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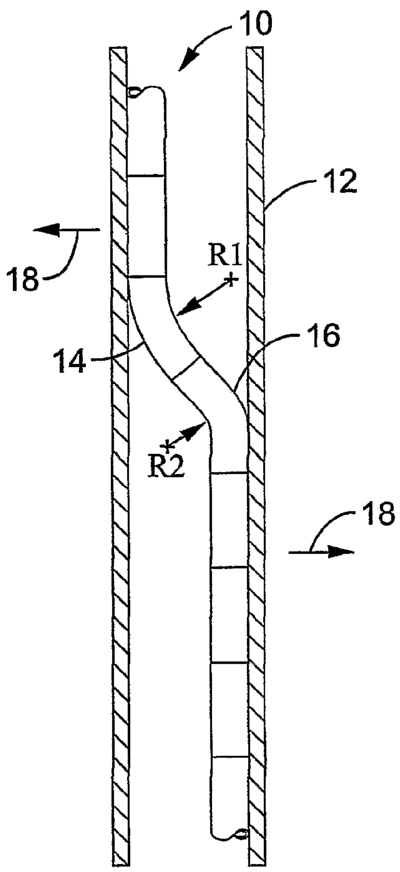
(54) Title: SYSTEMS AND METHODS FOR PERFORMING BI-LATERAL INTERVENTIONS OR DIAGNOSIS IN BRANCHED BODY LUMENS



(57) Abstract: Bifurcated delivery assemblies provide bilateral access to first and second branch lumens extending from a main body space or lumen in a patient. One or more interventional devices are combined with the delivery assemblies for delivery s into one or both of the branch lumens. Bilateral renal stenting or embolic protection procedures are performed using the combination del ivery/interventional device assemblies. Fluids may also be injected or aspirated from the assemblies. A bifurcated catheter has a first fluid port located on one bifurcation branch, a second fluid port located on a second branch of the bifurcation, and a third fluid port positioned so as to be located within a vena cava when the first and second ports are positioned bilaterally within first and second renal veins.

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TITLE OF THE INVENTION

SYSTEMS AND METHODS FOR PERFORMING BI-LATERAL INTERVENTIONS OR DIAGNOSIS IN BRANCHED BODY LUMENS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority from U.S. provisional application serial number 60/543,671 filed on February 9, 2004, incorporated herein by reference in its entirety.

[0002] This application claims priority from U.S. provisional application serial number 60/505,281 filed on September 22, 2003, incorporated herein by reference in its entirety.

[0003] This application claims priority from, and is a continuation-in-part of, PCT International Application Serial No. PCT/US2003/029744 filed on September 22, 2003, which designates the U.S., incorporated herein by reference in its entirety.

[0004] This application claims priority to U.S. provisional application 60/502,600 filed on September 13, 2003, incorporated herein by reference in its entirety.

[0005] This application claims priority from U.S. provisional application serial number 60/476,347 filed on June 5, 2003, incorporated herein by reference in its entirety.

[0006] This application claims priority from U.S. provisional application serial number 60/412,343 filed on September 20, 2002, incorporated herein by reference in its entirety.

[0007] This application claims priority from U.S. provisional application serial number 60/412,476 filed on September 20, 2002, incorporated herein by reference in its entirety.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0008] Not Applicable

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

[0009] Not Applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

[0010] This invention relates to the field of medical devices, and more particularly to a system and method for locally delivering materials within the body of a patient. Still more particularly, it relates to a system and method for locally delivering interventional medical devices into branch body lumens from a main lumen, and in particular into renal arteries or veins extending from an abdominal aorta or vena cava, respectively, in a patient.

2. Description of Related Art

[0011] Many different medical device systems and methods have been previously disclosed for locally delivering fluids or other agents or materials into various body regions, including body lumens such as vessels, or other body spaces such as organs or heart chambers. Local "fluid" delivery systems may include drugs or other agents, or may even include locally delivering the body's own fluids, such as artificially enhanced blood transport (e.g. either entirely within the body such as directing or shunting blood from one place to another, or in extracorporeal modes such as via external blood pumps etc.). Local "agent" delivery systems are herein generally intended to relate to introduction of a material as an agent into the body, which may include drug or other useful or active agent, and may be in a fluid form such as liquid or gas, or other form such as gels, solids, powders, gases, etc. It is to be understood that reference to only one of the terms fluid, drug, or agent with respect to local delivery descriptions may be made variously in this disclosure for illustrative purposes, but is not generally intended to be exclusive or omissive of the others; they are to be considered interchangeable where appropriate according to one of ordinary skill unless specifically described to be otherwise.

[0012] In general, local agent delivery systems and methods are often used for the benefit of achieving relatively high, localized concentrations of agent where injected within the body in order to maximize the intended effects there and while minimizing unintended peripheral effects of the agent elsewhere in the body. Where a particular dose of a locally delivered agent may be efficacious for an intended local effect, the same dose systemically delivered would be substantially diluted throughout the body before reaching the same location. The agent's intended local effect is equally diluted and efficacy is compromised. Thus systemic agent delivery requires higher dosing to achieve the required localized dose for efficacy, often resulting in compromised safety due to for example systemic reactions or side effects of the agent as it is delivered and processed elsewhere throughout the body other than at the intended target.

[0013] Various diagnostic systems and procedures have been developed using local delivery of dye (e.g. radiopaque "contrast" agent) or other diagnostic agents, wherein an external monitoring system is able to gather important physiological information based upon the diagnostic agent's movement or assimilation in the body at the location of delivery and/or at other locations affected by the delivery site. Angiography is one such practice using a hollow, tubular angiography catheter for locally injecting radiopaque dye into a blood chamber or vessel, such as for example coronary arteries in the case of coronary angiography, or in a ventricle in the case of cardiac ventriculography.

[0014] Other systems and methods have been disclosed for locally delivering therapeutic agent into a particular body tissue within a patient via a body lumen. For example, angiographic catheters of the type just described above, and other similar tubular delivery catheters, have also been disclosed for use in locally injecting treatment agents through their delivery lumens into such body spaces within the body. More detailed examples of this type include local delivery of thrombolytic drugs such as TPA™, heparin, cumadin, or urokinase into areas of existing clot or thrombogenic implants or vascular injury. In addition, various balloon catheter systems have also been disclosed for local administration of therapeutic agents into target body lumens or spaces, and in particular associated with blood vessels. More specific previously disclosed of this type include balloons with porous or perforated walls that elute drug agents through the balloon wall and into surrounding tissue such as blood vessel walls. Yet further examples for localized delivery of therapeutic agents include various multiple balloon catheters that have spaced balloons that are inflated to engage a lumen or vessel wall in order to isolate the intermediate catheter region from in-flow or out-flow across the balloons. According to these examples, a fluid agent delivery system may be coupled to this intermediate region in order to fill the region with agent such as drug that provides an intended effect at the isolated region between the balloons.

[0015] The diagnosis or treatment of many different types of medical conditions associated with various different systems, organs, and tissues, may also benefit from the ability to locally deliver fluids or agents in a controlled manner. In particular, various conditions related to the renal system would benefit a great deal from an ability to locally deliver of therapeutic, prophylactic, or diagnostic agents into the renal arteries.

[0016] Acute renal failure ("ARF") is an abrupt decrease in the kidney's ability to excrete waste from a patient's blood. This change in kidney function may be attributable to many causes. A traumatic event, such as hemorrhage, gastrointestinal fluid loss, or renal fluid loss without proper fluid replacement may cause the patient to go into ARF. Patients may also become vulnerable to ARF after receiving anesthesia, surgery, or α-adrenergic agonists because of related systemic or renal vasoconstriction. Additionally, systemic vasodilation caused by anaphylaxis, and anti-hypertensive drugs, sepsis or drug overdose may also cause ARF because the body's natural defense is to shut down, i.e., vasoconstriction of non-essential organs such as the kidneys. Reduced cardiac output caused by cardiogenic shock, congestive heart failure, pericardial tamponade or massive pulmonary embolism creates an excess of fluid in the body, which can exacerbate congestive heart failure. For example, a reduction in blood flow and blood pressure in the kidneys due to reduced cardiac output can in turn result in the retention of excess fluid in the patient's body, leading, for example, to pulmonary and systemic edema.

[0017] Previously known methods of treating ARF, or of treating acute renal insufficiency associated with congestive heart failure ("CHF"), involve administering drugs. Examples of such drugs that have been used for this purpose include, without limitation: vasodilators, including for example papavarine, fenoldopam mesylate, calcium channel blockers, atrial natriuretic peptide (ANP), acetylcholine, nifedipine, nitroglycerine, nitroprusside, adenosine, dopamine, and theophylline; antioxidants, such as for example acetylcysteine; and diuretics, such as for example mannitol, or furosemide. However, many of these drugs, when administered in systemic doses, have undesirable side effects. Additionally, many of these drugs would not be helpful in treating other causes of ARF. For example, a septic shock patient with profound systemic vasodilation often has concomitant severe renal vasoconstriction, administering vasodilators to dilate the renal artery to a patient suffering from systemic vasodilation would compound the vasodilation system wide. In addition, for patients with severe CHF (e.g., those awaiting heart transplant), mechanical methods, such as hemodialysis or left ventricular assist devices, may be implemented. Surgical device interventions, such as hemodialysis, however, generally have not been observed to be highly efficacious for long-term management of CHF. Such interventions would also not be appropriate for many patients with strong hearts suffering from ARF.

[0018] The renal system in many patients may also suffer from a particular fragility, or otherwise general exposure, to potentially harmful effects of other medical device interventions. For example, the kidneys as one of the body's main blood filtering tools may suffer damage from exposed to high-density radiopaque contrast dye, such as during coronary, cardiac, or neuro angiography procedures. One particularly harmful condition known as "radiocontrast nephropathy" or "RCN" is often observed during such procedures, wherein an acute impairment of renal function follows exposure to such radiographic contrast materials, typically resulting in a rise in serum creatinine levels of more than 25% above baseline, or an absolute rise of 0.5

mg/dl within 48 hours. Therefore, in addition to CHF, renal damage associated with RCN is also a frequently observed cause of ARF. In addition, the kidneys' function is directly related to cardiac output and related blood pressure into the renal system.

[0019] These physiological parameters, as in the case of CHF, may also be significantly compromised during a surgical intervention such as an angioplasty, coronary artery bypass, valve repair or replacement, or other cardiac interventional procedure. Therefore, the various drugs used to treat patients experiencing ARF associated with other conditions such as CHF have also been used to treat patients afflicted with ARF as a result of RCN. Such drugs would also provide substantial benefit for treating or preventing ARF associated with acutely compromised hemodynamics to the renal system, such as during surgical interventions.

[0020] There would be great advantage therefore from an ability to locally deliver such drugs into the renal arteries, in particular when delivered contemporaneous with surgical interventions, and in particular contemporaneous with radiocontrast dye delivery. However, many such procedures are done with medical device systems, such as using guiding catheters or angiography catheters having outer dimensions typically ranging between about 4 French to about 12 French, and ranging generally between about 6 French to about 8 French in the case of guide catheter systems for delivering angioplasty or stent devices into the coronary or neurovascular arteries (e.g. carotid arteries). These devices also are most typically delivered to their respective locations for use (e.g. coronary ostia) via a percutaneous, translumenal access in the femoral arteries and retrograde delivery upstream along the aorta past the region of the renal artery ostia. A Seldinger access technique to the femoral artery involves relatively controlled dilation of a puncture hole to minimize the size of the intruding window through the artery wall, and is a preferred method where the profiles of such delivery systems are sufficiently small. Otherwise, for larger systems a “cut-down” technique is used involving a larger, surgically made access window through the artery wall.

[0021] Accordingly, a local renal agent delivery system for contemporaneous use with other retrogradedly delivered medical device systems, such as of the types just described above, would beneficially allow for such interventional device systems, in particular of the types and dimensions just described, to pass upstream across the renal artery ostia (a) while the agent is being locally delivered into the renal arteries, and (b) while allowing blood to flow downstream across the renal artery ostia, and (c) in an overall cooperating system that allows for Seldinger femoral artery access. Each one of these features (a), (b), or (c), or any sub-combination thereof, would provide significant value to patient treatment; a local renal delivery system providing for the combination of all three features is so much the more valuable.

[0022] Notwithstanding the clear needs for and benefits that would be gained from such local drug delivery into the renal system, the ability to do so presents unique challenges as follows.

[0023] In one regard, the renal arteries extend from respective ostia along the abdominal aorta that are significantly spaced apart from each other circumferentially around the relatively very large aorta. Often, these renal artery ostia are also spaced from each other longitudinally along the aorta with relative superior and inferior locations. This presents a unique challenge to locally deliver drugs or other agents into the renal system on the whole, which requires both kidneys to be fed through these separate respective arteries via their uniquely positioned and substantially spaced apart ostia. This becomes particularly important where both kidneys may be equally at risk, or are equally compromised, during an invasive upstream procedure – or, of course, for any other indication where both kidneys require local drug delivery. Thus, an appropriate local renal delivery system for such indications would preferably be adapted to feed multiple renal arteries perfusing both kidneys.

[0024] In another regard, mere local delivery of an agent into the natural, physiologic blood flow path of the aorta upstream of the kidneys may provide some beneficial, localized renal delivery versus other systemic delivery methods, but various undesirable results still arise. In particular, the high flow aorta immediately washes much of the delivered agent beyond the intended renal artery ostia. This reduces the amount of agent actually perfusing the renal arteries with reduced efficacy, and thus also produces unwanted loss of the agent into other organs and tissues in the systemic circulation (with highest concentrations directly flowing into downstream circulation).

[0025] In still a further regard, various known types of tubular local delivery catheters, such as angiographic catheters, other "end-hole" catheters, or otherwise, may be positioned with their distal agent perfusion ports located within the renal arteries themselves for delivering agents there, such as via a percutaneous translumenal procedure via the femoral arteries (or from other access points such as brachial arteries, etc.). However, such a technique may also provide less than completely desirable results.

[0026] For example, such seating of the delivery catheter distal tip within a renal artery may be difficult to achieve from within the large diameter/high flow aorta, and may produce harmful intimal injury within the artery. Also, where multiple kidneys must be infused with agent, multiple renal arteries must be cannulated, either sequentially with a single delivery device, or simultaneously with multiple devices. This can become unnecessarily complicated and time consuming and further compound the risk of unwanted injury from the required catheter manipulation. Moreover, multiple dye injections may be required in order to locate the renal ostia for such catheter positioning, increasing the risks associated with contrast agents on kidney function (e.g. RCN) – the very organ system to be protected by the agent delivery system in the first place.

[0027] Still further, the renal arteries themselves, possibly including their ostia, may have pre-existing conditions that either prevent the ability to provide the required catheter seating, or that increase the risks associated with such mechanical intrusion. For example, the artery wall may be diseased or stenotic, such as due to atherosclerotic plaque, clot, dissection, or other injury or condition. Finally, among other additional considerations, much benefit would be provided from an efficacious and safe system and method for positioning these types of local agent delivery devices at the renal arteries through a common introducer or guide sheath shared with additional medical devices used for upstream interventions, such as angiography or guide catheters. In particular, to do so concurrently with multiple delivery catheters for simultaneous infusion of multiple renal arteries would further require a guide sheath of such significant dimensions that the preferred Seldinger vascular access technique would likely not be available, instead requiring the less desirable “cut-down” technique.

[0028] In addition to the various needs for locally delivering agents into branch arteries described above, much benefit may also be gained from simply locally enhancing blood perfusion into such branches, such as by increasing the blood pressure at their ostia. In particular, such enhancement would improve a number of medical conditions related to insufficient physiological perfusion into branch vessels, and in particular from an aorta and into its branch vessels such as the renal arteries.

[0029] Certain prior disclosures have provided surgical device assemblies and methods intended to enhance blood delivery into branch arteries extending from an aorta. For example, intra-aortic balloon pumps (IABPs) have been disclosed for use in diverting blood flow into certain branch arteries. One such technique involves placing an IABP in the abdominal aorta so that the balloon is situated slightly below (proximal to) the branch arteries. The balloon is selectively inflated and deflated in a counterpulsation mode (by reference to the physiologic pressure cycle) so that increased pressure distal to the balloon directs a greater portion of blood flow into principally the branch arteries in the region of their ostia. However, the flow to lower extremities downstream from such balloon system can be severely occluded during portions of this counterpulsing cycle. Moreover, such previously disclosed systems generally lack the ability to deliver drug or agent to the branch arteries while allowing continuous and substantial downstream perfusion sufficient to prevent unwanted ischemia.

[0030] It is further noted that, despite the renal risks described in relation to radiocontrast dye delivery, and in particular RCN, in certain circumstances local delivery of such dye or other diagnostic agents is indicated specifically for diagnosing the renal arteries themselves. For example, diagnosis and treatment of renal stenosis, such as due to atherosclerosis or dissection, may require dye injection into a subject renal artery. In such circumstances, enhancing the localization of the dye into the renal arteries may also be desirable. In one regard, without such localization larger volumes of dye may be required, and the dye lost into the downstream aortic flow may still be additive to impacting the kidney(s) as it circulates back there through the system. In another regard, an ability to locally deliver such dye into the renal artery from within the artery itself, such as by seating an angiography catheter there, may also be hindered in some limited circumstances by the same stenotic condition requiring the dye injection in the first place (as introduced above). Still further, patients may have stent-grafts that may prevent delivery catheter seating.

[0031] Accordingly, much benefit would result from providing the ability to effectively deliver agents from within a main artery, vessel, or lumen and locally into substantially only branch arteries, vessels, or lumens extending therefrom while allowing the passage of substantial flow (e.g. blood flow) and/or other medical devices through the main lumen past the branches. This is in particular the case with previously disclosed renal treatment and diagnostic devices and methods, which do not adequately provide for local delivery of agents into the renal system from a location within the aorta while allowing substantial blood flow continuously downstream past the renal ostia and/or while allowing distal medical device assemblies to be passed retrogradedly across the renal ostia for upstream use. Much benefit would be gained if agents, such as protective or therapeutic drugs or radiopaque contrast dye, could be delivered to one or both of the renal arteries in such a manner.

[0032] Several more recently disclosed advances have included local flow assemblies using tubular members of varied diameters that divide flow within an aorta adjacent to renal artery ostia into outer and inner flow paths substantially perfusing the renal artery ostia and downstream circulation, respectively. Such disclosures further include delivering fluid agent primarily into the outer flow path for substantially localized delivery into the renal artery ostia. These disclosed systems and methods represent exciting new developments toward localized diagnosis and treatment of pre-existing conditions associated with branch vessels from main vessels in general, and with respect to renal arteries extending from abdominal aortas in particular.

[0033] However, while these approaches in one regard provide benefit by removing the need to cannulate each renal artery of the bi-lateral renal system, substantial benefit would still be gained conversely from a device system and method that allows for direct bi-lateral renal artery infusion without the need to deploy flow diverters or isolators into the high-flow abdominal aorta. In one particular example, patients that suffer from abdominal aortic aneurysms may not be suitable for standard delivery systems with flow diverters or isolators that are sized for normal arteries. In another regard, direct renal artery infusion allows for reduced occlusion to downstream aortic blood flow, or conversely more downstream flow may be preserved. Still further, the ability to truly isolate drug to only the renal system, without the potential for downstream leaking or loss into the systemic circulation, may be maximized.

[0034] For renal cannulation and renal interventional device delivery in particular, current physician practice provides a limited number of shapes for the tip of a guiding catheter. If a specifically designed guiding catheter is available, the physician may be able to torque and manipulate the proximal end of the guiding catheter in order to steer the distal end of the guiding catheter into position to cannulate a target renal artery. The placement of the guiding catheter may cause some vessel trauma and damage due to large available sizes (5 French to 8 French), and conventional stiff distal tips and exposed edges without the use of a dilator. With the targeted renal artery cannulated, the physician may advance a guide wire into the renal artery to allow for placement and deployment of a guide wire based interventional device.

[0035] A second option that may be available to a physician is the use of a guiding catheter that is inserted and placed approximately near the targeted renal ostium. A guide wire is then advanced through the placed guiding catheter until the guide wire exits the guiding catheter roughly near the targeted renal ostium. Under fluoroscopic guidance, the physician manipulates the guide wire and tracks the wire into the renal arteries. This process may present a high risk of vessel perforation, dissection, and hematoma resulting from trauma as well as the release of emboli. Once the physician is able to track the guide wire to the target renal artery, the guide wire can then be used to further advance the guiding catheter, therefore allowing the exchange of interventional devices.

[0036] In the particular setting of interventional radiology and cardiology, numerous conditions exist that warrant placement of various intravascular devices into the renal arteries or veins. Such devices may include catheters and guide wires for diagnostic purposes, or systems for therapeutic or prophylactic applications such as drug infusion, monitoring/sampling, angioplasty and stenting, or embolic protection.

[0037] Current procedures to place such intravascular devices into the renal arteries or veins also involve the manipulation of guide wires and/or diagnostic or guiding catheters in the abdominal aorta/inferior vena cava in the area of the renal arteries/veins in order to gain access, and then following over (guide wires) or through (guiding catheters) these devices for placement of the intended interventional diagnostic, therapeutic, or prophylactic device. Such access procedures may require numerous expensive devices and be time consuming, increasing both the time of the procedure and its cost. As well, significant manipulation of various devices within the vasculature may lead to untoward clinical sequelae arising from trauma to the interior of the blood vessel walls or extensive x-ray or contrast media exposure.

[0038] Therefore, a need exists for a simpler, quicker, single device that may provide access to the renal vasculature for the delivery of interventional devices. There is in particular a need for such a device that may provide safe, quick, and easy access to both renals arteries or both renal veins simultaneously.

[0039] The particular need for rapid cannulation for percutaneous translumenal access to the renal system via the aorta is also illustrative of other procedures where rapid access to side-branch vessels from main vessels is required. These other situations also often require bilateral cannulation of multiple side branches from the main vessel. One such example is cannulation of right and left coronary artery systems from the aortic root, such as for coronary angiograms or other recanalization or stenting procedures. Another example may include cannulation of internal and external carotid arteries for certain procedures such as diagnosing or treating stroke, etc. In any event, while each particular anatomical location within the body is unique and requires special considerations in providing appropriate access systems and devices, certain general requirements and thus broad aspects of the system features may be common amongst such devices. For example, in cases where branches are to be cannulated via ostia located at unique positions along a substantially large vessel's wall (e.g. the aorta), conventional guide or delivery sheaths may be very difficult to find and seat into such discrete ostia from within the relatively expansive real estate of the main vessel.

[0040] Accordingly, there is also a need for an improved delivery device that is adapted to provide rapid, remote access for delivering interventional devices into a branch vessel extending at a unique location from a main vessel. There is in particular such a need for a bilateral delivery device assembly that is adapted to provide such access for interventional device delivery into multiple branch vessels extending at relatively unique locations from the main vessel.

[0041] Whereas various specific interventional procedures may benefit from such delivery systems, stenting and filtering methods are considered to reap particular benefit from an improved delivery modality. This in particular applies with respect to such procedures in the renal system.

[0042] Accordingly, there is a need for a stenting system and method that includes a stent assembly that cooperates with an improved delivery system for rapid cannulation and remote access and delivery of the stent assembly to at least one branch vessel extending from a main vessel. There is also a need for such stenting system and method that provides for at least bi-lateral cannulation and stent delivery into each of multiple branch vessels extending from a main vessel. Moreover, there is in particular a need for such stenting systems and methods just described that are in particular well suited and adapted for delivering stents into the renal arteries extending from renal ostia along an abdominal aorta wall.

[0043] In addition, there is also still a need for an embolic filtering system and method that includes an embolic filter assembly that cooperates with an improved delivery system for rapid cannulation and remote access and delivery of the filter assembly to at least one branch vessel extending from a main vessel. There is also a need for such filtering system and method that provides for at least bi-lateral cannulation and filter delivery into each of multiple branch vessels extending from a main vessel. Moreover, there is in particular a need for such filtering systems and methods just described that are in particular well suited and adapted for delivering embolic filters into the renal arteries extending from renal ostia along an abdominal aorta wall.

[0044] As will be seen below, certain of the problems and needs left unmet by prior disclosures and efforts are addressed by one or more of the various aspects, modes, embodiments, variations, or features of the current invention.

BRIEF SUMMARY OF THE INVENTION

[0045] Accordingly, various aspects of the invention are to be appreciated as follows.

[0046] One aspect of the invention is a renal delivery catheter that improves upon the ability to provide lumenal access into the renal arteries via the abdominal aorta.

[0047] Another aspect of the invention is a bifurcated delivery catheter configured for the placement of an inteventional device, such as a guide wire, stent, embolic protection assembly, etc. within the renal arteries of a patient.

[0048] Another aspect of the invention is a local renal delivery system that does not require a host of specially designed guiding catheters and thus reduces the associated clinical complications.

[0049] Another aspect of the invention is a device and method adapted to locally deliver agents and devices bi-laterally into each of two renal arteries perfusing both kidneys of a patient while a substantial portion of aortic blood flow is allowed to perfuse downstream across the location of the renal artery ostia and into the patient's lower extremities.

[0050] Another aspect of the invention is a device and method that is adapted to efficiently gaining percutaneous translumenal access into each side of the kidney system via their separate renal artery ostia along the abdominal aortic wall, such that procedures such as fluid agent or interventional device delivery may be performed locally within both sides of the renal system.

[0051] Another aspect of the invention is a device and method that is adapted to locally deliver a fluid agent into a renal vein or artery while performing an interventional procedure within the vein or artery.

[0052] Another aspect of the invention is a device and method adapted to locally deliver fluids, agents, and/or interventional devices into the renal arteries or veins of a patient, and while allowing other treatment or diagnostic devices and systems, such as angiographic or guiding catheter devices and related systems, to be delivered across the location of the respective renal vessel ostia.

[0053] Another aspect of the invention is a device and method that is adapted to locally deliver fluids, agents, or interventional devices into the renal arteries of a patient, for therapeutic, prophylactic or diagnostic procedures related to the kidneys.

[0054] Another aspect of the invention is a device and method for locally isolating delivery of fluids, agents, or interventional devices into the renal arteries or veins of a patient in order to treat, protect, or diagnose the renal system adjunctive to performing other contemporaneous medical procedures, such as angiograms, and in particular without limitation while performing other translumenal procedures upstream of the renal artery ostia.

[0055] Another aspect of the invention is a system and method that provides a local renal drug delivery system and at least one adjunctive distal interventional device, such as an angiographic or guiding catheter, through a common delivery sheath.

[0056] Another aspect of the invention is a system and method that is adapted to deliver both a local renal drug delivery system and at least one adjunctive distal interventional device, such as an angiographic or guiding catheter, angioplasty or stent assembly, embolic protection assembly, or guidewire through a single access site, such as a single femoral arterial puncture.

[0057] Another aspect of the invention is a system and method that is adapted to treat, and in particular prevent, ARF, and in particular relation to RCN or CHF, by locally delivering renal protective or ameliorative drugs into the renal arteries, such as contemporaneous with radiocontrast injections such as during angiography procedures.

[0058] Another aspect of the invention is a single delivery device that is adapted to provide access to the renal vasculature for the delivery of interventional devices. According to one mode of this aspect, the device provides such access to both renals arteries, or both renal veins, simultaneously.

[0059] Another aspect of the invention is a delivery system that is adapted to provide rapid cannulation for percutaneous translumenal access to multiple side-branch vessels from a main vessel.

[0060] According to one mode, this delivery system is adapted to provide bilateral cannulation of multiple side branches from the main vessel. In one embodiment, the delivery system provides such cannulation of right and left coronary artery systems from the aortic root. In further embodiments, one or more interventional devices adapted to conduct coronary angiograms or other recanalization or stenting procedures is combined with this delivery system. In another embodiment, the delivery system provides cannulation of internal and external carotid arteries. Further features related to this embodiment may further include the combination of further devices adapted to perform certain procedures in the cannulated vessels such as diagnosing or treating stroke, etc.

[0061] Another aspect of the invention is a delivery device that is adapted to provide rapid, remote access for delivering interventional devices into a branch vessel extending at a unique location from a main vessel. According to one mode, a bilateral delivery device assembly is provided that is adapted to provide such access for interventional device delivery into multiple branch vessels extending at relatively unique locations from the main vessel.

[0062] Another aspect of the invention is a stenting system and method that includes a stent assembly that cooperates with a delivery system that is adapted to cannulate at least one branch vessel extending from a main vessel and to deliver the stent assembly to the at least one branch vessel. According to one mode, the delivery system is adapted to provide bi-lateral cannulation and stent delivery into each of multiple branch vessels extending from a main vessel. In another mode, the delivery system is adapted to deliver the stent assembly into the renal arteries extending from renal ostia along an abdominal aorta wall. In another mode, the delivery system comprises a bifurcated catheter that is adapted to cannulate each of two renal arteries, and to deliver at least one of such stent assemblies into at least one of the two cannulated arteries. In a further mode, the bifurcated catheter is adapted to delivery first and second stent assemblies into first and second renal arteries that are both cannulated by branches of the bifurcated catheter.

[0063] Another aspect of the invention is a bifurcated catheter with a proximal end portion and a bifurcated distal end portion with first and second branches. A first angioplasty balloon is secured to the first branch. The bifurcated distal end portion is adapted to deliver the first branch into a first branch lumen extending from a main lumen in the body, such that the first angioplasty balloon is positioned within the first branch lumen.

[0064] According to one mode of this aspect, the first branch further comprises a fluid port in fluid communication with a proximal port along the proximal end portion. In a further embodiment of this mode, a source of renal protective agent is coupled to the proximal port.

[0065] According to another mode, a balloon expandable stent is mounted on the first angioplasty balloon.

[0066] According to another mode, the bifurcated distal end portion is adapted to deliver the second branch into a second branch lumen from the main lumen. In one embodiment of this mode, a second angioplasty balloon is secured to the second branch, such that the second branch positions the second angioplasty balloon within the second branch. In a further embodiment, at least one balloon expandable stent is mounted on at least the first or second angioplasty balloon. In another embodiment, first and second balloon expandable stents are mounted onto the first and second angioplasty balloons.

[0067] Another aspect of the invention is a bifurcated catheter with a proximal end portion and a bifurcated distal end portion with first and second branches. A first stent assembly is coupled to the first branch. The bifurcated distal end portion is adapted to deliver the first branch into a first branch lumen extending from a main lumen in the body, such that the first stent assembly is positioned within the first branch lumen.

[0068] According to one mode of this aspect, the first stent assembly comprises a balloon expandable stent. According to another mode, the first stent assembly comprises a self-expanding stent. In one embodiment of this mode, an adjustable retainer assembly is coupled to the self-expanding stent and is adjustable between first and second conditions. In the first condition, the self-expanding stent is retained in a radially collapsed configuration that is adapted to be delivered into the first branch lumen. In the second condition, the self-expanding stent is released from retention and is allowed to self-expand to a radially expanded configuration with a larger outer diameter than the radially collapsed configuration.

[0069] In another mode, a second stent assembly is coupled to the second branch. The bifurcated distal end portion is adapted to position the second branch within a second branch lumen from the main lumen, such that the second stent assembly is positioned within the second branch lumen.

[0070] Another aspect of the invention is a bilateral recanalization system that is adapted to provide bilateral lumenal recanalization within each of first and second occluded lumens extending from a main lumen or body space.

[0071] According to one mode, the bilateral recanalization system is adapted to deliver first and second recanalization assemblies into each of the first and second occluded lumens via a single percutaneous access site.

[0072] According to another mode, the bilateral recanalization system is adapted to deliver the first and second recanalization assemblies into each of the first and second occluded lumens via a single introducer sheath into the main lumen.

[0073] According to another mode of this aspect, the renal recanalization system comprises first and second distal embolic filters. According to another mode, the renal recanalization system comprises first and second proximal distal protection assemblies. According to one embodiment of this mode, each of the first and second proximal distal protection assemblies comprises an expandable member that is adapted to occlude the respective first or second branch lumens.

[0074] Another aspect of the invention is an embolic protection system with a first embolic protection assembly that cooperates with a delivery system that is adapted to cannulate a first branch lumen extending from a main lumen and to deliver the first embolic protection assembly into the first branch lumen.

[0075] According to one mode, the embolic protection system is adapted to deliver first and second embolic protection assemblies into each of the first branch lumen and a second branch lumen via a single percutaneous access site.

[0076] According to another mode, the embolic protection system is adapted to deliver first and second embolic protection assemblies into each of the first branch lumen and a second branch lumen via a single introducer sheath into the main lumen.

[0077] According to another mode, the delivery system includes a bifurcated catheter with first and second branches that are adapted to bi-laterally cannulate each of the first branch lumen and a second branch lumen, respectively, extending from the main lumen. A second embolic protection assembly is coupled to the second branch so as to be positioned within the second branch lumen simultaneously with the first embolic protection assembly positioned in the first branch lumen.

[0078] Another aspect of the invention is a renal embolic protection system that is adapted to provide bilateral renal embolic protection within each of two renal arteries via a single access site.

[0079] Another aspect of the invention is a renal embolic protection system that is adapted to provide bilateral renal embolic protection within each of two renal arteries via a single introducer sheath into the abdominal aorta.

[0080] Another aspect of the invention is an embolic protection system with a delivery catheter having a proximal end portion and a bifurcated distal end portion with first and second branches, and a first embolic protection assembly secured to the first branch. The bifurcated distal end portion is adapted to deliver the first branch into a first branch lumen extending from a main lumen or body space, such that the first embolic protection assembly is positioned within the first branch lumen. In one mode of this aspect, a second embolic protection assembly is secured to the second branch.

[0081] Another aspect of the invention is a renal thermal therapy system that includes a bifurcated delivery catheter with a first end portion and a bifurcated second end portion with first and second branches that are adapted to cannulate first and second renal arteries, respectively, from an abdominal aorta. A thermal therapy assembly is adapted to be coupled to at least one of the first and second branches in a manner that is adapted to adjust the temperature of fluid flowing within the respectively cannulated renal artery. In one further mode, the thermal therapy assembly is adapted to be coupled to each of the first and second branches so as to adjust the temperature flowing within each of the respectively cannulated renal arteries.

[0082] In addition to these particular benefits for local delivery of fluids, agents, or devices into a patient's renal arteries or veins via their ostia along the aorta or vena cava, respectively, other aspects of the invention include such devices and methods that are adapted to locally deliver such materials into other branch vessels or lumens extending from other main vessels or lumens, respectively, in a patient.

[0083] Another aspect of the invention is a local renal delivery system with two renal delivery members adapted to be positioned within first and second renal arteries and are both coupled to a proximal coupler assembly located externally of the patient's body for material delivery into the two separate arteries via the two delivery members.

[0084] In one mode of this aspect, a first renal delivery member has a first distal port that is adapted to be delivered to a first delivery position within a first renal artery via a first corresponding renal ostium located at a first location along an abdominal aorta wall of the abdominal aorta in a patient. A second renal delivery member has a second distal port that is adapted to be delivered to a second delivery position within a second renal artery via a second corresponding renal ostium located at a second location along the abdominal aorta wall that is different than the first location. The proximal coupler assembly is adapted to be located externally of the patient when the first and second distal ports are positioned at the first and second delivery positions, respectively. The proximal coupler assembly is also coupled to the first and second distal ports so as to deliver material from outside the patient's body via the proximal coupler assembly, through the first and second distal ports at the first and second delivery positions, respectively, and into the first and second renal arteries, also respectively.

[0085] In another mode of this aspect, the system further includes an anchor that is adjustable from a first configuration to a second configuration as follows. The anchor in the first configuration is adapted to be delivered to an anchoring position along one of the abdominal aorta or the first renal artery within the patient. The anchor is adjustable to the second configuration at the anchoring position and is thus adapted to secure the first renal delivery member with the first distal port substantially retained at the first delivery position within the first renal artery. The anchor in the second configuration at the anchoring position is also adapted to allow substantial blood flow across the anchoring position.

[0086] In another mode of this aspect, the first and second renal delivery assemblies together comprise a bi-lateral renal delivery system that cooperates with a vascular access system and a percutaneous translumenal interventional device as follows. The vascular access system has an elongate tubular body with at least one lumen extending between a proximal port and a distal port that is adapted to be positioned within a vessel having translumenal access to a location along the abdominal aorta associated with the first and second renal ostia when the proximal port is located externally of the patient. The percutaneous translumenal interventional device is adapted to be delivered to an intervention location across the location while the first and second distal ports are located at the first and second delivery positions, respectively. The bilateral renal delivery assembly and percutaneous translumenal interventional device are adapted to be delivered percutaneously into the vessel through the vascular access device, and are also adapted to be simultaneously engaged within the vascular access device.

[0087] Another aspect of the invention is a local renal delivery system with a renal delivery member adapted to be positioned within a renal artery via its ostium along an abdominal aorta wall and that is adapted to be coupled to a proximal coupler assembly located externally of the patient. An anchor is also provided to secure the renal delivery member within the renal artery without substantially occluding blood flow across the anchor.

[0088] In one mode of this aspect, the renal delivery member has a distal port that is adapted to be delivered to a delivery position within the renal artery via a corresponding renal ostium along an abdominal aorta wall. The proximal coupler assembly is adapted to be located externally of the patient when the distal port is positioned at the delivery position. The proximal coupler assembly is also fluidly coupled to the distal port so as to deliver material from outside the patient's body via the proximal coupler assembly, through the distal port at the delivery position and into the renal artery. The anchor is adjustable from a first configuration to a second configuration as follows. The anchor in the first configuration is adapted to be delivered to an anchoring position along one of the abdominal aorta or the renal artery within the patient. The anchor is adjustable from the first configuration to the second configuration at the anchoring position where it is adapted to secure the renal delivery member with the distal port substantially retained at the delivery position within the renal artery. In addition, the anchor in the second configuration at the anchoring position is adapted to allow substantial blood flow across the anchoring position.

[0089] In one embodiment of this mode, the system further includes a second renal delivery member with a second distal port. The second renal delivery member is adapted to be positioned at least in part within a second renal artery across a second renal ostium having a unique location with respect to the first location along an abdominal aorta wall of an abdominal aorta in the patient with respect, and such that the second distal port is located at a second position within the renal artery. The proximal coupler assembly is fluidly coupled to each of the first and second distal ports so as to deliver material from outside the patient's body via the proximal coupler assembly, through the first and second distal ports at the first and second respective delivery positions and into the first and second renal arteries, respectively.

[0090] Another aspect of the invention is a local renal delivery system with a vascular access system, a bi-lateral renal delivery assembly, and a percutaneous translumenal interventional device. The vascular access system is adapted to deliver the bi-lateral renal delivery assembly and the percutaneous translumenal interventional device simultaneously into the vasculature such that they can perform their respective functions.

[0091] In one mode of this aspect, the vascular access system has an elongate tubular body with at least one lumen extending between a proximal port and a distal port that is adapted to be positioned within a vessel when the proximal port is located externally of the patient. The bi-lateral renal delivery assembly includes first and second renal delivery members with first and second distal ports, respectively, that are adapted to be delivered to first and second respective delivery positions within first and second renal arteries, respectively, via first and second corresponding renal ostia, respectively, at unique relative locations along an abdominal aorta wall of the patient. The percutaneous translumenal interventional device is adapted to be delivered to an intervention location across the location while the first and second distal ports are located at the first and second delivery positions, respectively. The bi-lateral renal delivery assembly is adapted to simultaneously deliver material from an external location relative to the patient and directly into each of first and second renal arteries via first and second distal ports at the first and second delivery positions, respectively. The bilateral renal delivery assembly and percutaneous translumenal medical device are adapted to be delivered percutaneously into a vessel having translumenal access to the location through the vascular access device, and are also adapted to be simultaneously engaged within the vascular access device.

[0092] According to another mode, the system further includes an anchor that is adjustable from a first configuration to a second configuration as follows. The anchor in the first configuration is adapted to be delivered to an anchoring position along one of the abdominal aorta or the first renal artery within the patient. The anchor is adjustable to the second configuration at the anchoring position such that it is adapted to secure the first renal delivery member with the first distal port substantially retained at the first delivery position within the first renal artery. The anchor in the second configuration at the anchoring position is also constructed so as to allow substantial blood flow across the anchoring position.

[0093] According to a further embodiment of the foregoing aspects, modes, or embodiments providing first and second renal delivery members, an elongate body is provided that has a proximal end portion and a distal end portion that is adapted to be delivered to a location within the abdominal aorta when the proximal end portion extends externally from the patient. The first and second renal delivery members extend from the distal end portion of the elongate body.

[0094] In one beneficial variation of this embodiment, the first and second renal delivery members extend distally from the distal end portion of the elongate body in a bifurcated fashion.

[0095] In another beneficial variation, the distal end portion of the elongate body comprises first and second ports, and the first and second renal delivery members are moveable relative to the elongate body and are adjustable to extend from the elongate body through the first and second ports, respectively. According to a further feature of this variation, the distal end portion of the elongate body may terminate at a distal tip, the first and second ports are located at the distal tip, and the first and second renal delivery members are adjustable to extend distally from the distal tip of the elongate body through the first and second ports, respectively. According to another feature, the first and second ports are located at different positions spaced around the circumference of the elongate body proximally of the distal tip, and the first and second renal delivery members are adjustable to extend laterally from the elongate body relative to the longitudinal axis through the first and second ports.

[0096] In another beneficial variation, the first renal delivery member is substantially fixed and un-adjustable with respect to the elongate body, and the second renal delivery member is adjustable relative to the elongate body.

[0097] In another variation, a cannulation assembly is located along the distal end portion of the elongate body with a distal end, a proximal end, a length between the proximal and distal ends along a longitudinal axis, a circumference around the longitudinal axis. The first and second renal delivery members are located along the cannulation assembly at first and second circumferential locations spaced around the circumference. The cannulation assembly is adapted to be positioned at a location within the abdominal aorta associated with the first and second renal ostia. The cannulation assembly is longitudinally collapsible at the location such that the distal and proximal ends of the first and second renal delivery members are brought together with respect to each other. Accordingly, upon longitudinal collapse of the cannulation assembly, the first and second renal delivery members are biased to extend radially outward from the longitudinal axis at their respective circumferential locations such that the radially extended delivery members are adapted to cannulate the first and second renal arteries via their respective renal ostia along the location, respectively.

[0098] In another beneficial variation, the first and second delivery members are two of a plurality of more than two renal delivery members. Each delivery member extends laterally from the elongate body with a memory shape such that each terminates at a respective distal tip having a unique position circumferentially about the longitudinal axis. The memory shape of each of the plurality of renal delivery members is adapted to bias the renal delivery member against the abdominal aorta wall at a location along the abdominal aorta corresponding with the first and second renal ostia such that each renal delivery member contacts the wall at a unique lateral location around the circumference of the abdominal aorta wall relative to the other renal delivery members. The first and second renal delivery members are those renal delivery members of the plurality having their unique lateral locations corresponding with the unique locations of the first and second renal ostia, respectively. The system is further adapted to isolate delivery of material from outside the patient to only the first and second renal delivery members cannulated into the first and second renal arteries, respectively.

[0099] In still further variants to this feature, the distal tips of multiple ones of the pluralities of renal delivery members are further adapted to have unique longitudinal locations along the longitudinal axis. Or, in another regard, the first and second renal delivery members may be adjustable from a first orientation to a second orientation relative to the distal end portion of the elongate body upon cannulation of the first and second renal arteries as follows. In the first orientation the first and second distal ports of the first and second renal delivery members are not fluidly coupled to the proximal coupler assembly. In the second orientation the first and second distal ports of the first and second renal delivery members are fluidly coupled to the proximal coupler assembly.

[00100] According to another embodiment of the various aspects, modes, or embodiments providing two renal delivery members to cannulate and delivery material simultaneously to each of two renal arteries, one or both of the two renal delivery members is substantially self-cannulating with respect to the respective renal artery via the corresponding ostium along the abdominal aorta wall such that the member does not require controlled manipulation of its shape within the abdominal aorta for cannulation.

[00101] In one variation of this embodiment, the self-cannulating renal delivery member is flow-directed with respect to self-cannulation of the respective renal artery via the corresponding renal ostium along the abdominal aorta wall. In another variation, the self-cannulating renal delivery member is adapted to passively take a shape within the abdominal aorta that is adapted to self-cannulate the respective renal artery. In another variation, the self-cannulating renal delivery member is adjustable between a first shape and a second shape that is a memory shape configuration. It takes the first shape during placement within a radially confining outer sheath, and is self-adjustable from the first shape to the second shape when released from radial confinement outside of the radially confining outer sheath. The memory response toward the second shape is adapted to self-cannulate the respective renal artery.

[00102] According to another embodiment of the foregoing aspects, modes, or embodiments providing a bi-lateral renal infusion system with two renal delivery members, one or both of the renal delivery members is adapted to have a controllable shape and is selectively steerable when positioned within the abdominal aorta so as to selectively cannulate the respective renal artery via its corresponding renal ostium along the abdominal aorta wall.

[00103] According to one feature of this embodiment, a pull-wire has a distal end portion secured to the renal delivery member at a location so as to be positioned with the renal delivery member within the abdominal aorta, and a proximal end portion of the pull-wire extends proximally therefrom. Upon manipulation of the proximal end portion of the pull-wire, the distal end portion of the pull-wire manipulates the shape of the steerable renal delivery member such that it may selectively cannulate the respective renal artery via its corresponding renal ostium.

[00104] In another feature, the controllable renal delivery member has an elongate body with a stylet passageway that houses a stylet that is moveable relative to the elongate body of the at least one renal delivery member. The elongate body is adjustable from a first shape to a second shape by relative movement of the stylet between a first stylet position and a second stylet position, respectively, with respect to the elongate body of the at least one renal delivery member. The elongate body in the first shape is adapted to be delivered into the abdominal aorta through a radially confining outer sheath. The elongate body in the second shape is adapted to cannulate the respective renal artery via the corresponding ostium. The relative movement of the stylet relative to the renal delivery member controls the shape of the renal delivery member. In one further variant of this feature, the stylet has a shape; and the elongate body of the renal delivery member takes the second shape based upon the shape of the stylet. In another variant, the second shape is a memory shape condition for the elongate body, and the elongate body is adjusted from the second shape to the first shape by deflection of the elongate body of the at least one renal delivery member from the memory shape condition with the stylet.

[00105] According to another embodiment of the foregoing aspects, modes, and embodiments with a bi-lateral renal delivery system provided with two renal delivery members, the first renal delivery member is substantially self-cannulating with respect to the first renal artery via the first ostium, and the second renal delivery member is not substantially self-cannulating with respect to the second renal artery via the second ostium and has a controllable shape and is steerable so as to controllably cannulate the second renal artery via the second ostium.

[00106] According to another bi-lateral renal delivery system embodiment, the proximal coupler assembly comprises first and second proximal couplers as follows. The first proximal coupler is fluidly coupled to the first distal port, and the second proximal coupler is fluidly coupled to the second distal port.

[00107] In another bi-lateral renal delivery system embodiment, the proximal coupler assembly is a single common coupler that is fluidly coupled to each of the first and second distal ports via a common fluid passageway.

[00108] According to a further embodiment of the foregoing aspects, modes, or embodiments providing an anchor in the system, the anchor is a renal anchor, and the anchoring position is located along the first renal artery.

[00109] In one variation of this embodiment, the anchor includes a shapeable section of the first delivery member that is adjustable between first and second shapes that correspond with the first and second configurations, respectively, for the anchor. The anchor is adjustable from the first shape to the second shape at the anchoring position such that the second shape is biased to radially extend from the longitudinal axis of the first delivery member

and is adapted to engage a wall of the first renal artery with sufficient force to secure the first delivery member with the first distal port at the first delivery position.

[00110] According to one feature of this variation, the anchor may include a pull-wire with a distal end portion secured to the renal delivery member at a fixed location corresponding with the shapeable section of the first delivery member, and with a proximal end portion extending proximally from the fixed location. Upon manipulation of the proximal end portion of the pull-wire, the distal end portion of the pull-wire manipulates the shape of the first renal delivery member from the first shape to the second shape.

[00111] According to another feature of the variation, the first renal delivery member has a stylet passageway that houses a stylet that is moveable relative to the shapeable section. The shapeable section is adjustable from the first shape to the second shape by relative movement of the stylet between a first stylet position and a second stylet position, respectively, within the stylet passageway along the shapeable section. In one further variant of this feature, the stylet has a shape; and the shapeable section is deflectable from the first shape to the second shape by the shape of the stylet. In another variant, the second shape comprises a memory shape condition for the shapeable section, and the shapeable section is deflectable from the second shape to the first shape by adjusting the relative position of the stylet.

[00112] In another feature, the first delivery member includes proximal and distal sections that are located proximally and distally adjacent to the shapeable section. When the anchor is in the second shape at the anchoring position, the proximal and distal sections are positioned along opposite sides of the renal artery wall. In an alternative feature, when the anchor is in the second shape at the anchoring position, the proximal and distal sections are positioned along one side of the renal artery wall and the shapeable section is biased against a second opposite side of the renal artery wall.

[00113] In another variation, the anchor has a radially extendable member located along the elongate body and that is adjustable between first and second shapes that correspond with the first and second configurations for the anchor as follows. The radially extendable member in the second shape is biased to radially extend from the elongate body relative to the first shape and is adapted to radially engage a wall of the first renal artery with sufficient force to secure the first delivery member within the first renal artery with the first delivery port at the first delivery position.

[00114] According to one feature of this variation, the radially extendable member may extend at least in part between proximal and distal locations that are spaced by a distance along an outer surface of the elongate body and where the radially extendable member is respectively engaged with the elongate body as follows. The proximal location comprises a port that communicates with a lumen within the elongate body. The radially extendable member has a length between a proximal portion and a distal portion that is longer than the distance between proximal and distal locations, such that in the first shape the proximal portion of the radially extendable member extends proximally within the port and proximally along the lumen to an internal location such that the length extends between the internal location and the distal location. In the second shape the proximal portion of the radially extendable member is advanced distally from the internal location to generally correspond with the port at the proximal location such that the length of the radially extendable member extends along a radially extended path between the proximal and distal locations externally of the elongate body within the first renal artery.

[00115] In one variant of this feature, the radially extendable member extends directly between the proximal and distal locations in the first shape. In another variant, the radially extendable member extends around a circumference of the elongate body between the proximal and distal locations. The first shape of the radially extendable member is wrapped around the elongate body between the proximal and distal locations; the second shape includes an arc that is adapted to engage the wall of the first renal artery over a portion of the circumference of the first renal artery wall.

[00116] In another variant, the second shape is a memory shape for the radially extendable member, such that the radially extendable member is adjustable to the first shape within a radially confining outer sheath. The radially extendable member is self-adjustable at the anchoring position from the first shape to the second shape by releasing the radially extendable member from radial confinement. In still a further feature of this variant, the second shape may be a partial loop shape that extends along an arc between first and second locations around the circumference of the elongate body. In another, the anchor further comprises a second said radially extendable member with a second shape that is a partial loop shape that extends along an arc along an opposite side of the elongate body. The first and second partial loop shapes are adapted to engage the first renal artery wall on opposite sides with the elongate body located within the first renal artery therebetween.

