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(54) Title: INTRAVASCULAR CATHETER WITH A BALLOON COMPRISING SEPARATE MICROPOROUS REGIONS

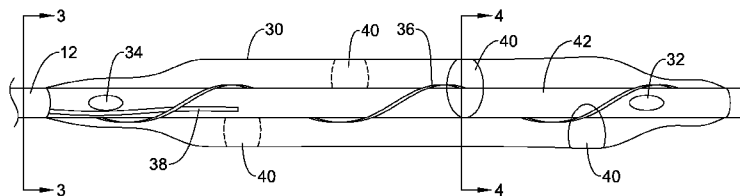


Figure 2

(57) Abstract: The disclosure pertains to an intravascular catheter (12), comprising an elongate member having a proximal end and a distal end, a balloon (30) having an interior surface, an exterior surface, a lumen defined by the interior surface and a cylindrical wall extending between the interior surface and the exterior surface, the cylindrical wall having a proximal end and a distal end, the balloon having a plurality of weeping windows (40) disposed in the wall and able to pass an electric current between the interior surface and the exterior surface, wherein the balloon wall is otherwise electrically insulative, and an electrode (36) disposed in the balloon. The intravascular system is suited for modulation of renal nerves, for example.



INTRAVASCULAR CATHETER WITH A BALLOON COMPRISING SEPARATE MICROPOROUS REGIONS

Cross-Reference to Related Applications

5 This application claims priority under 35 U.S.C. §119 to U.S. Provisional Application Serial No. 61/693,066, filed August 24, 2012, the entirety of which is incorporated herein by reference.

Field

 The invention generally pertains to percutaneous and intravascular devices for
10 nerve modulation and/or ablation.

Background

 Certain treatments require the temporary or permanent interruption or modification of select nerve function. One example treatment is renal nerve ablation
15 which is sometimes used to treat conditions related to congestive heart failure. The kidneys produce a sympathetic response to congestive heart failure, which, among other effects, increases the undesired retention of water and/or sodium. Ablating some of the nerves running to the kidneys may reduce or eliminate this sympathetic function, which may provide a corresponding reduction in the associated undesired
20 symptoms.

 Many body tissues such as nerves, including renal nerves, brain tissue, cardiac tissue and the tissue of other body organs are in close proximity to blood vessels or other body cavities and thus can be accessed percutaneously or intravascularly through the walls of the blood vessels. In some instances, it may be desirable to
25 ablate perivascular nerves using a radio frequency (RF) electrode. In other instances, the perivascular nerves may be ablated by other means including application of thermal, ultrasonic, laser, microwave, and other related energy sources to the vessel wall.

 In treatments involving perivascular nerves such as renal nerves, treatment
30 methods employing such energy sources have tended to apply the energy to the full circumference of the renal artery and/or vein to ensure that the nerves are modulated. However, such a treatment may result in thermal injury to the vessel wall near the electrode and other undesirable side effects such as, but not limited to, blood damage, clotting, weakened vessel wall, and/or fouling of the electrode.

Summary

It is therefore desirable to provide for alternative systems and methods for tissue treatment such as intravascular nerve modulation treatments that distribute ablation or modulation sites along and around the vessel or other body cavity.

5 Some embodiments of the invention are directed to a balloon catheter configured for tissue modulation such as nerve modulation and/or ablation. The balloon catheter includes an inflatable balloon at or proximate a distal end of the device. The wall of the balloon is constructed so as to only allow fluid through at desired locations.

10 An RF transmitter extends through the lumen of the balloon to supply the RF energy. In use, the balloon is inflated with an ionically conductive fluid such as saline and positioned at a desired location for treatment. In some embodiments, the balloon may be in circumferential contact with a wall such as a blood vessel wall at the treatment location. The RF transmitter is activated and the RF energy is converted to
15 ionic energy creating ionically charged fluid, which exits through micropores in the balloon wall to modulate or ablate tissue.

 The balloon may be a multilayer balloon with a first layer made from weeping material and a second layer made from an electrically insulative material. The weeping material comprises a plurality of micro-pores and therefore has a passageway
20 for fluid and hence ionic conduction. When a balloon is filled the micropores are therefore permeable to an ionically conductive fluid. The micropores may, or may not, permit any significant fluid flow. The weeping material may be formed by forming holes of the appropriate size in an otherwise fluid impermeable material or may be formed of a woven or knitted material to create a mesh-like structure. In other
25 embodiments, the balloon wall may be a balloon wall having a single layer of generally non-conductive and fluid-impermeable material with the windows created by forming a pattern of micro-pores through the layer of the balloon wall.

 The balloon catheter may include other elements such as a multi-lumen catheter shaft. The multi-lumen catheter shaft may include a guidewire lumen and one
30 or two fluid lumens as well as conductive members to connect the electrode and one or more sensors to a power and control system. For embodiments that include two fluid lumens, one fluid lumen may be used to introduce the conductive fluid into the balloon and the other fluid lumen may be used to evacuate the conductive fluid from the balloon. In this manner, the conductive fluid may be circulated through the

balloon. In some embodiments, it may be considered beneficial to influence the fluidic flow within the balloon by the placement of the inlet and outlet flow lumens. The RF transmitter may be constructed of any suitable material and geometry that efficiently converts RF energy to ionic energy and may, for example, be a ribbon electrode that is helically wound about the catheter shaft within the balloon lumen and may be made from any suitable material such as gold, copper, or silver.

In one illustrative method of use, a balloon catheter according to an embodiment of the invention is inserted percutaneously and/or intravascularly to a treatment location using a guidewire, a guide catheter or other conventional means. The balloon is inflated with the conductive fluid and the conductive fluid is circulated through the balloon. The transmitter is activated and RF energy is converted to ionic energy creating ionically charged fluid, which exits through micropores in the balloon wall into the tissue of the desired treatment area.

The treatment may be ended after a predetermined time or after a predetermined condition is met. For example, impedance may be measured through the electrode and the treatment may be ended after a predetermined change in the measured impedance. The above summary of some example embodiments is not intended to describe each disclosed embodiment or every implementation of the invention.

Brief Description of Drawings

The invention may be more completely understood in consideration of the following detailed description of various embodiments in connection with the accompanying drawings, in which:

Fig. 1 is a schematic view illustrating a renal nerve modulation system in situ.

Fig. 2 is a schematic view illustrating the distal end of a renal nerve modulation system.

Fig. 3 is a cross-sectional view of the renal nerve modulation system of Fig. 2.

Fig. 4 is another cross-sectional view of the renal nerve modulation system of Fig. 2.

Fig. 5 is a cross-sectional view of a renal nerve modulation system.

Fig. 6 is a schematic view illustrating the renal nerve modulation system of Fig. 2 in situ.

Fig. 7 is a projection view of the outer surface of a balloon of a renal nerve modulation system.

Fig. 8 is a projection view of the outer surface of a balloon of another renal nerve modulation system.

Fig. 9 is a cross-sectional view of a portion of a balloon window of a renal nerve modulation system.

5 Fig. 10 is a detail view of the outer surface of a balloon of another renal nerve modulation system illustrating an example window.

