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(71) Applicant *(for all designated States except US)*: **TIDAL WAVE TECHNOLOGY, INC.** [US/US]; 5597 St. Joseph Fairway, Memphis, TN 38120 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **HIMMELSTEIN, Steven** [US/US]; 5670 Vantage Point, Memphis, TX 38120 (US).

(74) Agent: **COHEN, Mark, S.**; Pearl Cohen Zedek Latzer, LLP, 1500 Broadway, 12th Floor, New York, NY 10036 (US).

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(54) Title: RADIO FREQUENCY ABLATION CATHETER DEVICE

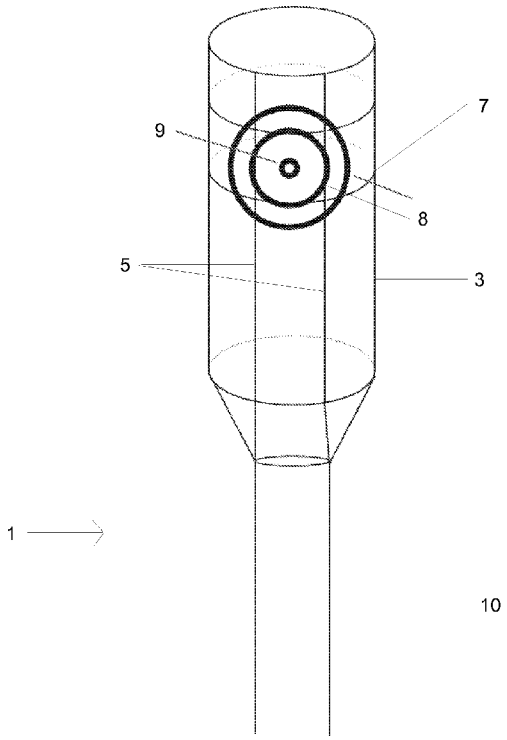

FIG. 1

(57) Abstract: A cylindrically shaped wire frame bearing one or more circularly-configured RF electrodes can be contacted against the inner surface of the aorta, e.g., at the renal artery ostium, such that the circular electrodes ablate the nerve activity circumferentially around the renal artery ostium. The wire frame has a shape memory and can be positioned in a collapsed, non-deployed position at the end of a catheter and encapsulated within a sheath and then advanced longitudinally through the blood vessel, e.g., over a guide wire, to the relevant location within the body lumen. The sheath is then withdrawn, allowing the wire frame to be expanded into its deployed position in which it conforms to the walls of the lumen, so as to thereby allow the electrodes to contact the lumen wall to perform the ablation. The circular RF elements can be positioned around the opening to the renal artery using an imaging catheter that is passed through the hole of the circular RF electrode and at least partially into the entrance of the renal artery, and a balloon can be placed through the imaging catheter into the proximal segment of the renal artery for improved positioning and stabilization. The sheath can also have a longitudinal cut out to allow the imaging catheter to protrude out of the wire frame and into the renal artery to position the device at the renal artery ostium, even while the wire frame is still in its collapsed, non-deployed configuration within the sheath. Once the device has been properly positioned, the sheath is withdrawn and the wire frame is expanded such that the RF electrodes are positioned against the renal artery ostium.

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RADIOFREQUENCY ABLATION CATHETER DEVICE

FIELD OF INVENTION

[0001] The present invention generally relates to a medical apparatus and method for treating vascular tissues through application of radiofrequency energy, and more particularly to an ablation apparatus for treating tissues in a patient by delivering therapeutic radiofrequency energy through a catheter and/or stent to a specific lesion site for nerve or atherosclerotic ablation.

BACKGROUND OF THE INVENTION

[0002] Arteries are the tube-shaped blood vessels that carry blood away from the heart to the body's tissues and organs and are each made up of outer fibrous layer, smooth muscle layer, connecting tissue and the inner lining cells (endothelium). Certain arteries comprise complex structures that perform multiple functions. For example, the aorta, which is a complex structure that performs multiple functions, houses a network of nerves that are helpful in maintaining vascular tone throughout the entire body and each individual organ, sodium and water excretion or reabsorption, and blood pressure control. The electrical activity to these nerves originates within the brain and the peripheral nervous system.

[0003] The kidneys have a dense afferent sensory and efferent sympathetic innervation and are thereby strategically positioned to be the origin as well as the target of sympathetic activation. Communication with integral structures in the central nervous system occurs via afferent sensory renal nerves. Renal afferent nerves project directly to a number of areas in the central nervous system, and indirectly to the anterior and posterior hypothalamus, contributing to arterial pressure regulation. Renal sensory afferent nerve activity directly influences sympathetic outflow to the kidneys and other highly innervated organs involved in cardiovascular control, such as the heart and peripheral blood vessels, by modulating posterior hypothalamic activity. These afferent and efferent nerves traverse via the aorta to their destination end-organ site.

[0004] Some studies suggest that conditions such as renal ischemia, hypoxia, and oxidative stress result in increased renal afferent activity. Stimulation of renal afferent nerves, which may be caused by metabolites, such as adenosine, that are formed during ischemia, uremic toxins, such as urea, or electrical impulses, increases reflex in sympathetic nerve activity and blood pressure.

[0005] An increase in renal sympathetic nerve activity increases renin secretion rate, decreases urinary sodium excretion by increasing renal tubular sodium reabsorption, and decreases renal blood flow and glomerular filtration rate. When nervous activity to the kidney is increased, sodium and water are reabsorbed, afferent and efferent arterioles constrict, renal function is reduced, and blood pressure rises.

[0006] Renin release may be inhibited with sympatholytic drugs, such as clonidine, moxonidine, and beta blockers. Angiotensin receptor blockers substantially improve blood pressure control and cardiovascular effects. However, these treatments have limited efficacy and adverse effects. In addition, many hypertensive patients present with resistant hypertension with uncontrolled blood pressure and end organ damage due to their hypertension.

[0007] Patients with renal failure and those undergoing hemodialysis treatment exhibit sustained activation of the sympathetic nervous system, which contributes to hypertension and increased cardiovascular morbidity and mortality. Signals arising in the failing kidneys seem to mediate sympathetic activation in chronic renal failure. Toxins circulating in the blood as a result of renal failure cause excitation of renal afferent nerves and may produce sustained activation of the sympathetic nervous system.

[0008] Abrogation of renal sensory afferent nerves and renal efferent nerves has been demonstrated to reduce both blood pressure and organ-specific damage caused by chronic sympathetic overactivity in various experimental models. Hence, functional denervation of the human kidney by targeting both efferent sympathetic nerves and afferent sensory nerves appears to be a valuable treatment strategy for hypertension and perhaps other clinical conditions characterized by increased overall nerve activity and particularly renal sympathetic nerve. Functional denervation in human beings may also reduce the potential of hypertension related end organ damage.

[0009] Destruction or reduction in size of cellular tissues in situ has been used in the treatment of many diseases and medical conditions, both alone and as an adjunct to surgical removal procedures. This procedure is often less traumatic than surgical procedures and may be the only alternative where other procedures are unsafe or ineffective. This method, known as ablative treatment, applies appropriate heat to the tissues and causes them to shrink and tighten. Ablative treatment devices have the advantage of using a destructive energy that is

rapidly dissipated and reduced to a nondestructive level by conduction and convection forces of circulating fluids and other natural body processes.

[0010] In many medical procedures, it is important to be able to ablate the undesirable tissue in a controlled and focused way without affecting the surrounding desirable tissue. Over the years, a large number of minimally invasive methods have been developed to selectively destroy specific areas of undesirable tissues as an alternative to resection surgery. There are a variety of techniques with specific advantages and disadvantages, which are indicated and contraindicated for various applications.

[0011] In one technique, elevated temperature (heat) is used to ablate tissue. When temperatures exceed 60°C, cell proteins rapidly denature and coagulate, resulting in a lesion. The lesion can be used to resect and remove the tissue or to simply destroy the tissue, leaving the ablated tissue in place. Heat ablation can also be performed at multiple locations to provide a series of ablations, thereby causing the target tissue to die and necrose. Subsequent to heating, the necrotic tissue is absorbed by the body or excreted.