[00117] According to another variant, the radially extendable member includes an inflatable balloon that is adjustable between a deflated configuration and an inflated configuration as follows. The deflated configuration characterizes the first shape, and the inflated configuration characterizes the second shape. In one feature of this variant, he second shape characterized by the inflated condition for the balloon may be a shape that is not round. Beneficially, it may be an oblong lobe with a first diameter that spans across the first renal artery transverse to the longitudinal axis of the first renal artery so as to engage to the first renal artery wall with sufficient force to anchor the first renal delivery member there, but with a second diameter transverse to the first diameter that is less than the diameter of the first renal artery. With this shape the oblong lobe does not completely occlude the first renal artery at the anchoring position.

[00118] The second shape may also include a plurality of such oblong lobes that are arranged about the circumference of the elongate body in spaced arrangement relative to each other. In this arrangement, in the second shape each oblong lobe is adapted to radially engage a unique portion of the first renal artery wall. Blood is thus allowed to flow in the spaces between the adjacent oblong lobes.

[00119] In yet another variation, the anchor includes a plurality of radially extendable members that are located at spaced intervals around the circumference of the elongate body. Each radially extendable member in the second shape is adapted to engage the wall of the first renal artery at a different location around the circumference of the first renal artery relative to the other radially extendable members.

[00120] According to another anchoring embodiment applicable to one or more of the various aspects, modes, or embodiments above, the system includes an anchor that is an aortic anchor deployable at an anchoring position that is located along the abdominal aorta.

[00121] In one variation of this embodiment, the aortic anchor includes a shapeable section of the first renal delivery member that is adjustable between first and second shapes that correspond with the first and second configurations, respectively, for the anchor as follows. The first delivery member has proximal and distal sections located proximally and distally adjacent the shapeable section and that includes the first distal port. The distal section includes the first distal port and is adapted to be positioned within the first renal artery with the first distal port at the first delivery location and with the shapeable section located along the anchoring position within the abdominal aorta. The proximal section extends along a longitudinal axis where it transitions to the shapeable section. The shapeable section is adjustable from the first shape to the second shape at the anchoring position such that the second shape is biased to radially extend from the longitudinal axis and is adapted to engage a wall of the abdominal aorta at the anchoring position with sufficient force to secure the first delivery member with the first distal port at the first delivery position.

[00122] According to one feature of this variation, the shapeable section has a proximal region and a distal region characterized as follows. In the second shape the proximal region is radially biased to a first side of the longitudinal axis so as to contact a first side of the abdominal aorta wall, and the distal region is radially biased to a second side generally opposite the first side of the longitudinal axis so as to contact a second side generally opposite the first side of the abdominal aorta wall. The proximal and distal regions cooperate to apply generally opposite forces against the first and second sides of the

abdominal aorta wall to thereby anchor the first delivery member at that location.

[00123] In a further variant of this feature, the distal region forms a loop that extends from the proximal region along the first side of the abdominal aorta, arcs across the abdominal aorta to engage the second side of the abdominal aorta, and arcs back across the abdominal aorta from the second side toward the first side. The distal section extends from the distal region extending across the abdominal aorta and into the first renal artery via the first renal ostium.

[00124] According to another anchored bi-lateral renal delivery embodiment, a second anchor is provided that is adjustable from a first configuration to a second configuration as follows. The second anchor in its respective first configuration is adapted to be delivered to a second anchoring position along one of either the abdominal aorta or the second renal artery within the patient. The second anchor in its respective second configuration at the second anchoring position is adapted to secure the second renal delivery member with the second distal port substantially retained at the second delivery position within the second renal artery. In addition, the second anchor in its respective second configuration at the second anchoring position is constructed so as to allow substantial blood flow from the abdominal aorta and along the second renal artery to the kidney.

[00125] In one variation of this embodiment, the first anchor is a renal anchor and the first anchoring position is within the first renal artery, and the second anchor is a renal anchor and the second anchoring position is within the second renal artery. In another variation, the first anchor is an aortic anchor and the first anchoring position is within the abdominal aorta, and the second anchor is an aortic anchor and the second anchoring position is within the abdominal aorta. Or, the first anchor may be a renal anchor with the first anchoring position located within the first renal artery, and the second anchor is an aortic anchor with the second anchoring position being located within the abdominal aorta.

[00126] According to a further embodiment of the various aspects of the invention noted above, the system further includes a source of material, and the first delivery member is adapted to deliver the material from a location externally of the patient through the first delivery port at the first delivery position and into the first renal artery.

[00127] In one highly beneficial variation of this embodiment, the source of material comprises a fluid agent, and in particular may be a renal protective agent. The fluid agent may be a diuretic, such as in particular Furosemide or Thiazide, or analog or derivative thereof. The fluid agent may be a vasopressor, such as in one particular beneficial example Dopamine, or an analog or derivative thereof. The fluid agent may be a vasodilator or otherwise a vasoactive agent. In other particular beneficial examples, the fluid agent includes Papaverine, a calcium-channel blocker, Nifedipine, Verapamil, fenoldapam mesylate, a dopamine DA_1 agonist, or analogs or derivatives thereof, or combinations or blends thereof.

[00128] According to further embodiments providing a bi-lateral renal delivery system in combination with a vascular access device and percutaneous translumenal interventional device, the percutaneous translumenal interventional device may be a delivery device to enable interventional therapy or diagnosis, such as a guiding catheter or an angiographic catheter, or may be a direct interventional device such as a recanalization device, e.g. balloon angioplasty, stenting, or atherectomy device, etc. In further variations, the system is adapted to provide such cooperative operation between these components in particular where the percutaneous translumenal interventional device is between about 4 French and about 8 French.

[00129] Another aspect of the invention is a local renal vein delivery system that provides controlled retrograde flow of material to the kidney via the renal vein as follows. The renal vein delivery member has a distal port that is adapted to be delivered to a delivery position within a renal vein via its ostium along a vena cava in a patient. A proximal coupler assembly is adapted to be located externally of the patient when the distal port is at the delivery position, and is fluidly coupled to the distal port such that a material may be delivered from outside of the patient through the proximal coupler assembly, through the distal port at the delivery position, and into the renal vein. An occlusion member is adjustable between a first configuration and a second configuration as follows. The occlusion member in the first configuration is adapted to be delivered to an occlusion position located toward ostium from the delivery position, such that the distal port and occlusion members are located at the delivery and occlusion positions, respectively. The occlusion member in the second configuration at the occlusion position is adapted to substantially occlude flow from the renal vein and into the vena cava. A control system is provided and is adapted to control cooperative operation of the renal vein delivery assembly and the occlusion member between first and second modes of operation as follows. In the first mode the occlusion member is in the first configuration at the occlusion position and venous blood is allowed to flow from the kidney and along the renal vein and into the vena cava. In the second mode the occlusion member is in the second configuration at the occlusion position, venous blood is substantially occluded from flowing from the kidney along the renal vein and into the vena cava, and a volume of fluid agent flows through the distal port at the delivery position and into the renal vein at sufficient pressure to provide retrograde flow into the respective kidney coupled to the renal vein.

[00130] According to one further mode of this aspect, a second renal delivery member is also provided and has a second distal port that is adapted to be delivered to a second delivery position within a second renal vein via a second ostium having a unique location along the vena cava relative to the first ostium. The proximal coupler assembly is fluidly coupled to each of the first and second distal ports such that the material may be delivered from outside of the patient through the proximal coupler assembly, through both of the first and second distal ports at the first and second respective delivery positions, and into the first and second renal veins, respectively. A second occlusion member is adjustable between a first configuration and a second configuration as follows. The second occlusion member in the first configuration is adapted to be delivered to a second occlusion position located toward the second ostium from the second delivery position, such that the second distal port and second occlusion members are located at the second delivery and second occlusion positions, respectively. The second occlusion member in the second configuration at the second occlusion position is adapted to substantially occlude flow from the renal vein and into the vena cava. In addition, the control system is further adapted to control cooperative operation of the second renal delivery assembly and the second occlusion member between third and fourth modes of operation as follows. In the third mode the second occlusion member is in the first configuration at the second occlusion position and venous blood is allowed to flow from the kidney and along the second renal vein and into the vena cava. In the second mode the second occlusion member is in the second configuration at the second occlusion position, venous blood is substantially occluded from flowing from the kidney along the renal vein and into the vena cava, and a volume of fluid agent flows through the second distal port at the second delivery position and into the second renal vein with retrograde flow into the respective kidney coupled to the second renal vein.

[00131] In a further embodiment of this mode, the first and third modes of operation are at least in part simultaneous, and the second and fourth modes of operation are at least in part simultaneous.

[00132] Additional aspects of the invention include various methods for treating a renal system in a patient as follows.

[00133] One method aspect includes: positioning a first distal port of a first renal delivery member at a first delivery position within a first renal artery via a first corresponding renal ostium located at a first location along an abdominal aorta wall of an abdominal aorta in a patient, and also positioning a second distal port of a second renal delivery member at a second delivery position within a second renal artery via a second corresponding renal ostium located at a second location along the abdominal aorta wall that is different than the first location. This method also includes positioning a proximal coupler assembly externally of the patient when the first and second distal ports are positioned at the first and second delivery positions, respectively. Also included is the step of delivering a material from outside the patient's body via

the proximal coupler assembly, through the first and second distal ports at the first and second delivery positions, respectively, and into the first and second renal arteries, also respectively.

[00134] Another method aspect includes: delivering a distal port of a renal delivery member to a delivery position within a renal artery via a corresponding renal ostium along an abdominal aorta wall, positioning a proximal coupler assembly externally of the patient when the distal port is positioned at the delivery position, delivering an anchor in a first configuration to an anchoring position along one of the abdominal aorta or the renal artery within the patient, and adjusting the anchor at the anchoring position from the first configuration to a second configuration that secures the renal delivery member with the distal port substantially retained at the delivery position within the renal artery. In addition, this method also includes allowing substantial blood flow across the anchoring position when the anchor is in the second configuration at the anchoring position, and delivering material from outside the patient's body via the proximal coupler assembly, through the distal port at the delivery position and into the renal artery.

[00135] Another method aspect of the invention includes: positioning a distal port of a tubular body of a vascular access system within a vessel having transvascular access to a location along an abdominal aorta associated with first and second renal ostia when a proximal port of the tubular body is located externally of the patient. Another step is introducing first and second renal delivery members of a bi-lateral local renal deliver assembly into the vessel through the tubular body. Another step is introducing a percutaneous translumenal interventional device into the vessel through the tubular body. A further step includes delivering first and second distal ports of the first and second renal delivery members, respectively, to first and second respective delivery positions within first and second renal arteries, respectively, via the first and second renal ostia, also respectively. Another step is delivering a distal end portion of the percutaneous translumenal interventional device to an intervention location across the location while the first and second distal ports are located at the first and second delivery positions, respectively. An

additional step includes simultaneously delivering material from an external location relative to the patient and directly into each of first and second renal arteries via the first and second distal ports at the first and second delivery positions, respectively. Accordingly, the bi-lateral renal delivery assembly and a proximal end portion of the percutaneous translumenal interventional device are simultaneously engaged within the tubular body of the vascular access assembly when the first and second distal ports are at the first and second delivery positions and the distal end portion of the percutaneous translumenal interventional device is at the intervention location.

[00136] Another method aspect according to the invention includes a method for preparing a bi-lateral renal delivery system for use in treating a patient as follows. This method includes: introducing first and second renal delivery members of a bi-lateral local renal delivery assembly into a tubular body of a vascular access system, and introducing a percutaneous translumenal interventional device into the tubular body.

[00137] In a further mode of this aspect, the various components used in these method steps are further characterized as follows. The bi-lateral renal delivery assembly and the percutaneous translumenal interventional device are simultaneously engaged within the tubular body of the vascular access assembly. The first and second renal delivery members have first and second distal ports, respectively, that are adapted to be delivered to first and second respective delivery positions within first and second renal arteries, respectively, via first and second renal ostia, also respectively, having unique locations along the abdominal aortic wall. The percutaneous translumenal interventional device has a distal end portion that is adapted to be delivered to an intervention location across a location along the abdominal aorta associated with the first and second renal ostia while the first and second distal ports are located at the first and second delivery positions, respectively. The first and second renal delivery members are coupled to a proximal coupler assembly that is adapted to deliver material from an external location relative to the patient and to the first and second distal ports so as to deliver the material directly into each of first and second renal arteries via the first and second distal ports at the first and second delivery positions, respectively. In addition, the tubular body of the vascular access system has a distal port that is adapted to be positioned within a vessel having transvascular access to the location along the abdominal aorta when a proximal port of the tubular body is located externally of the patient.

[00138] Another method aspect of the invention is a method for treating a renal system in a patient via a renal vein as follows. This method includes: delivering a distal port of a renal delivery member to a delivery position within a renal vein via its ostium along a vena cava in a patient, and positioning a proximal coupler assembly externally of the patient when the distal port is at the delivery position. The method also includes fluidly coupling the proximal coupler assembly to the distal port such that a material may be delivered from outside of the patient through the proximal coupler assembly, through the distal port at the delivery position, and into the renal vein. Another step is delivering an occlusion member in a first configuration to an occlusion position located toward ostium from the delivery position, such that the distal port and occlusion members are located at the delivery and occlusion positions, respectively. A further step includes adjusting the occlusion member at the occlusion position from the first configuration to a second configuration so as to substantially occlude flow from the renal vein and into the vena cava. In addition, this method also includes controlling co-operative operation of the renal delivery assembly and the occlusion member between first and second modes of operation as follows. In the first mode the occlusion member is in the first configuration at the occlusion position and venous blood is allowed to flow from the kidney and along the renal vein and into the vena cava. In the second mode the occlusion member is in the second configuration at the occlusion position, venous blood is substantially occluded from flowing from the kidney along the renal vein and into the vena cava, and a volume of fluid agent flows through the distal port at the delivery position and into the renal vein at sufficient pressure to provide retrograde flow into the respective kidney coupled to the renal vein.

[00139] Another method aspect of the invention includes flow directing a local renal delivery member from a location within an abdominal aorta and into a renal artery via its renal ostium along the aorta wall. In one further mode, two renal delivery members are flow directed into each of two separate renal ostia, such that bi-lateral local renal delivery may be performed.

[00140] Another method aspect of the invention includes cannulating a plurality of x branch lumens from a main lumen or body space by delivering y delivery members to the main lumen or body space that are adapted to be positioned at y unique locations along the main lumen or body space, such that x ones of the y delivery members are located to correspond with the x branch lumens so as to cannulate those branch lumens, wherein x and y are integers and y is greater than x.

[00141] It is to be further appreciated that the various foregoing aspects, modes, embodiments, and variations, etc. providing bi-lateral renal delivery, though highly beneficial, are also illustrative of additional broader aspects which are such systems or methods that are adapted to cannulate and deliver therapy directly into bi-lateral branch lumens extending from other main lumens or body spaces from a location externally of a patient.

[00142] Another aspect of the invention is a method for treating a renal system in a patient that includes: positioning an introducer sheath within an abdominal aorta at a location associated with first and second renal artery ostia associated with first and second renal arteries that perfuse first and second kidneys in the patient, and delivering a bi-lateral renal delivery assembly in a first configuration under radial confinement through the introducer sheath and to a first position along the location. This method further includes withdrawing the introducer with respect to the bi-lateral renal delivery assembly so as to remove the radial confinement. After removing the bi-lateral renal delivery assembly from radial confinement, the method further includes allowing first and second bifurcating delivery members to self-expand apart from each other and radially against an abdominal aorta wall at the location with shape memory recovery force to a second configuration.

[00143] A further mode of this aspect includes modifying the position of the self-expanded renal delivery assembly so as to self-cannulate at least one of

the delivery members into at least one of the renal arteries via its corresponding ostium along the abdominal aorta wall. In one particular further embodiment, the method further includes torquing the renal delivery assembly in the second configuration. In another embodiment, the method further includes modifying the longitudinal position of the renal delivery assembly in the second configuration.

[00144] Another aspect of the invention is a method for providing local therapy to a renal system in a patient that includes the following steps. A bi-lateral local renal delivery assembly is delivered to a location within an abdominal aorta corresponding with first and second renal ostium along an abdominal aorta wall of the patient. A percutaneous translumenal interventional device is delivered to an intervention location across the location corresponding with the renal ostia. A first delivery member of the bilateral local renal delivery assembly is positioned in a first renal artery via a first ostium along the abdominal aorta wall, whereas a second delivery member of the bilateral local renal delivery assembly is positioned within a second renal artery via a second ostium along the abdominal aorta wall. The bi-lateral local renal delivery assembly and percutaneous translumenal interventional device are inserted into the patient's vasculature through a common vascular access site.

[00145] A further mode of this aspect includes injecting radiocontrast dye into the patient at the intervention location with the percutaneous translumenal device.

[00146] Another aspect of the invention is a system for providing local renal therapy in a patient that includes an introducer sheath with a proximal end portion and a distal end portion that is adapted to be positioned at a location within an abdominal aorta associated with first and second renal ostia of first and second renal arteries, respectively, while the proximal end portion extends externally from the patient, and also with an introducer lumen extending between a proximal port located along the proximal end portion and a distal port located along the distal end portion. This system further includes a local injection assembly with an injection port assembly that is adapted to be delivered to the location through the introducer lumen and through the distal port in a first condition. The local injection assembly is adapted to be adjusted at the location from the first condition to a second condition that is advanced externally through the distal port at the location. In the second condition at the location the local injection assembly is adapted to be fluidly coupled to a source of fluid agent located externally from the patient. In the second condition at the location the local injection assembly is also adapted to position the injection port assembly so as to inject a volume of fluid agent substantially bilaterally into each of the two renal arteries. Further included in this system is a sensing mechanism that is adapted to sense a position of at least one of the injection port assembly or the distal port relative to at least one of the renal ostia without use of fluoroscopic or X-ray imaging.

[00147] According to one mode of this aspect, at least one marker is provided at a location that is adapted to indicate the location of at least one of the injection port assembly or the distal port with respect to a non-fluoroscopic sensor assembly located externally of the location.

[00148] In another mode, a marker assembly is located along the distal end portion of the introducer sheath and is adapted to indicate the relative location of the distal port within the location relative to at least one renal ostium.

[00149] In another mode, the local injection assembly includes first and second injection ports that are adapted to be delivered to first and second positions such that the volume of fluid agent is injected substantially into the first and second renal arteries via the first and second injection ports, respectively, at the first and second positions, also respectively. First and second markers are positioned relative to the first and second injection ports, respectively, so as to indicate the relative position of the injection ports relative to the first and second positions, also respectively.

[00150] In one beneficial embodiment of this mode, the local injection assembly includes first and second injection members, and the first and second injection ports are located along the first and second injection members, respectively. The first and second markers are located at first and second locations along the first and second injection members relative to the first and second injection ports.

[00151] In another mode, a sensor assembly is provided that is adapted to cooperate with at least one of the local injection assembly or the distal port of the introducer sheath such that the sensor assembly is adapted to be positioned within the location and to sense a parameter indicative of the relative position of the local injection assembly or distal port relative to the renal ostia at the location.

[00152] In one embodiment of this mode, a sensor is located along the distal end portion of the introducer sheath and is adapted to sense a parameter that is indicative of a relative location of the distal port relative to at least one renal ostium.

[00153] In another embodiment, at least one sensor is located relative to the injection port assembly so as to indicate the relative position of the injection port assembly.

[00154] According to one highly beneficial variation of this embodiment, the local injection assembly includes first and second injection ports that are adapted to be delivered to first and second positions such that the volume of fluid agent is injected substantially into the first and second renal arteries via the first and second injection ports, respectively, at the first and second positions, also respectively. First and second sensors are positioned relative to the first and second injection ports, respectively, so as to indicate the relative position of the injection ports relative to the first and second positions, also respectively. In still a further beneficial feature that may be incorporated according to this mode, the local injection assembly includes first and second injection members, and the first and second injection ports are located along the first and second injection members, respectively. Further to this feature, the first and second sensors are located at first and second locations along the first and second injection members relative to the first and second injection ports.

[00155] According to still further modes incorporating sensor assemblies, such may include an ultrasound sensor, a Doppler ultrasound sensor, an optical sensor, a pressure sensor, a flow velocity sensor, a flow rate sensor, or a chemical sensor, or combinations thereof.

[00156] Of further benefit, a monitoring assembly may also be provided for monitoring the sensed parameters externally of the patient.

[00157] Another aspect of the invention is a method for providing local renal therapy in a patient that includes in one regard delivering a distal end portion of an introducer sheath to a location within an abdominal aorta associated with first and second renal ostia of first and second renal arteries, respectively, while a proximal end portion of the introducer sheath extends externally from the patient, and also such that an introducer lumen within the introducer sheath extends between a proximal port located along the proximal end portion and a distal port located along the distal end portion at the location. A local injection assembly with an injection port assembly is delivered to the location through the introducer lumen and through the distal port in a first condition. The local injection assembly is adjusted at the location from the first condition to a second condition that is advanced externally through the distal port at the location. The local injection assembly in the second condition at the location is fluidly coupled to a source of fluid agent located externally from the patient. The injection port assembly is positioned so as to inject a volume of fluid agent from the source substantially bilaterally into each of the two renal arteries. In addition, a parameter indicative of a position of at least one of the injection port assembly or the distal port relative to at least one of the renal ostia is sensed without use of fluoroscopic or X-ray imaging.

[00158] According to further modes of this method, non-fluoroscopic positioning sensing the position may be accomplished an ultrasound sensor, a Doppler ultrasound sensor, by sensing an optical parameter with an optical sensor, by sensing a pressure parameter with a pressure sensor, by sensing a velocity of blood flow with a flow velocity sensor, by sensing a blood flow rate with a flow rate sensor, or by sensing a chemical parameter of blood with a chemical sensor, or by use of a combination of these modalities.

[00159] Where various of the aspects and modes noted above relate to local delivery or injection of materials or agents into branch lumens from main lumens, such as renal arteries or veins from abdominal aortas or vena cavae,

such methods or structures may be further modified or otherwise put to use for delivering interventional devices in similar manner to these locations, either instead of or in addition to the fluid agent delivery methods and related structures. Such further modifications and applications are considered further aspects of the invention.

[00160] It is also to be appreciated that each of the foregoing aspects, modes, embodiments, variations, features, or variants on such features is to be considered independently beneficial without necessarily requiring combination with other such components or steps unless expressly stated so. Notwithstanding the foregoing, it is also further appreciated that the various combinations and sub-combinations of such components or steps as would be apparent to one of ordinary skill in the art are further considered independently beneficial and within the intended scope hereof.

[00161] Further aspects of the invention will be brought out in the following portions of the specification and accompanying claims below, wherein the detailed description is for the purpose of fully disclosing preferred embodiments of the invention without placing limitations thereon.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)

[00162] The invention will be more fully understood by reference to the following drawings which are for illustrative purposes only:

[00163] FIG. 1 illustrates the distal section of a delivery catheter with a preformed shape to anchor in an artery according to the present invention.

[00164] FIG. 2A illustrates a method of deploying a preformed shaped catheter introduced in a sheath.

[00165] FIG. 2B illustrates the intermediate retraction of the sheath shown in FIG. 2A.

[00166] FIG. 2C illustrates further retraction of the sheath shown in FIG. 2A.

[00167] FIG. 3 illustrates a delivery catheter extending into a branch artery with a high flexibility deflectable section.

[00168] FIG. 4A illustrates a method of inserting a catheter with a deflectable section as shown in FIG. 3 using a stylet.

[00169] FIG. 4A illustrates a method of deploying a catheter with a deflectable section as shown in FIG. 3 using a stylet

[00170] FIG. 5 illustrates another embodiment of a delivery catheter with a preformed anchoring shape.

[00171] FIG. 6A illustrates a first step for deploying a preformed shape catheter as shown in FIG. 5 with a stylet.

[00172] FIG. 6B illustrates another step for deploying a preformed shape catheter as shown in FIG. 5 with a stylet.

[00173] FIG. 6C illustrates a further step for deploying a preformed shape catheter as shown in FIG. 5 with a stylet.

[00174] FIG. 6D illustrates a preformed shape catheter, deployed with a stylet, in an anchoring shape as shown in FIG. 5.

[00175] FIG. 7A illustrates a multilumen catheter using a flexible reinforcing element as an anchoring device.

[00176] FIG. 7B illustrates distal motion of the reinforcing element forming an expanded loop.

[00177] FIG. 7C illustrates a cross-sectional view of the catheter shown in FIG. 7B inserted in a body vessel.

[00178] FIG. 8A illustrates another embodiment of the catheter shown in FIG. 7A where the reinforcing element loops around the catheter in a helical configuration.

[00179] FIG. 8B illustrates the loop formed in FIG. 8A when the reinforcing element is extended.

[00180] FIG. 8C illustrates a section view of the catheter shown in FIG. 8B symmetrically anchored to the wall of an artery.

[00181] FIG. 9 is another embodiment of the device shown in FIG. 7A with two or more reinforcing elements for anchors.

[00182] FIG. 10 illustrates a multi-lumen catheter shown in FIG. 9 with four reinforcing elements, inserted and anchored in a branch artery.

[00183] FIG. 11A illustrates an anchoring catheter with a reinforcing element to anchor near the distal end.

[00184] FIG. 11B illustrates the anchoring catheter shown in FIG. 11A with the reinforcing element deployed.

[00185] FIG. 12A illustrates a method of constructing an anchoring catheter to form loops that provide an anchoring force as shown previously in FIG. 10.

[00186] FIG. 12B illustrates the anchoring catheter in FIG. 12A with loops deployed to bow outward.

[00187] FIG. 13A illustrates another anchoring catheter using two loops of shape retaining material.

[00188] FIG. 13B illustrates the anchoring catheter shown in FIG. 13A restricted in a sheath.

[00189] FIG. 13C illustrates the anchoring catheter shown in FIG. 13A deployed in a blood vessel.

[00190] FIG. 14A illustrates a side view of multilumen catheter with an asymmetrical, inflatable anchoring member according to the present invention.

[00191] FIG. 14B is a cross sectional view of the catheter in FIG. 14A with the inflatable anchoring member folded in a sheath.

[00192] FIG. 14C is a cross sectional view of the catheter in FIG. 14A deployed in a blood vessel.

[00193] FIG. 15A illustrates a multilumen catheter with a multi-lobed, symmetrical, inflatable anchoring member.

[00194] FIG. 15B is a cross sectional view of the catheter in FIG. 15A with the inflatable anchoring member folded in a sheath.

[00195] FIG. 15C is a cross sectional view of the catheter in FIG. 15A deployed in a blood vessel.

[00196] FIG. 16 illustrates the distal section of an anchoring renal catheter with a preformed compound shape.

[00197] FIG. 17 illustrates another embodiment of the renal catheter shown in FIG. 16 where the compound shape comprises a 270-degree loop.

[00198] FIG. 18A illustrates a bifurcated renal catheter with distal anchoring sections manipulated by control wires.

[00199] FIG. 18B illustrates a cross sectional view of the catheter shown in 18A taken along the lines 18B-18B.

[00200] FIG. 19 illustrates a preformed bifurcated catheter with distal sections having opposite preformed 90-degree loop shapes for anchoring.

[00201] FIG. 20 illustrates a variation of a preformed bifurcated catheter where one distal section is similar to that shown in FIG. 17 and the second distal section similar to that shown in FIG. 10.

[00202] FIG. 21 illustrates the cross section of bifurcated catheter as shown in FIG. 20 taken along the lines 21-21.

[00203] FIG. 22A illustrates a plan view of a multilumen catheter with a longitudinal slit near the distal end.

[00204] FIG. 22B illustrates a cross section view of FIG. 22A taken along the lines 22B-22B.

[00205] FIG. 22C illustrates a perforating crosscut forming hinges of the catheter shown in FIG. 22A with the hinges in the partly open position.

[00206] FIG. 22D illustrates the catheter shown in FIG. 22A inserted in a main artery with hinges flexed in the fully open position.

[00207] FIG. 23 illustrates two independent micro catheters each placed directly into a renal artery.

[00208] FIG. 24 illustrates a flow-guided catheter with flexible renal sub catheters and an inflatable member in an inflated state.

[00209] FIG. 25 illustrates the flow-guided catheter shown in FIG. 24 with the inflatable member in a deflated state.

[00210] FIG. 26 illustrates a flow-guided catheter for use with a brachial approach from above the renal arteries.

[00211] FIG. 27 is a flow-guided catheter for use with a brachial approach from above with an inflatable member.

[00212] FIG. 28 illustrates a truncated cone flow diverter that may be used adjunctively with flow-guided catheters using a brachial approach.

[00213] FIG. 29 illustrates a low profile flow-guided catheter using a brachial approach.

[00214] FIG. 30 illustrates the flow-guided catheter shown in FIG. 29 with sub catheters equipped with distal tip inflatable members.

[00215] FIG. 31 illustrates independent low profile flow guided sub-catheters using a brachial approach.

[00216] FIG. 32 illustrates the independent sub-catheters shown in FIG. 31 with

distal tip inflatable members.

[00217] FIG. 33 illustrates the distal end of a bifurcated renal catheter.

[00218] FIG. 34 illustrates the proximal end of the bifurcated catheter shown in FIG. 33 with a hub assembly and controls for pull wires.

[00219] FIG. 35 illustrates the non-supported, pre-formed distal extensions of a bifurcated renal infusion catheter.

[00220] FIG. 36 is a stylized illustration of the bifurcated catheter of FIG. 35 with the distal extensions positioned in the renal arteries.

[00221] FIG. 37 is another bifurcated renal delivery catheter with pre-formed distal extensions.

[00222] FIG. 38 is the bifurcated catheter as illustrated in FIG. 37 with offset distal extensions.

[00223] FIG. 39 is another embodiment of a bifurcated catheter as shown in FIG. 37 where a plurality of distal extensions are offset and located on one side.

[00224] FIG. 40 is a bifurcated catheter with a moveable distal extension controlled by a guide wire.

[00225] FIG. 41 is another bifurcated catheter as shown in FIG. 40 where both moveable distal extensions may be manipulated independently by guide wire.

[00226] FIG. 42 illustrates a bifurcated delivery catheter with four preformed distal extensions.

[00227] FIG. 43 is a stylized illustration of the catheter as shown in FIG. 42 with two extensions positioned in renal arteries.

[00228] FIG. 44 is a stylized illustration of the catheter as shown in FIG. 42 with four extensions positioned in renal arteries.

[00229] FIG. 45 illustrates another beneficial embodiment of a renal delivery catheter with multiple preformed distal extensions.

[00230] FIG. 46 illustrates a schematic cross section of an aorta at the intersection of the renal arteries with a multiple distal extension catheter deployed.

[00231] FIG. 47 is a stylized illustration of a delivery catheter with multiple pivoting distal extensions.

[00232] FIG. 48A illustrates a step in constructing a multiple distal extension catheter according to the present invention.

[00233] FIG. 48B illustrates another step in constructing a multiple distal extension catheter.

[00234] FIG. 48C illustrates a further step in constructing a multiple distal extension catheter.

[00235] FIG. 48D illustrates another step in constructing a multiple distal extension catheter.

[00236] FIG. 48E illustrates a further step in constructing a multiple distal extension catheter.

[00237] FIG. 48F illustrates another step in constructing a multiple distal extension catheter.

[00238] FIG. 48G illustrates a further step in constructing a multiple distal extension catheter.

[00239] FIG. 49 is an illustration of a drain catheter system for use in the venous system according to the present invention.

[00240] FIG. 50 is a detailed view of the distal tip of the drain catheter system shown in FIG. 49 and deployed in a renal vein.

[00241] FIG. 51 illustrates another embodiment of a distal tip for the drain catheter system shown in FIG. 50 with an expandable mesh deployed in a renal vein.

[00242] FIG. 52 illustrates a detailed view of another embodiment of a distal tip for the drain catheter system shown in FIG. 50 combining the embodiments shown in FIG. 50 and FIG. 51.

[00243] FIG. 53 illustrates a typical reversible roller pump at the proximal end of the drain catheter shown in FIG. 49.

[00244] FIG. 54 illustrates a proximal coupler system for delivering aortic devices adjunctively with a catheter.

[00245] FIG. 55 illustrates a cross-sectional view of the proximal coupler system as shown in FIG. 54.

[00246] FIG. 56A illustrates a proximal coupler assembly as shown in FIG. 54 coupled to a local delivery system.

[00247] FIG. 56B illustrates a proximal coupler assembly as shown in FIG. 56A with the local delivery system advanced in an introducer sheath.

[00248] FIG. 57 illustrates a proximal coupler assembly as shown in FIG. 54 through 56B with a delivery device deployed in the renal arteries and a catheter simultaneously deployed in the aorta.

[00249] FIG. 58 illustrates a renal therapy system with an introducer sheath system, a vessel dilator, a fluid delivery system and a bifurcated catheter.

[00250] FIG. 59 is a stylized illustration of a double Y assembly with two local delivery systems and an intervention catheter in an aorta system.

[00251] FIG. 60 shows a schematic side view of an illustrative bifurcated catheter adapted for use in combination assemblies and methods for delivering interventional devices into renal arteries.

[00252] FIG. 61 shows a side view of another bifurcated catheter for local renal device delivery, with certain internal detail of the catheter emphasized.

[00253] FIG. 62 shows a side view of another local renal delivery catheter for delivering a device into the renal system.

[00254] FIG. 63 shows a side view of another bifurcated local renal delivery catheter in vivo.

[00255] FIG. 64 shows a side view of another bifurcated local renal delivery catheter in vivo.

[00256] FIG. 65 shows a side view of another bifurcated local renal delivery catheter with two renal filters deployed within two renal arteries, respectively.

[00257] FIG. 66 shows a side view of another bifurcated local renal delivery catheter with two interventional devices deployed within two renal arteries, respectively, during a bi-lateral proximal renal filtering procedure.

[00258] FIG. 67 shows a side view of another bifurcated renal catheter with two expanded members in each of two renal arteries, respectively, in order to prevent aortic emboli from embolizing the renal system.

[00259] FIG. 68 shows a side view of another bifurcated local renal delivery catheter in a combination assembly with a balloon angioplasty catheter with a stent mounted onto the angioplasty balloon.

[00260] FIG. 69 shows a side view of another bifurcated local renal delivery

catheter in a combination assembly with a balloon angioplasty catheter and a renal filter assembly, and shows the combination assembly during balloon angioplasty of a renal artery cannulated by the delivery catheter and with distal renal protection with the renal filter deployed.

[00261] FIG. 70A shows a side view of another bifurcated local renal delivery catheter in a combination assembly with a balloon angioplasty catheter during one step of performing a renal angioplasty.

[00262] FIG. 70B shows a side view of the combination assembly shown in FIG. 70A, but during another step wherein proximal aspiration of emboli within the renal artery is being performed following completed renal angioplasty with the angioplasty balloon shown in a deflated state.

DETAILED DESCRIPTION OF THE INVENTION

[00263] As will be appreciated by reference to the detailed description below and in further respect to the Figures, the present invention is principally related to selective bi-lateral renal delivery systems and methods. Accordingly, the present invention is thus related to, and the present description is to be read in combination with, various aspects of the subject matter disclosed in the following prior filed, co-pending U.S. Patent Applications that are commonly owned with the present application (to the extent such disclosures are readily considered in conjunction with the present disclosure, as would be apparent to one of ordinary skill): Serial No. 09/229,390 to Keren et al., filed January 11, 1999; Serial No. 09/562,493 to Keren et al., filed May 1, 2000; and Serial No. 09/724,691 to Kesten et al., filed November 28, 2000. The disclosures of these prior patent applications are herein incorporated in their entirety by reference thereto.

[00264] The invention is also related to, and the present description should be considered in conjunction with, certain aspects of the subject matter disclosed in the following Published International Patent Applications (to the extent such published disclosures are readily considered in conjunction with the present disclosure as would be apparent to one of ordinary skill): WO 00/41612 to Libra Medical Systems, published July 20, 2000; and WO 01/83016 to Libra Medical Systems, published November 8, 2001. The disclosures of these

Published International Patent Applications are also herein incorporated in their entirety by reference thereto.

[00265] In particular, any modifications or improvements that are obvious to one of ordinary skill in the art based upon review of this present disclosure and those disclosures of the pending or published patent application references just listed above are contemplated as further embodiments hereunder.

[00266] In general, it is to be understood that the present invention relates to delivering certain interventional or diagnostic devices through the various delivery systems described hereunder in order to conduct certain desired diagnostic or therapeutic procedures (which may interchangeably include prophylaxis where apparent to ordinary skill in the art and unless specifically excluded otherwise). In particular highly beneficial modes, such delivery and interventional devices are combined in systems in order to provide renal therapy. This includes without limitation further beneficial modes where such renal therapy is provided bi-laterally within each of two renal artery systems perfusing each of two kidneys, and through each of two renal ostia along an abdominal aorta wall. In this regard, other bi-lateral delivery of such interventional devices may be performed in other body spaces using similar or appropriately modified devices and systems as herein described. In another regard, for particular procedures, and as described in certain detail in particular illustrative embodiments hereunder, the various delivery and therapeutic device combination assemblies may also be modified or put into appropriate use within only one such vessel or lumen.

[00267] As such, the delivery devices, systems and methods shown or described below by reference to FIGS. 1-59, are to be considered in combination with FIGS. 60-70B. More specifically, the delivery embodiments of FIGS. 1-59 are considered, where appropriate according to one of ordinary skill, to be modified or otherwise combined or used in combination with interventional devices for their delivery to remote internal body spaces such as for example the renal arteries or veins via the abdominal aorta or vena cava, respectively. In addition, the various methods of construction and use described variously for the embodiments of FIGS. 1-59 are to be considered applicable variously to the embodiments of FIGS. 60-70B, and visa versa, again where appropriate and obvious to one of ordinary skill in the art based upon the totality of this disclosure.

[00268] In one particular regard, where the embodiments of FIGS. 1-59 are described by reference to fluid, drug, agent, or material delivery assemblies, systems, or methods of use, such is to be further considered appropriately modified or otherwise put into use for delivering interventional devices as provided by reference to FIGS. 60-70B. The results constitute further embodiments contemplated hereunder. In another particular regard, where the embodiments of FIGS. 60-70B include within them certain aspects or features that provide particular benefits for improved local delivery devices or methods, such may also be appropriately combined with or into the prior embodiments of FIGS. 1-59 according to one of ordinary skill, also resulting in further embodiments hereunder.

[00269] Notwithstanding the foregoing, it is also understood that certain of the embodiments of FIGS. 1-59 are in particular beneficial for local fluid agent delivery, but may not be as particularly well adapted for delivering devices into localized, remote body regions contemplated. It is understood that each and every embodiment or combination thereof need not work flawlessly or even well in order for the other embodiments, or broad aspects or mode encompassed thereby, to be fully realized and appreciated. Moreover, to the extent any such delivery device embodiment may not be combined appropriately with further embodiments for device delivery, then the appropriate, obvious modifications to such delivery device in order to achieve such combination are contemplated. And, where such obvious modifications are not appropriate or can not be made, the non-combinable embodiment is considered background information and excluded from broad aspects of the present invention to which this disclosure pertains.

[00270] It will be appreciated that the devices and systems according to the embodiments provided hereunder may vary as to configuration and as to details of the parts, and that the methods may vary as to the specific steps and sequence, without departing from the basic concepts as disclosed herein.

[00271] The description herein provided relates to medical material delivery systems and methods in the context of their relationship in use within a patient's anatomy. Accordingly, for the purpose of providing a clear understanding, the term proximal should be understood to mean locations on a system or device relatively closer to the operator during use, and the term distal should be understood to mean locations relatively further away from the operator during use of a system or device. These present embodiments below therefore generally relate to local renal drug delivery generally from within the renal arteries themselves; however, it is contemplated that these systems and methods may be suitably modified for use in other anatomical regions and for other medical conditions without departing from the broad scope of various of the aspects illustrated by the embodiments.

[00272] In general, the disclosed material delivery systems will include a delivery assembly, a proximal coupler assembly and one or more elongated bodies, such as catheters. These elongated bodies may contain one or more delivery lumens and generally consist of a proximal region, a mid-distal region, and a distal tip region or regions in the case of multi-tipped embodiments. The distal tip region will typically have means for anchoring and means for delivering a material such as a fluid agent or interventional device. Radiopaque markers or other devices may be coupled to the specific regions of the elongated body to assist introduction and positioning.

[00273] The material delivery system is intended to be placed into position by a physician, typically either an interventionalist (cardiologist or radiologist) or an intensivist, a physician who specializes in the treatment of intensive-care patients. The physician will gain access to a femoral artery in the patient's groin, typically using a Seldinger technique of percutaneous vessel access or other conventional method.

[00274] Turning now to FIG.1, an embodiment of the distal section of an anchoring material delivery catheter 10 with a preformed shape to anchor in an artery 12 to prevent movement during medical procedures is generally shown. Material delivery catheters may move during medical procedures due to blood flow, body movement and movement of interventional catheters. It is highly beneficial that the distal portion of a catheter remain stationary within the branch blood vessel and deliver therapeutic agent throughout the procedure. The proximal shaft will play a significant role in the maintenance of catheter position within the patient anatomy. The mechanical characteristics of the proximal shaft region will influence the magnitude of the "anchoring" forces required on the wall of the main or branch artery by the apparatus discussed below. Therefore, the proximal shaft section of the catheter will require greater stiffness and column strength to withstand the forces imparted on the catheter by blood flow in the main vessel and possible patient repositioning or movement that can occur throughout the course of treatment. The pre-formed shape in this embodiment comprises a near distal section 14 with a memory shape defined by R1 and an adjacent second section 16 with memory shape defined by radius R2. Radius R1 and radius R2 are biased in the opposite direction so catheter 10 forms a generally S shape and exerts opposite spring forces in the direction of arrows 18 against the walls of artery 12 when section 14 and section 16 are in their natural state.

[00275] In one exemplary embodiment, the wall of the proximal shaft region includes a stainless-steel braid, coil or multiple independent longitudinal wire inclusions to increase column strength and flexural rigidity. The proximal shaft region is preferably constructed of a higher durometer polymeric material such as 60D to 70D polyurethane or a poly-ether-block-amide copolymer such as PEBAX.

[00276] FIG. 2A through FIG. 2C illustrates sequential steps in a method of deploying a pre-formed catheter 10 introduced in a radially confining sheath 22. Distal end 25 of the catheter 10 is released from sheath 22 by moving sheath 22 proximally as shown by directional arrow 24 or alternatively by advancing catheter 10 distally through the sheath as shown by directional arrow 26. FIG. 2B illustrates the position of the pre-formed catheter 10 with section 14, formed with memory shape defined radius R1, exposed from sheath 22. FIG. 2C illustrates the position of the pre-formed catheter 10 with second section 16 formed with radius R2 exposed.

[00277] FIG. 3 through FIG. 4B illustrate an anchoring material delivery catheter 30 extending through a main artery 32 and into a branch artery 34 with a shapeable section 36 deployed to form an S configuration defined by radius R1 and radius R2. Radius R1 is formed when shapeable section 36 is deformed by a guide wire (shown in FIG. 4A and FIG. 4B) or other deployment means. Radius R2 is formed by the contact of the distal end 38 on the wall of branch artery 34. The "S" shape of catheter 30 exerts anchoring force 40 proximal of the deflectable section 36 and anchoring force 42 distal of the shapeable section 36.

[00278] FIG. 4A and FIG. 4B illustrate a method of anchoring catheter 30 with a shapeable section 36. Pull wire 44 is attached to an inner lumen wall of shapeable section 36 at approximately median position 46 and extends to a control point at the proximal end of catheter 30 (not shown). When pull wire 44 is retracted, proximal segment 48 of shapeable section 36 takes a shape defined by radius R1 as shown in FIG 4B. Distal section 50 of shapeable section 36 takes a shape defined by radius R2 (shown in FIG. 3) by contact of distal end 38 of catheter to the artery wall 34. Control over anchor force 40 and anchor force 42 exerted on artery wall 34 (shown in FIG. 3) may be achieved by monitoring the tensile force exerted on pull wire 44.

[00279] Referring now to FIG. 5 through FIG. 6D, another embodiment of an anchoring material delivery catheter 52 with an anchoring memory shape is generally shown. In FIG. 5, catheter 52 is deployed in artery 12 where section 54 is configured with radius R1, section 56 is configured with radius R2 oriented opposite from R1, section 58 with radius R3 oriented towards R2 and section 60 with radius R4 oriented opposite from R3. The orientation of radii R1 through R4 create an anchor shape that exerts outward anchoring forces 62 and 64 and anchors catheter 52 in artery 12 when sections 54, 56, 58 and 60 assume their natural memory shape.

[00280] FIG. 6A through FIG. 6D illustrate a method of anchoring a pre-formed shaped material delivery member 52 as shown in FIG. 5. Stiff mandrel 66 is inserted in catheter 52 to position memory shaped sections 54, 56, 58, and 60 in a straightened configuration. In FIG. 6B, stiff mandrel 66 has been

retracted proximally as shown by arrow 68 to allow section 54 to assume a memory shape defined by radius R1. Note that radius R1 may vary during deployment as the catheter 52 is positioned. In FIG. 6C, stiff mandrel 66 has been retracted proximally past section 58 and section 56 assumes memory shape defined by radius R2 and section 58 assumes memory shape with radius R3. In FIG. 6D stiff mandrel 66 has been retracted proximally past section 60 with radius R4 and delivery member 52 assumes an anchoring shape as illustrated in FIG. 5.

[00281] FIG. 7A through FIG. 7C illustrate another embodiment of an anchoring multilumen delivery catheter 70 with a flexible reinforcing element 72 located in reinforcing element lumen 74 according to the present invention. In FIG. 7A, reinforcing element 72 exits the reinforcing element lumen 74 through first opening 76 and reenters the reinforcing element lumen 74 proximal of first opening 76 at second opening 78. Reinforcing element 72 is anchored in reinforcing element lumen 74 distal of second opening 78 at position 80.

[00282] FIG. 7B illustrates distal motion 82 of reinforcing element 72 in reinforcing element lumen 74 causing reinforcing element 72 to form an expanded loop 84 defined by radius R1 outside of catheter 70 and between first opening 76 and second opening 78.

[00283] FIG. 7C illustrates a section view of delivery member 70 shown in FIG. 7B asymmetrically anchored to a wall of artery 12 by force 86 exerted by expanded loop 84 and by force 88 exerted by the body of catheter 70.

[00284] FIG. 8A and FIG. 8B illustrate another embodiment of an anchoring multilumen delivery member 70 where reinforcing element 72 exits first opening 76 and loops around delivery member 70 in a helical configuration before entering second opening 78.

[00285] FIG. 8B illustrates the delivery member 70 in FIG. 8A with loop 90 formed around catheter 70 when reinforcing element 72 is pushed in direction 82.

[00286] FIG. 8C illustrates a sectional view of delivery member 70 shown in FIG. 8B symmetrically anchored to a wall of artery 12 by forces in the direction of arrow 92 that are exerted on the inner wall circumference artery 12 by expanded loop 90.

[00287] FIG. 9 Is another embodiment of an anchoring delivery catheter shown in FIG. 7A with two or more reinforcing elements 72 in a multilumen catheter 100 with a first opening 76 and corresponding second opening 78 for each reinforcing element 72. Three reinforcing elements 72 are illustrated in FIG. 9 with phantom lines of the reinforcing element lumens 74 omitted for clarity.

[00288] FIG. 10 illustrates a multilumen catheter 102, similar to catheter 100 in FIG. 9, with four reinforcing elements 72 inserted and anchored in a branch artery 34 of a main artery 32. When reinforcing elements 72 are extended, they bow outward into loops 104 which exert an anchoring force 106 against the inner wall of branch artery 34.

[00289] FIG. 11A and FIG. 11B illustrate an embodiment of an anchoring delivery catheter where reinforcing strut 110 is anchored near the distal end 112 of a catheter 114 and is attached to the distal end 116 of sheath 118 which encloses the catheter 114 proximal of distal end 112. In FIG. 11B, sheath 118 is advanced as shown by arrow 120 or alternatively, catheter 114 is retracted as shown by arrow 122. Reinforcing strut 110 bows outward as loop 124 which anchors the catheter 114 in similar to the anchor previously shown in FIG. 7C.

[00290] FIG. 12A and FIG. 12B illustrate a cut section view of an anchoring delivery catheter where catheter 130 is encased in flexible sheath 132 and anchored to sheath 132 at the distal end 134 near the distal end of catheter 130. Slits 136 are made in pairs lengthwise near the distal end of sheath 132 to form two or more struts 138. A pair of struts 138 is depicted in the embodiment shown in FIG. 12A and FIG. 12B. In FIG. 12B, sheath 132 is advanced in a distal direction shown by arrow 140 or alternatively, or in combination, catheter 130 is retracted in a proximal direction as shown by arrow 142. Sheath struts138 bow outward to form loops 144 which anchor catheter 130 against a vessel wall as shown previously in FIG. 10.

[00291] FIG. 13A through FIG. 13C illustrates an anchoring delivery catheter where two or more loops 150 of shape retaining material, such as nickel titanium wire, are attached near the distal end of catheter 152 so the coupling

154 of metal loops are proximal of the apex 156 of loops 150. Loops 150 are configured to bias the apex 156 away from the surface of catheter 152 when loops 150 are in their free state.

[00292] FIG. 13B illustrates catheter 152 shown in FIG. 13A with loops 150 attached that are encased in a radially confining sheath 158, such as an introducer sheath, which compresses the apex 156 of loops 150 near the surface of catheter 152 within sheath 158.

[00293] FIG. 13C illustrates catheter 152 shown in FIG. 13A inserted in artery 12 with sheath 158 retracted in the proximal direction shown by arrow 160. Loops 150 flex outwardly and loop apex 156 exerts outward anchoring force 162 against the inner wall of artery 12. When medical procedures are complete, sheath 158 is advanced over catheter 152 to collapse loops 150 to permit the removal of catheter 152.

[00294] FIG. 14A through FIG. 14C illustrates the distal section of another embodiment of an anchoring multilumen catheter 164 according to the present invention. Catheter 164 has an inflation lumen 166 fluidly connected to asymmetrical inflatable member 168, with an oblong lobe shape, shown in an inflated state.

[00295] FIG. 14B illustrates a cross section of catheter 164 encased in sheath 170 with asymmetrical inflatable member 168 in a deflated state and folded around catheter 164.

[00296] FIG. 14C illustrates a cross section of catheter 164 inserted in artery 12 with asymmetrical inflatable member 168 in an inflated state and exerting anchoring force 172 and anchoring force 174 against the inner wall of artery 12. The cross section of asymmetrical inflatable member 168 is a lobe shape to contact inner wall of artery 12 in one location when inflated and simultaneously allow free area 178 for blood flow in artery 12.

[00297] FIG. 15A through FIG. 15C illustrate another embodiment of an anchoring multilumen catheter 164 with inflation lumen 166 fluidly connected to a symmetrical inflatable member 180 generally comprising two or more symmetrically positioned lobes 182. In the embodiment illustrated in FIG. 15A, inflatable member 180 has 4 symmetrical lobes 182.

