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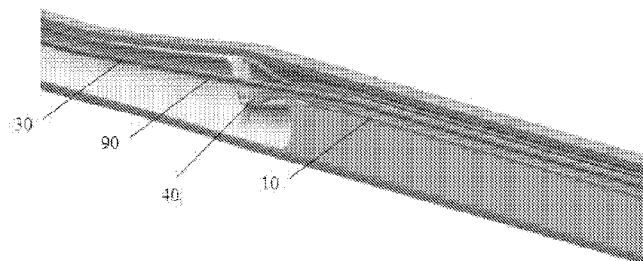


FIG. 1H

(57) Abstract: A device for bypassing an occlusion in a vessel is provided. The device includes an elongated device body having a central channel which configured for accommodating a guidewire. The distal portion of the device is configured for forcing apart tissue layers of a wall of the vessel to thereby angle a portion of an inner layer into a lumen of the vessel and pulling the angled inner tissue layer against a distal end of the elongated device body thereby enabling a guide-wire advanced through the central channel and out of the distal end to puncture through the inner tissue layer and into the lumen of the vessel downstream of the occlusion.



DEVICES AND METHODS FOR BYPASSING OCCLUSIONS IN VESSELS

FIELD OF THE INVENTION

The present invention generally relates to devices and methods for bypassing occlusions in biological vessels of a patient. Specifically, the present invention relates to a catheter-like device which can be used to angle an inner tissue layer of a vessel wall with respect to a distal end of the device thereby enabling a guidewire delivered through the distal end to puncture through the inner tissue layer and into the vessel lumen.

BACKGROUND OF THE INVENTION

The present invention relates to devices and methods for treating occlusions such as chronic total occlusions (CTOs) in blood vessels such as arteries.

A Chronic total occlusion (CTO) is characterized by heavy plaque burden within the artery, resulting in complete (or nearly complete) occlusion of the vessel. CTOs are the most common reason for failure of endovascular intervention and referral to open surgery. A prerequisite to endovascular treatment of these lesions is the crossing of the occlusions with a guide wire on which therapeutic interventions such as balloon dilation, stent placement and other interventions can be performed. In order to achieve this crossing consistently, reliably and safely, new devices and instrumentation are needed.

The most common cause of arterial occlusive disease is atherosclerosis. Atherosclerosis is a chronic, progressive disease of the arteries in which "plaques" made up of cholesterol deposits, calcium, and abnormal cells develop on the inner lining of the arteries.

Chronic total occlusions exist in both coronary and peripheral arteries, but have been histologically characterized mostly in the coronary arteries. It has been shown that their composition is irregular and changes over time. Specifically, the plaque is not homogenous and contains regions of different composition and structure with multiple neovascular channels.

Outside the lesion and within the outer layer of the arterial wall (the adventitia), the subintimal plane is a consistent potential space of loosely adherent layers. In an effort to avoid the complications associated with open surgical operations, wire-based devices for endovascular treatment of CTO have been introduced. Traditionally, it has been accepted that staying within the lumen and the plaque, rather than outside it, is preferred, so that when the

guide wire exits the occlusion, it is within the arterial lumen beyond it. However, traversing the plaque, which may be hard and calcified, is often difficult even with the use special high-end guide wires with very stiff tips. To increase the success rate, several devices have been or are being developed. These include among others the Frontrunner (Cordis, J&J), which is based on blunt microdissection, the Crosser (Flowcardia, Sunnyvale, CA), in which high-frequency vibration is used to facilitate guide wire navigation, the Safe-cross (Intraluminal Therapeutics, Carlsbad, CA), which uses radiofrequency ablation, the Excimer laser catheter (Spectranetics, Colorado Springs CO), CTOS oscillating guide wire (ReVascular therapeutics Sunnyvale CA), CiTop guide wire (Ovalum Medical Vision, Rehovot Israel) with steerable J-tip guide wire control, and the Niobe system for manipulating instrumentation within magnetic fields. In addition, pharmaco-therapy with local injection of collagenase (Bradley Strauss, Toronto) is being investigated.

Subintimal angioplasty

An important endovascular technique used to treat total occlusions is subintimal angioplasty, where a dissection plane is intentionally developed beside the occlusion in the subintimal plane (outside the natural arterial lumen and outside the atherosclerotic plaque, outside the intima and inside the adventitia). This plane is entered from the lumen distal to the occlusion and the device (wire or catheter) within it is advanced to beyond the occlusion. At this point and preferably not too far away from the termination of the occlusion, the lumen has to be re-entered.

The appeal of the subintimal route is that it is always available, irrespective of the structure and composition of the atherosclerotic plaque. It may be difficult to enter this plane with a guide wire, however, because it requires puncturing the intima at some point distal to the occlusion to reach this plane from the arterial lumen. Once inside this plane with a guide wire, the wire can usually be advanced with a relatively low resistance. The most difficult and least controlled step in this procedure is the reentry. This last step is occasionally difficult and if the guide wire does not re-enter the true lumen close to the occlusion the entire endovascular procedure may have to be abandoned. Once the guide wire has entered the lumen beyond the occlusion, the intervention proceeds as usual with balloon dilation and stent application, as required.

Three devices which have been designed to control the re-entry site are on the market. Two devices are similar and use a curved hollow needle, which is driven off center (sideways), to

perforate the intima and enter the lumen from the subintimal plane at the desired location. Through this needle, a guide wire is advanced to the distal lumen, and from this point on the procedure can proceed as usual.

One device is the Outback reentry catheter by Cordis J&J and the other is the Pioneer catheter by Medtronic. Both catheters have a large profile which is a disadvantage, especially for use in smaller arteries. Both catheters require precise rotational orientation, so that the needle is driven into the true lumen and not outside the adventitia and the artery. The outback relies on fluoroscopy and a radio-opaque rotation marker, the Pioneer incorporates an IVUS (intravascular ultrasound) catheter for orientation. A third device is a reentry balloon catheter where a flat low profile balloon helps orient the wire towards the lumen (Bridgepoint medical, Minneapolis, Minnesota)

Crossing of a CTO in practice

While techniques of crossing the occlusion through the plaque (i.e. intra-luminal) and subintimal angioplasty are presented above as two essentially different procedures, they are in essence quite similar. In fact, it is occasionally difficult to judge along which plane the guide wire has actually crossed the total occlusion, whether within the plaque or in the subintimal plane.

The interior of the occluding plaque is inhomogeneous in terms of composition and structure and even within the subintimal plane there may be varying resistance to guide wire advancement as well. Therefore a means to enhance passage of a guide wire to the desired site of reentry, may be helpful.

Thus, a device and method especially adapted to bypass occlusions remains a long-felt but as yet unmet need.

SUMMARY OF THE INVENTION

According to one aspect of the present invention there is provided a device for bypassing an occlusion in a vessel comprising an elongated device body including: (a) a channel (preferably central) configured for accommodating a guidewire therethrough; and (b) a distal portion being configured for: (i) forcing apart tissue layers of a wall of the vessel to thereby angle a portion of an inner layer of the tissue layers into a lumen of the vessel; and (ii) pulling the portion of the inner tissue layer against a distal end of the elongated device body; thereby enabling a guide-wire advanced through the central channel and out of the distal end to puncture through the inner tissue layer and into the lumen of the vessel downstream of the

occlusion.

According to further features in preferred embodiments of the invention described below, the distal portion includes an effector being expandable to force apart the tissue layers of the wall when positioned therebetween.

According to still further features in the described preferred embodiments (ii) is effected via suction.

According to still further features in the described preferred embodiments the effector is mechanically expandable.

According to still further features in the described preferred embodiments the device further comprises a hollow support element disposed within the channel.

According to still further features in the described preferred embodiments the hollow support element is selected from a group consisting of a micro-catheter, hollow element, tube-like element and any combination thereof.

According to still further features in the described preferred embodiments the hollow support element is movable along a longitudinal axis of the channel.

According to still further features in the described preferred embodiments the suction is provided by a vacuum port positioned at either said distal end or the proximal end of said device, such that suction force is applied at the a distal end of the device.

According to still further features in the described preferred embodiments the device further comprises a handle positioned at a proximal end of the elongated device body, the handle being for actuating the effector and the hollow support element.

According to still further features in the described preferred embodiments the effector is trapped between the hollow support element and the channel and expansion of the effector is effected by at least one selected from a group consisting of (a) longitudinally moving said hollow support element with respect to said channel; (b) pulling/pushing the hollow support element with respect to the channel; (c) pulling/pushing the effector with respect to the channel; (d) pulling/pushing the channel with respect to the effector; and any combination thereof.

According to still further features in the described preferred embodiments actuation of the effector includes movement thereof with respect to the elongated device body.

According to still further features in the described preferred embodiments the effector includes at least one wire capable of forming the effector when extended out of the channel of the elongated device body.

According to still further features in the described preferred embodiments the at least one wire forms at least one coil, at least one loop, a basket or a half ball when extended out of the elongated device body.

According to still further features in the described preferred embodiments the at least one loop includes a plurality of overlapping loops.

According to still further features in the described preferred embodiments the at least one wire is composed of a shape memory material.

According to still further features in the described preferred embodiments the shape memory material is Nitinol or cobalt chromium.

According to still further features in the described preferred embodiments the effector forms a toroid, a cone or a ball when expanded.

According to still further features in the described preferred embodiments the elongated device body is capable of articulation.

According to still further features in the described preferred embodiments the hollow support element is configured capable of advancement through the inner tissue layer.

According to still further features in the described preferred embodiments the vessel is an artery and the inner tissue layer is an intima.

According to another aspect of the present invention there is provided a system comprising the device described herein and a guide-wire.

According to still further features in the described preferred embodiments a distal tip of the guide-wire is configured for puncturing tissue.

According to still further features in the described preferred embodiments the elongated device body is configured such that it curves towards the lumen when the tissue layers of the wall of the vessel are forced apart.

According to still further features in the described preferred embodiments the device additionally comprising verification means for verifying the location at which said guide wire has penetrated said intima.

According to still further features in the described preferred embodiments the verification means are introduced through said hollow support element.

According to still further features in the described preferred embodiments the verification means are contrast agents.

According to another aspect of the present invention there is provided a method of bypassing an occlusion in a vessel comprising: (a) positioning a device between tissue layers of a wall of the vessel; (b) forcing apart the tissue layers of the wall of the vessel to thereby angle a portion of an inner tissue layer of the tissue layers into a lumen of the vessel; (c) pulling the portion of the inner tissue layer against a distal end of the elongated device body; and (d) advancing a guide-wire through the device and out of a distal end thereof to puncture through the inner tissue layer and into the lumen of the vessel thereby bypassing the occlusion.

According to still further features in the described preferred embodiments the method can further include the steps of (e) advancing an inner support tube (hollow support element) over the wire into the lumen to verify penetration by blood flow through the lumen of the hollow support element.

According to still further features in the described preferred embodiments the method additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.

According to still further features in the described preferred embodiments the method as defined above, wherein said verification means are introduced through said hollow support element.

According to still further features in the described preferred embodiments the verification means are contrast agents.

According to still further features in the described preferred embodiments the vessel is an artery and the inner tissue layer is an intima.

According to still further features in the described preferred embodiments (b) is effected via an effector being expandable between the tissue layers.

According to still further features in the described preferred embodiments (c) is effected via suction.

According to still further features in the described preferred embodiments the device includes an elongated device body having a central channel.

According to still further features in the described preferred embodiments (b) is effected via an effector being expandable to force apart the tissue layers of the wall when positioned therebetween.

According to still further features in the described preferred embodiments the effector includes at least one wire capable of forming the effector when extended out of the device.

According to still further features in the described preferred embodiments the method further comprises puncturing the inner tissue layer upstream of the occlusion prior to (a) to thereby position the device between the tissue layers of the wall of the vessel.

According to still further features in the described preferred embodiments the method further comprising step of providing said hollow support element as at least one selected from a group consisting of a micro-catheter, hollow element, tube-like element and any combination thereof.

According to still further features in the described preferred embodiments the method additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.

According to still further features in the described preferred embodiments the method as defined above, wherein said verification means are introduced through said hollow support element.

According to still further features in the described preferred embodiments the verification means are contrast agents.

According to another aspect of the present invention there is provided a catheter for bypassing an occlusion comprising: (a) a first tube having an inner lumen configured for accommodating a guidewire therethrough (b) an expandable wire structure attached to a distal end of said first tube; and (c) a second tube having a lumen for accommodating said first tube and said expandable wire structure therein such that moving said first tube with respect to said second tube releases and expands said expandable wire structure from a distal end of the catheter.

According to still further features in the described preferred embodiments the catheter further comprises a vacuum port for applying a suction force at the a distal end of the catheter.

According to still further features in the described preferred embodiments the catheter further comprises a vacuum port for applying suction force from proximal end of said catheter, such that suction is achieved at the distal end of the catheter. This enables that sufficient suction to at least a portion of the intima, so as to displace the same from its natural orientation, is provided.

Thus, it is another object of the present invention to provide a catheter for treatment of an occlusion in a vessel of a patient, comprising:

at least one open-bore type lumen in fluid contact with a source of suction, said lumen characterized by a distal end and a proximal end interconnected by a main longitudinal axis substantially parallel to the main longitudinal axis of said catheter, said proximal end located outside the body of said patient during the course of said treatment;

at least one hollow support element accommodated within said lumen, reciprocally maneuverable along said main longitudinal axis;

at least one guide wire, accommodated within said hollow support element, reciprocally maneuverable along and around said main longitudinal axis of said lumen; and,

at least one effector characterized by at least one inactive configuration and at least one active configuration, said active configuration characterized by:

at least a portion of the distal end of said effector protrudes from said distal end of said open-bore type lumen; and,

said open-bore type lumen and said effector, in said active configuration, are adapted to apply, by means of said source of suction, sufficient suction to at least a portion of the intima so as to displace the same from its natural orientation;

said effector defines, in said active configuration, a volume bounded on at least one side by a portion of the intima of said vessel that is displaced from its natural orientation to an orientation in which said guide wire will penetrate said intima and reenter said vessel;

wherein said support element provides support and stabilization to said guide wire when said effector is in said active configuration and the distal end of said guide wire is extended beyond the distal end of said lumen so as to enable said guide wire to penetrate said intima and reenter said lumen.

It is another object of the present invention to provide the catheter according as defined above, further comprising actuating means for actuating the reconfiguration of said effector between said active and inactive configurations.

It is another object of the present invention to provide the catheter according as defined above, wherein said actuating means is selected from the group consisting of magnetic means, heat means, electric means, mechanical means, and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said actuating means additionally comprises means for moving said distal end of said effector in and out of said lumen.

It is another object of the present invention to provide the catheter according as defined above, wherein said actuating mechanism comprises at least one wire mechanically connected to said effector.

It is another object of the present invention to provide the catheter according as defined above, wherein the area of the cross-section of said effector as measured in the plane perpendicular to the longitudinal axis of said catheter varies along said main longitudinal axis of said catheter.

It is another object of the present invention to provide the catheter according as defined above, wherein the area of the cross-section of said effector as measured in the plane perpendicular to the longitudinal axis of said catheter increases along said main longitudinal axis of said catheter.

It is another object of the present invention to provide the catheter according as defined above, wherein, when said effector is in said active configuration, the cross-sectional area of at least a portion of said part of said effector that protrudes from said catheter, as measured in a plane perpendicular to said longitudinal axis of said catheter, is greater than the cross-sectional area of said catheter as measured in a plane perpendicular to said longitudinal axis of said catheter.

It is another object of the present invention to provide the catheter according as defined above, wherein said effector, when in said inactive configuration, is disposed within said catheter, and further wherein the walls of said lumen constrain said effector from reconfiguration to said active configuration.

It is another object of the present invention to provide the catheter according as defined above, wherein the shape of at least a portion of said distal end of said effector is selected from the group consisting of at least one curled wire, at least one wire with a zigzag shape, at least one wire with a spring-like shape, and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said guide wire has a sharpened tip.

It is another object of the present invention to provide the catheter according as defined above, wherein said effector is disposed outside of said lumen when it is in said inactive configuration.

It is another object of the present invention to provide the catheter according as defined above, further comprising actuating means for reversibly moving said effector along and around said main longitudinal axis of said catheter.

It is another object of the present invention to provide the catheter according as defined above, wherein said source of suction provides sufficient suction (at said catheter's distal end) such that, when said effector is in said active configuration and suction is applied, said effector is fixed against the inner surface of said vessel, so as to enable said guide wire to reenter said lumen, thereby bypassing said occlusion.

It is another object of the present invention to provide the catheter according as defined above, wherein at least a portion of said effector is made of a material chosen from the group consisting of materials having shape memory properties, electroactive polymers (EAPs), and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said material having shape memory properties is selected from the group consisting of copper-based alloys, NiTi-based materials, and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said EAP is of a type selected from the group consisting of dielectric EAPs, ferroelectric polymers, liquid crystalline polymers, ionic EAPs, and any mixture thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said effector, in said active configuration, is adapted to provide a preset void volume; said preset void volume is defined by means of said effector, the distal end of said catheter and the inner surface between the subintimal space and the vessel; said source of suction is adapted to apply suction within said preset void volume, so as to enable said guide wire and to puncture the intima.

It is another object of the present invention to provide the catheter according as defined above, wherein said open-bore type lumen is provided with an articulation mechanism.

It is another object of the present invention to provide the catheter according as defined above, wherein said hollow support element is provided with an articulation mechanism.

It is another object of the present invention to provide the catheter according as defined above, wherein said effector is provided with an articulation mechanism.

It is another object of the present invention to provide the catheter according as defined above, wherein said guide wire is provided with an articulation mechanism.

It is another object of the present invention to provide the catheter according as defined above, additionally comprising verification means for verifying the location at which said guide wire has penetrated said intima.

It is another object of the present invention to provide the catheter according as defined above, wherein said verification means are chosen from the group consisting of a contrast

agent, observation of blood passing through a hole about the point of penetration of said intima by said guide wire and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said hollow support element is selected from a group consisting of a micro catheter, hollow element, tube-like element and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein verification means for verifying the location at which said guide wire has penetrated said intima is introduced through said hollow support element.

It is another object of the present invention to provide the catheter according as defined above, wherein said verification means are contrast agents.

It is another object of the present invention to provide the catheter according as defined above, additionally comprising at least one marker at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said at least one marker is adapted to indicate the relative position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector; with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector.

It is another object of the present invention to provide the catheter according as defined above, additionally comprising at least one marker disposed at the distal end of said catheter, adapted to indicate the full reconfiguration of said effector from said inactive configuration to said active configuration.

It is another object of the present invention to provide the catheter according as defined above, wherein said reconfiguration of said effector from said inactive configuration to said active configuration is provided by means selected from (a) pulling said catheter in said proximal direction; pushing said effector in said distal direction.

