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(54) **SYSTEM AND METHOD FOR DELIVERING AND DEPLOYING AN OCCLUDING DEVICE WITHIN A VESSEL**

Publication Classification

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(57) **ABSTRACT**

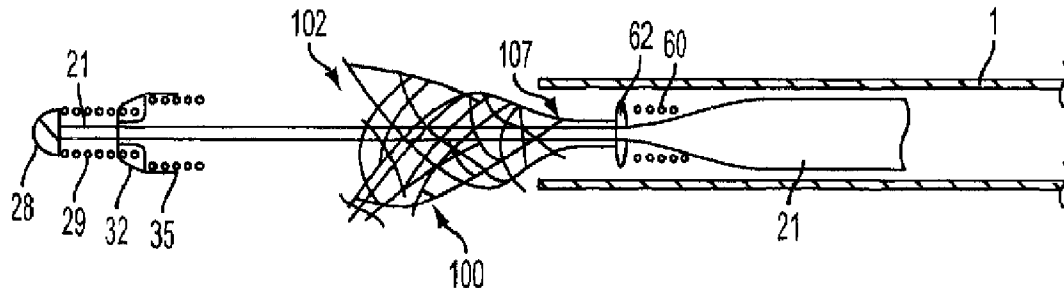
A system and method for deploying an occluding device that can be used to remodel an aneurysm within the vessel by, for example, neck reconstruction or balloon remodeling. The system comprises an introducer sheath and an assembly for carrying the occluding device. The assembly includes an elongated flexible member having an occluding device retaining member for receiving member for engaging a second end of the occluding device and a support surrounding a portion of the elongated flexible member over which the occluding device can be positioned. The elongated flexible member may be an integral portion formed thereof that form a coil portion.

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(22) Filed: **Aug. 28, 2012**

Related U.S. Application Data

(62) Division of application No. 12/426,560, filed on Apr. 20, 2009, now Pat. No. 8,273,101.



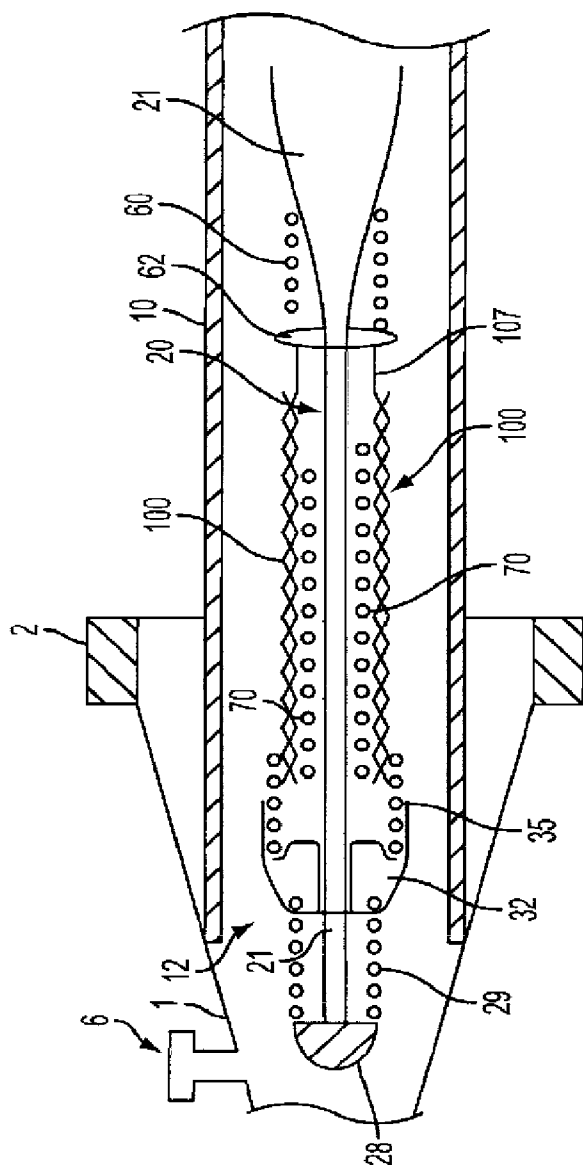


FIG. 1

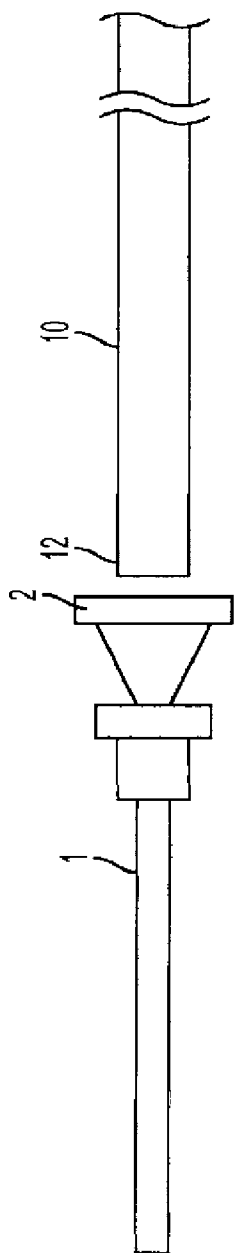


FIG. 2

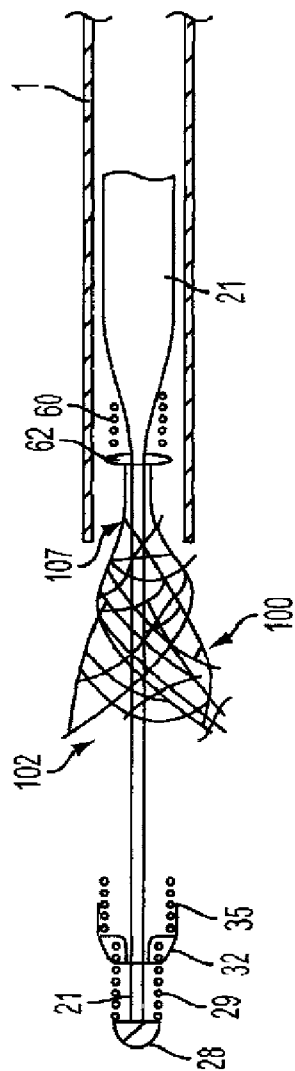


FIG. 9

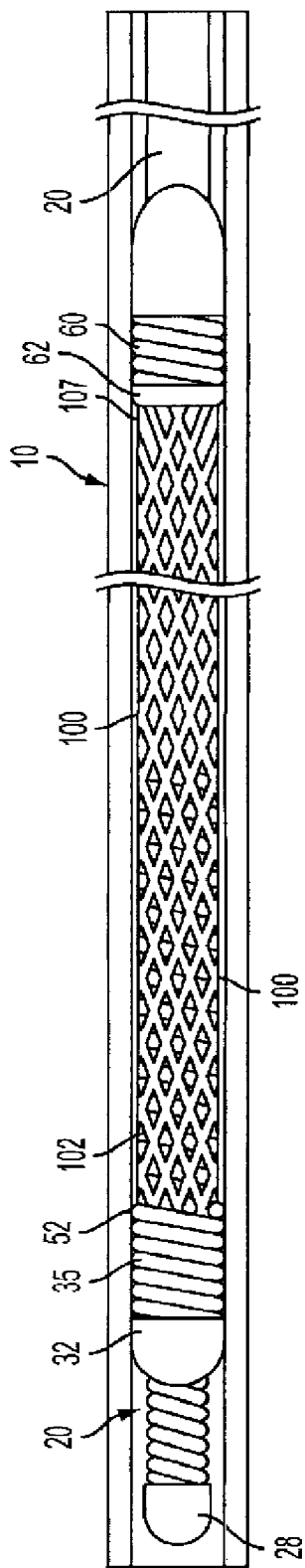
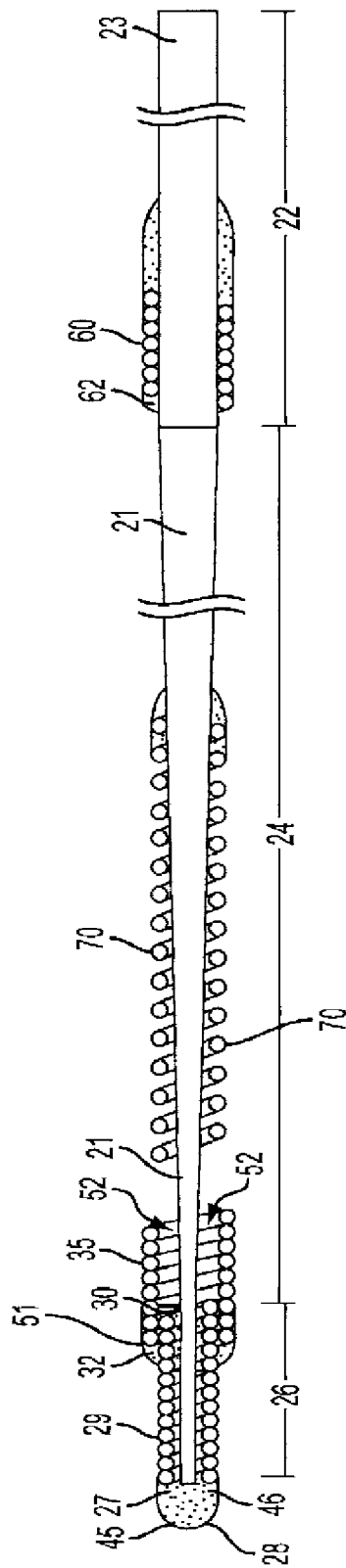