[00298] FIG. 15B illustrates a cross section of catheter 164 encased in a radial confinement sheath 170 with lobes 182 of symmetrical inflatable member 168 in a deflated state and folded around catheter 164.

[00299] FIG. 15C illustrates a cross section of catheter 164 inserted in artery 12 with radial confinement sheath 170 shown in FIG. 15B removed and symmetrical inflatable member 180 in an inflated state and exerting force 184 at the contact point of each lobe 182 against the inner wall of artery 12. The cross section of lobes 182 is shaped so each lobe 182 contacts inner wall of artery 12 when inflated and allow free area 186 for blood flow in artery 12. Each inflated lobe 182 exerts radial outward anchoring force 184.

[00300] FIG. 16 illustrates a distal section of an anchoring delivery catheter 190 of similar construction to one shown in FIG. 1 with a distal end 192. Radii R1 through R5 define a compound "S" anchoring shape, wherein R1 is generally configured to position distal end 192 of catheter 190 in artery 34 and against a wall of artery 34. Radii R2 and R3 are generally configured in an opposite direction of R1 and create a biased section that exerts outward force 194 against a wall of aorta 32. Radii R4 and R5 are generally configured opposite of radii R1 and R2 and create an adjacent section to exert an outward force 196 against a generally opposite wall of aorta 32. The specific configuration of radii R1 through R5 creates an anchoring shape that is generally larger than aorta 32 in its natural state.

[00301] FIG. 17 illustrates another anchoring catheter 198 with a distal end 200 similar to that shown in FIG. 16, wherein a compound shape 202 is defined by radii R1 and R2, wherein R1 and R2 are generally configured to form a 270-degree loop. The natural diameter of the loop of compound shape 202 is generally larger than the diameter of aorta 32 and exerts anchoring forces 204 against opposite walls of aorta 32. Radii R3 and R4, proximal of compound shape 202 on catheter 198, are generally configured opposite each other to facilitate optimum positioning of compound shape 202 and distal end 200 of catheter 198 in artery 34.

[00302] FIG. 18A and FIG. 18B illustrate a bifurcated anchoring catheter 208 in main artery 32 with a delivery sheath 210, a left distal section 212 and right

distal section 214 adapted to deliver a material. Distal sections 212, 214 are configured to preferentially select arteries 34 when delivery sheath 210 is retracted proximally. Distal section 212 is manipulated by control wire 216 and distal section 214 is independently manipulated by control wire 218, wherein distal sections 212, 214 are manipulated as previously described in FIG. 3 to anchor in arteries 34. FIG. 18B illustrates a cross section of bifurcated catheter 208 taken along the lines18B-18B in FIG. 18A with multilumen delivery sheath 210 enclosing distal sections 212, 214 with control wires 216, 218. Each distal section 212, 214 is capable of independent insertion and manipulation in a branch artery 34. Cross section of delivery sheath 210 may also be a single lumen or more than two lumens.

[00303] FIG. 19 illustrates an embodiment of a preformed bifurcated delivery catheter 220 with distal section 222 having a preformed 90-degree loop shape 226 and distal section 224 having the same but opposing 90-degree loop shape 226. The diameter of preformed loop shape 226 of distal section 222, 224 is generally larger than the diameter of main artery 32 and thereby exerts an anchor force outward on main artery 32 as previously described in FIG. 17. Distal section 222 and distal section 224 are configured to preferentially insert into opposing branch arteries 34.

[00304] FIG. 20 illustrates a variation of a bifurcated anchoring delivery catheter 228 wherein distal section 230, similar to catheter 198 previously described in FIG. 17, is combined with a distal section 232, similar to catheter 102 previously described in FIG. 10. The diameter of the 270-degree loop shape 234 on distal section 230 is generally larger than the diameter of main artery 32 and anchors catheter 228 in main artery 32 with distal section 230 in branch artery 34. Distal section 232 is anchored in a branch artery 34 and with reinforcing element loops 236.

[00305] FIG. 21 is a cross section taken along the lines 21--21 in FIG. 20 of a bifurcated catheter 228 with lumen 238 fluidly connected to distal section 230. Lumen 240 contains distal section 232 with a plurality of lumens 242 for reinforcing elements 236 and a delivery lumen 244.

[00306] FIG. 22A illustrates a plan view and FIG. 22B illustrates a cross section view taken along the lines 22B--22B in FIG. 22A. A multilumen catheter 250 with a center lumen 252 with control wire 254 and delivery lumen 256 in the right side 258 of catheter 250 and delivery lumen 260 in the left side 262 of catheter 250 are shown. A longitudinal slit 264 of a predetermined length is made in catheter 250 near the distal end 266 to separate right side 258 from left side 262. Slit 264 terminates a predetermined distance from distal end 266. Control wire 254 is anchored (not shown) at distal end 266. A perforating crosscut 268, medial of slit 264 is made part way into right side 258 through lumen 256 and part way into left side 262 through lumen 260.

[00307] FIG. 22C illustrates that the perforating cross-cut 268 does not extend completely through right side 258 and left side 260, thus forming hinges 270 when control wire 254 is retracted in proximal direction 272. Lumen 256 and lumen 260 are bisected at hinges 270.

[00308] FIG. 22D illustrates the multilumen catheter 250 shown in FIG. 22A inserted in main artery 32 and positioned adjacent to branch arteries 34. Control wire 254 is retracted, retracting distal end 266 proximally to flex hinges 270 outward placing bisected lumens 256 and 260 into branch arteries 34. Material 272 is delivered through lumen 256 and lumen 260 and into branch arteries 32 at hinges 270.

[00309] FIG. 23 illustrates two independent micro catheters 272 introduced through aorta 32 with introducer sheath 274 and each positioned directly into a renal artery 34, by methods previously described, for material delivery. Each micro catheter 272 has a distal tip adaptation 276, such as a small loop, to anchor and prevent backing out during delivery. Each micro catheter may be optionally equipped with a guide wire (not shown) to assist placement in renal artery 34. Several advantages are gained by this embodiment. In one regard, it is a direct cannulation system and technique used to perfuse both sides of the renal system. There is generally no question that once placed, 100% of drug will bilaterally enter the cannulated renal arteries. Moreover, whereas certain improved devices as provided herein generally result in an improved procedure, more conventional tools may be employed in many circumstances, and the most difficult part of procedure (accessing renal arteries) relies on well-accepted techniques and equipment. Still further, according to this embodiment, device surface area is minimized with a reduced potential for clotting.

[00310] FIG. 24 illustrates a flow-guided catheter 280 with distal, flexible renal sub-catheters 282 and a mid-distal inflatable member 284 placed in aorta 32 proximal to renal arteries 34. When inflatable member 284 is in an inflated state, aortic blood flow 286 is diverted into renal arteries 34 and sub catheters 282 are flow guided into renal arteries 34.

[00311] The principle of operation requires the flow guided catheter 280 to be placed into the region above the renal arteries 34. Inflatable member 284 is inflated and positioned just below the renal arteries 34. When inflatable member 284 is inflated, aortic blood flow is temporarily diverted into the renal arteries, and thus the flow-guided sub-catheters 282 are then advanced through the main catheter. Because all of the aortic blood flow is now directed into the renal arteries 34, the flow will guide the sub-catheters directly into each renal artery. Once these sub-catheters are inserted to an adequate depth, the inflatable member 284 is deflated, returning all aortic blood flow to normal. However, the flow-guided sub-catheters 282 remain within the renal arteries 34, and fluid agent infusion can then be accomplished with 100% being directed to the target organ.

[00312] Because the aorta 32 remains fully open during the drug infusion, the standard coronary procedures can occur simultaneously without undue interference from the flow guided catheter 280 and sub-catheters 282. The device is 'forgiving' relative to positioning and placement, and does not require exact positioning to accomplish the drug infusion objective. Because the flow-guided sub-catheters are placed directly into the renal arteries, there are no issues relating to quality of 'seal' as there is no requirement for a seal and the fluid agent is unlikely to leak into the aorta as the infusion system is so deeply seated into the renal arteries. There is no ongoing occlusion or even diversion of the aortic flow.

[00313] FIG. 25 illustrates the flow-guided catheter 280 previously described in FIG. 24 with inflatable member 284 in a deflated state. Sub-catheters 282 remains in renal arteries 34 while blood flow 286 is normal. Intervention catheters (not shown) may pass guided catheter 280 with inflatable member 284 in a deflated state. Sub-catheters 282 may be equipped with distal tip adaptations for anchoring as previously described.

[00314] FIG. 26 illustrates an embodiment of a flow-guided catheter 290 adapted for insertion from a brachial approach from above. Because approximately 30% of aortic blood flow enters the renal arteries, catheter 290 can be positioned just above the renal arteries and sub-catheters 292 will naturally flow into the renal arteries for material delivery. This embodiment has other advantages when the access and introduction occurs from the brachial approach, where the flow guided sub-catheters 292 have an even more natural 'flow' into the renal arteries. There is little risk of vessel trauma or other injury, as there are no 'seals' required, and thus any fitment issues and the associated risks of over sizing are eliminated.

[00315] FIG. 27 is another flow-guided catheter 294 adapted for a brachial approach configured with distal inflatable member 296. Inflatable member 296 is positioned in aorta 32 below renal arteries 34 in an inflated state. Increased blood flow to renal arteries 34 cause sub catheters 298 to flow naturally into renal arteries 34. When inflatable member 296 is in a deflated state, interventional catheters (not shown) can pass renal arteries 34 unobstructed for medical procedures.

[00316] FIG. 28 illustrates a catheter 294 adapted for a brachial approach and with a truncated cone flow diverter 300 that may be used to temporarily increase blood flow to renal arteries 34 adjunctively with flow guided renal catheters.

[00317] FIG. 29 illustrates a low profile flow-guided catheter 302 with distal sub-catheters 304 in renal arteries 34 and adjacent to interventional catheter 306. The position of flow-guided catheter 302 does not interfere with interventional catheter 306.

[00318] FIG. 30 illustrates a variation of low profile flow-guided catheter 302 shown in FIG. 29 positioned with sub-catheters 304 in renal arteries 34. Sub-catheters 304 are equipped with distal tip inflatable members 308 to assist flow-guided placement and anchoring. Flow-guided catheter 302 does not interfere with interventional catheter 306.

[00319] FIG. 31 illustrates a brachial approach for independent low profile sub-catheters 310 positioned in renal arteries 34 without interfering with interventional catheter 306.

[00320] FIG. 32 illustrates a variation of independent low profile sub-catheters 310 shown in FIG. 31 with distal tip inflatable members 308 to assist flow-guided placement and anchoring in renal arteries 34 and positioned without interfering with intervention catheter 306.

[00321] FIG. 33 shows the distal section of a bifurcated catheter 320 with the bifurcated distal ends 322 positioned to insert into the renal arteries. Catheter 324 contains one or more lumens (not shown) for guide wire(s) 326 and material delivery. Guide wires 326 manipulate the bifurcated ends 322 from a straight insertion position (not shown) to the material delivery position shown here. In one beneficial embodiment, bifurcated ends 322 can be maintained in a straight position by guide wires 326 to allow advancement and positioning without a radially confining sheath. This embodiment takes advantage of human anatomy, which provides for renal arteries to originate within a few millimeters of each other along the aorta and generally laterally or slightly dorsally. The origins of the renal arteries are also generally set apart from other vessels originating in the same manner, thus making it easy to locate the renal arteries. This allows for a single bifurcated catheter 320 with a bifurcated distal section 322 to be placed with its distal tips into the renal arteries, negating the need for two separate catheters. It also allows for a single device to reach both renal arteries simultaneously and to be adaptable to a majority of patients with a single size, again because of the relative uniformity and consistency of human anatomy in this respect. The use of pull wires in this embodiment provides for a relatively more rigid distal (beyond the bifurcation) catheter, but also allows for active placement via manipulation of the proximal control mechanism. An advantage of the pull wires is that they may be configured so as to make the distal catheter sections straight, allowing for sheath-less advancement, and then be manipulated to cause the bifurcated ends 322 to point toward the renal arteries.

[00322] FIG. 34 illustrates the proximal end of catheter 320 with guide wires 326 in sheath 324 extending down through a Y hub assembly 328. Guide wires 326 connect to respective handles 330 which are used for manipulation of the bifurcated distal ends 322 shown in FIG. 33. A proximal coupler assembly (not shown) is typically used for delivery of fluid agents through the catheter.

[00323] FIG. 35 illustrates a bifurcated renal catheter 332 with material delivery catheter 334 and non-supported, pre-formed tubular distal extensions 336. Distal extensions 336 exhibit a variation of a pre-formed shape to enhance cannulation of the renal arteries. In an exemplary embodiment, pre-formed distal extensions are made of a medium durometer Pebax material that will pop into branch arteries and maintain their relative position, but still exhibit a softness that will not cause intimal trauma when the distal tips contact vessel walls. In one embodiment, distal extensions 336 have a plurality of infusion ports (not shown). In another embodiment, the distal extensions 336 have radiopaque marker bands (not shown) to aid in positioning and cannulation of the renal arteries. Proper radiopaque markings, allows for the placement of the distal extensions 334 without the need to use contrast, as the physician would be able to see the extensions "pop" into the renal arteries as it moves down the aorta. In one beneficial embodiment, polymer tube 338 is coupled to bifurcated catheter 332 proximal of distal extensions 334. In one embodiment, polymer tube has radiopaque marker bands (not shown) to assist in positioning and cannulation of the renal arteries.

[00324] An introducer sheath (not shown) radially confines the distal extensions 336 during insertion and is retracted after insertion to allow distal extensions 336 to extend to their pre-formed shape. Material delivery catheter 334 may have a single delivery lumen or separate lumens for each distal extension 336.

[00325] FIG. 36 illustrates bifurcated catheter 332 shown in FIG. 35 inserted into aorta 32 with the introducer sheath omitted for clarity. Bifurcated catheter 332 is manipulated in aorta 32 in the vicinity of renal arteries 34 until the preformed distal extensions 336 pop into and anchor in the renal arteries 34.

[00326] FIG. 37 illustrates another embodiment of a bifurcated catheter 340 with preformed distal extensions 342 positioned for insertion into renal arteries. It is to be understood that variations of these preformed shapes for the distal extensions of bifurcated delivery catheters may be chosen for particular renal artery or ostial diameters. It is further understood that some variations of the pre-formed shapes enhance cannulation of branch arteries when moving up the aorta while other variations enhance cannulation moving down the aorta. Still further variations work equally well moving up or down the aorta. Testing has demonstrated the ability to "find " the renal ostia with these embodiments. Variations in the radius of the distal curves on the catheter extensions adapt the device to work particularly well for different shaped (e.g. diameter) renal arteries or ostia, and is generally considered to work in particular beneficial modes when the radius of curvature is smaller than the diameter of the renal arteries. Accordingly, kits may be provided to physicians with varied radii of curvature for the distal extensions and devices chosen to appropriately match the size of the vessel to cannulate.

[00327] FIG. 38 is another embodiment of a bifurcated catheter 340 previously illustrated in FIG. 37 with distal extensions 342 offset to provide access to offset renal arteries.

[00328] FIG. 39 is a further alternative embodiment of a bifurcated catheter 340 as shown in FIG. 37 where a plurality of pre-formed distal extensions 342 are configured on one side to accommodate a plurality of renal artery offset conditions (not shown). These distal extensions 347 may incorporate unique radiopaque markings so as to make them individually identifiable under fluoroscopic visualization. This embodiment typically incorporates one or more proximal coupler assemblies (not shown) for properly directing drug infusion to the proper distal extensions (those which are placed into the renal arteries).

[00329] FIG. 40 illustrates a bifurcated catheter 344 where distal end 346 is passive and distal extension 348 is movable through a guide wire 350 connected through a proximal coupler 352 to a handle 330 as shown

previously in FIG. 34. In this embodiment, the "easier" cannulation is done first with the passive extension 346 and the second cannulation accomplished using manipulation of distal extension 348 through control wire 350.

[00330] FIG. 41 is another embodiment of a bifurcated catheter 344 shown in FIG. 40 where each moveable distal extensions 348 may be manipulated independently by respective guide wires 350 connected through proximal coupler 354 to respective handles 330. This configuration allows the physician to guide each distal extension 348 into its respective target artery (not shown).

[00331] FIG. 42 illustrates a delivery catheter 360 with four preformed distal extensions 362 in their free state with introducer sheath 364 retracted. Distal extensions 362 may be adapted to include unique radiopaque markings (not shown) such that each distal extension can be uniquely identified under fluoroscopy.

[00332] FIG. 43 is a stylized illustration of catheter 360 shown in FIG. 43 in aorta 32 with two of the four distal extensions 362 positioned in renal arteries 34. By way of example and not of limitation, two of four distal extensions 362 in renal arteries 34 are sufficient to deliver required materials in particular cases. By way of additional example and not of limitation, individual distal extensions 362 may include various unique radiopaque markings (not shown) that correspond to identification on an adjustable fluid inlet manifold (also not shown) such that the user may select the proper infusion lumens corresponding to the cannulated distal extensions, and thus deliver selected agent only to the distal extensions in the renal arteries.

[00333] FIG. 44 is a stylized illustration of catheter 360 shown in FIG. 42 in aorta 32 with four distal extensions 362 positioned in renal arteries 34. As noted above, distal extensions 362 may incorporate unique radiopaque markings allowing them to be individually identified under fluoroscopy.

[00334] FIG. 45 illustrates another embodiment of catheter 360 with pre-formed distal extensions 364 in another beneficially pre-formed shape.

[00335] FIG. 46 illustrates a schematic cross section of an aorta 32 at the intersection of renal arteries 34 viewed looking down on the distal extensions

of the catheter 360. Delivery catheter 360, with a plurality of distal extensions 362, is positioned within the relatively narrow angle ά illustrating that this arrangement of distal extensions 362 will accommodate natural anatomy configurations without interference with the superior mesenteric artery 366 located above renal arteries 34. Testing demonstrates that at least one extension on each side will "find" that side's renal, providing for selective infusion. A proximal coupler assembly (not shown) can be configured to select the appropriate extensions for infusion (via a system of corresponding radiopaque markers on the extensions and the coupler assembly).

[00336] FIG. 47 is a stylized illustration of a delivery catheter 370 with a single infusion lumen 372. Details on the right of catheter 370 have been omitted for clarity. A pivot post 374 is positioned horizontally over a concave opening 376 of delivery catheter 370. Concave opening 376 is in fluid communication with infusion lumen 372. Tubular extensions 378 and 380 are configured to rotate on pivot post 374 at preformed bend 382. Delivery catheter 370 is inserted in aorta 32 near the renal arteries 34. Tubular extension 378 is positioned with its distal end 384 in contact with the wall of aorta 32 and its pivot end 386 is in contact with the surface of concave opening 376. In this position, tubular extension 378 is not in fluid communication with infusion lumen 372. As catheter 370 is manipulated in aorta 32, distal end 388 of tubular extension 380 enters renal artery 34 and rotates to a position on pivot post 374 such that pivot end 390 of tubular extension 380 is in fluid communication with infusion lumen 372 and can deliver materials directly into renal artery 34. Thus, if a tubular extension 388 selects a renal artery 34 (as it is no longer constrained by aortic wall 32), upon rotation around the pivot post 374, the selected tubular extension 388 is automatically placed into fluid communication with the catheter's infusion lumen 372.

[00337] FIGS 48A through FIG. 48G illustrate one sequence of steps in a method of constructing a single lumen delivery catheter with multiple distal extensions. Distal extensions may have pre-formed shapes for cannulation. In the embodiment shown in FIG. 48A, one or more tubular members T with dimensions of approximately .028 inches inside diameter and about .036

inches outside diameter and of material such as Pebax, is cut at 402 at an acute angle at proximal end 404. Cut tubular member T becomes distal extension 400.

[00338] In FIG. 48B, mandrels 406, preferably having a suitable nonstick coating such as TFE, is inserted in distal extensions 400 past the proximal end 404.

[00339] FIG. 48C illustrates a step where a flared tube 408 has a proximal end 410, a flared distal end 412, and is about .049 inches inside diameter to about .057 inches outside diameter. The proximal end 404 of distal extensions 400 with mandrels 406, are inserted into the flared distal end 412 of flared tube 408.

[00340] FIG. 48D illustrates a step where the outer cover 414 of a hypotube 416 is cut at the distal portion 418 to expose inner tube 420. Exposed inner tube 420 is inserted in proximal end 410 of flared tube 408.

[00341] FIG. 48E illustrates a step where flared tube 408 and exposed inner tube 420 is covered and fused with a thermal shrink-wrap 422.

[00342] FIG. 48F illustrates a step where preferably a tube 424 of about .055 inches inside diameter and about .064 inches outside diameter, and of material such as Pebax, is placed over thermal shrink wrap 422, to cover the proximal end 412 of flared tube 408 and the distal end 418 of the outer cover 414 of hypotube 416. Tube 424 is preferably fused to shrink wrap 422 at a temperature of about 400 °F.

[00343] FIG. 48G illustrates a step where a cover tube 426 of about .070 inches inside diameter and about .090 inches outside diameter and of material such as Pebax, is placed to cover the proximal end 412 of flared tube 408, tube 424 and the distal end 418 of the outer cover 414 of hypotube 416 in the embodiment shown. Cover tube 426 is fused to outer cover 414 of hypotube 416 and tube 424 at about 400 °F. The mandrels 406 are then removed from the distal extensions 400 resulting in multiple distal extensions 400 in fluid communication with hypotube 416.

[00344] FIG. 49 through FIG. 53 is a stylized illustration of another embodiment of an anchoring catheter for use in the venous system 450 with a femoral vein

452 and a renal vein 454. This embodiment is used to increase renal perfusion and function by reducing the venous pressure of the renal system. This may be particularly effective for patients displaying renal hypoperfusion resulting in fluid overload or threatened or actual acute renal failure. Further, using the device in the venous system reduces medical complications and trauma due to the lower pressures involved. In FIG. 49, a multilumen drain catheter 456 with a drain sleeve 458 at the distal tip 460 is inserted in renal vein 454 with return sleeve 462 at a mid proximal region of catheter 456 positioned in femoral vein 452. A proximal coupler assembly 464 is attached at the proximal end of catheter 456 and fluidly connects drain sleeve 458 and return sleeve 462 to a pump (see FIG. 53). An expandable member 466, such as a balloon, is positioned just proximal of the drain sleeve 458 and fluidly connected to an inflation lumen in multilumen catheter 456. The distal tip 460 is positioned in a renal vein 454 through the venous system 450 using conventional insertion methods. The expandable member 466 is inflated or deflated through operation of a syringe (not shown) or a pump (see FIG. 53) at inflation port 468 fluidly connected to the inflation lumen at the proximal coupler 464 (see FIG. 53).

[00345] FIG. 50 illustrates the distal tip 460 of the multilumen catheter 456 shown in FIG. 49 inserted in renal vein 454. When expandable member 466 is in an inflated state, renal vein 454 is occluded from venous system 450 and the pressure in renal vein 454 is actively reduced with a reversible pump 468 (shown in FIG. 53) and fluidly connected to drain sleeve 458 in renal vein 454. This configuration may also used to retro-deliver fluid agents to the renal system. In this configuration, the expandable member 466 is periodically inflated to temporarily occlude renal vein 454 from venous system 450. A fluid agent is introduced through a fluid agent lumen (not shown) to the drain sleeve 458 where it perfuses in an anti-grade fashion into the renal system.

[00346] FIG. 51 illustrates another embodiment of a distal tip 470 shown in FIG. 50 where an expandable mesh 472 is positioned to enclose drain sleeve 458 in the renal vein 454 and thereby prevent vein collapse from reduced blood pressure. The expandable mesh 472 is activated by a pull wire 490 (see FIG.

53) or other activation means through drain catheter 456.

[00347] FIG. 52 illustrates another embodiment of a distal tip 474 combining elements of the embodiments shown in FIG. 50 and FIG. 51. Expandable mesh 472 is positioned to enclose drain sleeve 458 at distal end 476 in the embodiment shown. Expandable member 466 is positioned just proximal of expandable mesh 472. Distal tip 474 is inserted in renal vein 454 where expandable member 466 occludes the renal vein 454 and expandable mesh 472 prevents collapse of renal vein 454 due to reduced pressure.

[00348] FIG. 53 illustrates a typical reversible roller pump 468 at the proximal end of the drain catheter 456 illustrated in FIG. 49 and connected through proximal coupler 478. Pump 468 extracts blood from distal tip 474 through a drain line 480 fluidly connected to drain sleeve 458 and inserts it back into the venous system through a return line 482 fluidly connected to return sleeve 452. Blood flow arrow 484 shows blood extraction location and blood flow arrow 486 shows blood return location. An inflation tube 488 fluidly connects pump 468 and expandable member 466. Pull wire 490 is attached proximally to control handle 492 and distally to expandable mesh 472 and activates expandable mesh 472. Reversing the direction of pump 468 reverses the blood flow at distal tip 474 and return sleeve 452. This reverse configuration may be used to retro-deliver fluid agents.

[00349] FIG. 54 through FIG. 57 illustrates an embodiment of a proximal coupler system 850 used to deploy and position anchoring delivery devices adjunctive with interventional catheters. FIG. 54 and FIG. 55 illustrate a proximal coupler system 850 in side view, and cut away section view, respectively. The Y Hub body 852 is configured with an introducer sheath fitting 854 at the distal end 856 of hub body 852 and a main adapter fitting 858 at the proximal end 860 of Y hub body 852. Main branch 862 has tubular main channel 864 aligned on axis 866. Main channel 862 fluidly connects introducer sheath fitting 854 and main adapter fitting 858. By way of example and not of limitation, one embodiment of main channel 864 is adapted to accommodate a 6 Fr guide catheter. Side port fitting 868 is positioned on main branch 862 and is fluidly connected to main channel 864. Secondary branch 870 has tubular branch channel 872 that intersects main channel 864 at predetermined transition angle β. The preferred transition angle β is approximately 20 degrees. Proximal end 874 of secondary branch 870 has secondary fitting 876. In one beneficial embodiment, a channel restriction 878 is molded into introducer sheath fitting 854. The Y hub body 852 may be molded in one piece or assembled from a plurality of pieces. Alternatively (but not shown) side port fitting 868 may be positioned on secondary branch 870 in a manner similar to positioning on main branch 862 as shown.

[00350] FIG. 56A and FIG. 56B illustrate a proximal coupler system 850 with a hemostasis valve 880 attached at main port 858 and Touhy Borst valve 882 attached at branch port 876. Fluid tube 884 is coupled to side port 868 and fluidly connects stop valve 886 and fluid port 888. Introducer sheath 890 with proximal end 892 and distal end 894 is coupled to Y hub body 852 at sheath fitting 854. Proximal coupler system 850 is coupled to a local fluid delivery system 900. A stiff tube 902, has a distal end 904 (shown in FIG. 57), a mid proximal section 906, and a proximal end 908. In one embodiment, stiff tube 902 is made of a Nickel-Titanium alloy. Stiff tube 902 is encased in delivery sheath 910 distal of mid proximal section 906. By way of example and not of limitation, delivery sheath 910 may be about 6 Fr to about 8 Fr in diameter. A torque handle 912 is coupled to stiff tube 902 at a mid proximal position 906. A material injection port 916 is positioned at the proximal end 908 of stiff tube 902. Material injection port 916 is coupled to an adapter valve 920 for introducing materials such as fluids. Side port fitting 922 is coupled to tube 924 and further coupled to stopcock 926 and fluid fitting 928. In an exemplary embodiment, adaptor 920 is a Luer fitting. In another exemplary embodiment, side port fitting 922 is used for injecting a saline solution. Delivery sheath handle 930 is positioned and attached firmly at the proximal end 932 of delivery sheath 910. Delivery sheath handle 930 has two delivery handle tabs 934. In an exemplary embodiment, delivery sheath handle 930 is configured to break symmetrically in two parts when delivery handle tabs 934 are forced apart.

[00351] In FIG. 56B, Delivery sheath 910 is inserted through Touhy Borst adapter 882 through secondary branch channel 872 until distal end (not shown) of delivery sheath 910 is against channel restriction 878 (see FIG. 55). At that point, force 940 is applied in a distal direction at torque handle 912 to push stiff tube 902 through delivery sheath 910. In FIG. 56B, stiff tube 902 has been advanced into introduction sheath 890. In one mode, delivery sheath handle 930 is split in two by pressing inwardly on delivery handle tabs 934. Delivery sheath 910 may be split by pulling delivery tabs 934 of handle 930 apart and retracted from Y hub body 852 to allow a medical intervention device like that shown in FIG. 57 to enter hemostasis valve 880 for further advancement through main channel 864 (see FIG. 55) and adjacent to stiff tube 902. As way of example and not of limitation, delivery sheath 934 may be removed from Y hub body 852 through Touhy Borst valve 882 before spitting and removing from stiff tube 902.

[00352] FIG. 57 is an illustration of the proximal coupler system 850 of FIG. 56B with introducer sheath 890 inserted in aorta system 32. Delivery sheath 910 (not shown) of local fluid delivery system 900 has been retracted proximally and removed and one or more fluid agent infusion devices 936 at distal end 904 of stiff tube 902 have been advanced and positioned at renal arteries 34. Interventional catheter 940 enters hemostasis valve 880 and is advanced through introducer sheath 890 and past fluid agent infusion device 936 for further medical intervention at a remote location distal to the renal arteries while fluid agent infusion device 936 remains in place at renal arteries 34. It is to be understood that proximal coupler systems can be further modified with additional branch ports to advance and position more than two devices through a single introducer sheath.

[00353] FIG. 58 illustrates a further embodiment of the proximal coupler assembly and fluid delivery assembly that is shown in FIG. 57. Renal therapy system 950 includes an introducer sheath system 952, a vessel dilator 954 and a fluid delivery system 956 with a bifurcated renal catheter 958. Details of channels, saline systems and fittings as shown previously in FIG. 54 through FIG. 57 are omitted for clarity. Introducer sheath system 952 has Y hub body 960 as shown previously in FIG. 54 and FIG. 55 configured various inner structures as shown previously in FIG. 55. Y hub body 960 has hemostasis valve 962 on proximal end 966 and Touhy Borst valve 968 on secondary end 970. Distal end 972 of Y hub body 960 is coupled to proximal end 974 of introducer sheath 976. Introducer sheath 976 has distal tip 978 that has a truncated cone shape and radiopaque marker band 980. In one embodiment, introducer sheath 976 is constructed with an inner liner of PTFE material, an inner coiled wire reinforcement and an outer polymer jacket. Introducer sheath 976 has predetermined length L measured from proximal end 974 to distal tip 978.

[00354] Vessel dilator 954, with distal end 980 and proximal end 982 is preferably a polymer, (e.g. extrusion tubing) with a center lumen for a guide wire (not shown). Distal end 980 is adapted with a taper cone shape. Proximal end 982 is coupled to a Luer fitting 984.

[00355] Fluid delivery system 956 has stiff tube 986, torque handle 988, and proximal hub 990 as previously described in FIG. 56A and FIG. 56B with bifurcated catheter 958 coupled at distal end 992. Bifurcated catheter 958 has two distal extensions 993, 994 composed partially of a memory shape material. Distal tips 995, 996 of each distal extension 993, 994 respectively, have a plurality of fluid ports (not shown) and radiopaque marker bands 997. Polymer tube 998 is positioned proximal of distal extensions 993, 994 and has radiopaque marker bands 1000. The proximal hub 990 of fluid delivery system 956 preferably has a Luer fitting 1002 for infusing a fluid agent that is fluidly coupled with the stiff tube 986.

[00356] A single lumen, tear-away delivery sheath 1004 has a distal end 1006, a proximal end 1008, and slidingly encases stiff tube 986. Delivery sheath 1004 is positioned between the torque handle 988 and the bifurcated catheter 958. The distal end 1006 of sheath 1004 has a shape and outer diameter adapted to mate with the channel restriction in the distal end of the main channel of the Y hub body as shown previously in FIG. 55. The proximal end 1008 of the delivery sheath 1004 is coupled to a handle assembly 1010 with two handles 1012 and a tear away cap 1014.

[00357] Dilator 954 is inserted through Touhy Borst valve 968 on secondary port 970 until distal end 980 protrudes from distal tip 978 of introducer sheath 976 to form a smooth outer conical shape. Distal tip 978 of introducer sheath 976 is positioned in the aorta system near the renal arteries (not shown). Dilator 954 is removed and fluid delivery device 956 is prepared by sliding delivery sheath 1004 distally until distal extensions 993, 994 of bifurcated catheter 958 are enclosed in delivery sheath 1004. Distal end 1006 of delivery sheath 1004 is inserted in Touhy Borst valve 968 and advanced to the restriction in the main channel of the Y hub body shown in FIG. 55. Bifurcated catheter 958 is advanced distally into introducer sheath 976. Tear away delivery sheath 1004 is retracted and removed through Touhy Borst valve 968 as shown previously in FIG. 56B. Bifurcated catheter 958 is advanced distally out of the distal tip 978 of introducer sheath 976 and distal extensions 993, 994 expand to their preformed shape to cannulate the renal arteries as shown in FIG 57.

[00358] FIG. 59 is a stylized illustration of a double Y proximal coupler 1150 with two local fluid delivery systems 1152, 1154 and an intervention catheter 1156 in an aorta system 1158. Details of local fluid delivery systems 1152, 1154 are shown in FIGS. 56A and 56B and are omitted here for clarity. The double Y proximal coupler 1150 is constructed similar to a proximal coupler assembly as shown in FIG. 54 and FIG. 55 but with another branch port added. Secondary branch 1160 accommodates local fluid delivery system 1152 for drug infusion in right renal artery 1162. Tertiary branch 1164 accommodates local fluid delivery system 1154 for drug infusion in left renal artery 1166. Intervention catheter 1156 enters double Y proximal coupler 1150 through hemostasis valve 1168. Introduction sheath 1170 is sized to accommodate local fluid delivery systems 1152, 1154 and catheter 1156 simultaneously. FIG. 59 illustrates secondary branch 1160 and tertiary branch 1164 on the same side of the double proximal coupler, however they may be positioned on opposite sides or in another beneficial configuration. By way of example and not of limitation, the cross section of local fluid delivery system 1152, 1154 may be oval shaped. By way of example and not of limitation, double Y proximal coupler 1150 may be adapted to advance a wide mix of medical devices such as guide wires, diagnostic catheters, flow diverters and infusion assemblies through introducer sheath 1170 and into a vascular system such as aorta system 1158.

[00359] Notwithstanding the particular benefits provided by the various embodiments described above, one particular highly beneficial embodiment of an overall renal therapy system as shown previously in FIG. 58 is provided as follows in order to further illustrate certain aspects of the invention considered suitable for bi-lateral local renal delivery of therapeutic agents in many circumstances.

[00360] An introducer sheath system is comprised of a Y hub body coupled to an introducer sheath. The Y hub body as shown previously in FIG. 54 through FIG. 55 is preferably made of a clear material and is configured with a main channel and a secondary channel that intersects the main channel. The distal end of the main channel is configured with a channel restriction as shown in FIG. 55. The Y hub body has an introducer sheath fitting at the distal end and a port for the introduction of a saline solution into the main channel of the Y hub body. A hemostasis valve is attached to the proximal fitting on the main branch of the Y hub body and is configured to accommodate a nominal 6 French diameter catheter. A Touhy Borst valve is attached to the secondary fitting on the secondary port of the Y hub body.

[00361] An introducer sheath is coupled to the introducer sheath fitting of the Y hub body and is constructed with an inner liner of TFE material, an inner coiled wire reinforcement and an outer polymer jacket. The nominal 8 French introducer sheath has an inner diameter of about 0.116 inches and an outer diameter of about 0.138 inches. The distal tip is shaped as a truncated cone to adapt with the distal tip of a vessel dilator and has a radiopaque marker band. The proximal end of the introducer sheath is comprised of the outer polymer jacket only and is flared to couple to the introducer sheath fitting on the Y hub body. In one highly beneficial embodiment, multiple introducer sheaths are provided with a renal therapy system to accommodate different anatomies. Introducer sheaths with nominal usable lengths L, as shown in FIG. 58, of about 30 cm, about 35 cm, about 40 cm, and about 45 cm are typically included, but other suitable lengths can be provided as well. In the present example, the different length introducer sheaths are each coupled to a Y body hub as an integrated introducer sheath system, however, the system may be packaged and sold separately for later assembly. In one example, a renal therapy system has a plurality of introducer sheath systems, each with a different length introducer sheath.

[00362] A vessel dilator is used with this renal therapy system to guide the distal tip of the introducer sheath to the proximal region of the renal arteries. The vessel dilator is a polymer extrusion, tapered at the distal end with an inner lumen of about 0.040 inches and adapted for passage of a guide wire of about 0.035 inches to about 0.038 inches in diameter. The vessel dilator useable length is at least nominally about 11 cm longer than the usable length of the corresponding introducer sheath to allow for placement through the introducer sheath and the Y hub body. The proximal end of the vessel dilator has a Luer fitting, primarily for flushing the inner lumen with a saline solution.

[00363] After the position of the renal arteries relative to the percutaneous entry point has been established using a guide wire with a diagnostic catheter and methods known to exist in the art, an integrated introducer sheath system of suitable length is selected. The vessel dilator is introduced through the Touhy Borst valve on the secondary branch of the Y hub and advanced until the distal tip of the vessel dilator protrudes from the distal tip of the introducer sheath resulting in a smooth outer conical shape. A saline flush is introduced through the port on the Y body and the proximal port of the vessel dilator. The introducer sheath with vessel dilator inserted is advanced on the guide wire through the percutaneous entry point and to the region in the aorta of the renal arteries. The marker band on the distal tip of the introducer sheath may be used with fluoroscopy to aid in positioning. When the distal tip of the introducer sheath is positioned at or near the renal arteries, the vessel dilator and guide wire are retracted, and removed, from the Y hub body through the Touhy Borst valve while the introducer sheath remains in place.

[00364] A fluid delivery system as previously shown in FIG. 56A is prepared for insertion into the Y hub body. In this embodiment, the fluid delivery system has a stiff tube made of Nitinol tubing and may be for example about 77 cm in usable length with a distal end, a mid proximal portion and a proximal end. A bifurcated catheter, as previously shown in FIG. 35, is coupled at the distal end of the stiff tube. The distal extensions of the bifurcated catheter have a memory shape and are made of a braid-reinforced polymer with an inner core of ribbon wire. Each distal extension in this example has a radiopaque marker band and two infusion ports at or near the distal tip. The outside diameter of each of the distal extensions may be generally for example about 3 French. There is a polymer tube encasing the bifurcated catheter in a position proximal of the union of the distal extensions. The polymer tube has two radiopaque markers positioned for example about 1 cm to about 1.5 cm proximal of the union of the distal extensions to aid in relative positioning of the bifurcated catheter and the introducer sheath.

[00365] The fluid delivery system has a torque handle coupled at the mid proximal portion of the stiff tube and a proximal hub coupled at the proximal end of the stiff tube. The proximal hub has a Luer fitting for infusing a fluid agent and a saline flush port fluidly coupled with the stiff tube.

[00366] A single lumen, tear-away delivery sheath slidingly encases the stiff tube and is positioned between the torque handle and the bifurcated catheter. The delivery sheath may be generally for example about 15 cm in length with a distal end and a proximal end. The distal end has a shape and outer diameter adapted to mate with the channel restriction in the distal end of the main channel of the Y hub body as shown previously in FIG. 55. The proximal end of the delivery sheath is coupled to a handle assembly with two handles. The handle assembly has a tear away cap on the proximal end and is configured to allow the handle assembly to separate into two portions when the tear-away cap is removed and the handles pulled apart. The circumferential profile of the delivery sheath is configured with opposing thin wall sections to facilitate splitting lengthwise in two pieces when the handles are pulled apart.

[00367] The fluid delivery system is prepared by flushing saline solution from the saline port in the stiff tube proximal hub through to infusion ports in the distal extension tips of the bifurcated catheter. The bifurcated catheter is loaded into the delivery sheath by pulling the catheter stiff tube or torque handle proximally relative to the delivery sheath handle until the tips of the distal extensions of the bifurcated catheter are completely within the delivery sheath.

[00368] The distal end of the delivery sheath, with the bifurcated catheter loaded, is inserted through the Touhy Borst valve on the secondary port of the Y hub body until the distal end seats in the channel restriction in the main channel. Distal force on the torque handle of the stiff tube advances the bifurcated catheter into the introducer sheath, preferably to at least about 15 cm (about the length of the tear away delivery sheath) into the introducer sheath to ensure the distal extensions are completely out of the tear away delivery sheath and into the introducer sheath.

[00369] The tear away delivery sheath is retracted from the Y hub body by pulling in a proximal position on the delivery sheath handle assembly as previously described in FIG 56B. During the delivery sheath retraction, the bifurcated catheter remains in position in the introducer sheath. When the distal end of the delivery sheath is removed from the Y hub body, the Touhy Borst valve is tightened on the stiff tube to prevent fluid loss. The tear away cap is removed from the delivery sheath handle assembly and the handles are pulled apart, tearing the delivery sheath longitudinally and into two pieces, which are removed from the stiff tube and discarded.

[00370] The bifurcated catheter is advanced to the distal tip of the introducer sheath by distal movement of the stiff tube at the torque handle relative to the Y hub body. Using fluoroscopic guidance, the bifurcated catheter is advanced out of the distal tip of the introducer sheath. The bifurcated catheter is manipulated through the torque handle, and the introducer sheath is simultaneously retracted, and the distal extensions bias toward their memory shape in the aorta and cannulate the renal arteries. Once the distal extensions are completely extended out of the distal tip of the introducer sheath and positioned in the renal arteries, the distal tip of the introducer sheath is retracted at least just proximal of the marker bands on the polymer tube of the bifurcated catheter to allow for interventional catheter advancement, while the bifurcated catheter remains in place. With the introducer sheath positioned, the Touhy Borst valve is tightened to prevent further movement of the bifurcated catheter in the introducer sheath.

[00371] The introducer sheath may be sutured or otherwise positionally controlled at or near the percutaneous entry site to prevent sheath movement during the subsequent procedure. Fluid agent may now be delivered through the proximal port of the fluid delivery system, through the stiff tube and into the renal arteries through the bifurcated catheter similar to that shown in FIG. 57.

[00372] Medical intervention procedures, such as coronary procedures, are initiated by inserting the appropriate guide wires and catheters through the hemostasis valve on the proximal fitting of the Y hub body. In this example, a nominal 6 French catheter will advance through the introducer sheath and along side the stiff tube without significant resistance.

[00373] When medical interventions are complete, the intervention catheters and guide wires are retracted and removed from the Y hub body through the hemostasis valve. Fluid agent delivery is typically then stopped, but may alternatively be continued for a period of time following therapy. The Touhy Borst valve is loosened and the torque handle of the stiff tube is pulled proximally relative to the Y hub body, withdrawing the distal extensions of the bifurcated catheter out of the renal arteries and into the introducer sheath. The introducer sheath is retracted from the percutaneous entry point and the entry point closed with standard medical procedures.

[00374] It is to be appreciated that various embodiments herein described are illustrative of certain broad aspects of the invention that are considered highly beneficial. In particular, the specifically named components, elements, or features for each embodiment may be similarly illustrative of certain broad aspects of the invention shared with other embodiments, though different names or labels may be given, or they may vary in insubstantial ways with respect to such broad aspect. Such would be apparent to one of ordinary skill based upon the totality of this disclosure.

[00375] Certain particular embodiments described above illustrate certain highly beneficial aspects of the invention that provide for bi-lateral self-cannulation of renal arteries via their respective ostia that are at spaced locations along an abdominal aorta wall. By “self-cannulation”, it is generally meant that the device may be guided to and inserted within the respective ostium without requiring a pre-seated guidewire to provide a railway into the artery. In further beneficial embodiments of this aspect, shape memory recovery following release from confinement distally from an introducer sheath, such as for the arms or legs of the bifurcated catheters, provides an efficient means for a natural outward force against the wall of the aorta. Simply positioning the outwardly biased tip at the correct position along the wall, such that it is registered with the renal ostium, allows it to spring open into the corresponding ostium. As such, helpful assistance may be found through basic torque transmission and longitudinal motion up and down the abdominal aorta to find the right position, and still be considered “self-cannulating” as a guidewire is not used. Or, more manipulative mechanisms may also still be provided, such as deflectability, shaping stylets, etc., in which case the result is considered “controlled self-cannulation”, though nonetheless considered self-cannulation if it gets there on its own and without a guide rail.

[00376] The various embodiments herein described for the present invention can be useful in treatments and therapies directed at the kidneys such as the prevention of radiocontrast nephropathy (RCN) from diagnostic treatments using iodinated contrast materials. As a prophylactic treatment method for patients undergoing interventional procedures that have been identified as being at elevated risk for developing RCN, a series of treatment schemes have been developed based upon local therapeutic agent delivery to the kidneys. Treatments may be beneficial for low risk patients as well. Among the agents identified for such treatment are normal saline (NS) and the vasodilators papaverine (PAP) and fenoldopam mesylate (FM).

[00377] The approved use for fenoldopam is for the in-hospital intravenous treatment of hypertension when rapid, but quickly reversible, blood pressure lowering is needed. Fenoldopam causes dose-dependent renal vasodilation

at systemic doses as low as approximately 0.01 mcg/kg/min through approximately 0.5 mcg/kg/min IV and it increases blood flow both to the renal cortex and to the renal medulla. Due to this physiology, fenoldopam may be utilized for protection of the kidneys from ischemic insults such as high-risk surgical procedures and contrast nephropathy. Dosing from approximately 0.01 to approximately 3.2 mcg/kg/min is considered suitable for most applications of the present embodiments, or about .005 to about 1.6 mcg/kg/min per renal artery (or per kidney). As before, it is likely beneficial in many instances to pick a starting dose and titrate up or down as required to determine a patient's maximum tolerated systemic dose. Recent data, however, suggest that about 0.2 mcg/kg/min of fenoldopam has greater efficacy than about 0.1 mcg/kg/min in preventing contrast nephropathy and this dose is preferred.

[00378] The dose level of normal saline delivered bilaterally to the renal arteries may be set empirically, or beneficially customized such that it is determined by titration. The catheter or infusion pump design may provide practical limitations to the amount of fluid that can be delivered; however, it would be desirable to give as much as possible, and is contemplated that levels up to about 2 liters per hour (about 25 cc/kg/hr in an average about 180 lb patient) or about one liter or 12.5 cc/kg per hour per kidney may be beneficial.

[00379] Local dosing of papaverine of up to about 4 mg/min through the bilateral catheter, or up to about 2 mg/min has been demonstrated safely in animal studies, and local renal doses to the catheter of about 2 mg/min and about 3 mg/min have been shown to increase renal blood flow rates in human subjects, or about 1 mg/min to about 1.5 mg/min per artery or kidney. It is thus believed that local bilateral renal delivery of papaverine will help to reduce the risk of RCN in patients with pre-existing risk factors such as high baseline serum creatinine, diabetes mellitus, or other demonstration of compromised kidney function.

[00380] It is also contemplated according to further embodiments that a very low, systemic dose of papaverine may be given, either alone or in conjunction with other medical management such as for example saline loading, prior to the anticipated contrast insult. Such a dose may be on the order for example of between about 3 to about 14 mg/hr (based on bolus indications of approximately 10-40mg about every 3 hours – papaverine is not generally dosed by weight). In an alternative embodiment, a dosing of 2 – 3 mg/min or 120- 180 mg/hr. Again, in the context of local bilateral delivery, these are considered halved regarding the dose rates for each artery itself.

[00381] Notwithstanding the particular benefit of this dosing range for each of the aforementioned compounds, it is also believed that higher doses delivered locally would be safe. Titration is a further mechanism believed to provide the ability to test for tolerance to higher doses. In addition, it is contemplated that the described therapeutic doses can be delivered alone or in conjunction with systemic treatments such as intraveneous saline.

[00382] It is to be understood that the invention can be practiced in other embodiments that may be highly beneficial and provide certain advantages. For example radiopaque markers are shown and described above for use with fluoroscopy to manipulate and position the introducer sheath and the intra renal catheters. The required fluoroscopy equipment and auxiliary equipment devices are typically located in a specialized location limiting the in vivo use of the invention to that location. Other modalities for positioning intra renal catheters are highly beneficial to overcome limitations of fluoroscopy. For example, non-fluoroscopy guided technology is highly beneficial for use in operating rooms, intensive care units, and emergency rooms, where fluoroscopy may not be readily available or its use may cause undue radiation exposure to users and others due to a lack of specific radiation safeguards normally present in angiography suites and the like. The use of non-fluoroscopy positioning allows intra renal catheter systems and methods to be used to treat other diseases such as ATN and CHF in clinical settings outside of the angiography suite or catheter lab.

[00383] In one embodiment, the intra renal catheter is modified to incorporate marker bands with metals that are visible with ultrasound technology. The ultrasonic sensors are placed outside the body surface to obtain a view. In one variation, a portable, noninvasive ultrasound instrument is placed on the

surface of the body and moved around to locate the device and location of both renal ostia. This technology is used to view the aorta, both renal ostia and the intra-renal catheter, or combinations or sub-combinations thereof.

[00384] In another beneficial embodiment, ultrasound sensors are placed on the introducer sheath and/or the intra-renal catheter itself; specifically at the tip of the distal extensions, along the distal extensions or at the distal end of the catheter. The intra-renal catheter with the ultrasonic sensors implemented therewith allows the physician to move the sensors up and down the aorta to locate both renal ostia.

[00385] A further embodiment incorporates Doppler ultrasonography with the intra-renal catheters. Doppler ultrasonography detects the direction, velocity, and turbulence of blood flow. Since the renal arteries are isolated along the aorta, the resulting velocity and turbulence is used to locate both renal ostia. A further advantage of Doppler ultrasonography is it is non-invasive and uses no X-rays. According to this mode, a Doppler sensor may be included for example along branch members to be cannulated into renal arteries via their ostia in order to indicate the relative positions versus what is desired.

[00386] A still further embodiment incorporates optical technology with the intra renal catheter. An optical sensor is placed at the tip of the introducer sheath. The introducer sheath's optical sensor allows visualization of the area around the tip of the introducer sheath to locate the renal ostia. In a further mode of this embodiment, a transparent balloon is positioned around the distal tip of the introducer sheath. The balloon is inflated to allow optical visual confirmation of renal ostium. The balloon allows for distance between the tip of the introducer sheath and optic sensor while separating aorta blood flow. That distance enhances the ability to visualize the image within the aorta. In a further mode, the balloon is adapted to allow profusion through the balloon wall while maintaining contact with the aorta wall. An advantage of allowing wall contact is the balloon can be inflated near the renal ostium to be visually seen with the optic sensor. In another mode, the optic sensor is placed at the distal tips of the intra renal catheter. Once the intra renal catheter is deployed within the aorta, the optic sensor allows visual confirmation of the walls of the aorta. The intra renal catheter is tracked up and down the aorta until visual confirmation of the renal ostia is found. With the optic image provided by this mode, the physician can then track the intra renal catheter into the renal arteries to a predetermined depth.