[0012] Electrical currents may be used to create the heat for ablation of the tissue. Radiofrequency ablation (RF) is a high temperature, minimally invasive technique in which an active electrode is introduced in the undesirable tissue and a high frequency alternating current of up to 500 kHz is used to heat the tissue to coagulation. Radiofrequency (RF) ablation devices work by sending alternating current through the tissue, creating increased intracellular temperatures and localized interstitial heat.

[0013] RF treatment exposes a patient to minimal side effects and risks, and is generally performed after first locating the tissue sites for treatment. RF energy, when coupled with a temperature control mechanism, can be supplied precisely to the apparatus-to-tissues contact site to obtain the desired temperature for treating a tissue. By heating the tissue with RF power applied through electrode tips emerging from a controlled radio-frequency (RF) instrument, the tissue is ablated.

[0014] The theory behind and practice of RF heat lesion has been known for decades, and a wide range of RF generators and electrodes for accomplishing such practice exist. RF therapeutic protocol has been proven to be highly effective when used by electrophysiologists for the treatment of tachycardia, by neurosurgeons for the treatment of Parkinson's disease, and by neurosurgeons and anesthetists for other RF procedures such as Gasserian

ganglionectomy for trigeminal neuralgia and percutaneous cervical cordotomy for intractable pains.

[0015] Denervation of the kidney can be accomplished via the renal artery ostium of the aorta, namely the orifice of the branch off the aorta that opens into the renal artery. Ablation of nerve activity at the renal artery ostium will not affect blood flow from the aorta into the renal artery but will cause the desired effect of denervation of the kidney. One problem in the art, however, is the providing of a treatment surface that can reach all of the desired treatment areas, such as the area circumferentially surrounding the renal artery ostium. While the use of a catheter to deploy energy may be known, it has been difficult to provide ablation about the entire opening of the ostium of an aortic branch blood vessel, such as the renal artery, so as to provide optimal uniform treatment.

[0016] There is an urgent need in the art to develop an approach to effectively ablate the nerve function within the kidney by means of disrupting nerve activity leading to the kidney. This mechanism may be accomplished by ablation of nerve activity at the level of the aorta and specifically at the level of the renal artery ostium. Such an approach would provide the advantage of improving volume status within the body and reducing blood pressure.

[0017] It is desirable to provide an apparatus and system for ablating the nerve function within the kidney by attacking the renal nerve via the renal artery ostium of the aorta.

SUMMARY OF THE INVENTION

[0018] In general, it is an object of the present invention to provide a method and an improved medical ablation apparatus for generating heat, to effectively ablate the nerve function directed to the kidney and within the kidney of a subject or patient.

[0019] It is another object of the present invention to deliver electrical energy, such as RF (radiofrequency) energy, to the inner layer of the aortic wall for ablation of aortic nerve activity.

[0020] It is a further object of the present invention to deliver electrical energy, such as RF (radiofrequency) energy, to the inner layer of the aortic wall for ablation of aortic nerve activity specifically to the kidney via the renal artery ostium of the aorta.

[0021] It is a further object of the present invention to measure nerve activity at the level of the aorta and within the renal artery so as to determine the success of the ablation procedure.

[0022] The present invention is directed to a device, system and method for delivering radiofrequency energy, to the inner layer of a body lumen, particularly the aorta, specifically to the renal artery ostium of the aorta, using a nonconductive catheter.

[0023] In one embodiment, the device comprises a wire frame or stent, e.g., cylindrically shaped, bearing one or more electrodes that are capable of conducting RF energy and that comes in contact with the body tissue. In one embodiment, the one or more electrodes have a circular configuration at one side of the wire frame. If more than one electrode is used, then the circular electrodes are positioned concentrically. The wire frame is contacted against the inner surface of the aorta at the renal artery ostium, such that the circular electrodes ablate the nerve activity circumferentially around the renal artery ostium.

[0024] The wire frame or stent is movable between a non-deployed position and a deployed position. In the non-deployed position, the wire frame is unexpanded, i.e., collapsed. The collapsed wire frame in its non-deployed position at the end of a catheter may be encapsulated within a sheath. The device is advanced longitudinally through the blood vessel, e.g., over a guide wire, to the relevant location within the body lumen, such as within the aorta, and into the desired position within the inner circumference of the vessel, such as at the renal artery ostium of the aorta.

[0025] The sheath is then withdrawn, exposing the wire frame or stent member and allowing the wire frame to be expanded into the deployed position, wherein it conforms to the walls of the lumen, so as to thereby allow the electrodes that are positioned about the wire frame to contact the lumen wall. Heat is then generated to the electrodes by supplying a suitable RF energy source to the apparatus, and the ablation is performed for the ablation of nerve activity, such as nerve activity that leads specifically to the kidney.

[0026] In one embodiment in which the wire frame can be expanded into the deployed position, the wire frame is formed from a material with a shape memory. The natural shape of the wire frame is in an expanded, generally cylindrical configuration, and the wire frame is positioned within the sheath in a collapsed configuration. When the sheath is withdrawn, the constraint on the wire frame keeping it in its collapsed configuration is released, allowing the wire frame to spontaneously expand to its remembered expanded configuration, in which it contacts the wall of the aorta.

[0027] Positioning the circularly-configured RF elements such that they are situated circumferentially around the opening to the renal artery ensures improved delivery of the RF

energy to the designated location at the level of the aortic wall. By including multiple RF elements in a single catheter system, more complete nerve ablation may ensue.

[0028] Furthermore, a mechanism is provided in the catheter design for positioning and securing the catheter at the desired location within the vessel, e.g., the aorta, such that the electrodes can operate at the precise location, namely around the renal artery ostium. This mechanism will properly center the circularly-configured RF electrodes circumferentially around the opening to the renal artery. If the device is not properly positioned, the electrodes can ablate tissue that is not intended to be harmed, causing irreversible damage to other aortic or arterial structures.

[0029] In one embodiment, the positioning mechanism comprises an imaging catheter that allows the user to properly center and position the RF electrodes circumferentially around the opening to the renal artery. The imaging catheter allows the user to view exactly where the renal artery ostium is located. The distal end of the imaging catheter extends from the proximal direction into the wire frame and passes out through the hole of the circularly-configured RF electrodes. The circularly-configured RF electrodes can be positioned at the renal artery ostium by inserting the distal end of the imaging catheter at least partially into the entrance of the renal artery, to allow the device to hold its position within the aorta relative to the renal artery. When the device is so positioned, the wire frame can be expanded to the inner surface of the aorta, allowing the RF electrodes to be centered about the renal artery ostium while they perform their ablative function. Additionally, a balloon can be placed through the imaging catheter into the proximal segment of the renal artery for improved positioning and stabilization of the aortic device as discussed below.

[0030] In certain embodiments, the sheath that envelopes the device has a longitudinal cut out to allow the imaging catheter/positioning device to protrude out of the wire frame and into the renal artery to position the device at the renal artery ostium, even while the wire frame is still in its collapsed, non-deployed configuration within the sheath and even while the sheath has not yet been withdrawn from over the wire frame. Once the device has been properly positioned, e.g., by insertion of the distal end of the imaging catheter at least partially into the entrance of the renal artery, the sheath is withdrawn and the wire frame is expanded. When the device has been properly positioned, expansion of the frame will result in its outer surface resting against the inside surface edges of the aorta, allowing the RF electrodes to be positioned against the renal artery ostium.

[0031] In another embodiment, the positioning mechanism comprises a balloon catheter with an inflatable balloon at its distal end that projects through the imaging catheter and into the entrance to the renal artery. This balloon catheter passes through the imaging catheter and the wire frame from the distal direction and passes through the hole of the circularly-configured RF electrodes, and is inserted at least partially into the entrance of the renal artery. The catheter sheath is then withdrawn and the balloon is then inflated, to allow the device to hold its position within the aorta relative to the renal artery. When the device is so positioned by virtue of the inflatable balloon, the device sheath is retracted so that the wire frame can be expanded to the inner surface of the aorta, allowing the RF electrodes to be positioned against the renal artery ostium so that they may perform their ablative function.

[0032] Also included in this design is a means to measure renal nerve afferent and efferent nerve activity prior to and following RF nerve ablation. By measuring renal nerve activity post procedure, a degree of certainty is provided that proper nerve ablation has been accomplished. Renal nerve activity will be measured through the same electrode mechanism as that required for energy delivery at the level of the renal artery ostium, but also along the renal artery positioning balloon.

