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(54) **RF RENAL DENERVATION CATHETER WITH MULTIPLE INDEPENDENT ELECTRODES**

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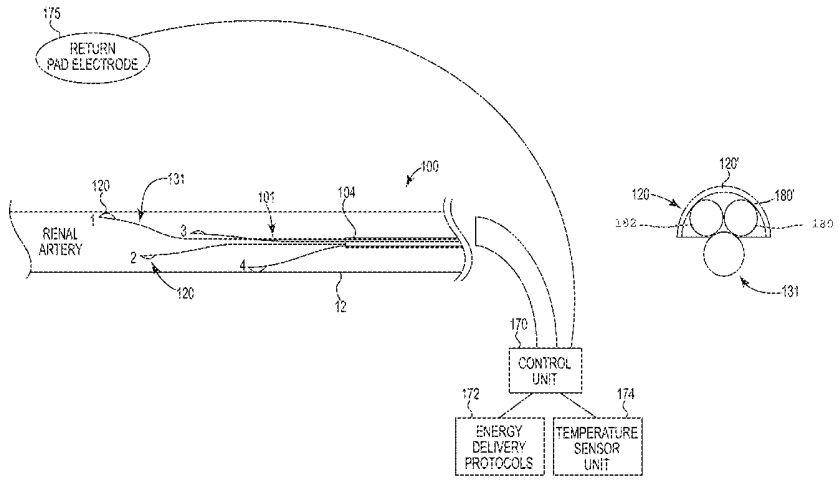
(57) **ABSTRACT**

A catheter includes a flexible shaft having a length sufficient to access a patient's renal artery relative to a percutaneous access location. The catheter includes a multiplicity of elongated resilient members each comprising a pre-formed curve and extendable beyond the catheter. The resilient members are constrained to a low profile when encompassed by a removable sheath, and expand outwardly to assume a predefined shape when removed from the sheath. An electrode assembly is provided at a distal end of each resilient member, and includes an electrode element coupled to an electrical conductor and a thermal sensor in thermal communication with the electrode element. The resilient members have a stiffness sufficient to maintain contact between the electrode elements and an inner wall of the renal artery including irregularities of the inner wall of the renal artery during ablation of perivascular renal nerve tissue.

22 Claims, 9 Drawing Sheets



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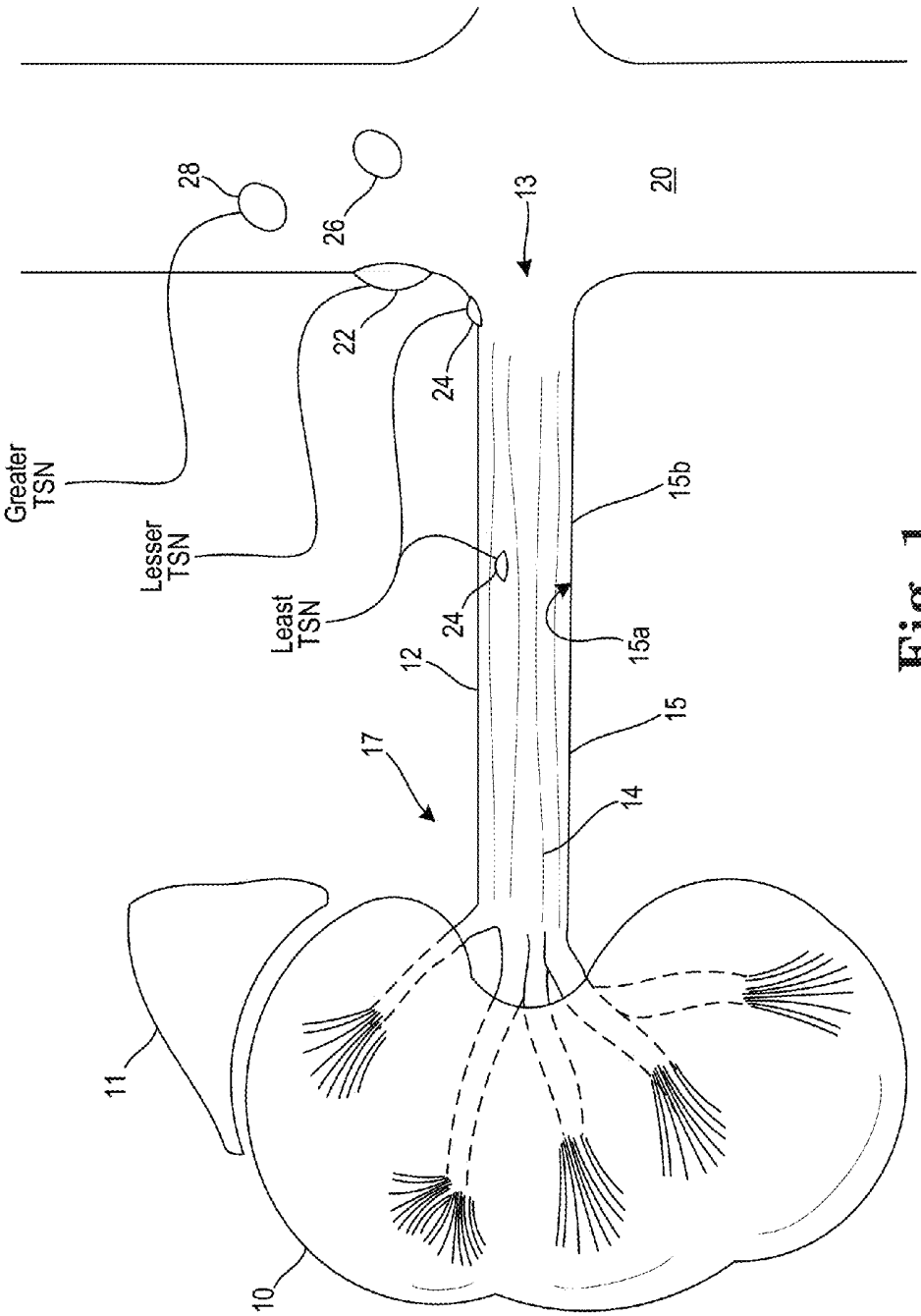
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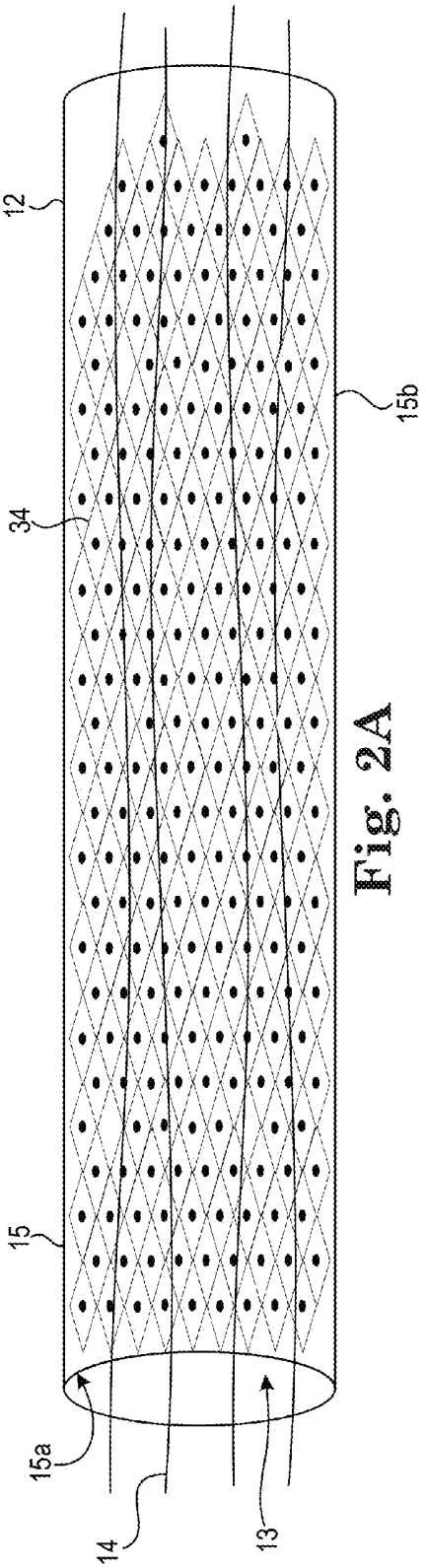

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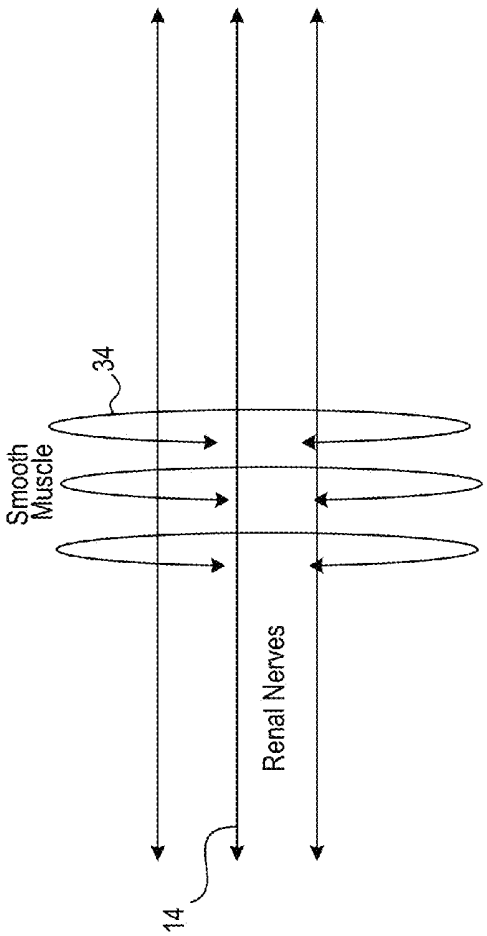