While the invention is amenable to various modifications and alternative forms, specifics thereof have been shown by way of example in the drawings and will be described in detail. It should be understood, however, that the intention is not to
10 limit aspects of the invention to the particular embodiments described. On the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention.

Detailed Description

15 The following description should be read with reference to the drawings wherein like reference numerals indicate like elements throughout the several views. The drawings, which are not necessarily to scale, are not intended to limit the scope of the claimed invention. The detailed description and drawings illustrate example embodiments of the claimed invention.

20 All numbers are herein assumed to be modified by the term “about.” The recitation of numerical ranges by endpoints includes all numbers subsumed within that range (e.g., 1 to 5 includes 1, 1.5, 2, 2.75, 3, 3.80, 4, and 5).

As used in this specification and the appended claims, the singular forms “a”, “an”, and “the” include the plural referents unless the content clearly dictates
25 otherwise. As used in this specification and the appended claims, the term “or” is generally employed in its sense including “and/or” unless the content clearly dictates otherwise.

It is noted that references in the specification to “an embodiment”, “some embodiments”, “other embodiments”, etc., indicate that the embodiment described
30 may include a particular feature, structure, or characteristic, but every embodiment may not necessarily include the particular feature, structure, or characteristic. Moreover, such phrases are not necessarily referring to the same embodiment. Further, when a particular feature, structure, or characteristic is described in

connection with an embodiment, it would be within the knowledge of one skilled in the art to effect such feature, structure, or characteristic in connection with other embodiments whether or not explicitly described unless clearly stated to the contrary.

While the devices and methods described herein are discussed relative to renal
5 nerve modulation through a blood vessel wall, it is contemplated that the devices and methods may be used in other applications where nerve modulation and/or ablation are desired. The term modulation refers to ablation and other techniques that may alter the function of affected nerves and other tissue such as brain tissue or cardiac tissue. When multiple ablations are desirable, they may be performed sequentially by
10 a single ablation device.

Fig. 1 is a schematic view of an illustrative renal nerve modulation system 10 in situ. System 10 may include one or more conductive element(s) 16, such as wires or the like, for providing power to a renal ablation system including a renal nerve modulation device 12 disposed within a delivery sheath 14, which may be adapted to
15 slidably contain the renal nerve modulation device 12 when the radially expanding region (not shown) of the elongate member is in a non-expanded configuration, the details of which can be better seen in subsequent figures. A proximal end of conductive element(s) 16 may be connected to a control and power element 18, which supplies necessary electrical energy to activate one or more electrodes to which the
20 distal end of conductive element(s) 16 are attached at or near a distal end of the renal nerve modulation device 12. When suitably activated, the electrodes are capable of ablating tissue as described below. The terms electrode and electrodes may be considered to be equivalent to elements capable of ablating adjacent tissue in the disclosure which follows. Suitable materials for the delivery sheath 14, device 12 and
25 elements capable of ablating adjacent tissue may include those materials disclosed herein (and/or other suitable materials) and may include internal and/or external layers of lubricious material(s). In some instances, return electrode patches 20 may be supplied on the legs or at another conventional location on the patient's body to complete the circuit. A proximal hub (not illustrated) having ports for a guidewire, an
30 inflation lumen and a return lumen may also be included. A conductive fluid source 24 such as a syringe, bag, or the like may be included. The conductive fluid source 24 may include a pump, regulator valve, or the like. The conductive fluid source 24 may be fluidly connected to the device by a line 22 or other conventional means. A fluid collection device 28 such as a bag may also be fluidly connected to the device by a

line 26. The fluid collection means may include an aspiration means such as a pump, syringe or the like.

The control and power element 18 may include monitoring elements to monitor parameters such as power, temperature, voltage, pulse size, impedance, and/or shape and other suitable parameters, with sensors mounted along the renal nerve modulation device 12, as well as suitable controls for performing the desired procedure. In some embodiments, the power element 18 may control a radio frequency (RF) electrode. The electrode may be configured to operate at a frequency of approximately 460 kHz. It is contemplated that any desired frequency in the RF range may be used, for example, from 450 - 500 kHz. It is further contemplated that other ablation devices may be used as desired, for example, but not limited to resistance heating, ultrasound, microwave, and laser devices and these devices may require that power be supplied by the power element 18 in a different form.

Fig. 2 illustrates the distal portion of a renal nerve modulation device 12. The renal nerve modulation device 12 includes a balloon 30 and an electrode 36. When in use, the balloon is preferably filled with a conductive fluid such as saline to allow the ablation energy to be transmitted from the electrode 36 through windows 40 that are permeable to RF radiation and/or energy transfer via ionic conductivity. Other appropriate conductive fluids include hypertonic solutions, contrast solution and mixtures of saline or hypertonic saline solutions with contrast solutions. The conductive fluid may be introduced through a fluid inlet port 32 and evacuated through a fluid outlet port 34, both in a central shaft 42. One or more sensors 38, such as a thermocouple, may be included and may be disposed on the shaft 42, on the balloon 30, or at another suitable location.

A cross-sectional view of the shaft 42 of the renal nerve modulation device 12 proximal to the balloon is illustrated in Fig. 3. The shaft 42 may include a guidewire lumen 46, a first lumen 48 (e.g., which may be connected to the fluid outlet 34), and a second lumen 50 (e.g., which may be connected to the fluid inlet 32). The electrode 36, or a conductive element to supply power to the electrode may extend along the outer surface of the shaft 42 or may be embedded within the shaft 42. The electrode 36 proximal to the balloon is preferably electrically insulated and is used to transmit power to the portion of the electrode disposed in the balloon. Conductors 44, two of which are illustrated in Fig. 3, may be used to supply power and to allow information to return from the one or more sensors 38. In some embodiments, the guidewire

lumen and/or one of the fluid lumens 48, 50 may be omitted. In some embodiments, the guidewire lumen 46 extends from the distal end of the device 12 to a proximal hub. In other embodiments, the guidewire lumen 46 can have a proximal opening that is distal the proximal portion of the system 10. In some embodiments, the fluid
5 lumens 48, 50 can be connected to a system to circulate the fluid through the balloon 30 or to a system that supplies new fluid and collects the evacuated fluid. It can be appreciated that embodiments may function with merely a single fluid lumen and a single fluid outlet into the balloon 30. It can also be appreciated that other lumen configurations are contemplated. For example, the three lumens may be disposed
10 within each other, may be concentric, or may be non-concentric. In some embodiments, the guidewire lumen may be the innermost lumen and may be surrounded by the fluid inlet lumen, which, in turn may be surrounded by the fluid outlet lumen. In another contemplated embodiment, only one of the fluid inlet and fluid outlet lumens is disposed around the guidewire lumen and the other of the fluid
15 inlet and fluid outlet lumens extends parallel to and spaced apart from the guidewire lumen. Another contemplated embodiment lacks the fluid outlet lumen and the fluid inlet lumen is disposed around or concentrically around the guidewire lumen. In another contemplated embodiment, the guidewire lumen is omitted and the system includes only the fluid inlet lumen or only the fluid inlet and outlet lumens. Of
20 course, it is also contemplated that any of these shaft variations may be included with any of the balloon and window variations discussed herein. These are just examples.

