate surfaces. The sloped distal end portion **35** which extends from the proximal most edge of the outflow lumen aperture **11** to the distal most edge of the third lumen **37** is approximately 5 mm, although the length will vary based on the angle of the slope. The angle of the sloped distal end portion **35** may be between approximately 15 degrees and 75 degrees from the axis of the catheter **1**. Preferably, the sloped distal end portion **35** is approximately 30 degrees relative to the axis of the catheter **1**.

**[0056]** In a key aspect of this invention, the sloped distal end portion **35** acts as a dilator to provide enhanced insertion and tracking functionality without compromising flow rates, as will be explained in greater detail below.

**[0057]** Distal portion **5**, defined as the length between the distal most edge of the inflow aperture **21** and the distal most edge of the guidewire exit aperture **39**, is approximately 2.5 cm, and in the depicted embodiment in FIG. 1, is substantially straight. The length between the distal most edge of the inflow aperture **21** and the proximal most edge of the outflow lumen aperture **11** is approximately 2 cm, so as to provide sufficient separation between the two lumens to minimize re-circulation of blood during dialysis. Recirculation is a complication of dialysis in which treated blood exiting from the outflow aperture **11** is pulled back into the catheter **1** through the inflow aperture **21** and re-processed by the dialysis machine. Recirculation reduces the efficiency of the cleansing process and results in inadequate dialysis if recirculation rates are too high. By spacing the inflow aperture **21** and outflow aperture **11** sufficiently apart, the recirculation rate during treatment is reduced to an acceptable level.

**[0058]** FIG. 2A illustrates an enlarged sectional view of the distal portion **5** of the catheter shaft **7** of FIG. 1. The outer wall **16** of the proximal portion **3** of the catheter shaft **7** surrounds an outflow lumen **9** and an inflow lumen **19**, which are separated by a dividing wall **17**. The outflow lumen **9** extends from the proximal most end of the catheter shaft **7** to aperture **11**, located in sloped distal end portion **35**. Inflow lumen **19** extends distally from the proximal most end of catheter shaft **7** to inflow aperture **21**.

**[0059]** The distal portion **5** of the catheter **1** includes a sloped distal end portion **35**, which is comprised of distal tip **8**, guidewire exit aperture **39**, and outflow lumen aperture **11**. The sloped profile of distal end portion **35** performs several key functions. The forward-facing slope provides a tapered leading edge to facilitate insertion and advancement of the catheter **1**. The forward-facing orientation of the slope is also advantageous in that it is angled away from the vessel wall to minimize engagement with the vessel wall, once inserted. The distal-most leading edge of the sloped end portion **35** terminates in a guidewire exit aperture **39** for optimized guidewire tracking. Distal end portion **35** also includes a forward-facing, full size outflow lumen **11**. Thus, in a key aspect of the invention, the sloped distal end portion **35** combines the features of a distal end profile capable of tracking over a guidewire and dilating the insertion track as well as minimizing vessel wall contact with an aperture that is not reduced in cross-sectional area.

[0060] The partial transitional guidewire lumen 37 that is adapted for insertion of a guidewire (not shown), allows for ease of insertion of the guidewire into the catheter 1 and also allows ease of insertion of the catheter 1 into a vessel over the guidewire. The guidewire lumen 37 has an inner diameter of approximately 0.037 inches, which closely fits around an inserted guidewire of approximately 0.035 inches. These dimensions allow the guidewire to slide within the lumen 37, while eliminating space between the outer diameter of the guidewire and the inner diameter of the lumen 37. This enhanced guidewire tracking prevents tissue from being snagged during advancement of the catheter 1 into a target location, and it provides a dilating function, thereby reducing trauma and tissue disruption to the vessel. The guidewire and catheter 1 may therefore be easily inserted into a vessel without requiring the use of an introducer sheath. Eliminating the introducer sheath is advantageous in several aspects, including reduced procedure time and costs, and minimized risk of air embolism due to absence of air gaps between the sheath and the catheter 1.

