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(54) Title: RADIOFREQUENCY ABLATION CATHETER DEVICE

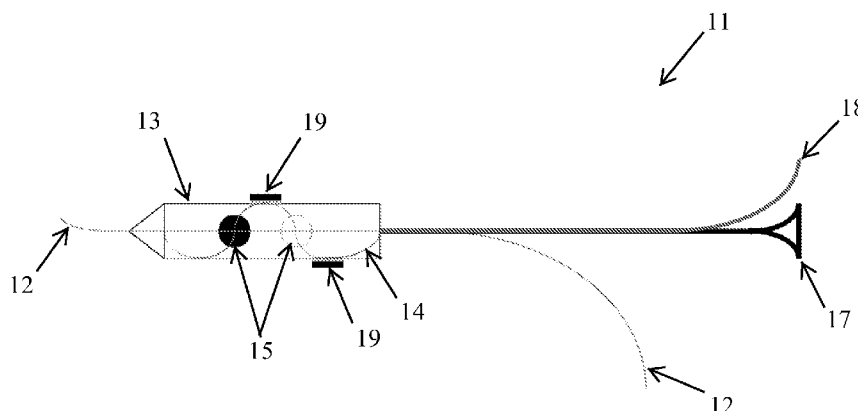


FIG. 1

(57) Abstract: A nerve ablation device comprises a wire frame bearing one or more electrodes that are capable of conducting RF energy. The electrodes may be positioned in a circumferential or helical arrangement about the wire frame, which is positioned about an expandable balloon contained within a catheter, e.g., at the end thereof, and is movable between a non-deployed position and a deployed position. The device, including the collapsed balloon and wire frame encapsulated within a sheath, is advanced over a guidewire through the blood vessel to the relevant location, such as within the renal artery, and positioned within the inner circumference of the vessel, such as the renal artery ostium. The sheath is then withdrawn to expose the balloon and wire frame on the catheter, and the wire frame or stent is then expanded by inflating the balloon at the end of the catheter.

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 renal artery houses a network of nerves that are helpful in maintaining renal vascular tone, 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.

[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 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 anesthesiologists for other RF procedures such as Gasserian ganglionectomy for trigeminal neuralgia and percutaneous cervical cordotomy for intractable pains.

[0015] One problem in the art is the providing of a treatment surface that can reach all of the desired treatment areas, such as the entire interior surface of an artery or other blood vessel. While the use of a catheter to deploy energy may be known, it has been difficult to provide ablation across the entire interior surface of a blood vessel 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. 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 from within the renal artery.

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 renal arterial wall for renal nerve ablation.

[0020] The present invention is directed to a device, system and method for delivering radiofrequency energy, to the walls of a body lumen, particularly the renal artery, using a nonconductive catheter.

[0021] In one embodiment, the device comprises a wire frame or stent bearing one or more electrodes that are capable of conducting RF energy. The one or more electrodes are positioned in a helical arrangement about the wire frame, which is positioned about an expandable balloon contained within a catheter, e.g., at the end thereof. The device is advanced over a guidewire within a sheath to the relevant location, such as within the renal artery, and positioned within the inner circumference of the vessel, such as the renal artery ostium. The sheath is then withdrawn to expose the balloon and wire frame on the catheter, and the wire frame or stent is then expanded by inflating the balloon at the end of the catheter. The wire frame or stent structure comprises at least one electrode that comes in contact with the body tissue when the system is expanded by the balloon.

[0022] The wire frame or stent is movable between a non-deployed position and a deployed position. In the non-deployed position, the balloon and wire frame are unexpanded, i.e., collapsed. The unexpanded balloon and wire frame in their non-deployed positions at the end of a catheter may be encapsulated within a sheath and advanced longitudinally through the blood vessel into the desired position, at which point the sheath may be withdrawn, exposing the unexpanded balloon and wire frame or stent member. The balloon is then expanded, thereby also expanding the wire frame 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.

[0023] In a preferred embodiment, the invention provides an apparatus comprising one or more ablation elements arranged in a helical fashion along the length of the expandable wire frame or stent that is positioned around the balloon catheter. In one embodiment of the invention, two or more, e.g., four, ablation elements are arranged in a helical fashion along the length of the expandable wire cage or stent that is positioned around the balloon catheter. In another embodiment of the invention, one linear array element is arranged in a helical fashion along the length of the expandable wire cage or stent that is positioned around the balloon catheter. In a further embodiment of the invention, two linear array elements separated from each other by a predetermined distance are arranged in a helical fashion along the length of the expandable wire cage or stent that is positioned around the balloon catheter.