FIG. 3



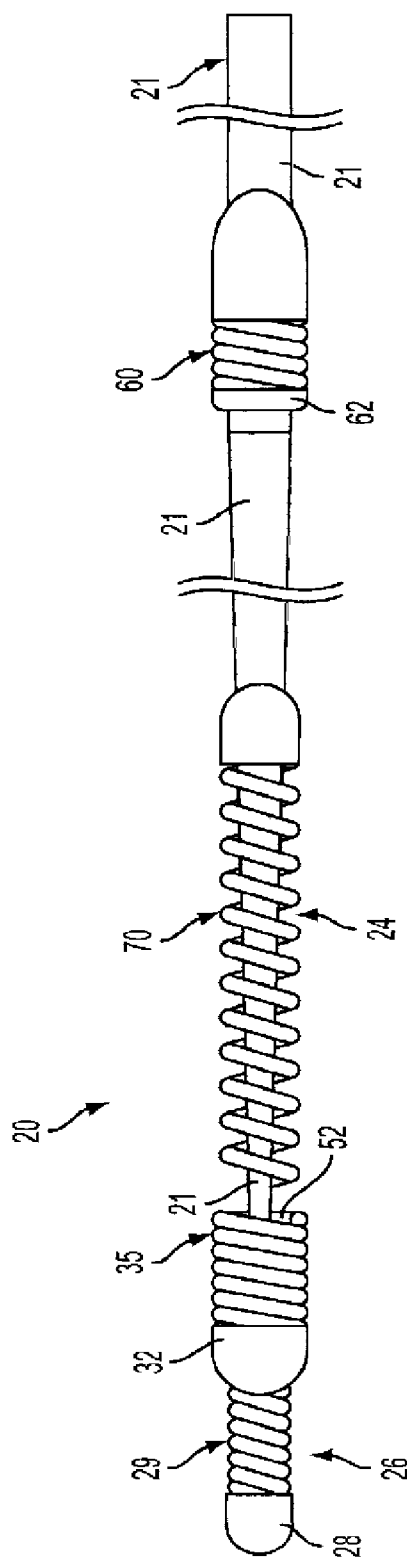


FIG. 5

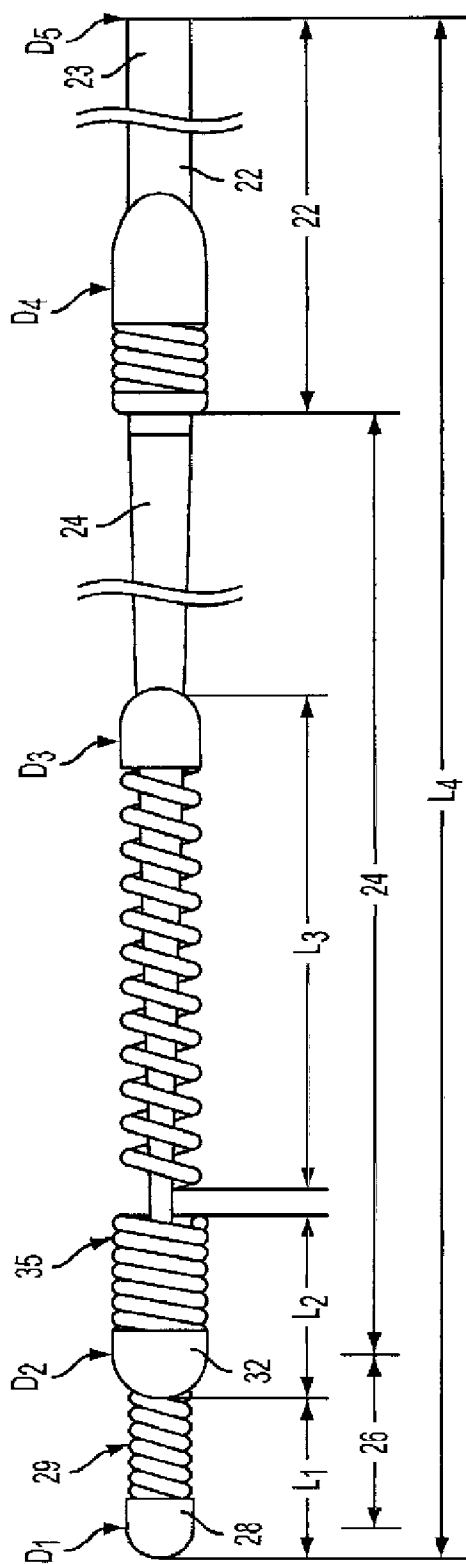


FIG. 6

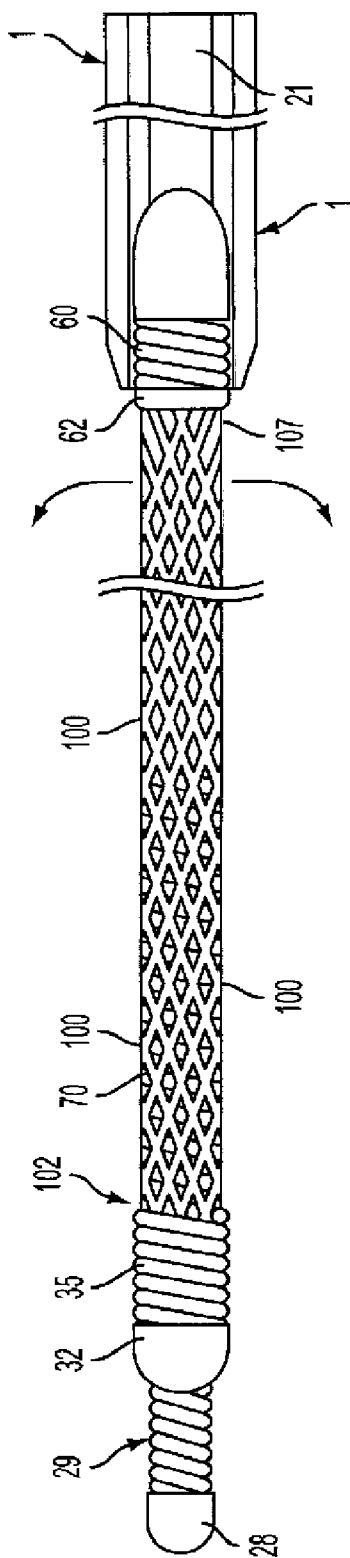


FIG. 7

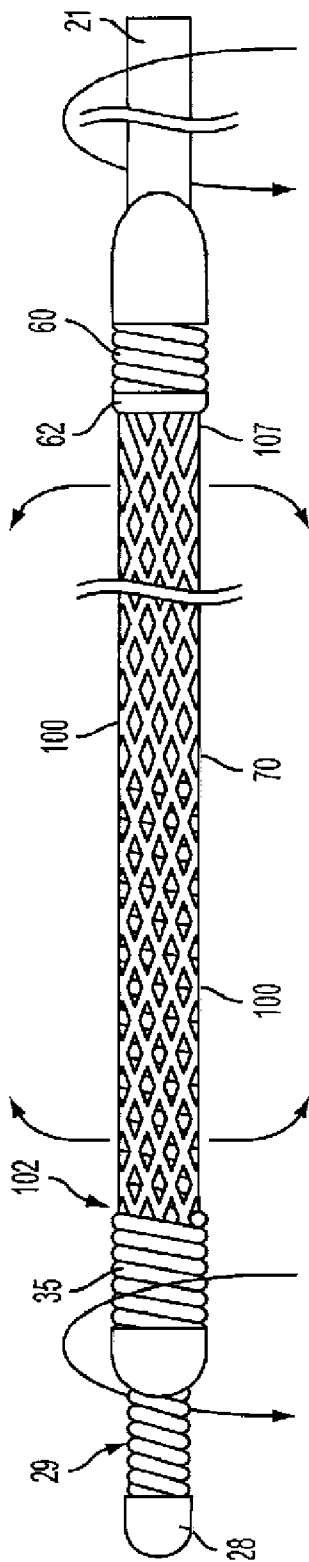


FIG. 8

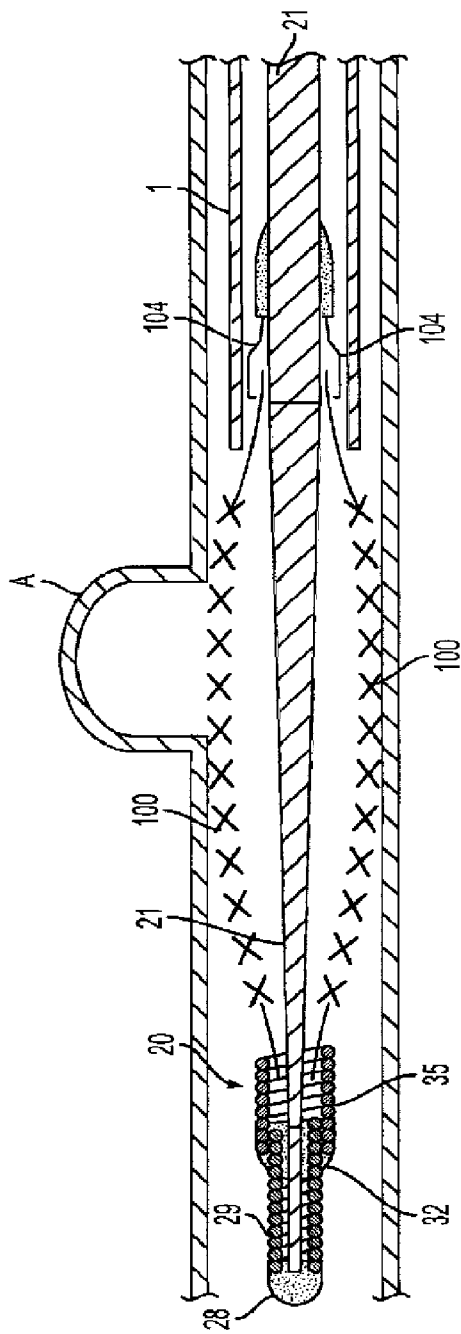


FIG. 10

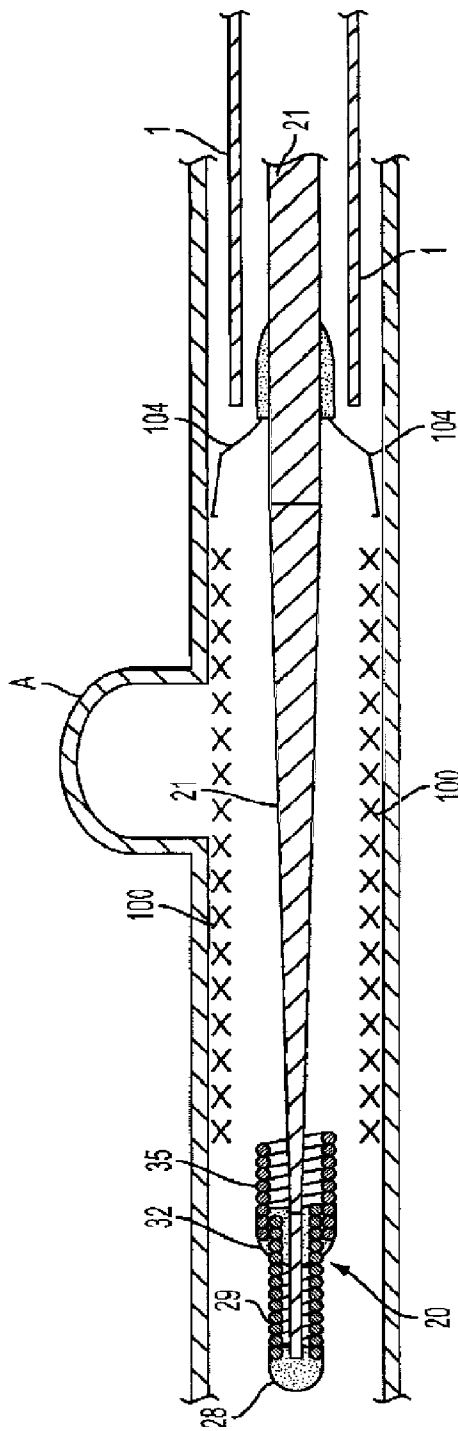


FIG. 11

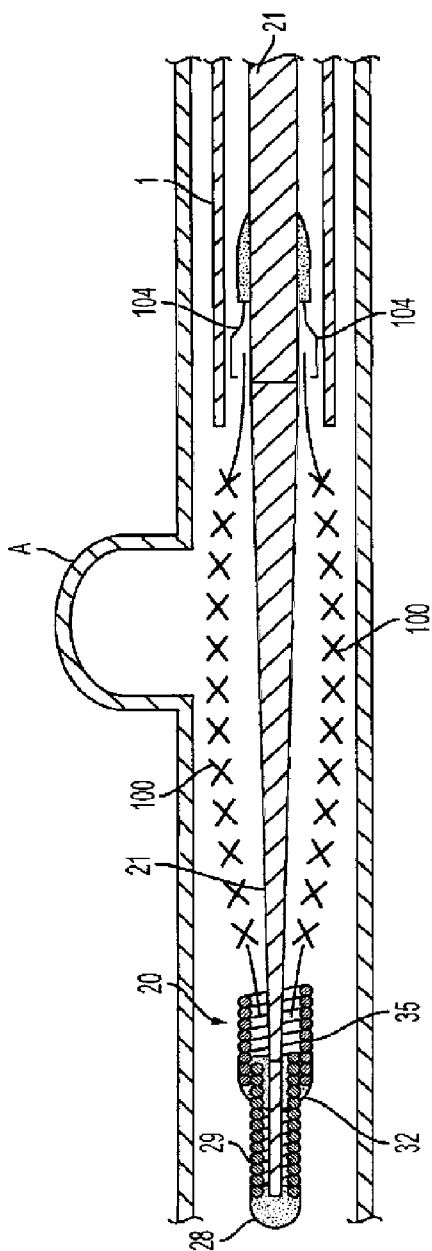


FIG. 12

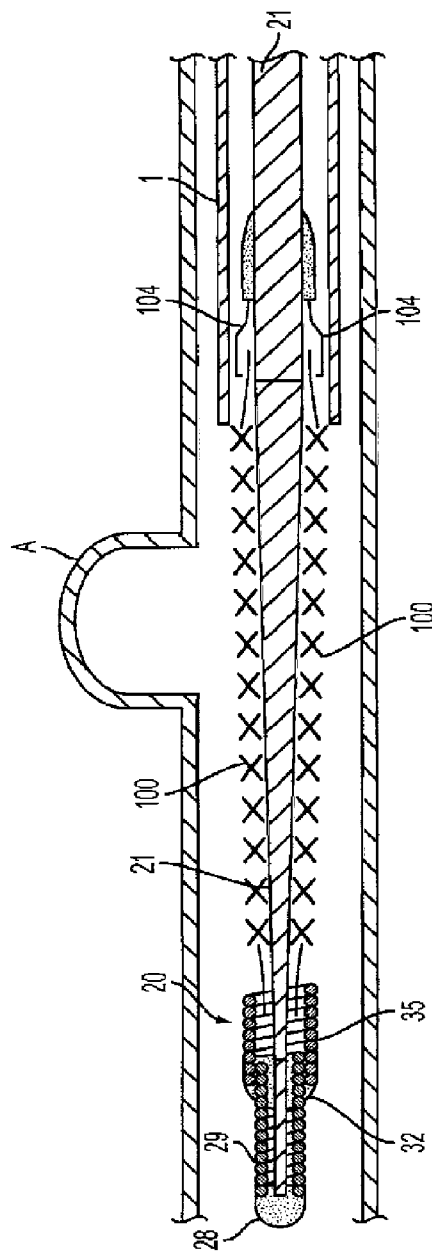


FIG. 13

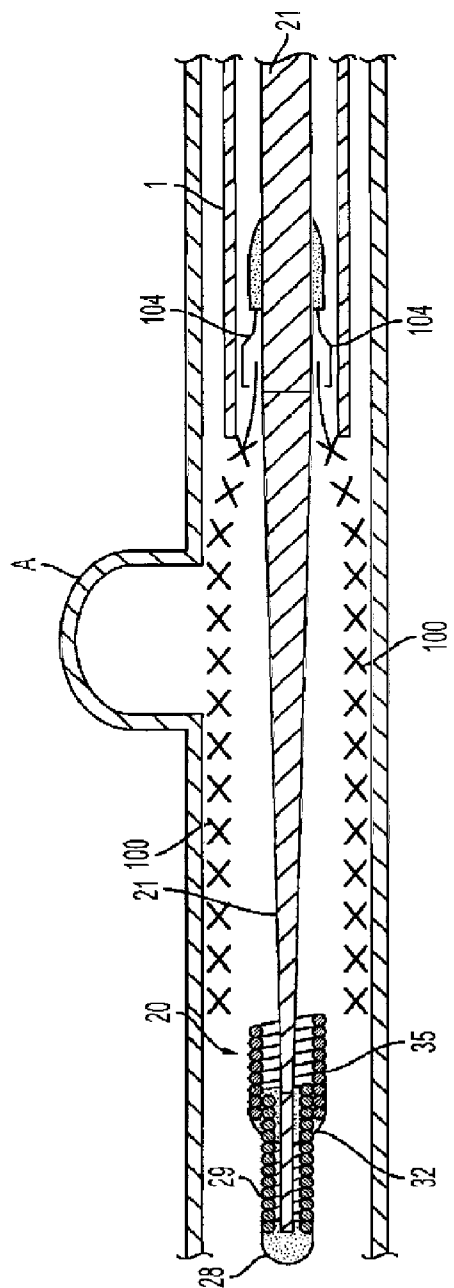


FIG. 14

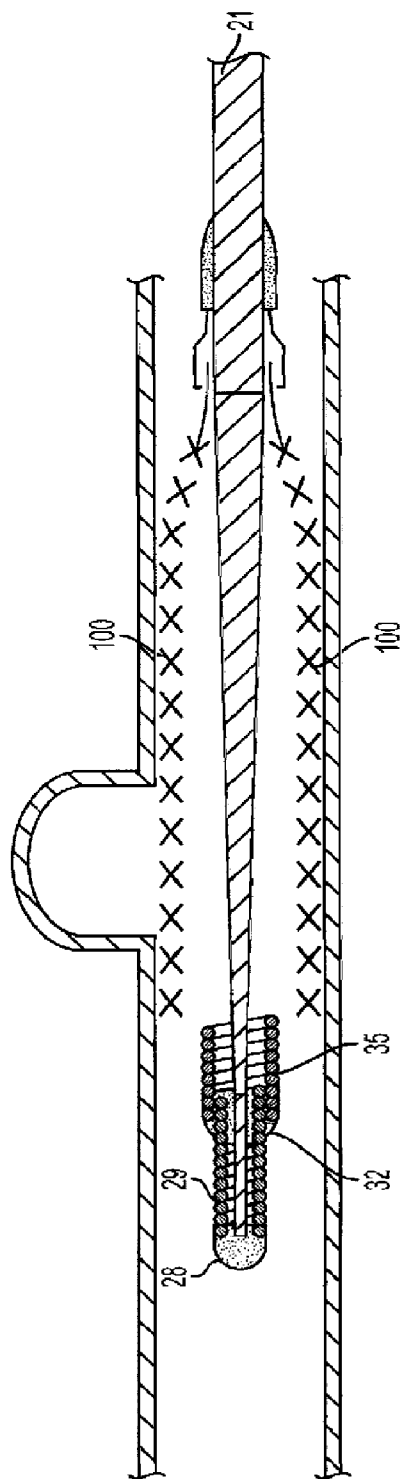


FIG. 15

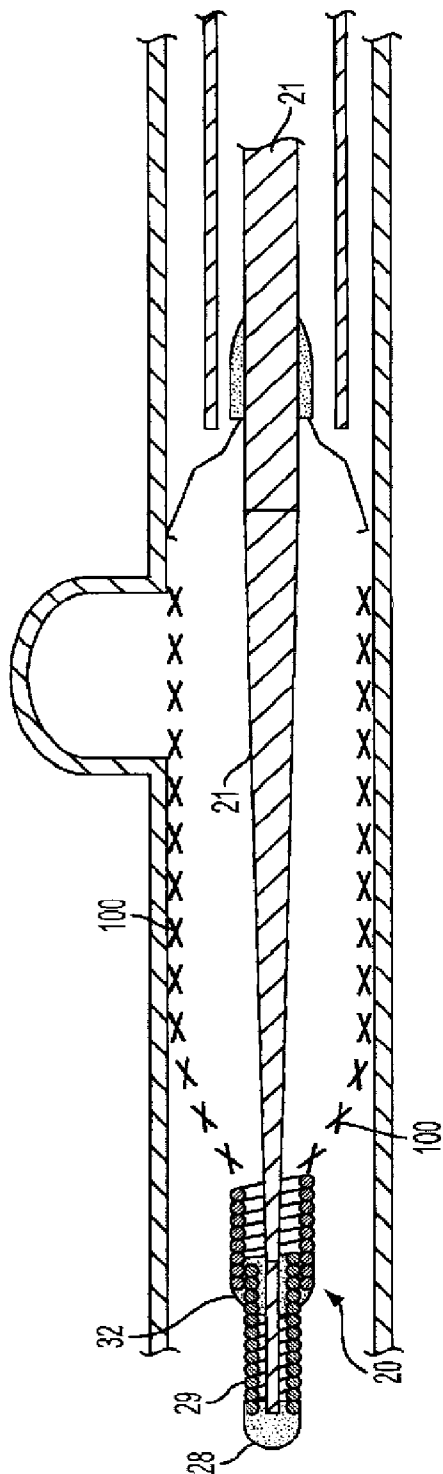


FIG. 16

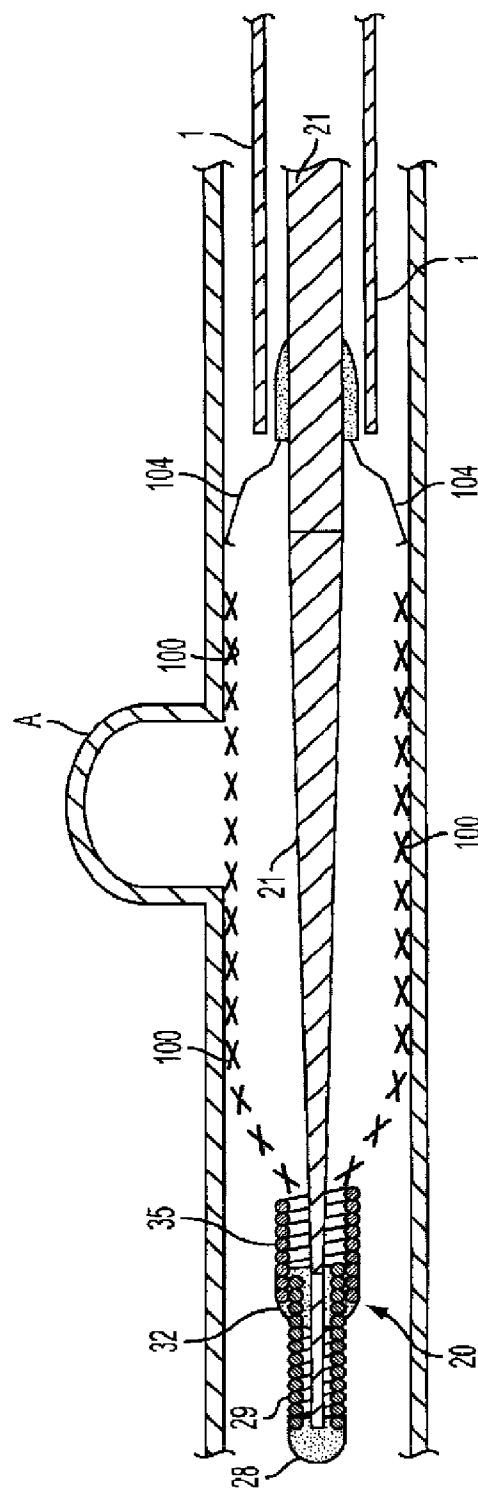


FIG. 17

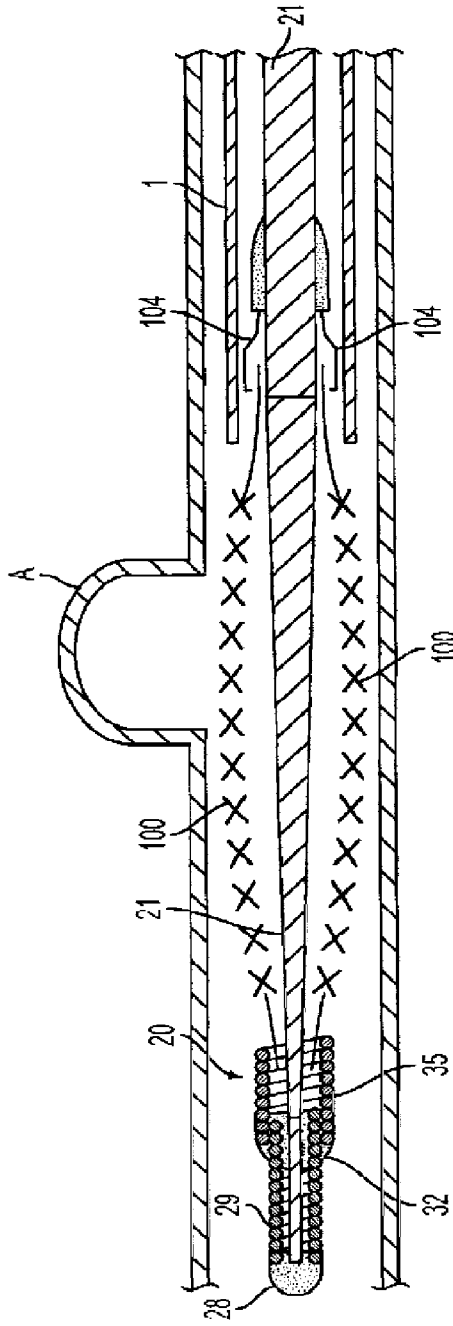


FIG. 18

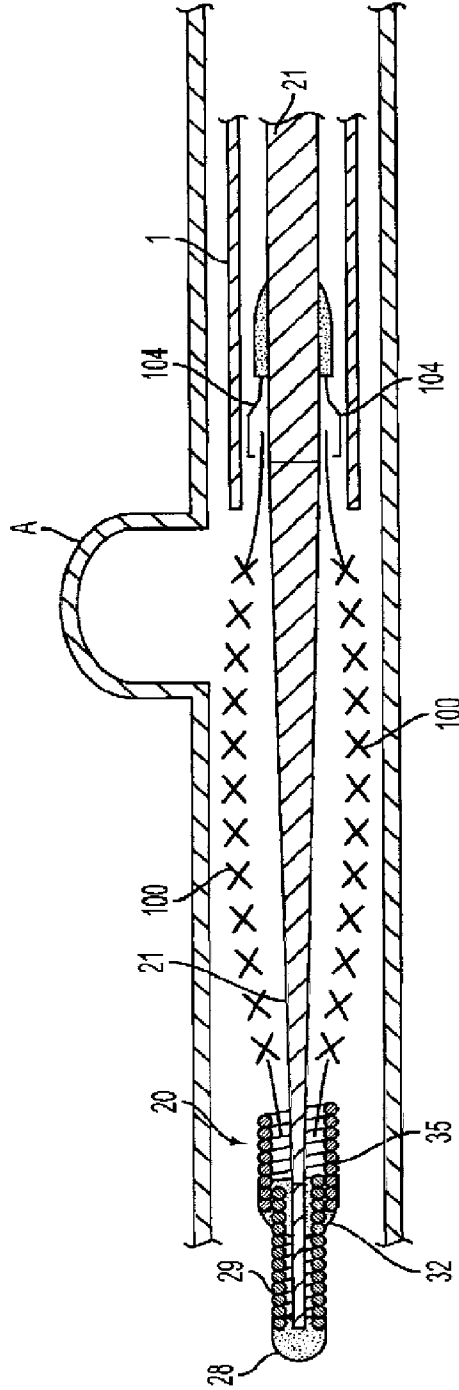


FIG. 19

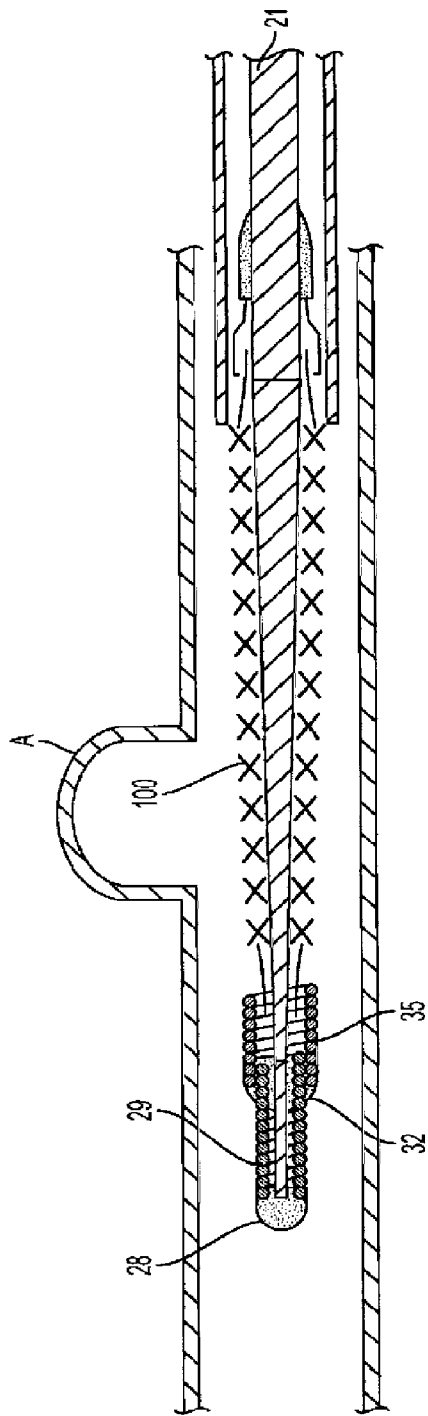


FIG. 20

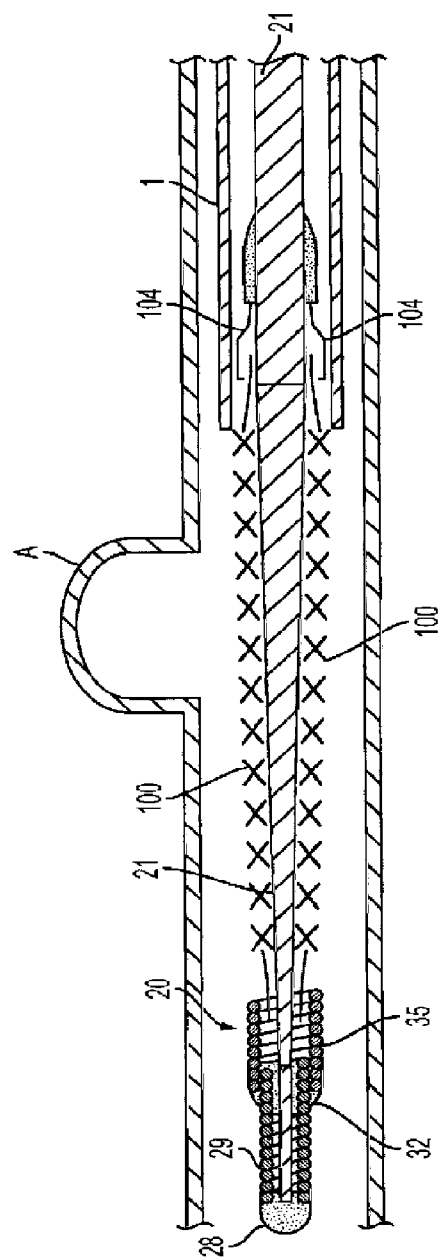


FIG. 21

FIG. 22

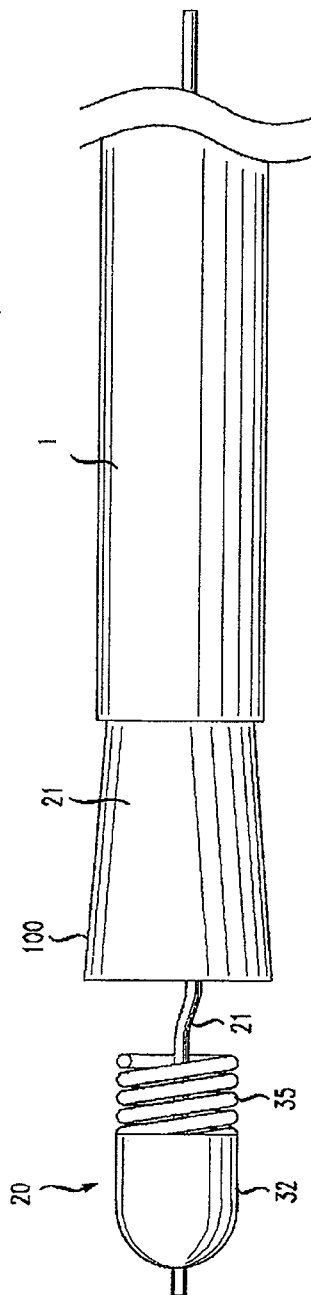


FIG. 23

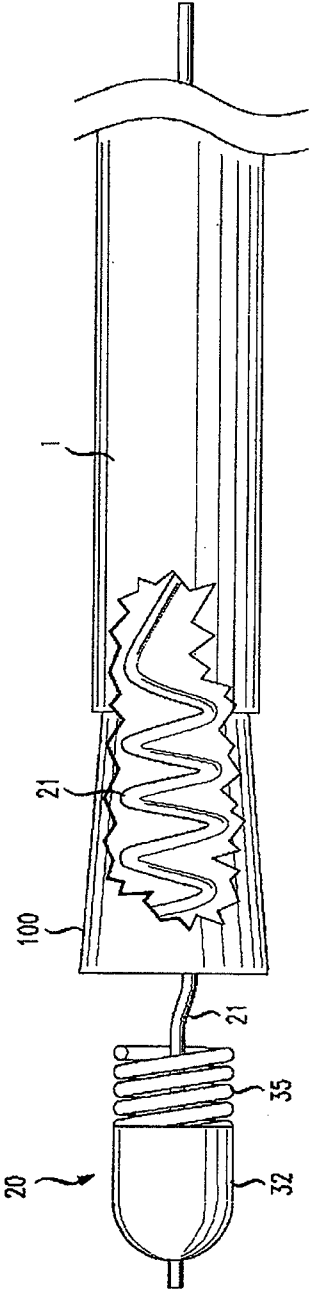


FIG. 24

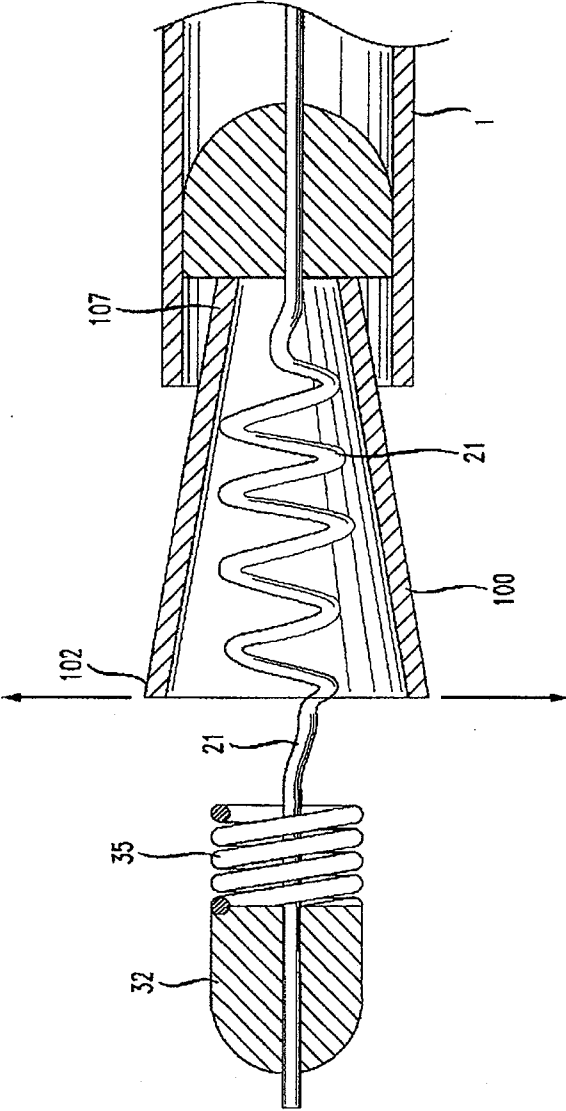
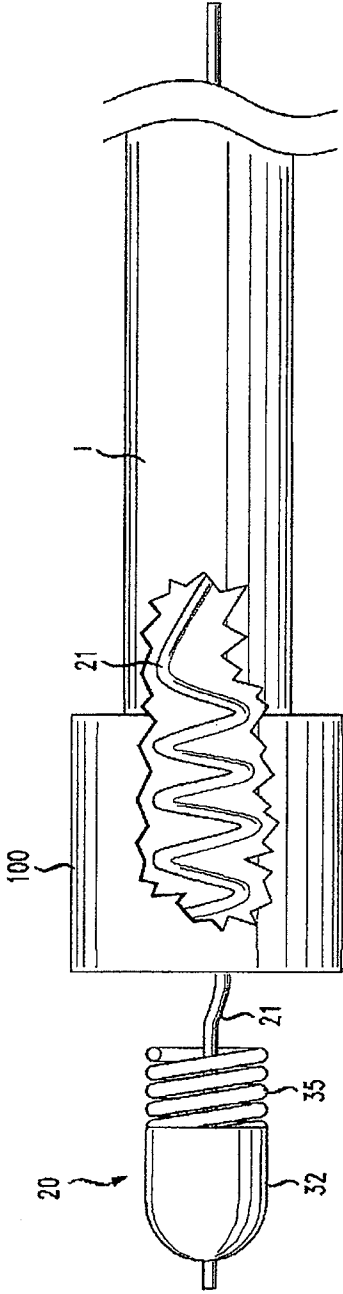


FIG. 25



SYSTEM AND METHOD FOR DELIVERING AND DEPLOYING AN OCCLUDING DEVICE WITHIN A VESSEL

[0001] This application is a divisional of U.S. application Ser. No. 12/426,560, filed Apr. 20, 2009, which is expressly incorporated herein by reference in its entirety.

FIELD OF THE INVENTION

[0002] The invention generally relates to a system and method for delivering and deploying a medical device within a vessel, more particularly, it relates to a system and method for delivering and deploying an endoluminal therapeutic device within the vasculature of a patient to embolize and occlude aneurysms, particularly cerebral aneurysms.

BACKGROUND ART OF THE INVENTION

