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(54) **SHEATH FOR USE IN PERIPHERAL INTERVENTIONS**

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(57) **ABSTRACT**

A dual lumen introducer sheath provides access to at least one renal artery and at least one peripheral blood vessel of a patient. The introducer sheath includes a proximal hub comprising first and second ports, a first lumen, and a second lumen. The first lumen extends from the first port to a first distal aperture and has sufficient length such that when the first port is positioned outside the patient the first distal aperture is positionable in the abdominal aorta at or near origins of the patient's renal arteries. The second lumen extends from the second port to a second distal aperture, has a shorter length than the length of the first lumen, and is configured to allow passage of a catheter device through the second lumen and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient.

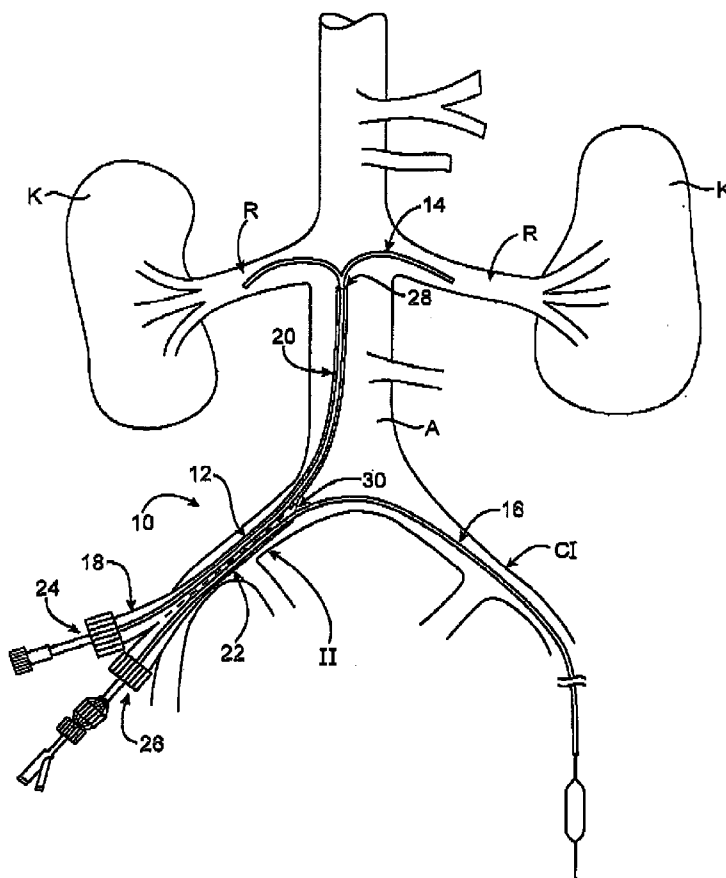
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**Related U.S. Application Data**

(60) Provisional application No. 60/550,632, filed on Mar. 4, 2004. Provisional application No. 60/550,774, filed on Mar. 5, 2004.



