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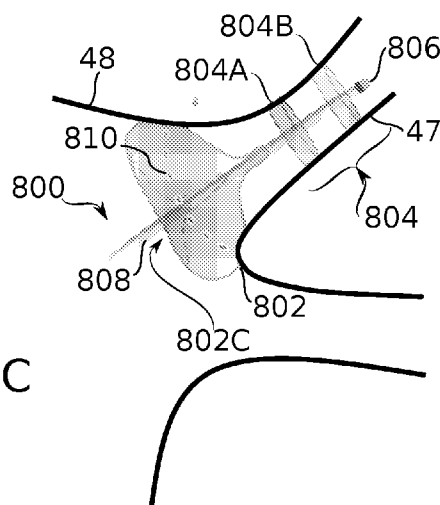


FIG. 8C

(57) Abstract: An ablation balloon catheter probe is described with a first balloon sized to inflate for pressing against an ostial and/or atrial surface surrounding a pulmonary vein, and a second balloon or balloon assembly, distal to the first, sized to inflate and anchor within the pulmonary vein. Optionally, either or both of the balloons comprise a ring of spaced electrodes configured for RF ablation to form a complete ablation scar around the ring.



INTRAVEIN ABLATION

RELATED APPLICATIONS

This application claims the benefit of priority under 35 USC § 119(e) of U.S. Provisional
5 Patent Application No. 62/518,623 filed June 13, 2017, the contents of which are incorporated
herein by reference in their entirety.

FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to the field of intrabody
10 catheters and more particularly, to treatment by catheter ablation.

Atrial fibrillation is a disease of the heart wherein the bio-electrical initiation of cardiac muscle
contraction becomes disordered. This may lead to inefficient (*e.g.*, overly rapid) contraction and
potentially serious consequences. Some treatments of atrial fibrillation target isolating triggering
sites of this disordered bio-electrical activity from the main body of the heart. Isolation may be
15 by ablation of tissue to form a barrier to electrical transmission. In such ablation treatments,
pulmonary veins (typically comprising four separate veins delivering oxygenated blood from the
lungs into the left atrium) are commonly targeted.

Among the devices and methods proposed and/or in use are various types of balloon
catheters, comprising a distally positioned, reversibly inflatable balloon that can be guided using
20 the catheter to the treatment site, inflated, positioned, and used to convey ablation energy (cold
and/or radio frequency energy, for example) to the ablation target at regions of contact.

SUMMARY OF THE INVENTION

There is provided, in accordance with some embodiments of the present disclosure, an
ablation catheter comprising: a first balloon, positioned near a distal end of the ablation catheter,
25 and sized to inflate, upon insertion to a human atrium, to a size hindering entry of the first
balloon into a human pulmonary vein; an anchoring balloon assembly positioned on the ablation
catheter distal to the first balloon, wherein the anchoring balloon assembly is inflatable upon
insertion to the human pulmonary vein to fittingly anchor against a lumenal wall of the human
pulmonary vein; and at least one ablation electrode positioned on at least one of the first balloon
30 and the anchoring balloon assembly.

In some embodiments, the ablation catheter is configured to anchor along a longitudinal
extent of the anchoring balloon assembly upon inflation while inserted to the human pulmonary
vein.

In some embodiments, the at least one ablation electrode comprises a plurality of electrodes positioned on the anchoring balloon assembly.

In some embodiments, the plurality of ablation electrodes of the anchoring balloon assembly is positioned to make contact with a luminal wall of the pulmonary vein for ablation of tissue thereof upon inflation of the anchoring balloon assembly to fittingly anchor the anchoring balloon assembly against the luminal wall of the human pulmonary vein.

In some embodiments, ablation electrodes of the anchoring balloon assembly are distributed around a balloon of the anchoring balloon assembly at a plurality of different longitudinal offsets relative to a longitudinal axis of the ablation catheter.

In some embodiments, each respective ablation electrode is longitudinally offset from its adjacent ablation electrodes by at least 25% of the longitudinal extent of at least half of the ablation electrodes.

In some embodiments, the at least one ablation electrode comprises a plurality of electrodes positioned on the first balloon.

In some embodiments, the plurality of electrodes of the first balloon are positioned on a distal side of the first balloon, and making contact with cardiovascular tissue for ablation thereof upon advancement of the inflated first balloon against an ostium of a human pulmonary vein.

In some embodiments, the ablation electrodes are distributed along a region encircling a longitudinal axis of the ablation catheter.

In some embodiments, the ablation electrodes are sized and spaced for ablation of an entirely transmural path through cardiovascular tissue when the tissue is positioned to encircle the longitudinal axis.

In some embodiments, the encircling region is ring-shaped.

In some embodiments, a contact surface of each ablation electrode extends between about 1.5 and 2.0 mm along the circumference of the ring-shaped region, and is separated along the circumference of the ring-shaped region from its circumferential neighbors by between about 2.0 and 2.5 mm.

In some embodiments, the encircling region comprises alternating extents of exposed ablation electrode surface and inter-electrode surface comprised of elastically expandable material.

In some embodiments, the plurality of electrodes comprise separately actuatable electrode groups, each electrode group comprising a plurality of electrically linked electrodes.

In some embodiments, each electrode group consists of a pair of electrically linked electrodes.

In some embodiments, the first balloon inflates to a diameter larger than a diameter of the human pulmonary vein.

In some embodiments, the anchoring balloon assembly comprises a first anchoring section and a second anchoring section sized to inflate to press against a blood vessel wall, anchoring the catheter therein; and the first anchoring section second anchoring section are separated by a narrowing.

In some embodiments, the first and second anchoring sections comprise first and second anchoring balloons, and the narrowing comprises a region between the first and second anchoring balloons.

In some embodiments, the anchoring balloon assembly inflates to contact the luminal wall of the human pulmonary vein along a substantially cylindrical longitudinal extent of the anchoring balloon assembly.

In some embodiments, the ablation catheter comprises a stimulation electrode extending in ring surrounding the substantially cylindrical longitudinal extent.

In some embodiments, the ring of the stimulation electrode extends around the substantially cylindrical longitudinal extent in a zig-zag shape.

In some embodiments, the first balloon inflates to a substantially spherical shape.

In some embodiments, the first balloon inflates to tapering shape which narrows from a more proximal to a more distal direction.

In some embodiments, the inflated first balloon comprises a cuff that circumferentially surrounds a hollow region between the first balloon and a catheter shaft of the ablation catheter.

In some embodiments, the ablation catheter comprises a tip ablation electrode positioned at a distal tip of the ablation catheter distal to the anchoring balloon assembly.

In some embodiments, the ablation catheter comprises a conduit configured to transfer cooling fluid from a cooling fluid source connector at one end of the conduit to at least one of the first balloon and the anchoring balloon assembly.

There is provided, in accordance with some embodiments of the present disclosure, a method of anchoring an ablation catheter to select an ablation region for bio-electrically isolating a human pulmonary vein from an atrium, comprising: inserting to the atrium a distal portion of an ablation catheter comprising a first balloon and a second balloon positioned on the ablation catheter distal to the first balloon; inflating the first balloon; inserting a second balloon from the atrium into the pulmonary vein, to a depth set by interference between the first balloon and an ostium leading into the pulmonary vein; inflating the second balloon to fittingly contact a luminal wall of the human pulmonary vein along a substantially cylindrical longitudinal extent

of the second balloon, thereby anchoring the ablation catheter; and ablating cardiovascular tissue using ablation electrodes of the ablation catheter positioned on at least one of the balloons, while the ablation catheter remains anchored in place.

5 In some embodiments, the ablation electrodes are positioned on the first balloon, and the region selected for ablation is within the ostium.

In some embodiments, the inflated first balloon presses each of the ablation electrodes against the ablated cardiovascular tissue to exclude blood from contact with all of the ablation electrodes at the same time.

10 In some embodiments, the ablation electrodes are positioned on the second balloon, and the region selected for ablation is within the pulmonary vein.

In some embodiments, the inflated second balloon presses each of the ablation electrodes against the ablated cardiovascular tissue to exclude blood from contact with all of the ablation electrodes at the same time.

15 In some embodiments, the fitting contact of the second balloon acts to anchor the second balloon within the human pulmonary vein.

There is provided, in accordance with some embodiments of the present disclosure, an ablation catheter comprising: a balloon positioned at the distal end of the ablation catheter, inflatable upon insertion to a human atrium to contact with a closed-loop contacting portion a region of cardiovascular tissue for electrical isolation of a human pulmonary vein; and a plurality
20 of ablation electrodes distributed around the contact portion; wherein a contact surface of each ablation electrode extends along a circumference of the contacting portion, separated along the circumference of the contacting portion from its circumferential neighbors by between about 75% and 125% of its own circumferential extent upon inflation of the balloon.

25 In some embodiments, each ablation electrode extends along the circumference of the contacting portion between about 1.5 mm and 2.0 mm.

In some embodiments, the longest extent of the contact surface of each ablation electrode in a direction perpendicular to the closed-loop contacting portion is between about 0.75 mm and 1.0 mm.

30 There is provided, in accordance with some embodiments of the present disclosure, an ablation catheter comprising: a balloon positioned at the distal end of an ablation catheter, wherein the balloon is inflatable to fittingly contact a luminal wall of a human pulmonary vein along a substantially smooth cylindrical longitudinal extent of the balloon; and a plurality of ablation electrodes distributed around the balloon at a plurality of different longitudinal offsets along the substantially cylindrical longitudinal extent.

In some embodiments, the plurality of ablation electrodes are positioned with a corresponding region of each respective ablation electrode positioned along the perimeter of an eccentric cylindric cross-section of the substantially cylindrical longitudinal extent.

In some embodiments, the eccentric cylindric cross-section is angularly offset from a cylindric cross-section perpendicular to a longitudinal axis of the substantially cylindrical longitudinal extent by at least 20°.

In some embodiments, each respective ablation electrode is longitudinally offset from its adjacent ablation electrodes by at least 1/4 of the longitudinal extent of the ablation electrode.

There is provided, in accordance with some embodiments of the present disclosure, an ablation catheter comprising: a catheter shaft; a balloon, circumferentially surrounding the catheter shaft; and a plurality of ablation electrodes arranged circumferentially on a distal surface of the balloon; wherein the balloon, when inflated, comprises a cuff that circumferentially surrounds a hollow region between the balloon and the catheter shaft.

In some embodiments, the cuff is shaped so that a proximal surface of the balloon, defining the hollow region, expands radially outward and distally forward as the balloon inflates.

In some embodiments, the hollow region tapers narrower in a proximal-to-distal direction.

There is provided, in accordance with some embodiments of the present disclosure, a vascular anchoring section of a catheter comprising: a catheter shaft; and a balloon assembly, circumferentially surrounding the catheter shaft, and comprising a first anchoring section and a second anchoring section sized to inflate to press against a blood vessel wall, anchoring the catheter therein; wherein the first anchoring section second anchoring section are separated by a narrowing.

In some embodiments, the first and second anchoring sections are sized to anchor within a pulmonary vein.

In some embodiments, the first and second anchoring sections comprise first and second catheter balloons, and the narrowing comprises a region between the first and second catheter balloons.

In some embodiments, the first and second catheter balloons are separately inflatable.

In some embodiments, the first and second anchoring sections comprise a single balloon, and the narrowing is a region of the single balloon narrower than the first and second anchoring sections.

In some embodiments, the catheter also includes a stopper balloon, mounted on the catheter shaft proximally to the balloon assembly.

There is provided, in accordance with some embodiments of the present disclosure, an ablation catheter comprising: a catheter shaft; a balloon, circumferentially surrounding the catheter shaft; and a plurality of ablation electrodes arranged circumferentially on a distal surface of the balloon; wherein the balloon is hingingly attached to the catheter shaft to allow proximal
5 deflection of the balloon upon urging of the electrodes distally against a tissue surface.

In some embodiments, the balloon, when inflated, comprises a cuff that circumferentially surrounds a hollow region between the balloon and the catheter shaft.

In some embodiments, the balloon, when inflated, tapers from a wider proximal portion to a narrower distal portion.

10 In some embodiments, at least a distal surface of the balloon tapers more gradually through a distal portion, than through a more proximal region of the distal surface.

In some embodiments, the plurality of ablation electrodes are positioned on the more proximal region of the distal surface.

In some embodiments, the hollow region is on a proximal side of the balloon.

15 In some embodiments, the catheter also includes an anchoring balloon assembly, mounted on the catheter shaft distally to the balloon.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be
20 used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

As will be appreciated by one skilled in the art, aspects of the present invention may be
25 embodied as a system, method or computer program product. Accordingly, aspects of the present invention may take the form of an entirely hardware embodiment, an entirely software embodiment (including firmware, resident software, micro-code, *etc.*) or an embodiment combining software and hardware aspects that may all generally be referred to herein as a “circuit,” “module” or “system.” Furthermore, some embodiments of the present invention may
30 take the form of a computer program product embodied in one or more computer readable medium(s) having computer readable program code embodied thereon. Implementation of the method and/or system of some embodiments of the invention can involve performing and/or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of some embodiments of the method and/or

system of the invention, several selected tasks could be implemented by hardware, by software or by firmware and/or by a combination thereof, *e.g.*, using an operating system.

For example, hardware for performing selected tasks according to some embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to some embodiments of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to some exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

Any combination of one or more computer readable medium(s) may be utilized for some embodiments of the invention. The computer readable medium may be a computer readable signal medium or a computer readable storage medium. A computer readable storage medium may be, for example, but not limited to, an electronic, magnetic, optical, electromagnetic, infrared, or semiconductor system, apparatus, or device, or any suitable combination of the foregoing. More specific examples (a non-exhaustive list) of the computer readable storage medium would include the following: an electrical connection having one or more wires, a portable computer diskette, a hard disk, a random access memory (RAM), a read-only memory (ROM), an erasable programmable read-only memory (EPROM or Flash memory), an optical fiber, a portable compact disc read-only memory (CD-ROM), an optical storage device, a magnetic storage device, or any suitable combination of the foregoing. In the context of this document, a computer readable storage medium may be any tangible medium that can contain, or store a program for use by or in connection with an instruction execution system, apparatus, or device.

A computer readable signal medium may include a propagated data signal with computer readable program code embodied therein, for example, in baseband or as part of a carrier wave. Such a propagated signal may take any of a variety of forms, including, but not limited to, electro-magnetic, optical, or any suitable combination thereof. A computer readable signal medium may be any computer readable medium that is not a computer readable storage medium and that can communicate, propagate, or transport a program for use by or in connection with an instruction execution system, apparatus, or device.

Program code embodied on a computer readable medium and/or data used thereby may be transmitted using any appropriate medium, including but not limited to wireless, wireline, optical fiber cable, RF, etc., or any suitable combination of the foregoing.

Computer program code for carrying out operations for some embodiments of the present invention may be written in any combination of one or more programming languages, including an object oriented programming language such as Java, Smalltalk, C++ or the like and conventional procedural programming languages, such as the "C" programming language or similar programming languages. The program code may execute entirely on the user's computer, partly on the user's computer, as a stand-alone software package, partly on the user's computer and partly on a remote computer or entirely on the remote computer or server. In the latter scenario, the remote computer may be connected to the user's computer through any type of network, including a local area network (LAN) or a wide area network (WAN), or the connection may be made to an external computer (for example, through the Internet using an Internet Service Provider).

Some embodiments of the present invention may be described below with reference to flowchart illustrations and/or block diagrams of methods, apparatus (systems) and computer program products according to embodiments of the invention. It will be understood that each block of the flowchart illustrations and/or block diagrams, and combinations of blocks in the flowchart illustrations and/or block diagrams, can be implemented by computer program instructions. These computer program instructions may be provided to a processor of a general purpose computer, special purpose computer, or other programmable data processing apparatus to produce a machine, such that the instructions, which execute via the processor of the computer or other programmable data processing apparatus, create means for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

These computer program instructions may also be stored in a computer readable medium that can direct a computer, other programmable data processing apparatus, or other devices to function in a particular manner, such that the instructions stored in the computer readable medium produce an article of manufacture including instructions which implement the function/act specified in the flowchart and/or block diagram block or blocks.

The computer program instructions may also be loaded onto a computer, other programmable data processing apparatus, or other devices to cause a series of operational steps to be performed on the computer, other programmable apparatus or other devices to produce a computer implemented process such that the instructions which execute on the computer or other

programmable apparatus provide processes for implementing the functions/acts specified in the flowchart and/or block diagram block or blocks.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example, and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIG. 1A is a flowchart schematically illustrating a method of ablation using a two-ballooned ablation catheter, according to some embodiments of the present disclosure;

FIG. 1B is a flowchart, schematically illustrating a more detailed method of ablation using a two-ballooned ablation catheter, according to some embodiments of the present disclosure;

FIGs. 2A–2C schematically illustrate deployment of an ablation catheter, according to some embodiments of the present disclosure;

FIG. 3A schematically illustrates a two-ballooned ablation catheter having electrodes on the more proximal balloon, according to some embodiments of the present disclosure;

FIG. 3B schematically illustrates a two-ballooned ablation catheter having a different configuration of electrodes on the more distal balloon, according to some embodiments of the present disclosure;

FIG. 3C schematically illustrates a two-ballooned ablation catheter having a different configuration of electrodes on both the more distal balloon and the more proximal balloon, according to some embodiments of the present disclosure;

FIG. 3D schematically illustrates a two-ballooned ablation catheter illustrating different balloon shapes, adapted for optional use with a separate electrode ring, according to some embodiments of the present disclosure;

FIGs. 4A-4C schematically illustrate electrodes of an ablation catheter and their connection traces, for use on the surface of an expandable balloon, according to some embodiments of the present disclosure;

FIG. 4D schematically illustrates an electrode arrangement on a balloon of an ablation catheter using the electrode and trace design of Figure 4A, according to some embodiments of the present disclosure;

FIG. 5 schematically illustrates electrodes of an ablation catheter and their connection traces, for use on the surface of an expandable balloon, according to some embodiments of the present disclosure;

FIGs. 6A–6C schematically illustrate an electrode arrangement on a balloon of an ablation catheter for creation of an intra-venous ablation pattern, according to some embodiments of the present disclosure;

FIG. 7A presents a dissected image of an intravenous ablation line in porcine pulmonary vein, according to some embodiments of the present disclosure;

FIG. 7B presents a dissected image of an atrial ablation line in a porcine left atrium, according to some embodiments of the present disclosure;

FIGs. 8A–8C schematically illustrate deployment of an ablation catheter, according to some embodiments of the present disclosure;

FIGs. 9A–9B schematically illustrate a three-balloon ablation catheter, according to some embodiments of the present disclosure;

FIG. 9C schematically illustrates a balloon anchor is made of two balloon widenings, separated by a narrowing, according to some embodiments of the present disclosure; and

FIG. 9D schematically illustrates a disk-shaped ablation/stopper, according to some embodiments of the present disclosure.

DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to the field of intrabody catheters and more particularly, to treatment by catheter ablation.

Overview

An aspect of some embodiments of the present invention relates to a two- or more-balloon ablation catheter probe, comprising a first balloon sized to inflate for pressing against an ostial and/or atrial surface surrounding a pulmonary vein, and a second balloon (optionally, a balloon assembly comprising a plurality of balloons) sized to inflate and anchor within the pulmonary vein.

In some embodiments, one or both of the balloons/balloon assemblies is provided with an ablation modality (*e.g.*, ablation electrodes), which operates to disrupt cellular structure along an ablation line so that bioelectrical impulse transmission across the ablation line is prevented. For

effective treatment, the ablation line should be continuous (gap free) along its length, and deep enough (transmural) so that bioelectrical impulse transmission cannot pass underneath.

In some embodiments, the ablation modality used is radio frequency (RF) ablation. RF ablation to electrically isolate a pulmonary vein can optionally be performed upon cardiac tissue of the left atrium itself, within the ostium connecting the left atrium with each pulmonary vein, and/or within the lumen of the pulmonary vein itself.

In some embodiments, ablation is performed using electrodes positioned on the first (more proximal) balloon, which optionally is substantially spherical (*e.g.*, spherical, ellipsoid, and/or ovoid) in shape, or generally conical and/or mushroom-cap shaped; and sized so that it makes contact with a tissue region surrounding the opening of the pulmonary vein when it is pressed against the opening. Such shapes are potentially well suited to insertion to a pulmonary vein ostium to form a fully radial region of tissue contact. However, normal anatomical variation may result in an interrupted and/or irregular contact surface with some balloon shapes. In some embodiments, the balloon is sufficiently elastic that it can deform upon contact to mitigate this problem. Optionally, the elastic deformation comprises being sufficiently elastic that an increase in inflation pressure and/or tissue contact pressure causes expansion of the balloon skin in positions away from the region of contact, where expansion is constrained by tissue contact. Herein, this is referred to as "bulging elasticity," wherein increasing pressure against tissue at the region of contact is compensated for by an increase in balloon volume allowed by balloon skin expansion somewhere else. In an example of bulging elasticity, pushing on a spherical balloon in one place results in an expansion of the balloon, *e.g.*, at a region opposite.

Additionally or alternatively, in some embodiments, the inflated balloon is shaped so that some elastic deformation occurs by a change in balloon shape which, as such, involves little or no change in the volume of the balloon, but relies rather some section of the balloon skin away from the region of contact *shrinking*, while another region closer to the region of tissue contact expands. Herein, this is referred to as "hinging elasticity" and/or "bending elasticity". In an example of hinging elasticity, pushing on a long cylindrical balloon in a direction perpendicular to the long axis of the cylinder at one end while the other end is held in place results in an expansion of the balloon skin on the side pressed, while the opposite side shrinks slightly. In some embodiments of the present invention, hinging elasticity is provided by a substantially conically-shaped balloon that inflates to a conical shape surrounding a smaller conical hollow, into which the balloon collapses when pushed upon from outside the cone. "Hinging elasticity" optionally increases mechanical advantage, allowing a greater distance of shape change as a function of applied force. For example, in the case of the conical balloon-with-hollow, a

relatively large deflection on the cone's periphery can be adjusted for by a relatively small shrinkage/expansion of the balloon skin near the tip of the cone. This in turn is a potential functional advantage, making the balloon act more compliantly in response to applied force. Another potential advantage of a smaller change in skin stretching is to reduce the amount of compliance needed by an electrode assembly (*e.g.*, the flexibility needed by a conductive trace connecting the electrode to a measuring device and/or power source).

There is no particular requirement that only one of hinging elasticity and bulging elasticity is provided. Hinging elasticity may be accompanied by bulging elasticity, for example, although hinging optionally decreases the amount of bulging a certain applied force elicits.

In some embodiments, flexibility is enhanced by positioning electrode contact surfaces as separate patches around a ring-shaped region, the electrodes being separated from one another by short extents of flexible balloon material or other flexible material, for example, a metal (*e.g.*, nitinol and/or stainless steel) strut and/or spring member. To avoid introducing lesion gaps, the electrodes are placed close enough to one another that lesion foci initiated at each electrode spread far enough to overlap one another.

In some embodiments, electrodes are separately activated (for example, to potentially reduce peak power supply requirements), and/or activated in small groups (for example, to potentially speed up the ablation process).

In some embodiments, ablation is performed using electrodes positioned on the second (more distal) balloon, which optionally is substantially cylindrical along a middle extent of its body. Such a shape is potentially well suited for fitted insertion to within the lumen of a pulmonary vein. Again, the balloon material, in some embodiments, is elastic enough to conform to the shape of the vein it is inflated within. In some embodiments, a plurality of spaced-apart ablation electrodes is provided, with the spacing remaining small enough that lesion foci formed at adjoining electrodes expand to overlap one another.

For any of the electrode configurations, the two-balloon/balloon assembly arrangement provides potential advantages with respect to positioning and/or anchoring.

If ablating using intra-vein positioned electrodes (on the "second", more distal balloon/balloon assembly), those electrodes should be positioned to a depth sufficiently deep to contact the surface of the venous lumen, but not so deep that they end up distal to sites that trigger electrical activity. In some embodiments, the electrodes are placed on an oblique ring, which has certain potential advantages for reducing a risk of blockage after ablation, but may restrict the longitudinal range of effective electrode placement. Another potential advantage of an oblique ring of electrodes is to reduce electrode contribution to the maximum bulge diameter

along a longitudinal axis of the folded balloon, since the electrodes are offset along the longitudinal axis, axially distributing their volume and/or effects on packing tightness.

The first balloon, in some embodiments, acts as a stopper to help control the distance to which the intravein electrodes are inserted. Optionally, the distance is selected for patients with different anatomies by choice of a catheter configured with a particular first balloon-to-second balloon electrodes distance (for example, 8 mm, 10 mm, 12 mm, 14 mm, 16 mm, 18 mm, 20 mm, or another larger, smaller or intermediate distance). Optionally, insertion distance is controlled by a combination of the degree of inflation of the first balloon, and a degree of force used to push the balloon into place. In some embodiments, the insertion distance is predetermined, for example, based on imaging of patient anatomy. In some embodiments, insertion distance is varied (*e.g.*, gradually increased) until good electrical contact is verified; for example, the shortest insertion distance resulting in electrical contact radially all around the balloon is used. Since the second (more distal) balloon/balloon assembly is configured, in some embodiments, to be expandable with sufficient force to anchor itself, the advancing optionally is performed with sub-anchoring pressures, and/or by intermittent partial deflations until good anchoring occurs.

If ablating using electrodes positioned outside the vein (on the “first”, more proximal balloon/balloon assembly), it is a potential advantage to lock these electrodes into place once they've reached their target position, so that reliable ablation can be performed. In some embodiments, the more distal balloon/balloon assembly expands to form an anchor that may reduce the chances that the ablating balloon will accidentally be dislodged from its selected position before ablation can be completed.

Another potential advantage of the distal balloon/balloon assembly is to serve as a controllable positioning aid. Upon inflation (optionally full or partial inflation), the distal balloon/balloon assembly may act to center the more proximal balloon around the opening to the pulmonary vein. However, should it be determined that an off-center position is preferable (*e.g.*, due to anatomical variation), the distal balloon/balloon assembly can be left uninflated, or inflated to a reduced degree. Another potential positioning advantage is that once centered, the catheter can be rotated in place while the proximal balloon maintains substantially the same ring of contact with the adjacent tissue. This may be of use in mitigating gaps which are found and/or suspected to remain after a first round of ablation, for example, by slightly rotating the electrode pattern so that it fits into the spaces that were inter-electrode spaces during the first ablation, and ablating for a second time.

In some embodiments, the balloon and electrode configuration allows monitoring and control of electrode-surface contact pressures for a plurality of ablation electrodes arranged around a tissue-contacting ring. In some embodiments, ablation electrodes on a catheter balloon are arranged on an elastic surface, with elastic material substantially surrounding each electrode (e.g., surrounding each electrode apart from the electrode's lead), and distributed around a ring encircling a portion of that elastic surface (that is, a ring surrounding a longitudinal axis passing through the portion). Individual electrodes are made relatively small (e.g., 1 mm by 2 mm) and well-separated from each other (e.g., by about 2 mm) so that the elastic properties of the balloon material can distribute pressure evenly around the balloon perimeter.

In some embodiments, when the catheter is properly positioned, the electrodes activated for ablation are each pressed firmly against the target tissue. Potentially, this excludes blood from contact with the electrodes during ablation, which may prevent the formation of blood clots. Moreover, due to the elasticity of the balloon, contact pressure is potentially equalized for each contacting electrode. Potentially, this makes individual electrodes act more reproducibly upon activation to ablate.

An aspect of some embodiments of the present invention relates to an obliquely oriented ring-shaped arrangement of ablation electrodes provided on a balloon of an ablation catheter, wherein the balloon is sized to press the ablation electrodes against the luminal surface of a blood vessel upon inflation of the balloon therein.

The balloon is configured, in some embodiments, to make contact with the luminal surface along a substantially cylindrical extent upon inflation. The electrode ring is thereby also pressed into contact with the luminal surface so that a lesion may be formed around the entire extent of the ring upon activation of the electrodes with RF energy.

Around the ring, the electrodes are spaced from one another at a sufficiently short distance (e.g., about 1.5 mm, 2.0 mm, 2.25 mm, 2.5 mm, or another larger, smaller or intermediate distance), that lesions formed at the position of each individual electrode merge into one another to form a continuous lesion line.

Upon lesioning, ablated tissue may swell due to edema and/or scarring. If too much swelling occurs, the resulting blockage can approach dangerous levels, e.g., leading to pulmonary edema.

The oblique orientation of ring-shaped arrangement of ablation electrodes potentially helps reduce the maximum cross-sectional area of blockage that results, since different electrodes form lesions positioned at different longitudinal offsets along the blood vessel. However, the oblique orientation is preferably set to be little-enough offset from orthogonal to

the longitudinal axis of the vein so that all parts of the ring of the ablation line may be positioned to be a barrier between the left atrium and potential electrogenic regions within the vein. For example, the angle of a plane passing through all of the ring's electrodes may be 10°, 15°, 20°, 25°, 30°, 40°, or another larger smaller or intermediate angle offset from orthogonal. The maximum relative axial offset of electrodes in an ablation ring is optionally in the range of about 2 mm to 8 mm, or another range having the same, larger, smaller, and/or intermediate bounds. Optionally, the maximum relative axial offset of electrodes is, for example, about 2 mm, 4 mm, 5 mm, 6 mm, 8 mm, or another larger, smaller, or intermediate offset. It is also noted that intravein ablation from an inflated balloon potentially helps to reduce effects of tissue shrinkage induced by ablation.

As used herein, the term "ring" (and other ring-related terms used herein; for example, "ring-shaped", "ring-like", "oblique ring" and "angled ring") refers to regions of tissue and/or arrangements of one or more electrodes that themselves form a closed-loop region encircling a longitudinal axis, and/or are distributed (for example, but not necessarily, evenly spaced) along a closed-loop path encircling a longitudinal axis. By "encircling" may be understood surrounding the longitudinal axis with a path portion occupying each angular offset around the axis; additionally or alternatively "encircling" may be understood as "extending fully around a perimeter" within which the longitudinal axis passes (the perimeter is not necessarily itself a circular perimeter).

In some embodiments, the "closed-loop" of a ring lesion (and/or an arrangement of one or more electrodes operable to ablate tissue to form a ring lesion) functionally comprises a fully circumferential blockage of bioelectrical impulse transmission across the ring lesion. Optionally, the surrounding is with exactly one loop of the closed-loop path. In some embodiments, the longitudinal axis extends along a lumen, for example, longitudinally along a lumen of a blood vessel, catheter tube and/or a balloon. In some embodiments, the region of the ring itself is defined on a surface extending along the longitudinal axis; for example, a lumen of a blood vessel, or an outer surface of a catheter balloon. "Oblique ring" and "angled ring" refer more particularly to rings which are non-orthogonal to the longitudinal axis, for example as described herein.

In some embodiments, a closed-loop path extending through and around the ring projects as a convex curve to a 2-D plane perpendicular to the longitudinal axis (that is, the closed path lies completely on one side of all of its tangent lines in a 2-D projection of the closed path to the perpendicular plane). In the case of a collapsible balloon, the closed-loop path is optionally convex upon suitable expansion of the balloon for use. In some embodiments, the closed-loop

path does not cross over itself in a 2-D projection onto the perpendicular plane. Positions along the closed-loop path are not necessarily all co-planar. For example, the closed-loop path may comprise waves, zigzags, and/or steps.

An aspect of some embodiments of the present invention relates to a balloon catheter comprising an elastic balloon having a portion with a cuff-like shape, and configured to urge a distal surface toward increasingly distal positions as the balloon inflates; wherein the distal urging of the distal surface comprises a proximal surface of the balloon expanding from around an internal cavity, shaped so that the proximal surface is *also* urged at least partially distally by the inflation.

In some embodiments, for example, the balloon inflates to a first position with a distal surface of the balloon at a first distal position, and then further inflates to a second position, with the distal surface in a second, more distal position. In some embodiment, electrodes on the distal surface (*e.g.*, a ring of electrodes) are urged distally as well. In some embodiments, the electrodes on the distal surface (along with the distal surface itself) are also urged in a radially outward direction as the distal surface moves forward (distally). In some embodiments, the distal balloon surface pivots radially outward and distally from a region of attachment to the shaft during inflation.

In some embodiments, the distal movement and/or pivoting of the distal surface is encouraged by the proximal surface of the balloon being shaped to surround a hollow region. The proximal surface thereby defines a relatively radially inner surface of the balloon, while the distal surface of the balloon is relatively a radially outer surface. This creates, in some embodiments, a cuff region and/or roughly toroidal region of the balloon. In some embodiments, one or both of the inner and outer cuff surfaces is oriented with a proximal-to-distal tapering shape. As the balloon expands between the first position and the second position, the inner surface of the cuff also expands. The inner surface is shaped (*e.g.*, with a tapering narrower in a proximal-to-distal direction) so that this expansion also produces a net distal displacement of the volume of the balloon, further encouraging distal movement of the distal surface.

The balloon is inflated, in some embodiments, to a size large enough to impede insertion of the stopper and/or ablation balloon into a pulmonary artery, for example, about 15 mm, 20 mm, 25 mm, 30 mm, or another larger or smaller diameter.

The distal urging movement is a potential advantage for achieving circumferential contact of electrodes mounted on the balloon distal surface against a tissue wall. For example, in some embodiments, the balloon catheter is anchored in place before full expansion of the balloon having a cuff portion and carrying the electrodes (the stopper and/or ablation balloon).

Optionally, the anchoring is by inflation of a balloon anchoring assembly. Then, the cuff portion is expanded by inflation (e.g., using saline liquid or gas). As it expands, in some embodiments, the cuff portion is urged distally by its shape, including the shape of an inner surface of the cuff which defines an inner hollow that tapers narrower in a proximal to distal direction. Since the balloon catheter is anchored, at circumferential locations where the distal motion of the distal balloon surface encounters a tissue wall, distal motion stops. Further inflation then is directed to force expansion at other circumferential wall locations, optionally until full contact is achieved all the way around the distal wall of the balloon.

An aspect of some embodiments of the present invention relates to a balloon catheter comprising an elastic balloon shaped to hingingly collapse in a proximal and axially central direction upon being urged distally against a tissue wall. In some embodiments, the elastic balloon is shaped substantially as a cone (or a "mushroom cap") when inflated; that is, tapering narrower from a proximal to a distal direction. The cone shaped balloon moreover, in some embodiments, surrounds a hollow area, which itself is also optionally substantially cone-shaped and tapering narrow from a proximal to a distal direction. In some embodiments, the "hinge" of the cone shaped balloon is in a region near a central axis of the cone, wherein the skin of the balloon here stretches (on the distal side) and optionally shrinks (on the proximal side) to allow the hinging collapse upon the balloon being urged distally against a tissue wall.

In some embodiments, the balloon is shaped like a thin disk upon full inflation, and thin enough relative to its radial extent (e.g., at least a 2:1, 3:1 or another ration) to bend proximally by hinging elasticity when urged distally against a tissue wall. A potential advantage of a conical shape is that its unconstrained inflated surface shape may be nearer to the shape of an ostial wall of a blood vessel against which the balloon is to be fitted in continuous circumferential contact.

An aspect of some embodiments of the present invention relates to a balloon catheter comprising an anchoring balloon assembly comprised of at least two anchoring surface elements separated by a narrower region ("neck region") which does not expand to a radial distance as wide as either of the at least two anchoring surface elements. In some embodiments, the balloon catheter comprises an anchoring balloon assembly comprised of a plurality of balloon elements, and the "neck region" comprises a region between the two balloon elements which does not expand at all. In some embodiments, the anchoring balloon assembly comprises a balloon which, upon expansion, has a greater radius in two or more wide regions than at any position in a narrowed region between the two wide regions. In some embodiments, the narrowed region is no more than 80%, 70%, 50%, 20%, or another fraction of the narrowest of its flanking wide regions.

A long anchoring assembly for anchoring within a blood vessel has a potential advantage over a short anchoring assembly, by suppressing pivoting around the anchoring region and/or increasing the certainty of the orientation of the balloon catheter device when it does anchor. This advantage is potentially greatest when there is firm anchoring in at least two sufficiently
5 separate regions along the blood vessel.