[0024] Positioning the RF elements in this helical fashion about the expandable wire cage or stent that is positioned around the catheter balloon allows the electrodes to be spaced along the surface of the renal artery, thereby ensuring improved delivery of the RF energy to the designated location within the renal arterial wall. By including multiple RF elements in a single catheter system, more complete nerve ablation is ensured. By contrast, positioning of electrodes circumferentially rather than helically, i.e., 360° around a cross-sectional surface of the balloon so as to ablate the nerve in a cross-sectional pattern, could cause scar tissue to form on the internal surface of the blood vessel 360° around at that location, thereby constricting the cross-sectional area of the blood vessel. An additional negative to circumferential electrode placement is the possibility of vessel rupture.

[0025] Furthermore, a mechanism is provided in the catheter design for positioning and securing the catheter at the desired position within the vessel.

[0026] In one example, the device is a nonconductive flexible catheter for introduction into the lumen of a blood vessel, wherein the catheter has, near its remote end, an inflatable balloon that is connected to a balloon inflation and deflation source. A conductive wire is formed into a frame or stent and is situated in a collapsed position around the balloon when the balloon is in its deflated, non-deployed position. The wire frame may be made of a memory material such that the wire frame is in a collapsed state when the balloon is not inflated but assumes a generally cylindrical or helical shape when the balloon is advanced out of the catheter through a port and inflated. Alternatively, the wire frame may comprise

interlocking or interwoven strands that are loosely interlocked or interwoven when the balloon is not inflated such that the wire frame is in a collapsed state and that, when the balloon is advanced out of the sheath and inflated, become more tightly interlocked or interwoven such that the wire frame assumes a generally cylindrical or helical shape and conforms to the walls of the lumen when the wire frame is in its deployed position.

[0027] Also included in this design is a mechanism to monitor catheter temperature during ablation.

[0028] 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.

[0029] In addition to the above noted functions, the device comprises a mechanism protecting the expandable balloon from high temperatures that might otherwise damage the integrity of the balloon. For example, the device could have an insulation pad that is situated between each RF electrode and the surface of the balloon for insulating the balloon from the high temperatures of the RF electrode. This insulation pad avoids potential damage to the catheter balloon while ablative energy is effectively transmitted to the vessel surface. This insulation pad also avoids heating of the blood vessel and the blood flowing within it.

[0030] The present invention is also directed to a method for radio-frequency (RF) heat ablation of tissue through the use of one or more RF electrodes, which are positioned in a helical arrangement around a wire frame or stent that is mounted about a balloon positioned at the distal end of a catheter. In a first step of the invention, the catheter is deployed in the body at the relevant location, such as 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.

[0031] In a second step of the invention, once the catheter is at the relevant location, the balloon is inflated so as to position the wire frame or stent and the RF electrodes that are mounted thereon against the inner surface of the vessel. In a third 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 inflated balloon and the inner surface of the vessel wall. This coolant function may provide a form of protection or insulation to the expanded balloon during RF energy activation as well as protection to the inner vessel wall surface during heat transfer.

[0032] In one embodiment of the invention method, the balloon centers the RF elements within the vessel, and is inflated. In this fashion, more selective ablation of nerve activity leading to the kidney can be accomplished.

[0033] In one embodiment, the ablation is performed for the ablation of renal nerve activity that leads specifically to the kidney.

[0034] 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

[0035] 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:

[0036] Figure 1 shows a first embodiment of a device for delivering radiofrequency energy to the walls of a body lumen;

[0037] Figure 2 shows a second embodiment of a device for delivering radiofrequency energy to the walls of a body lumen; and

[0038] Figure 3 shows a process flow drawing of a method for ablation of nerve function.

DETAILED DESCRIPTION OF THE INVENTION

[0039] 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.

[0040] 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.”

[0041] 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.

[0042] Figure 1 is a drawing of one embodiment of a device 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 **11**.

[0043] In one embodiment, the device includes a substantially tubular catheter **11**, namely a long, thin, tube-like device, having proximal and distal openings, preferably constructed from a nonconductive material. The catheter **11** 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 **11** is nonconductive.

