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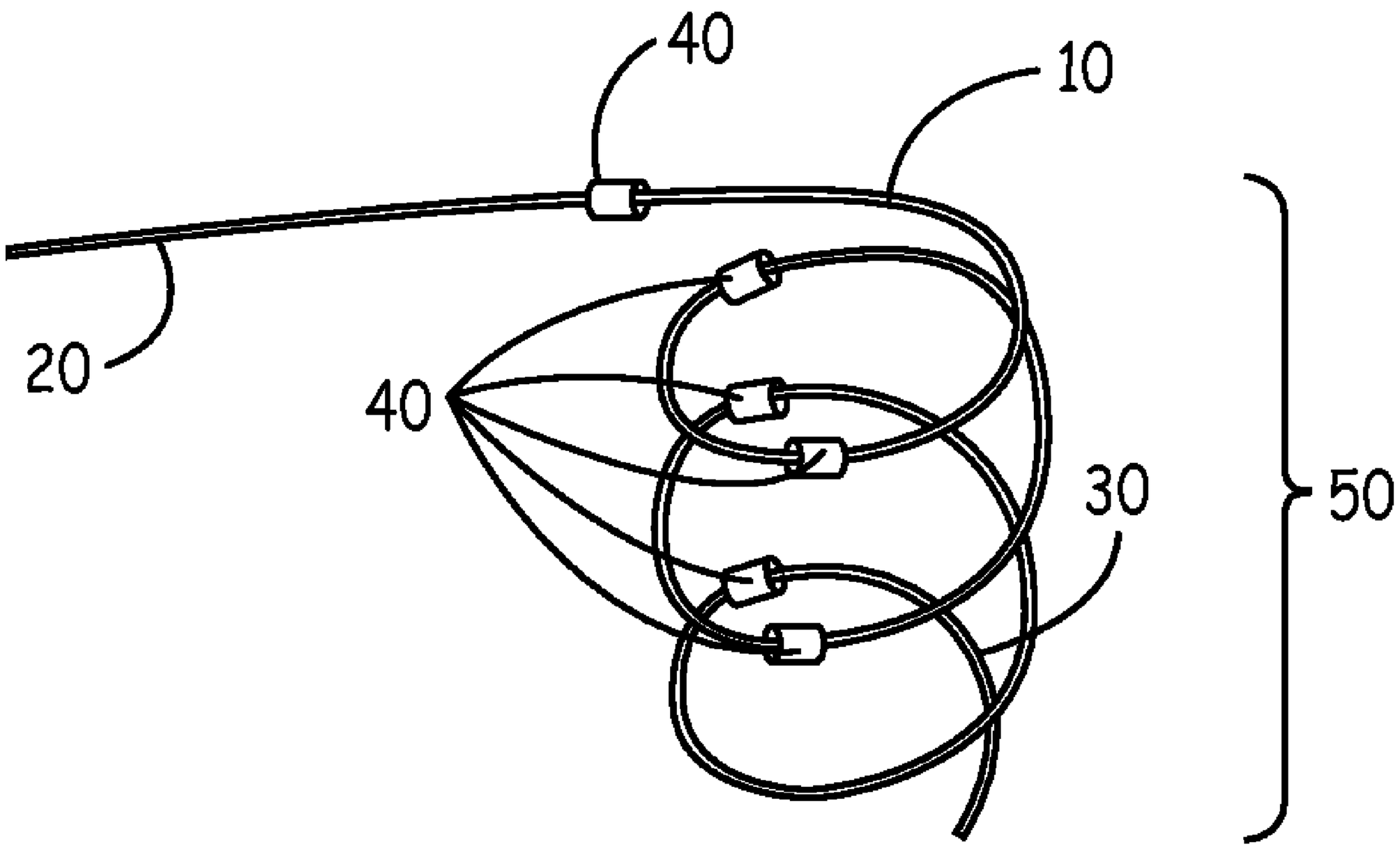

(57) **Abrégé/Abstract:**
A medical electrical lead and methods of implanting medical electrical leads in lumens. Leads in accordance with the invention employ preformed biases to stabilize the lead within a lumen and to orient electrodes in a preferred orientation.

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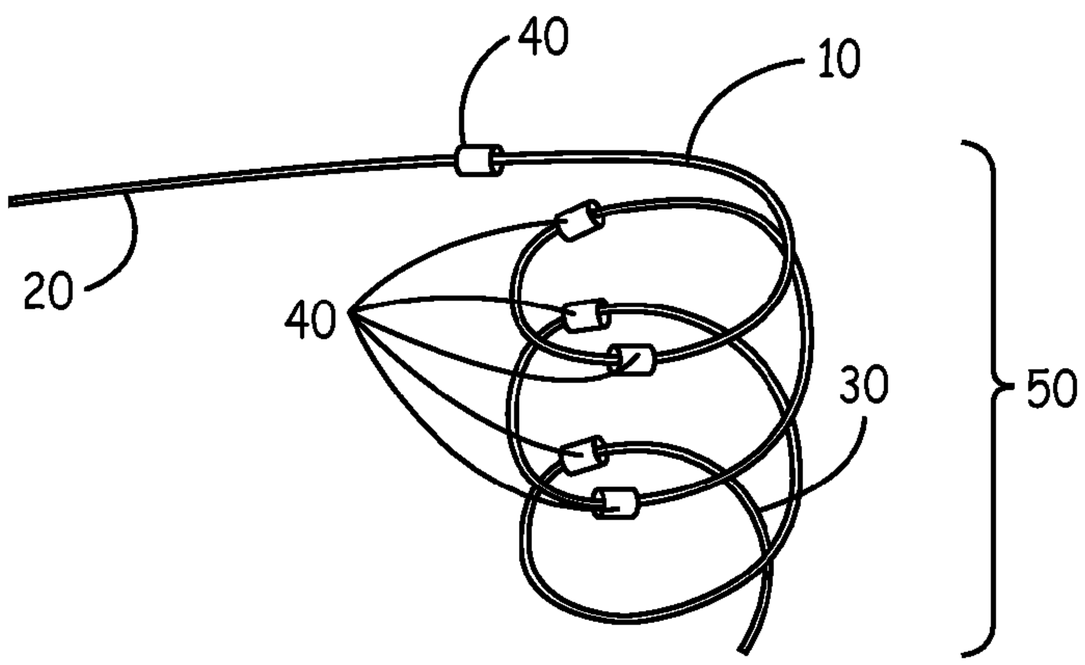

FIG. 1

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MEDICAL LEAD WITH PREFORMED BIAS

BACKGROUND

Electrical stimulation or sensing leads for providing medical therapy are being used in an increasing number of applications. Leads have been implanted in patients' hearts, along the spinal column, and in other loctions to deliver appropriate therapy or sense physiologic conditions. Increasingly leads are implanted in veins, arteries, or other lumens to stimulate or sense tissue near the lumens.

The implantation of electrical leads in lumens presents opportunites because the leads can be fed into the patient's body and implanted without the surgery necessary to install nerve cuffs and other surgically implanted electrodes. Implanting leads in lumens also reduces the possibility of post-surgical trauma or damage to the tissue being stimulated or sensed. Difficulties associated with implanting leads in lumens include issues with lead migration and difficulty orienting the lead and electrodes.

Typical electrical leads have a proximal end that is connected to an electrical pulse generator or to circuitry configured to process signals sensed by electrodes on the leads. The electrodes on the leads are connected to the distal end by flexible and durable conductors, which are ultimatley connected to an external or implantable medical device containing the requied circuitry to detect sensed signals ot to deliver stimulation therapy.