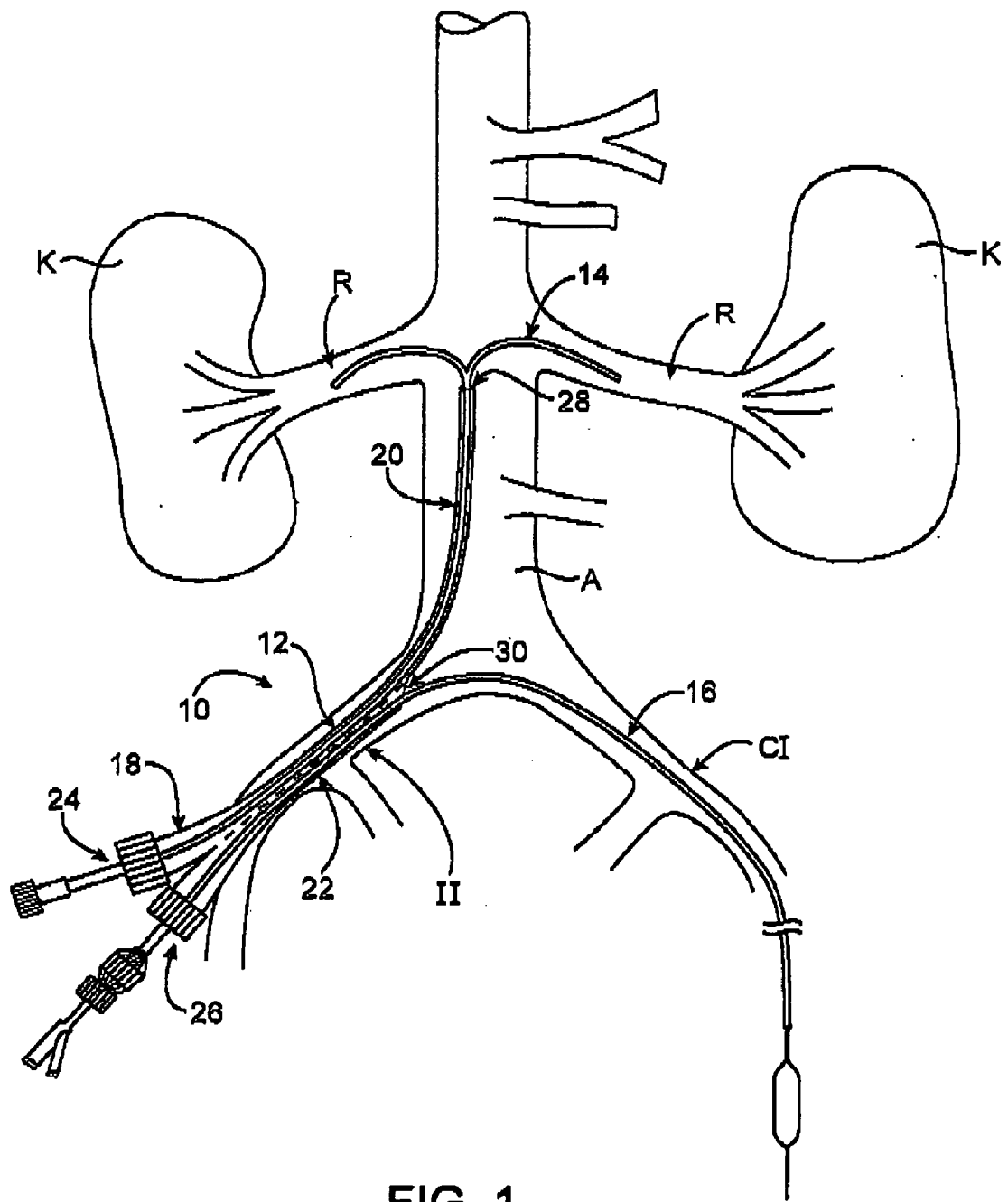


FIG. 1

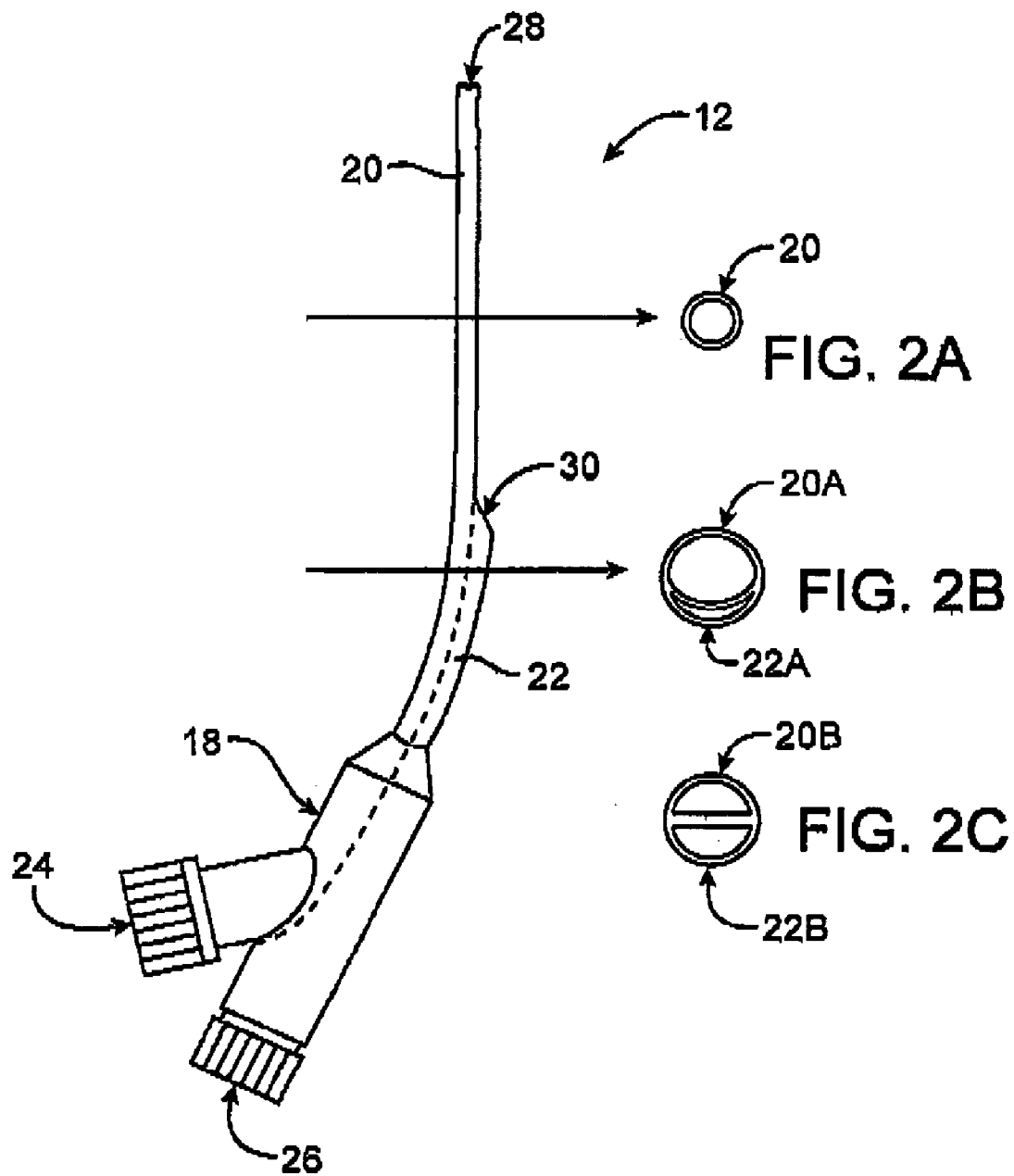


FIG. 2

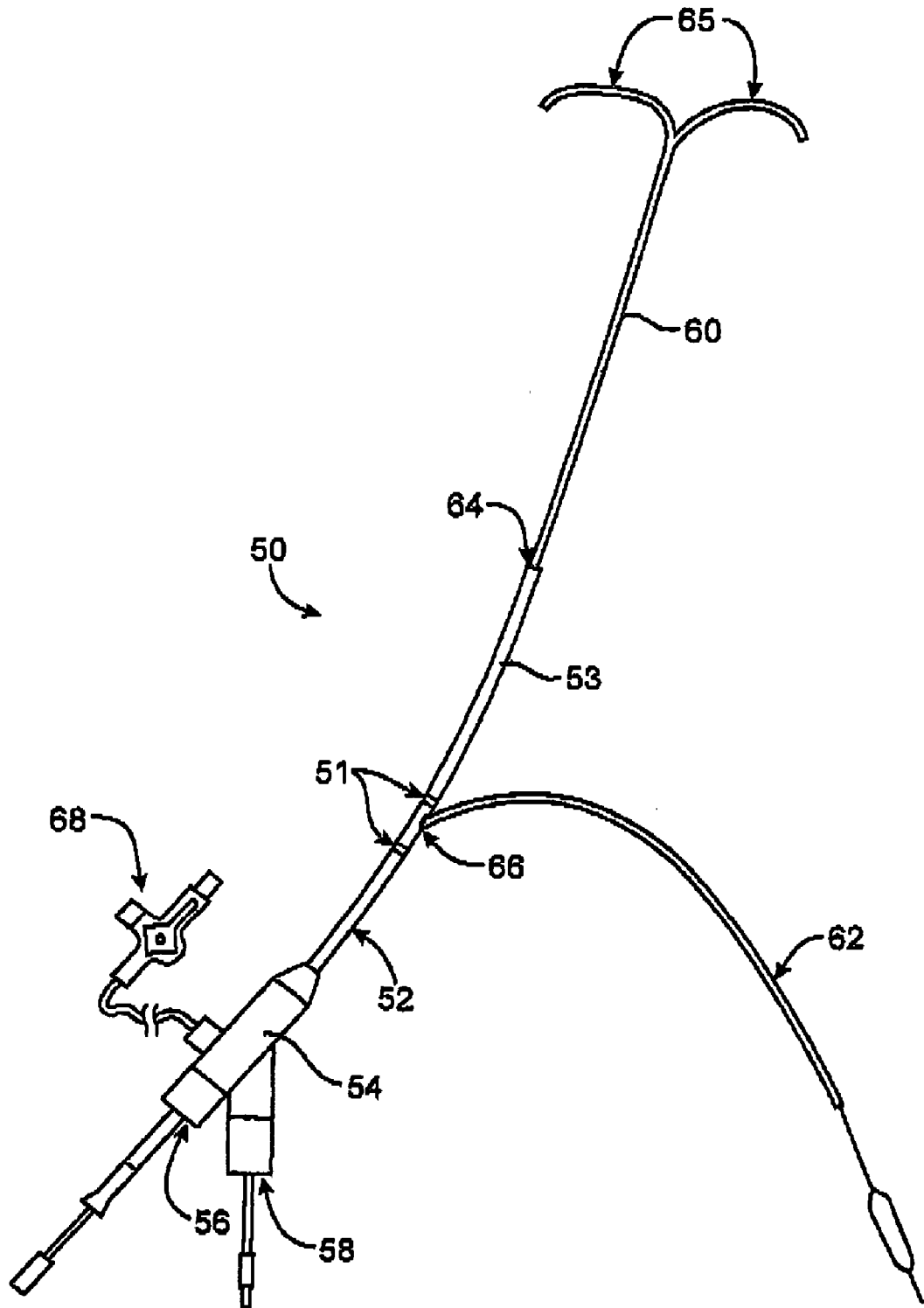


FIG. 3

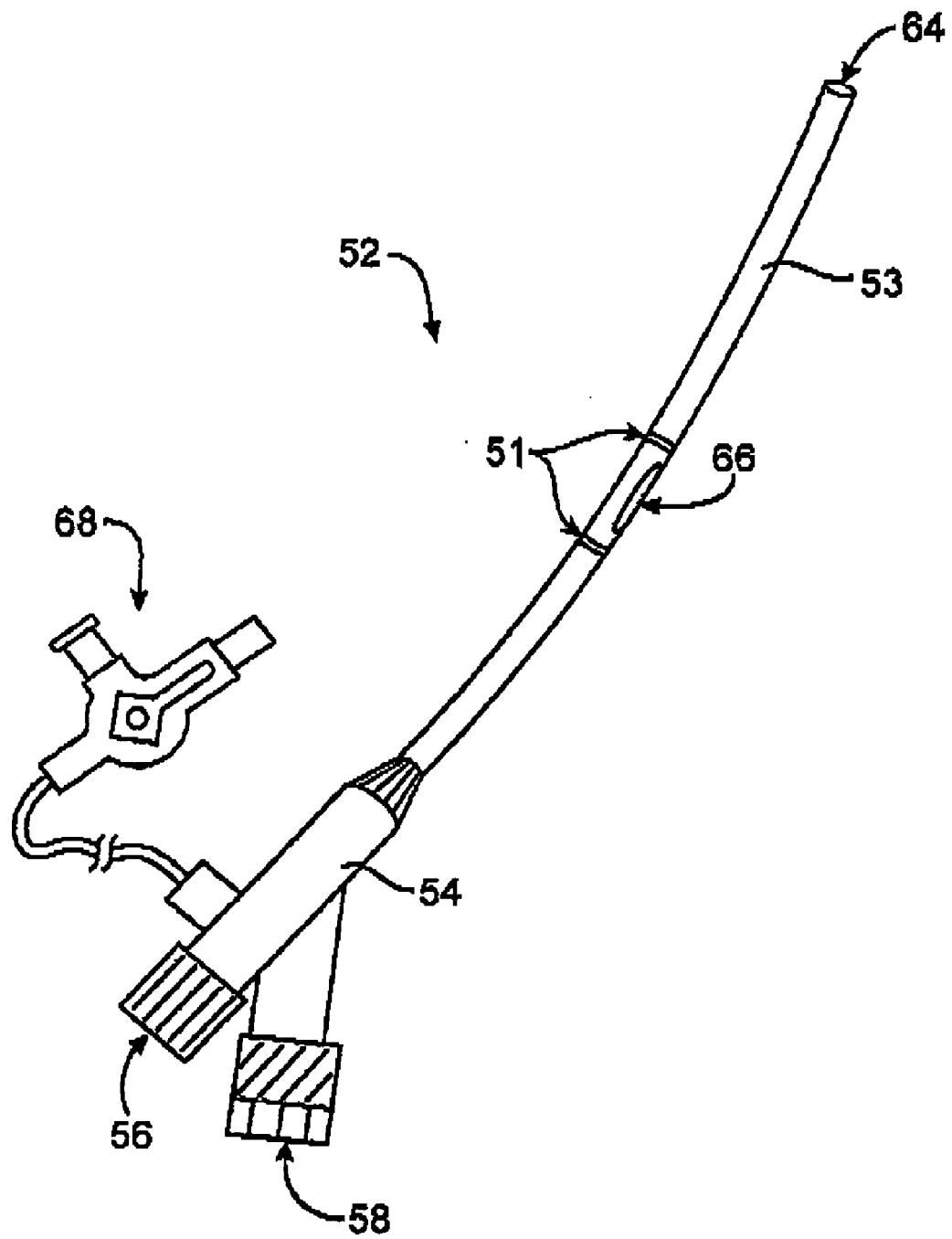


FIG. 4

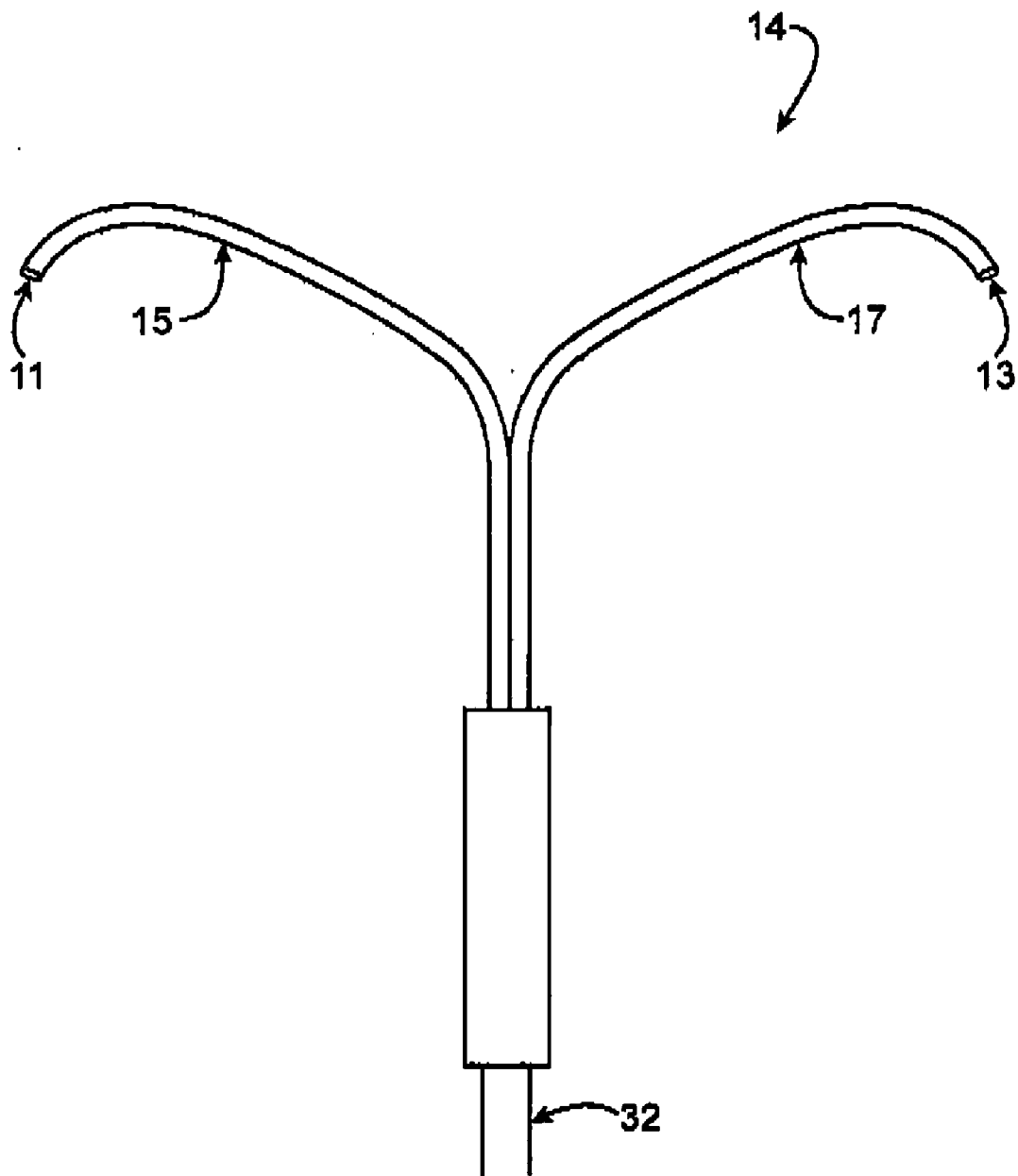


FIG. 5

## SHEATH FOR USE IN PERIPHERAL INTERVENTIONS

### CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims priority to U.S. Provisional Patent Application Nos.: 60/550,632 (original attorney docket number FLO5360.56P1), filed Mar. 4, 2004, and 60/550,774, (original attorney docket number FLO5360.56P2), filed Mar. 5, 2004, the full disclosures of which are hereby incorporated by reference.

### BACKGROUND OF THE INVENTION

[0002] The present invention is related to medical devices, methods and systems. More specifically, the invention is related to devices, methods and systems for accessing various blood vessels in a patient, such as one or both renal arteries and one or more peripheral vessels.

[0003] In the setting of interventional radiology, numerous conditions exist that warrant placement of various intravascular devices into the lower limb arteries (iliac, femoral, popliteal, etc.). Such devices may include catheters and guidewires for diagnostic purposes, or systems for therapeutic or prophylactic applications such as drug infusion, monitoring/sampling, angioplasty and stenting, possibly in conjunction with embolic protection. In any event, these procedures often involve the use of radiocontrast agents known to have detrimental effects on renal function.

[0004] In many instances, lower limb arteries intended for diagnosis or intervention are accessed via an "up-and-over" approach, which first involves gaining arterial access on one side of the patient, typically though not necessarily via a femoral artery. From that access point, one or more diagnostic, prophylactic, and/or treatment devices are advanced in a retrograde fashion through the iliac artery on the side of access to the aortic bifurcation and then down along the direction of blood flow on the contralateral side, through the contralateral iliac artery, into and possibly through the contralateral femoral artery, etc. to the site of treatment and/or diagnostic procedure. As mentioned above, performing the treatment and/or diagnostic procedure often involves injection of a radiocontrast agent to allow the physician(s) to visualize the treatment/diagnostic site.