[0044] As will be discussed in greater detail below, the catheter **11** is used as a delivery system for delivering a device containing radiofrequency electrodes **15,16** to the desired site for nerve ablation. In one embodiment, as is known in the art, a guide wire **12** may first be inserted into the patient’s vascular system and advanced to the desired location, and a catheter **11** is inserted into the patient and threaded over the guide wire **12** to the desired location.

[0045] In a preferred embodiment, the catheter **11** has a positioning element. In one embodiment, the positioning element includes an inflatable balloon **13**, of a type that is well known to those in the art, situated at the distal end of the catheter **11**. The balloon **13** is pneumatically connected to a port at the proximal end of the catheter **11** and is thereby connected to a balloon inflation and deflation source for inflation and deflation of the balloon **13**. In preferred embodiments, the catheter **11** is a compliant balloon design that 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. The uninflated balloon **13** may be situated within an outer catheter sleeve or sheath during insertion into the vessel, so as to prevent inadvertent inflation of the balloon **13** prior to placement at the desired site within the patient.

[0046] In a preferred embodiment, the catheter **11** also has a thermal electric field delivery apparatus. In one embodiment, the thermal electric field delivery apparatus comprises a wire frame **14** or stent positioned about the catheter’s expandable balloon **13**. In certain embodiments, the wire frame **14** is bonded to the balloon **13**, and in other embodiments it is

not. In certain embodiments, the wire frame **14** is conductive so as to be able to provide current to RF electrodes and temperature sensing functions.

[0047] The wire frame **14** is preferably situated in a collapsed position around the balloon **13** when the balloon **13** is in its deflated, non-deployed position. The wire frame **14** may be situated within an outer catheter sleeve during insertion into the vessel, so as to prevent inadvertent inflation of the balloon **13** and deployment of the wire frame **14**.

[0048] The wire frame **14** may be made of a memory material such that the wire frame **14** is in a collapsed state when the balloon **13** is not inflated but assumes a generally cylindrical shape when the balloon **13** is advanced out of the catheter **11** through a port and inflated.

[0049] The wire frame **14** may also comprise interlocking or interwoven strands that are loosely interlocked or interwoven when the balloon **13** is not inflated such that the wire frame **14** is in a collapsed state. Then, when the balloon **13** is advanced out of the sheath and inflated, the interlocking or interwoven strands of the wire frame **14** or stent become more tightly interlocked or interwoven such that the wire frame **14** assumes a generally cylindrical or helical shape. The wire frame **14** conforms to the walls of the lumen when the wire frame **14** and balloon **13** are in their deployed position.

[0050] The wire frame **14** or stent is thus movable between a non-deployed position when the balloon **13** is unexpanded and a deployed position when the balloon **13** is expanded. It is also preferable that the wire frame **14** be collapsible, along with the balloon **13**, back to its non-deployed position for retraction back into the catheter sheath along with the deflated balloon **13** after ablation is complete and when it is desired to withdraw the catheter **11** from the patient.

[0051] The wire frame **14** comprises at least one electrode **15,16** means that is capable of conducting RF energy and that comes in contact with the body tissue when the system is expanded by the balloon **13**. In one embodiment, there are two or more helically placed electrodes **15**. In a preferred embodiment, there are four electrodes **15**. Other preferred embodiments may have more or fewer than four electrodes **15**. By including multiple RF electrodes **15** in a single catheter system, more complete nerve ablation is ensured.

[0052] In one embodiment, the individual electrodes **15** that are positioned along the wire frame **14** or stent are known as spot electrodes because they deliver thermal energy to a specific spot, as opposed to a larger area.

[0053] RF electrodes **15** are attached to the balloon **13** by means of the wire frame **14** that imparts support to the catheter **11** structure as well as providing a means to deliver RF energy and temperature and nerve activity sensing. In one embodiment, the electrodes **15** contained in the set of electrodes are evenly spaced around the circumference of the catheter balloon **13**. In another embodiment, the RF electrodes **15** are positioned in a helical fashion around the outside of the balloon **13**. The purpose of positioning the electrodes **15** about the circumference of the catheter balloon **13** is so that the electrodes **15** would be situated along the circumference of the inside surface of the vessel, e.g., the renal artery, when the balloon **13** is expanded and the electrodes **15** are positioned against the vessel, for more effective ablation of, e.g., the renal nerve.