By dividing a long anchoring assembly into two or more balloon elements (and/or two wider anchoring regions separated by a narrower neck region), there is potentially provided to the anchor a greater independence of inflation diameter along the length of the anchor. For example, a blood vessel may comprise a deep anchoring region X having radius x , and a
10 shallower anchoring region Y having radius y , $y > x$. However, it may not be known for certain for a certain patient by how much, or even if, $y > x$. If, for example, one long, substantially cylindrical anchoring balloon is inserted to the vessel, the inflating balloon will anchor itself at anchoring region X before anchoring at Y. With increasing inflation and sufficient elasticity, the balloon may expand enough to also anchor at Y, but the expansion into region Y will potentially
15 be restricted (*e.g.*, "pulled inward") by the neighboring un-expanded balloon skin contacting anchoring region X, and unable to expand outward to accommodate an increase in pressure. Potentially, anchoring at Y cannot be achieved, or potentially excessive force has to be exerted on X in order to get adequate anchoring at Y.

With a different anchoring balloon provided for each of anchoring region X and Y, and/or
20 with a separating neck region, as in some embodiments, cross-site anchoring influences are potentially reduced. Optionally, different anchoring balloons are controlled separately, each with its own inflation pressure. Potentially, even if the two balloons are controlled by a single inflation pressure source (and/or in the case of embodiments comprising a single narrow-necked balloon), cross-site influence is reduced, since restriction at one site is not "pulling inward" on
25 the other. In the case of necked-balloon embodiments, even though the neck is narrow, it is potentially remains free to expand upon increasing pressure, so that it doesn't itself constrain further expansion of the un-anchored part of the balloon, and moreover potentially isolates the as-yet un-anchored portion of the balloon from constraining effects by the already anchored site.

Another potential advantage of an anchoring assembly comprised of a plurality of
30 balloon elements and/or a plurality of neck-separated anchoring regions is to create two (or more) separated regions of focused anchoring force on the blood vessel.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following

description and/or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Dual-Balloon Ablation Catheter Positioning

Reference is now made to *Figure 1A*, which is a flowchart schematically illustrating a method of ablation using a two-ballooned ablation catheter, according to some embodiments of the present disclosure.

Examples of two-balloon ablation catheters suitable for use with the method of *Figure 1A* are described herein, for example in relation to *Figures 2A–3D*. In some embodiments a catheter comprises a proximal balloon and a distal balloon. The proximal balloon optionally acts as a “stopper” which sets a penetration distance of the ablation catheter into an atrial ostium/pulmonary vein. The distal balloon optionally acts as an “anchor” which helps, upon inflation, to secure the ablation catheter into an atrial ostium/pulmonary vein. Optionally, one or both of the proximal balloon and the distal balloon comprise and/or are adapted to position ablation means, for example, suitable arrangements of electrodes and/or cryoablation elements. In some embodiments, the distal electrode comprises one or more stimulating electrodes, which are optionally used to map electrical activity and/or propagation; and/or optionally used to verify ablation results.

The method of *Figure 1A* begins, in some embodiments, with the ablation catheter positioned in an atrium, for example after navigation of the ablation catheter to the heart via arteries and/or veins of the patient.

At block **110**, in some embodiments, a proximal balloon (*e.g.*, balloon **202** of *Figure 2C*) is inflated. The balloon is inflated, in some embodiments, to a size large enough to impede insertion of the proximal balloon into a pulmonary artery, for example, about 15 mm, 20 mm, 25 mm, 30 mm, or another larger or smaller diameter. Optionally, inflation of the proximal balloon in block **110** is partial, *e.g.*, to provide a blocking function without yet providing full inflation used for sealing and/or to induce electrode contact forces used during ablation.

At block **112**, in some embodiments, a still-deflated distal balloon (*e.g.*, balloon **204** of *Figure 2C*) is advanced into a pulmonary vein ahead of the proximal balloon, resulting in insertion of the distal balloon to the pulmonary vein. The distal balloon is optionally fully deflated. Optionally the distal balloon is only partially inflated; little enough so that it does not interfere with the advancing. When the proximal balloon encounters interference from the ostium of the pulmonary vein, the advancing stops. The inflated distal balloon, in some embodiments, is between 7–15 mm in diameter, for example, 7 mm, 8 mm, 10 mm, 12 mm, 14 mm, 15 mm, or

another larger, smaller, or intermediate diameter. Optionally, the elastic balloon is inflatable to any selected diameter in the range of 7–15 mm, or another range having the same, larger, smaller, and/or intermediate bounds. The length of the distal balloon, in some embodiments, is between 10–30 mm; for example, 10 mm, 15 mm, 20 mm, 30 mm, or another larger, smaller, or intermediate diameter.

At block **114**, in some embodiments, the distal balloon is inflated to a size large enough that it acts as an anchor for the ablation catheter into the pulmonary vein. In some embodiments, anchoring is verified by monitoring of the pressure which maintains the distal balloon's current size. The distal balloon is, in some embodiments, sufficiently compliant that it normally stretches as pressure increases within a normal range of inflation sizes, resulting in a characteristic pressure:volume relationship (volume can be measured, for example, by measuring how much inflation fluid is delivered to the balloon). When inflation is constrained in volume by an encounter with the walls of a pulmonary vein, this characteristic relationship is changed, providing an indication that the distal balloon is beginning to press up against the pulmonary vein wall, potentially anchoring it. Optionally, inflation of the distal balloon in block **114** is partial, *e.g.*, to provide a guiding and/or partial anchoring function without yet providing full inflation used for sealing and/or to induce electrode contact forces used during ablation.

At block **115**, in some embodiments, the catheter position is verified. In some embodiments, verification comprises injection of contrast material (*e.g.*, through the same or another catheter) and identifying that the flow of contrast material (*e.g.*, as monitored by X-ray imaging) is consistent with blockage of the target pulmonary vein. In some embodiments, another type of verification is used. For example, stimulating electrodes intended to be positioned within the pulmonary vein and in contact with it are optionally operated, and electrical responses monitored. Optionally impedances at ablation electrodes are measured. Electrodes having poor contact are recognized, in some embodiments, by an impedance which is unusual with respect to a plurality of the other electrodes (*e.g.*, different for at least one test frequency by at least 25%, 50%, 75%, 100%, or another relative difference). Optionally, verification comprises attempting to gently dislodge the catheter from its position, using forces of pulling and/or pushing that should move an un-anchored catheter, but not dislodge an anchored catheter.

Optionally, balloon inflation of one or both of the proximal and distal balloons is adjusted to correct catheter position, finalize anchoring and/or finalize electrode contact forces. In some embodiments, one or more of the balloons is first at least partially deflated to allow movement of the catheter before reinflation.

At block **116**, in some embodiments, ablation is performed. Depending on the embodiment, ablation can be by the use of means provided on one or both of the distal and proximal balloons. Examples of ablation methods used in some embodiments include RF ablation via one or more electrodes and/or cryoablation. Further details relating catheter structure to ablation are provided, for example, in relation to particular two-balloon catheter embodiments described in relation to *Figures 2A–3D*.

Reference is now made to *Figure 1B*, which is a flowchart, schematically illustrating a more detailed method of ablation using a two-ballooned ablation catheter, according to some embodiments of the present disclosure. The method includes descriptions of some operations additional to the operations of *Figure 1A*, which are optionally performed in some embodiments of the invention.

At block **108**, in some embodiments, the ablation catheter is positioned in an atrium, for example by navigation of the ablation catheter to the heart via arteries and/or veins of the patient.

At blocks **110**, **112**, and **114**, in some embodiments, the proximal balloon is inflated, the distal balloon inserted to a vein, and the distal balloon also inflated, for example as described in relation to *Figure 1A*.

At block **115**, in some embodiments, the catheter position is verified and/or adjusted, for example as described in relation to block **115** of *Figure 1A*.

At block **116**, in some embodiments, ablation is performed, for example as described in relation to *Figure 1A*.

At block **120**, in some embodiments, the distal balloon is deflated. At block **122**, if all targeted pulmonary veins have not been subject to ablation yet, the next vein is selected and the flowchart resumes at block **112**.

Otherwise, in some embodiments, the flowchart continues at block **124** with optional use of a tip ablator. The tip ablator, in some embodiments, comprises a single-electrode ablation electrode positioned at the distal tip of the catheter. The tip ablator is optionally used to perform such operations as ablation of one or more ganglionic plexuses, and/or to perform “touch up” ablations, for example, to repair ablation rings which appear to be incomplete (*e.g.*, due to patient-specific anatomical abnormalities).

At block **126**, in some embodiments, the catheter is removed from the atrium, and the flowchart ends.

Reference is now made to *Figures 2A–2C*, which schematically illustrate deployment of an ablation catheter **200**, according to some embodiments of the present disclosure. In some embodiments, ablation catheter **200** is an intracardial ablation catheter.

In *Figure 2A*, ablation catheter **200** comprises a catheter shaft **208**, having a distal end comprising a first balloon **202**, a second balloon **204** distal to the first balloon **202**, and an optional tip-mounted ablation electrode **206**. The two balloons **202**, **204** are shown in an undeployed (fully collapsed) configuration; for example a collapsed configuration as the balloons would be in as they are initially guided to a site of deployment and use.

Also shown are cross-sections representing a portion of a blood vessel **45** such as a pulmonary vein, and a portion of a connected chamber wall **46**, for example, an ostium and/or wall of a left heart atrium.

In *Figure 2B*, first balloon **202** is shown in a deployed, *i.e.*, inflated state. In the inflated state, balloon **202** is large enough that it effectively acts as a stopper, setting a maximum depth of insertion of ablation catheter **200** into blood vessel **45**. In some embodiments, the diameter of balloon **202** is about 15 mm, 20 mm, 25 mm, 30 mm, or another larger or smaller diameter. In some embodiments, balloon **202** has a maximum diameter which is larger than the maximum diameter of the blood vessel **45** by of at least 25%, 33%, 50%, 66%, 75%, 100%, or another larger, smaller, or intermediate fraction. For reference, in adult humans, a typical maximum pulmonary vein diameter is about 9–13 mm, but this diameter may be larger or smaller at the vein orifice. It is noted that pulmonary veins may be non-circular (oblong) in cross-section at their orifice, *e.g.*, having a shorter axis transverse to the maximum pulmonary vein diameter.

In *Figure 2C*, second balloon **204** is also expanded. In some embodiments, second balloon **204** comprises one or both of a ring of spaced ablation electrodes **212** (used, in some embodiment, for delivering tissue-ablating RF energy), and a ring stimulating electrode **210** or other arrangement of stimulating electrodes. In some embodiments, RF ablation (*e.g.*, ablation at a radio frequency of about 500 kHz) is delivered from a given electrode (or plurality of electrodes operated simultaneously) for a duration in the range of about 10 seconds to about 60 seconds, or another range of durations having the same, larger, smaller, and/or intermediate bounds. Optionally, the duration of ablation is, for example, about 10 s, 15 s, 20 s, 30 s, 60 s; or another larger, smaller, or intermediate duration. In some embodiments, power of ablation is in the range of about 5 W-50 W, or another range of powers having the same, larger, smaller, and/or intermediate bounds. Optionally, the ablation power is, for example, about 5 W, 10 W, 20 W, 50 W; or another larger, smaller, or intermediate duration. In some embodiments, pressure of ablation electrode contact with adjacent tissue is in the range of about 5 grams-force per electrode (that is, for each electrode, 5 grams-force distributed over the surface area of the electrode) to 30 grams-force per electrode, or another range of forces having the same, larger, smaller, and/or intermediate bounds. Optionally, the contact pressure is, for example, about 5, 10,

20, 30, or another larger, smaller, or intermediate grams-force per electrode. For purposes of illustration, electrical connections of the electrodes are not shown in *Figure 2C*. An example of optionally flexible electrical traces which may be used to electrically interconnect electrodes **212**, **210** with ablation, stimulation, and/or recording current supplies are shown, for example, in *Figures 4A–5*.

In *Figure 2C*, second balloon **204** is expanded to comprise a substantially cylindrical portion **213** (that is, a portion which, when inflated in an unconstrained position, inflates to a substantially cylindrical shape), along which the electrodes **212**, **210** of the balloon are pressed into electrical contact with the luminal wall of blood vessel **45**. In some embodiments, the surface of contact is substantially continuous (considering both regions of electrical contact and inter-electrode regions) in a ring (e.g., a ring shaped like a wall of a right or oblique cylinder) extending all the way around the balloon **204**.

In some embodiments, one or both of balloons **202**, **204** is comprised of a compliant or semi-compliant material such as a silicone rubber. Optionally, an inflation state of balloon **204** relative to the enclosing blood vessel **45** is determined by monitoring its inflation pressure. Optionally, monitoring of inflation pressure changes is with respect to a total and/or incremental amount of inflation fluid (e.g., saline liquid or gas) supplied. Liquid inflation fluid provides a potential advantage for safety, such as prevention of bubble entering the bloodstream in the case of a leak. Liquid inflation fluid may also serve as a coolant during ablation. Gas (for example, helium) used as an inflation fluid has a potential advantage for allowing a smaller supply lumen (e.g., due to decreased viscosity), potentially allowing overall catheter diameter to be decreased.

Insofar as the balloon **204** is compliant, it will tend to expand with increasing inflation supply (thereby relieving pressure) until it begins to be constrained by the walls of the vascular lumen. The change in supply/pressure behavior can be noted, and used to determine when inflation within the blood vessel **45** is complete. Optionally, compliance allows a balloon which is naturally (i.e., in the absence of asymmetrically exerted external pressures) circularly cylindrical to change shape as it inflates to fill a more oblong lumen cross-sectional shape. In some embodiments, a balloon is manufactured with a naturally oblong inflated cross-section (e.g., an approximately elliptical cross-section having an eccentricity of 5%, 10%, 20%, 30%, or another larger, smaller or intermediate eccentricity). As part of deployment, the oblong cross-sectioned balloon **204** is optionally rotated by manipulation of the catheter to any suitable orientation for filling the pulmonary vein and making contact with the lumen wall, preferably substantially all the way around the balloon's circumference.

With respect to the positions of ablation electrodes **212**, luminal wall contact of balloon **204** along a continuous ring is a potential advantage for producing an isolating ablation line ring. A region of poor contact, and/or a gap in contact can result in failure to sufficiently ablate at the affected region/gap, so that electrical impulses continue to be transmittable across the lesion line. For effective isolation, ablation should generally be both transmural (that is, extending all the way across the thickness of the electrically conductive tissue), and continuous around the ablated ring.

It should be noted that the contact regions of ablation electrodes **212** themselves are optionally physically and/or electrically non-continuous with each other. In some embodiments, electrodes **212** are electrically addressable as individuals, pairs, and/or small groups for delivery of ablation energy. This has the potential advantage of requiring lower peak power (*e.g.*, RF power) for ablation. Moreover, it allows delivering ablation power with reduced risk of one of the electrodes acting as a low-impedance power shunt compared to another, so that a complete ablation ring becomes more difficult to obtain. Another potential advantage of the separation between electrodes is for accommodating stretching due to the compliant structure of the balloon, while maintaining mechanical and electrical integrity of the electrodes themselves.

In some embodiments, electrodes **212** are separated from one another by a spacing which is small enough to maintain continuous (and preferably continuously transmural) lesioning, while reducing mere redundancy of overlap in the ablated volumes of tissue surrounding each electrode. In some embodiments, each electrode extends about 1.5 mm along the ring of ablation, while each electrode is separated from its adjacent neighbors by about 2.5 mm. In some embodiments, another geometry is used, for example, 2 mm electrodes separated by 2 mm gaps. In some embodiments the periodicity (sum of electrode length and one inter-electrode gap length) is about 3 mm, 4 mm, 5 mm, 6 mm, or another larger, smaller, or intermediate distance. In some embodiments, the ratio of electrode length coverage to inter-electrode gap length is about 1:3, 3:5, 1:1, 5:3, 3:1, or another larger, smaller, or intermediate ratio.

In some embodiments, stimulation electrode **210** is provided as a ring electrode. A potential advantage of the ring configuration is to allow simultaneous stimulation of fibers extending along substantially all circumferential positions of blood vessel **45**. Optionally, stimulation electrode **210** is provided in a “zigzag” configuration. A potential advantage of this is to allow a degree of compliant expansion of the ring electrode, while maintaining circumferentially continuous electrical contact. Another configuration of stimulation electrodes is shown in relation to *Figures 3B–3C*, herein.

Tip-mounted ablation electrode **206** is an optional feature of ablation catheter **206** which is optionally used for any additional ablations which a physician may choose to perform in a procedure together with the ring ablation. Optionally, tip-mounted ablation electrode **206** is used to perform ablations of the ganglionic plexus of the heart as is sometimes performed in the treatment of arterial fibrillation.

Dual Balloon Ablation Catheter Examples

Reference is now made to *Figure 3A*, which schematically illustrates a two-ballooned ablation catheter **300** having electrodes **312** on the more proximal balloon **302**, according to some embodiments of the present disclosure.

In *Figure 3A*, ablation catheter **300** comprises a catheter shaft **308**, having a distal end comprising a first balloon **302**, a second balloon **304** distal to the first balloon **302**, and an optional tip-mounted ablation electrode **306**. The two balloons **302**, **304** are shown in a deployed (fully expanded) configuration; for example a deployed configuration as the balloons would be in during ablation itself.

In ablation catheter **300**, the ablation electrodes **312** are illustrated on the first balloon **302** (*i.e.* the balloon that remains largely outside the pulmonary vein). In operation, ablation electrodes **312** are optionally pressed against tissue to be ablated (*e.g.*, of the vein ostium).

Optionally, the geometry of ablation electrodes **312** is as described for any of the embodiments of ablation electrodes **212** herein, *e.g.*, in terms of relative and/or absolute dimensions.

In some embodiments, ablation electrodes **312** are wedge-shaped, being slightly narrower nearer to the catheter axis, and slightly wider further away. Optionally, ablation electrodes **312** are longer in a radial direction than they are in a direction extending along (generally tangential to) the ablation ring. In some embodiments, the ratio is, for example, about 4:1, 3:1, 2:1 3:2, or another larger, smaller, or intermediate ratio. A potential advantage of this extra length is to provide an increased likelihood that the first balloon **302** will make electrical contact with tissue of the ostium at least somewhere along the electrode length. Optionally, first balloon **302** is manufactured with sufficient compliance to allow it, while inflated, to adjust to conform to the shape of the ostium upon being pressed into it, *e.g.*, at a force of about 5, 10, 20, or 30 grams-force/electrode; or another larger, smaller, or intermediate force. Interaction between a balloon's elasticity and the balloon's internal pressure may induce the balloon to adjust its shape to fit the ostium shape. The higher the pressure inside the balloon, potentially better the fit between the balloon and the ostium.