It is another object of the present invention to provide the catheter according as defined above, additionally comprising at least one marker at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof, adapted to indicate the position of at least one selected from a group consisting of said guide wire, said hollow support element, said

lumen, said catheter, said effector and any combination thereof with respect to said vessel or said intima.

It is another object of the present invention to provide the catheter according as defined above, wherein said hollow support element is adapted to penetrate said intima and reenter said lumen.

It is another object of the present invention to provide the catheter according as defined above, wherein said catheter is provided with a mechanism adapted to enable linear movement along said main longitudinal axis of at least one selected from a group consisting of said guide wire, said hollow support element, said effector and any combination thereof with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said effector and any combination thereof.

It is another object of the present invention to provide the catheter according as defined above, wherein said effector is a stent-like effector, a bagel shape braded effector, cone shaped effector.

It is another object of the present invention to provide a method for bypassing an occlusion in a vessel of a patient, comprising:

- providing a catheter as defined above;

- inserting said catheter into said vessel;

- reconfiguring said effector into said active configuration at a location proximal to the distal end of said occlusion, at a location desired for reentry, thereby defining a volume bounded at least partially by said effector and by a portion of the intima of said vessel at least part of which is proximal to said distal end of said occlusion;

- applying sufficient suction to at least a portion of the intima so as to displace the same from its natural orientation;

- actuating said hollow support element such that the distal end of said hollow support element is within said volume;

- actuating said guide wire such that the distal end of said guide wire protrudes from said hollow support element; and,

- penetrating the intima with said guide wire at a point within said portion of said intima that bounds said volume, thereby reentering into said vessel at a point proximal to said distal end of said occlusion, bypassing said occlusion;

wherein said method additionally comprises a step of stabilizing said guide wire by means of said hollow support element until said guide wire has penetrated said intima.

It is another object of the present invention to provide the method according as defined above, further comprising a step of advancing said guide wire through said lumen.

It is another object of the present invention to provide the method according as defined above, further comprising a step of reconfiguring the effector into said inactive configuration.

It is another object of the present invention to provide the method according as defined above, further comprising a step of removing said catheter from said vessel while leaving said guide wire within said vessel.

It is another object of the present invention to provide the method according as defined above, further comprising a step of removing said hollow support element from said vessel while leaving said guide wire within said vessel.

It is another object of the present invention to provide the method according as defined above, further comprising a step of penetrating said intima of said vessel by said guide wire at a point proximal to said occlusion prior to said step of penetrating said intima of said vessel with said guide wire at a point proximal to said occlusion.

It is another object of the present invention to provide the method according as defined above, further comprising a step of penetrating said intima of said vessel by said lumen at a point proximal to said occlusion.

It is another object of the present invention to provide the method according as defined above, further comprising a step of introducing said catheter into said vessel at the point at which said guide wire reentered said vessel.

It is another object of the present invention to provide the method according as defined above, further comprising at least one step chosen from the group consisting of (a) injecting a substance into said vessel and (b) visualizing said vessel.

It is another object of the present invention to provide the method according as defined above, wherein said step of applying suction is initiated subsequent to said step of reconfiguring said effector into its active configuration.

It is another object of the present invention to provide the method according as defined above, wherein said step of applying suction comprises applying suction that is sufficiently strong to fix said effector to said intima.

It is another object of the present invention to provide the method according as defined above, further comprising a step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means.

It is another object of the present invention to provide the method according as defined above, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means additionally comprising at least one step selected from applying magnetic means, applying heat means, applying electrical means, applying mechanical means, and any combination thereof.

It is another object of the present invention to provide the method according as defined above, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means additionally comprising step of linearly moving said distal end of said effector in and out of said lumen.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said effector with an area of the cross-section, as measured in the plane perpendicular to the longitudinal axis of said catheter, that varies along said main longitudinal axis of said catheter.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said effector with an area of the cross-section, as measured in the plane perpendicular to the longitudinal axis of said catheter, that increases along said main longitudinal axis of said catheter.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said effector, wherein, when said effector is in said active configuration, the cross-sectional area of at least a portion of said part of said effector that protrudes from said catheter, as measured in a plane perpendicular to said longitudinal axis of said catheter, is greater than the cross-sectional area of said catheter as measured in a plane perpendicular to said longitudinal axis of said catheter.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of reversibly moving said effector along and around said main longitudinal axis of said catheter.

It is another object of the present invention to provide the method according as defined above, wherein said step of applying suction additionally comprising step of providing sufficient suction such that, when said effector is in said active configuration and suction is applied, said

effector is fixed against the inner surface of said vessel, so as to enable said guide wire to reenter said lumen, thereby bypassing said occlusion.

It is another object of the present invention to provide the method according as defined above, wherein said step of applying suction additionally comprising step of providing sufficient suction such that, when said effector is in said active configuration and suction is applied, a preset void volume is provided; said preset void volume is defined by means of said effector, the distal end of said catheter and the inner surface between the subintimal space and the vessel; said source of suction is adapted to apply suction within said preset void volume, so as to enable said guide wire and to puncture the intima.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing at least a portion of said effector from a material chosen from the group consisting of materials having shape memory properties, electroactive polymers (EAPs), and any combination thereof.

It is another object of the present invention to provide the method according as defined above, wherein said material having shape memory properties is selected from the group consisting of copper-based alloys, NiTi-based materials, and any combination thereof.

It is another object of the present invention to provide the method according as defined above, wherein said EAP is of a type selected from the group consisting of dielectric EAPs, ferroelectric polymers, liquid crystalline polymers, ionic EAPs, and any mixture thereof.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said open-bore type lumen with an articulation mechanism.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said hollow support element with an articulation mechanism.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said effector with an articulation mechanism.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said guide wire with an articulation mechanism.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of selecting said verification means from the group consisting of a contrast agent, observation of blood passing through a hole about the point of penetration of said intima by said guide wire and any combination thereof.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing said hollow support element as a at least one selected from a group consisting of micro catheter, hollow element, tube-like element and any combination thereof.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.

It is another object of the present invention to provide the method according as defined above, wherein said verification means are introduced through said hollow support element.

It is another object of the present invention to provide the method according as defined above, wherein said verification means are contrast agents.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing at least one marker at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of indicating, by means of said at least one marker, the relative position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector; with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing at least one marker disposed at the distal end of said catheter, to indicate the full reconfiguration of said effector from said inactive configuration to said active configuration.

It is another object of the present invention to provide the method according as defined above, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration is provided by means selected from (a) pulling said catheter in said proximal direction; (b) pushing said effector in said distal direction.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of providing at least one marker disposed at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof, adapted to indicate the position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof with respect to said vessel or said intima.

It is another object of the present invention to provide the method according as defined above, additionally comprising step of penetrating said intima and reenter said lumen by means of said hollow support element

The present invention successfully addresses the shortcomings of the presently known configurations by providing a device which is capable of bypassing occlusions in biological vessels without need to deflect or angle a guidewire carried thereby.

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

BRIEF DESCRIPTION OF THE FIGURES

In order to better understand the invention and its implementation in a practice, a plurality of embodiments will now be described, by a way of non-limiting example only, with reference to the accompanying drawings, in which

FIGs. **1A-1Q** schematically illustrate use of the present catheter in bypassing an occlusion in a vessel.

FIG. 2 schematically illustrates a catheter comprising an effector with dispersed wired arms active configuration, according to certain embodiments of the present invention;

FIG. 3A schematically illustrates a catheter comprising an effector with a coiled shape active configuration, according to certain embodiments of the present invention;

FIG. 3B schematically illustrates a catheter comprising two effectors with a spring-like shaped active configuration according to an embodiment of the present invention;

FIG. 3C schematically illustrates a catheter comprising three effectors with a spring-like shaped active configuration according to certain embodiments of the invention;

FIG. 4A schematically illustrates a catheter comprising an effector with separated zigzag shaped wires, according to some embodiments of the present invention;

FIG. 4B schematically illustrates a top view of the effector presented in FIG. 4A;

FIG. 5 schematically illustrates an alternative active configuration of the effector having loops interconnected in several locations, according to some preferred embodiments of the invention. (laser cut from tube + shaping , Nitinol)

FIG. 6A schematically illustrates a catheter comprising an effector having a helical active configuration, according to certain embodiments of the invention;

FIG. 6B schematically illustrates a preferred embodiment of the catheter of FIG. 6A;

FIGs. 7-8 schematically illustrate a catheter comprising an effector comprising separate zigzag shaped wires, constructing a hollow spherical like active configuration, according to certain embodiments of the invention; and,

FIGs. 9A-9B illustrate an embodiment in which the effector is a cone-shaped stent-like effector.

FIGs. 10A-10B illustrate an embodiment in which the effector is a bagel shape braded effector.

FIGs. 11A-11B illustrate an embodiment in which the effector is a cone shaped effector.

FIG. 12 illustrates the hollow support element and effector portions of a prototype constructed in accordance to the teachings of the present invention. (single layer braded effector)

FIG. 13 illustrates bench testing of a prototype catheter constructed in accordance to the teachings of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The following description is provided to enable any person skilled in the art to make use of said invention and sets forth the best modes contemplated by the inventor of carrying out this invention. Various modifications, however, will remain apparent to those skilled in the art, since the generic principles of the present invention have been defined specifically to provide a catheter for treating occlusions in a vessel of a patient.

As used herein, the term "**bore type lumen**" refers in a non-limiting manner to a channel, conduit, tube, pipe, hole, passageway, facilitated space, or other cavity with a tubular structure, adapted, i.e. by means of size and shape, to accommodate, according to certain embodiments, at least one of the following: at least a portion of the guide wire, at least a portion of the hollow support element, at least a portion of the effector and at least a portion of an actuating mechanism.

As used herein, the term "**guide wire**" refers to a long and flexible fine spring or spring-like member that may be used to introduce and position an intravascular angiographic catheter, usually used in the Seldinger technique.

As used herein, the term "**distal**" refers to a direction away from the operator (of the present device), and the term "proximal" to a direction toward the operator.

Thus, as a non-limiting example, in treatment of an occlusion with the catheter disclosed herein, the distal end of the catheter (with guide-wire) enters the vessel wall at the proximal side of the occlusion and the guide-wire punctures back into the vessel lumen on the distal side of the occlusion thereby achieving the bypass.

As used herein, the term "**effector**" refers in a non limiting manner to a member or actuator adapted to cause or achieve a result or to produce an outcome or to accomplish an effect (e.g. forcing apart the tissue layers of the vessel wall).

As used herein, the term "**hollow support element**" refers in a non limiting manner to an element (hollow thin channel) that is adapted to (a) mechanically support the guide wire; and, (b) enable introduction of any substance (e.g., contrast agent) into the intima puncturing point. According to a preferred embodiment of the present invention the hollow support element is a micro catheter. Alternatively the hollow support element can be any hollow (tube-like) element.

Catheters for bypassing occlusions in vessels (e.g. arteries) through the sub-intimal space are known in the art. Such catheters are designed to allow a guide-wire advanced therethrough to puncture the intima upstream of the occlusion, bypass the occlusion through a sub-intimal space and puncture out of the intima to re-enter the vessel lumen downstream of the occlusion. Initial puncturing of the intima and advancement of a guide-wire into the sub-intimal space is considered fairly straightforward, however, reentry into the vessel lumen can be challenging since it requires angling (bending) of the guide-wire with respect to its advancement axis. Such angling is typically achieved via deflection mechanisms mounted on the delivery catheter or by use of angled guide-wires. While deflection of the guide-wire can be used to achieve re-entry, it carries several inherent limitations. Deflection requires correct orientation of the guide-wire in the direction of the lumen and it reduces the amount of force that the guide-wire tip applies to the intima (due to guide-wire angling and buckling).

While reducing the present invention to practice, the present inventors have devised a catheter which can be used to bypass an occlusion while being free of the above limitations. As is further described herein and illustrated in Figures **1a-g**, the present catheter is configured for angling the intima with respect to the guide-wire rather than angling the guide-wire with respect to the intima. Such angling of the intima is achieved via an expandable catheter mechanism (referred to herein as effector) that deflects and essentially wedges out ('tents') a portion of the intima (Figure **1F**) into the lumen and a vacuum mechanism that pulls the deflected intimal wall against the distal end of catheter thereby presenting the tip of a guide-wire advanced along the longitudinal axis of the catheter with a substantially perpendicular puncturing surface.

As is well known in the art, the vacuum source is located outside of the body and the vacuum is achieved at the distal end of the catheter such that sufficient suction (at said catheter's distal end) to at least a portion of the intima, so as to displace the same from its natural orientation, is provided.

Thus, according to another embodiment of the present invention, the catheter further comprises a vacuum port for applying suction force, by means of a source of suction (e.g., a vacuum pump) from the proximal end of said catheter, such that suction is achieved at the distal end of the catheter. This enables that sufficient suction to at least a portion of the intima, so as to displace the same from its natural orientation, is provided.

Such an intimal-deflection mechanism ensures that a guide-wire advanced through the catheter of the present invention always reenters the vessel lumen regardless of catheter orientation and maximizes force transfer to the guide-wire tip through puncturing. Thus, according to one aspect of the present invention there is provided a device for bypassing an occlusion in a biological vessel such as a blood vessel (e.g. artery).

The device includes an elongated device body having a central channel (also referred to herein as "open bore-type lumen") configured for accommodating a guidewire therethrough, in that sense, the present device provides catheter-like functionality.

The present device also includes a distal portion which is provided with an effector configured for forcing apart tissue layers of a wall of the vessel to thereby angle a portion of an inner layer of the tissue layers into a lumen of the vessel. Such forcing apart of the tissue layers essentially 'tents' a portion of the inner tissue layer into the lumen of the vessel (see Figure 1F). The distal portion is also configured with a mechanism for pulling (via, for an example, suction) the angled portion of the inner tissue layer against a distal end of said elongated device body (see Figure 1G).

Such angling and pulling of the inner tissue layer enables a guide-wire advanced through the central channel and out of said distal end to puncture through the inner tissue layer and into said lumen of the vessel downstream of the occlusion (Figure 1G).

Figures 1-11 illustrate embodiments of the present device which is also referred to herein as catheter 10.

Reference is made now to FIGs. 1a-1g, illustrating catheter 10 and a procedure using same.

According to this embodiment, the catheter 10 comprises (a) at least one open-bore type lumen in fluid contact with a source of suction, said lumen characterized by a distal end and a proximal end interconnected by a main longitudinal axis substantially parallel to the main longitudinal axis of said catheter, said distal end located outside the body of said patient during the course of said treatment; (b) at least one hollow support element 90 accommodated within said lumen, reciprocally maneuverable along said main longitudinal axis; (c) at least one guide wire 30, accommodated within said hollow support element, reciprocally maneuverable along and around said main longitudinal axis of said lumen; and, (d) at least one effector 40 characterized by at least one inactive configuration and at least one active configuration. The active configuration characterized by at least a portion of the proximal end of said effector protrudes from said proximal end of said open-bore type lumen.

The open-bore type lumen and said effector, in said active configuration, are adapted to apply, by means of said source of suction, sufficient suction (at the catheter's distal end) to at least a portion of the intima so as to displace the same from its natural orientation. The effector **40** defines, in said active configuration, a volume bounded on at least one side by a portion of the intima of said vessel that is displaced from its natural orientation to an orientation in which said guide wire will penetrate said intima and reenter said vessel.

It is acknowledged that the support element **90** provides support and stabilization to said guide wire when said effector is in said active configuration and the proximal end of said guide wire is extended beyond the proximal end of said lumen so as to enable said guide wire to penetrate said intima and reenter said lumen.

It is acknowledged that the hollow support element **90** may be made of any biologically compatible material that is sufficiently flexible to bend with the catheter, but sufficiently stiff that the unsupported portion thereof can hold its configuration without sagging.

According to a preferred embodiment of the present invention, the hollow support element **90** is a micro catheter adapted to (a) mechanically support the guide wire; and, (b) enable introduction of any substance (e.g., contrast agent) into the intima puncturing point.

It should be emphasized that the hollow support element **90** can also be configured as any hollow (tube-like) element.

Figures **1a-g** illustrate the steps of a bypass procedure as effected using catheter **10** of the present invention.

Figure **1a** illustrates a blood vessel **100** having an occlusion **89**. Figures **1b** illustrates puncturing of the intima upstream of occlusion **89** via guidewire **30** having a sharpened tip. Guidewire **30** is then advanced through the intima - into the sub-intimal space and farther along the occluded section to the downstream end of the occlusion (Figure **1c**). Catheter **10** is then advanced over the wire through the opening in the intima and positioned in the sub-intimal space with the distal end of catheter **10** positioned downstream of occlusion **89** (Figure **1d**).

The outer tube of catheter **10** is then pulled back with respect to hollow support element **90** thereby releasing effector **40** trapped within the outer tube of catheter **10** (Figures **1e-f**). Deployment (i.e., expansion) of effector **40** forces the relatively compliant intima layer into the lumen (Figure **1f**) and angles a portion of the intima layer with respect to guide-wire **30**. In preferred embodiments of the present invention, the proximal end of the catheter is

attached to a suction source (e.g. vacuum pump, syringe), and suction is applied through the catheter to pull in the angled portion of the intima against the distal end of catheter **10**. The suction is preferably applied once the effector is in its active configuration (expanded) and in contact with the intima.

It should be pointed out that the effector **40** can be deployed (and thereby expand) by at least one movement selected from:

- (a) longitudinally moving said hollow support element with respect to said channel;
- (b) pulling/pushing the hollow support element with respect to the channel;
- (c) pulling/pushing the effector with respect to the channel; (d)
- (d) pulling/pushing the channel with respect to the effector; and any combination thereof

The suction is sufficiently strong to stabilize effector **40** in position (300-700 mmHg and stretch the intima against the effector distal tip).

Guide-wire **30** is then extended beyond the distal end of catheter **10**, while being supported and stabilized by hollow support element **90** (which extends into a 'volume' defined by effector **40**). This ensures that guide-wire **30** is supported through penetration of the intima and re-entry into the lumen and ensures that guide wire **30** does not deflect from the longitudinal axis set by hollow support element **90**.

While reducing the present invention to practice, the present inventors have uncovered that in order to effectively puncture the intima and reenter the lumen, the guidewire requires mechanical support.

An unsupported guide-wire tends to buckle under push forces against the intima. Such buckling could deflect the guide-wire from its path and lead to undesired penetration of other tissue layers of the vessel and vessel lumen re-entry failure (and possibly outer vessel wall puncturing). Use of hollow support element **90** stabilizes guide-wire **30** thereby enabling transmission of push forces to the tip of guide-wire **30** and effective intima puncturing and vessel lumen re-entry.

Thus, as mentioned above, ideally, the guide wire penetrates the intima, thereby reentering the vessel lumen, at a location substantially along the longitudinal axis of the catheter, but support element **90** ensures that it will not puncture any part of the intima other than that being held in place by the effector (i.e. distorted from its natural orientation and about perpendicular to the motion of the guide wire).