[00387] Another embodiment uses sensors that measure pressure, velocity, and/or flow rate to locate renal ostia without the requirement of fluoroscopy equipment. The sensors are positioned at the tip of distal extensions of the intra renal catheter. The sensors display real time data about the pressure, velocity, and/or flow rate. With the real-time data provided, the physician locates both renal ostia by observing the sensor data when the intra renal catheter is around the approximate location of the renal ostia. In a further mode of this embodiment, the intra renal catheter has multiple sensors positioned at a mid distal and a mid proximal position on the catheter to obtain mid proximal and mid distal sensor data. From this real time data, the physician can observe a significant flow rate differential above and below the renal arteries and locate the approximate location. With the renal arteries being the only significant sized vessels within the region, the sensors would detect significant changes in any of the sensor parameters.

[00388] In a still further embodiment, chemical sensors are positioned on the intra renal catheter to detect any change in blood chemistry that indicates to the physician the location of the renal ostia. Chemical sensors are positioned at multiple locations on the intra renal catheter to detect chemical change from one sensor location to another.

[00389] It is to be appreciated therefore that the immediately preceding embodiments relate to a more general aspect of the invention that provides for sensor-assisted guidance to locate the bilateral renal delivery system without the need for, or certain substantially reduced requirement of, fluoroscopic imaging. In particular such reduces a need for radiocontrast delivery to position the respective devices appropriately in reference to the renal arteries, wherein radiocontrast is problematic to begin with for the renal systems of many patients to be given therapy according to the present embodiments. Moreover, it is also to be appreciated such alternative modes just described may be incorporated in combination with other(s) of such modes, or in combination with radiopaque markers or dye delivery to provide a versatile enhanced system. Still further, such beneficial modes according to the embodiments just described are contemplated for use with other bilateral renal delivery systems, such as for example: systems adapted to cannulate each of two renal arteries; systems adapted to position one or more injection ports at desired positions within the abdominal aorta so as to inject agent into regions of blood flowing into the renal arteries via their ostia; and systems adapted to provide isolation, occlusion, or diversion of certain regions of abdominal aortic flow in order to either enhance flow of blood or injected agents into the renal system via their ostia along the abdominal aorta wall. Moreover, the use of such sensors may be performed by monitoring changes in sensed parameters, indicating a change in environment indicative of a desired or un-desired placement. Or, such may be performed by recognition of one or more signature signals of such parameter that are empirically known to indicate a particular position within a patient's anatomy.

[00390] The following embodiments illustrate further aspects of the invention directed toward the unilateral or bilateral disposition of an interventional device in the renal arteries of a patient to provide therapy to the renal arteries or the kidneys alone or in combination with other procedures. The design of the guiding catheter, according to one aspect of the invention, allows for very low vessel trauma during insertion, and, in the case of renal cannulation, without the need for multiple manipulations. The guiding catheter aspect of the present invention is generally provided with a low OD profile, smooth transitions and no exposed edges; therefore reducing the risk of vessel damage during insertion and withdrawal. However, it is to be appreciated that such optimizations are examples of features with are highly beneficial in many circumstances, but are generally not intended to be limiting to certain other broad aspects of the invention which are herein described.

[00391] The embodiments described below are illustrative modifications of a bifurcated infusion catheter such according to one or more of the embodiments of FIGS. 1-59 above.

[00392] It will also be appreciated that the various local renal injection assemblies adapted to provide bilateral local delivery of therapeutic agents to the renal system via renal arteries may also be appropriately applied for bi-lateral therapies and diagnostic uses via the venous system. In one particular beneficial regard, dual injection member structures described for cannulating and injecting agents into the renal arteries bilaterally may also be used to cannulate each of two renal veins drawing blood away from the kidneys. This may be used for example in order to draw blood for testing and measurements to monitor renal function or other parameters of the patient such as drug or radiopaque agent clearance. Such may for example be performed in conjunction with bilateral cannulation of the renal arteries for drug delivery there, while drawing blood from the other side of the kidneys with the bilateral renal system. Various features of the system shown and described for example by reference to FIGS. 49 to 53 above may be incorporated into such branch structures. Moreover, retroperfusion of fluid agents as therein described may also be accomplished in a bilateral fashion.

[00393] The infusion catheter embodiments described with particularity in FIGS. 1-59 above generally provide a lumen that is bifurcated at the distal end with, in one illustrative embodiment, two metal supported braided polymer branches (which may be generally similar in construction, shape, and size, or may differ to suit a particular need). This illustrative catheter is configured to allow cannulation of the individual ostium of both renal arteries without the guidance of guide wires. The branches of the catheter are bilaterally disposed in the renal arteries via the aorta. The tips of the branches have two infusion ports to permit the flow of therapeutic agents to the renal arteries to the kidneys.

[00394] One present further embodiment of the bifurcated infusion catheter is configured with a guide wire lumen through the inner diameter or ID of the bifurcated infusion catheter. Once the catheter has been positioned within the target renal arteries, the guide wire can be advanced and tracked through the guide wire lumen to the target site. The catheter lumen may be designed to incorporate any guide wire size, to suit a particular purpose and anatomical considerations, as would be apparent to one of ordinary skill.

[00395] In another present embodiment, two separate lumens are provided, which may include at the proximal hub in order to distinguish the two infusion branches and guide wire lumens. This embodiment allows for infusing liquid through the infusion holes along the diameter of the infusion branch. In another embodiment, the catheter tip incorporates a third infusion hole at the distal end of the tip that can also be used as the guide wire lumen. The lumen can be designed to facilitate any size of guide wire.

[00396] In alternative embodiments, a stylet-type mechanism is used to deliver and track a guide wire to the target renal arteries. One particular illustrative embodiment utilizes for example a NiTi ribbon within the infusion branch, such as shown in FIG. 18 above. The ribbon wire assists with maintaining the pre-determined shape. In this embodiment, the ribbon wire is modified to a stylet concept. The stylet-type modification gives the ribbon wire the ability to be removed therefore creating a guide wire lumen in its absence. The presence of the ribbon wire would allow the infusion branch to maintain the shape required to cannulate both renal arteries and position the distal tips of the branched catheter as described in the disclosure above. With the movement or removal of the ribbon wire, the infusion branch shape can also be adjusted according to the specific renal arteries shape requirements. The addition of the stylet would allow generally for a lower profile infusion branch because no extra guide wire lumen is required. The stylet concept would also allow for the cannulation of only one target renal artery through the manipulation of only one stylet.

[00397] Accordingly, the overall concept of this patent discloses the use of the bifurcated infusion catheter for placement of a guide wire within the renal arteries. Once the guidewire is efficiently seated in the renal artery, further procedures may be performed thereover, such as for example placement of another guiding catheter allowing the physician to complete any multiple of interventional procedures.

[00398] Notwithstanding the substantial benefits for bilateral cannulation of the renal arteries and/or veins as just described, other bilateral renal delivery assemblies may also be applied on the venous side. This includes, for

example, use of flow diverters or isolation assemblies adapted to isolate regions of blood flow within the main vessel, in this case the vena cava, such that blood flowing from the renal vein ostia may be substantially isolated within the vena cava. Such intra-vena cava embodiments would be of particular benefit for diagnostic purposes, so that for example measurements may be taken.

[00399] It is also to be appreciated that the venous side of the circulation flows in an opposite direction vertically with respect to the patient. Thus, with respect to delivery of such assemblies upward along the vena cava from the femoral veins, such would be considered antegrade to the physiologic flow versus the retrograde orientation on the arterial side in the abdominal aorta. Accordingly, certain flow-dependent assemblies would thus be appropriately modified to accommodate for such different environment. In a similar regard, flow rates and pressures are different in the vena cava and renal veins than in the abdominal aorta and renal arteries, respectively, as are the compliant natures of the respective vessel walls. Such considerations may be taken into account by one of ordinary skill in order to suitably modify the prior disclosures to suit a particular purpose consistent with this disclosure or obvious variations herefrom.

[00400] Likewise, the various catheter assemblies previously described can also be used in clinical treatments and diagnostic procedures unrelated to treatment radiocontrast nephropathy such as hepatorenal syndrome, renal angiography, renal flow studies and renal blood vein sampling (e.g. use on the venous side for rennin sampling) and the like.

[00401] According to various of the embodiments herein described, an intravascular catheter with a bifurcated distal end is provided, with each end being shaped so as to allow for safe, quick, and easy cannulation of a renal artery or vein. The bifurcated design of the catheter may be beneficially adapted such that cannulation of both renal arteries (or both renal veins) may be achieved substantially simultaneously, without the need for additional guide wires or catheters. The discussion and embodiments that follow may allude to only one or both of the arterial or venous aspects of the design;

though such particular arterial or venous application may be of particular benefit for a given case, such is also to be considered illustrative and not limiting in scope to the exclusion of the other side of the cardiovascular system. In many cases the same application of the device may be appreciated in both the renal arteries or the renal veins.

[00402] This novel renal device therefore may itself perform an indicated renal diagnostic or therapeutic (or prophylactic) procedure, or may be adapted to allow for the introduction of another device or devices that serve these functions. In either case the use of a single device for bilateral renal access may reduce procedural time, cost, and possible harm to the patient, thereby improving clinical outcomes concurrent with achieving an economic benefit.

[00403] A schematic of the bifurcated distal end portion 1201 of such a device 1200 is shown in FIG. 60 and is illustrative of other embodiments elsewhere herein shown and described. This schematic demonstrates a specific embodiment of the device, and though highly beneficial is considered illustrative and not meant to be limiting to certain broad aspects herein described.

[00404] A device 1200 such as in FIG. 60 may be delivered in a collapsed condition via a radially confining sheath to the abdominal aorta in the vicinity of the renal arteries, or alternatively to the inferior vena cava in the vicinity of the renal veins. 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 the device. For the purposes of this disclosure the device is considered to be in its free state as shown in FIG. 60, and compressed via the constraint of the delivery/introduction sheath or other means during delivery. Thus the device “self-expands” upon deployment, to an extent determined by the constraint of the blood vessel. It is this outward contact with the blood vessel that allows for easy cannulation of multiple vessels, as the device naturally seeks its lower energy state by opening into branch vessels. When deployed in the aorta (or vena cava), in a procedure where it is desired to access the renal arteries (or veins) for any number of

clinical reasons, the device will exit its vascular access sheath and the distal branches 1202,1206 will seek to open to their natural, at-rest state. This will bias the branches 1202,1206 away from each other and against the inner wall of the vessel. In particular beneficial embodiments, this may be approximately 180° apart from each other, more or less centering the main device shaft in the vessel.

[00405] The proximal end of the device (not shown) may be manipulated via standard technique (e.g., a "torque device" may be supplied, as is common with intravascular guide wires). In beneficial exemplary modes, this is done such that the arms are more or less aligned near the target renal arteries' ostia (or those of the renal veins), and so that with a relatively little amount of axial or rotational manipulation, bilateral renal artery (or vein) cannulation can be achieved.

[00406] While the specific embodiment just described is considered highly beneficial, various modifications may be made without departing from various broad aspects of the invention. For example, though such particular self-expanding configuration just described is considered highly beneficial, the device could be modified to instead have the collapsed condition as the memory default condition and be actively opened once deployed. Furthermore, the branches 1202,1206 may be separated by other arcs or variations of degrees than the approximate 180degree orientation just described, and may have different shapes, lengths, diameters, relative locations between the branched cannulas along the long axis of the device or aorta, or numbers of such branches.

[00407] Among the other many benefits herein described or otherwise apparent to one of ordinary skill upon review of this disclosure, it is appreciated that the multiple present embodiments benefit by providing access to multiple vessels simultaneously through a single vascular access point, alone of in combination with other diagnostic or therapeutic procedures.

[00408] As well, and as described below herein, certain applications may benefit from a device such as that described above but requiring only one functional branch. For example, the embodiment shown in FIG. 61 includes a delivery catheter 1210 with a bifurcated distal end portion 1211 having a first working branch 1212 with a delivery lumen 1215 for delivering for example a fluid agent or interventional device into a renal vessel. However, the distal end portion 1211 of this embodiments has a second branch 1216 that is a "dummy" branch generally without lumenal access through its tip. Such dummy branch 1216 is adapted to provide the desired bias for the working branch 1212 to push away from one wall and toward an opposite wall to cannulate a target vessel through its ostium. This is beneficially achieved in most circumstances without the requirement of a guidewire according to this embodiment.

[00409] An exemplary construction is shown for dummy branch 1216 and includes a wire braided reinforcement 1217 in the wall, in addition to a longitudinal reinforcing member 1218, which may be disposed for example within a lumen contained therein and which is closed at tip 1219. The longitudinal reinforcing member 1218 may be for example a stylet, or a fixed wire within dummy branch 1216. This construction is considered beneficial for optimal performance in the biasing role for the other working branch 1212.

[00410] However, it is to be appreciated that other constructions may be employed to achieve the general stated objective without departing from the intended broad scope of this embodiment. For example, the closed tip 1219 beneficially prevents blood fluids from unnecessarily entering the device where no benefit would be provided by such access. Also, the possibility of harmful air emboli from any catheter lumen should be generally prevented where possible, and is prevented by such tip closure. However, despite this particular and appreciable benefit, tip 1219 need not necessarily be closed for all cases. Moreover, the braid 1217 may be replaced by a wound reinforcement, or none may be needed in a particular design. Such also applies to the longitudinal reinforcement 1218. Furthermore, dummy branch 1216 may be a solid member and not contain a lumen that would be either open or closed to the surrounding environs.

[00411] Another embodiment shown in FIG. 62 includes a delivery catheter 1220 that has a branched catheter end portion 1221 with a working branch

1222 and a dummy branch 1226. This is shown for further illustration during in-vivo use wherein working branch 1222 is cannulated within a renal vessel. Working branch 1222 in the particular illustrative embodiment shown includes a side delivery port 1223 and adjacent marker 1224 located to assist in positioning port 1223 within the renal artery according to one or more of the various visualization and positioning embodiments herein described.

[00412] However, in this particular embodiment of FIG. 62, dummy branch 1226 includes an elongated wire-type member 1228 that terminates in a rounded tip 1229 that is shown as an enlarged ball. This rounded tip 1229 provides less traumatic contact to aortic wall against which dummy branch 1226 is forced during expansion to bias working branch 1222 toward the opposite aorta wall and into the cannulated renal vessel.

[00413] These two prior embodiments illustrate examples of branched catheters incorporating dummy branches that are mechanically sufficient such that the advantages of a bifurcated device are achieved, for example in terms of quickness and ease of use for renal cannulation. But, such dummy branches are not required to be generally functional themselves in terms of diagnostic, therapeutic, or prophylactic function. Thus such embodiments may be employed in situations for example where only one vessel is to be accessed, such as when only one kidney requires treatment or only one kidney is present. The "dummy" branch may be of the same shape configuration as the functional branch, or may be of a different configuration that maintains the overall device performance by acting in a similar manner to the functional arm in more or less centering the device within the aorta/vena cava and providing the proper biasing of the device to allow for the same quick and easy cannulation afforded by the functionally bifurcated device. Moreover, a bi-laterally functional branched delivery system may be used in a manner where only one branch is utilized, though both branches are "intervention" capable.

[00414] As previously mentioned, a device such as according to the various embodiments herein disclosed may be useful in diagnostic, therapeutic, and prophylactic procedures. The use of the device may then benefit from certain

particular specific features, such as size, structural integrity, lumen configurations, one or two functional branches, etc. Descriptions of various preferred embodiments are given below. In many cases, where use in the renal vasculature is given as the primary indication, such devices generally incorporate usable lengths in the range of between about 50cm to about 100cm, assuming standard femoral artery access. In the cases where another access point is used, longer or shorter device lengths may be indicated. As well, in non-renal applications, required device configurations including lengths may vary according to the specific needs of the indications.

[00415] Various diagnostic indications and uses are contemplated for the various bifurcated renal catheters herein shown and described. These indications may include for example: angiography, intravascular imaging (i.e., IVUS or angioscopy), blood sampling, and temperature and flow measurements.

[00416] For angiographic indications, among beneficial features to be incorporated into the device is the capability to provide a high enough flow rate of contrast medium such that enough contrast medium can be delivered to the renal arteries to be visualized, and such that the dispersion of the contrast medium is well mixed with the renal artery blood flow so that the images obtained are accurate for diagnostic purposes. In order to satisfy these desired capabilities for a given situation, typically an adequate internal lumen size in combination with a satisfactory pressure rating would be provided, so as to allow the passage of contrast medium at an acceptable rate. Also, the branches are typically to be provided with infusion end/side holes so as to achieve desired distribution and mixing of the contrast material.

[00417] For further illustration, FIG. 63 shows another embodiment of a delivery catheter 1230 during in-vivo use wherein a branched distal end portion 1231 includes first and second radially separated branches 1232,1236 cannulated within first and second renal arteries. Further to this embodiment, as shown for branch 1236 for illustration, a tip region 1238 for each branch is provided in a loop configuration with a plurality of delivery ports 1239 arranged in a spaced array around the loop. This provides for efficient delivery and mixing during fluid injection within the flowing vessel.

[00418] Therefore, one exemplary embodiment of the device for this indication may include a single-lumen catheter that bifurcates into two distal branches, each with its own lumen. For further illustration, each may include lumen diameters for example of approximately 0.020" or larger for each branch and approximately 0.030" or larger for the common lumen proximal to the bifurcation. Each branch beneficially has multiple side-holes for infusion of contrast agent in a dispersed pattern in the embodiment shown within the vessel. This particular combination of dimensions and design considerations would then yield for example a device with outer diameters within the range of about 2.5F to about 6F. Such a device may provide for simultaneous bilateral renal imaging with a single device and a single fluoro shot, reducing both the x-ray and contrast exposure to the patient, as well as the cost and time of the procedure.

[00419] Other modified forms of the tip region for a branch of the catheter are further shown in FIG. 63 for further illustration as follows. Alternative tip region 1240 is shown to include a single end hole port 1242 for end-hole injection or delivery of devices, fluids, or other materials. Alternative tip region 1244 is shown to include a side port 1246 for delivery. Alternative tip region 1248 includes a plurality of side ports 1249 arranged in a spaced array. This may represent one configuration for the looped configuration of end portion 1238 shown in FIG. 63, such as for delivery through a sheath to the general region, or under the straightening force of a stylet for example. Or, it may simply be another different shape or configuration. Of course, various combinations or modifications of these particular alternative embodiments are contemplated.

[00420] For intravascular imaging indications, involving ultrasound or angioscopy technology, the design of the device will necessarily be limited by the constraints of the ultrasound or angioscopy hardware. It is envisioned that size requirements for such a device, particularly in the area of angioscopy, would be larger than those needed for diagnostic or other indications. However, the desire for a fluid-passing lumen would be diminished or

eliminated if the need to perform angiography through the device may not be required. This may still yield a somewhat larger device than would be used for other diagnostic purposes, for example in the outer diameter range of about 3F to about 8F. However, again for many patients and procedures the benefit of using a single, self-cannulating device to provide simultaneous bilateral renal imaging is clear.

[00421] Clinical situations exist where bilateral renal blood sampling is indicated, and doing so rapidly is generally desired. In particular, renal venous blood sampling is beneficial to determine the efficacy of the kidneys' filtration of a particular blood toxin; such a determination can be made by comparison of systemic blood levels of a given toxin versus that in the renal veins. This may allow for an easier assessment of renal clearance than more traditional timed interval measurements by allowing for the gathering of all necessary data at a single point in time. Therefore, an embodiment of the device could be adapted for use in the venous circulation, with lumens of sufficient size to allow for blood withdrawal, for example in the range of about 0.020" to about 0.050". If desired, the device could involve two proximal lumens, so as to give the ability to identify each kidney's function independently, or, if this is not necessary, a simpler design with a single shared proximal lumen could be employed.

[00422] In a further embodiment shown by way of illustration in FIG. 64, a delivery catheter 1240 includes a bifurcated distal end portion 1241 with first and second radially spaced branches 1242,1246 cannulated within first and second renal arteries. These branches 1242 each are shown to include, for illustration via a more particular embodiment, first and second end-hole ports 1243,1247, respectively, and first and second visualization markers 1245,1249, also respectively.

[00423] However in this particular embodiment of FIG. 64, a third port 1250 is provided, shown in the particular illustrative variation to be located generally at the region of the bifurcation of the branches 1242,1246. This third port 1250 may serve for example as an inlet port with its own retrieval lumen, which may be for example sized (e.g. diameter) similarly to the other collection lumen(s).

This may be provided in combination with various of the embodiments herein shown or described.

[00424] In one particular mode of construction and operation shown (e.g. by way of flow arrow in FIG. 64 pointing antegrade with the direction of the distal end portion 1241 of catheter 1240), the catheter 1240 may be adapted such taht third port 1250 is arranged for placement at a site remote to the renal veins (i.e., upstream in the vena cava), to allow for sampling of "systemic" levels of a given toxin for comparison purposes as described herein. In this manner a single device could be used for taking all of the blood samples required for an estimation of kidney clearance of a given toxin or toxins, at a single point in time, allowing for a quicker, cheaper procedure in which the patient exposure to devices and x-ray are limited. For a three-lumen, three-ported device as described, the outer diameters may range for example from about 2.5F to about 9F.

[00425] It is often desired to assess the clinical consequence of renal vascular disease. In many cases, various lesions, such as calcium deposits, other plaques, etc., may have a detrimental effect of distal function (in this case, kidney function) and in other cases their effect may be so small so as not to warrant treatment. Therefore the ability to diagnostically analyze the effect of a vascular lesion in a means other than simple angiography may be desired. Measurements of blood flow, pressure changes, and temperature changes across a given vascular lesion have all been described as means to determine the severity of any distal effect and the likelihood of the lesion to rupture or proliferate, and thus can provide valuable information with regards to the necessity of treatment. The ability to make such bilateral renal diagnosis quickly and easily, with a single device and a reduced amount of contrast media or x-ray time required, provides a distinct advantage over traditional methods. Such a device may be designed that incorporates certain features also found in other flow, temperature, and pressure sensing catheters and guide wires, provided that certain profound differences are beneficially provided according to the various embodiments herein described. In particular, certain of the present embodiments variously incorporate the bifurcated configuration and the distal shapes and flexibility profiles adapted to provide for substantially quick and relatively easy (when compared to conventional techniques) bilateral cannulation. Not withstanding possible separate aspects providing for fluid lumens, this may yield a device for example with outer diameters ranging from about 1F to about 6F.

[00426] Numerous therapeutic indications would generally benefit from simultaneous treatment of the renal arteries. These include selective pharmaceutical or other agent infusion, including embolic agents and devices, angioplasty and stenting, thrombus removal, and selective tissue heating or cooling.

[00427] Selective bilateral renal artery pharmaceutical or other agent infusion may be indicated in multiple clinical situations, including but not limited to decompensated congestive heart failure or renal failure.

[00428] In cases of decompensated congestive heart failure, systemic edema may reach clinically unacceptable levels, necessitating rapid fluid removal via the kidneys. Local administration of diuretics, vasodilators, and the like may help expedite this process without causing the possible untoward side effects of systemic delivery. For example, local administration of papaverine hydrochloride, fenoldopam mesylate, or B-type natriuretic peptide may serve to increase renal blood flow locally, and therefore increase urine production, without causing systemic hypotension that may occur if these vasodilatory agents, or similar ones, are administered systemically, and local delivery may require smaller doses as well. Local delivery of diuretics such as furosemide may also have the advantage of reducing the required effective dose.

[00429] Likewise, local renal delivery of other pharmaceuticals or agents may be indicated in cases of renal failure, independently or as an adjunct to acute or chronic dialysis. According to the local renal delivery embodiments variously provided hereunder, an advantage may be in many cases a reduction in necessary dose. An example of this might include the local renal delivery of amifostine or allopurinol to reduce nephrotoxic side effects in the setting of *Cisplatin* or other chemotherapy drugs that may be given for cancer treatment, while reducing possible side effects such as hypotension. In any

event, embodiments of the disclosed device to be used for selective bilateral renal artery pharmaceutical or agent infusion must necessarily have luminal dimensions and configurations in keeping with the delivery of said pharmaceuticals or agents. Lumens are generally adapted to allow for flow at indicated infusion rates and at pressures allowable by standard commercial infusion pumps; in certain cases luminal sizes may range for example from about 0.010" to about 0.040", with outer diameters within the range of about 2F to about 6F.

[00430] Chemoembolization procedures have become increasing popular in the setting of hepatic carcinoma. In these cases an embolic agent (such as PVA or cyanoacrylate) is injected directly in to a tumor site via the vasculature in combination with a chemotherapeutic agent (such as *cis*-platinum, lipiodol, or the like). Certain typical advantages to this type of procedure include the reduction or elimination of systemic side effects of the chemotherapeutic agent due to its direct delivery, and the added two-pronged approach of local delivery of the chemotherapeutic agents along with simultaneous removal of the tumor's blood supply via embolization. The liver provides a uniquely "low-risk" environment in which to perform this procedure, as compared to tumors in other areas of the body, as the liver receives a majority of its blood supply from the portal vein while the hepatic artery usually feeds any tumors. Thus, embolization of a substantial portion of the hepatic artery may not be detrimental to liver function, and any untoward effects are most certainly positively outweighed by stopped the tumor growth. Therefore there exists a potential application for the bifurcated catheter technology according to various of the embodiments herein described for treatment of hepatic carcinomas via chemoembolization or other embolization such as coils, etc.

[00431] In particular but without limitation, this setting is a well suited application for the single functional branch and a "dummy" branch device design embodiments. As well, this type of device may find indications in focal renal lesions that may be selectively accessed among branch vessels of the renal arterial system, preventing side effect damage to the entire kidney, and various desired benefits of renal chemoembolization have been previously disclosed. Owing to the relatively high viscosity of various chemotherapeutic and embolic agents, larger delivery lumens may be required than are typical of microcatheter-sized devices. Luminal sizes from about 0.025" to about 0.040" may be indicated, with corresponding outer diameter profiles generally between about 3F to about 6F.

[00432] Localized renal temperature changes may be employed for such uses as adjusting blood flow, kidney filtering properties, oxygen requirements of kidney tissues, and the like, or even for causing temporary or permanent damage to tissues if so indicated. Adjusting blood flow patterns or filtration by inducing temperature gradients across the kidney may be effected by placement of a heating or cooling device in either the renal arteries or veins, as previously described. Such a gradient may be induced across the kidney's vasculature to increase blood flow, or may be done so as to create a gradient within the filtrations mechanisms to promote increased or decreased function as desired. Cooling on the arterial side in particular may secondarily lower the temperature of the surrounding tissue and possibly reduce its oxygen requirements on a temporary basis. These are generally instances where a functionally bifurcated device might be indicated. Localized extreme heating or cooling may be employed to effect tissue damage, such as the freezing of recently expanded stenotic lesions to prevent restenosis or the ablation of renal pressure receptors to interrupt the renal-cardiac cascade that may lead to multi-organ failure in instances of hepatorenal syndrome and the like. These instances are generally ones in which a single functional branch device design might be indicated. In any event heating and cooling devices must be designed around the mechanism used to create the temperature change, such as direct resistive heating, fluid exchange, RF, etc. For further illustration, exemplary devices of the type just described may have outer diameters for example in the range of about 2F to about 8F, depending on particular requirements.

[00433] Due to the interrelation of renal disease with other acute and systemic co-morbidities, prevention or attenuation of anticipated renal failure is of great interest to the healthcare community. There exist numerous situations in which such preventative measures may be indicated, and in which a simple and easy-to-use bifurcated renal catheter would either allow for new therapies or would be quite an advantage over traditional therapeutic methods.

[00434] Incidence of acute tubular necrosis (ATN) manifesting in acute or chronic renal failure is a rare (<5%) but well-known side effect associated with major surgical interventions in which general anesthesia and/or cardiopulmonary bypass are employed. Patients at greater risk for developing renal failure (i.e., elevated baseline SCr, reduced Cr clearance, etc.) may be identified as candidates for prophylactic therapy. Administration of various agents to the renal arteries may improve outcomes in these patients, and that availability of a simple bifurcated renal catheter would aid in such administration. Typical agents that might be beneficial include for example various vasodilators (i.e., papaverine hydrochloride, fenoldopam mesylate, natriuretic peptide), which can serve to selectively dilate the renal vasculature, increasing (or preventing a decrease in) local blood flow without untoward side effects of systemic vasodilatation such as hypotension. Other agents may include for example diuretics or hyper-oxygenated blood or a blood substitute. Specific design considerations of a device for this application may be similar to those listed previously hereunder with respect to therapeutic pharmaceutical or other agent infusion. Cooling of the kidneys may also be indicated to reduce oxygen requirements and possibly prevent damage due to the systemic shock of cardiopulmonary bypass. As well, it may be advantageous to provide a mechanism for placement of the device in this application without fluoroscopy, which may not be available in a more traditional surgical setting, and also to consider alternate device working lengths to adapt for vascular access from locations other than the standard femoral puncture used in most intravascular interventions.

[00435] The nephrotoxicity of radiocontrast agents has been well established. In patients with known risk factors, such as those listed in the above discussion of ATN in the surgical setting, radiocontrast nephropathy (RCN) is a prevalent adverse effect of interventional procedures utilizing organically bound iodine-based contrast imaging agents. The detrimental results of RCN on morbidity and mortality are well documented, and local agent administration to the renal arteries during the time of contrast media exposure is a desired prophylactic measure to mitigate the development of RCN in many cases. Agents in this case may include for example vasodilators, diuretics, or hyper-oxygenated blood or blood substitute. As well, the catheter may also be used for exchange purposes, for example to remove blood laden with contrast media and replace it with filtered blood, such as in further embodiments via use of an external blood filter/pump. A bifurcated renal catheter as disclosed herein and in numerous previous files is particularly well suited to this application, as it can be particularly adapted to be used adjunctively to another intravascular interventional procedure. Again, the particular considerations as to certain features to be incorporated into such an embodiment may be similar to those described elsewhere hereunder for therapeutic and other agent infusion.

[00436] In further embodiments below, the delivery devices herein described would be further adapted to provide for adjunctive compatibility with other interventional tools. Such would apply in many circumstances to meet varied specific and general needs, including among other things various aspects of the foregoing medical indications for therapy or prophylaxis.

[00437] In particular, embolic protection in the renal arteries may be indicated in instances of renal angioplasty with or without stenting, or in cases of other aortic or other up-stream interventions (e.g. generally upstream of the renal ostia), and in any case under circumstances that have a known risk or a potential for generating renal emboli. Such procedures may include for example endovascular repair of aortic aneurysms, a procedure that is becoming more and more common.

[00438] A bifurcated renal catheter with integrated embolic protection features is considered well suited and highly beneficial for such protection. Such protection features may include for example distal "basket" or mesh filters, or proximal or distal occlusive means, with or without aspiration. Certain exemplary, though highly beneficial, embodiments follow.

[00439] Multiple embodiments featuring various mechanisms and features adapted to provide embolic protection are illustrated for further example in FIGS. 65-67 as follows.

[00440] A simple deployment into the renal arteries prior to beginning the main procedure would allow for renal protection in a simple manner without interference to the main therapy. And, because the primary procedure may involve radiocontrast agents (as in the case of endovascular stent-grafting) the inventive device could be configured so as to simultaneously provide for embolic protection while delivering prophylactic or therapeutic agents as noted above. The infusion of heparin or other clot prevention or lysing agents may also be indicated in cases where embolic protection is desired, and could be accomplished via the same device in further beneficial embodiments.

[00441] One particular embodiment for embolic renal protection is provided for purpose of further illustration in FIG. 65. Here a delivery catheter 1260 includes a bifurcated distal end portion 1261 with first and second branches 1262,1266 cannulated within first and second renal arteries. Extending from these first and second branches 1262,1266 are first and second embolic filter assemblies 1264,1268, respectively. These filter assemblies 1264,1268 are shown in FIG. 65 in their deployed configuration within the respective renal arteries, such that emboli 1269 that may be for example flowing in the aorta and into the renal arteries are caught and prevented from damaging the more distal renal flow and anatomy. Typically, such filters may be retrieved subsequent to the procedure in a manner that does not substantially damage the renal vessel wall and that captures and retrieves the emboli 1269 which has been caught.

[00442] The distal protection embolic filter assemblies 1264,1268 may be constructed in a similar manner to many of the other embolic protection filters previously described, such as baskets, cages, mesh structures, or membranes having particular porosity that allow blood components of a particular size or type to pass, though preventing components over a predetermined size from passing. Examples of previously disclosed embolic protection or filter assemblies, one or more of which may be appropriately modified or otherwise applied for use according to the present embodiments, are disclosed in the following issued U.S. Patents: 6,027,520; 6,042,598; 6,168,579; 6,270,513; 6,227,139; 6,290,710; 6,319,242; 6,336,934; and 6,371,969. Further examples are provided in the following published PCT International Patent Applications: WO 00/67664; WO 00/67668; WO 00/67671; WO 01/49215; WO 01/52768; WO 01/80776; WO 01/80777; WO 02/22046; WO 02/40090; WO 02/43595; and WO 99/23976. The disclosures of these references are herein incorporated in their entirety by reference thereto.

[00443] Another embolic protection embodiment is shown in FIG. 66. Here a delivery catheter 1270 includes a bifurcated distal end portion 1271 with first and second radially separated branches 1272,1276 cannulated within first and second spaced renal arteries. However, in this particular embodiment expandable balloons 1274,1278 extend beyond the end of the respective branches 1272,1276 and are expanded to substantially occlude the respective cannulated artery. This blocks flow of emboli 1279 into the distal portions of the renal arteries, and in fact may present stasis proximal within the artery such that the embolic blood flows downstream, bypassing the arterial ostia of the branches (as shown by curved flow arrows at the respective ostia). However, for further protection the particular illustrative embodiment shown provides for proximal suction through ports 1273,1277 generally at the tips of the respective branches proximally of the expanded balloons 1274,1278. This is illustrated by way of retrograde arrows extending proximally from balloons 1274,1278 and into ports 1273,1277, respectively. In the event emboli do flow into the respective cannulated arteries, this combination of blockage from the balloons and suction through the ports allows aspiration of such embolic fluid as a further protection.

[00444] It is to be appreciated that the preceding embodiment is illustrative of “proximal distal protection” wherein proximal aspiration from a region prevents distal embolization beyond that aspirated region. Accordingly, a variety of specific structures and methods may be used, including as may be previously disclosed for this general type of procedure.

[00445] Moreover, the balloons 1274,1278 may be coupled to the respective branches 1272,1276 in a relatively fixed fashion, e.g. integrated as a unit via an extension coupler as shown by illustration at member 1279 in FIG. 66. Or, as would be apparent to one of ordinary skill such balloon assemblies may be slideably disposed within lumens of the respective branches as separate cooperating units that may have adjustable positioning relative to the respective engaged branch. In such alternative combination assembly embodiment, the balloons themselves may be integral over a shaft or wire chassis, or may furthermore be constructed on their own balloon catheter shafts that ride over a guidewire in a three component system (wire, balloon catheter, bifurcated delivery catheter). In any event, the balloons may be beneficially provided with adjustable diameters, such as via relatively compliant materials that allow for blockage of multiple sized vessels at relatively low pressures and reduced vessel wall trauma.

[00446] For further illustration of the broad intended scope of embolic protection aspects of the present invention, another embodiment is illustrated in FIG. 67. Here a delivery catheter 1280 is shown with a bifurcated distal end portion 1281 having first and second radially separated branches 1282,1286 cannulated within first and second renal arteries from within an abdominal aorta. In some respects similar to the previous embodiment shown in FIG. 66, balloons 1284,1288 are provided via the branches 1282,1286, respectively, to prevent aortic emboli 1289 from flowing into the renal system. However, unique to this embodiment, the balloons 1284,1288 are provided truly integral to the branches 1282,1286, and in fact are located over the shafts of those branches proximally from the respective end-hole delivery ports 1283,1287. This provides a simpler integrated unit that may be sufficient to prevent renal embolization in many cases without the requirement of proximal aspiration through the ports 1283,1287. Also provided is the ability to isolate the distal renal circulation distal to the balloons 1284,1288, which may be advantageous for many local delivery procedures for certain drugs, dye, or devices outside of a high blood flow environment.

[00447] In certain cases involving endovascular stent-grafting, the bifurcated device may be provided in a configuration so as to operate from above (i.e., brachial artery access), such as in cases of abdominal aneurysm repair; or the device and respective delivery method may be adapted for an approach from below (more traditional femoral artery access), such as for example in certain cases of thoracic aneurysm repair. Such considerations generally adapt the delivery systems and methods so as not to interfere with the primary aneurysm repair procedure. Having a device in the renal arteries during such procedures may also aid the operating physician by providing a reference point in the vasculature helping to prevent inadvertent occlusion of the renal arteries by the stent graft. Devices incorporating simultaneous embolic protection and agent delivery could be constructed with a common fluid lumen branching into two distally, and possibly independent, mechanisms for controlling the embolic protection apparatus. The particular form and function of such mechanism may vary depending on the type of protection employed. For further illustration however, one exemplary device may have for example outer diameters in the ranges of about 2.5F to about 8F.

[00448] Renal angioplasty and stenting are procedures that are increasingly performed as interventional cardiologists and radiologists expand practice and newer devices are developed specifically for the renal arteries. An advantage is provided for these procedures by providing a bifurcated renal delivery device according to the present embodiments in combination assemblies that could access both renal arteries and provide for angioplasty or stenting of one artery or both. A further advantage is provided by allowing such intervention into both vessels simultaneously.

[00449] Typically, the majority of time spent in a renal angioplasty or stenting procedure is that taken to locate, access, and then advance the therapeutic device into the renal artery being treated. This time is doubled if both renal arteries are to be treated. Thus a single treatment device that cannulates both renal arteries more simply or efficiently, such as for example using only a single angiographic image, for further example without the aid of additional guide wires or catheters, can provide a more expeditious route. Benefit is also found by using less contrast media and x-ray exposure, less manipulation of devices in the patient's vasculature, and less overall procedural time.

[00450] For example, FIG. 68 shows a further embodiment with a delivery catheter 1290 that includes a bifurcated distal end portion 1291 with first and second branches 1292,1296 adapted to cannulate each of first and second renal arteries via the abdominal aorta. However, in this particular embodiment a balloon catheter 1300 extends beyond the distal tip 1293 of branch 1292. This includes an angioplasty balloon 1302 with a stent 1304 mounted thereon for balloon expansion and implantation within a target renal artery, such as to recanalize an occluded segment of the artery.

[00451] This balloon catheter 1300 further includes a distal wire segment 1306, which may be shaped or shapeable, and steerable via torque from proximal portion thereof externally of the patient. Such wire segment 1306 may be secured in a relatively integrated assembly with the balloon 1302, such as in a "fixed wire" balloon catheter design, or may be moveable relative to the balloon 1302. In the latter case, such may be nonetheless integrated in a manner allowing certain relative movement, either rotationally or longitudinally, though the combination is still maintained in an overall integrated assembly. Or, an "over the wire" arrangement may be provided where the wire 1306 and balloon catheter 1300 are separate units that cooperate together in slideable engagement, e.g. either coaxially within a guidewire lumen (not shown) of the balloon catheter 1300, or in a shortened lumen or rider segment for a "rapid exchange" or "monorail" arrangement. These various arrangements have been widely described for balloon angioplasty and stenting assemblies, and various specific forms may be provided for this component for appropriate use in the embodiments described. Moreover, the balloon catheter 1300 may be integral with the bifurcated delivery catheter 1290, such as affixed or otherwise coupled to the respective branch 1292.

[00452] In addition, it is to be appreciated that while only branch 1292 is shown in FIG. 68 to deliver a balloon catheter 1300, the other branch 1296 may be put to similar combination use. Such may be done in series, or simultaneously, in each of two branch lumens cannulated by the respective branches 1292,1296. Or, as described elsewhere herein, the second branch 1296 may provide fluid agent delivery or other function, or may be a "dummy"

branch as herein described.

[00453] In one particular embodiment, a balloon catheter may be provided with a catheter body or chassis having the general shape and configuration as shown for the previous embodiment above, with an angioplasty balloon adapted to be affixed or otherwise delivered by each branch. From an initial angiogram, the physician can measure the renal artery diameters and then select the proper device. Notwithstanding however the benefits of such integral assembly of branched delivery chassis and integral balloon (or other integral component elsewhere herein described), it is to be further appreciated that such branched delivery chassis may nonetheless be beneficially used in combination with guidewire or other delivery-system based balloons, stents, filters, or other adjunctive devices, such as is herein described by way of further illustrative embodiments.

[00454] Certain particular indications of the present embodiment may illustrate instances in which a single branch of a particular function would be desired. For example, a single renal artery may be treated but the access advantages of the bifurcated catheter design into that artery are retained by using that single functional branch in combination a "dummy" branch or provide a mechanical bias toward the wall of the main vessel for the branch vessel cannulation.

[00455] In any event, because in various of the present embodiments a single device is used for renal access and treatment, there is generally not a need for guide wires or specially shaped unilateral renal guide catheters to locate the renal arteries in most cases. However, the design may be adapted to function compatibly with standard or specialized guide wires and catheters if it is so desired.

[00456] For further illustration, one particular embodiment provides such a device as described above that may have outer diameters similar to current renal balloon technology, where crossing profiles of about 0.040" to about 0.090" are typical and standard, and may vary depending on whether the device incorporates a balloon with or without a stent pre-mounted. Profiles may be reduced for particular embodiments that remove the provision for

guide wire lumens, thus providing for example only lumens used for balloon inflation, and further whereas such lumens generally do not have the same restrictions on size of uniform circular cross-section as guide wire lumens.

[00457] In the setting of kidney transplantation, the local administration of pharmaceuticals or other agents may be indicated for localized immunosuppression in the recipient or for organ preservation in a donor on life support prior to transplantation. These agents may include for example immunosuppressants, agents to increase blood flow (i.e., vasodilators), or antibiotics. The use of hyper-oxygenated blood or blood substitute in this case may also be beneficial. As well, it may be desired to alter the temperature of the end organ (kidney), particularly lowering the temperature of the organ prior to transplantation may help in preservation, much in the same way as was discussed above in the setting of surgical/bypass-induced ATN. Device considerations in this setting may be similar to those discussed under the topic of ATN applications above.

[00458] There are other renal applications as well, in which a bifurcated device such as the one disclosed herein could be used. Namely, these include the use of a bifurcated device as the device to gain renal access for any number of procedures. This may include using the bifurcated catheter as a guide or diagnostic catheter, through which other devices may be placed, for any number of possible indications including those above for which individual embodiments of the bifurcated device were described. In this fashion the bifurcated device would provide benefit in allowing for rapid bilateral renal cannulation, without the need for additional catheters or guide wires, and then the desired renal intervention could be performed through the bifurcated device, with any number of standard commercial devices as desired.

[00459] For this application, it is envisioned that the bifurcated device would generally provide at least one delivery lumen of sufficient size to accommodate additional interventional tools such as balloon angioplasty catheters, stent delivery systems, or embolic protection devices, and thus may have outer diameters for example in the range of about 4F to about 12F. One illustrative embodiment as a bifurcated renal guide catheter is shown in FIG.

68.

[00460] Moreover, since many traditional intravascular interventional tools are dependent on tracking over a previously placed guide wire, the bifurcated catheter could be adapted to allow for easier wire placement. The bifurcated catheter would again provide the renal access, and through it a guide wire could be placed, and then the bifurcated catheter could be exchanged for the desired interventional device, such as a balloon catheter or drug delivery catheter. In this manner renal cannulation is simplified and the need for specialized catheters and guide wires to obtain cannulation may be removed for many or even most cases. In the embodiment for guide wire placement, the device may have outer diameters ranging from about 2F to about 4F for the placement of small (0.014"-0.018") guide wires or from about 4F to about 6F for the placement of larger (0.035") wires.

[00461] Additional applications exist for bifurcated device technology, in both functional bifurcated and single functional branch forms. Multiple branches (more than 2) may also be indicated in some instances. It is envisioned that the ease of branch vessel cannulation and the ability to simultaneously access multiple branch vessels with a single device through a single arterial access point may have distinct advantages in many if not all areas of interventional radiology, cardiology, and neuroradiology. Applications of the various aspects described herein for the renal anatomy may be applicable to many other areas of the body. These may include for example, without limitation, indications such as: bifurcated lesion stenting in the coronary vasculature, simultaneous embolic delivery from multiple feeder vessels to a cerebral AVM, or localized pharmaceutical delivery to a specific level of the spine via multiple lumbar arteries.

[00462] In addition to the foregoing, it is also to be further appreciated that the various aspects, modes, embodiments, features, and/or variations herein described may be further applied or appropriately modified for use in other systems of the body, such as for example the pulmonary, gastro-intestinal, lymphatic, reproductive (e.g. uterus and fallopian tubes) systems. In this regard, further applications of these devices, systems and methods may be found anywhere where cannulation of structures branching from main body spaces is desired, and in particular where delivery of devices or agents is desired. Such applications may be accomplished with or without modifications where appropriately indicated, as would be apparent to one of ordinary skill based upon review of this disclosure in combination with other available information.

[00463] It is also to be appreciated from the foregoing disclosure that the various embodiments herein described may use bi-lateral branched catheters with multiple arms having similar designs and/or functions between them for the purpose of providing certain bilateral therapy, prophylaxis, or diagnosis into branch vessels from a main vessel. Or, one branch may include certain functional attributes as herein described, while providing the other branch as a "dummy" branch adapted principally to provide a transverse bias across a main vessel for cannulation of the first functional branch into a desired branch vessel or ostium. However, it is to be further appreciated that each of the two branches may be adapted to provide such therapeutic, prophylactic, or diagnostic benefits, though differing as to the exact nature of such respective structures and functions between them.

[00464] The various bifurcated delivery devices and related methods herein described by reference to the Figures and accompanying text are considered highly beneficial on their own, and in particular for use in combination with other devices, materials, or methods. In addition, it is to be appreciated that those combinations as are apparent to one of ordinary skill based upon this disclosure are also considered highly beneficial assemblies, in addition to overall systems. Such may be provided separately for later combination use, or may be packaged or sold together as kits, assemblies, or systems for combined benefits in medical procedures. Accordingly, the scope to be afforded the present invention should contemplate each such embodiment alone as independently beneficial, in addition to contemplating the further independent benefits of these various combinations.

[00465] For example, FIG. 69 illustrates a delivery catheter 1320 with a bifurcated distal end portion 1321 that includes two radially separated branches 1322,1326 cannulated within each of two separate renal arteries via their ostia along an abdominal aorta wall. However, according to this embodiment, the catheter 1320 is utilized as a guide such that extending from distal end 1327 of branch 1326 is a balloon/stent delivery system 1330 and an embolic protection assembly 1336. A guide wire 1338 is also shown extending from filter assembly 1336, and may be integral therewith or in slideable engagement. Moreover, filter assembly 1336 may be integral with balloon assembly 1330, or may be in slideable engagement such as for example as a "filter wire". Still further, balloon 1330 may be affixed to branch 1326, or may be in slideable engagement therewith.

[00466] According to another example combining embodiments from above, FIGS. 70A-B illustrate various modes of using a delivery catheter 1340 with branched distal end portion 1341 in a combination assembly with proximal embolic protection and balloon/stenting. More specifically, distal end portion 1341 includes first and second branches 1342,1346 cannulated within first and second renal arteries. However, an expandable occlusion balloon 1348 is located along the bifurcated delivery branch 1346, and a balloon/stent delivery system extends distally from end 1347 of delivery branch 1346 (and distal to balloon 1348). This illustrates another system, which may be for example in a complete system context. FIG. 70A shows the assembly during stenting or balloon angioplasty using balloon 1348 in the expanded configuration engaging the wall of the respective engaged renal artery. FIG. 70B shows the assembly following stenting or angioplasty with balloon 1348 in a collapsed condition and with fluid and possible emboli being aspirated proximally into a port at distal tip 1347 of branch 1346 (while proximal balloon 1348 is expanded to isolate the region during aspiration).

[00467] The various aspects, modes, embodiments, features, and variations thereof that are herein described generally relate to and expand upon, with various modifications and improvements, various aspects of the following previously filed and co-pending PCT Patent Applications filed on 22 September 2003: PCT/US03/29740; PCT/US03/29744; PCT/US03/29995; PCT/US03/29743; PCT/US03/29585; PCT/US03/29586. The disclosures of these references are herein incorporated in their entirety by reference thereto. Accordingly, this disclosure is to be read in combination therewith to the extent consistent with the present embodiments and objects thereof; the various combinations of the elements between this disclosure and those herein incorporated, and modifications thereof, which are apparent to one of ordinary skill based upon the totality of each disclosure comprise further contemplated aspects of the present invention. Moreover, for further convenience, the disclosure of previously filed and co-pending U.S. provisional application serial number 60/505,281 filed on 22 September 2003 is also herein incorporated in its entirety by reference hereto.

[00468] Additional modifications or improvements may be made by the embodiments shown and described herein without departing from the intended scope of the invention which is considered to be broadly beneficial according to various independent aspects described. For example, various modifications to or combinations with the present embodiments may be made in view of other available information to one of ordinary skill in the art upon review of this disclosure and remain within the intended scope of the invention.

[00469] Although the description above contains many details, these should not be construed as limiting the scope of the invention but as merely providing illustrations of some of the presently preferred embodiments of this invention. Therefore, it will be appreciated that the scope of the present invention fully encompasses other embodiments which may become obvious to those skilled in the art, and that the scope of the present invention is accordingly to be limited by nothing other than the appended claims, in which reference to an element in the singular is not intended to mean "one and only one" unless explicitly so stated, but rather "one or more." All structural, chemical, and functional equivalents to the elements of the above-described preferred embodiment that are known to those of ordinary skill in the art are expressly incorporated herein by reference and are intended to be encompassed by the present claims. Moreover, it is not necessary for a device or method to address each and every problem sought to be solved by the present invention, for it to be encompassed by the present claims. Furthermore, no element, component, or method step in the present disclosure is intended to be dedicated to the public regardless of whether the element, component, or method step is explicitly recited in the claims. No claim element herein is to be construed under the provisions of 35 U.S.C. 112, sixth paragraph, unless the element is expressly recited using the phrase "means for."

CLAIMS

What is claimed is:

1. A medical device assembly for performing an interventional procedure in at least one branch lumen extending from a main lumen in a body of a patient, comprising:

a bifurcated catheter assembly having a proximal end portion and a distal end portion with first and second branches;

an interventional device assembly;

wherein the first branch is adapted to be positioned within a first branch lumen extending from the main lumen; and

wherein the first branch is adapted to at least in part position the interventional device within the first branch lumen.

2. The assembly of claim 1, wherein the interventional device assembly comprises a stent.

3. The assembly of claim 1, wherein the interventional device assembly comprises an embolic protection assembly.

4. The assembly of claim 1, wherein the interventional device assembly comprises a stent and an embolic protection assembly.