In some embodiments, stimulation electrode **310** is provided as a ring electrode, for example a zigzag electrode as described in relation to stimulation electrode **210** of *Figure 2C*; or another electrode design, for example as described in relation to electrodes **330** of *Figures 3B–3C*.

Reference is now made to *Figure 3B*, which schematically illustrates a two-ballooned ablation catheter **320** having a different configuration of electrodes on the more distal balloon **304**, according to some embodiments of the present disclosure. Reference is also made to *Figure 3C*, which schematically illustrates a two-ballooned ablation catheter having a different configuration of electrodes on both the more proximal balloon **302** and the more distal balloon **304**, according to some embodiments of the present disclosure.

In the embodiment illustrated in *Figure 3B*, electrodes **322** are arranged in a ring similar to the ring of electrodes **212** shown in *Figure 2C*. In the embodiment illustrated in *Figure 3C*, electrodes **342** are arranged in a ring similar to the ring of electrodes **312** shown in *Figure 3A*. Electrical connections of these electrodes are not shown, but they may be, for example, arranged as described in relation to *Figures 4A–5*.

In the embodiments of *Figures 3B–3C*, the electrodes are arranged so that the width of electrodes (that is, electrode size in a direction approximately transverse to the electrode ring), is about 50% of electrode length. For example, each electrode is optionally about 2 mm long (in the direction of the plane of the electrode ring, and about 1 mm wide (perpendicular to the plane of the electrode ring).

In some embodiments, the ratio of electrode width to electrode length is about 1:3 1:2, 2:3, 1:1, 3:2, 2:1, 3:1, or another larger, smaller or intermediate ratio. Smaller width:length ratios (*e.g.*, ratios less than 1) provide a potential advantage for encouraging narrower ablation lines, potentially avoiding excessive weakening of tissue.

In some embodiments, inter-electrode spacing along the direction of the electrode ring is about 2 mm; or for example, about 1 mm, 1.5 mm, 1.75 mm, 2.25 mm, 2.5 mm, 3 mm, or another larger, smaller, or intermediate spacing. Observations by the inventors of ablations produced by an electrode configuration of about 2 mm (ring-direction length) by about 1 mm (ring-transverse width) indicate that an inter-electrode distance (in the ring direction) of about 2 mm maintains continuous lesioning, while providing an inter-electrode spacing large enough to allow for electrical isolation and/or balloon stretching. In *in vitro* tests, 1 mm width appeared to be large enough to provide transmural lesioning, without being excessively larger than the minimum required to achieve transmurality. Similarly, 2 mm electrode length was long enough to achieve a ring of continuous transmurality while still allowing an inter-electrode separation

large enough (e.g., about 2 mm) so that the balloon retains good flexibility for conforming to surrounding tissue shapes.

It is noted that stimulation electrodes **330** are optionally provided as a ring of discrete electrodes (electrical connections of electrodes are not shown), as an alternative to the continuous ring stimulation electrode **210** shown in *Figure 2C*. A potential benefit of discrete electrodes is to allow stretching of balloon material between the electrodes. Potentially, this results in a lower potential for damage to the electrodes and/or their connections, and/or helps to allow a tighter fit of the inflated balloon with the vein to which it is inserted. Optionally, the stimulation electrodes **330** are individually addressable, which potentially helps in diagnosis of incomplete ablation rings.

Reference is now made to *Figure 3D*, which schematically illustrates a two-ballooned ablation catheter illustrating different balloon shapes, adapted for optional use with a separate electrode ring **382**, according to some embodiments of the present disclosure.

In *Figure 3D*, ablation catheter **360** comprises a catheter shaft **308**, having a distal end comprising a first balloon **362**, a second balloon **364** distal to the first balloon **302**, and an optional tip-mounted ablation electrode **306**. The two balloons **362**, **364** are shown in a deployed (fully expanded) configuration; for example a deployed configuration as the balloons would be in during ablation itself.

Distal balloon **364** is shown as a substantially spherical balloon, but it may also be a substantially cylindrical balloon, for example as shown in *Figures 3B–3C*. Optionally balloon **364** has no electrodes, and is used primarily for anchoring/centering purposes. Optionally, balloon **364** is provided with electrodes around its outermost periphery, for example stimulation electrodes **330** of a design similar to that of *Figures 3B–3C*.

Proximal balloon **363** is shown without its own electrodes. Instead, electrodes are optionally supplied as part of a second, ring-shaped probe **382** (for example, a “lasso” probe, which may comprise an initially linear probe deployed and curved to form a nearly-closed loop on one end), which is optionally slipped over the distal end of catheter **360** and pulled back so that it fits against a bracing surface **363A** of balloon **362**. In some embodiments bracing surface **3673A** is provided as a surface linking two stepped regions **365**, **363** of balloon **362** having different diameters. For example, the diameter of region **365** is sized to ensure that probe **382** is centered, while region **363** expands far enough to prevent probe **382** from slipping too far proximally.

Catheters with Tapered Stopper Balloon and/or Two-Widening Balloon Anchor

Reference is now made to *Figures 9A–9B*, which schematically illustrate a three-balloon ablation catheter **800**, according to some embodiments of the present disclosure. Reference is also made to *Figure 9C*, which schematically illustrates a balloon anchor **804C** is made of two balloon widenings **804D**, **804E**, separated by a narrowing **804F**, according to some embodiments of the present disclosure. Further reference is made to *Figure 9D*, which schematically illustrates a disk-shaped ablation/stopper **802E**, according to some embodiments of the present disclosure.

Ablation catheter **800** comprises a catheter shaft **808**, having a distal end comprising an ablation and/or stopper balloon **802**, and (distal to the ablation/stopper balloon **802**) an balloon anchor **804**, which is a balloon assembly comprising a first anchoring balloon **804A** and a second anchoring balloon **804B** distal to the first anchoring balloon **804A** along the catheter shaft **808**. Balloon sizes should be understood to be, for example, as described for the various balloon functions of anchoring, stopping, and/or ablating in relation to *Figure 1A*.

In some embodiments, anchoring balloons **804A**, **804B** act together as segments of balloon anchor **804** for anchoring the ablation catheter in a pulmonary vein. Optionally, anchoring balloons **804A**, **804B** are coupled so that they inflate together. Optionally, anchoring balloons **804A**, **804B** are inflatable under individual control. Optionally, a plurality of anchoring balloons are used. For example, two segments are shown; in some embodiments, balloon anchor **804** comprises three or more anchoring balloons. In some embodiments, anchoring balloons **804A**, **804B** are substantially cylindrical in shape (*e.g.*, as shown). Optionally, one or more of anchoring balloons **804A**, **804B** is another shape, for example, substantially cylindrical, ellipsoidal, or another shape.

A potential advantage of a two (or more) -segment anchor (whether segmented by use of a plurality of balloons, as in balloon anchor **804**, or a plurality of widenings, as in balloon anchor **804C**) is to reduce degrees of freedom of movement of the anchored device, while increasing likelihood of obtaining two or more anchoring positions. With a single short anchoring segment, the catheter shaft **808** is potentially free to pivot around the short anchoring segment (*e.g.*, within a roughly cone-shaped region), leading to less-certain positioning of the electrodes of the ablation/stopper balloon. With one long anchor segment, the narrowest anchoring point in a blood vessel potentially interferes with inflation of the anchor segment to press against other regions of the blood vessel, which again potentially permits pivoting. Two segments are potentially better able to anchor and center the balloon catheter in a blood vessel which is changing in diameter and/or curved. An anchor comprising a plurality of inflating segments potentially allows more inflation-diameter independence along its length, potentially increasing

anchoring contact to reduce pivoting. Flexibility of the catheter between segments potentially allows bends to be introduced between inflating segments, accommodating the curvature of a potentially non-straight blood vessel.

Ablation balloon **802**, in some embodiments, carries ablation electrodes **810**, optionally arranged in a ring, for example as described in relation to *Figures 3A* and *3C*. Optionally, the ablation electrodes **810** themselves are configured, for example, as described in relation to *Figure 5*, and/or *Figures 4A–4C*. Optionally, one or more stimulation electrodes **812** are provided, *e.g.*, in a ring configuration as shown, or in another configuration. Optionally, one or more of the anchoring balloons and/or anchoring widenings **804A**, **804B**, **804D**, **804E** (additionally or alternatively to placement of electrodes on ablation/stopper balloon **802**) is provided with stimulating and/or ablation electrodes, for example, as described in relation to *Figures 2C* and/or *3A–3C*.

In some embodiments, ablation/stopper balloon **802** comprises a balloon which inflates to a distally tapering (narrowing in a distal direction) shape also referred to herein as “cone” or “mushroom cap-shaped”. In some embodiments, ablation/stopper balloon **802** comprises a tip region **802A** and a cuff region **802B** which inflates to a diameter wider than and generally proximal of tip region **802A**.

Tip region **802A**, in some embodiments, includes a region of attachment to catheter shaft **808** through which inflation is performed. Cuff region **802B** is optionally arranged, when deflated, in a collapsed configuration around catheter shaft **808**, *e.g.*, a configuration extending proximally from tip region **802A**. As balloon **802** inflates, cuff region **802B** expands into an approximately conical or mushroom cap-shaped form extending proximally from tip region **802A**. Cuff region **802B**, when inflated, defines within it a hollow **802D**. In some embodiments, hollow **802D** is itself distally tapering. In some embodiments, hollow **802D** is open on a proximal side where cuff **802** surrounds but is not attached to catheter shaft **808**. Hollow **802D** terminates distally, in some embodiments, at a position where tip region **802A** of ablation/stopper balloon **802** connects to catheter shaft **808**.

In some embodiments, a balloon with a generally conical or mushroom-cap shaped outer surface (*e.g.*, as described for balloon **802**) has a distal-surface region **807** which tapers more gradually before the balloon flares into cuff region **802B**. This potentially has the effect of keeping more distal portions of the balloon surface away from the wall, so that the electrodes **810** on the flare of cuff region **802B** are more likely to be what contacts the tissue surface wall. Optionally, the more gradual taper of distal-surface region **807** defines a distal-side hollow,

wherein the hollow is created by a recessed curvature, compared to the straight walls of a constant-tapering cone-shape.

In some embodiments, another shape besides substantially cone-shaped is provided to an ablation/stopper balloon, *e.g.*, as illustrated by disk-shaped ablation/stopper balloon **802E**.

Balloon **802E** attaches to catheter shaft **808** at a narrow attachment region **802F**. Optionally, disk-shaped balloon **802E** has hollow at one or both of its distal and proximal sides (*e.g.*, proximal-side hollow **802G**, and/or distal-side hollow **802H**). Proximal-side hollow **802G** optionally helps to remove interfering bulk when portions of balloon **802E** hinge proximally, and/or promotes thinness at the attachment region **802F**. Distal-side hollow **802H** optionally helps to ensure that the balloon portion that contacts tissue is the portion that bears electrodes **810**, similar to a function of the more gradually tapered distal surface region **807** of balloon **802**.

In *Figure 8B*, two different (*e.g.*, sequential) inflation states of ablation/stopper balloon **802** are shown superimposed. As balloon **802** inflates from state **802B** to **802C**, electrodes move, for example, between relatively proximal and central positions **810A**, **812A** to relatively distal and peripheral positions **810B**, **8012B** (*e.g.*, relative to a central axis extending along catheter shaft **808**). In some embodiments, distal movement of the electrodes during inflation helps to adjust electrode contact during use: greater inflation moves the electrodes more distally so that they potentially have an increased chance of contacting tissue.

Conversely, and as also shown in relation to *Figures 8A–8C*, a potential advantage of hollow **802D** is to increase the compliance of balloon **802** as it interacts with a chamber wall, for example, an ostium and/or wall of a left heart atrium. Thus, depending on the shape of the tissue wall, one portion of balloon **802** can potentially be moved more distally by increased inflation pressure, while another portion of balloon **802**, already in contact with a tissue wall, retains enough compliance (by being able to hinge into unpressurised hollow **802D**) to give way as pressure from the wall increases, rather than become so rigid that it exerts force sufficient to potentially dislodge balloon anchor **804**, **804C**.

It should be understood that although ablation/stopper balloon **802** and balloon anchor **804** are shown within a single embodiment for purposes of description, they are not necessarily dependent on each other for their individual functions. Optionally, either of ablation/stopper balloon **802** balloon anchor **804** are provided with a different arrangement performing the complementary function (*e.g.*, balloon **302** is optionally provided on a catheter including a balloon anchor **804**, and/or a balloon **304**, **804C** is provided on a catheter including ablation/stopper balloon **802**). In some embodiments, the tapered ablation/stopper balloon **802** is provided without any balloon anchor, *e.g.*, it is optionally pressed into place with sufficient force,

and while exhibiting sufficient compliance, that use of the balloon anchor may be dispensed with. In some embodiments, a balloon anchor **804** comprising a plurality of balloons and/or a balloon anchor **804C** comprising a plurality of widenings separated by one or more narrow regions is provided without a corresponding stopper balloon; *e.g.*, an anchor **804**, **804C** is provided alone and with ablation electrodes to allow ablation from within a blood vessel at a wider range of selectable depths.

Reference is now made to *Figures 8A–8C*, which schematically illustrate deployment of an ablation catheter **800**, according to some embodiments of the present disclosure. In some embodiments, ablation catheter **800** is an intracardial ablation catheter.

Shown in addition to elements of ablation catheter **800** described in relation to *Figures 9A–9B* are cross-sections representing a portion of a blood vessel **47** and a portion of a connected chamber wall **48**, *e.g.*, blood vessel **47** is optionally a pulmonary vein, and wall portion **48** is optionally an ostium of a pulmonary vein.

In *Figure 8A*, the balloons **802**, **804A**, **804B** are shown partially inflated as they are guided to a site of deployment and use (in some embodiments, balloon anchor **804C**, for example, replaces balloons **804A**, **804B**). In the partially inflated state, first balloon **802** is large enough that it effectively acts as a stopper, setting a maximum depth of insertion of ablation catheter **800** into blood vessel **47**.

In *Figure 8B*, balloon anchor **804** is shown in a further inflated state. In this state, balloon anchor **804** enables anchoring and alignment of the ablation catheter **800** central axis with the central longitudinal axis of blood vessel **47**.

In *Figure 8C*, ablation balloon **802** is also expanded until a good contact (*e.g.*, continuous contact along a ring of electrodes **810**) with the chamber wall is achieved. Potentially, the presence of hollow **802C** provides balloon **802** with additional compliance, so that it more easily deforms to maintain circumferential contact with wall portion **48**.

In some embodiments, a radius of contact along ring of electrodes **810** by balloon **802** is set by varying the insertion depth of balloon anchor **804** into blood vessel **47**. With a greater insertion depth, electrodes **810** potentially make contact upon a lower expansion of balloon **802**, and thus at a narrower radius.

Ablation Electrodes for Use with Elastic Balloons

Reference is now made to *Figures 4A–4C* and 5, which schematically illustrate electrodes of an ablation catheter and their connection traces, for use on the surface of an expandable balloon, according to some embodiments of the present disclosure. Reference is also made to

Figure 4D, which schematically illustrates an electrode arrangement on a balloon of an ablation catheter using the electrode and trace design of *Figure 4A*, according to some embodiments of the present disclosure.

Figure 4A schematically illustrates an electrode arrangement **416** of a plurality of electrodes **427** electrically linked on a common supply connection, each by its own connecting branch **425**, **426**. Two electrodes are shown, but three or more are optionally provided on a single supply connection. Optionally, each electrode is about 2 mm long by 1 mm wide, and separated from its neighbor(s) by about 2 mm along the long axis of the electrode. Optionally, electrodes are elliptical in shape, but another shape is optionally used such as a rectangular and/or rectangular with round corners. Electrodes without sharp corners provide a potential advantage for more uniform application of RF power, *e.g.*, avoiding focusing at corners. Combining electrodes **327** into electrode arrangements **416** provides a potential advantage for simplifying control, and/or for matching electrode surface area with available activation power. A potential advantage for linking electrodes in groups each comprising a plurality of electrodes (*e.g.*, 2, 3, 4 or more) is to reduce the amount and length of electrode wires on the balloon. Additionally or alternatively, grouped electrodes may be viewed as single electrodes broken into a plurality of smaller segments, potentially increasing the balloon extendability and/or flexibility, and/or the balloon's ability to be folded to a small diameter during catheter delivery.

Figure 4B illustrates a plurality of electrode arrangements **416** themselves arranged together to form a ring (for example, rings such as are described in relation to *Figures 2C–3C*, herein). Eight electrode arrangements **416** are shown. In some embodiments, a larger or smaller number of electrode arrangements **416** are provided; for example, 5, 6, 7, 9, 10, 11, or another number. For reference in the following descriptions, electrode arrangements **416** are numbered between #1 and #8. Electrodes **427** themselves are numbered between #1 and #16, with electrodes #1 and #2 belonging to electrode arrangement #1, electrodes #3 and #4 belonging to electrode arrangement #2, and so on.

Electrode arrangements are optionally paired to be activated with opposite phases, such as #1-#5, #2-#6, #3-#7, and #4-#8. However, in some embodiments, ablation using the electrodes of *Figure 4B* comprises RF activation of electrode arrangements **416** in any suitable order and/or combination.

A more particular implementation of a structure shown schematically in *Figure 4A* is shown in *Figure 4C*. *Figure 4D* shows an image of a catheter comprising the electrode and trace structure of *Figure 4C*. The electrical assembly comprising the electrodes and traces of *Figure 4C*, in some embodiments, is provided as flexible circuitry integrated with an ablation

catheter such as ablation catheter **200**, **300**. An assembly supporting activation of two ablation electrodes is shown, however it is to be understood that each assembly can have one, two, three, four, or more electrodes attached to it. In some embodiments, a plurality of assemblies such as that of *Figure 4F* are provided to a single ablation catheter.

