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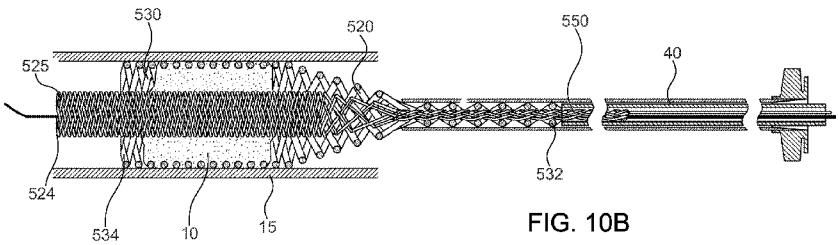

FIG. 10B

(57) Abstract: A device arranged to at least partially remove an occlusion occluding a small blood vessel, the device constituted of a generally tubular inner member and an outer member in communication with the generally tubular inner member. The generally tubular inner member is expandable to a large diameter state, which is no more than an at rest state and which is in one embodiment no more than 50% of the diameter of the small blood vessel at the occlusion location. The generally tubular outer member is expandable to a large diameter state which is greater than the at rest outer diameter state of the generally tubular inner member, and wherein in one embodiment the outer member meets the inner walls of the small blood vessel at the occlusion location. At least a portion of the occlusion is contained between the generally tubular inner member in the large diameter state and the outer member in the large diameter state.

METHOD AND APPARATUS FOR OCCLUSION RETRIEVAL

BACKGROUND OF THE INVENTION

[0001] The invention relates generally to the field of medical devices, specifically to medical devices that are useful in treating stroke, and more particularly to a device aiding in retrieval of an occlusion.

[0002] Stroke is a leading cause of disability, death and health care expenditure. Most strokes are ischemic, i.e. caused by a decrease in the blood supply to a portion of the brain due to a clot obstructing the flow of blood. A total or hemodynamically significant occlusion of a cerebral artery in an acute ischemic stroke is mostly due to thrombus formation, an embolus, and/or other unwanted matter. When an artery is obstructed, tissue ischemia (lack of oxygen and nutrients) quickly develops. The organ most sensitive to ischemia is the brain. Ischemia will rapidly progress to tissue infarction (cell death) if the occlusion of blood flow persists. In patients experiencing a typical large vessel acute ischemic stroke, it has been estimated that within each hour of no cerebral perfusion, about 20 million neurons are lost. Therefore, cerebral artery occlusions that lead to stroke require swift and effective therapy to reduce the morbidity associated with the disease. The term occlusion as used herein is meant to include any partial or complete blockage of a blood vessel, as by thrombosis, embolism or gradual narrowing.

[0003] The functionally impaired region that surrounds the infarct core and is threatened by cell death has been termed the ischemic penumbra. The ischemic penumbra, although physiologically impaired, is potentially salvageable tissue, however the window of opportunity for recovery of the reversibly injured neurons in the ischemic penumbra is relatively short. Failure to timely restore blood flow triggers a biochemical and metabolic cascade ultimately leading to irreversible brain injury by progressive transformation of the ischemic penumbra into infarcted tissue, i.e. the infarct core expands as the penumbra tissue experiences necrosis.

[0004] Traditionally, emergency management of acute ischemic stroke consisted of mainly general supportive care, e.g. hydration, monitoring neurological status, blood pressure control, and/or anti-platelet or anti-coagulation therapy. In 1996 intra-arterial administration of tissue plasminogen activator (t-PA) was approved by the FDA for the treatment of acute ischemic stroke in selected cases within the first few hours from onset. More recently percutaneous catheter-based technologies have

been advanced, including: placing a microcatheter near the clot and infusing a thrombolytic agent in order to dissolve the clot; extracting the clot by distal embolectomy devices in which various wire corkscrews and baskets are advanced distally through the clot in order to capture it; and using proximal devices in which the clot is aspirated or captured and removed. Other methods of removing or disrupting the clot, include: facilitating fibrinolysis by an outside energy source such as ultrasound or laser energy; mechanical manipulation of the clot by primary angioplasty; and employing stents permanently or transiently are also widely used.

[0005] Often, more than one method is required until arterial patency is restored. Such treatment approaches have a common purpose of restoring artery patency as quickly as possible by removing or disrupting the obstructing clot. Achieving artery patency by any of these above methods or any combination of them (multimodal therapy) is often complex, requires multiple steps and is time consuming. Even if the treatment is successful, during the treatment progressive transformation of the penumbra into infarcted tissue occurs.

[0006] A key therapeutic goal of acute ischemic stroke treatment consists of re-establishment of arterial potency prior to cell death. The sooner arterial patency is achieved the greater the clinical benefit, therefore early restoration of blood flow in the affected territory of the brain may save brain tissue.

[0007] Cells within an infarction zone have dramatically reduced blood flow to less than 20% of normal blood flow. As a result, cells within this infarction zone will be irreversibly damaged within a few minutes. The blood flow in the ischemic penumbra, surrounding the infarction zone, is between 20% and 50% of normal. Cells in this area are endangered, but not irreversibly damaged. Studies have indicated that a critical focal stenosis of ~ 75% decrease in diameter is usually required to compromise flow in a major cerebral artery, in face of insufficient collateral flow from other arteries.

[0008] In summary, prompt action is required in the case of an occlusion to remove the occlusion, and preferably to maintain patency of blood flow sufficient to prevent cell death.

SUMMARY OF THE INVENTION

[0009] In view of the discussion provided above and other considerations, the present disclosure provides methods and apparatuses for enabling at least partial

retrieval of the occlusion, while preferably sustaining patency through the occlusion. This is accomplished in certain embodiments by providing an occlusion retrieval member constituted of a generally tubular inner member in communication with an outer member, the outer member arranged to meet the inner walls of the blood vessel at the occlusion. In one embodiment the generally tubular inner member is arranged to provide and/or sustain at least partial patency of a small blood vessel exhibiting an occlusion.

[00010] The generally tubular inner member comprises a tubular body expandable from a small diameter state for manipulation adjacent, and/or through, the occlusion of the small blood vessel and a large diameter state, which may extend up to an at rest diameter state. The at rest diameter state is less than the inner diameter of the blood vessel at the occlusion and preferably is less than 50% of the inner diameter of the blood vessel at the occlusion.

[00011] The occlusion retrieval member is particularly designed for use with small blood vessels, i.e. blood vessels of 5mm or less of inner diameter and may be constituted of an intracranial blood vessel.

[00012] The outer member is in one embodiment similarly constituted, however it is arranged to meet the inner walls of the body lumen at the occlusion, thereby enclosing at least a portion of the occlusion between the outer member and the generally tubular inner member. Removal of the occlusion retrieval member, with the occlusion securely contained therein, results in at least partial retrieval of the occlusion.

[00013] The present embodiments enable a device arranged to at least partially remove an occlusion occluding a small blood vessel, the device comprising: a generally tubular inner member; and an outer member in communication with the generally tubular inner member, wherein: the generally tubular inner member exhibits a small diameter state for manipulation to, and through, the occlusion of the small blood vessel, the generally tubular inner member expandable to a large diameter state, the outer diameter of the generally tubular member in the large diameter state being no more than an at rest diameter of the generally tubular inner member, wherein the at rest diameter of the generally tubular inner member is less than the inner diameter of the small blood vessel at the occlusion location; and the outer member exhibits a small diameter state for manipulation to, and through, the occlusion of the small blood vessel, the outer member expandable to a large diameter state wherein the inner

diameter of the outer member in the large diameter state is greater than the outer diameter of the generally tubular inner member in the large diameter state, wherein at least a portion of the occlusion is contained between the generally tubular inner member in the large diameter state and the outer member in the large diameter state.

[00014] In one further embodiment the outer diameter of the outer member in the large diameter state meets the inner walls of the small blood vessel at the occlusion location. In another further embodiment the at rest diameter of the generally tubular inner member is no more than 50% of the diameter of the small blood vessel at the occlusion location.

[00015] In one further embodiment the generally tubular inner member and the outer member are removable from the body lumen, thus retrieving the occlusion. In another further embodiment the outer member exhibits a resting state, wherein the outer diameter of the outer member in the resting state is greater than the inner diameter of the small blood vessel. Preferably the outer diameter of the outer member in the resting state is at least 0.5 millimeters greater than the inner diameter of the small blood vessel. Further preferably the outer diameter of the outer member in the resting state is 0.5 – 1.5 millimeters greater than the inner diameter of the small blood vessel.

[00016] In one further embodiment the device comprises a distal filtering extension coupled to the distal end of the generally tubular inner member, the distal filtering extension arranged to meet the inner walls of the body lumen distal of the occlusion when the generally tubular inner member is large diameter state. In another further embodiment the generally tubular inner member comprises a first connecting portion, and wherein a proximal end of the outer member is connected to the generally tubular inner member via the first connecting portion. In one yet further embodiment the generally tubular inner member further comprises a second connecting portion, and wherein a distal end of the outer member is connected to the generally tubular inner member via the second connecting portion.

[00017] In one further embodiment at least one of the generally tubular inner member and the outer member are constituted of self expanding braided filaments. In another further embodiment the device is constituted of braided filaments, and wherein the generally tubular inner member and the outer member are constituted of a single braid. In yet another further embodiment the small blood vessel is an intracranial blood vessel.

[00018] Independently a method of occlusion retrieval is enabled, the method comprising: providing an occlusion retrieval member exhibiting a generally tubular inner member and an outer member; manipulating the provided occlusion retrieval member in a small diameter state through a body lumen to, and through, an occlusion of a small blood vessel; expanding the generally tubular inner member of the provided occlusion retrieval member up to a large diameter state, the outer diameter of the generally tubular member in the large diameter state being no more than an at rest diameter of the generally tubular inner member, wherein the at rest diameter of the generally tubular inner member is less than the inner diameter of the small blood vessel at the occlusion location; expanding the outer member of the provided occlusion retrieval member up to a large diameter state wherein the inner diameter of the outer member is greater than the outer diameter of the generally tubular inner member in the large diameter state so as to contain at least a portion of the occlusion between the generally tubular inner member and the outer member; and withdrawing the provided occlusion retrieval member to thereby at least partially retrieve the occlusion.

[00019] In one further embodiment the expanding the outer member of the provided occlusion retrieval member up to a large diameter state comprises expanding the outer member so as to meet the inner walls of the small blood vessel at the occlusion location. In another further embodiment the at rest diameter of the generally tubular inner member is no more than 50% of the diameter of the small blood vessel at the occlusion location.

[00020] In one further embodiment the outer member of the provided occlusion retrieval member exhibits a resting state, wherein the outer diameter of the outer member in the resting state is greater than the inner diameter of the small blood vessel at the occlusion location. In one yet further embodiment the outer diameter of the provided outer member in the resting state is at least 0.5 millimeters greater than the inner diameter of the small blood vessel at the occlusion location. In another yet further embodiment the outer diameter of the provided outer member in the resting state is 0.5 – 1.5 millimeters greater than the inner diameter of the small blood vessel at the occlusion location.

[00021] In one further embodiment the method further comprises providing a distal filtering extension coupled to a distal end of the provided generally tubular inner member, the distal filtering extension arranged to meet the inner walls of the

body lumen distal of the occlusion. In another further embodiment the generally tubular inner member of the provided occlusion retrieval member comprises a first connecting portion, and wherein a proximal end of the outer member of the occlusion retrieval member is connected to the generally tubular inner member via the first connecting portion. In one yet further embodiment the generally tubular inner member further comprises a second connecting portion, and wherein a distal end of the outer member is connected to the generally tubular inner member via the second connecting portion.

[00022] Additional features and advantages of the invention will become apparent from the following drawings and description.

BRIEF DESCRIPTION OF THE DRAWINGS

[00023] For a better understanding of the invention and to show how the same may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings in which like numerals designate corresponding elements or sections throughout.

[00024] With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice. In the accompanying drawings:

[00025] FIG. 1 illustrates a high level schematic diagram of a sectioned view of a first embodiment of a temporary endovascular conduit system, comprising a self expanding device;

[00026] Figs. 2A – 2E illustrate high level schematic diagrams of partially sectioned views of the distal portion of the temporary endovascular perfusion conduit system of FIG. 1, showing sequential steps in the deployment of the self expanding device in a vessel according to an exemplary embodiment;

[00027] FIG. 3 illustrates a high level schematic diagram of a partially sectioned view of the distal portion of the temporary endovascular perfusion conduit system of FIG. 1 and a delivery mechanism for intra-arterial administration of a medicament according to an exemplary embodiment;

[00028] FIG. 4 illustrates a high level schematic diagram of a sectioned view of a second embodiment of a temporary endovascular conduit system, comprising an expanding device;

[00029] Figs. 5A – 5D illustrate high level schematic diagrams of partially sectioned views of the distal portion of the temporary endovascular perfusion conduit system of FIG. 4, showing sequential steps in the deployment of the expanding device in a vessel according to an exemplary embodiment;

[00030] FIG. 6 illustrates a high level schematic diagram of a partially sectioned view of the distal portion of the temporary endovascular perfusion conduit system of FIG. 4 and a delivery mechanism for intra-arterial administration of a medicament according to an exemplary embodiment;

[00031] FIG. 7A illustrates a high level schematic diagram of a sectioned view of an embodiment of a temporary endovascular perfusion conduit exhibiting a distal filtering extension member;

[00032] FIG. 7B illustrates a high level schematic diagram of a sectioned view of an embodiment of a temporary endovascular perfusion conduit exhibiting a proximal securing member and a distal filtering extension member;

[00033] FIG. 8 illustrates a high level flow chart of a method of providing temporary endovascular perfusion;

[00034] FIG. 9A illustrates a high level schematic diagram of a perspective view of an embodiment of an occlusion retrieval device comprising a generally tubular inner member and an outer member;

[00035] FIG. 9B illustrates a high level schematic diagram of a sectioned view of the occlusion retrieval device of FIG. 9A disposed within a body lumen at an occlusion;

[00036] FIGs. 10A – 10C illustrate a high level schematic diagram of a sectioned view of an embodiment of an occlusion retrieval device comprising a generally tubular inner member and an outer member constituted of a pair of self expanding meshes in communication at the proximal end thereof secured within a catheter, the various figures showing sequential steps in the deployment of the

occlusion retrieval device within a body lumen at an occlusion according to an exemplary embodiment;

[00037] FIG. 11 illustrates a high level perspective view of an occlusion retrieval device wherein the generally tubular inner member and the outer member are constituted of a single mesh;

[00038] FIG. 12 illustrates a high level schematic diagram of a sectioned view of an embodiment of an occlusion retrieval device comprising a generally tubular inner member and an outer member and further comprising a distal filtering extension; and

[00039] FIG. 13 illustrates a high level flow chart of a method of providing occlusion retrieval.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[00040] Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is applicable to other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[00041] FIG. 1 illustrates a high level schematic diagram of a sectioned view of a first embodiment of a temporary endovascular conduit system, denoted temporary endovascular conduit system 50, deployed in an occlusion 10 occluding a body lumen 15. Temporary endovascular conduit system 50 comprises: a catheter 40, exhibiting a proximal portion 60 and a distal portion 80; a hub 90; a pair of members 26 and 26A; a guide wire 30; and a self expanding device 20, exhibiting a proximal end 22 and a distal end 24, illustrated in a large diameter state. The diameter of body lumen 15 in the area of occlusion 10 is denoted D2, and the inner diameter of self expanding device 20 in the large diameter state, denoted D1, is preferably between 1/3 and 1/2 of D2. Body lumen 15 is a small blood vessel, exhibiting an inner diameter D2 of 5mm or less, as described above. Advantageously, providing a conduit exhibiting an inner diameter for blood flow of at least 1/3 of D2 allows a sufficient blood flow, in the

absence of sufficient collateral flow from other arteries, to prevent or delay cell death, since this provides for a resultant stenosis of less than 75%.

[00042] Proximal end 22 of self expanding device 20 is positioned proximally to occlusion 10 and distal end 24 of self expanding device 20 is positioned distally to occlusion 10. Self expanding device 20 in the large diameter state provides a conduit for limited blood flow from proximal end 22 to distal end 24. In one non-limiting embodiment the length of self expanding device 20 in the large diameter, denoted L, is at least 5 times D1. In another non-limiting embodiment length L is at least 10 times D1. In another non-limiting embodiment length L is at least 15 times D1. In another non-limiting embodiment length L is at least 20 times D1. In another non-limiting embodiment length L is at least 30 times D1. In one particular non-limiting embodiment length L is at least 14 times D1. Thus, a conduit of sufficient length to extend from a point proximal of occlusion 10 to a point distal of occlusion 10 is provided. Hub 90 is attached to proximal portion 60 of catheter 40. In one embodiment members 26 and 26A are respectively connected to proximal end 22 and distal end 24 of self expanding device 20. Members 26, 26A and guide wire 30 run through catheter 40 and hub 90 and out therefrom, and are provided to be long enough so as to be accessible.

[00043] The structure of self expanding device 20 can be of any kind, provided it is hollow, including, but not limited to, a tubular tube, a shield tube and a self expanding structure manufactured by any one of weaving, coiling, laser cutting and braiding a plurality of filaments. Optionally, self expanding device 20 is a self expandable braided tubular member, as illustrated. The braid construction that forms self expanding device 20 can be produced from many different materials, including, but not limited to, metals, polymers and composites. More specifically, these materials can include cobalt-chrome alloys, stainless steel, nylon, and polyesters. In one embodiment, superelastic materials such as some nickel titanium alloys, are used. In one particular embodiment a formulation of nickel titanium alloy comprising about 51% - 56% nickel and about 44% - 49% titanium is used.

[00044] In one embodiment each filament comprising self expanding device 20 has a round cross section, the diameter of the cross section usually ranging between about 0.0005 inches and 0.01 inches and optionally between 0.001 inches and 0.004 inches, and the number of filaments comprising the braided construction ranges between 4 and 288. In another embodiment the filaments comprising self expanding

device 20 are flat wires with non-circular cross sections, the number of filaments ranging between 8 and 64, optionally between 12 and 24. In one embodiment the braiding angle is between 60° and 150°. In one particular embodiment the braiding angle is 90°. In one embodiment the braiding pattern is a regular pattern known also as herringbone or 1x2 pattern. In another embodiment a braiding pattern of 1x1 is used, with such a braiding pattern also known as a "one over one under" pattern. In one embodiment self expanding device 20 is permeable to fluids. The inner diameter of self expanding device 20 is in the small diameter state, denoted D0, when self expanding device 20 is held within catheter 40 as illustrated in FIG. 2A described further below. In some embodiments D0 is between 0.5 mm and 1.5 mm, optionally between 0.8 mm and 1.2 mm and diameter D1 is between 0.8 mm and 2 mm, optionally between 1 mm and 1.5 mm. In certain embodiments the length of self expanding device 20 stays fixed when the diameter of self expanding device 20 changes, and in other embodiments, the length of self expanding device 20 is reduced when the inner diameter of self expanding device 20 increases. Alternatively, self expanding device 20 is substantially not expanded or only slightly expands when elongated to length L.

[00045] In one embodiment the braid construction that forms self expanding device 20 is coated with a non-porous elastic material, illustrated in FIG. 3 as a coating 95. Coating over the porous braid construction of self expanding device 20 forms a solid tubular conduit within occlusion 10. The elastic material can be any of a plurality of materials, including, but not limited to: polymers such as silicones, polyethers, polyurethanes, polyamides, hydrogels such as polyvinyl alcohol or polyvinyl pyrrolidone, and other polymers suitable for intravascular use; permeable, semi-permeable and non-permeable membranes; and expandable foams. The elastic material is preferably formed into a fabric mesh and placed around self expanding device 20. Optionally, the elastic material is porous, preferably less permeable than self expanding device 20.