[0005] The nephrotoxicity of radiocontrast agents has been well established. In patients with known risk factors, radiocontrast nephropathy (RCN) is a prevalent adverse effect of interventional procedures utilizing organically bound iodine-based contrast imaging agents. While the full mechanism of RCN is not known, its detrimental results on morbidity and mortality are well documented, and it is hypothesized that local agent administration to the renal arteries during the time of contrast media exposure may mitigate the development of RCN. Agents in this case may include vasodilators, diuretics, or hyper-oxygenated blood or blood substitute. As well as agent infusion, the exchange of blood laden with contrast media and replacement of it with filtered blood, via use of an external blood filter/pump might be warranted.

[0006] Various apparatus and methods for providing local delivery of substances to renal arteries have been described by the inventors of the present invention in U.S. patent appli-

cation Ser. No. 09/724,691 (Attorney Docket No. FLO5360.3A), filed Nov. 28, 2000; Ser. No. 10/422,624 (Attorney Docket No. FLO5360.03.A1), filed Apr. 23, 2003; Ser. No. 10/251,915 (Attorney Docket No. FLO5360.05A), filed Sep. 20, 2002; Ser. No. 10/636,359 (Attorney Docket No. FLO5360.05A1), filed Aug. 6, 2003; and Ser. No. 10/636,801 (Attorney Docket No. FLO5360.05A2), filed Aug. 6, 2003, the full disclosures of which are all incorporated herein by reference. Apparatus and methods for renal delivery of substances have also been described in PCT Patent Application Nos.: PCT/US03/029744 (Attorney Docket No. FLO5360.48FP), filed Sep. 22, 2003; PCT/US03/29995 (Attorney Docket No. FLO5360.49FP), filed Sep. 22, 2003; PCT/US03/29743 (Attorney Docket No. FLO5360.50FP), filed Sep. 22, 2003; and PCT/US03/29585 (Attorney Docket No. FLO5360.51FP), filed Sep. 22, 2003, the full disclosures of which are all incorporated herein by reference.