5 The assembly shown is divided into four main sections. Section **412** comprises a thick, insulated trace **421**, optimized for low resistance. In a section **410** of the catheter requiring increased flexibility (*e.g.*, for accommodation of catheter bending), the conductive part of the trace **423** (*e.g.*, comprising copper, silver, gold, and/or another conductive material) is optionally reduced in cross-section compared to the insulating portion **422**. Section **414** includes a plurality
10 of bends **424**. This creates slack suitable for integration (*e.g.*, by gluing of a flexible printed circuit board, and/or adhesion by conductive ink) with the compliant material of balloons such as balloons **202**, **204**, **302**, **304**, allowing the trace to expand and contract along with the balloon material. Finally, section **416** comprises the ablation electrodes **427**. Optionally, each ablation electrode **427** of an assembly is provided with its own stalk **425**, **426**, configured to allow
15 flexible expansion of balloon material between electrodes.

In *Figure 4D*, proximal balloon **402** comprises ablation electrodes **427**, stalks **426**, and bends **424**. Distal balloon shows a trace-and-electrode design for stimulation electrodes **430**, which are electrically connected to the catheter via traces **431**. As shown, electrodes **430** are tied to a single electrical bus **432**. Optionally, electrodes **430** are addressable in sub-groups and/or
20 individually. Also shown is catheter shaft **408**.

Figure 5 illustrates construction details of region **500** of *Figure 4C*, relating to an ablation electrode **427**. Insulating material **422** covers conductive material **423**, except for a window at region **501**. Optionally, region **501** is electroplated with a biocompatible and/or corrosion resistant metal, for example, gold and/or platinum.

25 **Oblique Ablation Electrode Ring**

Reference is now made to *Figures 6A–6C*, which schematically illustrate an electrode arrangement on a balloon of an ablation catheter for creation of an intra-venous ablation pattern, according to some embodiments of the present disclosure.

Figure 6A shows a magnified version of the second balloon **304** of *Figure 3B* (used as an
30 example), including ablation electrodes **322** and stimulation electrode **330**. Ring **624** indicates a portion of the balloon **304** comprised in a right-angled intersection of a plane with a longitudinal axis **625** of balloon **304**. It can be seen that the ring defined by electrodes **322** is angled compared to ring **624**, falling instead along ring **622**. In some embodiments, ring **622** is angled

about 25° off the perpendicular from longitudinal axis **625**. Optionally, ring **622** deviates from the perpendicular by another angle, for example, 15°, 20°, 30°, 35°, 40°, 45°, or another larger, smaller, or intermediate angle. In some embodiments, the offset comprises offsetting each electrode from its neighbors by some amount. Optionally, the amount is about 20%, 25%, 33%, 40%, 50%, 66%, or another larger, smaller, or intermediate amount of the longitudinal length of each electrode. Optionally, the offset from each immediately neighboring electrode is about 0.25 mm, 0.5 mm, 0.75 mm, 1 mm, 1.25 mm, 1.5 mm, or another larger, smaller, or intermediate offset. As shown, the offsets are such that the electrodes are positioned substantially along an ellipse. However, in some embodiments, electrodes are staggered to be positioned along another shape, for example, a stepped, zigzag, spiral (optionally with joined ends), or another shape. Preferably, the electrodes are arranged along a substantially closed loop (e.g., so that each electrode **322** is bordered on either side by another electrode). Optionally, electrodes **322** are arranged along a plurality of rings.

In *Figures 6B–6C*, a potential advantage of angled ring **622** is illustrated with respect to the reduction of ablation-induced venous stenosis. The left side of *Figure 6B* shows a view of electrodes **322** from alongside a balloon **304** inflated within a vein (e.g. the lines representing venous lumen **613** extend along a longitudinal axis of both a balloon **204** and a vein **45**). The electrodes **322** are distributed along a ring **604** (seen from the side) which is heavily offset from the perpendicular (by about 45° as shown). The plane of orthogonal view **605** is indicated by the dotted line and arrows. In that view, occlusions **611** represent stenosis of the venous lumen **613** induced by lesioning just within the plane of view **605**. In nearer and further planes, the stenosis would appear lower or higher within the cross-section, because of the angling of ring **604**. The middle-ground region, where the stenosis is about symmetrical on either side within a plane, is potentially the plane of maximum total stenosis.

With decreased off-perpendicular angling (as shown by ring **606**), stenosis in the plane of maximum stenosis (view **607** of occlusions **612**) is potentially increased. One view of this is that there is potentially increased interaction of lesioning effects between adjacent electrodes within the plane of maximum stenosis. Longitudinal offsetting may decrease this. Additionally or alternatively, effects from adjacent electrodes potentially are visible for a longer distance around the perimeter of venous lumen **613**. A completely perpendicular ring, to take the extreme example, could show stenosis extending circularly all around the lumen interior.

A potential mechanism for ablation-induced stenosis is scarring that causes tissue to shrink. If the ablation line is perpendicular to the vein longitude, the vein internal diameter at that point will shrink and the area that is open for blood flow will decrease. With increase off-

perpendicular angling, tissue shrinkage along the vein is at different distal distance from the ostium and therefore the impact on the blood flow decreases. Shrinking is also potentially mitigated by pressure from the balloon against the vein.

5 Ablation Result Examples

Reference is now made to *Figure 7A*, which presents a dissected image of an intravenous ablation line **702** in porcine pulmonary vein **701**, according to some embodiments of the present disclosure. After *in vitro* ablation by an intravenously placed ring of ablation electrodes (*e.g.*, electrodes **322** of *Figure 3B*), the heart tissue was dissected, allowing an internal-surface view of the atrium **700**, including slitting open of the ablated pulmonary vein **701** so that ablation line **702** appears as a curved stripe of fibrotic tissue.

Reference is now made to *Figure 7B*, which presents a dissected image of an atrial ablation line **704** in a porcine left atrium **700**, according to some embodiments of the present disclosure. Here the vein **701** is left intact, allowing viewing of the ring-like darkening of tissue indicated by path **704**. Differences in lightness/darkness of scarred regions in *Figures 7A–7B* appear to be due to differences in lighting and imaging conditions.

As used herein with reference to quantity or value, the term “about” means “within $\pm 10\%$ of”.

The terms “comprises”, “comprising”, “includes”, “including”, “having” and their conjugates mean: “including but not limited to”.

The term “consisting of” means: “including and limited to”.

The term “consisting essentially of” means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form “a”, “an” and “the” include plural references unless the context clearly dictates otherwise. For example, the term “a compound” or “at least one compound” may include a plurality of compounds, including mixtures thereof.

The words “example” and “exemplary” are used herein to mean “serving as an example, instance or illustration”. Any embodiment described as an “example” or “exemplary” is not necessarily to be construed as preferred or advantageous over other embodiments and/or to exclude the incorporation of features from other embodiments.

The word “optionally” is used herein to mean “is provided in some embodiments and not provided in other embodiments”. Any particular embodiment of the invention may include a plurality of “optional” features except insofar as such features conflict.

As used herein the term “method” refers to manners, means, techniques and procedures for accomplishing a given task including, but not limited to, those manners, means, techniques and procedures either known to, or readily developed from known manners, means, techniques and procedures by practitioners of the chemical, pharmacological, biological, biochemical and medical arts.

As used herein, the term “treating” includes abrogating, substantially inhibiting, slowing or reversing the progression of a condition, substantially ameliorating clinical or aesthetical symptoms of a condition or substantially preventing the appearance of clinical or aesthetical symptoms of a condition.

Throughout this application, embodiments of this invention may be presented with reference to a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as “from 1 to 6” should be considered to have specifically disclosed subranges such as “from 1 to 3”, “from 1 to 4”, “from 1 to 5”, “from 2 to 4”, “from 2 to 6”, “from 3 to 6”, *etc.*; as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein (for example “10-15”, “10 to 15”, or any pair of numbers linked by these another such range indication), it is meant to include any number (fractional or integral) within the indicated range limits, including the range limits, unless the context clearly dictates otherwise. The phrases “range/ranging/ranges between” a first indicate number and a second indicate number and “range/ranging/ranges from” a first indicate number “to”, “up to”, “until” or “through” (or another such range-indicating term) a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numbers therebetween.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

WHAT IS CLAIMED IS:

1. An ablation catheter comprising:
 - a first balloon, positioned near a distal end of the ablation catheter, and sized to inflate, upon insertion to a human atrium, to a size hindering entry of the first balloon into a human pulmonary vein;
 - an anchoring balloon assembly positioned on the ablation catheter distal to the first balloon, wherein the anchoring balloon assembly is inflatable upon insertion to the human pulmonary vein to fittingly anchor against a luminal wall of the human pulmonary vein; and
 - at least one ablation electrode positioned on at least one of the first balloon and the anchoring balloon assembly.
2. The ablation catheter of claim 1, wherein the ablation catheter is configured to anchor along a longitudinal extent of the anchoring balloon assembly upon inflation while inserted to the human pulmonary vein.
3. The ablation catheter of any one of claims 1-2, wherein the at least one ablation electrode comprises a plurality of electrodes positioned on the anchoring balloon assembly.
4. The ablation catheter of claim 3, wherein the plurality of ablation electrodes of the anchoring balloon assembly is positioned to make contact with a luminal wall of the pulmonary vein for ablation of tissue thereof upon inflation of the anchoring balloon assembly to fittingly anchor the anchoring balloon assembly against the luminal wall of the human pulmonary vein.
5. The ablation catheter of claim 3, wherein ablation electrodes of the anchoring balloon assembly are distributed around a balloon of the anchoring balloon assembly at a plurality of different longitudinal offsets relative to a longitudinal axis of the ablation catheter.
6. The ablation catheter of claim 5, wherein each respective ablation electrode is longitudinally offset from its adjacent ablation electrodes by at least 25% of the longitudinal extent of at least half of the ablation electrodes.

7. The ablation catheter of claim 1, wherein the at least one ablation electrode comprises a plurality of electrodes positioned on the first balloon.

8. The ablation catheter of claim 7, wherein the plurality of electrodes of the first balloon are positioned on a distal side of the first balloon, and making contact with cardiovascular tissue for ablation thereof upon advancement of the inflated first balloon against an ostium of a human pulmonary vein.

9. The ablation catheter of claim 3, wherein the ablation electrodes are distributed along a region encircling a longitudinal axis of the ablation catheter.

10. The ablation catheter of claim 9, wherein the ablation electrodes are sized and spaced for ablation of an entirely transmural path through cardiovascular tissue when the tissue is positioned to encircle the longitudinal axis.

11. The ablation catheter of claim 9, wherein the encircling region is ring-shaped.

12. The ablation catheter of claim 11, wherein a contact surface of each ablation electrode extends between about 1.5 and 2.0 mm along the circumference of the ring-shaped region, and is separated along the circumference of the ring-shaped region from its circumferential neighbors by between about 2.0 and 2.5 mm.

13. The ablation catheter of claim 9, wherein the encircling region comprises alternating extents of exposed ablation electrode surface and inter-electrode surface comprised of elastically expandable material.

14. The ablation catheter of claim 3, wherein the plurality of electrodes comprise separately actuatable electrode groups, each electrode group comprising a plurality of electrically linked electrodes.

15. The ablation catheter of claim 14, wherein each electrode group consists of a pair of electrically linked electrodes.

16. The ablation catheter of claim 1, wherein the first balloon inflates to a diameter larger than a diameter of the human pulmonary vein.

17. The ablation catheter of claim 1, wherein:
- the anchoring balloon assembly comprises a first anchoring section and a second anchoring section sized to inflate to press against a blood vessel wall, anchoring the catheter therein; and
- the first anchoring section second anchoring section are separated by a narrowing.
18. The ablation catheter of claim 17, wherein the first and second anchoring sections comprise first and second anchoring balloons, and the narrowing comprises a region between the first and second anchoring balloons.
19. The ablation catheter of claim 1, wherein the anchoring balloon assembly inflates to contact the luminal wall of the human pulmonary vein along a substantially cylindrical longitudinal extent of the anchoring balloon assembly.
20. The ablation catheter of claim 19, comprising a stimulation electrode extending in ring surrounding the substantially cylindrical longitudinal extent.
21. The ablation catheter of claim 20, wherein the ring of the stimulation electrode extends around the substantially cylindrical longitudinal extent in a zig-zag shape.
22. The ablation catheter of claim 1, wherein the first balloon inflates to a substantially spherical shape.
23. The ablation catheter of claim 1, wherein the first balloon inflates to tapering shape which narrows from a more proximal to a more distal direction.
24. The ablation catheter of claim 23, wherein the inflated first balloon comprises a cuff that circumferentially surrounds a hollow region between the first balloon and a catheter shaft of the ablation catheter.
25. The ablation catheter of claim 1, comprising a tip ablation electrode positioned at a distal tip of the ablation catheter distal to the anchoring balloon assembly.

26. The ablation catheter of claim 1, wherein the ablation catheter comprises a conduit configured to transfer cooling fluid from a cooling fluid source connector at one end of the conduit to at least one of the first balloon and the anchoring balloon assembly.

27. A method of anchoring an ablation catheter to select an ablation region for bio-electrically isolating a human pulmonary vein from an atrium, comprising:

inserting to the atrium a distal portion of an ablation catheter comprising a first balloon and a second balloon positioned on the ablation catheter distal to the first balloon;

inflating the first balloon;

inserting a second balloon from the atrium into the pulmonary vein, to a depth set by interference between the first balloon and an ostium leading into the pulmonary vein;

inflating the second balloon to fittingly contact a luminal wall of the human pulmonary vein along a substantially cylindrical longitudinal extent of the second balloon, thereby anchoring the ablation catheter; and

ablating cardiovascular tissue using ablation electrodes of the ablation catheter positioned on at least one of the balloons, while the ablation catheter remains anchored in place.

28. The method of claim 27, wherein the ablation electrodes are positioned on the first balloon, and the region selected for ablation is within the ostium.

29. The method of claim 28, wherein the inflated first balloon presses each of the ablation electrodes against the ablated cardiovascular tissue to exclude blood from contact with all of the ablation electrodes at the same time.

30. The method of claim 27, wherein the ablation electrodes are positioned on the second balloon, and the region selected for ablation is within the pulmonary vein.

31. The method of claim 30, wherein the inflated second balloon presses each of the ablation electrodes against the ablated cardiovascular tissue to exclude blood from contact with all of the ablation electrodes at the same time.

32. The method of claim 27, wherein the fitting contact of the second balloon acts to anchor the second balloon within the human pulmonary vein.

33. An ablation catheter comprising:

a balloon positioned at the distal end of the ablation catheter, inflatable upon insertion to a human atrium to contact with a closed-loop contacting portion a region of cardiovascular tissue for electrical isolation of a human pulmonary vein; and

a plurality of ablation electrodes distributed around the contact portion;

wherein a contact surface of each ablation electrode extends along a circumference of the contacting portion, separated along the circumference of the contacting portion from its circumferential neighbors by between about 75% and 125% of its own circumferential extent upon inflation of the balloon.

34. The ablation catheter of claim 33, wherein each ablation electrode extends along the circumference of the contacting portion between about 1.5 mm and 2.0 mm.

35. The ablation catheter of claim 33, wherein the longest extent of the contact surface of each ablation electrode in a direction perpendicular to the closed-loop contacting portion is between about 0.75 mm and 1.0 mm.

36. An ablation catheter comprising:

a balloon positioned at the distal end of an ablation catheter, wherein the balloon is inflatable to fittingly contact a luminal wall of a human pulmonary vein along a substantially smooth cylindrical longitudinal extent of the balloon; and

a plurality of ablation electrodes distributed around the balloon at a plurality of different longitudinal offsets along the substantially cylindrical longitudinal extent.

37. The ablation catheter of claim 36, wherein the plurality of ablation electrodes are positioned with a corresponding region of each respective ablation electrode positioned along the perimeter of an eccentric cylindric cross-section of the substantially cylindrical longitudinal extent.

38. The ablation catheter of claim 37, wherein the eccentric cylindric cross-section is angularly offset from a cylindric cross-section perpendicular to a longitudinal axis of the substantially cylindrical longitudinal extent by at least 20°.

39. The ablation catheter of claim 36, wherein each respective ablation electrode is longitudinally offset from its adjacent ablation electrodes by at least 1/4 of the longitudinal extent of the ablation electrode.

40. An ablation catheter comprising:

a catheter shaft;

a balloon, circumferentially surrounding the catheter shaft; and

a plurality of ablation electrodes arranged circumferentially on a distal surface of the balloon;

wherein the balloon, when inflated, comprises a cuff that circumferentially surrounds a hollow region between the balloon and the catheter shaft.

41. The ablation catheter of claim 40, wherein the cuff is shaped so that a proximal surface of the balloon, defining the hollow region, expands radially outward and distally forward as the balloon inflates.

42. The ablation catheter of any one of claims 40-41, wherein the hollow region tapers narrower in a proximal-to-distal direction.

43. A vascular anchoring section of a catheter comprising:

a catheter shaft; and

a balloon assembly, circumferentially surrounding the catheter shaft, and comprising a first anchoring section and a second anchoring section sized to inflate to press against a blood vessel wall, anchoring the catheter therein;

wherein the first anchoring section second anchoring section are separated by a narrowing.

44. The vascular anchoring section of claim 43, wherein the first and second anchoring sections are sized to anchor within a pulmonary vein.

45. The vascular anchoring section of any one of claims 43-44, wherein the first and second anchoring sections comprise first and second catheter balloons, and the narrowing comprises a region between the first and second catheter balloons.

46. The vascular anchoring section of claim 45, wherein the first and second catheter balloons are separately inflatable.

47. The vascular anchoring section of any one of claims 43-44, wherein the first and second anchoring sections comprise a single balloon, and the narrowing is a region of the single balloon narrower than the first and second anchoring sections.

48. The vascular anchoring section of claim 43, wherein the catheter also includes a stopper balloon, mounted on the catheter shaft proximally to the balloon assembly.

49. An ablation catheter comprising:

a catheter shaft;

a balloon, circumferentially surrounding the catheter shaft; and

a plurality of ablation electrodes arranged circumferentially on a distal surface of the balloon;

wherein the balloon is hingingly attached to the catheter shaft to allow proximal deflection of the balloon upon urging of the electrodes distally against a tissue surface.

50. The ablation catheter of claim 49, wherein the balloon, when inflated, comprises a cuff that circumferentially surrounds a hollow region between the balloon and the catheter shaft.

