

DESCRIPTION

A RADIOFREQUENCY ABLATION CATHETER WITH MESHED TUBULAR STENT STRUCTURE HAVING SHAPE STABILIZATION DESIGNS AND METHODS OF MANUFACTURING THE SAME

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FIELD OF THE INVENTION

The present disclosure is related to a radiofrequency ablation catheter apparatus having stabilized interstices, a radiofrequency ablation catheter system comprising the apparatus, and methods of manufacturing and using the radiofrequency ablation catheter apparatus.

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BACKGROUND OF THE INVENTION

In radiofrequency ablation systems, radiofrequency electrodes are key elements for contacting or approaching human tissues being treated, and releasing radiofrequency energy thereto. Radiofrequency electrodes are commonly used for converting the radio frequency signal into heat, and for treating human tissues through thermal effects. During the surgery, whether the radiofrequency electrodes effectively contact a wall such as a blood vessel internal wall has a decisive effect for the radiofrequency ablation treatment.

In the radiofrequency ablation catheter, the radiofrequency electrodes are mounted on a carrier, such as a stent, at the front end of the radiofrequency ablation catheter. The stent is used for carrying the radiofrequency electrodes, expanding and contacting the wall before the radiofrequency energy begins to be released, and contracting and retracting after the release is completed. Since the radiofrequency ablation is directly performed in the human blood vessels, the expansion dimension of the stent should fit the diameter of the human blood vessels.

The diameter of the human blood vessels varies from person to person, and there are also differences in the diameters of the blood vessels in the human body due to different sites to be ablated. The diameters of most of the human blood vessels are ranged widely from about 2 mm to about 12 mm. In the conventional technique, the expansion dimension of the electrode end of a single radiofrequency ablation catheter is usually constant, cannot be adapted to the different diameters of the blood vessels in human bodies, and has narrow coverage for the human blood vessels having different diameters. Therefore, for the radiofrequency ablation operation in different patients, it is usually needed to change different specifications and types

of the radiofrequency ablation catheters for performing ablation. Even so, in some situations, the radiofrequency electrode still cannot contact the wall at the same time during the surgery, thereby affecting the surgical results. Therefore, a new radiofrequency ablation catheter is needed, which has a special stent having effective expansion and adaptability to the blood vessels of different diameters, can be applied to the blood vessels of different diameters during the surgery, and ensures that a plurality of the electrodes contact the wall at the same time, thereby improving the coverage of the apparatus.

In addition, the adaptability of the conventional radiofrequency ablation catheter to the curved blood vessels is generally poor. Sometimes, even the stent can be adapted to the curved blood vessel for once, it may be irreversibly distorted, collapsed, deformed or bent, and cannot resume its original configuration when it is moved to another treatment site. The electrodes of most of the radiofrequency ablation catheters in the curved blood vessels cannot effectively contact the wall. Hence, if a new radiofrequency ablation catheter can also improve the coverage for the curved blood vessels, and maintain or stabilize its original stent configuration, the application scope of the radiofrequency ablation will be greatly broadened, the effect of the radiofrequency ablation will be improved at the same time, and there will be a positive effect on the promotion of radiofrequency ablation usage.

SUMMARY OF THE INVENTION

One aspect of the present disclosure provides a catheter apparatus including an elongated shaft having a proximal portion and a distal portion; and a carrier carrying at least one therapeutic assembly. The carrier is located at, or proximate to, the distal portion of the elongated shaft, and the therapeutic assembly includes at least one therapeutic member for intravascular treatment. The carrier is configured to vary between a delivery configuration and a deployed configuration. The distal portion of the shaft is configured for intravascular delivery of the carrier. The carrier includes m right-handed helical wires and n left-handed helical wires that are plainly or bi-axially woven into a tubular structure, $m \geq 2$, and $n \geq 2$. The carrier includes at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other. The at least one therapeutic assembly wraps around at least one of the four helical wire segments, so as to stabilize the at

least one interstice, to maintain structural integrity of the carrier, and to prevent tangling of the helical wires, when the carrier is being distorted intravascularly.

Another aspect of the present disclosure provides a method of stabilizing structural integrity of a carrier of a catheter apparatus comprising an elongated shaft having a proximal portion and a distal portion, and preventing tangling of helical wires of the carrier, wherein the carrier is located at, or proximate to, the distal portion of the elongated shaft, and wherein the therapeutic assembly includes at least one therapeutic member for intravascular treatment; wherein the carrier is configured to vary between a delivery configuration and a deployed configuration; wherein the distal portion of the shaft is configured for intravascular delivery of the carrier; the method includes:

simply intersecting or bi-axially weaving $m \geq 2$ right-handed helical wires and $n \geq 2$ left-handed helical wires into each other to prepare a carrier including at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and

wrapping at least one therapeutic assembly around at least one of the four helical wire segments to stabilize the at least one interstice, to maintain structural integrity of the carrier, and to prevent tangling of the helical wires, when the carrier is being distorted intravascularly.

Still another aspect of the present disclosure provides a catheter system including the catheter apparatus as described above, an energy generator such as a RF energy generator configured to generate an energy with selected form and magnitude for delivery to a target treatment site via the therapeutic member, a cable electrically coupling the energy generator and the catheter apparatus, and an external dispersive electrode electrically connected to the energy generator and attached to an exterior of a patient.

A further aspect of the present disclosure provides a method of manufacturing the catheter apparatus as described above. The method includes (i) providing m right-handed helical wires and n left-handed helical wires that are woven, $m \geq 2$, and $n \geq 2$; (ii) simply intersecting or bi-axially weaving the helical wires into a tubular structure as the carrier; (iii) forming at least one interstice that is defined by four helical wire segments of two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and (iv) wrapping at least one

therapeutic assembly around at least one of the four helical wire segments to stabilize the interstice.

The above and other features and advantages of the present disclosure are readily apparent from the following detailed description of the best modes for carrying out the invention when taken in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE ACCOMPANYING DRAWINGS

The present disclosure is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings and in which same reference numerals refer to similar elements. All the figures are schematic and generally only show parts which are necessary for elucidation of the invention. For simplicity and clarity of illustration, elements shown in the figures and discussed below have not necessarily been drawn to scale. Well-known structures and devices are shown in simplified form, omitted, or merely suggested, in order to avoid unnecessarily obscuring the present disclosure.

Figure 1 schematically shows a catheter system in accordance with an exemplary embodiment of the present disclosure.

Figure 2 shows different configurations of a carrier in accordance with an exemplary embodiment of the present disclosure.

Figure 3 is a cross-sectional view along C-C of an elongated shaft near a carrier in accordance with an exemplary embodiment of the present disclosure.

Figure 4 is a cross-sectional view along D-D of a therapeutic assembly and its position and orientation in a blood vessel in accordance with an exemplary embodiment of the present disclosure.

Figure 5 depicts a specific structure of a carrier in accordance with an exemplary embodiment of the present disclosure.

Figure 6 schematically shows a carrier including right-handed helical wires and left-handed helical wires in accordance with an exemplary embodiment of the present disclosure.

Figure 7 shows how wires are simply intersected or bi-axially woven in accordance with an exemplary embodiment of the present disclosure.

Figure 8 shows a therapeutic assembly wrapping around a helical wire segment in

accordance with an exemplary embodiment of the present disclosure.

Figure 9A shows various structures of a therapeutic assembly in accordance with an exemplary embodiment of the present disclosure.

5 Figure 9B shows other structures of a therapeutic assembly in accordance with an exemplary embodiment of the present disclosure

Figure 10 shows various geometries of an interstice stabilized by a therapeutic assembly in accordance with an exemplary embodiment of the present disclosure.

Figure 11 is a flow chart of a general method of manufacturing a catheter apparatus in accordance with an exemplary embodiment of the present disclosure.

10 Figure 12 demonstrates a method of manufacturing a catheter apparatus in accordance with an exemplary embodiment of the present disclosure.

Figure 13 demonstrates another method of manufacturing a catheter apparatus in accordance with an exemplary embodiment of the present disclosure.