A cross-sectional view of the shaft 42 distal to the fluid outlet port 34 is illustrated in Fig. 4. The guidewire lumen 46 and the fluid inlet lumen 50 are present, as well as an electrode 36. In the presently illustrated embodiment, conductors 44,
25 which are connected to one or more sensors 38, are not present in this cross-sectional view. It can be appreciated that in embodiments that have one or more distal sensors, one or more conductors 44 may be present to connect with them.

Balloon 30 is shown in cross-section as having a first layer 54 and a second layer 56. A window 40 is formed in the balloon 30 by the absence of the second layer
30 56. The first layer 54 is preferably made from a weeping material. A weeping material is a material that permits only insignificant fluid flow and does not permit the transmission of ordered streams or jets of fluid. A suitable material may be one in which micropores are formed. Micro-pores are pores having a maximum width of less than 40 micro-inches, less than 35 micro-inches, less than 30 micro-inches, or

less than 25 micro-inches. Further, the micropores may have a mean pore size of between 15 and 30 micro-inches. Such a material may be formed by forming holes of a suitable size in an otherwise fluid impermeable material or by providing a material formed of a tight mesh or weave. Suitable materials include polymers materials with
5 micropores and are produced by microporous processing of, for example, PET, nylon 12, polyamid block copolymer, polyester block copolymer, fluoropolymers such as PTFE or ePTFE, and Goretex materials; or mesh or woven materials using many polymers such as nylon or PEBA. Some embodiments may further include a reinforced substructure or a braided substructure. Suitable materials for the fibers of
10 the substructure include UHMWPE, Kevlar, PET, carbon, and the like.

The second layer 56 may include an electrically non-conductive polymer such as a non-hydrophilic polyurethane, Pebax, nylon, polyester or block-copolymer. Other suitable materials include any of a range of electrically non-conductive polymers. In some embodiments, the materials of the first layer and the second layer
15 may be selected to have good bonding characteristics between the two layers. In other embodiments, a suitable tie layer (not illustrated) may be provided between the two layers. As illustrated, the windows 40 are formed in the wall 52 of the balloon 30 by the absence of the second layer 56.

Figure 5 illustrates a cross-sectional view of another embodiment of a renal
20 nerve modulation device. The cross-section is taken along the same lines as that of Figure 4 and the device is similar to that of Figures 2-4 except as otherwise noted herein. The device of Figure 5 has a balloon wall 52 that has a single layer 56. The layer 56 is a generally non-conductive and fluid impervious material except for the windows 40, which are formed by providing micro-pores through the balloon wall 52
25 at the area where the window is desired. Figure 9 illustrates an example cross-sectional view through a portion of a window 40 through a balloon wall 52. Micropores 62a-62g illustrate some of the profiles a micropore may take. Micropores 62a-62g may be formed by a laser or through some other suitable means. Figure 10 is a detail view illustrating an example window 40. The window 40 comprises a
30 plurality of micropores 62. Micropores 62 may be provided in a random pattern within the boundaries of a predetermined window shape or may be provided in a regular and repeating pattern.

The device illustrated in Fig. 6 is similar to that of the distal end of device 12 in situ. Preferably, the device 12 is available in various sizes, and a size is selected

that will allow the windows 40 of the balloon 30 to contact the wall of a blood vessel 60.

The particular balloon illustrated in Fig. 5 may be suitable for use in a renal nerve modulation application. The renal nerve extends generally longitudinally around the outside of a renal artery. This means that one can vary the longitudinal position of any particular circumferential treatment and achieve the same nerve modulation effect. Thus windows 40 are arranged to achieve complete circumferential coverage of the blood vessel while spaced apart longitudinally. In this particular case, the four windows 40 each cover a different 90 degree arc of the blood vessel. Each window may cover more than a 90 degree arc. For example, the windows 40 may cover a 100 or 110 degree arc to allow for some overlapping coverage of the windows 40. Windows 40 of this embodiment are four in number and generally circular in shape. It can be appreciated that variations in the number of windows and the shape of the windows are contemplated. For example, embodiments are contemplated which include 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 or more windows and which include windows that are circular, oval, rectangular, or polygonal. Moreover, the windows having a different length and width may be oriented so that the largest dimension is parallel to the longitudinal axis, perpendicular to the longitudinal axis, or at another angle with respect to the longitudinal axis such as a 45 degree angle. In some embodiments, each window may have an aspect ratio of 2:1, 3:1 or 4:1, where the major dimension is perpendicular to the longitudinal axis of the balloon. In some embodiments, the window or windows may have a custom pattern to provide a particular treatment pattern.

The electrode 36 may be a flat ribbon electrode made from platinum, gold, stainless steel, cobalt alloys, or other non-oxidizing materials. In some instances, titanium, tantalum, or tungsten may be used. The electrode 36 may extend along substantially the whole length of the balloon 30 or may extend only as far as the distal edge of the most distal window 40. The electrode 36 may have a generally helical shape and may be wrapped around the shaft 42. In some cases, the electrode 36 may be bonded to the shaft 42. The electrode 36 and windows 40 may be arranged so that the electrode extends directly under the windows 40. In some embodiments, the electrode 36 may be a wire or may be a tubular member disposed around the shaft 42. In some embodiments, a plurality of electrodes 36 may be used and each of the plurality may be fixed to the shaft 42 under the windows 40 and may share a common

connection to the conductive element 16. In other embodiments that include more than one electrode, each electrode may be separately controllable. In such embodiments, the balloon may be partitioned into more than one chamber and each chamber may include one or more electrodes. The electrode may be selected to
5 provide a particular level of flexibility to the balloon to enhance the maneuverability of the system. It can be appreciated that there are many variations contemplated for electrode 36.

Figs. 7-8 illustrate projections of the cylindrical central portion of a balloon wall 52 (i.e. the figure illustrates the cylindrical central portion of the balloon wall as if it were cut open and laid flat). The balloon wall 52 of these figures may be readily
10 incorporated into any of the nerve modulation systems described herein. The balloon 30 includes a plurality of windows 40. The windows may be defined by an absence of a second layer 56 as in the Fig. 4 embodiment, or by a pattern of micropores through a single layer as in the Fig. 5 embodiment. The windows are arranged on the
15 balloon such that their greatest dimension extends circumferentially (i.e. along a circumference of the cylindrical balloon wall) and their narrowest dimension extends axially (i.e. in the direction of the central longitudinal axis of the balloon 30). The windows 40 are arranged such that any line drawn from the proximal end of the cylindrical balloon wall to the distal end of the cylindrical balloon wall passes through
20 at least one window.

The windows may overlap circumferentially while being spaced apart axially. If a line drawn from the proximal end of the cylindrical balloon wall to the distal end of the cylindrical balloon wall passes through two windows, those two windows are said to circumferentially overlap.