It is also within the scope of the present invention to disclose a method for treating an occlusion in a vessel that uses the catheter herein disclosed. In this method, the guide wire penetrates the intima at a position proximal to the occlusion. The catheter (and guide wire, hollow support element, and effector within) are then advanced through the vessel between the intima and the vessel's outer wall. After the catheter has been advanced sufficiently far that its distal end is beyond the distal end of the occlusion, the guide wire penetrates the intima a second time according to the procedure illustrated in FIGs. **1a-1g**, thereby reentering the vessel lumen and bypassing the occlusion.

In some embodiments of the invention, at least one of the lumen and the catheter are articulated. As with the guide wire, the primary advantage of articulating one or both of the lumen and the catheter is that such articulation allows for more precise positioning of the distal end of the device in order to ensure that the guide wire will penetrate the tissue at the point desired by the operator. Any type of articulated catheter or lumen known in the art may be used.

In some embodiments of the invention, it additionally comprises means for verifying that the guide wire has penetrated the intima at the desired location. Such means are well-known in the art. In some embodiments of the invention, the verification means comprise a contrast agent that has been injected into the vessel. In other embodiments, the verification means comprise observation of blood exiting the vessel through a hole cut around the point at which the guide wire penetrates the intima. In preferred embodiments, following guide wire reentry into the vessel, the hollow support element is advanced over the wire into the vessel, the wire is then removed from the catheter and once blood flows out of the catheter proximal end reentry is verified.

Reference is now made to Figs. **1H- 1J** illustrating another embodiment of the present invention in which contrast agent is introduced through said support element **90**.

According to a preferred embodiment of the present invention, the contrast agent is introduced by means of said support element **90**. In other words the contrast agent is introduced through said support element **90**. Said contrast agent is provided so as to verify that the guide wire has penetrated the intima at the desired location.

As seen in Figs. **1H**, after the guide wire **30** has penetrated the intima, the support element **90** follows the same and penetrates the intima,

In Figs. **1I-1J** the guide wire is pulled back and extracted. The support element **90** is maintained at its position. At this point, contrast agent **201** is introduced through said support element **90**. Then, by using imaging means, verification that the support element **90** (and thus, the guide wire **30**) penetrated the intima at the desired location is provided.

Once the verification is obtained, the guide wire is re-introduced (see Fig. **1K**); and the following actions are taken:

- a) the hollow support element **90** is extracted (see Fig. **1L**);
- b) the effector **40** is reconfigured to its inactive configuration and is retracted into the catheter **10** (see Figs. **1M-1N**);
- c) lastly, the catheter **10** is extracted (see Figs. **1O-1P**).

Reference is now made to Fig. **1Q** illustrating again the catheter according to some embodiments of the present invention. Fig. **1Q**, again, illustrates the catheter **10**, the effector **40**, the hollow support element **90** and the guide-wire **30**. It should be pointed out that each of the above mentioned elements (the catheter **10**, the effector **40**, the hollow support element **90** and the guide-wire **30**) can be independently and linearly moved one with respect to the other.

In some embodiments of the invention, at least one marker is placed on at least part of the effector, the distal end of the catheter, the lumen, the hollow support element, or the guide wire. In embodiments in which the effector comprises a plurality of components, a marker may be placed on each of them. The markers are used to enable the operator to determine the exact location of the distal end of the component of the system on which the marker has been placed. In addition, markers placed on the effector enable the operator to determine directly whether the effector is in its active or inactive configuration. Such markers are well known in the art. Non-limiting examples of markers useful in the present apparatus include visual markers (e.g. dye or paint), ultrasonic transducers, etc.

In another embodiment of the invention, the effector is at least partially made of a shape memory alloy (e.g., Nitinol) with a front segment which, when unconstrained, takes on a three dimensional form to prevent collapse of tissue into its interior. One non-limiting example of a possible shape is a helix/coil with a diameter similar to or somewhat larger than that of the guide wire or catheter. Other non-limiting examples of shapes that are within the scope of the invention include a variety of patterns (mesh/basket) creating a three dimensional shape such as a toroid, a sphere, a cone, a cylinder or an ovoid. The tip (front end) of the thin preformed

spacing wire can be, for example, a sphere with a diameter which may be larger than that of the catheter, or it can be tightly curled up so that it does not have a sharp pointing tip and thus would not cause trauma to surrounding tissues.

The hollow support element can move reciprocally within the lumen, at least to the extent of being extendable at least several mm from the distal end of the lumen. As will be described in more detail below, the hollow support element can be maneuvered independently of the guide wire, and the guide wire independently of the hollow support element, although the two can be maneuvered together (i.e. both move relative to the lumen but not relative to each other) if necessary. In typical embodiments of the invention, the hollow support element is accommodated within the lumen. An airtight fit within the lumen is not desirable not only because the hollow support element must be able to move relative to the lumen, but also because there must be an uninterrupted fluid connection between the proximal and distal ends of the catheter so that suction may be applied to the distal end.

According to another embodiment of the present invention, the catheter, as described above, further comprising actuating means for actuating the reconfiguration of said effector between said active and inactive configurations.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein said actuating means is selected from the group consisting of magnetic means, heat means, electric means, mechanical means, and any combination thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein said actuating means additionally comprises means for moving the effector in and out of said lumen.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the actuating mechanism comprises at least one wire mechanically connected to the effector.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the distal end of the effector is open.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the area of the cross-section of said effector as measured in the plane perpendicular to the longitudinal axis of the catheter varies along said main longitudinal axis of the catheter.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the area of the cross-section of the effector as measured in the plane perpendicular to the longitudinal axis of the catheter increases along said main longitudinal axis of said catheter.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein, when the effector is in said active configuration, the cross-sectional area of at least a portion of said part of the effector that protrudes from the catheter, as measured in a plane perpendicular to the longitudinal axis of said catheter, is greater than the cross-sectional area of the catheter as measured in a plane perpendicular to the longitudinal axis of the catheter.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the guide wire has a sharpened tip (e.g. beveled).

It is a further object of this invention to disclose a catheter as defined in any of the above, further comprising actuating mechanism for reversibly moving the effector along and around the main longitudinal axis of said catheter.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the source of suction provides sufficient suction (at the catheter's distal end) such that, when the effector is in the active configuration and suction is applied, the effector is fixed against the inner surface of the vessel, so as to enable said guide wire to reenter the vessel lumen, and bypass the occlusion.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein at least a portion of the effector is made of a material having shape memory properties, electroactive polymers (EAPs), and any combination thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the material having shape memory properties is a cobalt-based alloy, a NiTi-based material, or any combination thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the EAP is a ferroelectric polymer, a liquid crystalline polymer, an ionic EAP, or any mixture thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the open-bore type lumen (central channel) is provided with an articulation mechanism.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the hollow support element is provided with an articulation mechanism.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the effector is provided with an articulation mechanism.

It is a further object of this invention to disclose a catheter which also includes an element for verifying the location at which the guide wire has penetrated the intima.

It is a further object of this invention to disclose a catheter which also includes at least one marker at the distal end of the guide wire, the hollow support element, the lumen (central channel), the catheter body (also referred to herein as "elongated device body"), the effector and any combination thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the marker is adapted to indicate the relative position of between the guide wire, the hollow support element, the lumen, the catheter, and/or the effector.

It is a further object of this invention to disclose a catheter which also includes at least one marker disposed at the distal end of the catheter, and is adapted to indicate the full reconfiguration of the effector from the inactive configuration (non-expanded) to the active configuration (expanded).

It is a further object of this invention to disclose a catheter adapted to enable linear movement along the main longitudinal axis of the guide wire, the hollow support element, the effector or any combination thereof with respect to the guide wire, the hollow support element, the effector or any combination thereof.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the effector is a cone-shaped stent-like effector (see Figs. **9a** and **9b**), a bagel shape braded effector (see Figs. **10a** and **10b**), and cone shaped braded effector (see Figs. **11a** and **11b**).

Reference is now made to FIGs. **9A-9B** illustrating the present catheter having a cone-shaped stent-like effector. Fig. **9B** provides a cross sectional view of the effector as presented in Fig. **9A**.

Reference is now made to FIGs. **10A-10B** illustrating the catheter as any of the defined above, wherein the effector is a bagel shape braded effector. Fig. **10B** provides a cross sectional view of the effector as presented in Fig. **10A**.

Reference is now made to FIGs. **11A-11B** illustrating the catheter as any of the defined above, wherein the effector is a cone shaped effector. Fig. **11B** provides a cross sectional view of the effector as presented in Fig. **11A**.

According to another embodiment of the present invention the reconfiguration of the effector from the inactive configuration to the active configuration (and vice versa) is performed either actively or passively using an actuation mechanism.

As disclosed above, the actuating mechanism can be by e.g., application of magnetic force, application of heat, application of an electrical field, application of mechanical force (via cables/strut linkages) or any combination thereof.

Furthermore, it should be understood that passively reconfiguring the effector from the inactive configuration to the active configuration (and vice versa) is provided by providing the effector from materials such that when at least a portion of the distal end of the effector protrudes from the distal end of the catheter it passively (i.e., without any external actuation from the user) reconfigures from inactive configuration to the active configuration.

In other words, in the passive reconfiguration of the effector, when the effector is maintain within the catheter, the effector is constrained by the catheter; and, hence is maintained in the inactive configuration. When at least a portion of the effector protrudes out of the catheter, the same is no longer constrained by the diameter of the catheter and hence can be converted to the active configuration.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein at least a portion of the distal face of said effector, can, when in the active configuration buckle (flatten) against the tissue.

It is a further object of this invention to disclose a catheter as defined in any of the above, wherein the effectors wires branch such that expansion of the effector results in at least partial encircling of the distal end of said catheter.

The following disclosure provide a further detail on the catheter as being able to at least partially buckle in the proximal direction.

In one aspect of the invention, the active configuration of the at least one effector includes a conformation in which at least a portion of the distal end of the at least one effector is adapted to at least partially encircle or surround or enclose at least part of the outer circumference or outer rim of the distal end of the catheter.

In a further aspect of the invention, at least a portion of the distal end of the at least one effector is adapted to be at least partially buckled towards the distal end of the catheter whilst at least partially encircling at least part of the outer circumference of the distal end of said catheter. In another aspect of the invention, the distal end of the at least one effector, in its active configuration, is diverged in a non single-point assembled manner, such that the distal end of the effector is open, or is assembled into a single point positioned at the distal end of the guide wire such that the distal end of the at least one effector is converged to a single point. In both cases the distal end of the at least one effector is located adjacent to the occlusion site within the vessel.

An active configuration as herein disclosed may preferably include three dimensional conformations comprising loop-like, helix-like and coiled, curled, spiral, spring-like, or branch-like elements, structures or conformations or a combination thereof. In some embodiments of the invention, at least a portion of the at least one effector in its active configuration has a conformation or shape selected from a group consisting of sphere, cone, cylinder, egg-like, loop-like, ball-like, ovoid-like, globular-like, globe-like, orbicular-like, polygonal having n ribs, n is an integer greater than 2, and any combination thereof.

According to certain embodiments of the invention, the effector conforms or reconfigured into the active configuration by an either passively or actively facilitated actuating mechanism.

In some embodiments of the invention, the inactive configuration of the effector is at least partially disposed within the lumen and thus is constrained from reconfiguring into its active configuration by the lumen of the catheter. In other embodiments of the invention, in its inactive configuration, the effector is at least partially located outside the lumen protruding out of the distal end of the catheter.

In preferred embodiments of the invention, at least a portion of the effector is made of materials having shape memory properties. Non-limiting examples of suitable shape memory materials include copper-zinc-aluminum-nickel, copper-aluminum-nickel, and nickel-titanium (NiTi) based materials such as Nitinol, and mixtures thereof.

In other embodiments of the invention, at least a portion of the effector is made of materials comprising electroactive polymers. As used herein, the term "Electroactive Polymers" (EAPs) refers to polymers that exhibit a change in size or shape when stimulated by an electric field. EAPs are characterized by the ability to substantially undergo deformation while sustaining large forces. Such materials are commonly used in actuators and sensors.

Non-limiting examples of EAPs suitable for use in the present invention include dielectric EAPs, ferroelectric polymers, liquid crystalline polymers, ionic EAPs, and mixtures thereof.

In some embodiments of the invention, reconfiguration of the effector between the inactive and active configurations is performed by means of an actuating mechanism. Non-limiting examples of such actuating mechanisms include electric current, hydraulic pressure, pneumatic pressure, application of heat, application of a magnetic field, mechanical means or any combination thereof. Means and methods for performing such reconfiguration are well-known in the art.

According to a further main aspect of the invention, the distal end of the effector is open in its active configuration. Such an open configuration enables the guide wire to pass or protrude through the effector in order to penetrate the intima and to reenter the vessel at a point distal to the occlusion, thereby bypassing it.

In certain embodiments, the open configuration (for example FIG. 7a) enables the effector to reconfigure into the inactive configuration by being pulled back into the catheter, while the guide wire remains exposed within the inner surface of the vessel.

Reference is made now to FIG. 2, which illustrates schematically a catheter **10** comprising an effector **40** with dispersed wired arms **45**. The catheter **10** is adapted to accommodate within its longitudinal lumen **20** a guide wire **30** and at least a portion of the effector.

In preferred embodiments of the invention, the catheter **10** has an external diameter of about 0.8-2 mm.

The lumen **20** has an internal diameter of approximately 0.014" (0.36 mm).

After insertion of the catheter adjacent to an occlusion within a vessel, the effector is reconfigured from the inactive configuration to the active configuration so as to emerge from lumen **20** and hence from the catheter.

After emerging from the distal end of the catheter, the effector assumes its active configuration. In the embodiment shown in FIG. 2, at least a portion of the distal end of the effector comprises a plurality of dispersed wired arms **45**. In the non-limiting example shown in the figure, the distal end of the effector comprises six wired arms **45**.

In some embodiments of the invention, each of the wired arms comprises more than one segment **55**.

In the active configuration, the arms are disposed so as to at least partially encircle at least the distal end of the catheter.

In some embodiments of the invention, the wired arms are buckled or bent backwards in the proximal direction. In some embodiments of the invention, in the inactive configuration, the wired arms are disposed within the lumen **20** but protrude from the lumen in the active configuration.

In some embodiments of the present invention, in the inactive configuration the wired arms protrude from of the lumen **20** and in the active configuration the wired arms buckle or bend backwards (proximally).

According to another embodiment of the present invention, once the wired arms protrude from the lumen **20** they can either be passively buckled or bent backwards or be actively buckled or bent backwards.

In the active buckling mode, an actuation mechanism activates the wired arms and reconfigures them from the initial configuration to the buckled configuration, in which said wired arms at least partially encircle or enclose at least a portion of the catheter. In this mode the wired arms are made of material with elastic properties, such as shape memory alloys, EAPs or other materials with elastic or flexible elements.

In the passive buckling mode the wired arms are reconfigured from the initial configuration to the buckled configuration without use of an external actuation mechanism. This may be accomplished, for example, by having the wired arms being constructed such that they naturally assume the active configuration, but until the effector exits the lumen, they are prevented from undergoing such expansion by the walls of the lumen. In this mode the wired arms are made of material with elastic properties, such as spring-like properties, shape memory alloys, EAPs or other materials with elastic or flexible elements. If the wired arms are made of, e.g., spring-like material, once they are extracted from lumen **20**, the constraints of the lumen are removed and the wired arms buckle.

It is thus within the scope of the invention to provide an effector made of a plurality of individual flexible wires **45** characterized by a spring-like characteristics. The wires can be fabricated via extrusion or laser-cut from a flat sheet or tube (e.g. Nitinol tube).

Alternatively, the emergence of the effector from the catheter can be facilitated by a pushing member **60** (in some embodiments, a wire) mechanically connected to the distal end of the effector branches **45**.

In another embodiment, the effector is reconfigured into its active configuration by an active mechanism, for example by an actuating means.

As illustrated in FIG. 2, the wired arms of the effector in its active configuration are folded or curled backward, such that at least a portion of the distal ends of the arms encircle the distal end of the catheter. Such an active configuration is designed to define a volume through which the guide wire 30 can bypass the occlusion.

Reference is now made to FIG. 3A, which illustrates schematically a catheter 10 comprising an effector 40 with a coiled or spring like shaped wire. Once the effector emerges from the distal end of the lumen 20, the distal end of the effector 40 deforms into a coiled three dimensional conformation.

As shown in this figure, the effector is reconfigured to a spring- like or curled shape with two helices or loop-like structures 42 that encircle at least a portion of the distal portion of the catheter in a symmetrical manner, with respect to the main longitudinal axis of the lumen.

In this configuration, a void volume or space is defined within the vessel, enabling the catheter accommodating the guide wire 30 to approach the occlusion such that the distal end of the guide wire at least partially extends from the distal end of lumen 20 and may penetrate the intima at downstream of the occlusion and to reenter the vessel lumen, thereby bypassing the occlusion.

Reference is now made to FIG. 3B, which schematically illustrates a catheter comprising two effectors with a spring-like shape as in FIG. 3A.

In this figure, each of the effectors 40 has a helical shape in its unconstrained active, encircling the distal part of the outer circumference of the catheter 10.

As illustrated in the figure, the two effectors comprise wires extending from the distal end of the lumen 20 of the catheter 10 that are tightly curled into a spring like configuration encircling the outer rim of the catheter 10 and providing the effector with substantial mechanical strength, stabilizing and fixing the effector in the inner surface of the vessel.

Effectors in the shape of springs with a constant pitch and those in the shape of springs with a variable pitch 47 are contemplated by the inventor as being within the scope of the invention.

In certain embodiments of the invention the spring-like configuration comprises a plurality of n loops 42, each of which is characterized by a radius R_n . The radius may vary from loop to loop (i.e., in some embodiments, $R_n \neq R_m$ for at least some values of $m \neq n$).

Alternatively, as shown in FIG. 3C, the catheter may comprise three separate effecters **40** characterized by three separate curled wires protruding from the distal end of the lumen **20** of the catheter **10** and configured into a tightly coiled spring-like configuration encircling at least a portion of the outer rim of the catheter **10**.

Reference is now made to FIG. 4, schematically illustrating an alternative embodiment of the present invention. In the figure, the effector is shown in its active configuration. In the figure, the unconstrained effector comprises three separate wired parts **45** or branches extruding out of the distal end of the catheter **10**.

In a preferred embodiment, at least a portion of the distal end of the wired arms is deformed into a zigzag shaped configuration at least partially encircling the distal part of the catheter **10**.

As shown in FIG. 4A, the effector may comprise more than one member (the three separate wired members illustrated in the figure exemplify one embodiment and are not intended to limit the invention). Each one of the effector members deforms into its predetermined conformation upon emerging from the distal end of the lumen of the catheter, thereby forming a three dimensional structure enclosing the main longitudinal axis of the lumen.

FIG. 4B illustrates a front view of the effector shown in FIG. 4A. The front view schematically presents the upper part of an embodiment in which the effector is characterized by three sections **45** dispersed in three directions, encircling the outer borders of the catheter **10**.