15 Figure 14 illustrates using a multi-lumen bundler in organizing wires for weaving a carrier in accordance with an exemplary embodiment of the present disclosure.

Figure 15 illustrates using a bobbin and a multi-lumen bundler in simply intersecting or bi-axially weaving helical wires into a tubular structure in accordance with an exemplary embodiment of the present disclosure.

20 Figure 16 is a flow chart of a method of stabilizing structural integrity of a carrier of a catheter apparatus in accordance with an exemplary embodiment of the present disclosure.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

25 In the following description, for the purposes of explanation, numerous specific details are set forth in order to provide a thorough understanding of the present disclosure. It is apparent, however, to one skilled in the art that the present disclosure may be practiced without these specific details or with an equivalent arrangement.

30 Where a numerical range is disclosed herein, unless otherwise specified, such range is continuous, inclusive of both the minimum and maximum values of the range as well as every value between such minimum and maximum values. Still further, where a range refers to integers, only the integers from the minimum value to and including the maximum value of such range are included. In addition, where multiple ranges are provided to describe a feature

or characteristic, such ranges can be combined.

As used herein, the terms “distal” and “proximal” define a position or direction with respect to the treating clinician or clinician’s control device (e.g., a handle assembly). “Distal” or “distally” refers to a position distant from or in a direction away from the clinician or clinician’s control device. “Proximal” or “proximally” refers to a position near or in a direction toward the clinician or clinician’s control device.

Figure 1 illustrates a catheter system including a catheter apparatus 1 that can be operably coupled to an energy source or energy generator 8. The catheter apparatus 1 includes an elongated shaft 2 having a proximal portion 3, a handle assembly 4 at a proximal region of the proximal portion 3, and a distal portion 5 extending distally relative to the proximal portion 3. The catheter apparatus 1 further includes an expandable carrier 6 (preferable embodiment thereof is the meshed tubular stent structure mentioned in the subject matter) carrying at least one therapeutic assembly 70 including a therapeutic member 7 for intravascular treatment. The carrier 6 is located at, or proximate to, the distal portion 5 of the elongated shaft 2.

As shown in Figure 2, the carrier 6 (or preferred meshed tubular stent structure 6, *sic passim*) is configured to be delivered to a blood vessel in a compressed (or low-profile, or delivery, or compacted) configuration. The carrier 6 in compressed configuration can be stored within a protective tube 20. Upon delivery to the target site within the blood vessel, the carrier 6 may be deployed into an expanded (or treatment, or deployed) configuration, bringing the therapeutic member 7 in contact with the walls of the blood vessel. In various embodiments, the therapeutic member 7 is configured to deliver energy at the treatment site and provide therapeutically-effective, electrically-induced and/or thermally-induced medical effect. In some embodiments, the carrier 6 may be placed in the deployed configuration or arrangement via remote actuation, e.g., via an actuator 11, such as a knob, pin, or lever carried by the handle 4, as shown in Figure 1. In other embodiments, however, the carrier 6 may be movable between the delivery and deployed configurations by using other suitable mechanisms or techniques (e.g., self-expanding). For example, the carrier 6 may be deployed into a natural configuration without any external force imposed thereon, i.e. the carrier 6 is neither compressed nor expanded, also bringing the therapeutic member 7 in contact with the walls of the blood vessel. In some embodiments, a delivery sheath (not shown) is used for deploying the carrier 6. The carrier 6 can self-expand and self-lengthen when the delivery sheath is retracted.

The carrier 6 is capable of expanding to have a maximum diameter 21 that is larger than a collapsed diameter, as shown in Figure 2. Further, the carrier 6 may be sized so that the maximum diameter 21 is larger than the lumen diameter of the blood vessel. In some embodiments, when inserted into a patient, the carrier 6 expands radially to span the blood vessel lumen. In other examples, the largest transverse dimension of the carrier 6 is approximately or slightly less than the diameter of the blood vessel lumen, so as to provide room for other parts projecting outwardly from the carrier 6. A small amount of vessel distension may be caused without undue injury, and the carrier 6 may expand such that its largest transverse dimension is slightly more than the natural lumen diameter of the blood vessel, or such that the therapeutic member 7 is slightly pressed into the wall of the blood vessel. Sometimes, the carrier 6 that causes slight and non-injurious distension of an artery wall may advantageously provide stable contact force between the therapeutic member 7 and the artery wall and/or hold the therapeutic member 7 in place even when the artery moves with respiratory motion and pulsing blood flow. In some embodiments, the blood vessel lumen diameter can restrict the expansion of the carrier 6 and provide a limit to the maximum diameter 21. This restriction can cause the carrier 6 to form a cylindrical tapered shape more often than a prolate spheroid shape. Because the lumen diameter varies from patient to patient, the carrier 6 may be capable of assuming a range of diameters between the compressed diameter 22 and the maximum diameter 21, as shown in Figure 2.

The carrier 6 may be characterized by its length 23 along the axis of the elongated shaft 2 or the axis of the control wire 19. As the carrier 6 expands, its diameter 21 increases, and its length 23 decreases. That is, when the carrier 6 expands, its distal end moves axially towards its proximal end. Accordingly, the expanded length 23 is shorter than the unexpanded or natural, or collapsed or compressed, length. In some embodiments, only the proximal end or only the distal end of the carrier 6 is fixedly coupled to the elongated shaft 2. In such a configuration, the distance between the proximal end and the distal end of the carrier 6 changes as the carrier 6 moves between the expanded and collapsed configurations.

The dimensions of the carrier 6 are influenced by its physical characteristics and its configuration (e.g., expanded configuration vs. unexpanded configuration), which in turn may be selected depending on the blood vessel geometry in investigation. The expanded configuration length 23 of the carrier 6 is less than the corresponding or counterpart length 23

in the compressed configuration. In some embodiments, the expanded configuration length 23 may be less than about 50%, 55%, 60%, 65%, 70%, 75%, 80%, 85%, or 90% of the corresponding or counterpart compressed length 23. Further, in some embodiments, the expanded configuration diameter 21 may be at least 1.2x, 1.25x, 1.5x, 1.75x, 2x, 2.25x, 2.5x, 2.75x, 3x, 3.25x, 3.5x, 3.75x, 4x, 4.25x, 4.5x, 4.75x, 5x, 10x, 15x, 20x, 30x or 40x of the compressed diameter 22.

The axial length 23 of the carrier 6 may be selected to be not longer than a patient's target blood vessel. A blood vessel may constrict, dilate or move in response to blood flow changes or changes in a patient's breathing, etc. The carrier 6 may be selected to be used in conjunction with a particular blood vessel lumen diameter, taking into account that this lumen diameter may change (e.g., up to 20%) during the time period in which the carrier 6 is in place. As such, the largest diameter 21 of the carrier 6 may be sufficiently oversized relative to the blood vessel to allow for additional expansion during use. In one embodiment, the largest diameter 21 may be at least 1.2x, 1.5x, or 2x of an estimated lumen diameter of the targeted blood vessel. In addition, a stable contact with the blood vessel is facilitated by the contact force of the carrier 6 against the blood vessel wall. This contact force is influenced by the materials and construction of the carrier 6. The carrier 6 may be fabricated with super-elastic material such as nickel titanium alloy (nitinol) or composite nitinol with polymer coating for insulation.

Referring to Figures 1 and 2, the carrier 6 may carry two or more therapeutic members 7 for intravascular treatment. The therapeutic member 7 may be for example an electrode or a heating element, which is configured to deliver energy such as electrical energy, radiofrequency (RF) electrical energy, pulsed electrical energy, and thermal energy to a target blood vessel after being advanced via a catheter along a percutaneous transluminal path. For example, an energy generator 8 may supply a continuous or pulsed RF electric field to the therapeutic member 7. Although a continuous delivery of RF energy is desirable, the application of RF energy in the form of pulses may allow for the application of relatively higher instantaneous power (e.g., higher power), longer or shorter total duration times, and/or better controlled intravascular therapy. The pulsed energy may also allow for the use of a smaller therapeutic member 7.