[00046] In the absence of a non-porous elastic material coating, any particles from occlusion 10 which pass through the relatively small openings forming self expanding device 20 flow out therefrom, thereby avoiding harmful disruption of blood flow or occlusion of a vessel thereof.

[00047] Self expanding device 20 in the large diameter state, as shown, provides and/or sustains a perfusion conduit exhibiting a minimum inner diameter D1

for sufficient blood flow to the region distal of occlusion 10 and from there to the affected area, thereby reducing the infarction rate of penumbral tissue. As a result, the effective time window for performing endovascular attempts to remove or disrupt occlusion 10 is expanded. Shortening the length and/or increasing the hollow cross-section diameter of self expanding device 20 may result in greater cerebral blood flow to the region distal to occlusion 10 and from there to the affected area, resulting in a greater reduction in the infarction rate of penumbral tissue. In one embodiment length L of self expanding device 20 in a maximum expanded state is provided to be as short as possible, while being longer than the length of occlusion 10, optionally between 2 mm and 40 mm longer than the length of occlusion 10, and the diameter of the hollow cross-section of self expanding device 20 in a maximum expanded state is provided to be between 1/3 and 1/2 of diameter D2 of body lumen 15, as described above. In one embodiment, where occlusion 10 is 10 mm long, length L is 20 mm, thereby extending 5 mm proximally of occlusion 10 and 5 mm distally of occlusion 10. In another embodiment, where occlusion 10 is 20 – 30 mm long, length L between 40 mm and 50 mm, thereby extending between 5 mm and 15 mm proximally of occlusion 10 and between 5 mm and 15 mm distally of occlusion 10. Self expanding device 20 provides enough radial force at diameters up to the unstressed maximum expanded state of 1/2 of D2 so as to prevent movement of self expanding device 20 in occlusion 10. In one non-limiting embodiment, the inside diameter of self expanding device 20 in its maximum expanded state represents a conduit with a cross section of at least 0.685 mm^2. When self expanding device 20 is at its maximum expanded state it is considered to be at its resting state, since no radial expansion force is exhibited by self expanding device 20, in particular self expanding device 20 does not urge to expand beyond said second large diameter state. Thus, self expanding device 20 may exhibit outward radial force when within occlusion 10, until expansion has reached the unstressed maximum expanded state of 1/2 of D2. Once self expanding device 20 has reached the unstressed maximum expanded state of 1/2 of D2 minimal radial force is applied to occlusion 10. Furthermore no radial force is applied to the walls of body lumen 15 distally and proximally of occlusion 10.

[00048] Members 26, 26A are provided in order to facilitate the deployment of self expanding device 20 into occlusion 10, particularly aiding in control of localization and further procedures, and/or the ultimate retraction of self expanding device 20 therefrom. Members 26 and 26A are in one embodiment each constituted

of one of a flexible rod, a filament or a bundle of filaments. In one embodiment the cross section of each of members 26 and 26A are on the same order as the cross section of guidewire 30, with guidewire 30 preferably being a 0.014" (0.3556 mm) guidewire known to the art exhibiting a cross-sectional area of less than 0.1 mm^2. In the embodiment in which member 26 is connected to proximal end 22 of self expanding device 20 and member 26A is connected to distal end 24 of self expanding device 20, stretching and compressing of self expanding device 20 is enabled by respectively relatively pulling and pushing members 26 and 26A to expand and decrease the length between proximal end 22 and distal end 24. Stretching self expanding device 20 reduces its cross-sectional area and enables an operator to change the placement of self expanding device 20 easily. Compressing self expanding device 20 enlarges its hollow cross-sectional area so as to allow more blood flow there through, as described above. As will be described below in relation to FIG. 2D, self expanding device 20 can be retracted into catheter 40 by pulling member 26 or by pulling and pushing members 26, 26A, respectively, and withdrawn from the patient body along with the retraction of catheter 40.

[00049] In another embodiment members 26,26A are inherently connected to self expanding device 20, i.e. members 26,26A are thin local elongated protrusions of self expanding device 20. There is no requirement that a single catheter 40 be provided for both delivery of self expanding device 20 and withdrawal of self expanding device 20. In one embodiment, withdrawal of self expanding device 20 comprises reduction in radial size to a size greater than the radial size of self expanding device when first delivered to occlusion 10.

[00050] In order to enable visualization of the construction that forms self expanding device 20 under fluoroscopy, in one embodiment numerous radiopaque materials such as gold, platinum, or tungsten can be applied using various methods such as marker, electroplating, ion deposition, and coating. In some embodiments, self expanding device 20 is at least partially coated with a radiopaque polymer such as silicone mixed with tantalum powder thus providing visualization.

[00051] Optionally, self expanding device 20 is secured in location within occlusion 10 by catheter 40 or by another anchoring means secured externally of the patient body, such as by members 26, 26A and 26B, to be described further below.

[00052] Figs. 2A - 2E illustrate high level schematic diagrams of partially sectioned views of the distal portion of temporary endovascular conduit system 50 of

FIG. 1, showing sequential steps in the deployment of self expanding device 20 within body lumen 15 across occlusion 10 according to an exemplary embodiment, the description of Figs. 2A – 2E being taken together. In FIG. 2A self expanding device 20 is in a collapsed state, i.e. a small diameter state, and secured within catheter 40, and particulary in a distal portion of catheter 40. Self expanding device 20 is pre-loaded or back-loaded onto guidewire 30 while secured within catheter 40. Guidewire 30 is manipulated through body lumen 15 from an entry site, such as the femoral artery, to the region of body lumen 15 occluded by occlusion 10. A distal tip 32 of guidewire 30 is advanced across occlusion 10 using appropriate guidewire and crossing techniques known in the art. Once distal tip 32 of guidewire 30 passes through the distal end of occlusion 10, catheter 40 is advanced through occlusion 10. In one embodiment, after distal tip 32 of guidewire 30 has passed through the distal end of occlusion 10, a micro catheter can be used to visualize the patency of both the vasculature proximal to occlusion 10 and the vasculature distal to occlusion 10 using conventional radiographic techniques, prior to advancing catheter 40 over guidewire 30.

[00053] In FIG. 2B temporary endovascular conduit system 50 comprising catheter 40 constraining self expanding device 20 is advanced through occlusion 10, with distal portion 80 of catheter 40 and distal end 24 of self expanding device 20 extending distally of occlusion 10. In one embodiment, a radiographic solution may be injected through hub 90 of FIG. 1 prior to advancing temporary endovascular conduit system 50 into occlusion 10, thus after the positioning of catheter 40 across occlusion 10 the length of occlusion 10 can be determined, thereby allowing an operator to determine the desired positions of distal end 24 and proximal end 22 of self expanding device 20. In another embodiment, determining of the length of occlusion 10 is performed prior to inserting temporary endovascular conduit system 50 in the patient body, thus enabling the operator to choose a specific self expanding device 20 with desired final length and expanded large diameter. Various methods can be applied to visualize proximal end 22 and distal end 24 of self expanding device 20 under fluoroscopy, as described above in relation to FIG. 1.

[00054] In FIG. 2C catheter 40 is partially retracted from restraining self expanding device 20, while members 26, 26A are held in place, thereby partially releasing self expanding device 20 from catheter 40 through distal portion 80. Due to self expanding properties the exposed part of self expanding device 20 automatically

performs an outward radial expansion and preferably forms into a generally circular configuration. Optionally, inner diameter D1 of self expanding device 20 in the large diameter state is no greater than twice, optionally no greater than 1.5 times, and further optionally no greater than 1.2 times the inner diameter D0 of self expanding device 20 in the small diameter state when held within catheter 40.

[00055] In FIG. 2D catheter 40 is retracted until self expanding device 20 is fully released. Self expanding device 20 expands to its large diameter state, presenting a conduit for blood flow through occlusion 10. Catheter 40 may be fully retracted from the patient body. In one embodiment guidewire 30 remains positioned in occlusion 10 to provide guidance for maneuvering medical means to the site of occlusion 10. In another embodiment guidewire 30 is removed from the patient body and member 26 and/or member 26A provides guidance for maneuvering medical means to the site of occlusion 10, thus enabling extended medical procedures without the need of guidewire 30.

[00056] Temporary endovascular conduit system 50 can be fully retracted out of the patient body, whenever necessary. In one embodiment this is accomplished by expanding the length of self expanding device 20 by manipulation of members 26, 26A thereby reducing the diameter of self expanding device 20. Once the diameter of self expanding device 20 has been reduced, catheter 40 is preferably advanced over self expanding device 20 while self expanding device 20 is held in the small diameter state by members 26, 26A, and catheter 40 containing therein self expanding device 20 is then removed from the patient body. Alternatively, catheter 40 is held stationary and self expanding device 20 in the small diameter state is withdrawn from the area of occlusion 10 towards distal portion 80 of catheter 40, and then drawn within catheter 40. In an alternative embodiment, self expanding device 20 is maintained in the small diameter state by the manipulation of members 26, 26A and removed from the patient body by further manipulation of members 26, 26A.

[00057] Advantageously, since self expanding device 20 may be collapsed and returned within catheter 40, numerous deployments of self expanding device 20 at various locations may be performed as a single endovascular procedure.

[00058] In another embodiment illustrated in FIG. 2E, a member 26B constituted of one of a flexible rod, a filament or a bundle of filaments is attached to proximal end 22 of self expanding device 20. Member 26B can be produced by many different techniques, including but not limited to looping, tying, stitching,

interweaving, gluing, welding and soldering, to one or more locations within proximal end 22. In a preferred embodiment member 26B is looped into the collapsible braided construction of proximal end 22 and thus reduces the diameter of self expanding device 20 while tensioned. Self expanding device 20 can be retracted into catheter 40 by tensioning holding member 26B and advancing distal portion 80 of catheter 40 from proximal end 22 to distal end 24 of self expanding device 20. In this particular embodiment a stopper 27 with an outer diameter fits into the inner diameter of catheter 40 and facilitates deployment of self expanding device 20 into occlusion 10 since stopper 27 is in contact with proximal end 22 of self expanding device 20 when retracting catheter 40 out of its position across occlusion 10.

[00059] FIG. 3 illustrates a high level schematic diagram of a partially sectioned view of the distal portion of temporary endovascular conduit system 50 of FIG. 1 and a delivery mechanism 70 for intra-arterial administration of t-PA according to an exemplary embodiment, with device 20 illustrated with coating 95. Coating 95 is in some embodiments non-permeable, and in other embodiments permeable. Self expanding device 20 is shown in its large diameter state, i.e. its fully expanded uncompressed state, inside occlusion 10, thereby sustaining at least some blood flow through occlusion 10, as described above. Thus, penumbral tissue preservation is facilitated, thereby prolonging the time window for any effective catheter based recanalization procedure, as described above. In one embodiment, temporary endovascular conduit system 50 is temporarily deployed, so as to supply oxygenated blood to the ischemic penumbrae, and thereafter removed prior to any endovascular procedure for attempting to remove or disrupt occlusion 10, and optionally redeployed between repeated procedures for attempting to remove or disrupt occlusion 10. In another embodiment, as illustrated in FIG. 3, temporary endovascular conduit system 50 is deployed prior to any endovascular procedure for recanalization of lumen 15, and self expanding device 20 remains expanded inside occlusion 10 during the procedure, thereby maintaining blood flow during the procedure. Optionally, coating 95 is permeable, and thus allows for the passage of a fluid from delivery mechanism 70 to occlusion 10. In such an embodiment, delivery mechanism 70 is preferably delivered to be within self expanding device 20 optionally formed of a mesh exhibiting openings such that fluid exiting delivery mechanism 70 is received to the circumference of self expanding device 20 deployed across occlusion 10. In another embodiment catheter 40 is used as a passage of a fluid from

outside of the body to the occlusion site eliminating the need for delivery mechanism 70.

[00060] Delivery mechanism 70 is manipulated through body lumen 15 from an entry site, such as the femoral artery, to a region proximal to occlusion 10. In the embodiment in which temporary endovascular conduit system 50 has been removed and guidewire 30 has been left in place, delivery mechanism 70 can be manipulated over guidewire 30. In the embodiment in which guidewire 30 has also been removed, or in the embodiment in which temporary endovascular conduit system 50 has not been removed, as illustrated, delivery mechanism 70 can be manipulated over a dedicated additional guidewire and/or through a guiding catheter, or by using any other technique known in the art. Delivery mechanism 70 administers a drug such as a neuro-protective agent, or a thrombolytic agent such as t-PA or any other antithrombotic agent into occlusion 10, thus breaking down occlusion 10. In another embodiment, other means of removing or disrupting occlusion 10, such as: thrombolytic agent infusing techniques; distal or proximal embolectomy devices; various wire corkscrews and baskets; clot capturing devices; and clot aspiration and removing devices, can be used. Other methods of removing or disrupting occlusion 10, such as: facilitating fibrinolysis by an outside energy source such as ultrasound or laser energy; and mechanical manipulation of occlusion 10 by primary angioplasty and/or by employing stents permanently or transiently, may be used.

[00061] FIG. 4 illustrates a high level schematic diagram of a sectioned view of a second embodiment of a temporary endovascular perfusion conduit system, denoted temporary endovascular perfusion conduit system 150, deployed in an occlusion 10 occluding a body lumen 15. Temporary endovascular perfusion conduit system 150 comprises: a catheter 40, exhibiting a proximal portion 60 and a distal portion 80; a hub 90; a pair of members 126 and 126A; and an expanding device 120, exhibiting a proximal end 122 and a distal end 124, illustrated in a large diameter state. A guide wire 30 is also provided. The diameter of body lumen 15 in the area of occlusion 10 is denoted D2, and the inner diameter of expanding device 120 in the large diameter state denoted D1, is between 1/3 and 1/2 of D2. Advantageously providing a conduit exhibiting an inner diameter for blood flow of at least 1/3 of D2 allows a sufficient blood flow, in the absence of sufficient collateral flow from other arteries, to prevent or delay cell death since this provides for a resultant stenosis of less than 75%.

[00062] Proximal end 122 of expanding device 120 is positioned proximally to occlusion 10 and distal end 124 of expanding device 120 is positioned distally to occlusion 10. Expanding device 120 in the large diameter state provides a conduit for limited blood flow from proximal end 122 to distal end 124. Optionally, the length of expanding device 120 in the large diameter, denoted L, is at least 5 times D1. In another non-limiting embodiment length L is at least 10 times D1. In another non-limiting embodiment length L is at least 15 times D1. In another non-limiting embodiment length L is at least 20 times D1. In another non-limiting embodiment length L is at least 30 times D1. In one particular non-limiting embodiment length L is at least 14 times D1. Thus, a conduit of sufficient length to extend from a point proximal of occlusion 10 to a point distal of occlusion 10 is provided.

[00063] Hub 90 is attached to proximal portion 60 of catheter 40. In one embodiment members 126 and 126A are respectively connected to one or both of proximal end 122 and distal end 124 of expanding device 120. In one particular embodiment member 126 is connected to proximal end 122 of expanding device 120 and member 126A is connected to distal end 124 of expanding device 120, as will be described further hereinto below. Members 126 and 126A and guide wire 30 run through catheter 40 and hub 90 and out therefrom, and are provided to be long enough so as to be accessible.

[00064] The structure of expanding device 120 can be of any kind, providing it is hollow, including, but not limited to, a tubular tube, a shield tube and a self expanding structure manufactured by weaving, braiding, laser cutting, or by coiling a filament. Optionally expanding device 120 is a self expandable coiled tubular member, as illustrated, formed by winding a filament spirally and closely over a predetermined diameter and arranged such that when in a fully expanded state each wind is in contact with an adjacent wind, thereby forming a solid tubular shape. The coil forming expanding device 120 can be produced from many different materials, including, but not limited to, metals, polymers and composites. More specifically, these materials can include cobalt-chrome alloys, stainless steel, nylon, and polyesters. In a preferred embodiment, superelastic materials such as some nickel titanium alloys, are used. Further preferably, a formulation of nickel titanium alloy comprising about 51% - 56% nickel and about 44% - 49% titanium is used. Optionally, expanding device 120 is not self-expandable, but is instead balloon-

expandable, shape memory altered by temperature change or externally stretchable without limitation.

[00065] In one embodiment the filament comprising expanding device 120 has a round cross section, the diameter of the cross section usually ranging between about 0.001 inches and 0.006 inches and optionally between 0.001 inches and 0.0035 inches. In another embodiment the filament comprising expanding device 120 is a flat wire with a non-circular cross section.

[00066] In one embodiment (not shown) the coil forming expanding device 120 is coated with a non-porous elastic material. Coating over the porous coil will form a solid tubular conduit within occlusion 10. The elastic material can be any of a plurality of materials, including, but not limited to: polymers such as silicone, polyethers, polyurethanes, polyamides, hydrogels such as polyvinyl alcohol or polyvinyl pyrrolidone, and other polymers suitable for intravascular use; permeable, semi-permeable and non-permeable membranes; and expandable foams. The elastic material is formed into a fabric mesh and placed around expanding device 120. Optionally, the elastic material is porous, preferably less permeable than expanding device 120.

[00067] In the absence of a non-porous elastic material coating any particles from occlusion 10 which pass through the relatively small openings forming expanding device 120 flow out therefrom, thereby avoiding harmful disruption of blood flow or occlusion of a vessel thereof.

[00068] Expanding device 120 in the large diameter state, as shown, provides and sustains a conduit exhibiting an inner diameter D1 for sufficient blood flow to the region distal of occlusion 10 and from there to the affected area, thereby reducing the infarction rate of penumbral tissue. As a result, the effective time window for performing endovascular attempts to remove or disrupt occlusion 10 is expanded. Shortening the length and/or increasing the hollow cross-section diameter of expanding device 120 may result in greater cerebral blood flow to the region distal to occlusion 10 and from there to the affected area, resulting in a greater reduction in the infarction rate of penumbral tissue. In one embodiment length L of expanding device 120 in a maximum expanded state is provided to be as short as possible, while being longer than the length of occlusion 10, optionally between 2 mm and 40 mm longer than the length of occlusion 10, and the diameter of the hollow cross-section of expanding device 120 in a maximum expanded state is provided to be between 1/3

and 1/2 of diameter D2 of body lumen 15, as described above. In one embodiment, where occlusion 10 is 10mm long, length L is 20 mm, thereby extending 5mm proximally of occlusion 10 and 5mm distally of occlusion 10. In another embodiment, where occlusion 10 is 20 – 30mm long, length L between 40mm and 50mm, thereby extending between 5mm and 15mm proximally of occlusion 10 and between 5mm and 15mm distally of occlusion 10.

[00069] Expanding device 120 provides enough radial force at diameters up to the unstressed maximum expanded state of 1/2 of D2 so as to prevent movement of expanding device 120 in occlusion 10. In one non-limiting embodiment, the inside diameter of expanding device 120 in its maximum expanded state represents a conduit with a cross section of at least 0.685 mm^2. When expanding device 120 is at its maximum expanded state it is considered at resting state, since no radial expansion force is exhibited by expanding device 120, in particular expanding device 120 does not urge to expand beyond the large diameter state. Thus, expanding device 120 may exhibit outward radial force when within occlusion 10, until expansion has reached the unstressed maximum expanded state of 1/2 of D2. Once expanding device 120 has reached the unstressed maximum expanded state of 1/2 of D2 minimal radial force is applied to occlusion 10. Furthermore no radial force is applied to the walls of body lumen 15 distally and proximally of occlusion 10.

[00070] Further preferably the hollow cross-sectional area of expanding device 120 is small enough so as to allow simultaneous use of expanding device 120 and a device for dislodging, removing and/or dissolving the clot, as will be described below in relation to FIG. 6.