5. The assembly of claim 1, wherein the interventional device assembly comprises a guidewire.

6. The assembly of claim 1, wherein the interventional device assembly comprises a filter wire and a stent that is adapted to be delivered to the first branch lumen via the filter wire and the first branch.

7. The assembly of claim 1, wherein the interventional device assembly is attached to the first branch.

8. The assembly of claim 1, wherein second branch is adapted to contact a wall of the main lumen with a force sufficient to assist positioning the first branch within the first branch lumen via the first ostium.

9. The assembly of claim 1, wherein the second branch is adapted to be positioned within a second branch lumen via a second ostium along the main lumen.

10. The assembly of claim 9, wherein the first and second branches are adapted to be located within the first and second branch lumens via the first and second ostia, respectively, simultaneously.

11. The assembly of claim 10, wherein the first and second branches are adapted to be located within first and second branch blood vessels via first and second ostia, respectively, via a main blood vessel simultaneously.

12. The assembly of claim 11, wherein the first and second branches are adapted to be located within first and second renal blood vessels via first and second renal ostia, respectively, via the main blood vessel simultaneously.

13. The assembly of claim 12, wherein the first and second branches are adapted to be located within first and second renal arteries via first and second renal artery ostia, respectively, via an abdominal aorta simultaneously.

14. The assembly of claim 12, wherein the first and second branches are adapted to be located within first and second renal veins via first and second renal vein ostia, respectively, via a vena cava simultaneously.

15. The assembly of claim 10, wherein the interventional device assembly comprises a first interventional device assembly, and further comprising a second interventional device assembly, and wherein the first branch is adapted to deliver the first interventional device assembly into the first branch lumen, and the second branch is adapted to deliver the second interventional device assembly into the

second branch lumen.

16. The assembly of claim 15, wherein each of the first and second interventional device assemblies comprises a stent.

17. The assembly of claim 15, wherein each of the first and second interventional device assemblies comprises an embolic protection assembly.

18. The assembly of claim 15, wherein the first interventional device assembly comprises a stent, and the second interventional device assembly comprises an embolic protection assembly.

19. The assembly of claim 15, wherein each of the first and second interventional device assemblies comprises a guidewire.

20. The assembly of claim 1, wherein the interventional device assembly comprises a sensor.

21. The assembly of claim 1, further comprising:

a source of fluid agent; and

wherein the bifurcated catheter assembly is adapted to couple to the source and to deliver the fluid agent into at least one of the first and second branch vessels.

22. The assembly of claim 21, wherein the fluid agent comprises a renal protective agent.

23. The assembly of claim 21, wherein the fluid agent comprises saline.

24. The assembly of claim 2, wherein the stent is a self-expandable stent.

25. The assembly of claim 2, wherein the stent comprises a balloon-expandable stent.

26. The assembly of claim 2, wherein the stent comprises a drug eluting stent.

27. The assembly of claim 3, wherein the embolic protection assembly comprises a proximal embolic protection assembly.

28. The assembly of claim 27, further comprising a vacuum source coupled to the first branch in a manner adapted to aspirate material from the first branch lumen.

29. The assembly of claim 3, wherein the embolic protection assembly comprises a distal embolic filter assembly.

30. The assembly of claim 29, wherein the distal embolic filter assembly comprises an adjustable porous wall having as first position that is adapted to be delivered to the first branch vessel at a filter location and a second position that is adapted to span substantially across the first branch vessel at the filter location, and wherein the porous wall in the second position at the filter location is adapted to substantially block passage of emboli over a predetermined size.

31. The assembly of claim 1, further comprising:

a delivery sheath with a proximal end portion and a distal end portion;

wherein the distal end portion is adapted to be positioned within the main lumen; and

wherein the delivery sheath is adapted to deliver the bifurcated catheter to the main lumen at a location associated with the first ostium.

32. The assembly of claim 1, wherein the first and second branches are substantially self-cannulating within first and second branch lumens without generally requiring a guidewire or guide catheter.

33. The assembly of claim 1, wherein the first branch comprises a first distal port that is fluidly coupled to a first proximal port located along the proximal end portion.

34. The assembly of claim 33, wherein the second branch comprises a second distal port that is fluidly coupled to a second proximal port located along the proximal end portion.

35. The assembly of claim 33, wherein the second branch does not comprise a delivery port and is not adapted to deliver material therefrom.

36. The assembly of claim 1, wherein the first branch comprises an expandable member secured thereto.

37. The assembly of claim 36, wherein the second branch comprises an expandable member secured thereto.

38. The assembly of claim 36, wherein the expandable member comprises an inflatable balloon.

39. The assembly of claim 38, wherein the expandable member is adapted to expand to an adjustable outer diameter so as to occlude a variety of diameters for the first branch lumen.

40. A medical device assembly, comprising:

an elongate catheter body with a proximal end portion and a distal end portion with a bifurcated region having first and second branches that terminate distally at first and second ends, respectively;

a distal port located along the distal end portion;

wherein at least the first end of the first branch is adapted to be cannulated within a first branch lumen extending from a main lumen; and

wherein the distal port is located relative to the first end such that when the first end is positioned within the first branch lumen the distal port is located within the main lumen.

41. The assembly of claim 40, wherein:

the second end of the second branch is adapted to be cannulated within a second branch lumen extending from the main lumen when the first end of the first branch is positioned within the first branch lumen and when the distal port is located within the main lumen.

42. The assembly of claim 41, wherein the first and second branches are adapted to be cannulated within first and second renal veins when the distal port is located within a vena cava of a patient.

43. The assembly of claim 42, further comprising a suction source coupled to the distal port.

44. The assembly of claim 42, further comprising a first branch port located along the first branch and a second branch port located along the second branch, and wherein the first and second branch ports are adapted to be fluidly coupled externally of the patient when the first and second branches are positioned within the first and second branch lumens, respectively.

45. The assembly of claim 44, further comprising at least one suction source coupled to the distal port and the first and second branch ports.

46. The assembly of claim 45, wherein the at least one suction source comprises:

a first suction source coupled to the first branch port;

a second suction source coupled to the second branch port;

a third suction source coupled to the distal port; and

wherein the first, second, and third suction sources are relatively substantially fluidly isolated from each other.

47. A method for performing an interventional medical device procedure in at least one branch lumen that extends from a main lumen or body space in a patient, comprising:

positioning a bifurcated distal end portion of a delivery catheter assembly within the main lumen;

positioning a first branch of the bifurcated distal end portion within a first branch lumen via a first ostium along the main lumen; and

positioning a first interventional device into the first branch lumen using the first branch.

48. The method of claim 47, further comprising:

delivering a fluid agent to the first branch lumen; and

wherein the fluid agent delivered into the first branch lumen is adapted to affect renal function.

49. The method of claim 47, wherein the first interventional device assembly comprises an embolic protection assembly, and further comprising:

protecting the first branch lumen from emboli with the embolic protection assembly delivered into the first branch lumen via the first branch.

50. The method of claim 49, wherein the embolic protection assembly comprises a proximal embolic protection assembly, and further comprising:

performing the embolic protection by proximally aspirating materials from the first branch lumen at least in part by applying suction to the first branch so as to aspirate emboli from the first branch lumen.

51. The method of claim 50, further comprising:

expanding an expandable member along the first branch so as to substantially occlude the first branch lumen during the proximal aspiration of materials from the first branch lumen and into the first branch.

52. The method of claim 49, wherein the embolic protection assembly comprises a distal embolic filter assembly, and further comprising:

performing a distal embolic filtering operation in the first branch lumen with the distal embolic filter assembly.

53. The method of claim 47, wherein the first interventional device assembly comprises a stent, and further comprising:

implanting the stent within the first branch lumen.

54. The method of claim 53, further comprising balloon expanding the stent within the first branch lumen.

55. The method of claim 53, further comprising allowing the stent to self-expand within the first branch lumen.

56. The method of claim 47, further comprising:

contacting a first wall of the main lumen with a second branch of the distal end portion of the bifurcated catheter assembly with a force; and

biasing the first branch toward a second wall of the main lumen opposite the first wall and such that the first branch is assisted in cannulating the first branch lumen.

57. The method of claim 47, further comprising:

positioning a second branch of the bifurcated distal end portion within a second branch lumen extending from the main lumen; and

wherein the first and second branches are adapted to be positioned within the first and second branch lumens simultaneously.

58. The method of claim 57, further comprising:

positioning a second interventional device into the second branch lumen using the second branch.

59. The method of claim 58, wherein each of the first and second interventional devices comprises an angioplasty balloon.

60. The method of claim 58, wherein each of the first and second interventional devices comprises a stent.

61. The method of claim 58, wherein each of the first and second interventional devices comprises a guidewire.

62. The method of claim 47, further comprising:

delivering the bifurcated distal end portion to a location within the main lumen in a first condition such that the first branch and a second branch of the bifurcated distal end portion are configured in radially collapsed positions relative to each other and with respect to a longitudinal axis of the main lumen; and

adjusting the distal end portion to a second condition at the location such that the first and second branch lumens extend radially from each other and transverse to the longitudinal axis and toward the wall of the main lumen.

63. The method of claim 47, wherein the first branch lumen is a first renal vessel.

64. The method of claim 47, wherein the main lumen is an abdominal aorta, and the first branch lumen is a first renal artery.

65. The method of claim 47, wherein the main lumen is a vena cava, and the first branch lumen is a first renal vein.

66. The method of claim 32, further comprising:

introducing the bifurcated distal end portion, first interventional device, and a second interventional device into the main lumen via a common introducer sheath; and

wherein the second interventional device is positioned along the main lumen and across a location where the first branch lumen extends from the main lumen while the first branch and first interventional device are positioned within the first branch lumen.

67. An interventional medical device system, comprising:

a bifurcated delivery assembly with a proximal end portion and a bifurcated distal end portion with first and second branches; and a first interventional device assembly secured to the first branch.

68. The system of claim 67, further comprising:

a second interventional device assembly secured to the second branch.

69. The system of claim 67 or 68, wherein the first interventional device assembly comprises an angioplasty balloon.

70. The system of claim 67 or 68, wherein the first interventional device assembly comprises a stent.

71. The system of claim 67 or 68, wherein the first interventional device assembly comprises an embolic protection assembly.

72. The system of claim 67 or 68, wherein the first interventional device assembly comprises a guidewire.

73. The system of claim 68, wherein each of the first and second interventional device assemblies comprise an angioplasty balloon.

74. The system of claim 68, wherein each of the first and second interventional device assemblies comprises a stent.

75. The system of claim 68, wherein each of the first and second interventional device assemblies comprises an embolic protection assembly.

76. The system of claim 68, wherein each of the first and second interventional device assemblies comprises a guidewire.

77. A local renal delivery system, comprising:

a first renal delivery member with a first distal port that is adapted to be delivered to a first delivery position within a first renal artery via a first corresponding renal ostium along an abdominal aortic wall of an abdominal aorta in a patient;

a second renal delivery member with a second distal port that is adapted to be delivered to a second delivery position within a second renal artery via a second corresponding renal ostium along the abdominal aorta wall;

a proximal coupler assembly that is adapted to be located externally of the patient when the first and second distal ports are positioned at the first and second delivery positions, respectively;

a first interventional device that is adapted to be delivered by the first renal delivery member into the first renal artery;

a second interventional device that is adapted to be delivered by the second renal delivery member into the second renal artery; and

an introducer sheath that is adapted to deliver the first and second renal delivery members to the abdominal aorta at a location associated with the first and second renal ostia.

78. A local renal delivery system, comprising:

a renal delivery member with a distal port that is adapted to be delivered to a delivery position within the renal artery via a corresponding renal ostium along an abdominal aortic wall;

a proximal coupler assembly that is adapted to be located externally of the patient when the distal port is positioned at the delivery position and is fluidly coupled to the distal port so as to deliver material from outside the patient's body via the proximal coupler assembly, through the distal port at the delivery position and into the renal artery;

an anchor that is adjustable from a first configuration to a second configuration;

wherein the anchor in the first configuration is adapted to be delivered to an anchoring position along one of the abdominal aorta or the renal artery within the patient;

wherein the anchor in the second configuration at the anchoring position is adapted to secure the renal delivery member with the distal port substantially retained at the delivery position within the renal artery;

wherein the anchor in the second configuration at the anchoring position is adapted to allow substantial blood flow across the anchoring position; and

an interventional device that is adapted to be delivered into the renal artery via the renal delivery member.

79. A local renal delivery system, comprising:

a vascular access system with an elongate tubular body with at least one lumen extending between a proximal port and a distal port that is adapted to be positioned within a vessel when the proximal port is located externally of the patient;

a bi-lateral renal delivery assembly with first and second renal delivery members having first and second distal ports, respectively, that are adapted to be delivered to first and second respective delivery positions within first and second renal arteries, respectively, via first and second corresponding renal ostia, respectively, at unique relative locations along an abdominal aortic wall of the patient;

a percutaneous translumenal interventional device that is adapted to be delivered to an intervention location across the location while the first and second distal ports are located at the first and second delivery positions, respectively;

wherein the bi-lateral renal delivery assembly is adapted to simultaneously deliver material from an external location relative to the patient and directly into each of first and second renal arteries via first and second distal ports at the first and second delivery positions, respectively;

wherein the bilateral renal delivery assembly and percutaneous translumenal medical device are adapted to be delivered percutaneously into a vessel having translumenal access to the location through the vascular access system, and are also adapted to be simultaneously engaged within the vascular access system; and

first and second interventional devices that are coupled to the first and second renal delivery members and are adapted to be positioned at least in part by the first and second delivery members within the first and second arteries, respectively.

80. A method for treating a renal system in a patient, comprising:

positioning a first distal port of a first renal delivery member at a first delivery position within a first renal artery via a first corresponding renal ostium located at a first location along an abdominal aorta wall of an abdominal aorta in a patient;

positioning a second distal port of a second renal delivery member at a second delivery position within a second renal artery via a second corresponding renal ostium located at a second location along the abdominal aortic wall that is different than the first location;

positioning a proximal coupler assembly externally of the patient when the first and second distal ports are positioned at the first and second delivery positions, respectively; and

delivering first and second interventional devices from outside the patient's body via the proximal coupler assembly, through the first and second distal ports, respectively, at the first and second delivery positions, also respectively, within the first and second renal arteries, also respectively.

81. A method for treating a renal system in a patient, comprising:

delivering a distal port of a renal delivery member to a delivery position within a renal artery via a corresponding renal ostium along an abdominal aortic wall;

positioning a proximal coupler assembly externally of the patient when the distal port is positioned at the delivery position;

delivering an anchor in a first configuration to an anchoring position along one of the abdominal aorta or the renal artery within the patient;

adjusting the anchor at the anchoring position from the first configuration to a second configuration that secures the renal delivery member with the distal port substantially retained at the delivery position within the renal artery;

allowing substantial blood flow across the anchoring position when the anchor is in the second configuration at the anchoring position; and

delivering a first interventional device from outside the patient's body via the proximal coupler assembly, through the distal port at the delivery position and into the renal artery.

82. A method for treating a renal system in a patient, comprising:

positioning a distal port of a tubular body of a vascular access system within a vessel having transvascular access to a location along an abdominal aorta associated with first and second renal ostia when a proximal port of the tubular body is located externally of the patient;

introducing first and second renal delivery members of a bi-lateral local renal delivery assembly into the vessel through the tubular body;

delivering first and second distal ports of the first and second renal delivery members, respectively, to first and second respective delivery positions within first and second renal arteries, respectively, via the first and second renal ostia, also respectively;

introducing a percutaneous translumenal interventional device into the vessel through the tubular body;

delivering a distal end portion of the percutaneous translumenal interventional device to an intervention location across the location while the first and second distal ports are located at the first and second delivery positions, respectively;

simultaneously delivering first and second interventional devices from an external location relative to the patient and directly into each of first and second renal arteries via the first and second distal ports at the first and second delivery positions, respectively; and

wherein the bi-lateral renal delivery assembly and a proximal end portion of the percutaneous translumenal interventional device are simultaneously engaged within the tubular body of the vascular access assembly when the first and second distal ports are at the first and second delivery positions and the distal end portion of the percutaneous translumenal interventional device is at the intervention location.

83. A method for preparing a bi-lateral renal delivery system for use in treating a patient, comprising:

coupling first and second interventional devices with first and second renal delivery members of a bi-lateral local renal delivery assembly;

introducing the first and second renal delivery members of the bi-lateral local renal delivery assembly into a tubular body of a vascular access system;

introducing a percutaneous translumenal interventional device into the tubular body;

wherein the bi-lateral renal delivery assembly and the percutaneous translumenal interventional device are simultaneously engaged within the tubular body of the vascular access assembly;

wherein the first and second renal delivery members have first and second distal ports, respectively, that are adapted to be delivered to first and second respective delivery positions within first and second renal arteries, respectively, via first and second renal ostia, also respectively, having unique locations along the abdominal aorta wall;

wherein the percutaneous translumenal interventional device comprises a distal end portion that is adapted to be delivered to an intervention location across a location along the abdominal aorta associated with the first and second renal ostia while the first and second distal ports are located at the first and second delivery positions, respectively;

wherein the first and second renal delivery members are coupled to a proximal coupler assembly that is adapted to deliver material from an external location relative to the patient and to the first and second distal ports so as to deliver the material directly into each of first and second renal arteries via the first and second distal ports at the first and second delivery positions, respectively; and

wherein the tubular body of the vascular access system has a distal port that is adapted to be positioned within a vessel having transvascular access to the location along the abdominal aorta when a proximal port of the tubular body is located externally of the patient.

84. A method for treating a renal system in a patient, comprising:

positioning a first port of a first lumen along a first branch of a bifurcated catheter within a first renal vein;

positioning a second port of a second lumen along a second branch of the bifurcated catheter within a second renal vein;

positioning a third port of a third lumen along the bifurcated catheter within a vena cava; and

fluidly coupling the first, second, and third distal ports with first, second, and third proximal ports located externally of the patient.

85. A method for treating a renal system in a patient, comprising:

positioning an introducer sheath within an abdominal aorta at a location associated with first and second renal artery ostia associated with first and second renal arteries that perfuse first and second kidneys in the patient;

delivering a bi-lateral renal delivery assembly in a first configuration under radial confinement through the introducer sheath and to a first position along the location;

withdrawing the introducer with respect to the bi-lateral renal delivery assembly so as to remove the radial confinement;

after removing the bi-lateral renal delivery assembly from radial confinement, allowing first and second bifurcating delivery members to self-expand apart from each other and radially against an abdominal aorta wall at the location with shape memory recovery force to a second configuration;

modifying the position of the self-expanded renal delivery assembly so as to self-cannulate at least one of the delivery members into at least one of the renal arteries via its corresponding ostium along the abdominal aorta wall; and

delivering a first interventional device into the first renal artery with the first delivery member.

86. A method for providing local therapy to a renal system in a patient, comprising:

delivering a bi-lateral local renal delivery assembly to a location within an abdominal aorta corresponding with first and second renal ostium along an abdominal aorta wall of the patient;

delivering a percutaneous translumenal interventional device to an intervention location across the location corresponding with the renal ostia;

positioning a first delivery member of the bilateral local renal delivery assembly in a first renal artery via a first ostium along the abdominal aorta wall;

positioning a second delivery member of the bilateral local renal delivery assembly in a second renal artery via a second ostium along the abdominal aorta wall;

inserting the bi-lateral local renal delivery assembly and percutaneous translumenal interventional device into the patient's vasculature through a common vascular access site; and

delivering a first interventional device into the first renal artery with the first delivery member.

87. A system for providing local renal therapy in a patient, comprising:

an introducer sheath with a proximal end portion and a distal end portion that is adapted to be positioned at a location within an abdominal aorta associated with first and second renal ostia of first and second renal arteries, respectively, while the proximal end portion extends externally from the patient, and also with an introducer lumen extending between a proximal port located along the proximal end portion and a distal port located along the distal end portion;

a local delivery assembly with a delivery port assembly that is adapted to be delivered to the location through the introducer lumen and through the distal port in a first condition;

wherein the local delivery assembly is adapted to be adjusted at the location from the first condition to a second condition that is advanced externally through the distal port at the location;

wherein in the second condition at the location the local delivery assembly is adapted to be coupled to first and second interventional devices located externally from the patient;

wherein the second condition at the location the local delivery assembly is adapted to position the delivery port assembly so as to deliver the first and second interventional devices substantially bilaterally into each of the two renal arteries; and

further comprising means for monitoring a position of at least one of the delivery port assembly or distal port relative to at least one of the renal ostia without use of fluoroscopic or X-ray imaging.

88. The system of claim 87, wherein the means for monitoring comprises:

at least one marker at a location that is adapted to indicate the location of at least one of the injection port assembly or the distal port with respect to a non-fluoroscopic sensor assembly located externally of the location.

89. The system of claim 88, wherein the at least one marker comprises an ultrasonically visible marker.

90. The system of claim 89, wherein the means for monitoring further comprises an ultrasound imaging sensor that is adapted to be positioned at a second location sufficient to monitor the location of the ultrasonically visible marker at the location.

91. The system of claim 88, wherein the at least one marker comprises a marker located along the distal end portion of the introducer sheath and that is adapted to indicate the relative location of the distal port within the location relative to at least one renal ostium.

92. The system of claim 88, wherein:

the local delivery assembly comprises first and second delivery ports that are adapted to be delivered to first and second positions such that the first and second interventional devices are adapted to be delivered substantially into the first and second renal arteries via the first and second delivery ports, respectively, at the first and second positions, also respectively; and

the at least one marker comprises first and second markers that are positioned relative to the first and second delivery ports, respectively, so as to indicate the relative position of the delivery ports relative to the first and second positions, also respectively.

93. The system of claim 92, wherein:

the local delivery assembly comprises first and second delivery members;

the first and second delivery ports are located along the first and second delivery members, respectively; and

the first and second markers are located at first and second locations along the first and second delivery members relative to the first and second delivery ports.

94. The system of claim 87, wherein the means for monitoring comprises:

a sensor assembly that is adapted to cooperate with at least one of the local delivery assembly or the distal port of the introducer sheath such that the sensor assembly is adapted to be positioned within the location and to sense a parameter indicative of the relative position of the local delivery assembly or distal port relative to the renal ostia at the location.

95. The system of claim 94, wherein the sensor assembly comprises a sensor located along the distal end portion of the introducer sheath and is adapted to sense a parameter that is indicative of a relative location of the distal port relative to at least one renal ostium.

96. The system of claim 94, wherein the sensor assembly comprises at least one sensor located at a position relative to the delivery port assembly so as to indicate the relative position of the delivery port assembly.

97. The system of claim 96, wherein:

the local delivery assembly comprises first and second delivery ports that are adapted to be delivered to first and second positions such that the first and second interventional devices are adapted to be delivered into the first and second renal arteries via the first and second delivery ports, respectively, at the first and second positions, also respectively; and

the at least one sensor comprises first and second sensors that are positioned relative to the first and second delivery ports, respectively, so as to indicate the relative position of the delivery ports relative to the first and second positions, also respectively.

98. The system of claim 97, wherein:

the local delivery assembly comprises first and second delivery members;

the first and second delivery ports are located along the first and second delivery members, respectively; and

the first and second sensors are located at first and second locations along the first and second delivery members relative to the first and second delivery ports.

99. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises an ultrasound sensor.

100. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises an Doppler ultrasound sensor.

101. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises an optical sensor.

102. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises a pressure sensor.

103. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises a flow velocity sensor.

104. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises a flow rate sensor.

105. The system of claim 94, 95, 96, 97, or 98, wherein the sensor assembly comprises a chemical sensor.

106. The system of claim 94, 95, 96, 97, or 98, further comprising a monitoring assembly located externally of the patient and that is adapted to couple to the sensor assembly at the location and to monitor at least one sensed parameter that is sensed by the sensor assembly at the location.

107. The system of claim 106, further comprising a display that is adapted to display the monitored parameter.

108. The system of claim 107, further comprising indicia for indicating a desired

relative position of the sensor assembly relative to at least one renal ostium.

109. A method for providing local renal therapy in a patient, comprising:

delivering a distal end portion of an introducer sheath to a location within an abdominal aorta associated with first and second renal ostia of first and second renal arteries, respectively, while a proximal end portion of the introducer sheath extends externally from the patient, and also such that an introducer lumen within the introducer sheath extends between a proximal port located along the proximal end portion and a distal port located along the distal end portion at the location;

delivering a local delivery assembly with a delivery port assembly to the location through the introducer lumen and through the distal port in a first condition;

adjusting the local delivery assembly at the location from the first condition to a second condition that is advanced externally through the distal port at the location;

coupling first and second interventional devices with the local delivery assembly in the second condition at the location;

positioning the delivery port assembly so as to deliver the first and second interventional devices substantially bilaterally into each of the two renal arteries; and

sensing a parameter indicative of a position of at least one of the delivery port assembly or the distal port relative to at least one of the renal ostia without use of fluoroscopic or X-ray imaging.