For example, the purposeful application of energy to tissue by therapeutic member(s) 7

may induce one or more desired thermal heating effect on localized regions of the blood vessel and adjacent regions thereof. The thermal heating effects can include both thermal ablation and non-ablative thermal alteration or damage (e.g., via sustained heating and/or resistive heating). Desired thermal heating effects may include raising the temperature of the target tissue above a
5 desired threshold for achieving non-ablative thermal alteration, or above a higher temperature for achieving ablative thermal alteration. For example, the target temperature can be above a body temperature (e.g., approximately 37 °C) but less than about 45 °C for non-ablative thermal alteration, or the target temperature can be about 45 °C or higher for the ablative thermal alteration.

10 When therapeutic members 7 are employed, they may function independently (i.e., may be used in a monopolar fashion), for example, to deliver power; or, they may function simultaneously, selectively, or sequentially; and/or they may deliver power between any desired combinations of the members 7 (i.e., may be used in a bipolar fashion). Furthermore, the doctor optionally may be permitted to choose which therapeutic member(s) 7 is/are used to
15 function medically, such as power delivery in order to form highly customized lesion(s) within the blood vessel, as desired. For example, an RF electric field causes lesion formation via resistive heating of tissue exposed to the electric field. As will be described in more details, the therapeutic member 7 is mounted or integrated into the carrier 6. As the carrier 6 is expanded, the therapeutic member 7 is placed in contact with the wall of a blood vessel. The carrier 6
20 ensures the contact force of the therapeutic member 7 does not exceed a maximum force, thus advantageously providing a more consistent contact force which may allow for more consistent lesion formation.

Referring back to Figure 1, the energy source or energy generator 8 (e.g., a RF energy generator) may be configured to generate an energy with selected form and magnitude via the
25 therapeutic member 7, for delivery to the target treatment site. The energy generator 8 can be electrically coupled to the catheter apparatus 1 via a cable 9. A control mechanism (not shown), such as foot pedal, may be connected (e.g., pneumatically connected or electrically connected) to the energy generator 8 to allow the doctor to initiate, terminate and, optionally, adjust various operational characteristics of the energy generator, for example, power delivery. The
30 energy generator 8 can be configured to deliver the treatment energy via an automated control algorithm and/or under the control of the doctor. In addition, the energy generator 8 may

include one or more evaluation or feedback algorithm to provide feedback to the doctor before, during, and/or after the intravascular treatment. The generator 8 may be part of a device or monitor which may include processing circuitry, such as a microprocessor. The processing circuitry may be configured to execute stored instructions relating to the control algorithm. The monitor may be configured to communicate with the catheter apparatus 1 to control power to the therapeutic member 7 and/or to obtain signals from the therapeutic member 7 or any associated sensors within or outside the therapeutic assembly 70. The monitor may be configured to provide indications of power levels or sensor data, such as audio, visual or other indications, or may be configured to communicate the information to another device.

In some embodiments, the catheter apparatus 1 may be configured to provide delivery of a monopolar electric field via the therapeutic member 7 (e.g. an electrode). In such embodiments, a skin electrode 40 (as shown in Figure 1) may be electrically connected to the energy generator 8 and attached to the exterior of the patient, and may function as a neutral or dispersive electrode during the intravascular treatment.

As shown in Figure 3, at least one supply wire 10 (such as RF wire 10) passes along the elongated shaft 2 or passes through a lumen in the elongated shaft 2 to the therapeutic member 7 and transmits the treatment energy from the energy source/generator 8 to the therapeutic member 7.

With reference to Figure 4, one or more sensors measuring temperature (e.g., thermocouple 12, thermistor, etc.), impedance, pressure, optical, flow, chemical or other parameters, may be located proximate to the therapeutic member 7, e.g. within the therapeutic assembly 70 (i.e. as a part of the therapeutic assembly 70), or not within the therapeutic assembly 70 (i.e. not a part of the therapeutic assembly 70). For example, a total of two supply wires such as thermocouple wires 13 and 14 as shown in Figure 3 may be included, in which both wires 13 and 14 could transmit the signal from the sensor such as the thermocouple 12, and one of the wires 13 and 14 could serve for dual purpose, i.e., it can also convey RF energy to the therapeutic member 7 (e.g. a RF electrode) without a separate RF wire 10. Alternatively, both wires 13 and 14 could transmit energy to the therapeutic member 7 (e.g. a RF electrode) without a separate RF wire 10.

In various embodiments, energy delivery may be controlled and monitored via data collected with the sensor(s), such as temperature sensors (e.g., thermocouples, thermistors, etc.),

impedance sensors, pressure sensors, optical sensors, flow sensors, chemical sensors, etc., which may be incorporated into or on the therapeutic member 7, e.g. within the therapeutic assembly 70, the carrier 6, and/or in/on adjacent areas on the distal portion 5. The sensor(s) may be incorporated into the therapeutic assembly 70 in such a manner that the therapeutic member 7 specifies whether the sensor(s) is/are in contact with a tissue at the treatment site and/or is/are facing the blood flow. It is important to specify a placement of the temperature sensor relative to the tissue and the blood flow, because a temperature gradient across the electrode from the side facing the blood flow to the side in contact with the blood vessel wall may be about 15 °C (for platinum-iridium electrodes) at most. For gold electrodes, this temperature gradient can be around, for example, 1°C to 2°C. In some embodiments, the temperature gradient can vary based, at least in part, on the electrode configuration/material. Significant gradients across the electrode in other sensed data (e.g., flow, pressure, impedance, etc.) can also take place.

The sensor(s) may, for example, be incorporated on or near the side of the therapeutic member 7 that contacts the blood vessel wall at the treatment site during power and energy delivery, or may be incorporated, for example, on the opposing side of the therapeutic member 7 that faces the blood flow during energy delivery, and/or may be incorporated at any suitable regions of the therapeutic member 7 (e.g., distal, proximal, quadrants, etc.). In some embodiments, multiple sensors may be provided at multiple positions along the therapeutic member 7, the therapeutic assembly 70, or the carrier 6, and/or relative to the blood flow. For example, a plurality of circumferentially and/or longitudinally spaced sensors may be provided. In one embodiment, a first sensor may face the blood vessel wall during treatment, and a second sensor may face the blood flow.

Additionally or alternatively, various microsensors may be used to acquire data corresponding to the therapeutic member 7, the blood vessel wall and/or the blood flowing across the therapeutic member 7. For example, micro thermocouples and/or impedance sensors may be utilized to acquire data along the therapeutic member 7 or other parts of the carrier 6. Sensor data may be acquired or monitored prior to, simultaneous with, or after the delivery of energy or in between pulses of energy. The monitored data may be used in a feedback loop to better control a therapy, e.g., to determine whether to continue or stop the treatment, and it may facilitate controlled delivery of the therapy with an increased or reduced power, or a longer or

shorter time duration.

When the catheter apparatus 1 is being used, the distal portion 5 of the elongated shaft 2 as well as the carrier 6 may be moved through an intravascular path by following a path defined by a guide catheter, a guide wire, or a sheath, for example, from a percutaneous access site in the femoral, brachial, radial or auxiliary artery, to a targeted site within the blood vessel. A section of the proximal portion 3 of the shaft 2 is exposed externally of the patient. By manipulating the proximal portion 3 of the shaft 2 from the outside of the intravascular path (e.g., via the handle assembly 4), the doctor may advance the shaft 2 through the sometimes tortuous intravascular path, and remotely manipulate or actuate the distal portion 5 of the shaft 2. Image guidance, e.g., computed tomography (CT), fluoroscopy, intravascular ultrasound (IVUS), optical coherence tomography (OCT), and any other suitable guidance modality or combinations thereof, may be used to aid the doctor's manipulation. In some embodiments, image guidance components (e.g., IVUS, OCT) may even be incorporated into the catheter apparatus 1 itself. After the carrier 6 is adequately positioned in the blood vessel, it can be expanded or otherwise deployed by using the handle 4 or other suitable means until the therapeutic member 7, such as RF electrodes, is in stable contact with the inner wall of the blood vessel.