[0003] Walls of the vasculature, particularly arterial walls, may develop areas of pathological dilatation called aneurysms. As is well known, aneurysms have thin, weak walls that are prone to rupturing. Aneurysms can be the result of the vessel wall being weakened by disease, injury or a congenital abnormality. Aneurysms could be found in different parts of the body with the most common being abdominal aortic aneurysms and brain or cerebral aneurysms in the neurovasculature. When the weakened wall of an aneurysm ruptures, it can result in death, especially if it is a cerebral aneurysm that ruptures.

[0004] Aneurysms are generally treated by excluding the weakened part of the vessel from the arterial circulation. For treating a cerebral aneurysm, such reinforcement is done in many ways including: (i) surgical clipping, where a metal clip is secured around the base of the aneurysm; (ii) packing the aneurysm with small, flexible wire coils (micro-coils); (iii) using embolic materials to “fill” an aneurysm; (iv) using detachable balloons or coils to occlude the parent vessel that supplies the aneurysm; and (v) intravascular stenting.

[0005] Intravascular stents are known in the medical arts for the treatment of vascular stenoses or aneurysms. Stents are prostheses that expand radially or otherwise within a vessel or lumen to provide support against the collapse of the vessel.

[0006] In conventional methods of introducing a compressed stent into a vessel and positioning it within an area of stenosis or an aneurysm, a guiding catheter having a distal tip is percutaneously introduced into the vascular system of a patient. The guiding catheter is advanced within the vessel until its distal tip is proximate the stenosis or aneurysm. A guidewire positioned within an inner lumen of a second, inner catheter and the inner catheter are advanced through the distal end of the guiding catheter. The guidewire is then advanced out of the distal end of the guiding catheter into the vessel until the distal portion of the guidewire carrying the compressed stent is positioned at the point of the lesion within the vessel. Once the compressed stent is located at the lesion, the stent may be released and expanded so that it supports the vessel.