25 The degree of circumferential overlap may be expressed in terms of the circumferential dimension of a window 40, in terms of the circumference of the balloon or in terms of an absolute dimension. For example, two adjacent windows may exhibit circumferential overlap that is between 0.2 and 2.0 mm, that is between 0.3 and 0.7 mm, that is between 0.4 and 0.6 mm, that is at least 0.3 mm, that is at least
30 0.4 mm, or that is at least 0.5 mm, or that is between 20% and 30% of the circumferential dimension of one of the two windows, that is between 24% and 26% of the circumferential dimension of one of the two windows, that is between 5% and 15% of a circumferential dimension of the cylindrical balloon, that is between 6% and

7% of a circumferential dimension of the cylindrical balloon, or that is between 10% and 14% of a circumferential dimension of the cylindrical balloon, for example.

The windows 40 preferably have a greater circumferential dimension than axial dimension. For example, the ratio of circumferential dimension to axial dimension for a window may be greater than 1.5:1, greater than 2:1, greater than 7 to 1 or some other suitable number. A window may have an axial dimension of 1 mm, 1.25 mm, 1.5 mm, 1.75 mm, 2 mm, 2.25 mm, 2.5 mm or other suitable dimension and a circumferential dimension of greater than 3 mm such as 3 mm, 3.5 mm, 4 mm, 4.5 mm, 5 mm, or 7 mm. The circumferential dimension of a window 40 may be 20%, 25%, 30%, 100% or other suitable percentage of the circumferences of the cylindrical portion of the balloon wall.

The windows 40 of Figs. 7 and 8 are shown as being arranged in a generally helical manner in that each adjacent window is offset axially and circumferentially (while overlapping circumferentially) from the previous window. Any number of windows sufficient to provide complete circumferential coverage may be used. In the embodiment of Figure 6, five windows 40 are illustrated. Some embodiments may include 3, 4, 5, 6, 7, 8, 9, 10 or more windows and, if arranged helically as illustrated in Fig. 6, may extend for more than one turn around the balloon wall. It will be appreciated that a helical configuration is not necessary to provide complete circumferential coverage. Complete circumferential coverage means that the windows are arranged such that any axially parallel line drawn from the proximal end of the cylindrical balloon wall to the distal end of the cylindrical balloon wall passes through at least one window. The windows may be any suitable shape such as oval, oblong, bowtie or diamond shaped.

Multilayer balloons 30 having windows 40 may be made according to one of the methods described herein or by another suitable method. In one method, the first layer 54 and the second layer 56 of the balloon are manufactured separately, using blow-molding techniques or other suitable methods. Holes to define the windows 40 are formed in second layer 56 by a laser, hole punch, mechanical or hydraulic cutting element or other suitable technique. The first layer 54 is positioned inside of the second layer 56 and the two layers 54, 56 are fused together using heat, a chemical solvent, an adhesive or other suitable technique. In some cases, the two layers may be positioned inside of a mold and/or pressure may be exerted inside inner layer 54 to fuse the two layers in an expanded position using heat, solvents, or adhesives. In

some instances, the two layers are not directly joined but rather are separately attached to shaft 42.

In another method of manufacture, the inner layer 54 is formed over a flexible mandrel. The flexible mandrel has a shape like that of the inner layer 54 in the expanded position but it is made from a material, such as silicon, that does not adhere well to the material of the inner layer 54. The inner layer 54 may be formed over the flexible mandrel by dip coating, spray coating, blow molding or other suitable techniques. A masking material is applied over the inner layer where the one or more windows 40 are desired. The masking material may be fixed to the inner layer using a removable or temporary adhesive. The flexible mandrel, with the inner layer and masking material thereon is then dip coated again using a non-conductive polymer to form the outer layer 56. The outer layer is cut at the edges of the masking material and the masking material along with the outer layer material that is on the masking material is removed, thus forming the balloon 30. Finally, the flexible mandrel is removed from within the balloon 30.

In use, a renal ablation system such as system 10 is provided. The system may be used with a standard guide catheter such as a 6 French guide catheter. Then the system 10 may be introduced percutaneously as is conventional in the intravascular medical device arts by using a guide catheter and/or a guide wire. For example, a guide wire such as a 0.014" diameter guidewire may be introduced percutaneously through a femoral artery and navigated to a renal artery using standard radiographic techniques. In some embodiments, a delivery sheath 14 may be introduced over the guide wire and the guide wire may be withdrawn, and the device 12 may be then introduced through the delivery sheath. In other embodiments, the device 12 may be introduced over the guidewire, or the system, including a delivery sheath 14 may be introduced over a guidewire. In embodiments involving a delivery sheath 14, the device 12 may be delivered distally from the distal end of the delivery sheath 14 into position, or the delivery sheath may be withdrawn proximally to expose the device 12. A conductive fluid 58 is introduced into the balloon through fluid inlet lumen 50 and fluid inlet port 32. The conductive fluid expands the balloon to the desired size. The balloon expansion may be monitored indirectly by monitoring the volume of conductive fluid introduced into the system or may be monitored through radiographic or other conventional means. Optionally, once the balloon is expanded to the desired size, fluid may be circulated within the balloon by continuing to

introduce fluid through the fluid inlet port 32 while withdrawing fluid from the balloon through the fluid outlet port 34. The rate of circulation of the fluid may be between 0 and 100 ml/min, 2 and 45 ml/min, 3 and 30 ml/min, or other desired rate of circulation. The rate of weeping, or seepage, through the balloon windows 40 may be
5 between 0 mL/min and 15 mL/min, between 0.1 microliter/min and 0.1 mL/min, or other desired rate (with a possible dependence on pore size and pore count). The balloon may be kept at or near a desired pressure such as an absolute pressure of between 1 and 6 atmospheres, between 1.5 and 4 atmospheres, between 2.5 and 3.5 atmospheres or other desired pressure. The electrode 36 is then activated by
10 supplying energy to the electrode. The energy may be supplied at 400-500 kHz and at between 1 and 50 watts. The energy is transmitted through the medium of the conductive fluid and through the windows 40 to the blood vessel wall to modulate or ablate the tissue. The lack of a conductive pathway through the non-window portions of the balloon may prevent effective energy transmission through the balloon wall
15 except at the window 40 and like structures. The progress of the treatment may be monitored by monitoring changes in impedance through the electrode. Other measurements such as pressure and/or temperature measurements may be conducted during the procedure as desired. The circulation of the conductive fluid 58 may mitigate the temperature rise of the tissue of the blood vessel 60 in contact with the
20 windows 40. The electrode 36 is preferably activated for an effective length of time, such as 1 minute or 2 minutes. Once the procedure is finished at a particular location, the balloon 30 may be partially or wholly deflated and moved to a different location such as the other renal artery, and the procedure may be repeated at another location as desired using conventional delivery and repositioning techniques.

25 Various modifications and alterations of this invention will become apparent to those skilled in the art without departing from the scope and principles of this invention, and it should be understood that this invention is not to be unduly limited to the illustrative embodiments set forth hereinabove. All publications and patents are herein incorporated by reference to the same extent as if each individual publication
30 or patent was specifically and individually indicated to be incorporated by reference.