Referring back to Figure 2, the compressed, collapsed or delivery configuration of the carrier 6 facilitates insertion and/or removal of the catheter apparatus 1 and, in certain embodiments, repositioning of the catheter apparatus 1 within the blood vessel. In the collapsed configuration, the carrier 6 is sized and shaped to fit within the blood vessel and has a diameter which is less than a blood vessel lumen diameter. The carrier 6 is expected to provide stable contact of the therapeutic member 7 with the inner wall of a blood vessel without occluding the blood flow within the blood vessel. As the carrier 6 is fabricated or woven from wires, blood can flow through the carrier 6 via interstices 15, the structure of which will be described in more details.

Referring now to Figure 5, the distal end of the carrier 6 may be coupled to an end piece 16 (e.g., a collar, shaft, or cap) having a rounded distal portion 17 to facilitate atraumatic insertion of the carrier 6 into a blood vessel. Alternatively, a rounded part that is radiopaque (or visible to X-ray imaging such as CT) may replace the rounded distal portion 17 to facilitate atraumatic insertion of the carrier 6 and to track the location of the carrier 6. The proximal end

of the carrier 6 may be connected to, or coupled to, the elongated shaft 2 by using a multi-lumen coupling part 18. The coupling part 18, for example, may be an integrally formed end of the elongated shaft 2 (e.g., may not be a separate piece) or may be a separate piece that is associated with the distal region of the elongated shaft 2. The coupling part 18 may be formed from the same type of material as the elongated shaft 2, or may be formed from a different material. In one embodiment, the coupling part 18 may be formed from a collar, such as a radiopaque band, that surrounds and secures the carrier 6 to an external surface of the elongated shaft 2.

The elongated shaft 2, the coupling part 18, the carrier 6, and the end piece 16 may include passages sized and shaped to accommodate a control wire or pull/push wire 19 that is fixed to the distal end of the carrier 6 or the end piece 16 and passes through the elongated shaft 2 to the proximal portion 3 of the elongated shaft 2. The control wire 19 facilitates the expansion and/or contraction of the carrier 6 when it is pulled or pushed to shorten or lengthen the carrier 6. For example, pulling (i.e., an increase in tension) the control wire 19 proximally relative to the shaft 2 may trigger expansion of the carrier 6 by drawing the end piece 16 to be closer to the coupling part 18. Conversely, pushing (i.e., an increase in compression) the control wire 19 distally relative to the shaft 2 may lengthen the carrier 6 to a compressed configuration by axially separating the end piece 16 from the coupling part 18. It will be understood that either the shaft 2 or the control wire 19 may be held in a fixed position with respect to the patient while the other element is translated to make the relative movements described above. In some embodiments the carrier 6 has elastic or super-elastic shape memory properties such that when the force is removed, the carrier 6 elastically returns to a relaxed state or a natural state as shown in Figure 2. Force may be applied by the control wire 19 to deform the carrier 6 into one state, and when the force is removed, the meshed carrier 6 returns to its relaxed state. For example, a relaxed or “natural” state of the carrier 6 may be a half-way expanded configuration as shown in Figure 2, and the control wire 19 may be pushed to lengthen the carrier 6 and reduce the diameter of the carrier 6 so that the carrier 6 is placed in a collapsed or “compressed” configuration as shown in Figure 2. Alternatively, a relaxed state of the carrier 6 may be a collapsed or compressed configuration, and the control wire 19 may be pulled (with tension applied) to shorten the carrier 6 and increase the diameter of the carrier 6 so that the carrier 6 is placed in an expanded configuration. In some embodiments, the control

wire 19 may be a solid or stranded wire or cable made from a metal or polymer. In other embodiments, the control wire 19 may be a hollow tube that can be passed over a guide wire to facilitate insertion through an intravascular path to a targeted site in the blood vessel.

As shown in Figure 5, the carrier 6 includes structural elements, e.g., wires 24 (or strands, filaments or fibers) arranged to define interstices 15 (or interstitial spaces) therebetween. Because the change in diameter and axial length of the carrier 6 may involve realignment of wires 24 and variations of the geometry of the interstices 15, the constitution of the wires 24 and the geometry of the interstices 15 may, at least in part, define how much the diameter and length of the carrier 6 change as a result of its configuration changes.

The wires 24 may be formed from biocompatible metals, polymers, or composite materials. For example, suitable metals can include stainless steel, spring steel, cobalt chromium, gold, platinum, platinum-iridium, stainless steel, or combinations thereof. In one particular embodiment, the carrier 6 may be composed of nitinol and plated with gold to enhance radiopacity and/or conductivity. Suitable polymer materials can include, for example, polyethylene terephthalate (PET), polyamide, polyimide, polyethylene block amide copolymer, polypropylene, or polyether ether ketone (PEEK) polymers. In some embodiments, the carrier 6 may be a combination of electrically conductive and nonconductive materials.

In some embodiments, the carrier 6 may be formed, at least in part, from radiopaque materials that are capable of being imaged fluoroscopically to allow a doctor to determine whether the carrier 6 is appropriately placed and/or deployed in the blood vessel. Radiopaque materials may include barium sulfate, bismuth trioxide, bismuth subcarbonate $(\text{BiO})_2\text{CO}_3$, powdered tungsten, powdered tantalum, or various formulations of certain metals including gold and platinum, and these materials may be directly incorporated into the wires 24 or may form a partial or complete coating of the carrier 6.

The carrier 6 may be designed to apply a desired outward radial force to a blood vessel wall when inserted and expanded to contact the inner surface of the wall. The radial force may be selected to avoid injury from stretching or distending the blood vessel when the carrier 6 is expanded against the wall within the patient. Radial forces that may avoid injuring the blood vessel and still provide adequate stabilization force may be determined by calculating the radial force exerted on a blood vessel wall by typical blood pressure. For example, a suitable radial force may be less than about 300 mN/mm (e.g. less than 200 mN/mm). Fibers 24 formed from

stiffer materials (e.g. metals) may be thinner relative to fibers 24 formed by highly flexible polymers to achieve similar flexibilities and radial force characteristics. The outward pressure of the carrier 6 may be assessed in vivo by an associated pressure transducer.

The carrier 6 with more open structures (e.g., bigger interstices 15, or lower material per square inch ratios) may have less radial stiffness and strength than more closed structures (smaller interstices 15, or high material density structures). The thickness of fibers 24 also affects outward pressure, radial strength and stiffness. Certain secondary processes, including heat treating and annealing, may harden or soften the fiber material to affect strength and stiffness. In particular, for shape-memory alloys such as nitinol, these secondary processes may be varied to provide the same starting material with different final properties. For example, the elastic range or softness may be increased to impart improved flexibility. The secondary processing of shape memory alloys influences the transition temperature, i.e., the temperature at which the structure exhibits a desired radial strength and stiffness. This temperature may be set as normal body temperature (e.g. 37 °C).

The carrier 6 may be braided, knit, or woven to form a conformable structure (e.g., a tubular, barrel-shaped, parachute-shaped, or spherical structure) through which fluids may pass. In an embodiment, the carrier 6 may include 4-48 fibers. It should be understood that fiber 24 may be formed from a single filament (monofilament) or by a plurality of filaments twisted or otherwise grouped together to form a multifilar fiber. In addition, the carrier 6 may be characterized by its braid pitch, which may be between 1 pick-10 picks (i.e., windings) along its axial length. In preferred embodiments, the carrier 6 may be helically braided with right-handed helix wires and left-handed helix wires into a generally ovoid, tubular, barrel-shaped, or other shaped structure.

In some embodiments, the carrier 6 may be generally symmetrical and coaxial with respect to the elongated shaft 2 or control wire 19. However, it is also contemplated that the carrier 6 may conform to any irregularities in the blood vessel (e.g. a shape of fortune cookie), which may be assessed by imaging or other techniques. For example, particular sizes and types of the carrier 6 may be used in conjunction with a patient's particular anatomic features.