[0007] For the reasons described above, in some diagnostic and treatment procedures performed in the peripheral vasculature, especially in patients with renal risk factors, it may be desirable to concurrently provide for a means of renal protection via site-specific agent delivery to the renal arteries. Thus, a need exists for devices, methods and systems that provide access to one or more renal arteries and to one or more peripheral vessels. Ideally, such devices, methods and systems would allow for access and substance delivery through a common introducer device that provides access via a femoral artery. At least some of these objectives will be met by the present invention.

### BRIEF SUMMARY OF THE INVENTION

[0008] In one aspect of the present invention, a single lumen introducer sheath for accessing at least one renal artery and at least one peripheral blood vessel of a patient includes a proximal hub comprising first and second ports and a lumen extending from the ports and having proximal and distal apertures. The lumen extends from the first and second ports and has sufficient length such that when the ports are positioned outside the patient a distal end of the lumen is positionable in the abdominal aorta at or near origins of the patient's renal arteries. The proximal aperture in the lumen is configured to allow passage of a vascular catheter device through the proximal aperture and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient. The distal aperture at the distal end of the lumen is configured to allow passage of a bifurcated renal catheter device out of the distal aperture to enter at least one of the renal arteries. Typically, though not necessarily, the proximal aperture comprises a side aperture in the lumen.

[0009] For purposes of the present application, the term "contralateral" refers to the side of the patient that is opposite the side in which an introducer sheath is placed. Various embodiments of the sheath described herein may be placed on either side of a patient, typically though not necessarily via a femoral artery access site. Thus, in one example where a sheath is inserted into a patient's right femoral artery, then the left side of the patient's body would be the contralateral side. If a sheath is inserted into a patient's left femoral artery, then the contralateral side is the right side.