[0054] In another embodiment, the electrode is in the form of a ribbon-shaped electrode **16** that is positioned in a helical fashion around the outside of the balloon **13**. In such an embodiment where there is only one electrode **16** within the subject's body, known as a monopolar design, another electrode is positioned outside the subject's body, e.g., on the subject's skin.

[0055] In a further embodiment, the electrode is in the form of two ribbon-shaped electrodes **16** that are positioned in a double-helical fashion around the outside of the balloon **13** (similar to a DNA strand). In such an embodiment where there are two electrodes **16** within the subject's body, known as a bipolar design, the two ribbon-shaped electrodes **16** are separated by a predetermined distance.

[0056] At the proximal end thereof, the catheter **11** includes at least two ports. A first port **17** is for connection to an air source for inflation and deflation of the balloon **13** and can be coupled to a pump or other apparatus to inflate or deflate the balloon **13** of the catheter **11**. The balloon positioning device is pneumatically connected to the air source through the first port **17**. This same port **17** may be used to circulate coolant to the inside of the balloon **13** for the purpose of cooling the balloon **13** during RF energy activation.

[0057] Another port **18** 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 **15,16** are electrically coupled to the RF energy source through the second port **18**. The catheter **11** 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.

[0058] In one embodiment, the RF electrodes **15,16** operate to provide radiofrequency energy for heating of the desired location during the nerve ablation procedure. Electrodes **15,16** may be constructed of any suitable conductive material, as is known in the art. Examples include stainless steel and platinum alloys.

[0059] RF electrode **15,16** may operate in either bipolar or monopolar mode, as discussed above, with a ground pad electrode. In a monopolar mode of delivering RF energy, a single electrode **15,16** 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 **15,16** are used, either spot electrodes **15** or ribbon electrodes **16**. Electrodes **15,16** can be attached to an electrode delivery member by the use of soldering methods which are well known to those skilled in the art.

[0060] The RF electrodes **15,16** also function to measure afferent and efferent nerve activity before and after vessel and nerve ablation.

[0061] Each electrode **15,16** can be disposed to treat tissue by delivering Radiofrequency (RF) energy. The radiofrequency energy delivered to the electrode **15,16** 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.

[0062] In a preferred embodiment, the electrodes **15,16** 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. Different patterns of lesions, ablated, bulked, plumped, desiccated or necrotic regions can be created by selectively operating different electrodes **15,16**. Production of different patterns of treatment makes it possible to remodel tissues and alter their overall geometry with respect to each other. In addition, varying the placement distance between bipolar electrodes will generate electrical fields allowing for temperature penetration of varying depths through the tissue.

[0063] An electrode selection and control switch may include an element that is disposed to select and activate individual electrodes **15,16**.

[0064] RF power source may have multiple channels, delivering separately modulated power to each electrode **15,16** or array. This reduces preferential heating that occurs when more energy is delivered to a zone of greater conductivity and less heating occurs around electrodes

15,16 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.

[0065] RF energy delivered through the electrodes **15,16** 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 **15,16** 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.

[0066] In certain embodiments, the catheter **11** comprises an insulation pad **19** that is situated between each RF electrode **15,16** and the surface of the balloon **13** for insulating and protecting the balloon **13** from the high temperatures of the RF electrode **15,16**. This insulation pad **19** avoids potential damage to the catheter balloon **13** while ablative energy is effectively transmitted to the vessel surface. The insulation pad **19** also avoids potential damage to the subject's blood due to heating of the blood that has pooled behind the expanded balloon **13**.

[0067] In certain embodiments, the device comprises a cooling pad **19** between the RF electrodes **15,16** and the wire cage **14**, for example so as to chill the surface of the balloon **13**, thus protecting this surface from the direct effects of the RF energy, or the blood that has pooled behind the expanded balloon **13**, thus protecting the subject's blood from the direct effects of the RF energy.

[0068] 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.

[0069] 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 **11** positioned within the proximal segment of the renal artery. Action potentials will be measured from the segment of the catheter **11** 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 **15,16** 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.

[0070] In another embodiment, the RF electrodes **15,16** operate 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.

[0071] Each electrode **15,16** 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 **15,16**.

[0072] The catheter **11** can be coupled to a visualization apparatus, such as a fiber optic device, a flourescopic 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 **11**.