SUMMARY

In one embodiment in accordance with the invention, a medical electrical lead includes a lead body having a preformed helical bias with a coil diameter. The lead also has at least one electrode, and the ratio of the coil diameter to the length of the at least one electrode is at least 4:1. In other embodiments, this ratio is at least 5:1 or 6:1.

In another embodiment in accordance with the invention, a medical electrical lead includes a lead body having a preformed helical bias with a coil diameter. The preformed helical bias of this embodiment is a converging helical bias and the coil diameter is defined as the diameter of the smallest coil of the bias. The lead also has at least one electrode, and the ratio of the coil diameter to the length of the at least one electrode is at least 4:1. In other embodiments, this ratio is at least 5:1 or 6:1.

In another embodiment in accordance with the invention, a medical electrical lead includes a lead body having a preformed helical bias with a coil diameter. The preformed helical bias of this embodiment is a diverging helical bias and the coil diameter is defined as the diameter of the smallest coil of the bias. The lead also has at least one electrode, and the ratio of the coil diameter to the length of the at least one electrode is at least 4:1. In other embodiments, this ratio is at least 5:1 or 6:1.

In another embodiment in accordance with the invention, a medical electrical lead includes a lead body having preformed helical bias with a coil diameter. The lead of this embodiment includes a plurality of electrodes, and at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias. In another embodiment, each of the electrodes has a length such that ratio of the coil diameter to the lengths of the electrodes is at least 4:1. In other embodiments, this ratio is at least 5:1 or 6:1.

In yet another embodiment in accordance with the invention, a medical electrical lead includes a lead body having a lead body axis. There is a preformed bias in the lead body, and the bias has a bias axis. The angle between the lead body axis and the bias axis of this embodiment is greater than thirty degrees. In other embodiments, the angle between the lead body axis and the bias axis is greater than forty-five degrees.

Another embodiment in accordance with the in vention is a method of implanting a lead in a lumen including the steps of inserting a lead in a lumen, the lead having a helical bias and a plurality of electrodes wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias. The method also has a step of positioning the lead within the lumen so that a tissue of interest is within the quadrant as the quadrant extends outward radially.

In another embodiment, a method of implanting a lead in a lumen includes the steps of inserting a lead in a lumen, the lead having a helical bias and a plurality of electrodes wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias. The method also includes a step of positioning the lead within the lumen so that a tissue of interest is within the quadrant as the quadrant extends outward radially.wherein the lumen includes the right brachiocephalic vein and the tissue of interest comprises the right phrenic nerve. In other

embodiments the lumen includes the left brachiocephalic vein and the tissue of interest includes the left phrenic nerve, the lumen includes the superior vena cava and the tissue of interest includes the right phrenic nerve, the lumen includes the right internal jugular vein and the tissue of interest includes the hypoglossal nerve, or the lumen comprises the junction between the right brachiocephalic vein and the right subclavian vein.

According to one aspect of the invention there is provided a medical electrical lead comprising:

A) a lead body having a preformed helical bias with a coil diameter;

B) a plurality of electrodes;

C) wherein the ratio of the coil diameter to the length of the at least one electrode is at least 4:1 and wherein at least two of the electrodes of the plurality of electrodes are at different radial positions on the helical bias within the single quadrant of the helical bias; and

D) wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias.

According to another aspect of the present invention, there is provided a method of implanting a lead in a lumen, the method comprising:

A. inserting a lead in a lumen, the lead having a helical bias with a central axis and a coil diameter defined by a line perpendicular to the central axis that intersects the central axis and the line having ends that intersect with two points on the helical bias and a plurality of electrodes wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias and wherein each of the electrodes has a length such that a ratio of the coil diameter to the length of each of the electrodes is at least 4:1; and

B. positioning the lead within the lumen so that a tissue of interest is within the quadrant as the quadrant extends outward radially.

According to another aspect of the present invention, there is provided a medical electrical lead comprising:

a lead body having a preformed helical bias with a coil diameter;

a plurality of electrodes;

wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 4:1, and

wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias

wherein at least two of the plurality of electrodes are at different radial positions on the helical bias within the single quadrant of the helical bias.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a perspective view of a lead in accordance with embodiments of the invention.

Figure 2 is a perspective view of a lead in accordance with embodiments of the invention.

Figure 3 is a perspective view of a lead in accordance with embodiments of the invention.

Figure 4 is a perspective view of a lead in accordance with embodiments of the invention.

Figure 5 is a plan view of a lead in accordance with embodiments of the invention.

Figure 6 is a schematic view of a lead in accordance with embodiments of the invention implanted in a patient.

Figure 7 is a schematic view of a lead in accordance with embodiments of the invention implanted in a patient.

Figure 8 is a schematic drawing of a lead in accordance with embodiments of the invention implanted in a cross section of a lumen.

Figure 9 is a schematic drawing of a lead in accordance with embodiments of the invention as in Figure 8 from a view along an axis such as B.

DETAILED DESCRIPTION

Figure 1 is a perspective view of a lead in accordance with embodiments of the invention. The lead has a lead body 10 with a proximal portion 20 and a distal end 30. Electrodes 40 are distributed along a distal portion of the lead body 10. A bias region 50 near the distal end is formed in a helical or circular fashion. This bias region 50 may be formed by wrapping the lead around a spindle of other shape imparting structure and heat treating or otherwise shaping the lead body 10 in a way that the lead

will be biased to return to this preformed shape. The lead body may be constructed from a shape memory polymer or metal or of any material suitable for the purpose. If constructed from a shape memory polymer, for example polyurethane, the thickness or diameter of the lead body or other parameters may be varied to adjust the degree of rigidity of the bias.

The bias may be helical or generally circular. The primary difference between what is described herein as a helical bias and a circular bias is the pitch of the helix. A circular bias is one in which the pitch of the helix is less than or equal to the thickness of the lead. That is the coils of the helix touch or overlap with one another when the lead is in its unstressed position. If the pitch of the helix is greater than the thickness of the lead, the bias is referred to herein as helical. For the purposes of this discussion, circular and helical biases are interchangeable unless specifically noted as the pitch is essentially the only difference.

The bias 50 shown in Figure 1 is generally is a helix of a constant diameter. This embodiment is usable to secure a lead within a relatively large lumen. In practice, the diameter of the helix is designed to be slightly larger than the lumen in which it is implanted, and the pressure of the bias against the lumen wall retains the lead within the lumen. Once so retained, the electrodes are in a position to sense activity in nearby tissues or electrically stimulate nearby tissues.

As an example, the embodiment of Figure 1 could be implanted within the right or left brachiocephalic vein or superior vena cava of a patient. Both the right and left brachiocephalic veins are similar in size, ranging from approximately 15mm to 22mm in diameter. An embodiment for this application may, for example, have a helix/coil diameter of 20mm. The helix/coil length, measured along the axis of the helix from the first curvature to the end of the lead, may in this example be 30-40mm.

Figure 2 is a perspective view of a lead in accordance with embodiments of the invention. Like the embodiment in Figure 1, this embodiment has a lead body 10 with a proximal portion 20 and a distal end 30. Electrodes 40 are disposed generally distally on the lead body. A bias 50 is formed in a helical or circular fashion near the distal end. This bias 50 is formed as a converging circle or helix, with the coils having a decreasing diameter from the proximal portion 20 toward the distal end 30.

A lead in accordance with Figure 2 could be usable to secure electrodes within lumens at a junction of two or more lumens. If a lumen or vessel diverges to form two, for example, this lead could be employed such that the larger diameter coils of the helix are deployed within the larger diameter region where the lumens diverge while the smaller diameter coils reside within the single lumen formed by the junction. In this manner, a consistent anchoring pressure may be provided in a region of diverging diameters due to a junction of lumens.