SUMMARY OF THE INVENTION

[0007] Aspects of the present invention include a system and method of deploying an occluding device within a vessel. The occluding device can be used to remodel an aneurysm within the vessel by, for example, neck reconstruction or

balloon remodeling. The occluding device can be used to form a barrier that retains occlusion material such as a well known coil or viscous fluids, such as “ONYX” by Micro-therapeutics, within the aneurysm so that introduced material will not escape from within the aneurysm. Also, during deployment, the length of the occluding device can be adjusted in response to friction created between the occluding device and an inner surface of a catheter. When this occurs, the deployed length and circumferential size of the occluding device can be changed as desired by the physician performing the procedure.

[0008] An aspect of the present invention includes a system for supporting and deploying an occluding device. The system comprises an introducer sheath and an assembly for carrying the occluding device. The assembly includes an elongated flexible member having an occluding device retaining member for receiving a first end of the occluding device, a proximally positioned retaining member for engaging a second end of the occluding device and a support surrounding a portion of the elongated flexible member over which the occluding device can be positioned.

[0009] Another aspect of the present invention includes a system for supporting and deploying an occluding device. The system comprises an assembly for carrying the occluding device. The assembly comprises an elongated member including a flexible distal tip portion, a retaining member for receiving a first end of the occluding device, and a support surrounding a portion of the elongated flexible member for supporting the occluding device.