[0061] The transitional partial guidewire lumen 37 is also advantageous because, in addition to providing enhanced guidewire tracking, the outer diameter of the catheter 1 does not have to be increased to accommodate the partial lumen 37 adjacent to the outflow lumen aperture 11 at the distal most edge of the distal tip 8. This allows the cross-sectional area of the outflow lumen 9 to be maintained and provides for maximum blood flow.

[0062] FIG. 2B illustrates four different cross-sectional views of the catheter shaft 7 of the first embodiment. The lumen configuration of the catheter 1 transitions from a double-D lumen, illustrated along line A-A, to a single-D lumen, illustrated along line B-B, to a single round outflow lumen 9 illustrated along line C-C, finally ending in a single round outflow lumen 9 at the distal most tip of the catheter 1, with a guidewire lumen 37 located adjacent the outflow lumen 9, which is illustrated along line D-D.

[0063] The first cross-sectional view, A-A, illustrates the double-D lumen configuration of the catheter shaft 7 which extends to just proximal of line B-B, where the inflow lumen 19 terminates at aperture 21. Although the lumens of the catheter 1 of the present invention preferably have a double-D configuration, the catheter 1 may have any suitable cross-sectional lumen shape as required for the particular use of the catheter 1. The advantage of a double-D lumen configuration is that it allows for maximal flow rates for a catheter 1 circular in cross-sectional profile, which fact is well known in the art. The outflow lumen 9 and the inflow lumen 19 are shown separated by a dividing wall 17. The outflow lumen 9 has an inner wall 13. The inflow lumen 19 has an inner wall 25. As illustrated in line A-A, the dividing wall 17 has a width of approximately 0.144 inches. In this embodiment, the preferred height of each double-D lumen is approximately 0.064 inches.

[0064] A cross-sectional view of line B-B in the distal portion 5 of the catheter 1 is also illustrated. Outer wall 16 and inner wall 25 define the inflow lumen 19, which is shown as an end view, terminating proximally of line B-B. The outflow lumen 9 extends distally of the inflow lumen 19, which terminates at inflow aperture 21, proximal to line B-B. At the termination point of inflow aperture 21, the double-D lumen also terminates and is continued as a single-D lumen 9.

[0065] At line C-C, the single-D shaped lumen has transitioned to a single round shaped outflow lumen 9. In this view,

the transitional wall 14 represents the inner wall of the dividing wall 17 of the outflow lumen 9 at the double-D lumen section. At line C-C, the outflow lumen 9 has an inner diameter of approximately 0.095 inches and an outer diameter of approximately 0.140 inches. The rounded outer profile of the catheter shaft 7 at line C-C is of a smaller outer cross-sectional diameter than the cross-sectional diameter of the catheter shaft 7 at line B-B, which measures 0.203 inches. The reduced diameter facilitates insertion and advancement of the distal end of the catheter 1 through the tissue track and into the vessel.

[0066] A cross-sectional end view of the catheter 1, as taken along line D-D, is also illustrated. The cross-sectional end view, taken along lines D-D of FIG. 2B illustrates the guidewire lumen 37. Lumen 37 has a substantially circular shape defined by an inner wall 43. The inner diameter of the guidewire lumen 37 is approximately 0.037 inches. The guidewire lumen 37 is capable of receiving a guidewire that is approximately 0.035 inches.

[0067] Lumen 37 is surrounded by an expanded guidewire wall segment 100 which separates lumen 37 from outflow lumen 9. Wall segment 100 may be formed using several techniques well known in the art including re-forming existing shaft material, or using a supplemental tip-forming or a molding process. In a key aspect of the invention, lumen 37 is positioned within guidewire wall segment 100 to ensure that the cross-sectional area of outflow lumen 9 at the sloped distal end portion 35 is equivalent to the proximal portion 3 of the lumen 9.

[0068] The catheter 1 of the present invention is advantageous because although the profiles of the lumens 19 and 9 change at different sections of the catheter 1, the cross-sectional lumen areas are maintained throughout the length of the catheter 1. Specifically, the cross-sectional area of each of the double-D lumens, taken along line A-A, which is approximately 0.00702 inches<sup>2</sup>, is substantially equal to the cross-sectional area of the catheter 1 taken along line D-D, which is approximately 0.00708 inches<sup>2</sup>. This substantially equivalent cross-sectional area allows for optimal and consistent blood flow within the catheter 1 throughout treatment of the patient.