[00071] Optionally, expanding device 120 is secured in location within occlusion 10 by catheter 40 or by another anchoring means secured externally of the patient body, such as by members 126, 126A or 126B to be described further below

[00072] Optional members 126,126A are provided in order to facilitate the deployment of expanding device 120 into occlusion 10 particularly aiding in control of localization and further procedures, and/or the ultimate retraction of expanding device 120 therefrom. Members 126 and 126A are in one embodiment each constituted of one of a flexible rod, a filament or a bundle of filaments. In one embodiment the cross section of each of members 126 and 126A are on the same order as the cross section of guidewire 30, with guidewire 30 preferably being a 0.014" (0.3556 mm) guidewire known to the art exhibiting a cross-sectional area of

less than 0.1 mm^2. In the embodiment in which member 126 is connected to proximal end 122 of expanding device 120 and member 126A is connected to distal end 124 of expanding device 120, stretching and compressing of expanding device 120 is enabled by respectively relatively pulling and pushing members 126 and 126A to expand and decrease the length between proximal end 122 and distal end 124. Stretching expanding device 120 reduces its cross-sectional area and enables an operator to change the placement of expanding device 120 easily. Compressing expanding device 120 enlarges its hollow cross-sectional area so as to allow more blood flow there through, as described above. As will be described below in relation to FIG. 5D, expanding device 120 can be retracted into the catheter 40 using members 126, 126A and withdrawn from the patient body along with the retraction of catheter 40.

[00073] In another embodiment members 126,126A are inherently connected to expanding device 120, i.e. members 126,126A are thin local elongated protrusions of expanding device 120. There is no requirement that a single catheter 40 be provided for both delivery of expanding device 120 and withdrawal of expanding device 120. In one embodiment, withdrawal of expanding device 120 comprises reduction in radial size to a size greater than the radial size of expanding device when first delivered to occlusion 10.

[00074] In order to enable visualization of the coil that forms expanding device 120 under fluoroscopy, in one embodiment numerous radiopaque materials such as gold, platinum, or tungsten can be applied using various methods such as marker, electroplating, ion deposition, and coating. In a preferred embodiment, expanding device 120 is coated with a radiopaque polymer such as silicone mixed with tantalum powder.

[00075] Figs. 5A – 5E illustrate high level schematic diagrams of partially sectioned views of the distal portion of temporary endovascular perfusion conduit system 150 of FIG. 4, showing sequential steps in the deployment of expanding device 120 within body lumen 15 across occlusion 10 according to an exemplary embodiment, the description of Figs. 5A – 5D being taken together. In FIG. 5A expanding device 120 is in a collapsed state, i.e. a small diameter state, and secured within catheter 40, and particularly in a distal portion of catheter 40. Expanding device 120 is pre-loaded or back-loaded onto guidewire 30 while secured within catheter 40. Guidewire 30 is manipulated through body lumen 15 from an entry site, such as the femoral artery, to the region of body lumen 15 occluded by occlusion 10.

A distal tip 32 of guidewire 30 is advanced across occlusion 10 using appropriate guidewire and crossing techniques known in the art. Once distal tip 32 of guidewire 30 passes through the distal end of occlusion 10, catheter 40 is advanced through occlusion 10. In one embodiment, after distal tip 32 of guidewire 30 has passed through the distal end of occlusion 10, a micro catheter can be used to visualize the patency of both the vasculature proximal to occlusion 10 and the vasculature distal to occlusion 10 using conventional radiographic techniques, prior to advancing catheter 40 over guidewire 30.

[00076] In FIG. 5B temporary endovascular conduit system 150 comprising catheter 40 constraining expanding device 120 is advanced through occlusion 10, with distal portion 80 of catheter 40 and distal end 124 of expanding device 120 extending distally of occlusion 10. In one embodiment, a radiographic solution may be injected through hub 90 of FIG. 4 prior to advancing temporary endovascular conduit system 150 into occlusion 10, thus after the positioning of catheter 40 across occlusion 10 the length of occlusion 10 can be determined, thereby allowing an operator to determine the desired positions of distal end 124 and proximal end 122 of expanding device 120. In another embodiment, determining of the length of occlusion 10 is performed prior to inserting temporary endovascular conduit system 150 in the patient body, thus enabling the operator to choose a specific expanding device 120 with a desired final length and expanded large diameter. Various methods can be applied to visualize proximal end 122 and distal end 124 of expanding device 120 under fluoroscopy, as described above in relation to FIG. 4.

[00077] In FIG. 5C catheter 40 is partially retracted from expanding device 120 while members 126,126A are held in place, thereby partially releasing expanding device 120 from catheter 40 through distal portion 80. In the embodiment in which expanding device 120 is self expandable, due to self expanding properties the exposed part of expanding device 120 automatically performs an outward radial expansion and preferably forms into a generally circular configuration. Optionally, inner diameter D1 of expanding device 120 in the large diameter state is no greater than twice, optionally no greater than 1.5 times, and further optionally no greater than 1.2 times the inner diameter of expanding device 120 in the small diameter state when held within catheter 40, denoted D0.

[00078] In FIG. 5D catheter 40 is retracted until expanding device 120 is fully released. Expanding device 120 expands to its large diameter state presenting a

conduit for blood flow through occlusion 10. Catheter 40 may be fully retracted from the patient body. In one embodiment guidewire 30 remains positioned in occlusion 10 to provide guidance for maneuvering medical means to the site of occlusion 10. In another embodiment guidewire 30 is removed from the patient body and member 126 and/or member 126A provides guidance for maneuvering medical means to the site of occlusion 10, thus enabling extended medical procedures without the need of a guide wire 30.

[00079] Temporary endovascular perfusion conduit system 150 can be fully retracted out of the patient body, whenever necessary. In one embodiment this is accomplished by expanding the length of expanding device 120 by manipulation of members 126, 126A thereby reducing the diameter of expanding device 120. Once the diameter of expanding device 120 has been reduced, catheter 40 is preferably advanced over expanding device 120 while expanding device 120 is held in the small diameter state by members 126, 126A, and catheter 40 containing therein expanding device 120 is then removed from the patient body. Alternatively, catheter 40 is held stationary and expanding device 120 in the small diameter state is withdrawn from the area of occlusion 10 towards proximal end 80 of catheter 40, and then drawn within catheter 40. In an alternative embodiment, expanding device 120 is maintained in the small diameter state by the manipulation of members 126, 126A and removed from the patient body by further manipulation of members 126, 126A.

[00080] Advantageously, since expanding device 120 may be collapsed and returned within catheter 40, numerous deployments of expanding device 120 at various locations may be performed as a single endovascular procedure.

[00081] In another embodiment illustrated in FIG. 5E, expanding device 120 can be retracted into catheter 40 by a holding member 126B by tensioning holding member 26B and advancing distal portion 80 of catheter 40 from proximal end 122 to distal end 124 of expanding device 120. In this particular embodiment a stopper 27 exhibiting an outer diameter fits into the inner diameter of catheter 40 and facilitates the deployment of expanding device 120 into occlusion 10 by keeping stopper 27 in constant contact against the proximal end 122 of expanding device 120 and pushing it gradually during the retraction of catheter 40 out of its position across occlusion 10.

[00082] FIG. 6 illustrates a high level schematic diagram of a partially sectioned view of the distal portion of temporary endovascular perfusion conduit system 150 of FIG. 4 and a delivery mechanism 70 for intra-arterial administration of

t-PA according to an exemplary embodiment. Expanding device 120 is shown in its large diameter state, i.e. its fully expanded state, inside occlusion 10, thereby sustaining at least some blood flow through occlusion 10, as described above. Expanding device 120 urges towards the at rest state, which thus represents a maximum for the large diameter state. Thus, penumbral tissue preservation is facilitated, thereby prolonging the time window for any effective catheter based recanalization procedure, as described above. In one embodiment, temporary endovascular perfusion conduit system 150 is temporarily deployed, so as to supply oxygenated blood to the ischemic penumbrae, and thereafter removed prior to any endovascular procedure for attempting to remove or disrupt occlusion 10, and optionally redeployed between repeated procedures for attempting to remove or disrupt occlusion 10. In another embodiment, illustrated in FIG. 6, temporary endovascular perfusion conduit system 150 is deployed prior to any endovascular procedure for attempting to remove or disrupt occlusion 10, and expanding device 120 remains expanded inside occlusion 10 during the procedure, thereby maintaining blood flow during the procedure. Optionally, expanding device 120 is permeable, and thus allows for the passage of a fluid from delivery mechanism 70 to occlusion 10. In such an embodiment, delivery mechanism 70 is preferably delivered to be within expanding device 120 optionally formed as a spiral winding wherein successive turns are not in contact with previous turns thus forming a structure such that fluid exiting delivery mechanism 70 is received to the circumference of expanding device 120 deployed across occlusion 10. In another embodiment catheter 40 is used as a passage of a fluid from outside of the body to the occlusion site eliminating the need for delivery mechanism 70.

[00083] Delivery mechanism 70 is manipulated through body lumen 15 from an entry site, such as the femoral artery, to a region proximal to occlusion 10. In the embodiment in which temporary endovascular perfusion conduit system 150 has been removed and guidewire 30 has been left in place, delivery mechanism 70 can be manipulated over guidewire 30. In the embodiment in which guidewire 30 has also been removed, or in the embodiment in which temporary endovascular perfusion conduit system 150 has not been removed, as illustrated, delivery mechanism 70 can be manipulated over a dedicated additional guidewire and/or through a guiding catheter, or by using any other technique known in the art. Delivery mechanism 70 administers a drug such as a neuro-protective agent, or a thrombolytic agent such as t-

PA, or any other antithrombotic agent, into occlusion 10, thus breaking down occlusion 10. In another embodiment, other means of removing or disrupting occlusion 10, such as: thrombolytic agent infusing techniques; distal or proximal embolectomy devices; various wire corkscrews and baskets; clot capturing devices; and clot aspiration and removing devices, can be used. Other methods of removing or disrupting occlusion 10, such as: facilitating fibrinolysis by an outside energy source such as ultrasound or laser energy; and mechanical manipulation of occlusion 10 by primary angioplasty and/or by employing stents permanently or transiently, may be used.

[00084] FIG. 7A illustrates a high level schematic diagram of a sectioned view of an embodiment of a temporary endovascular perfusion conduit 220 exhibiting a distal filtering extension member 240, coupled to distal end 24 of self expanding device 20 via transition portion 230. Self expanding device 20 is substantially as described above in relation to FIG. 1, exhibiting an inner diameter between 1/3 and 1/2 of D2, i.e. the diameter of body lumen 15 in the area of occlusion 10. In an exemplary embodiment distal filtering extension member 240 is sized so as to meet the inner walls of lumen 15 in the area distal of occlusion 10. In an exemplary embodiment, distal filtering extension member 240 is arranged to be at the resting state for diameters of 0.25 mm – 1.5 mm larger than the inner walls of lumen 15 in the area distal of occlusion 10, thus ensuring that distal filtering extension member 240 meets the inner walls of lumen 15 and further optionally provides a securing or anchoring functionality. Transition portion 230 is optionally a flared portion, and both transition portion 230 and distal filtering extension member 240 may be provided in a single integrated braid using an appropriately shaped mandrel, as described in U.S Patent S/N 7,093,527 issued August 22, 2006 to Rapaport et al, entitled "Method and Apparatus for Making Intraluminal Implants and Construction Particularly Useful in such Method and Apparatus", the entire contents of which is incorporated herein by reference. In an exemplary embodiment, distal filtering extension member 240 is arranged to trap particles greater than a predetermined size. In one preferred embodiment the predetermined size is 500 microns. In another embodiment the predetermined size is 350 microns. In another embodiment the predetermined size is 200 microns, and in yet another embodiment the predetermined size is 80 microns.

[00085] In another embodiment transition portion 230 and distal filtering extension member 240 are of a different element than that of temporary endovascular

perfusion conduit 220, such as of silicon or rubber. The distal portion of distal filtering extension member 240 may be open, may exhibit a filter, or be closed in the area opposing transition portion 230 without exceeding the scope. The filter of distal filtering extension member 240 may be more or less permeable than the walls of temporary endovascular perfusion conduit 220 without exceeding the scope.

[00086] FIG. 7B illustrates a high level schematic diagram of a sectioned view of an embodiment of a temporary endovascular perfusion conduit 320 exhibiting distal filtering extension member 240 coupled to distal end 24 of self expanding device 20 via transition portion 230, and further exhibiting a proximal securing member 330 coupled to proximal end 22 of self expanding device 20 via a transition portion 340. Self expanding device 20 is substantially as described above in relation to FIG. 1, exhibiting an inner diameter between 1/3 and 1/2 of D2, i.e. the diameter of body lumen 15 in the area of occlusion 10 and distal filtering extension member 240 is substantially as described above in relation to FIG. 7A.

[00087] Proximal securing member 330 is preferably sized so as to meet the inner walls of lumen 15 in the area proximal of occlusion 10, thus occlusion 10 is completely encased by the combination of self expanding device 20, distal filtering extension member 240 and proximal securing member 330. In an exemplary embodiment, proximal securing member 330 is arranged to be at resting state for diameters of 0.25 mm – 1.5 mm larger than the inner walls of lumen 15 in the area proximal of occlusion 10, thus ensuring that proximal securing member 330 meets the inner walls of lumen 15, thus securing particles detached from occlusion 10 to flow out therefrom, thereby avoiding harmful disruption of blood flow or occlusion of a vessel thereof, and optionally providing a securing or anchoring functionality. Transition portion 340 is preferably a flared portion, and both transition portion 340 and proximal securing member 340 may be provided in a single integrated braid using an appropriately shaped mandrel, as described in U.S Patent S/N 7,093,527 incorporated above by reference.

[00088] FIG. 8 illustrates a high level flow chart of a method for providing temporary endovascular perfusion. In stage 1000, an expandable tubular body is provided, preferably selected so as to exhibit a small diameter state and a large diameter state. The expandable tubular body exhibits a diameter in the large diameter state no more than 50% of the diameter of a target blood vessel at the sight of the

occlusion. The large diameter state of the expandable tubular body may exhibit a diameter of up to the at rest state diameter of the expandable tubular body.

[00089] In optional stage 1010, the length of the expandable tubular body of stage 1000 is selected so as to be at least 14 times the inner diameter of the expandable tubular body in the large diameter state. In optional stage 1020, the inner diameter of the expandable tubular body of stage 1000 in the large diameter state is selected so as to be no greater than twice the diameter of the expandable tubular body of stage 1000 in the small diameter state. The inner diameter of the small diameter state may not be inherent, and in an exemplary embodiment is defined by the parameters of the delivery catheter, such as catheter 40.

[00090] In stage 1030, the expandable tubular body of stage 1000 is advanced in the small diameter state through the occlusion. Alternatively or additionally, a distal portion or a tip of the catheter is first broached through the occlusion thereby opening and/or widening a passage therethrough, later to be occupied and sustained by the expandable tubular body, as the catheter is further advanced. Optionally, the expandable tubular body is manipulated through the body and advanced through the occlusion while loaded onto the distal portion of a delivery catheter, such as catheter 40.

[00091] In stage 1040, the advanced tubular body of stage 1030 is expanded to the large diameter state, thus providing a conduit through the expanded tubular body to maintain blood flow patency through the occlusion. There is no requirement that the expansion be complete to the at rest state diameter, and the only requirement is that sufficient blood flow patency is restored by providing blood flow of at least 25% of the unoccluded blood flow volume. Advantageously, by proper selection of the large diameter state, and particularly the at rest state diameter, the advanced tubular body of stage 1030 occupies the widened passage opened by the catheter that first broached through the occlusion so no additional radial force is supplied by the expanded tubular body to the occlusion, thus preventing unintended and uncontrolled break up.

[00092] In optional stage 1050, a medicament is delivered to the occlusion. Preferably the tubular body is permeable by the medicament when in the large diameter state and thus the medicament is delivered through the tubular body to the occlusion surrounding the tubular body.

[00093] In optional stage 1060, a distal filtering extension is provided distal of the tubular body of stage 1000, the distal filtering extension being expanded to meet the blood vessel walls distal of the occlusion. Advantageously, the distal filtering extension traps any dislodged fragments of the occlusion.

[00094] In optional stage 1070, the tubular body is contracted, preferably to the small diameter state, and withdrawn from the blood vessel.

[00095] FIG. 9A illustrates a high level schematic diagram of a perspective view of an embodiment of an occlusion retrieval device 420 comprising a generally tubular inner member 425 in communication with an outer member 430, wherein generally tubular inner member 425 is illustrated without limitation as self expanding device 20 as described above, and FIG. 9B illustrates a high level schematic diagram of a sectioned view of occlusion retrieval device 420 shown disposed within body lumen 15 at occlusion 10, FIGs. 9A and 9B being described together. Occlusion retrieval device 420 is in all respects similar to self expanding device 20 of FIG. 1, with the addition of outer member 430 constituted of an additional braid external to that of generally tubular inner member 425, the additional braid of outer member 430 constituted of a plurality of filaments 435. In one embodiment, outer diameter D3 of outer member 430 in an at rest state is 0.5 mm – 1.5 mm larger than diameter D2 of the inner walls of body lumen 15 in the area of occlusion 10. As a result, when outer member 430 is in a large diameter state, i.e. in an expanded state within body lumen 15, outer member 430 exerts outward radial force and a portion of filaments 435 of outer member 430 meets the inner walls of body lumen 15 through occlusion 10 and exerts outward radial force thereon. In one particular embodiment, wherein outer diameter D3 in the at rest state is 4 mm, which is 1 mm larger than the inner walls D2 of body lumen 15, the pressure applied to the inner walls of body lumen 15, applied at each contact point of outer member 430 with the inner walls of body lumen 15, is at least 15,000 pascals. Advantageously, this is at least 2.5 times greater than the local pressure applied by a standard stent for recanalization procedure and/or occlusion retrieval of the prior art, thus preferably ensuring contact between a portion of filaments 435 and the inner walls of body lumen 15.

[00096] Outer member 430 is in one embodiment an open braid constituted of filaments 435 and thus expands to trap within holes 440 of outer member 430 portions 470 of occlusion 10. In one particular embodiment, the largest open dimension of each hole 440 is about 0.9 millimeters, the number of holes/ cm^2 is about 80, the

length of each filament 435 per area of outer member 430 is about 200 mm/cm^2 and the amount of actual filament 430 surface area per surface area of the outer member 430 is about 30 mm/cm^2. Advantageously, the hole size is significantly smaller than the equivalent dimension of a stent for recanalization procedure and/or occlusion retrieval of the prior art, thus limiting the amount of occlusion 10 which is dislodged, and the number of holes per cm^2 is significantly greater than stents for recanalization procedure and/or occlusion retrieval of the prior art thus ensuring greater surface contact between occlusion retrieval 430 and occlusion 10. Further preferably, the ratio of actual filament 435 surface over the total body area of outer member 430 is less than 90%. Occlusion 10 is trapped between generally tubular inner member 425 and outer member 430, and thus breakup of occlusion 10 is prevented.

[00097] In one embodiment the number of filaments constituting outer member 430 is of the same order of the number of filaments constituting self expanding device 20. In one embodiment the number of filaments constituting outer member 430 is between 14 – 20 and the number of filaments constituting generally tubular inner member 425 is between 8 – 16. In one non-limiting embodiment outer member 430 is constituted of 16 filaments and generally tubular inner member 425 is constituted of 14 filaments. In one embodiment each filament 435 of outer member 430 is constituted of a spring alloy wire material such as cobalt-chrome alloys, stainless steel, and nickel titanium alloys. In one embodiment the diameter of each filament constituting outer member 430 is between 40 microns – 65 microns. In one embodiment at least one filament 435 of outer member 430 is constituted of a radiopaque material such as gold, platinum, or tungsten wire that is visible under fluoroscopy. In one embodiment a length L1 of outer member 430 is between 10 mm – 20 mm less than a length L2 of self expanding device 20.