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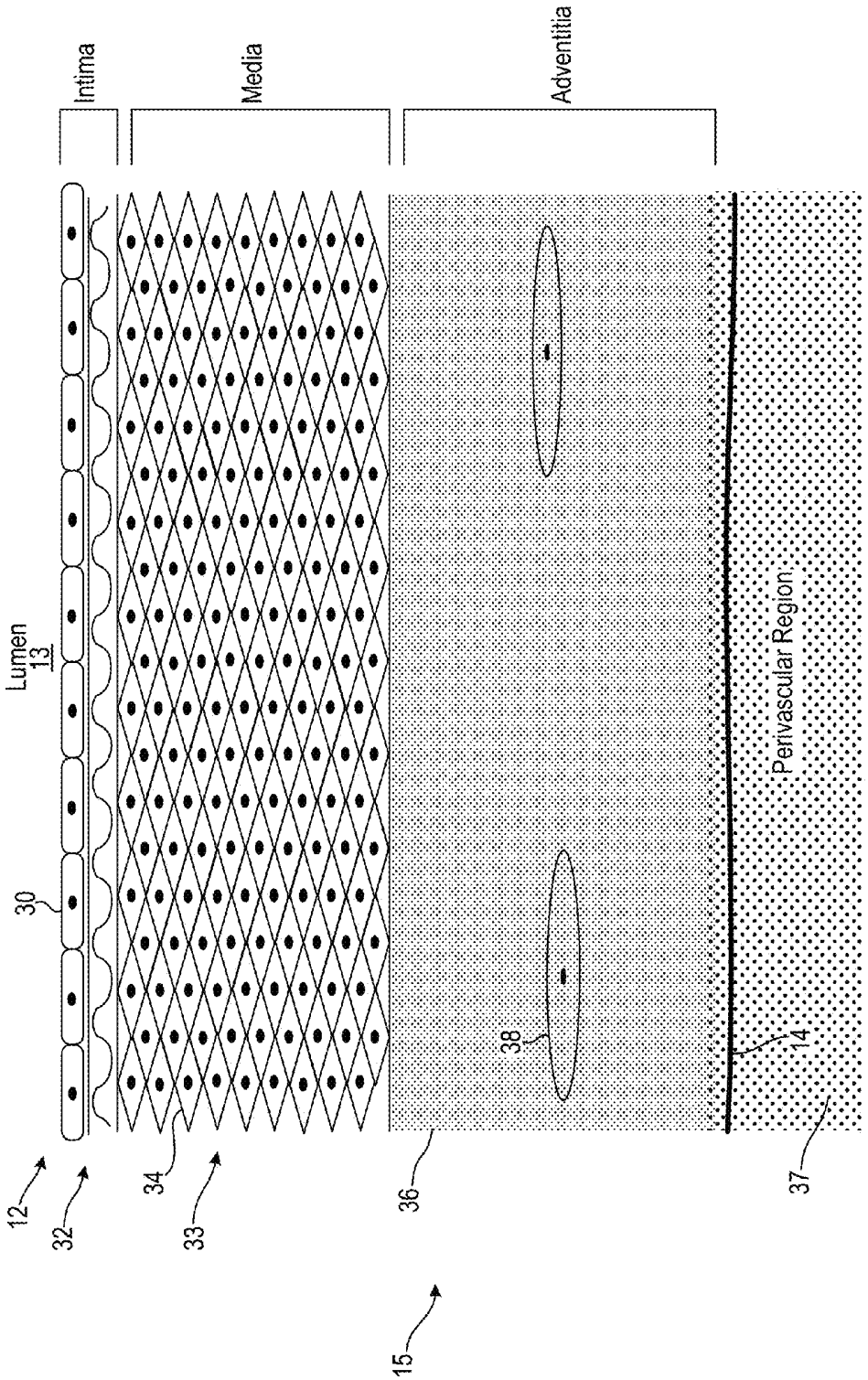
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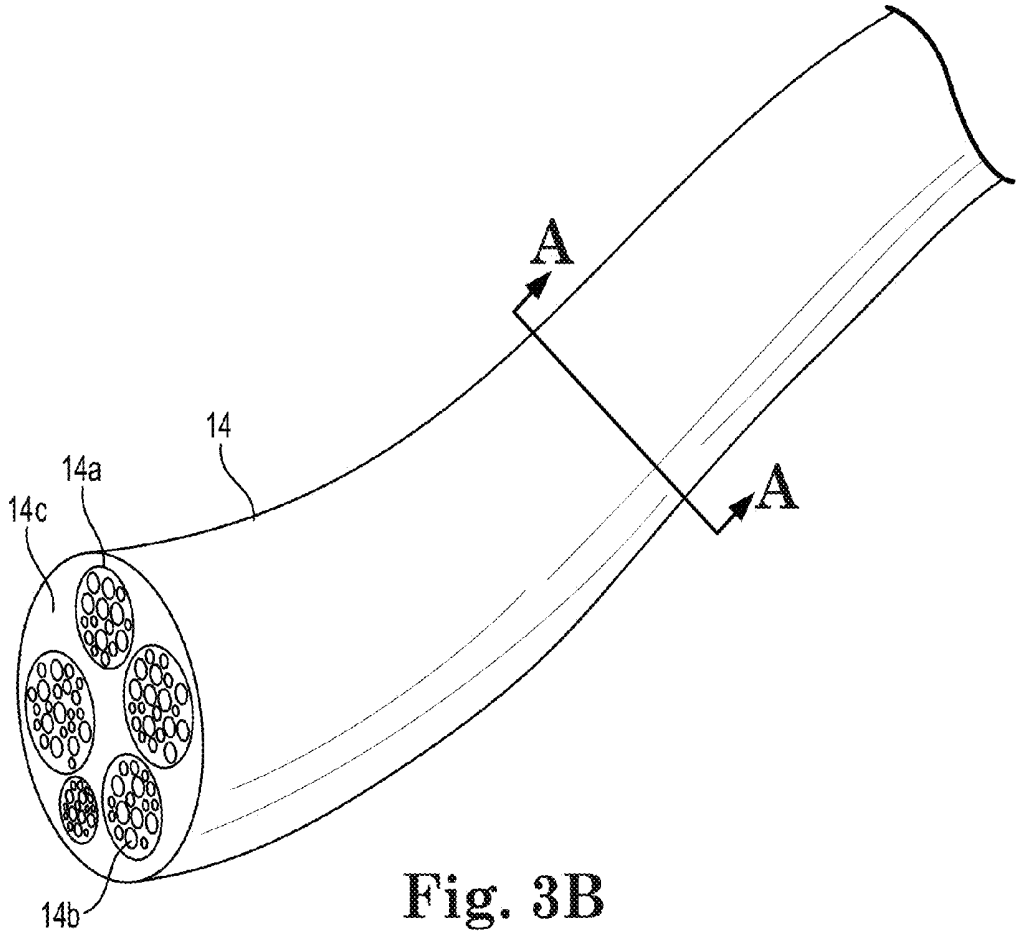

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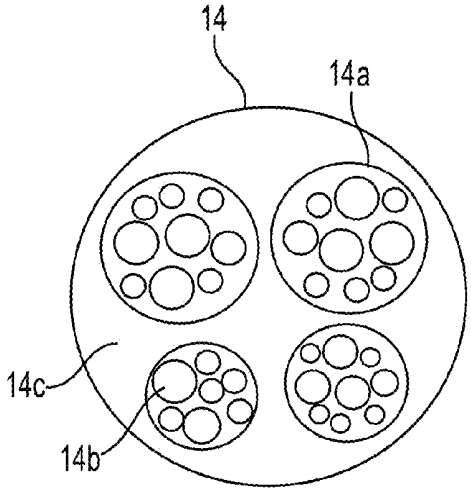

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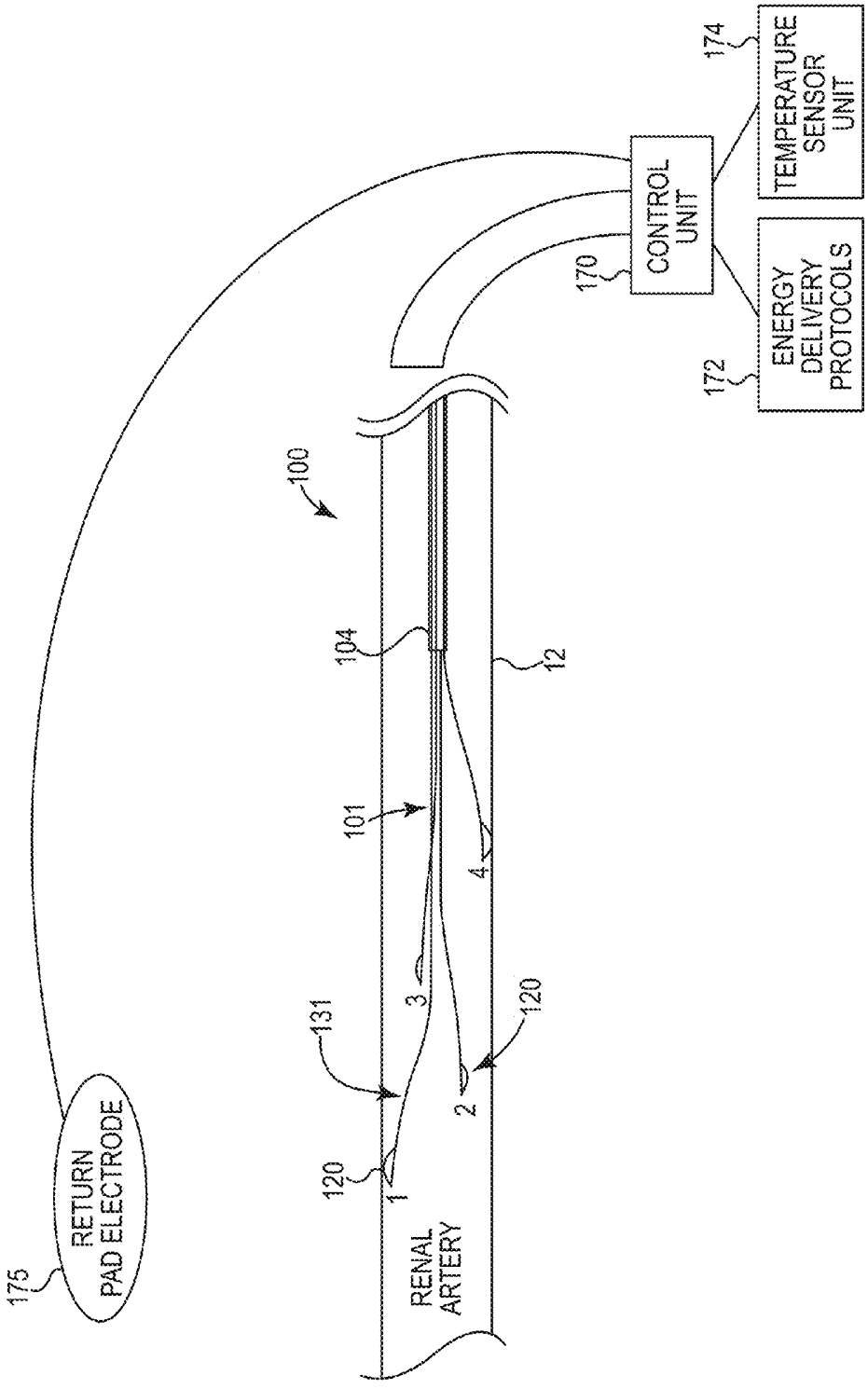
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ENERGY DELIVERY PROTOCOLS
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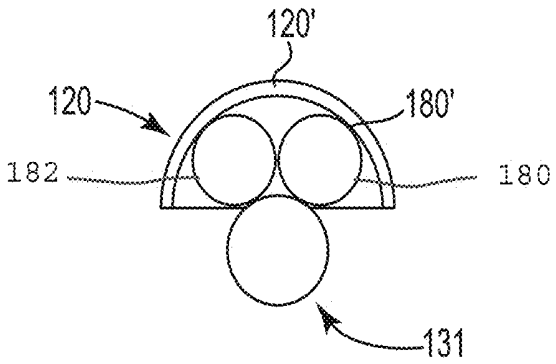
TEMPERATURE SENSOR UNIT