Figure 3 is a perspective view of a lead in accordance with embodiments of the invention. The embodiment of Figure 3 includes a lead body 10 having a proximal portion 20 and a distal end 30. One or more electrodes 40 are disposed along the lead body. A bias 50 is formed proximate the distal end 30. The bias in this embodiment has a diverging circle or helix, in which the diameter of the coils increases from the proximal portion 20 to the distal end 30. If a two lumens or vessels converge to form one, for example, this lead could be employed such that the larger diameter coils of the helix are deployed within the larger diameter region where the lumens come together while the smaller diameter coils reside within the single lumen formed by the junction. In this manner, a consistent anchoring pressure may be provided in a region of converging diameters due to a junction of lumens.

Figure 4 is a perspective view of a lead in accordance with embodiments of the invention. The embodiment of Figure 4 includes a lead body 10 having a proximal portion 20 and a distal end 30. A circular or helical bias 50 is proximate the distal end. Electrodes 40 are disposed along the lead body generally in one quadrant of the helical portion, as defined by illustrative planes 60. Illustrative planes 60 meet at line 70, which defines the axis of the bias 50. At least some portion of each electrode of this embodiment is in this quadrant. By distributing the electrodes in this fashion, the area to be stimulated or sensed by the electrodes upon implantation can have the maximum number of electrodes oriented nearby.

For example, if the lead of Figure 4 were implanted in a right brachiocephalic vein with the desired effect of stimulating the right phrenic nerve or sensing nerve traffic, the quadrant of the bias 50 defined by planes 60 could be oriented

along the right lateral side of the brachiocephalic vein to maximize the effectiveness of any stimulation or signal sensing provided by the electrodes 40.

Figure 5 is a plan view of a lead in accordance with embodiments of the invention. This embodiment has a lead body 10 having a proximal portion and a distal end. A bias 50 of a circular or helical basis is proximate the distal end 30. Electrodes are 40 distributed such that at least a portion of each electrode is within a quadrant of the helix 50 as defined by illustrative planes 60. This view is of a lead as in Figure 4, and is taken along line 70.

Implanting a lead in accordance with embodiments of the invention involves advancing the lead to the desired location with the aid of some sort of stiffening or straightening device, such as an internal wire or stylet or external guide catheter. The lead is advanced to the desired location and the stiffening device is removed, allowing the bias to revert to its imparted or natural shape. The lead position is evaluated through X-ray and standard venography techniques. The lead can be advanced or retracted as necessary, with or without the stiffening device in place. The lead can also be rotated as necessary, again, with or without the stiffening member. In fact, without the stiffening member in place, the lead can be rotated to reposition the electrodes or in some instances to "tighten" or "loosen" or "expand" the bias 50. In cases where the electrodes on the lead are arranged so that least a portion of each electrode is located within a quadrant of the bias, the lead is oriented so that the tissue of interest to be sensed or stimulated falls within an extension of that quadrant. That is, if one extends the planes 60 of Figures 4 and 5 radially away from line 70 while the lead is implanted, the tissue of interest would fall within the quadrant, and preferably toward the center of the quadrant.

Figure 6 is a schematic view of a lead in accordance with embodiments of the invention implanted in a patient. The lead has a lead body 10 having a proximal portion 20 and a distal end 30. Electrodes 40 are disposed on the lead body, which includes a bias portion 50. The lead is disposed in the right brachiocephalic vein 80 of the patient through the subclavian vein 130 and extends into the superior vena cava 90. The transition from the right brachiocephalic to the superior vena cava is imprecise, and references to the right brachiocephalic vein within this disclosure refer to both the right brachiocephalic and superior vena cava unless otherwise indicated. The electrodes 40 are

configured to stimulate, or to sense nerve activity of, the right phrenic nerve 100 of the patient. In this embodiment the bias 50 could be a consistent coil diameter, a converging coil diameter, or a diverging coil diameter.

Veins within the thorax are subject to intrathoracic pressures caused by diaphragmatic contraction. When the diaphragm contracts, it creates negative intrathoracic pressures that cause veins within the thorax to dilate, increasing venous volume and enlarging the cross sectional area of the vein. In addition there is a downward translation of the heart 110 and lungs that can stretch and elongate the superior vena cava 90 and brachiocephalic 80, 120 veins. Pulsing from the cardiac cycle also can be translated to the superior vena cava 90 and brachiocephalic 80, 120 veins. These physiologic dynamics create many challenges, which inventors have overcome in leads in accordance with embodiments of the invention.

The shape of the bias 50 of some embodiments is circular, in the helical form or in the true circular form. The circular and helical shapes exert force against the inner luminal surface of the vein creating a frictional force that retains the lead in the vein. This radial fixation force is created by forming a shape or bias in the lead that is "slightly" larger diameter than the vessel diameter. This relationship can be described in some embodiments as a bias diameter to vessel diameter ratio of between 1.1:1 and 1.3:1. The bias 50 diameter in these embodiments is slightly larger because some of the larger veins in which these embodiments are implanted are fairly malleable and the inventors have found that these veins do not significantly constrain the leads, resulting in bias orientations upon implantation that are substantially similar to the bias' unconstrained position prior to implantation. Inventors have used this knowledge to create desired biases shapes that are then implanted in much the same configuration.

The bias 50 can be formed in a constant diameter fashion, a diverging helix or circle, or a converging helix or circle. The different shapes may be more or less suitable for varying anatomy and different locations. If the lead is intended for the junction of the subclavian vein 130 and brachiocephalic vein 80, a converging helix may provide superior fixation and electrode contact. If the targeted site involves the brachiocephalic vein junction or superior vena cava the diverging helix may be superior. In each case the varying diameters of the coils may be proved more intimate contact with

the vessel wall for better fixation and electrode contact. The most proximal portions of the helix (the first ½ to full revolution) may serve as a mechanism of decoupling. This feature may decouple external forces (i.e. arm, shoulder, etc. motion) from the electrodes. It may also permit the bias 50 of the lead, that part that engages the vein, to move (this motion comes from respiration, coughing, sneezing, cardiac impulse) independent from the proximal lead portion 20.

In some embodiments, the electrodes 40 are arranged within a quadrant of the bias 50 so that they are more apt to stimulate or sense the tissue of interest. In the case where the right phrenic nerve 100 is of interest, the lead may be situated so that the most proximal electrode is located in the subclavian vein and the quadrant of the bias 50 that includes the electrodes 40 is places on the right lateral portion of the right brachiocephalic 80. In cases where the electrodes on the lead are oriented so at least a portion of each electrode is within a defined quadrant, the lead could be further oriented so that the quadrant, when extended, includes a significant portion of the right phrenic nerve.

Figure 7 is a schematic view of a lead in accordance with embodiments of the invention implanted in a patient. The lead has a lead body 10 having a proximal portion 20 and a distal end 30. Electrodes 40 are disposed on the lead body, which includes a bias portion 50. The lead is disposed in the left brachiocephalic vein 150 of the patient. The electrodes 40 are configured to stimulate, or to sense nerve activity of, the left phrenic nerve 140 of the patient. In this embodiment the bias 50 could be or a consistent coil diameter, a converging coil diameter, or a diverging coil diameter.

The left phrenic nerve 140 passes behind or anterior to the left brachiocephalic vein 150 at a somewhat skew angle to the vein 150. In some embodiments the electrodes 40 may be arranged in the bias 50 so that they are in the anterior quadrant of the bias 50 as the lead is implanted. In some of these and other embodiments, the pitch of the coil of the bias 50 may be relatively more circular than helical to concentrate the electrodes more closely to where the nerve 140 passes closest to the vein 150. As discussed above, in some embodiments the bias is implanted in the lead and adopts a configuration substantially similar to that of the unstressed unimplanted lead.