[00098] In one embodiment proximal end 432 of outer member 430 is connected to a proximal connecting portion 460 of generally tubular inner member 425 and distal end 434 of outer member 430 is connected to distal connecting portion 450 of generally tubular inner member 425. In one embodiment outer member 430 is a self expanding device, as described above in relation to self expanding device 20. In one embodiment outer member 430 is thus retrieved responsive to the action of member 26 as described above in relation to FIGs. 1 and 2D. In another embodiment additional members similar to members 26 and 26A are provided associated with

outer member 430, thereby allowing independent stretching and compressing of outer member 430.

[00099] Portions 470 of occlusion 10 are trapped within holes 440 of outer member 430 and are furthermore trapped between outer member 430 and generally tubular inner member 425, as an inner diameter D5 of outer member 430 in the large diameter state, i.e. when expanded within body lumen 15, is greater than outer diameter D4 of generally tubular inner member 425. As described above, outer diameter D4 of generally tubular inner member 425 is no greater than the at rest state diameter of generally tubular inner member 425. Retrieval of outer member 430, preferably in combination with retrieval of generally tubular inner member 425 thus removes portions 470 of occlusion 10 from body lumen 15. In many situations, the increased surface area connection between the combination of generally tubular inner member 425 and outer member 430 with occlusion 10 will result in complete removal of occlusion 10. In one non-limiting embodiment generally tubular inner member 425 provides and/or sustains a conduit for blood passage having a diameter for sufficient blood flow to the region distal of occlusion 10, as described above in relation to self expanding device 20.

[000100] Production of occlusion retrieval device 420 is in one embodiment performed by braiding generally tubular inner member 425 with additional filaments coupled to inherent structural filaments of outer member 430. The additional filaments will ultimately appear only in outer member 430. Proximal connecting portion 460 of generally tubular inner member 425 is braided and then additional filaments are braided over generally tubular inner member 425 to form outer member 430. The filaments of generally tubular inner member 425 and the additional filaments of outer member 430 are cut to lengths L2 and L1 respectively or connected together to form distal connecting portion 450.

[000101] In one embodiment, as generally tubular inner member 425 is braided to proximal connecting portion 460, the additional filaments of outer member 430 are removed from the braiding machine, and generally tubular inner member 425 is braided to portion 450. A tube with a desired length at the at rest state of outer member 430 and an inner diameter larger than that of generally tubular inner member 425 and an outer diameter of the desired diameter at the at rest state of outer member 430 is placed over the braided portion of generally tubular inner member 425. The additional filaments of proximal connecting portion 460 are then braided over the tube

to a desired length, the length defined at the resting state of outer member 430, and then braided to distal connecting portion 450. The additional filaments of distal connecting portion 450 are then removed, and all filaments, including the filaments of generally tubular inner member 425 and the additional filaments are cut to lengths L2 and L1 respectively or connected together to form distal connecting portion 450. The connection between the filaments of generally tubular inner member 425 and the additional filaments in distal connecting portion 450 can be produced by many different techniques, including but not limited to braiding, looping, tying, stitching, interweaving, gluing, welding and soldering.

[000102] The above has been described in an embodiment in which occlusion retrieval device 420 is a braided device, however this is not meant to be limiting in any way. In another embodiment occlusion retrieval device 420 is manufactured by any one of weaving, coiling and laser cutting.

[000103] FIG. 10A illustrates a high level schematic diagram of a sectioned view of an embodiment of an occlusion retrieval device 520 comprising a generally tubular inner member 525 in communication with an outer member 530. In one non-limiting embodiment generally tubular inner member 525 is in all respects similar to self expanding device 20. FIG. 10A illustrates occlusion retrieval device 520 in a collapsed state, i.e. a small diameter state, and secured within catheter 40 as described above in relation to FIG. 2A. FIG. 10B illustrates a high level schematic diagram of a sectioned view of an embodiment of occlusion retrieval device 520 of FIG. 10A in a partially expanded state; and FIG. 10C illustrates a high level schematic diagram of a sectioned view of occlusion retrieval device 520 of FIG. 10A in a large diameter state within body lumen 15 at occlusion 10. FIGs. 10A, 10B and 10C will be described together for simplicity and clarity.

[000104] Occlusion retrieval device 520 is in all respects similar to occlusion retrieval device 420 of FIGs. 9A, 9B, except that, in one embodiment, the distal end 534 of outer member 530 is not connected distally to generally tubular inner member 525. A proximal end 532 of outer member 530 is thus connected to a proximal end 542 of generally tubular inner member 525 via a proximal connecting portion 550. In one embodiment distal end 534 of outer member 530 is open, i.e. it does not converge to meet a distal end 524 of self expanding device 20. In another embodiment distal end 534 of outer member 530 converges to meet distal end 524 of self expanding device 20.

[000105] As described above in relation to outer member 430 of FIGs. 9A, 9B, outer member 530 is in one embodiment a self expanding device. During deployment catheter 40 is guided by guide wire 30 into occlusion 10 and retracted, as described above in relation to FIG. 2C, thereby releasing generally tubular inner member 525 and outer member 530. In the embodiment where both generally tubular inner member 525 and outer member 530 are self expanding devices, generally tubular inner member 525 thus self expands towards the at rest state to achieve a large diameter state, with a maximum outer diameter equal to the at rest state diameter, and outer member 530 self expands to meet the inner walls of body lumen 15. In the embodiment where members 26 and 26A are utilized for stretching and compressing of generally tubular inner member 525, the same members, or additional members may be utilized for stretching and compressing outer member 530, as described above in relation to FIG. 9A.

[000106] In the large diameter state, as illustrated in FIG. 10C, outer member 530 preferably meets the inner wall of body lumen 15, and occlusion 10 is secured between outer member 530 and generally tubular inner member 525. In one embodiment patency is ensured by generally tubular inner member 525. Occlusion 10 experiences a large contact area with generally tubular inner member 525 and outer member 530, since portions of occlusion 10 are in communication with each of generally tubular inner member 525 and outer member 530. Additionally, any break up of occlusion 10 is limited by the outer surface of generally tubular inner member 525, which in an exemplary embodiment is constituted of an open braid. Advantageously, a meshed braid exhibiting windows allows for increased contact area with occlusion 10, since constituent portions of occlusion 10 may partially penetrate into windows of the open braid of generally tubular inner member 525.

[000107] FIG. 11 illustrates a high level perspective view of an embodiment of an occlusion retrieval device 620 in a large diameter state within body lumen 15, occlusion retrieval device 620 comprising a generally tubular inner member 625 in communication with an outer member 630, wherein generally tubular inner member 625 and outer member 630 are constituted of a single mesh 640. Production of occlusion retrieval device 620 is in one embodiment performed by braiding filaments over a mandrel exhibiting two diameters. A first portion 650 of mesh 640 is formed by braiding filaments over a small diameter mandrel to form generally tubular inner member 625 and a second portion 660 of mesh 640 is formed by braiding filaments

over a larger diameter mandrel to form outer member 630. A connecting portion 670, wherein first portion 650 merges into second portion 660 of mesh 640 constitutes a proximal end 622 of generally tubular inner member 625 and a proximal end 632 of outer member 630. After formation is completed, second portion 660 of mesh 640 is rolled over first portion 650 of mesh 640 at connecting portion 670 to place outer member 630 over generally tubular inner member 625, thereby at least partially enclosing generally tubular inner member 625. As described above in relation to FIGS. 9A and 9B, in one embodiment length L1 of outer member 630 is between 10 mm – 20 mm less than the length L2 of generally tubular inner member 625.

[000108] FIG. 12 illustrates a high level schematic diagram of a sectioned view of an embodiment of an occlusion retrieval device 720 in a partially expanded state, occlusion retrieval device 720 comprising a generally tubular inner member 725 in communication with an outer member 730. In one non-limiting embodiment generally tubular inner member 725 is constituted of self expanding device 20. Generally tubular inner member 725 further exhibits a distal filtering extension member 740, coupled to distal end 724 of generally tubular inner member 725 via a transition portion 750, as described above in relation to FIG. 7A. In one embodiment, distal filtering extension 740 is arranged to expand to meet the inner walls of body lumen 15 distal of occlusion 10. Outer member 730 can be realized as any of outer members 430, 530 and 630 of FIGs 9A, 9B, 10A, 10B, 10C and 11, respectively. In one embodiment, when outer member 730 is opened, axial motion of outer member 730 may break apart a portion, or portions, of occlusion 10. Distal filtering extension member 740 is arranged to trap any portions of occlusion 10 which have been broken apart by outer member 730, thus not allowing any dislodged portions of occlusion 10 to enter the blood stream distal of distal filtering extension member 740. Furthermore, during retraction of outer member 730 distal filtering extension member 740 encloses occlusion 10 at its distal end, thereby assuring full removal of occlusion 10 as outer member 730 is retrieved from body lumen 15.

[000109] FIG. 13 illustrates a high level flow chart of a method of providing occlusion retrieval. In stage 2000, an occlusion retrieval member exhibiting a generally tubular inner member and an outer member is provided. In one optional embodiment the outer member exhibits an at rest state diameter greater than the inner wall of the body lumen at the target occlusion, in a process known as over sizing. In one optional embodiment the outer member exhibits an at rest state diameter 0.5 mm

greater than that of the inner wall of the body lumen at the site of the occlusion. In one optional embodiment the outer member exhibits an at rest state diameter 0.5 mm to 1.5 mm greater than that of the inner wall of the body lumen at the site of the occlusion. Preferably the generally tubular inner member exhibits an at rest state wherein the outer diameter is no more than 50% of the diameter of the small blood vessel at the occlusion location, as described above in relation to FIG. 1. As described above, the generally tubular inner member when allowed to expand urges towards the at rest state diameter, achieving a large diameter state, and exhibits minimal expansive force once expanded to the at rest state diameter.

[000110] In stage 2010, the provided occlusion retrieval member of stage 2000 is manipulated in a small diameter state through a body lumen to, and through, an occlusion of small blood vessel. In an exemplary embodiment the small blood vessel is an intracranial blood vessel.

[000111] In stage 2020, the generally tubular inner member is expanded to a large diameter state, thereby preferably maintaining blood flow patency there through, as described above in relation to self expanding device 20. Preferably, generally tubular inner member achieves, or nearly achieves, an outer diameter equal to the at rest state diameter. In stage 2030, the outer member is expanded to meet the inner wall of the body lumen at the occlusion site. The occlusion occluding the small blood vessel is thus at least partially contained between the outer diameter of the generally tubular inner member and the inner walls of the outer member. Preferably, the outer member is provided with windows, and portions of the occlusion are further trapped within the windows of the outer member. There is no requirement for stage 2020 to be performed before stage 2030, and in one embodiment stages 2020 and 2030 are performed simultaneously.

[000112] In optional stage 2040, a distal filtering extension is provided for the generally tubular inner member of stage 2000, the distal filtering extension arranged to meet the inner walls of the body lumen distal of the occlusion when the generally tubular inner member is in the expanded state. Advantageously, the distal filtering extension traps any dislodged fragments of the occlusion.

[000113] In one optional embodiment, as described at stage 2050, the generally tubular inner member and outer member are connected at proximal ends thereof via a first connecting portion. In one further optional embodiment, as described at stage

2060, the generally tubular inner member and outer member are further connected at distal ends thereof thereby at least partially encasing the occlusion.

[000114] In stage 2070, the occlusion retrieval member is withdrawn from the body lumen, preferably in the expanded state, thereby retrieving the occlusion. Advantageously the large surface area provided by the combination of the generally tubular inner member and outer member ensures nearly complete withdrawal of the occlusion.

[000115] 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 sub-combination.

[000116] Unless otherwise defined, all technical and scientific terms used herein have the same meanings as are commonly understood by one of ordinary skill in the art to which this invention belongs. Although methods similar or equivalent to those described herein can be used in the practice or testing of the present invention, suitable methods are described herein.

[000117] All publications, patent applications, patents, and other references mentioned herein are incorporated by reference in their entirety. In case of conflict, the patent specification, including definitions, will prevail. In addition, the materials, methods, and examples are illustrative only and not intended to be limiting.

[000118] It will be appreciated by persons skilled in the art that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined by the appended claims and includes both combinations and sub-combinations of the various features described hereinabove as well as variations and modifications thereof, which would occur to persons skilled in the art upon reading the foregoing description.

We claim:

1. A device arranged to at least partially remove an occlusion occluding a small blood vessel, the device comprising:

a generally tubular inner member; and

an outer member in communication with said generally tubular inner member, wherein:

said generally tubular inner member exhibits a small diameter state for manipulation to, and through, the occlusion of the small blood vessel, said generally tubular inner member expandable to a large diameter state, the outer diameter of said generally tubular member in the large diameter state being no more than an at rest diameter of said generally tubular inner member, wherein the at rest diameter of said generally tubular inner member is less than the inner diameter of the small blood vessel at the occlusion location; and

said outer member exhibits a small diameter state for manipulation to, and through, the occlusion of the small blood vessel, said outer member expandable to a large diameter state wherein the inner diameter of said outer member in the large diameter state is greater than the outer diameter of said generally tubular inner member in the large diameter state,

wherein at least a portion of the occlusion is contained between said generally tubular inner member in the large diameter state and said outer member in the large diameter state.

2. The device according to claim 1, wherein the outer diameter of said outer member in the large diameter state meets the inner walls of the small blood vessel at the occlusion location.

3. The device according to claim 1, wherein the at rest diameter of said generally tubular inner member is no more than 50% of the diameter of the small blood vessel at the occlusion location.

4. The device according to claim 1, wherein said generally tubular inner member and said outer member are removable from the body lumen, thus retrieving the occlusion.

5. The device according to claim 1, wherein said outer member exhibits a resting state, wherein the outer diameter of the outer member in the resting state is greater than the inner diameter of the small blood vessel.

6. The device according to claim 5, wherein the outer diameter of the outer member in the resting state is at least 0.5 millimeters greater than the inner diameter of the small blood vessel.

7. The device according to claim 6, wherein the outer diameter of the outer member in the resting state is 0.5 – 1.5 millimeters greater than the inner diameter of the small blood vessel.

8. The device according to claim 1, further comprising a distal filtering extension coupled to the distal end of said generally tubular inner member, said distal filtering extension arranged to meet the inner walls of the body lumen distal of the occlusion when said generally tubular inner member is large diameter state.

9. The device according to claim 1, wherein said generally tubular inner member comprises a first connecting portion, and wherein a proximal end of said outer member is connected to said generally tubular inner member via said first connecting portion.

10. The device according to claim 9, wherein said generally tubular inner member further comprises a second connecting portion, and wherein a distal end of said outer member is connected to said generally tubular inner member via said second connecting portion.

11. The device according to claim 1, wherein at least one of said generally tubular inner member and said outer member are constituted of self expanding braided filaments.

12. The device according to claim 1, wherein said device is constituted of braided filaments, and wherein said generally tubular inner member and said outer member are constituted of a single braid.

13. The device according to claim 1, wherein the small blood vessel is an intracranial blood vessel.

14. A method of occlusion retrieval, the method comprising:

providing an occlusion retrieval member exhibiting a generally tubular inner member and an outer member;

manipulating said provided occlusion retrieval member in a small diameter state through a body lumen to, and through, an occlusion of a small blood vessel;

expanding the generally tubular inner member of the provided occlusion retrieval member up to a large diameter state, the outer diameter of said generally tubular member in the large diameter state being no more than an at rest diameter of said generally tubular inner member, wherein the at rest diameter of the generally tubular inner member is less than the inner diameter of the small blood vessel at the occlusion location;

expanding the outer member of the provided occlusion retrieval member up to a large diameter state wherein the inner diameter of the outer member is greater than the outer diameter of the generally tubular inner member in the large diameter state so as to contain at least a portion of the occlusion between the generally tubular inner member and the outer member; and

withdrawing the provided occlusion retrieval member to thereby at least partially retrieve the occlusion.

15. The method according to claim 14, wherein said expanding the outer member of the provided occlusion retrieval member up to a large diameter state comprises expanding the outer member so as to meet the inner walls of the small blood vessel at the occlusion location.

16. The method according to claim 14, wherein the at rest diameter of the generally tubular inner member is no more than 50% of the diameter of the small blood vessel at the occlusion location.

17. The method according to claim 14, wherein the outer member of the provided occlusion retrieval member exhibits a resting state, wherein the outer diameter of the outer member in the resting state is greater than the inner diameter of the small blood vessel at the occlusion location.

18. The method according to claim 17, wherein the outer diameter of the provided outer member in the resting state is at least 0.5 millimeters greater than the inner diameter of the small blood vessel at the occlusion location.

19. The method according to claim 17, wherein the outer diameter of the provided outer member in the resting state is 0.5 – 1.5 millimeters greater than the inner diameter of the small blood vessel at the occlusion location.

20. The method according to claim 14, further comprising providing a distal filtering extension coupled to a distal end of the provided generally tubular inner member, the distal filtering extension arranged to meet the inner walls of the body lumen distal of the occlusion.

21. The method according to claim 14, wherein the generally tubular inner member of the provided occlusion retrieval member comprises a first connecting portion, and wherein a proximal end of the outer member of the occlusion retrieval member is connected to the generally tubular inner member via said first connecting portion.

22. The method according to claim 21, wherein the generally tubular inner member further comprises a second connecting portion, and wherein a distal end of the outer member is connected to the generally tubular inner member via the second connecting portion.