Fig. 4



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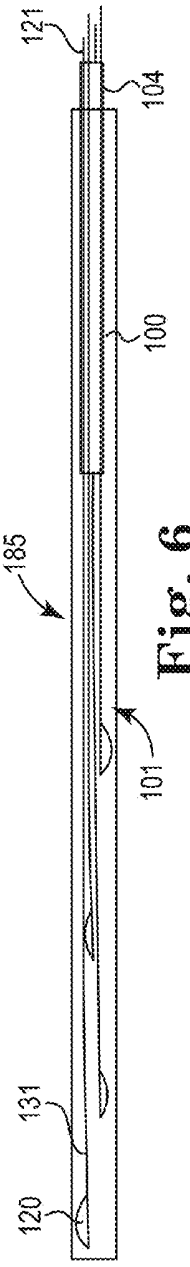

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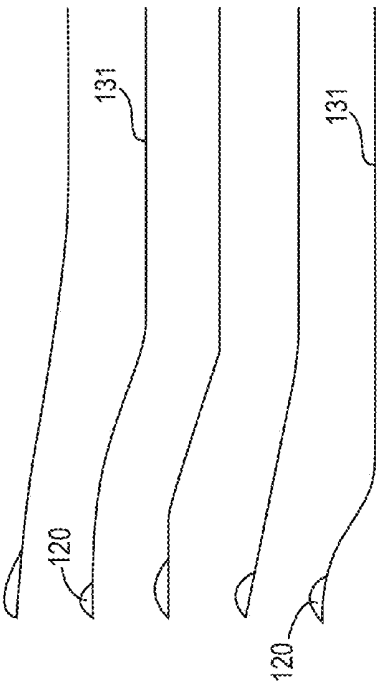

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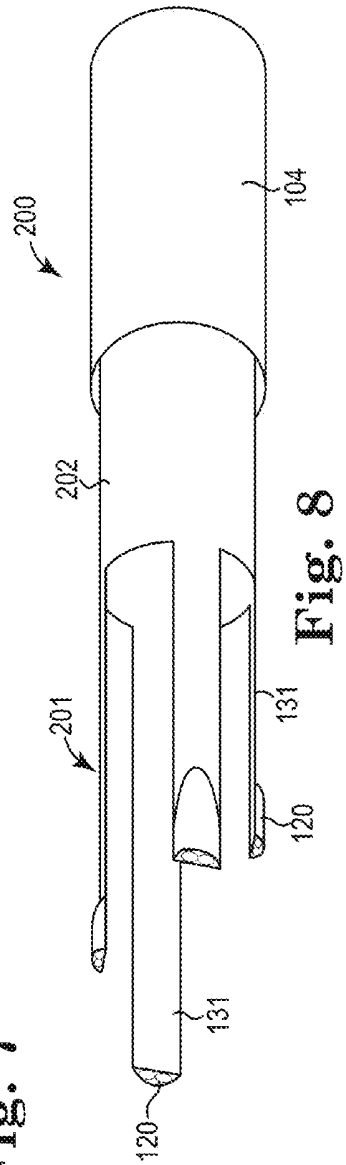

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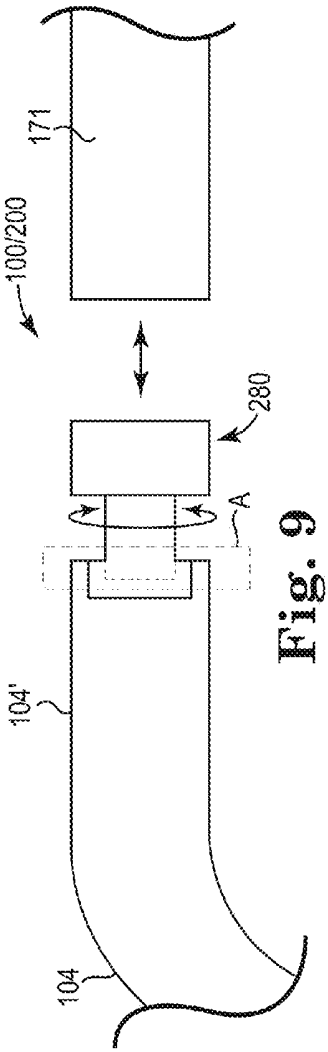
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Fig. 9

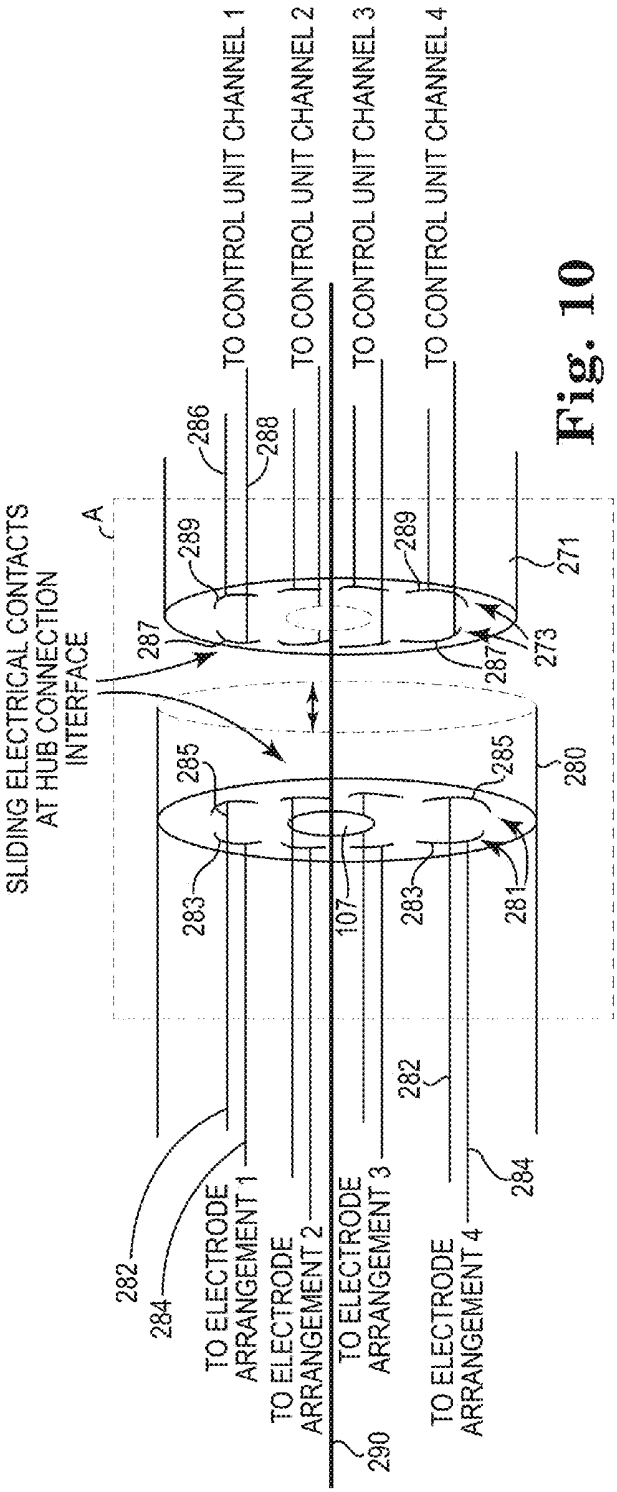
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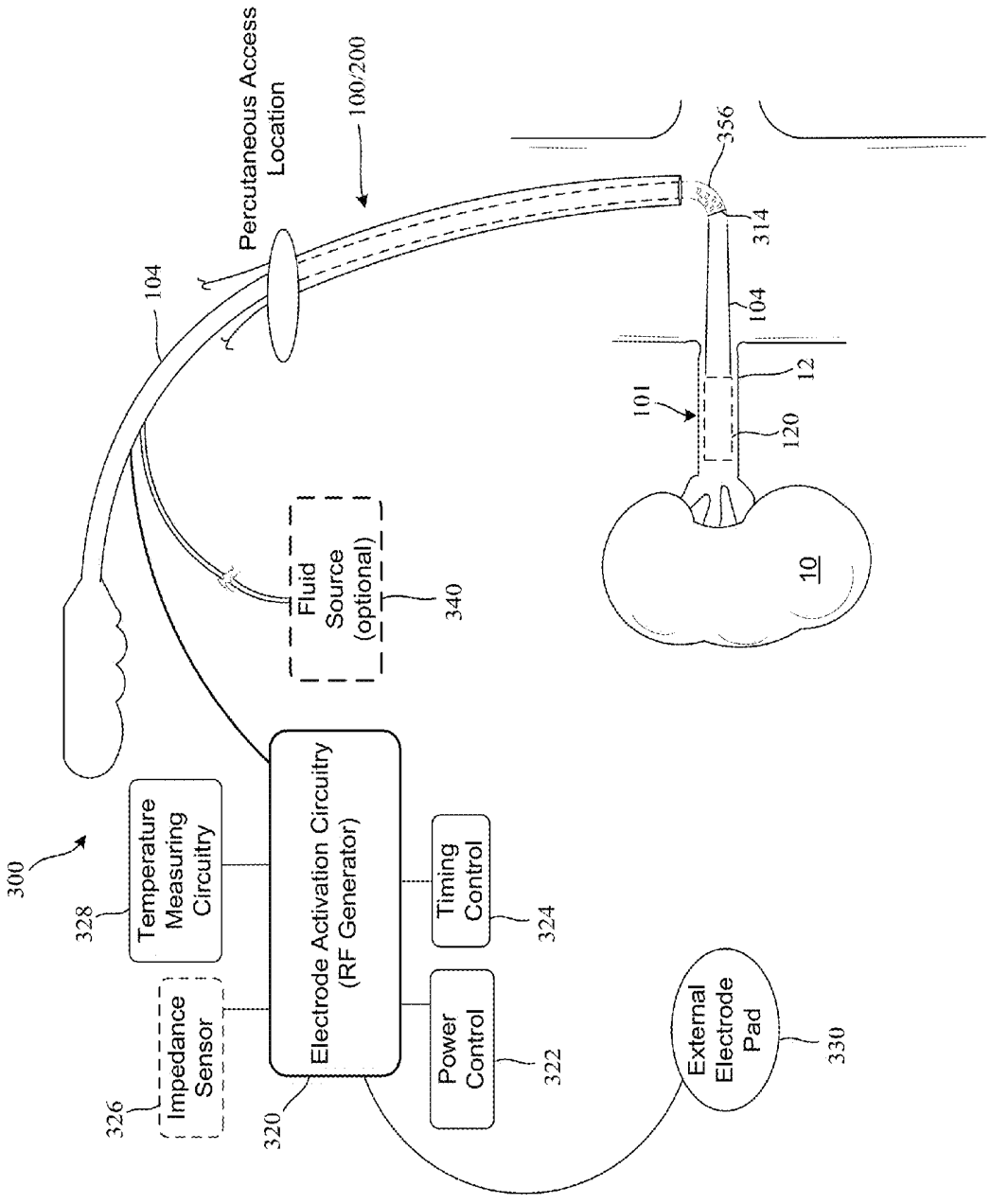
Fig. 10

Fig. 11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326
Impedance Sensor
320
Electrode Activation Circuitry (RF Generator)
Power Control
322
Timing Control
324
External Electrode Pad
330

RF RENAL DENERVATION CATHETER WITH MULTIPLE INDEPENDENT ELECTRODES

RELATED PATENT DOCUMENTS

This application claims the benefit of Provisional Patent Application Ser. No. 61/407,324 filed Oct. 27, 2010, to which priority is claimed pursuant to 35 U.S.C. §119(e) and which are hereby incorporated herein by reference.