Figure 8 is a schematic drawing of a lead in accordance with embodiments of the invention implanted in a cross section of a lumen. The lead has a lead body 10 and electrodes 40 disposed thereon. The lead body 10 has a preformed bias 50 that forces at least portions of the lead body 10 against the walls 160 of a lumen. The lumen has a main axis B that is coaxial with the bias axis, also B. The lead body has a main axis A, in this case measured at an exemplary electrode. The angle C between the coil axis B and lead axis A can be generally described as skew. If the lead body 10 has an axis A more parallel to the coil axis B, the lead body 10 tends to define an elongated helix that is potentially more susceptible to motion artifact. Inventors have learned that lead bodies with their axes A perpendicular to the coil axis B define a helix with greater stability within a lumen, possibly due to a greater force applied transverse to the lumen wall 160.

The fact that the angle C is skew to a significant degree means that the lead body is traversing laterally across the lumen more so than coaxially. This means that in order for the lead 10 and electrodes 40 to be close to the lumen wall 160 for stimulation or sensing, the lead 10 and electrode 40 combination must approximate the curvature of the lumen wall.

Figure 9 is a schematic drawing of a lead in accordance with embodiments of the invention as in Figure 8 from a view along an axis such as B. The lead has a lead body 10 form in a circular or helical bias 50, of which one coil is shown, and an electrode 40. The coil has a diameter D and the electrode has a length L. In some embodiments, electrodes are appropriately sized in length L relative to coil diameter D. In some cases if the electrode is too long, a circular discontinuity that can separate, or push away, or prevent intimate contact of the electrode with the vessel wall is created, leading to a gap 170.

Inventors have found that for some embodiments the ratio of the length L of the electrode to the diameter D of the coils of the bias 50 can be relevant. For coils configured for implantation into vessels the size of the right or left brachiocephalic veins, for example, an effective D:L ratio may be 4:1 or greater. This ratio is particularly relevant when the main lead axis A is particularly skew to the lumen axis B as discussed with respect to Figure 8. A sufficient L:D ratio may result in the lead body adopting a more continuous circular shape that rests against the luminal surface 160. It is

conceivable that a more continuous circular shape will induce less stress, lower opportunity for lumen damage, and thus lower probability of negative tissue response at the electrode site than a shape with periodic flat areas/sections with corners. This ratio has application to both the in situ helical and circular shapes.

One skilled in the art will appreciate that the invention can be practiced with embodiments other than those disclosed. The disclosed embodiments are presented for purposes of illustration and not limitation, and the invention is limited only by the claims that follow.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A medical electrical lead comprising:

a lead body having a preformed helical bias with a coil diameter;

a plurality of electrodes;

wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 4:1, and

wherein at least a portion of each of the plurality of electrodes is within a single quadrant of the helical bias

wherein at least two of the plurality of electrodes are at different radial positions on the helical bias within the single quadrant of the helical bias.

2. The medical electrical lead of claim 1, wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 5:1.

3. The medical electrical lead of claim 1, wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 6:1.

4. The medical electrical lead of claim 1, wherein the preformed helical bias is a converging helical bias and the coil diameter is defined as the diameter of the smallest coil of the bias.

5. The medical electrical lead of claim 4, wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 5:1.

6. The medical electrical lead of claim 4, wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 6:1.

7. The medical electrical lead of claim 1, wherein the preformed helical bias is a diverging helical bias and the coil diameter is defined as the diameter of the smallest coil of the bias.

8. The medical electrical lead of claim 7, wherein the ratio of the coil diameter to the length of each of the plurality of electrodes is at least 5:1.

9. The medical electrical lead of any one of claims 1 to 8 further comprising:

the lead body having a lead body axis; and

the preformed bias having a bias axis,

wherein an angle between the lead body axis and the bias axis is greater than thirty degrees.

10. The medical electrical lead of claim 9, wherein the angle between the lead body axis and the bias axis is greater than forty-five degrees.