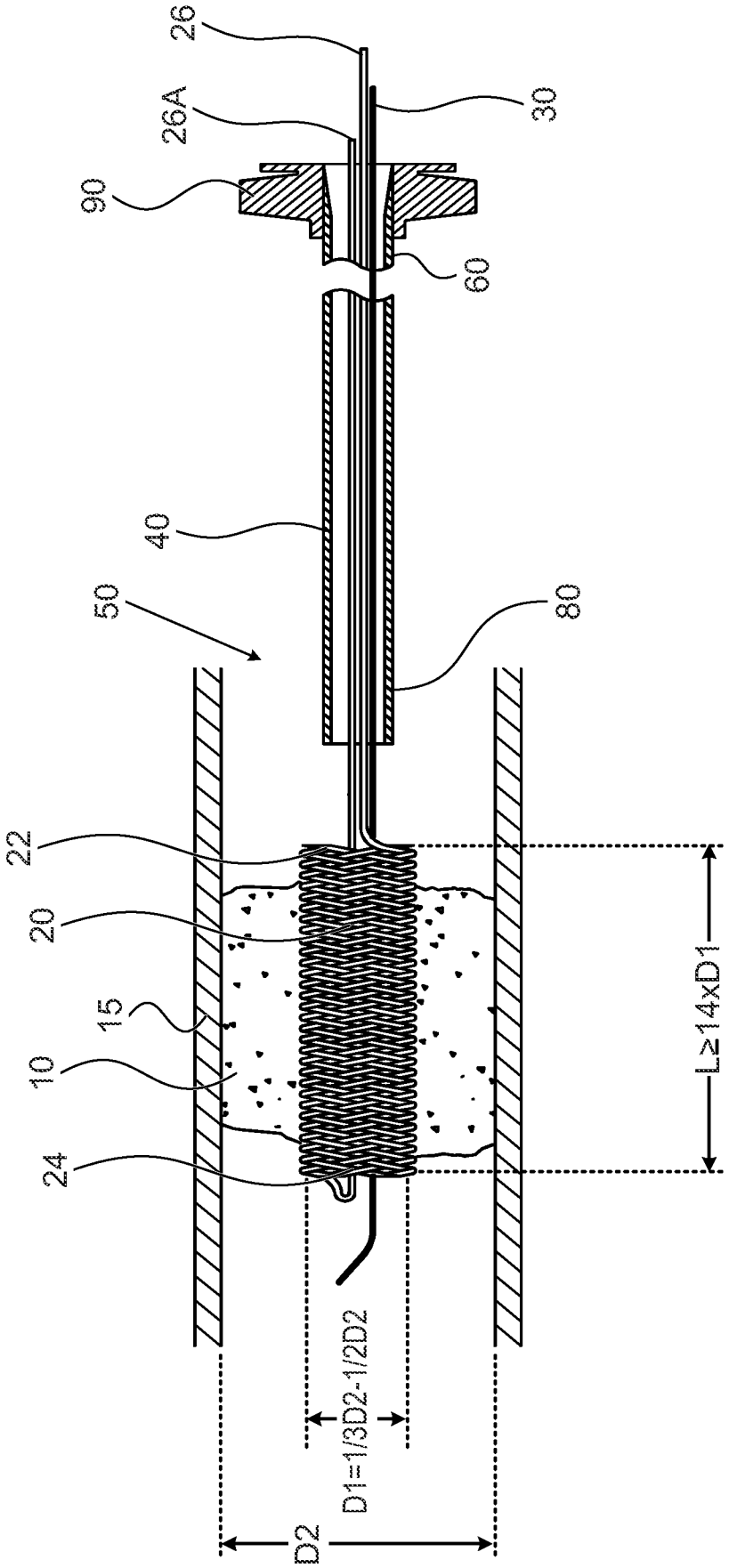

FIG. 1

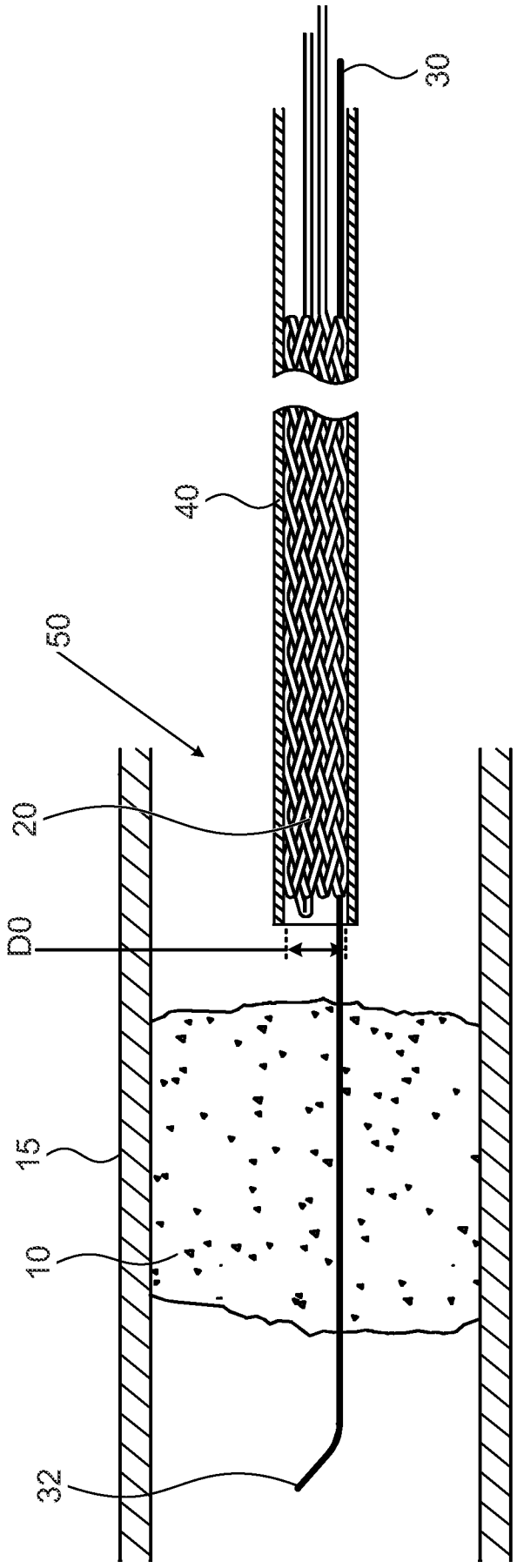

FIG. 2A

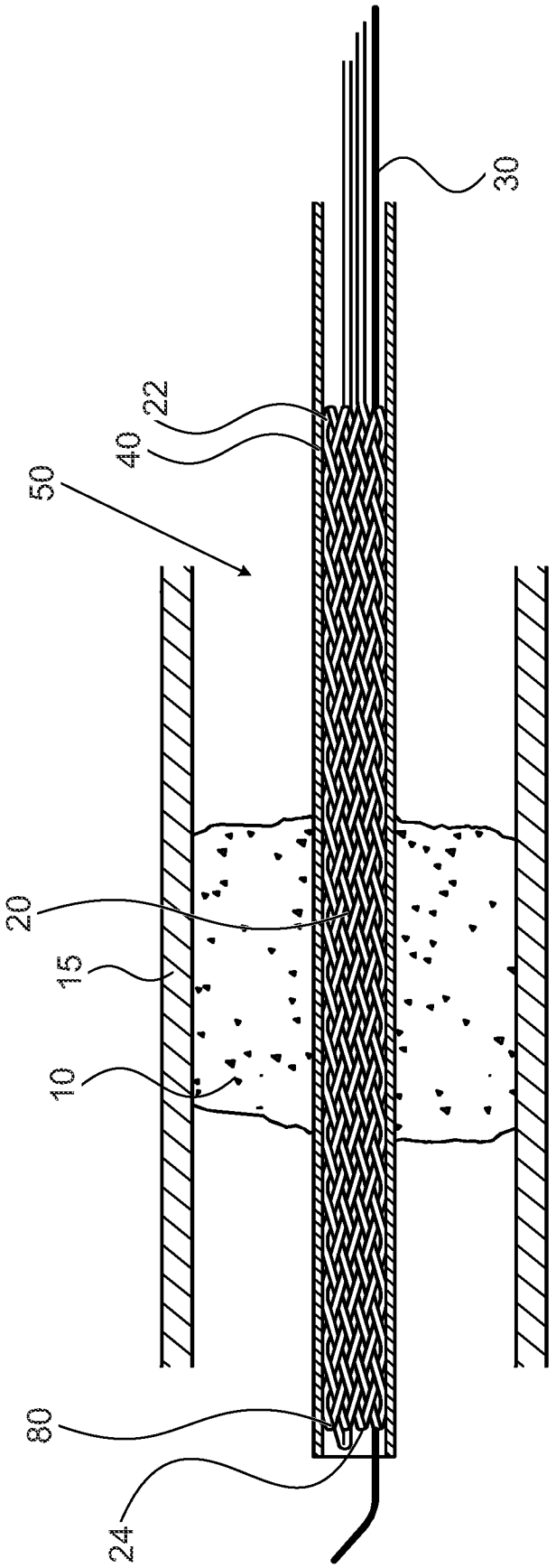

FIG. 2B

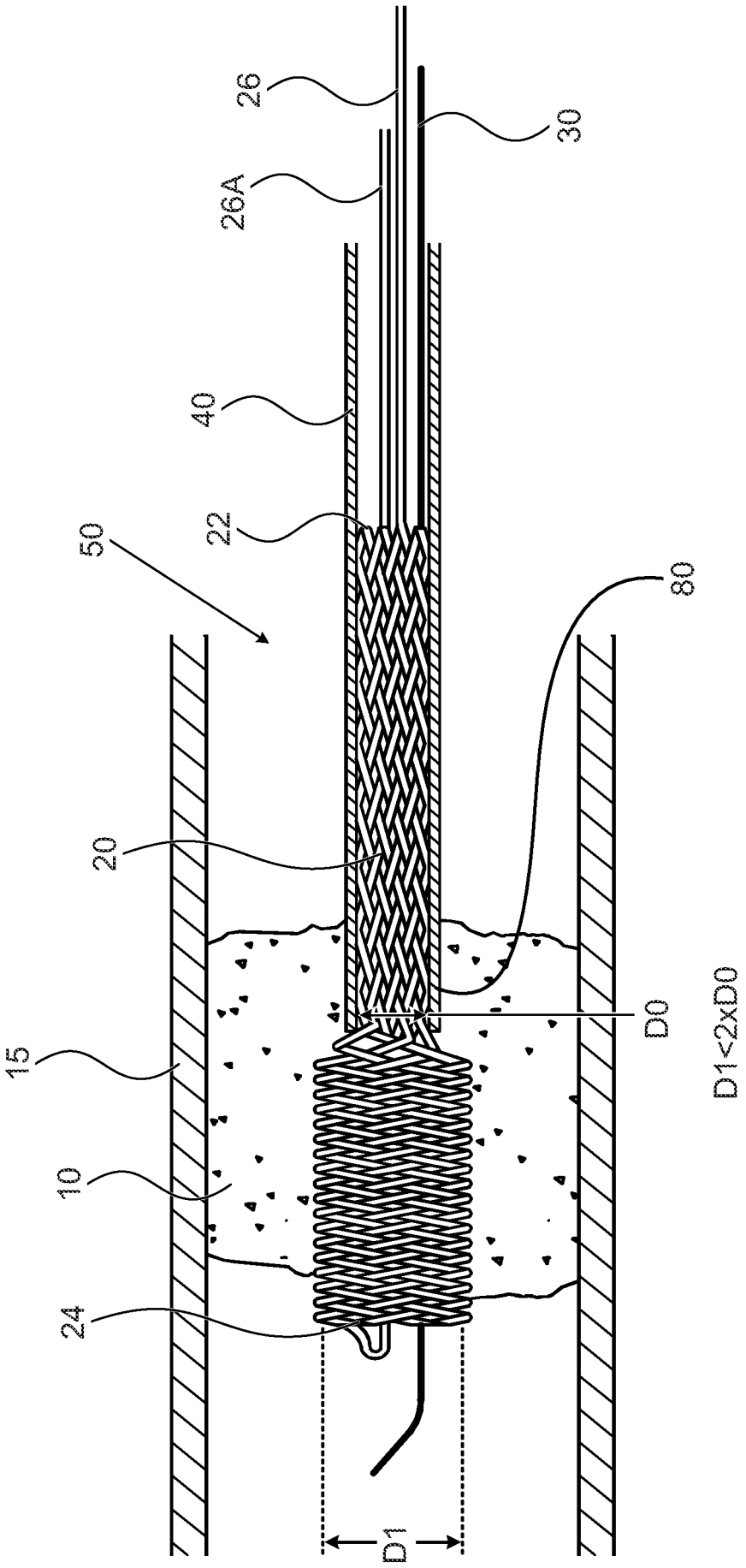

FIG. 2C

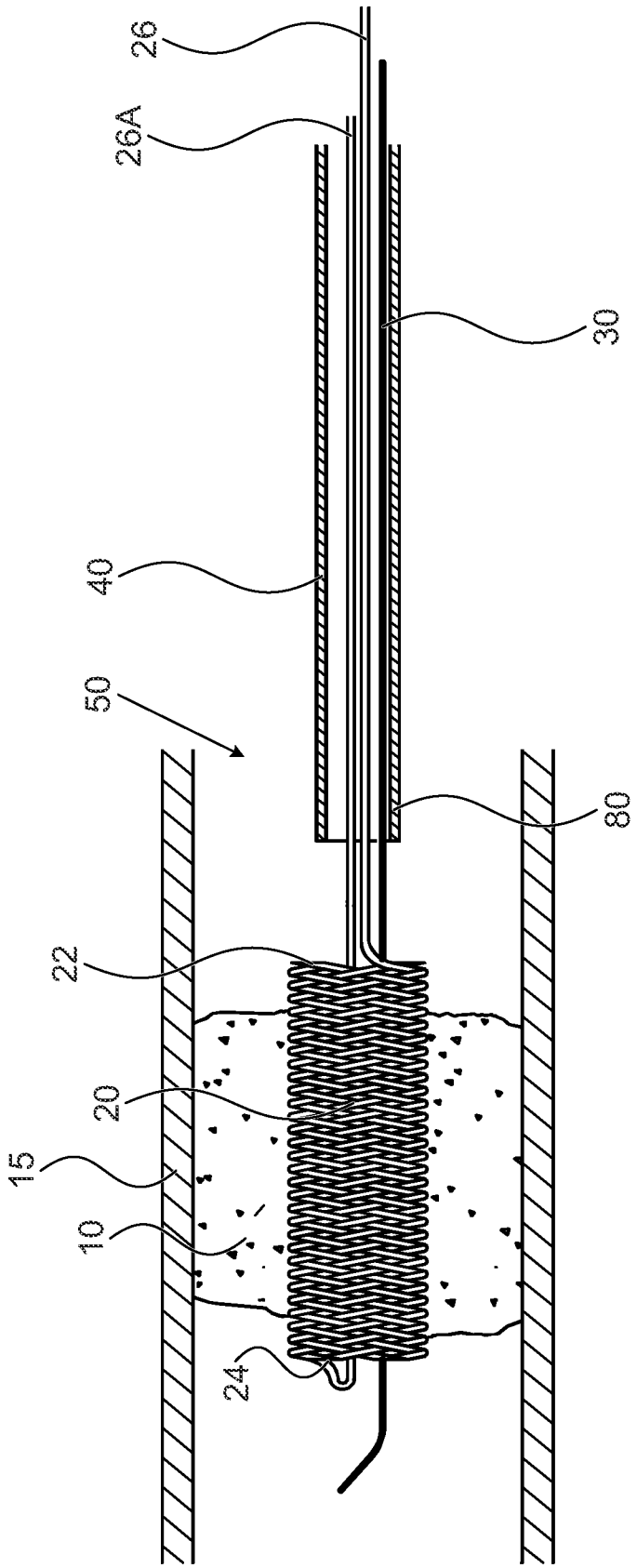

FIG. 2D

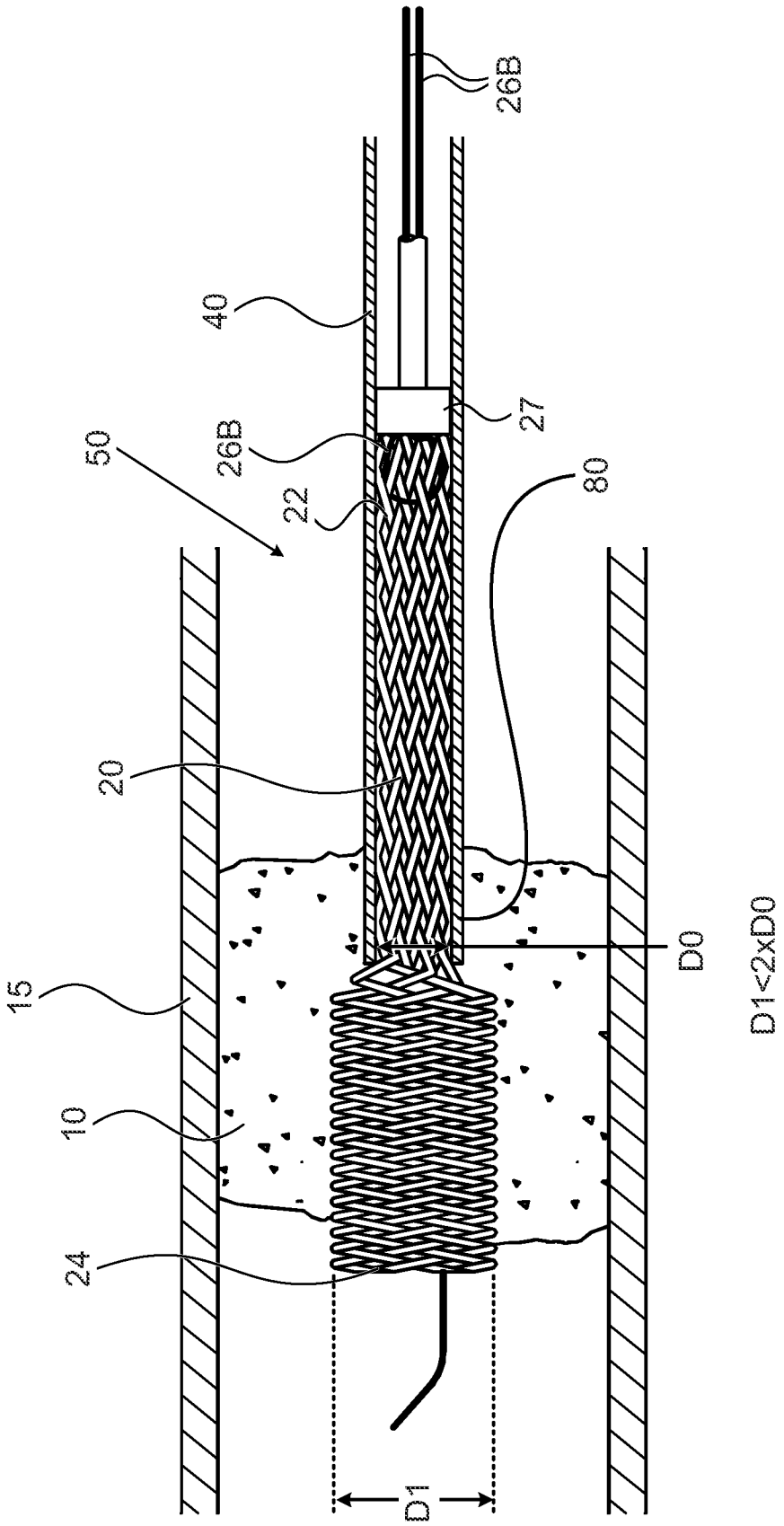

FIG. 2E

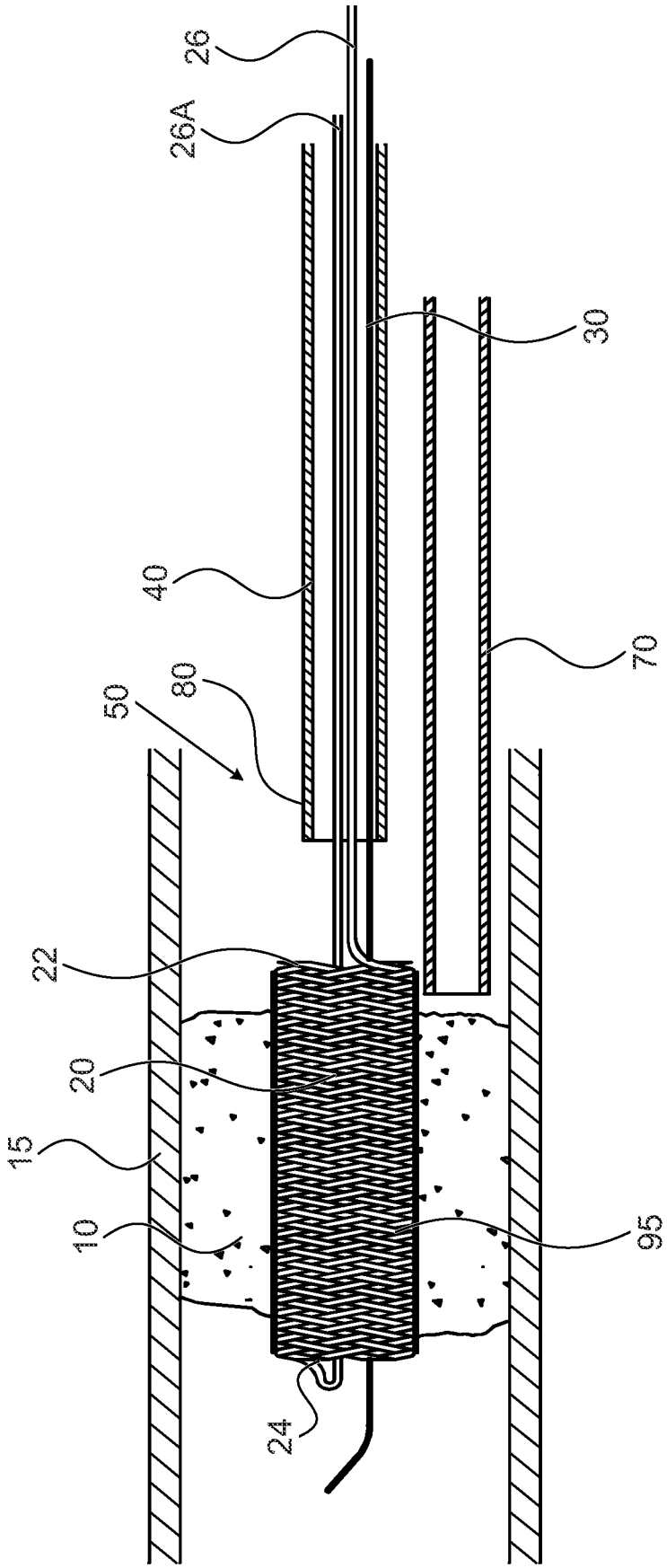

FIG. 3

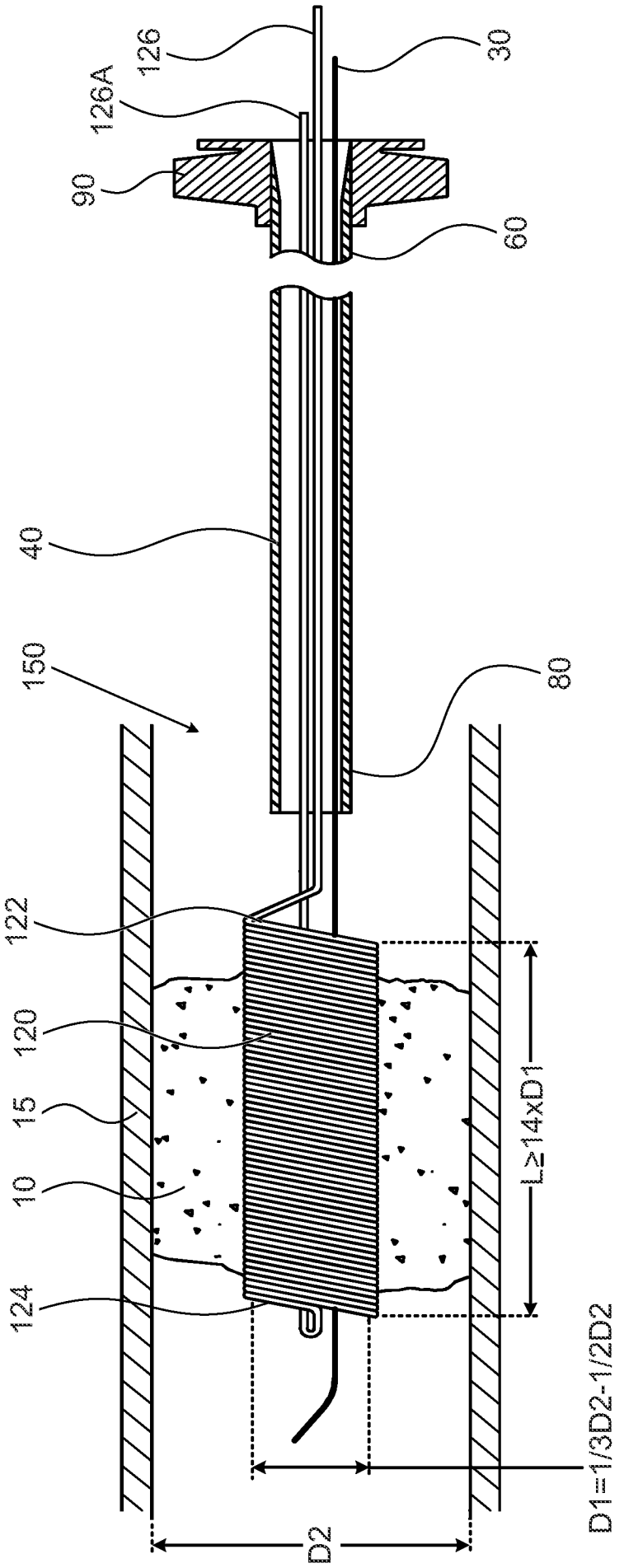
126
30
126A
90
60
40
150
80
122
120
15
10
124
L≥14xD1
D1=1/3D2-1/2D2
D2

