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(72) Inventor; and

(71) Applicant: **HOROWITZ, Michael, Bruce** [US/US]; 5305 Westminister Place, Pittsburgh, Pennsylvania 15232 (US).(74) Agent: **AMBROZIAK, Jeffrey, R.** et al.; GTC Law Group PC & Affiliates, One University Avenue, Suite 302B, Westwood, MA 02090 (US).(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

(54) Title: CATHETER BASED RETRIEVAL DEVICE WITH PROXIMAL BODY HAVING AXIAL FREEDOM OF MOVEMENT

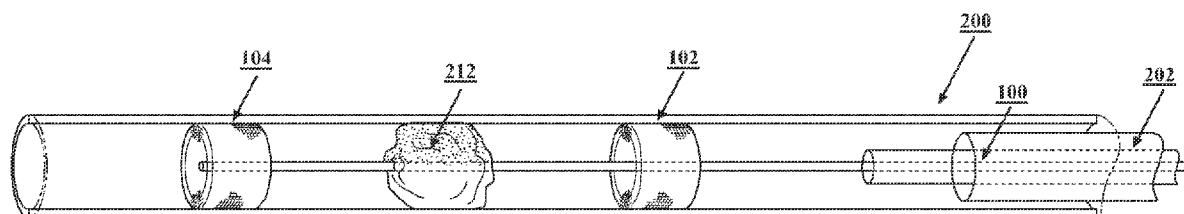


FIG. 3

(57) Abstract: Provided herein are methods and systems for the removal of anatomical occlusions, and an occlusion removal device comprising a first body adapted to be mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire, and a second body adapted to be mounted to the delivery wire. A first proximal body may be oriented proximally to a second distal body. The proximal body and the distal body may be adapted to expand upon exiting a delivery catheter. The proximal body may be releasably engaged by a mechanically breakable connection or an electrolytically or heat disconnectable connection, the electrolytically disconnectable connection being broken upon an application of electric current to the electrolytically disconnectable connection.



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CATHETER BASED RETRIEVAL DEVICE WITH PROXIMAL BODY HAVING AXIAL FREEDOM OF MOVEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of and is a continuation of the following U.S. Utility Applications: U.S. Utility Application No. 15/953,151 filed April 13, 2018 (HORW-0004-U01); U.S. Utility Application No. 15/953,173 filed April 13, 2018 (HORW-0004-U02); and U.S. Utility Application No. 15/953,186 filed April 13, 2018 (HORW-0004-U03) each of which is hereby incorporated by reference in its entirety.

[0002] This application claims the benefit of the following United States Provisional Applications, each of which is hereby incorporated by reference in its entirety:

[0003] U.S. Provisional Application Serial No. 62/573,006 filed October 16, 2017 (HORW-0001-P01); U.S. Provisional Application Serial No. 62/606,993 filed October 16, 2017 (HORW-0002-P01); U.S. Provisional Application Serial No. 62/589,613 filed November 22, 2017 (HORW-0003-P01); and U.S. Provisional Application Serial No. 62/653,247 filed April 5, 2018 (HORW-0003-P02).

FIELD OF THE INVENTION

[0004] The disclosure generally relates to methods and systems for the catheter-based removal of occlusions and unwanted matter from vessels, ducts and other cavities or lumens of an organism.

BACKGROUND OF THE INVENTION

[0005] Current medical devices that are used for the removal of occlusions, such as thrombi from the vessels (such as those in the brain), have limitations that reduce their effectiveness, reliability, and ease of use. For example, current devices are designed exclusively for the vascular system, and may not be used for extraction of material from ducts, ureters, urethra, or other anatomical features. Current devices are not appropriate for use in large vascular structures such as aorta, vena cava and many peripheral vascular applications, and often do not work well with calcified, organized material due to inability of the wire structures often used to compress into the embolic material prior to an attempted extraction. Current devices often have a wire structure that must incorporate into a thrombus to remove a clot and provide poor distal protection from secondary emboli during thrombus extraction due to open ended stent retriever or partial grasping of thrombus. This may result in an intended thrombectomy procedure causing distal clot embolization and occlusion of previously patent arterial branches

and collaterals. Current devices may be less effective when used with associated arterial stenoses due to device collapse and tendency for a stenosis to strip and debride thrombus from device as it is retracted through the stenotic vessel segment. Current devices often require operators to choose a predetermined device length at time of device insertion, but the chosen device length might not match the size of the target thrombus once the operator is in the vessel and provided a closer view of the target thrombus.

[0006] Current catheter-based methods and systems for the removal of foreign bodies from an artery, duct, ureter or other interior physical space, often require multiple co-axial (or concentric) sleeves or delivery catheters, some of which are intended for placement on the proximal side of an occlusion, some for direction through the occlusion for placement on the distal side of the occlusion, and still others for holding inflatable balloons, thrombus removal devices and the like. The presence of multiple catheters increases manufacturing complexity and cost, in addition to increasing complexity of usage during an intervention, with greater moving parts and the required ordering of operation aligned with the function of the multiple catheters. Current catheter-based methods and systems are also manufactured and deployed in the clinical setting with a specific catheter, meaning that if during an intervention a clinician wants to deploy (“load”), for example, a retrieval device having a different size than that first deployed in a vessel, the entire catheter-based tool must be withdrawn and a new catheter-based device with the preferred diameter loaded inserted. Additional limitations of the current catheter-based systems include, but are not limited to, a reliance on fixed-diameter instrumentation and/or inflatable bodies (e.g., balloons) for encapsulation of a foreign body or occlusion. As an example, catheters using an inflatable balloon for a distal body and/or proximal body may require that an interventionist pre-select a balloon model and size prior to entering a vessel or cavity because inflatable balloons have a manufactured minimum and maximum inflation diameter. Thus, if the incorrect balloon size is selected, or the clinical setting requires flexibility in the expansion or contraction diameter of the distal or proximal bodies, the intervention may be interrupted to allow for size adaptation of equipment. Incorrect sizing may also increase the likelihood for negative clinical sequelae, such as embolization and release of occlusive matter if, for example, distal protection is lost.

[0007] Therefore, there is a need for methods and systems of thrombus, or other matter, removal in which an object targeted for removal may be dynamically surrounded by a retrieval device, rather than incorporated into the target object, wherein the retrieval device can surround the target and may be physically adjusted to match the size of the target object while within the vessel or other cavity.

SUMMARY

[0008] Provided herein are occlusion removal devices, and methods and systems of capturing and removing occlusions, thrombi, biological matter and foreign objects from anatomical systems, including the vascular system, ducts, ureters, urethra, or other anatomical features.

[0009] Embodiments of the present disclosure include an occlusion removal device comprising a first body adapted to be mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire, and a second body adapted to be mounted to the delivery wire. A first proximal body may be oriented proximally to a second distal body. The proximal body and the distal body may be adapted to expand upon exiting a delivery catheter. The proximal body may be releasably engaged by a mechanically breakable connection or an electrolytically or heat disconnectable connection, the electrolytically disconnectable connection being broken upon an application of electric current to the electrolytically disconnectable connection. The proximal and distal bodies may be mesh, and may be made of nitinol.

[0010] Embodiments of the present disclosure include a method of removing an occlusion comprising inserting a guide catheter into a body lumen of a patient, and advancing a delivery catheter through the guide catheter, the delivery catheter having a delivery wire therein, the delivery wire having a proximal body and a distal body mounted to the delivery wire, the proximal body releasably engaged to the delivery wire. The delivery catheter may be advanced through the occlusion, and the distal body expanded at a point distal to the occlusion, and the proximal body expanded at a point proximal to the occlusion. The proximal body may be moved in a direction along the delivery wire such that the proximal body and the distal body surround the occlusion, and the proximal body, distal body, delivery wire, delivery catheter, and guide catheter retracted from the patient to remove the occlusion.

[0011] Embodiments of the present disclosure include a method to retrieve an occlusion in a lumen of a patient comprising inserting a delivery wire, sheathed by a delivery catheter, through the occlusion, and withdrawing the delivery catheter from a distal end of the delivery wire, wherein the withdrawal leaves the delivery wire protruding through the occlusion and expands a first body distal to the occlusion. A second body may be expanded that is attached to the delivery wire on a proximal side of the occlusion. The delivery wire may be withdrawn such that the first body is in contact with the distal side of the occlusion, and the second body may be advanced distally by advancing the delivery catheter distally until the second body

contacts the proximal side of the occlusion. The occlusion may be removed from the lumen by withdrawing the first body and the second body, the delivery wire and the delivery catheter from the lumen.

[0012] Embodiments of the present disclosure include an occlusion removal system comprising a. a delivery wire comprising (i) a proximal end having an opening, (ii) a distal end, (iii) an outer surface, (iv) a lengthwise cavity, and (v) a first opening to the lengthwise cavity, the opening being in the outer surface of the delivery wire. A first tether having a proximal end and a distal end that may traverse the lengthwise cavity, the proximal end of the first tether having a length outside of the opening in the proximal end of the delivery wire and the distal end of the first tether having a length outside the opening in the outer surface of the delivery wire. A first body may be attached to the distal end of the first tether, the first body adapted to be slidably mounted to the delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire. In embodiments, a second tether may have a proximal end and a distal end and traversing the lengthwise cavity, the proximal end of the second tether having a length outside of the opening in the proximal end of the delivery wire and the distal end of the second tether having a length outside the second opening in the outer surface of the delivery wire.

[0013] Embodiments of the present disclosure include an occlusion removal system comprising a (i) delivery catheter (ii) a delivery wire at least partially within the delivery catheter, (iii) a tether having a proximal end and a distal end, the proximal end of the tether having a length outside of the delivery catheter, and (iv) a first body attached to the distal end of the tether, the first body slidably mounted to the delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire.

[0014] Embodiments of the present disclosure include an occlusion removal system comprising inserting a guide catheter into a body lumen of a patient, and advancing an access catheter through the guide catheter, advancing a delivery catheter through the access catheter, the delivery catheter having a delivery wire therein, the delivery wire having a first body mounted thereto in a fixed position at a distal end of the delivery wire. The delivery catheter may be advanced through the occlusion, expanding the first body distal to the occlusion. A second body may be loaded onto the delivery wire. The second body may be advanced over the delivery wire to the occlusion, and the delivery wire, delivery catheter, access catheter, and guide catheter may be retracted from the patient.

[0015] Embodiments of the present disclosure include an occlusion removal system comprising a first body mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire. A second body may be mounted to the delivery wire, and an incorporation structure may be placed between the first body and the second body.

[0016] These and other systems, methods, objects, features, and advantages of the present disclosure will be apparent to those skilled in the art from the following detailed description of the preferred embodiment and the drawings. All documents mentioned herein are hereby incorporated in their entirety by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] The disclosure and the following detailed description of certain embodiments thereof may be understood by reference to the following figures:

[0018] Figures 1-5 illustrate deployment stages of an embodiment of the retrieval device, with Figure 1 showing the proximal and distal bodies deployed on a delivery wire.

[0019] Figure 2 illustrates the pre-deployment stage of the proximal and distal bodies, where the proximal and distal bodies are restrained or unexpanded.

[0020] Figure 3 illustrates the expanded or released position of the proximal and distal bodies from the delivery catheter.

[0021] Figure 4 illustrates advancing the proximal body of the retrieval device axially along the delivery wire to trap and compress a thrombus.

[0022] Figure 5 illustrates the removal of a thrombus using the deployed proximal and distal bodies of an embodiment of the retrieval device.

[0023] Figures 6-14 illustrate deployment stages of an embodiment of the retrieval device, with Figure 6 showing a thrombus lodged in an artery.

[0024] Figure 7 illustrates a guide catheter positioned in proximal feeding artery with balloon deflated.

[0025] Figure 8 illustrates the guide catheter of Figure 7 with balloon inflated thus arresting antegrade blood flow through vessels.

[0026] Figure 9 illustrates a delivery catheter positioned proximal to the thrombus with the delivery wire across the thrombus.

[0027] Figure 10 illustrates a delivery catheter advanced over the delivery wire and across the thrombus.

[0028] Figure 11 illustrates the retrieval device advanced through the delivery catheter and positioned, with the bodies still restrained, proximal and distal to the thrombus.

[0029] Figure 12 illustrates the delivery catheter withdrawn proximally thus deploying the proximal and distal mesh bodies proximal and distal to the thrombus.

[0030] Figure 13 illustrates the proximal body released from its engagement with the delivery wire and advanced axially along the delivery wire by advancing the delivery catheter to trap and compress the thrombus between the proximal and distal bodies.

[0031] Figure 14 illustrates the delivery catheter with the bodies and compressed thrombus being removed as a single unit while suction is applied to the guide catheters.

[0032] Figure 15 illustrates an embodiment having an active segment having a section spanning the length of a thrombus, and a delivery segment containing incorporation structure that is suture material between the proximal and distal bodies.

[0033] Figure 16 illustrates an active segment having a section spanning the length of a thrombus, and a delivery segment containing incorporation structure that is collapsible sinusoidal wire material between the proximal and distal bodies.

[0034] Figure 17A illustrates the retrieval device with a single tether arrangement attached to the proximal body.

[0035] Figure 17B illustrates the retrieval device with a double tether arrangement attached to the proximal body.

[0036] Figures 18-27 illustrate deployment stages of and embodiment with Figure 18 showing the placement of a temporary balloon occlusion guide catheter into common carotid artery.

[0037] Figure 19 illustrates an advancing access catheter into a vessel.

[0038] Figure 20 illustrates advancing the delivery catheter and delivery wire to the origin of an occlusion.

[0039] Figure 21 illustrates temporary inflation of a balloon on a guide catheter to arrest antegrade flow.

[0040] Figure 22 illustrates advancing the delivery wire, with the retrieval device loaded thereon, and delivery catheter across the thrombus and positioning the tip of the delivery catheter distal to the thrombus.

[0041] Figure 23 illustrates deploying the bodies of the retrieval device and advancing the bodies device through the delivery catheter and deploying the bodies distal to the thrombus.

[0042] Figure 24 illustrates the proximal and distal bodies drawn proximally to the thrombus and opening to a larger diameter when transitioning from M1 to M2 and in the process of being withdrawn proximally.

[0043] Figure 25 illustrates the proximal body being moved proximally by the tether.

[0044] Figure 26 illustrates withdrawing the thrombus towards the access catheter containing suction.

[0045] Figure 27 illustrates removal of the thrombus using the access catheter containing suction.

DETAILED DESCRIPTION

[0046] In embodiments of the present disclosure, the retrieval device, as shown in Figures 1 and 2, may be a catheter-delivered tool used to remove a foreign body, such as a thrombus or clot, from an artery, vein, duct, or other interior physical space. The retrieval device may be interchangeably referred to herein as “the device” or a “removal device”, the “removal” or “retrieval” of the foregoing may be modified by a variety of terms such as “thrombus,” “occlusion,” “foreign body,” etc. The retrieval device may be used as a foreign body retriever and as a thrombectomy device in the arterial and venous system. The device may be used in the vascular system and in non-vascular structures such as ureters, ducts, airways, and any other accessible space that contains a material (biologic or foreign) that necessitates removal or retrieval.