According to preferred embodiments of the invention, such an active configuration is adapted to form a defined volume within the vessel throughout which the guide wire **30** protrudes to bypass the occlusion.

Reference is now made to FIG. 5, schematically illustrating another embodiment of the effector in its active configuration. The effector shown in this figure comprises a plurality of n loops **80** encircling the outer circumference of the catheter **10**. The loops are interconnected to each other in at least one location by wired elongated members **85** or buckled towards the distal end of the catheter **10** (backwards).

Reference is now made to FIG. 6A, schematically illustrating a catheter comprising an effector with a spring-like active configuration **40**. In FIG. 6A, the spring protrudes out of the distal end of the lumen **20**, forming a spring-like shape comprising a helical structure **42**.

In one embodiment, the loops are characterized by a constant radius R. In another embodiment, the loops are characterized by radius which varies as a function of the position of the loop along the longitudinal axis of the effector. Non-limiting examples of such a variable-radius effector include a constantly increasing radius as one advances in the distal direction, a constantly decreasing radius as one advances in the proximal direction, a radius that increases to a maximum and then decreases, etc. As illustrated in FIGs. 6a-6b, such an active configuration is adapted to define a volume throughout which the guide wire 30 can be moved.

As mentioned above, in some embodiments of the present invention, the effector is characterized by an open distal end.

Reference is now made to FIG. 7A, which illustrates schematically a catheter comprising an effector with wired elements 45 that have an open distal end in the active configuration. In this active configuration, after emergence of the effector from the catheter confines, the guide wire 30 is adapted to be insertable throughout the space or volume defined by the arm-like elements of the effector, to enable the guide wire to penetrate the intima at the distal end of the occlusion reenter the vessel at the distal end of the occlusion, thereby bypassing the occlusion.

Reference is now made to FIG. 8, which schematically illustrates a catheter comprising an effector comprising several segments or parts 45, each part forming a zigzag shaped active configuration.

It is within the scope of the invention that the wired segments define a hollow spherical or essentially spherical volume or space.

The wired segments protrude out of the distal end of the catheter 20, and are re-assembled into one location 100 positioned at the distal part of the guide wire 30, enabling the guide wire to bypass the occlusion. An actuating mechanism 70 is adapted to activate the effector. In the embodiment illustrated in FIG. 8, the actuating mechanism 70 is simply a wire that reciprocally moves along the main longitudinal axis of the catheter such that the linear movement reconfigures the effector 40 from its inactive configuration, in which the segments 45 are compressed and packed together; to the active configuration in which the segments 45 are deployed.

In some embodiments of the invention, the catheter has an outer diameter of between about 0.035" and about 0.078" (0.89 – 2 mm).

In some embodiments of the invention, the guide wire has a diameter of between about 0.008" and about 0.018" (0.2 – 0.46 mm).

In another embodiment of the invention, the effector is at least partially made of a shape memory alloy (e.g., Nitinol) with a front segment which, when unconstrained, takes on a three dimensional form to prevent collapse of tissue into its interior. One non-limiting example of a possible shape is a helix with a diameter similar to or somewhat larger than that of the guide wire or catheter. Other non-limiting examples of shapes that are within the scope of the invention include a variety of patterns creating a surface contour of a sphere, a cone, a cylinder or an egg-like form. The tip (front end) of the thin preformed spacing wire can be, for example, a sphere with a diameter which may be larger than that of the catheter, or it can be tightly curled up so that it does not have a traumatic tip.

As used herein the term "about" refers to $\pm 10\%$.

Additional objects, advantages, and novel features of the present invention will become apparent to one ordinarily skilled in the art upon examination of the following examples, which are not intended to be limiting. Additionally, each of the various embodiments and aspects of the present invention as delineated hereinabove and as claimed in the claims section below finds experimental support in the following examples.

EXAMPLES

Reference is now made to the following examples, which together with the above descriptions, illustrate the invention in a non limiting fashion.

Bench Testing a prototype of the present device

A prototype of the present device was constructed by attaching eight close ended 125 micron nitinol wire braid ('effector') to a polyamide support tube ('hollow support element') having an outer diameter of 1.6 mm and a lumen with a diameter of 0.5 mm (Figure 12) for accommodating a standard guide-wire. The support tube and attached effector were threaded into an over-tube (fabricated from PTFE) and the complete assembly ('catheter') with the effector trapped in a compressed configuration by the over-tube was inserted through an incision into a tissue pocket of excised porcine tissue. The over-tube was pulled back to

release and expand the effector and wedge out a tissue wall of the tissue pocket. Several different vacuum pressures (up to 700 mmHg vacuum) were applied through the lumen and a guidewire was threaded through the support tube out the distal end of the catheter (through the expanded effector) and used to puncture out of the tissue wall (Figure 13) simulating lumen re-entry.

The study showed that tissue penetration (reentry) by the wire was dependent on the vacuum force applied to the tissue, no penetration was observed at a vacuum force lower than 250 mmHg. In addition, it was observed that the effector could radially collapse under vacuum levels close to 700 mmHg. It was thus concluded that a vacuum of at least 300 mmHg should be used and that the effector should be braided using more wires or thicker wires to handle the radial loads applied by the vacuum.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

CLAIMS:

1. A device for bypassing an occlusion in a vessel comprising an elongated device body including:
 - (a) a channel configured for accommodating a guidewire therethrough; and
 - (b) a distal portion being configured for:
 - (i) forcing apart tissue layers of a wall of the vessel to thereby angle a portion of an inner layer of said tissue layers into a lumen of the vessel; and
 - (ii) pulling said portion of said inner tissue layer against a distal end of said elongated device body;thereby enabling a guide-wire advanced through said central channel and out of said distal end to puncture through said inner tissue layer and into said lumen of the vessel downstream of the occlusion.
2. The device of claim 1, wherein said distal portion includes an effector being expandable to force apart said tissue layers of said wall when positioned therebetween.
3. The device of claim 1, wherein (ii) is effected via suction.
4. The device of claim 2, wherein said effector is mechanically expandable.
5. The device of claim 2, further comprising a hollow support element disposed within said channel.
6. The device of claim 5, wherein said hollow support element is selected from a group consisting of a micro-catheter, hollow element, tube-like element and any combination thereof.
7. The device of claim 6, wherein said hollow support element is movable along a longitudinal axis of said channel.
8. The device of claim 3, wherein said suction is provided by a vacuum port positioned at either said distal end or the proximal end of said device, such that suction force is applied at the a distal end of the device.
9. The device of claim 2, further comprising a handle positioned at a proximal end of said elongated device body, said handle being for actuating said effector and the hollow support element.
10. The device of claim 7, wherein said effector is trapped between said hollow support element and said channel and expansion of said effector is effected by at least one

selected from a group consisting of (a) longitudinally moving said hollow support element with respect to said channel; (b) pulling/pushing the hollow support element with respect to the channel; (c) pulling/pushing the effector with respect to the channel; (d) pulling/pushing the channel with respect to the effector; and any combination thereof.

11. The device of claim 9, wherein actuation of said effector includes movement thereof with respect to said elongated device body.
12. The device of claim 9, wherein said effector includes at least one wire capable of forming said effector when extended out of said elongated device body.
13. The device of claim 12, wherein said at least one wire forms at least one coil, at least one loop, a basket or a half ball preshaped braid when extended out of said elongated device body.
14. The device of claim 13, wherein said at least one loop includes a plurality of overlapping loops.
15. The device of claim 12, wherein said at least one wire is composed of a shape memory material.
16. The device of claim 15, wherein said shape memory material is Nitinol.
17. The device of claim 2, wherein said effector forms a toroid, a cone or a ball when expanded.
18. The device of claim 1, wherein said elongated device body is capable of articulation.
19. The device of claim 2, wherein said hollow support element is configured capable of advancement through said inner tissue layer.
20. The device of claim 1, wherein the vessel is an artery and said inner tissue layer is an intima.
21. A system comprising the device of claim 1 or 6 and a guide-wire disposed within said channel or said hollow support element.
22. The device of claim 16, wherein a distal tip of said guide-wire is configured for puncturing tissue.
23. The device of claim 1, wherein said elongated device body is configured such that it curves towards said lumen when said tissue layers of said wall of the vessel are forced apart.
24. The device of claim 6, additionally comprising verification means for verifying the location at which said guide wire has penetrated said intima.

25. The device of claim **24**, wherein said verification means are introduced through said hollow support element.
26. The device of claims **24** or **25**, wherein said verification means are contrast agents.
27. A method of bypassing an occlusion in a vessel comprising:
 - (a) positioning a device between tissue layers of a wall of the vessel;
 - (b) forcing apart said tissue layers of said wall of the vessel to thereby angle a portion of an inner tissue layer of said tissue layers into a lumen of the vessel;
 - (c) pulling said portion of said inner tissue layer against a distal end of said elongated device body;
 - (c) advancing a guide-wire through said device and out of a distal end thereof to puncture through said inner tissue layer and into said lumen of the vessel thereby bypassing the occlusion.
28. The method of claim **27**, wherein the vessel is an artery and said inner tissue layer is an intima.
29. The method of claim **27**, wherein (b) is effected via an effector being expandable between said tissue layers.
30. The method of claim **27**, wherein (c) is effected via suction.
31. The method of claim **27**, wherein said device includes an elongated device body having a central channel.
32. The method of claim **27**, wherein (b) is effected via an effector being expandable to force apart said tissue layers of said wall when positioned therebetween.
33. The method of claim **32**, wherein said effector includes at least one wire capable of forming said effector when extended out of said device.
34. The method of claim **27**, further comprising puncturing said inner tissue layer upstream of said occlusion prior to (a) to thereby position said device between said tissue layers of said wall of the vessel.
35. The method of claim **27**, further comprising step of providing said device with a hollow support element disposed within said channel.
36. The method of claim **35**, wherein said hollow support element is selected from a group consisting of a micro-catheter, hollow element, tube-like element and any combination thereof.
37. The method of claim **35**, additionally comprising step pr providing verification means for verifying the location at which said guide wire has penetrated said intima.

38. The device of claim **37**, wherein said verification means are introduced through said hollow support element.
39. The method of claims **37** or **38**, wherein said verification means are contrast agents.
40. A catheter for bypassing an occlusion comprising:
- (a) a first tube having an inner lumen configured for accommodating a guidewire therethrough
 - (b) an expandable wire structure attached to a distal end of said first tube; and
 - (c) a second tube having a lumen for accommodating said first tube and said expandable wire structure therein such that moving said first tube with respect to said second tube releases and expands said expandable wire structure from a distal end of the catheter.
41. The catheter of claim **40**, further comprising a vacuum port for applying a suction force at the distal end of the catheter.
42. A catheter for treatment of an occlusion in a vessel of a patient, comprising:
- at least one open-bore type lumen in fluid contact with a source of suction, said lumen characterized by a distal end and a proximal end interconnected by a main longitudinal axis substantially parallel to the main longitudinal axis of said catheter, said proximal end located outside the body of said patient during the course of said treatment;
 - at least one hollow support element accommodated within said lumen, reciprocally maneuverable along said main longitudinal axis;
 - at least one guide wire, accommodated within said hollow support element, reciprocally maneuverable along and around said main longitudinal axis of said lumen; and,
 - at least one effector characterized by at least one inactive configuration and at least one active configuration, said active configuration characterized by:
 - at least a portion of the distal end of said effector protrudes from said distal end of said open-bore type lumen; and,
 - said open-bore type lumen and said effector, in said active configuration, are adapted to apply, by means of said source of suction, sufficient suction to at least a portion of the intima so as to displace the same from its natural orientation;
 - said effector defines, in said active configuration, a volume bounded on at least one side by a portion of the intima of said vessel that is displaced from its natural orientation to an orientation in which said guide wire will penetrate said intima and reenter said vessel;

wherein said support element provides support and stabilization to said guide wire when said effector is in said active configuration and the distal end of said guide wire is extended beyond the distal end of said lumen so as to enable said guide wire to penetrate said intima and reenter said lumen.

43. The catheter according to claim 42, further comprising actuating means for actuating the reconfiguration of said effector between said active and inactive configurations.
44. The catheter according to claim 43, wherein said actuating means is selected from the group consisting of magnetic means, heat means, electric means, mechanical means, and any combination thereof.
45. The catheter according to claim 43, wherein said actuating means additionally comprises means for moving said distal end of said effector in and out of said lumen.
46. The catheter according to claim 43, wherein said actuating mechanism comprises at least one wire mechanically connected to said effector.
47. The catheter according to claim 42, wherein the area of the cross-section of said effector as measured in the plane perpendicular to the longitudinal axis of said catheter varies along said main longitudinal axis of said catheter.
48. The catheter according to claim 42, wherein the area of the cross-section of said effector as measured in the plane perpendicular to the longitudinal axis of said catheter increases along said main longitudinal axis of said catheter.
49. The catheter according to claim 42, wherein, when said effector is in said active configuration, the cross-sectional area of at least a portion of said part of said effector that protrudes from said catheter, as measured in a plane perpendicular to said longitudinal axis of said catheter, is greater than the cross-sectional area of said catheter as measured in a plane perpendicular to said longitudinal axis of said catheter.
50. The catheter according to claim 42, wherein said effector, when in said inactive configuration, is disposed within said catheter, and further wherein the walls of said lumen constrain said effector from reconfiguration to said active configuration.
51. The catheter according to claim 42, wherein the shape of at least a portion of said distal end of said effector is selected from the group consisting of at least one curled wire, at least one wire with a zigzag shape, at least one wire with a spring-like shape, and any combination thereof.
52. The catheter according to claim 42, wherein said guide wire has a sharpened tip.

53. The catheter according to claim **42**, wherein said effector is disposed outside of said lumen when it is in said inactive configuration.
54. The catheter according to claim **42**, further comprising actuating means for reversibly moving said effector along and around said main longitudinal axis of said catheter.
55. The catheter according claim **42**, wherein said source of suction provides sufficient suction such that, when said effector is in said active configuration and suction is applied, said effector is fixed against the inner surface of said vessel, so as to enable said guide wire to reenter said lumen, thereby bypassing said occlusion.
56. The catheter according to claim **42**, wherein at least a portion of said effector is made of a material chosen from the group consisting of materials having shape memory properties, electroactive polymers (EAPs), and any combination thereof.
57. The catheter according to claim **56**, wherein said material having shape memory properties is selected from the group consisting of copper-based alloys, NiTi-based materials, and any combination thereof.
58. The catheter according to claim **56**, wherein said EAP is of a type selected from the group consisting of dielectric EAPs, ferroelectric polymers, liquid crystalline polymers, ionic EAPs, and any mixture thereof.
59. The catheter according to claim **42**, wherein said effector, in said active configuration, is adapted to provide a preset void volume; said preset void volume is defined by means of said effector, the distal end of said catheter and the inner surface between the subintimal space and the vessel; said source of suction is adapted to apply suction within said preset void volume, so as to enable said guide wire and to puncture the intima.
60. The catheter according to claim **42**, wherein said open-bore type lumen is provided with an articulation mechanism.
61. The catheter according to claim **42**, wherein said hollow support element is provided with an articulation mechanism.
62. The catheter according to claim **42**, wherein said effector is provided with an articulation mechanism.
63. The catheter according to claim **42**, wherein said guide wire is provided with an articulation mechanism.
64. The catheter according to claim **42**, additionally comprising verification means for verifying the location at which said guide wire has penetrated said intima.

65. The catheter according to claim **64**, wherein said verification means are chosen from the group consisting of a contrast agent, observation of blood passing through a hole about the point of penetration of said intima by said guide wire and any combination thereof.
66. The catheter according to claim **42**, wherein said hollow support element is selected from a group consisting of a micro catheter, hollow element, tube-like element and any combination thereof.
67. The catheter according to claim **66**, wherein verification means for verifying the location at which said guide wire has penetrated said intima is introduced through said hollow support element.
68. The catheter according to claim **67**, wherein said verification means are contrast agents.
69. The catheter according to claim **42**, additionally comprising at least one marker at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof.
70. The catheter according to claim **69**, wherein said at least one marker is adapted to indicate the relative position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector; with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector.
71. The catheter according to claim **42**, additionally comprising at least one marker disposed at the distal end of said catheter, adapted to indicate the full reconfiguration of said effector from said inactive configuration to said active configuration.
72. The catheter according to claim **42**, wherein said reconfiguration of said effector from said inactive configuration to said active configuration is provided by means selected from (a) pulling said catheter in said proximal direction; pushing said effector in said distal direction.
73. The catheter according to claim **42**, additionally comprising at least one marker at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof, adapted to indicate the position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof with respect to said vessel or said intima.

74. The catheter according to claim **42**, wherein said hollow support element is adapted to penetrate said intima and reenter said lumen.
75. The catheter according to claim **42**, wherein said catheter is provided with a mechanism adapted to enable linear movement along said main longitudinal axis of at least one selected from a group consisting of said guide wire, said hollow support element, said effector and any combination thereof with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said effector and any combination thereof.
76. The catheter according to claim **42**, wherein said effector is a stent-like effector, a bagel shape braded effector, cone shaped effector.
77. A method for bypassing an occlusion in a vessel of a patient, comprising:
providing a catheter as defined in claim **42**;
inserting said catheter into said vessel;
reconfiguring said effector into said active configuration at a location proximal to the distal end of said occlusion, at a location desired for reentry, thereby defining a volume bounded at least partially by said effector and by a portion of the intima of said vessel at least part of which is proximal to said distal end of said occlusion;
applying sufficient suction to at least a portion of the intima so as to displace the same from its natural orientation;
actuating said hollow support element such that the distal end of said hollow support element is within said volume;
actuating said guide wire such that the distal end of said guide wire protrudes from said hollow support element; and,
penetrating the intima with said guide wire at a point within said portion of said intima that bounds said volume, thereby reentering into said vessel at a point proximal to said distal end of said occlusion, bypassing said occlusion;
wherein said method additionally comprises a step of stabilizing said guide wire by means of said hollow support element until said guide wire has penetrated said intima.
78. The method according to claim **77**, further comprising a step of advancing said guide wire through said lumen.
79. The method according to claim **77**, further comprising a step of reconfiguring the effector into said inactive configuration.

