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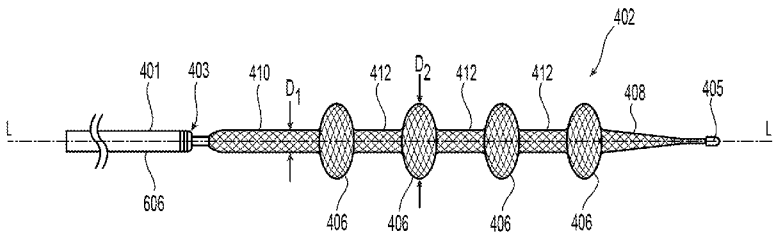

Fig. 5B

(57) Abstract: A method and apparatus for treating a clot in the blood vessel of a patient, and particularly the treatment of a pulmonary embolism is disclosed. The treatment includes restoring flow through the clot followed by clot removal, either partially or substantially completely. The clot treatment device is expandable into the blood vessel and may contain radial extensions that assist in restoring flow as well as in removing clot material.

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METHODS AND APPARATUS FOR TREATING EMBOLISM

RELATED APPLICATIONS

[0001] This application claims priority to U.S. Patent Application No. 13/843,742, filed on March 15, 2013, and entitled Methods and Apparatus for Treating Embolism, which examples priority to U.S. Provisional Application Serial No. 61/750,277 filed January 8, 2013 entitled Devices and Methods for Treatment of Vascular Occlusion and U.S. Provisional Application Serial No. 61/728,775 filed November 20, 2012 entitled Devices and Methods for Treatment of Vascular Occlusion, all of which are hereby incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

[0002] This invention relates to the apparatus and methods of endovascular treatment of blood clots obstructing passageways in the circulatory system and particularly the endovascular treatment of pulmonary embolism.

BACKGROUND OF THE INVENTION

[0003] Thromboembolism is the formation in a blood vessel of a clot (thrombus) that breaks loose (embolizes) and is carried by the blood stream to another location in the circulatory system resulting in a clot or obstruction at that new location. For example, a clot may embolize and plug a vessel in the lungs (pulmonary embolism), the brain (stroke), the gastrointestinal tract, the kidneys, or the legs. Thromboembolism is a significant cause of morbidity (disease) and mortality (death), especially in adults. A thromboembolism can be sudden and massive or it may be small and multiple. A thromboembolism can be any size and a thromboembolic event can happen at any time.

[0004] When a thrombus forms in the venous circulation of the body it often embolizes to the lungs. Such a thrombus typically embolizes from the veins of the legs, pelvis, or inferior vena cava and travels to the right heart cavities and then into the pulmonary arteries thus resulting in a pulmonary embolism.

[0005] A pulmonary embolism results in right heart failure and decreased blood flow through the lungs with subsequent decreased oxygenation of the lungs, heart and the rest of the body. More specifically, when such a thrombus enters the pulmonary arteries, obstruction and spasm of the different arteries of the lung occurs which further decreases blood flow and gaseous exchange through the lung tissue resulting in pulmonary edema. All of these factors decrease the oxygen in the blood in the left heart. As a result, the oxygenated blood supplied by the coronary arteries to the musculature of both the left and right heart is insufficient for proper contractions of the muscle which further decreases the entire oxygenated blood flow to the rest of the body. This often leads to heart dysfunction and specifically right ventricle dysfunction.

[0006] This condition is relatively common and has many causes. Some of the more common causes are prolonged inactivity such as bed rest, extended sitting (e.g., lengthy aircraft travel), dehydration, extensive surgery or protracted disease. Almost all of these causes are characterized by the blood of the inferior peripheral major circulatory system coagulating to varying degrees and resulting in permanent drainage problems.

[0007] There exist a number of approaches to treating thromboembolism and particularly pulmonary embolism. Some of those approaches include the use of anticoagulants, thrombolytics and endovascular attempts at removal of the emboli from the pulmonary artery. The endovascular attempts often rely on catheterization of the affected vessels and application of chemical or mechanical agents or both to disintegrate the clot. Invasive surgical intervention in which the emboli is removed by accessing the chest cavity, opening the embolized pulmonary artery and/or its branches and removing the clot is also possible.

[0008] The prior approaches to treatment, however, are lacking. For example, the use of agents such as anticoagulants and/or thrombolytics to reduce or remove a pulmonary embolism typically takes a prolonged period of time, e.g., hours and even days, before the treatment is effective. In some instances, such agents can cause hemorrhage in a patient. Moreover, the known mechanical devices for removing an

embolism are typically highly complex, prone to cause undue trauma to the vessel, and can be difficult and expensive to manufacture.

[0009] Lastly, the known treatment methods do not emphasize sufficiently the goal of urgently restoring blood flow through the thrombus once the thrombus has been identified. In other words, the known methods focus primarily and firstly on overall clot reduction and removal instead of first focusing on relief of the acute blockage condition followed then by the goal of clot reduction and removal. Hence, known methods are not providing optimal patient care, particularly as such care relates to treatment of a pulmonary embolism.

SUMMARY OF THE PRESENT TECHNOLOGY

[0010] In view of the foregoing, several embodiments of the present technology to provide a method and system that initially restores an acceptable level of oxygenated blood to the patient's circulatory system followed by safe and effective removal of the thrombus.

[0011] Several embodiments of the present technology treat pulmonary embolism in a minimally invasive manner.

[0012] Several embodiments of the present technology can also provide a system that does not cause undue trauma to the vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] These and other objects, aspects, features and advantages of which the present technology is capable will be apparent from the following description of embodiments of the present technology, reference being made to the accompanying drawings, in which

[0014] Fig. 1A is a schematic view of a patient with a pulmonary embolism;

[0015] Fig. 1B is an enlarged view of the lung area of the patient depicted in Fig. 1A;

[0016] Fig. 1C is an enlarged view of the introducer device depicted being used in the femoral vein of the patient in Fig. 1A;

[0017] Fig. 2 is a cross-sectional view of a patient's heart;

[0018] Fig. 3 is a perspective view of a patients main pulmonary artery and right and left pulmonary arteries with a clot located in the left pulmonary artery;

[0019] Fig. 4 is a cross-sectional view of an embodiment of a clot treatment device in accordance with the present technology in a compressed, undeployed state;

[0020] Fig. 5A is a side cross-sectional view of a clot treatment device in a compressed, undeployed state within a delivery catheter in accordance with the present technology;

[0021] Fig. 5B is a top view of the a clot treatment device in a deployed state in accordance with the present technology;

[0022] Figs. 6A-6F are a series of cross-sectional views of embodiments of the method and device of the present technology;

[0023] Figs. 7A-7B are a series of cross-sectional views of embodiments of the method and device of the present technology;

[0024] Fig. 8 is a cross-sectional view of another embodiment of the method and device of the present technology; and,

[0025] Figs. 9A-9G show cross-sectional views of embodiments of a clot treatment device in accordance with the present technology.

[0026] Fig. 10 is a cross-sectional view of a clot treatment device in accordance with another embodiment of the present technology.

[0027] Figs. 11 and 12 are detailed cross-sectional views of a distal portion and a proximal portion, respectively, of an expandable member of a clot treatment device in accordance with an embodiment of the present technology.

[0028] Figs. 13 and 14 are detailed cross-sectional views of a proximal portion and a distal portion, respectively, of an expandable member of a clot treatment device in accordance with another embodiment of the technology.

[0029] Figs. 15-18 are side views of guide catheters for use with clot treatment devices and methods in accordance with embodiments of the present technology.

[0030] Fig, 19 is a side view of a clot treatment device including arcuate clot engagement members configured in accordance with an embodiment of the present technology.

[0031] Figs. 20-23 show embodiments of arcuate clot engagement members configured in accordance with the present technology.

[0032] Figs. 24-25 are side views of clot treatment devices configured in accordance with embodiments of the present technology.

[0033] Fig. 26 is a circumferential structure including arcuate clot engagement members in accordance with embodiments of the present technology.

[0034] Fig. 27 is a side view of a clot treatment device having a distal radially extending member configured in accordance with another embodiment of the present technology.

DESCRIPTION OF EMBODIMENTS

[0035] Specific embodiments of the present technology will now be described with reference to the accompanying drawings. This present technology may, however, be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will be thorough and complete, and will fully convey the scope of the present technology to those skilled in the art. The terminology used in the detailed description of the embodiments illustrated in the accompanying drawings is not intended to be limiting of the present technology. In the drawings, like numbers refer to like elements.

[0036] Referring to Figures 1A-1C, these drawings show the typical locations in a human patient where clots 100, such as pulmonary embolisms, thromboses, or other obstructions, occur in the pulmonary arteries and further discloses the pathway through which access to such clots 100 is achieved. In particular, an introducer device (e.g., a hemostatic valve) 102 which supports relatively large diameter devices is inserted into the patient into the femoral vein FV in the pelvic area of the patient. The tools and devices needed to treat the pulmonary embolism are then inserted through the introducer 102 into the femoral vein FV through the inferior vena cava IVC to the patient's heart.

[0037] It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and which are consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to right atrium RA of the patient's heart may be attractive as this will reduce the length of the instruments needed to reach the pulmonary embolism.

[0038] Referring to Figs. 2 and 3, the tools/devices are then guided through the right atrium RA through the tricuspid valve TV, into the right ventricle RV, through the pulmonary valve PV into the main pulmonary artery (MPA). Depending on the location of the embolism 100, the tools/devices are then guided to one or more of the branches of the right pulmonary artery RPA or the left pulmonary artery LPA, including deeper branches thereof, to the location of the pulmonary embolism 100.

[0039] Referring to Figure 4, an embodiment of a clot treatment device 402 for restoring blood flow through the clot 100 and for removing at least a portion of the clot is depicted in its undeployed, or compressed state. The device 402 is constrained by a delivery catheter 606. In many embodiments, the device 402 comprises a braided material having ends that are captured distally by a tip 405 and proximally by an attachment member 403 that connects to a wire 401 configured to push and/or pull the clot treatment device 402.

[0040] In alternative embodiments, the clot treatment device 402 may be an "over the wire" device, in which case, the wire 401 is a tube or coil having a lumen, and the attachment member 403 and the tip 405 have a hollow central lumen for receiving a guide wire.

[0041] In yet a further embodiment, the distal end of the clot treatment device shall have a flexible, atraumatic extension from the device. In an alternative embodiment, the tip 405 is tapered to better penetrate the clot material in the vessel.

[0042] In preferred embodiments the clot treatment device 402 of the present technology has a generally cylindrical shape that, during use, creates a flow lumen through the clot material that restores significant blood flow across a clot. The treatment device 402 is not, however, limited to a generally cylindrical shape. For example, the shape can be generally conical, generally concave or generally convex along its axis such that the clot treatment device 402 creates a lumen for restoring the blood flow.

[0043] Fig. 5A shows one embodiment of the treatment device 402 in a low-profile, undeployed state in which the clot treatment device is configured to fit within a delivery catheter, and Fig. 5B shows the clot treatment device 402 of Fig. 5A in a deployed state configured to restore blood flow and capture clot material for removal. Referring to Fig. 5A, the clot treatment device 402 is compressed to fit within the diameter D_L of a lumen 607 of the delivery catheter 606 in the undeployed state. In the deployed state shown in Fig. 5B, the clot treatment device 402 has a plurality of capture elements, such as a series of radially extending capture portions 406 which are separated from each other by flow restoration portions 412. The flow restoration portions 412 are configured to expand outwardly from the low-profile undeployed state within the delivery catheter lumen 607 to a first cross-sectional dimension D_1 (e.g., diameter) in the deployed state. For example, the flow restoration portions 412 can be generally cylindrical braided sections that expand radially outward from the undeployed stated to the deployed state. In many applications, the first cross-sectional dimension D_1 is greater than the diameter D_L of the delivery catheter lumen 607. The capture portions 406 are configured to expand outwardly from the low-profile undeployed state to a second cross-sectional dimension D_2 greater than the first cross-sectional dimension D_1 in the deployed state.

As explained in more detail below, the capture portions 406 can project into the clot such that they extend transverse to a longitudinal axis L-L of the clot treatment device 402, while the flow restoration portions 412 expand radially outward into the clot to open a passage through which blood can quickly resume flow through the vessel. The clot treatment device 402 can be porous so blood flows therethrough. In this regard, many embodiments of the clot treatment device 402 are made from a mesh or braided material. The material can be a super-elastic material such as Nitinol or an alternative material such as cobalt chrome alloy. The device can be made from a wire lattice, wire braid or stent. Specific preferred embodiments are discussed throughout this specification.

[0044] Referring again to Fig. 5B, the clot treatment device 402 can comprise a single mesh structure that is generally cylindrical in the low-profile undeployed state (shown in Fig. 5A). The series of radially extending capture portions 406 accordingly extend from the same mesh as the corresponding series of flow restoration portions 412. The flow restoration portions 412 can be generally cylindrical sections in the deployed state, or in other embodiments the flow restoration portions 412 may taper in the distal direction individually and/or collectively to form a conical lumen (not shown). Each of the capture portions 406 can be a radial or otherwise transversely projecting disk that projects outward relative to the flow restoration portions 412.

[0045] The clot treatment device 402 can self-expand from the undeployed state to the deployed state. For example, the clot treatment device 402 can be a shape-memory material, such as Nitinol, and may be formed as a braid or a stent that is set to have the expanded configuration of the deployed state shown in Fig. 5B unless it is otherwise deformed or constrained, such as being elongated along the longitudinal axis L-L to fit within the delivery catheter 606 as shown in Fig. 5A. In other embodiments, the clot treatment device 402 can be actuated by a push/pull wire, tube or coil to move from the low-profile undeployed state to the expanded deployed state as explained in more detail below with reference to Figs. 10-12.

[0046] Figs. 1-6F show embodiments of methods for restoring blood flow and retrieving/removing clot material with the clot treatment device 402 in a body lumen L.

[0047] Referring to Figs. 1A, 1B and 6A, a guide wire 602 is inserted into the patient via an introducer 102 and maneuvered through the femoral vein FV into the inferior vena cava IVC to the heart. As stated above, access can also be achieved through one of the veins leading to the superior vena cava SVC. The guide wire 602 is then urged through the right atrium RA, through the tricuspid valve TV, through the right ventricle RV, through the pulmonary valve PV to the main pulmonary artery MPA and then to a location of the clot 100 in one of the branches or lumens L of either the right or left pulmonary artery RPA, LPA. In several embodiments, the guide wire 602 is extended through the clot 100 in the body lumen L as shown in Fig. 6A.

[0048] Referring to Fig. 6B, a guide catheter 604 is placed over the guide wire 602 and moved to a location where a distal end of the guide catheter 604 is positioned proximal to the clot 100. At this point, the guide wire can optionally be withdrawn. However, in the embodiment shown in Fig. 6C, the guide wire 602 remains positioned through the clot 100 and a delivery catheter 606 is then moved through the guide catheter 604 over the guide wire 602 and pushed through the clot 100.

[0049] Referring to Figure 6D, the guide wire 602 is then withdrawn and the clot treatment device 402 in its undeployed (i.e., compressed) state is then moved through the delivery catheter 606 until it is positioned at the distal end of the delivery catheter 606. Alternatively, if an over-the-wire device configuration (as shown in Figure 10) is used, the guide wire 602 may be left in place while the treatment device 402 is deployed and retracted. Referring to Fig. 6E, the delivery catheter 606 is then retracted in a proximal direction while maintaining forward pressure on the clot retrieval device 402 via the pusher wire 401 so that the clot treatment device 402 is exposed and released from the delivery catheter 606. The clot treatment device 402 radially expands into the clot 100 and, in some embodiments, at least a portion of the clot treatment device 402 expands distal of the clot 100. For example, at least one of the radially extending capture portions 406 of the clot treatment device 402 is located distal to the clot 100 upon expansion of the clot treatment device 402. Additionally, the flow restoration portions 412 between the capture portions 406 also expand outwardly against a portion of the clot 100 to form a flow passage 430 though the clot treatment device 402.