[0033] In addition to the above noted functions, the device comprises a mechanism for cooling the aortic wall in order to limit potential damage to the endothelial surface of the aorta while ablative energy is effectively transmitted to the adventitial layer.

[0034] The present invention is also directed to a method for radio-frequency (RF) heat ablation of tissue through the use of one or more circularly-shaped RF electrodes, which are mounted on one side of a cylindrically-shaped wire frame or stent that is mounted in a compressed configuration at the distal end of a catheter within a sheath. In a first step of the invention, the catheter is deployed in the body at the relevant location, such as in the aorta at the location of the ostium of the renal artery. The catheter may be inserted into the body via a natural orifice, a stoma or a surgically created opening that is made for the purpose of inserting the catheter, and insertion of the catheter may be facilitated with the use of a guide wire or a generic support structure or visualization apparatus.

[0035] In the next step, the device must be positioned at the renal artery ostium of the aorta. This positioning can be done via a positioning mechanism, as discussed herein. In one embodiment, an imaging catheter may extend out of the wire frame so as to assist the user in determining where the renal artery ostium is. In an alternative embodiment, a balloon

catheter may extend out of the wire frame, and the balloon is inflated and centers the circular RF elements circumferentially around the ostium of the renal artery.

[0036] In the next step of the invention, once the catheter is at the relevant location, the wire frame is expanded so as to position the wire frame or stent and the RF electrodes that are mounted thereon against the inner surface of the aorta, at the ostium of the desired branch artery. In one embodiment, the RF electrodes are positioned about the opening of the renal artery so as to surround the renal artery ostium.

[0037] In the next step of the invention, RF energy is applied to the RF electrodes that are mounted on the wire frame or stent in order to effect changes in the target tissue. Heat is generated by supplying a suitable energy source to the apparatus, which is comprised of at least one electrode that is in contact with the body tissues through the wire frame or stent. Additionally, coolant -- either stagnant or circulating -- may be employed to cool the inner surface of the vessel wall. This coolant function may provide a form of protection or insulation to the inner vessel wall surface during RF energy activation and heat transfer.

[0038] In one embodiment, the ablation is performed for the ablation of aortic nerve activity that leads specifically to the kidney.

[0039] Other features and advantages of the present invention will become apparent from the following detailed description examples and figures. It should be understood, however, that the detailed description and the specific examples while indicating preferred embodiments of the invention are given by way of illustration only, since various changes and modifications within the spirit and scope of the invention will become apparent to those skilled in the art from this detailed description

BRIEF DESCRIPTION OF THE DRAWINGS

[0040] Embodiments of the invention will be understood and appreciated more fully from the following detailed description in conjunction with the figures, which are not to scale, in which like reference numerals indicate corresponding, analogous or similar elements, and in which:

[0041] Figure 1 shows a first embodiment of a device for delivering radiofrequency energy to the renal artery ostium;

[0042] Figure 2 shows a cross-sectional exploded perspective view of the first embodiment of the device for delivering radiofrequency energy to the walls of a body lumen; and

[0043] Figure 3 shows a further cross-sectional view of the first embodiment of the device for delivering radiofrequency energy to the walls of a body lumen; and

[0044] Figure 4 shows a further cross-sectional view of the first embodiment of the device for delivering radiofrequency energy to the walls of a body lumen; and

[0045] Figure 5 shows a perspective view of a sheath for use in the first embodiment of the device for delivering radiofrequency energy to the walls of a body lumen.

DETAILED DESCRIPTION OF THE INVENTION

[0046] As used herein, "proximal" refers to a portion of an instrument closer to an operator, while "distal" refers to a portion of the instrument farther away from the operator.

[0047] As used herein, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. For example, the term "a wire" includes one or more wires and can be considered equivalent to the term "at least one wire."

[0048] The term "subject" or "patient" refers in one embodiment to a mammal including a human in need of therapy for, or susceptible to, a condition or its sequelae. The subject or patient may include dogs, cats, pigs, cows, sheep, goats, horses, rats, and mice and humans.

[0049] Figure 1 is a drawing of one embodiment of a device 1 for delivering radiofrequency energy to the walls of a body lumen. In one embodiment, radiofrequency energy is delivered to the walls of the renal artery or aorta. In one embodiment of the device, radiofrequency energy is delivered using a nonconductive catheter.

[0050] In one embodiment, the device 1 includes a substantially tubular catheter (not shown), namely a long, thin, tube-like device, having proximal and distal openings, preferably constructed from a nonconductive material. The catheter can be any type of catheter, as are well known to those in the art, having a proximal end for manipulation by an operator and a distal end for operation within a patient. The distal end and proximal end preferably form one continuous piece. In a preferred embodiment, the catheter is nonconductive. As will be discussed in greater detail below, the catheter is used as a delivery system for delivering a device containing radiofrequency electrodes to the desired site for nerve ablation.

[0051] In one embodiment, as is known in the art, a guide wire 11, such as one having 0.035" thickness, may first be inserted into the patient's vascular system via a natural orifice,

a stoma or a surgically created opening that is made for the purpose of inserting the catheter, e.g. through the groin, and advanced to the desired location.

[0052] Next, a catheter is inserted into the patient and threaded over the guide wire to the desired location. In preferred embodiments, the device 1 is advanced to the desired location within the patient's vascular system with, e.g., a rapid exchange (RX) or over-the-wire wire (OTW) delivery system. Radiographic contrast media may be injected at the beginning of the procedure, e.g., through the imaging catheter port, in order to assist in manipulation of the instruments.

[0053] In one embodiment, the device 1 comprises a wire frame or stent 3 bearing one or more electrodes 8 that are capable of conducting RF energy and that come in contact with the body tissue. In one embodiment, the one or more electrodes 8 have a generally circular configuration at one side of the wire frame 3. If more than one electrode 8 is used, then the circular electrodes 8 are positioned concentrically. The wire frame 3 is expanded so as to contact against the inner surface of the aorta at the juncture of the renal artery, such that the circular electrodes 8 are situated about the renal artery ostium.

[0054] In one embodiment, the wire frame or stent 3 is generally cylindrically shaped, so that, when positioned within the aorta, its outside surfaces rest against the inner surface of the aorta. In one embodiment, such as shown in Fig. 1, the structure of the wire frame or stent 3 has two or more elongated supports 5 that are connected to two or more circular rings 7. In one embodiment, the structure of the wire frame or stent 3 has two to four elongated supports 5, although more or fewer elongated supports 5 can be used, as necessary. In one embodiment, the structure of the wire frame or stent 3 has two to four circular rings 7 positioned substantially transverse to the elongated supports 5, although more or fewer circular rings 7can be used, as necessary. The elongated supports 5 are connected to the circular rings 7 by any method, e.g., welding. Fig. 2 shows these elongated supports 5 and circular rings 7 in an exploded configuration.

[0055] In one embodiment, the wire frame 3 is formed from a material that is flexible and has a shape memory, e.g., nitinol. The natural shape of the wire frame 3 is in an expanded, generally cylindrical configuration, as shown in Fig. 1. In particular, the elongated supports 5 have a natural straight configuration, and the transverse rings 7 have a natural circular configuration. However, the elongated supports 5 and circular rings 7 of the wire frame 3 are formed from a material that is sufficiently flexible and elastic so as to allow them to be flexed

and deformed into other shapes, such as a collapsed configuration, upon application of an external force. The material of the wire frame 3has a sufficient shape memory such that the elongated supports 5 and circular rings 7 of the wire frame 3 will return to their natural configurations when the external force is released.

[0056] The wire frame or stent 3 is selectively movable between a non-deployed position and a deployed position. In the non-deployed position, the wire frame 3 is stored unexpanded, i.e., in a collapsed configuration. The collapsed wire frame 3 in its non-deployed position may be positioned or encapsulated within a sheath 10 at the end of the catheter.