80. The method according to claim 77, further comprising a step of removing said catheter from said vessel while leaving said guide wire within said vessel.
81. The method according to claim 77, further comprising a step of removing said hollow support element from said vessel while leaving said guide wire within said vessel.
82. The method according to claim 77, further comprising a step of penetrating said intima of said vessel by said guide wire at a point proximal to said occlusion prior to said step of penetrating said intima of said vessel with said guide wire at a point proximal to said occlusion.
83. The method according to claim 83, further comprising a step of penetrating said intima of said vessel by said lumen at a point proximal to said occlusion.
84. The method according to claim 83, further comprising a step of introducing said catheter into said vessel at the point at which said guide wire reentered said vessel.
85. The method according to claim 84, further comprising at least one step chosen from the group consisting of (a) injecting a substance into said vessel and (b) visualizing said vessel.
86. The method according to claim 77, wherein said step of applying suction is initiated subsequent to said step of reconfiguring said effector into its active configuration.
87. The method according to claim 86, wherein said step of applying suction comprises applying suction that is sufficiently strong to fix said effector to said intima.
88. The method according to claim 77, further comprising a step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means.
89. The method according to claim 88, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means additionally comprising at least one step selected from applying magnetic means, applying heat means, applying electrical means, applying mechanical means, and any combination thereof.
90. The method according to claim 88, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration by means of an actuating means additionally comprising step of linearly moving said distal end of said effector in and out of said lumen.

91. The method according to claim 77, additionally comprising step of providing said effector with an area of the cross-section, as measured in the plane perpendicular to the longitudinal axis of said catheter, that varies along said main longitudinal axis of said catheter.
92. The method according to claim 77, additionally comprising step of providing said effector with an area of the cross-section, as measured in the plane perpendicular to the longitudinal axis of said catheter, that increases along said main longitudinal axis of said catheter.
93. The method according to claim 77, additionally comprising step of providing said effector, wherein, when said effector is in said active configuration, the cross-sectional area of at least a portion of said part of said effector that protrudes from said catheter, as measured in a plane perpendicular to said longitudinal axis of said catheter, is greater than the cross-sectional area of said catheter as measured in a plane perpendicular to said longitudinal axis of said catheter.
94. The method according to claim 77, additionally comprising step of reversibly moving said effector along and around said main longitudinal axis of said catheter.
95. The method according to claim 77, wherein said step of applying suction additionally comprising step of providing sufficient suction such that, when said effector is in said active configuration and suction is applied, said effector is fixed against the inner surface of said vessel, so as to enable said guide wire to reenter said lumen, thereby bypassing said occlusion.
96. The method according to claim 77, wherein said step of applying suction additionally comprising step of providing sufficient suction such that, when said effector is in said active configuration and suction is applied, a preset void volume is provided; said preset void volume is defined by means of said effector, the distal end of said catheter and the inner surface between the subintimal space and the vessel; said source of suction is adapted to apply suction within said preset void volume, so as to enable said guide wire and to puncture the intima.
97. The method according to claim 77, additionally comprising step of providing at least a portion of said effector from a material chosen from the group consisting of materials having shape memory properties, electroactive polymers (EAPs), and any combination thereof.

98. The method according to claim **97**, wherein said material having shape memory properties is selected from the group consisting of copper-based alloys, NiTi-based materials, and any combination thereof.
99. The method according to claim **97**, wherein said EAP is of a type selected from the group consisting of dielectric EAPs, ferroelectric polymers, liquid crystalline polymers, ionic EAPs, and any mixture thereof.
100. The method according to claim **77**, additionally comprising step of providing said open-bore type lumen with an articulation mechanism.
101. The method according to claim **77**, additionally comprising step of providing said hollow support element with an articulation mechanism.
102. The method according to claim **77**, additionally comprising step of providing said effector with an articulation mechanism.
103. The method according to claim **77**, additionally comprising step of providing said guide wire with an articulation mechanism.
104. The method according to claim **77**, additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.
105. The method according to claim **104**, additionally comprising step of selecting said verification means from the group consisting of a contrast agent, observation of blood passing through a hole about the point of penetration of said intima by said guide wire and any combination thereof.
106. The method according to claim **77**, additionally comprising step of providing said hollow support element as at least one selected from a group consisting of a micro catheter, hollow element, tube-like element and any combination thereof.
107. The method according to claim **106**, additionally comprising step of providing verification means for verifying the location at which said guide wire has penetrated said intima.
108. The method according to claim **107**, wherein said verification means are introduced through said hollow support element.
109. The catheter according to claim **107**, wherein said verification means are contrast agents.
110. The method according to claim **77**, additionally comprising step of providing at least one marker at the distal end of at least one selected from a group consisting of said guide wire,

said hollow support element, said lumen, said catheter, said effector and any combination thereof.

111. The method according to claim **110**, additionally comprising step of indicating, by means of said at least one marker, the relative position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector; with respect to at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, and said effector.
112. The method according to claim **77**, additionally comprising step of providing at least one marker disposed at the distal end of said catheter, to indicate the full reconfiguration of said effector from said inactive configuration to said active configuration.
113. The method according to claim **77**, wherein said step of reconfiguring said effector from said inactive configuration to said active configuration is provided by means selected from (a) pulling said catheter in said proximal direction; (b) pushing said effector in said distal direction.
114. The method according to claim **77**, additionally comprising step of providing at least one marker disposed at the distal end of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof, adapted to indicate the position of at least one selected from a group consisting of said guide wire, said hollow support element, said lumen, said catheter, said effector and any combination thereof with respect to said vessel or said intima.
115. The method according to claim **77**, additionally comprising step of penetrating said intima and reenter said lumen by means of said hollow support element.

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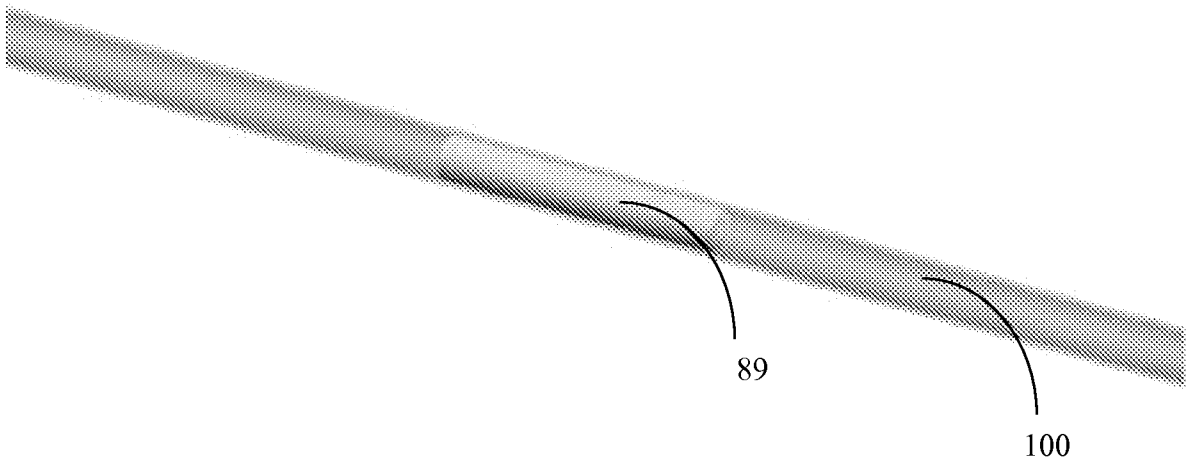


FIG. 1A

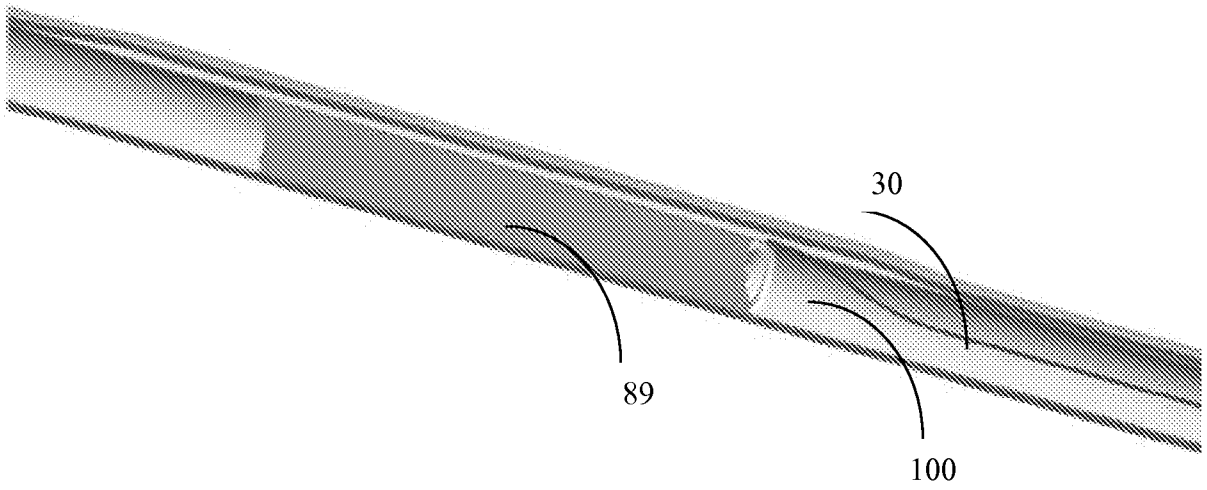


FIG. 1B

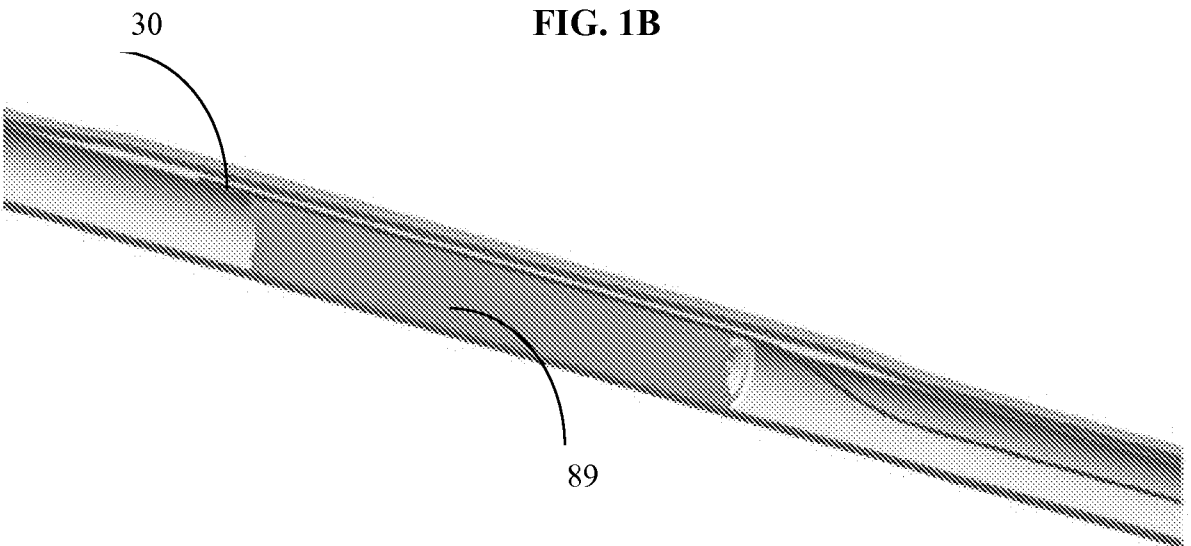


FIG. 1C

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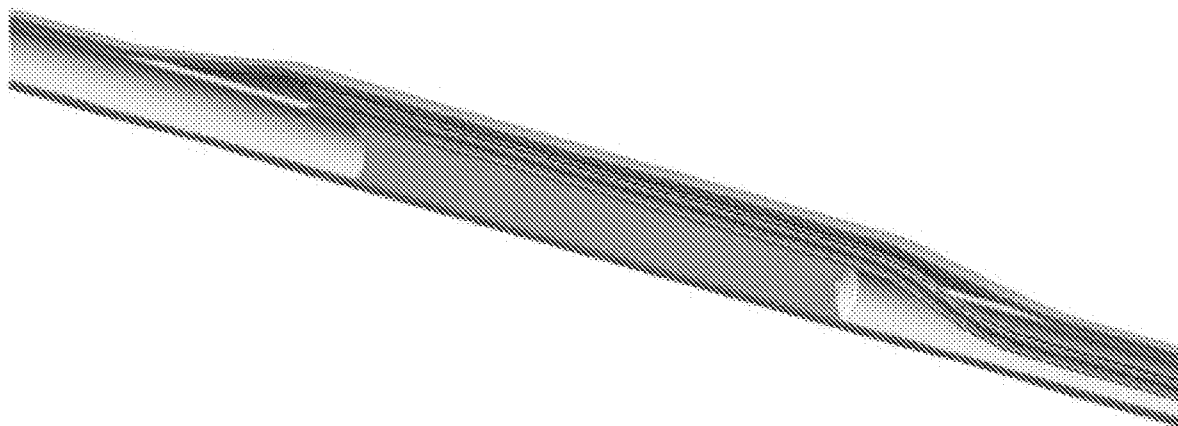


FIG. 1D

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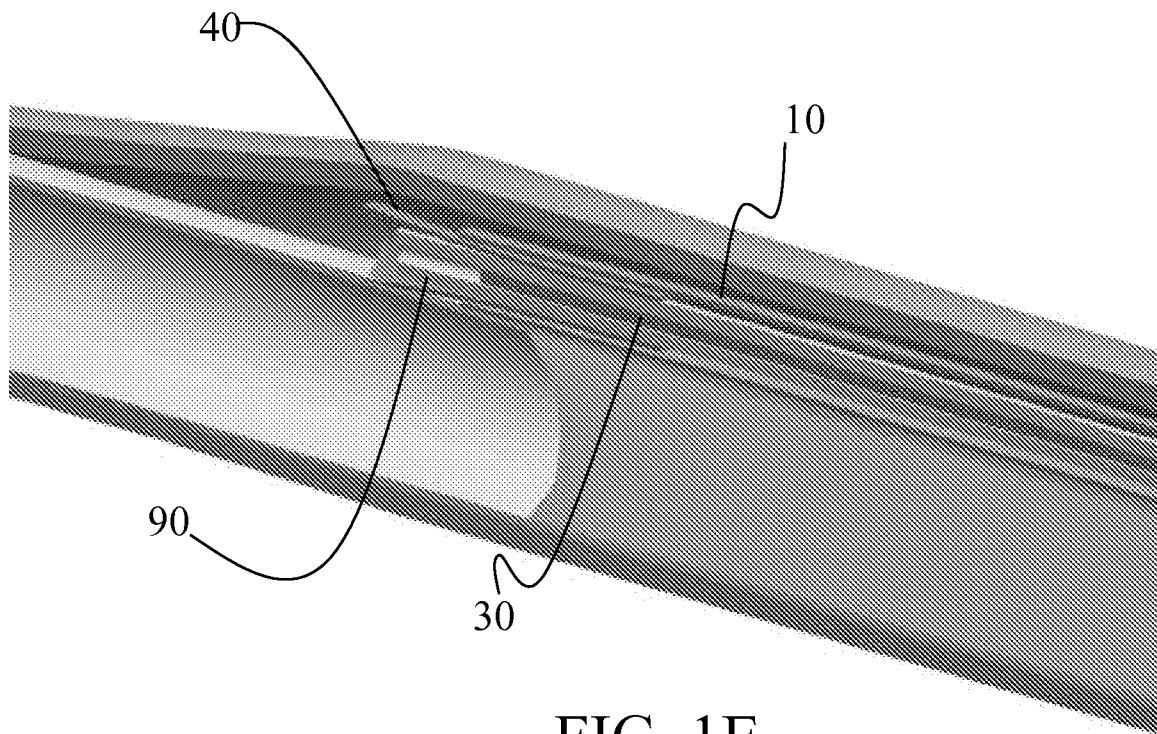