[0050] The clot treatment device 402 accordingly restores blood flow through the clot 100 immediately or at least quickly after expanding to the deployed state as shown by arrows 407 in Fig. 6E. More specifically, the blood freely moves through the mesh of the clot treatment device 402, travels through the device lumen and exits the clot treatment device 402 distal to the clot 100. As a result, the acute condition of blockage is mediated thus immediately improving the circulation of oxygenated blood in the patient.

[0051] The restoration of blood flow is anticipated to equate with restoration of a substantial portion of the normal blood flow rate for the patient. In less severe. e.g., "sub-massive," pulmonary embolism patients, the clot treatment device 402 may increase blood flow rate by at least about 50 ml/min, at least about 150 ml/min or between about 100 to 250 ml/min. In severe, e.g., "massive," pulmonary embolism patients, a larger amount of the pulmonary artery flow is compromised. Hence, in some embodiments, at least about 500 ml/min of blood flow rate may be restored. Moreover, at least a portion of the flow restoration is expected to occur prior to the removal of the clot 100, or any portion thereof.

[0052] The restoration of blood flow by the clot treatment device 402 can be achieved in a low pressure environment. For example, the pressure in the target vessel can be less than 60 mmHg and the blood can be venous blood, substantially non-oxygenated blood or low oxygenated blood.

[0053] In addition to restoring blood flow, the expansion of the clot treatment device 402 also deforms the clot material by pushing, penetrating and/or otherwise cutting into the clot material. This enhances the subsequent removal of the clot 100 since portions of the clot 100 may be captured and retained (1) between the radially extending portions 406; (2) through the pores of the mesh forming the radially extending portions 406; (3) along the longitudinal cylindrical sections 412 between the radially extending portions 406 of the removal device 402; and (4) within the clot treatment device 402 itself.

[0054] As can be understood from the above description and figures, the deployment of the clot treatment device 402 results in an outwardly expanding generally cylindrical

force being urged against an inner surface of the clot 100 because the flow restoration portions 412 expand to the first cross-sectional dimension D_1 greater than the diameter D_L of the delivery catheter lumen 607. This force pushes the clot material outwardly and creates a lumen through which blood flow is restored. As can also be appreciated, the presence of the radially extending capture portions 406 on the clot treatment device 402 causes the outwardly expanding generally cylindrical force to vary in magnitude along the axis of the clot treatment device 402. The force on the clot material may be greater at the locations of the radially extending capture portions 406.

[0055] In braided embodiments of the clot treatment device 402, deployment/expansion of the device leads the filaments of the braid to change their angular orientation with respect to the axis of the device. This angular change may improve or enhance adherence of clot material to the clot treatment device 402.

[0056] After the clot treatment device 402 has been expanded and blood flow restored, the user then retracts the clot treatment device 402 in a proximal direction as shown in Fig. 6F. Since the capture portions 406 extend transverse to the longitudinal dimension of the vessel, the capture portions 406 form transverse surfaces relative to the force exerted against the clot 100 as the clot treatment device 402 is pulled in the proximal direction. The capture portions 406 accordingly enhance the ability of the clot treatment device 402 to securely dislodge and retain the clot 100 as the clot treatment device 402 is moved axially along the vessel to retrieve the clot 100 from the patient. In one embodiment, the clot treatment device 402 and the delivery catheter 606 are pulled back simultaneously into the guide catheter 604. This is followed by the entire apparatus (e.g., clot treatment device 402, delivery catheter 606 and guide catheter 604) being withdrawn through the heart and the venous circulation and out from the body.

[0057] As further shown in Fig. 6F, the clot treatment device 402 may elongate as it is being withdrawn into the guide catheter 604 due to the resistance it encounters from the presence of clot material of the clot 100. The presence of the radially extending portions 406 may allow elongation that enhances the capability of the device 402 to capture the maximum amount of clot material. This is further discussed below with

respect to the surface area and expansion ratio of preferred embodiments of the clot treatment device 402.

[0058] It will be appreciated that variations in the above-described method are contemplated. For example, in certain circumstances a guide catheter 604 may not be necessary or desirable and the user may choose to use only the delivery catheter 606 for placing and manipulation of the clot treatment device 402. As a further example, the clot may be of such a nature that the user may desire repeat the above-described process, or at least portions of it, in order to more fully remove the clot 100 or clot material.

[0059] Referring next to Figs. 7A-7B, it may be advantageous to include the use of a collection or funnel catheter 612 to assist in the removal of the clot 100. Such a funnel catheter 612 has an expandable portion 614 at its distal end and may be situated between the guide catheter 604 and the delivery catheter 608 or may be part of the guide catheter 604. In the presence of the collection catheter 612, the clot treatment device 402 is pulled proximally into the collection catheter 612 such that the clot or portions of it are captured within the collection catheter 612. In an alternative embodiment, the collection catheter 612 can be pushed distally over the clot treatment device 402 such that the collection catheter 612 captures the clot or portions thereof. If the collection catheter 612 is separate from the guide catheter 606, the collection catheter with the clot treatment device 402 is then pulled into the guide catheter for ultimate removal of all devices (and the clot) from the patient.

[0060] In certain circumstances, it may be advisable to remove the clot 100 without capturing it in the guide catheter 606 or the collection catheter 612 (if used) and remove the clot 100 by withdrawing the entire system, e.g., guide catheter 605, delivery catheter 604, clot treatment device 402 and collection catheter 612 (if used) simultaneously.

[0061] In several embodiments, the expandable portion 614 of the collection catheter 612 is a conical funnel or other tapered member constructed from a mesh, braid or stent structure. Such structure assists in retrieving and containing the clot material in the withdrawal process. In yet further preferred embodiments, the collection catheter 612

contains structural features to assist in the expansion of the expandable portion 614 and to hold the expandable portion 614 open towards the wall of the blood vessel. Such features (not shown) include interwoven support struts, self expanding material (e.g., Nitinol), longitudinal wire supports, stent supports, polymeric webbing, etc.

[0062] In another embodiment of the present invention, a vacuum apparatus may be used to aid in the removal of the clot material. Referring to Fig. 8, a syringe 802 is shown connected to a vacuum manifold 806 that is in fluid communication with the proximal end of the guide catheter 604. At the time the clot treatment device 402 (and clot material) is being withdrawn into the guide catheter 604 (or the collection catheter 612), vacuum is applied by pulling on the syringe. Alternative sources of vacuum 804 are also acceptable, e.g., a vacuum pump. A system is also contemplated whereby vacuum is actuated automatically when the clot treatment device 402 (and the clot material) is being withdrawn. A representation of the effect of the use of vacuum can be seen with reference to Fig. 7B which shows how vacuum causes flow 701 into the catheter 612.

[0063] Referring now to Figs. 9A-9H, alternative preferred embodiments of the clot treatment device 402 are disclosed.

[0064] Referring to Fig. 9A, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rounded triangular cross-section.

[0065] Referring to Fig. 9B, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rounded triangular cross-section wherein the diameter of the disk increases along the length of the device 402 thus forming a conical exterior extent.

[0066] Referring to Fig. 9C, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rectangular cross-section.

[0067] Referring to Fig. 9D, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a linear (non-rounded) triangular cross-section.

[0068] Referring to Fig. 9E, some of the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a cylindrical disk shape with a rounded cross-section and others have a rectangular cross section.

[0069] Referring to Fig. 9F, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 alternate between cylindrical disk shape with a T-shaped cross-section and a flare-shaped cross-section.

[0070] Referring to Fig. 9G, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by a partial cylindrical disk shapes.

[0071] Referring to Fig. 9H, the radially extending portions 406 between the generally cylindrical sections 412 of the clot treatment device 402 are defined by tabs and bumps or protuberances arising from the cylindrical surface of the device 402.

[0072] Fig. 10 is a cross-sectional view of another embodiment of the clot treatment device 402 in accordance with the technology having an expandable member 1010, an elongated inner member 1020, and an elongated outer member 1022. The expandable member 1010 is configured to have an undeployed state in which the expandable member 1010 is elongated axially to have a low profile that fits within a delivery catheter as shown in Fig. 4. The expandable member 1010 is further configurable into a deployed state in which the expandable member 1010 forms a flow channel 1012 for restoring blood flow through the region obstructed by the clot. The expandable member 1010, for example, can be a mesh, braid, stent-type device, or other suitable member through which blood flows in the deployed state. In one embodiment, the expandable member 1010 is a continuous braid formed from a shape-memory material that has been heat set such that, in the deployed state, the expandable member 1010 has a

plurality of flow restoration portions 412 that expand to the first cross-sectional dimension D_1 to form the flow channel 1012 and a plurality of capture portions 406 that expand to the second cross-section dimension D_2 greater than the first cross-sectional dimension D_1. The flow restoration members 412 accordingly exert an outward force (arrows O) against clot material (not shown) to create the flow channel 1012, and the capture portions 406 accordingly exert a longitudinal force L (arrows L) against the clot material as the clot treatment device 402 is moved proximally.

[0073] The elongated inner member 1020 can be a tube or coil having inner lumen configured to receive the guidewire 602 for over-the-wire or rapid exchange delivery of the expandable member 1010 to the clot. The outer elongated member 1022 can be a tube or coil having a lumen configured to receive the inner elongated member 1020 such that the inner elongated member 1020 and/or the outer elongated member 1022 can move relative to each other along the longitudinal dimension of the clot treatment device 402.

[0074] Figs. 11 and 12 are detailed views of a distal portion 1011a (Fig. 11) and a proximal portion 1011b (Fig. 12) of the expandable member 1010 of the clot treatment device 402 shown in Fig. 10. Referring to Fig. 11, the distal portion 1011a is attached to a distal end of the inner elongated member 1020 by the tip 405. The tip 405 can be blunt as described above with reference to the embodiment of the clot treatment device 402 shown in Fig. 4, or the tip 405 can have a tapered distal portion 1040 configured to pass through the clot as shown in Fig. 11. Additionally, the tip 405 can have a proximal opening 1042 configured to receive the distal end of the inner elongated member 1020 and the distal end of the expandable member 1010. Referring to Fig. 12, the proximal portion 1011b is attached to the distal end of the outer elongated member 1022 by a proximal hub 1030. For example, the distal and proximal portions 1011a and 1011b can be attached to the inner elongated member 1020 and the outer elongated member 1022, respectively, using welds, adhesives, crimping or clamping forces, and/or other suitable attachment mechanisms.

[0075] In the operation of the clot treatment device 402 shown in Figs. 10-12, the expandable member 1010 can self-expand from the undeployed state to the deployed

state without an actuator. For example, as a delivery catheter is drawn proximally to release the expandable member 1010, the inner elongated member 1020 can be held in place to hold the distal portion 1011a of the expandable member 1010 distally of the clot. As the distal end of the delivery catheter moves proximally, the outer elongated member 1022 will slide distally as the expandable member 1010 expands until the expandable member 1010 reaches its predetermined deployed size or otherwise reaches equilibrium with the clot. In other embodiments, the inner elongated member 1020 and/or the outer elongated member 1022 can be actuators that are moved proximally and/or distally to control the radial expansion and/or the radial contraction of the expandable member 1010.

[0076] Figs. 13 and 14 are detailed views of the proximal and distal portions 1011b and 1011a, respectively, of an expandable member 1010 and other components of a clot treatment device 402 in accordance with another embodiment of the technology. In this embodiment, the clot treatment device 402 has a proximal tube 1410 (Fig. 13) and an expansion element 1420 having one end attached to the proximal tube 1410 and another end attached to the distal portion 1011a (Fig. 14) of the expandable member 1010. The expansion element 1420, for example, can be a coil or spring that is stretched from its normal state when the expandable member 1010 is the low-profile, undeployed state inside the delivery catheter. As the distal portion 1011a and then the proximal portion 1011b of the expandable member 1010 are released from the delivery catheter, the expansion element 1420 contracts axially under its own stored spring force causing the expandable member 1010 to contract axially and expand radially outward. In the embodiments where the expandable member 1010 is self-expanding, the expansion element 1420 assists the expansion of the expandable member 1010. In other embodiments, the expandable member 1010 may not be self-expanding or may be inherently spring-biased into the low-profile undeployed state, and the expansion element 1420 can have enough stored energy when it is stretched in the low-profile undeployed state to pull the distal portion 1011a and the proximal portion 1011b of the expandable member 1010 toward each other and thereby radially expand the expandable member 1010.

[0077] In the foregoing embodiments, the radially extending capture portions 406 provide more surface area along the device than a device that is uniformly cylindrical. Moreover, the radially extending capture portions 406 extend transversely to the longitudinal dimension of the device to more effectively transfer the axial force as the device is moved axially along the vessel after deployment. Such increased surface area facilitates the treatment and/or retrieval of a much larger portion of the clot 100 than is generally feasible with a uniformly cylindrical device. For example, in a preferred embodiment of the clot treatment device 402, the device will have an external surface area between 1.5x and 6x the surface area of a uniformly cylindrical device of the same general diameter of the cylindrical sections 412. In other preferred embodiments the ratio will be 2x to 4x.

[0078] This is advantageous particularly during retraction of the clot treatment device 402 through the clot 100. As shown in Fig. 6F, the clot treatment device 402 may become elongated as it is being withdrawn through the clot 100. Such elongation causes the clot material to encounter greater surface area of the clot treatment device 402 than would otherwise occur with a device that was only generally cylindrical, i.e., that did not incorporate radially extending portions 406. Accordingly the clot treatment device 402 is particularly adept at capturing the maximum amount of clot material during withdrawal.

[0079] The clot treatment device 402 is intended for use in large vessels, i.e., vessels with a diameter greater than 8mm. For example, the diameter of the pulmonary arteries typically range from 15 to 30mm whereas the first branches of the pulmonary arteries typically range from 10 to 15mm and the secondary and tertiary branches typically range from 5 to 10mm. At the same time, however, it is important to minimize the size of catheter providing access to the clot 100. Accordingly, the clot treatment device 402 has a large expansion ratio. In a preferred embodiment the expansion ratio from the diameter of the cylindrical sections 412 in the collapsed state to the expanded state will be between 4 and 8. In another preferred embodiment the ratio will be between 5 and 7. The large expansion ratio also enables the formation of a flow channel in the clot 100 that is large, e.g., on the order of 4-8mm.

[0080] The radially extending portions 406, in their fully expanded position are intended to have a size that matches the diameter of the target blood vessel. However, the diameters may be slightly larger than the vessel diameter so to apply greater radial force against the blood vessel (without causing trauma) in those circumstances when it is desirable to improve clot collection. Similarly, in those circumstances where there is a concern of creating trauma on delicate blood vessels, the radially extending portions 406 may have a diameter that is smaller than the vessel diameter. It is contemplated that different sizes of the device 402 will be available for selection by the user for a particular presentation of the patient.

[0081] As for the length of the clot treatment device 402, it is known that a typical pulmonary embolism will have a length within the range between about 2 cm and 10 cm and sometimes between about 1 cm and 20 cm. Accordingly, in a preferred embodiment, the clot treatment device 402 will have a length that exceeds the length of the embolism so that a portion of the clot treatment device is positioned distal of the clot 100 during expansion.

[0082] With regard to the delivery catheter 606, in a preferred embodiment for use with a pulmonary embolism, the size will be around 1F-6F. Smaller diameters will pass through the clot 100 more easily. In addition, the delivery catheter 606 may have stiffness characteristics to assist in making sure the delivery catheter 606 passes through the clot in a smooth manner. Such stiffness characteristics include self expanding Nitinol wire braids or stent structures that are contained within the structure of the delivery catheter 606. The delivery catheter 606 also has sufficient flexibility so that it may carry the clot treatment device 402 and still pass through a tortuous vessel path as described above starting with insertion of the delivery catheter 606 in the femoral vein FV.