SUMMARY

Embodiments of the disclosure are directed to an apparatus which includes a catheter having a flexible shaft and a multiplicity of elongated resilient members each comprising a pre-formed curve and extendable beyond a distal end of the catheter. The resilient members are constrained to a low profile when encompassed by a wall of a removable sheath or a lumen wall of the shaft. When removed from the removable sheath or lumen of the shaft, the resilient members expand outwardly and assume a shape of the pre-formed curve. An electrode assembly is provided at a distal end of each of the resilient members. Each of the electrode assemblies include an electrode element coupled to an electrical conductor and a thermal sensor in thermal communication with the electrode element. The resilient members preferably have a stiffness sufficient to maintain contact between the electrode elements and an inner wall of a target vessel of the body including irregularities of the inner wall of the target vessel.

According to various embodiments, and apparatus includes a catheter having a flexible shaft with a proximal end, a distal end, and a length. The length of the shaft is preferably sufficient to access a patient's renal artery relative to a percutaneous access location. The catheter includes a multiplicity of elongated resilient members each comprising a pre-formed curve and extendable beyond the distal end of the catheter. The resilient members are constrained to a low profile when encompassed by a wall of a removable sheath or a lumen wall of the shaft. When removed from the removable sheath or lumen of the shaft, the resilient members expand outwardly and assume a shape of the pre-formed curve. An electrode assembly is provided at a distal end of each of the resilient members. Each of the electrode assemblies includes an electrode element coupled to an electrical conductor and a thermal sensor in thermal communication with the electrode element. The resilient members preferably have a stiffness sufficient to maintain contact between the electrode elements and an inner wall of the renal artery including irregularities of the inner wall of the renal artery.

In accordance with other embodiments, a method involves constraining a multiplicity of electrode assemblies each supported by one of a multiplicity of elongated support members to a low profile configuration within a removable sheath or a lumen of a catheter shaft. The method also involve moving the electrode assemblies and elongated support members free of the sheath or catheter shaft lumen within a target vessel to allow the electrode assemblies to assume a pre-formed shape and expand outwardly to contact an inner wall of the target vessel. The method further involves resiliently maintaining contact between each electrode assembly and the inner wall of the target vessel including irregularities of the inner wall of the target vessel, and ablating target tissue using the electrode assemblies.

These and other features can be understood in view of the following detailed discussion and the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a right kidney and renal vasculature including a renal artery branching laterally from the abdominal aorta;

FIGS. **2**A and **2**B illustrate sympathetic innervation of the renal artery;

FIG. **3**A illustrates various tissue layers of the wall of the renal artery;

FIGS. **3**B and **3**C illustrate a portion of a renal nerve;

FIG. **4** illustrates an apparatus for ablating target tissue of a vessel of the body in accordance with various embodiments;

FIG. **5** schematically illustrates a cross-section of an electrode assembly mounted at a distal end of a resilient support member in accordance with various embodiments;

FIG. **6** shows a catheter which incorporates a therapy element in a low-profile introduction configuration in accordance with various embodiments;

FIG. **7** shows different configurations of a resilient support member and an electrode assembly in accordance with various embodiments;

FIG. **8** illustrates a treatment element of an ablation catheter which includes a unitary multiple-electrode and resilient support member structure in accordance with various embodiments;

FIGS. **9** and **10** show a swiveling electrical hub for establishing connection with a connector of an external control unit in accordance with various embodiments; and

FIG. **11** shows a representative RF renal therapy apparatus in accordance with various embodiments of the disclosure.

DETAILED DESCRIPTION

Embodiments of the disclosure are directed to apparatuses and methods for ablating extravascular target tissue from within a vessel. Embodiments of the disclosure are directed to apparatuses and methods for ablating perivascular renal nerves from within the renal artery or other nearby vessel for the treatment of hypertension. Apparatuses are directed to an RF catheter with multiple independent electrode arrangements disposed on radially extensible resilient members protruding from a distal tip of an ablation catheter for delivering ablation therapy to target tissue from within a vessel.

Ablation of perivascular renal nerves has been used as a treatment for hypertension. RF electrodes placed in the renal artery can be used to ablate the nerves, but with risk of artery wall injury. To control injury to the artery wall, one approach is to ablate at discrete locations along and around the artery. Maintaining good electrode contact with the artery wall during ablation of perivascular renal nerves has been difficult, often resulting in poor control of tissue temperatures for effective ablation and risk of significant artery damage. In addition, reliable control of electrode position has been difficult. Overcoming catheter or electrode "whip" as it is moved around in the artery, for example, makes desired electrode positioning challenging. Also, multiple repositioning and ablation cycles are considered undesirable and time-consuming.

Embodiments of the disclosure include electrode assemblies provided on pre-formed curved ends of resilient members extending from a distal tip of an ablation catheter. Each of the electrode assemblies include an electrode element, a thermal sensor in thermal communication with the electrode

element, and an electrical conductor electrically coupled to the electrode element. According to various embodiments, the resilient members have a stiffness sufficient to maintain contact between the electrode elements and an inner wall of the renal artery including irregularities of the inner wall of the renal artery when the resilient members are removed from a removable sheath for deployment within the renal artery.

Multiple electrodes spaced circumferentially and axially can be used to ablate the perivascular renal nerves while minimizing renal artery injury. Some prior approaches have included use of a temperature sensor on an ablation catheter system, but a single temperature sensor may provide insufficient information to properly control a system with multiple electrodes placed at various circumferential and axial locations. Embodiments of the disclosure advantageously place multiple electrodes in a predictable pattern, in good contact with the artery wall, and with local temperature monitoring for each electrode.

Embodiments of the disclosure are directed to apparatuses and methods for RF ablation of perivascular renal nerves for treatment of hypertension. Various embodiments disclosed herein are directed to apparatuses and methods that utilize multiple electrodes on a single device for reliable positioning at different axial and circumferential locations in the artery, with temperature and/or impedance monitoring for each electrode, in a simple structure. In some embodiments, the distal portion of an ablation device includes multiple electrode assemblies in a desired spacing and pattern for effective ablation of perivascular renal nerves, so that no repositioning of electrodes is required.

Each electrode assembly includes a curved, protruding electrode structure configured to contact the artery wall during use, a power wire to supply RF energy from an external control unit, and a thermocouple or other temperature sensor. Each electrode assembly is a mounted at the distal portion of an elastic metal apposition wire or ribbon.

According to some embodiments, temperature at or near the electrode elements and/or electrode-tissue can be measured using an optical fiber that extends along the catheter shaft, along the apposition wire, and terminates at or near the electrode assembly. In some configurations, temperature measurements can made by an optical fiber that has evanescent loss that varies with temperature, or by analyzing the Raman scattering of the optical fiber. In some embodiments, the electrical voltage or electric field during ablation can be sensed by nonlinear optical effects in specially-doped optical fiber, which alter the polarization of light as a function of voltage or electric field.

According to some embodiments, impedance can be measured and monitored for each electrode assembly, in a unipolar configuration, or between electrode assemblies, in a bipolar configuration. Changes in tissue impedance due to heating and ablation can be monitored by an external control unit, alone or along with temperature monitoring, to enable automatic or semi-automatic control of an ablation procedure.

The apposition wires may be constructed of superelastic nickel titanium alloy, stainless steel, or other spring-like or self-expanding type materials, and are formed so that they are biased outward to force the electrode assemblies against the artery wall. An external sheath can be used to constrain the electrodes for introduction and delivery of the ablation device. The apposition wires are preferably pre-curved with a relaxed configuration that self-deploys to press the electrode against the artery wall. A variety of curved and bent shapes can be utilized. A wide variety of useful electrode shapes are contemplated.

In other embodiments, a similar multiple-electrode structure is provided. Rather than using multiple separate elastic wires, a single metallic tube is cut to form multiple longitudinal strips or ribbons, with the electrodes mounted at the distal ends of the strips. For example, a Nitinol hypo tube can have strips formed at the distal end by laser cutting or other fabrication method, so that the ends of the strips are at different axial and circumferential locations. An electrode assembly is provided at the distal end of each strip, with a power wire, a thermocouple, and a protruding electrode structure. An external sheath is provided to constrain the device in a low-profile configuration for introduction and advancement within the vasculature.

An external control unit can be coupled to the ablation catheter to provide RF energy and temperature monitoring. A swiveling electrical connector or hub can be provided at the proximal end of the ablation catheter, to allow the catheter hub to rotate. The swiveling electrical connector at the hub end of the ablation catheter is configured to couple to a cable or connector of an external control unit. The swiveling electrical connector provides for rotation of the catheter while being navigated within the vasculature. The swiveling electrical connector can utilize multiple sliding electrical contacts for unlimited rotation, or a multifilament wire structure which allows limited catheter rotation by winding up or unwinding the multifilament structure.

Various embodiments of the disclosure are directed to apparatuses and methods for renal denervation for treating hypertension. Hypertension is a chronic medical condition in which the blood pressure is elevated. Persistent hypertension is a significant risk factor associated with a variety of adverse medical conditions, including heart attacks, heart failure, arterial aneurysms, and strokes. Persistent hypertension is a leading cause of chronic renal failure. Hyperactivity of the sympathetic nervous system serving the kidneys is associated with hypertension and its progression. Deactivation of nerves in the kidneys via renal denervation can reduce blood pressure, and may be a viable treatment option for many patients with hypertension who do not respond to conventional drugs.

The kidneys are instrumental in a number of body processes, including blood filtration, regulation of fluid balance, blood pressure control, electrolyte balance, and hormone production. One primary function of the kidneys is to remove toxins, mineral salts, and water from the blood to form urine. The kidneys receive about 20-25% of cardiac output through the renal arteries that branch left and right from the abdominal aorta, entering each kidney at the concave surface of the kidneys, the renal hilum.

Blood flows into the kidneys through the renal artery and the afferent arteriole, entering the filtration portion of the kidney, the renal corpuscle. The renal corpuscle is composed of the glomerulus, a thicket of capillaries, surrounded by a fluid-filled, cup-like sac called Bowman's capsule. Solutes in the blood are filtered through the very thin capillary walls of the glomerulus due to the pressure gradient that exists between the blood in the capillaries and the fluid in the Bowman's capsule. The pressure gradient is controlled by the contraction or dilation of the arterioles. After filtration occurs, the filtered blood moves through the efferent arteriole and the peritubular capillaries, converging in the interlobular veins, and finally exiting the kidney through the renal vein.