[0069] In addition, unlike current unitary catheter designs, the catheter 1 of the current invention allows for insertion over a guidewire utilizing a leading distal end guidewire aperture without increasing the overall diameter of the catheter 1 and without compromising the cross-sectional luminal area of the outflow lumen 9. The cross-sectional diameter of the sloped distal portion 35 taken along the axis of the catheter shaft 7 is preferably 0.160 inches, but may range from 0.150 to 0.180 inches. The reduced cross-sectional diameter of the outflow lumen 9 at line D-D, which is approximately 0.043 inches less than the proximal portion 3 of the catheter shaft 7, which has a cross-sectional diameter of approximately 0.203 inches, which thus facilitates insertion and advancement of the catheter 1 into a patient's body without compromising the cross-sectional luminal area of the outflow lumen 9.

[0070] Accordingly, in one aspect of the invention, a catheter 1 with a non-conical sloped dilating distal portion 35 is provided that maintains a consistent, uniform luminal area throughout the entire length of the catheter shaft 7. The substantially completely open sloped face geometry of the outflow lumen aperture 11 of the distal tip 8 allows for maximum blood flow because the cross-sectional area of the outflow lumen 9 is maintained from the proximal portion 3 to the distal portion 5 of the catheter 1, while the outer diameter of

the catheter **1** is not increased. Because of its size and orientation, the outflow lumen aperture **11** is not likely to occlude, compared with typical conical-tapered or blunt tip catheters with smaller side wall lumen openings.

[0071] FIG. 3A illustrates another embodiment of the catheter **1** of the present invention. In this embodiment, the catheter shaft **7** has a double-D lumen configuration at its proximal portion **3**, which transitions to a circular configuration with inflow and outflow apertures, similar to the embodiment illustrated in FIG. 1. The catheter shaft **7** of FIG. 3A is different from FIG. 1 in that it has a substantially curved distal portion **5** instead of a straight distal portion **5**. The distal portion **5** of catheter shaft **7** may have any suitable curved shape configuration, including, but not limited to a curved, bent or semi-helical shape.

[0072] As further distinguished from the first embodiment of catheter **1** illustrated in FIGS. 1 and 2, the distal portion **5** of the catheter **1**, is defined by a guard portion **29**. The guard portion **29** has an apex **31**. The apex **31** is located at the outermost point of the guard portion **29** and is equal to or greater in height than the outer wall **16** of the inflow aperture **21**. The guard portion **29** is also defined by an inner angle **33** opposite the inflow apex **31**. The inner angle **33** may be between approximately 45 degrees and 135 degrees. Preferably, the inner angle **33** of the guard portion **29** is equal to or greater than about 90 degrees, depending on the curvature of the guard portion **29**. Most preferably, the inner angle is approximately 90 degrees. The curved distal portion **5** may have substantially straight portions on either side of the inner angle **33**, or the curved distal portion **5** may be a substantially continuous series of arcuate arcs.

[0073] FIG. 3B illustrates the distal portion **5** of the catheter **1** of FIG. 3A along line E-E. The apex **31** of the guard portion **29** is illustrated. The distal end of inflow aperture **21** is partially visible, being protected by apex **31**. The outer wall **15** of the distal portion **5** of the catheter **1** transitions into a shared outer wall **18** of the outflow lumen **9** and guidewire lumen **37**, which has an inside wall **43**. The transition point of the guidewire aperture **41**, where the guidewire lumen **37** joins the outflow lumen **9**, is visible inside of the outflow lumen **9**.