FIG. 1E

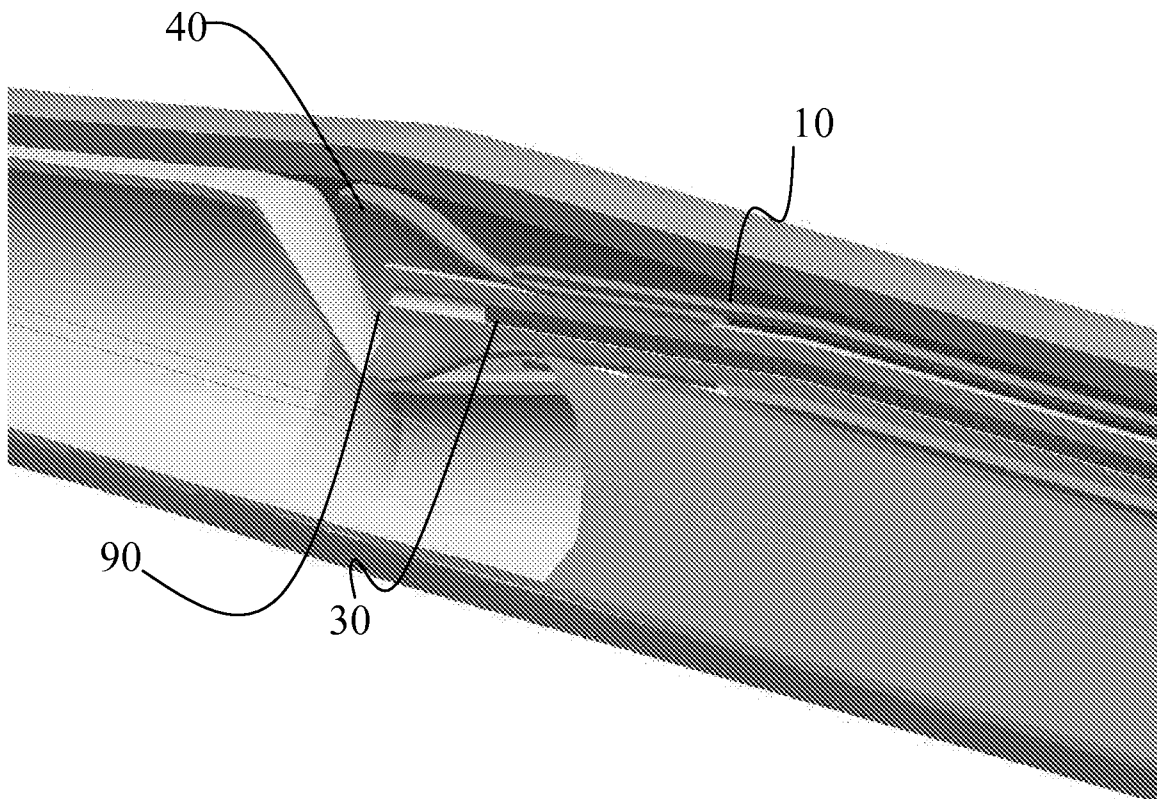


FIG. 1F

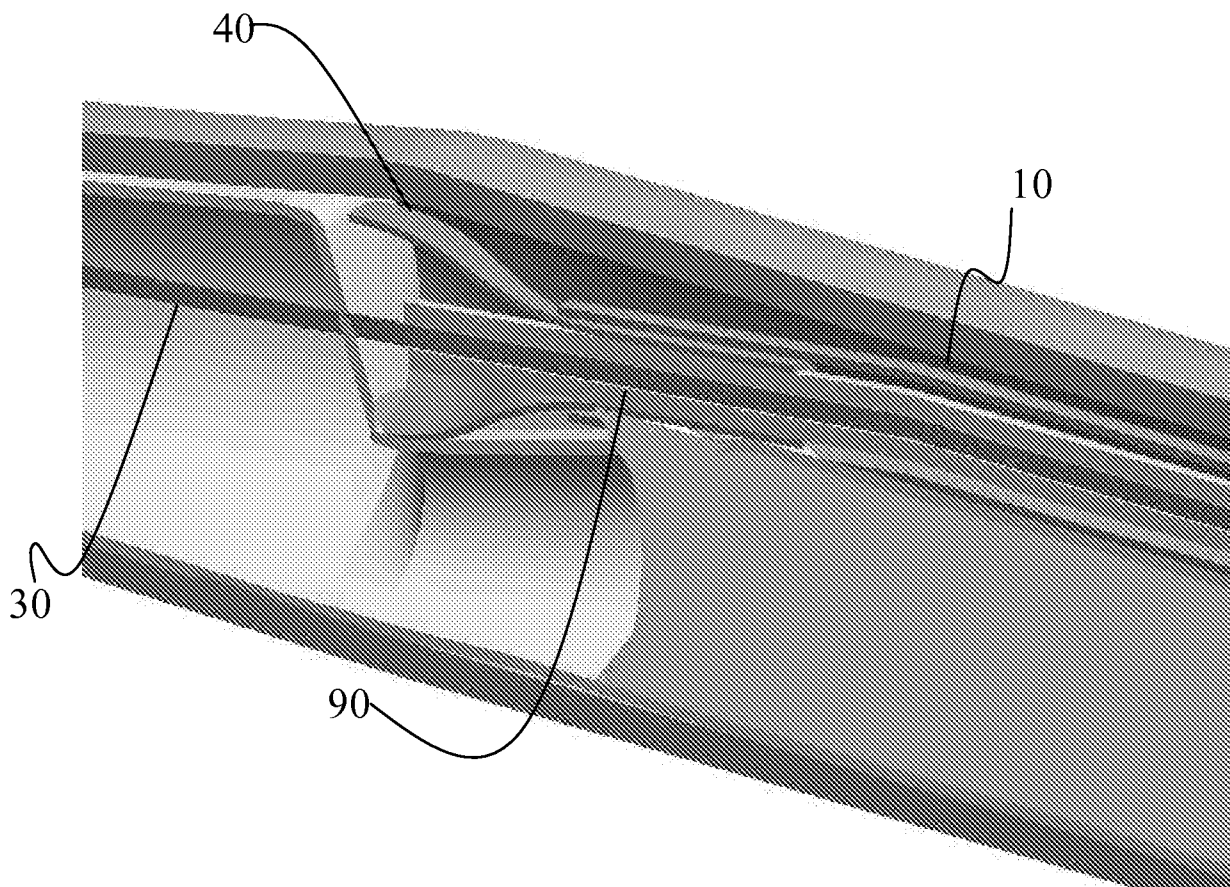


FIG. 1G

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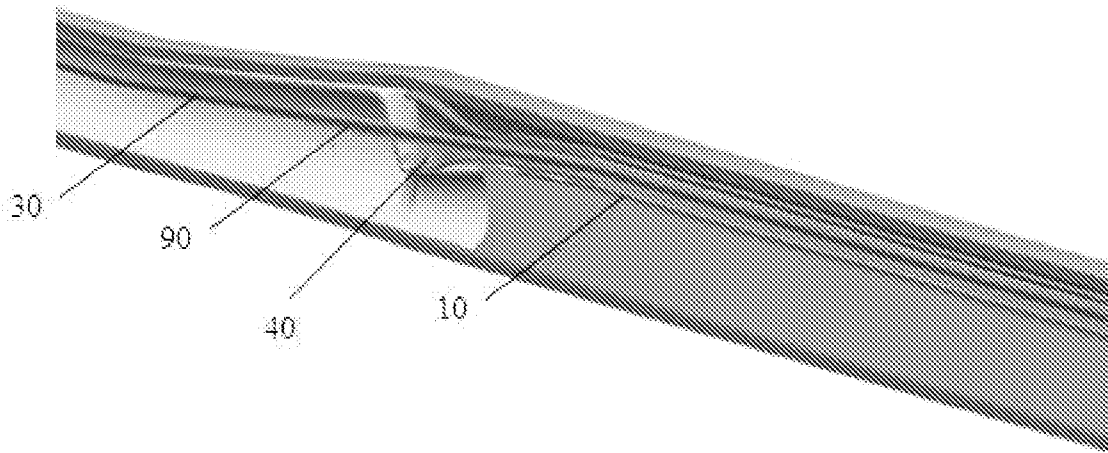


FIG. 1H

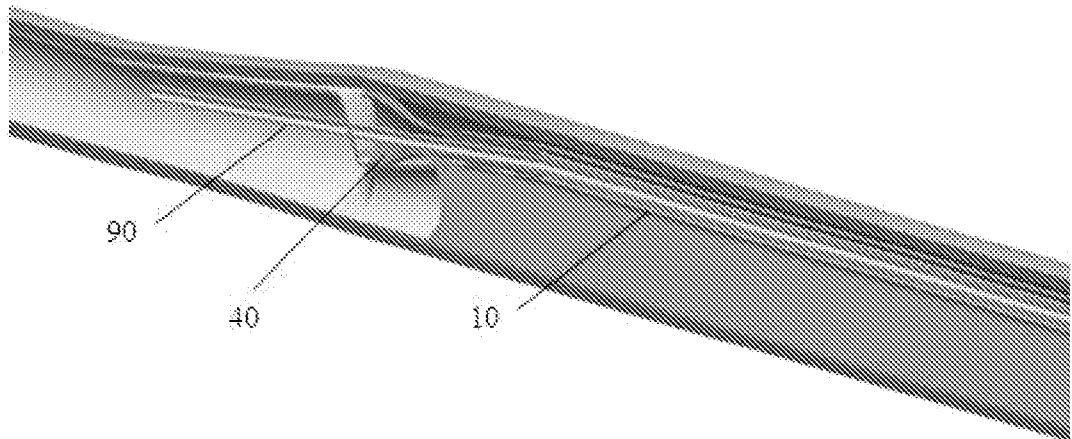


FIG. 1I

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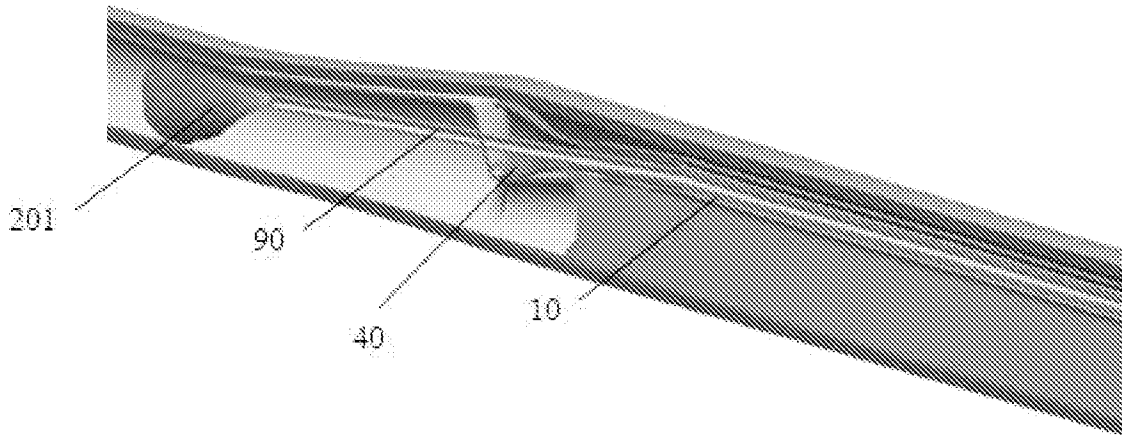


FIG. 1J

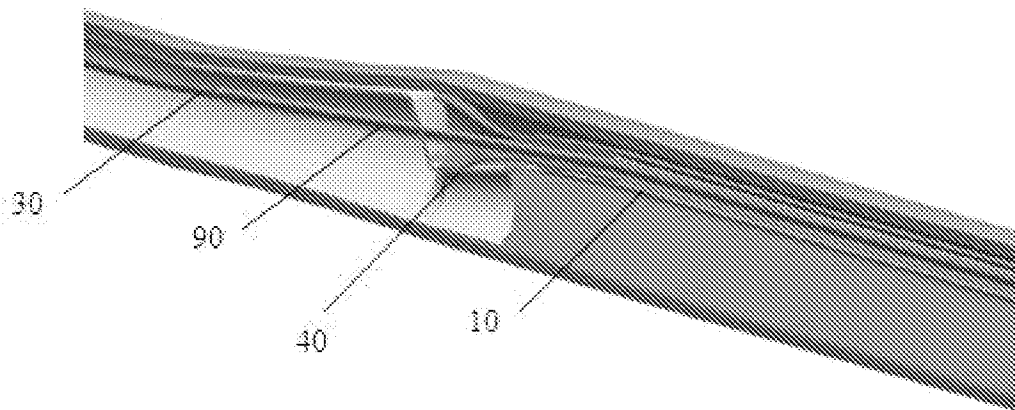


FIG. 1K

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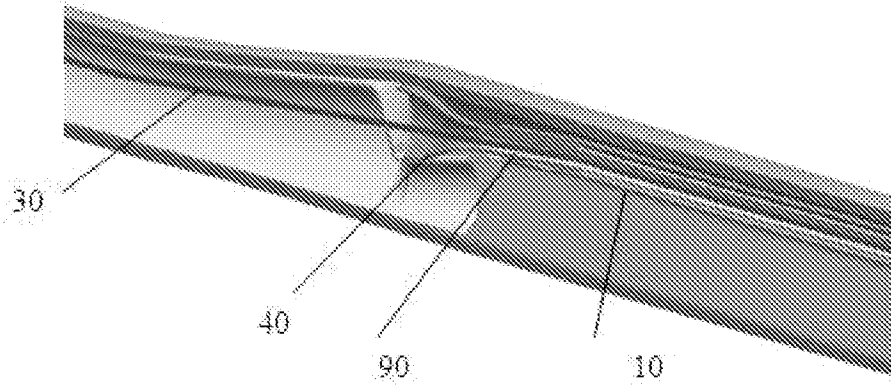


FIG. 1L

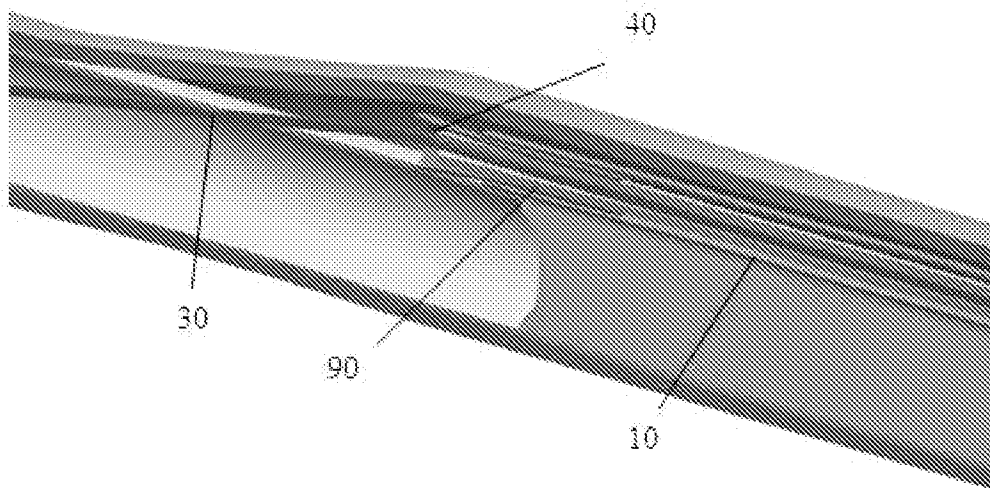


FIG. 1M

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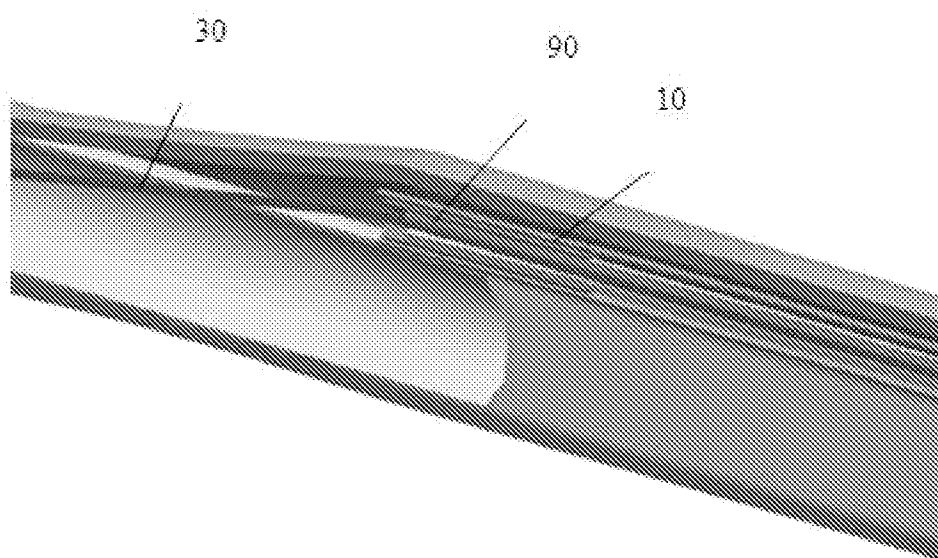


FIG. 1N

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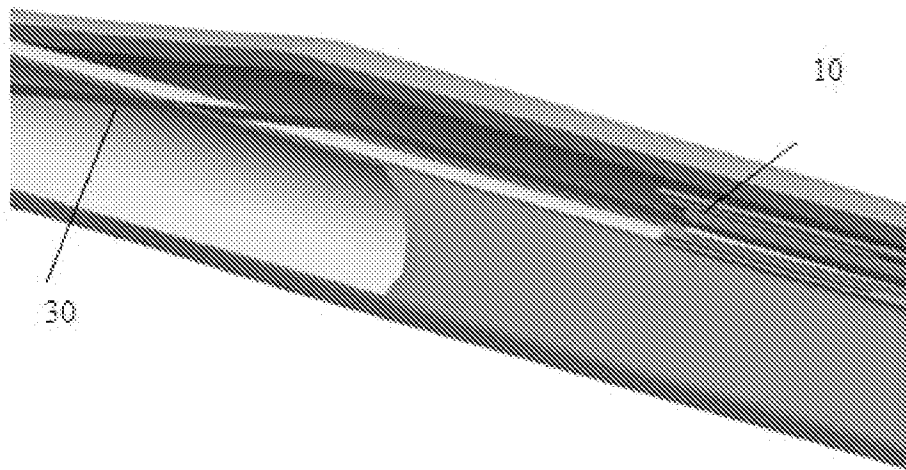


FIG. 10

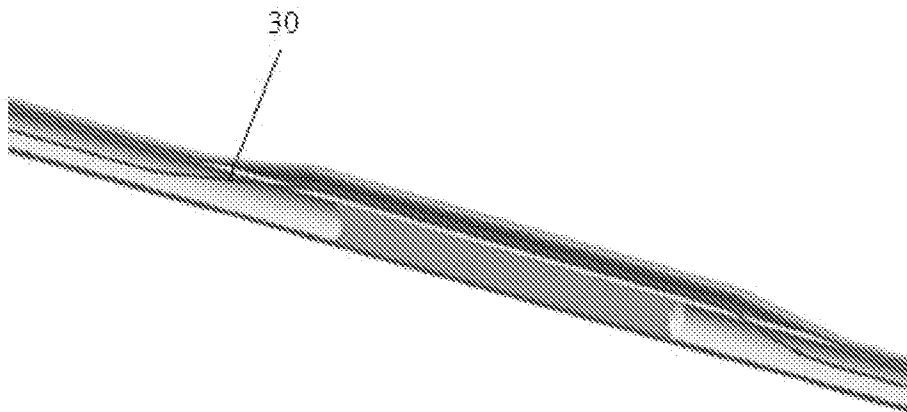


FIG. 1P

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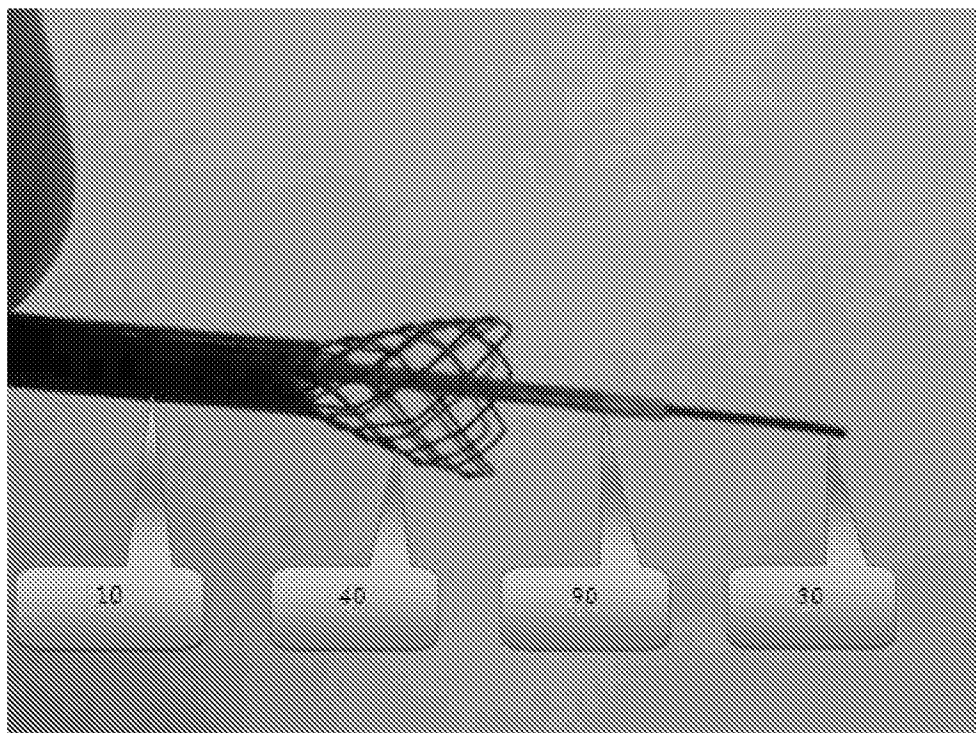