[0010] In another aspect of the present invention, a dual lumen introducer sheath for accessing at least one renal

artery and at least one peripheral blood vessel of a patient includes a proximal hub comprising first and second ports, a first lumen, and a second lumen. The first lumen extends from the first port to a first distal aperture and has sufficient length such that when the first port is positioned outside the patient the first distal aperture is positionable in the abdominal aorta at or near origins of the patient's renal arteries. The second lumen extends from the second port to a second distal aperture and has a shorter length than the length of the first lumen. The second lumen is configured to allow passage of a catheter device through the second lumen and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient.

**[0011]** In some embodiments, the first and second lumens are disposed side-by-side in a proximal portion of the introducer sheath, and the first lumen extends beyond the proximal portion. In some embodiments, the first lumen is configured to accept a bifurcated catheter for delivering one or more substances into the renal arteries. The second lumen may be configured to accept, for example, a balloon angioplasty catheter device for performing an angioplasty procedure in one or more peripheral arteries.

**[0012]** In another aspect of the present invention, a method for advancing at least two catheter devices into vasculature of a patient first involves positioning a single lumen introducer sheath in the patient such that the sheath extends from a proximal, two-port hub outside the patient into one of the patient's iliac arteries, and thus to a distal end in an abdominal aorta at or near origins of renal arteries of the patient. Next, a bifurcated renal artery catheter device is advanced through the distal end of the sheath's lumen to extend into the renal arteries, and a vascular catheter device is advanced through a proximal aperture in the lumen into at least one peripheral vessel of the patient on a contralateral side of the patient relative to an insertion point of the sheath. In various embodiments, the vascular catheter may be advanced through the introducer sheath before or after the renal catheter is advanced.

**[0013]** In some embodiments, the method further involves delivering at least one substance into at least one of the renal arteries through the bifurcated renal artery catheter device. For example, substances which may be delivered through the renal artery catheter device include, but are not limited to, vasodilators, diuretics, hyper-oxygenated blood, hyper-oxygenated blood substitutes and filtered blood. In some embodiments, the method further involves delivering at least one additional substance into peripheral vessel(s) of the patient through the vascular catheter device. For example, such an additional substance may include, but is not limited to, a radiocontrast agent. Optionally, the method may further include performing an interventional procedure in at least one peripheral vessel of the patient, using the vascular catheter device. One example of such a procedure is an angioplasty procedure.

**[0014]** In another aspect of the present invention, a method for advancing at least two catheter devices into vasculature of a patient involves positioning a dual lumen introducer sheath in the patient such that the sheath extends from a proximal hub outside the patient into one of the patient's iliac arteries, and thus to a first distal aperture of a first lumen in the abdominal aorta at or near origins of renal arteries of the patient and to a second distal aperture of a

second lumen in or near the iliac artery in which the sheath is positioned. The method then involves advancing a bifurcated renal artery catheter device through the first lumen and first distal aperture to extend into the renal arteries. The method then involves advancing a vascular catheter device through the second lumen and second distal aperture into at least one peripheral vessel of the patient on a contralateral side of the patient relative to an insertion point of the sheath. Again, in various embodiments, the vascular catheter may be advanced through the sheath either before or after the renal catheter is advanced.

**[0015]** In another aspect of the invention, a system for accessing at least one renal artery and at least one peripheral blood vessel of a patient includes a single lumen introducer sheath, a bifurcated renal artery catheter device for advancing through the first lumen to access the renal arteries, and a vascular catheter device for advancing through the second lumen and into or through the contralateral iliac artery. The single lumen sheath includes a proximal hub, a lumen, a proximal aperture in the lumen, and a distal aperture at the distal end of the lumen, as described above. The sheath may include any of the features previously described.

**[0016]** In some embodiments, the bifurcated renal artery catheter device is configured to expand from a constrained configuration within the introducer sheath to a deployed configuration in which two oppositely directed distal ends are positioned within the two renal arteries or the patient. In some embodiments, one of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into one of the renal arteries. In alternative embodiments, each of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into one of the renal arteries. The vascular catheter may comprise any diagnostic and/or treatment catheter device suitable for accessing and performing a function in a blood vessel. In one embodiment, for example, the vascular catheter device comprises a balloon angioplasty catheter.

**[0017]** In another aspect of the present invention, a system for accessing at least one renal artery and at least one peripheral blood vessel of a patient includes a dual lumen introducer sheath, a bifurcated renal artery catheter device for advancing through the first lumen to access the renal arteries, and a vascular catheter device for advancing through the second lumen and into or through the contralateral iliac artery. The dual lumen introducer sheath includes a proximal hub, a first lumen, and a second lumen, as described above. The introducer sheath may include any of the features previously described.

**[0018]** These and other aspects and embodiments of the invention will be described in further detail below, with reference to the attached drawing figures.

#### BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]** FIG. 1 is a side view of a dual lumen sheath and catheter system for accessing renal arteries and peripheral vessels, shown in situ, according to one embodiment of the present invention.

**[0020]** FIG. 2 is a side view of a dual lumen sheath for providing access to renal arteries and peripheral vessels, according to one embodiment of the present invention.



[0021] FIGS. 2A and 2B are end-on cross-sectional views of the dual lumen sheath of FIG. 2, at different points along the length of the sheath.

[0022] FIG. 2C is an end-on cross-sectional view of a dual lumen sheath, according to an alternative embodiment of the present invention.

[0023] FIG. 3 is a side view of a single lumen sheath and catheter system for accessing renal arteries and peripheral vessels, according to an alternative embodiment of the present invention.

[0024] FIG. 4 is a side view of the single lumen sheath of FIG. 3.

[0025] FIG. 5 is a side view of a bifurcated renal artery catheter device for use with a sheath of the present invention, according to one embodiment.

#### DETAILED DESCRIPTION OF THE INVENTION

[0026] Referring to FIG. 1, a vascular access system 10 in one embodiment suitably includes a dual lumen introducer sheath 12, a bifurcated renal catheter 14 and an additional vascular catheter device 16. As will be described in further detail below, in alternative embodiments, introducer sheath 12 may have only one lumen, with distal and proximal apertures. In the embodiment shown in FIG. 1, introducer sheath 12 includes a proximal hub 18 having two having first and second ports 24, 26, a first lumen 20 in fluid communication with first port 24 and a first distal aperture 28, and a second lumen 22 in fluid communication with second port 26 and a second distal aperture 30. Introducer sheath 12 is typically, though not necessarily, introduced into a patient through a femoral artery and advanced into an iliac artery, which in FIG. 1 is referred to as the ipsilateral iliac artery II. Upon positioning of sheath 12, first lumen 20 extends into the patient's aorta A such that first distal aperture 28 locates at or near the origins of the patient's renal arteries R, which lead from the aorta A to the kidneys K. Meanwhile, second lumen 22 ends more proximally in second distal aperture 30, which upon positioning of sheath 12 typically resides in or near the ipsilateral iliac artery II.