[0074] As shown in FIG. 3B, the space between the apex **31** and the outer wall **16** of the inflow aperture **21** functions as a guard to prevent aperture **21** from moving up against the vessel wall and potentially occluding the inflow aperture **21** as long as the height of the apex **31** is equal to or greater than the height of the outer wall **16** of inflow aperture **21**. When the negative pressure of a blood draw into the inflow lumen causes the catheter **1** to move toward the vessel wall, the apex **31** of the guard **29** will abut up against the vessel wall rather than the inflow aperture **21**. More specifically, the difference in height between the apex **31** of the guard portion **29** and the proximal most portion of the inflow aperture **21** helps the guard portion **29** to act as a guard and prevent inflow aperture **21** from contacting or resting against the vessel wall. Guard portion **29** thus functions to ensure that aperture **21** remains positioned away from the vessel wall so as to avoid being partially or completely blocked and compromising outcome of the treatment session.

[0075] Apex **31** provides an additional clinical advantage over prior art dialysis catheters. Apex **31**, with its extended height, provides a separating barrier between the inflow aperture **21** and the outflow aperture **9**, to further minimize mixing cleansed and uncleaned blood during a dialysis session and decreasing recirculation problems.

[0076] The guidewire lumen **37** shared outer wall **18**, combined with the forward-facing orientation of the sloped distal end portion **35** also protects the outflow aperture **11** from being blocked if the catheter **1** comes into contact with the vessel wall. Still referring to FIG. 3A, the catheter shaft **7** may be oriented such that it abuts the vessel wall at distal tip **8** rather than at apex **31**. In this orientation, the distal tip **8** with guidewire exit aperture **39** contacts with the vessel wall and provides a spacing function similar to the guard **29** to protect the outflow aperture **11** from contacting and being blocked by the vessel wall. The forward-facing angle of the sloped distal end portion **35** is oriented away from the vessel wall and will not become occluded by the vessel wall because it is protected by the distal tip **8**.

[0077] FIG. 4A illustrates yet another embodiment of catheter shaft **7** of the present invention. The substantially bent distal portion **5** of the catheter **1** of this embodiment defines an angle of greater than about 90 degrees from the axis of the catheter **1**, such that the distal tip **8** is greater in height than the proximal most edge of the inflow lumen aperture **21**. The advantages described above in relation to the embodiment of the distal portion **5** of the catheter **1** illustrated in FIGS. 3A and 3B also apply to the embodiment illustrated in FIGS. 4A and 4B. The embodiment illustrated in FIG. 4 has an additional clinical advantage of a more direct blood flow path through lumen **9** which may enhance flow rates during dialysis.

[0078] A method of inserting the catheter **1** of the present invention into a blood vessel is also disclosed herein and illustrated in FIGS. 5A and 5B. Although FIGS. 5A and 5B illustrate use of the catheter **1** embodied in FIGS. 3A and 3B, the method of inserting the catheter **1** may encompass the use of any of the embodiments of the catheter **1** described herein and illustrated in FIGS. 1 through 7. The method involves providing the catheter **1** described in any of FIGS. 1 through 7, inserting a guidewire **61** into a vessel **57** in a patient body; inserting the proximal end of the guidewire **61** into the guidewire exit aperture **39** of the guidewire lumen **37**; advancing the guidewire **61** through the guidewire lumen **37** and into the outflow lumen **9**; inserting the catheter **1** into a vessel **57** in a patient body over the guidewire **61**; positioning the distal portion of the catheter at a desired location within the target vessel **57**; and removing the guidewire **61** from the catheter. If the catheter **1** of the embodiments illustrated in any of FIG. 3 or 4 is used, the method may further involve providing a catheter with a substantially curved or bent distal portion **5**. The method may further involve straightening the distal portion of the catheter upon insertion of the guidewire **61** into the guidewire lumen **37**. After the guidewire **61** is inserted into the guidewire lumen **37**, the entire inserted guidewire **61** and the distal portion of the catheter become approximately parallel with the axis of the catheter shaft **7**, as illustrated in FIG. 5A.

[0079] FIG. 5A illustrates the tapered profile of sloped distal end portion **35** with its leading distal tip **8**. This profile provides an atraumatic dilating function by gradually expanding the tissue track from the approximate size of a guidewire, typically 0.035 inches, to the slightly larger diameter of the distal tip **8**, to the diameter of the catheter shaft **7** at the proximal most edge of outflow aperture **11**, which is approximately 0.160 inches, to the maximum diameter of the catheter shaft **7** at inflow aperture **21**, which is approximately

0.203 inches. Because of the dilating profile of the catheter **1** of the current invention, use of an introducer sheath is not necessary.