For some patients, it may be desirable to configure the therapeutic members 7 in such a manner that they can create either a single lesion or a pattern of multiple localized lesions that are spaced apart circumferentially and/or spaced apart axially along the longitudinal axis of the

blood vessel. Alternatively or additionally, a single localized lesion with desired longitudinal and/or circumferential dimensions, one or more fully circumferential lesions, multiple circumferentially spaced localized lesions at common longitudinal positions, spiral-shaped lesions, interrupted spiral-shaped lesions, generally linear lesions, and/or multiple longitudinally spaced localized lesions along a line parallel to the axis of the blood vessel may be created. In other embodiments, the therapeutic member(s) 7 may be used to create lesions having a variety of other geometric shapes or patterns.

Depending on the size, shape, and number of the therapeutic member(s) 7, the lesions as created may be circumferentially spaced around the blood vessel in a single transverse plane, or the lesions may also be spaced apart longitudinally. In some embodiments, it is desirable for each lesion to cover at least 10% of a circumference of the blood vessel. It is also desirable that each lesion is sufficiently deep to penetrate into and beyond the adventitia. However, lesions that are too deep may run the risk of interfering with non-target tissue and tissue structures, and therefore a controlled depth of treatment is also desirable.

In general embodiments, the therapeutic member(s) 7 may be circumferentially repositioned relative to the blood vessel during treatment. This angular repositioning may be achieved, for example, by compressing the carrier 6 and rotating the elongated shaft 2 via the handle assembly 4. In addition to the angular or circumferential repositioning of the therapeutic member(s) 7, it/they optionally may also be repositioned along the length direction or the longitudinal dimension of the blood vessel. This longitudinal repositioning may be achieved, for example, by translating the elongated shaft 2 via the handle assembly 4, and may occur before, after, or concurrently with angular repositioning of the therapeutic member(s) 7. Repositioning the therapeutic member(s) 7 in both the longitudinal and angular dimensions places it/them in contact with the interior wall of the blood vessel at a second treatment site. RF Energy then may be delivered via the therapeutic member 7 to form a second localized lesion at this second treatment site. For embodiments in which multiple therapeutic members 7 are associated with the carrier 6, the initial treatment may result in two or more lesions, and repositioning may allow additional lesions to be created. One or more additional localized lesions optionally may be formed via additional repositioning of the carrier. In preferred embodiments, the carrier 6 carries a sufficient number of therapeutic member(s) 7 (e.g. RF electrodes), and it does not have to be selectively repositioned within the blood vessel to

provide a number of locations for e.g. RF energy delivery.

In certain embodiments, the lesions created via repositioning of the carrier 6 circumferentially and longitudinally compensate for the initial lesion(s) around the angular and lengthwise dimensions of the blood vessel, respectively. The composite lesion pattern created along the blood vessel by the initial energy application and all subsequent energy applications after any repositioning of the therapeutic member(s) 7 may effectively result in a discontinuous lesion (i.e., it is formed from multiple, longitudinally and angularly spaced treatment sites).

Sometimes, it may be desirable to configure the therapeutic member(s) 7 by creating a composite lesion pattern in such a manner that, as viewed from a proximal or distal end of the blood vessel, at least approximately the entire circumference of the blood vessel is under treatment. In other words, each formed lesion covers an arc of the circumference, and each of the lesions, as viewed from an end of the blood vessel, is abutted against or overlapped with adjacent lesion(s) to create a virtually circumferential lesion. The formed lesions defining an actual circumferential lesion lie in a single plane perpendicular to a longitudinal axis of the blood vessel. A virtually circumferential lesion is defined by multiple lesions that may not all lie in a single perpendicular plane, although more than one lesion of the pattern can be so formed. At least one of the formed lesions including the virtually circumferential lesion is axially spaced apart from other lesions.

For example, a cylindrical carrier 6 having therapeutic members 7 affixed to wires 24 in a helical pattern such that therapeutic members 7 circumferentially and axially compensate with one another. The circumferential compensation arcs, or corresponding radial angles, may be selected so that when energy is applied to the blood vessel via therapeutic members 7, a roughly helical lesion pattern is formed therein. Depending on the number and position of the therapeutic members 7 selectively mounted on wires 24, a helical lesion pattern with any desired number of turns (e.g. 1, 2, 3 or more) may be formed by using only a single RF energy application. In other embodiments, the therapeutic members 7 may have a variety of different arrangements relative to each other (e.g., linear, interrupted helix, or continuous helix arrangement).

In a non-limiting example, the therapeutic members 7 are configured in such a manner that they create a virtually circumferential lesion including six lesions created in a single helical pattern along the blood vessel; and each lesion spans an arc extending along at least one

sixth (or 60°) of the blood vessel circumference such that the resulting pattern of lesions completely encompasses the blood vessel circumference, when viewed from an end of the blood vessel. In other examples, however, a virtually circumferential lesion can include a different number of lesions.

5 The axial distance between axially adjacent therapeutic members 7 may be selected so that the edges of the lesions formed by each individual therapeutic member 7 on the blood vessel wall 55 are either overlapping or non-overlapping. The axial distance may be about 2 mm to about 1 cm. In a particular embodiment, the axial distance may be in the range of about 2 mm to about 5 mm. In another representative embodiment, the axially adjacent therapeutic
10 members 7 may be spaced apart by about 10 mm -50 mm.

Therapeutic member(s) 7 may be coupled to leads 10L, which may be e.g. a part of a RF wire 10 or electrically connected to the RF wire 10. The leads 10L may be separate from the carrier 6, or may be loosely or tightly coupled to, adhered to, wrapped around, or integrated into the carrier 6 (e.g. around/on/with/to a wire 24) to prevent twisting or kinking of the leads.

15 In particular embodiments, to facilitate the stable contact of the therapeutic member(s) 7 with the blood vessel, the therapeutic assembly 70 may be coupled to the carrier 6 by weaving lead(s) into the wires 24 of the mesh or threading leads through interstices in the mesh of the carrier 6. At least a part of the therapeutic member(s) 7 is positioned on an external surface of the carrier 6. The position of the therapeutic member(s) 7 on the external surface may be
20 associated with a desired lesion pattern. Alternatively, as shown in Figures 2 and 5, the therapeutic assembly 70 may be directly coupled to the wire 24. The therapeutic assembly 70 is coupled to the wire 24, for example via adhesion or by threading the wire 24 through an internal bore 25, as shown in Figure 4.

25 The therapeutic member 7 may be in the form of an electrically conductive tube. As shown in Figure 4, the tube electrode 7 may be wound about (or wrapped around) the wire 24. In other words, a wire 24 inserts into and passes through the tube electrode 7. For example, six tube electrodes 7 may form a “dotted”, interrupted or discontinuous helix with great pitch or small pitch. Regions of the tube electrode 7 that do not contact the blood vessel wall may contribute to cooling of the electrode. Alternatively, as shown in Figure 4, only a portion 71 of
30 the tube electrode 7 may be electrically conductive with the blood vessel wall tissue. That is, the tube electrode 7 can include an insulated portion 72 and an uninsulated portion 71 in which

the insulation is removed. For example, the flow of blood over the portion 72 (which is not contacting the blood vessel wall) provides conductive and convective cooling of a RF electrode 7, thereby carrying excess thermal energy away from the interface between the blood vessel wall and the electrode 7. Electrode cooling can be alternatively or additionally achieved by injecting or infusing cooling fluids such as saline (e.g., room temperature saline or chilled saline) over the electrode and into the blood stream. It may also be desirable to provide enhanced cooling by inducing an additional native blood flow across the carrier 6. For example, techniques may be implemented by the doctor to increase perfusion through the target blood vessel or to the carrier 6. These techniques include positioning partial occlusion elements (e.g., balloons) within upstream vascular bodies such as the aorta, or within a portion of the target blood vessel to improve the flow across the carrier 6. Because cooling of the electrode 7 is mediated by blood flow, improved cooling may be achieved by redirecting a faster blood flow into the target blood vessel or into the carrier 6 so that the blood flowing around the electrode 7 is relatively faster. Sometimes, without a proper cooling, resistive heating of the tissue may be too aggressive and excess thermal energy may not be carried away sufficiently, resulting in excessive heat generation and increased potential for stenotic injury, thrombus formation and undesirable lesion size.