Particles and fluid filtered from the blood move from the Bowman's capsule through a number of tubules to a collecting duct. Urine is formed in the collecting duct and then exits through the ureter and bladder. The tubules are surrounded by the peritubular capillaries (containing the filtered blood). As the filtrate moves through the tubules and toward the collect-

ing duct, nutrients, water, and electrolytes, such as sodium and chloride, are reabsorbed into the blood.

The kidneys are innervated by the renal plexus which emanates primarily from the aorticorenal ganglion. Renal ganglia are formed by the nerves of the renal plexus as the nerves follow along the course of the renal artery and into the kidney. The renal nerves are part of the autonomic nervous system which includes sympathetic and parasympathetic components. The sympathetic nervous system is known to be the system that provides the bodies "fight or flight" response, whereas the parasympathetic nervous system provides the "rest and digest" response. Stimulation of sympathetic nerve activity triggers the sympathetic response which causes the kidneys to increase production of hormones that increase vasoconstriction and fluid retention. This process is referred to as the renin-angiotensin-aldosterone-system (RAAS) response to increased renal sympathetic nerve activity.

In response to a reduction in blood volume, the kidneys secrete renin, which stimulates the production of angiotensin. Angiotensin causes blood vessels to constrict, resulting in increased blood pressure, and also stimulates the secretion of the hormone aldosterone from the adrenal cortex. Aldosterone causes the tubules of the kidneys to increase the reabsorption of sodium and water, which increases the volume of fluid in the body and blood pressure.

Congestive heart failure (CHF) is a condition that has been linked to kidney function. CHF occurs when the heart is unable to pump blood effectively throughout the body. When blood flow drops, renal function degrades because of insufficient perfusion of the blood within the renal corpuscles. The decreased blood flow to the kidneys triggers an increase in sympathetic nervous system activity (i.e., the RAAS becomes too active) that causes the kidneys to secrete hormones that increase fluid retention and vasorestriction. Fluid retention and vasorestriction in turn increases the peripheral resistance of the circulatory system, placing an even greater load on the heart, which diminishes blood flow further. If the deterioration in cardiac and renal functioning continues, eventually the body becomes overwhelmed, and an episode of heart failure decompensation occurs, often leading to hospitalization of the patient.

FIG. **1** is an illustration of a right kidney **10** and renal vasculature including a renal artery **12** branching laterally from the abdominal aorta **20**. In FIG. **1**, only the right kidney **10** is shown for purposes of simplicity of explanation, but reference will be made herein to both right and left kidneys and associated renal vasculature and nervous system structures, all of which are contemplated within the context of embodiments of the disclosure. The renal artery **12** is purposefully shown to be disproportionately larger than the right kidney **10** and abdominal aorta **20** in order to facilitate discussion of various features and embodiments of the present disclosure.

The right and left kidneys are supplied with blood from the right and left renal arteries that branch from respective right and left lateral surfaces of the abdominal aorta **20**. Each of the right and left renal arteries is directed across the crus of the diaphragm, so as to form nearly a right angle with the abdominal aorta **20**. The right and left renal arteries extend generally from the abdominal aorta **20** to respective renal sinuses proximate the hilum **17** of the kidneys, and branch into segmental arteries and then interlobular arteries within the kidney **10**. The interlobular arteries radiate outward, penetrating the renal capsule and extending through the renal columns between the renal pyramids. Typically, the kidneys receive about 20% of total cardiac output which, for normal persons, represents about 1200 mL of blood flow through the kidneys per minute.

The primary function of the kidneys is to maintain water and electrolyte balance for the body by controlling the production and concentration of urine. In producing urine, the kidneys excrete wastes such as urea and ammonium. The kidneys also control reabsorption of glucose and amino acids, and are important in the production of hormones including vitamin D, renin and erythropoietin.

An important secondary function of the kidneys is to control metabolic homeostasis of the body. Controlling hemostatic functions include regulating electrolytes, acid-base balance, and blood pressure. For example, the kidneys are responsible for regulating blood volume and pressure by adjusting volume of water lost in the urine and releasing erythropoietin and renin, for example. The kidneys also regulate plasma ion concentrations (e.g., sodium, potassium, chloride ions, and calcium ion levels) by controlling the quantities lost in the urine and the synthesis of calcitrol. Other hemostatic functions controlled by the kidneys include stabilizing blood pH by controlling loss of hydrogen and bicarbonate ions in the urine, conserving valuable nutrients by preventing their excretion, and assisting the liver with detoxification.

Also shown in FIG. **1** is the right suprarenal gland **11**, commonly referred to as the right adrenal gland. The suprarenal gland **11** is a star-shaped endocrine gland that rests on top of the kidney **10**. The primary function of the suprarenal glands (left and right) is to regulate the stress response of the body through the synthesis of corticosteroids and catecholamines, including cortisol and adrenaline (epinephrine), respectively. Encompassing the kidneys **10**, suprarenal glands **11**, renal vessels **12**, and adjacent perirenal fat is the renal fascia, e.g., Gerota's fascia, (not shown), which is a fascial pouch derived from extraperitoneal connective tissue.

The autonomic nervous system of the body controls involuntary actions of the smooth muscles in blood vessels, the digestive system, heart, and glands. The autonomic nervous system is divided into the sympathetic nervous system and the parasympathetic nervous system. In general terms, the parasympathetic nervous system prepares the body for rest by lowering heart rate, lowering blood pressure, and stimulating digestion. The sympathetic nervous system effectuates the body's fight-or-flight response by increasing heart rate, increasing blood pressure, and increasing metabolism.

In the autonomic nervous system, fibers originating from the central nervous system and extending to the various ganglia are referred to as preganglionic fibers, while those extending from the ganglia to the effector organ are referred to as postganglionic fibers. Activation of the sympathetic nervous system is effected through the release of adrenaline (epinephrine) and to a lesser extent norepinephrine from the suprarenal glands **11**. This release of adrenaline is triggered by the neurotransmitter acetylcholine released from preganglionic sympathetic nerves.

The kidneys and ureters (not shown) are innervated by the renal nerves **14**. FIGS. **1** and **2A-2B** illustrate sympathetic innervation of the renal vasculature, primarily innervation of the renal artery **12**. The primary functions of sympathetic innervation of the renal vasculature include regulation of renal blood flow and pressure, stimulation of renin release, and direct stimulation of water and sodium ion reabsorption.

Most of the nerves innervating the renal vasculature are sympathetic postganglionic fibers arising from the superior mesenteric ganglion **26**. The renal nerves **14** extend generally axially along the renal arteries **12**, enter the kidneys **10** at the

hilum **17**, follow the branches of the renal arteries **12** within the kidney **10**, and extend to individual nephrons. Other renal ganglia, such as the renal ganglia **24**, superior mesenteric ganglion **26**, the left and right aorticorenal ganglia **22**, and celiac ganglia **28** also innervate the renal vasculature. The celiac ganglion **28** is joined by the greater thoracic splanchnic nerve (greater TSN). The aorticorenal ganglia **26** is joined by the lesser thoracic splanchnic nerve (lesser TSN) and innervates the greater part of the renal plexus.

Sympathetic signals to the kidney **10** are communicated via innervated renal vasculature that originates primarily at spinal segments T**10**-T**12** and L**1**. Parasympathetic signals originate primarily at spinal segments S**2**-S**4** and from the medulla oblongata of the lower brain. Sympathetic nerve traffic travels through the sympathetic trunk ganglia, where some may synapse, while others synapse at the aorticorenal ganglion **22** (via the lesser thoracic splanchnic nerve, i.e., lesser TSN) and the renal ganglion **24** (via the least thoracic splanchnic nerve, i.e., least TSN). The postsynaptic sympathetic signals then travel along nerves **14** of the renal artery **12** to the kidney **10**. Presynaptic parasympathetic signals travel to sites near the kidney **10** before they synapse on or near the kidney **10**.

With particular reference to FIG. **2**A, the renal artery **12**, as with most arteries and arterioles, is lined with smooth muscle **34** that controls the diameter of the renal artery lumen **13**. Smooth muscle, in general, is an involuntary non-striated muscle found within the media layer of large and small arteries and veins, as well as various organs. The glomeruli of the kidneys, for example, contain a smooth muscle-like cell called the mesangial cell. Smooth muscle is fundamentally different from skeletal muscle and cardiac muscle in terms of structure, function, excitation-contraction coupling, and mechanism of contraction.

Smooth muscle cells can be stimulated to contract or relax by the autonomic nervous system, but can also react on stimuli from neighboring cells and in response to hormones and blood borne electrolytes and agents (e.g., vasodilators or vasoconstrictors). Specialized smooth muscle cells within the afferent arteriole of the juxtaglomerular apparatus of kidney **10**, for example, produces renin which activates the angiotension II system.

The renal nerves **14** innervate the smooth muscle **34** of the renal artery wall **15** and extend lengthwise in a generally axial or longitudinal manner along the renal artery wall **15**. The smooth muscle **34** surrounds the renal artery circumferentially, and extends lengthwise in a direction generally transverse to the longitudinal orientation of the renal nerves **14**, as is depicted in FIG. **2**B.

The smooth muscle **34** of the renal artery **12** is under involuntary control of the autonomic nervous system. An increase in sympathetic activity, for example, tends to contract the smooth muscle **34**, which reduces the diameter of the renal artery lumen **13** and decreases blood perfusion. A decrease in sympathetic activity tends to cause the smooth muscle **34** to relax, resulting in vessel dilation and an increase in the renal artery lumen diameter and blood perfusion. Conversely, increased parasympathetic activity tends to relax the smooth muscle **34**, while decreased parasympathetic activity tends to cause smooth muscle contraction.

FIG. **3**A shows a segment of a longitudinal cross-section through a renal artery, and illustrates various tissue layers of the wall **15** of the renal artery **12**. The innermost layer of the renal artery **12** is the endothelium **30**, which is the innermost layer of the intima **32** and is supported by an internal elastic membrane. The endothelium **30** is a single layer of cells that contacts the blood flowing though the vessel lumen **13**. Endothelium cells are typically polygonal, oval, or fusiform, and have very distinct round or oval nuclei. Cells of the endothelium **30** are involved in several vascular functions, including control of blood pressure by way of vasoconstriction and vasodilation, blood clotting, and acting as a barrier layer between contents within the lumen **13** and surrounding tissue, such as the membrane of the intima **32** separating the intima **32** from the media **34**, and the adventitia **36**. The membrane or maceration of the intima **32** is a fine, transparent, colorless structure which is highly elastic, and commonly has a longitudinal corrugated pattern.