[0080] FIG. 5B illustrates a partial sectional side view of the catheter of FIG. 5A deployed within a vessel **57** inside of a patient body after the guidewire **61** has been removed from the catheter shaft **7**. When the guidewire **61** is removed from the catheter shaft **7**, the distal portion of the catheter **1** then resumes its substantially curved configuration. The distal portion of the catheter has flexibility and a shaped memory, formed during the manufacturing process of the catheter, which allows the substantially curved distal portion of the catheter **1** to return to its original curved unstressed state after the guidewire **61** has been removed. Thus, the inner angle **33** of the guard portion **29** returns to an angle equal to or greater than about 90 degrees from the catheter shaft **7** axis.

[0081] When the catheter **1** is deployed in the vessel **57**, the catheter **1** may migrate from the center of the vessel lumen **63** and abut up against the inner wall **59** of the vessel **57**, as shown in FIG. 5B. The guard **29** contacts the inner vessel wall **59** at apex **31**. The apex **31** of the guard portion **29** acts as a shield, preventing the aperture **21** from being occluded by vessel wall **59**. It also provides a recirculation barrier between the inflow aperture **21** and the outflow aperture **11**.

[0082] Also shown in FIG. 5B, the guard **29** also acts to orient outflow aperture **11** more centrally within the vessel **57** where blood volume is highest, thereby further minimizing recirculation rates, increasing the efficiency of the dialysis session, and reducing vessel wall **59** trauma caused by sustained contact with the catheter.

[0083] FIG. 6A illustrates yet another embodiment of the catheter **1** at line G-G of the present invention. In this embodiment, the catheter **1** is identical to the embodiment illustrated in FIG. 1, except that the catheter **1** has a guidewire lumen **27** which extends substantially the entire length of the catheter **1** from the distal tip **8** to bifurcate **49**, where the guidewire **27** lumen fluidly joins to extension tube **54**.

[0084] FIG. 6B illustrates the cross-sectional area of the catheter **1** of FIG. 6A taken along line G-G and H-H. The cross-sectional view along line G-G illustrates the outflow lumen **9** and the inflow lumen **19** separated by a dividing wall **17** and a guidewire lumen **27** defined by an outer wall **43**. The outer diameter of the catheter **1** is approximately 0.203 inches, equivalent to previous embodiments. To accommodate the guidewire lumen **27** within the double-D section of the catheter **1** without increasing the outer diameter of the catheter **1**, the dividing wall **17** is positioned slightly off-center. This balances the cross-sectional area of each lumen providing consistent even flow in both directions. The resulting cross-sectional area of each lumen **19** and **9** is approximately 0.0065 inches<sup>2</sup>, which is approximately 0.00052 inches less than the transitional guidewire lumen embodiments previously illustrated. This luminal area reduction of 0.00052 is insignificant in terms of impact on flow rates.

[0085] Along line H-H at the distal portion **5** of the catheter **1**, the double-D lumen has transitioned to a single round outflow lumen **9**. Also illustrated along line H-H, the cross-sectional lumen area of outflow lumen **9** is maintained at its largest diameter to distal aperture **11**, as with the previous embodiments.

[0086] The embodiment illustrated in FIGS. 6A and 6B has several clinical advantages. The guidewire lumen **27**, which is fluidly connected with extension tube **54**, may be used for the delivery of drugs, injections of fluids, such as contrast media,

and for blood sampling, eliminating the need for the practitioner to place a secondary vascular access device. In addition, the cross-sectional luminal areas of previous embodiments are maintained without having to increase the outer diameter of the catheter **1**. The substantially straight shape of the catheter **1** provides for direct blood flow paths and optimal flow rates in addition to minimal guidewire friction in comparison to curved embodiments. The continuous guidewire lumen **27** allows for the guidewire exchange or re-insertion, if necessary, after the catheter **1** has been placed in a vessel. The distal portion **5** of the catheter **1** is concentrically aligned within the outer circumference of the proximal portion **3** of the catheter shaft **7**, as best illustrated in FIG. 6B, along line H-H. This alignment provides a structural barrier separating the inflow and outflow lumens **19** and **9**, thereby minimizing recirculation rates during the dialysis session.