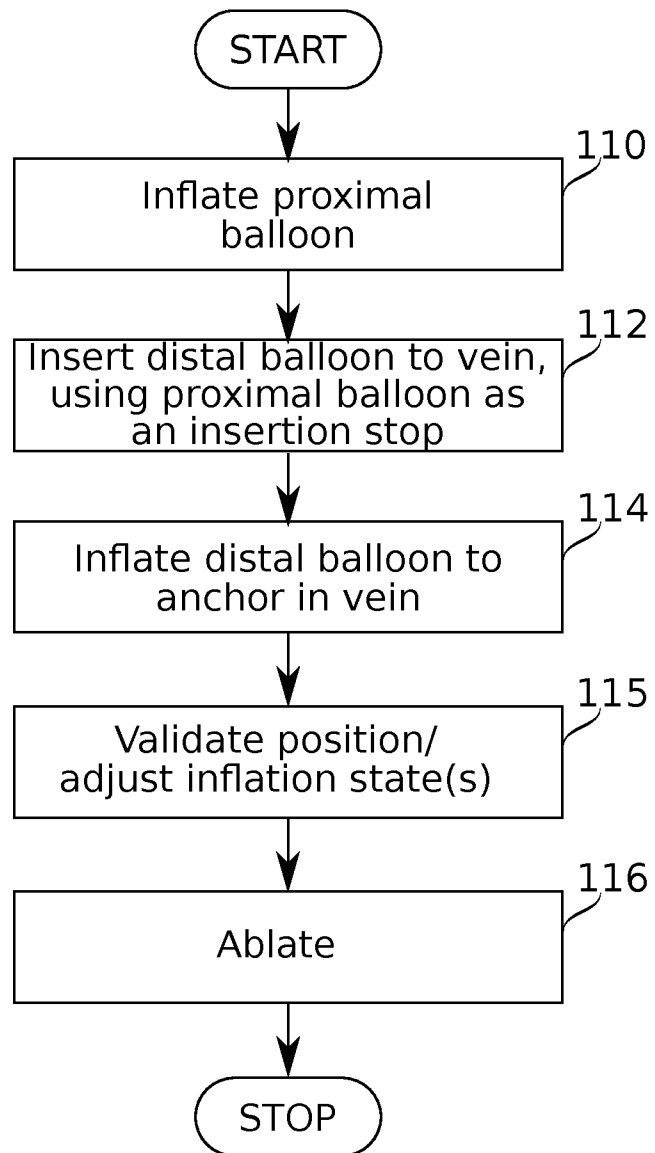


FIG. 1A

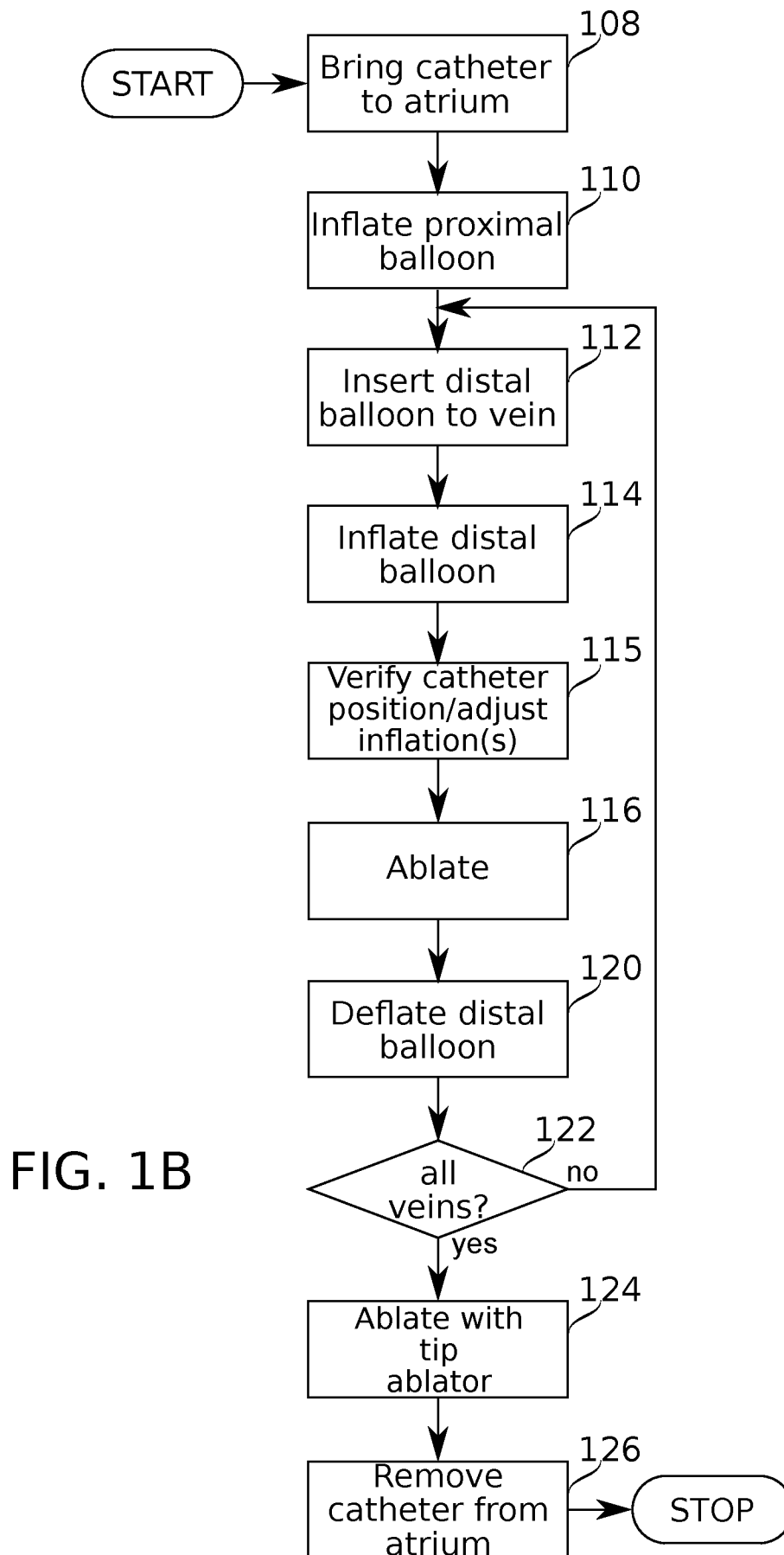


FIG. 2A

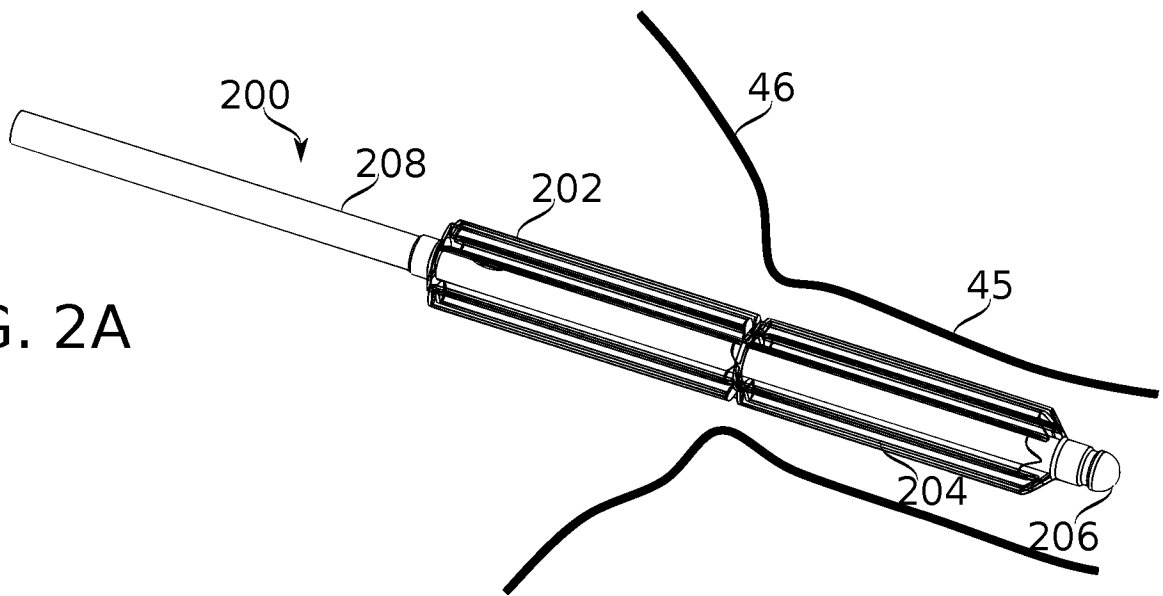


FIG. 2B

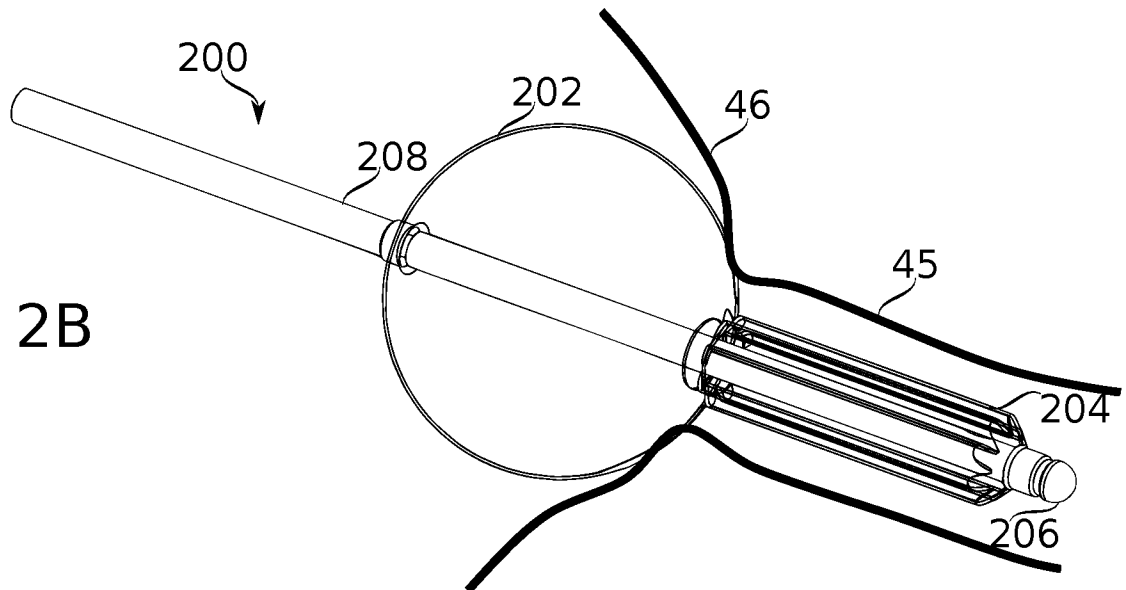
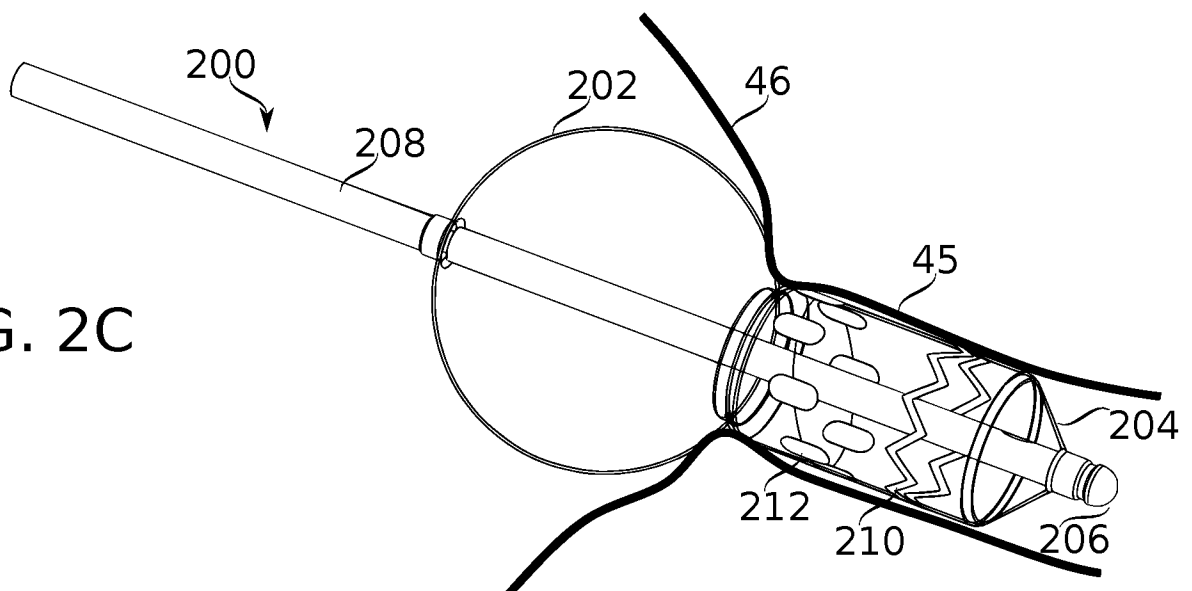
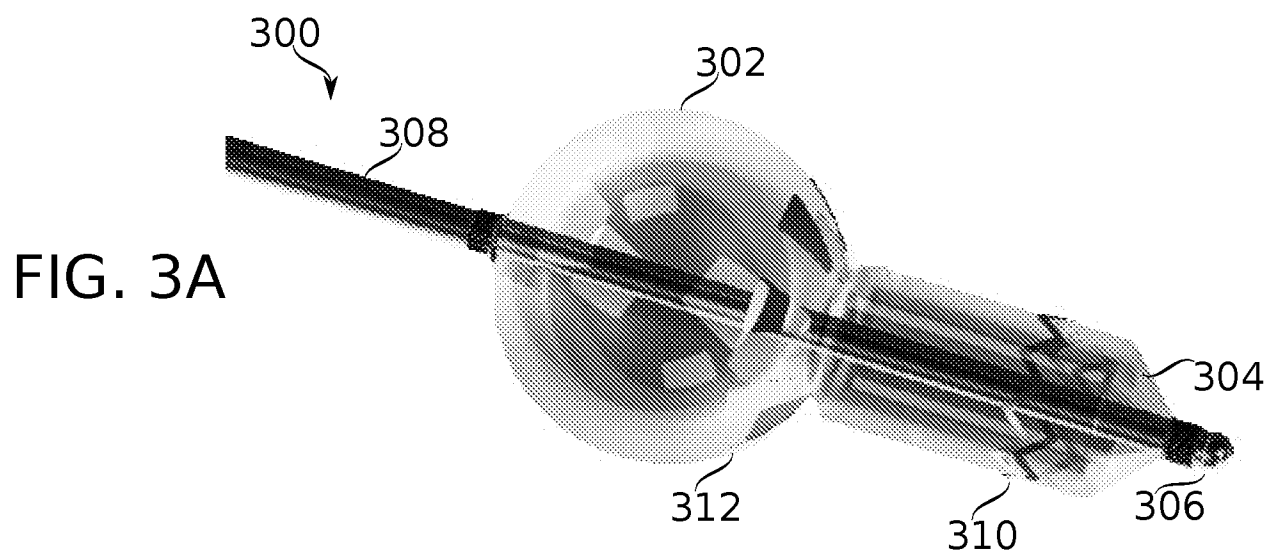
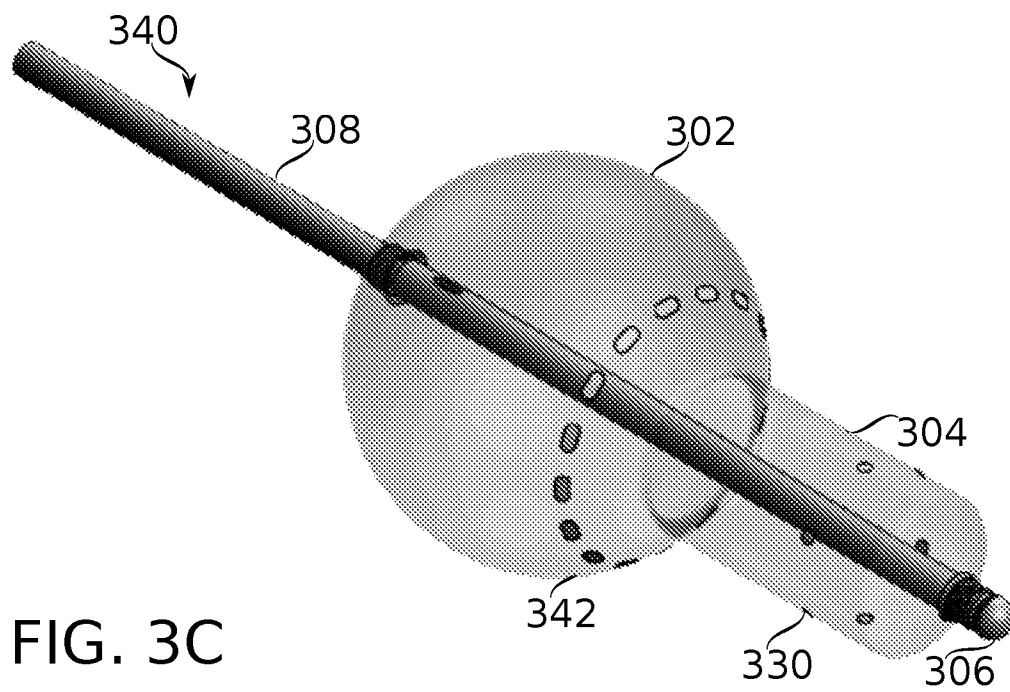
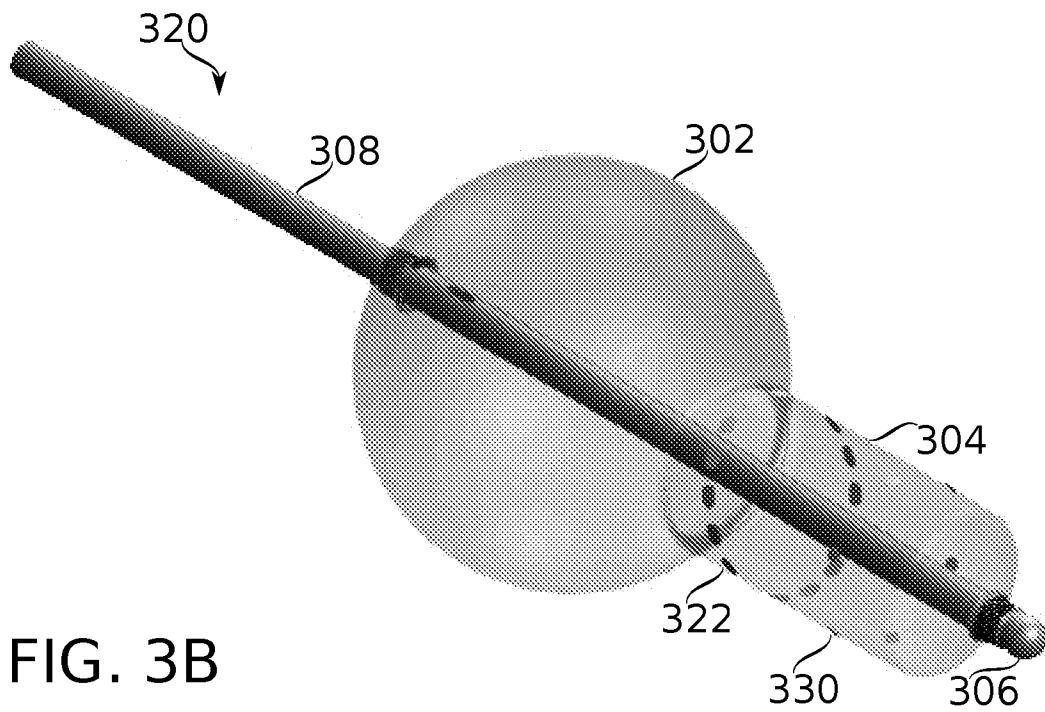