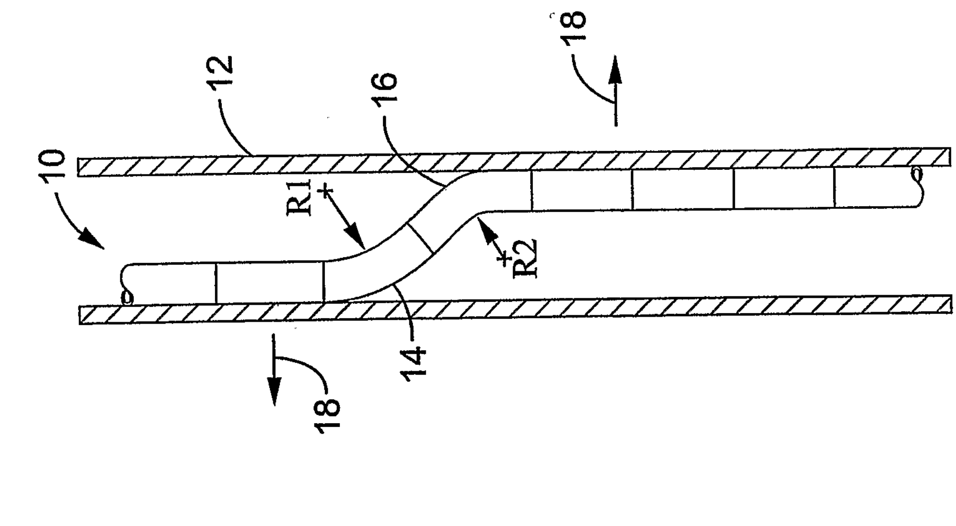

FIG. 1

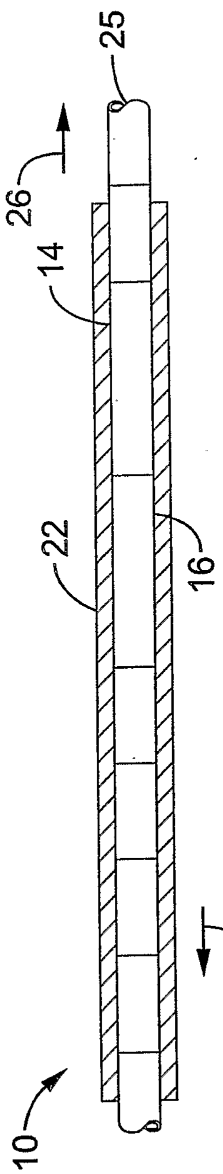

FIG. 2A

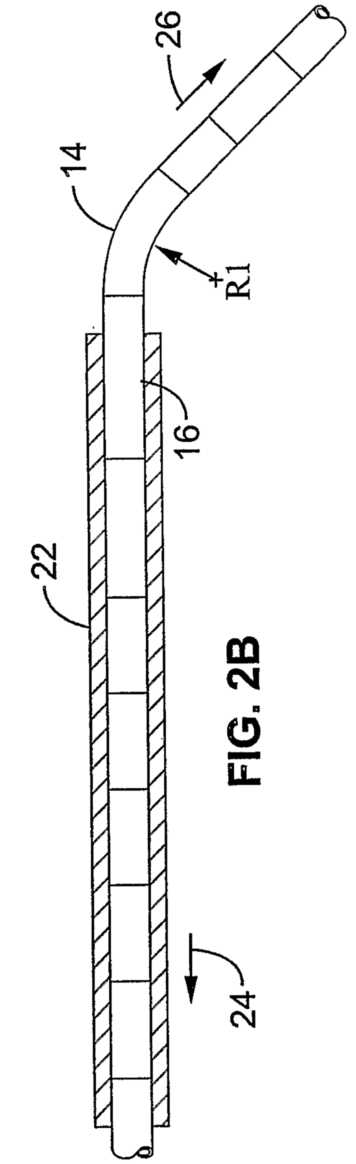

FIG. 2B

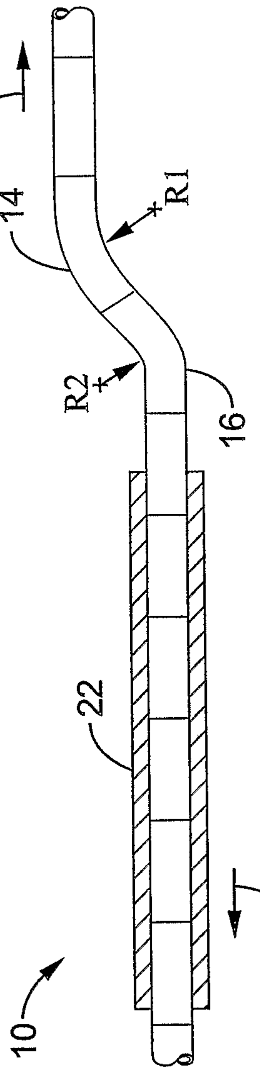

FIG. 2C

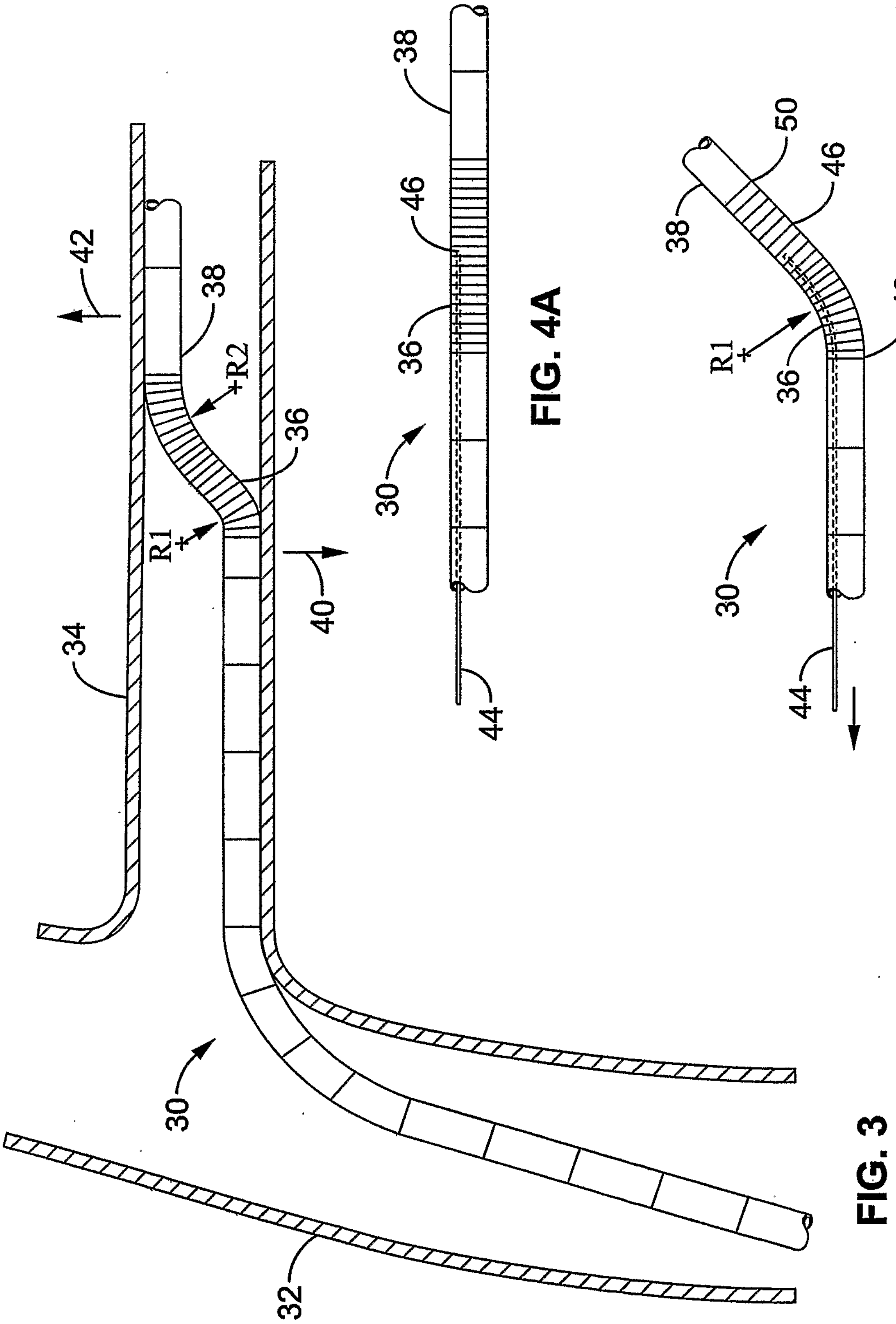

FIG. 3

FIG. 4A

FIG. 4B

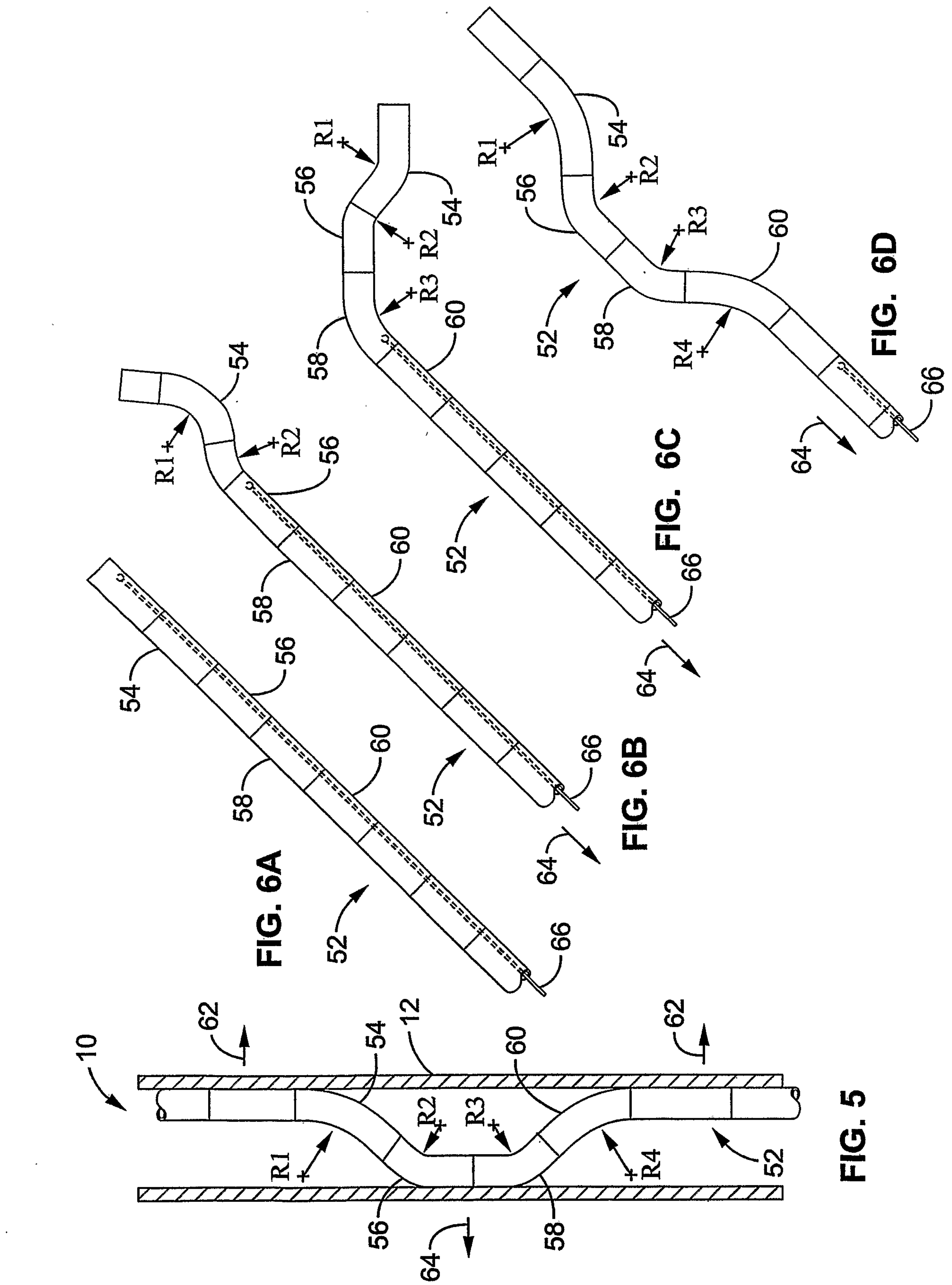

FIG. 5

FIG. 6A

FIG. 6B

FIG. 6C

FIG. 6D

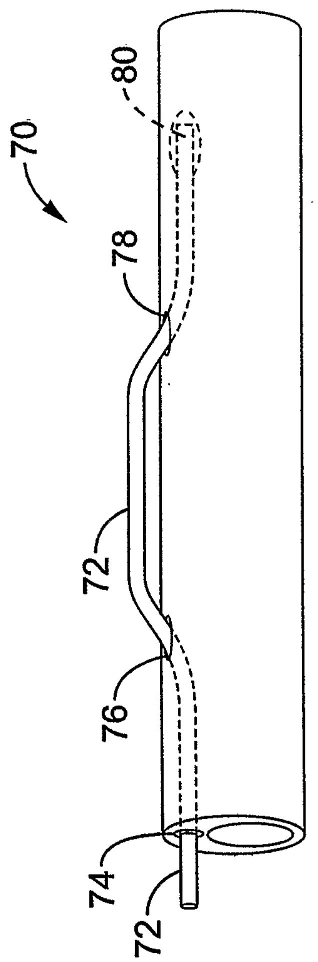

FIG. 7A

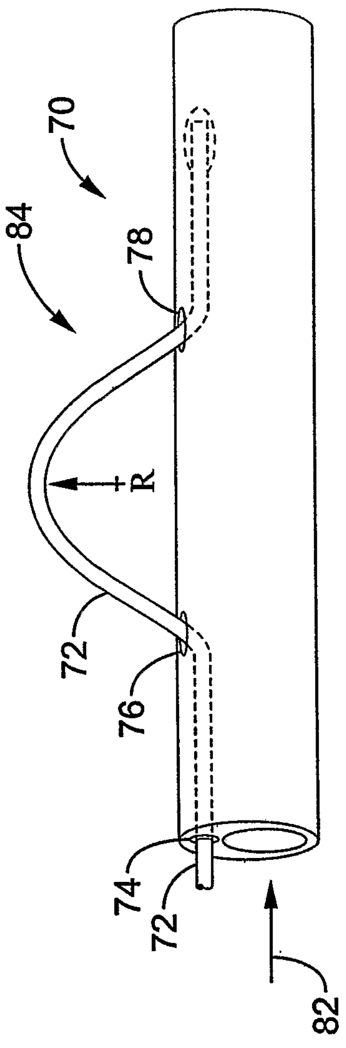

FIG. 7B

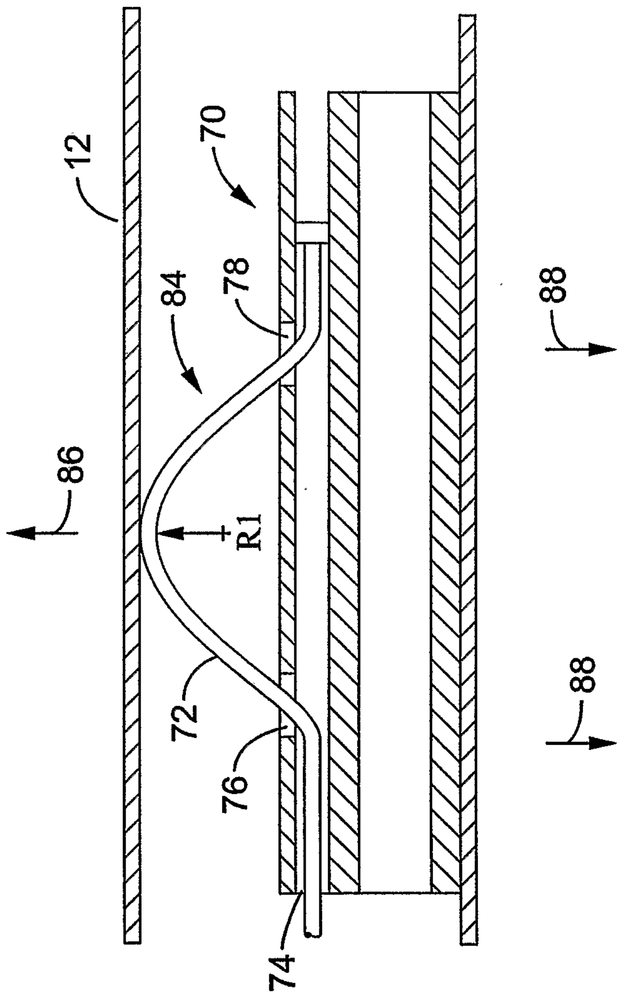

FIG. 7C

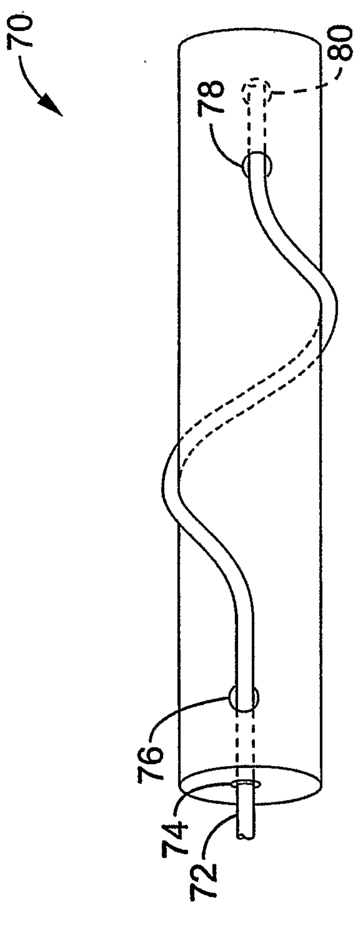

FIG. 8A

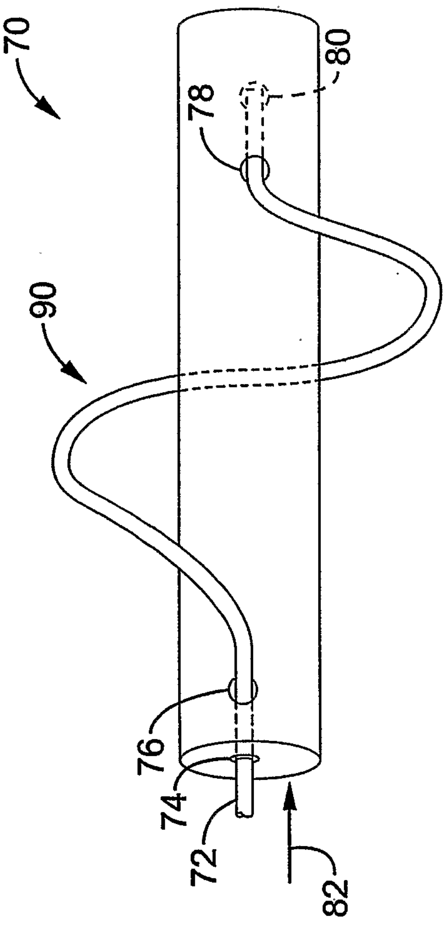

FIG. 8B

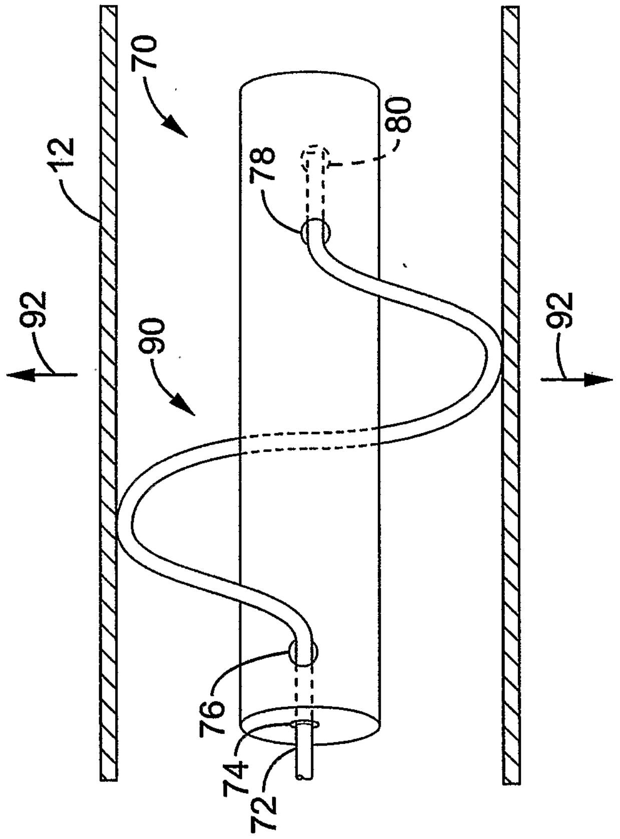

FIG. 8C

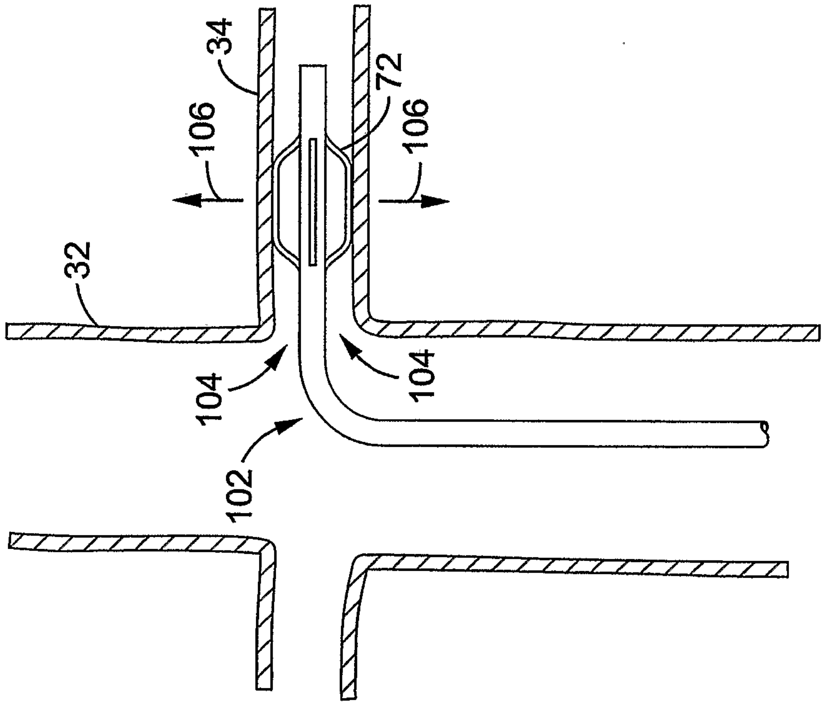

FIG. 10

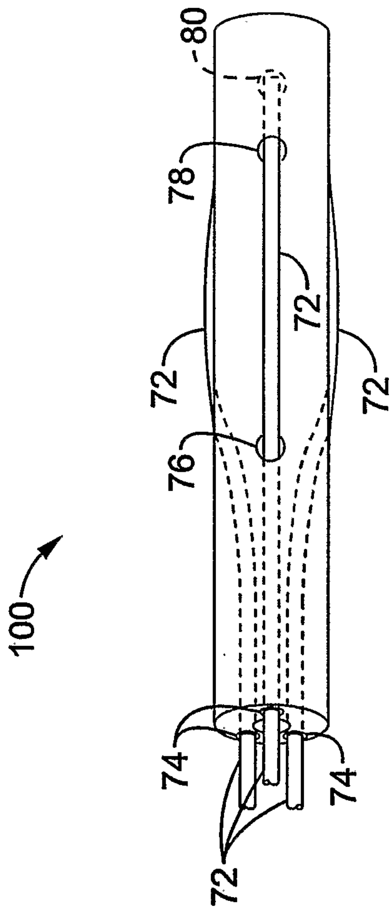

FIG. 9

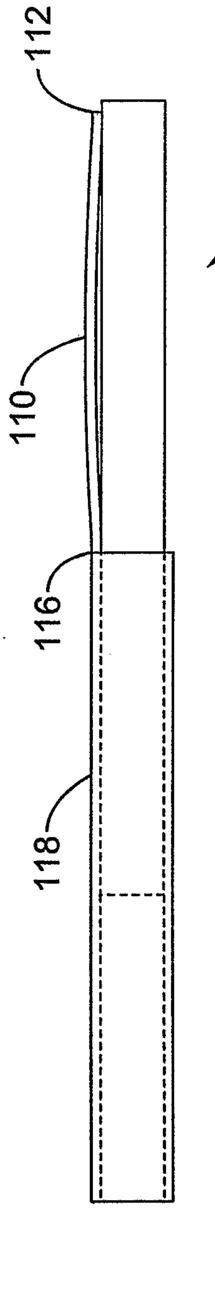

FIG. 11A

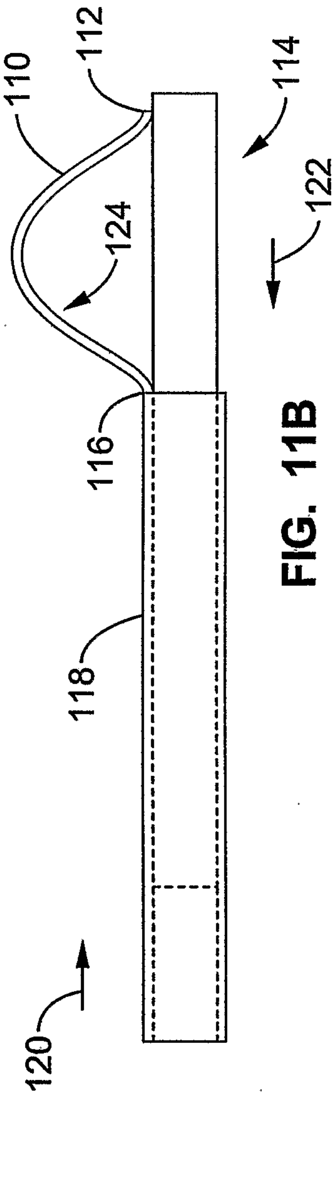

FIG. 11B

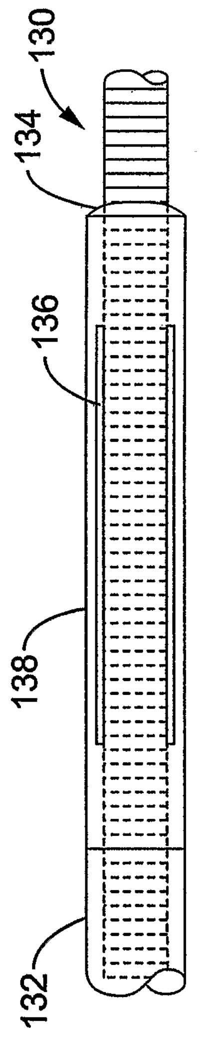

FIG. 12A

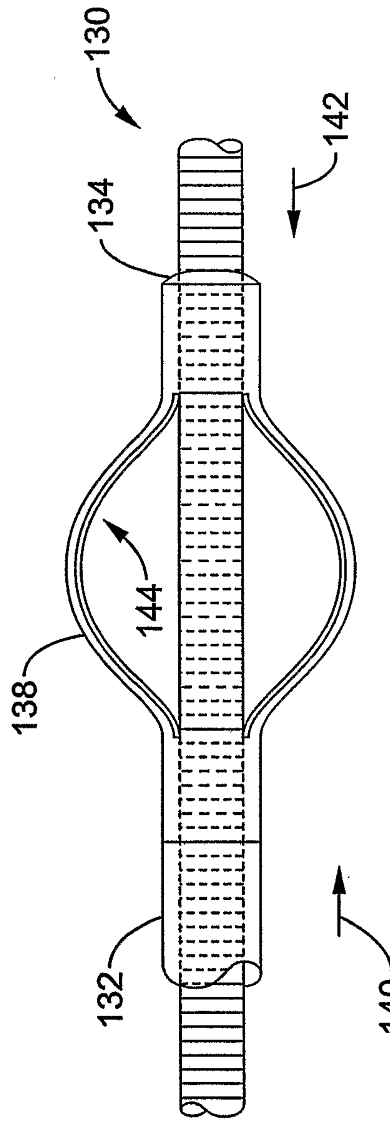

FIG. 12B

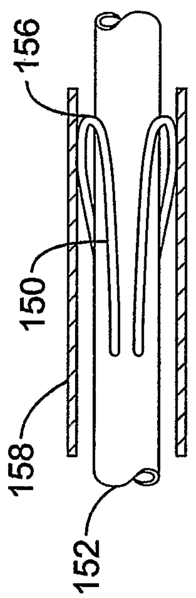

FIG. 13B

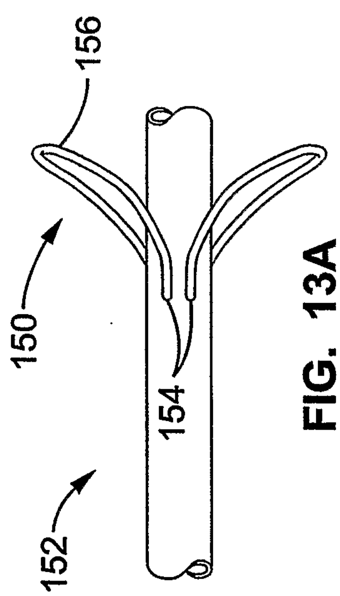

FIG. 13A

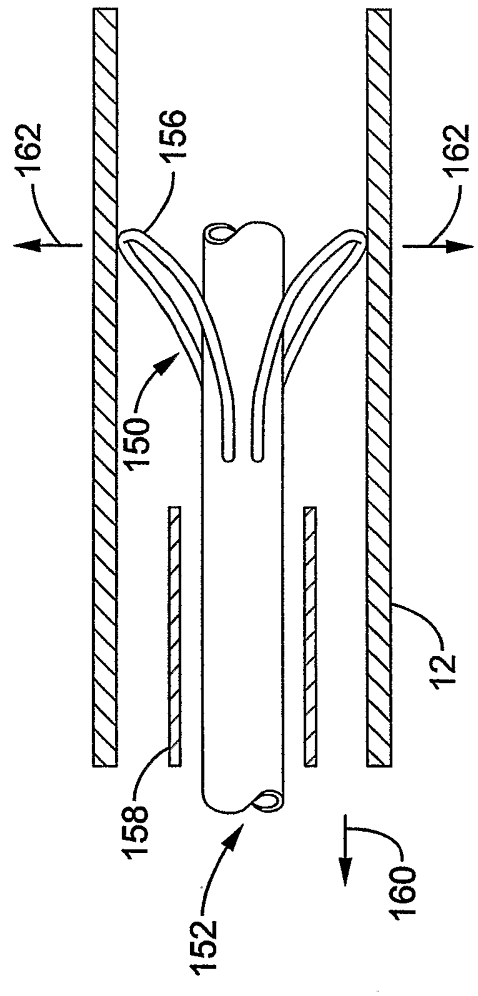

FIG. 13C

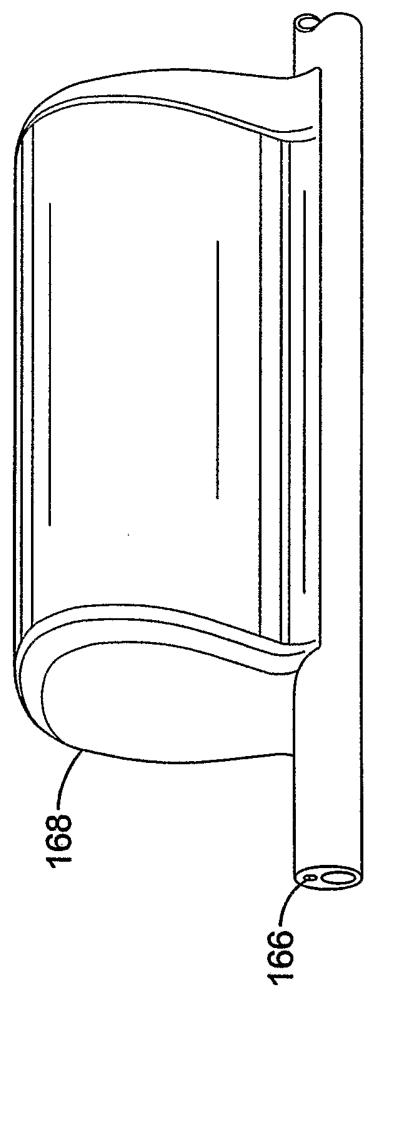

FIG. 14A

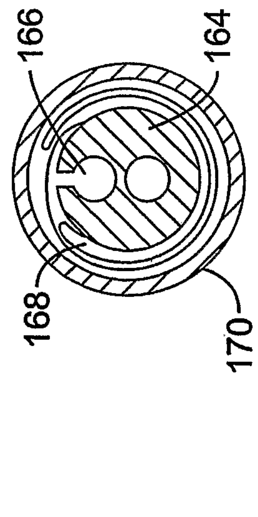

FIG. 14B

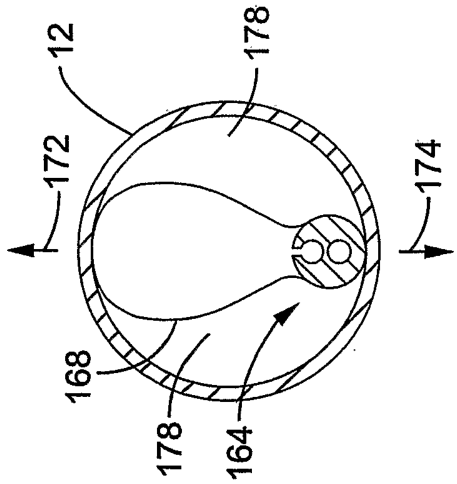

FIG. 14C

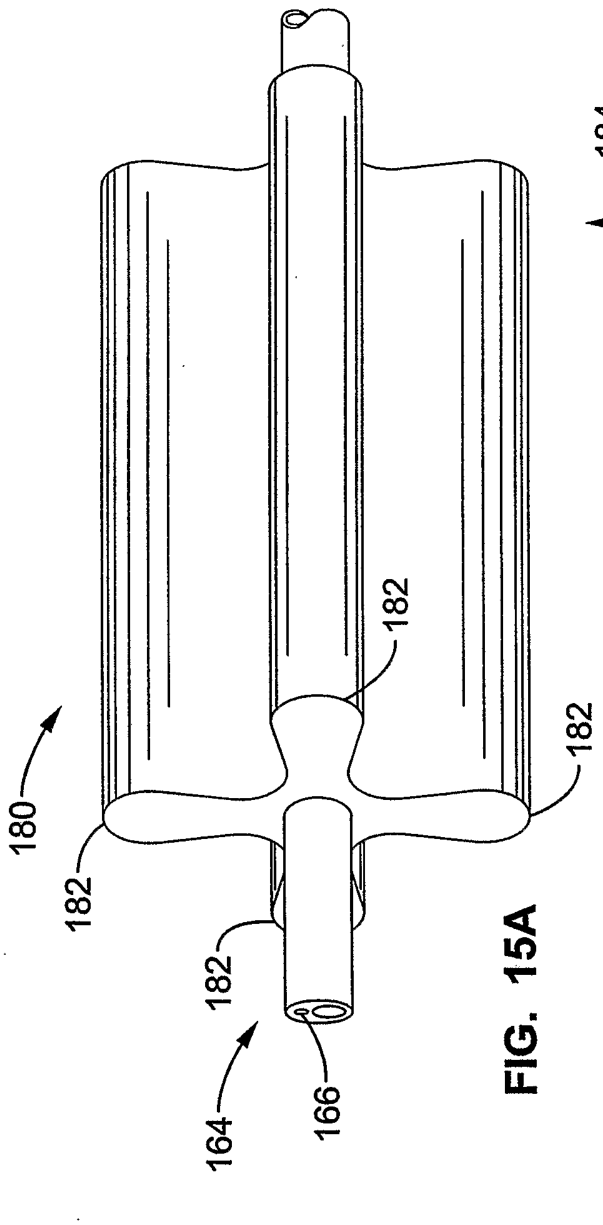

FIG. 15A

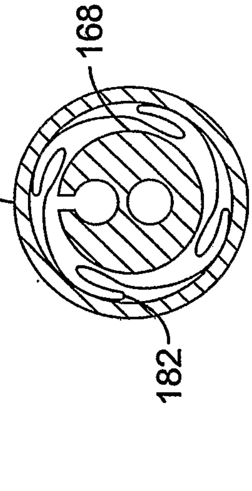

FIG. 15B

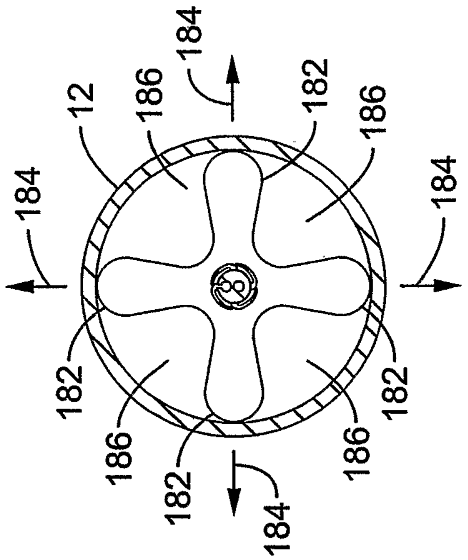

FIG. 15C

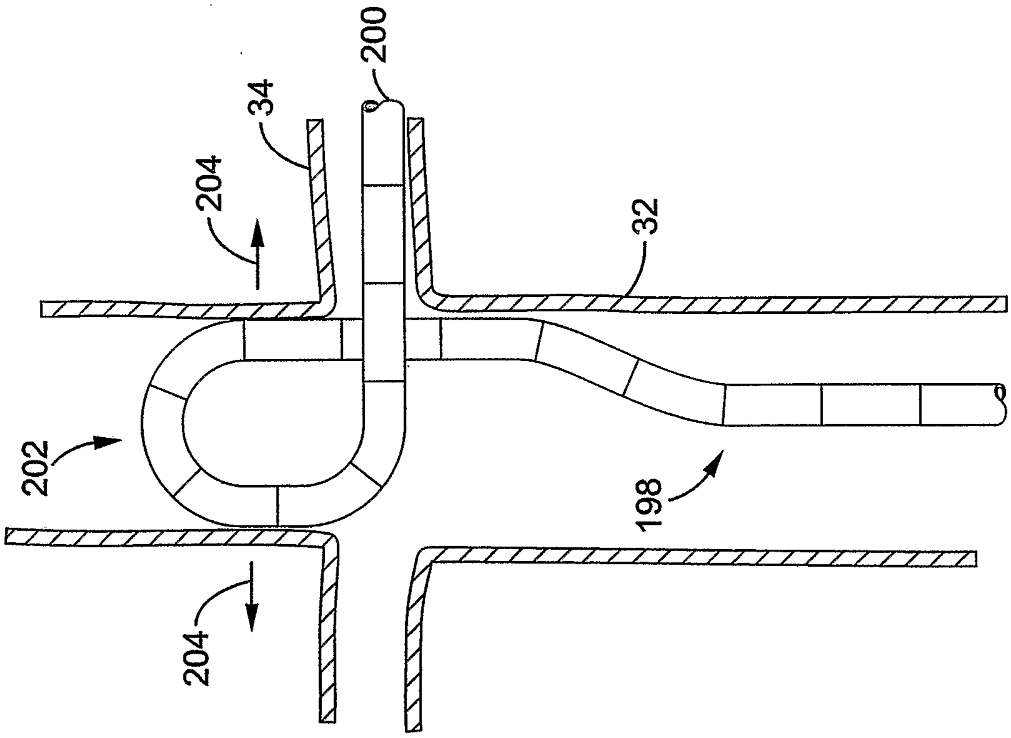

FIG. 17

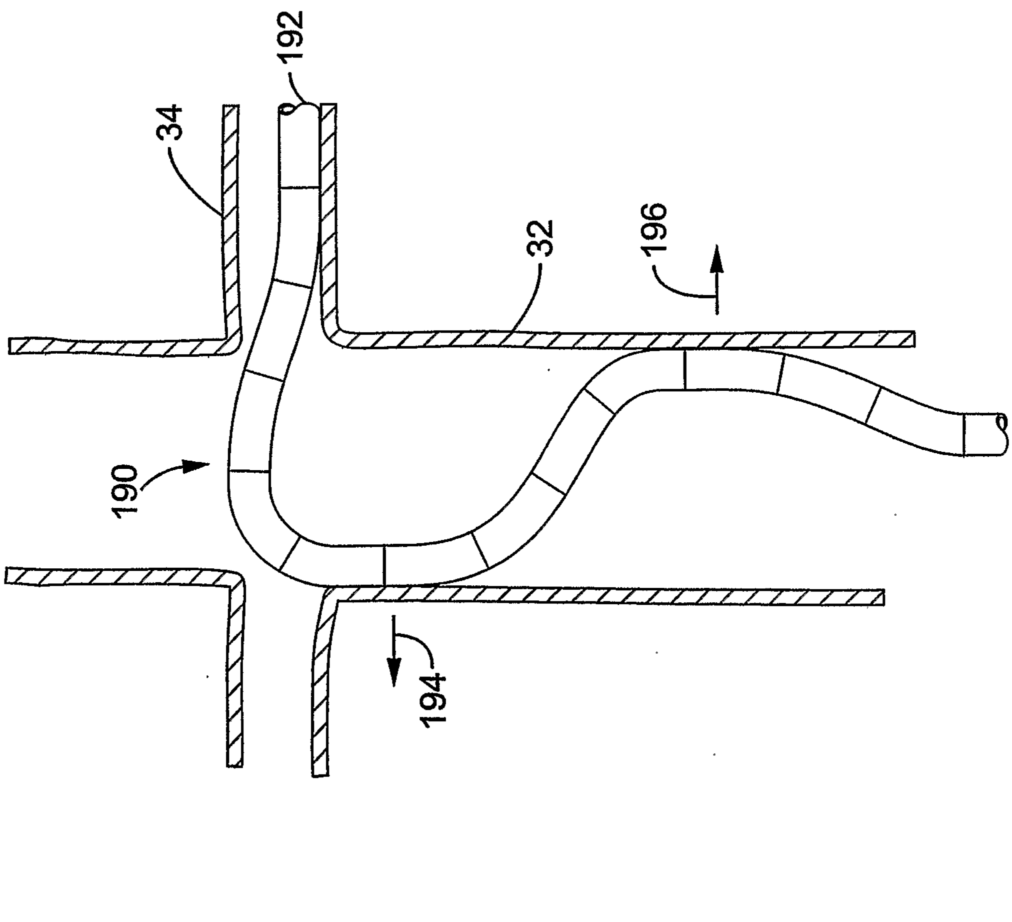

FIG. 16

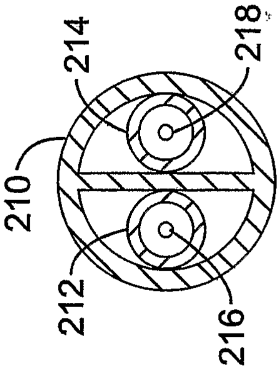

FIG. 18B

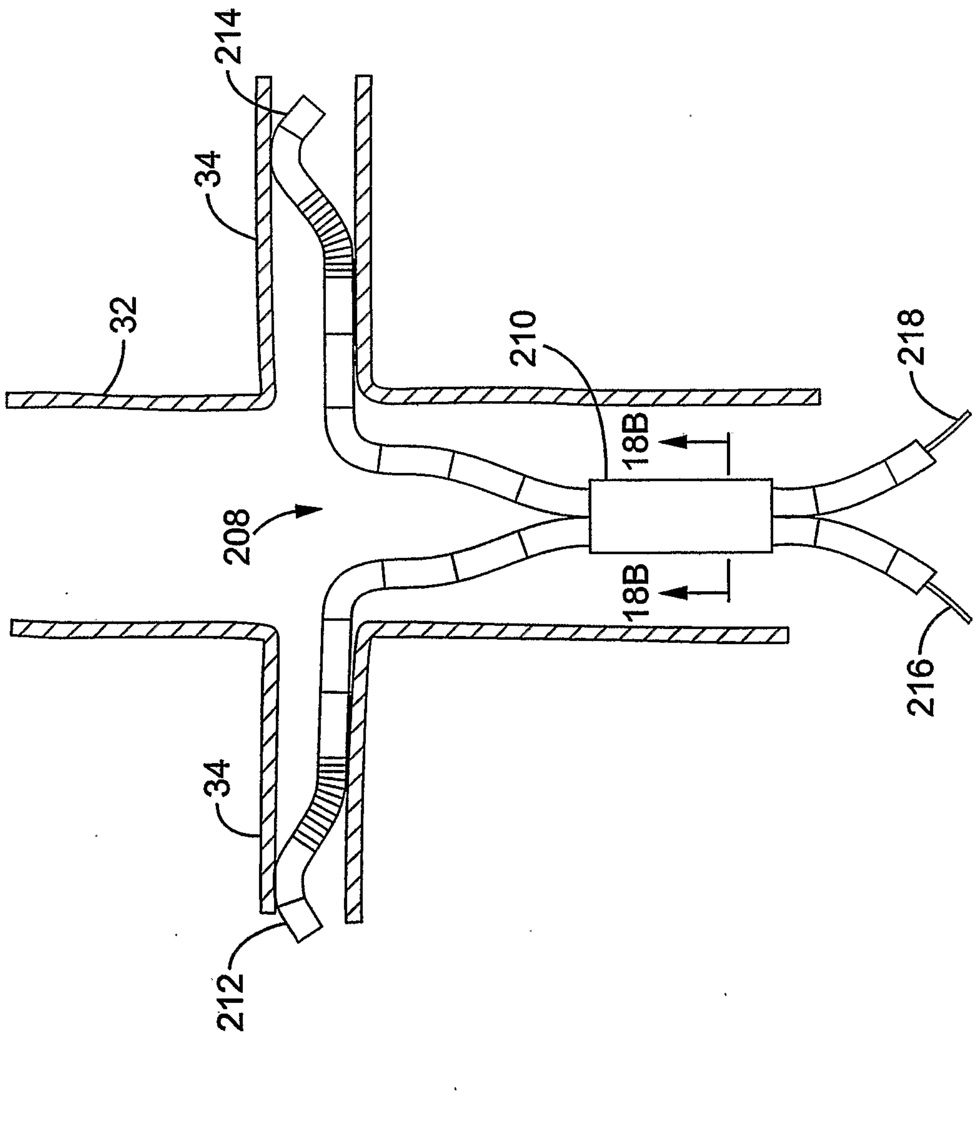

FIG. 18A

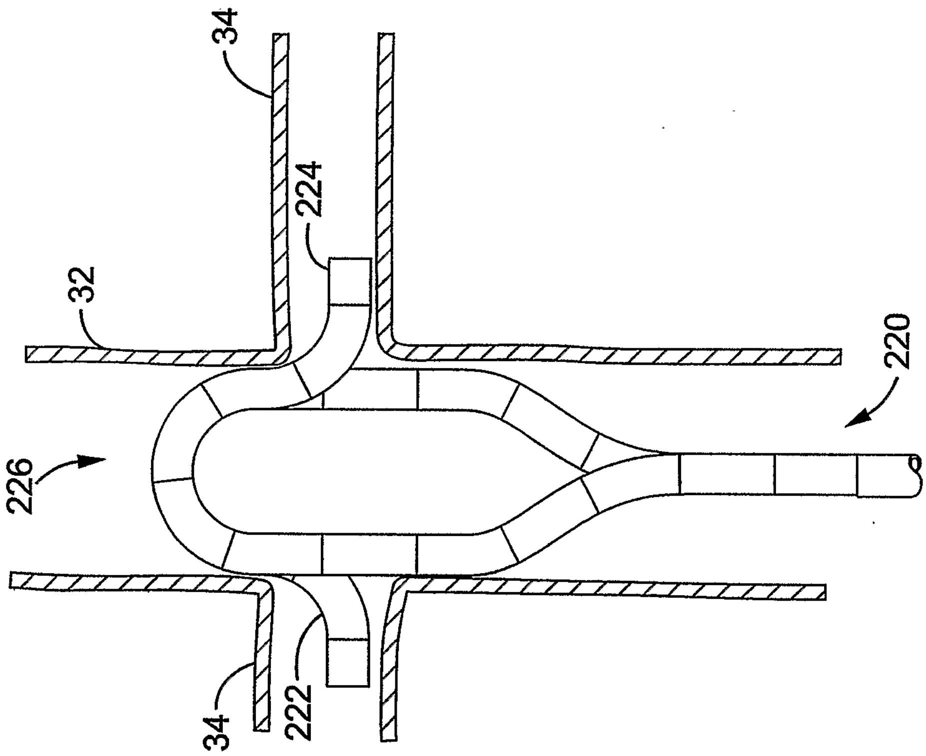

FIG. 19

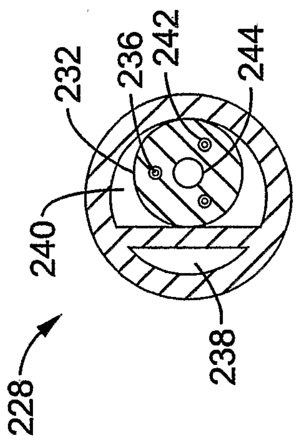

FIG. 21

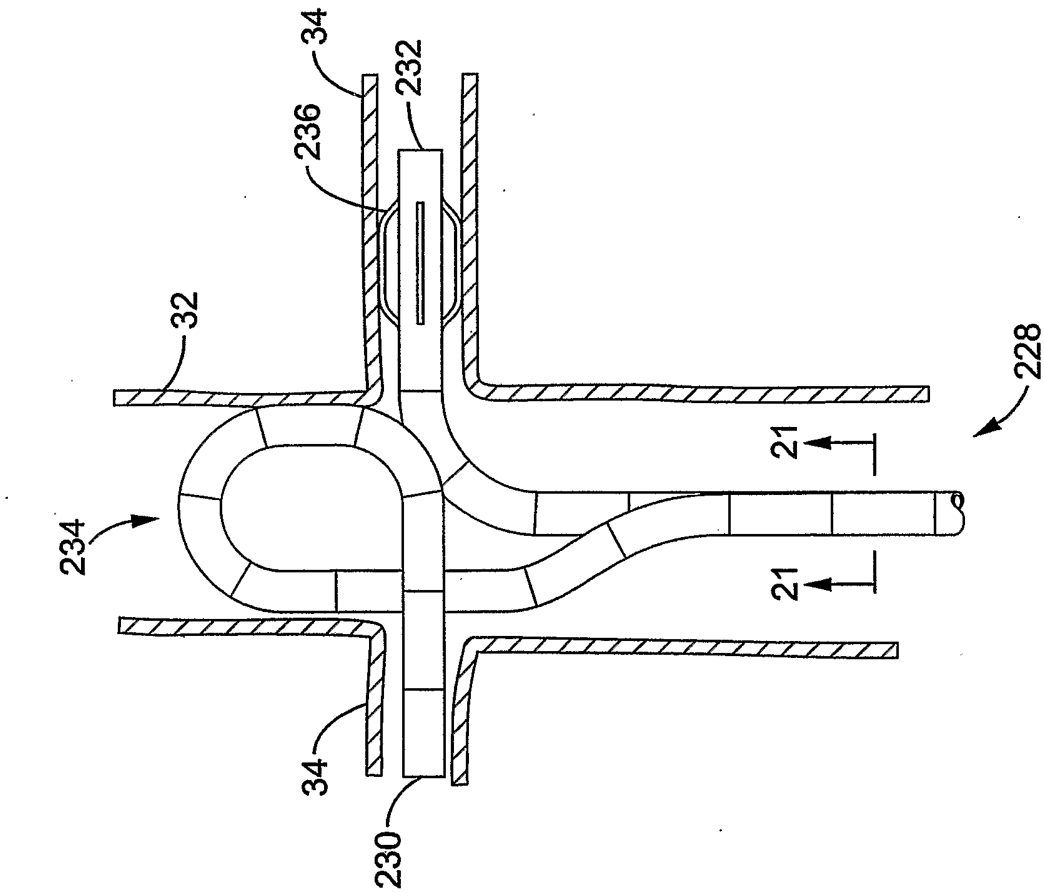

FIG. 20

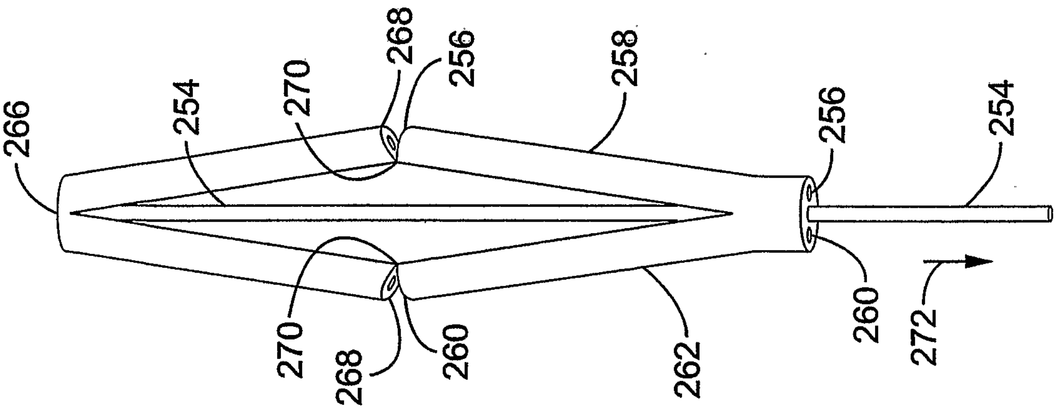

FIG. 22C

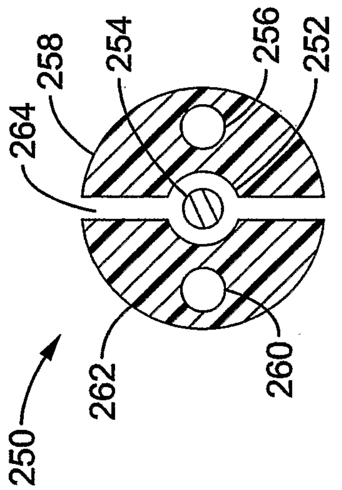

FIG. 22B

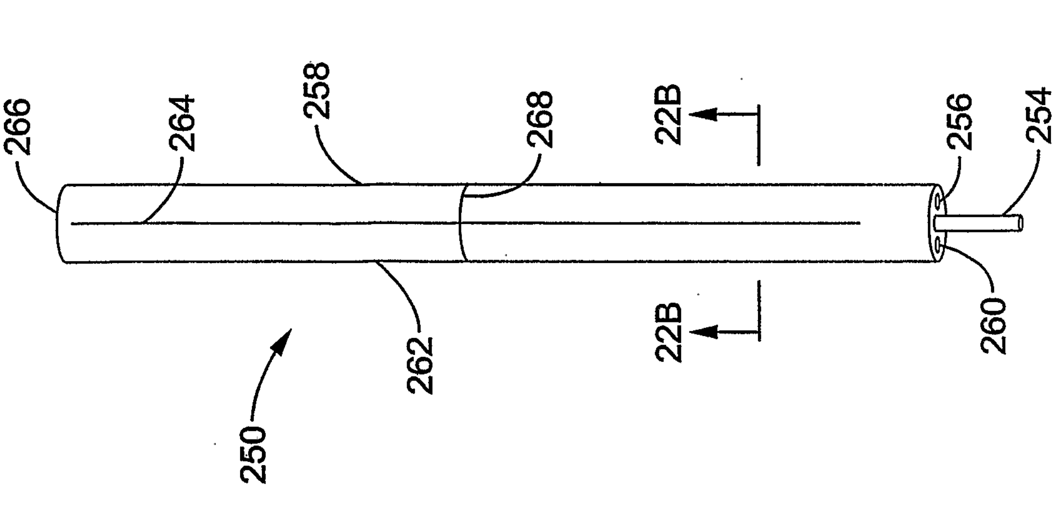

FIG. 22A

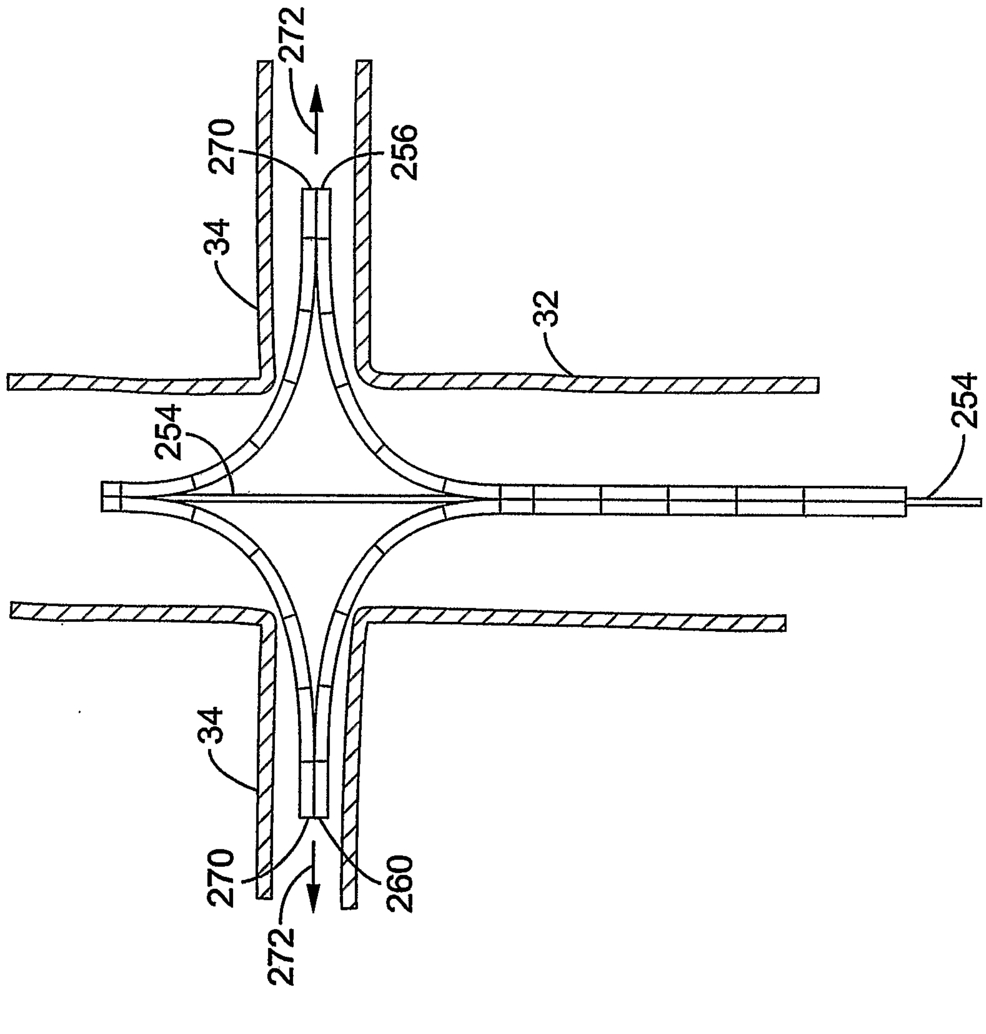

FIG. 22D

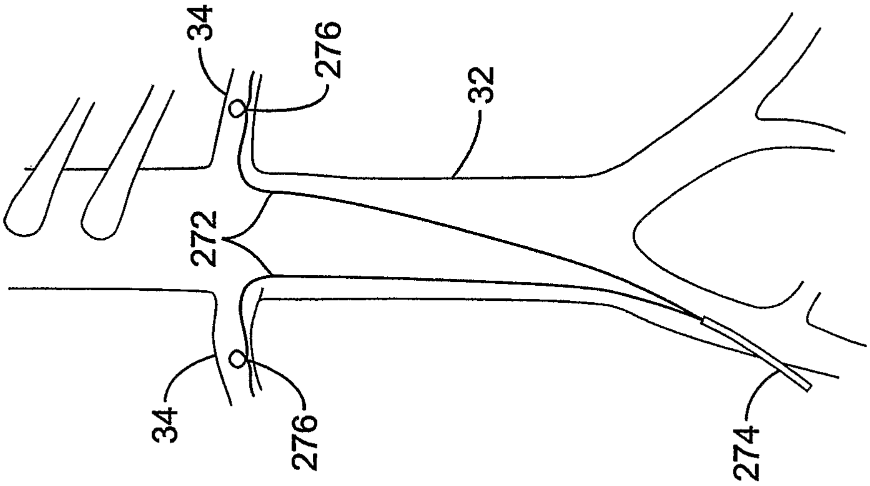

FIG. 23

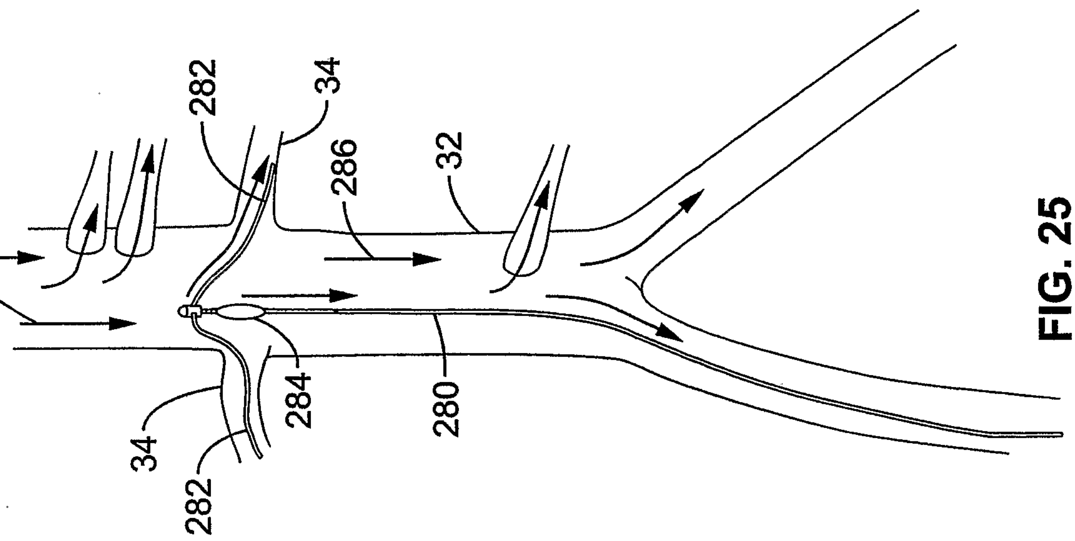

FIG. 25