[0047] Figure 1 depicts the deployed retrieval device with a distal body 104, which in this embodiment is a body mounted to the delivery wire 100 such that it remains in a fixed position. Referring to all embodiments disclosed herein, it should be noted that prior to deployment of the delivery wire 100, a guide wire may be used to position any element of the system disclosed herein, including a delivery catheter 202, guide catheter 204, and delivery wire 100 into the preferred position within a vessel or other interior. The “bodies” referred to herein may be a mesh, and they may be made of nitinol or other suitable expandable biocompatible material. The mesh construct of the distal 104 and proximal 102 bodies may reduce the risk of distal embolization of portions of a clot since the mesh construct may capture embolic material within its interstices. The distal body 104 may, in embodiments, have differently-sized mesh or may comprise a selectively permeable material, or it may be non-permeable. A proximal body 102 is also shown. The proximal body 102 is mounted to the delivery wire 100 and is temporarily affixed thereto such that it remains in a fixed position. The temporary affixed aspect referred to above is releasable such that upon release

the proximal body 102 may move along the wire, which is referred to herein as “axial movement” along the wire, while remaining engaged to the wire 100. This aspect is referred to as being in “releasable engagement” or being “releasably engaged” to the delivery wire 100. Such releasable engagement may be achieved, for example, by using breakable connection 108, which in embodiments, may be an electrolytically or heat disconnectable connection or mechanical connection that can be selectively disconnected by the clinician. In the case of an electrolytically or heat disconnectable connection, for example, the clinician may apply a current to the connection, (in embodiments via the wire which may be conductive) wherein the electrical current breaks or melts the connection. The connection may include, without limitation, a breakable connection 108, linking a proximal body 102 to the delivery wire 100, that may be eroded and/or disintegrated through the application of electrical current. The breakable connection 108 may be preloaded onto the retrieval device in order to secure the proximal body 102 in a preferred location and/or configuration. The breakable connection may have a plurality of shapes and designs, including but not limited to a straight post extending from the delivery wire 100 to the proximal 102 or other body, a loop configuration of the breakable connection passing through the material of the proximal 102 or other body, and/or a “nail” configuration in which a straight post extends from the delivery wire to the proximal 102 or other body, wherein the post has an enlarged end, or nail head, within the body that may be eroded by the application of electric current to release the body. Embodiments of the present invention include a proximal 102 or other body that may be secured to the delivery wire 100 using more than one breakable connection 108. In an example, a proximal body 102 may be secured with multiple breakable connections, each having a different length and a different release threshold, allowing the breakable connections to be sequentially released. In embodiments, more than one proximal body may be secured to the delivery wire 100 using a breakable connection 108. Melting of a breakable connection may be caused by the application of electrical current, fluid, and/or chemical compounds. Melting may occur in a physical member that is used to secure the proximal or distal body and/or may occur within an adhesive that binds the physical member to the proximal, and/or the delivery wire 100. Breakable connection techniques and methods, including but not limited to those shown in U.S. patents 5,683,451, 5,855,578, 6,245,076, 8,273,116. and U.S. patent applications 20070100414A1, 20090062726A1, and 20100268251A1, may be used to release a proximal body and/or distal body, as described herein. In the case of a mechanically breakable connection, the breakable connection 108 may be made of a suture, brace, thread or other material that is able to be broken upon

application of force to the breakable connection 108. In embodiments, the distal motion of a catheter, such as the delivery catheter, with a force above the threshold holding force of the breakable connection 108 may cause the connection 108 to break or release, thus allowing the body 102 to move along the wire in the manners described herein. The “bodies” referred to herein may be of various geometric shapes including a disc or sphere. In embodiments, the distal body 104 and/or proximal body 102 may be an inflatable device, including but not limited to an inflatable balloon. In embodiments, a retrieval device, as described herein, may include a distal body 104 and a proximal body 102 made of differing materials, for example a proximal body 102 may be an inflatable balloon and a distal body 104, on the same retrieval device, may be made of a mesh material. In embodiments, by adjusting the manufactured radial force, body diameter, and strength of the bodies, foreign body extraction, as described herein, may also be used for the removal of stones, pulmonary emboli, or some other type of obstruction. In embodiments, a proximal and/or distal body may have variable radial force, or stiffness across sub-regions of the body itself. For example, the upper hemisphere of a spherical body may have a difference radial force characteristic than the lower hemisphere of the body. In embodiments, the proximal and distal bodies may be substantially the same. In other embodiments, the proximal and distal bodies may be heterogeneous, having different compositions and characteristics including, without limitation, shape, size (e.g., thickness, diameter), configuration, pore size (e.g., mesh pore size), coating, or some other differing characteristic. In embodiments, the proximal and/or distal bodies may have anti-platelet, or some other type of, coatings to reduce adhesion and provide a less thrombogenic environment during clinical application. The proximal and/or distal bodies, and any material (e.g., wires) between these bodies, may be coated with control release agents including, but not limited to, thrombolytic agents.

[0048] The “delivery wire” 100 referred to herein may be a wire or a hypo tube. The delivery wire 100 may not require a coaxial system of catheters as disclosed herein in embodiments.

[0049] The “delivery catheter” 202 referred to herein may be referred to as a microcatheter, and may form a plurality of shape configurations based on the clinical application in which it is used, for example, which type of vessel the delivery catheter is used within, the vessel size, the vessel shape, or some other application characteristic. In embodiments, a delivery wire and/or hypo tube may be used within a microcatheter. For purposes of this disclosure, the microcatheter 202 is commonly called a “delivery catheter”, although it should be understood that the terms can be used interchangeably.

[0050] Referring to Figure 2, prior to deployment of the distal 208 and proximal 210 bodies (which are shown as being restrained or in their unexpanded form and thus having different reference numerals from the FIGS 1, and 3-5) the delivery catheter 202 surrounds the delivery wire and restrains both bodies 208, 210. In embodiments, a guide catheter 204 is navigated into place, in embodiments, over a guide wire, said guide wire in some embodiments being removed. The delivery catheter 202 may be passed through an object, such as a thrombus or clot 212, the bodies 208, 210 may be released from the delivery catheter 202 either by retracting the delivery catheter 202 or advancing the wire 100, such that expandable bodies are no longer restrained by the delivery catheter 202. The distal body 104 remains fixed to the delivery wire 100, but the proximal body 102 (once released from its releasable engagement) can freely move along its axis and longitudinally along the delivery wire 100 when pushed by the delivery catheter 202. Also, the delivery wire 100 “pushing” the body (210 or 102 once expanded) must be understood as relative pushing. That is, the retraction of the delivery wire 100 while the delivery catheter 202 is kept in place may serve to move the proximal body 102 axially along the wire. The term “pushing” as is used herein will refer to both forms of movement mentioned above. Once the proximal and distal bodies are positioned adjacent to both sides of the clot (which has been referred to herein as “surrounded” or “surrounding” the clot) by movement of the proximal body 102, the clot may be removed by retrieving the device from the cavity and pulling the clot free. The terms “clot,” “thrombus,” “occlusion,” “occlusive substance” and “foreign body” may be used interchangeably herein.

[0051] In embodiments, the freedom of movement of the proximal body 102 on the delivery wire 100 axially may allow for the compression of the occlusive substance and obviate the need for pre-measuring or estimating the required distance between the distal and proximal bodies prior to entering the vessel 200; sizing may take place in situ within the vessel 200 upon the interventionist encountering it.

[0052] In embodiments of the present disclosure, the retrieval device may consist of a distal body 104 and a proximal body 102, each of which in embodiments may be collapsible geometric forms. Although the distal and proximal bodies are presented for diagrammatic purposes as spherical, the distal and proximal bodies may also be other geometric forms such as a disc, cone, oblong-shaped form, etc. As mentioned above, the distal and proximal bodies may be a mesh in structure. The mesh cell size may be manufactured to have different sizes based on factors such as the expected properties of the target foreign matter to be removed, such as the density of the matter. The distal body 104 is mounted on a delivery wire 100 such

that it remains fixed. In embodiments, the mounting of the proximal body 102 occurs by running the wire through one of the mesh opening. In other embodiments, the proximal body 102 itself may have an opening through which the wire may pass. In either case of mounting the proximal body 102, the body is able to slide along the wire in an axial direction along the wire. This may be referred to herein as “slidably mounted”. In some embodiments, the distal body 104 may be slidably mounted in the way described above. As described above, the proximal body may be detachable (thus releasably engaged) using mechanical, electrolytic or some other type of control release format. In embodiments, the proximal body 102 will be slidable along the wire one released while the distal body 104 remains fixed. In other embodiments, both the proximal and distal bodies may be releasably engaged and thus slidable or movable along the delivery wire 100. Still in other embodiments, the proximal body 102 may be comprised of multiple bodies, and the distal body 104 may be comprised of multiple bodies. The mesh material of the distal and proximal bodies may have advantages over other material types, including but not limited to inflatable balloons. Inflatable material may be susceptible to rupture, such as that caused by over inflation. The clinical setting may also be associated with complications related to the use of inflatable balloons within a lumen. For example, a calcified thrombus may increase the risk of balloon rupture. In another example, if an occlusion itself includes metallic material, this may also increase the risk of rupture or other malfunction of an inflatable balloon. Rupture of a balloon may in turn increase the risk of an air embolus forming within the vessel or cavity of intervention. In embodiments, the mesh material of the distal and proximal bodies may allow for the bodies to expand upon release to the diameter and configuration of the cavity in which it is placed, such as a vessel 200 in which a thrombus 212 is located. Such meshes may be made of a shape memory substance such as nitinol. For example, a body made of nitinol mesh may expand to a first dimension outside of a vessel 200 or catheter, but may be designed to expand to a continuum of smaller dimensions than the first dimensions corresponding to different lumen sizes. In this way the bodies may fit the unique variations in diameter found in a lumen at the point of release and/or point of placement near an occlusion, such as a thrombus. Mesh material may also allow for improved distal flow during an intervention. The irregularity and/or texture of the expanded mesh material may facilitate the mesh material becoming entangled or otherwise incorporated with a clot or occlusive substance, thereby increasing adhesion of the distal and/or proximal body with the occlusion and facilitating its removal.

[0053] In embodiments, when the proximal body 102 is released, it may be free to move/slide on its axis along the delivery wire 100 in a longitudinal and/or rotational fashion. Referring to Figure 3 when the distal body 104 is placed distal to the target thrombus 212 for retrieval and the proximal body 102 is placed proximal to the thrombus 212, the distal and proximal bodies will straddle and contain the thrombus 212 intended for removal from the vessel. The proximal body 102 may now be advanced in the direction of the thrombus 212 in a variety of mechanical fashions. As shown in Figure 4, a coaxially placed microcatheter, also referred to herein as a “delivery catheter” 202, may be pushed forward (once the proximal body is released) and used to physically advance the proximal body 102 to ultimately capture and compress the thrombus 212. Alternatively, the delivery catheter 202 may be used to hold the proximal body 102 in a fixed position while the delivery wire 100 is withdrawn thus moving the fixed distal body 104 towards the proximal body 102 and ultimately capturing and compressing the thrombus 212. As shown in Figure 5, once the thrombus 212 is captured/compressed between the distal body 104 and the proximal body 102, the entire retrieval device may be removed from the patient via withdrawal of the delivery wire 100 by, for example, withdrawing the proximal and distal bodies with the compressed material back to, and against, the delivery catheter and then removing the delivery catheter, bodies and compressed material through the guide catheter. Once this is removed, the guide catheter may be withdrawn from the vessel.

[0054] In embodiments of the present disclosure, the retrieval device may be employed as part of the removal of an occlusive object or substance from a human vessel, such as performing arterial thrombectomy. This procedure may include the following generalized steps. Figure 6 shows an occlusion in the proximal left internal carotid artery (ICA). Figure 7 shows an embodiment having a guide catheter 700 with a balloon 702 (“balloon catheter”). In embodiments, suction may be applied through the guide catheter 700, in effect utilizing the guide catheter 700 as a suction catheter, as a given intervention may require. The balloon 702 is deflated and inserted into the ICA over a guide wire 704. Figure 8 shows a delivery catheter 202 advanced through the balloon catheter over the guide wire 704, which has been advanced. Figure 9 shows a guide wire 704 being advanced through and distal to the occlusion 212. Figure 10 shows the delivery catheter 202 being advanced through and distal to the occlusion over the guide wire 704. The guide wire 704 is then removed (not shown) and Figure 11 shows the retrieval device (delivery with distal 208 and proximal 210 bodies mounted on a delivery wire 100 as described herein) inserted into the delivery catheter 202 and still retrained (unexpanded) in the delivery catheter 202. In Figure 12 the delivery

catheter 202 has been withdrawn (moved relative to the delivery wire 100) such that the proximal 102 and distal 100 bodies expand on either side of the occlusion 212. The proximal body 102 having been released is then advanced distally (shown in Figure 13) by force of the delivery catheter 202 (either by pushing the delivery catheter 202 or by pulling the delivery wire 100 while restraining the position delivery catheter 202). Figure 14 shows withdrawal of the retrieval device from the ICA, balloon 702 still inflated to arrest antegrade flow.

[0055] The retrieval device may remove both organized and unorganized thrombi since, in embodiments, the bodies of the retrieval device do not need to be incorporated into the thrombus 212 to affect its removal. The retrieval device may also remove calcified, atherosclerotic material since, in embodiments, the bodies of the retrieval device do not need to be incorporated into the material to affect its removal. The retrieval device may be used centrally and peripherally by selecting the appropriate diameter and characteristics of the bodies, such as appropriate radial force or stiffness, appropriate shape, whether the bodies are substantially identical or homogenous, mesh opening size in the bodies, and the like.

[0056] The methods, system and apparatus, as described herein, may have a plurality of sizes loaded within a common catheter, and a clinician may self-load, for example, different and/or additional proximal bodies, as described herein, rather than having to fully replace a deployed catheter for a second catheter-based device and system. This may reduce manufacturing costs and improve intervention efficiency.

[0057] Figures 15 and 16 show embodiments having a structure to incorporate into the thrombus 212, referred to herein as an “incorporation structure”. In some embodiments, the incorporation structure is part of the delivery wire 100, in others it is separate. Referring to Figures 15 and 16, the delivery wire 100 (which in all embodiments disclosed herein may be a hypo tube) comprises a segment having characteristics different from that of the main segment of the delivery wire 100, or a structure mounted to the delivery wire 100 that may expand. In the case where the incorporation structure is part of the delivery wire 100, the segment will be referred to herein as the “active segment” while the remainder of wire will be referred to as the “delivery segment”. The active segment is the segment having a section intended to span the length of the thrombus 212. In embodiments, the active segment comprises a cross-sectional shape that differs from the delivery segment. In embodiments, the delivery segment contains a suture material 1500 between the proximal 102 and distal 100 bodies. The suture material 1500 gathers and moves along the delivery wire 100 as the proximal body 102 is advanced. Once the proximal body 102 is in position, the suture material 1500 will be gathered in the area between the two bodies which will enhance

incorporation characteristics of the active area. Note that the active area in the above example is the area between the two bodies, which in this case, has suture material 1500 gathered therebetween. As mentioned above, in embodiments the incorporation structure can be an additional expandable structure between the proximal 102 and distal 100 bodies that expands and incorporates into the thrombus 212. The incorporation structure may comprise other mechanisms to enhance thrombus-incorporation, such as flanges, hooks, sutures, sinusoidal wire 1600, or some other material configuration.

[0058] In embodiments, the delivery wire 100 may include a distal body 104 that may be affixed, mounted, adhered or otherwise connected to a delivery wire 100 or hypo tube as described herein. Prior to deployment, such as a thrombectomy, the distal body 104 may be affixed, mounted, adhered or otherwise connected to the delivery wire 100 or hypo tube in a collapsed or compressed state. Compression of the distal body 104 may be provided by the delivery catheter 202, and/or multiple catheters which surround the distal body 104 and delivery wire 100 (as described herein). Once the delivery catheter 202 is inserted through an object, such as a thrombus, the distal body 104 may be released from inside the delivery catheter 202 as described herein, thus expanding. Following removal of the delivery catheter 202, suction may be applied to the thrombus or other blockage. (It is to be noted that a suction step, as described herein, may be applied to any of the embodiments of this disclosure, and may be applied through the guide catheter, access catheter, specialized suction catheter, or some other type of catheter). In an example, the Seldinger technique may be initiated using a large bore suction catheter that is advanced over the delivery wire 100 (or a guide wire) and positioned proximal to the thrombus 212, with the distal body 104 distally positioned to the thrombus. Suction may be applied to remove all or a portion of the thrombus. The positioning of the distal body 104, on the distal side of the thrombus, may be used to retract the thrombus in the direction of the suction device, thereby increasing the effectiveness of the suction device in removing the thrombus. The distal body 104 may also provide distal protection from distal embolization during the suction device's placement and/or during the suctioning procedure. Note that in the above example, a proximal body has not yet been included in the procedure. There are situations and thus embodiments where an optional proximal body 102 may be added to the procedure, for example, by slidably mounting a proximal body 102 to the delivery wire 100. As such, in embodiments the inclusion of a proximal body 102 is optional.

[0059] In some clinical scenarios the suction procedure may result in only a partial removal of the thrombus 212 or other obstruction. In such scenarios, mechanical removal of the

thrombus 212, using a distal body and an added proximal body 102, may be advantageous and/or required. Following the application of suction within the guide catheter 700, a proximal body 102 may be added to the delivery wire 100, where this proximal body 102 is proximal to the thrombus 212 or other obstruction. Once the proximal body 102 is placed on the delivery wire 100, it may be advanced towards the distal end of the delivery wire 100 by advancing the delivery wire 100. In another example, the proximal body 210, in a restrained position, may be advanced towards the distal end of the delivery wire 100 using a hypo tube that is placed within the delivery catheter 202 over the delivery wire. As the hypo tube is pushed towards the distal end of the delivery wire 100, the proximal body 210 may be moved axially to a desired location. Once the proximal body 210 is in the desired physical position, relative to the thrombus 212 or other obstruction, the proximal body 210 may be released from inside the delivery catheter 202 to form the expanded proximal body 102 in a manner already described herein. The coaxially placed hypo tube may be pushed forwards and used to physically advance the proximal body 102 to ultimately capture and compress the thrombus 212. Once the thrombus 212 is captured/compressed between the distal body 104 and the proximal body 102, the entire retrieval device may be removed from the body via coaxially placed catheters/tubes thus permitting removal of the thrombus 212 from its prior resting place within the vessel.