FIG. 1Q

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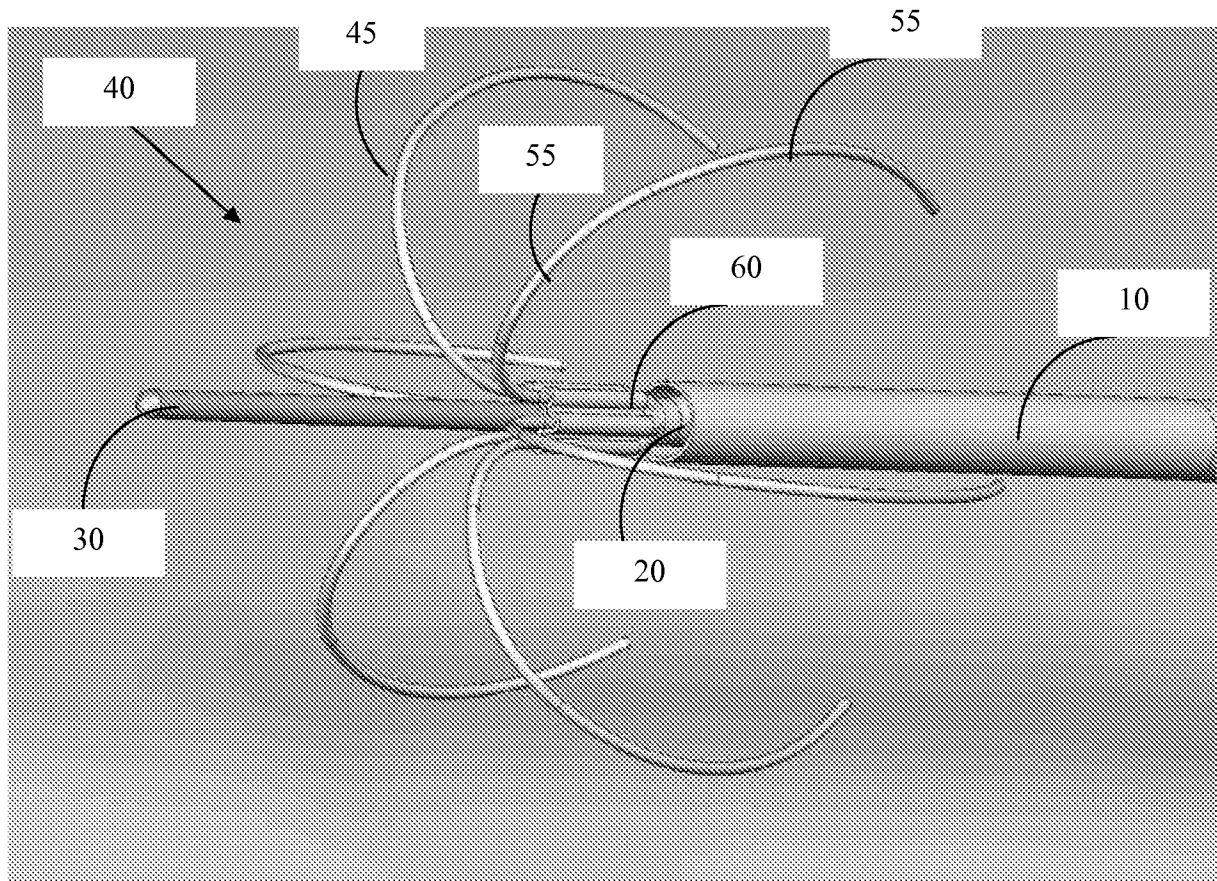


Fig. 2

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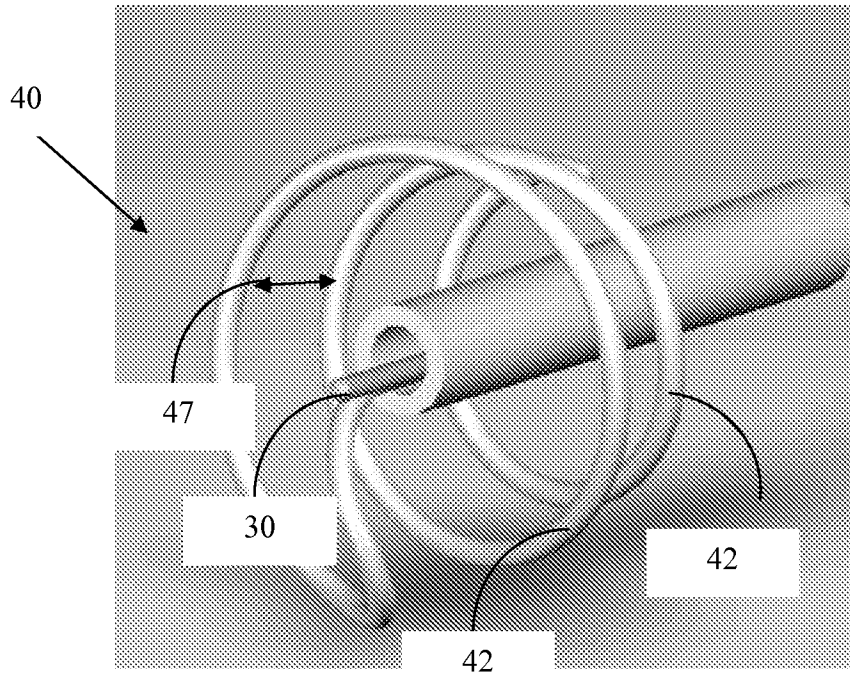


Fig. 3a

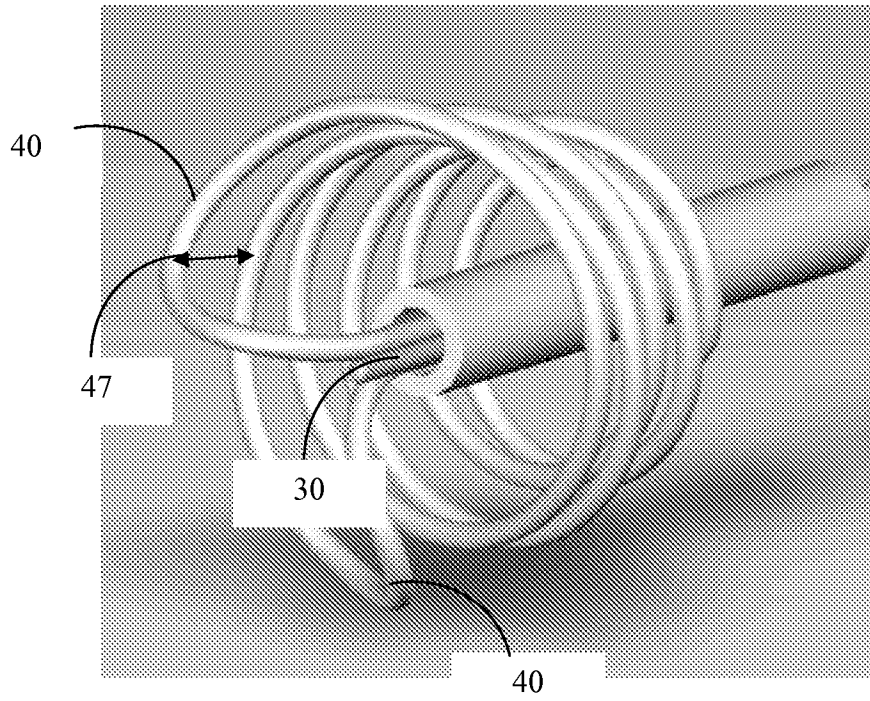


Fig. 3b

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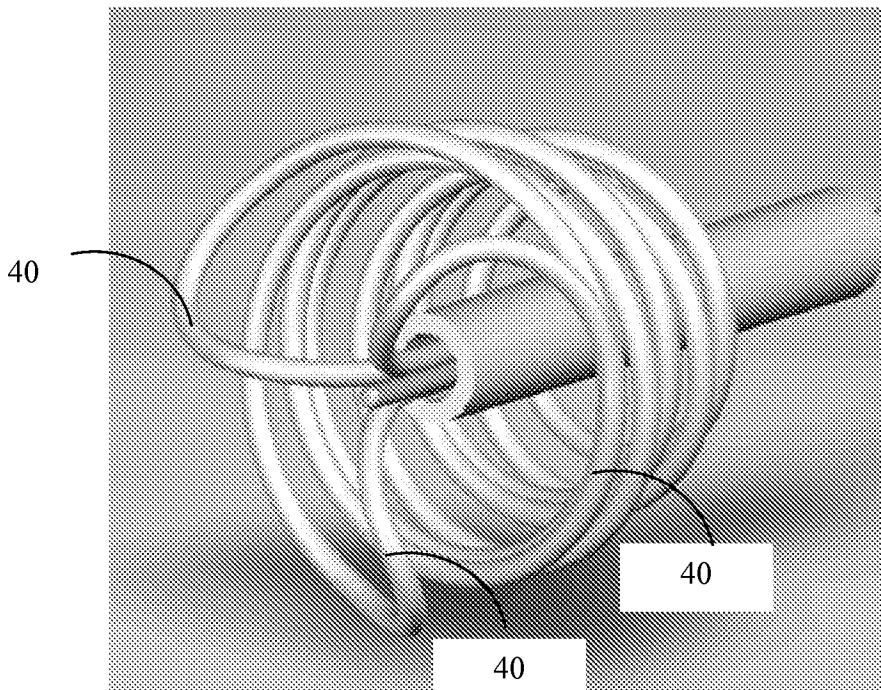


Fig. 3c

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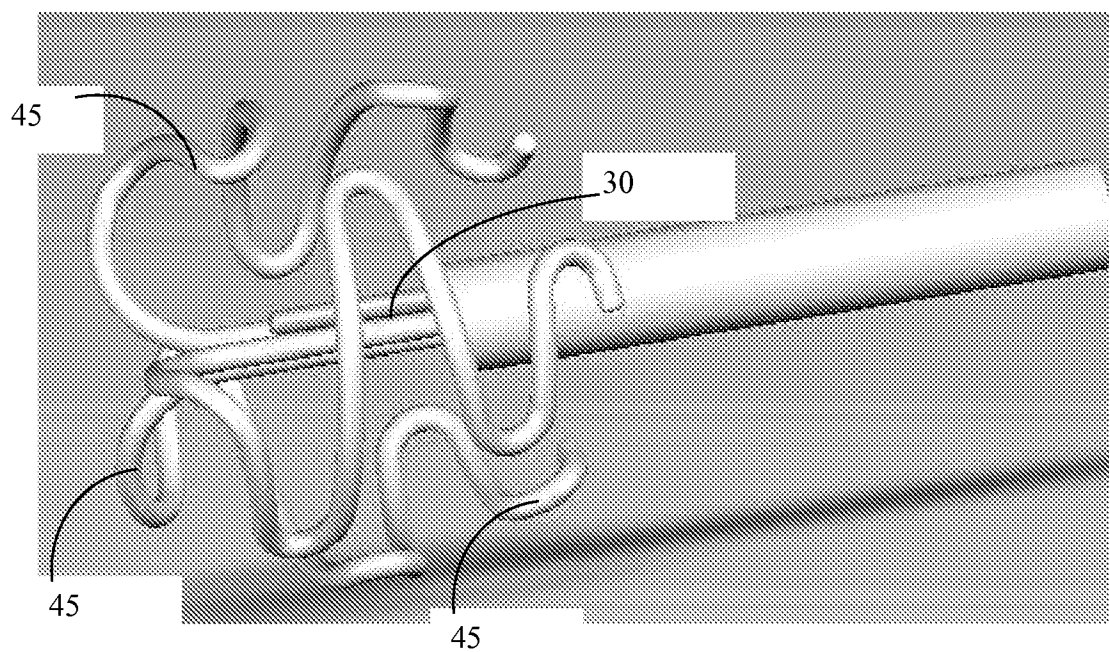


Fig. 4a

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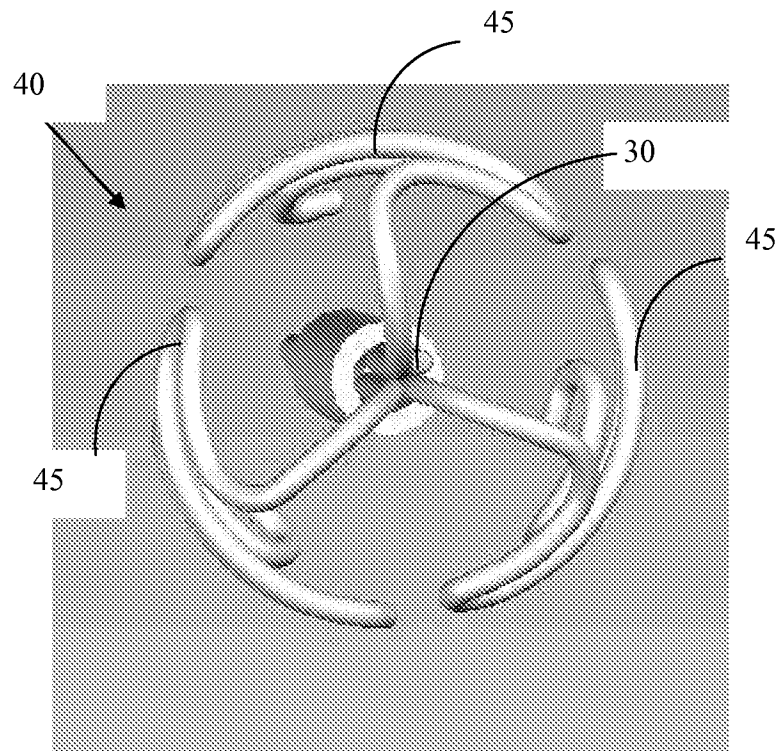


Fig. 4b

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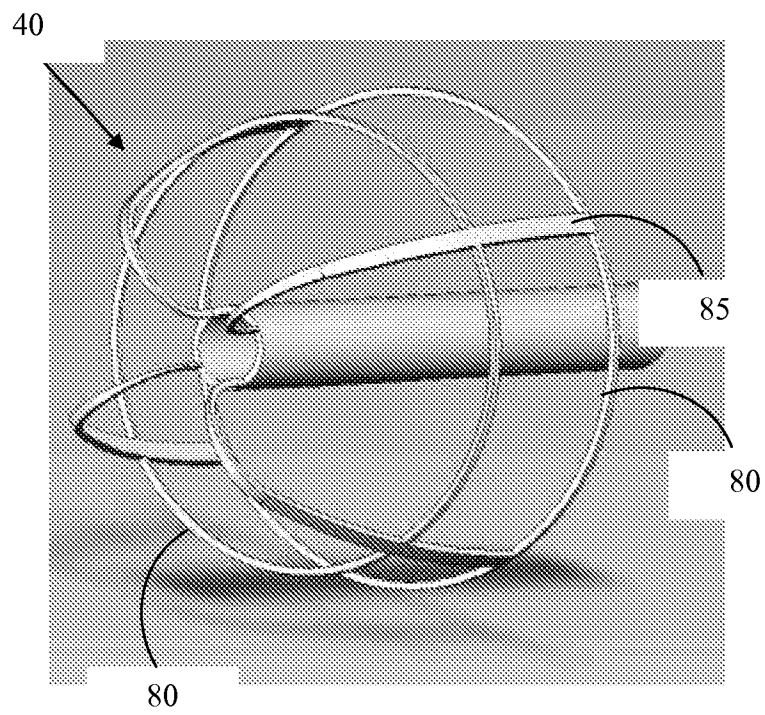


Fig. 5

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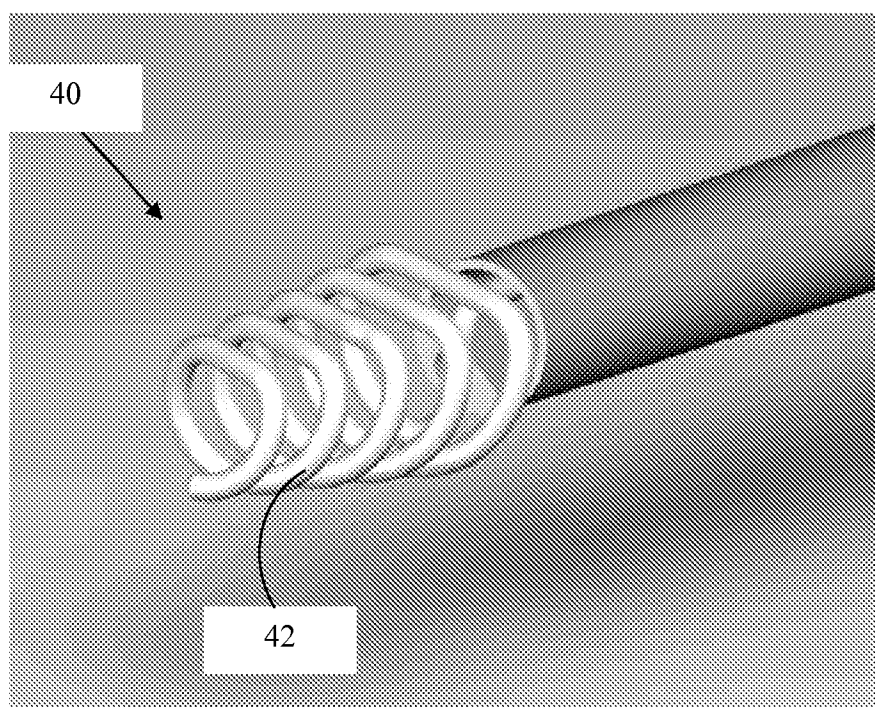


Fig. 6a

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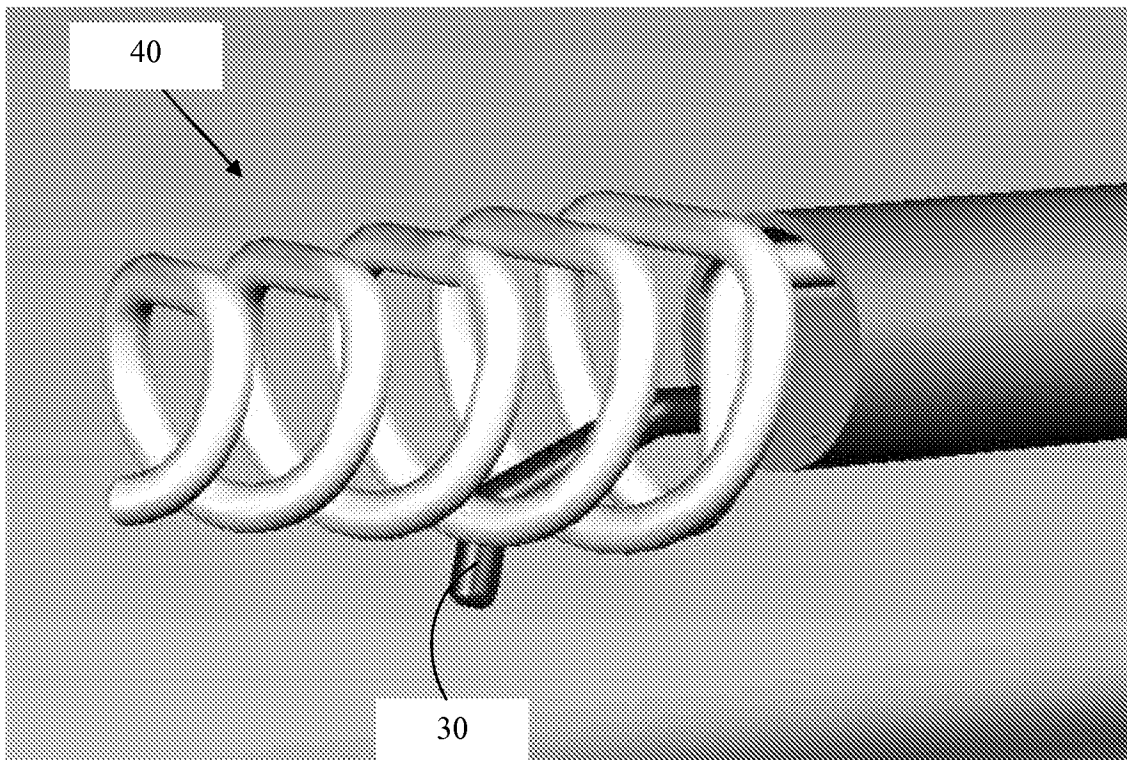