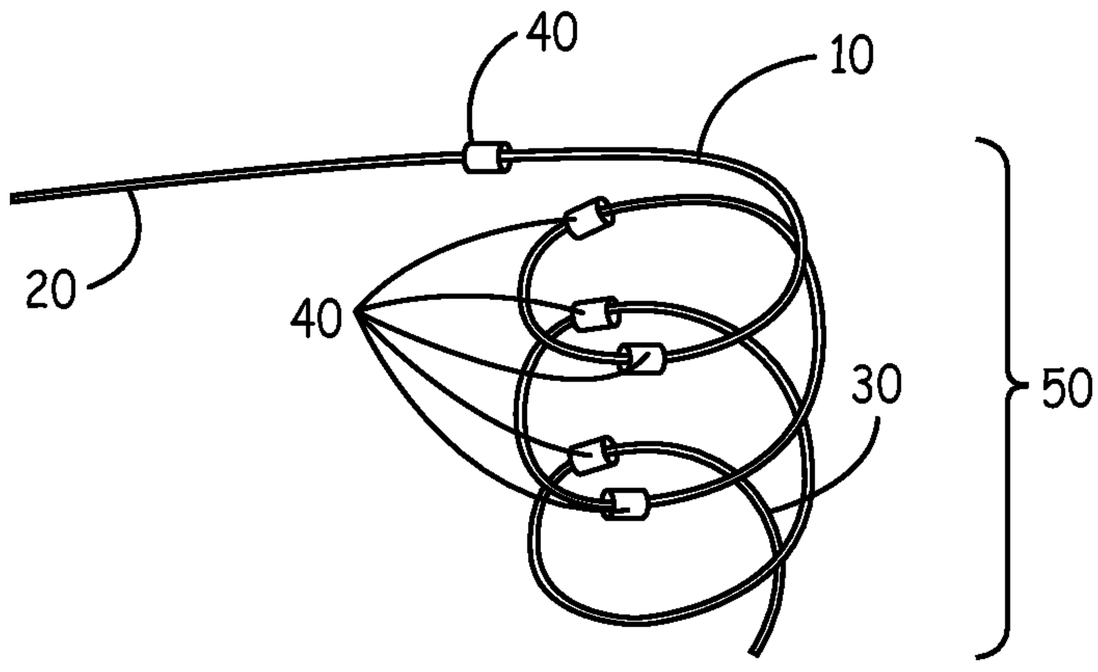


FIG. 1

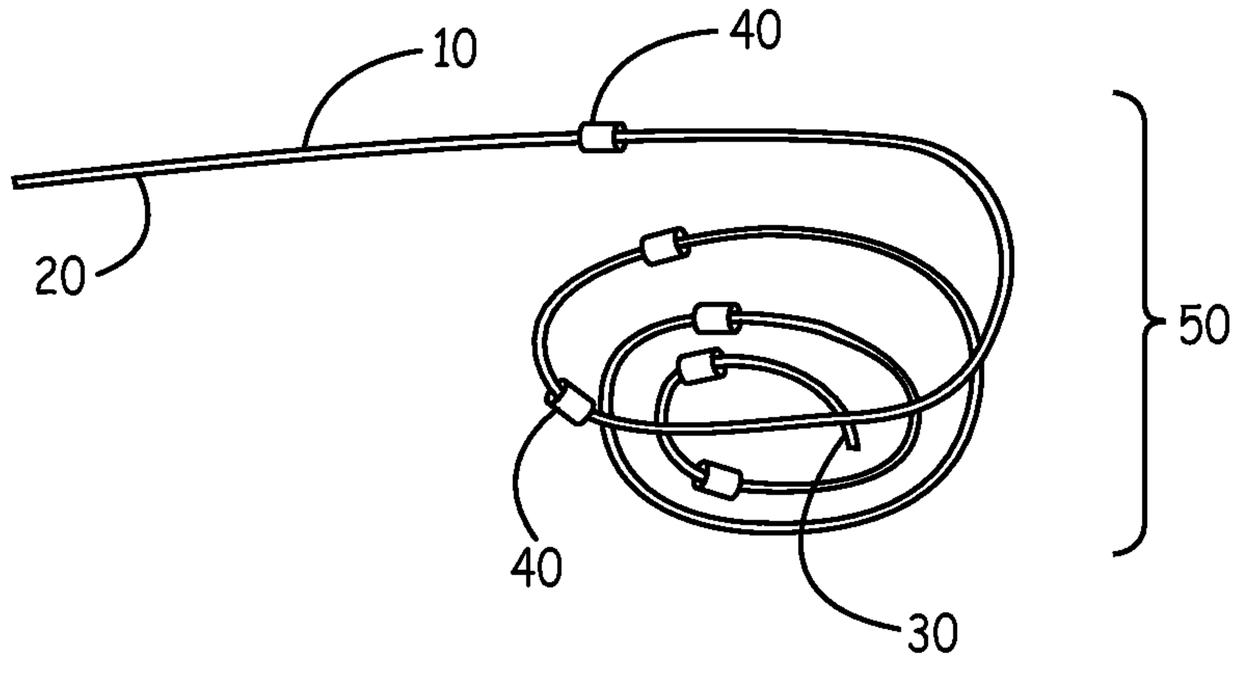


FIG. 2

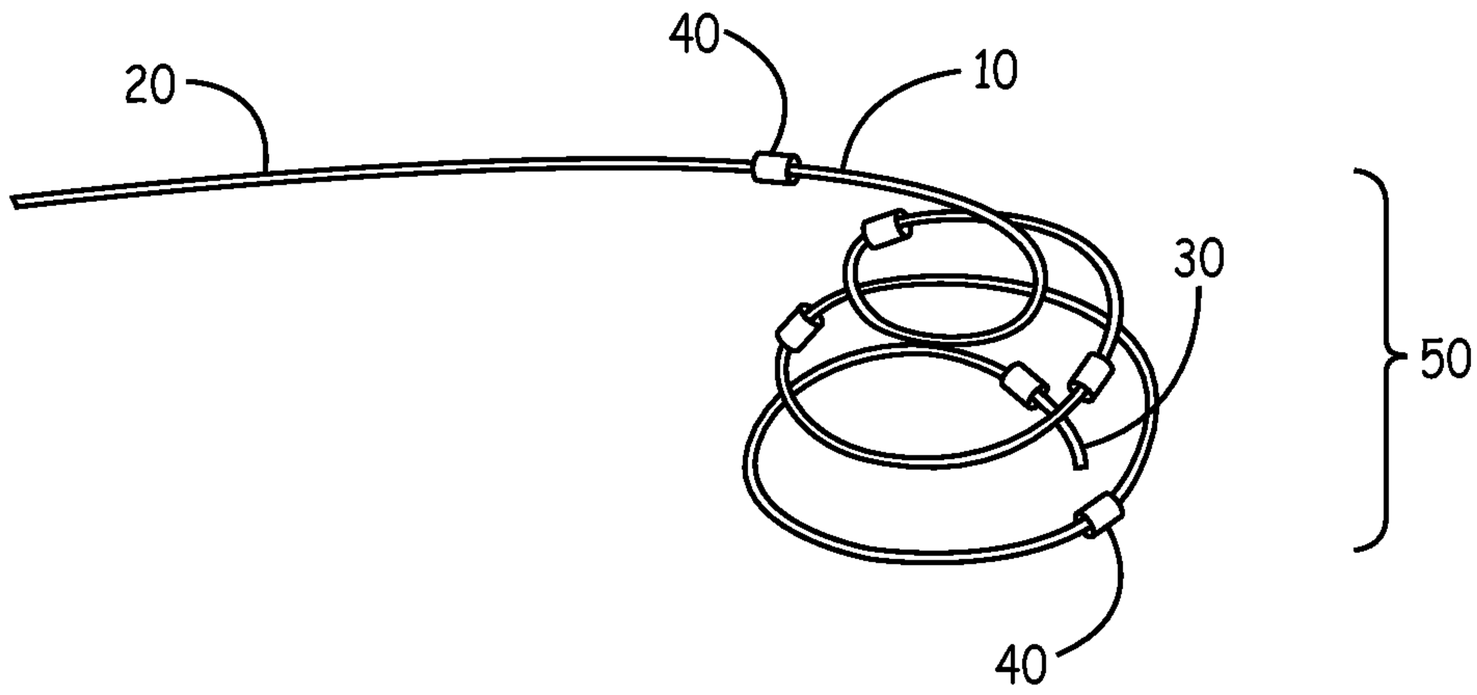