[0060] Referring to Figures 17A and 17B, the proximal body may be moved along the delivery wire via application of force to a tether or multiple tethers. As shown in Figure 17A, a single proximal tether 1700 may be attached to the proximal body 102, the proximal body 102 being slidably mounted and in releasable engagement to a delivery wire (or hypo tube), as described herein. The proximal tether 1700 may be pulled to move the proximal body back, proximally along the wire 100 after the proximal body 102 has been released and positioned in the manner described herein. The proximal tether 1700 may run parallel and within the delivery catheter (not shown) or, as shown in Figure 17A, the proximal tether 1700 may run within a hollowed-out portion of the delivery wire or hypo tube and emerge through an opening 117A. The proximal end 1710 of the proximal tether 1700 is accessible to the interventionist who can pull it to pull back, proximally to the proximal body 102 at least to the point adjacent to the opening 117A.

[0061] Figure 17B shows a two-tether embodiment. As with the embodiment shown in Figure 17A, the tethers may run parallel and within the delivery catheter (not shown) or, as shown in Figure 17B, the proximal tether 1700 and distal tether 1702 may run within a hollowed-out portion of the delivery wire or hypo tube and emerge through openings 117A

and 117B, where the proximal tether 1700 emerges from opening 117A and the distal tether 1702 emerges from opening 117B. Movement of the proximal body via the proximal tether, in the proximal direction, is the same as mentioned above. In this embodiment, the interventionist can pull the end of the distal tether 1720 to move the proximal body 102 adjacent to the opening 117B, which results in a distal movement of the proximal body 102 without the need for distal movement via the delivery catheter as described herein.

[0062] In addition to the steps of deployment mentioned above, the following steps may also or alternatively be followed for using the retrieval device in embodiments.

Figure 18 shows the common carotid artery (CCA) having an occlusion therein 212. A guide catheter 1800 having a flow arrest balloon 702 is inserted into the CCA (in embodiments over a guide wire). Figure 18 shows the flow arrest balloon 702 as deflated. Figure 19 shows the advancement of an access catheter 1900 distally through the guide catheter 1800 (in embodiments over a guide wire (not shown)). Figure 20 shows the distal advancement of a delivery catheter 202 via a guide wire 704 to the origin of the inclusion (i.e., the base of the thrombus 212). Figure 21 shows the flow arrest balloon 702 being temporarily inflated to arrest antegrade flow in the CCA as well as the delivery catheter 202 being advanced distal to the occlusion 212 via the guide wire 704 and, in this case, in M1. The guide wire 704 is removed (not shown). The delivery wire 100 with restrained proximal 210 and restrained distal 208 bodies thereon is inserted into and through the delivery catheter 202 with the tip emerging the delivery catheter as shown in Figure 22. In this example, the delivery wire 100 has within it a proximal tether 1700 and a distal tether 1702.

[0063] In Figure 23, the proximal 102 and distal 104 bodies are deployed distally to the occlusion 212, the deployment being in the manner described herein. The delivery catheter 202 is withdrawn from patient to increase open luminal area in access catheter 1900, which allows for better suction when suction is applied to access catheter 1900. Figure 23 also shows the proximal tether 1700 and the distal tether 1702, as described herein, attached to the proximal body 102. Figure 23 also shows the deflation of flow arrest balloon 702 on the guide catheter 1800 to end flow arrest. Due to mesh construct of the proximal 102 and distal 104 bodies which are now deployed, antegrade flow into vessels will be reestablished with protection (established via the expanded proximal 102 and distal 104 bodies) from distal embolization of occlusion when flow is reestablished. Suction may be applied to the access catheter 1900 at this point. The proximal body 102 may be released from its releasable engagement 108 as described herein, while the distal body 104 remains fixed to the wire.

[0064] With both the proximal 102 and distal 104 bodies providing protection (most commonly initially in an M2 branch for an M1 occlusion or covering the M1 bifurcation for an ICA terminus) an interventionist may slowly pull the delivery wire 100 in a proximal direction. This will draw both bodies proximally (see Figures 23-25). The proximal 102 and distal 104 bodies will open to a larger diameter when they transition from M1 to M2 and in the process of being withdrawn proximally will begin the thrombectomy process (see Figure 25).

[0065] Once the distal body 104 opens at the M1 bifurcation, both superior and inferior M2 protection has been established (see Figures 24 and 25). Using a proximal tether 1700 and a distal tether 1702 that connect to the proximal body 102 and exit from the delivery wire 100 either via an opening in the outer surface or via the opening on the end of the delivery wire 100 (see Figures 17A and 17B), the proximal body 102 can be moved along the M1 and possibly ICA lumen back and forth (i.e., proximally and distally axially along the delivery wire) by pulling the ends of the tethers 1710, 1720 as described herein and as desired by the clinician to mobilize occlusion and loosen and draw it proximally towards the suction device. If the initial placement of the proximal body 102 is determined to be too far in the distal direction, the interventionist may use the proximal tether 1700 that is attached to the proximal body 102 to pull the proximal body 102 back in the proximal direction to place it farther from the distal end of the retrieval device. This allows the interventionist to adjust the proximal body's position along the wire 100 instead of only being able to advance the proximal body 102 in the distal direction. In an example, the proximal body 102 may have a Kevlar tether that exits the delivery wire (or hypo tube) 100 at an opening distance about 1-2 cm proximal to the proximal side of the proximal body 102 to which it is attached. Therefore, while the two bodies are initially adjacent to each other, the proximal body 102, once electrolytically detached, can be withdrawn a distance proximally along the delivery wire 100 axis 1-1.5 cm by pulling on the proximal tether 1700. (All distances herein may be adjusted according to the need). It may be advanced by pushing it forward with the delivery catheter 202 and/or a second, distal tether 1702 may exit the wire at opening 117B distally to the proximal body 102 which when pulled can pull the proximal body 102 distally back towards the distal body and adjacent to the opening 117B. Therefore, by pulling proximal tether 1700 and/or the distal tether 1702 the proximal body 102 may slide backwards and forwards along the delivery wire 100. In this example, this configuration provides the proximal body 102 with 1-1.5cm of travel distance back and forth along the delivery wire 100. Despite anterograde flow, the distal body 104 may provide protection against distal embolization of

loosened/floating occlusion thus eliminating/reducing the risk of distal embolization of this material (see Figure 25).

[0066] Once the thrombus 212 has been removed/evacuated through the access catheter 1900, the proximal and distal bodies can be removed by withdrawing them through the delivery catheter 202. This process will also mechanically draw any thrombus 212 that sits on the tip of the access catheter 1900 (cleans the catheter tip) into the catheter 1900 so that it does not embolize off the catheter tip and back into the intracranial circulation (see Figures 25-27).

[0067] In embodiments, the following steps may be followed for using the retrieval device, as described herein, for a foreign body (e.g., lost coil or fractured filter) capture and extraction intervention, such as an aneurysm coil lodged at an M1 bifurcation (proximal and distal bodies may be sized according to vessel size where the foreign body is located):

1. Guide catheter 1800 already in ICA from coiling procedure.
2. Advance a delivery catheter 202 distal to the foreign body.
3. Advance the retrieval device through the delivery catheter 202 (the “retrieval device”, again is the delivery wire 100 with the proximal and distal bodies mounted thereon in a manner described in this disclosure).
4. When the distal body 104 reaches the end of the delivery catheter 202, the interventionist may optionally detach the releasable engagement of proximal body 102 so it is free to move axially along the delivery wire 100.
5. Pull the proximal tether 1700 and draw the proximal body 102 proximally in the delivery catheter 202 so that there is a space, in some embodiments a 1 cm space, between the two non-deployed bodies which are still constrained within the delivery catheter 202.
6. Slowly retract the delivery catheter 202 proximally. This will allow the distal body 104 to open in the vessel 200 distal to the foreign body.
7. Holding the wire in place, continue drawing the delivery catheter 202 proximally until the proximal body 102 is unsheathed. The proximal body 102 will now be opened proximal to the foreign body/coil.
8. The foreign body is now trapped/isolated between the distal and proximal bodies.
9. While holding the distal body 104 in place by holding the delivery wire 100, the proximal body 102 can now be approximated along the wire to the distal body 104

by either using the tethers as described herein or by simply pushing it forward with the delivery catheter 202 or drawing the distal body 104 proximally.

10. The foreign body/coil is now trapped between the two bodies and can be removed from the vessel 200. By pulling the entire system down to or into the guide catheter 1800.

CLAIMS

What is claimed is:

1. An occlusion removal device comprising:
a first body adapted to be mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release the first body is movable axially along the delivery wire; and
a second body adapted to be mounted to the delivery wire,
wherein the first body is releasably engaged to the delivery wire by a electrolytically disconnectable connection, the electrolytically disconnectable connection being broken upon an application of electric current to the electrolytically disconnectable connection.
2. The device of claim 1, wherein the first body is oriented proximally to the second body.
3. The device of claim 2, wherein the first body is a proximal body and the second body is a distal body.
4. The device of claim 3 wherein the proximal body and the distal body are expandable.
5. The device of claim 4 wherein the proximal body and the distal body are adapted to expand upon exiting a delivery catheter.
6. The device of claim 5 wherein the proximal body is movable axially along the delivery wire by contact with the delivery catheter.
7. The device of claim 4 wherein the proximal body and the distal body are made of nitinol.
8. The device of claim 7 wherein the proximal body and the distal body are mesh.

9. An occlusion removal device comprising:
a first body adapted to be mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release is movable axially along the delivery wire; and
a second body adapted to be mounted to the delivery wire,
wherein the first body is releasably engaged to the delivery wire by a mechanical connection.
10. The device of claim 9, wherein the first body is oriented proximally to the second body.
11. The device of claim 10, wherein the first body is a proximal body and the second body is a distal body.
12. The device of claim 11 wherein the proximal body and the distal body are expandable.
13. The device of claim 12 wherein the proximal body and the distal body are adapted to expand upon exiting a delivery catheter.
14. The device of claim 13 wherein the proximal body is movable axially along the delivery wire by contact with the delivery catheter.
15. The device of claim 12 wherein the proximal body and the distal body are made of nitinol.
16. The device of claim 15 wherein the proximal body and the distal body are mesh.
17. The device of claim 9 wherein the mechanical connection is a tether adapted to break upon application of a pulling force.
18. A method of removing an occlusion comprising:
inserting a guide catheter into a body lumen of a patient;
advancing a delivery catheter through the guide catheter, the delivery catheter having a delivery wire therein, the delivery wire having a proximal body and a distal body mounted to the delivery wire, the proximal body releasably engaged to the delivery wire;

advancing the delivery catheter through the occlusion;
expanding the distal body distal to the occlusion;
expanding the proximal body proximal to the occlusion;
releasing the proximal body from engagement to the delivery wire;
moving the proximal body in a direction along the delivery wire such that the proximal body and the distal body surround the occlusion; and
retracting the proximal body, the distal body, the delivery wire, the delivery catheter, and the guide catheter from the patient.

19. The method of claim 18, wherein the direction is distal.
20. The method of claim 18, wherein the proximal body is moved in a distal direction by moving the delivery catheter distally.
21. The method of claim 18, wherein the direction is proximal.
22. The method of claim 21, further comprising moving the proximal body in a proximal direction by pulling a tether attached to the proximal body.
23. The method of claim 18 wherein the guide catheter comprises a balloon, the method further comprising inflating the balloon.
24. The method of claim 18 further comprising applying suction.
25. A method to retrieve an occlusion in a lumen of a patient comprising:
inserting a delivery wire, sheathed by a delivery catheter, through the occlusion;
withdrawing the delivery catheter from a distal end of the delivery wire, wherein the withdrawing leaves the delivery wire protruding through the occlusion and expands a first body distal to the occlusion;
expanding a second body that is attached to the delivery wire on a proximal side of the occlusion;
withdrawing the delivery wire such that the first body is in contact with the distal side of the occlusion;

advancing the second body distally by advancing the delivery catheter distally until the second body contacts the proximal side of the occlusion; and
removing the occlusion from the lumen by withdrawing the first body and the second body, the delivery wire and the delivery catheter from the lumen.

26. An occlusion removal system comprising:

a delivery wire comprising:

a proximal end having an opening;

a distal end;

an outer surface;

a lengthwise cavity; and

a first opening to the lengthwise cavity, the opening being in the outer surface of the delivery wire;

a first tether having a proximal end and a distal end and traversing the lengthwise cavity, the proximal end of the first tether having a length outside of the opening in the proximal end of the delivery wire and the distal end of the first tether having a length outside the opening in the outer surface of the delivery wire; and

a first body attached to the distal end of the first tether, the first body adapted to be slidably mounted to the delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire.

27. The system of claim 26 wherein the first tether is adapted to move the first body in a proximal direction when the first tether is pulled.

28. The system of claim 27 further comprising a second body mounted to the delivery wire.

29. The system of claim 28, wherein the first body is oriented proximally to the second body.

30. The system of claim 29, wherein the first body is a proximal body and the second body is a distal body.

31. The system of claim 30 wherein the proximal body and the distal body are expandable.

32. The system of claim 31 wherein the proximal body and the distal body are adapted to expand upon exiting a delivery catheter.
33. The system of claim 32 wherein the proximal body is moved axially along the delivery wire by contact with the delivery catheter in a distal direction.
34. The system of claim 26 the first body is releasably engaged by an electrolytically disconnectable connection, the electrolytically disconnectable connection being broken upon an application of an electric current to the electrolytically disconnectable connection.
35. The system of claim 26 the first body is releasably engaged by a mechanical connection.
36. The system of claim 26, wherein the delivery wire is a hypo tube.
37. The system of claim 26 further comprising a second opening to the lengthwise cavity oriented distally to the first opening.
38. The system of claim 37 further comprising a second tether having a proximal end and a distal end and traversing the lengthwise cavity, the proximal end of the second tether having a length outside of the opening in the proximal end of the delivery wire and the distal end of the second tether having a length outside the second opening in the outer surface of the delivery wire.
39. The system of claim 38, wherein the second tether is adapted to move the first body in a distal direction when the second tether is pulled.
40. The system of claim 37, wherein the second opening is in the outer surface of the delivery wire.
41. The system of claim 37, wherein the delivery wire is a hypo tube.
42. The system of claim 40, wherein the delivery wire is a hypo tube.
43. An occlusion removal system comprising:
a delivery catheter;

a delivery wire at least partially within the delivery catheter;
a tether having a proximal end and a distal end, the proximal end of the tether having a length outside of the delivery catheter; and
a first body attached to the distal end of the tether, the first body slidably mounted to the delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire.

44. The occlusion removal system of claim 43 wherein the tether is adapted to move the first body in a proximal direction when the tether is pulled.

45. The occlusion removal system of claim 44 further comprising a second body mounted to the delivery wire.

46. The occlusion removal system of claim 45, wherein the first body is oriented proximally to the second body.

47. The occlusion removal system of claim 46, wherein the first body is a proximal body and the second body is a distal body.

48. The occlusion removal system of claim 47 wherein the proximal body and the distal body are expandable.

49. The occlusion removal system of claim 48 wherein the proximal body and the distal body are adapted to expand upon exiting the delivery catheter.

50. The occlusion removal system of claim 49 wherein the proximal body is moved axially along the delivery wire by contact with the delivery catheter.

51. The occlusion removal system of claim 43 wherein the first body is releasably engaged by disconnectable electrolytic connection, the disconnectable electrolytic connection being broken upon an application of an electric current to the disconnectable electrolytic connection.

52. The occlusion removal system of claim 43 wherein the first body is releasably engaged by a mechanical connection.

53. An occlusion removal method comprising:

- inserting a guide catheter into a body lumen of a patient;
- advancing an access catheter through the guide catheter;
- advancing a delivery catheter through the access catheter, the delivery catheter having a delivery wire therein, the delivery wire having a first body mounted thereto in a fixed position at a distal end of the delivery wire;
- advancing the delivery catheter through an occlusion;
- expanding the first body distal to the occlusion;
- loading a second body on to the delivery wire;
- advancing the second body over the delivery wire to the occlusion; and
- retracting the delivery wire, the delivery catheter, the access catheter, and the guide catheter from the patient.

54. The method of claim 53 further comprising applying suction to the access catheter.

55. The method of claim 54 wherein the guide catheter comprises a balloon.

56. The method of claim 55 wherein further comprising a step of arresting anterograde flow in the body lumen of the patient by inflating the balloon.

57. An occlusion retrieval device comprising:

- a first body mounted to a delivery wire and releasably engaged to the delivery wire, wherein while engaged the first body remains fixed on the delivery wire and upon release moves axially along the delivery wire;
- a second body mounted to the delivery wire; and
- an incorporation structure between the first body and the second body.

58. The device of claim 57, wherein the incorporation structure is suture material.

59. The device of claim 57, wherein the incorporation structure is sinusoidal wire material.

60. The device of claim 57, wherein the first body is oriented proximally to the second body.

61. The device of claim 60, wherein the first body is a proximal body and the second body is a distal body.

62. The device of claim 61 wherein the proximal body and the distal body are expandable.

63. The device of claim 62 wherein the proximal body and the distal body are adapted to expand upon exiting the delivery wire.