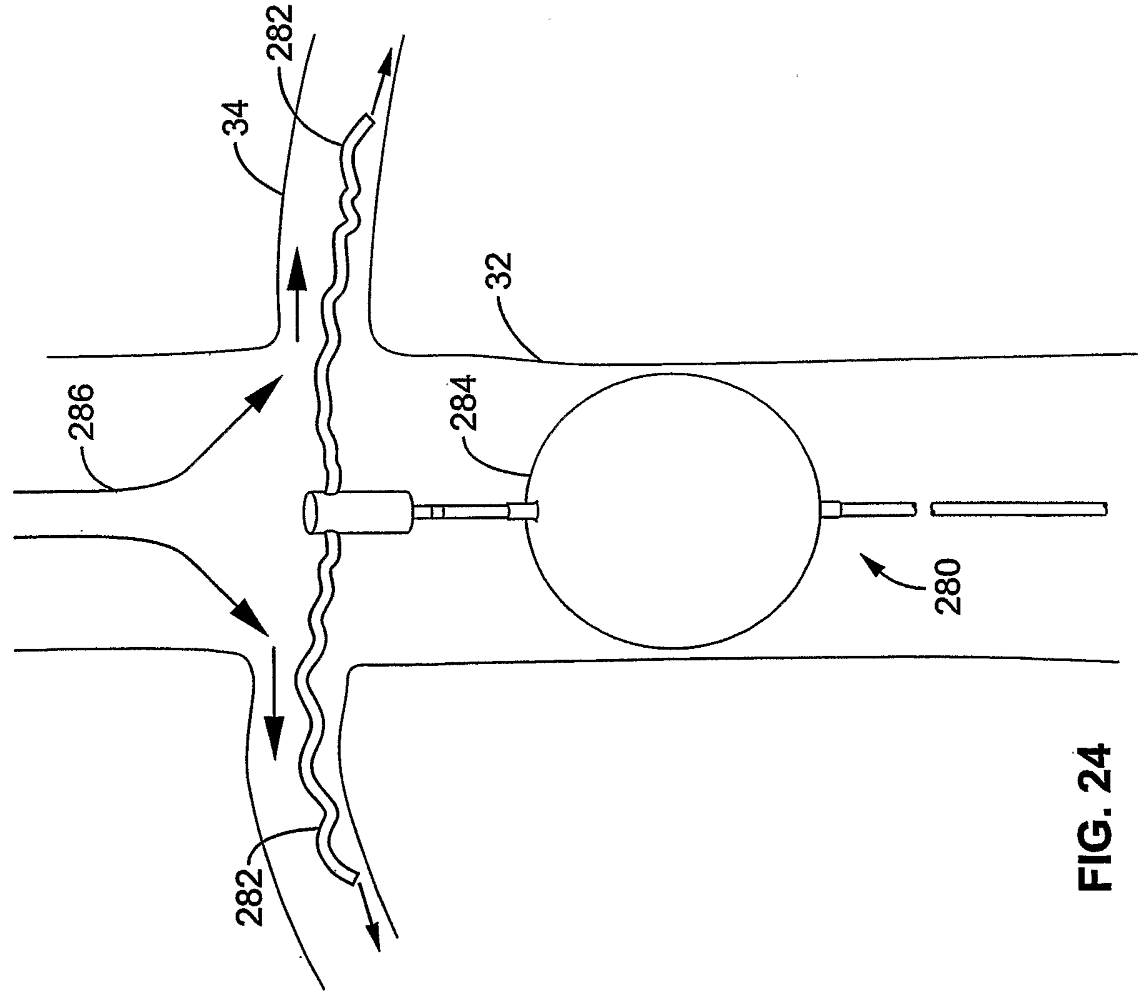

FIG. 24

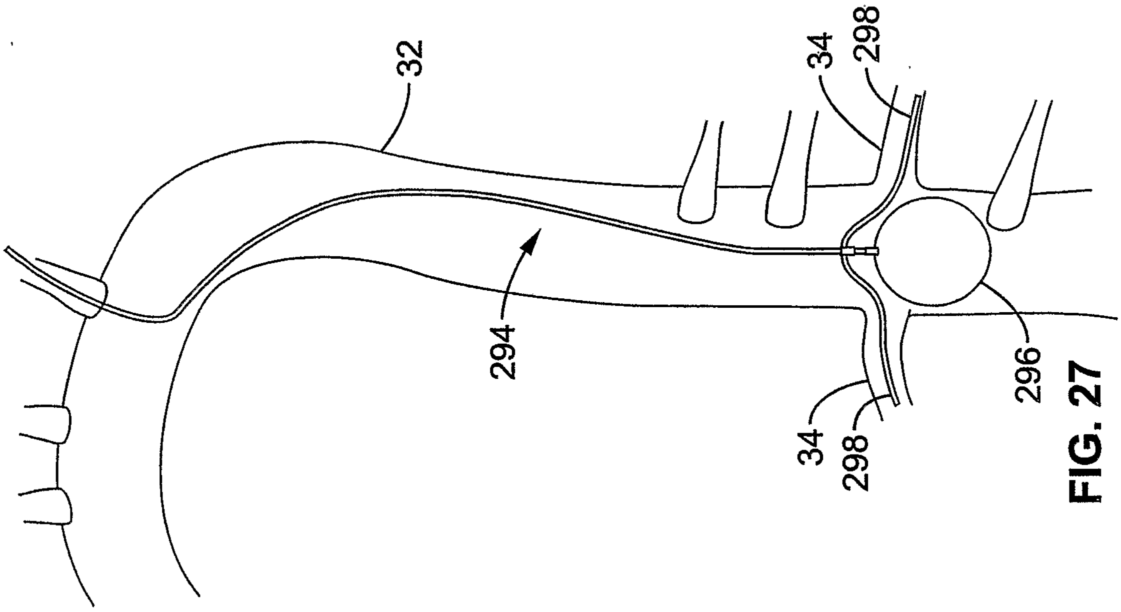

FIG. 27

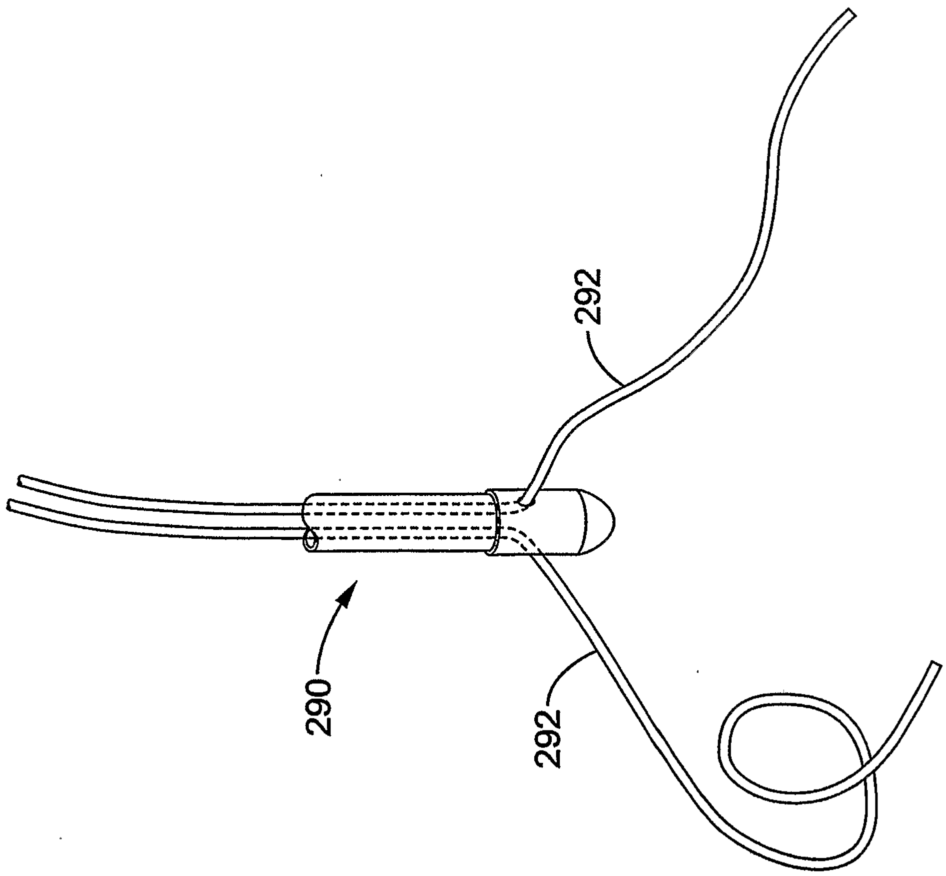

FIG. 26

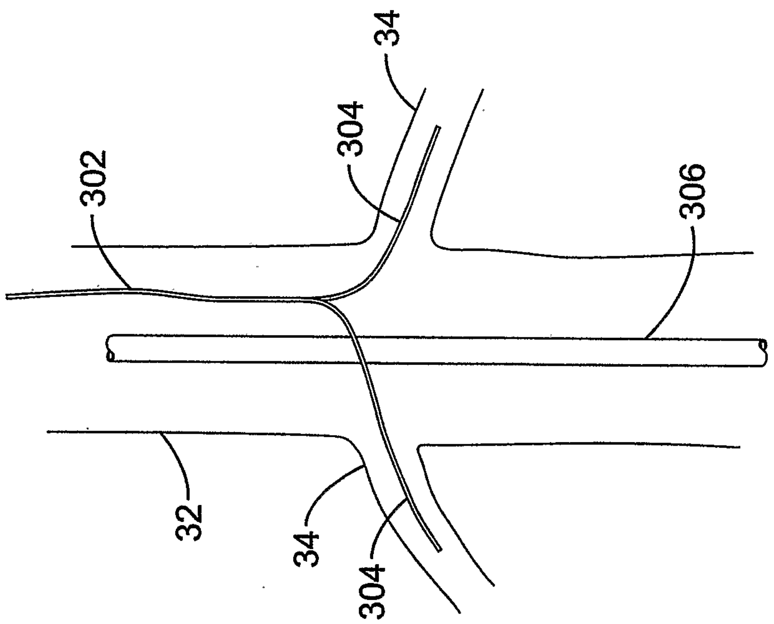

FIG. 29

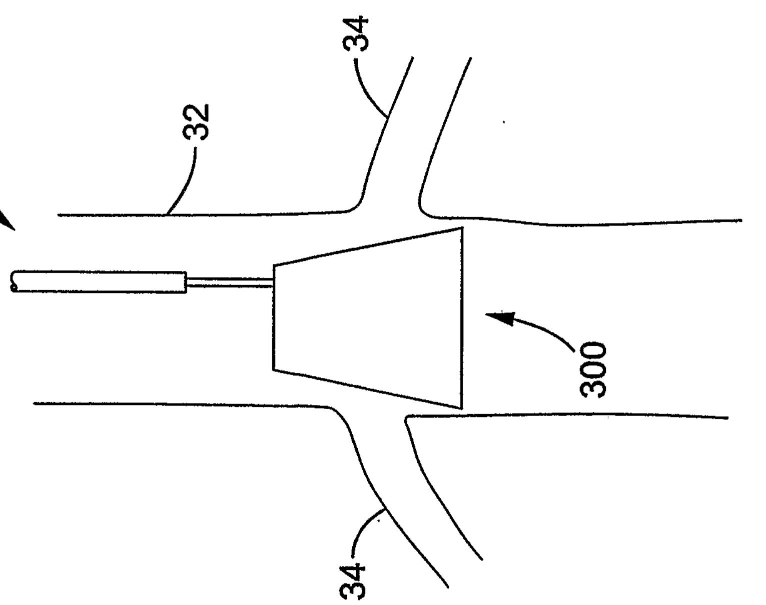

FIG. 28

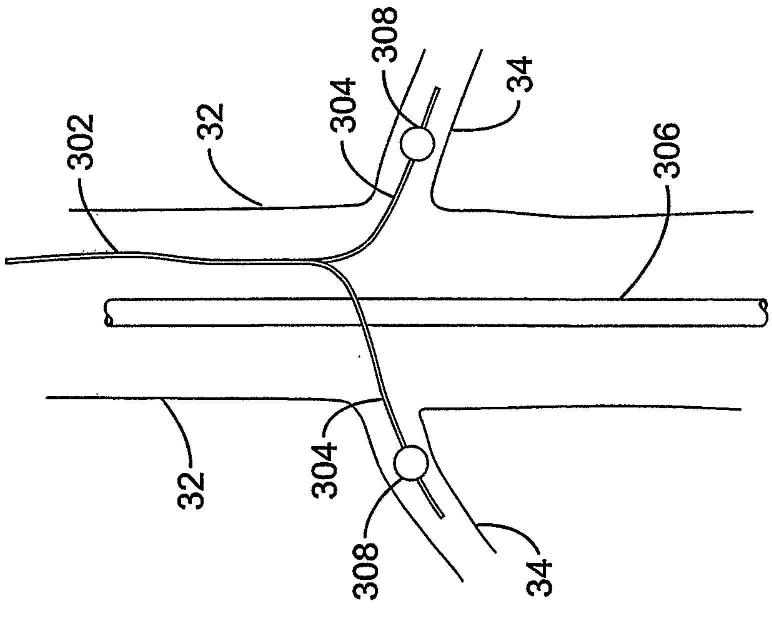

FIG. 30

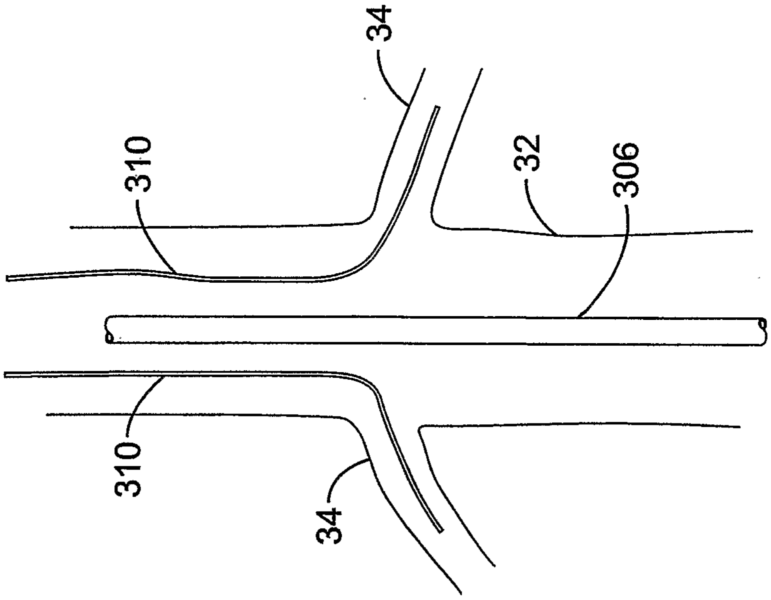

FIG. 31

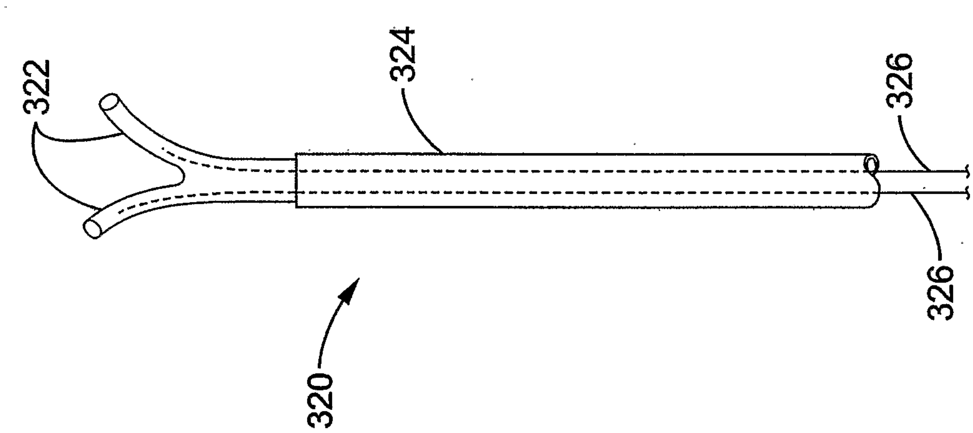

FIG. 33

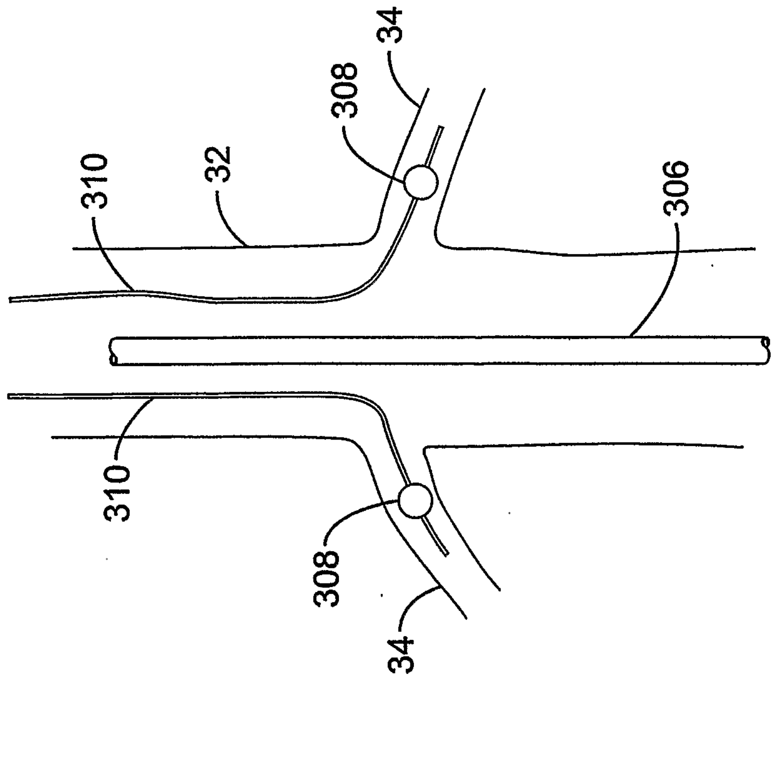

FIG. 32

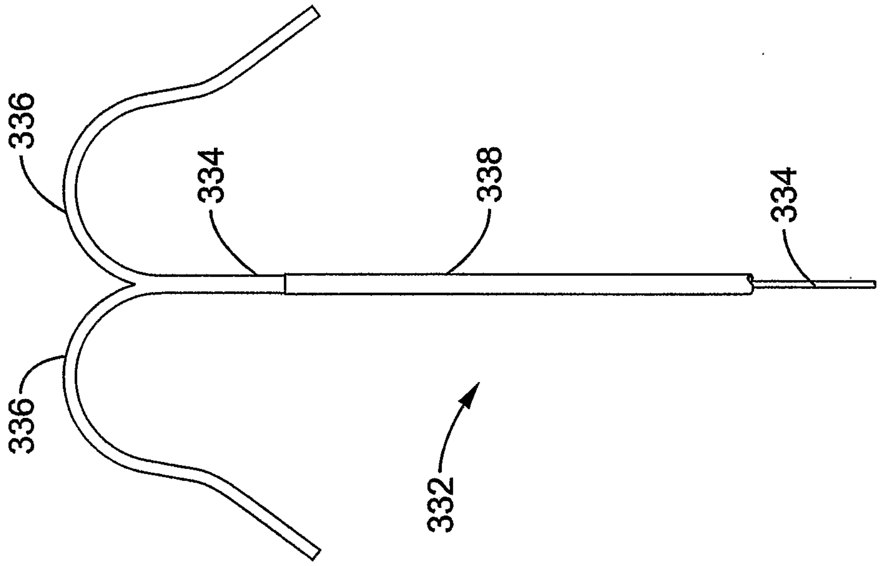

FIG. 35

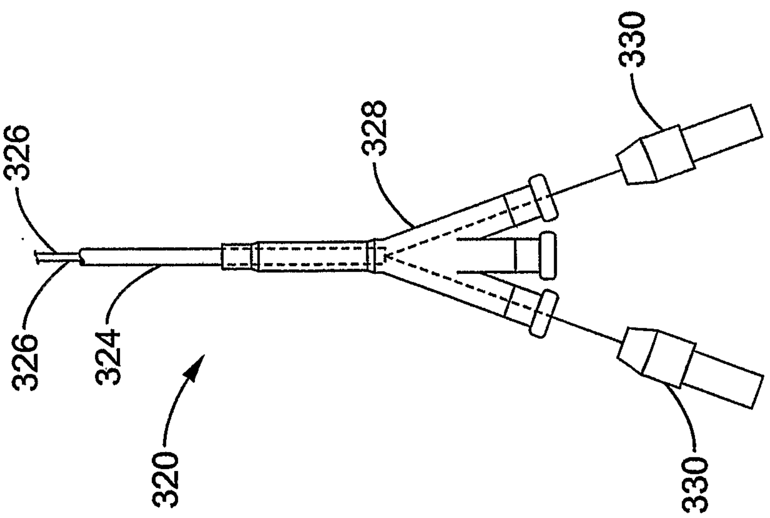

FIG. 34

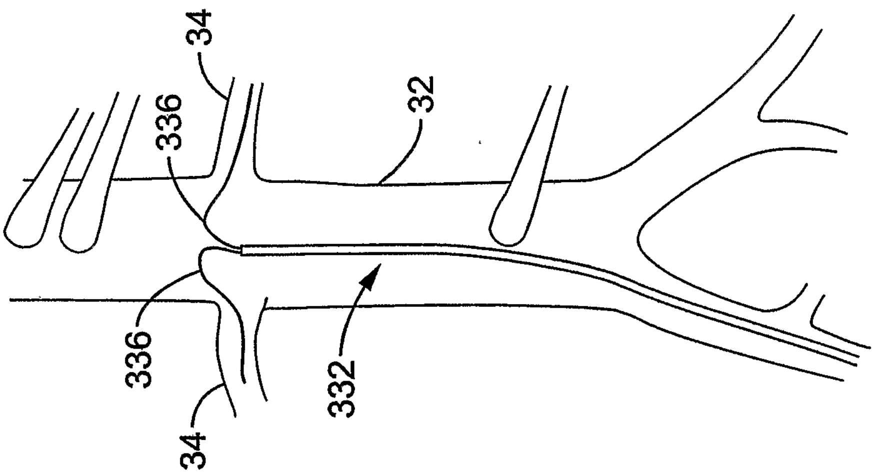

FIG. 36

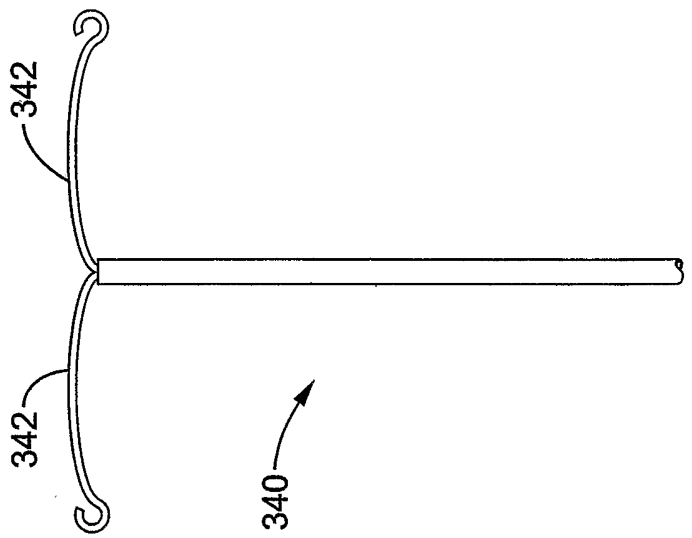

FIG.37

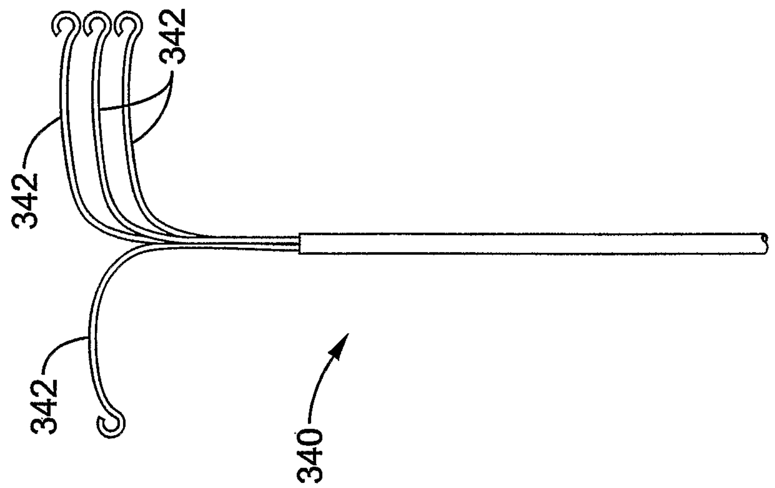

FIG. 39

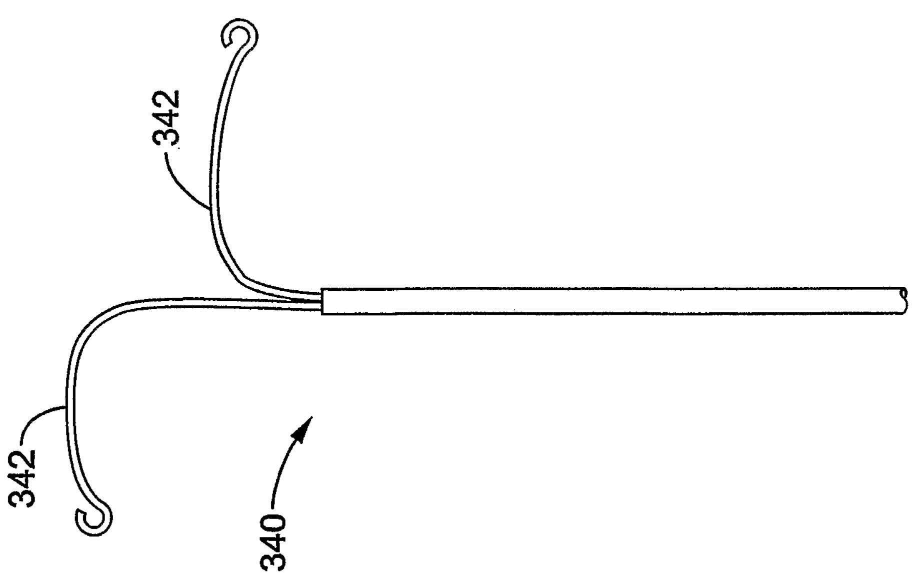

FIG. 38

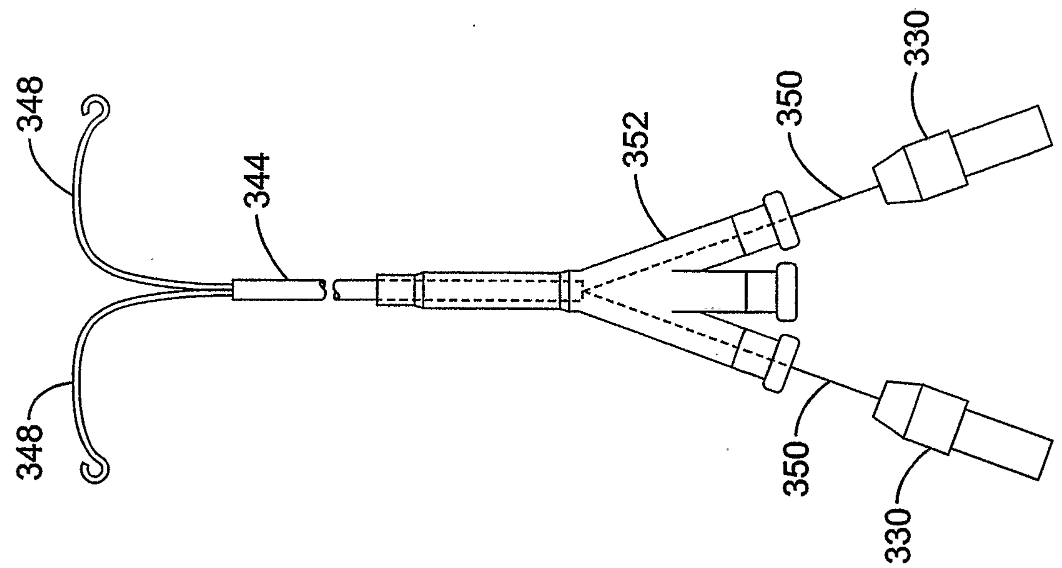

FIG. 41

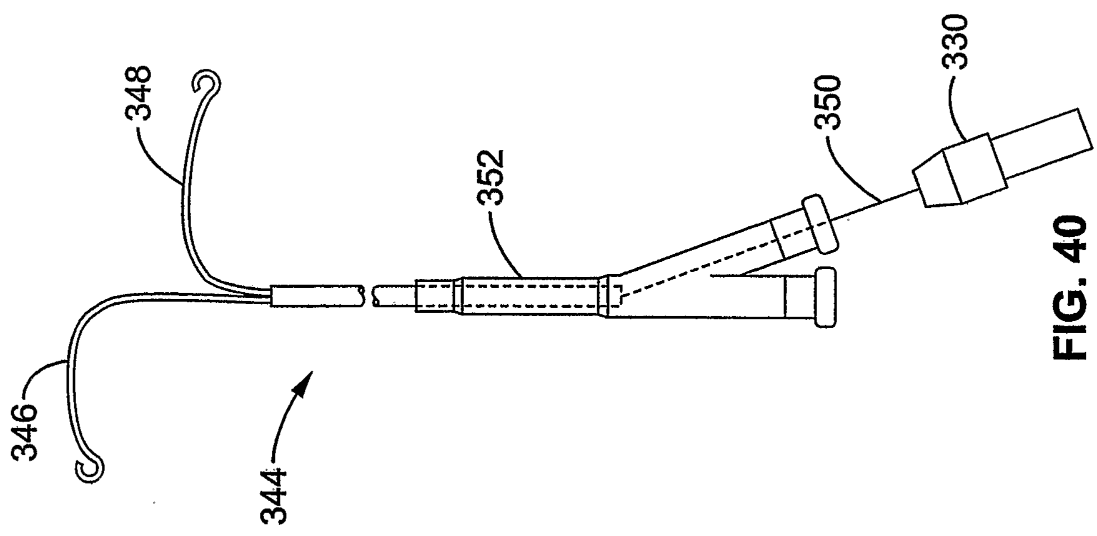

FIG. 40

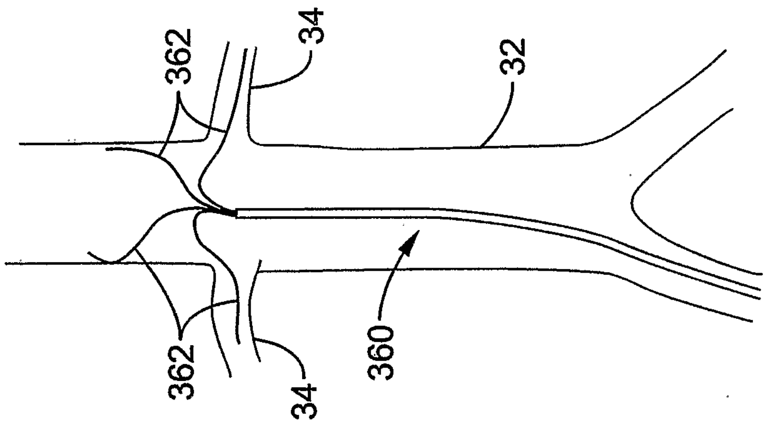

FIG. 43

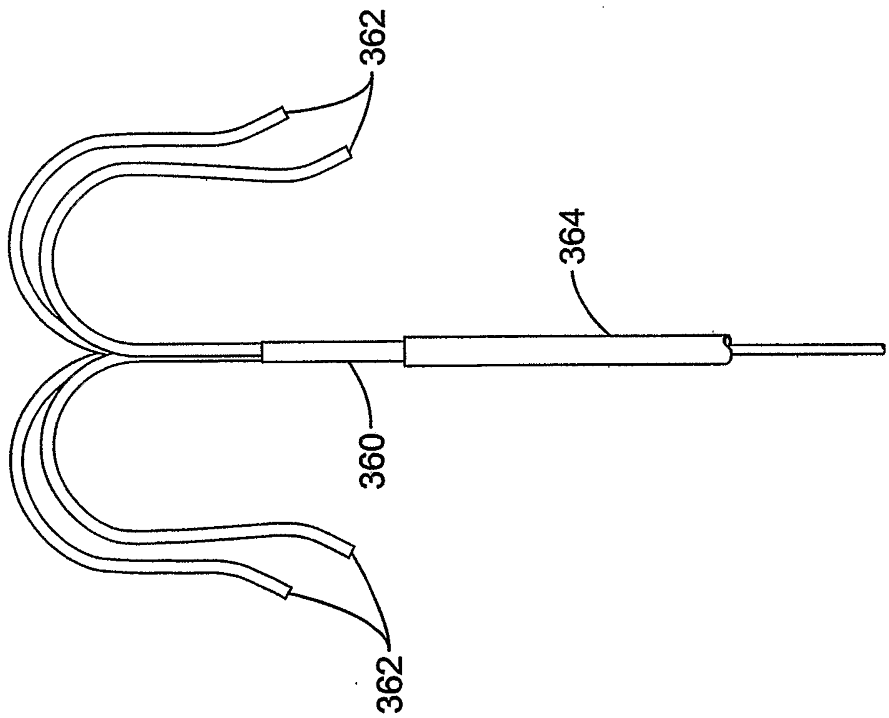

FIG. 42

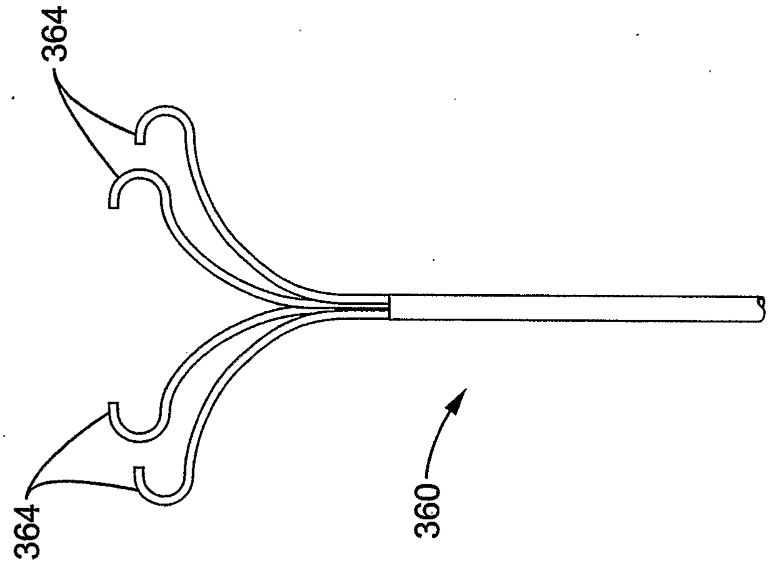

FIG. 45

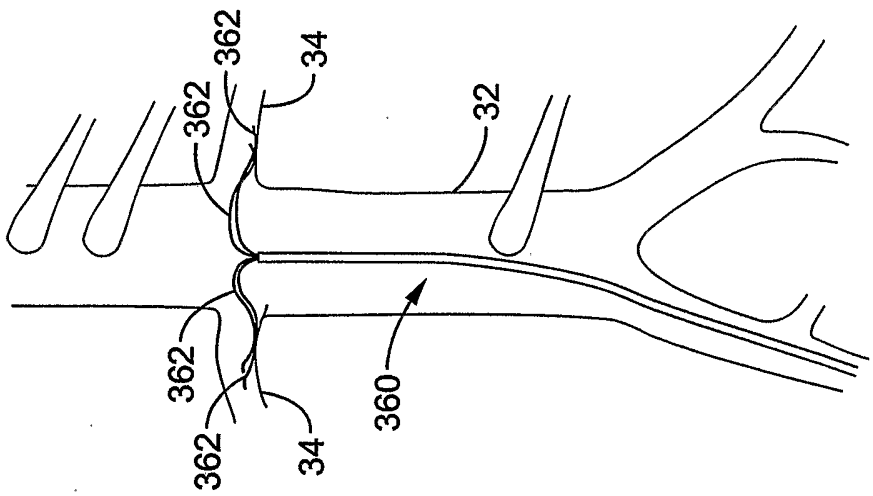

FIG. 44

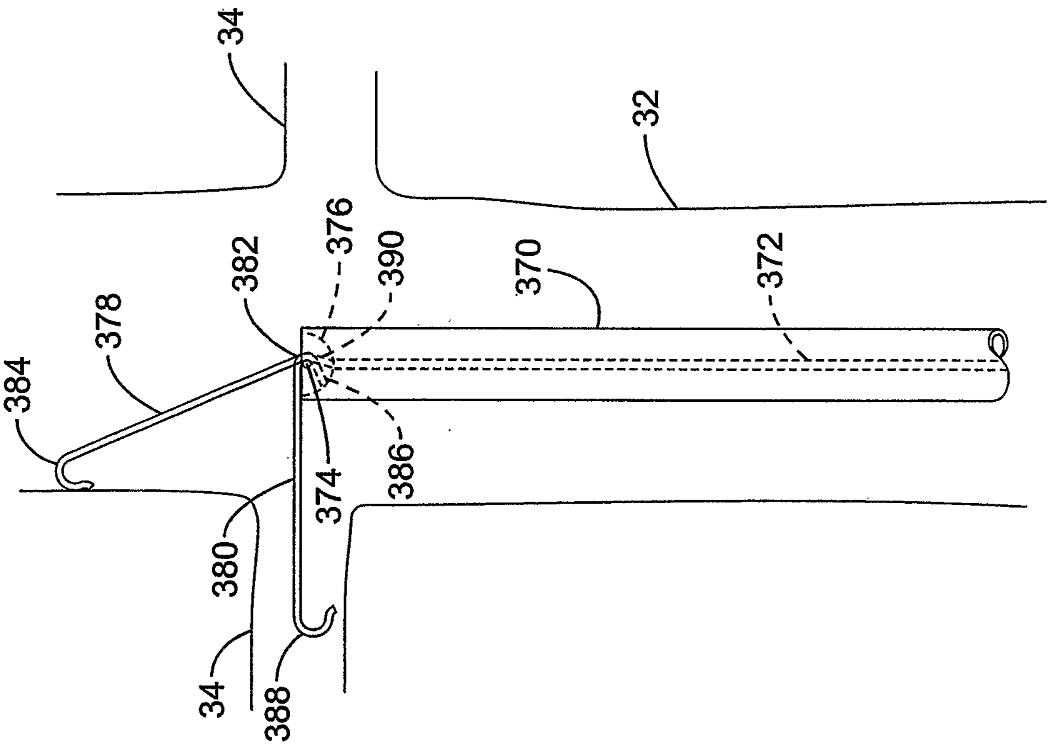
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FIG. 47

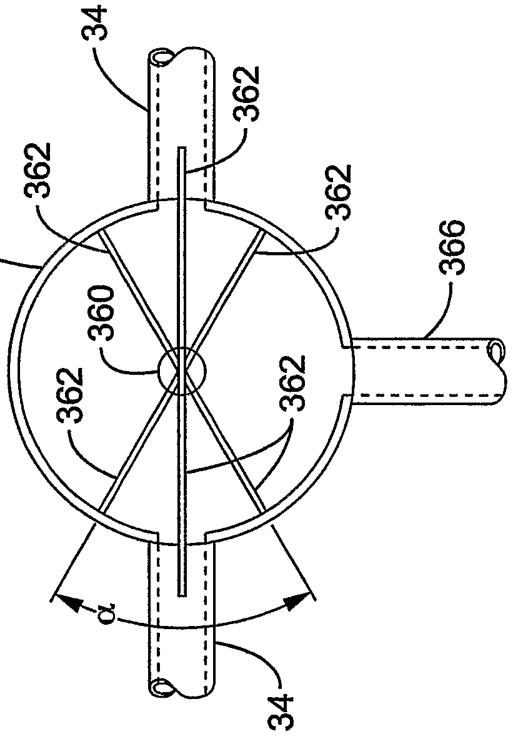
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FIG. 46

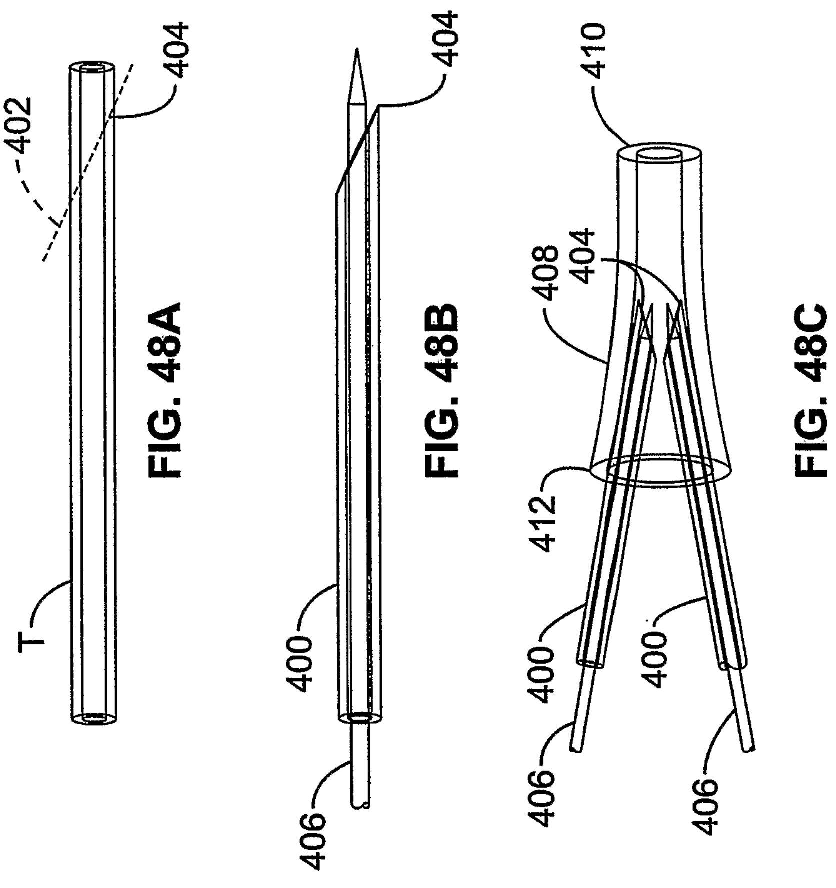

FIG. 48A

FIG. 48B

FIG. 48C

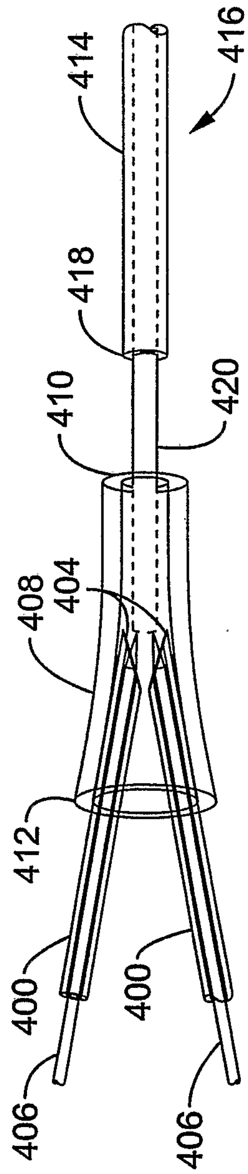

FIG. 48D

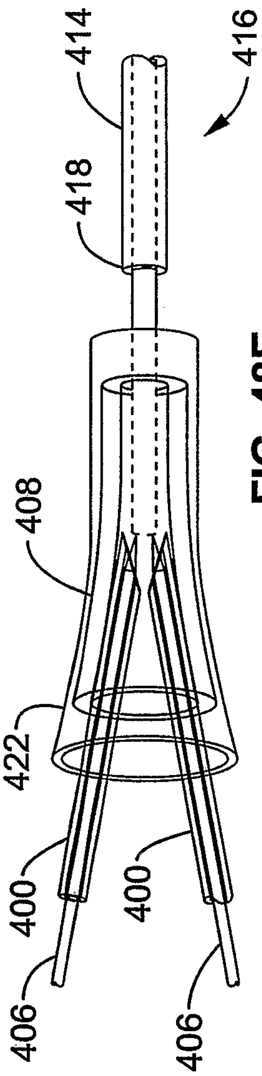

FIG. 48E

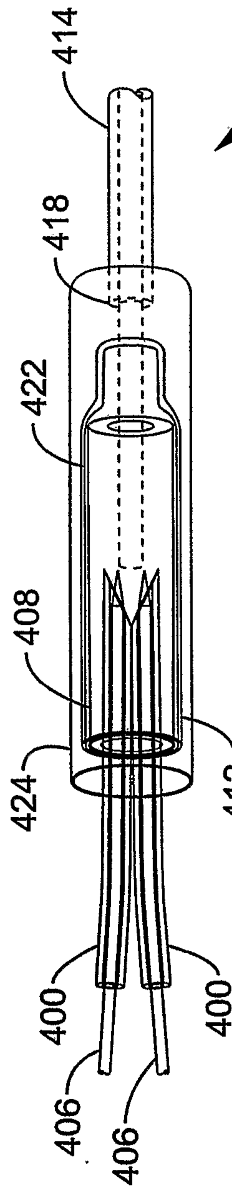

FIG. 48F

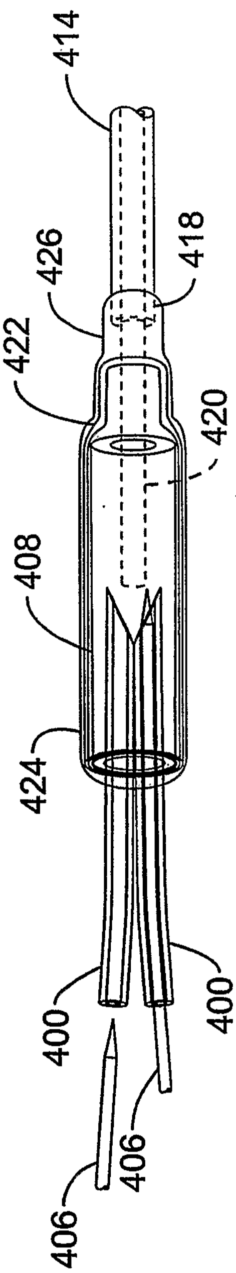

FIG. 48G

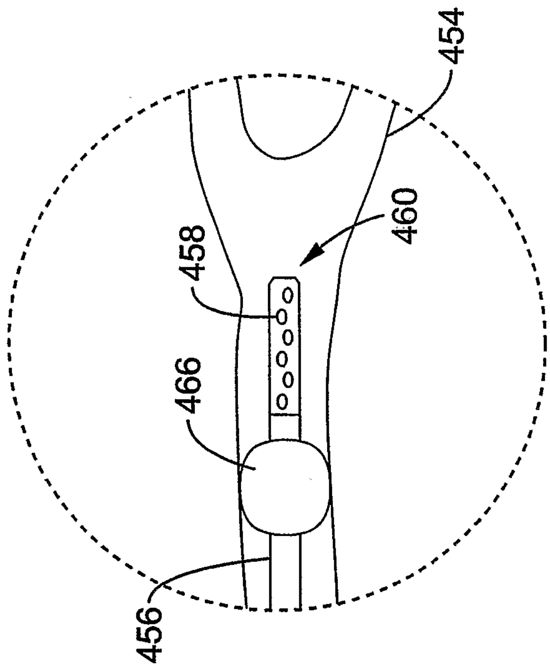

FIG. 50

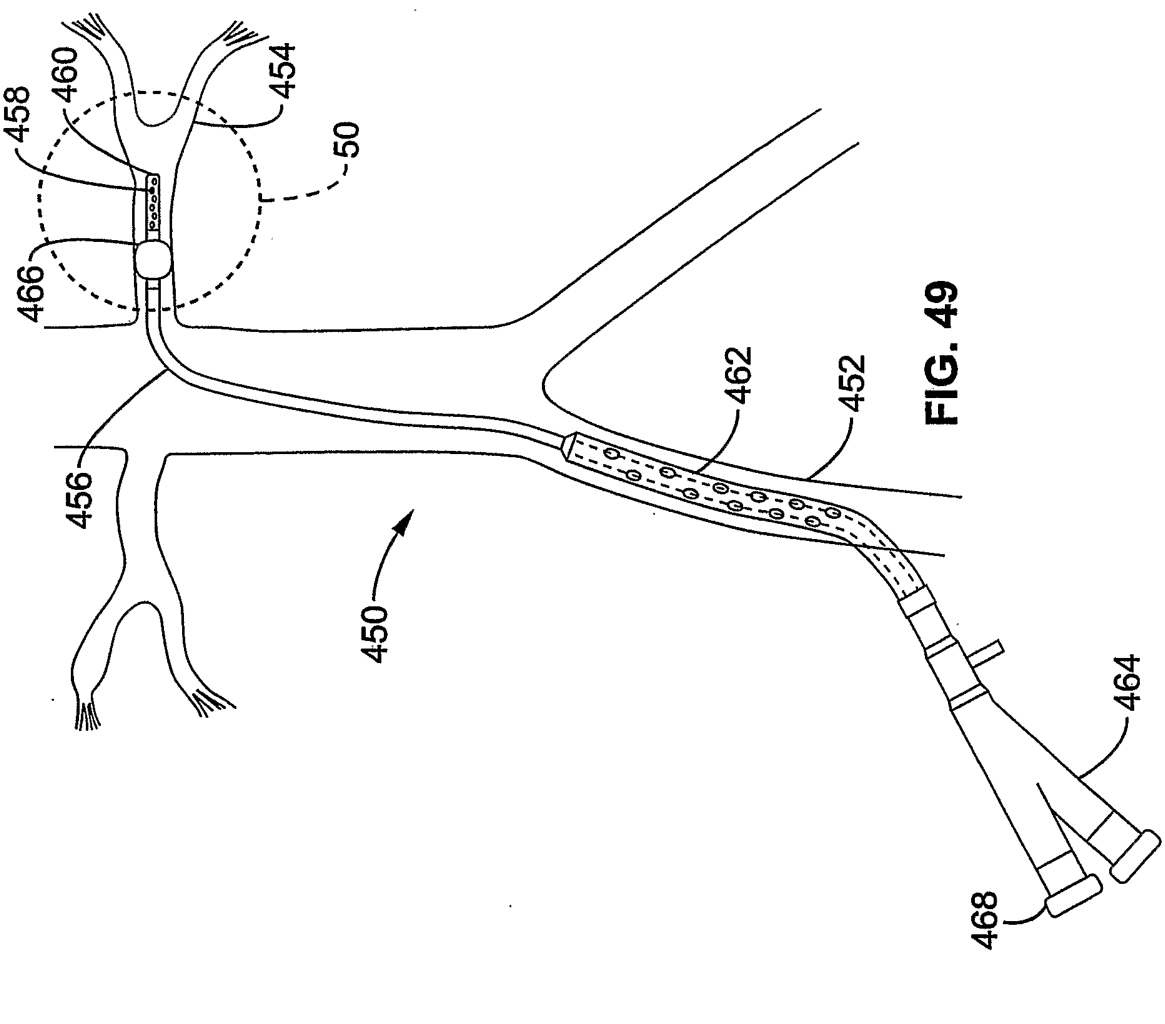

FIG. 49

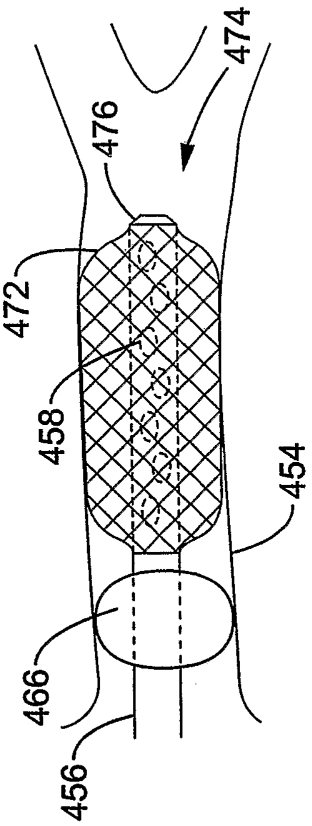

FIG. 52

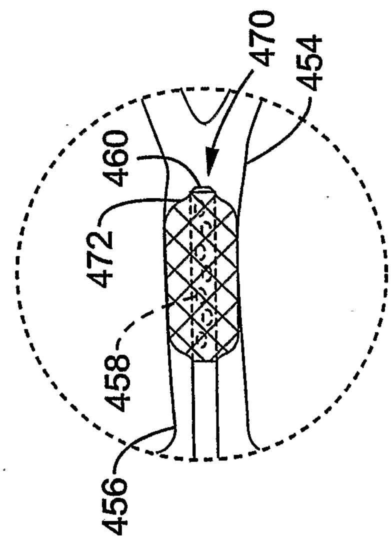

FIG. 51

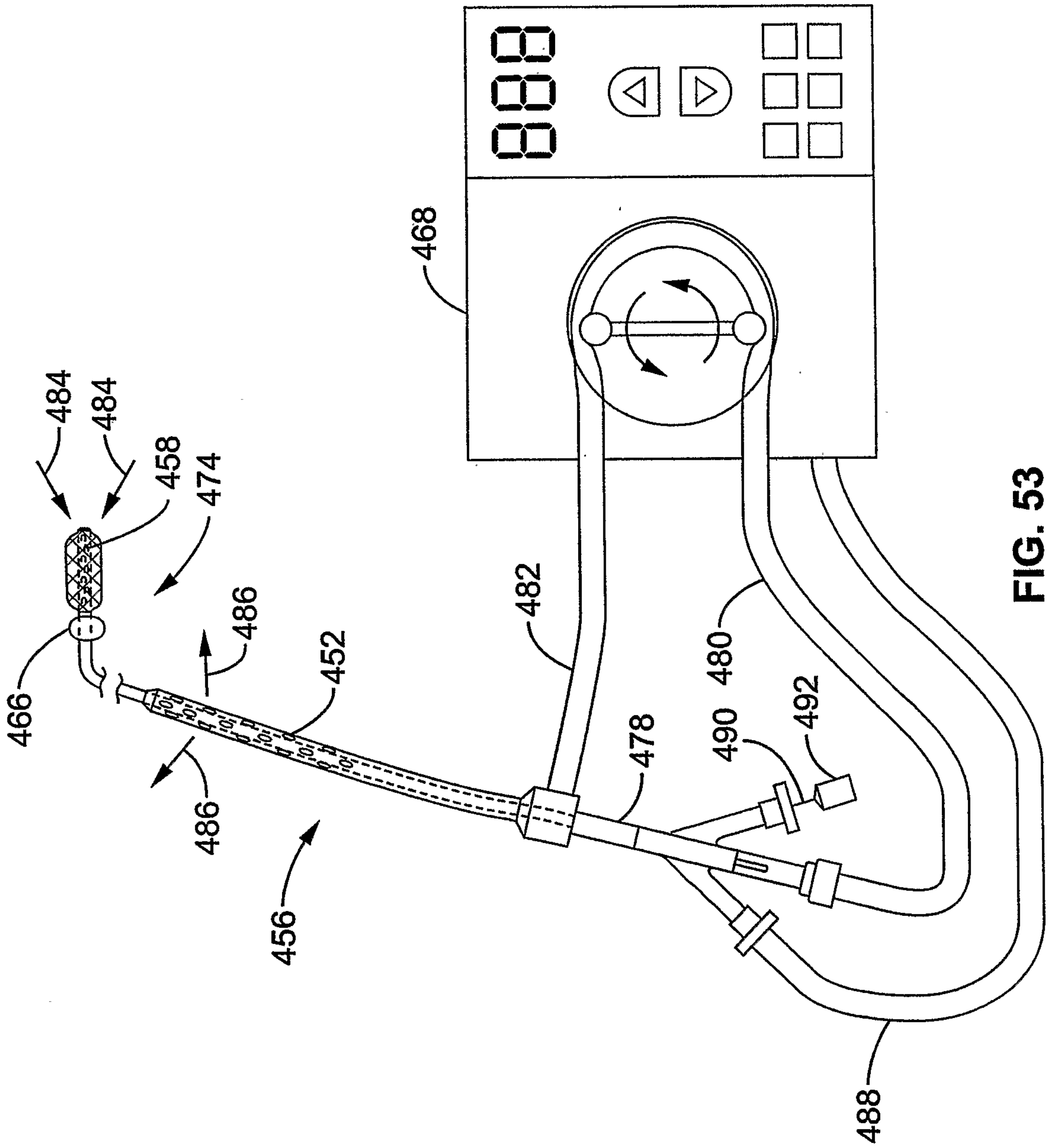

FIG. 53

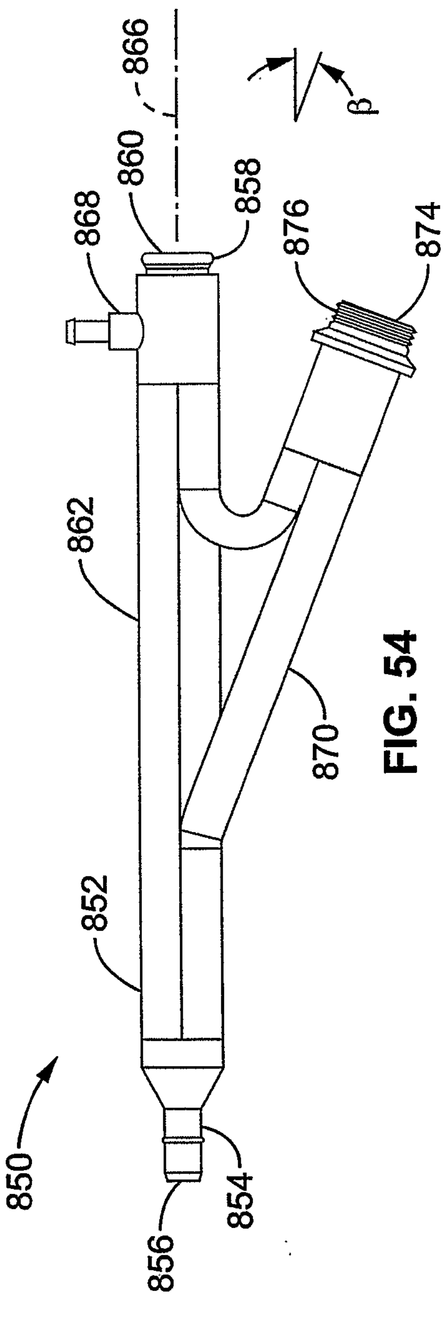
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FIG. 54

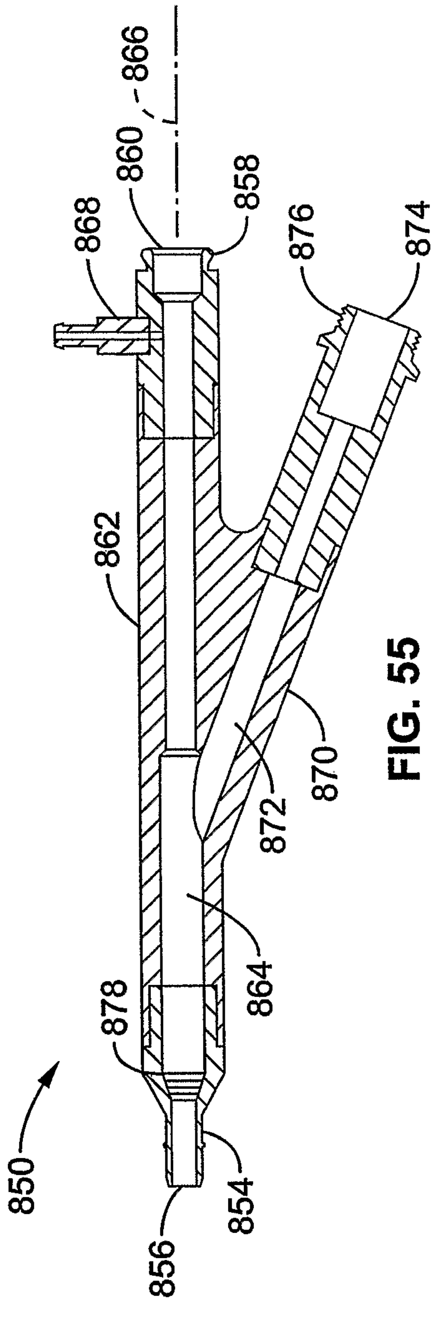
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FIG. 55

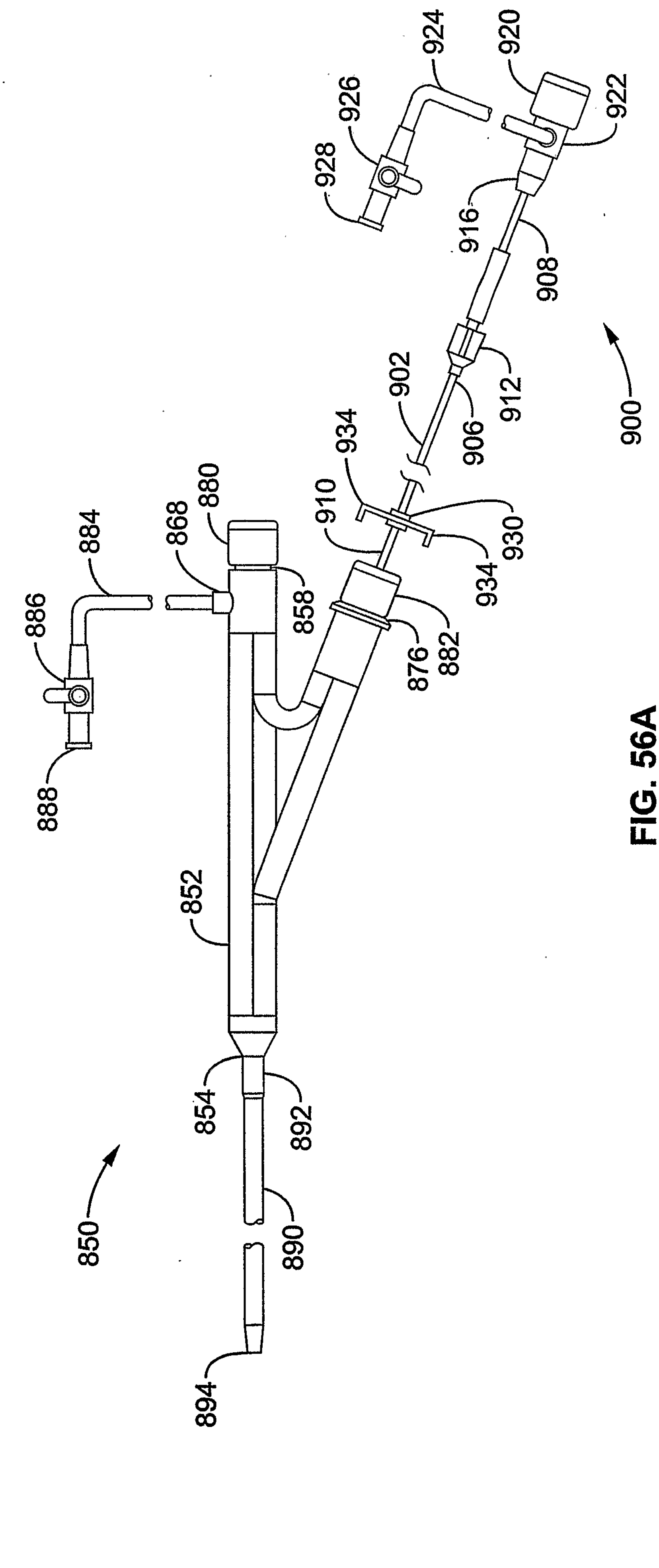
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FIG. 56A