[0057] In one embodiment, a guide wire 11 may first be inserted into the patient's vascular system via a natural orifice, e.g. through the groin, and advanced to the desired location. A cap 13 at the distal end of the guide wire 11 (see Fig. 3) facilitates entrance through the skin, and the cap and guide wire may be later separated from the sheath 10 for later deployment of the ablative elements. The catheter comprising the sheath 10 is advanced longitudinally through the blood vessel, e.g., over the guide wire 11, to the relevant location within the body lumen, such as within the aorta, and into the desired position within the inner circumference of the vessel, such as at the renal artery ostium of the aorta.

[0058] The sheath 10 is then withdrawn, thereby removing the constraint that kept the wire frame 3 in its collapsed configuration. Withdrawing the sheath 10 exposes the wire frame 3 or stent member 3 and allows the wire frame 3 to spontaneously expand into its natural cylindrical configuration, i.e., the deployed position, wherein it conforms to the walls of the lumen.

[0059] The wire frame or stent 3 is also movable between the deployed, expanded position and a non-deployed, collapsed position. It is desirable for the wire frame 3 to be collapsible back to its non-deployed position for retraction back into the catheter sheath 10 after ablation is complete and when it is desired to withdraw the catheter from the patient.

[0060] The wire frame 3 comprises at least one electrode 8 that is capable of conducting RF energy and that comes in contact with the body tissue. In one embodiment, there is one circularly shaped electrode 8. In another one embodiment, there are two or more circularly shaped electrodes 8. By including multiple RF electrodes in a single catheter system, more complete nerve ablation is ensured.

[0061] As shown in Fig. 1, RF electrodes 8 are attached to the wire frame 3 as a means to deliver RF energy to the body lumen, as well as temperature and nerve activity sensing. In one embodiment, the electrodes 8 positioned on the outside of one side of the wire frame 3. In another embodiment, the electrodes 8 are attached to two elongated supports 5 on one side of the wire frame 3. The purpose of positioning the electrodes 8 on one side of the wire frame 3 is so that, when the wire frame 3 is expanded within the aorta and the against the insides of the aorta, the electrodes 8 would be situated on one specific side of the aorta, e.g., the side that branches off to the renal artery for more effective ablation of, e.g., the renal nerve, called the renal artery ostium.

[0062] In one embodiment, the elongated supports 5 to which the RF electrodes 8 are attached are adapted to conduct RF energy from the RF control unit to the RF electrodes 8. In this embodiment, these two elongated supports 5 serve to house connections from the RF control unit and the attached RF electrodes for temperature control and ablative energy.

[0063] When the wire frame 3 is changed into its deployed position by withdrawal of the sheath, the electrodes 8 that are positioned on the wire frame directly contact the lumen wall. If the wire frame 3 has been properly positioned before the withdrawal of the sheath 10, then the electrodes 8 contact the lumen wall at the desired location, e.g., the renal artery ostium. Heat is then generated to the electrodes 8 by supplying a suitable RF energy source to the apparatus, and the ablation is performed for the ablation of nerve activity, such as nerve activity that leads specifically to the kidney.

[0064] In a preferred embodiment, the device 1 has a positioning element or mechanism for positioning and securing the device at the desired location within the vessel, e.g., the aorta. Such a mechanism is necessary so that the electrodes can operate at the precise location, namely around the renal artery ostium. Otherwise, if the device is not properly positioned, the electrodes 8 can ablate tissue that is not intended to be harmed, causing irreversible damage. In the embodiment wherein the RF electrodes 8 are circularly shaped, the positioning mechanism should properly center the electrodes circumferentially around the renal artery ostium, namely the opening to the renal artery.

[0065] In one embodiment, as shown in Fig. 3, the positioning element or mechanism includes an imaging catheter 15 that allows the user to view exactly where the renal artery ostium is and to properly position the device 1, and specifically the RF electrodes 8, through use of visual means. In one embodiment, the imaging catheter 15 comprises a proximal end

that is external to the patient and manipulated by the user along with the operating end of the device 1, and also comprises a distal end that is situated within the wire frame 3 of the device 1. The distal end of the imaging catheter 15 extends from the proximal direction into the wire frame 3 and passes out of the wire frame 3 in a direction transverse to the longitudinal direction of the wire frame 3. In one embodiment, the distal end of the imaging catheter 15 passes out of the wire frame 3 through the center hole 9 of the circularly-configured RF electrodes 8, as shown in Fig. 3.

[0066] In another embodiment, as shown in Fig. 4, the positioning element or mechanism includes a catheter that comprises an inflatable balloon 16 at its distal end that is projected into the entrance to the renal artery. This inflatable positioning balloon 16 passes through the imaging catheter 15 and the wire frame 3 from the distal direction and passes through the hole 9 of the circularly-configured RF electrodes 8, in the manner of the imaging catheter. In one embodiment, the balloon catheter comprises a proximal end that is external to the patient and manipulated by the user along with the operating end of the device 1, and also comprises a distal end that is situated within the wire frame 3 of the device 1. The distal end of the balloon catheter 16 extends from the proximal direction into the wire frame 3 and passes out of the wire frame 3 in a direction transverse to the longitudinal direction of the wire frame 3. In one embodiment, the distal end of the balloon catheter 16 passes out of the wire frame 3 through the center hole 9 of the circularly-configured RF electrodes 8, as shown in Fig. 3.

[0067] The inflatable positioning balloon 16 is situated at the distal end of the balloon catheter. The balloon catheter 16 may be inserted at least partially into the entrance of the renal artery, and the catheter sheath 10 is then withdrawn, exposing the balloon 16 at the end thereof. The balloon is then inflated against the inner walls of the renal artery, to allow the device 1 to hold its position within the aorta relative to the renal artery. The diameter of the balloon 16, when expanded, is dependent upon the internal diameter of the branch artery at which positioning is desired. Generally, a balloon 16 with an expanded diameter of approximately 4 to 5 mm is sufficient. When the device is so positioned by virtue of the inflatable balloon 16, the wire frame can be expanded to the inner surface of the aorta, such as by retraction of the device sheath, allowing the RF electrodes 8 to be positioned against the renal artery ostium so that they may perform their ablative function.

[0068] In a further embodiment, the imaging catheter 15 and the balloon catheter 16 may both comprise an outer sheath 10 that is inserted into the wire frame 3 using a guide wire 11, through which sheath 10 the imaging device and the balloon device may be inserted. For

example, an imaging catheter 15 may be inserted and used and then removed, leaving the sheath therefrom remaining within the patient and extending through the wire frame 3 and into the renal artery ostium. The balloon 16 may be advanced through the sheath (e.g., over a guide wire 11) and into the renal artery ostium for anchoring of the device therein. Radiographic contrast media injected at the beginning of the procedure may assist in manipulation of the instruments.

[0069] In these embodiments, the positioning element or mechanism operates to position the circularly-configured RF electrodes 8 at the renal artery ostium, and specifically around the opening to the branch renal artery off the ostium. This is accomplished by insertion of the distal end of the imaging catheter 15 or balloon catheter 16 that has exited the wire frame 3 of the device through the center hole 9 of the circularly-configured RF electrodes 8 at least partially into the entrance of the renal artery so as to serve, either by itself or by inflation of the balloon 16 that is exposed from within, as an anchor for the device 1 within the aorta. When the distal end of the imaging catheter 15 or the balloon 16 that is exposed from the distal end of the balloon catheter 16 is so positioned, the device 1 is able to hold its position within the aorta relative to the renal artery, and the wire frame 3 can be expanded to abut against the inner surface of the aorta. When the wire frame 3 is expanded against the inner surface of the aorta, the RF electrodes 8 can be centered circumferentially around the opening to the renal artery, i.e., the renal artery ostium, so that the RF electrodes 8 can perform their ablative function.

[0070] It should be noted that, in this embodiment, the distal end of the positioning mechanism, whether the imaging catheter 15 or the balloon catheter 16, is inserted at least partially into the entrance of the renal artery so as to serve as an anchor even before the wire frame 3 has been expanded. However, in the embodiment wherein the wire frame 3 is comprised of shape memory material such that the wire frame 3 expands spontaneously when released from the constraints that keep it in the collapsed position, the wire frame 3 cannot expand until and unless the sheath 10 covering the entire device is withdrawn. Therefore, there must be a way for the positioning mechanism to protrude out of the wire frame 3 and device 1 and extend into the entrance of the renal artery so as to position the device 1 at the renal artery ostium, even while the wire frame 3 is still in its collapsed, non-deployed configuration within the sheath 10 and even while the sheath 10 has not yet been withdrawn from over the wire frame 3.