[0087] In an alternative embodiment of the present invention, as illustrated in FIGS. 7A and 7B, the guidewire lumen **27** may have a liner **64** placed along the inner wall **43** of the lumen **27**. The liner **64** is a tubular structure that functions to increase the burst pressure of the guidewire lumen **27**. Burst pressure is defined herein as the amount of pressure that the lumen **27** may withstand during high pressure applications, such as contrast media injections, before rupturing. The liner **64** allows a higher burst pressure of the lumen **27** by providing a liner **64** material with a higher yield stress than the material of the catheter shaft **7**. The liner **64** may be made of any suitable material that may increase the burst pressure of the lumen **27**, such as, but not limited to nylon or polyamide. The liner **64** may also reduce friction over the guidewire **61**, thereby further enhancing guidewire **61** tracking capabilities of the lumen **27**.

[0088] The liner **64** may have a wall thickness of between approximately 0.002 and 0.005 inches. The liner **64** may optionally be constructed of a higher strength material than the catheter shaft **7**, so as to allow thinner surrounding catheter wall sections **102**, thereby minimizing reduction in luminal cross-sectional area of the inflow **19** and outflow **9** lumens. The liner **64** disclosed herein may also be placed inside of the partial guidewire lumen **37** described herein in the previous embodiments and illustrated in FIGS. 1 through 5.

[0089] The above disclosure is intended to be illustrative and not exhaustive. This description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein, which equivalents are also intended to be encompassed by the claims.

[0090] Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all prior claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction (e.g., each claim depending directly from claim **1** should be alternatively taken as depending from all previous claims). In jurisdictions

where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from a prior antecedent-possessing claim other than the specific claim listed in such dependent claim below.

[0091] This completes the description of the selected embodiments of the invention. Those skilled in the art may recognize other equivalents to the specific embodiments described herein which equivalents are intended to be encompassed by the claims attached hereto.

1-27. (canceled)

28. A method of inserting a vascular access catheter into a vessel, wherein the method comprises:

- a. providing a vascular access catheter, wherein the catheter comprises a proximal portion and a distal portion, wherein the distal portion has a distal end portion, and wherein the distal end portion has a distal tip and is substantially sloped with a sloped face; and at least two lumens, wherein each lumen has at least one aperture that communicates between the lumen and the exterior of the lumen: and a first lumen aperture, wherein the first lumen aperture exits the distal portion adjacent the distal tip, and wherein the first lumen aperture is substantially completely open in the sloped face; and a third lumen located at least in the region of the distal portion, wherein the third lumen is capable of receiving a guidewire, and wherein the third lumen has a proximal aperture and a distal aperture, and wherein the distal aperture of the third lumen exits the distal portion distally of the first lumen aperture; and

- b. inserting the guidewire into a vessel in a patient body; and
- c. inserting a guidewire into the distal aperture of the third lumen; and
- d. advancing the guidewire through the third lumen and into the first lumen; and
- e. inserting the catheter into a vessel in a patient body over the guidewire; and
- f. positioning the distal portion of the catheter at a desired location; and
- g. removing the guidewire from the third lumen.

29. The method of claim 28, further comprising providing a catheter, wherein the third lumen exits at the distal most edge of the sloped distal end portion.

30. The method of claim 28, further comprising providing a catheter, wherein the third lumen extends a partial length of the catheter.

31. The method of claim 28, further comprising providing a catheter, wherein the catheter comprises a substantially curved distal portion.

32. The method of claim 31, further comprising straightening the curved distal portion of the catheter upon insertion of the guidewire into the third lumen.

33. The catheter of claim 28, wherein the distal portion is substantially bent in its unstressed state.

34. The method of claim 33, further comprising straightening the bent distal portion of the catheter upon insertion of the guidewire into the third lumen.

35. The method of claim 28, further comprising providing a catheter, wherein the catheter is a hemodialysis catheter.

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