The therapeutic member 7 may be sized and configured to contact an internal wall of the blood vessel during the treatment. For example, the therapeutic member 7 may take the form of an electrode which is sized and configured to apply an electrical field of RF energy from the energy generator 8 to a blood vessel wall. As described above, the electrode 7 may be operated in a monopolar or unipolar mode. In this arrangement, a return path for the applied RF electric field is established, e.g., by an external dispersive electrode or skin electrode 40 (as shown in Figure 1), also called indifferent electrode or neutral electrode. The monopolar application of RF electric field energy serves to ohmically or resistively heat a tissue in the vicinity of the electrode 7. The application of the RF electrical field thermally injures the tissue. For example, a treatment objective may be to thermally induce neuromodulation (e.g., necrosis, thermal alteration or ablation) in the targeted neural fibers. The thermal injury forms a lesion in the blood vessel wall. Alternatively, a RF electrical field may be delivered with an oscillating intensity that does not thermally injure the tissue, while the neuromodulation in the targeted nerves is accomplished by electrical modification of the nerve signals.

The term “active surface area” of the electrode 7 is defined as the energy transmitting area of the electrode 7 that may be placed in intimate contact against the tissue. Too much contact between the electrode and the blood vessel wall may create unduly high temperatures at or around the interface between the tissue and the electrode, thereby creating excessive heat generation at this interface. This excessive heat may create a lesion that is circumferentially too large. In some instances, too much contact can also lead to small, shallow lesions. Too little contact between the electrode 7 and the blood vessel wall may result in superficial heating of the blood vessel wall, thereby creating a lesion that is too small (e.g., <10% of the vessel circumference) and/or too shallow.

As described above, the carrier 6 may be helically braided with right-handed helix wires and left-handed helix wires into a generally ovoid, tubular, barrel-shaped, or other shaped structure. In preferred embodiments as shown in Figure 6, the carrier 6 includes m ($m \geq 2$) right-handed helical wires such as 6 R-helices $R1 \sim R6$ and n ($n \geq 2$) left-handed helical wires such as 6 L-helices $L1 \sim L6$. With the line of sight along the helix’s axis, if a clockwise screwing motion moves the helix away from the observer, then it is called a right-handed helix; if the clockwise screwing motion moves the helix towards the observer, then it is a left-handed helix. Handedness or chirality (symbolized as R- and L-) is a property of the helix, not of the perspective. A right-handed helix cannot be turned to look like a left-handed one unless it is viewed in a mirror, and vice versa. In some embodiments, the carrier 6 includes m right-handed helical wires and n left-handed helical wires that are simply intersected or bi-axially woven into a tubular structure, $2 \leq m \leq 30$ and $2 \leq n \leq 30$, such as $3 \leq m \leq 20$ and $3 \leq n \leq 20$; $4 \leq m \leq 15$ and $4 \leq n \leq 15$; $5 \leq m \leq 10$ and $5 \leq n \leq 10$. For example, helices $R1 \sim R6$ and $L1 \sim L6$ are simply intersected or bi-axially woven into a carrier 6 with a tubular structure, as shown in Figure 6.

The term “simply intersected or bi-axially” is defined and explained with reference to Figure 7. Any right-handed helical wire R (e.g. R_x) is woven into (or between) at least two immediately adjacent left-handed helical wires L_s (e.g. L_y and L_{y+1}), in such a manner that one L wire (e.g. L_y) is beneath wire R (e.g. R_x), while the other L wire immediately next to L_y (e.g. L_{y+1}) is above R_x . In other words, L_y and L_{y+1} are located on the opposite sides of wire R_x . A right-handed helical wire R_{x+1} , that is immediately next to (or adjacent to) wire R_x , is also woven into (or between) two wires L_y and L_{y+1} , but in an opposite manner to produce an opposite configuration in which wire L_y is above wire R_{x+1} while wire L_{y+1} is beneath R_{x+1} .

By the same token, any left-handed helical wire Ly is woven into at least two immediately adjacent right-handed helical wires Rx and $Rx+1$, in such a manner that wire Rx is above wire Ly while wire $Rx+1$ is below Ly . In other words, Rx and $Rx+1$ are located on the opposite sides of wire Ly . A left-handed helical wire $Ly+1$, that is immediately next to (or adjacent to) wire Ly , is woven into two wires Rx and $Rx+1$, in an opposite manner to produce an opposite configuration in which wire Rx is beneath wire $Ly+1$ while wire $Rx+1$ is above $Ly+1$.

In such a pattern, the four wires (Rx , $Rx+1$, Ly , and $Ly+1$) will have four intersectional points (or cross-over points) A, B, C and D which are not fixed and are movable relative to their two corresponding crossed-over wires. For example, point A is moveable relative to wire Rx and/or Ly as wire Rx slides over Ly and/or Ly slides over Rx . Points B, C and D are also moveable for similar reasons and in similar fashions. As a result, the carrier 6 includes at least one interstice 15 that is defined by four helical wire segments AB, BC, CD and DA selected from two immediately adjacent right-handed helical wires (Rx and $Rx+1$) and two immediately adjacent left-handed helical wires (Ly and $Ly+1$) which are simply intersected or bi-axially woven into each other.

As shown in Figure 8, at least one therapeutic assembly 70 is configured to wrap around at least one of the four helical wire segments AB, BC, CD and DA (e.g. segment AB) to stabilize the at least one interstice 15. The lengths of helix segments AB, BC, CD and DA vary when the carrier 6's shape is being changed. In some embodiments, only one therapeutic assembly 70 wraps around only one of the four helical wire segments AB, BC, CD and DA (e.g. only segment AB) to stabilize the interstice 15, and does not wrap around any one of the other three helical wire segments (e.g. segments BC, CD and DA). In a preferred embodiment, the therapeutic assembly 70 has a rotational axis (e.g. when it has a cylinder shape), and the helical wire segment AB penetrates through the therapeutic assembly 70 approximately along the rotational axis. By "approximately", it means that the distance between the helical wire segment AB and the rotational axis is always less than 50% of the distance between an edge (or a side surface) of the therapeutic assembly 70 and the rotational axis, along any plane perpendicular to the rotational axis. In particularly preferred embodiments, $m=n=6$, and the carrier 6 carries six therapeutic assemblies 70a-70f as shown in Figure 6, each of which includes an electrode 7 as the therapeutic member 7, providing six electrodes in total. The six electrodes may be configured to create interrupted spiral-shaped but fully circumferential

lesions on an internal wall of a target blood vessel.

As shown in Figure 9A, the therapeutic assembly 70 may include a main body 701 such as a single cylinder-shaped body 701, without any terminal bodies. Alternatively, the assembly 70 may further include two terminal bodies 702 and 703, both of which may be cylinder-shaped, and the main body 701 may be positioned between the two terminal bodies 702 and 703. In other embodiments, terminal bodies 702 and 703 may have a cone shape, tapering down from the main body 701. A cross-sectional area of the main body 701 along a plane perpendicular to an elongation direction of the helical wire segment AB being wrapped around is larger than cross-sectional areas of both terminal bodies 702 and 703 along the plane perpendicular to the elongation direction of the helical wire segment AB being wrapped around, which are larger than a cross-sectional area of the helical wire segment AB itself along the plane perpendicular to the elongation direction of the helical wire segment AB. The dimension and shape of the terminal body 702 may be the same as, or different from, those of the terminal body 703.

As shown in Figure 9A, all the corner areas formed between the main body 701 (when there is no terminal body) and the wire Rx, between the main body 701 and the terminal body 702 (if present), between the main body 701 and the terminal body 703 (if present), between the terminal body 702 (if present) and the wire Rx, and between the terminal body 703 (if present) and the wire Rx may be used to accommodate wires Ly and Ly+1, as long as the simply intersected or bi-axially woven pattern of R- and L-wires is maintained.

At least one (preferably all) of the two terminal bodies 702/703, if any, and the main body 710 may include one or more grooves for snugly accommodating or guiding one or more helical wires to slide over the wire segment around which the therapeutic assembly wraps. For example, the body 701/702/703 can be provided with grooves 781, 782, 783 and 784 near the corner areas for snugly accommodating sliding wires Ly and Ly+1 in a more stable manner, as shown in Figure 9A. Wires Ly and Ly+1 can slide over the wire Rx by using the grooves as guides.