What is claimed is:

1. An intravascular catheter, comprising:
an elongate member having a proximal end and a distal end;
a balloon having an interior surface, an exterior surface, a lumen defined by the interior surface and a balloon wall extending between the interior surface and the exterior surface, the balloon having a plurality of windows disposed in the balloon wall that are capable of passing an electric current between the interior surface and the exterior surface and wherein the balloon wall is otherwise electrically insulative, each window comprising a plurality of micropores; and
an electrode disposed within the balloon.
2. The catheter of claim 1, wherein the balloon wall includes a first layer and a second layer,
wherein the first layer comprises the plurality of micropores,
wherein the second layer comprises a fluid-impermeable material, and
wherein the plurality of windows are formed by the selective omission of the second layer from portions of the balloon wall.
3. The catheter of claim 2, wherein the first layer comprises a woven material.
4. The catheter of claim 2, wherein the first layer comprises an expanded polymer material.
5. The catheter of claim 2, wherein the first layer is inside the second layer.
6. The catheter of claim 2, wherein the second layer is inside the first layer.
7. The catheter of any one of claims 1-6, wherein at least one of the plurality of windows extends further in a circumferential direction than in an axial direction.

8. The catheter of any one of claims 1-7, wherein at least one of the plurality of windows is circular.

9. The catheter of any one of claims 1-8, wherein at least one of the plurality of windows is non-circular.

10. The catheter of any one of claims 1-9, wherein the plurality of windows are spaced axially from each other.

11. The catheter of any one of claims 1-10, wherein the plurality of windows are arranged in a spiral shape on the balloon wall.

12. The catheter of any one of claims 1-11, wherein at least two windows circumferentially overlap about the balloon.

13. The catheter of any one of claims 1-12, further comprising a temperature sensor disposed on the elongate member.

14. The catheter of any one of claims 1-13, wherein the electrode is helically disposed about the elongate member.

15. An intravascular catheter, comprising:
an elongate member having a proximal end and a distal end;
a balloon having an interior surface, an exterior surface, a lumen defined by the interior surface and a balloon wall extending between the interior surface and the exterior surface, the balloon having a plurality of weeping windows disposed in the balloon wall and able to pass an electric current between the interior surface and the exterior surface and wherein the balloon wall is otherwise electrically insulative; and
an electrode disposed in the balloon.