Adjacent the intima **32** is the media **33**, which is the middle layer of the renal artery **12**. The media is made up of smooth muscle **34** and elastic tissue. The media **33** can be readily identified by its color and by the transverse arrangement of its fibers. More particularly, the media **33** consists principally of bundles of smooth muscle fibers **34** arranged in a thin plate-like manner or lamellae and disposed circularly around the arterial wall **15**. The outermost layer of the renal artery wall **15** is the adventitia **36**, which is made up of connective tissue. The adventitia **36** includes fibroblast cells **38** that play an important role in wound healing.

A perivascular region **37** is shown adjacent and peripheral to the adventitia **36** of the renal artery wall **15**. A renal nerve **14** is shown proximate the adventitia **36** and passing through a portion of the perivascular region **37**. The renal nerve **14** is shown extending substantially longitudinally along the outer wall **15** of the renal artery **12**. The main trunk of the renal nerves **14** generally lies in or on the adventitia **36** of the renal artery **12**, often passing through the perivascular region **37**, with certain branches coursing into the media **33** to enervate the renal artery smooth muscle **34**.

Embodiments of the disclosure may be implemented to provide varying degrees of denervation therapy to innervated renal vasculature. For example, embodiments of the disclosure may provide for control of the extent and relative permanency of renal nerve impulse transmission interruption achieved by denervation therapy delivered using a treatment apparatus of the disclosure. The extent and relative permanency of renal nerve injury may be tailored to achieve a desired reduction in sympathetic nerve activity (including a partial or complete block) and to achieve a desired degree of permanency (including temporary or irreversible injury).

Returning to FIGS. **3**B and **3**C, the portion of the renal nerve **14** shown in FIGS. **3**B and **3**C includes bundles **14***a* of nerve fibers **14***b* each comprising axons or dendrites that originate or terminate on cell bodies or neurons located in ganglia or on the spinal cord, or in the brain. Supporting tissue structures **14***c* of the nerve **14** include the endoneurium (surrounding nerve axon fibers), perineurium (surrounds fiber groups to form a fascicle), and epineurium (binds fascicles into nerves), which serve to separate and support nerve fibers **14***b* and bundles **14***a*. In particular, the endoneurium, also referred to as the endoneurium tube or tubule, is a layer of delicate connective tissue that encloses the myelin sheath of a nerve fiber **14***b* within a fasciculus.

Major components of a neuron include the soma, which is the central part of the neuron that includes the nucleus, cellular extensions called dendrites, and axons, which are cable-like projections that carry nerve signals. The axon terminal contains synapses, which are specialized structures where neurotransmitter chemicals are released in order to communicate with target tissues. The axons of many neurons of the peripheral nervous system are sheathed in myelin, which is formed by a type of glial cell known as Schwann cells. The myelinating Schwann cells are wrapped around the axon, leaving the axolemma relatively uncovered at regularly

spaced nodes, called nodes of Ranvier. Myelination of axons enables an especially rapid mode of electrical impulse propagation called saltation.

In some embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes transient and reversible injury to renal nerve fibers **14***b*. In other embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes more severe injury to renal nerve fibers **14***b*, which may be reversible if the therapy is terminated in a timely manner. In preferred embodiments, a treatment apparatus of the disclosure may be implemented to deliver denervation therapy that causes severe and irreversible injury to renal nerve fibers **14***b*, resulting in permanent cessation of renal sympathetic nerve activity. For example, a treatment apparatus may be implemented to deliver a denervation therapy that disrupts nerve fiber morphology to a degree sufficient to physically separate the endoneurium tube of the nerve fiber **14***b*, which can prevent regeneration and re-innervation processes.

By way of example, and in accordance with Seddon's classification as is known in the art, a treatment apparatus of the disclosure may be implemented to deliver a denervation therapy that interrupts conduction of nerve impulses along the renal nerve fibers **14***b* by imparting damage to the renal nerve fibers **14***b* consistent with neruapraxia. Neurapraxia describes nerve damage in which there is no disruption of the nerve fiber **14***b* or its sheath. In this case, there is an interruption in conduction of the nerve impulse down the nerve fiber, with recovery taking place within hours to months without true regeneration, as Wallerian degeneration does not occur. Wallerian degeneration refers to a process in which the part of the axon separated from the neuron's cell nucleus degenerates. This process is also known as anterograde degeneration. Neurapraxia is the mildest form of nerve injury that may be imparted to renal nerve fibers **14***b* by use of a treatment apparatus according to embodiments of the disclosure.

A treatment apparatus may be implemented to interrupt conduction of nerve impulses along the renal nerve fibers **14***b* by imparting damage to the renal nerve fibers consistent with axonotmesis. Axonotmesis involves loss of the relative continuity of the axon of a nerve fiber and its covering of myelin, but preservation of the connective tissue framework of the nerve fiber. In this case, the encapsulating support tissue **14***c* of the nerve fiber **14***b* is preserved. Because axonal continuity is lost, Wallerian degeneration occurs. Recovery from axonotmesis occurs only through regeneration of the axons, a process requiring time on the order of several weeks or months. Electrically, the nerve fiber **14***b* shows rapid and complete degeneration. Regeneration and re-innervation may occur as long as the endoneural tubes are intact.

A treatment apparatus may be implemented to interrupt conduction of nerve impulses along the renal nerve fibers **14***b* by imparting damage to the renal nerve fibers **14***b* consistent with neurotmesis. Neurotmesis, according to Seddon's classification, is the most serious nerve injury in the scheme. In this type of injury, both the nerve fiber **14***b* and the nerve sheath are disrupted. While partial recovery may occur, complete recovery is not possible. Neurotmesis involves loss of continuity of the axon and the encapsulating connective tissue **14***c*, resulting in a complete loss of autonomic function, in the case of renal nerve fibers **14***b*. If the nerve fiber **14***b* has been completely divided, axonal regeneration causes a neuroma to form in the proximal stump.

A more stratified classification of neurotmesis nerve damage may be found by reference to the Sunderland System as is known in the art. The Sunderland System defines five degrees of nerve damage, the first two of which correspond closely with neurapraxia and axonotmesis of Seddon's classification. The latter three Sunderland System classifications describe different levels of neurotmesis nerve damage.

The first and second degrees of nerve injury in the Sunderland system are analogous to Seddon's neurapraxia and axonotmesis, respectively. Third degree nerve injury, according to the Sunderland System, involves disruption of the endoneurium, with the epineurium and perineurium remaining intact. Recovery may range from poor to complete depending on the degree of intrafascicular fibrosis. A fourth degree nerve injury involves interruption of all neural and supporting elements, with the epineurium remaining intact. The nerve is usually enlarged. Fifth degree nerve injury involves complete transection of the nerve fiber **14***b* with loss of continuity.

Turning now to FIG. **4**, there is illustrated an apparatus for ablating target tissue of a vessel of the body in accordance with various embodiments. According to some embodiments, and as shown in FIG. **4**, a catheter **100** includes a flexible shaft **104** having a proximal end, a distal end, and a length. The length of the shaft is sufficient to access a target vessel of the body, such as a patient's renal artery **12**, relative to a percutaneous access location.

The catheter shaft **104** typically includes a number of lumens, one of which is dimensioned to receive a treatment element **101**. The treatment element **101** includes a multiplicity of resilient support members **131** and an electrode assembly **120** supported by a respective support member **131**. Each of the support members **131** defines an apposition member or wire that preferably incorporates a pre-formed curve. In some embodiments, the treatment element **101** is fixedly disposed within the lumen of the shaft **104** and is delivered to a target vessel using a flexible sheath. In other embodiments, the treatment element **101** is displaceably disposed within the lumen of the shaft **104**, and can be retracted within and extended beyond the distal end of the catheter shaft **104**. In further embodiments, individual or pairs of the support members **131** is/are displaceable within a respective lumen of the shaft **104**. The catheter **100** can be configured as a guiding catheter or may be delivered to a target vessel using a guiding catheter and/or a flexible delivery sheath. The resilient support members **131** can be constrained to a low profile when encompassed by a wall of a removable sheath or a lumen wall of the shaft **104** and, when removed from the removable sheath or lumen of the shaft **104**, the resilient support members **131** expand outwardly and assume a shape of the preformed curve.

In FIG. **4**, four electrodes **120** are shown for purposes of explanation. It is understood that fewer or greater than four electrodes may be provided in various embodiments, and each electrode can be configured to treat a predefined arc of a target vessel (e.g., 30°, 45°, 60°). For example, between three and six electrodes **120** and corresponding support members **131** may be provided so that at least one full revolution of a target vessel's wall can be treated without having to reposition the catheter shaft **104** to complete the ablation procedure.

As discussed above, the resilient support members **131** are constructed to be collapsible when encompassed by a wall of a removable sheath or lumen wall of the shaft **104**, and expand outwardly when removed from the removable sheath or extended from the shaft lumen. The resilient support members **131** are preferably constructed as a single or a multiple element structure, providing high or superelastic properties and good electrical conduction properties. For example, the resilient support members **131** can be constructed to have a shape memory, such that the resilient support members **131**

expand outwardly and assume a shape of the pre-formed curve when in a deployed configuration. The resilient support members **131** may be constructed as apposition wires fabricated from superelastic nickel titanium alloy, stainless steel, or other spring-like or self-expanding type materials, and are formed so that they are biased outward to force the electrodes **120** against the wall of a target vessel, such as the renal artery **12**. The resilient support members **131** can include both a structural spring-like element (such as elastic or superelastic nitinol or a spring-like stainless steel) and a superior electrical conductor (such as stainless steel or platinum), or a single element can provide both the spring-like support and the electrical conductivity properties.

In some embodiments, the resilient support members **131** are constructed to assume different shapes, such that at least some of the resilient support members **131** expand both longitudinally and circumferentially to assume the shape of their respective pre-formed curves. For example, a distal region of the resilient support members **131**, including their respective electrodes **120**, can take on a longitudinally spaced configuration when deployed. By way of further example, a distal region of the resilient support members **131**, including their respective electrodes **120**, can take on a longitudinally spaced and circumferentially offset configuration when deployed. The resilient support members **131** preferably have a stiffness sufficient to maintain contact between the electrodes **120** and an inner wall of the renal artery **12** including irregularities of the renal artery's inner wall.

According to various embodiments, each of the resilient support members **131** is constructed from an electrically conductive material and configured as a wire. Each of the conductive resilient support members **131** is coupled to an electrical conductor disposed in a lumen of the catheter shaft **104**. The conductive resilient support members **131** preferably include an electrically insulating material or coating, and the electrical conductors coupled to the resilient support members **131** are electrically insulated from one another (e.g., by way of insulating material/coating or separate lumens within the shaft **104**). Electrically insulating the respective resilient support members **131** provides for individual activation and deactivation of each electrode **120** in accordance with a predefined energy delivery protocol.

In accordance with various embodiments, each of the resilient support members **131** is either configured as, or coupled to, an individual conductor that extends along the length of the shaft **104** and configured to couple to a control unit **170**. The control unit **170** includes an RF generator that can be controlled to deliver different RF therapies according to various predefined energy delivery protocols **172**.