[0071] Accordingly, in certain embodiments, as shown in Fig. 5, the sheath 10 that envelopes the device has a longitudinal cut out 20 from its distal-most edge. This cut out 20 should be wide enough to allow the positioning device to pass through to allow the imaging catheter 15 or the balloon catheter 16 to be positioned within the entrance of the renal artery even while the sheath 10 is still in position around the wire frame 3 and keeping the wire frame in a collapsed and non-deployed position.

[0072] In this embodiment, while the wire frame 3 is within the sheath 10, the imaging catheter 15 or the balloon catheter 16 may be manipulated to that it is positioned within the wire frame 3 but just behind the circularly-configured RF electrodes 8, as shown in cross-sectional view in Fig. 3. When it is desired for the imaging catheter 15 or the balloon catheter 16 to serve as a positioning mechanism to position the device within the aorta, the sheath is rotated about its longitudinal axis so that the cut out 20 is oriented over the center hole 9 of the circularly-configured RF electrodes 8. This exposes the center hole 9 of the circularly-configured RF electrodes 8, allowing the imaging catheter 15 or balloon catheter 16 to be pushed through the center hole 9 of the circularly-configured RF electrodes 8 and into the entrance of the renal artery.

[0073] In the case where the positioning mechanism comprises an imaging catheter 15, the device 1 is considered to be properly positioned within the aorta once the imaging catheter 15 is positioned at least partially within the entrance of the renal artery. In the case where the positioning mechanism comprises a balloon catheter 16, even if the balloon catheter 16 is positioned at least partially within the entrance of the renal artery, the device 1 is not considered to be properly positioned within the aorta until the sheath of the balloon catheter 16 is withdrawn and the balloon 16 is expanded. Once the balloon 16 is expanded within the entrance of the renal artery, the balloon catheter 16, as well as the device from which the balloon catheter 16 protrudes, is held securely therein.

[0074] Once the device 1 has been properly positioned, e.g., by insertion of the distal end of the imaging catheter 15 at least partially into the entrance of the renal artery, the sheath 10 is withdrawn or retracted, and the wire frame 3 and its attached RF electrode(s) 8 are exposed, allowing the wire frame 3 to be expanded. Then, if the device has been properly positioned, expansion of the wire frame 3 will result in its outer surface resting against the inside surface edges of the aorta. And, because the imaging/positioning catheter 15 has passed through the center hole 9 of the circularly-configured RF electrodes 8 and into the entrance of the renal

artery, expansion of the wire cage 3 will cause the RF electrodes 8 to be positioned directly against the renal artery ostium.

[0075] At the proximal end thereof, the catheter includes at least one port. This port is for connection to a source of radiofrequency (RF) power and can be coupled to a source of Radiofrequency (RF) energy, such as RF in about the 300 kilohertz to 500 kilohertz range. The electrodes 8 are electrically coupled to the RF energy source through this port. The catheter may also be connected to a control unit for sensing and measurement of other factors, such as temperature, conductivity, pressure, impedance and other variables, such as nerve energy.

[0076] The catheter may also be connected to a second port for connection to an air source. This port would be used when it is needed for inflation and deflation of a balloon, such as in an embodiment when a balloon 16 is used in a positioning mechanism. This port can be pneumatically coupled to a pump or other apparatus to inflate or deflate the balloon. This same port may be used to circulate coolant to the inside of the balloon for the purpose of cooling the balloon during RF energy activation.

[0077] In one embodiment, the RF electrodes 8 operate to provide radiofrequency energy for heating of the desired location during the nerve ablation procedure. Electrodes 8 may be constructed of any suitable conductive material, as is known in the art. Examples include stainless steel and platinum alloys.

[0078] RF electrode 8 may operate in either bipolar or monopolar mode, with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode is used in combination with an indifferent electrode patch that is applied to the body to form the other electrical contact and complete an electrical circuit. Bipolar operation is possible when two or more electrodes are used, such a two concentric electrodes. Electrodes 8 can be attached to an electrode delivery member, such as the wire frame 3, by the use of soldering or welding methods which are well known to those skilled in the art.

[0079] In the embodiment wherein the one or more RF electrodes 8 are circular, the diameter of the circular RF electrodes 8 is determined by the width of the aortic artery branch for which denervation is desired. If the diameter of the RF electrode 8 is smaller than the diameter of the aortic artery branch for which denervation is desired, the RF electrode 8 would not actually be in contact with tissue, and no ablation would occur. For example, when denervation is desired for the renal artery, which is approximately 6-7 mm in diameter

at the ostium of the aorta, the diameter of the circular RF electrodes 8 must be at least that distance, i.e., 7 mm, in order to properly provide ablation at the renal artery ostium.

[0080] Where the device comprises two circularly-configured RF electrodes 8 that are arranged concentrically, the spacing between the two RF electrodes 8 determines the depth in the tissue to which ablation is accomplished. The father apart the electrodes 8 are, the deeper the tissue denervation that is accomplished. For denervation of the renal artery, a spread of approximately 2-6 mm between the electrodes 8 provides sufficient depth of penetration into the tissue to accomplish the desired level of ablation such that denervation occurs. For example, in one embodiment, if the inner RF electrode 8 has a diameter of approximately 10 mm, then the outer RF electrode 8 would have a diameter of approximately 12-17 mm.

[0081] In an embodiment wherein an imaging catheter protrudes from the wire frame 3 from within the circularly-configured RF electrodes, the diameter of the RF electrodes 8 may be calculated with reference to the imaging catheter 15. For example, for an imaging catheter 15 whose distal end has a diameter of approximately 2 mm, the RF electrodes 8 that surround the imaging catheter 15 may be centered at 5 mm and 10 mm, respectively, from the center location of the imaging catheter 15.

[0082] Each electrode 8 can be disposed to treat tissue by delivering Radiofrequency (RF) energy. The radiofrequency energy delivered to the electrode has a frequency of about 5 kilohertz (kHz) to about 1 GHz. In specific embodiments, the RF energy may have a frequency of about 10 kHz to about 1000 MHz; specifically about 10 kHz to about 10 MHz; more specifically about 50 kHz to about 1 MHz; even more specifically about 300 kHz to about 500 kHz.

[0083] In a preferred embodiment, the electrodes 8 can be operated separately or in combination with each other as sequences of electrodes disposed in arrays. Treatment can be directed at a single area or several different areas of a vessel by operation of selective electrodes.

[0084] An electrode selection and control switch may include an element that is disposed to select and activate individual electrodes.

[0085] RF power source may have multiple channels, delivering separately modulated power to each electrode. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes that are placed into less conductive tissue. If the level of tissue hydration or the blood infusion rate in

the tissue is uniform, a single channel RF power source may be used to provide power for generation of lesions relatively uniform in size.

[0086] RF energy delivered through the electrodes 8 to the tissue causes heating of the tissue due to absorption of the RF energy by the tissue and ohmic heating due to electrical resistance of the tissue. This heating can cause injury to the affected cells and can be substantial enough to cause cell death, a phenomenon also known as cell necrosis. For ease of discussion for the remainder of this application, cell injury will include all cellular effects resulting from the delivery of energy from the electrodes up to, and including, cell necrosis. Cell injury can be accomplished as a relatively simple medical procedure with local anesthesia. In one embodiment, cell injury proceeds to a depth of approximately 1-5 mms from the surface of the mucosal layer of sphincter or that of an adjoining anatomical structure.

[0087] In certain embodiments, as shown in Fig. 2, the catheter comprises an insulation pad 19 that is situated between each RF electrode 8 and the wire frame 3, for example so as to protect the wire frame 3 from the direct effects of the RF energy. This insulation pad 19 may also avoid potential damage to the body to the subject's blood while ablative energy is effectively transmitted to the vessel surface and the blood that has passes through the wire frame.

[0088] Also included in this design is a means to measure renal nerve afferent activity prior to and following RF nerve ablation. By measuring renal nerve activity post procedure, a degree of certainty is provided that proper nerve ablation has been accomplished. Renal nerve activity will be measured through the same mechanism as that required for energy delivery and electrodes on the renal artery placed positioning balloon.