64. The device of claim 63 wherein the proximal body is moved axially along the delivery wire by contact with the delivery wire.

65. The device of claim 57 the first body is releasably engaged by a electrolytically disconnectable connection, the electrolytically disconnectable connection being broken upon an application of electric current to the electrolytically disconnectable connection.

66. The device of claim 57 the first body is releasably engaged by a mechanical connection.

67. The device of claim 66 wherein the mechanical connection is a tether adapted to break upon application of a pulling force.

68. The device of claim 61 wherein the proximal body and the distal body are made of nitinol.

69. The device of claim 68 wherein the proximal body and the distal body are mesh.

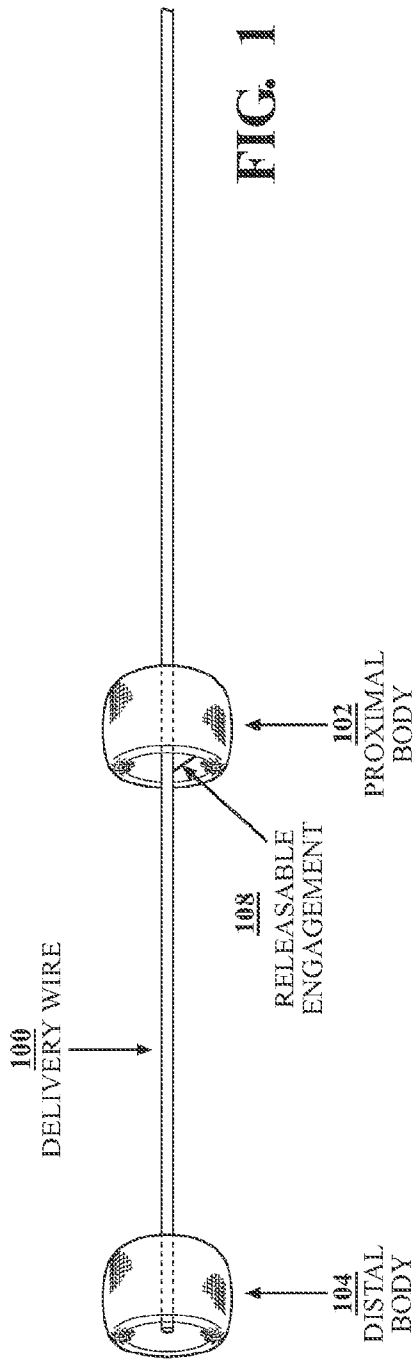


FIG. 1

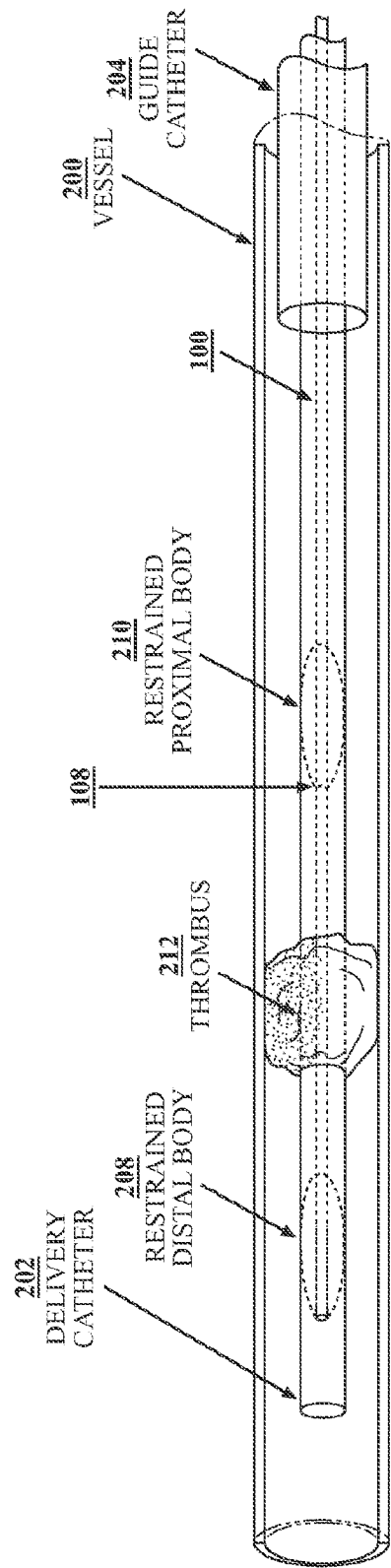


FIG. 2

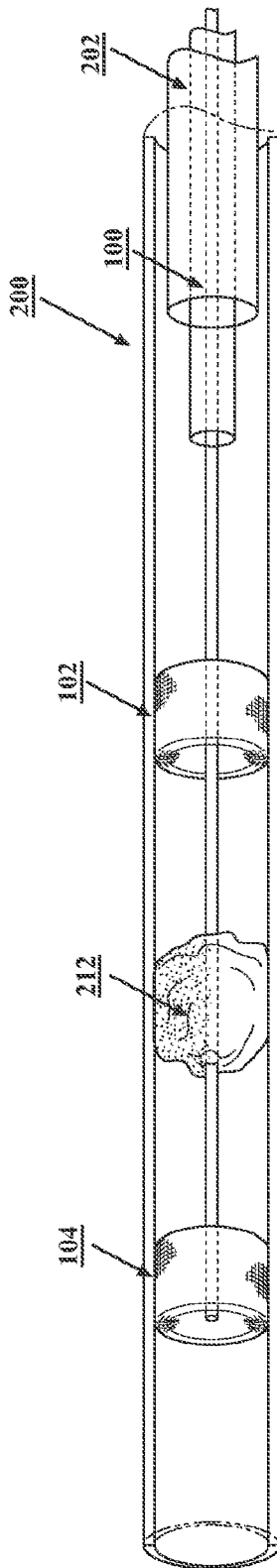


FIG. 3

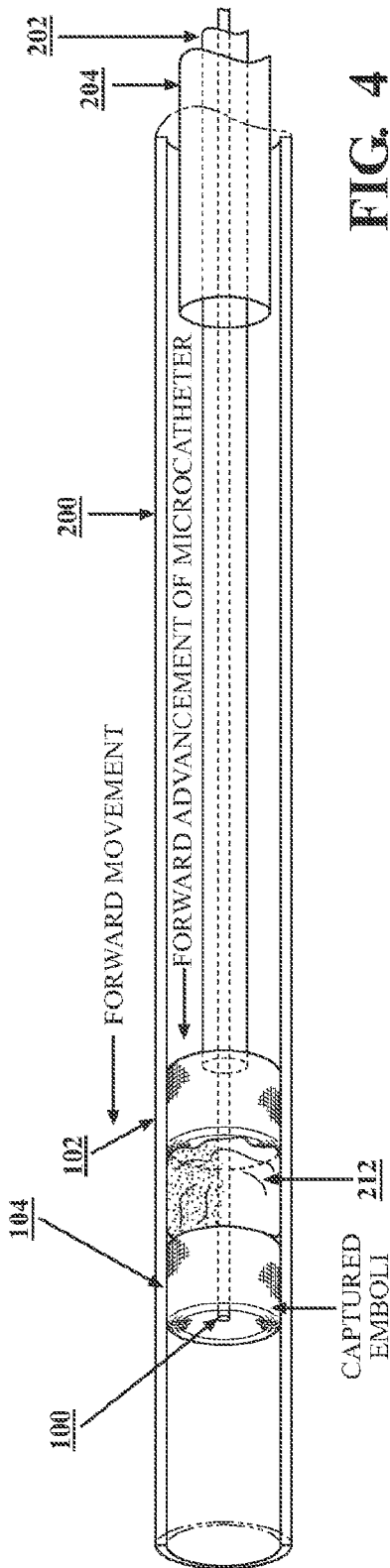


FIG. 4

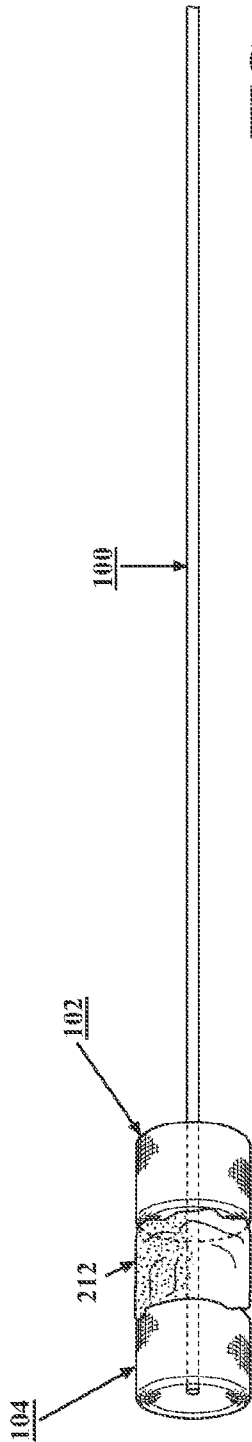


FIG. 5

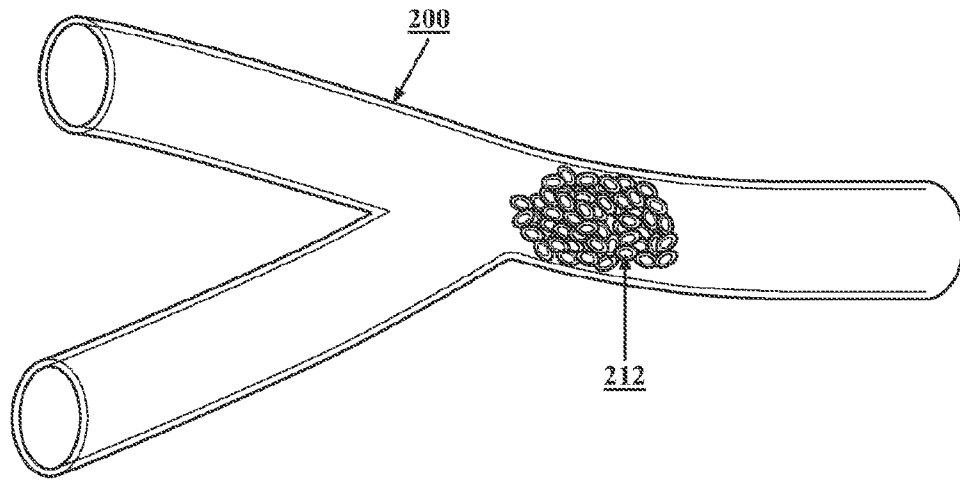


FIG. 6

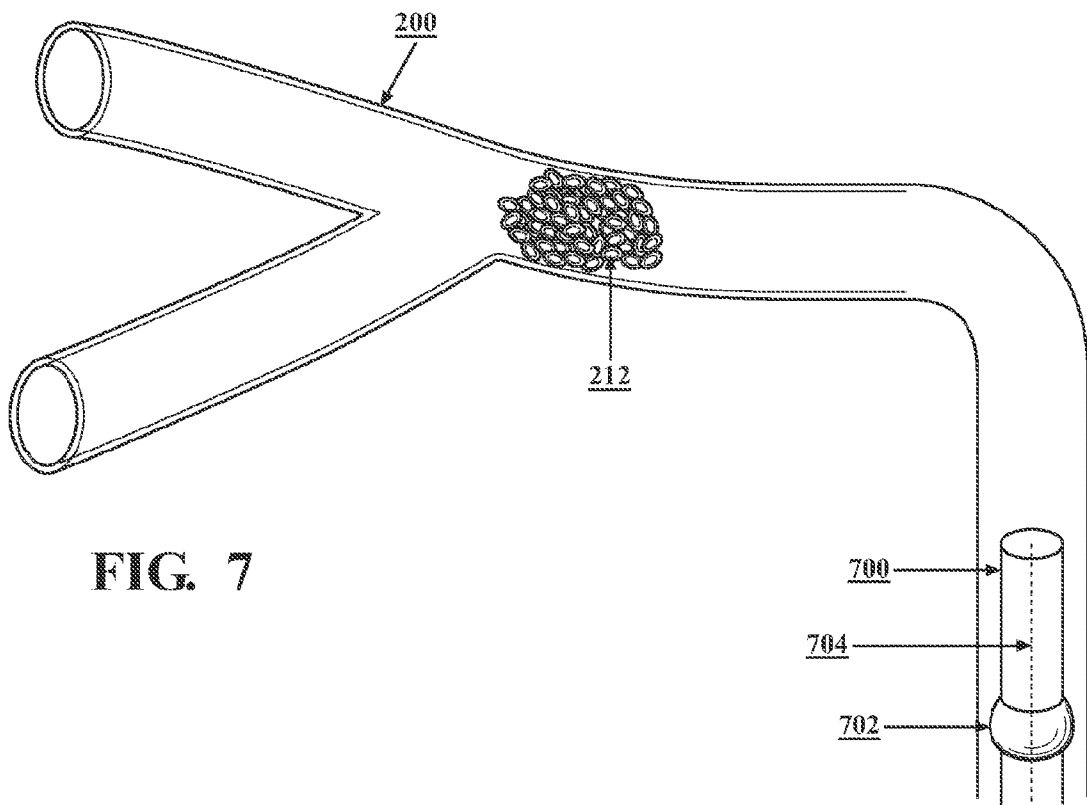
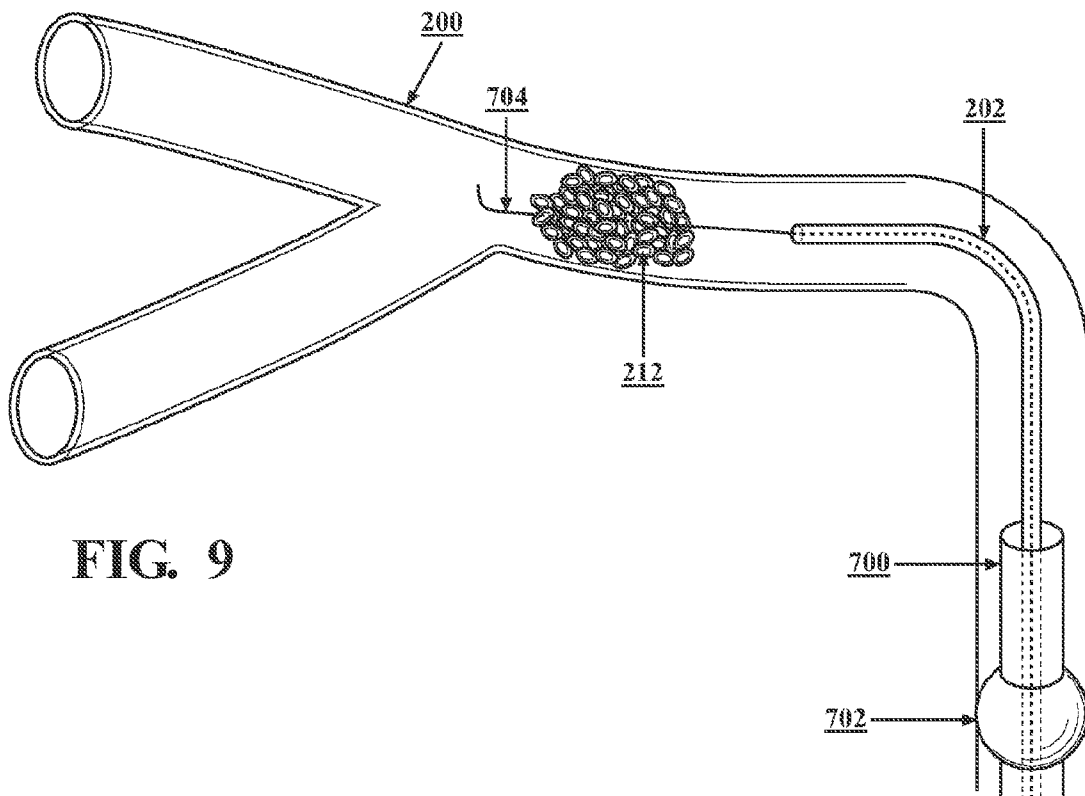
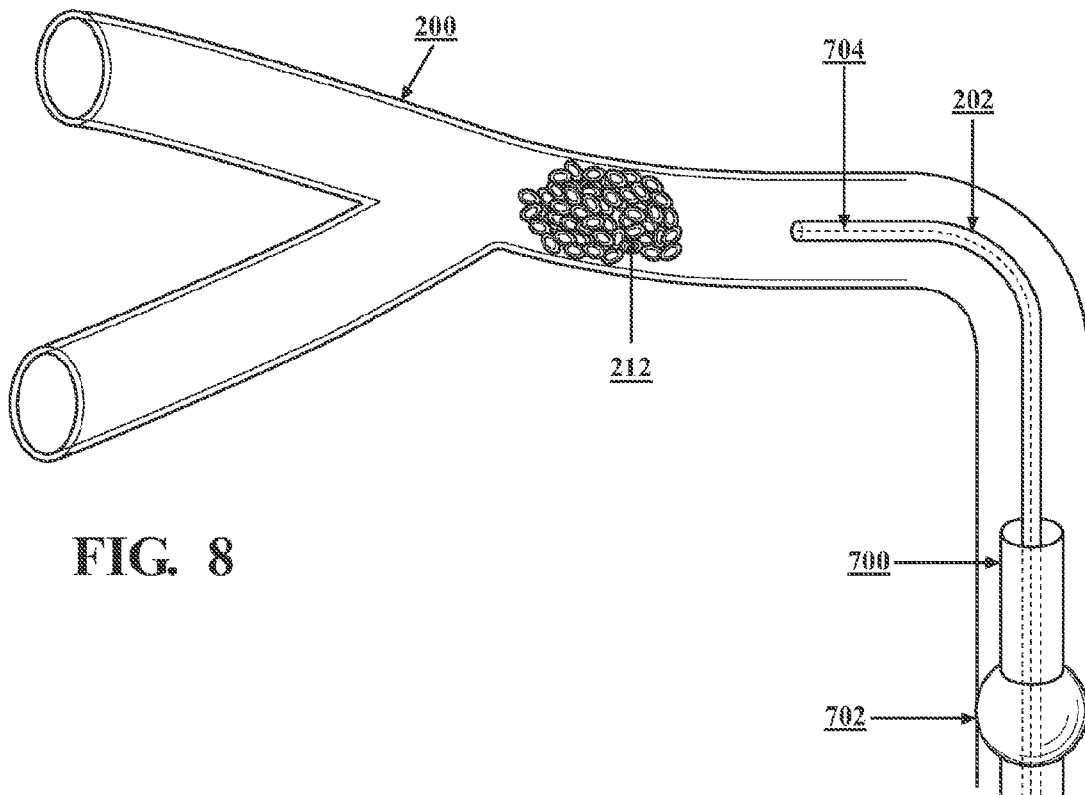
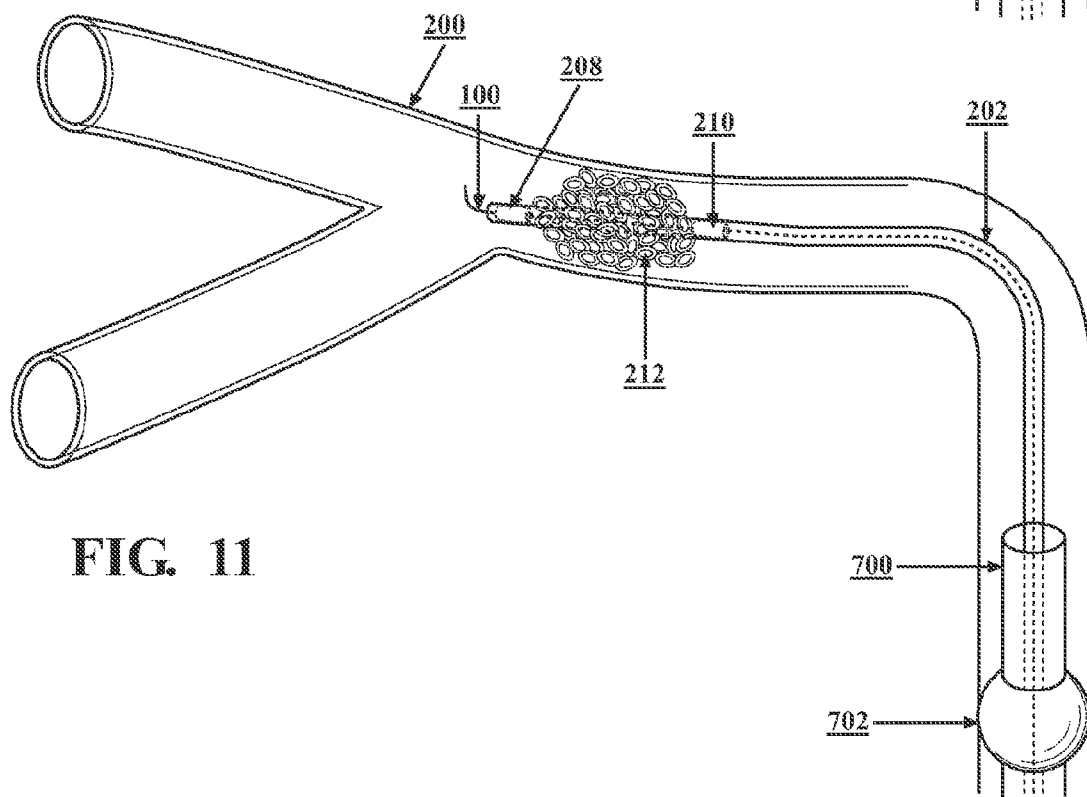
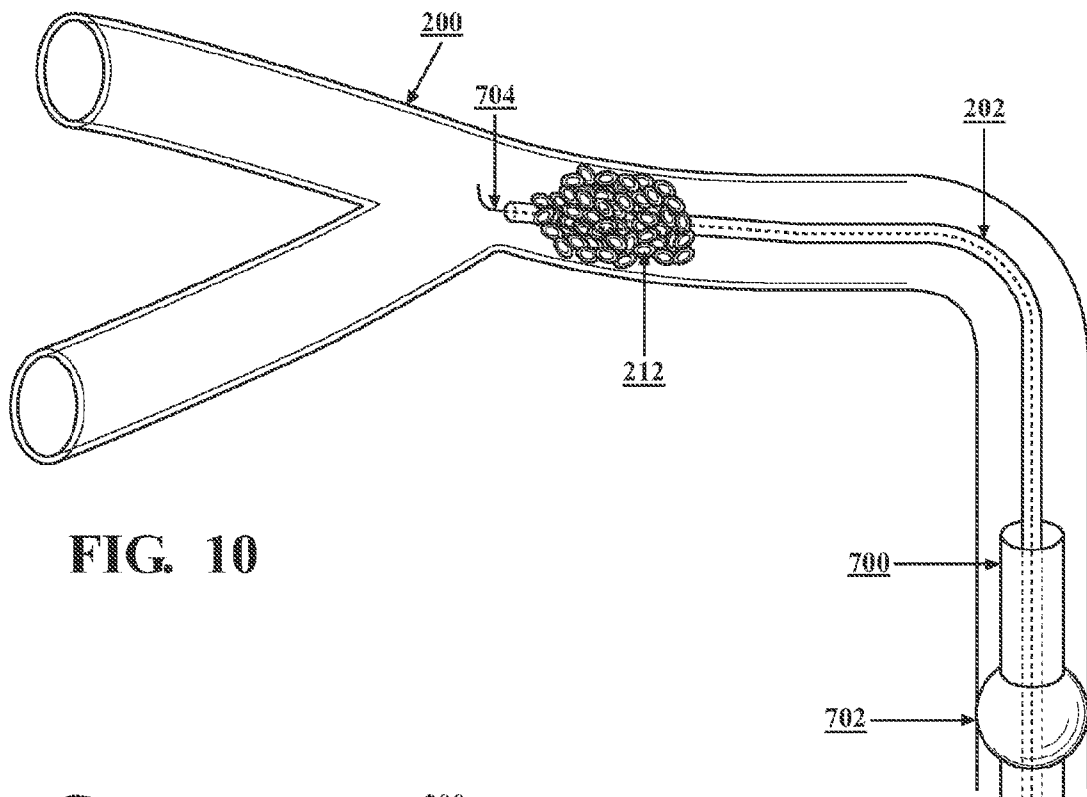


FIG. 7





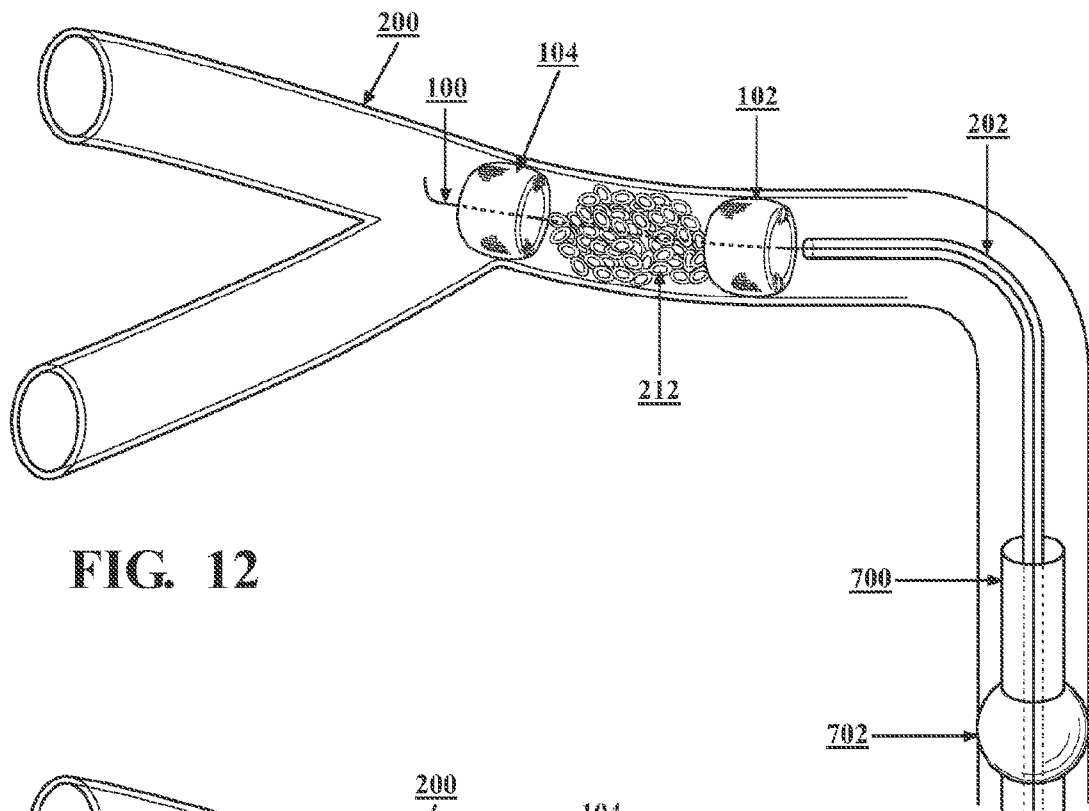


FIG. 12

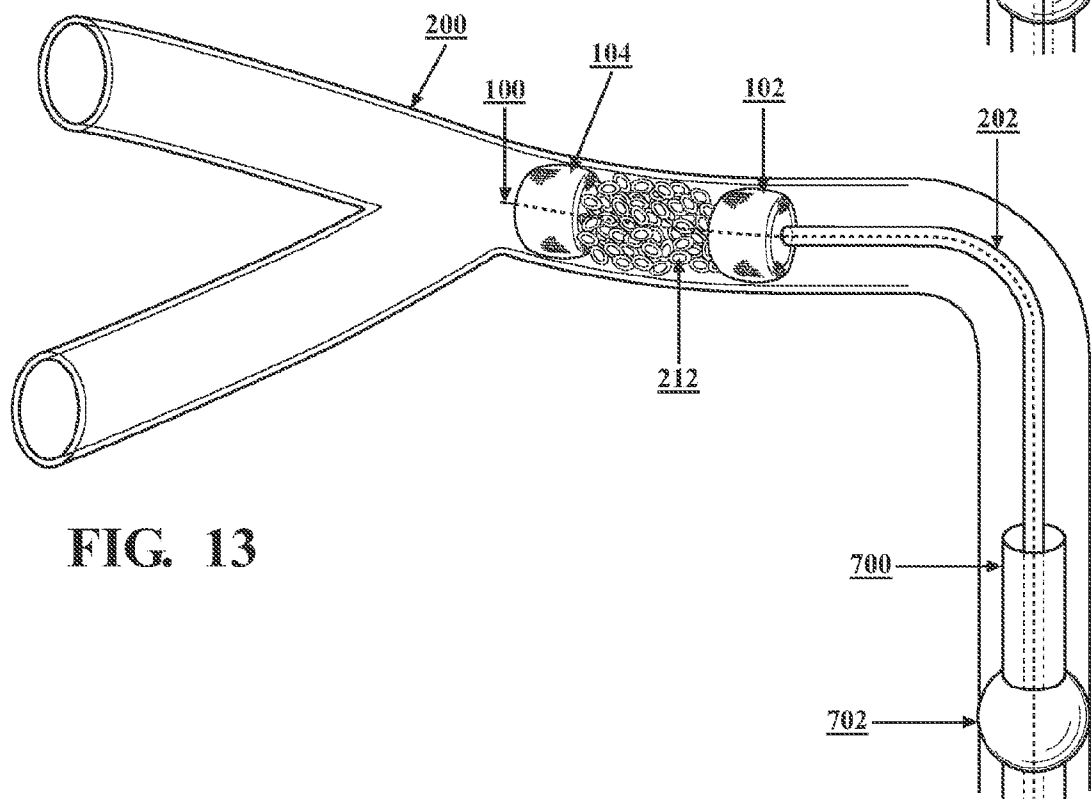
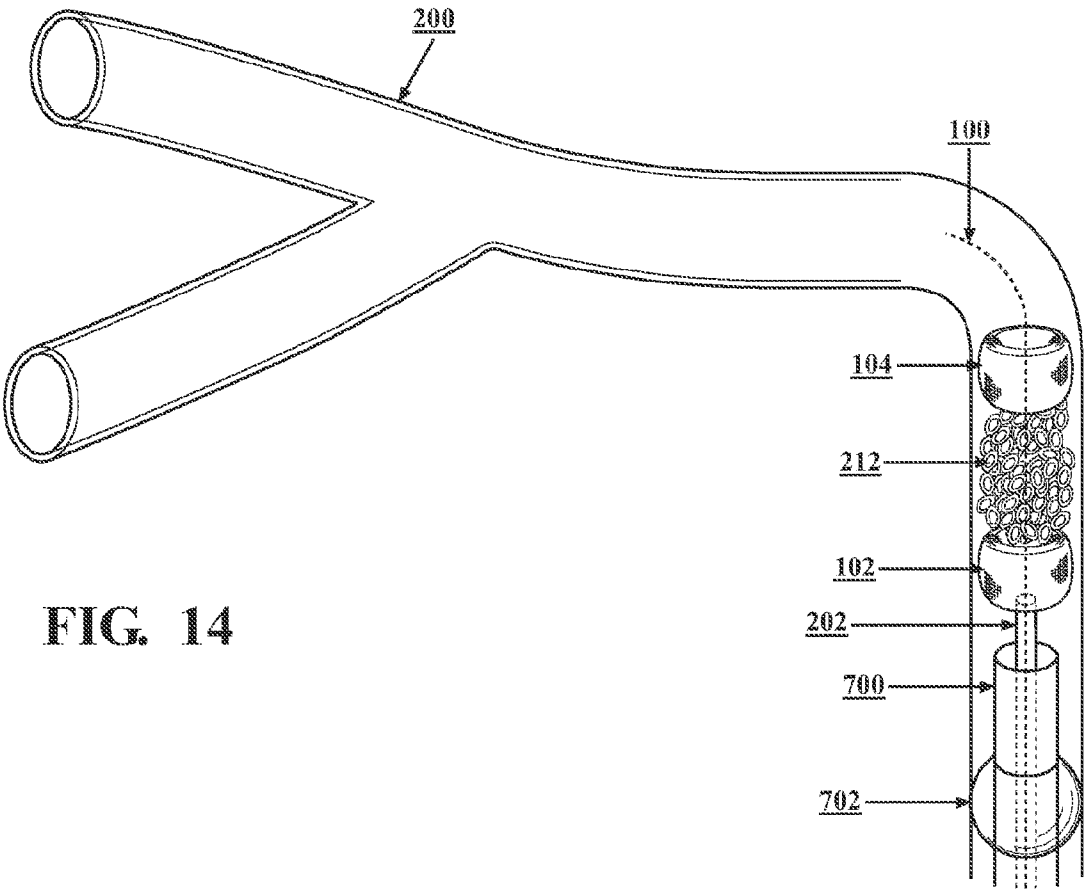
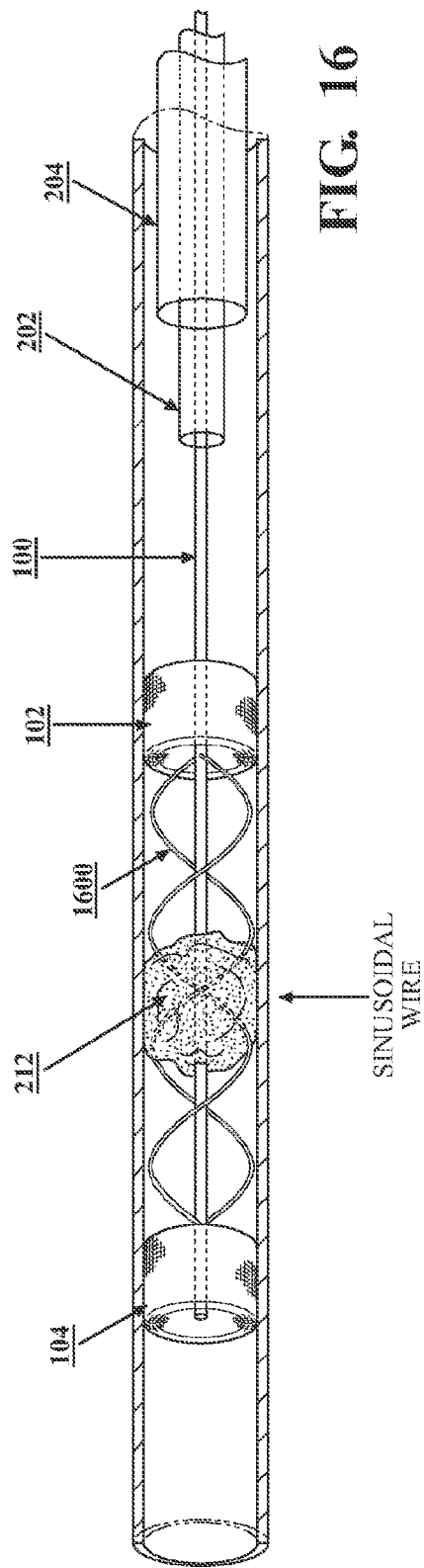
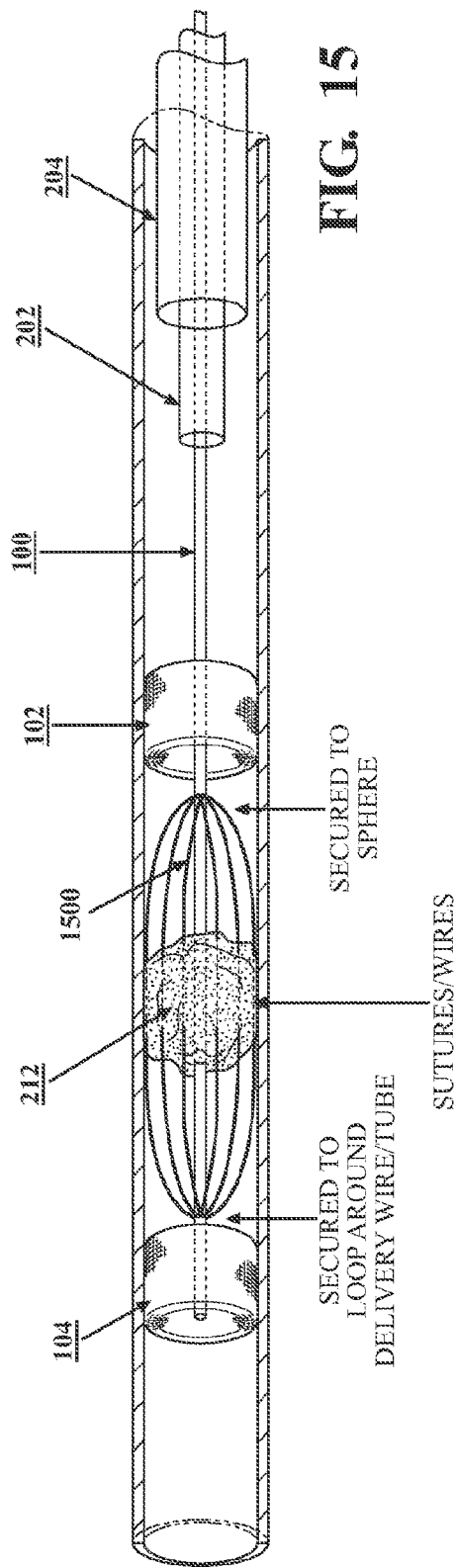
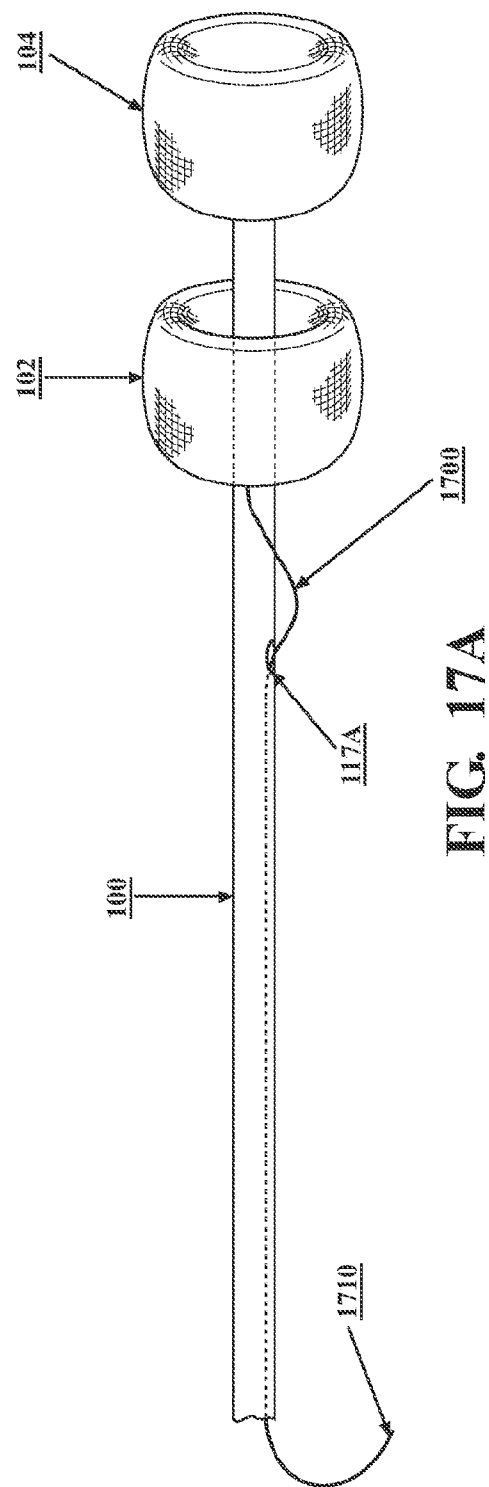