[0073] In another embodiment, the catheter **11** 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 **11** 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 **11** through an injection port, thereby enabling localization by fluoroscopy or angiography.

[0074] Figure 3 is a process flow drawing of a method for ablation of nerve function within the kidney using the device described hereinabove. The method is performed by a system including a catheter **11** 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.

[0075] First (step **301**), the patient is positioned on a treatment table in an appropriate position for the insertion of a device, and the device is prepared.

[0076] At flow point **a**, electrical energy port is coupled to a source of electrical energy.

[0077] At step **b**, the visualization port is coupled to the appropriate visualization apparatus, such as a flouroscope, an endoscope, a display screen or other visualization device. The choice of visualization apparatus is responsive to judgments by medical personnel.

[0078] At step **c**, the therapeutic energy port is coupled to the source of RF energy.

[0079] In step **d**, suction and inflation apparatus is coupled to the irrigation and aspiration control ports **17** so that the catheter balloon **13** may be later be inflated.

[0080] At step **302**, the most distal end of the treatment balloon **13** is lubricated and introduced into the patient. In a preferred embodiment, the balloon **13** is completely deflated during insertion. The catheter **11** 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.

[0081] In step **303**, the catheter **11** is threaded through the vessel until the balloon **13** is situated entirely within the vessel to be treated. An introducer sheath or guide tube may also be used to facilitate insertion.

[0082] In step **304**, the position of the catheter **11** is checked using visualization apparatus coupled to the visualization port. This apparatus can be continually monitored by medical professionals throughout the procedure.

[0083] In step **305**, the irrigation and aspiration control port **17** is manipulated so as to inflate the balloon **13**, causing the wire frame **14** to revert to its expanded configuration, in which the wire frame **14** expands to fit within the vessel interior

[0084] In a step **306**, electrodes **15,16** are selected using the electrode selection and control switch. In a preferred embodiment, all electrodes **15,16** are deployed at once. In another preferred embodiment, electrodes **15,16** may be individually selected. This step may be repeated at any time prior to step 306.

[0085] In a step **307**, the therapeutic energy port **18** is manipulated so as to cause a release of energy from the electrodes **15,16**. The duration and frequency of energy are responsive to judgments by medical personnel. This release of energy creates a pattern of lesions in the lumen.

[0086] Steps **306** and **307** are repeated as many times as necessary.

[0087] In a step **308**, the irrigation and aspiration control port **17** is manipulated so as to cause the balloon **13** to deflate and the wire frame **14** to revert to its collapsed state.

[0088] In a step **309**, the catheter **11** is withdrawn from the patient.

[0089] 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 balloon catheter;
at least two radiofrequency (RF) electrodes positioned in a circular or helical configuration around the outer surface of the balloon catheter and attached to the balloon catheter by a wire frame,
wherein the balloon catheter is separated from the RF electrodes by an insulation pad that protects the balloon catheter from high temperatures.
2. The nerve ablation device of claim 1, wherein the balloon catheter is provided with a rapid delivery (RX) wire system.
3. The nerve ablation device of claim 1, wherein the balloon catheter comprises two ports along the back end of the balloon catheter, and wherein one of the two ports is a balloon inflation port and the other port is a control unit for connection to the RF energy and temperature and nerve sensing.
4. The nerve ablation device of claim 1 having a rapid exchange configuration.
5. The nerve ablation device of claim 1, wherein each RF electrode is arranged as a circular hole having a diameter of 1.5 mm along the length of the balloon catheter.
6. The nerve ablation device of claim 1, further comprising four RF electrodes.
7. The nerve ablation device of claim 1, wherein said RF electrodes are positioned a helical fashion around the outer surface of the balloon catheter.
8. The nerve ablation device of claim 1, wherein said RF electrodes are evenly spaced around the circumference of the balloon catheter.
9. The nerve ablation device of claim 1, wherein said at least two RF electrodes comprise at least two ribbon-shaped electrodes positioned in a double-helical fashion around the outside of the outer surface of the balloon catheter.
10. The nerve ablation device of claim 9, wherein said ribbon-shaped electrodes are separated by a predetermined distance.
11. The nerve ablation device of claim 1, wherein said at least two RF electrodes can be operated separately or in combination with each other.
12. The nerve ablation device of claim 11, further comprising an electrode selection and control switch to select and activate individual RF electrodes.