[0010] A further aspect of the present invention comprises a method of introducing and deploying an occluding device within a vessel. The method includes the steps of introducing an elongated sheath including an introducer sheath carrying a guidewire assembly into a catheter and advancing the guidewire assembly out of the sheath and into the catheter. The method also includes the steps of positioning an end of the catheter proximate an aneurysm, advancing a portion of the guidewire assembly out of the catheter and rotating a portion of the guidewire assembly while deploying the occluding device in the area of the aneurysm.

[0011] In another aspect an elongated flexible member supports and deploys an occluding device and the occluding device may be expanded and retracted based on input pressure. For example, air or fluid pressure may be applied to the occluding device via the flexible member to cause the occluding device to expand or retract.

[0012] In another aspect the present invention includes a system for supporting and deploying an occluding device. The system comprises an assembly including a guidewire and a first end and a second end of the occluding device. The first end and the second end of the occluding device move in relation to each other as the occluding device is deployed.

[0013] A further aspect of this invention is the guidewire curling when the first end of the occluding device and the second end of the occluding device move in relation to each other. The guidewire may curl into the shape of a coil. A portion of the guidewire may curl within the self-expandable occluding device.

[0014] Another aspect of the present invention includes a method for deploying an occluding device within a vessel. This method includes introducing a guidewire assembly into the catheter, positioning an end of the catheter proximate to an aneurysm and advancing at least a portion of the guidewire assembly out of the catheter. The method further includes the