As shown in Figure 9B, at least one (preferably all) of the two terminal bodies 702/703, if any, and the main body 710 may include one, two or more protrusions 788. The gap(s) between segment AB and protrusion(s) 788, and the gap(s) between the protrusion(s) 788 themselves, are configured for accommodating or guiding one or more helical wires Ly or

Ly+1 that slide(s) along different directions (represented by the dotted lines Ly) over the wire segment AB around which the therapeutic assembly 70 wraps. When there are three or more protrusions 788, it is preferred that no three protrusions 788 are located along a straight line. As such, it may provide “Ly guiding directions” as many as possible.

As a result, a length of the wire segment AB being wrapped around now may be controlled, depending on where wires Ly and Ly+1 are positioned, to be equal to, or longer than, the main body 701's length along the elongation direction of the wire segment AB, with or without terminal bodies. It may also be controlled to be equal to, or longer than, the main body 701's length plus the length of only one of the two terminal bodies (702 or 703) along the elongation direction of the wire segment AB. Alternatively, the length of the wire segment AB being wrapped around may be controlled to be equal to, or longer than, the main body 701's length plus the total length of both two terminal bodies (702 and 703) along the elongation direction of the wire segment AB. As such, various minimal lengths of the wire segment AB may be maintained to be greater than a certain positive value when the carrier 6 is being expanded, compressed, or moved along a curved blood vessel, as shown in Figure 10. With such minimal lengths of the helical wire segment AB, wires Ly and Ly+1 are prevented from entangling with each other, and the regular shape of the carrier 6 may be quickly recovered after the carrier is seriously bent or distorted.

The present disclosure further provides a method of manufacturing the catheter apparatus as described above. As shown in Figure 11, the method may include: (i) providing m right-handed helical wires and n left-handed helical wires, $m \geq 2$, and $n \geq 2$; (ii) simply intersecting or bi-axially weaving the helical wires into a tubular structure as the carrier; (iii) forming at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and (iv) wrapping at least one therapeutic assembly around at least one of the four helical wire segments to stabilize the interstice.

In particularly preferred embodiments as shown in Figure 12, at least one of the m right-handed helical wires (e.g. one of the 6 R-helices R1~R6, as shown in Figure 6) and at least one of the n left-handed helical wires (e.g. one of the 6 L-helices L1~L6, as shown in Figure 6) are made from one single wire, e.g. one of RL-paired wires P1~P6. The single wire

(e.g. P1) includes a first portion of right-handed helical wire Rp, e.g. one of Rp1~Rp6 that are equivalent to R1~R6; and a second portion of left-handed helical wire Lp, e.g. one of Lp1~Lp6 that are equivalent to L1~L6, by folding or bending the single wire (P1~P6) at a point (F1~F6) between the first portion and the second portion by an angle of approximately 160°~180°.

5 As such, step (i) may include the steps of (ia) providing one single wire having a first portion of right-handed helical wire and a second portion of left-handed helical wire; and (ib) folding or bending the single wire at a point between the first portion and the second portion to provide a right-handed helical wire and a left-handed helical wire.

10 In other particularly preferred embodiments as shown in Figure 13, the method further includes a step of cutting the bent single wire at or near the bending point (F1~F6) to make a separate right-handed helical wire and a separate left-handed helical wire.

15 In another embodiment, RL-paired wires P1, P2, P3, P4, P5 and P6 are bundled together at their ends of the bending points by using a multi-lumen bundler. Referring to Figure 14, the multi-lumen bundler 1400 has a cylinder body 1401. A number of lumens #1~#6 pass axially through the cylinder body 1401 along the longitudinal axis of the cylinder body 1401, and may be arranged in a circular configuration. For a single RL-paired wire, the first portion Rp of right-handed helical wire may be inserted into a lumen and pass through the lumen, and the second portion Lp of left-handed helical wire may be inserted into another lumen and pass through the another lumen. The first portion of right-handed helical wire and the second portion of left-handed helical wire from a same wire may be inserted into and pass through two different lumens. The folding point or bending point of the RL-paired wire is placed between two mouths of the two lumens. In exemplary embodiment as shown in Figure 14, for a single RL-paired wire P1, the first portion Rp1 of right-handed helical wire may be inserted into a lumen #1 and may pass through the lumen #1, and the second portion Lp1 of left-handed helical wire may be inserted into a lumen #2 and pass through the lumen #2. The folding point or bending point F1 of the RL-paired wire P1 is placed between two mouths of the two lumens #1 and #2, preferably, F1 is located at a middle point between the two mouths of the two lumens #1 and #2. For RL-paired wire P2, the first portion Rp2 of right-handed helical wire may be inserted into the lumen #2 and may pass through the lumen #2, and the second portion Lp2 of left-handed helical wire may be inserted into a lumen #3 and pass through the lumen #3. The folding point or bending point F2 of the RL-paired wire P2 is placed between two mouths of

the two lumens #2 and #3, preferably, F2 is located at a middle point between the two mouths of the two lumens #2 and #3. For P3, Rp3 may be inserted into and pass through the lumen #3, and Lp3 may be inserted into and pass through a lumen #4. Folding point F3 is placed between two mouths of the two lumens #3 and #4, preferably at a middle point there-between. For P4, 5 Rp4 and Lp4 may be inserted into and pass through lumens #4 and #5, respectively, and F4 is placed between two mouths of the two lumens #4 and #5, preferably at a middle point there-between. In a similar fashion, Rp5 and Lp5 may be inserted into and pass through lumens #5 and #6, respectively, and F5 is placed between two mouths of the two lumens #5 and #6, preferably at a middle point there-between. Rp6 and Lp6 may be inserted into and pass through 10 lumens #6 and #1, respectively, and F6 is placed between two mouths of the two lumens #6 and #1, preferably at a middle point there-between. The number of wire-accepting lumens may be no less than the number of wires. The number of wire-accepting lumens may be equal to the number of wires. For example, an optional central lumen #7 in parallel with lumens #1~#6 may be included in the bundler 1400, not for accepting any RL-paired wire, but for allowing e.g. the 15 control wire or pull/push wire 19 to pass there-through, if needed. After RL-paired wires P1~P6 are properly placed in lumens #1~#6 as described above, a liquid adhesive material may be filled into or dropped into lumens #1~#6. After the liquid adhesive material is solidified, RL-paired wires P1~P6 will be permanently glued and fixed to the multi-lumen bundler 1400.

When step (ii), i.e. simply intersecting or bi-axially weaving the helical wires into a 20 tubular structure as the carrier, is implemented, a bobbin may be used as a scaffold. As shown in Figure 15, the bobbin 1501 thereon has an array of holes 1500, into which pins 1511 are to be inserted. Between any two pins 1511, or between two rows of pins 1511, a wire such as one of P1~P6 may be wound. The pins 1511 may function as flanges for the bobbin 1501. The multi-lumen bundler 1400 may optionally be used with the bobbin 1501. When it is used, the 25 multi-lumen bundler 1400 with loose RL-paired wires P1~P6 is placed on a top tip of the bobbin 1501, and functions as a start point of the weaving process. After the weaving process is completed, pins 1511 are removed from the bobbin 1501, leaving behind a tubular structure as the carrier of the present disclosure.

Another aspect of the present disclosure provides a method of stabilizing structural 30 integrity of a carrier of a catheter apparatus including an elongated shaft having a proximal portion and a distal portion, and preventing tangling of helical wires of the carrier, wherein the

carrier is located at, or proximate to, the distal portion of the elongated shaft, and wherein the therapeutic assembly includes at least one therapeutic member for intravascular treatment; wherein the carrier is configured to vary between a delivery configuration and a deployed configuration; wherein the distal portion of the shaft is configured for intravascular delivery of the carrier. As shown in Figure 16, the method includes:

(A) simply intersecting or bi-axially weaving $m \geq 2$ right-handed helical wires and $n \geq 2$ left-handed helical wires into each other to prepare a carrier including at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and

(B) wrapping at least one therapeutic assembly around at least one of the four helical wire segments to stabilize the at least one interstice, to maintain structural integrity of the carrier, and to prevent tangling of helical wires, when the carrier is being distorted intravascularly.