FIG. 13







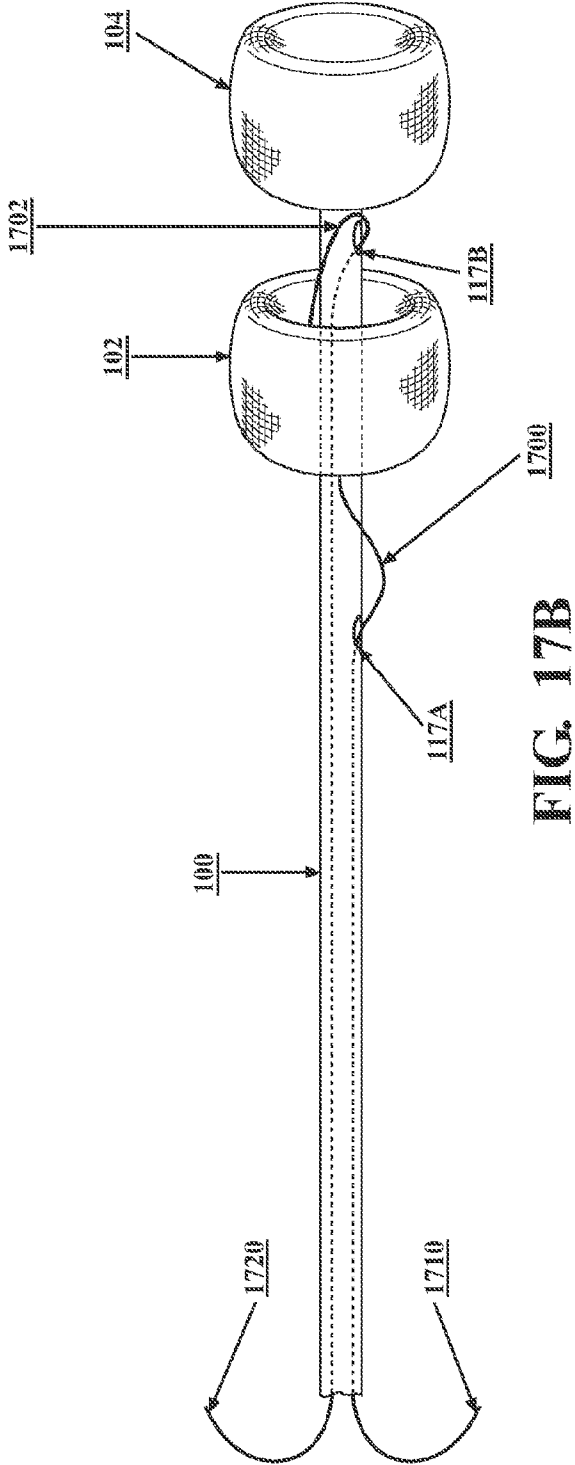


FIG. 17B

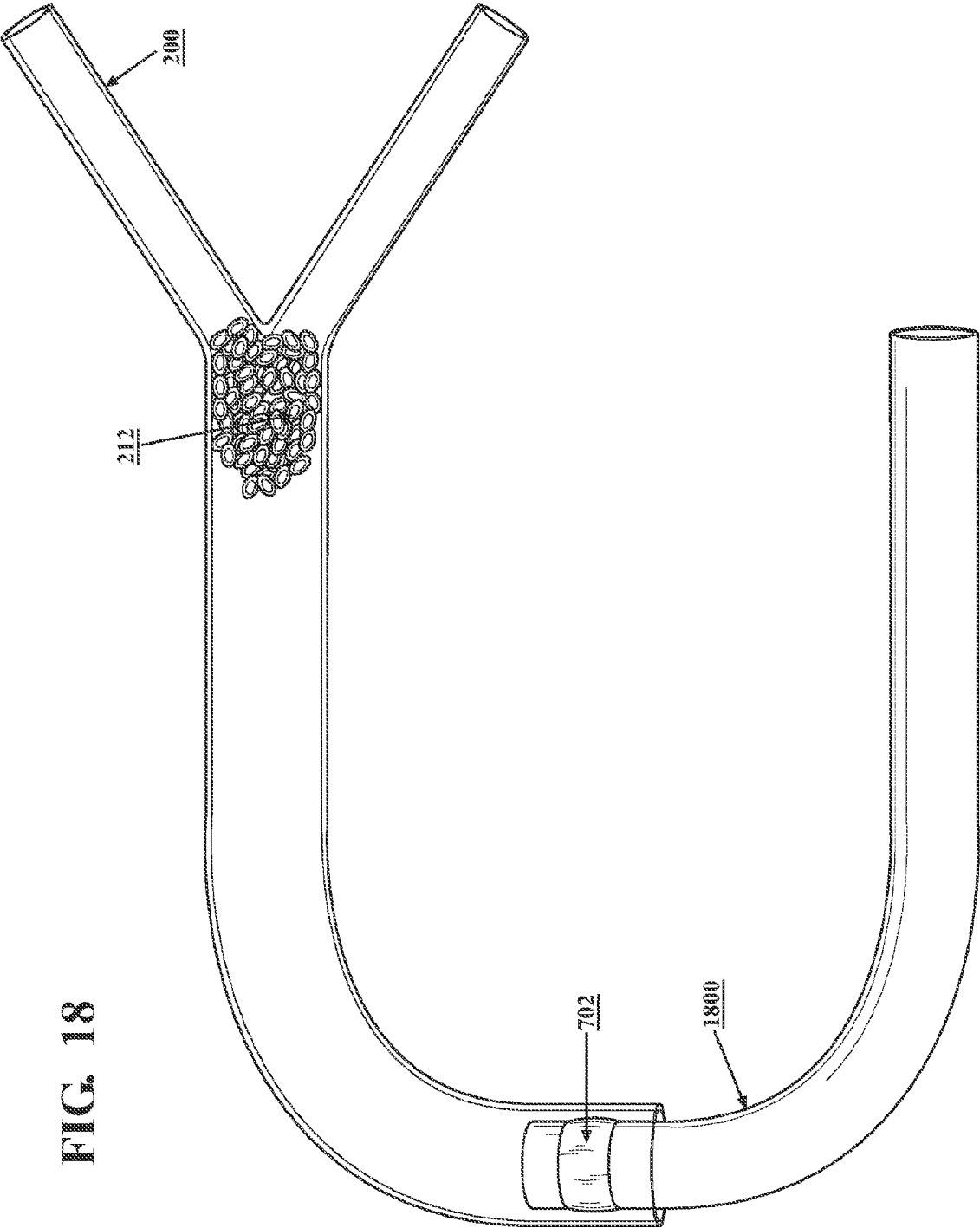


FIG. 19

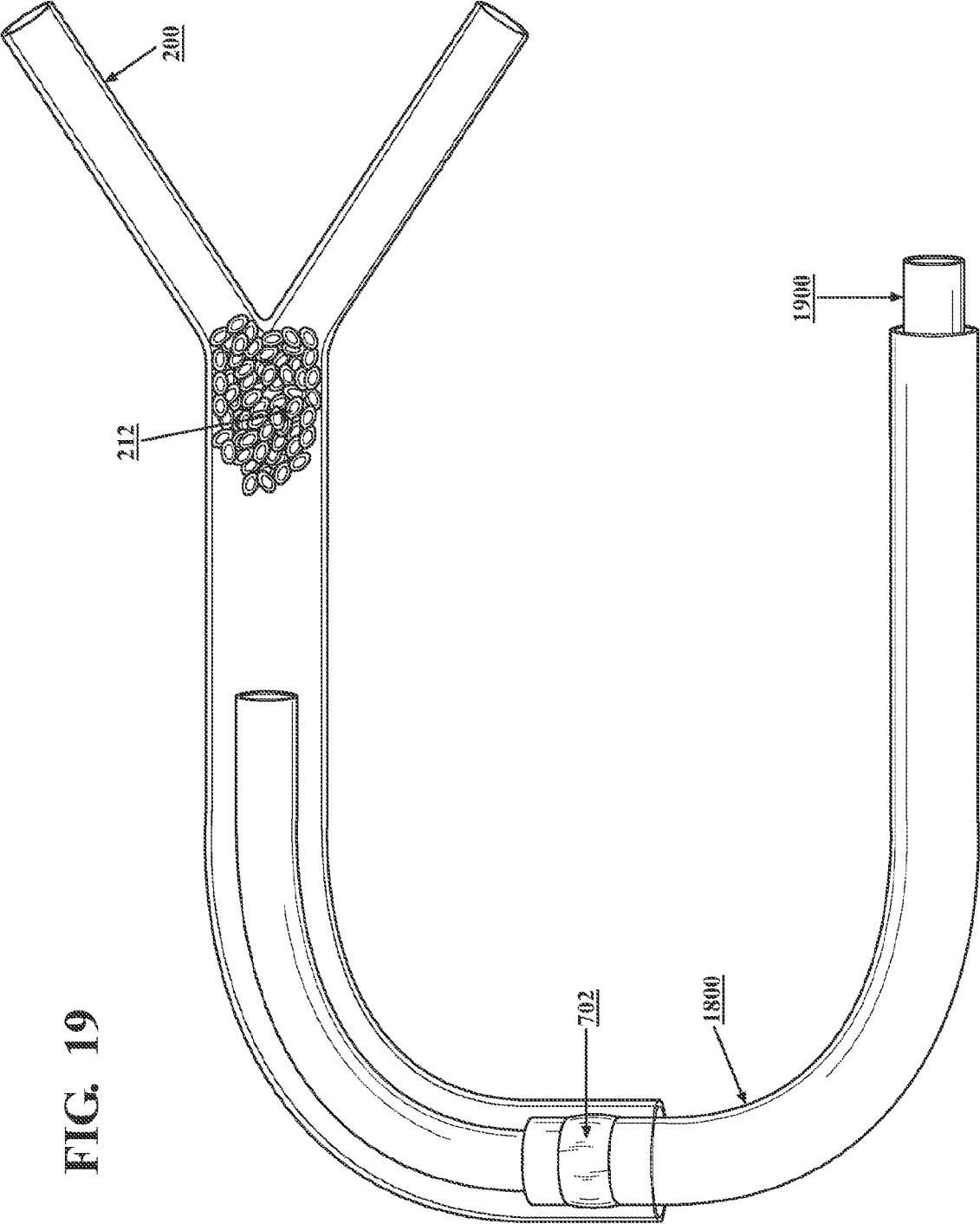


FIG. 20

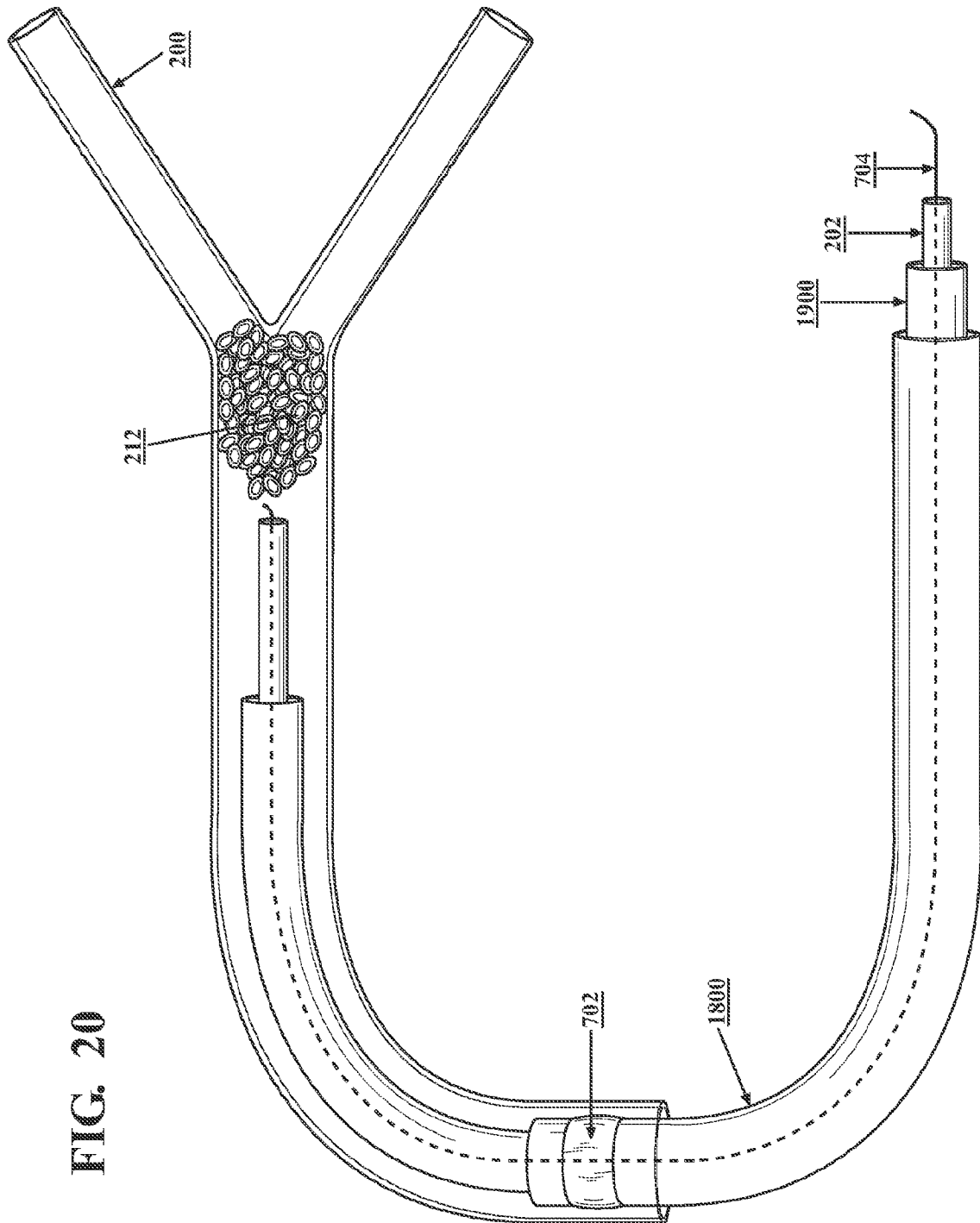