[0089] Nerve activity may be measured by one of two means. Proximal renal nerve stimulation will occur by means of transmitting an electrical impulse to the catheter positioned within the proximal segment of the renal artery. Action potentials will be measured from the segment of the catheter situated within the more distal portion of the renal artery. The quantity of downstream electrical activity as well as the time delay of electrical activity from the proximal to distal electrodes will be provide a measure of residual nerve activity post nerve ablation. The second means of measuring renal nerve activity will be to measure ambient electrical impulses prior to and post nerve ablation within a site more distal within the renal artery.

[0090] In another embodiment, the RF electrodes operate 8 to provide radiofrequency energy for both heating and temperature sensing. Thus, in this embodiment, the RF elements can be used for heating during the ablation procedure and can also be used for sensing of nerve activity prior to ablation as well as after ablation has been done.

[0091] Each electrode 8 may be coupled to at least one sensor or control unit capable of measuring such factors as temperature, conductivity, pressure, impedance and other variables. For example, the device may have a thermistor that measures temperature in the lumen, and a thermistor may be a component of a microprocessor-controlled system that receives temperature information from the thermistor and adjusts wattage, frequency, duration of energy delivery, or total energy delivered to the electrode.

[0092] The catheter can be coupled to a visualization apparatus, such as a fiber optic device, a fluoroscopic device, an anoscope, a laparoscope, an endoscope or the like. In one embodiment, devices coupled to the visualization apparatus are controlled from a location outside the body, such as by an instrument in an operating room or an external device for manipulating the inserted catheter.

[0093] In another embodiment, the catheter may be constructed with markers that assist the operator in obtaining a desired placement, such as radio-opaque markers, etchings or microgrooves. Thus, the catheter may be constructed to enhance its imageability by techniques such as ultrasounds, CAT scan or MRI. In addition, radiographic contrast material may be injected through a hollow interior of the catheter through an injection port, thereby enabling localization by fluoroscopy or angiography.

[0094] The invention herein also comprises a method for ablation of renal artery nerve function within the aorta using the device described hereinabove. The method is performed by a system including a catheter and a control assembly. Although the method is described serially, the steps of the method can be performed by separate elements in conjunction or in parallel, whether asynchronously, in a pipelined manner, or otherwise. There is no particular requirement that the method be performed in the same order in which this description lists the steps, except where so indicated.

[0095] At flow point a, electrical energy port is coupled to a source of electrical energy. The patient is positioned on a treatment table in an appropriate position for the insertion of a catheter.

[0096] At step b, the visualization port is coupled to the appropriate visualization apparatus, such as a fluoroscope, an endoscope, a display screen or other visualization device. The choice of visualization apparatus is responsive to judgments by medical personnel.

[0097] At step c, the therapeutic energy port is coupled to the source of RF energy.

[0098] In step d, suction and inflation apparatus is coupled to the irrigation and aspiration control ports so that the catheter balloon may be later be inflated.

[0099] At step e, the most distal end of the treatment balloon is lubricated and introduced into the patient. In a preferred embodiment, the balloon is completely deflated during insertion. The catheter may be inserted into the body lumen through its outer surface, and insertion may be percutaneous or through a surgically created arteriotomy or during an open surgical procedure.

[00100] In step f, the catheter, including the wire frame and positioning device, i.e., imaging or balloon catheter, is threaded through the vessel until the wire frame is situated entirely within the vessel to be treated. An introducer sheath or guide tube may also be used to facilitate insertion.

[00101] In step g, the position of the catheter is checked using visualization apparatus coupled to the visualization port. This apparatus can be continually monitored by medical professionals throughout the procedure.

[00102] At step h, a positioning mechanism is positioned such that it protrudes through the circular electrodes into the ostium of the renal or another artery.

[00103] In step i, the irrigation and aspiration control port is manipulated so as to inflate the balloon of the positioning mechanism, causing the catheter top be rendered stable in its position within the lumen.

[00104] At step j, the device sheath is retracted, causing the wire frame to revert to its expanded configuration, in which the wire frame expands to fit within the vessel interior

[00105] In a step k, electrodes are selected using the electrode selection and control switch. In a preferred embodiment, all electrodes are deployed at once. In another preferred embodiment, electrodes may be individually selected. This step may be repeated at any time prior to step j.

[00106] In a step l, the therapeutic energy port is manipulated so as to cause a release of energy from the electrodes. The duration and frequency of energy are responsive to

judgments by medical personnel. This release of energy creates a circular pattern of lesions at the renal artery ostium.

[00107] In a step m, the device sheath is advanced over the wire frame so as to cause the wire frame to revert to its collapsed state.

[00108] In a step n, the irrigation and aspiration control port is manipulated so as to cause the positioning device balloon to deflate.

[00109] In a step o, the positioning device, either the balloon catheter or the imaging catheter, is withdrawn from the renal artery ostium, into the device.

[00110] Once ablation is completed and the wire frame, the balloon and the imaging/positioning catheters are withdrawn into the sheath, the device is available for positioning at another location within the patient, e.g., the contralateral (or accessory) renal artery, and the steps above may be repeated for each ablation site.

[00111] In a step p, the catheter is withdrawn from the patient.

[00112] Having described preferred embodiments of the invention with reference to the accompanying drawings, it is to be understood that the invention is not limited to the precise embodiments, and that various changes and modifications may be effected therein by those skilled in the art without departing from the scope or spirit of the invention as defined in the appended claims.

CLAIMS

1. A nerve ablation device, comprising:

a wire frame;

at least one radiofrequency (RF) electrode having a circular configuration positioned on an outer surface of the wire frame.

2. The nerve ablation device of claim 1, further comprising a rapid delivery (RX) wire system.

3. The nerve ablation device of claim 1, further comprising a retractable sheath around said wire frame

4. The nerve ablation device of claim 3, wherein said wire frame comprises a shape memory material.

5. The nerve ablation device of claim 4, wherein said wire frame is deformable by application of an external force and will return to a predetermined configuration upon release of said external force.

6. The nerve ablation device of claim 1, further comprising a positioning catheter that extends within said wire frame.

7. The nerve ablation device of claim 6, wherein a distal end of said positioning catheter may be moved out of said wire frame.

8. The nerve ablation device of claim 7, wherein said distal end of said positioning catheter may be moved out of said wire frame through a center of said circular configured RF electrode.

9. The nerve ablation device of claim 7, wherein said positioning catheter comprises an expandable balloon.

10. The nerve ablation device of claim 9, further comprising two ports along a proximal end thereof, and wherein one of the two ports is a balloon inflation port and the other port is a control unit for connection to an RF energy, temperature and nerve sensing control unit.

11. The nerve ablation device of claim 1 having a rapid exchange configuration.

12. The nerve ablation device of claim 1, wherein said RF element is arranged as a circular hole having a diameter of 1.5 mm along the length of the balloon catheter.

elements, wherein said RF elements are concentrically positioned.

14. A method for performing ablation of a nerve at an artery ostium of the aorta in a subject in need thereof, comprising:

inserting into said aorta a catheter comprising a wire frame and at least one radiofrequency (RF) electrode having a circular configuration positioned on an outer surface thereof,

positioning said wire frame such that said electrode is positioned about the artery ostium of the aorta; and

delivering radiofrequency energy at a designated location within the renal arterial wall.

15. The method of claim 13, wherein the wire frame delivers RF energy while sensing temperature and nerve activity.

16. The method of claim 13, wherein said step of positioning said wire frame comprises inflating a balloon catheter within the artery.

17. The method of claim 13, further comprising measuring renal nerve afferent activity before and after nerve ablation.

18. The method of claim 13, wherein renal nerve ablation lowers hypertension, improves kidney function, increases renal plasma flow, reduces muscle sympathetic-nerve activity, improves cardiac baroreflex and reduces ventricular mass in the subject.