FIG. 2C







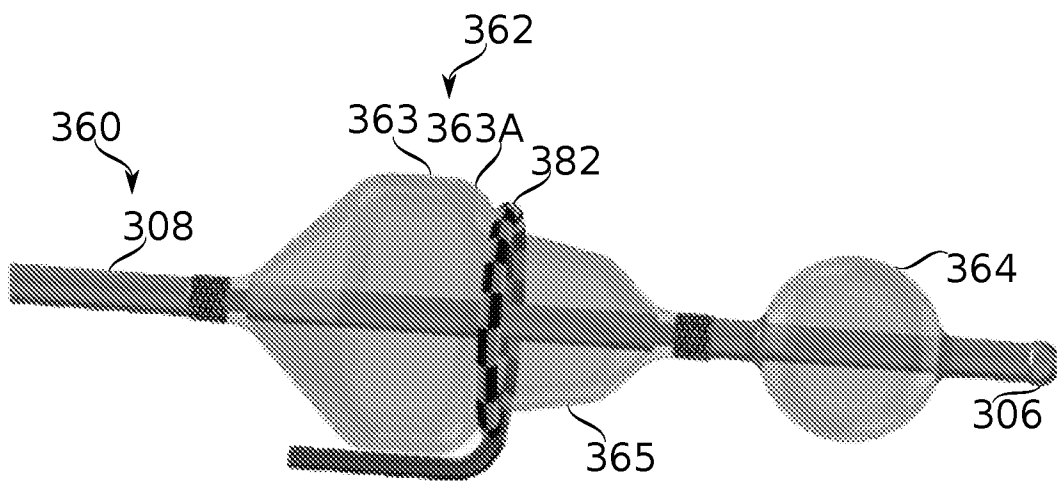


FIG. 3D

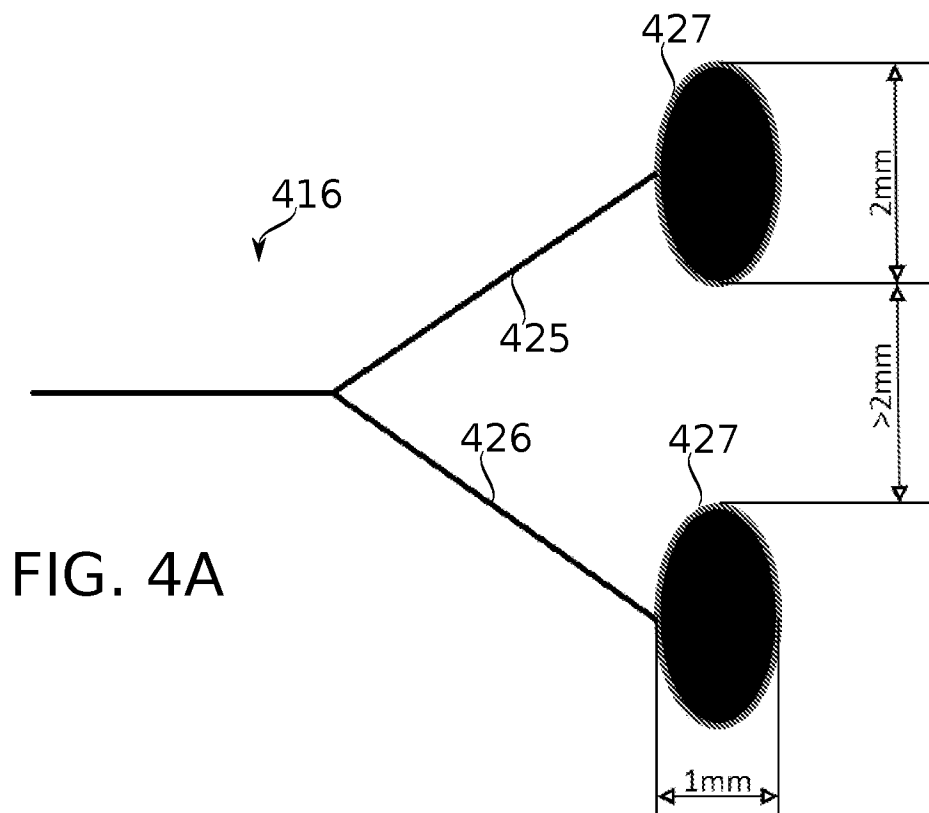


FIG. 4A

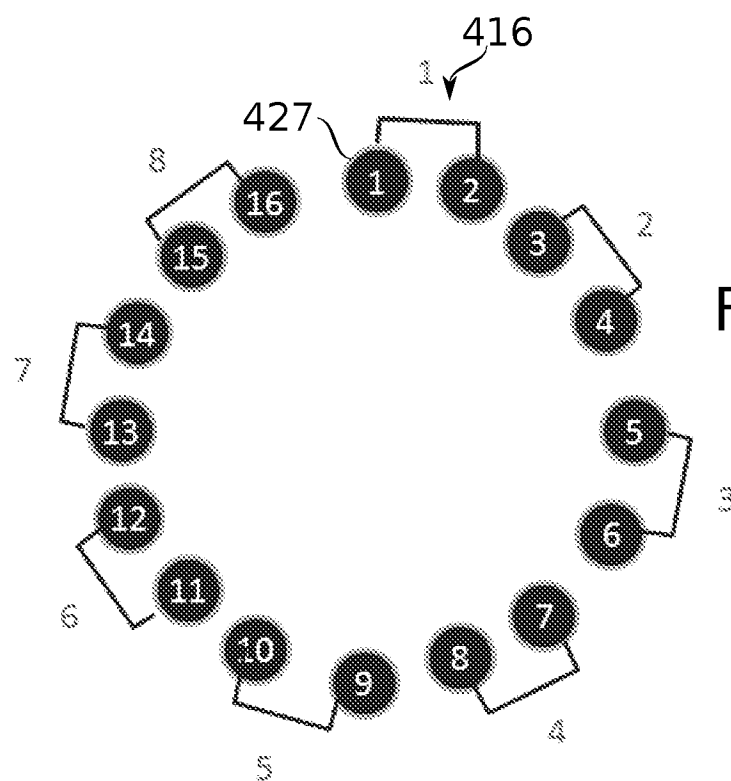


FIG. 4B

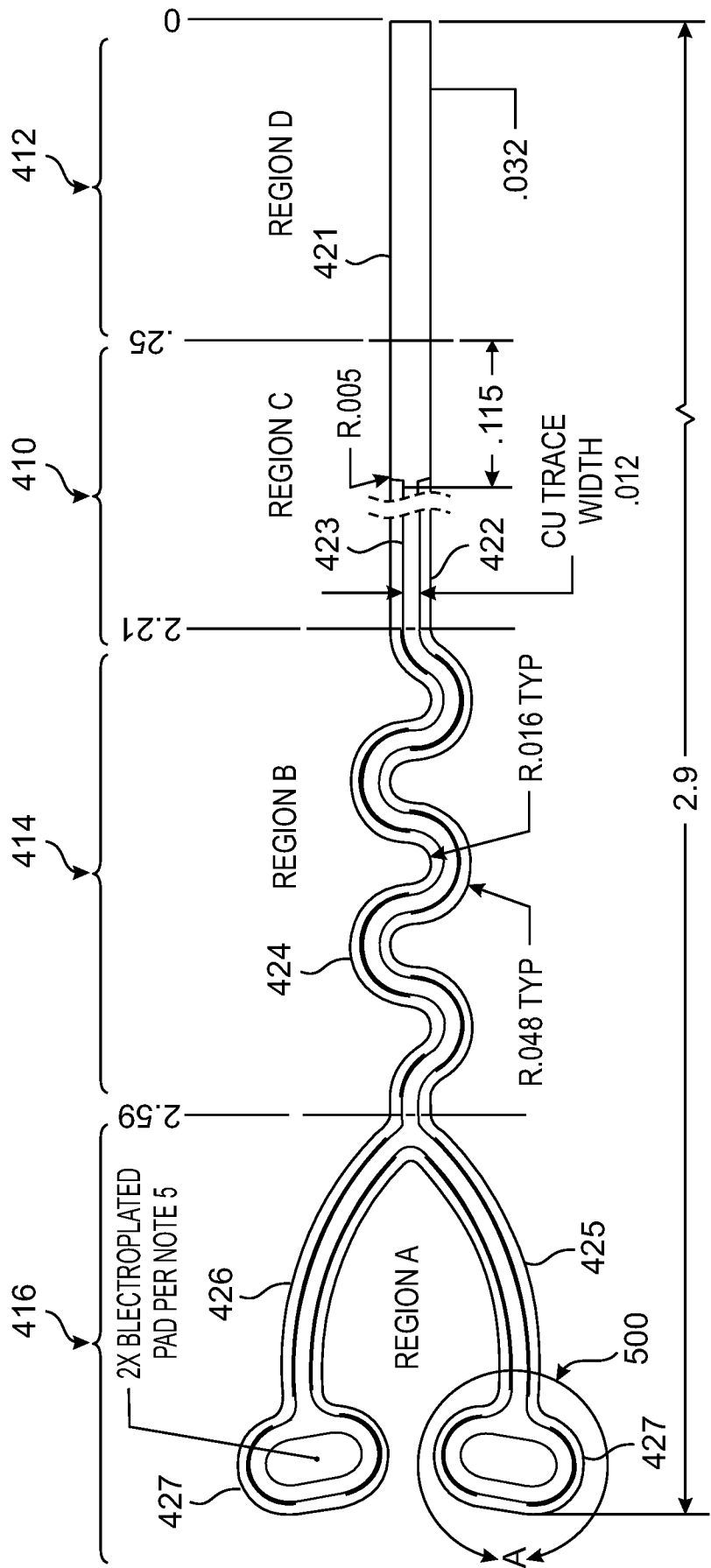


FIG. 4C

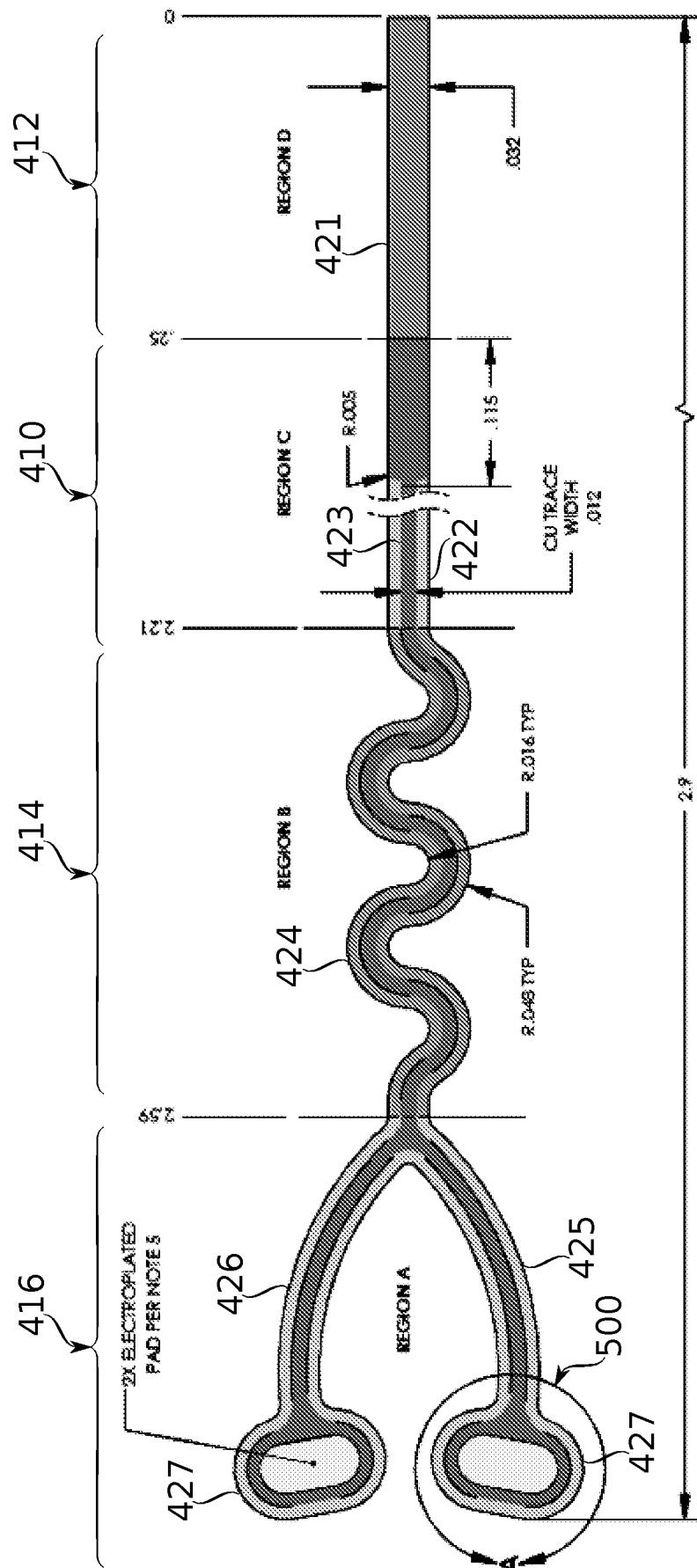


FIG. 4C

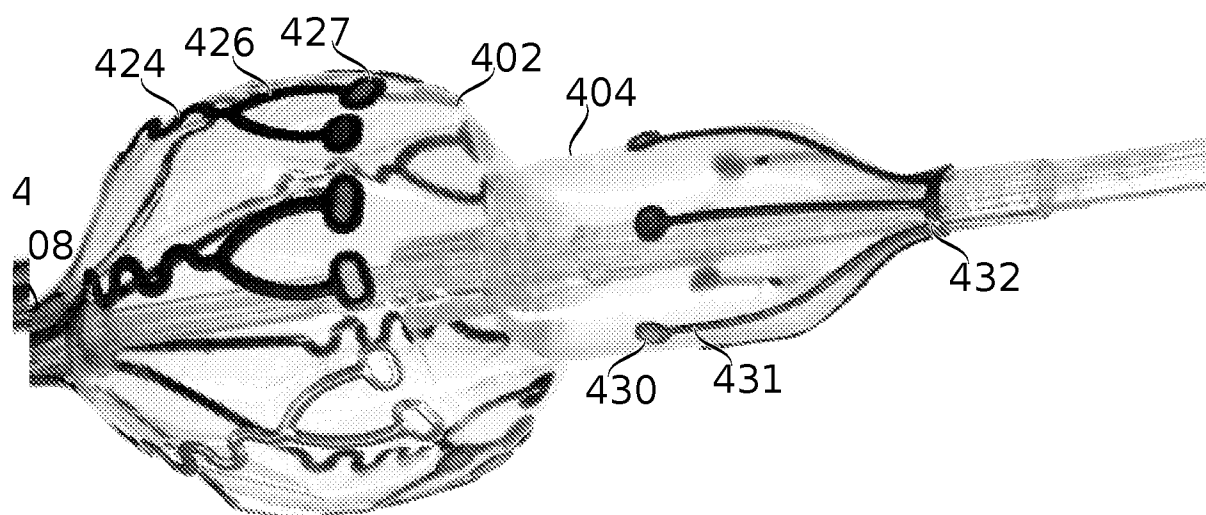


FIG. 4D

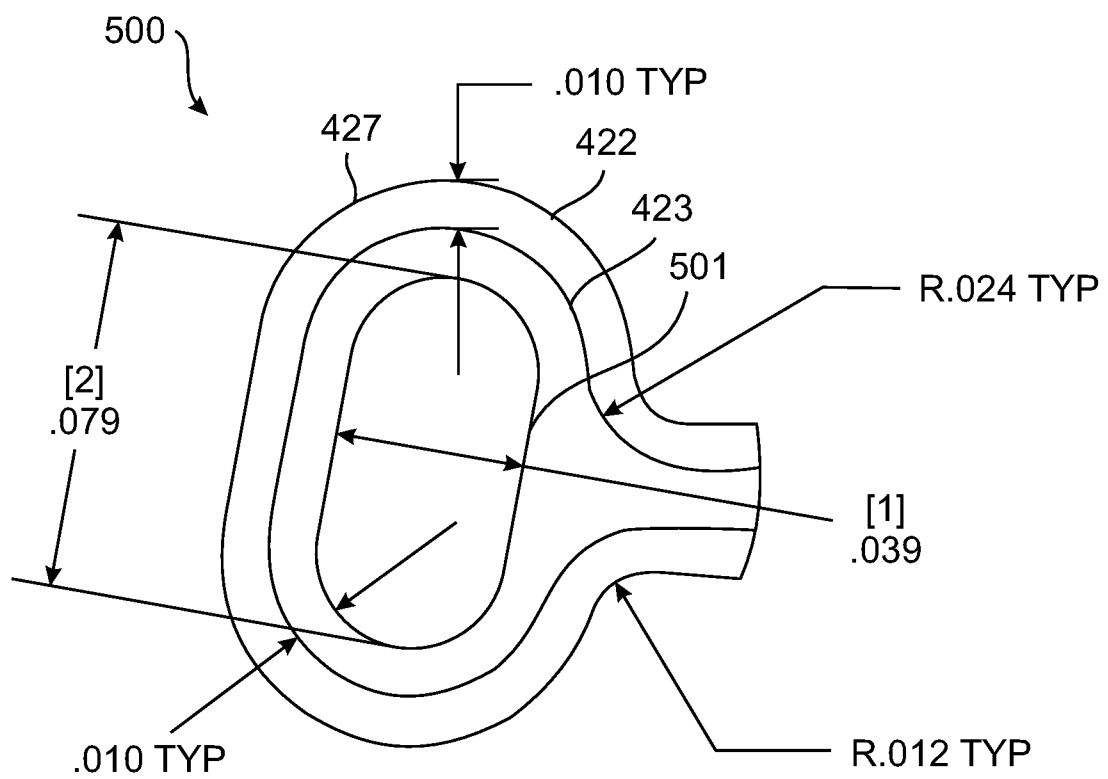


FIG. 5

FIG. 6A

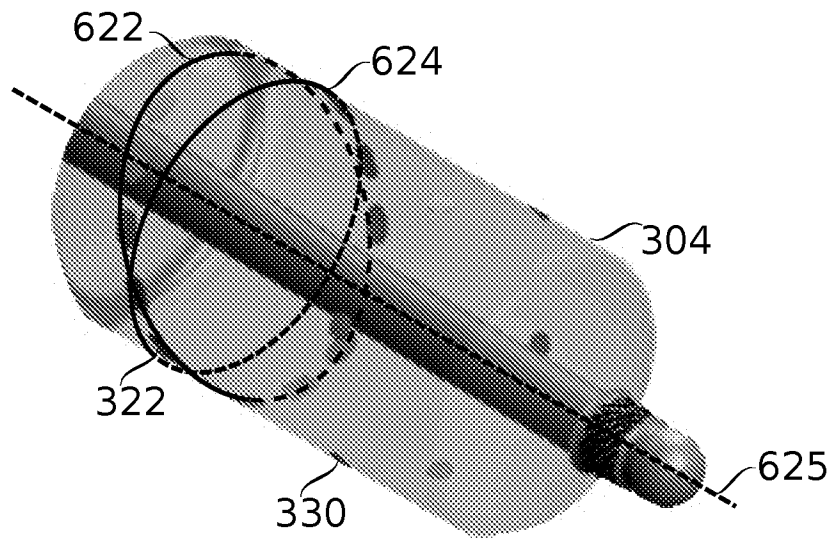


FIG. 6B

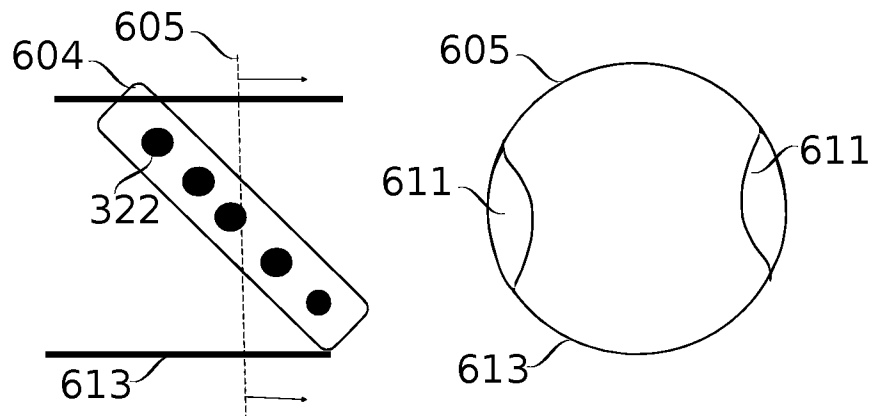


FIG. 6C