FIG. 21

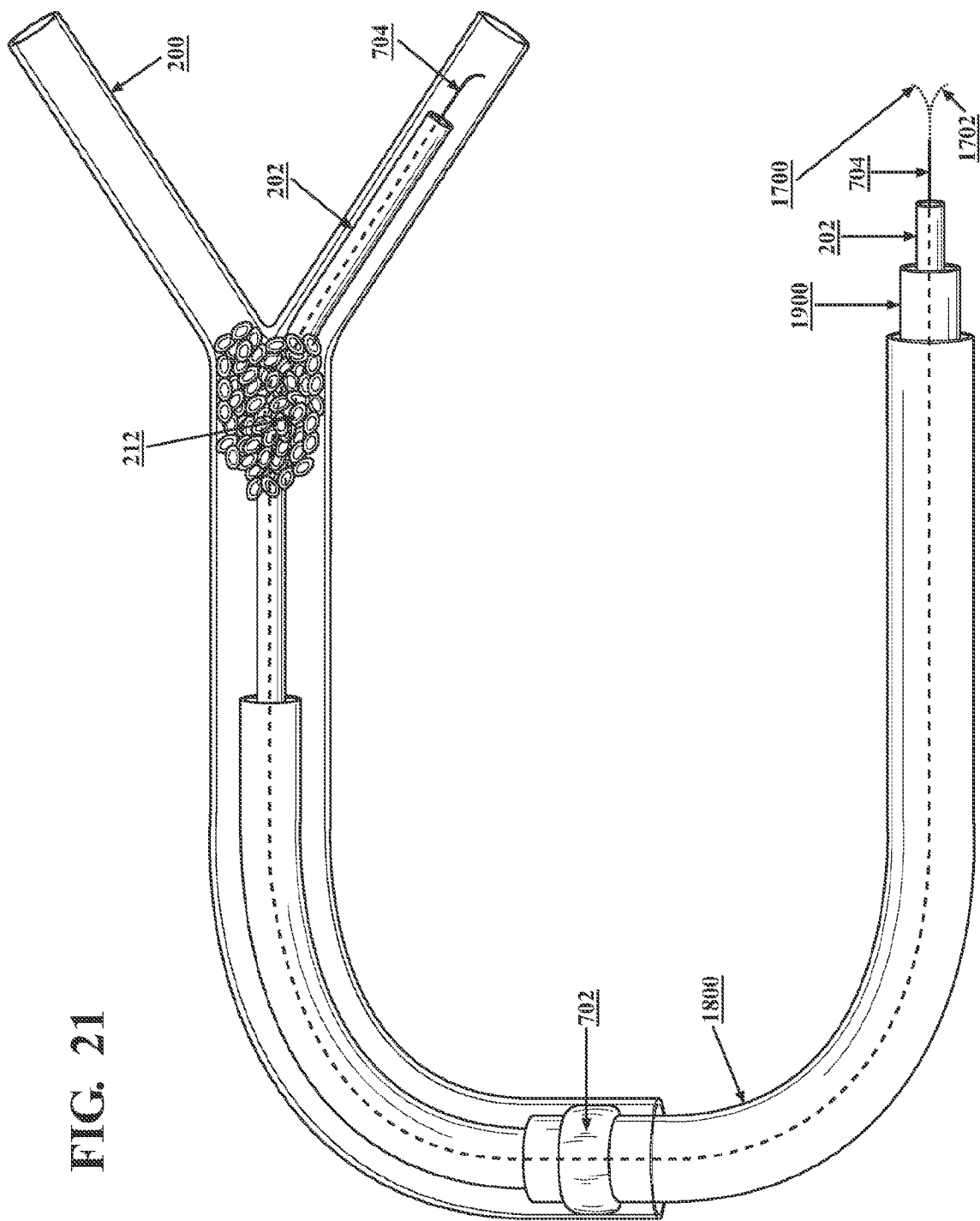
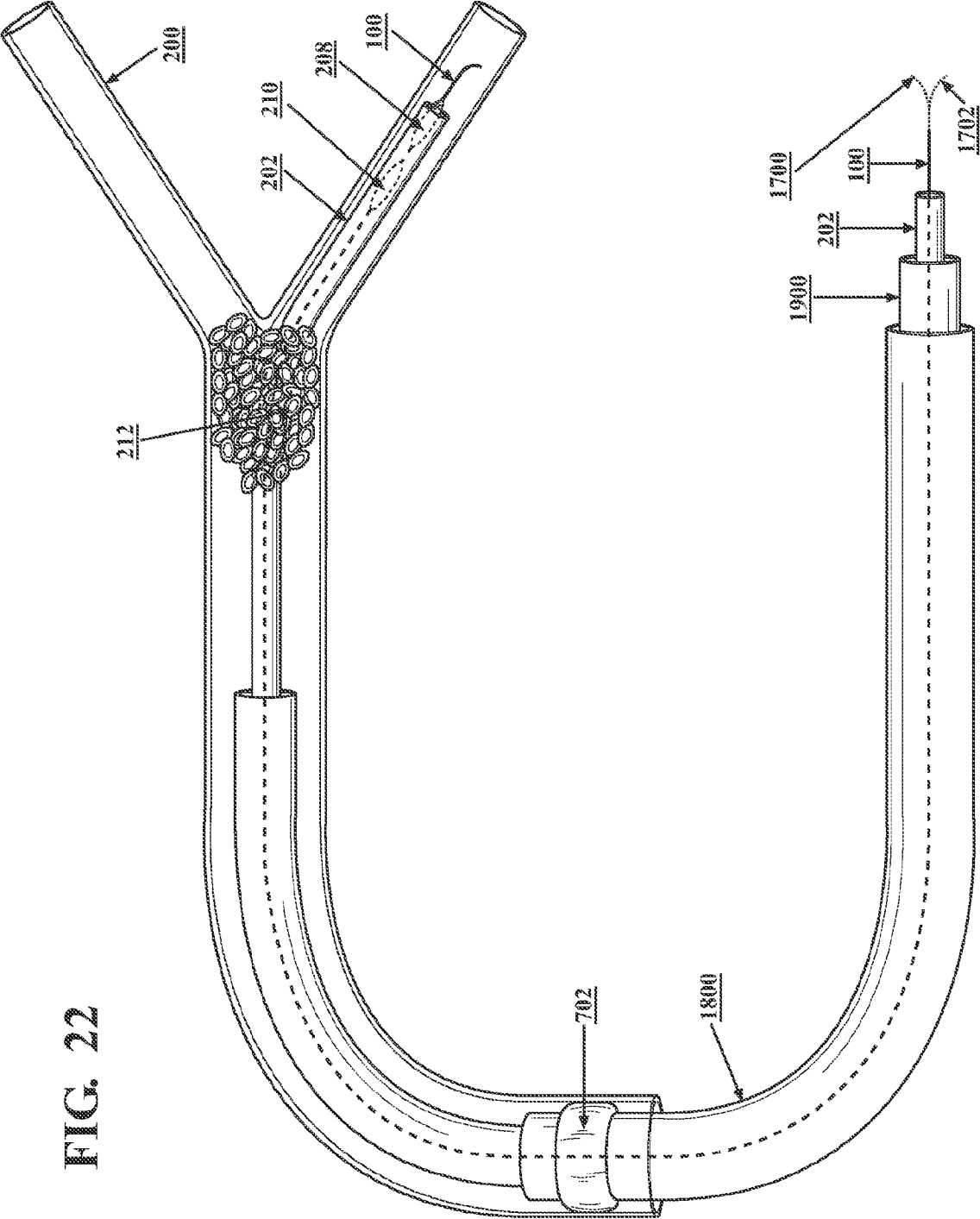


FIG. 22



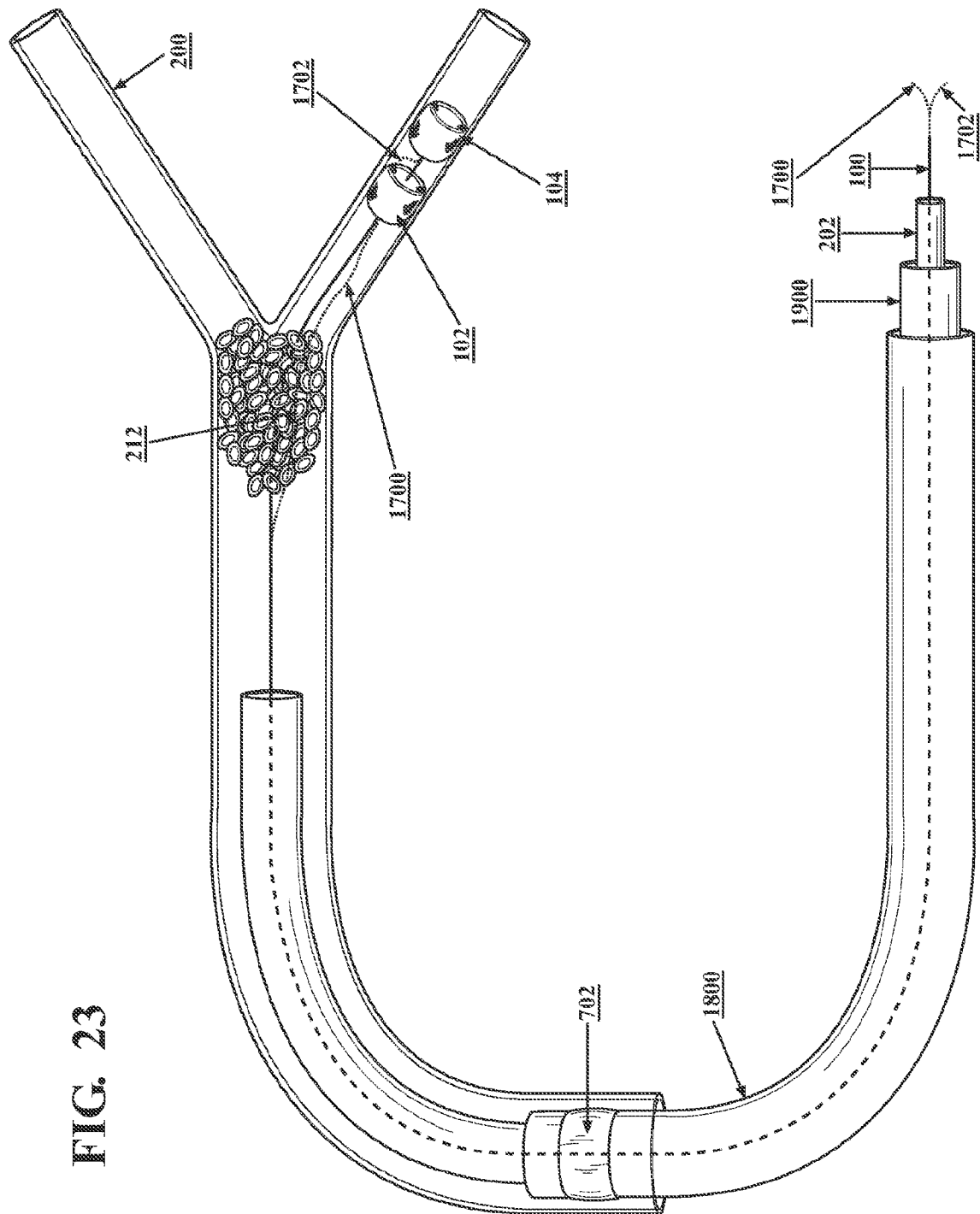
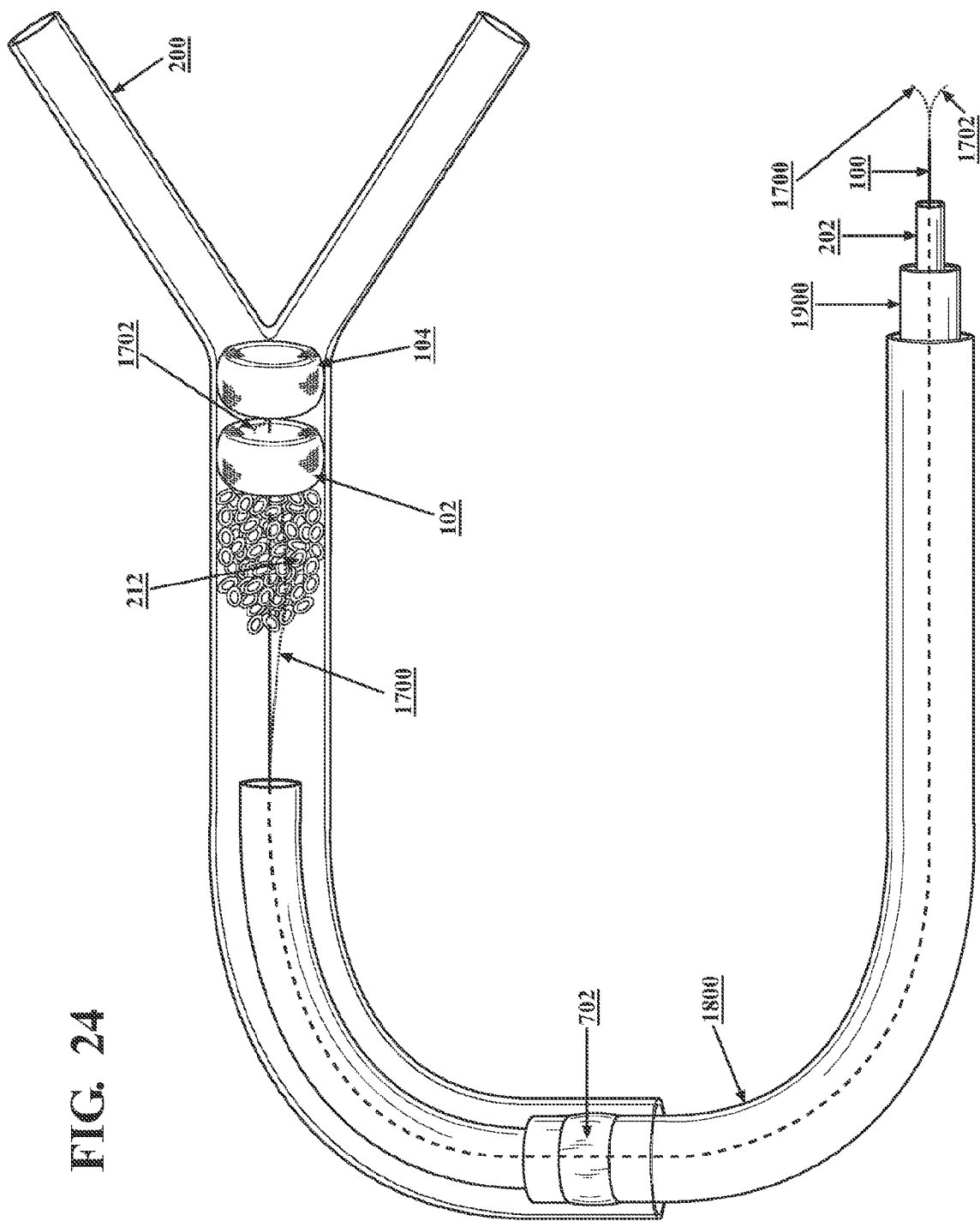