[0027] Introducer sheath 12 is generally adapted to be placed at the desired in-vivo location via traditional vascular access technique. After this placement, bifurcated renal artery catheter 14 is delivered into first entry port 24 on hub 18 and advanced through first lumen 20 to extend out first distal aperture 28, such that each of its two branches is positioned within a renal artery R. In various embodiments, bifurcated renal artery catheter 14 may be any of a number of suitable renal catheter devices, many examples of which are described in the patent applications incorporated by reference above in the background section. In some embodiments, bifurcated catheter 14 may be adapted to access both renal arteries, while in alternative embodiments only one renal artery may be accessed, and the opposite arm of the bifurcated catheter may act as an anchor or support. Once it is placed in a desired position, bifurcated renal artery catheter 14 may be used to selectively infuse one or more agents, typically renal protective agents, into the renal arteries. Such agents may include, but are not limited to, vasodilators, saline, diuretics, hyper-oxygenated blood, hyper-oxygenated blood substitutes and filtered blood. In

other embodiments, other agent(s) may be used prevent or reduce negative effects of one or more radiocontrast agents that are subsequently or simultaneously delivered elsewhere. In some embodiments, system 10 may include a source of such agent(s).

[0028] In some embodiments, once renal catheter 14 is positioned, vascular catheter device 16 may then be advanced into second entry port 26 on hub 18, advanced through second lumen 22 and second distal aperture 30, and further advanced into and possibly through the contralateral iliac artery CI. Depending on the desired treatment and/or diagnosis site, vascular catheter 16 may be advanced into the contralateral femoral artery or through the contralateral femoral artery into one or more peripheral vessels. Vascular catheter device 16 itself may comprise any of a number of suitable devices, such as an a balloon angioplasty catheter (as shown), an atherectomy catheter, an ultrasound catheter, an infusion catheter or the like. Once placed in a desired position in the contralateral peripheral vasculature of the patient, vascular catheter 16 may then be used to perform one or more diagnostic and/or therapeutic procedures. Many of such procedures involve the introduction of one or more radiocontrast dyes or agents, and any adverse effects of such agents on the kidneys K will be mitigated by the substance(s) delivered via bifurcated renal artery catheter 14.

[0029] In various embodiments, system 10 may include additional, fewer and/or alternative components or devices. Furthermore, in various embodiments of a method for using system 10, the various steps may be performed in a different order and/or steps may be added or eliminated. For example, in one embodiment, a renal protective substance may be delivered via renal catheter 14 at the same time that a radiocontrast agent is delivered via vascular catheter 16. In another embodiment, the method may involve multiple infusions of renal protective substance(s) and/or multiple infusions of radiocontrast material(s) in any of a number of different orders. Thus, the described method is but one preferred way in which vascular access system 10 may be used.

[0030] With reference now to FIG. 2-2C, dual lumen introducer sheath 12 is shown in greater detail. Again, sheath includes Y-shaped proximal hub 18, which allows for introduction of multiple (in the exemplary case two) devices simultaneously. In some embodiments, hub 18, first lumen 20 and second lumen 22 may each be sized to allow passage of devices up to about 10 French in outer diameter, or possibly even more, with a preferred embodiment being compatible with a renal catheter via first lumen 20 and a 5 Fr. to 8 Fr. peripheral diagnostic or interventional catheter via second lumen 22. FIG. 2A shows a cross-section of first lumen 20, FIG. 2B shows a cross-section of first and second lumens 20, 22, in a more proximal portion of sheath 12, and FIG. 2C shows a cross-section of an alternative embodiment of the more proximal portion, with a different design of first and second lumens 20, 22. The overall usable length of sheath 12 is generally such that it allows for standard femoral access (or other access point), and also allows first distal aperture 28 in first lumen 20 to reach a location at or near the renal arteries in order to deliver the bifurcated renal catheter. Again, various lengths for this device may also be provided to suit individual patients' anatomies, such as in a kit that allows for a particular device to be chosen for a particular case. Should an independently collapsible and

expandable renal catheter be employed, the sheath's overall length may be reduced as desired.

[0031] Because sheath 12 may be delivered to the peri-renal aorta, past the aortic bifurcation, sheath 12 may be further adapted to allow for the diagnostic or interventional device performing the lower limb procedure to exit along its length at a pre-determined or variable location so as to allow for the "up-and-over" delivery about the aortic bifurcation as previously discussed. In one particular embodiment, this may involve an aperture or other opening in the side wall of sheath 12 at an appropriate point. In an alternative embodiment, as shown in FIGS. 1-2C and as described above, a dual-lumen design may be adapted to deliver one device to the peri-renal aorta and the other to the area of the bifurcation. In a further embodiment, a valve apparatus (or multiple apparatuses) in combination with one or both of the other designs may be employed. In any event, sheath 12 may provide a mechanism for delivering one device (such as for example the renal catheter) to the level of the peri-renal aorta while simultaneously or contemporaneously allowing for another device (such as for example the peripheral diagnostic or interventional device) to exit lower at the area of the bifurcation. In the case of an independently collapsible and expandable renal catheter, a shorter sheath may be used that reaches just to or below to the level on the aortic bifurcation (i.e., still in the iliac artery on the side of access). Both devices may be simultaneously or contemporaneously deployed to their respective sites.

[0032] Referring now to FIGS. 3 and 4, an alternative embodiment of a vascular access system 50 and a single lumen introducer sheath 52 are shown. In FIG. 3, vascular access system includes single lumen introducer sheath 52, a bifurcated renal catheter 60 and a vascular catheter device 62, which in this example is a balloon angioplasty device. Single lumen sheath 52 includes a hub 54 with first 56 and second 58 ports and connected to a fluid infusion device 68, and a single lumen 53 having a proximal aperture 66, a distal aperture 64, and two radiopaque markers 51 for facilitating visualization of the proximal aperture 66 location. In this embodiment, renal catheter 60 and vascular catheter 62 are as described previously above, but in various embodiments any suitable alternative devices may be substituted.

[0033] A method for using system 50 is much the same as the method described above with reference to FIG. 1. Sheath 52 is placed via a femoral artery using a standard technique or any other desired access technique, such that distal aperture 64 is positioned at or near the ostia of the renal arteries. Renal catheter 60 may then be inserted through first port 56 and advanced through lumen 53 and distal aperture 64 to position its branches 65 within the renal arteries. Before, after or simultaneously with that step, vascular catheter 62 is inserted through second port 58 and advanced through lumen 53 and proximal aperture 66 to extend into the contralateral iliac artery and as far peripherally as desired by the physician. One or more renal substances are then infused into the renal arteries via renal catheter 60, and a radiocontrast substance is infused into the peripheral vessel(s) via vascular catheter 62. In some embodiments, vascular catheter 62 is then used to perform a procedure in one or more vessels. Optionally, infusion device 68 may be used to deliver one or more substances into lumen 53.