[0083] In some preferred embodiments, the method and device in accordance with the present invention may reduce the Mean Resting Pulmonary Artery Pressure (MRPAP). Upon at least partial relief from the clot 100, MRPAP may be reduced by about 20-50mmHg to a normal range of 8-20 mmHg. In some embodiments, the reduction in MRPAP may be about 25-50%. In some embodiments, the reduction in

MRPAP may be about 15% to 40% and in other embodiments between about 30% and 75%.

[0084] Such a reduction in MRPAP can occur in two steps. A first step is when the clot treatment device 402 is first deployed and blood flow is at least partially restored. A second step may be when the clot treatment device 402 is retracted and at least some of the clot 100 is removed from the vessel. A third step may be after the clot treatment device 402 has been removed and the effect of the body's own processes and/or thrombolytic drugs that may have been used before, during or after the procedure take effect upon clot that has been disrupted by the clot treatment device.

[0085] Fig. 15 is a side view of an embodiment of a guide catheter 1500 for use with any of the foregoing embodiments of the clot treatment devices 402 (not shown in Fig. 15). The guide catheter 1500 can include a shaft 1502 having a sufficiently large lumen to accommodate the delivery catheter 606 (Figs. 4 and 5A). The guide catheter 1500 can further include an expandable guide member 1510 at the distal end of the shaft 1502 configured to expand radially outward to contact or nearly contact the vessel wall VW. The guide member can be formed from a permeable, radially expanding material, such as a mesh or other macroporous structure (e.g., a braid of wires or filaments). The guide member 1510, for example, may be formed from a tubular braid of elastic or super-elastic filaments such as Nitinol that has been heat set into the desired expanded shape. The permeable, radially expanding guide member 1510 may have advantages over an occlusive member such as a balloon or impermeable funnel. For example, the guide member 1510 allows a substantial amount of blood flow BF to continue flowing through the blood vessel where therapy is being directed. In addition, the guide member 1510 positions the shaft 1502 and delivery catheter 606 at or near the center of the vessel. The clot treatment device 402 (not shown in Fig. 15) may also be substantially self-centering upon deployment, and the guide member 1510 may further guide the clot material captured by the clot treatment device 402 into the shaft 1502 as the clot treatment device 402 moves into proximity of the distal end of the shaft 1502. This is expected to enhance aspiration of the clot material. For example, in the embodiment shown in Fig. 15, the radially expanding guide member 1510 has a funnel

shape adjacent the distal end of the shaft 1502 to guide thrombus material into the distal opening of the shaft 1502 where it can be more readily aspirated.

[0086] The radially expanding guide member 1510 may also be formed by conventional machining, laser cutting, electrical discharge machining (EDM) or other means known in the art to make a fenestrated, mesh or porous structure that can be affixed near the distal end of the shaft 1502. In some embodiments the radially expanding guide member 1510 may self-expand, but in other embodiments it may be actuated by an operator using, for example, electrical or electromechanical means. By having a porous radially expanding guide member 1510, the guide catheter 1500 may be substantially centered within a vessel without blocking a large portion of the flow around the catheter. In some embodiments, the radially expanding guide member 1510 may block less than about 50% of the flow about the catheter and in other embodiments less than about 25% of the flow. When the guide member 1510 is made with a braid of filaments (e.g. wires), it may be formed from a tubular braid. In some embodiments, the tubular braid may be formed with approximately 12 to approximately 144 filaments, or in other embodiments from about 36 to about 96 filaments. The pores as measured by the largest circle that can be inscribed within an opening of the mesh may be between about 0.5 mm and 5 mm.

[0087] Figs. 16 and 17 show additional embodiments of guide members 1610 and 1710, respectively, that can be used instead of or in addition to the guide member 1510. Referring to Figs. 15 and 16, one or both ends of the tubular braid of the guide members 1510 and 1610 may be inverted and attached to the catheter body. Referring to Fig. 17, neither end of the guide member 1710 is inverted. With the distal end inverted, it advantageously may form a funnel adjacent the distal opening of the catheter that may enhance clot capture and aspiration.

[0088] Fig. 18 shows an embodiment of a guide catheter 1900 having a shaft 1902 and a guide member 1910 in accordance with another embodiment of the technology. In the embodiment shown in Fig. 18, the guide member 1910 has a tapered or funnel shape, and includes a non-permeable portion 1912 and a permeable portion 1914. The permeable portion 1914 can comprise a flared radially expanding mesh that has, at least

in part, a tapered or funnel shape, and the non-permeable portion 1912 may have a substantially non-porous or otherwise non-permeable material or coating over the mesh. Preferably, the non-permeable material is a highly elastic material such as polyurethane, silicone, latex rubber and the like so that it can flex with the expansion of the mesh. In some embodiments, the non-permeable material covers a proximal portion of the mesh as shown in Fig. 18. The non-permeable portion 1912 may divert some flow away from the distal end of the catheter. The covering may cover a portion of the mesh to a diameter "d". In some embodiments, the diameter d of the covering is less than about 75% of the diameter "D" of the mesh funnel. In some embodiments, the diameter d may be less than about 50% of diameter D. The concept of a non-permeable material can also be applied to the guide catheter 1500 shown above in Fig. 15. For example, the expandable member 1510 of the guide catheter 1500 can have a non-permeable portion 1512 at the proximal portion of the expandable guide member 1510 similar to the non-permeable portion 1912 shown and described with reference to Fig. 18.

[0089] Figs. 19-27 show additional embodiments of clot treatment devices 402 in accordance with the present technology. The embodiments of the clot treatment devices 402 shown in Figs. 19-27 can restore blood flow and capture clot material in a manner similar to the embodiments of the clot treatment devices 402 described above with respect to Figs. 4-18. The embodiments of the clot treatment devices 402 related to Figs. 19-27 can also be made from the same materials and be deployed in the same manner as described above with respect to Figs. 4-18. As such, many of the features, materials and benefits of the clot treatment devices 402 shown in Figs. 4-18 are applicable to the clot treatment devices shown in Figs. 19-27.

[0090] Fig. 19 shows an embodiment of the clot treatment device 402 that includes a plurality of capture elements, such as clot engagement ("CE") members 1952. The CE members 1952 can be (a) arcuate as shown in Fig. 19, (b) bent at one or more angles (e.g., 30°, 45°, 60°, 90°, 135°, etc.), and/or (c) straight (e.g., project outward along a straight line). In some embodiments, the clot treatment device 402 can include a combination of arcuate, angled and/or straight CE members. In other embodiments, the

clot treatment device 402 can include a single CE member 1952. The CE members 1952 can be interwoven into the mesh structure of the device 402 (see Fig. 21). The CE members 1952 can also be bonded, soldered, welded, tied or otherwise secured to the mesh structure or mechanically interlocked with the mesh structure. As the clot treatment device 402 is unsheathed during deployment, the CE members 1952 can radially extend and form a heat-set shape configured to penetrate and fasten the clot to the treatment device 402. The CE members 1952 can accordingly define hook-like capture elements in several embodiments of the present technology.

[0091] The CE members 1952 can be disposed about an exterior surface of the device 402. For example, as shown in Fig. 19, the CE members 1952 can be arranged in one or more circumferential rows 1954 that are evenly positioned along a longitudinal axis of the device 402. In other embodiments, the CE members 1952 can have any suitable arrangement and/or positioning about the device (e.g., arranged in a helical pattern, off-set rows, random, or irregular or otherwise uneven/non-uniform spacing, etc.).

[0092] As shown in Fig. 19, the CE members 1952 can curve proximally such that a concave portion 1956 of the CE members 1952 face a proximal region 402b of the device 402. In some embodiments, the CE members 1952 can curve distally such that a concave portion of the CE members 1952 face a distal region 402a of the device 402 (not shown). In particular embodiments, the clot treatment device 402 includes both distally-curving and proximally-curving CE members.

[0093] The CE members can have a single radius of curvature or have regions with different radii or have a complex or changing radius of curvature. For example, as shown in Fig. 20, one or more of the CE members 1952 can have a first portion 1958 that has a first radius R and a second portion 1960 (e.g., the distal region of the CE member 1952) that has a second radius r that is smaller than the first radius R. In some embodiments, the first radius R may range from about 2 mm to about 15 mm, and the second radius r may range from about 0.25 mm to about 5 mm. Additionally, the CE members 1952 can have a range of arc lengths. For example, in some embodiments

the CE members 1952 can have an arc length greater than 180 degrees. In certain embodiments, the arc length can be between 180 degrees and 330 degrees.

[0094] Fig. 22 shows another embodiment of a CE member 2202 having a V-shaped base 2204 that branches into a first arm 2206a and a second arm 2206b. The V-shaped base 2204 and/or any portion of the first and/or second arms 2206a, 2206b can be interwoven into the mesh structure of the clot treatment device 402, as shown in Figs. 24 and 25. In some embodiments, the angle α between the first and second arms 2206a, 2206b may be between about 40 degrees and about 100 degrees. Although Fig. 24 shows a plurality of such CE members 2202 disposed about a clot treatment device 402, in other embodiments the device 402 can only include a single CE member 2202.

[0095] As shown in Fig. 25, the first arm 2206a and the second arm 2206b can extend into a first distal portion 2208a and a second distal portion 2208b, respectively, where the first distal portion 2208a and the second distal portion 2208b are generally arcuate. As shown in Fig. 24, in some embodiments the first distal portion 2208a and the second distal portion 2208b can be generally linear.

[0096] Referring to Fig. 26, two or more CE members can be connected to form a circumferential structure 2602 that extends around at least a portion of a circumference of a clot treatment device 402. The device 402 can include one or more circumferential structures 2602 spaced along a longitudinal axis of the device. These circumferential structures 2602 can allow for the CE members to flex with the mesh structure as it expands and contracts. In some embodiments, the angle θ formed by the circumferential structure 2602 can be between about 40 degrees and about 100 degrees.

[0097] Fig. 23 shows one embodiment of an CE member 2302 having a double-wire arcuate portion 2306. Referring to Fig. 27, in some embodiments, the clot treatment device 402 can include a plurality of CE member 1952 and a radially extended member 406 at a distal end. The radially extended member 406 could be a disc, balloon, screen or other clot capture member.

Examples

[0098] Several examples of the present technology are as follows:

1. A device for treating a pulmonary embolism, comprising:
an expandable flow restoration portion; and
a plurality of capture elements including at least a first capture element and a second capture element, wherein the flow restoration portion is between the first and second capture elements, and wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state such that the flow restoration portion forms a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

2. The device of example 1 wherein the flow restoration portion and the capture elements comprise an expandable braided material that is heat set to have the deployed state.

3. The device of any of examples 1 and 2 wherein the flow restoration portion and the capture elements are integrally formed from a common braided material.

4. The device of any of examples 1-3, further comprising a plurality of flow restoration portions and the capture elements comprise a series of radially extending capture portions, and wherein the radially extending capture portions are separated from each other by individual flow restoration portions.

5. The device of example 4 wherein the flow restoration portions comprise expandable cylindrical sections and the capture elements comprise radially expandable disk-like capture portions of the braided material.

6. The device of example 1 wherein the flow restoration portion comprises a radially expandable cylindrical braided material and the capture elements comprise protuberances projecting from the flow restoration portion.

7. The device of any of examples 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:4 to 1:8.

8. The device of any of examples 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:5 to 1:7.

9. The device of any of examples 1-8 wherein the flow restoration portion has a diameter of approximately 4-8 mm in the deployed state to restore blood flow through a pulmonary embolism.

10. The device of any of examples 1-9 wherein the flow restoration portions and the capture elements comprises a self-expanding braided material, and the capture elements comprise capture portions that have a second diameter greater than the first cross-sectional dimension of the flow restoration portions in the deployed state.

11. The device of any of examples 1-3 and 6-9 wherein the flow restoration portion comprises a single expandable braided tube, and the capture elements comprise clot engagement members configured to project from the flow restoration portion in the deployed state.

12. The device of example 11 wherein the clot engagement members comprise arcuate members that form hook-like elements projecting from the flow restoration portion.

13. The device of example 11 wherein the clot engagement members are formed from wires of the expandable braided tube that defines the flow restoration portion.

14. The device of example 11 wherein the clot engagement members are formed from separate wires that project through interstices of the expandable braided tube that defines the flow restoration portion.

15. A pulmonary embolism treatment device, comprising:

an outer elongated member having a distal end;

an inner elongated member within the outer elongated member, wherein the inner elongated member and/or the outer elongated member slides relative to the other, and wherein the inner elongated member has a distal end; and

an expandable member having a proximal portion attached to the distal end of the outer elongated member and a distal portion attached to the distal end of the inner elongated member, the expandable member having a flow restoration portion and a plurality of capture elements arranged along the flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

16. The pulmonary embolism treatment device of example 15 wherein the expandable member comprises a braided material.

17. The pulmonary embolism treatment device of example 15 wherein the device has a plurality of flow restoration portions and the capture elements are separated by individual flow restoration portions, and wherein (a) the capture elements comprise capture portions formed from a continuous shape-memory braided material heat-set to the deployed state and (b) the capture portions project from the flow restoration portions to a second cross-sectional dimension in the deployed state.

18. The pulmonary embolism treatment device of example 17 wherein the flow restoration portions comprise cylindrical portions and the first cross-sectional dimension comprises a first diameter in the deployed state, and the capture portions comprise disk-like projections having a second diameter greater than the first diameter in the deployed state.

19. The pulmonary embolism treatment device of any of examples 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:4 to 1:8.

20. The pulmonary embolism treatment device of any of examples 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:5 to 1:7.

21. The pulmonary embolism treatment device of any of examples 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises an inner tube within the outer tube.

22. The pulmonary embolism treatment device of any of examples 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises a coil within the outer tube.

23. The pulmonary embolism device of any of examples 11-20 wherein the first elongated member comprises an outer coil and the second elongated member comprises an inner coil.

24. The pulmonary embolism treatment device of any of examples 11-23 wherein the flow restoration portion(s) and the capture elements comprise a self-expanding braided material.

25. The pulmonary embolism treatment device of any of examples 11-24 wherein the outer elongated member is configured to slide distally with respect to the inner

elongated member to move the expansion member from the undeployed state to the deployed state.

26. The pulmonary embolism treatment device of any of examples 11-25, further comprising a guide catheter having a shaft with a distal end and an expandable guide member at the distal end of the shaft, wherein the shaft has a lumen configured to receive the expandable member in the undeployed state.

27. The pulmonary embolism treatment device of example 26 wherein the expandable guide member comprises radially expandable mesh.

28. The pulmonary embolism treatment device of example 27 wherein the radially expandable mesh comprises a braided material.

29. The pulmonary embolism treatment device of any of examples 26-28 wherein the expandable guide member has a funnel shape.

30. The pulmonary embolism treatment device of any of examples 26-29 wherein at least a portion of the expandable guide member is permeable to allow blood to flow through the expandable guide member when the expandable guide member is expanded.

31. The pulmonary embolism treatment device of any of examples 26-29 wherein the expandable guide member has a non-permeable portion at the distal end of the shaft and a permeable portion extending distally from the non-permeable portion.

32. A pulmonary embolism treatment device, comprising:
an elongated member having a distal end;
an expansion portion having a proximal end attached to the distal end of the elongated member, and the expansion portion having a distal end; and
an expandable member having a proximal portion attached to the distal end of the elongated member and a distal portion attached to the distal end of the

expansion portion, the expandable member having at least one of flow restoration portion and a plurality of capture elements arranged such that the capture elements are separated by individual flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which (a) the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and (b) the capture elements project outwardly from the flow restoration portion, and wherein the expansion portion is stretched from a normal state when the expandable member is in the undeployed state such that the expansion portion is configured to axially contract the expandable member from the undeployed state to the deployed state.