guidewire curling when a first end of the occluding device moves in relation to a second end of the occluding device.

[0015] Another aspect of the present invention includes a system for supporting and deploying an occluding device. The system includes the means for introducing a guidewire assembly into a catheter, the means for positioning and end of the catheter proximate an aneurysm, and the means for advancing at least a portion of the guidewire assembly out of the catheter. The system also includes the means for curling the guidewire when a first end and a second end of the occluding device move in relation to each other.

BRIEF DESCRIPTION OF THE FIGURES

[0016] FIG. 1 is a cross section of an occluding device delivery assembly and occluding device according to an aspect of the invention;

[0017] FIG. 2 illustrates a catheter and introducer sheath shown in FIG. 1;

[0018] FIG. 3 is a partial cut away view of the introducer sheath of FIG. 2 carrying a guidewire assembly loaded with an occluding device;

[0019] FIG. 4 is a cross section of the guidewire assembly illustrated in FIG. 3;

[0020] FIG. 5 is a schematic view of the guidewire assembly of FIG. 4;

[0021] FIG. 6 is a second schematic view of the guidewire assembly of FIG. 4;

[0022] FIG. 7 illustrates the occluding device and a portion of the guidewire assembly positioned outside the catheter, and how a proximal end of the occluding device begins to deploy within a vessel;

[0023] FIG. 8 illustrates a step in the method of deploying the occluding device;

[0024] FIG. 9 illustrates the deployment of the occluding device according to an aspect of the present invention;

[0025] FIG. 10 is a schematic view of a guidewire assembly according to another embodiment of the present invention; and

[0026] FIG. 11 is a schematic view of the deployed occluding device after having been deployed by the guidewire assembly of FIG. 10.