[0034] FIG. 4 shows single lumen introducer sheath 52 in greater detail. Radiopaque markers 51 may be placed in any of a number of various configurations and locations in various embodiments, to facilitate visualization and localization of proximal aperture 66, distal aperture 64 and/or any other features of sheath 52.

[0035] Referring now to FIG. 5, a distal portion of bifurcated renal catheter 14 includes two branches 15, 17, each including a distal aperture 11, 13, and a proximal catheter body. Each branch 15, 17 provides a means to deliver one or more substances to the renal artery in which it is placed. Overall usable length of the renal catheter 14 would generally be such that renal access from a typical femoral artery vascular access point (or other access point) is achieved without an undue length of catheter remaining outside of the patient. Again, various embodiments and features of bifurcated renal catheters are described more fully in U.S. patent application Ser. Nos. 09/724,691, 10/422,624, 10/251,915, 10/636,359 and 10/636,801, and in PCT Patent Application Nos. PCT/US03/029744, PCT/US03/29995, PCT/US03/29743 and PCT/US03/29585, which were previously incorporated by reference.

[0036] Renal catheter 14 may be delivered in a collapsed condition via sheath 12 to the abdominal aorta in the vicinity of the renal arteries. Once deployed, it may expand to contact the walls of the vessel, in an attempt to regain the shape configuration as demonstrated above. This expansion and contraction may be active or passive, as desired, based on the design of renal catheter 14. For the purposes of illustration, the device is considered to be in its free state as pictured in FIG. 3 and compressed via the constraint of the introducer sheath 12 or other means during delivery. Thus renal catheter 14 would "self-expand" upon deployment, to an extent determined by the constraint of the blood vessel. However, renal catheter 14 could alternatively be designed to have the collapsed condition as default and be actively opened once deployed. Such may be accomplished for example by use of integrated pull-wires, etc. In any event, the outward contact with the blood vessel (aorta) allows for easy cannulation of multiple vessels, as the device naturally seeks its lower energy state by opening into branch vessels.

[0037] When deployed in the aorta, in a procedure where it is desired to access the renal arteries, renal catheter 14 will exit introducer sheath 12, and branches 15, 17 will seek to open to their natural, at-rest state. This will bias branches 15, 17 away from each other and against the inner wall of the vessel, at approximately 180° apart from each other, more or less centering catheter body 32 in the aorta. The proximal end of renal catheter 14 may be manipulated via standard technique (i.e., the use of a supplied "torque device" as is common with intravascular guidewires) so that branches 15, 17 are more or less aligned near the target renal arteries' ostia, and with a minimal amount of axial or rotational manipulation, bilateral renal artery cannulation can be achieved.

[0038] Previous disclosures by the inventors of the present invention have also addressed the merits of various embodiments of bifurcated renal catheters 14 in providing access to multiple vessels simultaneously through a single vascular access point, alone or in combination with other diagnostic or therapeutic interventions or other procedures. For example, such disclosures include U.S. Provisional Patent

Application Nos.: 60/476,347 (Attorney Docket No. FLO5360.44P1), filed Jun. 5, 2003; 60/486,206 (Attorney Docket No. FLO5360.47P1), filed Jul. 9, 2003; 60/502,600 (Attorney Docket No. FLO5360.48P1), filed Sep. 13, 2003; 60/502,339 (Attorney Docket No. FLO5360.51P1), filed Sep. 13, 2003; 60/505,281 (Attorney Docket No. FLO5360.53P), filed Sep. 22, 2003; 60/493,100 (Attorney Docket No. FLO5360.54P1), filed Aug. 5, 2003; 60/502,468 (Attorney Docket No. FLO5360.54P2), filed Sep. 13, 2003; 60/543,671 (Attorney Docket No. FLO5360.55P1), filed Feb. 9, 2004; 60/550,632 (Attorney Docket No. FLO5360.56P1), filed Mar. 4, 2004; 60/550,774 (Attorney Docket No. FLO5360.56P2), filed Mar. 5, 2004; 60/571,057 (Attorney Docket No. FLO5360.57P1), filed May 14, 2004; 60/612,731 (Attorney Docket No. FLO5360.57P2), filed Sep. 24, 2004; and 60/612,801 (Attorney Docket No. FLO5360.60P1), filed Sep. 24, 2004, the full disclosures of which are all hereby incorporated by reference. Similar and alternative embodiments are described in PCT Patent Application Nos.: PCT/US03/029744 (Attorney Docket No. FLO5360.48FP), filed Sep. 22, 2003; PCT/US04/008573 (Attorney Docket No. FLO5360.55FP), filed Mar. 19, 2004; PCT/US03/029586 (Attorney Docket No. FLO5360.54FP), filed Sep. 22, 2003; and PCT/US03/029585 (Attorney Docket No. FLO5360.51FP), filed Sep. 22, 2003, the full disclosures of which are hereby incorporated by reference.

[0039] Bifurcated renal catheter **14** may be similar to that previously described in the above-referenced patent applications or may have any other suitable design and features for bilateral renal cannulation. The example provided and discussed herein for illustration includes, without limitation, a passively self-expanding branched assembly that uses outer sheath constraint to allow delivery to the area of the renal arteries and then expands upon delivery out of the sheath. However, in further embodiments the catheter may also be of the type that is independently collapsible and expandable, if so desired. Various features may be further included. In one particular beneficial embodiment, two distal arms are provided whose shapes and flexibility profile allow for fast bilateral renal artery cannulation with a minimum of required manipulation and such that there is no induced vascular trauma. Exemplary catheter shaft and distal arms may be in the range for example of about 1 Fr. to about 4 Fr. outer diameter. Exemplary arm lengths may be for example in the range of about 2 cm to about 5 cm.

[0040] Dimensions and other particular features such as shape, stiffness, etc. may be varied according to the scale of the patient's anatomy, and thus a kit of devices may be provided from which a healthcare provider may choose one particular device to meet a particular need for a particular patient. For example, multiple renal catheters may be provided having small, medium, and large sizes, respectively. Upon being provided a particular patient parameter, such as anatomical dimensions, a person could refer to the device sizes offered and simply match the chosen size to the parameter given. In this regard, a chart may be provided which assists in matching a measured or estimated patient parameter with the appropriate catheter choice.

[0041] Although the foregoing is a complete and accurate description of various embodiments of the present invention, any of a number of changes, additions or deletions may be made to one or more embodiments without departing from the scope of the invention. Therefore, the foregoing descrip-

tion is provided for exemplary purposes and should not be interpreted to limit the scope of the invention as set forth in the claims.

What is claimed is:

1. A single lumen introducer sheath for accessing at least one renal artery and at least one peripheral blood vessel of a patient, the introducer sheath comprising:

- a proximal hub comprising first and second ports;
- a lumen extending from the first and second ports and having sufficient length such that when the ports are positioned outside the patient a distal end of the lumen is positionable in an abdominal aorta at or near origins of the patient's renal arteries;

a proximal aperture in the lumen, configured to allow passage of a vascular catheter device through the proximal aperture and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient; and

a distal aperture at the distal end of the lumen, configured to allow passage of a bifurcated renal catheter device out of the distal aperture to enter at least one of the renal arteries.