33. A method of treating a pulmonary embolism, comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device has a plurality of capture elements separated by an expandable cylindrical section;

deploying the embolectomy device within the pulmonary embolism by expanding the cylindrical section into the pulmonary embolism so that the cylindrical section forms an expanded flow channel through the pulmonary embolism and thereby restores blood flow through the pulmonary embolism and by expanding the capture elements to a greater extent than the cylindrical section so that at least a portion of the pulmonary embolism is captured the capture elements;

moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

34. The method of example 33 wherein deploying the embolectomy device comprises expanding a plurality of radial extendable capture elements of the embolectomy device.

35. The method of example 34, wherein at least one of the plurality of radial extendable capture elements is expanded distal relative to the pulmonary embolism.

36. The method of example 33, further comprising applying vacuum while withdrawing the embolectomy device.

37. The method of example 36, wherein withdrawing the embolectomy device includes urging the portion of the pulmonary embolism into a funnel catheter.

38. The method of example 37, wherein deploying the embolectomy device comprises expanding the device such that a surface area of the embolectomy device expands within a range of at least 200% to 400% of the surface area of a uniformly cylindrical device.

39. The method of example 33 wherein deploying the embolectomy device comprises expanding the generally cylindrical section by 400% to 800% of its diameter in the undeployed state.

40. The method according to and of examples 33-39 wherein deploying the embolectomy device comprises expanding a braided material into a preset shape having a plurality of radially extending disk-like capture portions that define the capture elements.

[0099] Although the invention has been described in terms of particular embodiments and applications, one of ordinary skill in the art, in light of this teaching, can generate additional embodiments and modifications without departing from the spirit of or exceeding the scope of the exampleed invention. Accordingly, it is to be understood

that the drawings and descriptions herein are proffered by way of example to facilitate comprehension of the invention and should not be construed to limit the scope thereof.

What is claimed is:

1. A device for treating a pulmonary embolism, comprising:
an expandable flow restoration portion; and
a plurality of capture elements including at least a first capture element and a second capture element, wherein the flow restoration portion is between the first and second capture elements, and wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state such that the flow restoration portion forms a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

2. The device of claim 1 wherein the flow restoration portion and the capture elements comprise an expandable braided material that is heat set to have the deployed state.

3. The device of any of claims 1 and 2 wherein the flow restoration portion and the capture elements are integrally formed from a common braided material.

4. The device of any of claims 1-3, further comprising a plurality of flow restoration portions and the capture elements comprise a series of radially extending capture portions, and wherein the radially extending capture portions are separated from each other by individual flow restoration portions.

5. The device of claim 4 wherein the flow restoration portions comprise expandable cylindrical sections and the capture elements comprise radially expandable disk-like capture portions of the braided material.

6. The device of claim 1 wherein the flow restoration portion comprises a radially expandable cylindrical braided material and the capture elements comprise protuberances projecting from the flow restoration portion.

7. The device of any of claims 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:4 to 1:8.

8. The device of any of claims 1-6 wherein the flow restoration portion has an expansion ratio from the undeployed state to the deployed state of approximately 1:5 to 1:7.

9. The device of any of claims 1-8 wherein the flow restoration portion has a diameter of approximately 4-8 mm in the deployed state to restore blood flow through a pulmonary embolism.

10. The device of any of claims 1-9 wherein the flow restoration portions and the capture elements comprises a self-expanding braided material, and the capture elements comprise capture portions that have a second diameter greater than the first cross-sectional dimension of the flow restoration portions in the deployed state.

11. The device of any of claims 1-3 and 6-9 wherein the flow restoration portion comprises a single expandable braided tube, and the capture elements comprise clot engagement members configured to project from the flow restoration portion in the deployed state.

12. The device of claim 11 wherein the clot engagement members comprise arcuate members that form hook-like members projecting from the flow restoration portion.

13. The device of claim 11 wherein the clot engagement members are formed from wires of the expandable braided tube that defines the flow restoration portion.

14. The device of claim 11 wherein the clot engagement members are formed from separate wires that project through interstices of the expandable braided tube that defines the flow restoration portion.

15. A pulmonary embolism treatment device, comprising:

an outer elongated member having a distal end;

an inner elongated member within the outer elongated member, wherein the inner elongated member and/or the outer elongated member slides relative to the other, and wherein the inner elongated member has a distal end; and

an expandable member having a proximal portion attached to the distal end of the outer elongated member and a distal portion attached to the distal end of the inner elongated member, the expandable member having a flow restoration portion and a plurality of capture elements arranged along the flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which the flow restoration portion have a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and the capture elements project outwardly from the flow restoration portion.

16. The pulmonary embolism treatment device of claim 15 wherein the expandable member comprises a braided material.

17. The pulmonary embolism treatment device of claim 15 wherein the device has a plurality of flow restoration portions and the capture elements are separated by individual flow restoration portions, and wherein (a) the capture elements comprise capture portions formed from a continuous shape-memory braided material heat-set to the deployed state and (b) the capture portions project from the flow restoration portions to a second cross-sectional dimension in the deployed state.

18. The pulmonary embolism treatment device of claim 17 wherein the flow restoration portions comprise cylindrical portions and the first cross-sectional dimension comprises a first diameter in the deployed state, and the capture portions comprise disk-like projections having a second diameter greater than the first diameter in the deployed state.

19. The pulmonary embolism treatment device of any of claims 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:4 to 1:8.

20. The pulmonary embolism treatment device of any of claims 11-18 wherein the flow restoration portion(s) have an expansion ratio from the undeployed state to the deployed state from 1:5 to 1:7.

21. The pulmonary embolism treatment device of any of claims 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises an inner tube within the outer tube.

22. The pulmonary embolism treatment device of any of claims 11-20 wherein the first elongated member comprises an outer tube and the second elongated member comprises a coil within the outer tube.

23. The pulmonary embolism device of any of claims 11-20 wherein the first elongated member comprises an outer coil and the second elongated member comprises an inner coil.

24. The pulmonary embolism treatment device of any of claims 11-23 wherein the flow restoration portion(s) and the capture elements comprise a self-expanding braided material.

25. The pulmonary embolism treatment device of any of claims 11-24 wherein the outer elongated member is configured to slide distally with respect to the inner

elongated member to move the expansion member from the undeployed state to the deployed state.

26. The pulmonary embolism treatment device of any of claims 11-25, further comprising a guide catheter having a shaft with a distal end and an expandable guide member at the distal end of the shaft, wherein the shaft has a lumen configured to receive the expandable member in the undeployed state.

27. The pulmonary embolism treatment device of claim 26 wherein the expandable guide member comprises radially expandable mesh.

28. The pulmonary embolism treatment device of claim 27 wherein the radially expandable mesh comprises a braided material.

29. The pulmonary embolism treatment device of any of claims 26-28 wherein the expandable guide member has a funnel shape.

30. The pulmonary embolism treatment device of any of claims 26-29 wherein at least a portion of the expandable guide member is permeable to allow blood to flow through the expandable guide member when the expandable guide member is expanded.

31. The pulmonary embolism treatment device of any of claims 26-29 wherein the expandable guide member has a non-permeable portion at the distal end of the shaft and a permeable portion extending distally from the non-permeable portion.

32. A pulmonary embolism treatment device, comprising:
an elongated member having a distal end;
an expansion portion having a proximal end attached to the distal end of the elongated member, and the expansion portion having a distal end; and
an expandable member having a proximal portion attached to the distal end of the elongated member and a distal portion attached to the distal end of the

expansion portion, the expandable member having at least one of flow restoration portion and a plurality of capture elements arranged such that the capture elements are separated by individual flow restoration portion, wherein the flow restoration portion and the capture elements are configured to move from a low-profile undeployed state sized to fit within a delivery catheter to a deployed state in which (a) the flow restoration portion has a first cross-sectional dimension greater than that of the low-profile state that defines a flow channel through the device and (b) the capture elements project outwardly from the flow restoration portion, and wherein the expansion portion is stretched from a normal state when the expandable member is in the undeployed state such that the expansion portion is configured to axially contract the expandable member from the undeployed state to the deployed state.

33. A method of treating a pulmonary embolism, comprising:

delivering an embolectomy device through the heart to a pulmonary embolism that at least partially restricts blood flow through a pulmonary vessel, wherein the embolectomy device has a plurality of capture elements separated by an expandable cylindrical section;

deploying the embolectomy device within the pulmonary embolism by expanding the cylindrical section into the pulmonary embolism so that the cylindrical section forms an expanded flow channel through the pulmonary embolism and thereby restores blood flow through the pulmonary embolism and by expanding the capture elements to a greater extent than the cylindrical section so that at least a portion of the pulmonary embolism is captured the capture elements;

moving the embolectomy device and at least a portion of the pulmonary embolism along the pulmonary vessel; and

withdrawing the embolectomy device and at least a portion of the pulmonary embolism from the pulmonary vessel.

34. The method of claim 33 wherein deploying the embolectomy device comprises expanding a plurality of radial extendable capture elements of the embolectomy device.

35. The method of claim 34, wherein at least one of the plurality of radial extendable capture elements is expanded distal relative to the pulmonary embolism.

36. The method of claim 33, further comprising applying vacuum while withdrawing the embolectomy device.

37. The method of claim 36, wherein withdrawing the embolectomy device includes urging the portion of the pulmonary embolism into a funnel catheter.

38. The method of claim 37, wherein deploying the embolectomy device comprises expanding the device such that a surface area of the embolectomy device expands within a range of at least 200% to 400% of the surface area of a uniformly cylindrical device.

39. The method of claim 33 wherein deploying the embolectomy device comprises expanding the generally cylindrical section by 400% to 800% of its diameter in the undeployed state.

40. The method according to and of claims 33-39 wherein deploying the embolectomy device comprises expanding a braided material into a preset shape having a plurality of radially extending disk-like capture portions that define the capture elements.