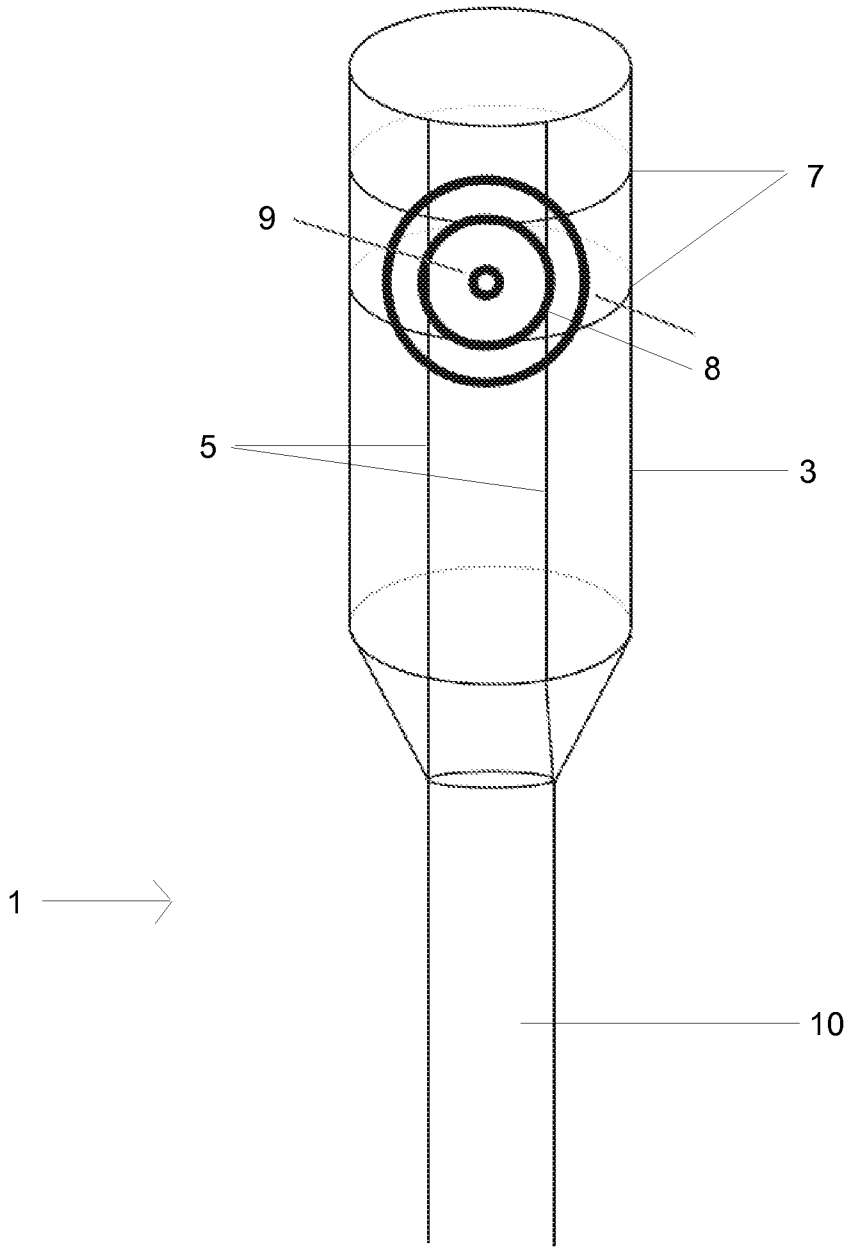

FIG. 1

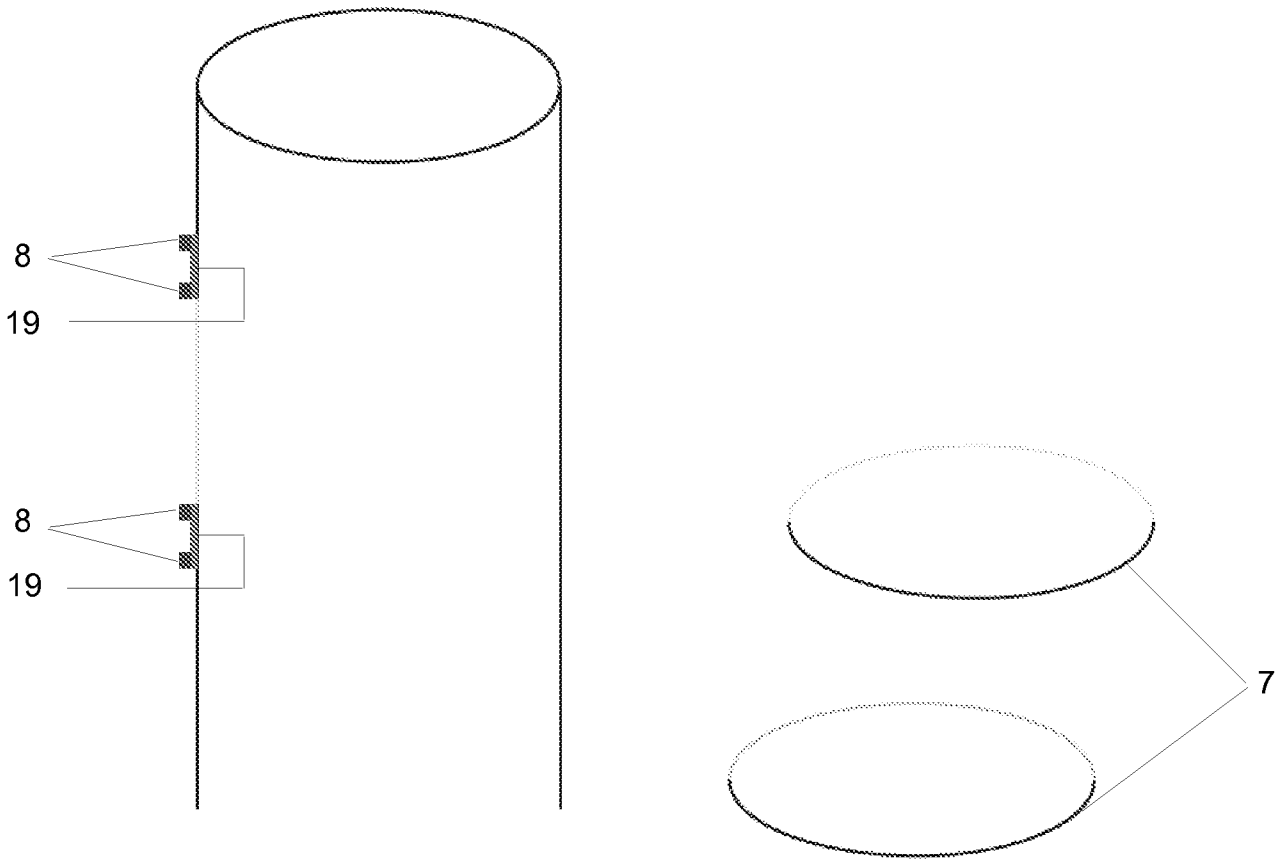

FIG. 2

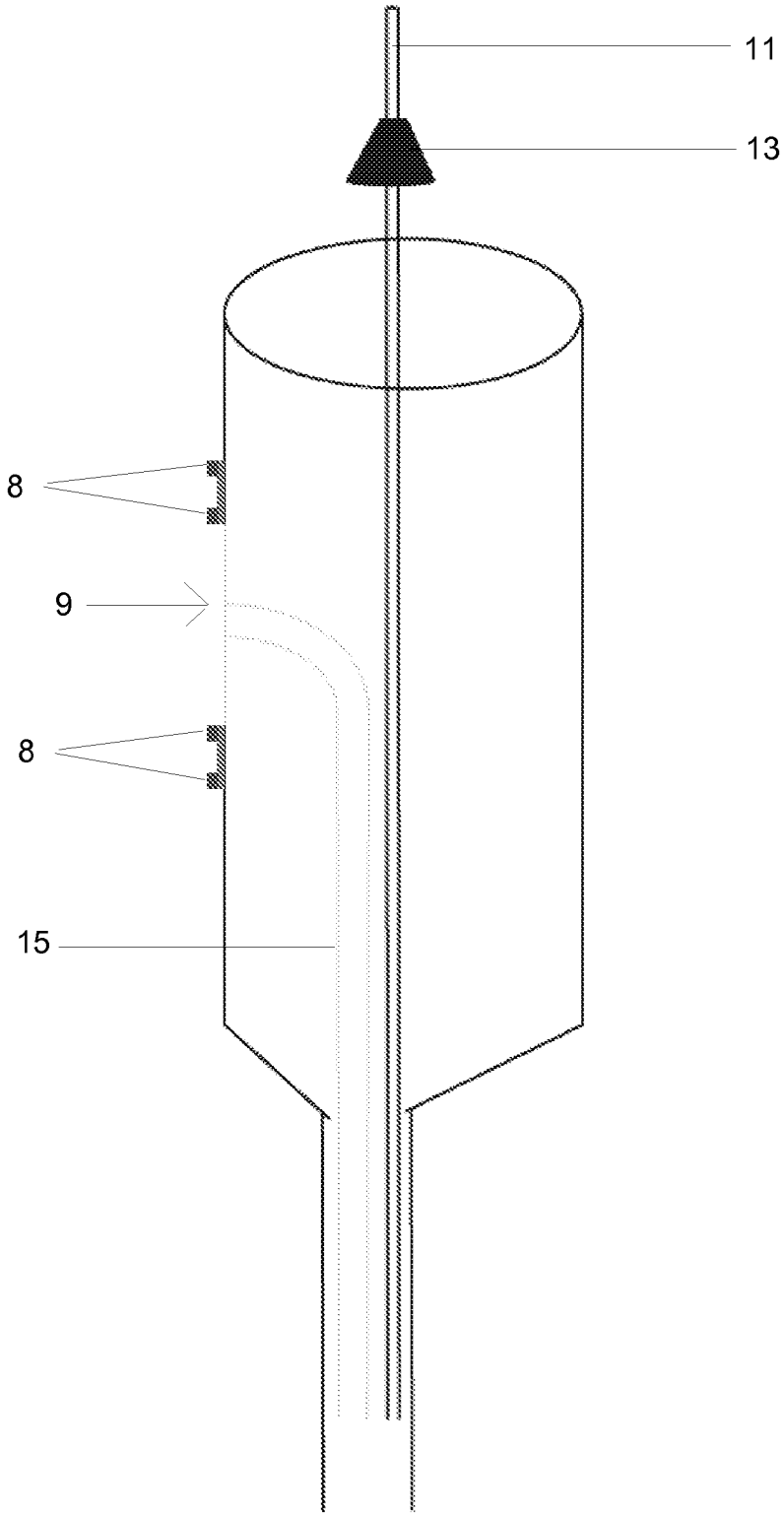