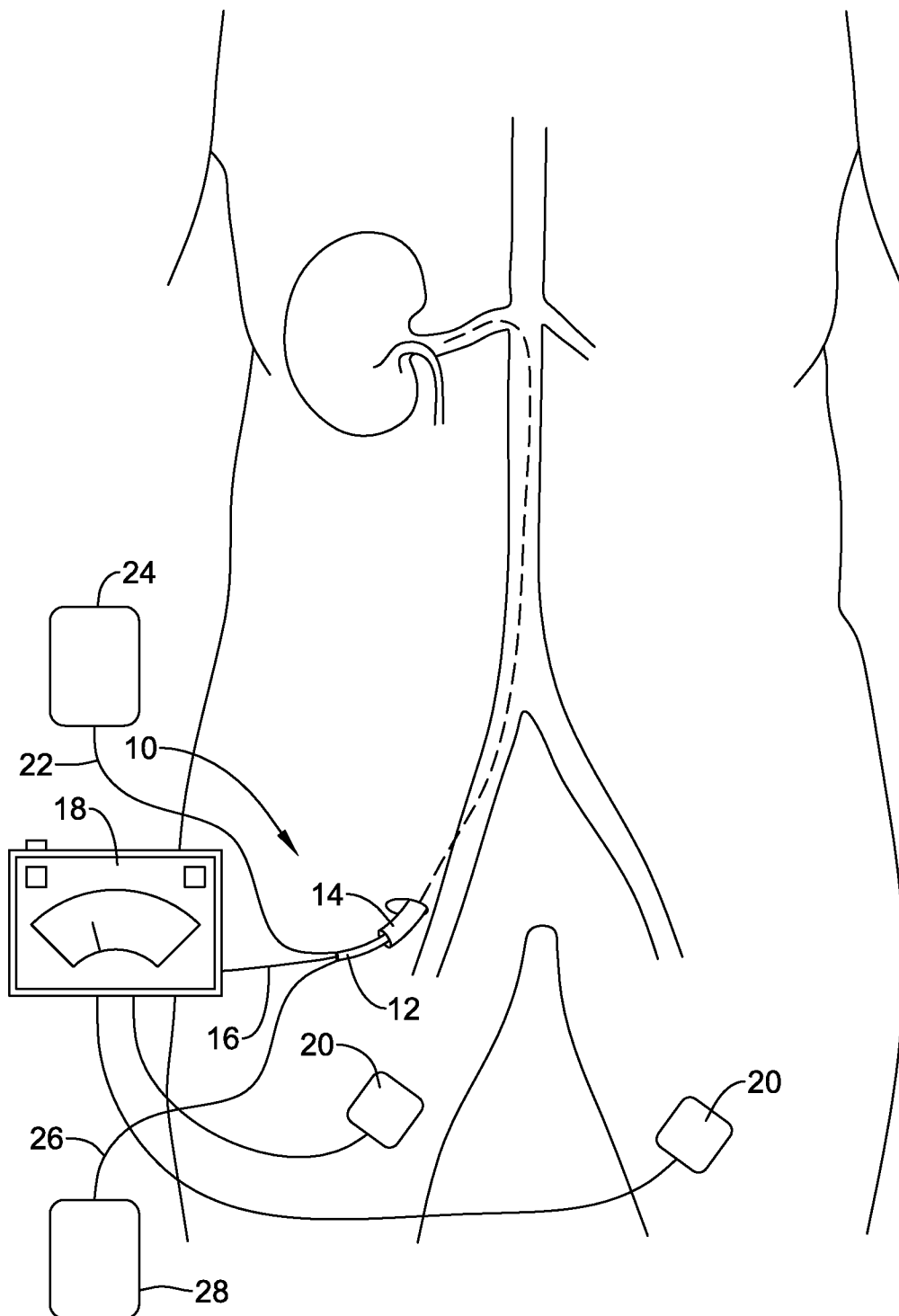


Figure 1

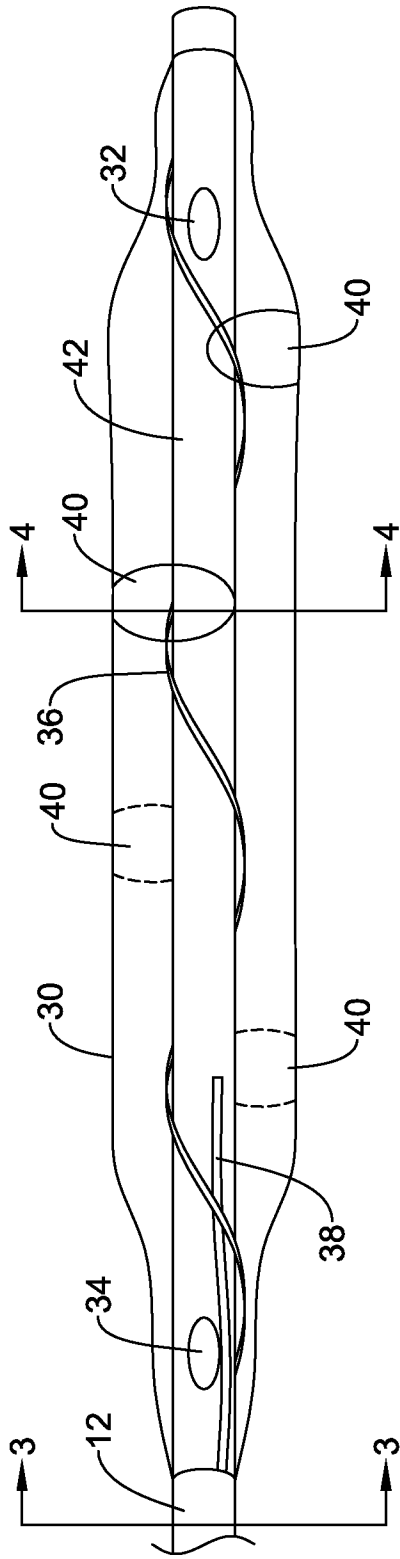


Figure 2

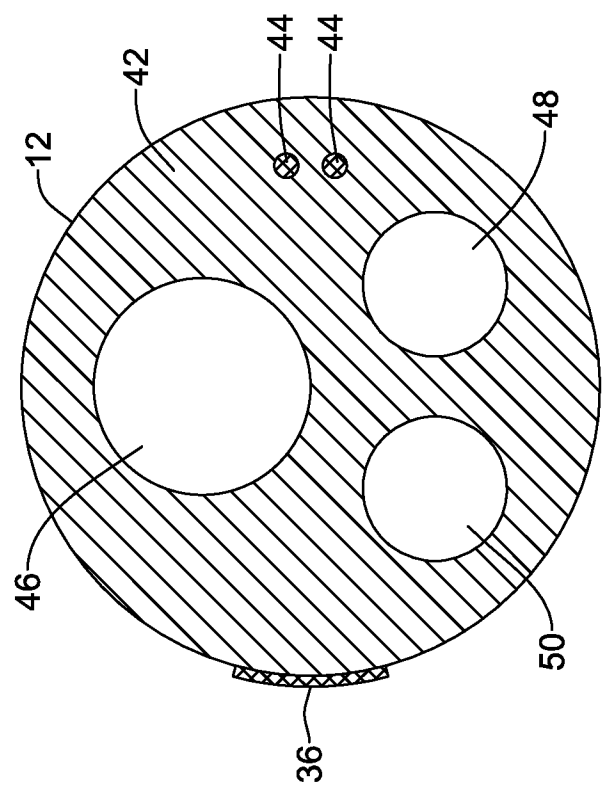


Figure 3

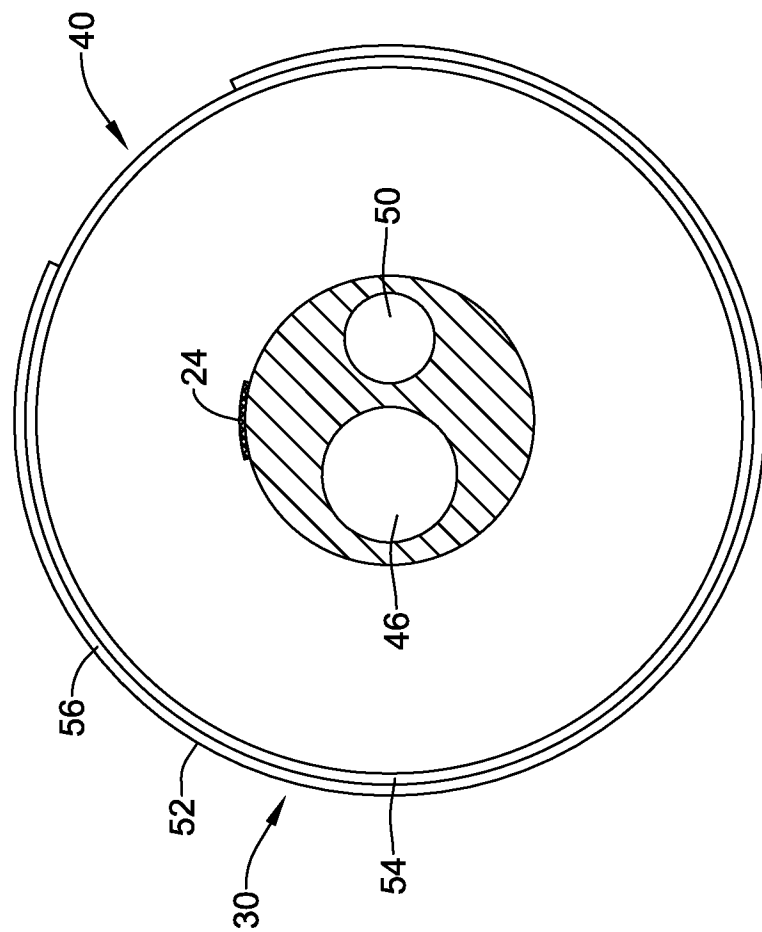


Figure 4

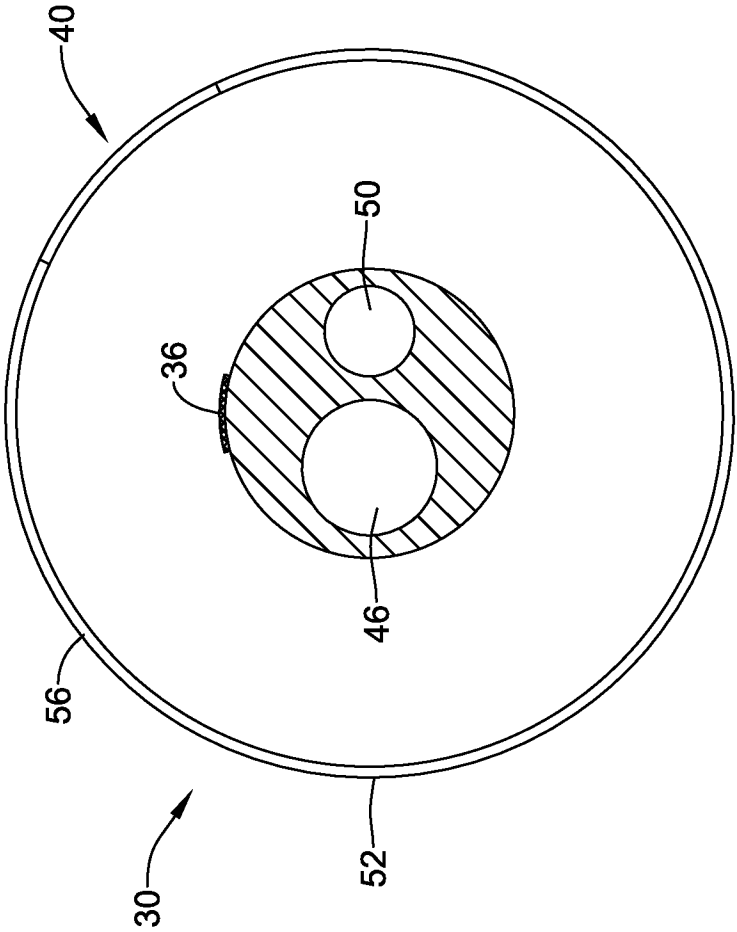


Figure 5

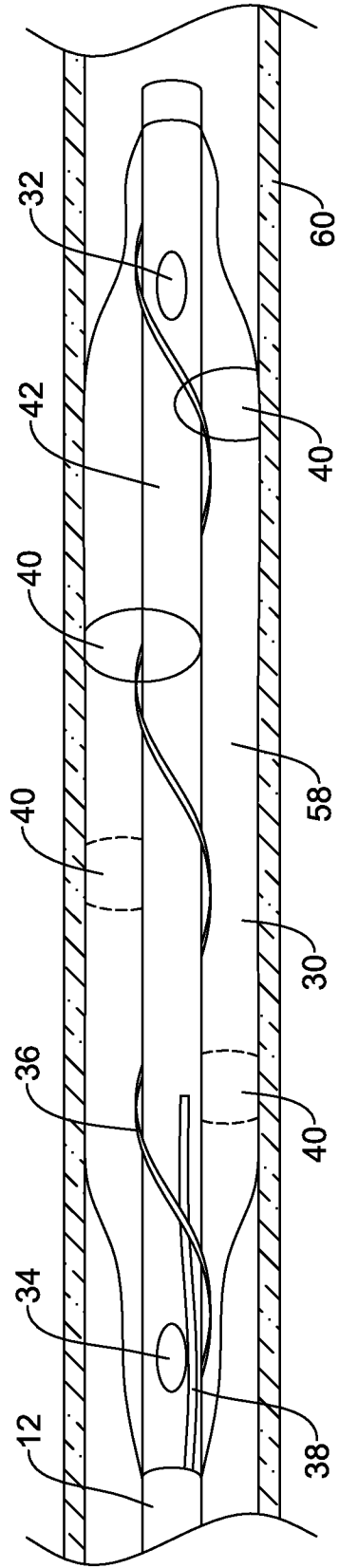


Figure 6

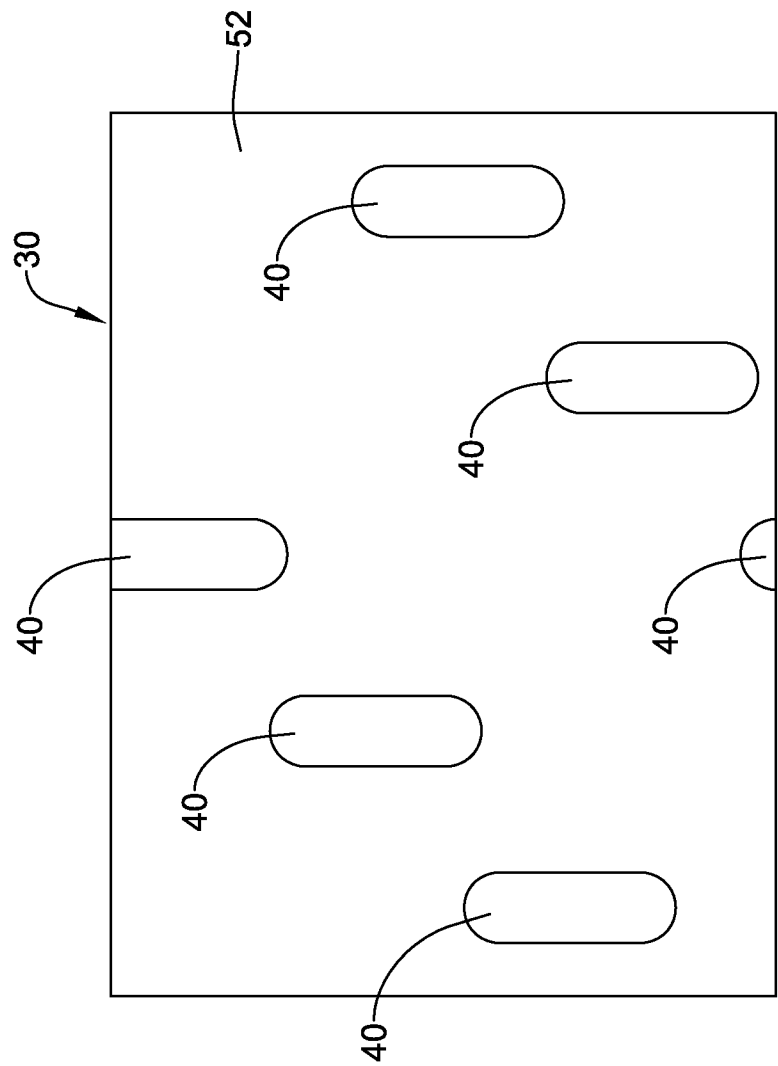


Figure 7

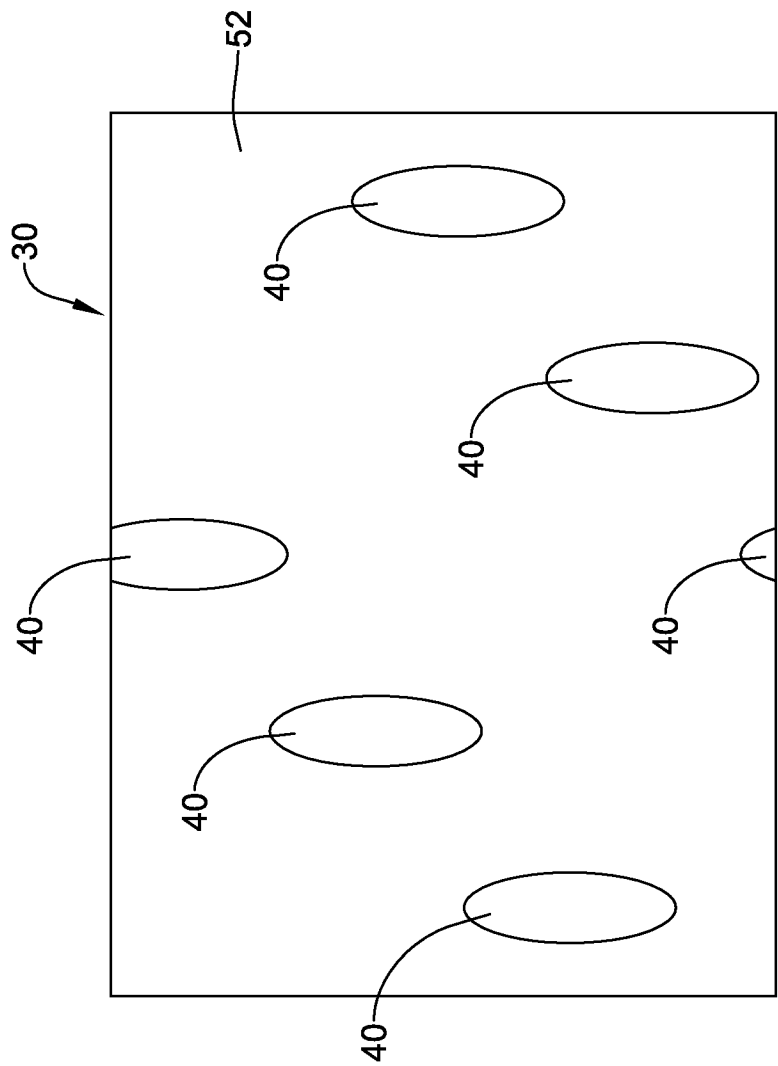


Figure 8

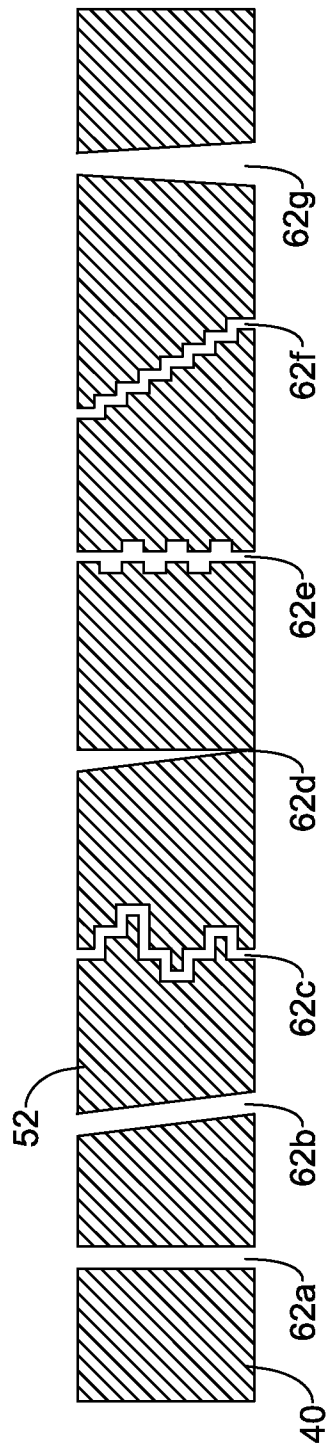


Figure 9

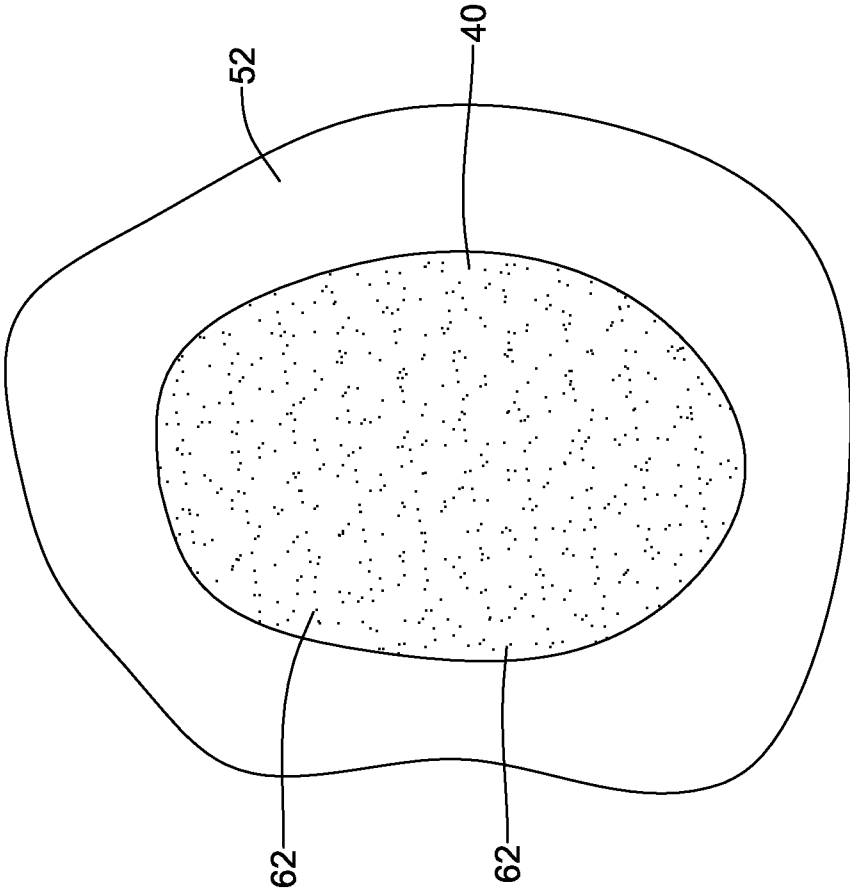


Figure 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/056488

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61M25/10
ADD.

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)
A61B A61M

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 475 213 B1 (SWANSON DAVID K [US] ET AL) 5 November 2002 (2002-11-05)	1,7-10, 12,15
Y	column 5, line 18 - line 44 column 6, line 29 - column 7, line 5 column 7, line 52 - column 8, line 19 column 13, line 17 - line 32; figures 1, 2, 4, 11, 12	2-6,11, 13,14