In the foregoing specification, embodiments of the present disclosure have been described with reference to numerous specific details that may vary from implementation to implementation. The specification and drawings are, accordingly, to be regarded in an illustrative rather than a restrictive sense. The sole and exclusive indicator of the scope of the invention, and what is intended by the applicant to be the scope of the invention, is the literal and equivalent scope of the set of claims that issue from this application, in the specific form in which such claims issue, including any subsequent correction.

CLAIMS

1. A catheter apparatus comprising:

an elongated shaft having a proximal portion and a distal portion;

5 a carrier that is preferably in a meshed tubular stent structure and carries at least one therapeutic assembly, wherein the carrier is located at, or proximate to, the distal portion of the elongated shaft, and wherein the therapeutic assembly comprises at least one therapeutic member for intravascular treatment;

10 wherein the carrier is configured to vary between a delivery configuration and a deployed configuration;

wherein the distal portion of the shaft is configured for intravascular delivery of the carrier;

wherein the carrier comprises m right-handed helical wires and n left-handed helical wires which are simply intersected or bi-axially woven into each other, $m \geq 2$, and $n \geq 2$;

15 wherein the carrier comprises at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and

20 wherein the at least one therapeutic assembly wraps around at least one of the four helical wire segments to stabilize the at least one interstice, to maintain structural integrity of the carrier, and to prevent tangling of the helical wires, when the carrier is being distorted intravascularly.

25 2. The catheter apparatus according to claim 1, wherein the at least one therapeutic member is an electrode or a heating element configured to deliver energy such as electrical energy, radiofrequency (RF) electrical energy, pulsed electrical energy, and thermal energy to a target blood vessel.

3. The catheter apparatus according to claim 1, wherein the carrier comprises m right-handed helical wires and n left-handed helical wires which are simply intersected or bi-axially woven into a tubular structure, $2 \leq m \leq 30$, $2 \leq n \leq 30$, and $m = n$.

30 4. The catheter apparatus according to claim 3, wherein the carrier carries six therapeutic assemblies, each of which comprises an electrode as the therapeutic member, providing six

electrodes in total.

5. The catheter apparatus according to claim 4, wherein the six electrodes are configured to create interrupted spiral-shaped but fully circumferential lesions on an internal wall of a target blood vessel.

6. The catheter apparatus according to claim 1, wherein at least one of the m right-handed helical wires and at least one of the n left-handed helical wires are made from one single wire having a first portion of right-handed helical wire and a second portion of left-handed helical wire by folding or bending the single wire at a point between the first portion and the second portion by an angle from about 160° to 180°.

7. The catheter apparatus according to claim 1, wherein the therapeutic assembly wraps around only one of the four helical wire segments to stabilize the interstice.

8. The catheter apparatus according to claim 7, wherein the therapeutic assembly comprises two terminal bodies and a main body positioned between the two terminal bodies; and

wherein a cross-sectional area of the main body along a plane perpendicular to an elongation direction of the helical wire segment being wrapped around is larger than cross-sectional areas of the terminal bodies along the plane perpendicular to the elongation direction of the helical wire segment being wrapped around, and the cross-sectional areas of the terminal bodies along the plane perpendicular to the elongation direction of the helical wire segment being wrapped around are larger than a cross-sectional area of the helical wire segment being wrapped around along the plane perpendicular to the elongation direction of the helical wire segment.

9. The catheter apparatus according to claim 8, wherein a length of the helical wire segment being wrapped around is maintained to be equal to, or longer than, the main body's length along the elongation direction of the helical wire segment being wrapped around.

10. The catheter apparatus according to claim 8, wherein a length of the helical wire segment being wrapped around is maintained to be equal to, or longer than, the main body's length plus a length of one of the two terminal bodies along the elongation direction of the helical wire segment being wrapped around, or the length of the helical wire segment being wrapped around is maintained to be equal to, or longer than, the main body's length plus a total length of the two terminal bodies along the elongation direction of the helical wire segment

being wrapped around.

11. The catheter apparatus according to claim 6, further comprising a multi-lumen bundler for converging the folded or bent helical wires at the folded or bent portion, and the helical wires are permanently glued and fixed to the multi-lumen bundler with a liquid adhesive material.

12. The catheter apparatus according to claim 8, wherein at least one of the two terminal bodies and the main body includes at least one of:

(1) one or more grooves for accommodating or guiding one or more helical wires to slide over the helical wire segment around which the therapeutic assembly wraps; and

(2) one, two or more protrusions, wherein a gap between the protrusion and the helical wire segment around which the therapeutic assembly wraps, and a gap between protrusions themselves, are configured for accommodating or guiding one or more helical wires that slide(s) over the helical wire segment around which the therapeutic assembly wraps.

13. A method of stabilizing structural integrity of a carrier of a catheter apparatus comprising an elongated shaft having a proximal portion and a distal portion, and preventing tangling of helical wires of the carrier, wherein the carrier is located at, or proximate to, the distal portion of the elongated shaft, and wherein the therapeutic assembly comprises at least one therapeutic member for intravascular treatment; wherein the carrier is configured to vary between a delivery configuration and a deployed configuration; wherein the distal portion of the shaft is configured for intravascular delivery of the carrier; the method comprises:

simply intersecting or bi-axially weaving $m \geq 2$ right-handed helical wires and $n \geq 2$ left-handed helical wires into each other to prepare a carrier comprising at least one interstice that is defined by four helical wire segments from two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and

wrapping at least one therapeutic assembly around at least one of the four helical wire segments to stabilize the at least one interstice, to maintain structural integrity of the carrier, and to prevent tangling of the helical wires, when the carrier is being distorted intravascularly.

14. A method of manufacturing the catheter apparatus according to claim 1, comprising:

- (i) providing m right-handed helical wires and n left-handed helical wires, $m \geq 2$, and $n \geq 2$;
- (ii) simply intersecting or bi-axially weaving the helical wires into a tubular structure as

the carrier;

(iii) forming at least one interstice that is defined by four helical wire segments of two immediately adjacent right-handed helical wires and two immediately adjacent left-handed helical wires which are simply intersected or bi-axially woven into each other; and

5 (iv) wrapping at least one therapeutic assembly around at least one of the four helical wire segments to stabilize the interstice.

15. The method according to Claim 14, wherein step (i) comprises:

(ia) providing one single wire having a first portion of right-handed helical wire and a second portion of left-handed helical wire; and

10 (ib) folding or bending the single wire at a point between the first portion and the second portion to provide a right-handed helical wire and a left-handed helical wire.

16. The method according to Claim 15, further comprising cutting the bent single wire near the bending point to make a separate right-handed helical wire and a separate left-handed helical wire.

15 17. The method according to Claim 14, wherein step (i) comprises:

(iA) providing a number of wires, each of the wires having a first portion of right-handed helical wire and a second portion of left-handed helical wire;

(iB) folding or bending each of the wires at a point between the first portion and the second portion to provide a right-handed helical wire and a left-handed helical wire; and

20 (iC) bundling the wires together at ends of the bending points of the wires with a multi-lumen bundler, wherein the multi-lumen bundler has a cylinder body, and a number of lumens pass axially through the cylinder body along a longitudinal axis of the cylinder body; and wherein the first portion of right-handed helical wire and the second portion of left-handed helical wire from a same wire are inserted into and pass through two different lumens.

25 18. The method according to Claim 17, wherein the number of lumens is no less than the number of wires.

19. The method according to Claim 14, wherein step (ii) comprises: simply intersecting or bi-axially weaving the helical wires, around a bobbin having an array of holes, into a tubular structure as the carrier, wherein pins are inserted into at least some of the holes during weaving,
30 and the pins are removed from the holes after the weaving is completed.

20. The method according to Claim 19, further comprising placing a multi-lumen

bundler with wires bundled at one end and loose at the other end on a top tip of the bobbin, before the weaving of the wires starts.