13. The nerve ablation device of claim 1, wherein said wire frame is conductive so as to provide current to said RF electrodes
14. The nerve ablation device of claim 1, wherein said wire frame is bonded to the balloon catheter.
15. The nerve ablation device of claim 1, wherein said wire frame is movable between a collapsed position around said balloon when said balloon is in a collapsed, non-deployed position and an expanded position around said balloon when said balloon is in an expanded, deployed position.
16. The nerve ablation device of claim 1, further comprising a catheter sleeve into which said balloon catheter, wire frame and RF electrodes may be situated during insertion into a body lumen.
17. The nerve ablation device of claim 1, wherein said wire frame is formed of a shape memory material to allow said wire frame to assume a remembered shape when removed from said catheter sleeve.
18. A method for performing circumferential and or helical ablation of a renal nerve in a subject in need thereof comprising:
 - inserting a compliant balloon catheter comprising at least two radiofrequency (RF) electrodes positioned in a helical fashion around the outer surface of the balloon catheter and attached to the balloon catheter by a wire backbone into a renal arterial wall of the subject, and
 - delivering radiofrequency energy at a designated location within the renal arterial wall.
19. The method of claim 18, wherein the wire backbone provides support to the balloon catheter and delivers RF energy while sensing temperature and nerve activity.
20. The method of claim 18, wherein the balloon catheter is separated from the RF elements by an insulation pad that protects the balloon catheter from high temperatures.
21. The method of claim 18, further comprising inflating the balloon catheter with coolant of a stagnant or circulating nature.
22. The method of claim 18, further comprising monitoring the catheter balloon temperature during ablation.