[0027] FIG. 12 illustrates an example of an expanded occluding device that expands responsive to pressure.

[0028] FIG. 13 illustrates the occluding device of FIG. 12 after a negative pressure is applied to the occluding device.

[0029] FIG. 14 illustrates an example of release of the distal end of the occluding device while the proximal end of the occluding device remains attached to the delivery device.

[0030] FIG. 15 illustrates an example of a partially deployed occluding device.

[0031] FIG. 16 illustrates another example of a partially deployed occluding device.

[0032] FIG. 17 illustrates the example of FIG. 16 in which the occluding device is repositioned proximally in the blood vessel.

[0033] FIG. 18 illustrates an example of an expanded occluding device.

[0034] FIG. 19 illustrates the example of FIG. 18 after the occluding device is repositioned within a blood vessel.

[0035] FIG. 20 illustrates an example of the occluding device in a retracted state.

[0036] FIG. 21 illustrates an example of repositioning the occluding device while the occluding device is retracted.

[0037] FIG. 22 illustrates an example of the guidewire beginning to curl after the distal end of the device is detached from the capturing mechanism.

[0038] FIG. 23 illustrates an example of the guidewire curled into a coil-shape after the distal end of the occluding device is deployed.

[0039] FIG. 24 illustrates an example of the guidewire curling while the occluding device is expanding and being pushed out of the catheter.

[0040] FIG. 25 illustrates an example of the guidewire curled into a coil-shape within the occluding device after the occluding device is fully deployed and expanded.

DETAILED DESCRIPTION OF THE INVENTION

[0041] An occluding device delivery assembly having portions with small cross section(s) and which is highly flexible is described herein. FIG. 1 illustrates an introducer sheath **10** according to an aspect of the present invention that receives, contains and delivers an occluding device **100** to a flexible micro-catheter **1** for positioning within the vasculature of an individual. The occluding device **100** can include those embodiments disclosed in copending U.S. patent application titled "System and Method for Delivering and Deploying an Occluding Device Within a Vessel", U.S. Ser. No. 11/420, 023, filed May 24, 2006, which is a continuation-in-part of copending U.S. patent application titled "Flexible Vascular Occluding Device", U.S. Ser. No. 11/136,395, filed on May 25, 2005, which are both expressly hereby incorporated by reference in their entirety.

[0042] A distal end **12** of the introducer sheath **10** is sized and configured to be received within a hub **2** of the micro-catheter **1**, as shown in FIGS. 1 and 2. The hub **2** can be positioned at the proximal end of the micro-catheter **1** or at another location spaced along the length of the micro-catheter **1**. The micro-catheter **1** can be any known micro-catheter that can be introduced and advanced through the vasculature of a patient. In an embodiment, the micro-catheter has an inner diameter of 0.047 inch or less. In another embodiment, the micro-catheter has an inner diameter of about 0.027 inch to about 0.021 inch. In an alternative embodiment, the micro-catheter could have an inner diameter of about 0.025 inch. However, it is contemplated that the micro-catheter **1** can have an inner diameter that is greater than 0.047 inch or less than 0.021 inch. After the introducer sheath **10** is positioned within the catheter hub **2**, the occluding device **100** can be advanced from the introducer sheath **10** into the micro-catheter **1** in preparation for deploying the occluding device **100** within the vasculature of the patient.

[0043] The micro-catheter **1** may have at least one fluid introduction port **6** located adjacent the hub **2** or at another position along its length. The port **6** is preferably in fluid communication with the distal end of the micro-catheter **1** so that a fluid, e.g., saline, may be passed through the micro-catheter **1** prior to insertion into the vasculature for flushing out air or debris trapped within the micro-catheter **1** and any instruments, such as guidewires, positioned within the micro-catheter **1**. The port **6** may also be used to deliver drugs or fluids within the vasculature as desired.

[0044] FIG. 3 illustrates the introducer sheath **10**, an elongated flexible delivery guidewire assembly **20** that is movable within the introducer sheath **10** and the occluding device **100**. As shown, the guidewire assembly **20** and the occluding device **100**, carried by the guidewire assembly **20**, have not been introduced into the micro-catheter **1**. Instead, as illus-

trated, they are positioned within the introducer sheath **10**. The introducer sheath **10** may be made from various thermoplastics, e.g., PTFE, FEP, HDPE, PEEK, etc., which may optionally be lined on the inner surface of the sheath or an adjacent surface with a hydrophilic material such as PVP or some other plastic coating. Additionally, either surface may be coated with various combinations of different materials, depending upon the desired results.

[0045] The introducer sheath **10** may include drainage ports or purge holes (not shown) formed into the wall near the area covering the occluding device **100**. There may be a single hole or multiple holes, e.g., three holes, formed into introducer sheath **10**. These purge holes allow for fluids, e.g., saline, to readily escape from in between the introducer sheath **10** and the guidewire assembly **20** when purging the sheath prior to positioning the introducer sheath **10** in contact with the catheter hub **2**, e.g., to remove trapped air or debris.

[0046] As shown in FIG. 4, the guidewire assembly **20** includes an elongated flexible guidewire **21**. The flexibility of the guidewire **21** allows the guidewire assembly **20** to bend and conform to the curvature of the vasculature as needed for positional movement of the occluding device **100** within the vasculature. The guidewire **21** may be made of a conventional guidewire material and have a solid cross section. Alternatively, the guidewire **21** can be formed from a hypotube. In either embodiment, the guidewire **21** has a diameter D_5 , ranging from about 0.010 inch to about 0.020 inch. In an embodiment, the largest diameter of the guidewire **21** is about 0.016 inch. The material used for the guidewire **21** can be any of the known guidewire materials including superelastic metals, e.g., Nitinol. Alternatively, the guidewire **21** can be formed of metals such as stainless steel. Length L_4 of the guidewire can be from about 125 to about 190 cm. In an embodiment, the length L_4 is about 175 cm.

[0047] The guidewire assembly **20** can have the same degree of flexion along its entire length. In an alternative embodiment, the guidewire assembly **20** can have longitudinal sections, each with differing degrees of flexion/stiffness. The different degrees of flexions for the guidewire assembly **20** can be created using different materials and/or thicknesses within different longitudinal sections of the guidewire **21**. In another embodiment, the flexion of the guidewire **21** can be controlled by spaced cuts (not shown) formed within the delivery guidewire **21**. These cuts can be longitudinally and/or circumferentially spaced from each other. The cuts can be formed with precision within the delivery guidewire **21**. Different sections of the delivery guidewire **21** can include cuts formed with different spacing and different depths to provide these distinct sections with different amounts of flexion and stiffness. In any of the above embodiments, the guidewire assembly **20** and the guidewire **21** are responsive to torque applied to the guidewire assembly **20** by the operator. As discussed below, the torque applied to the guidewire assembly **20** via the guidewire **21** can be used to release the occluding device **100** from the guidewire assembly **20**.

[0048] The size and shape of the cuts formed within the delivery guidewire **21** may be controlled so as to provide greater or lesser amounts of flexibility. Because the cuts can be varied in width without changing the depth or overall shape of the cut, the flexibility of the delivery guidewire **21** may be selectively altered without affecting the torsional strength of the delivery guidewire **21**. Thus, the flexibility and torsional strength of the delivery guidewire **21** may be selectively and independently altered.

[0049] Advantageously, longitudinally adjacent pairs of cuts may be rotated about 90 degrees around the circumference of the delivery guidewire **21** from one another to provide flexure laterally and vertically. However, the cuts may be located at predetermined locations to provide preferential flexure in one or more desired directions. Of course, the cuts could be randomly formed to allow bending (flexion) equally, non-preferentially in all directions or planes. In one embodiment, this could be achieved by circumferentially spacing the cuts.

[0050] The flexible delivery guidewire **21** can include any number of sections having the same or differing degrees of flexion. For example, the flexible delivery guidewire **21** could include two or more sections. In the embodiment illustrated in FIG. 4, the flexible delivery guidewire **21** includes three sections, each having a different diameter. Each section can have a diameter of about 0.003 inch to about 0.025 inch. In an embodiment, the diameter of one or more sections can be about 0.010 inch to about 0.020 inch. A first section **22** includes a proximal end **23** that is located opposite the position of the occluding device **100**. The first section **22** can have a constant thickness along its length. Alternatively, the first section **22** can have a thickness (diameter) that tapers along its entire length or only a portion of its length. In the tapered embodiment, the thickness (diameter) of the first section **22** decreases in the direction of a second, transition section **24**. For those embodiments in which the guidewire **21** has a circular cross section, the thickness is the diameter of the section.