FIG. 3

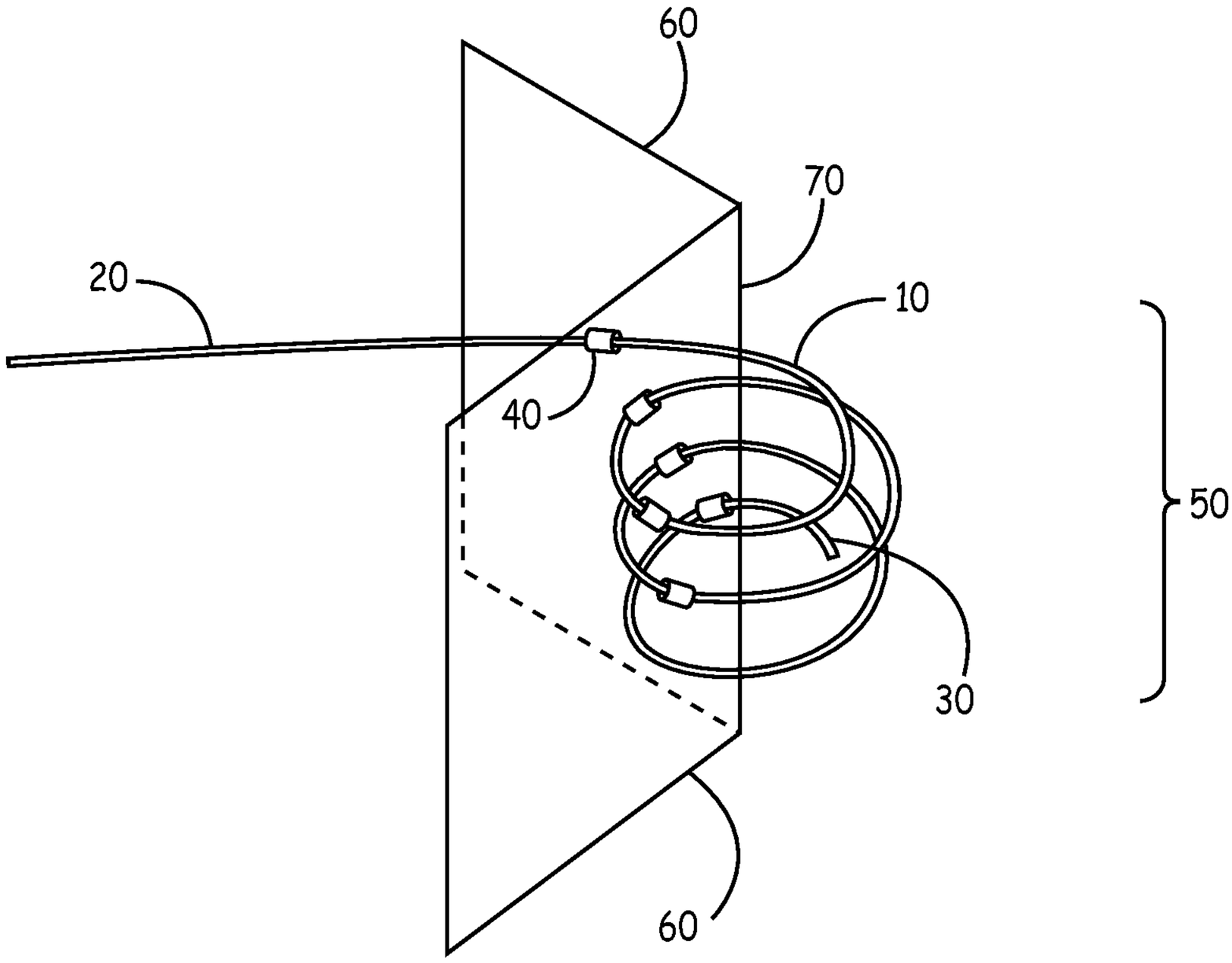


FIG. 4

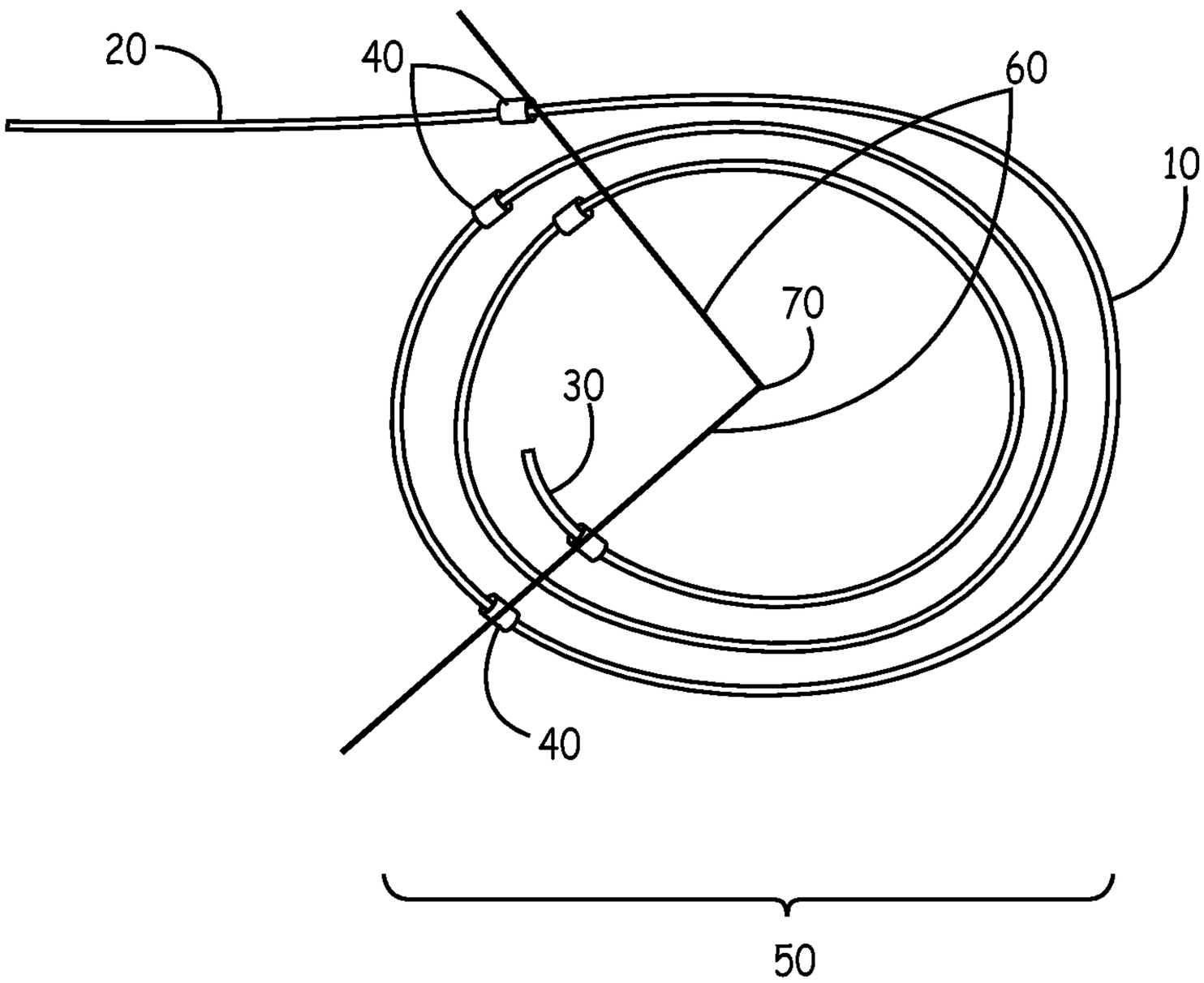


FIG. 5