In some approaches, the electrode assemblies **120** can be configured to simultaneously deliver electrical current to the renal artery wall in accordance with a predefined energy delivery protocol implemented by the control unit **170**. In other approaches, the electrode assemblies **120** can be configured to sequentially deliver electrical current to the renal artery wall in accordance with a predefined energy delivery protocol implemented by the control unit **170**. A unipolar energy delivery configuration can be employed by use of an external pad electrode **175**. A bipolar energy delivery configuration can be implemented by selectively activating combinations of the electrode assemblies **120**. It is noted that multiple electrodes **120** can be situated on an individual resilient support member **131** each of which is coupled to an individual electrical conductor for operation in a bipolar configuration. In some embodiments, as discussed below, the control unit **170** may include a temperature sensor unit **174** that receives signals from a temperature sensor situated at or near the electrodes **120**. The RF generator can be automatically controlled based on temperature at the electrode-tissue interface as indicated by the temperature sensor unit **174**.

FIG. **5** schematically illustrates a cross-section of an electrode assembly **120** mounted at a distal end of a resilient support member **131** in accordance with various embodiments. According to the embodiment shown in FIG. **5**, each electrode assembly has a curved, protruding electrode structure **120'** that defines the energy delivery element of the electrode assembly **120**. The curvature of the protruding electrode structure **120'** allows for inclusion of other components of the electrode assembly **120** within a void defined within the electrode structure **120'**. The outer surface of the electrode structure **120'** is configured to contact the wall of a target vessel, such as the renal artery, during use. A power wire or other type of electrical conductor **180** is electrically coupled to the electrode structure **120'** at an electrical contact location **180'** within the void of the electrode structure **120'**. A temperature sensor **182**, such as a thermocouple, is situated within the electrode structure void and in thermal contact with the electrode structure **120'**. In some embodiment, the temperature sensor **182** is mounted on the outer surface of the electrode **120** or next to the electrode **120** on resilient support member **131**. A proximal section of the electrical conductor **180** and sensor conductor coupled to the temperature sensor **182** may include or be coated with an electrically insulating material.

According to some embodiments, the resilient support member **131**, formed of an electrically conductive material, is coupled to a wire or other elongated conductive member that extends from the resilient support members **131** to the proximal end of the catheter shaft **104**. The wire or elongated conductive member is preferably covered with an electrically insulating material or coating up to a location where the wire or elongated conductive member couples to the electrode **120**.

FIG. **6** shows a catheter **104** which incorporates a therapy element **101** in a low-profile introduction configuration in accordance with various embodiments. FIG. **6** shows an embodiment where the resilient support members **131** are fixedly positioned at the distal end of the catheter shaft **104** and constrained by the lumen wall of a removable delivery sheath **185**. According to one delivery approach, a guidewire (not shown) is advanced through a lumen of the catheter shaft **104** and maneuvered into a destination vessel. The delivery sheath **185** can be advanced over the guidewire and into the destination vessel, and the catheter **100** can be advanced through the delivery sheath **185**, with the resilient support members **131** being constrained to a low profile while encompassed by the delivery sheath **185**.

According to another delivery approach, a guiding catheter and/or a guidewire can be used to access the destination vessel, and an introducer sheath can be advanced over the guiding catheter/guidewire. The guiding catheter/guidewire are removed and the delivery sheath **185** is advanced through the introducer sheath and into the destination vessel. The introducer sheath may be removed or retracted, and the catheter **100** can be advanced through the delivery sheath **185**, with the resilient support members **131** being constrained to a low profile while encompassed by the delivery sheath **185**. It is noted that the catheter **100** may be pre-loaded within the delivery sheath **185** prior to advancement through the introducer sheath and into the destination vessel.

With the therapy element **101** situated at a desired location within the destination vessel (e.g., right renal artery), the delivery sheath **185** is retracted, allowing the resilient support members **131** to expand outwardly, assume their pre-determined curved shape, and establish spring-biased contact

between the electrode assemblies **120** and discrete locations of the destination vessel wall. Ablation of target tissue adjacent the vessel wall may then be performed. After ablating the target tissue, the sheath **185** and/or catheter **100** may be move axially so that the treatment element **101** is retracted into the lumen of the sheath **185**. The catheter **100** and sheath **185** may then be advanced to another destination vessel (e.g., left renal artery), if desired, and the therapy element deployment and ablation procedure repeated. The catheter **100** and sheath **185** may be removed from the body after completion of the ablation procedure(s).

In some embodiments, one or more of the resilient support members **131** can be actively deflectable, such as by actuation of an actuation arrangement (e.g., a pull wire or other elongated member) coupled to the one or more resilient support members **131**. For example, a distal end of the pull wire can be connected to a resilient support member **131** at a location proximal of the electrode **120**. Tensioning of the pull wire causes the distal end of the resilient support member **131** which includes the electrode **120** to bend outwardly, while relaxation of the pull wire allows the distal end of the resilient support member **131** to straighten. In some, embodiments, a resilient support member **131** equipped with a pull wire can be formed from a biocompatible metal that does not have a shape memory or other spring-like or self-expanding action. In other embodiments, a resilient support member **131** equipped with a pull wire can be formed to have a preferred bending action, which causes resilient support member **131** to bend in a desired direction(s) when actuated by the pull wire.

In some embodiments, a multiplicity of pull wires can extend along the length of the catheter shaft **104** and be coupled to respective resilient support members **131**, enabling a clinician to control the deflection of individual resilient support members **131**. In other embodiments, a single pull wire can extend along the length of the catheter shaft **104**, and be coupled to a coupling arrangement situated at the distal end of the catheter shaft **104**. One or more of the resilient support members **131** can be coupled to the coupling arrangement via individual pull wires. A tensile force applied to the single pull wire is translated to the coupling arrangement, which causes tensioning of each individual pull wire and corresponding outward bending of the resilient support members **131**. Relaxation of the single pull wire is also translated to the coupling arrangement, which causes each individual pull wire to relax with corresponding straightening of the resilient support members **131**.

FIG. **7** shows different configurations of a resilient support member **131** in accordance with various embodiments. A variety of curved and bent shapes can be utilized in the construction of the resilient support members **131**. FIG. **7** also shows that a wide variety of useful electrode shapes are possible, some examples of which are illustrated in FIG. **7**.

In accordance with various embodiments, and with reference to FIG. **8**, a treatment element **201** of an ablation catheter **200** is shown which includes a unitary multiple-electrode and resilient support member structure. Rather than using multiple separate elastic wires as in the case of various embodiments discussed hereinabove, a single metallic tube **202** can be cut to form multiple longitudinal strips or ribbons **131**, with electrode assemblies **120** mounted at the distal ends of the strips **131**. For example, a Nitinol hypo tube **202** can have strips formed at the distal end by laser cutting or other fabrication method, so that the ends of the strips **131** are at different axial and circumferential locations. An electrode assembly **120** is provided at the distal end of each strip **131**. Each of the electrode assemblies includes a power wire or other electrical conductor, a temperature sensor (e.g., thermocouple), and a protruding electrode structure of a type previously discussed. An external sheath is preferably used to constrain the device in a low-profile configuration for introduction and advancement within the vasculature.

FIGS. **9** and **10** illustrate a swiveling electrical coupler for coupling a proximal end of an ablation catheter **100/200** to a cable or connector of an external control unit in accordance with various embodiments. The swiveling electrical coupler provides for rotation of the ablation catheter **100/200** as it is guided within the vasculature. FIG. **9** shows a swiveling electrical hub **280** situated at the proximal end **104'** of a catheter shaft **104**. Electrical contacts of the electrical hub **280** are configured to matingly engage electrical contacts of the control unit cable or connector **171**. Engagement features of the electrical hub **280** and connector **171** are configured to allow for limited or unlimited relative rotation (swiveling) therebetween. This relative rotation provided between the electrical hub **280** and connector **171** enhances the maneuverability of the catheter **100/200** as it is navigated through the vasculature.

FIG. **10** shows additional details of a swiveling electrical hub **280** in accordance with various embodiments. In FIG. **10**, the electrical hub **280** includes four sets **281** of sliding electrical contacts **283**, **285**, and the control unit connector **171** includes four sets **273** of sliding electrical contacts **287**, **289**. The sliding electrical contacts **283**, **285** of the electrical hub **280** are coupled to respective power and temperature sensor conductors **282** and **284** for each of four electrode assemblies of the treatment element provided at the distal end of the catheter **100/200**. The sliding electrical contacts **287**, **289** of the control unit connector **171** are coupled to respective power and temperature sensor conductors **286** and **288** for each of four control unit channels. The sliding electrical contact arrangement shown in FIGS. **9** and **10** provides for unlimited relative rotation between the control unit connector **171** and catheter **100/200**. In other embodiments, a multifilament wire structure can be used, which allows limited catheter rotation by winding up or unwinding the multifilament structure.

In the embodiment illustrated in FIG. **10**, the hub **280** includes a central bore **107** dimensioned to allow passage of a guidewire **290** therethrough. In other embodiments, the hub **280** need not include a central bore **107**, but may instead include a guidewire port (not shown) located distal of the hub **280** which is dimensioned to allow passage of a guidewire **290** therethrough. In further embodiments, a swivel hub **280** need not be included in configurations where wind up is not a significant concern.

FIG. **11** shows a representative RF renal therapy apparatus **300** in accordance with various embodiments of the disclosure. The apparatus **300** illustrated in FIG. **11** includes external electrode activation circuitry **320** which comprises power control circuitry **322** and timing control circuitry **324**. The external electrode activation circuitry **320**, which includes an RF generator, is coupled to temperature measuring circuitry **328** and may be coupled to an optional impedance sensor **326**. The catheter **100/200** includes a shaft **104** that incorporates a lumen arrangement configured for receiving a variety of components, such as conductors, pharmacological agents, actuator elements, obturators, sensors, or other components as needed or desired.

The RF generator of the external electrode activation circuitry **320** may include an external pad electrode **330** configured to comfortably engage the patient's back or other portion of the body near the kidneys. Radiofrequency energy produced by the RF generator is coupled to the treatment element

101 at the distal end of the catheter 100/200 by a conductor arrangement disposed in the lumen of the catheter's shaft 104.

Renal denervation therapy using the apparatus shown in FIG. 11 is typically performed using the electrode assemblies 120 of the treatment element 101 positioned within the renal artery 12 and the external pad electrode 330 positioned on the patient's back, with the RF generator operating in a unipolar mode. In this implementation, the electrode assemblies 120 are configured for operation in a unipolar configuration. In other implementations, the electrode assemblies 120 can be configured for operation in a bipolar configuration, in which case the external electrode pad 330 is not needed. The radiofrequency energy flows through the electrode assemblies 120 in accordance with a predetermined activation sequence (e.g., sequential or concurrent) and ablates target tissue which includes renal nerves.

In general, when renal artery tissue temperatures rise above about 113° F. (50° C.), protein is permanently damaged (including those of renal nerve fibers). If heated over about 65° C., collagen denatures and tissue shrinks. If heated over about 65° C. and up to 100° C., cell walls break and oil separates from water. Above about 100° C., tissue desiccates.