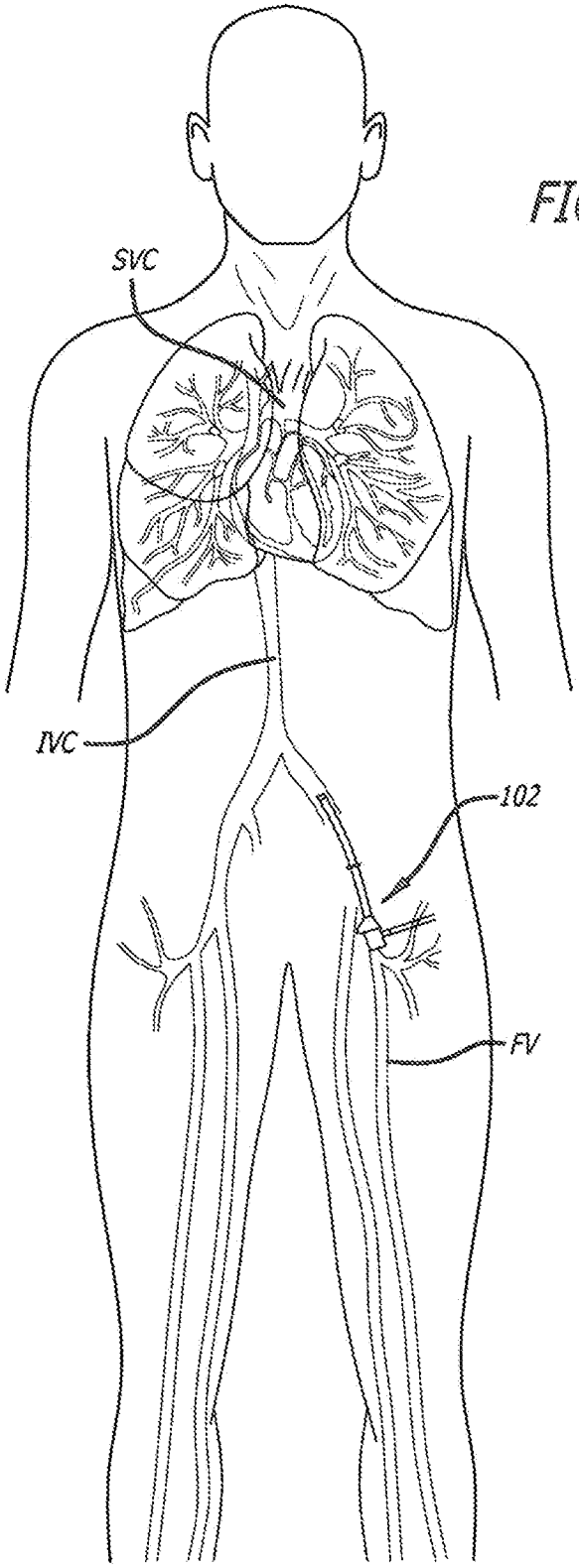


FIG. 1A

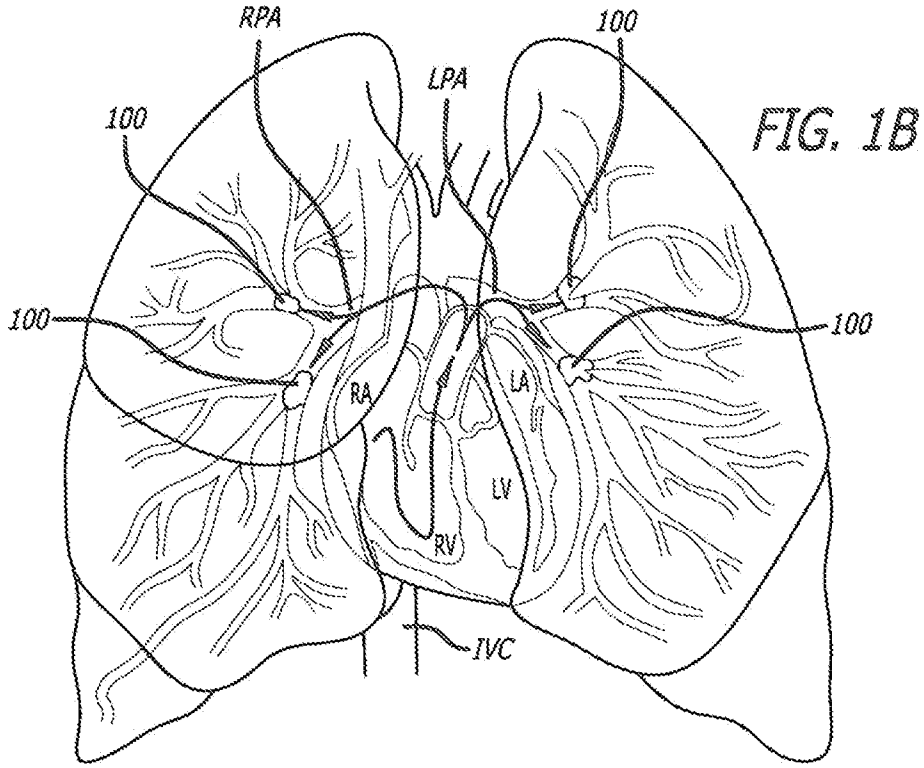


FIG. 1B

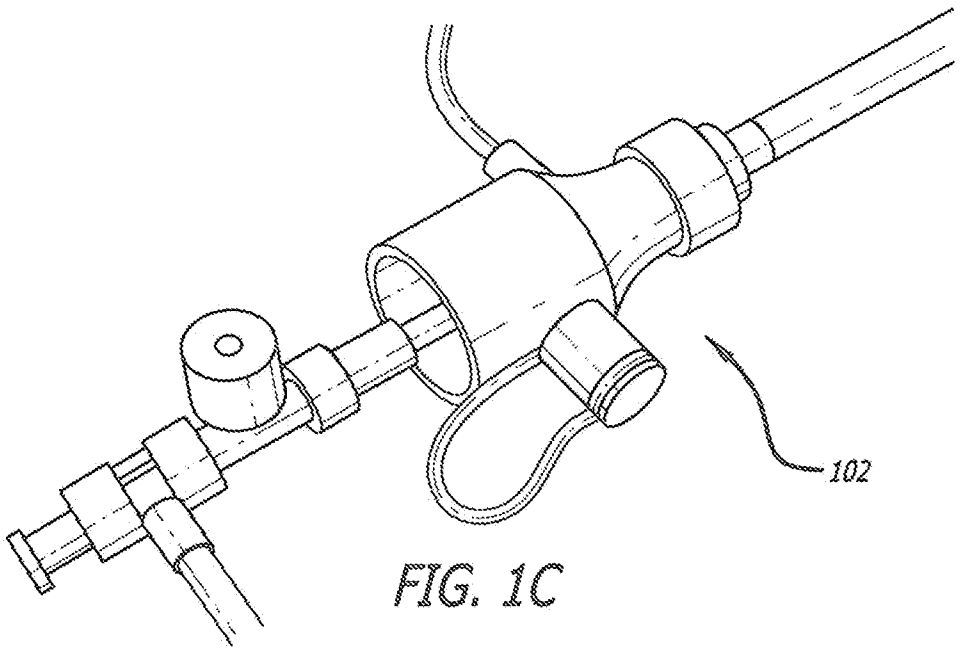


FIG. 1C

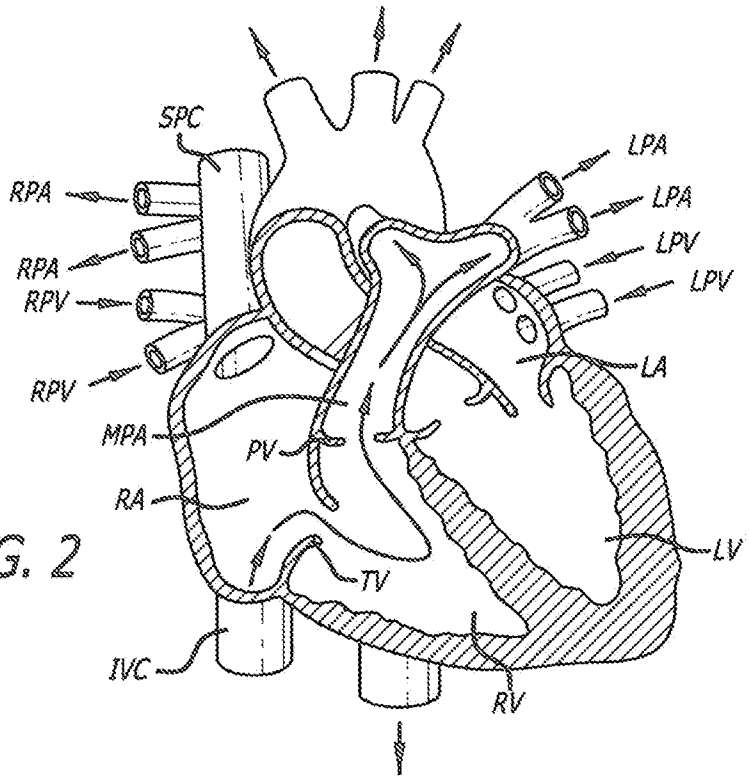

SPC
RPA
RPA
RPV
RPV
MPA
RA
IVC
PV
TV
LPA
LPA
LPV
LPV
LA
LV
RV

FIG. 2

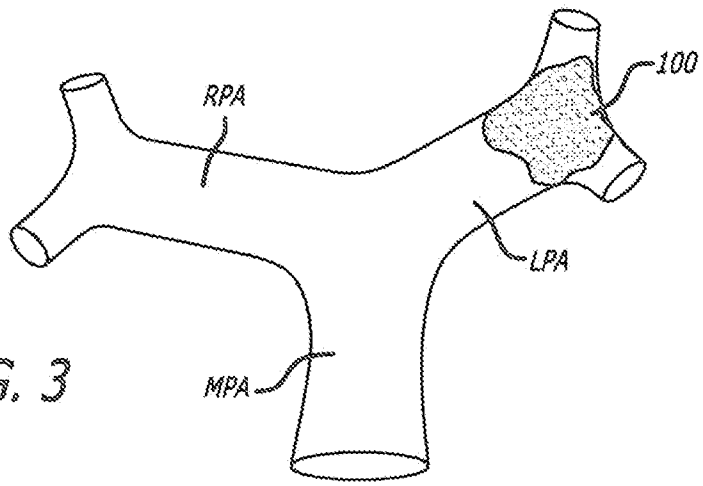

100
RPA
LPA
MPA

FIG. 3

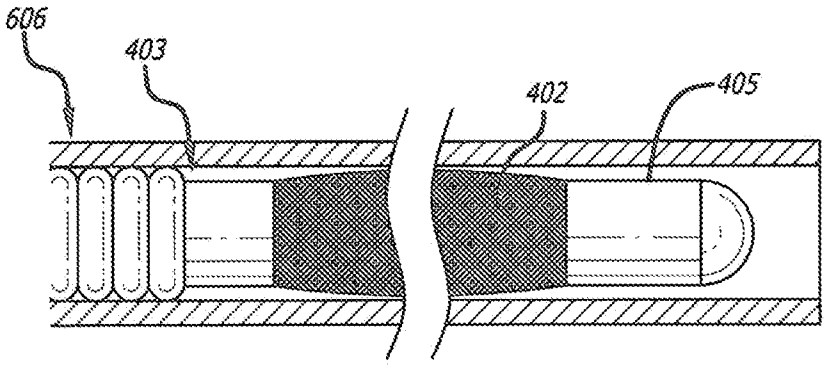


FIG. 4

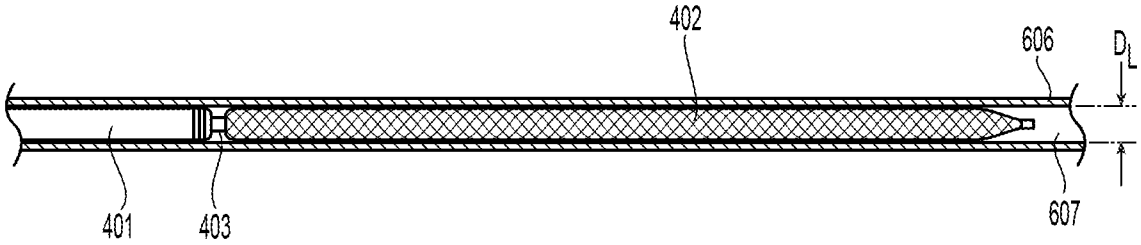
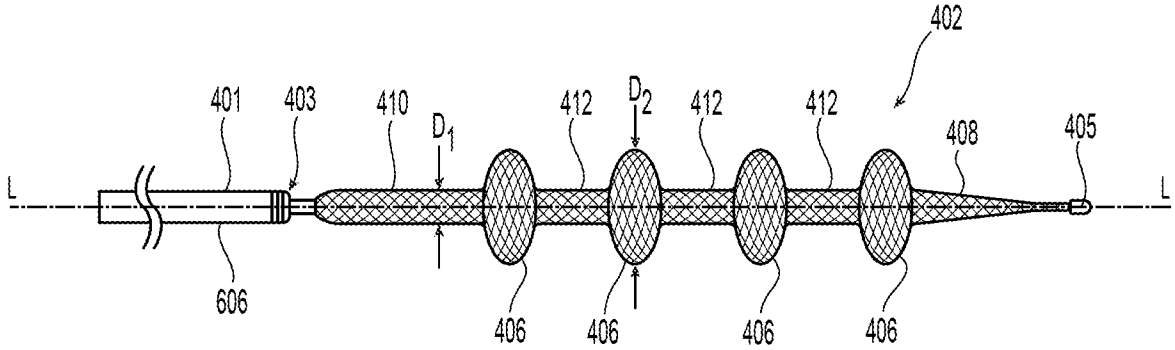

402
606
D_L
401
403
607

Fig. 5A


402
401
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D_1
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D_2
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408
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L
L
606
406
406
406
406