FIG. 3

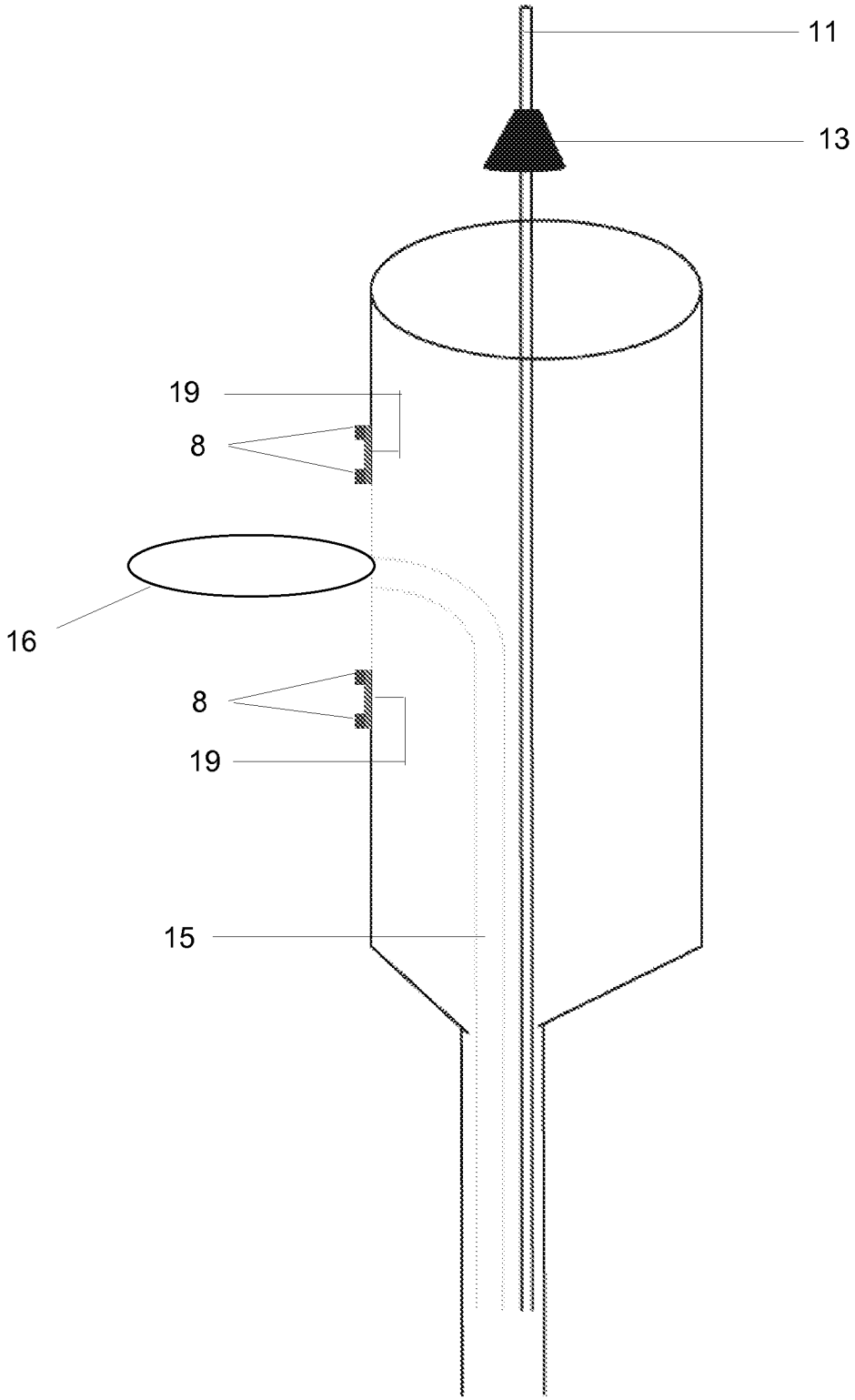

FIG. 4

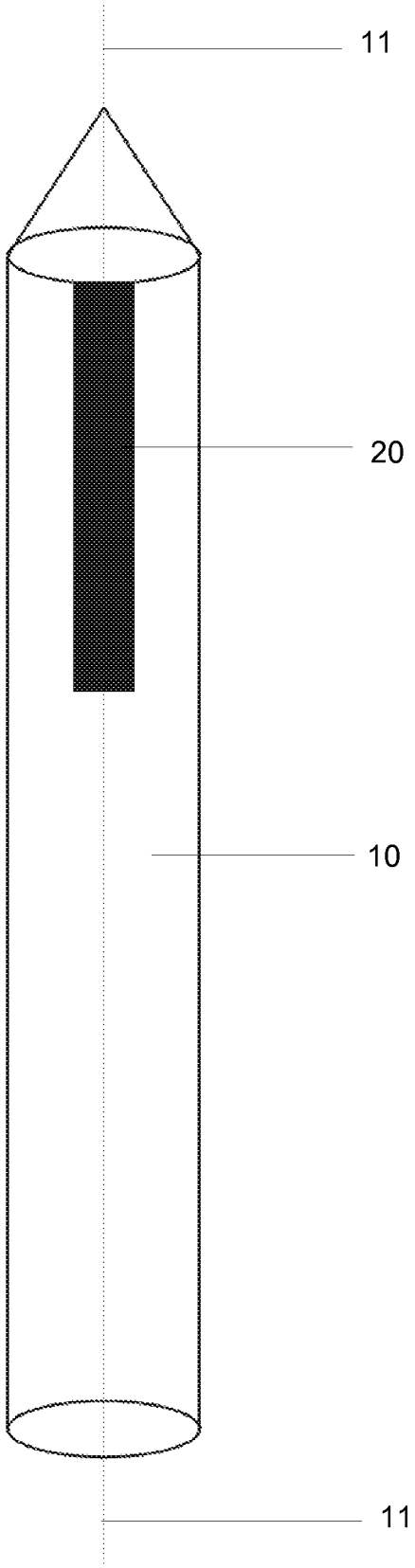

FIG. 5