23. The method of claim 18, further comprising measuring renal nerve afferent activity before and after nerve ablation.

24. The method of claim 18, 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.

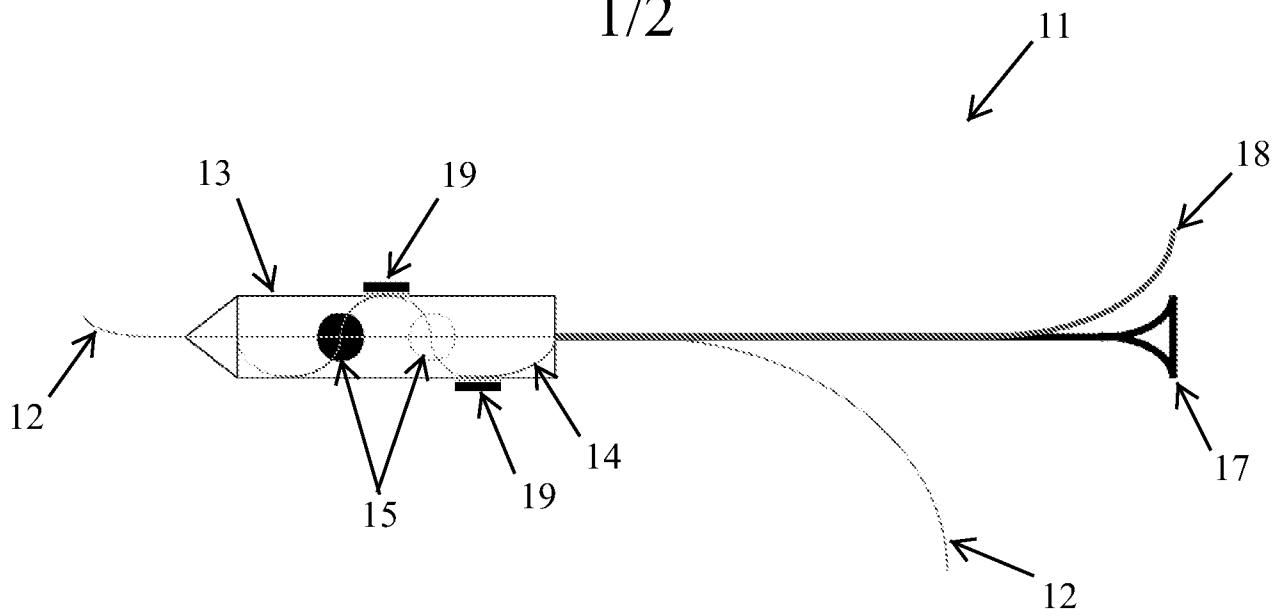
$1/2$ 

FIG. 1

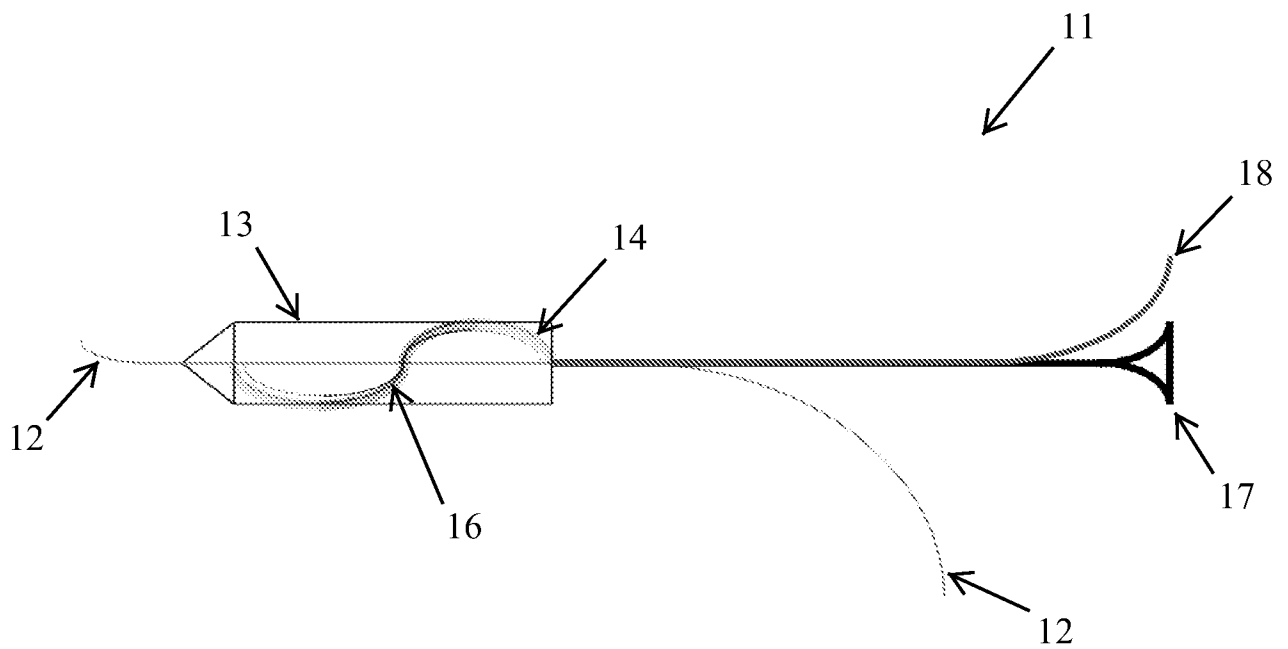


FIG. 2

2/2

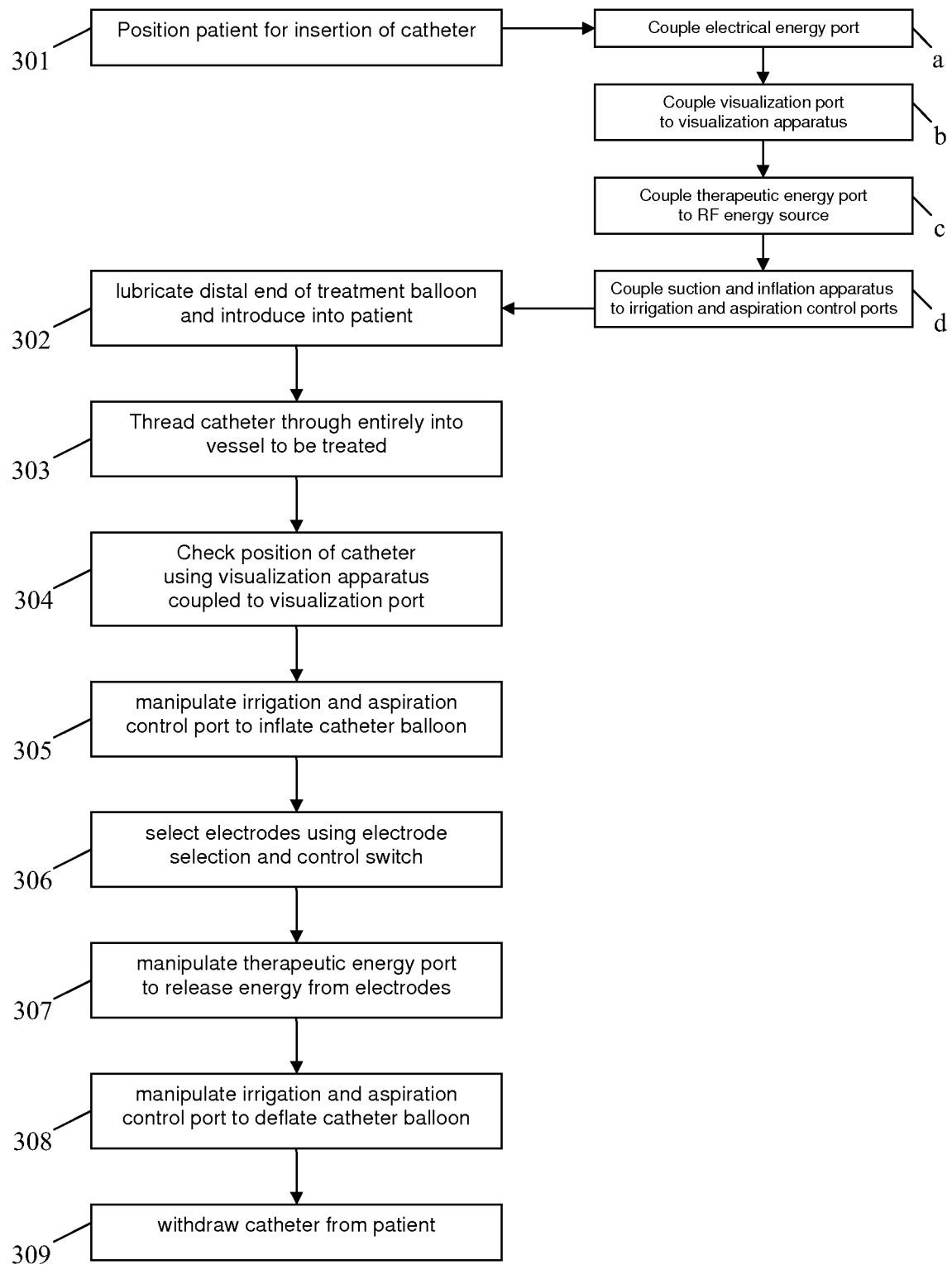


FIG. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 12/27849

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 18/18 (2012.01)

USPC - 606/41

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC -- 606/41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

USPC -- 606/1, 32, 34, 42, 49

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PubWEST (USPT, PGPB, JPAB, EPAB); Google

Search Terms: Balloon catheter radiofrequency electrode ablation wire frame insulating pad helical circular ribbon controller conductive sensor temperature coolant pump