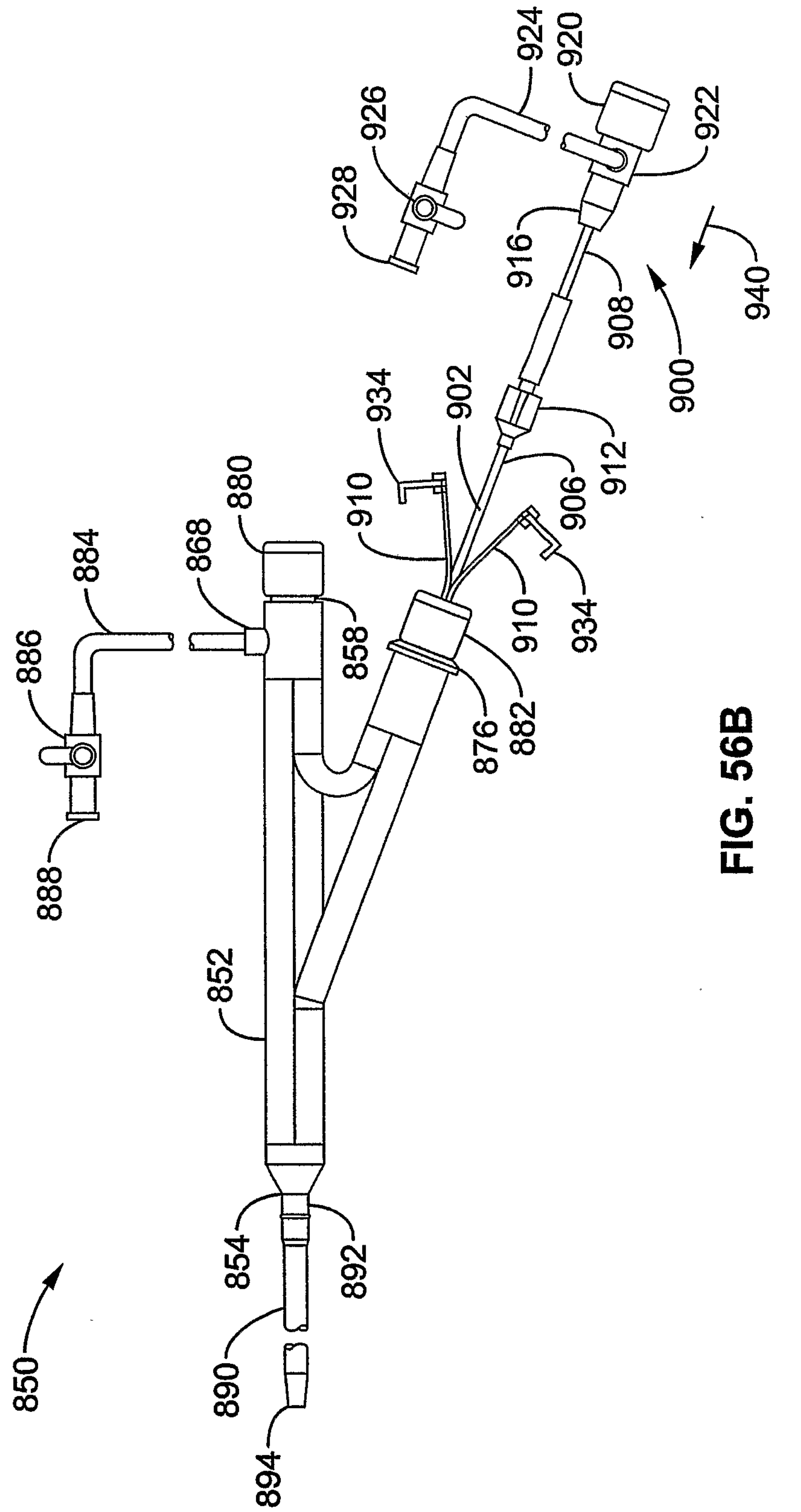
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FIG. 56B

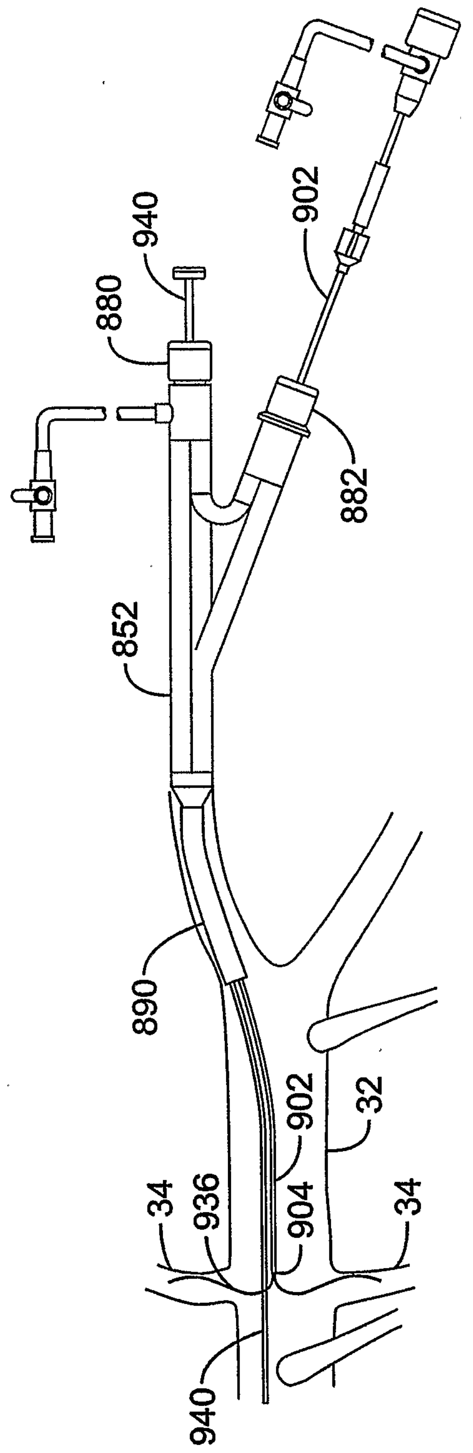

FIG. 57

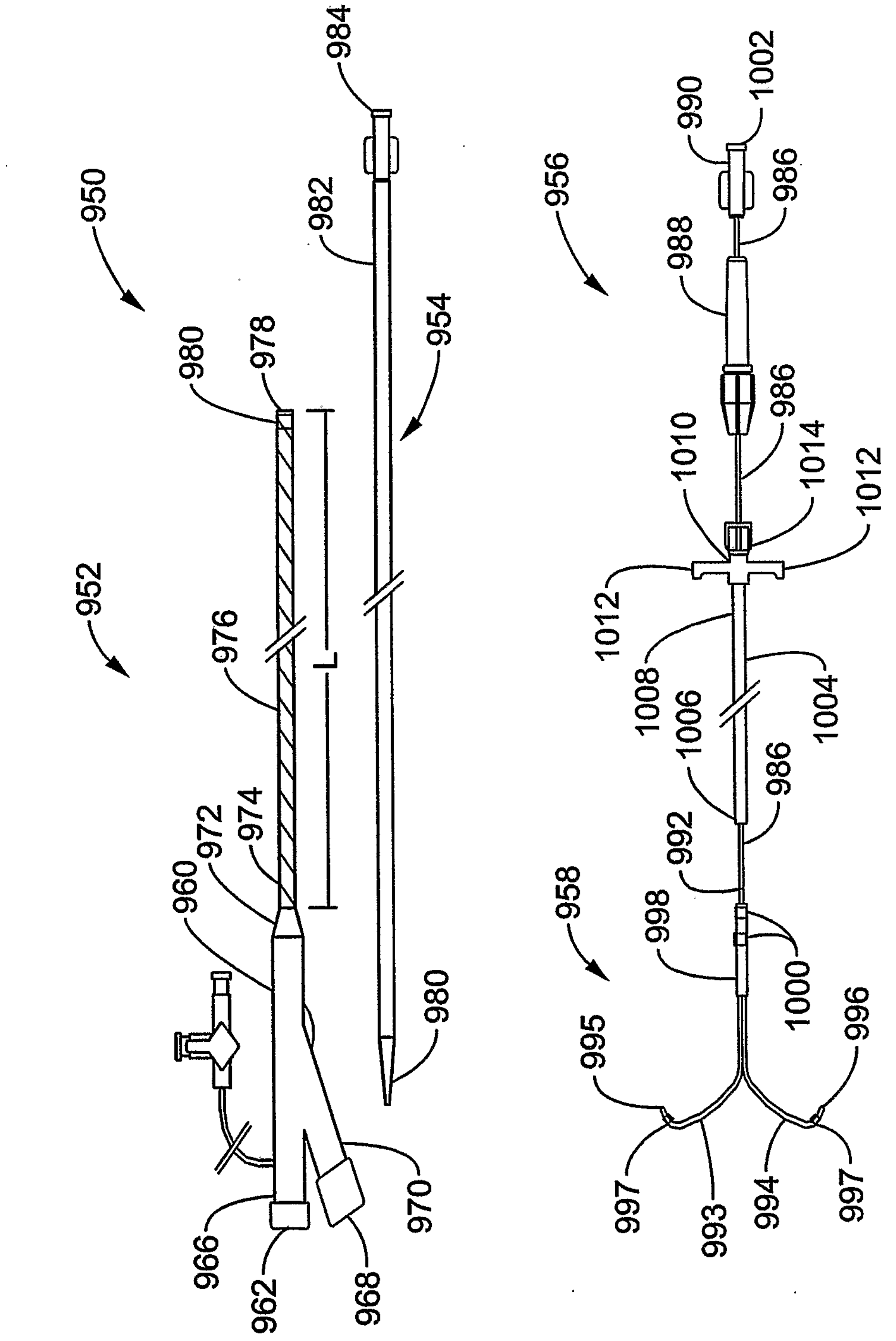
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FIG. 58

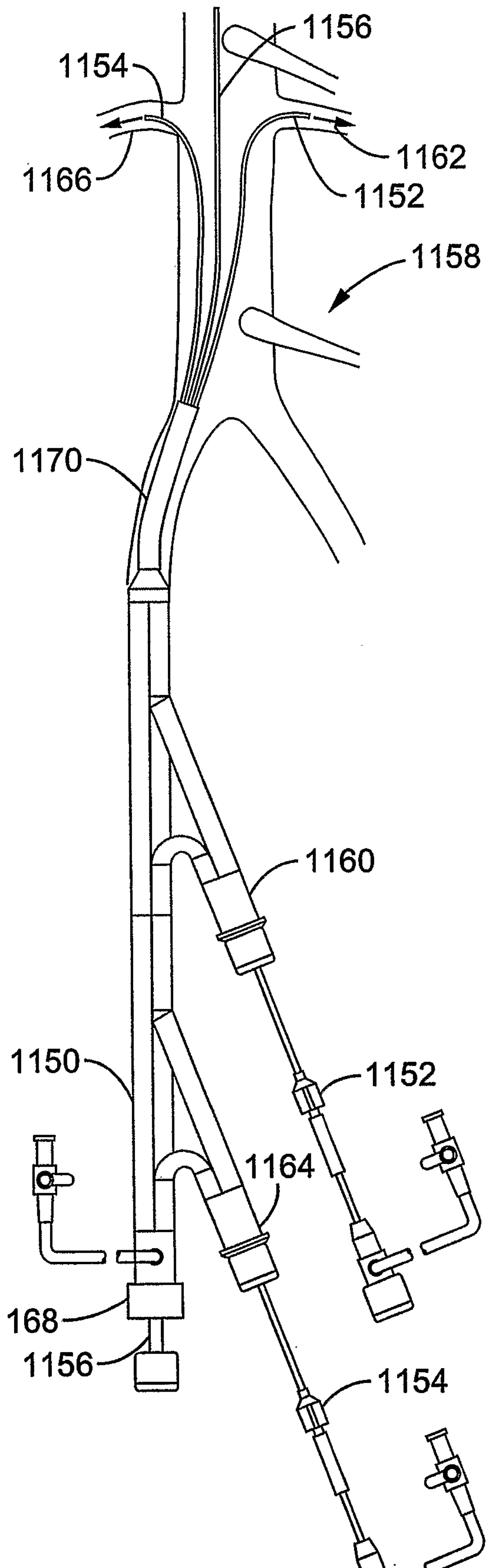
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FIG. 59

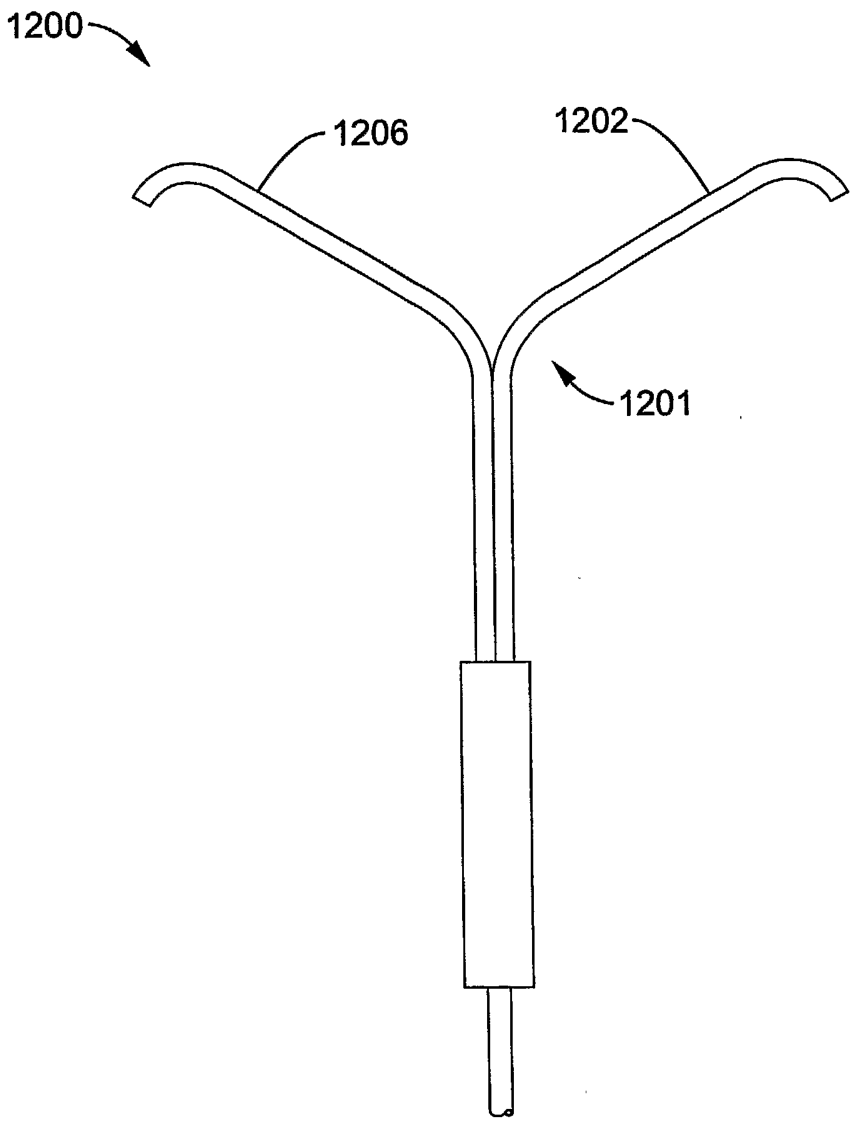

FIG. 60

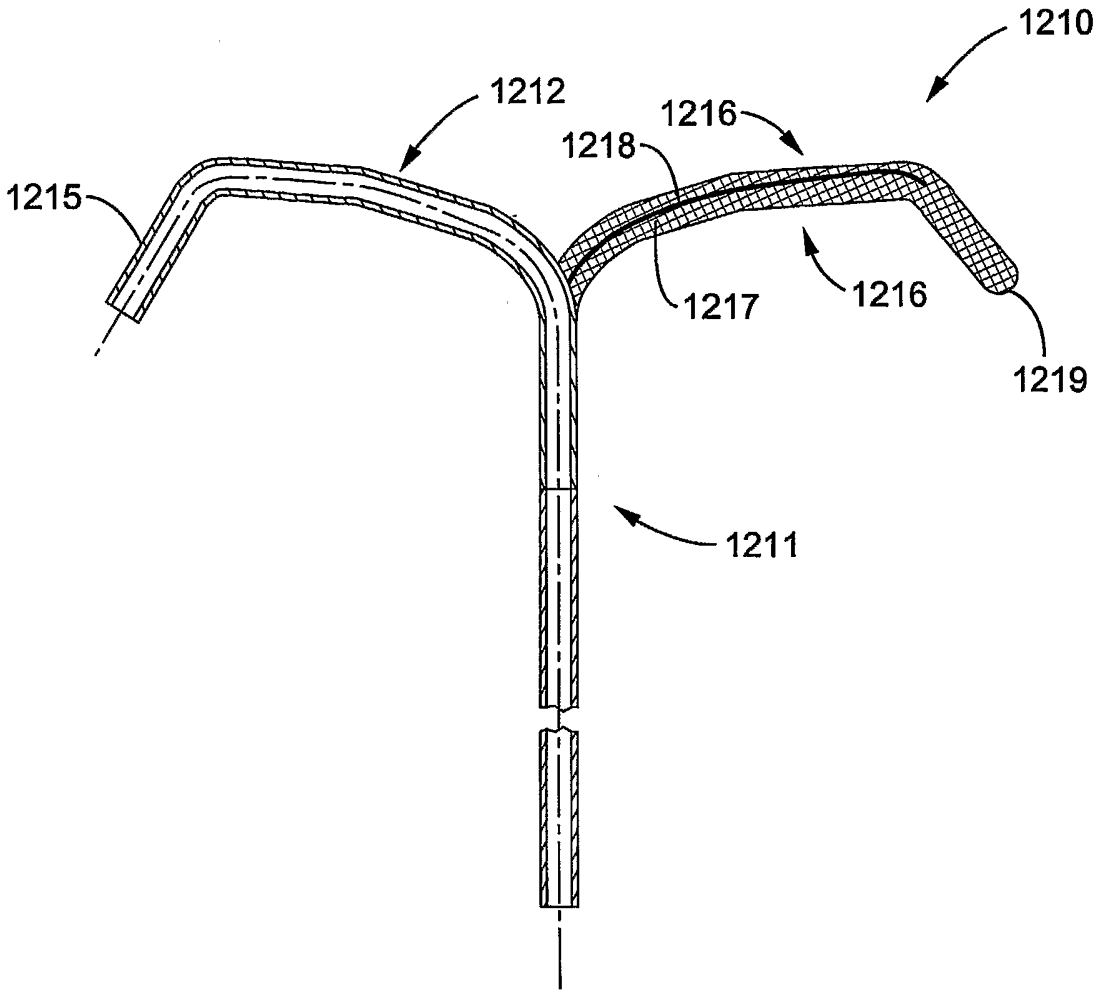

FIG. 61

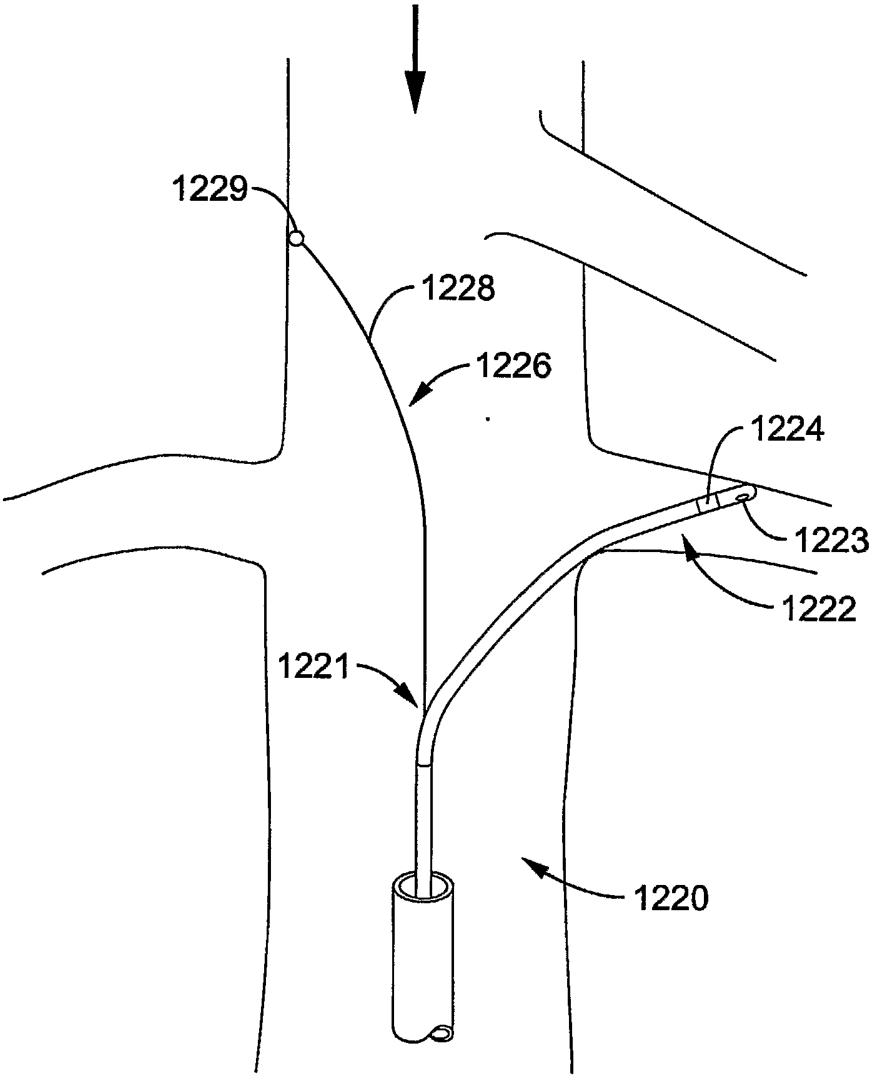

FIG. 62

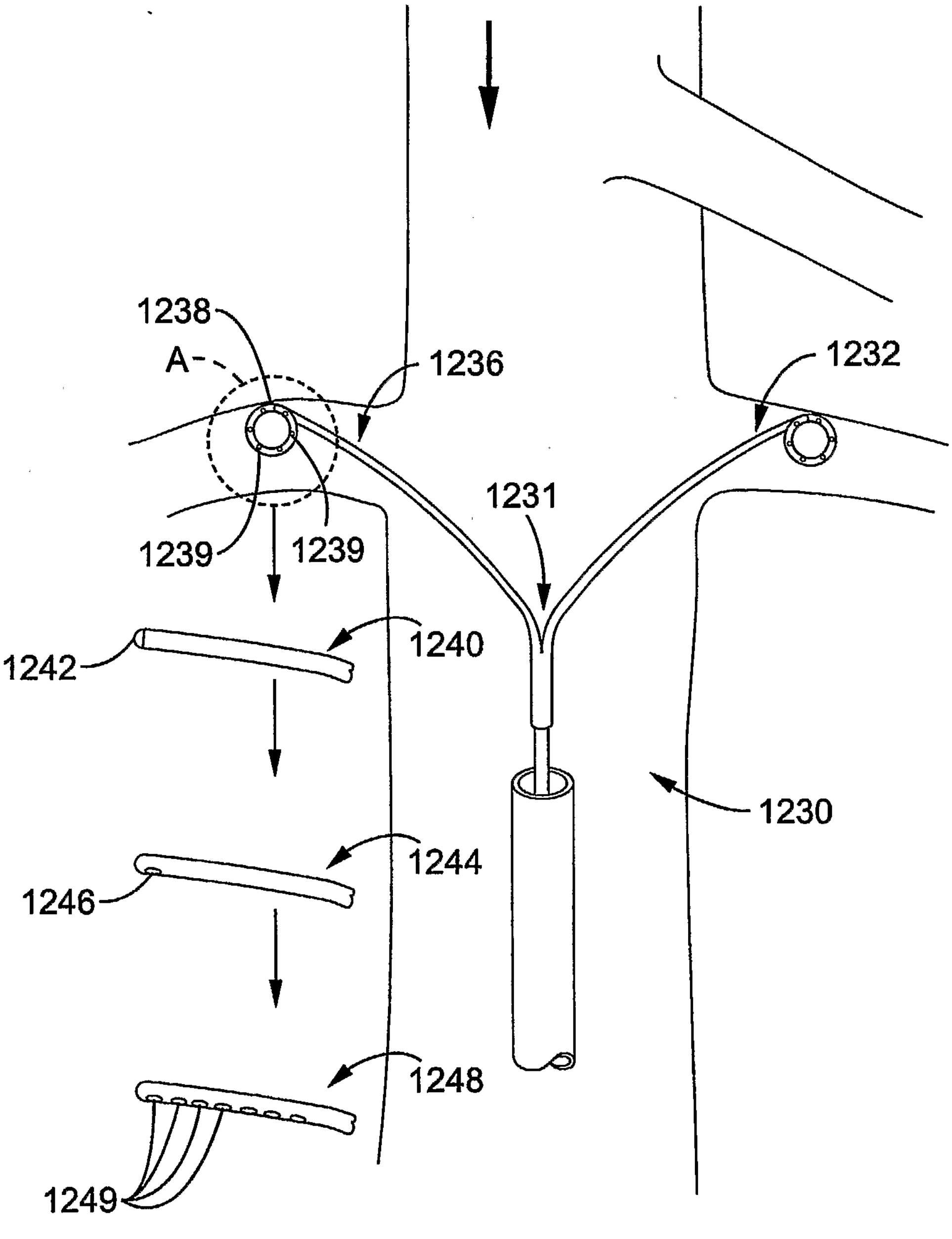
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FIG. 63

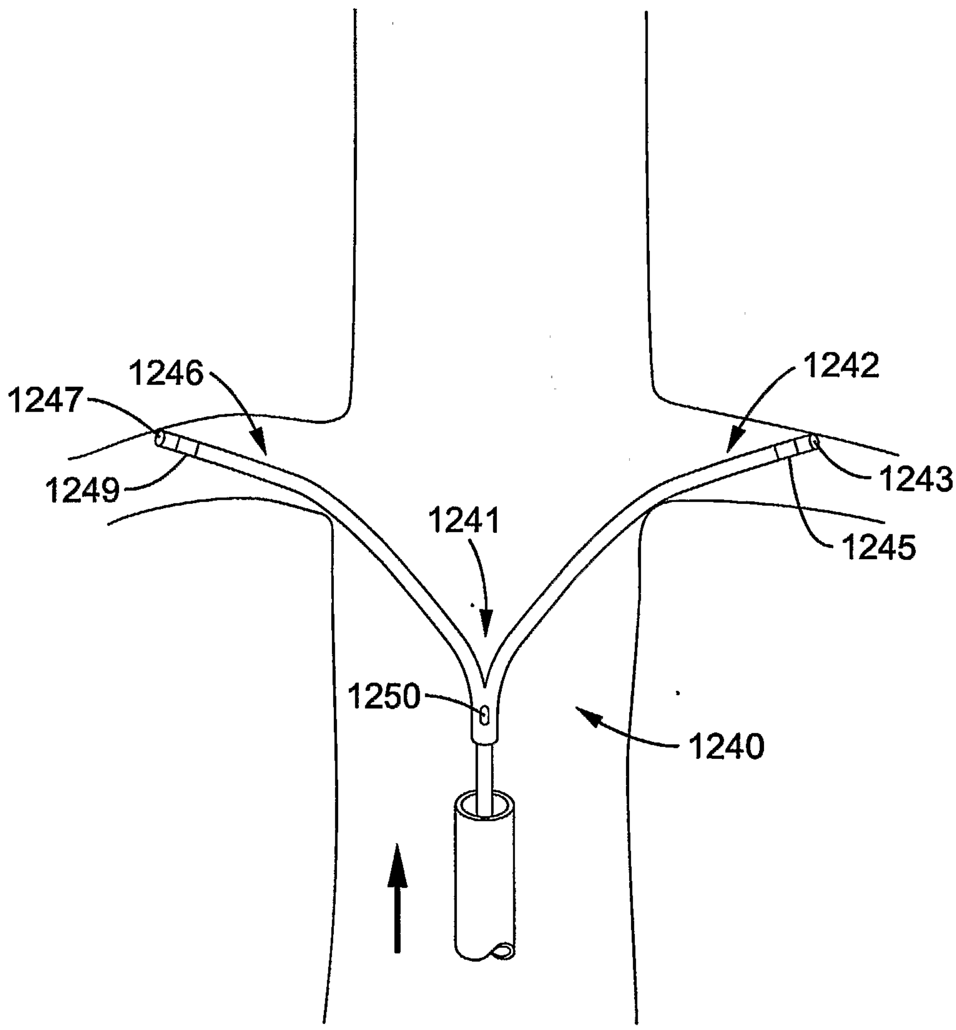

FIG. 64

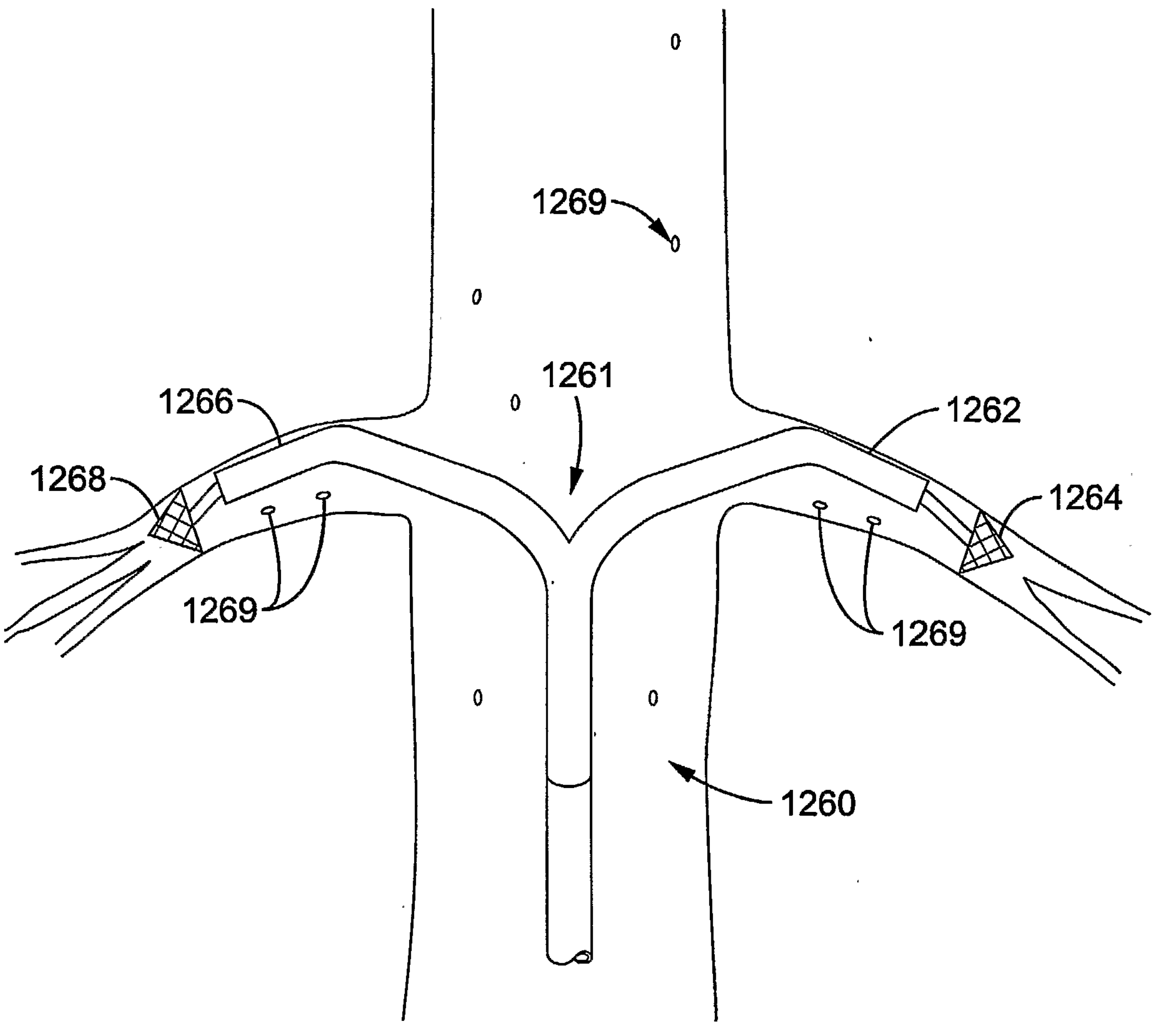

FIG. 65

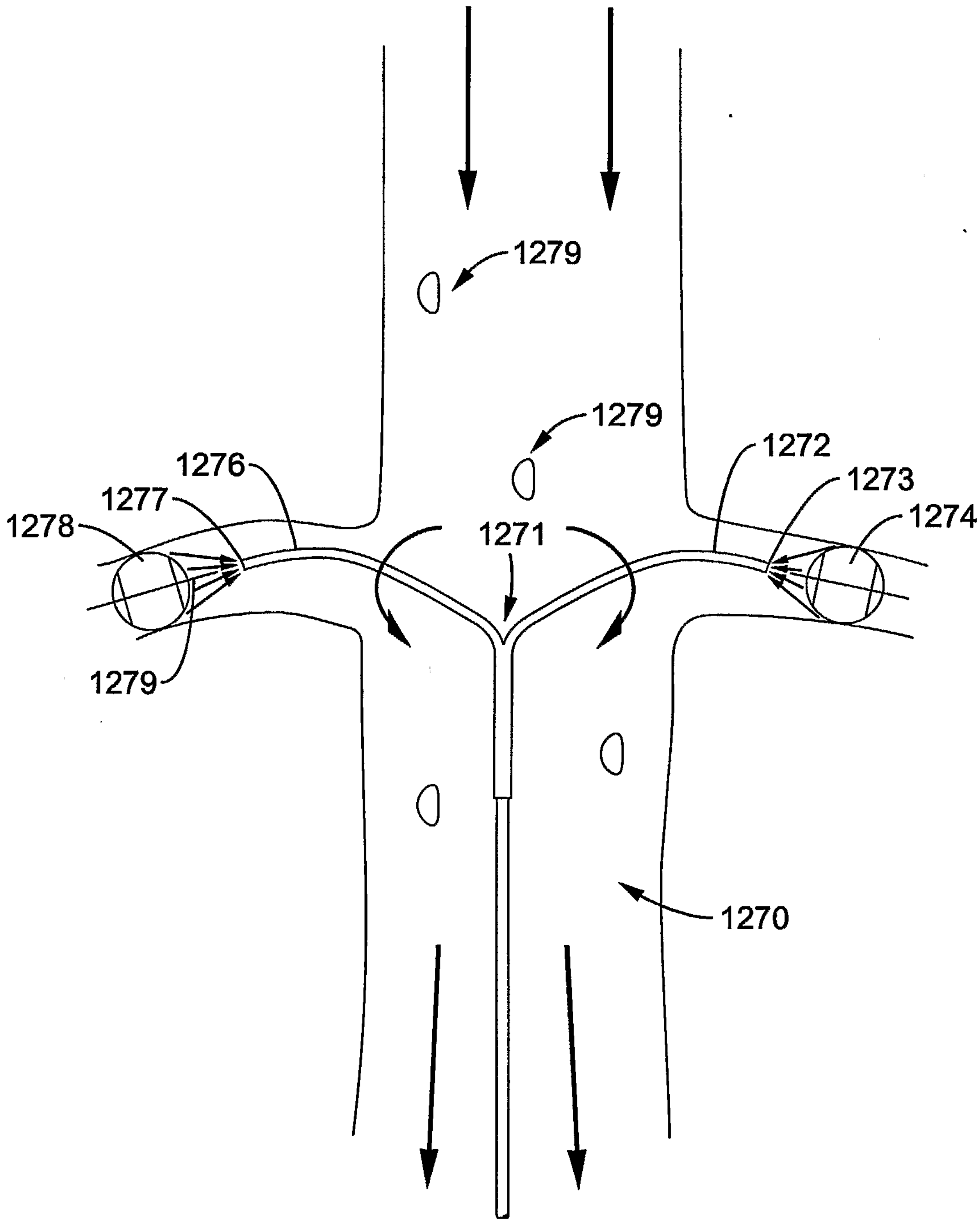

FIG. 66

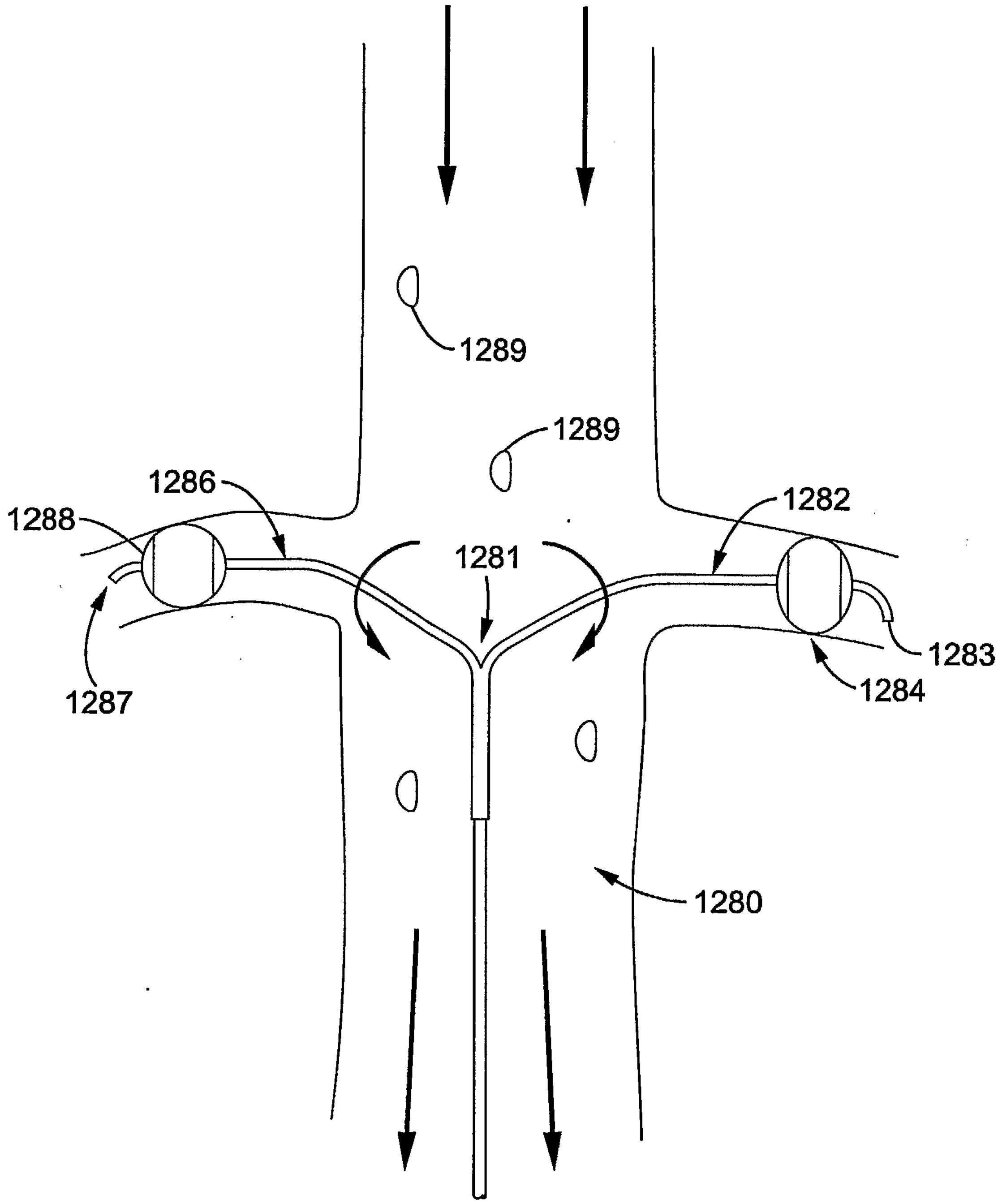

FIG. 67

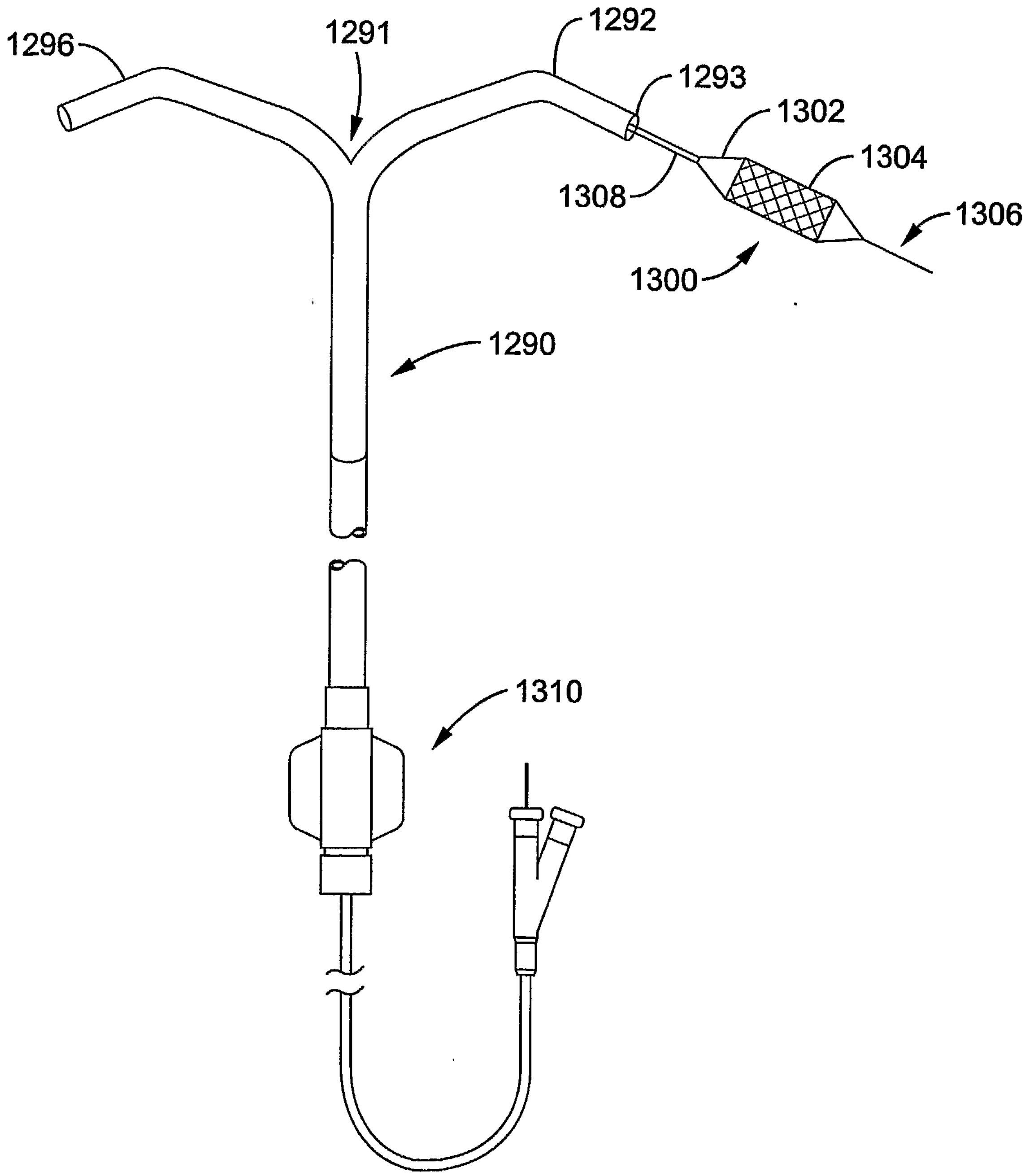

FIG. 68

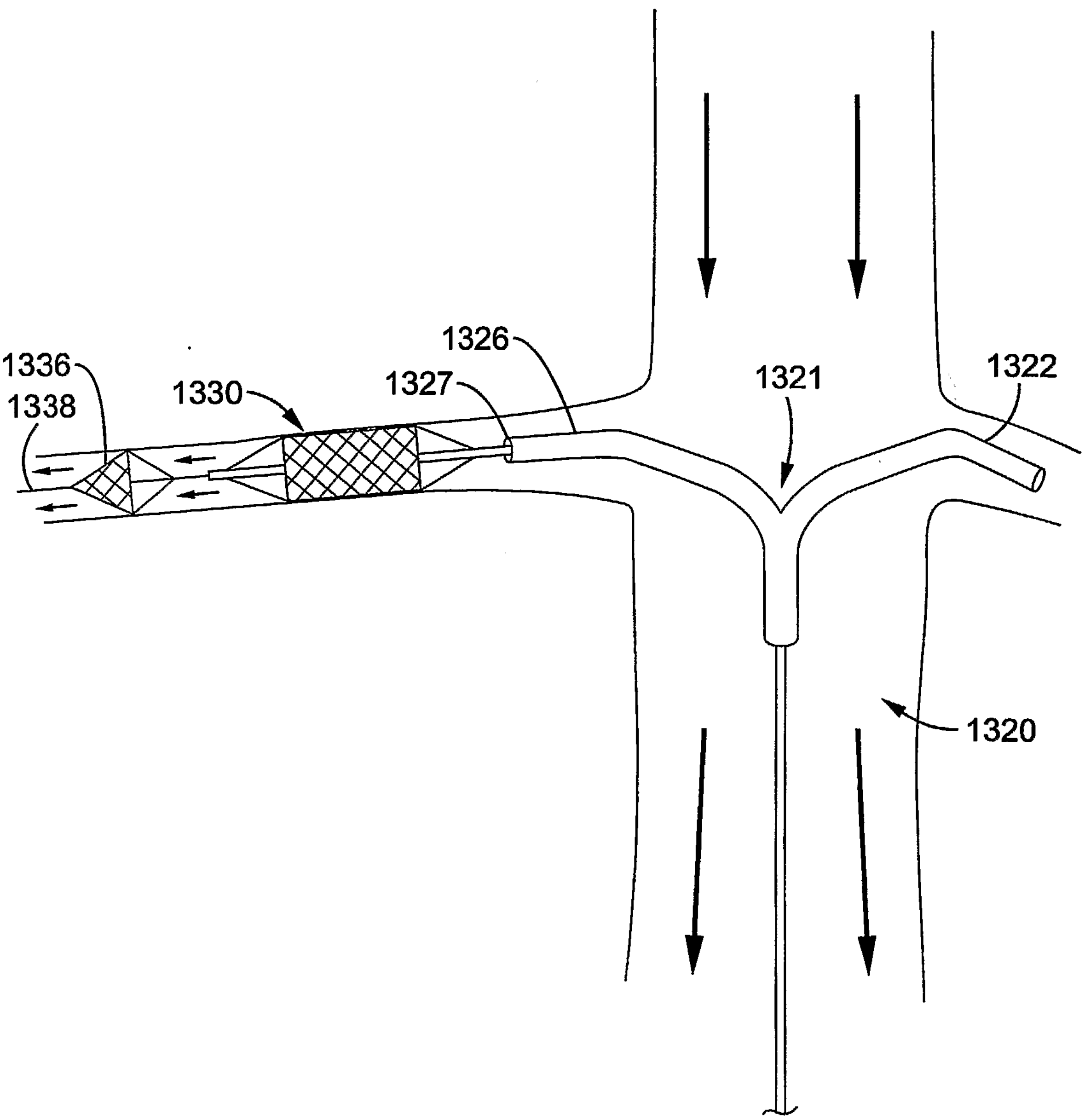

FIG. 69

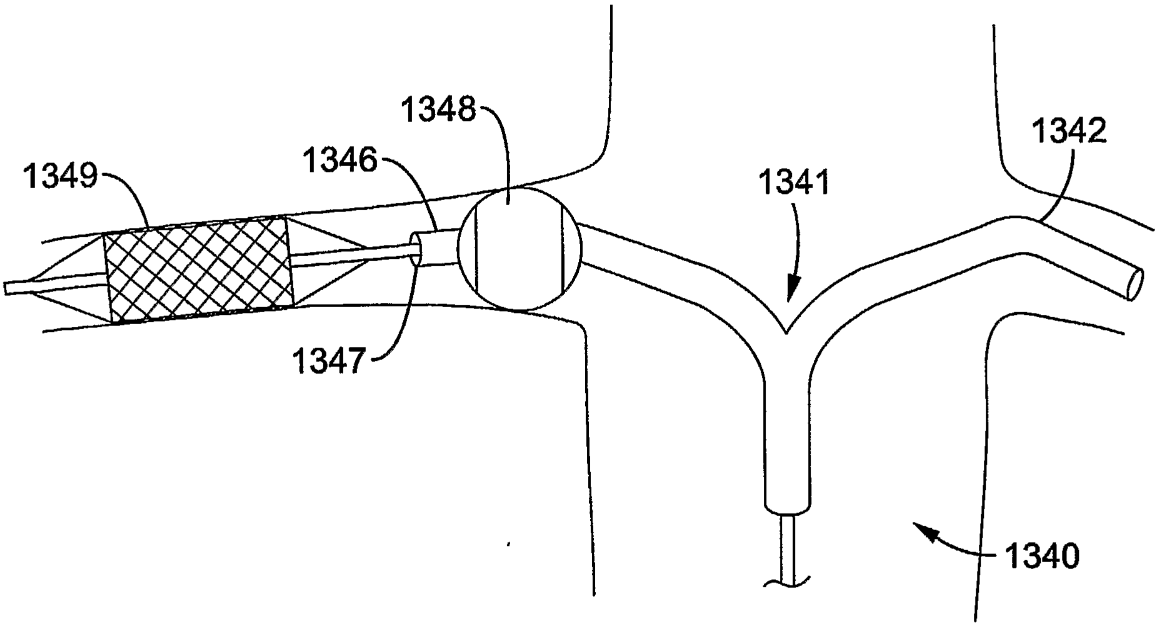

FIG. 70A

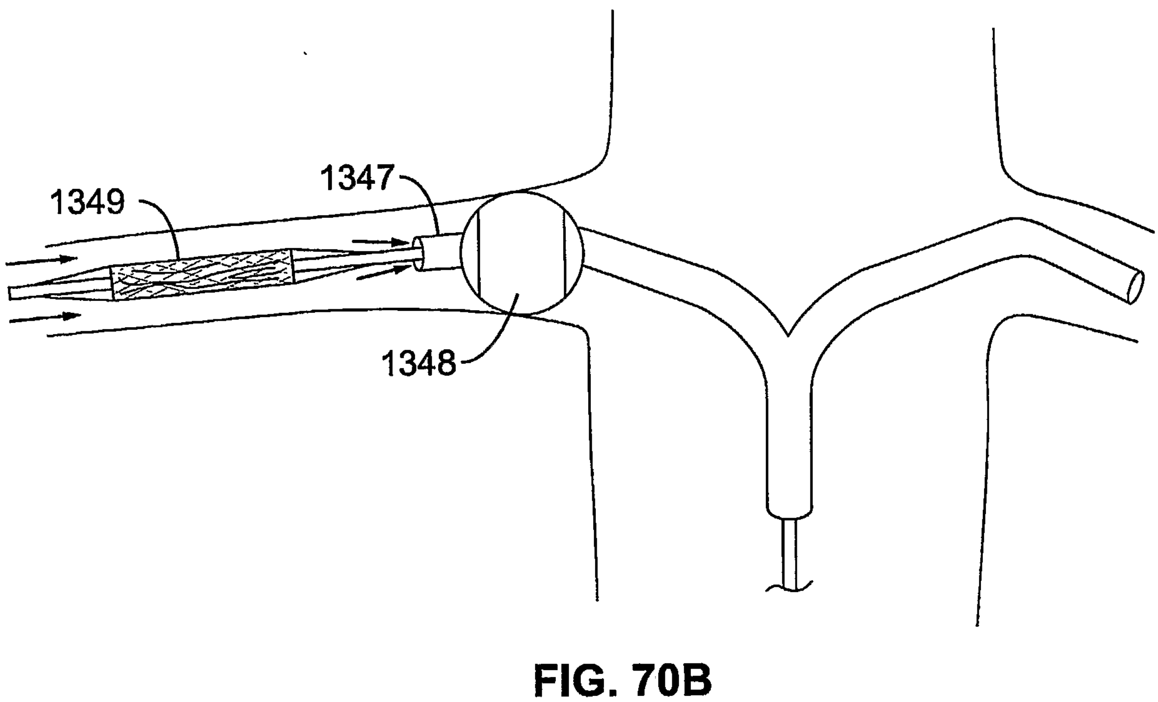

FIG. 70B