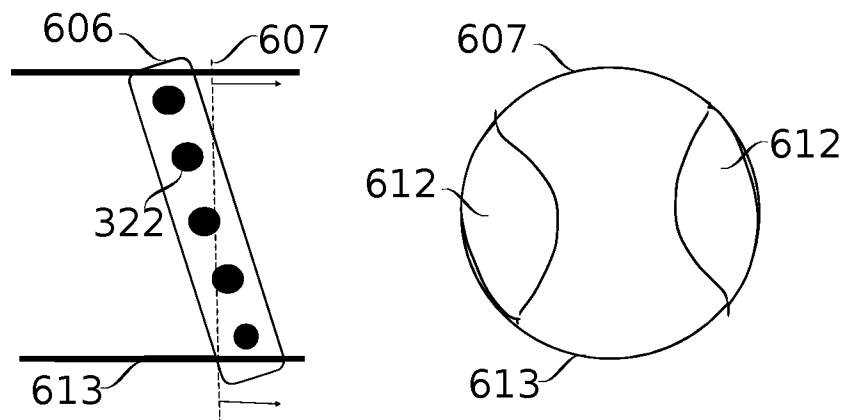


FIG. 7A

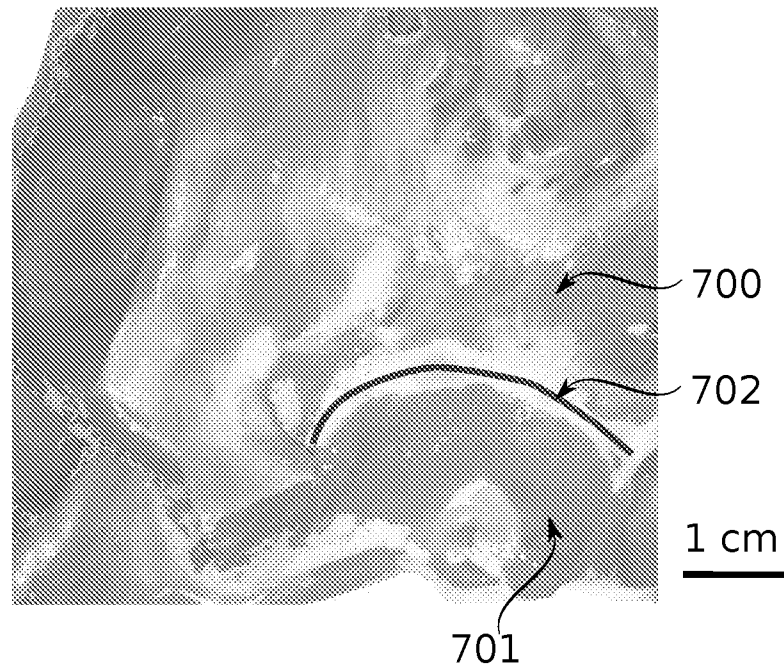
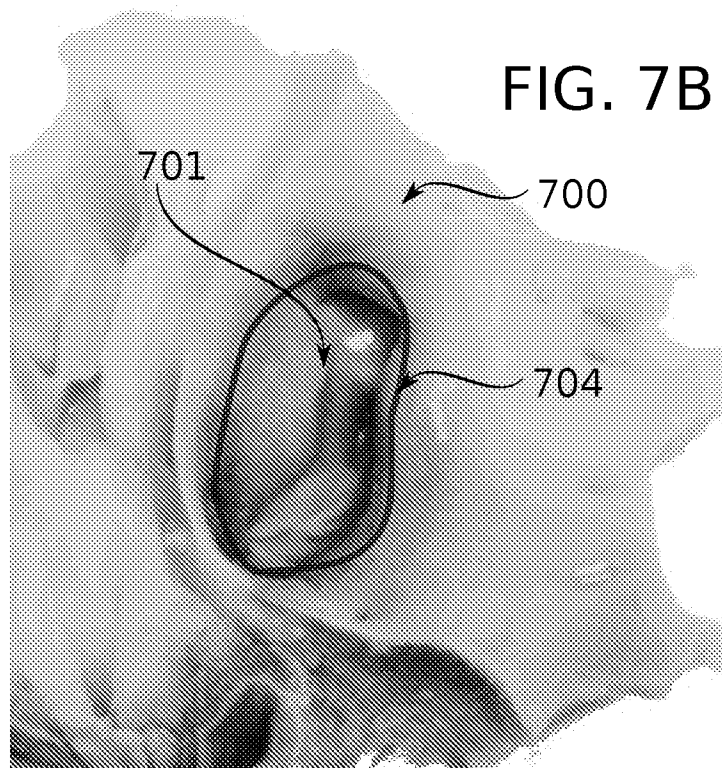


FIG. 7B



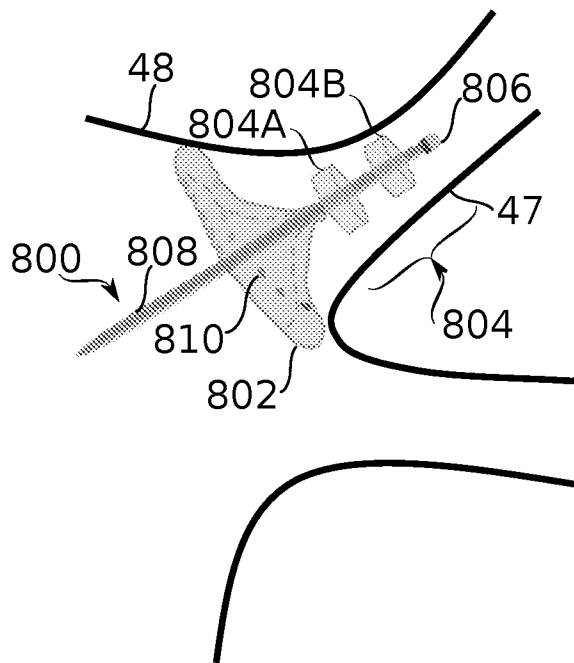


FIG. 8A

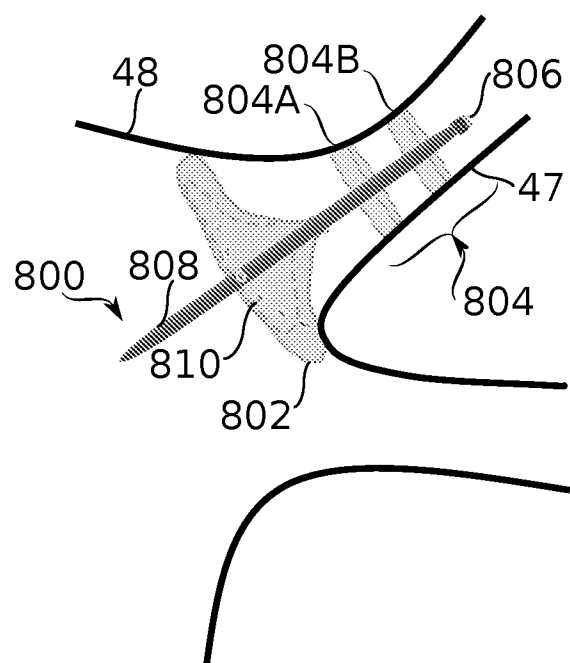


FIG. 8B

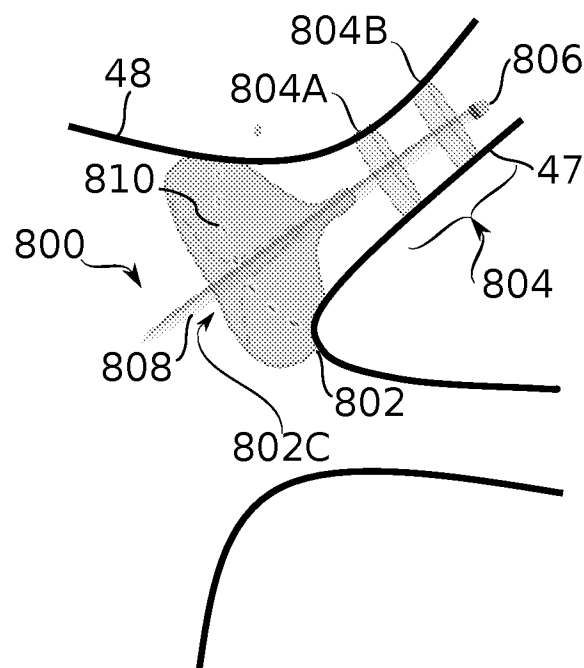


FIG. 8C

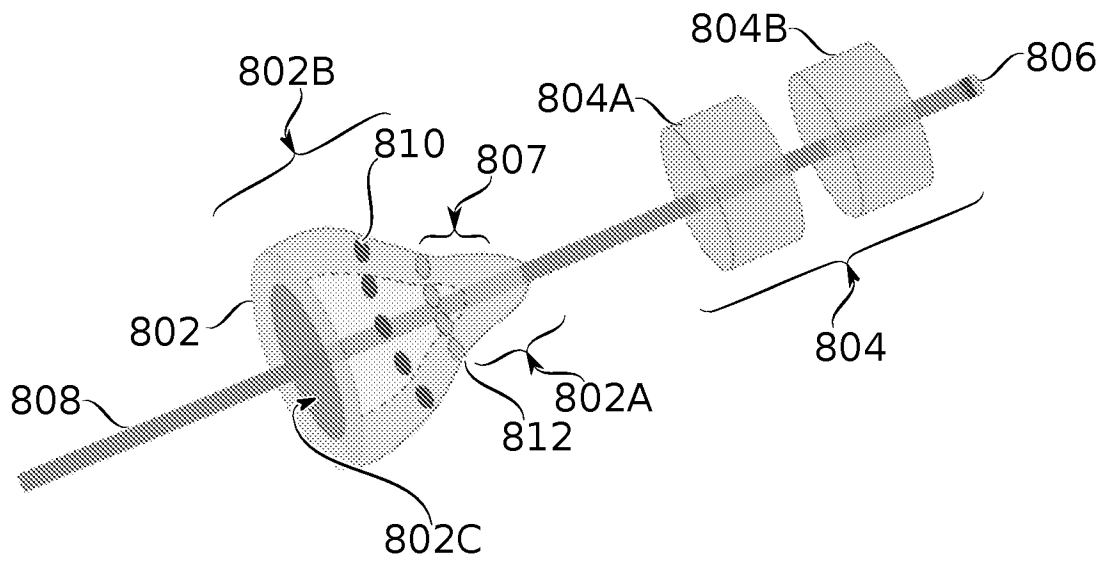


FIG. 9A

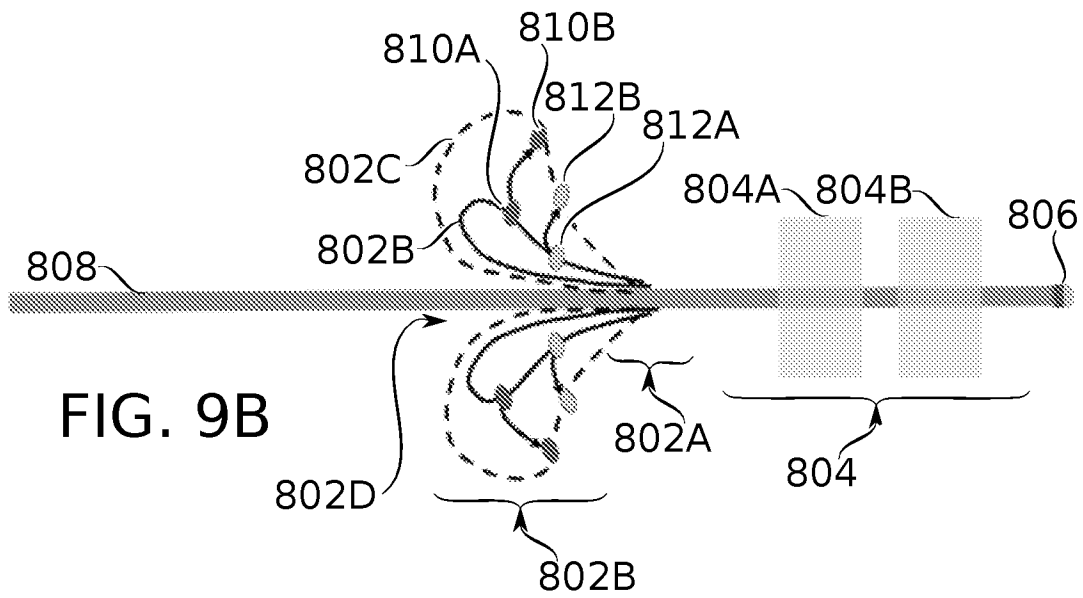


FIG. 9B

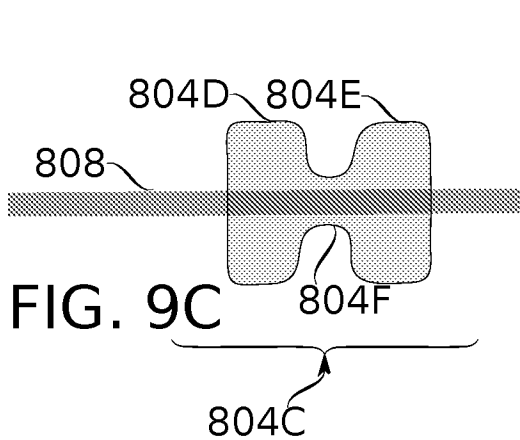


FIG. 9C

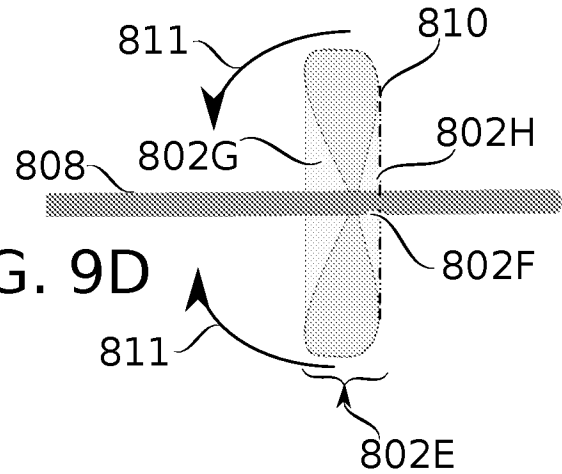


FIG. 9D