Fig. 5B

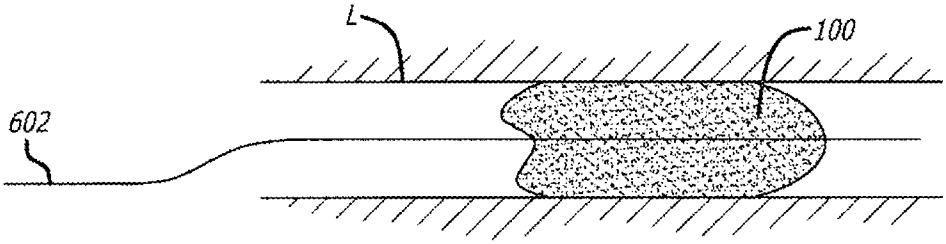

FIG. 6A

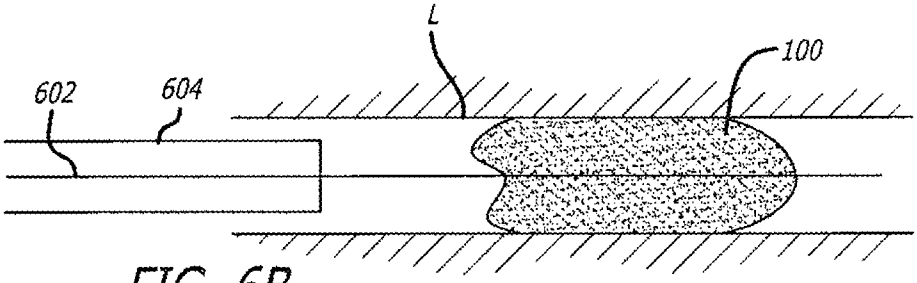

FIG. 6B

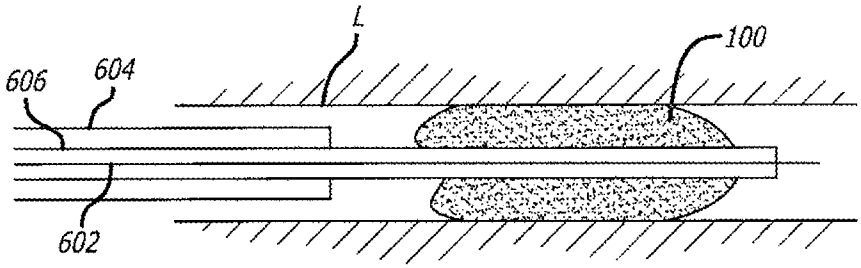

FIG. 6C

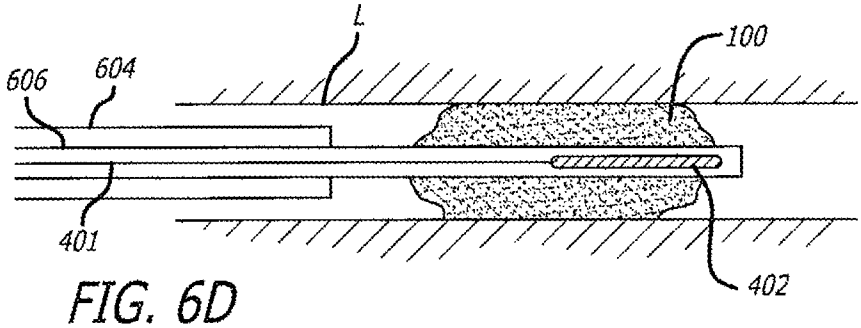

FIG. 6D

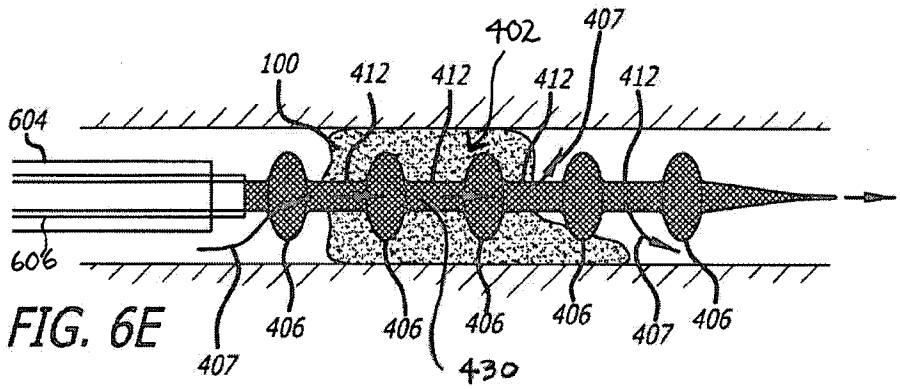

FIG. 6E

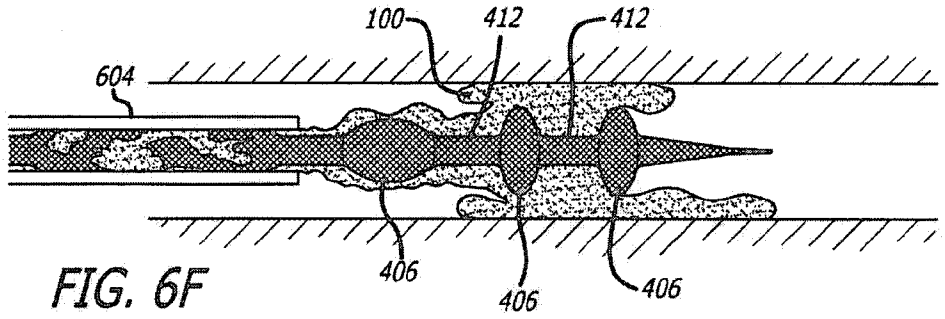

FIG. 6F

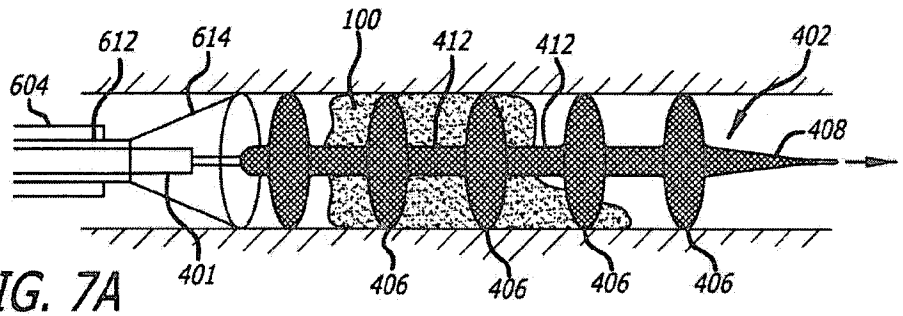

FIG. 7A

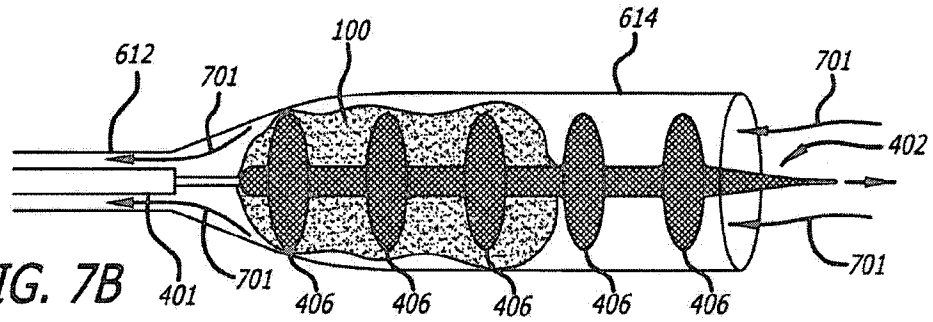

FIG. 7B

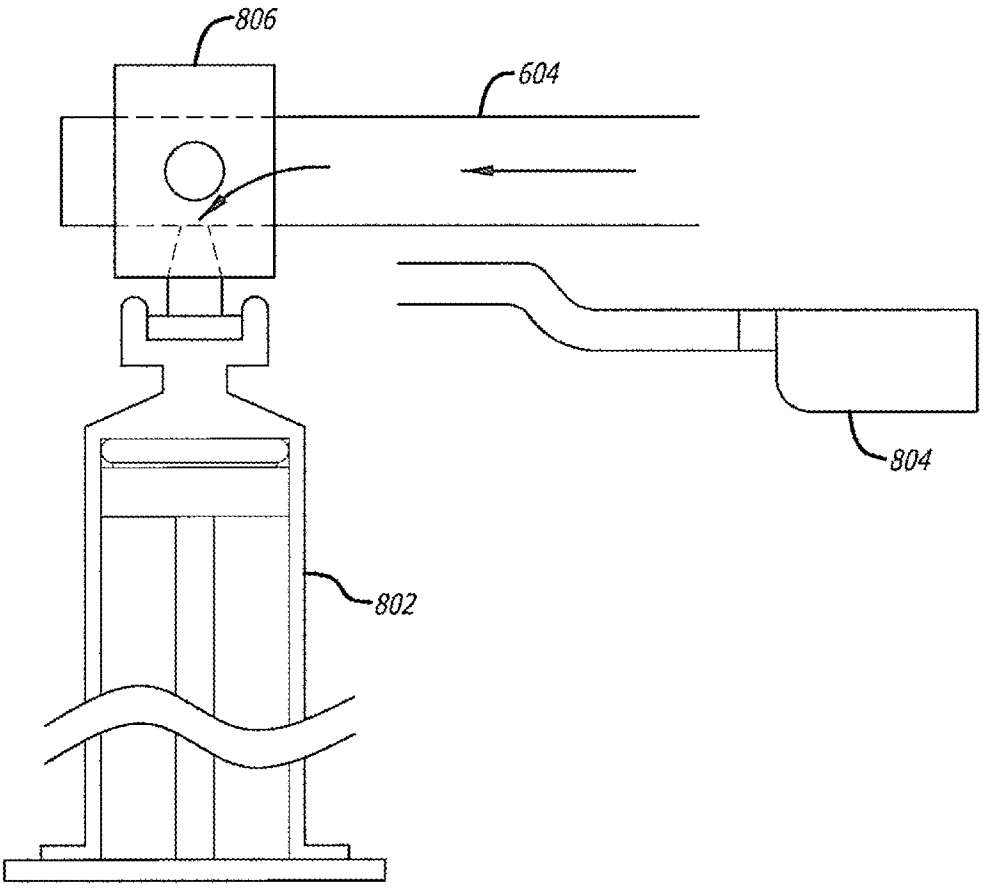

FIG. 8

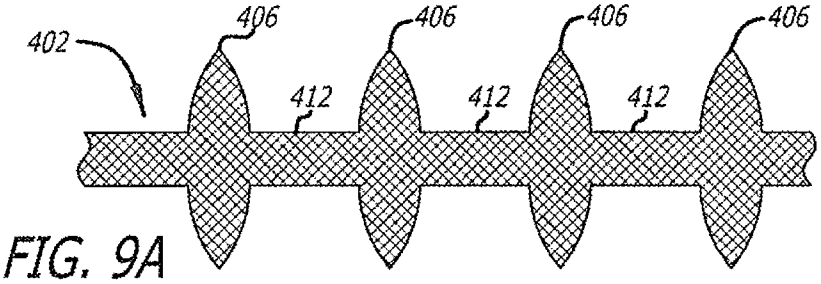

FIG. 9A

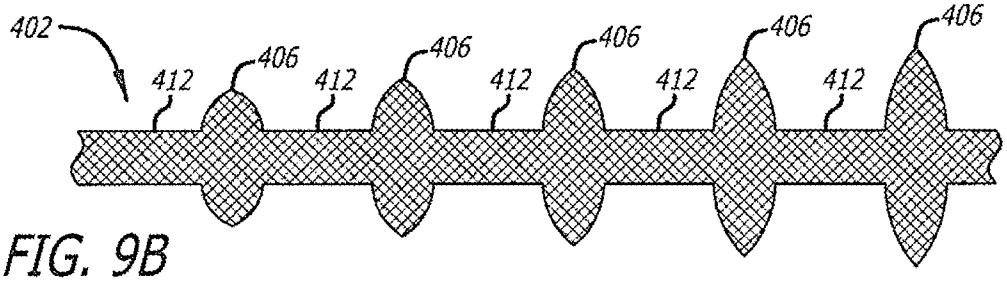

FIG. 9B

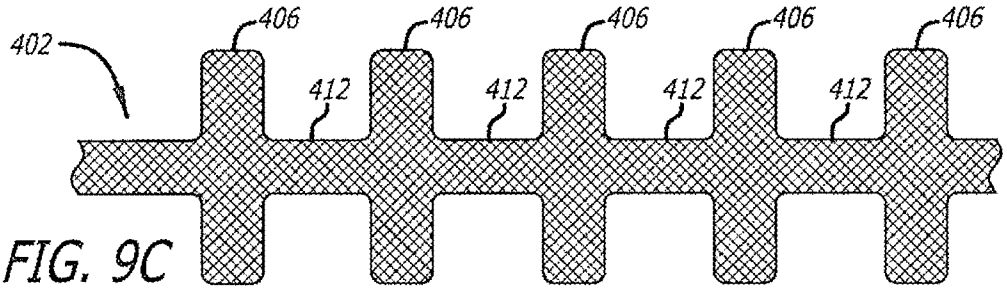

FIG. 9C

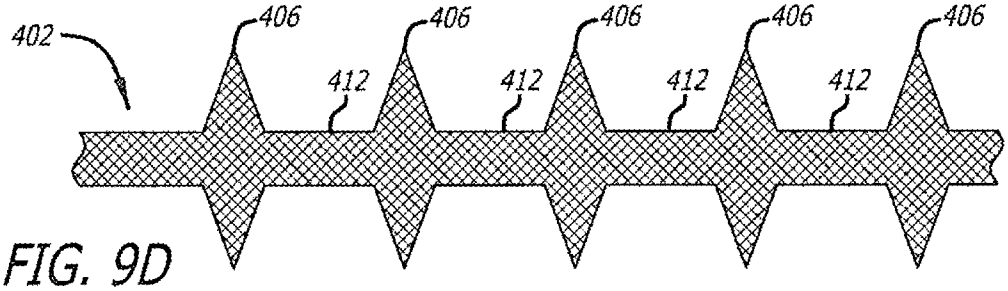

FIG. 9D

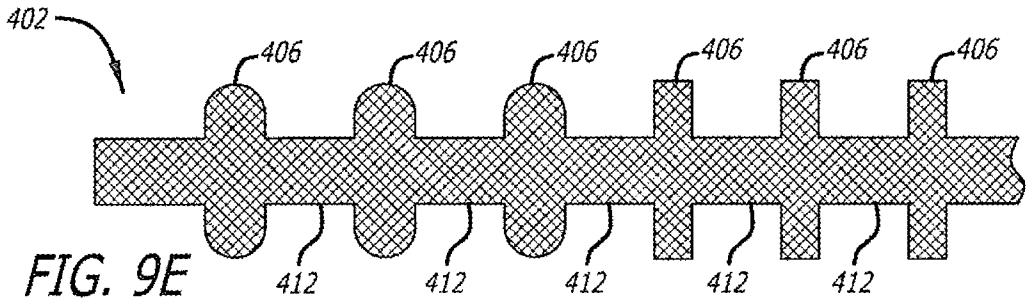

FIG. 9E

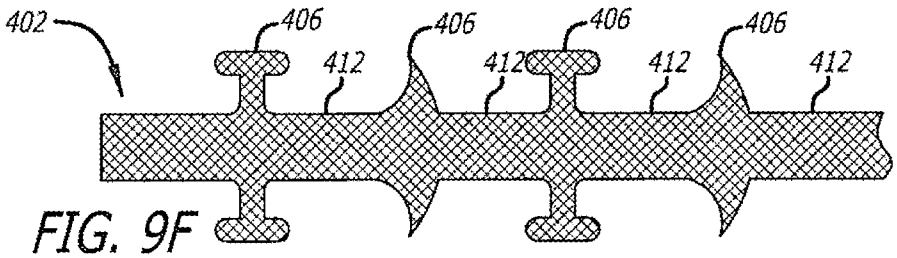

FIG. 9F

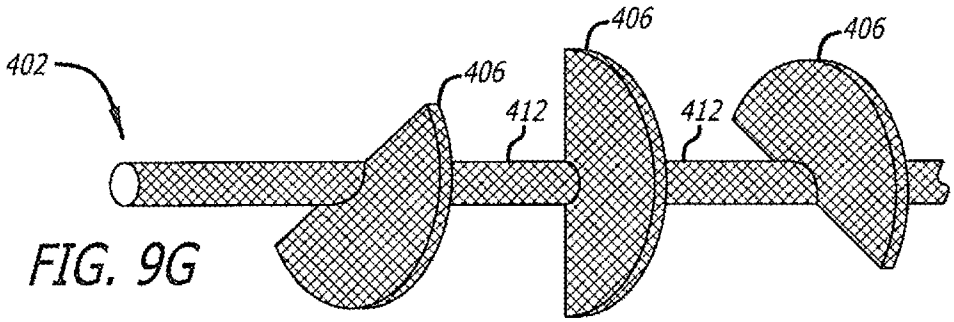

FIG. 9G

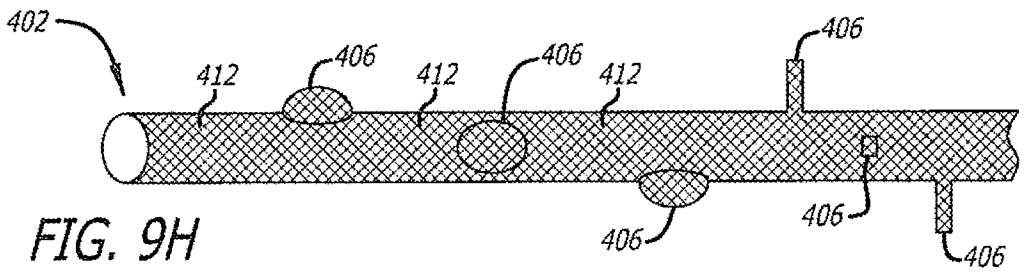

FIG. 9H

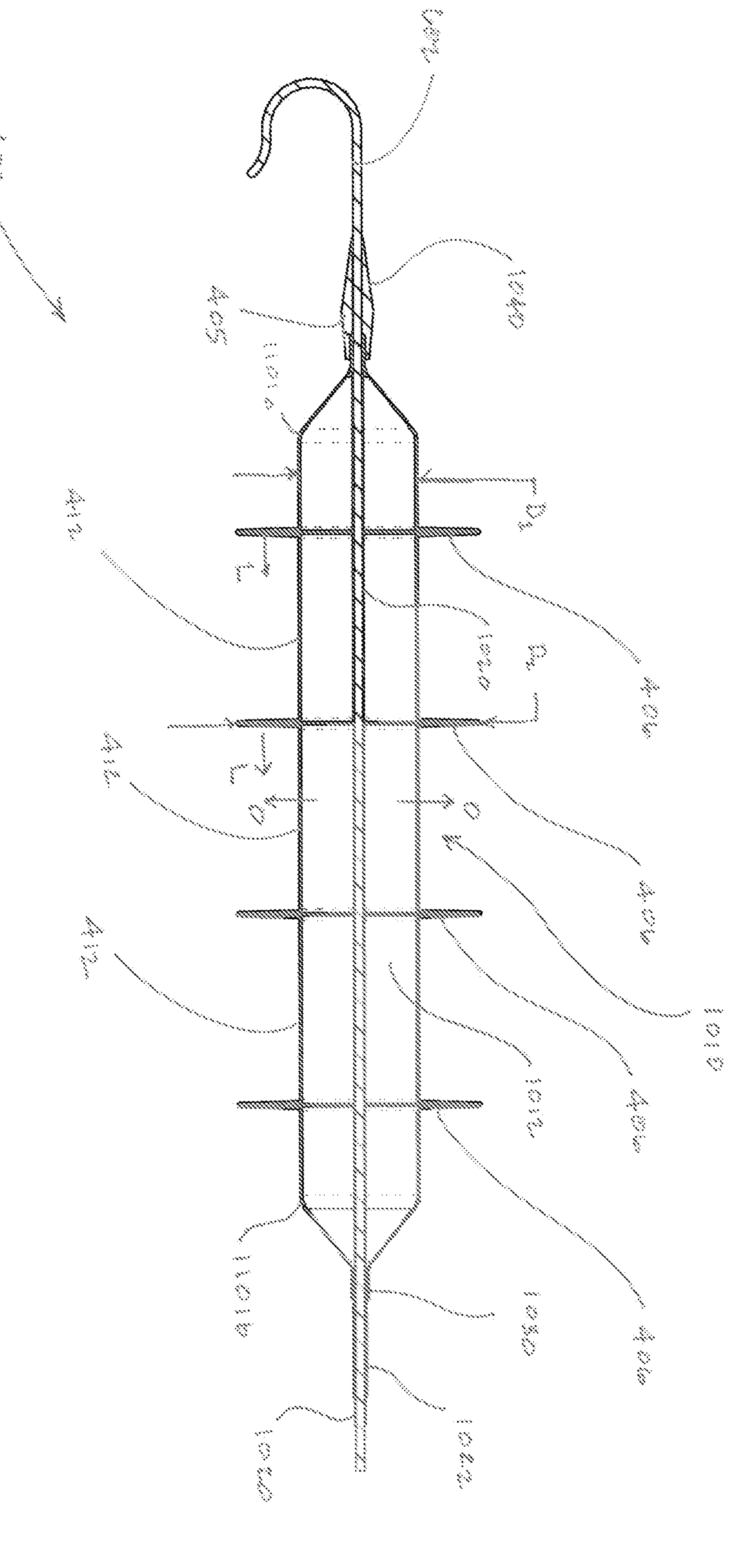

Fig. 10

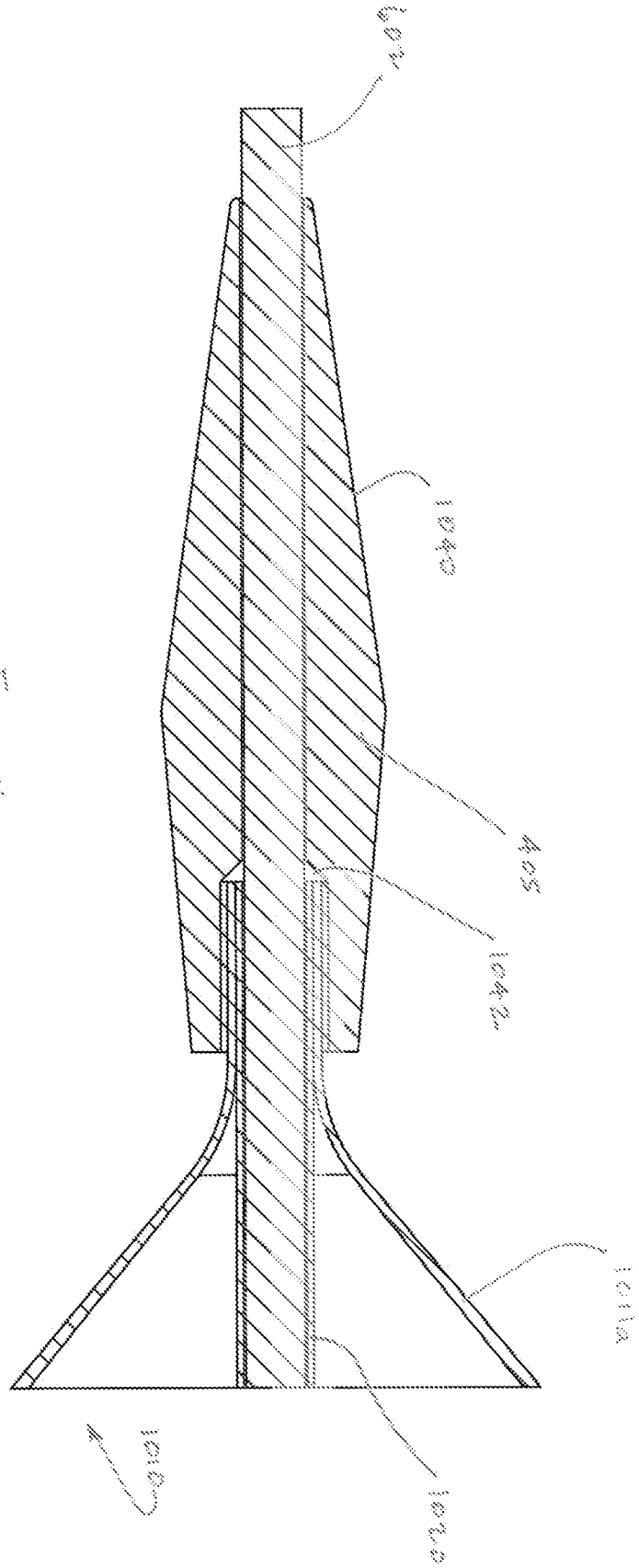

Fig. 11

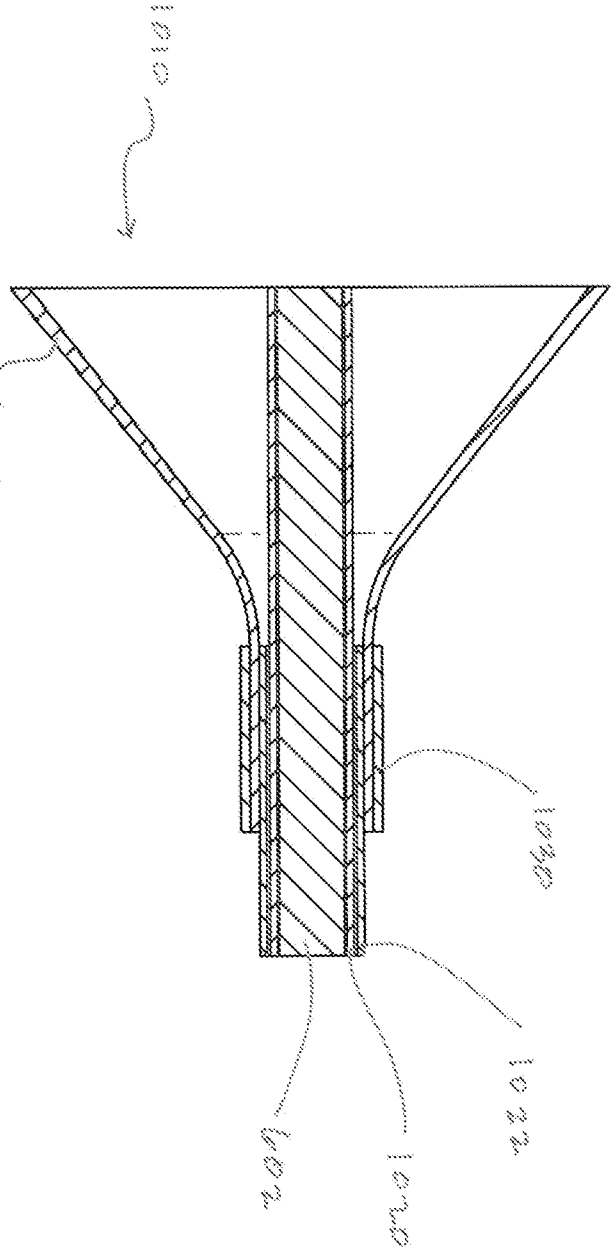

Fig. 12

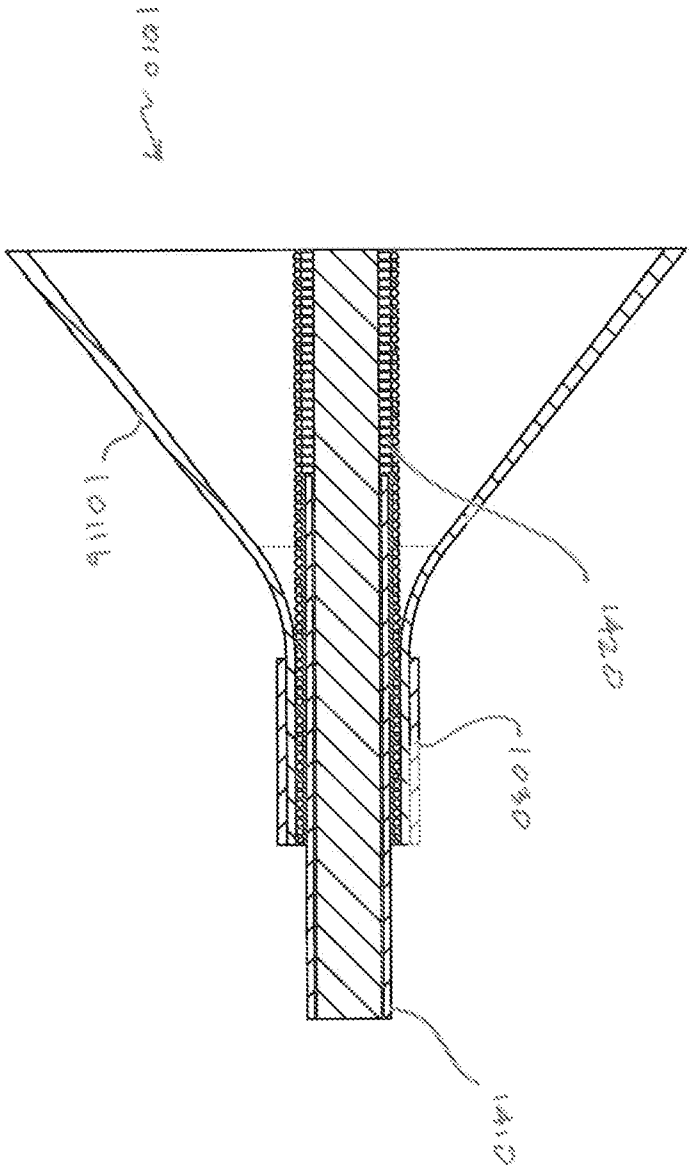

Fig. 16

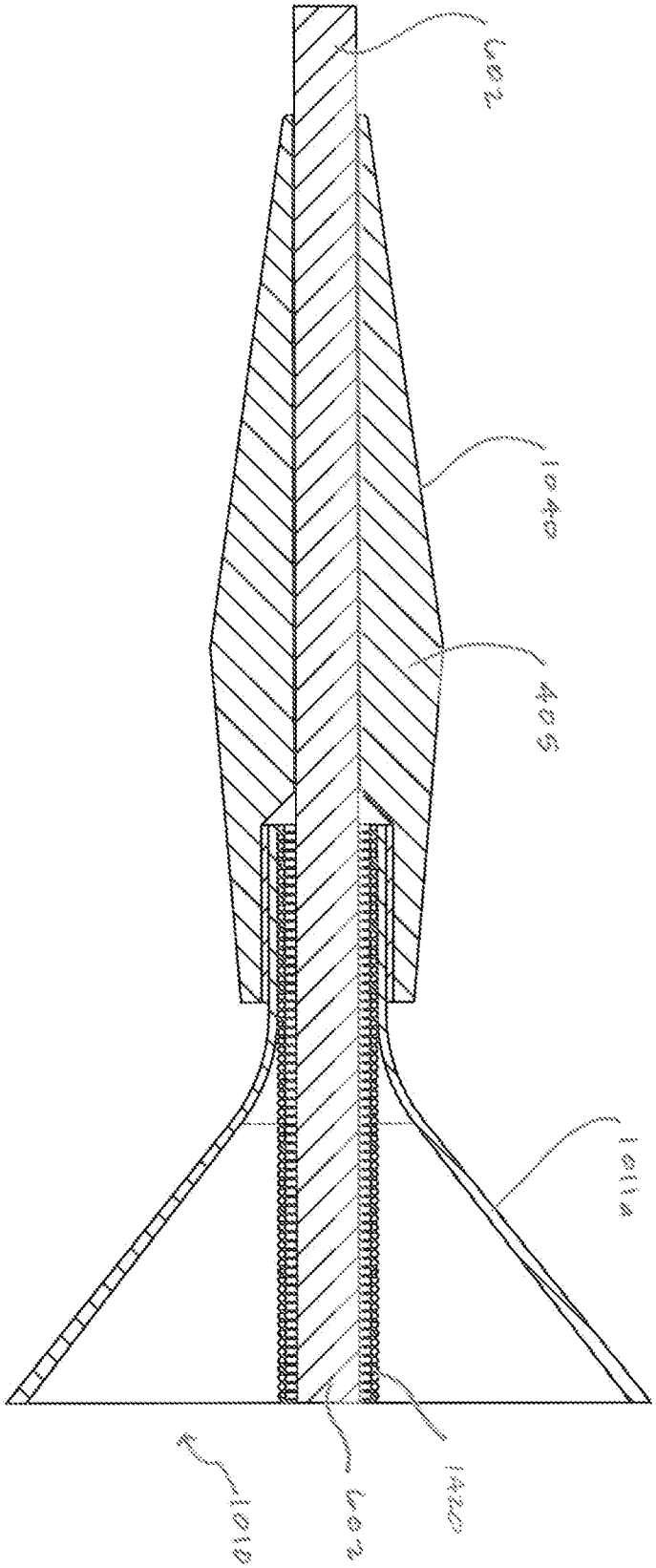

Fig. 14

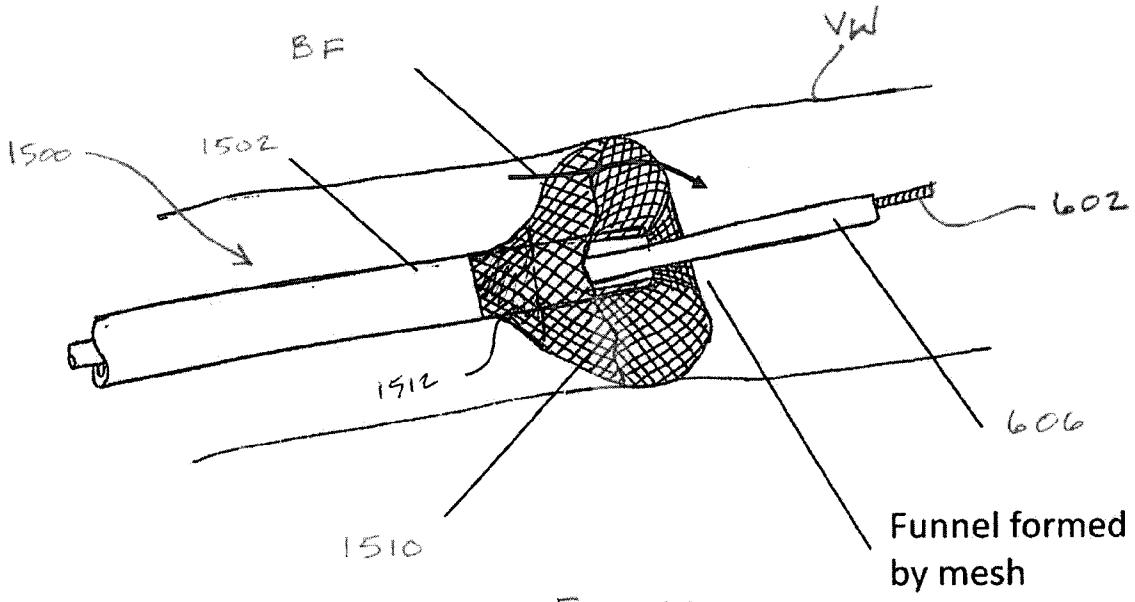

Fig. 15

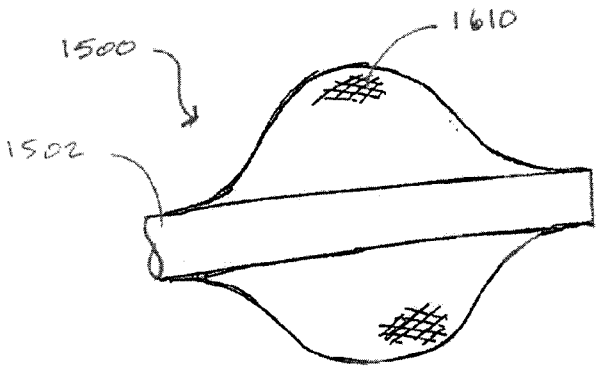

Fig. 16

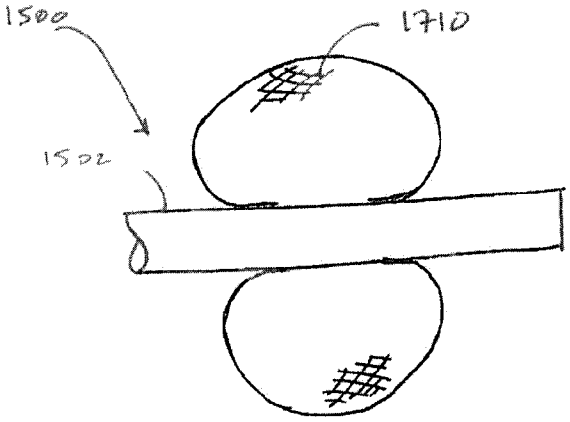

Fig. 17

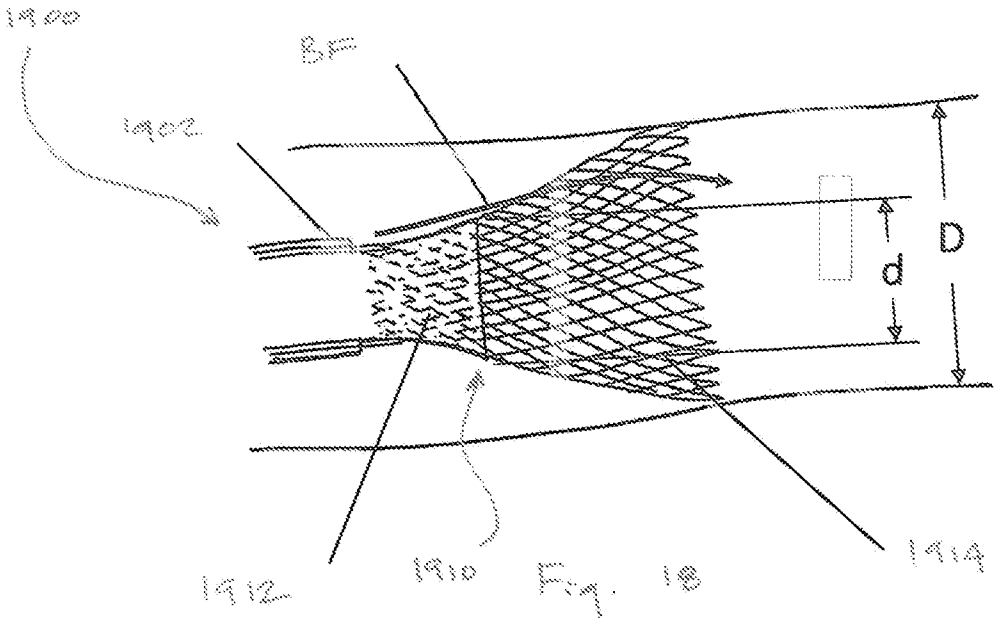

Fig. 18

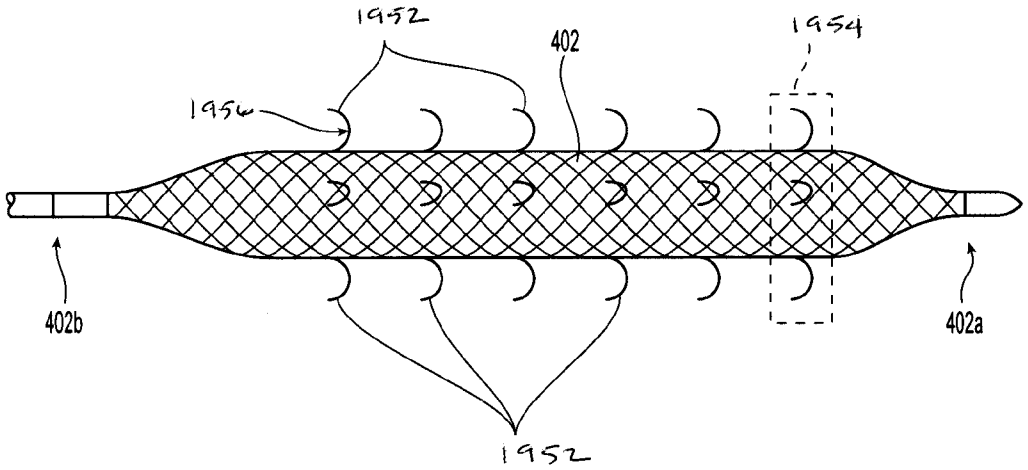

Fig. 19

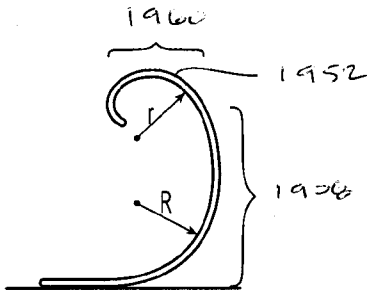

Fig. 20

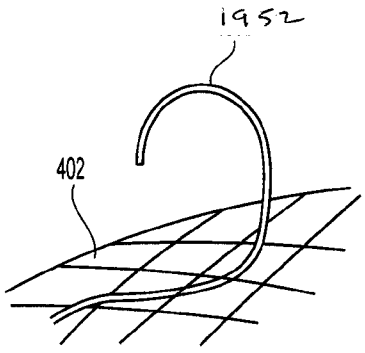

Fig. 21

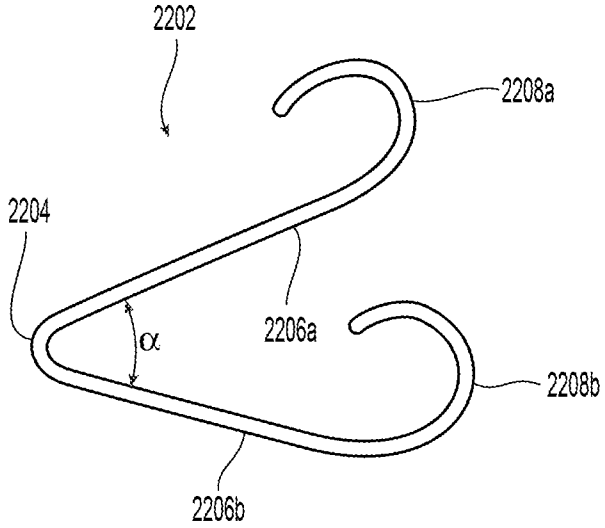

Fig. 22

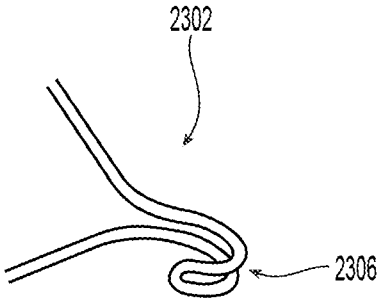

Fig. 23

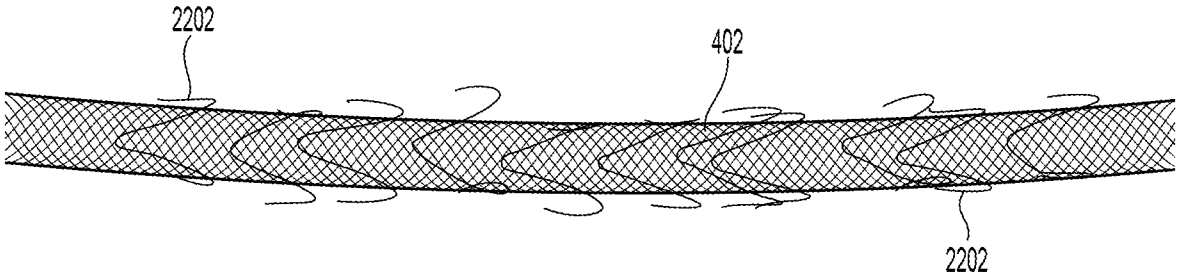

Fig. 24

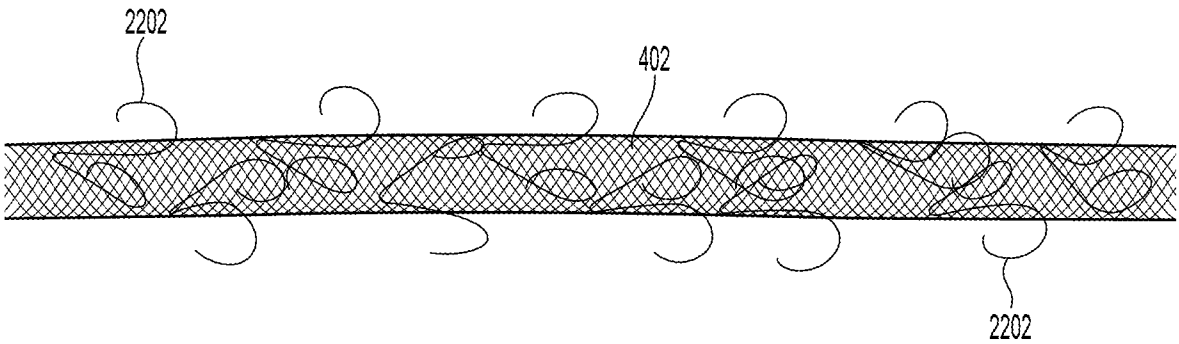

Fig. 25

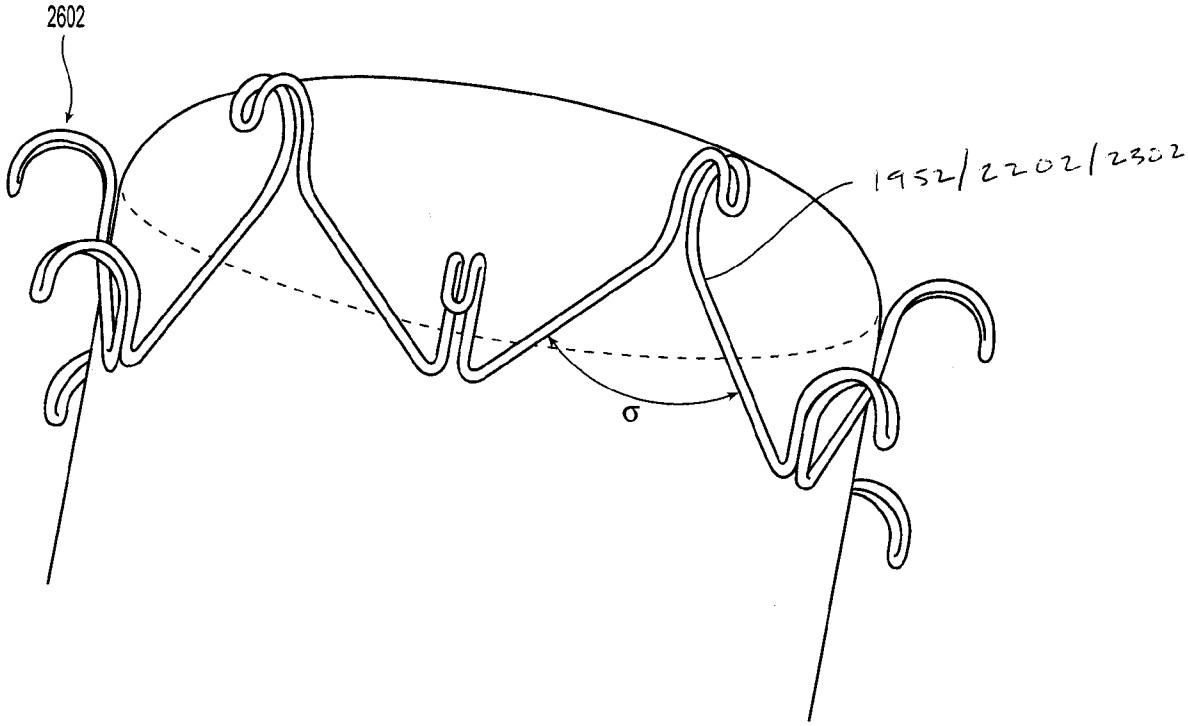

Fig. 26

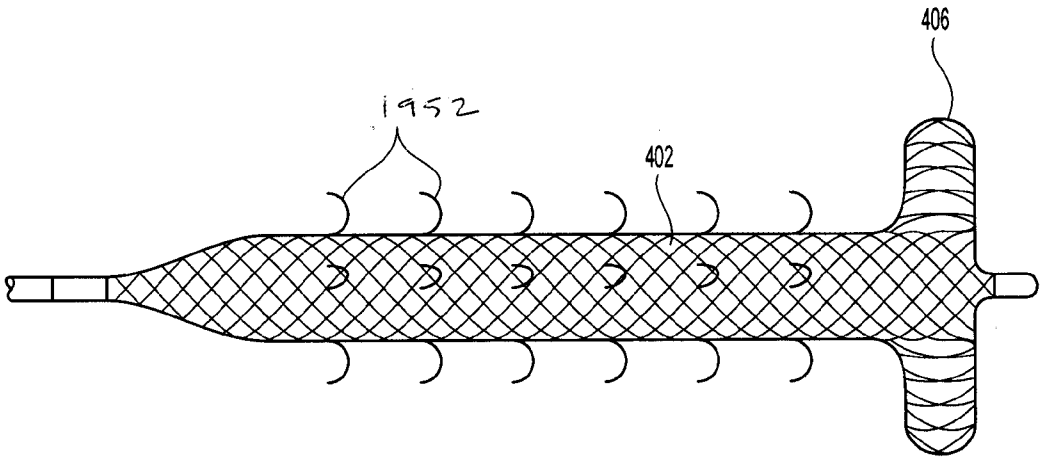

Fig. 27

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071101

A. CLASSIFICATION OF SUBJECT MATTER