FIG. 4

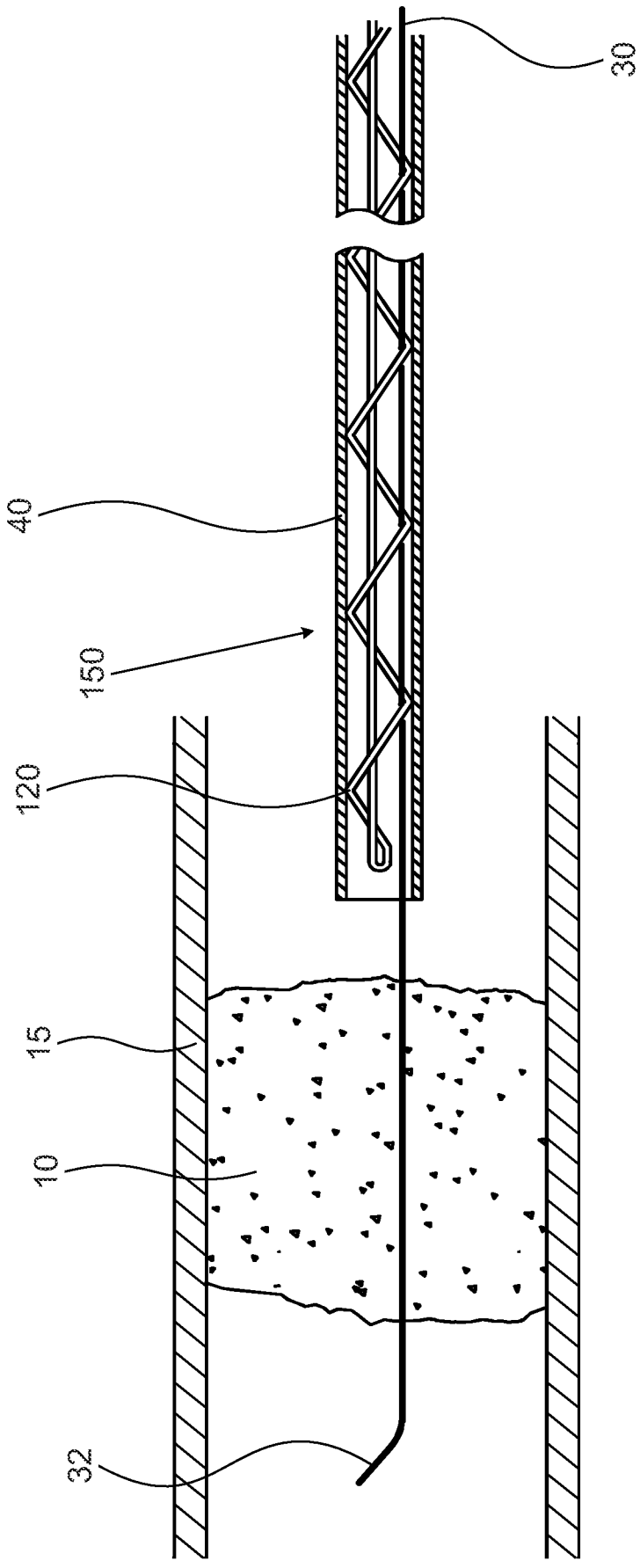

FIG. 5A

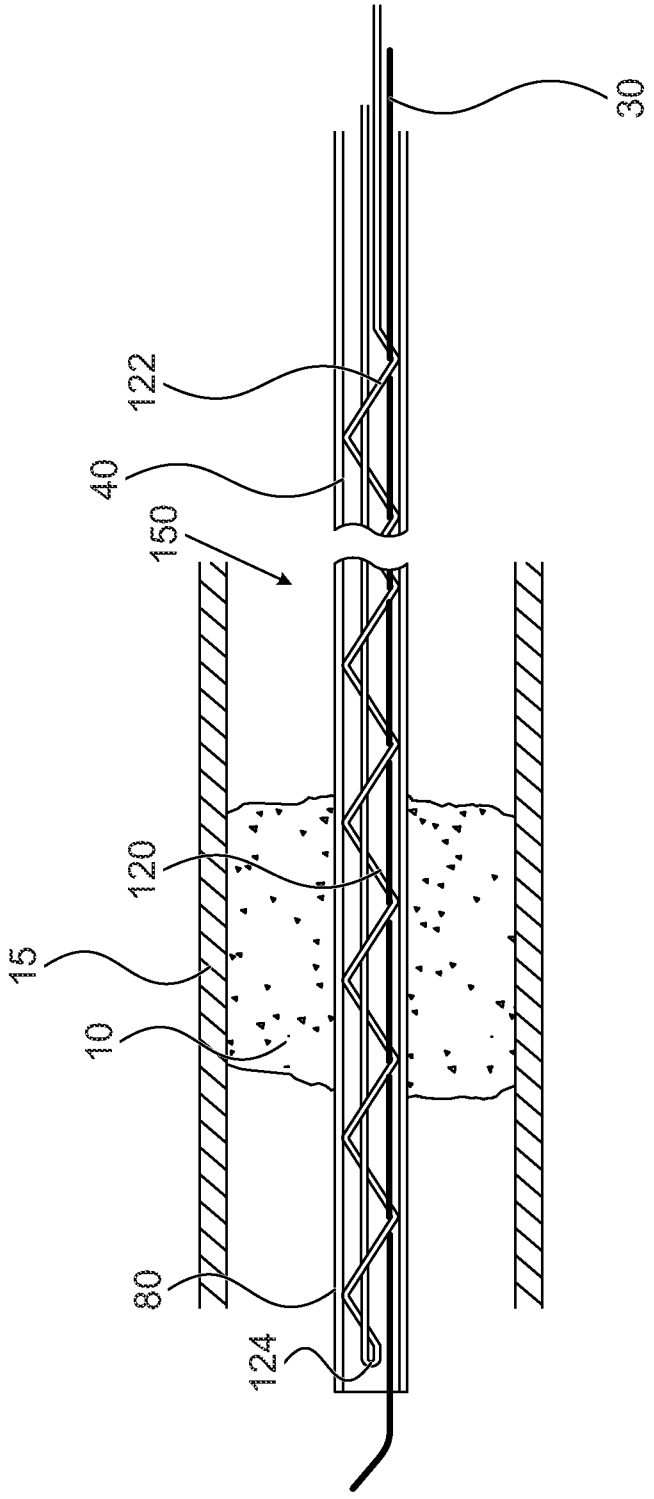

FIG. 5B

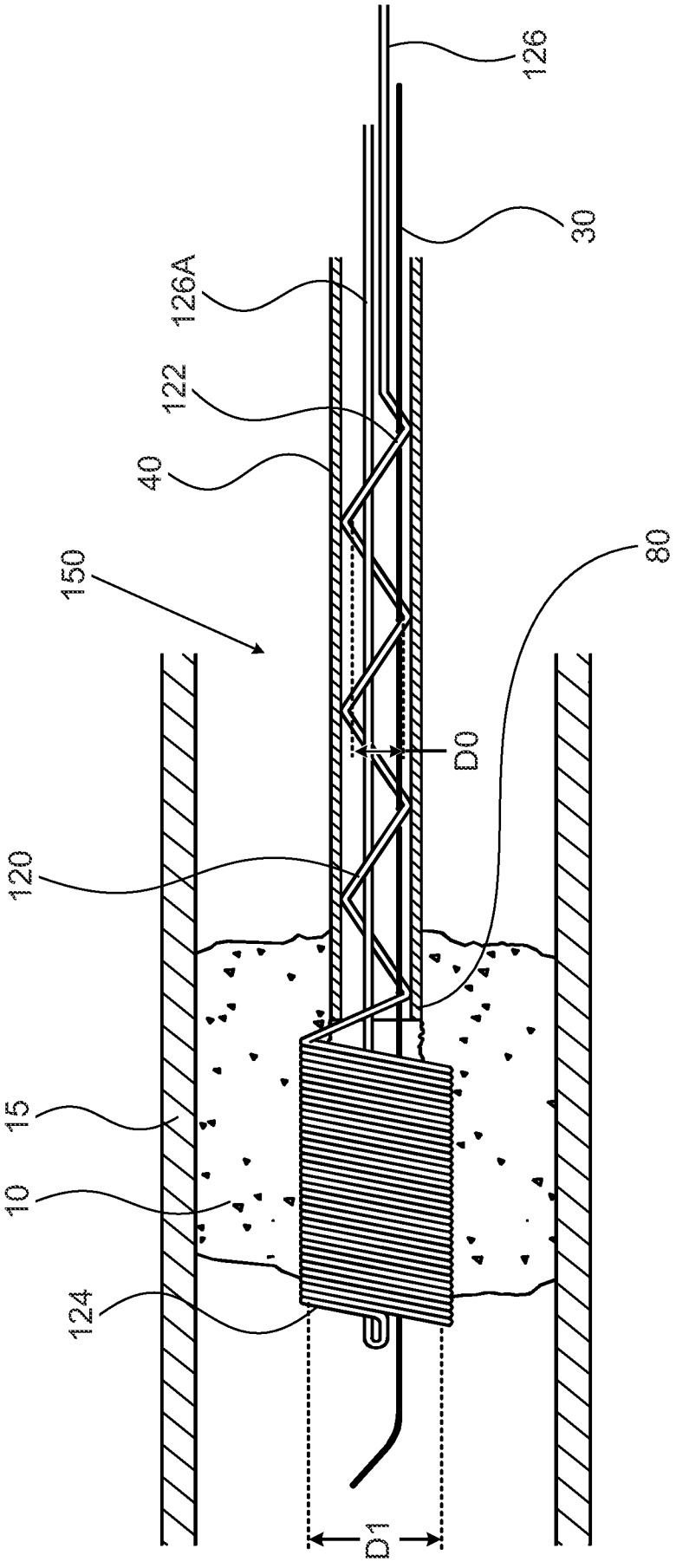

FIG. 5C

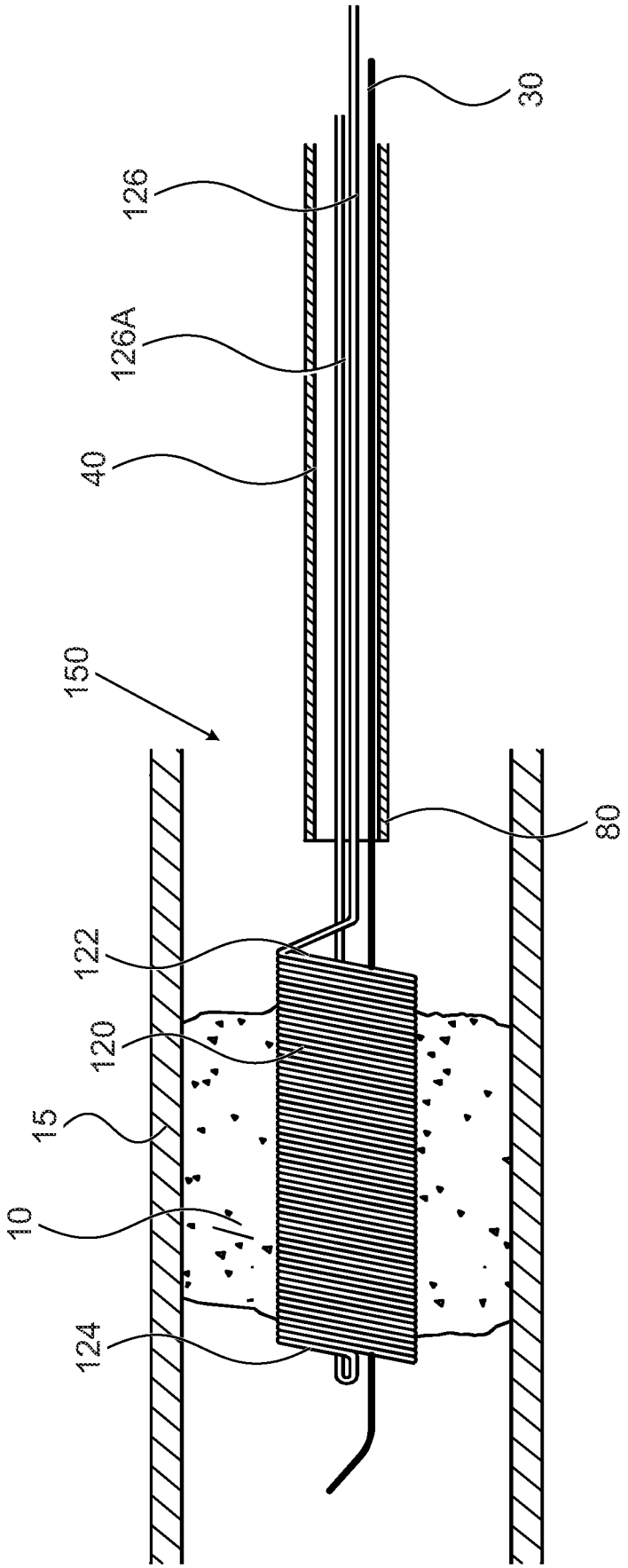

FIG. 5D

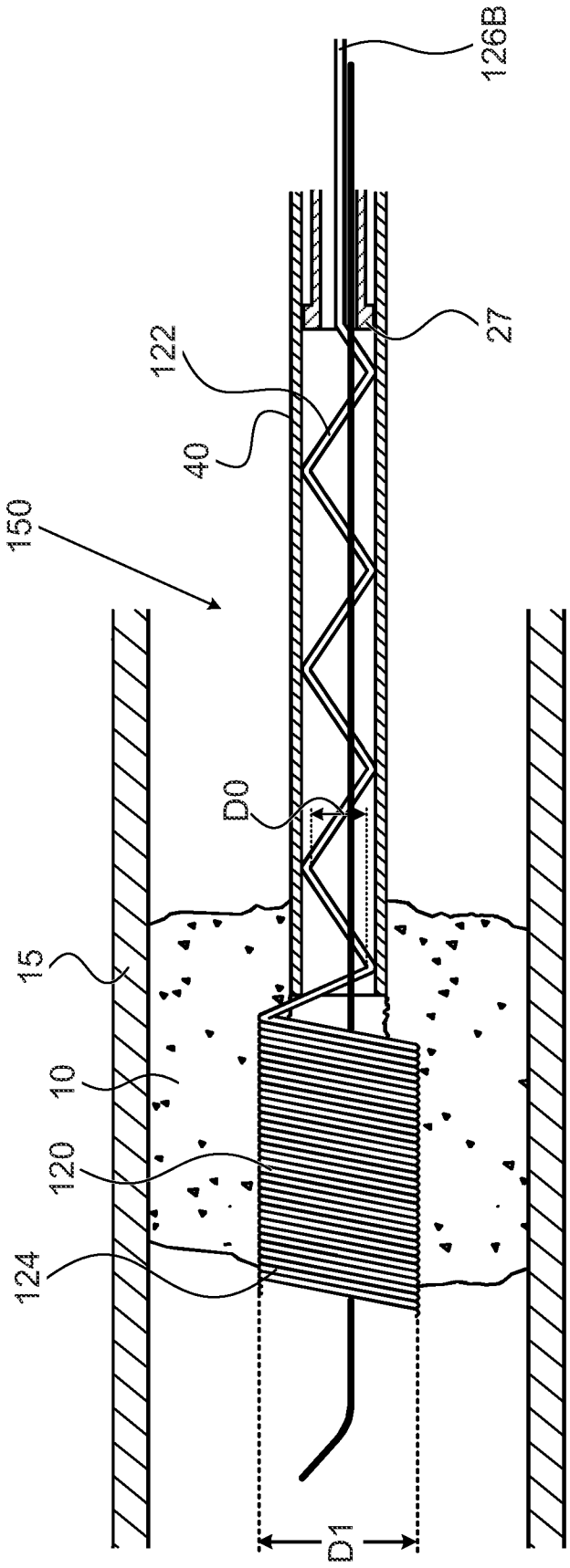

FIG. 5E

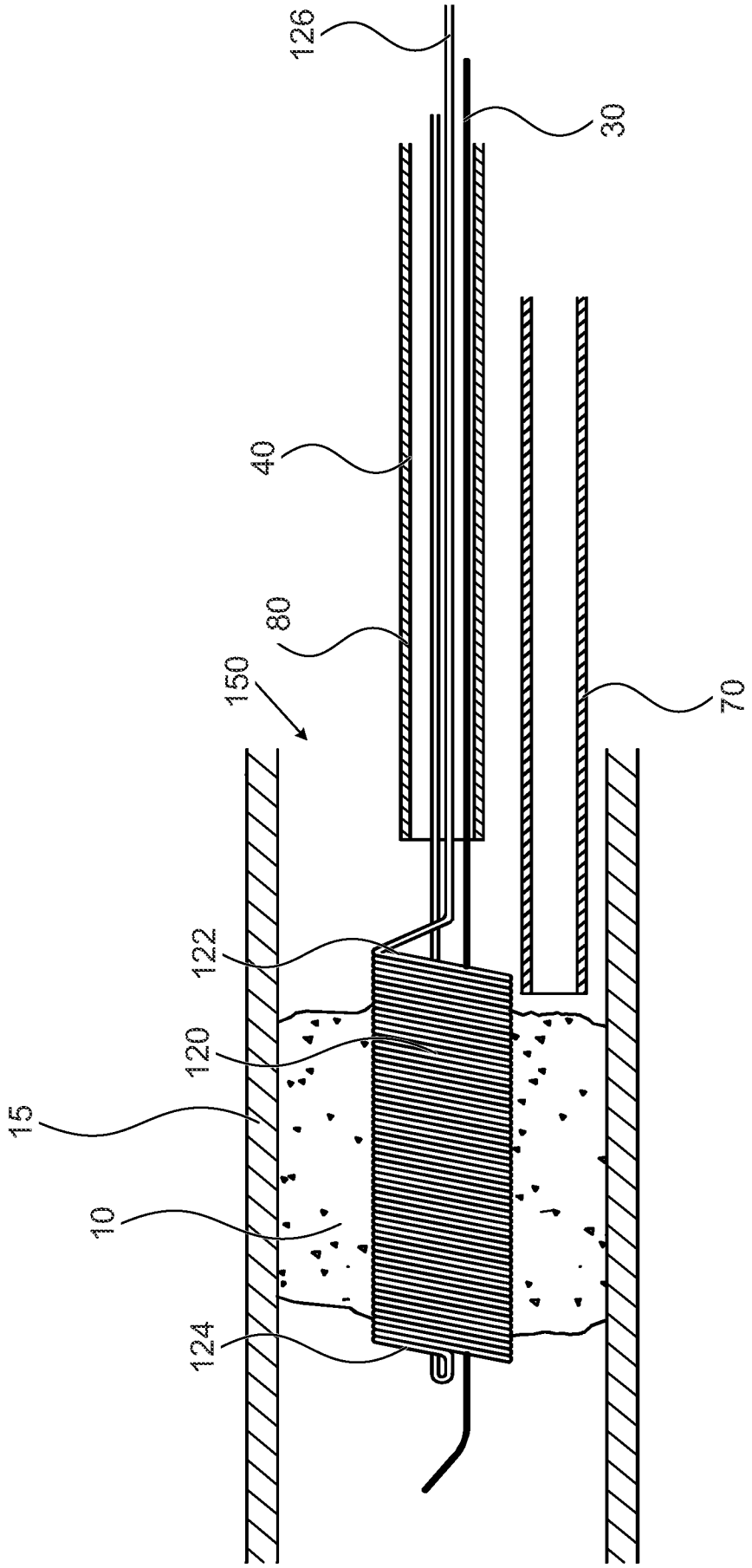

FIG. 6

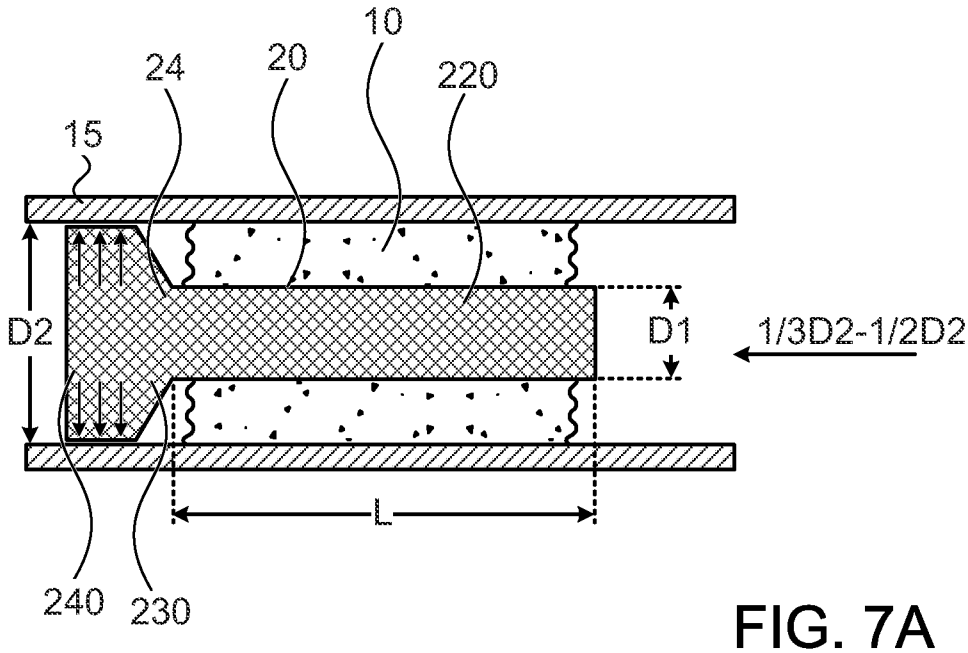
10
24
20
220
15
D2
D1
1/3D2-1/2D2
L
240
230

FIG. 7A

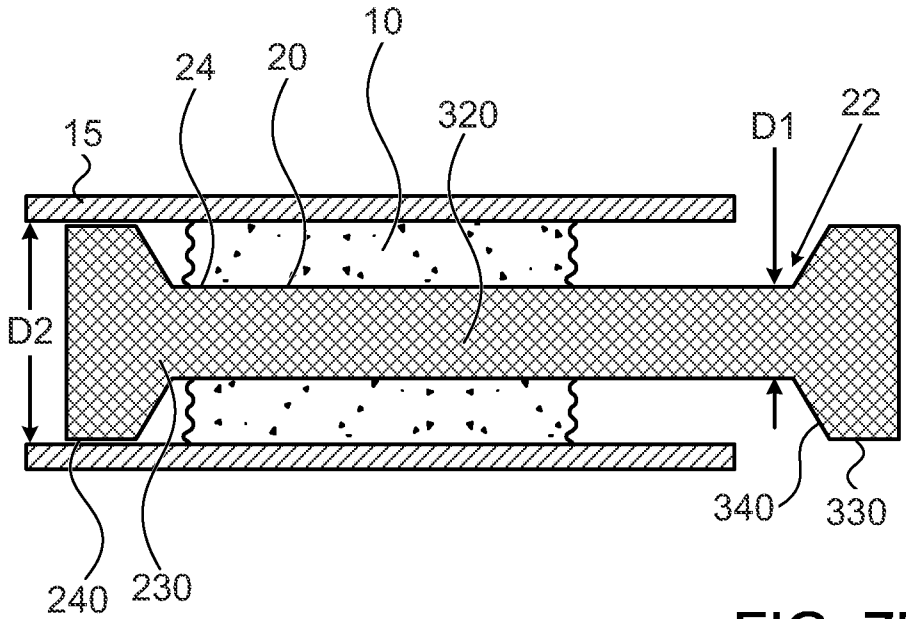
10
24
20
320
22
D1
15
D2
340
330
240
230

FIG. 7B

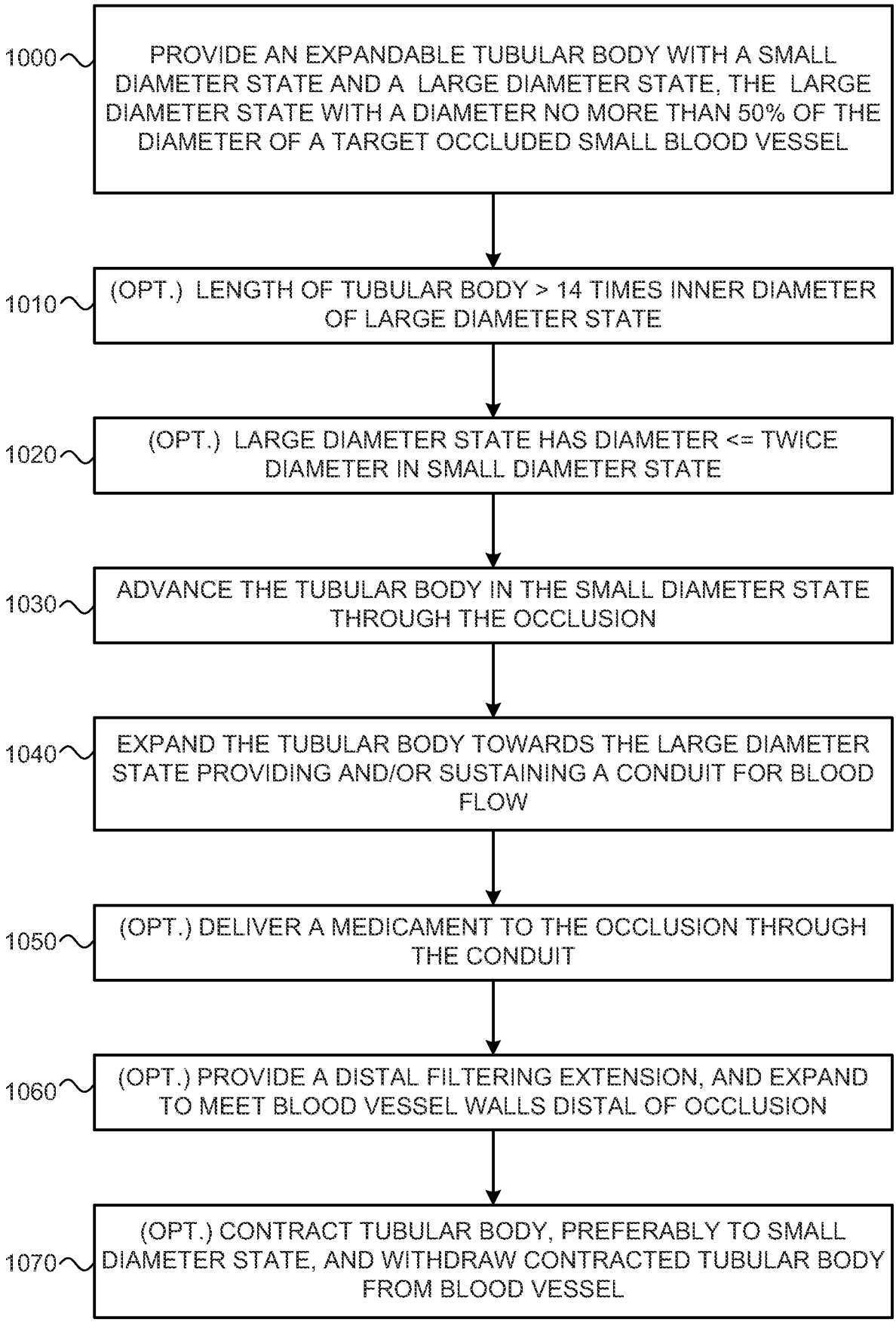
1000
PROVIDE AN EXPANDABLE TUBULAR BODY WITH A SMALL DIAMETER STATE AND A LARGE DIAMETER STATE, THE LARGE DIAMETER STATE WITH A DIAMETER NO MORE THAN 50% OF THE DIAMETER OF A TARGET OCCLUDED SMALL BLOOD VESSEL
1010
(OPT.) LENGTH OF TUBULAR BODY > 14 TIMES INNER DIAMETER OF LARGE DIAMETER STATE
1020
(OPT.) LARGE DIAMETER STATE HAS DIAMETER <= TWICE DIAMETER IN SMALL DIAMETER STATE
1030
ADVANCE THE TUBULAR BODY IN THE SMALL DIAMETER STATE THROUGH THE OCCLUSION
1040
EXPAND THE TUBULAR BODY TOWARDS THE LARGE DIAMETER STATE PROVIDING AND/OR SUSTAINING A CONDUIT FOR BLOOD FLOW
1050
(OPT.) DELIVER A MEDICAMENT TO THE OCCLUSION THROUGH THE CONDUIT
1060
(OPT.) PROVIDE A DISTAL FILTERING EXTENSION, AND EXPAND TO MEET BLOOD VESSEL WALLS DISTAL OF OCCLUSION
1070
(OPT.) CONTRACT TUBULAR BODY, PREFERABLY TO SMALL DIAMETER STATE, AND WITHDRAW CONTRACTED TUBULAR BODY FROM BLOOD VESSEL