According to some embodiments, the electrode activation circuitry 320 is configured to control activation and deactivation of the electrode assemblies 120 in accordance with a predetermined energy delivery protocol and in response to signals received from temperature measuring circuitry 328. The electrode activation circuitry 320 controls radiofrequency energy delivered to the electrode assemblies 120 so as to maintain the current densities at a level sufficient to cause heating of the target tissue to at least a temperature of 55° C.

Temperature sensors 123 situated at the treatment element 101 provide for continuous monitoring of renal artery tissue temperatures, and RF generator power is automatically adjusted so that the target temperatures are achieved and maintained. An impedance sensor arrangement 326 may be used to measure and monitor electrical impedance during RF denervation therapy, and the power and timing of the RF generator 320 may be moderated based on the impedance measurements or a combination of impedance and temperature measurements. The size of the ablated area is determined largely by the size, number, and shape of the electrodes of the electrode sets 120*a*-120*n* at the treatment element 101, the power applied, and the duration of time the energy is applied.

Marker bands 314 can be placed on one or multiple parts of the treatment element 101 to enable visualization during the procedure. Other portions of the catheter 100/200, such as one or more portions of the shaft 104 (e.g., at hinge mechanism 356), may include a marker band 314. The marker bands 314 may be solid or split bands of platinum or other radiopaque metal, for example. This relatively bright image aids the user in determining specific portions of the catheter 100, such as the distal tip of the catheter 100/200, the treatment element 101, and the hinge 356, for example. A braid and/or electrodes of the catheter 100/200, according to some embodiments, can be radiopaque.

In some embodiments, an expandable arrangement, such as a balloon, basket, or mesh structure, can be situated at the distal end of the catheter 100/200. The expandable arrangement is preferably transformable between a low-profile introduction configuration and a deployed configuration. When the distal end of the catheter 100/200 is advanced into a destination vessel, such as a renal artery 12, the expandable arrangement can be activated, such as by pressurizing a balloon or actuating a push/pull member. Deployment of the expandable arrangement vessel serves to center the treatment element 101 within the vessel 12 and provide stabilization for the treatment element 101 during ablation. After completion of the ablation procedure, the expandable structure can be transformed from its deployed configuration to its low-profile introduction configuration, such as by depressurizing a balloon or actuating a push/pull member.

The embodiments shown in the figures have been generally described in the context of intravascular-based ablation of perivascular renal nerves for control of hypertension. It is understood, however, that embodiments of the disclosure have applicability in other contexts, such as energy delivery from within other vessels of the body, including other arteries, veins, and vasculature (e.g., cardiac and urinary vasculature and vessels), and other tissues of the body, including various organs. Various features and functionality of the ablation catheters disclosed in commonly owned co-pending U.S. patent application Ser. No. 13/188,687, filed on Jul. 22, 2011 and incorporated herein by reference, can be incorporated into a treatment catheter in accordance with various embodiments of the disclosure.

It is to be understood that even though numerous characteristics of various embodiments have been set forth in the foregoing description, together with details of the structure and function of various embodiments, this detailed description is illustrative only, and changes may be made in detail, especially in matters of structure and arrangements of parts illustrated by the various embodiments to the full extent indicated by the broad general meaning of the terms in which the appended claims are expressed.

What is claimed is:

1. An apparatus, comprising:

a catheter comprising a flexible shaft having a proximal end, a distal end, and a length, the length of the shaft sufficient to access a patient's renal artery relative to a percutaneous access location;

a plurality of elongated resilient members each comprising a pre-formed curve and extendable beyond the distal end of the catheter, the resilient members constrained to a low profile when encompassed by a wall of a removable sheath or a lumen wall of the shaft and, when removed from the removable sheath or lumen of the shaft, expanding outwardly and assuming a shape of the pre-formed curve, each of the plurality of elongated resilient members including a front side and opposite back side, and an electrical conductor extending along the elongated resilient member; and

an electrode assembly provided at a distal end of each of the resilient members, each of the electrode assemblies comprising:

a curved protruding electrode element disposed over the resilient member and only on the front side of the member, wherein the electrode element protrudes laterally from only a front side of the resilient member, its curvature defining a void, the curved electrode element coupled to the electrical conductor extending along the elongated resilient member and into the void defined by the curved electrode element; and

a thermal sensor situated within the void defined by the curved electrode element, the thermal sensor in thermal communication with the electrode element;

the resilient members having a stiffness sufficient to maintain contact between the electrode elements and an inner wall of the renal artery including irregularities of the inner wall of the renal artery.

2. The apparatus of claim **1**, further comprising the removable sheath, the removable sheath having a length sufficient to access the patient's renal artery relative to the percutaneous access location.

3. The apparatus of claim 1, wherein the catheter shaft comprises a lumen dimensioned to receive a guidewire.

4. The apparatus of claim 1, wherein the thermal sensor further comprises a conductor that extends from the thermal sensor and along the resilient member.

5. The apparatus of claim 1, wherein:

the electrical conductor is electrically coupled to an electrode conductor arrangement of the catheter shaft; and

the thermal sensor further comprises a conductor that extends from the thermal sensor, along the resilient member, and is coupled to a sensor conductor arrangement of the catheter shaft.

6. The apparatus of claim 1, further comprising a swiveling electrical connector provided at a hub end of the catheter, the swiveling electrical connector configured to facilitate catheter hub rotation relative to a non-rotatable cable of an external control unit.

7. The apparatus of claim 6, wherein the catheter shaft and the swiveling electrical connector comprise a lumen dimensioned to receive a guidewire.

8. The apparatus of claim 1, wherein individual elongated resilient members comprise longitudinal metal strips or ribbons, one of the electrode assemblies mounted at the distal end of one of the plurality of longitudinal metal strips or ribbons.

9. The apparatus of claim 1, wherein each of the resilient members comprises an electrically conductive wire constructed from a highly elastic or superelastic material.

10. The apparatus of claim 1, wherein a distal region of each of the resilient members including the respective electrode assemblies take on a longitudinally spaced configuration.

11. The apparatus of claim 1, wherein a distal region of each of the resilient members including the respective electrode assemblies take on a longitudinally spaced and circumferentially offset configuration.

12. The apparatus of claim 1, further comprising an active deflection arrangement coupled to one or more of the resilient members wherein actuation of the active deflection arrangement causes one or more of the resilient members to expand outwardly and assume the shape of the pre-formed curve.

13. An apparatus, comprising:

a catheter comprising a flexible shaft;

a plurality of elongated resilient members each comprising a pre-formed curve and extendable beyond a distal end of the catheter, the resilient members constrained to a low profile when encompassed by a wall of a removable sheath or a lumen wall of the shaft and, when removed from the removable sheath or lumen of the shaft, expanding outwardly and assuming a shape of the pre-formed curve, each of the plurality of elongated resilient members including a front side and opposite back side, and an electrical conductor extending along the elongated resilient member; and

an electrode assembly provided at a distal end of each of the resilient members, each of the electrode assemblies comprising:

a curved protruding electrode element disposed over the resilient member and only on the front side of the member, wherein the electrode element protrudes laterally from only the front side of the resilient member, its curvature defining a void, the curved electrode element coupled to the electrical conductor extending along the elongated resilient member and into the void defined by the curved electrode element; and

a thermal sensor situated within the void defined by the curved electrode element, the thermal sensor in thermal communication with the electrode element;

the resilient members having a stiffness sufficient to maintain contact between the electrode elements and an inner wall of a target vessel of the body including irregularities of the inner wall of the target vessel.

14. The apparatus of claim 13, wherein the catheter shaft comprises a lumen dimensioned to receive a guidewire.

15. The apparatus of claim 13, further comprising a swiveling electrical connector provided at a hub end of the catheter, the swiveling electrical connector configured to facilitate catheter hub rotation relative to a non-rotatable cable of an external control unit.

16. The apparatus of claim 15, wherein the catheter shaft and the swiveling electrical connector comprise a lumen dimensioned to receive a guidewire.

17. The apparatus of claim 13, wherein individual elongated resilient members comprise longitudinal metal strips or ribbons, one of the electrode assemblies mounted at the distal end of one of the plurality of longitudinal metal strips or ribbons.

18. The apparatus of claim 13, further comprising an active deflection arrangement coupled to one or more of the resilient members, wherein actuation of the active deflection arrangement causes the one or more of the resilient members to expand outwardly and assume the shape of the pre-formed curve.

19. A method, comprising:

constraining a plurality of resilient electrode assemblies each supported by one of a plurality of elongated support members to a low profile configuration within a removable sheath or a lumen of a catheter shaft, wherein each of the electrode assemblies has a front side and opposite back side and includes:

a curved protruding electrode element disposed over the elongated support member and only on the front side of the member, wherein the electrode element protrudes laterally from only the front side of the support member, its curvature defining a void, the curved electrode element coupled to an electrical conductor extending along the elongated support member and into the void defined by the curved electrode element; and

a thermal sensor situated within the void defined by the curved electrode element, the thermal sensor in thermal communication with the electrode element;

moving the electrode assemblies and elongated support members free of the sheath or catheter shaft lumen within a target vessel to allow the electrode assemblies to assume a pre-formed curved shape and expand outwardly to contact an inner wall of the target vessel;

resiliently maintaining contact between each electrode assembly and the inner wall of the target vessel including irregularities of the inner wall of the target vessel by the stiffness of the resilient members; and

ablating target tissue using the electrode assemblies.

20. The method of claim 19, further comprising measuring one or both of temperature and impedance at or proximate the electrodes, and moderating target tissue ablation in response to one or both of temperature and impedance measurements.

21. The method of claim 19, further comprising:

after completing ablation, constraining the electrode assemblies and elongated support members to the low profile configuration within the removable sheath or the lumen of the catheter shaft; and

removing the electrode assemblies and elongated support members from the target vessel while in the low profile configuration.

22. The method of claim **19**, wherein the target vessel comprises a renal artery and the target tissue comprises perivascular renal nerves.

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专利名称(译)	具有多个独立电极的RF肾去神经导管		
公开(公告)号	US9220558	公开(公告)日	2015-12-29
申请号	US13/281962	申请日	2011-10-26
[标]申请(专利权)人(译)	WILLARD MARTIN		
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发明人	WILLARD, MARTIN		
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优先权	61/407324 2010-10-27 US		
其他公开文献	US20120116392A1		
外部链接	Espacenet USPTO		

摘要(译)

导管包括柔性轴，该柔性轴的长度足以相对于经皮进入位置进入患者的肾动脉。导管包括多个细长的弹性构件，每个弹性构件包括预先形成的曲线并且可延伸超过导管。当被可移除的护套包围时，弹性构件被约束到低轮廓，并且当从护套移除时，弹性构件向外扩展以呈现预定形状。电极组件设置在每个弹性构件的远端，并且包括耦合到电导体的电极元件和与电极元件热连通的热传感器。弹性构件具有足以保持电极元件和肾动脉内壁之间接触的刚度，包括在血管周围肾神经组织消融期间肾动脉内壁的不规则性。