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X ----- Y	US 2005/0288730 A1 (Deem et al.) 29 December 2005 (29.12.2005), Abstract, para [0025], [0026], [0030]-[0034], [0038], [0040], [0087]-[0092], [0095], [0096], [0099], [0109], [0130], [0131], [0134]; Fig. 6, 8	18, 23, 24 ----- 1-17, 19-22
Y	US 2010/0305562 A1 (Winkler et al.) 02 December 2010 (02.12.2010), Abstract, para [0055]-[0057], [0071], [0073], [0078], [0083], [0087], [0090], [0091], [0093], [0098], [0099], [0113]; Fig. 21	1-17, 19-22
Y	US 5,690,642 A (Osborne et al.) 25 November 1997 (25.11.1997), Abstract, col 2, ln 10-30	2, 4
Y	US 2010/0256629 A1 (Wylie et al.) 07 October 2010 (07.10.2010), para [0058]-[0060]; Fig. 5-7	5
Y	US 2009/0018534 A1 (Taimisto et al.) 15 January 2009 (15.01.2009), para [0045]	9, 10
A	US 2009/0157066 A1 (Satake) 18 June 2009 (18.06.2009), Abstract, para [0036], [0041], [0058], [0064], [0084]	1-24

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

27 Jun 2012 (27.06.2012)

Date of mailing of the international search report

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Name and mailing address of the ISA/US

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