Fig. 6b

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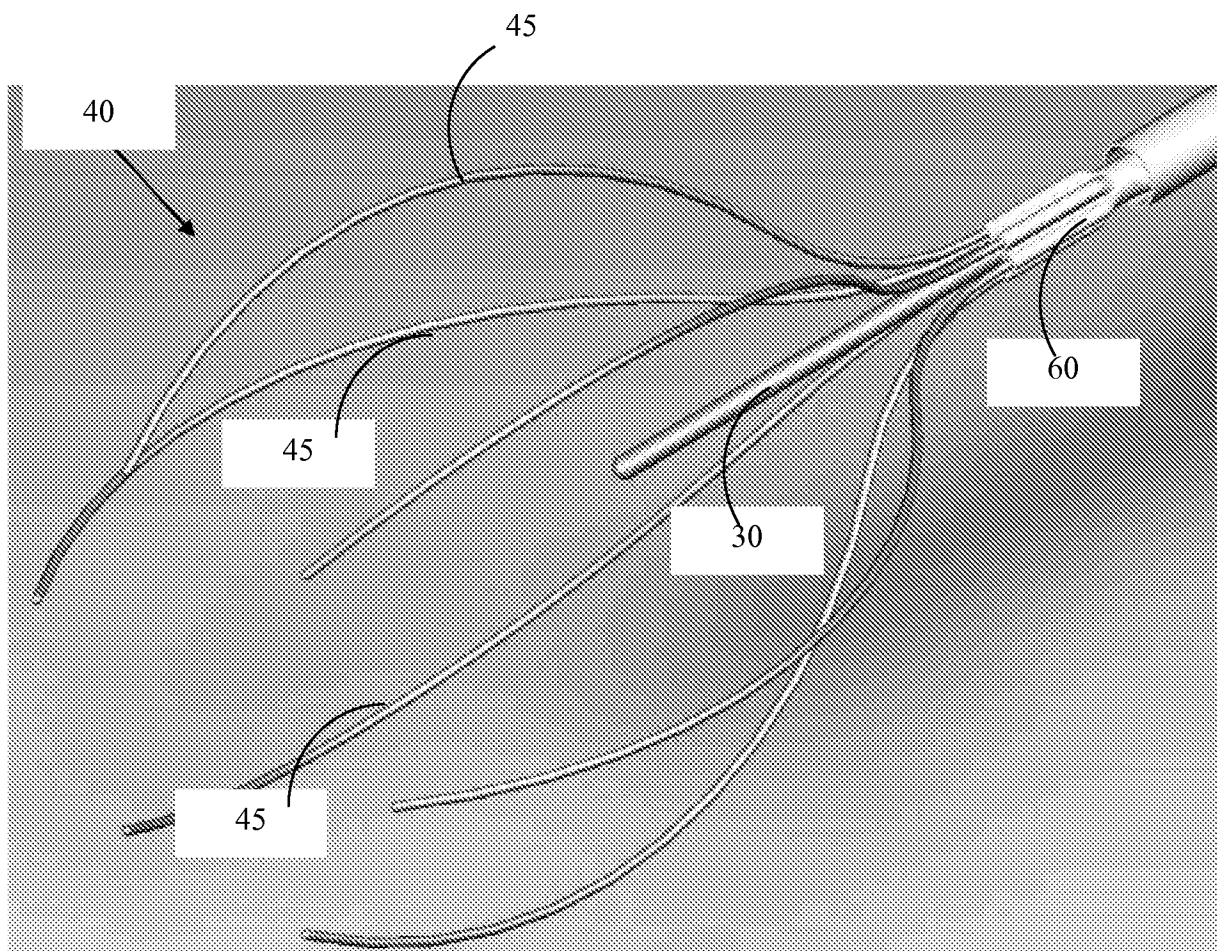


Fig. 7a

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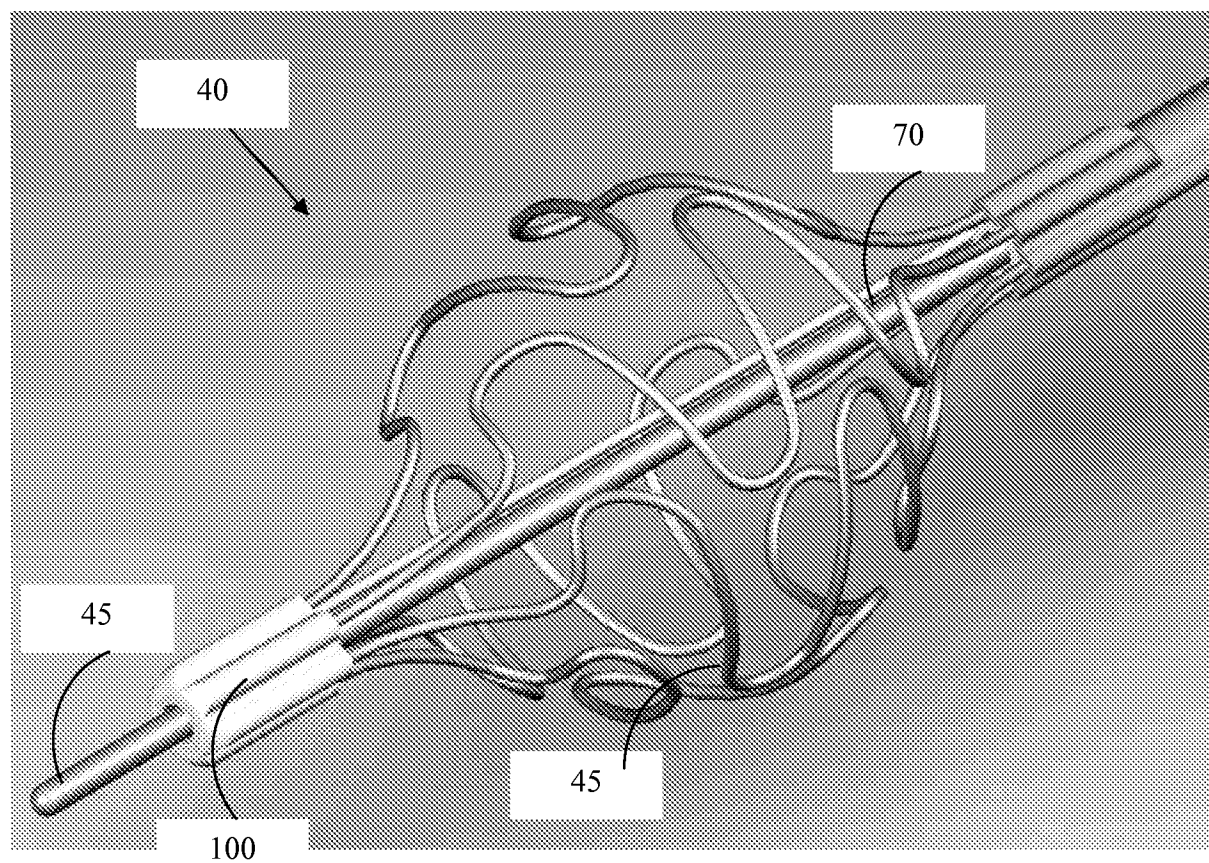


Fig. 8

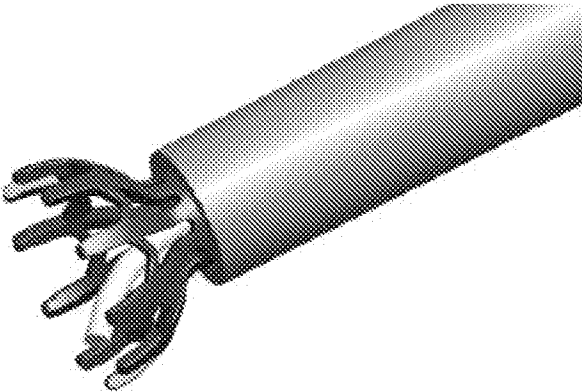


FIG. 9A

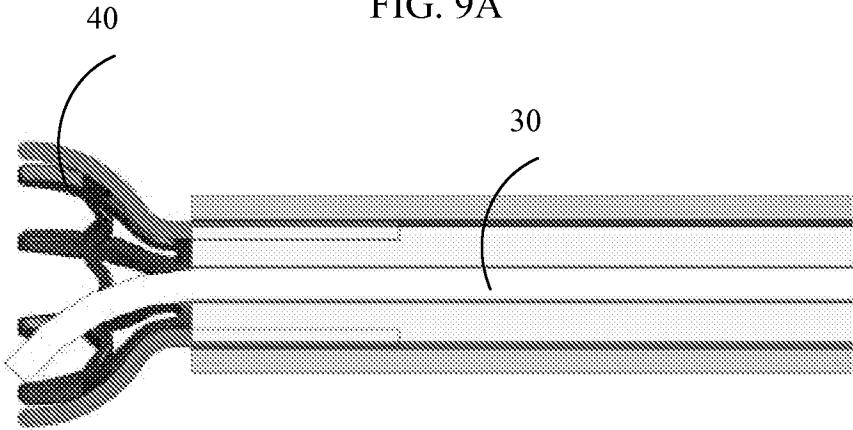


FIG. 9B

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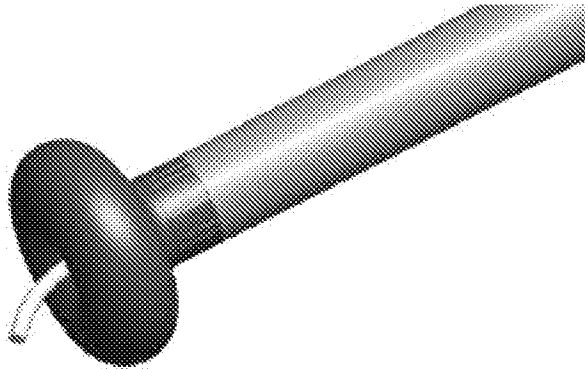


FIG. 10A

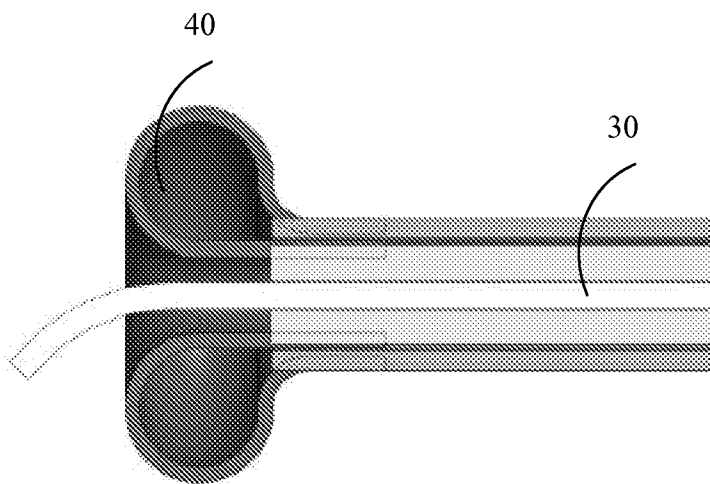


FIG. 10B

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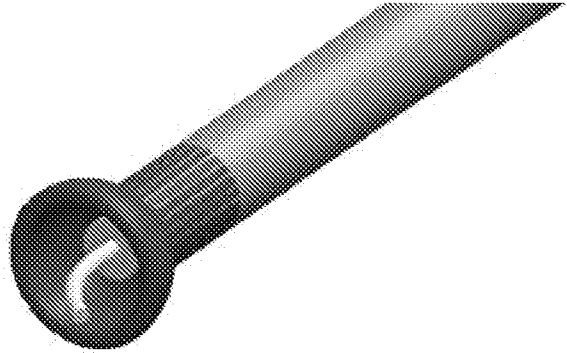


FIG. 11A

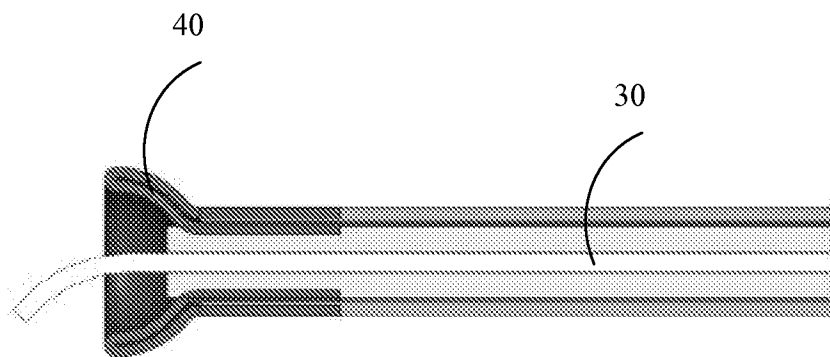


FIG. 11B

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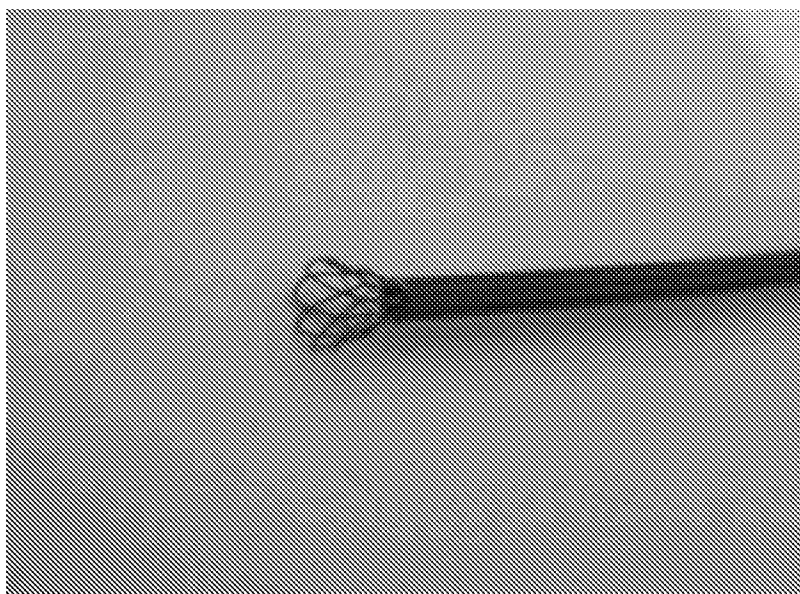


FIG. 12

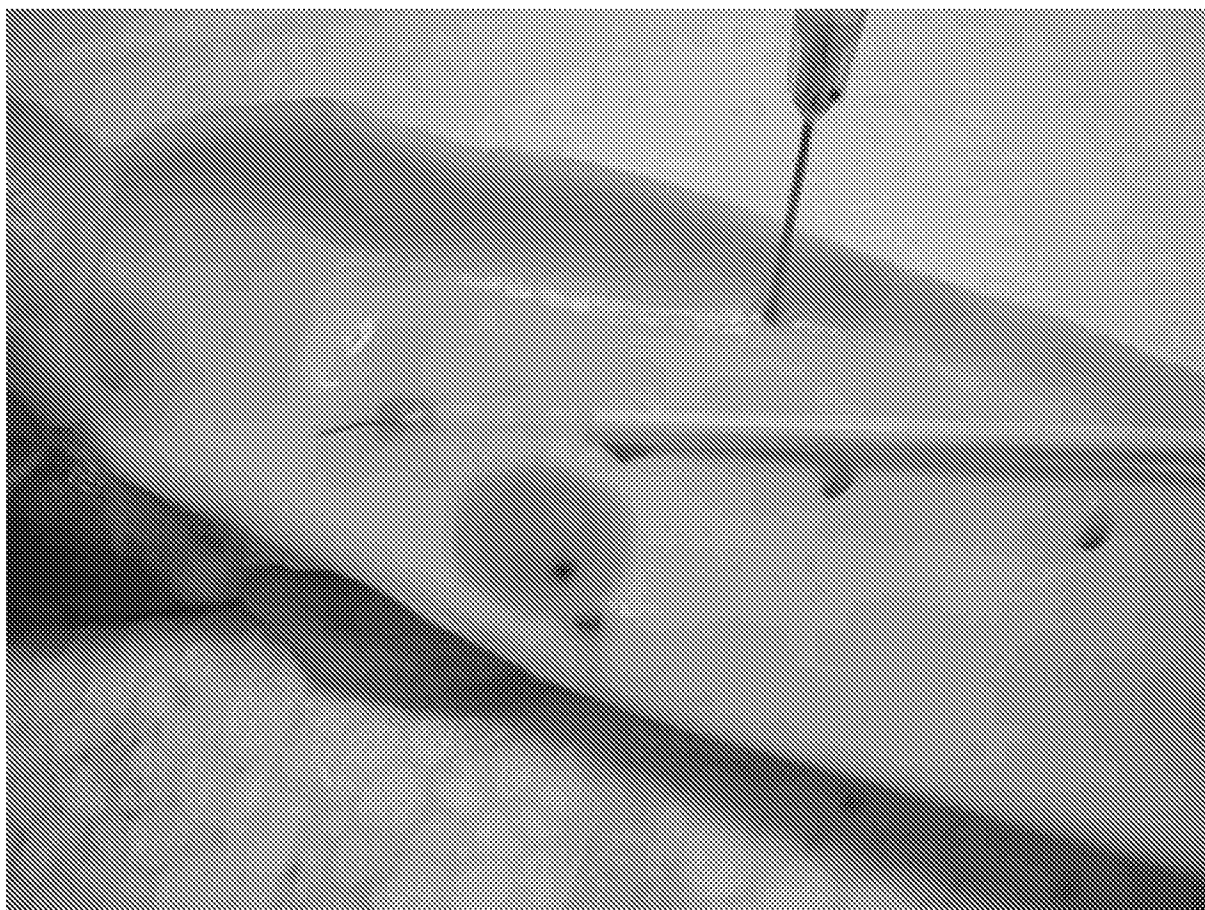


FIG. 13