2. An introducer sheath as in claim 1, wherein the proximal aperture comprises a side aperture in the lumen.

3. A dual lumen introducer sheath for accessing at least one renal artery and at least one peripheral blood vessel of a patient, the introducer sheath comprising:

- a proximal hub comprising first and second ports;
- a first lumen extending from the first port to a first distal aperture and having sufficient length such that when the first port is positioned outside the patient the first distal aperture is positionable in an abdominal aorta at or near origins of the patient's renal arteries; and
- a second lumen extending from the second port to a second distal aperture and having a shorter length than the length of the first lumen,

wherein the second lumen is configured to allow passage of a catheter device through the second lumen and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient.

4. An introducer sheath as in claim 3, wherein the first and second lumens are disposed side-by-side in a proximal portion of the introducer sheath, and wherein the first lumen extends beyond the proximal portion.

5. An introducer sheath as in claim 3, wherein the first lumen is configured to accept a bifurcated catheter for delivering one or more substances into the renal arteries.

6. An introducer sheath as in claim 3, wherein the second lumen is configured to accept a balloon angioplasty catheter device for performing an angioplasty procedure in one or more peripheral arteries.

7. A method for advancing at least two catheter devices into vasculature of a patient, the method comprising:

- positioning a single lumen introducer sheath in the patient such that the sheath extends from a proximal, two-port hub outside the patient into one of the patient's iliac arteries, and thus to a distal end in an abdominal aorta at or near origins of renal arteries of the patient;

advancing a bifurcated renal artery catheter device through the distal end of the sheath's lumen to extend into the renal arteries; and

advancing a vascular catheter device through a proximal aperture in the lumen into at least one peripheral vessel of the patient on a contralateral side of the patient relative to an insertion point of the sheath.

**8.** A method as in claim 7, further comprising delivering at least one substance into at least one of the renal arteries through the bifurcated renal artery catheter device.

**9.** A method as in claim 8, wherein the at least one substance is selected from the group consisting of vasodilators, saline, diuretics, hyper-oxygenated blood, hyper-oxygenated blood substitutes and filtered blood.

**10.** A method as in claim 8, further comprising delivering at least one additional substance into peripheral vessel(s) of the patient through the vascular catheter device.

**11.** A method as in claim 10, wherein the additional substance comprises a radiocontrast agent.

**12.** A method as in claim 10, further comprising performing an interventional procedure in at least one peripheral vessel of the patient, using the vascular catheter device.

**13.** A method as in claim 12, wherein the interventional procedure comprises an angioplasty procedure.

**14.** A method for advancing at least two catheter devices into vasculature of a patient, the method comprising:

positioning a dual lumen introducer sheath in the patient such that the sheath extends from a proximal hub outside the patient into one of the patient's iliac arteries, and thus to a first distal aperture of a first lumen in an abdominal aorta at or near origins of renal arteries of the patient and to a second distal aperture of a second lumen in or near the iliac artery in which the sheath is positioned;

advancing a bifurcated renal artery catheter device through the first lumen and first distal aperture to extend into the renal arteries; and

advancing a vascular catheter device through the second lumen and second distal aperture into at least one peripheral vessel of the patient on a contralateral side of the patient relative to an insertion point of the sheath.

**15.** A method as in claim 14, further comprising delivering at least one substance into at least one of the renal arteries through the bifurcated renal artery catheter device.

**16.** A method as in claim 15, wherein the at least one substance is selected from the group consisting of vasodilators, saline, diuretics, hyper-oxygenated blood, hyper-oxygenated blood substitutes and filtered blood.

**17.** A method as in claim 15, further comprising delivering at least one additional substance into peripheral vessel(s) of the patient through the vascular catheter device.

**18.** A method as in claim 17, wherein the additional substance comprises a radiocontrast agent.

**19.** A method as in claim 17, further comprising performing an interventional procedure in at least one peripheral vessel of the patient, using the vascular catheter device.

**20.** A method as in claim 19, wherein the interventional procedure comprises an angioplasty procedure.

**21.** A system for accessing at least one renal artery and at least one peripheral blood vessel of a patient, the system comprising:

a single lumen introducer sheath comprising:

a proximal hub comprising first and second ports;

a lumen extending from the first and second ports and having sufficient length such that when the ports are positioned outside the patient a distal end of the lumen is positionable in an abdominal aorta at or near origins of the patient's renal arteries;

a proximal aperture in the lumen, configured to allow passage of a vascular catheter device through the proximal aperture and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient; and

a distal aperture at the distal end of the lumen, configured to allow passage of a bifurcated renal catheter device out of the distal aperture to enter at least one of the renal arteries.

a bifurcated renal artery catheter device for advancing through the first lumen to access the renal arteries; and

a vascular catheter device for advancing through the second lumen and into or through the contralateral iliac artery.

**22.** A system as in claim 21, wherein the bifurcated renal artery catheter device is configured to expand from a constrained configuration within the introducer sheath to a deployed configuration in which two oppositely directed distal ends are positioned within the two renal arteries or the patient.

**23.** A system as in claim 22, wherein one of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into one of the renal arteries.

**24.** A system as in claim 22, wherein each of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into each of the renal arteries.

**25.** A system as in claim 21, wherein the vascular catheter device comprises a balloon angioplasty catheter.

**26.** A system for accessing at least one renal artery and at least one peripheral blood vessel of a patient, the system comprising:

a dual lumen introducer sheath comprising:

a proximal hub comprising first and second ports;

a first lumen extending from the first port to a first distal aperture and having sufficient length such that when the first port is positioned outside the patient the first distal aperture is positionable in the abdominal aorta at or near origins of the patient's renal arteries; and

a second lumen extending from the second port to a second distal aperture and having a shorter length than the length of the first lumen,

wherein the second lumen is configured to allow passage of a catheter device through the second lumen and into or through an iliac artery contralateral to an insertion point of the introducer sheath into the patient;

a bifurcated renal artery catheter device for advancing through the first lumen to access the renal arteries; and

a vascular catheter device for advancing through the second lumen and into or through the contralateral iliac artery.

**27.** A system as in claim 26, wherein the first and second lumens of the sheath are disposed side-by-side in a proximal portion of the introducer sheath, and wherein the first lumen extends beyond the proximal portion.

**28.** A system as in claim 26, wherein the bifurcated renal artery catheter device is configured to expand from a constrained configuration within the introducer sheath to a deployed configuration in which two oppositely directed distal ends are positioned within the two renal arteries or the patient.

**29.** A system as in claim 28, wherein one of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into one of the renal arteries.

**30.** A system as in claim 28, wherein each of the two distal ends includes an aperture for allowing passage of fluid from the bifurcated renal artery catheter into each of the renal arteries.

**31.** A system as in claim 26, wherein the vascular catheter device comprises a balloon angioplasty catheter.

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