Y	----- US 2004/260277 A1 (MAGUIRE MARK A [US]) 23 December 2004 (2004-12-23) paragraph [0131] - paragraph [0136] paragraph [0220] - paragraph [0222]; figure 2 ----- -/--	2-5,14



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

25 November 2013

Date of mailing of the international search report

09/12/2013

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Authorized officer

Sigurd, Karin

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/056488

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2010/189876 A1 (KOKISH LYUDMILA [US] ET AL) 29 July 2010 (2010-07-29) paragraph [0030] - paragraph [0036] paragraph [0047] - paragraph [0050]; figures 3C, 4 -----	2,6
Y	WO 2005/122938 A1 (ARTHROCARE CORP [US]; CRAWFORD DARREN [US]) 29 December 2005 (2005-12-29) page 53, line 31 - page 54, line 25 page 57, line 28 - page 58, line 20; figures 29, 30, 32 -----	11
Y	US 2007/021746 A1 (TAIMISTO MIRIAM H [US] ET AL) 25 January 2007 (2007-01-25) paragraph [0027] - paragraph [0034] paragraph [0040] - paragraph [0043]; figure 2B -----	13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/056488

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 6475213	B1	05-11-2002	NONE
US 2004260277	A1	23-12-2004	AT 325581 T 15-06-2006
		AU 765444 B2	18-09-2003
		AU 4173300 A	09-10-2000
		CA 2361157 A1	28-09-2000
		DE 60027904 T2	14-12-2006
		EP 1210021 A2	05-06-2002
		JP 4491149 B2	30-06-2010
		JP 2002538932 A	19-11-2002
		US 6500174 B1	31-12-2002
		US 2002198521 A1	26-12-2002
		US 2003083653 A1	01-05-2003
		US 2004260277 A1	23-12-2004
		WO 0056237 A2	28-09-2000
US 2010189876	A1	29-07-2010	EP 2512542 A1 24-10-2012
		US 2010189876 A1	29-07-2010
		WO 2011075309 A1	23-06-2011
WO 2005122938	A1	29-12-2005	EP 1768595 A1 04-04-2007
		WO 2005122938 A1	29-12-2005
US 2007021746	A1	25-01-2007	CA 2569578 A1 22-12-2005
		EP 1753358 A1	21-02-2007
		JP 2008501440 A	24-01-2008
		US 2005273095 A1	08-12-2005
		US 2007021746 A1	25-01-2007
		WO 2005120378 A1	22-12-2005