FIG. 23

FIG. 24



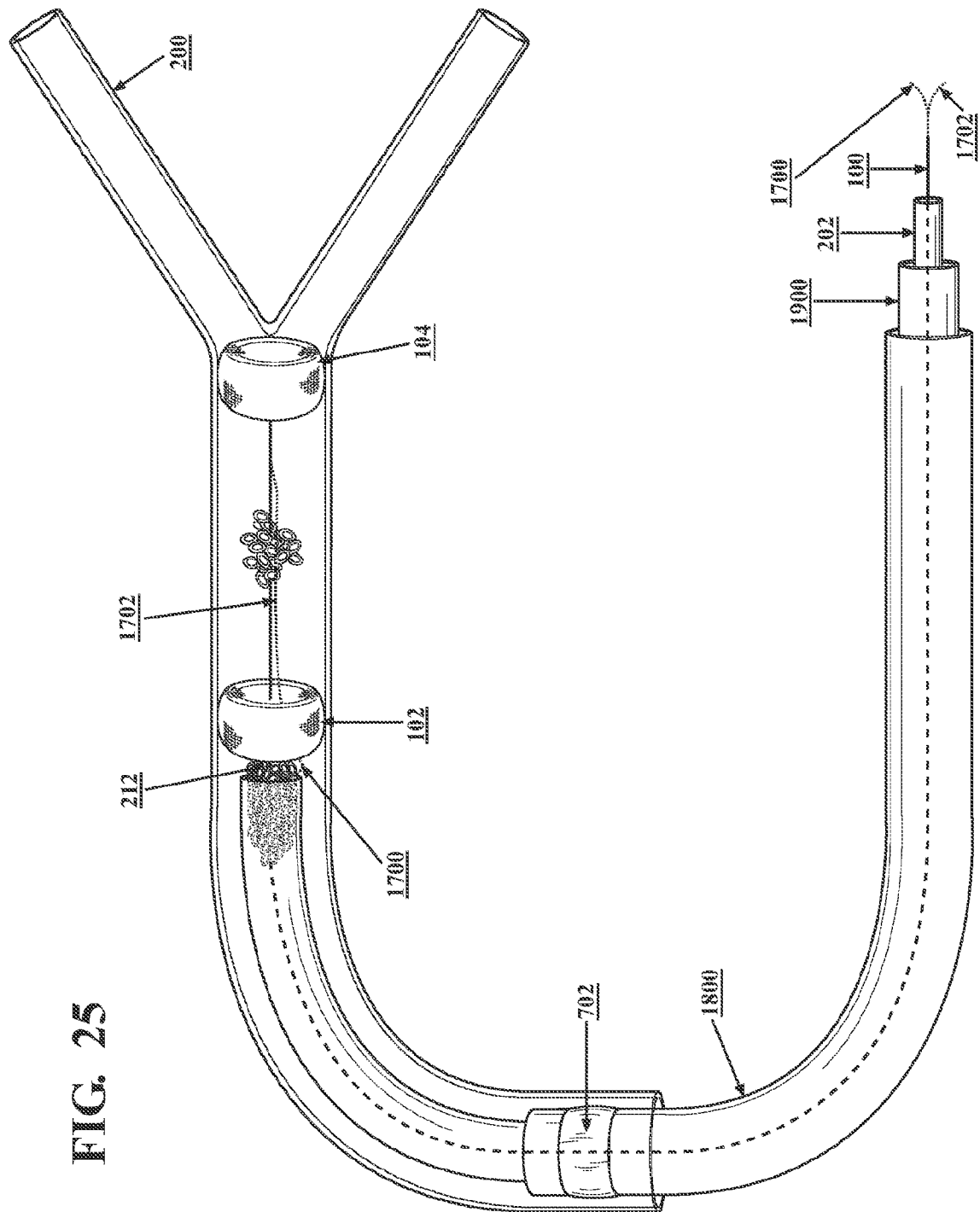
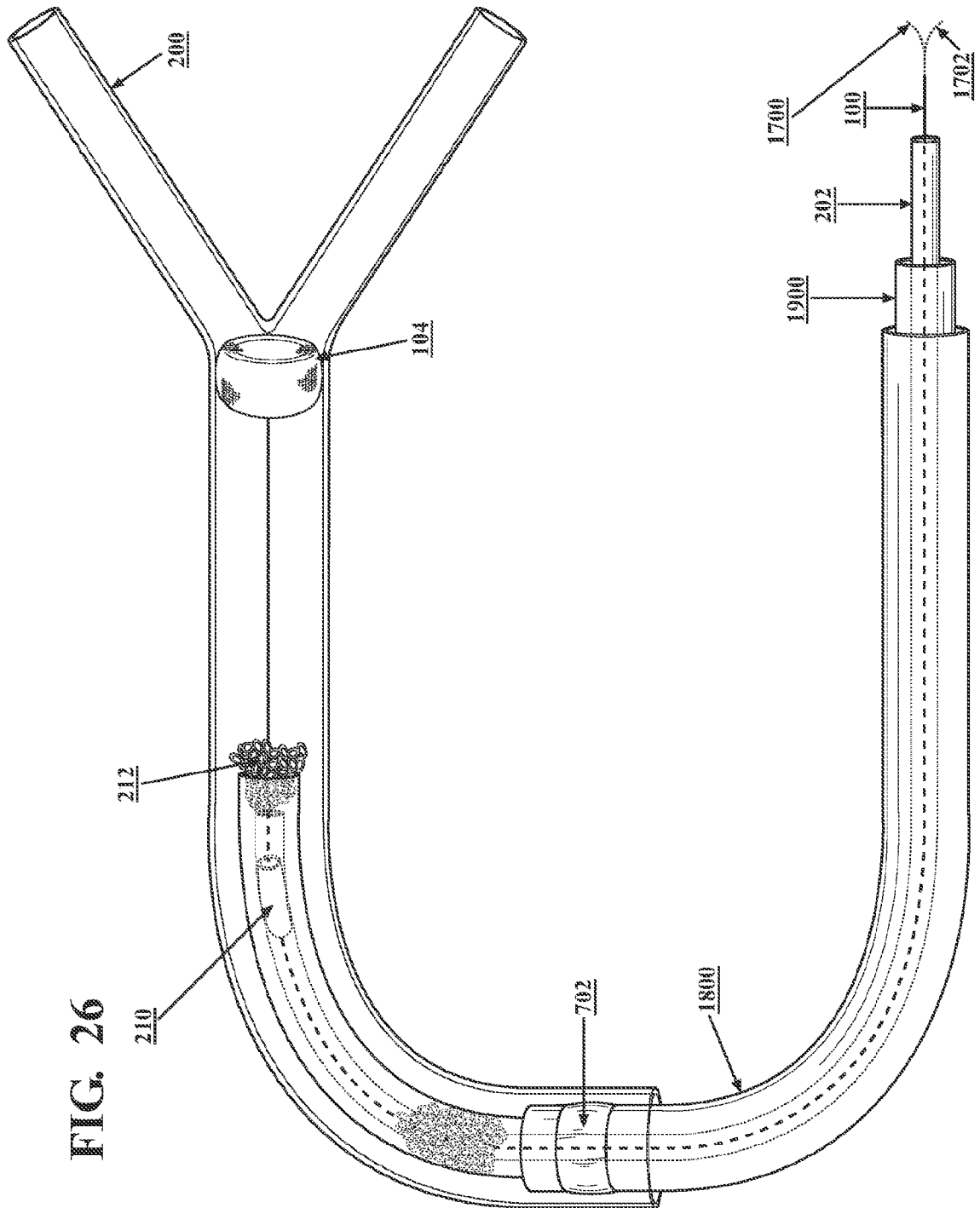
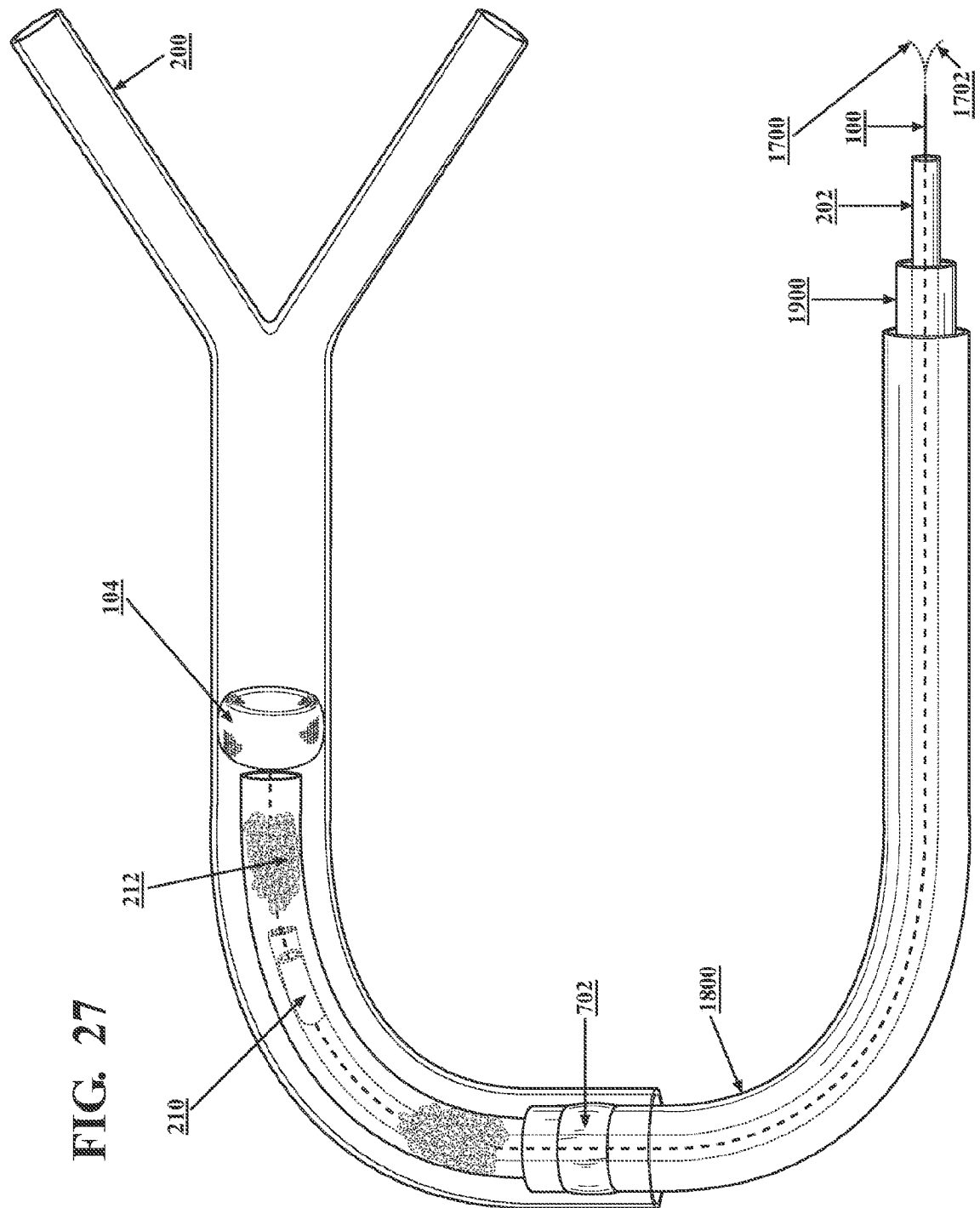


FIG. 26





INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/55606

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 17/22; A61B 17/00; A61B 17/221 (2019.01)

CPC - A61B 17/22; A61B 17/00; A61B 17/22031; A61B 17/221; A61B 2017/22034; A61B 2017/22035; A61B 2017/22072; A61B 2017/22074; A61M 25/0026; A61M 25/01

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)

See Search History Document

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

See Search History Document

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

See Search History Document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2015/0190155 A1 (LEGACY VENTURES LLC) 9 July 2015 (09.07.2015); entire document, especially para [0121]-[0123], [0162], [0173], and Fig. 10 and 15A-G.	1-25, 43-56
A	US 6,530,934 B1 (JACOBSEN et al.) 11 March 2003 (11.03.2003); especially col 3 ln 56 to col 4 ln 24, and Fig. 1-8.	1-24
A	US 2014/0276922 A1 (COOK MEDICAL TECHNOLOGIES LLC) 18 September 2014 (18.09.2014); especially para [0024], and Fig. 1.	43-52
A	US 7,645,290 B2 (LUCAS) 12 January 2010 (12.01.2010); especially col 3 ln 66 to col 4 ln 43, and Fig. 1-7.	53-56
A	US 2007/0156170 A1 (HANCOCK et al.) 5 July 2007 (05.07.2007); entire document.	1-25, 43-56
A	US 2014/0128905 A1 (COVIDIEN LP) 8 May 2014 (08.05.2014); entire document.	1-25, 43-56
A	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014); entire document.	1-25, 43-56
A	US 2017/0119408 A1 (NEUROVASC TECHNOLOGIES, INC.) 4 May 2017 (04.05.2017); entire document.	1-25, 43-56
A	US 2015/0112376 A1 (COVIDIEN LP) 23 April 2015 (23.04.2015); entire document.	1-25, 43-56
A	US 8,100,935 B2 (ROSENBLUTH et al.) 24 January 2012 (24.01.2012); entire document.	1-25, 43-56
A	US 2009/0105722 A1 (FULKERSON et al.) 23 April 2009 (23.04.2009); entire document.	1-25, 43-56

☐ 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

28 January 2019

Date of mailing of the international search report

14 FEB 2019

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-8300

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 18/55606

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.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-25 and 43-56 directed to an occlusion removal device having a releasable connection, a delivery catheter, and a guide catheter.

Group II: Claims 26-42 directed to an occlusion removal device having a delivery wire with a lengthwise cavity, and a first and second tether.

Group III: Claims 57-69 directed to an occlusion retrieval device having an incorporation structure.

-*- See Supplemental Box -*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-25, 43-56

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.

-* Box III.0 - Explanations where unity of invention is lacking -*

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of wherein the first body is releasably engaged to the delivery wire by an electrolytically disconnectable connection, the electrolytically disconnectable connection being broken upon an application of electric current to the electrolytically disconnectable connection, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a lengthwise cavity and a first opening to the lengthwise cavity, the opening being in the outer surface of the delivery wire, not required by the claims of Group I or III.

The invention of Group III includes the special technical feature of an incorporation structure between the first body and the second body, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of an occlusion removal device comprising a delivery wire, and a first body releasably engaged to said delivery wire and a second body mounted to said delivery wire. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2015/0190155 A1 (LEGACY VENTURES LLC) (hereinafter Legacy), which teaches an occlusion removal device (collectively Fig. 8; para [0121], [0123]; for removing obstructions like 12) comprising a delivery wire (16; Fig. 8), and a first body releasably engaged to said delivery wire (76; Fig. 8) and a second body mounted to said delivery wire (72; Fig. 8).

Groups I-II share the common technical feature of an occlusion removal device comprising a tether. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2005/0216050 A1 (SEPETKA et al.) (hereinafter Sepetka), which teaches an occlusion removal device (collectively Fig. 5-6; para [0084]-[0085]) comprising a tether (140; Fig. 5-6).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.