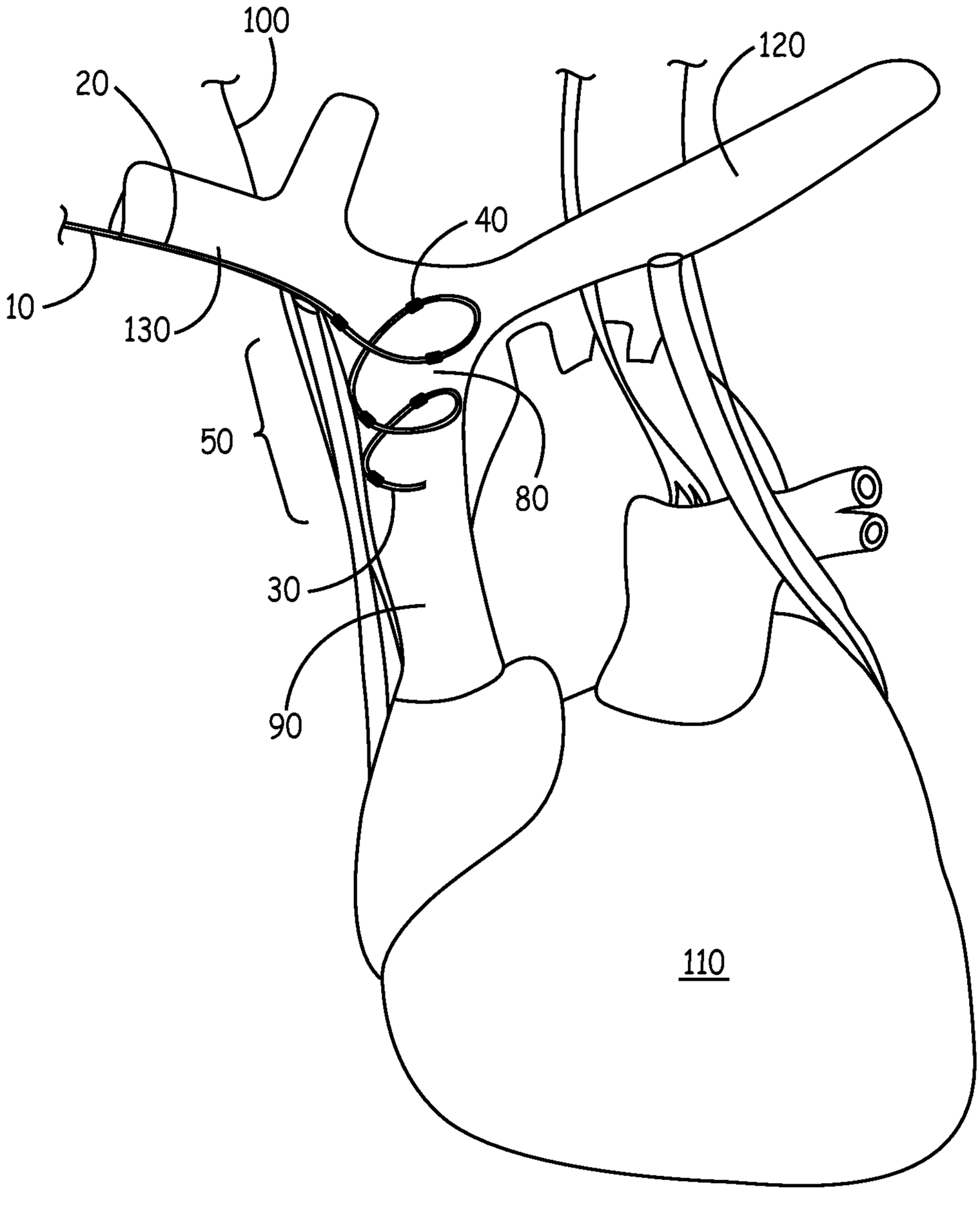


FIG. 6

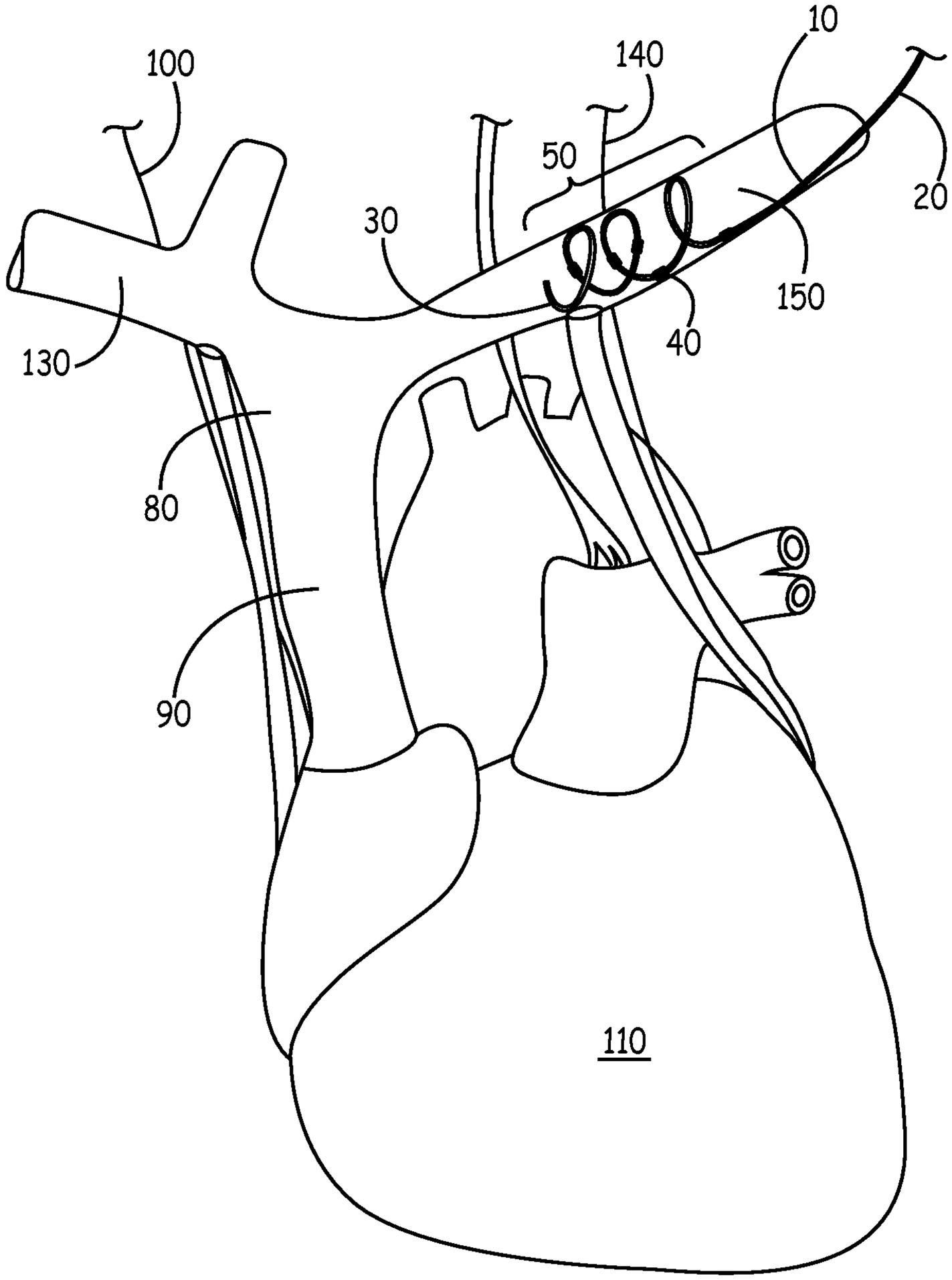


FIG. 7

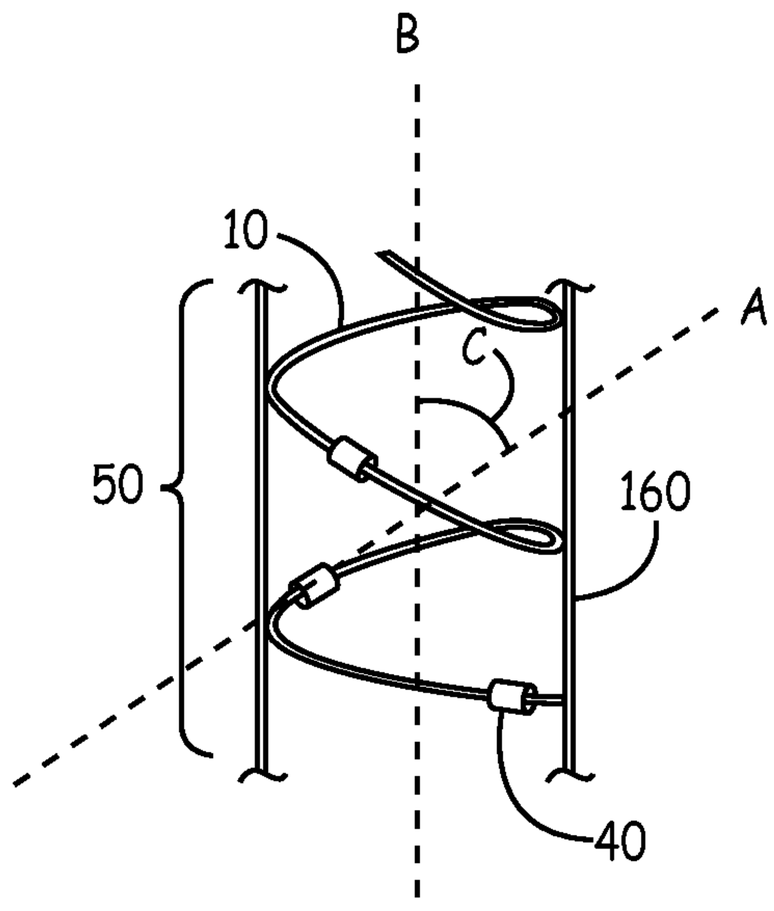


FIG. 8