A61M 25/01(2006.01)i, A61M 25/08(2006.01)i, A61M 25/09(2006.01)i

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)
A61M 25/01; A61M 29/00; A61M 25/08; A61M 25/09

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: embolism, pulmonary, expand, stent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2011-0213403 A1 (ABOYTES, M.) 1 September 2011 See abstract; figs. 4A, 4B, and 7; paragraphs [0084]-[0089] and [0099]-[0101]; claims 1, 7, and 11.	1-3,6,15-18
Y		32
Y	US 6645222 B1 (PARODI, J. C. et al.) 11 November 2003 See abstract; fig. 6A; claim 1.	32
A	US 2008-0167678 A1 (MORSI, H.) 10 July 2008 See abstract; fig. 3; claims 1 and 2.	1-3,6,15-18,32
A	US 6254571 B1 (HART, C. C.) 3 July 2001 See abstract; figs. 1A and 1B; claims 1 and 2.	1-3,6,15-18,32
A	US 2006-0282111 A1 (MORSI, H.) 14 December 2006 See abstract; fig. 3; claim 1.	1-3,6,15-18,32

☐ Further documents are listed in the continuation of Box C.

☒ 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 application or patent 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
28 March 2014 (28.03.2014)	**31 March 2014 (31.03.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
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Facsimile No. +82-42-472-7140

Authorized officer
CHOI, Sung Hee
Telephone No. +82-42-481-8740

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/071101

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. ☒ Claims Nos.: 33-40
because they relate to subject matter not required to be searched by this Authority, namely:
Claims 33-40 pertain to methods for treatment of the human body by surgery and thus relate to a subject-matter which this International Searching Authority is not required, under Article 17(2)(a)(i) of the PCT and Rule 39.1(iv) of the Regulations under the PCT, to search.

2. ☒ Claims Nos.: 5, 12-14, 27, 28
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:
Claims 5, 12-14, 27 and 28 are unclear, since they either directly or indirectly refer to one of claims which are not drafted in accordance with PCT Rule 6.4(a) (PCT Article 6).

3. ☒ Claims Nos.: 4, 7-11, 19-26, 29-31
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 addtional 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 any 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

Information on patent family members

International application No.
PCT/US2013/071101

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2011-0213403 A1	01/09/2011	None	
US 6645222 B1	11/11/2003	EP 1061846 A2	27/12/2000
		EP 1061846 B1	03/03/2010
		EP 1210142 A2	05/06/2002
		EP 1210142 B1	19/01/2011
		EP 1416993 A2	12/05/2004
		EP 1427460 A2	16/06/2004
		EP 1427460 B1	31/08/2011
		EP 1545685 A1	29/06/2005
		EP 1545685 B1	17/11/2010
		EP 2236170 A2	06/10/2010
		EP 2236170 A3	29/06/2011
		EP 2236170 B1	27/03/2013
		EP 2311519 A1	20/04/2011
		EP 2335770 A1	22/06/2011
		US 2001-0044598 A1	22/11/2001
		US 2002-0022859 A1	21/02/2002
		US 2002-0087119 A1	04/07/2002
		US 2002-0107479 A1	08/08/2002
		US 2002-0151922 A1	17/10/2002
		US 2002-0173815 A1	21/11/2002
		US 2003-0023204 A1	30/01/2003
		US 2005-0131453 A1	16/06/2005
		US 2005-0228432 A1	13/10/2005
		US 2006-0041228 A1	23/02/2006
		US 2010-0204724 A1	12/08/2010
		US 2011-0160762 A1	30/06/2011
		US 6206868 B1	27/03/2001
		US 6413235 B1	02/07/2002
		US 6423032 B2	23/07/2002
		US 6540712 B1	01/04/2003
		US 6582396 B1	24/06/2003
		US 6632236 B2	14/10/2003
		US 6682505 B2	27/01/2004
		US 6905490 B2	14/06/2005
		US 6908474 B2	21/06/2005
		US 6936060 B2	30/08/2005
		US 6960222 B2	01/11/2005
		US 7927347 B2	19/04/2011
		WO 2004-002564 A1	08/01/2004
US 2008-0167678 A1	10/07/2008	US 7914549 B2	29/03/2011
		WO 2008-086180 A1	17/07/2008
US 6254571 B1	03/07/2001	WO 97-38631 A1	23/10/1997
US 2006-0282111 A1	14/12/2006	WO 2006-135823 A2	21/12/2006
		WO 2006-135823 A3	27/12/2007