FIG. 8

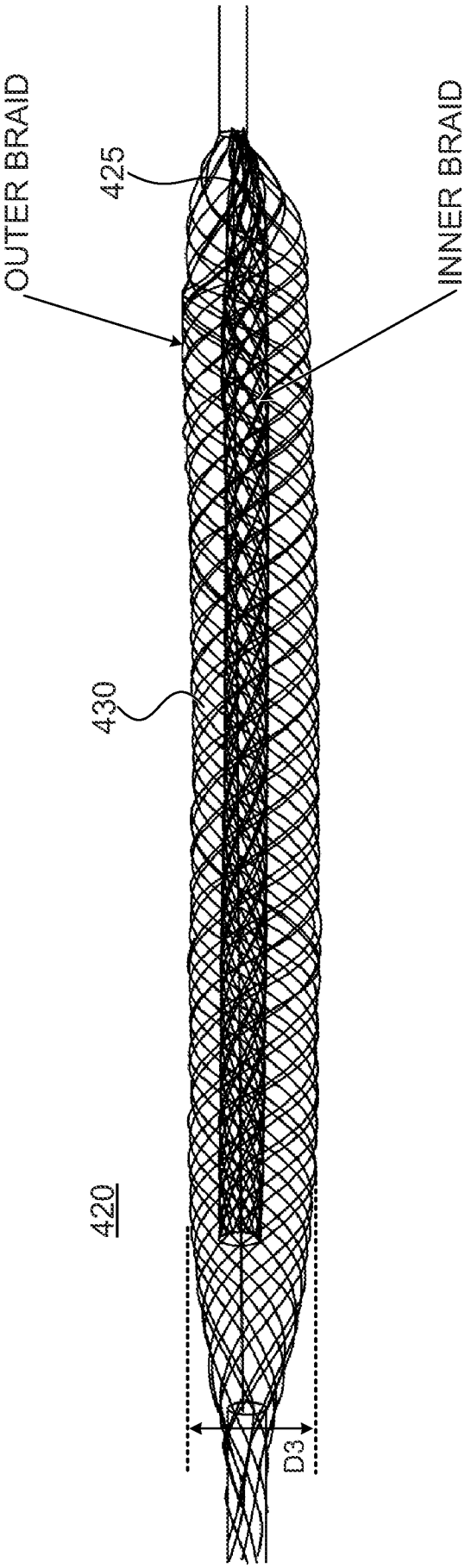

FIG. 9A

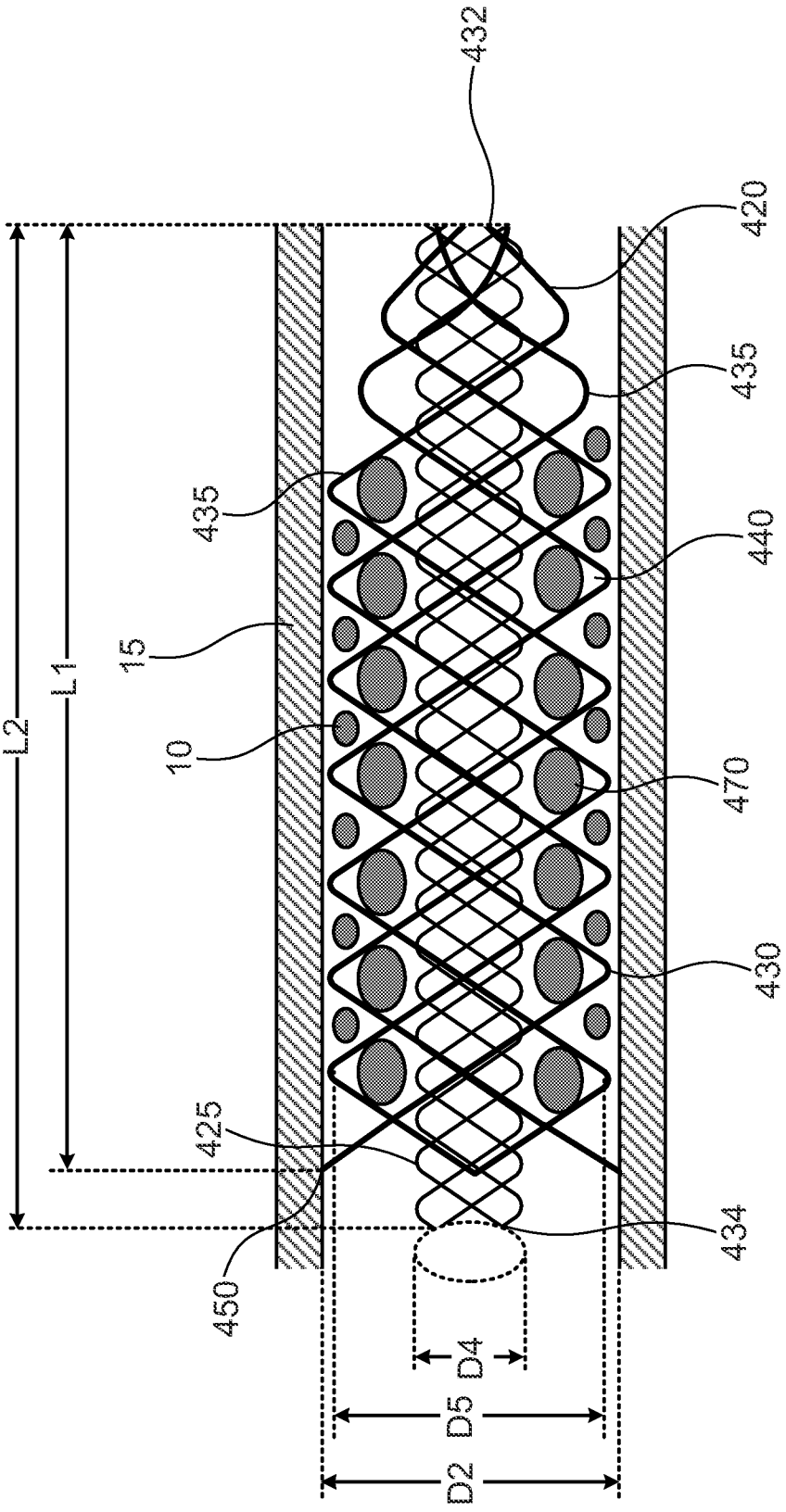

FIG. 9B

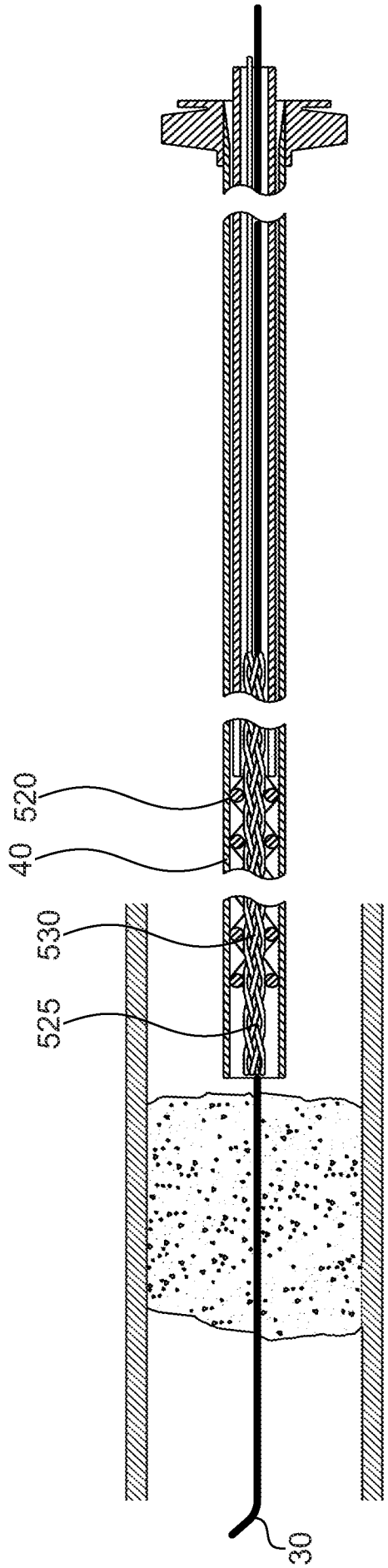

FIG. 10A

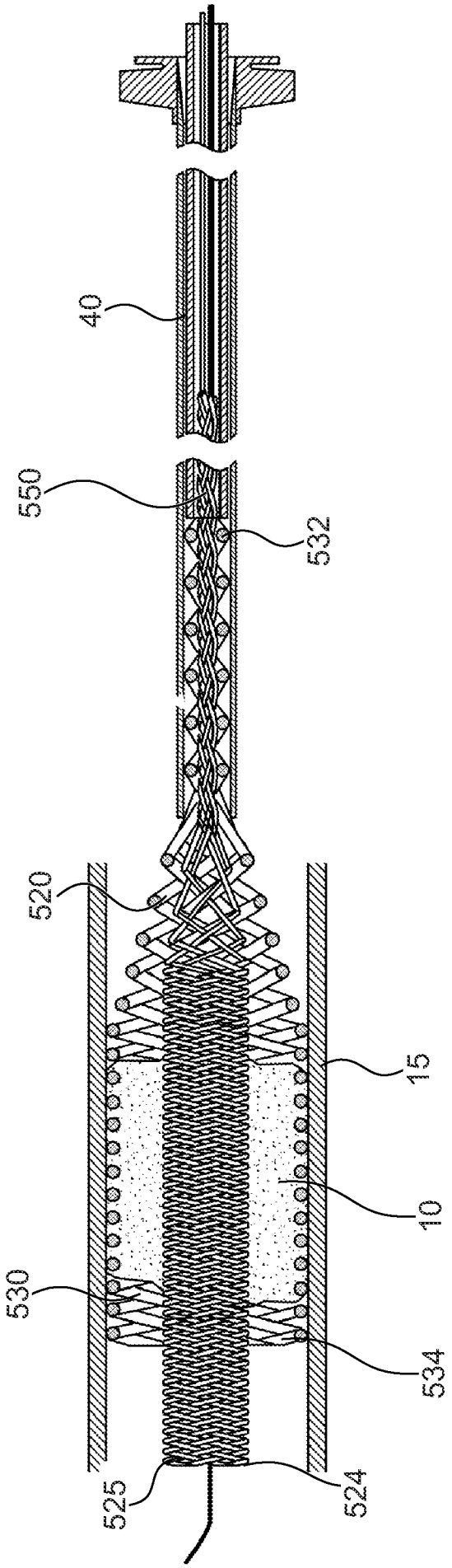

FIG. 10B

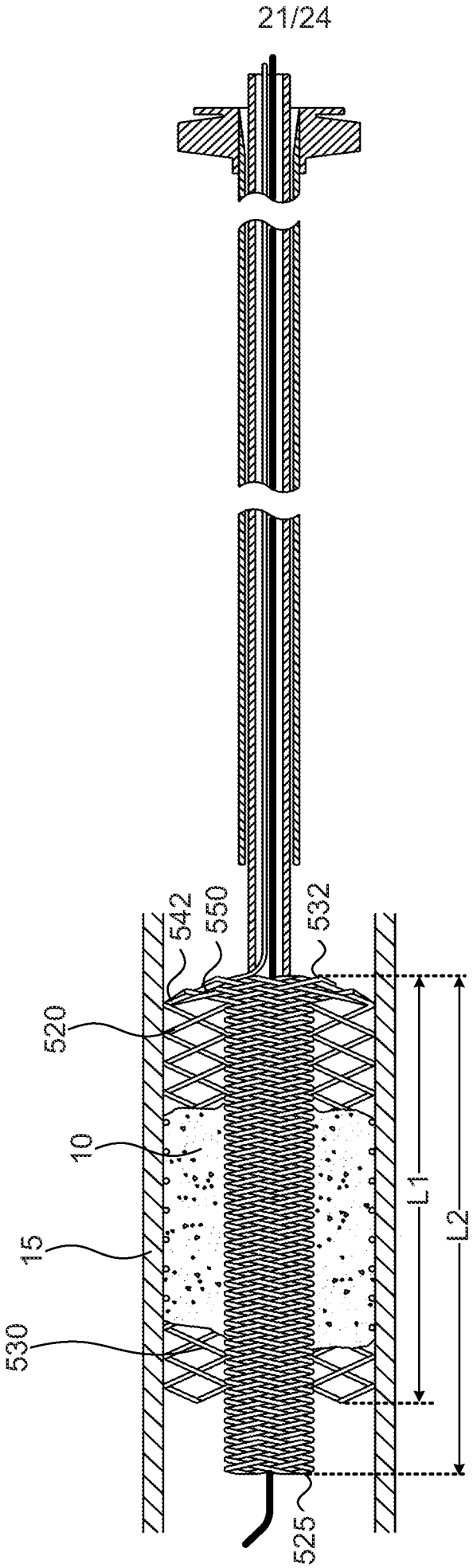

FIG. 10C

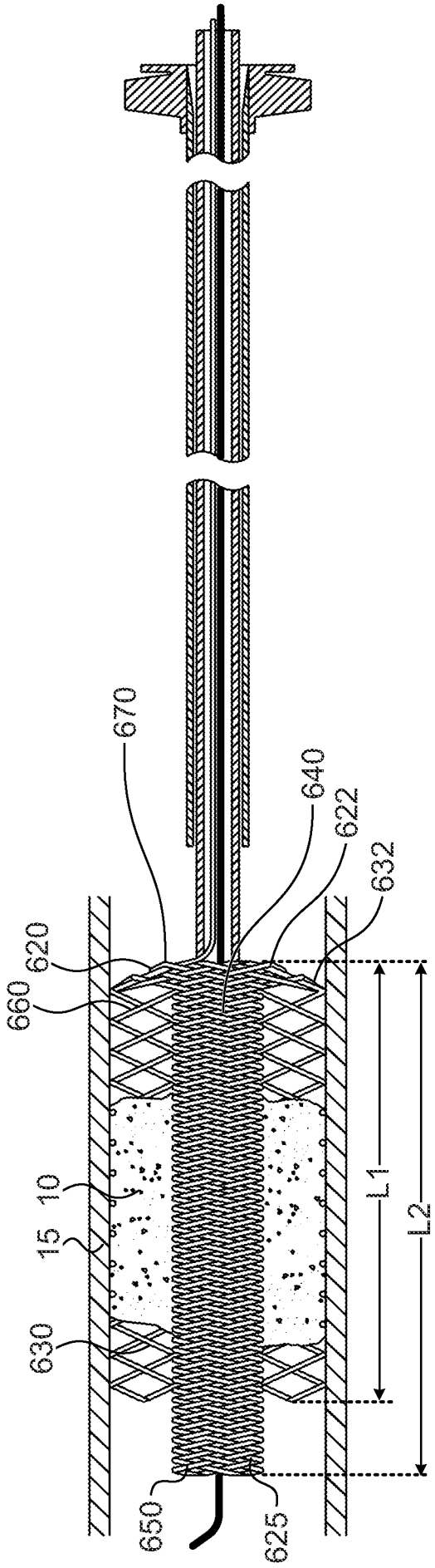

FIG. 11

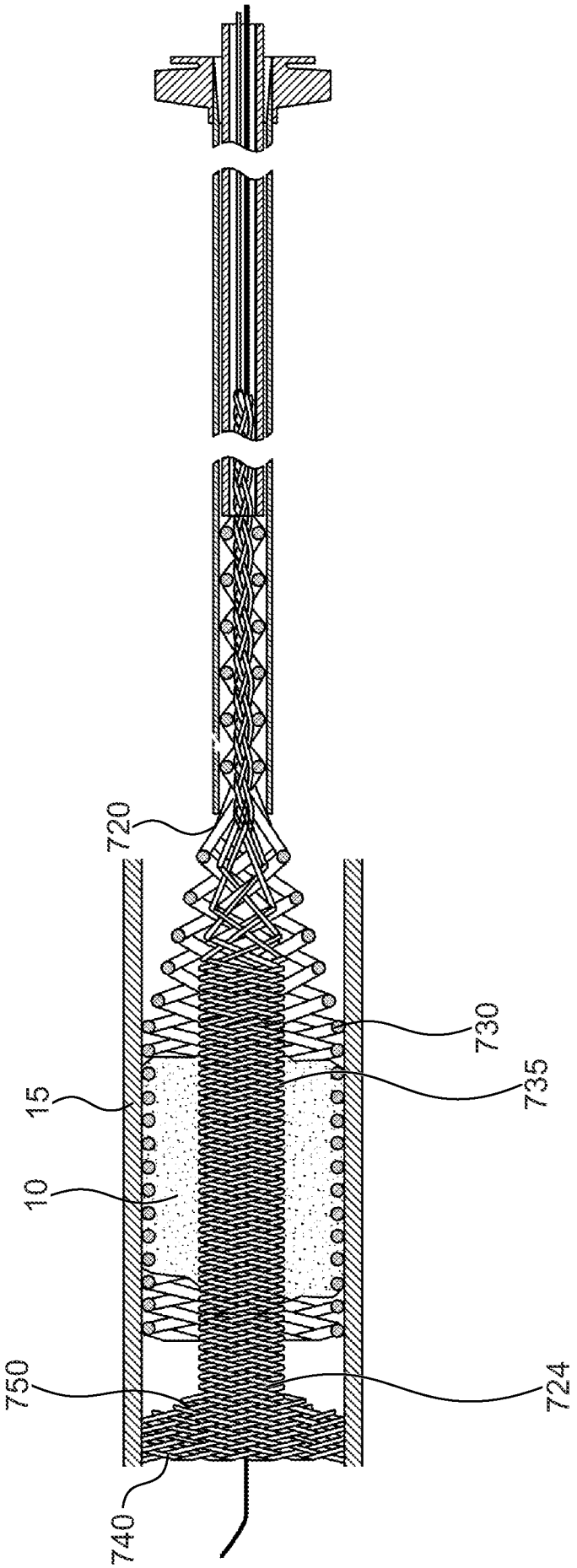

FIG. 12

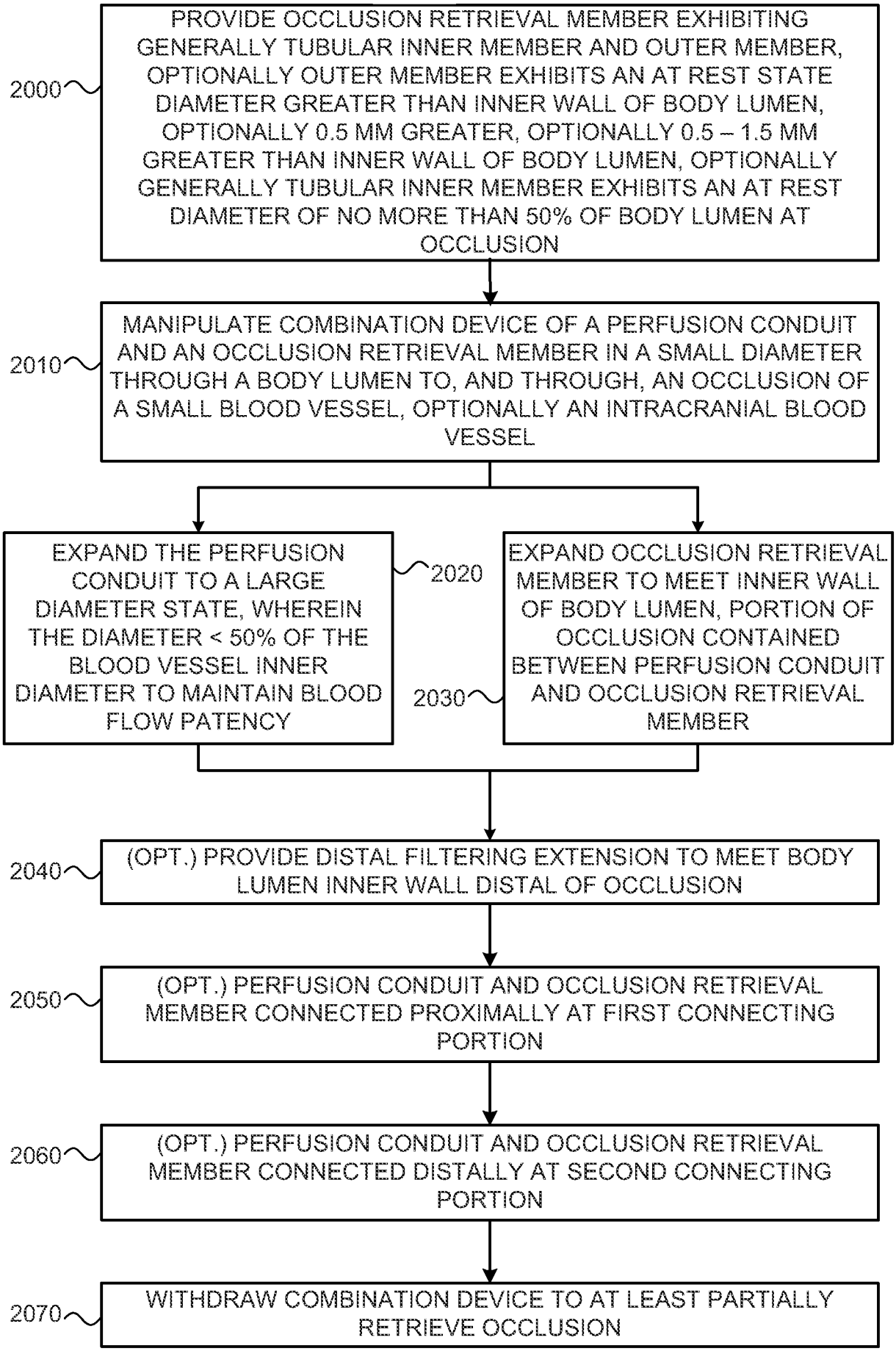
2000
PROVIDE OCCLUSION RETRIEVAL MEMBER EXHIBITING GENERALLY TUBULAR INNER MEMBER AND OUTER MEMBER, OPTIONALLY OUTER MEMBER EXHIBITS AN AT REST STATE DIAMETER GREATER THAN INNER WALL OF BODY LUMEN, OPTIONALLY 0.5 MM GREATER, OPTIONALLY 0.5 – 1.5 MM GREATER THAN INNER WALL OF BODY LUMEN, OPTIONALLY GENERALLY TUBULAR INNER MEMBER EXHIBITS AN AT REST DIAMETER OF NO MORE THAN 50% OF BODY LUMEN AT OCCLUSION
2010
MANIPULATE COMBINATION DEVICE OF A PERFUSION CONDUIT AND AN OCCLUSION RETRIEVAL MEMBER IN A SMALL DIAMETER THROUGH A BODY LUMEN TO, AND THROUGH, AN OCCLUSION OF A SMALL BLOOD VESSEL, OPTIONALLY AN INTRACRANIAL BLOOD VESSEL
EXPAND THE PERFUSION CONDUIT TO A LARGE DIAMETER STATE, WHEREIN THE DIAMETER < 50% OF THE BLOOD VESSEL INNER DIAMETER TO MAINTAIN BLOOD FLOW PATENCY
2020
EXPAND OCCLUSION RETRIEVAL MEMBER TO MEET INNER WALL OF BODY LUMEN, PORTION OF OCCLUSION CONTAINED BETWEEN PERFUSION CONDUIT AND OCCLUSION RETRIEVAL MEMBER
2030
2040
(OPT.) PROVIDE DISTAL FILTERING EXTENSION TO MEET BODY LUMEN INNER WALL DISTAL OF OCCLUSION
2050
(OPT.) PERFUSION CONDUIT AND OCCLUSION RETRIEVAL MEMBER CONNECTED PROXIMALLY AT FIRST CONNECTING PORTION
2060
(OPT.) PERFUSION CONDUIT AND OCCLUSION RETRIEVAL MEMBER CONNECTED DISTALLY AT SECOND CONNECTING PORTION
2070
WITHDRAW COMBINATION DEVICE TO AT LEAST PARTIALLY RETRIEVE OCCLUSION

FIG. 13

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2011/050058

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/221 A61B17/22
ADD. A61B17/3207 A61F2/86

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 1 832 240 A2 (TERUMO CORP [JP]) 12 September 2007 (2007-09-12) paragraph [0080] - paragraph [0195]; figures 11-25 -----	1-9, 11-13 10
X	US 2009/292307 A1 (RAZACK NASSER [US]) 26 November 2009 (2009-11-26) paragraph [0028] - paragraph [0039]; figures 1-17 -----	1-13
A	US 2005/059993 A1 (RAMZIPOOR KAMAL [US] ET AL) 17 March 2005 (2005-03-17) paragraph [0016] - paragraph [0022]; figures 1-2 ----- -/--	1-13

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 March 2012	02/04/2012

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Neef, Tatjana

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2011/050058

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 14-22
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/IL2011/050058

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2007/089897 A2 (CLEVELAND CLINIC FOUNDATION [US]) 9 August 2007 (2007-08-09) page 5, line 12 - page 22, line 31; figures 1-8	1-13
A	US 2007/208371 A1 (FRENCH RON [US] ET AL) 6 September 2007 (2007-09-06) paragraph [0098] - paragraph [0121]; figures 1-46	1-13
A	US 2004/254633 A1 (RAPAPORT AVRAHAM [IL] ET AL) 16 December 2004 (2004-12-16) paragraph [0038] - paragraph [0080]; figures 1-15	1-13
X,P	WO 2010/146581 A1 (PERFLOW MEDICAL LTD [IL]; RAPAPORT AVRAHAM [IL]; CIBULSKI GILAD [IL]) 23 December 2010 (2010-12-23) paragraph [0098] - paragraph [0103]	1-13

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/IL2011/050058

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		WO 2008088920 A2	24-07-2008
US 2004254633 A1	16-12-2004	NONE	
WO 2010146581 A1	23-12-2010	US 2010318178 A1	16-12-2010
		WO 2010146581 A1	23-12-2010