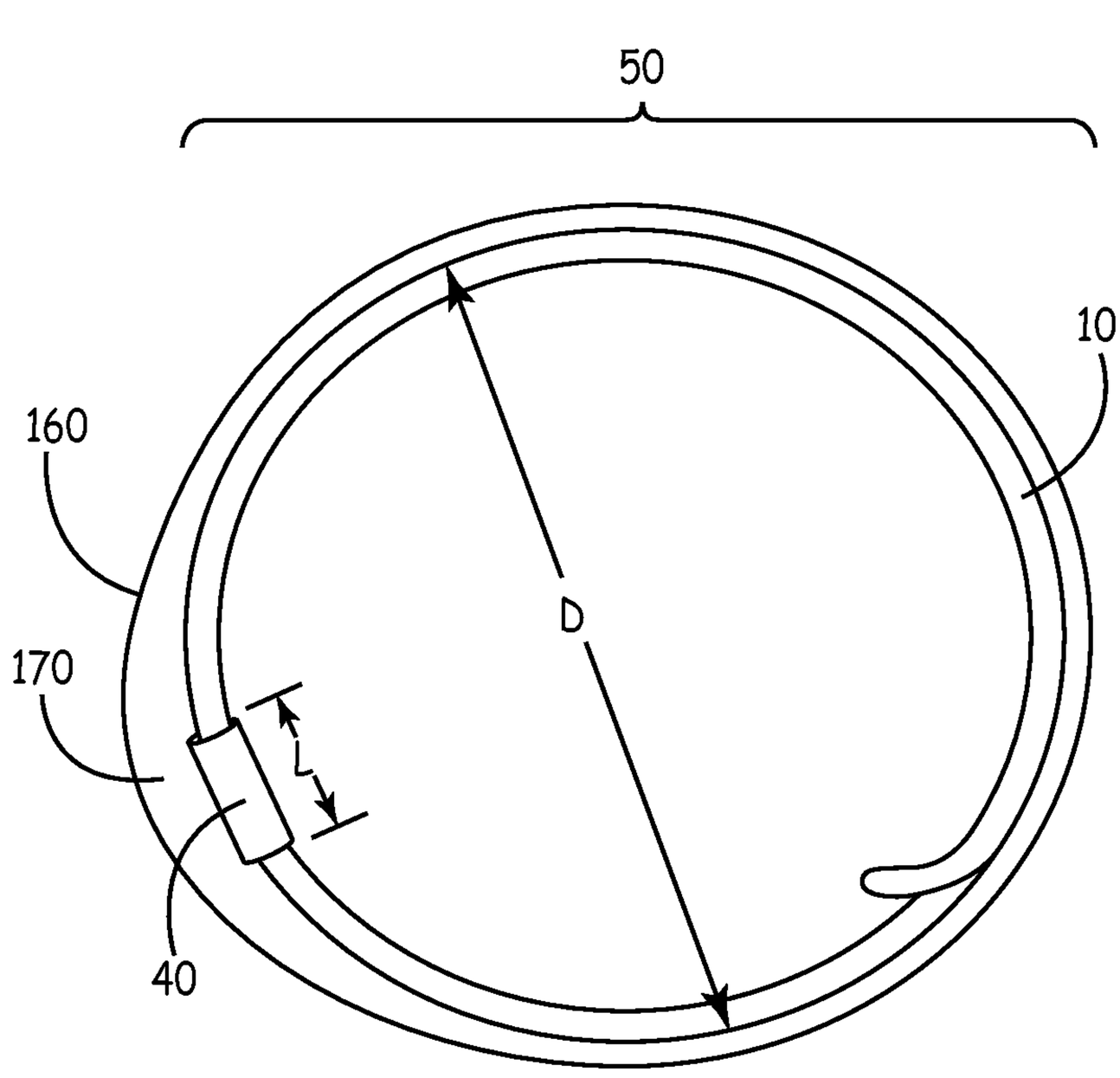
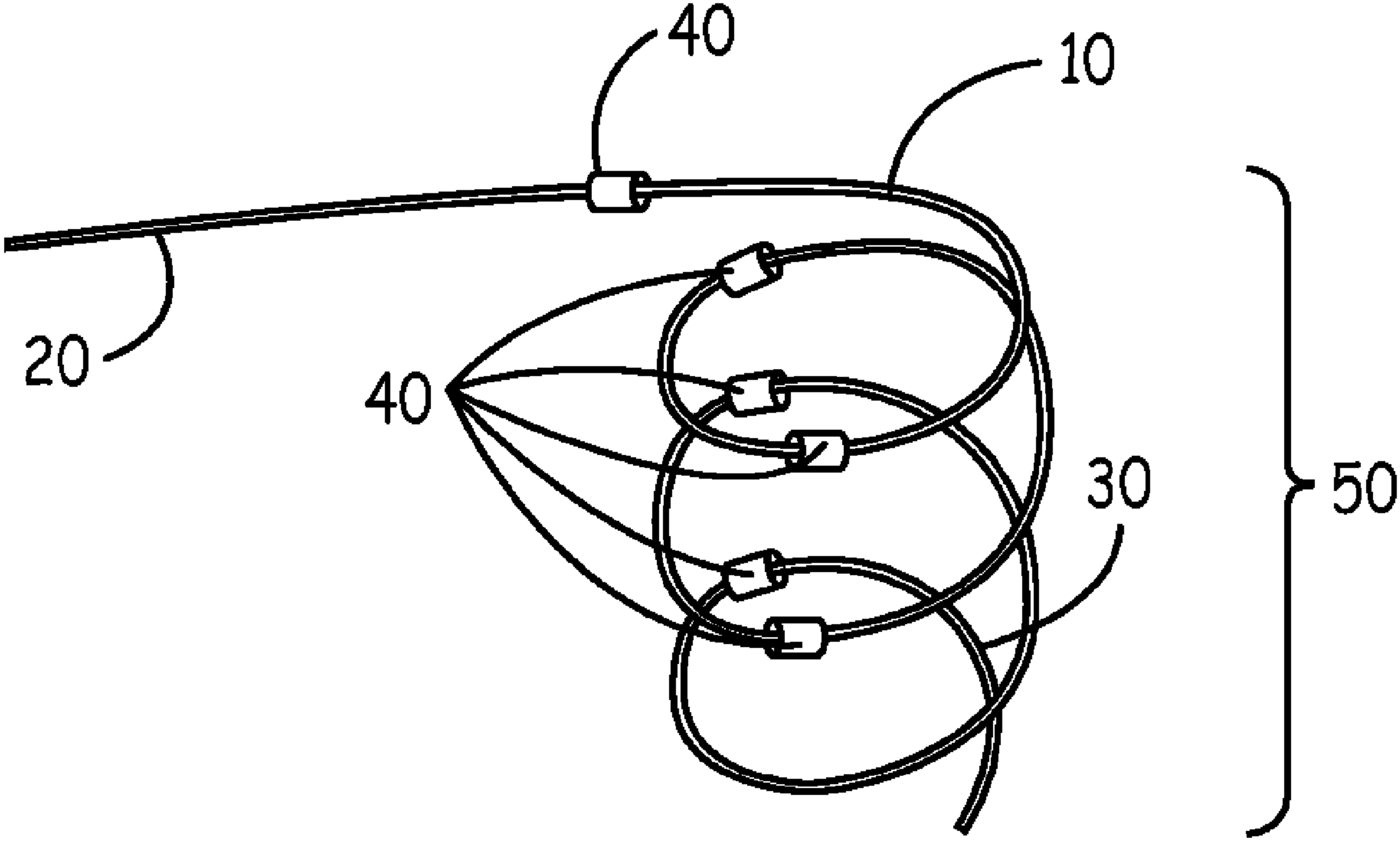


FIG. 9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