[0051] The second, transition section **24** extends between the first section **22** and a third, distal section **26**. The second section **24** tapers in thickness from the large diameter of the first section **22** to the smaller diameter of the third section **26**. As with the first section **22**, the second section **24** can taper along its entire length or only a portion of its length.

[0052] The third section **26** has a smaller thickness compared to the other sections **22**, **24** of the delivery guidewire **21**. The third section **26** extends away from the tapered second section **24** that carries the occluding device **100**. The third section **26** can taper along its entire length from the second section **24** to the distal end **27** of the delivery guidewire **21**. Alternatively, the third section **26** can have a constant diameter or taper along only a portion of its length. In such an embodiment, the tapering portion of the third section **26** can extend from the second section **24** or a point spaced from the second section **24** to a point spaced from distal end **27** of the delivery guidewire **21**. Although three sections of the delivery guidewire **21** are discussed and illustrated, the delivery guidewire **21** can include more than three sections. Additionally, each of these sections can taper in their thickness (diameter) along all or only a portion of their length. In any of the disclosed embodiments, the delivery guidewire **21** can be formed of a shape memory alloy such as Nitinol.

[0053] A tip **28** and flexible tip coil **29** are secured to the distal end **27** of the delivery guidewire **21** as shown in FIGS. 4 and 5. The tip **28** can include a continuous end cap or cover as shown in the figures, which securely receives a distal end of the tip coil **29**. Flexion control is provided to the distal end portion of the delivery guidewire **21** by the tip coil **29**. However, in an embodiment, the tip **28** can be free of the coil **29**. The tip **28** has a non-percutaneous, atraumatic end face. In the illustrated embodiment, the tip **28** has a rounded face. In alternative embodiments, the tip **28** can have other non-percutaneous shapes that will not injure the vessel in which it is

introduced. As illustrated in FIG. 4, the tip 28 includes a housing 45 that securely receives the distal end of the guidewire 21 within an opening 46 in the interior surface of the housing 45. The guidewire 21 can be secured within the opening by any known means.

[0054] As shown in FIG. 4, the tip coil 29 surrounds a portion of the guidewire 21. The tip coil 29 is flexible so that it will conform to and follow the path of a vessel within the patient as the tip 28 is advanced along the vessel and the guidewire 21 bends to follow the tortuous path of the vasculature. The tip coil 29 extends rearward from the tip 28 in the direction of the proximal end 23, as shown.

[0055] The tip 28 and coil 29 have an outer diameter D_1 of about 0.010 inch to about 0.018 inch. In an embodiment, their outer diameter D_1 is about 0.014 inch. The tip 28 and coil 29 also have a length L_1 of about 0.1 cm to about 3.0 cm. In an embodiment, they have a total length L_1 of about 1.5 cm.

[0056] A proximal end 30 of the tip coil 29 is received within a housing 32 at a distal end 24 of a protective coil 35, as shown in FIGS. 1 and 4. The housing 32 and protective coil 35 have an outer diameter D_2 of about 0.018 inch to about 0.038 inch. In an embodiment, their outer diameter D_2 is about 0.024 inch. The housing 32 and protective coil 35 have a length L_2 of about 0.05 cm to about 0.2 cm. In an embodiment, their total length L_2 is about 0.15 cm.

[0057] The housing 32 has a non-percutaneous, atraumatic shape. For example, as shown in FIG. 5, the housing 32 has a substantially blunt profile. Also, the housing 32 can be sized to open/support the vessel as it passes through it. Additionally, the housing 32 can include angled sidewalls sized to just be spaced just off the inner surface of the introducer sheath 10.

[0058] The housing 32 and protective coil 35 form a distal retaining member that maintains the position of the occluding device 100 on the flexible guidewire assembly 20 and helps to hold the occluding device 100 in a compressed state prior to its delivery and deployment within a vessel of the vasculature. The protective coil 35 extends from the housing 32 in the direction of the proximal end 23 of the delivery guidewire 21, as shown in FIG. 4. The protective coil 35 is secured to the housing 32 in any known manner. In a first embodiment, the protective coil 35 can be secured to the outer surface of the housing 32. In an alternative embodiment, the protective coil 35 can be secured within an opening of the housing 32 so that the housing 32 surrounds and internally receives the distal end 51 of the protective coil 35 (FIG. 4). As shown in FIGS. 3 and 4, the distal end 102 of the occluding device 100 is retained within the proximal end 52 so that the occluding device 100 cannot deploy while positioned in the sheath 10 or the micro-catheter 1.

[0059] At the proximal end of the occluding device 100, a bumper coil 60 and cap 62 prevent lateral movement of the occluding device 100 along the length of the guidewire 21 in the direction of the proximal end 23, see FIG. 3. The bumper coil 60 and cap 62 have an outer diameter D_4 of about 0.018 inch to about 0.038 inch. In an embodiment, their outer diameter D_4 is about 0.024 inch. The cap 62 contacts the proximal end 107 of the occluding device 100 and prevents it from moving along the length of the guidewire 21 away from the protective coil 35. The bumper coil 60 can be in the form of a spring that contacts and pressures the cap 62 in the direction of the protective coil 35, thereby creating a biasing force against the occluding device 100. This biasing force (pressure) aids in maintaining the secured, covered relationship

between the distal end 102 of the occluding device 100 and the protective coil 35. As with any of the coils positioned along the delivery guidewire 21, the bumper coil 60 can be secured to the delivery guidewire 21 by soldering, welding, RF welding, glue, and/or other known adhesives.

[0060] In an alternative embodiment illustrated in FIG. 10, the bumper coil 60 is not utilized. Instead, a proximal end 107 of the occluding device 100 is held in position by a set of spring loaded arms (jaws) 104 while positioned within the introducer sheath 10 or the micro-catheter 1. The inner surfaces of the micro-catheter 1 and the introducer sheath 10 limit the radial expansion of the arms 104. When the proximal end of the occluding device passes out of the micro-catheter 1, the arms 104 would spring open and release the occluding device as shown in FIG. 11.

[0061] In another example, the occluding device 100 in the introducer sheath 10 or the micro-catheter 1 may expand within a vessel under pressure. FIG. 12 illustrates an example of an expanded occluding device 100 that expands responsive to pressure. Pressure may be applied through the micro-catheter 1 or the introducer sheath 10 as the occluding device 100 passes out of the micro-catheter 1. The pressure may be exerted through application of air, fluid, or any material for increasing the internal pressure of the occluding device. The increase in pressure within the occluding device 100 when the occluding device 100 passes out of the micro-catheter 1 may cause the occluding device to expand within the vessel. Conversely, a negative pressure may be exerted at the occluding device 100. FIG. 13 illustrates the occluding device 100 of FIG. 12 after a negative pressure is applied to the occluding device 100. The negative pressure may be applied via the micro-catheter 1 or the introducer sheath 10 and may cause the occluding device 100 to retract or decrease in size. In one example, a negative pressure is exerted at the occluding device 100 after the occluding device 100 is passed out of the micro-catheter 1 and expanded in the vessel. The negative pressure causes the occluding device 100 to retract. Upon retraction, the occluding device 100 may be reduced in size. In another example, the occluding device 100 may be replaced back into the microcatheter 1 after retraction. The negative pressure may be applied in a variety of ways. For example, the negative pressure may be applied by suction of air from the micro-catheter 1 or by removal or suction of fluid from the micro-catheter 1.

[0062] Also, in another example, the occluding device 100 may be expanded, for example, by application of increased pressure within the occluding device. The increased pressure may be administered via the delivery device by, for example, injecting air or fluid via the delivery device to the occluding device 100. The occluding device 100 may thus be expanded in a vessel such that the occluding device 100 may come into contact with the internal aspect of the wall of the vessel. In this way, at least a portion of the occluding device 100, while in the expanded state, may contact the wall of the vessel.

[0063] While in the expanded state, the occluding device 100 may be repositioned within the vessel. FIG. 18 illustrates an example of an expanded occluding device 100. FIG. 19 illustrates the example of FIG. 18 after the occluding device is repositioned within a blood vessel. In this example, the occluding device 100 may be expanded in a longitudinal axis along the vessel such that the occluding device 100 may move within the vessel while expanded. Pressure may be exerted by a user at a proximal end of the occluding device 100 such that the proximal end is moved distally within the vessel lumen. At

the same time, frictional forces between the wall of the vessel and the more distal portions of the occluding device may prevent immediate movement of the more distal portions of the occluding device. When the pressure or force exerted at the proximal end exceeds a threshold level, the force may be transmitted to the more distal portions of the occluding device to cause the more distal portions of the occluding device to move distally in the lumen of the vessel. In this way, the occluding device may move distally in the vessel lumen and may be repositioned at a desired location within the vessel by the user. FIG. 19 illustrates distal repositioning of the occluding device in a blood vessel.

[0064] Similarly, the occluding device may be repositioned more proximally in the vessel lumen by the user. For example, the user may provide a force or pressure at a distal portion of the occluding device in a proximal direction. The distal portion of the occluding device may move proximally while frictional forces between the more proximal portions of the occluding device prevent initial movement of the more proximal portions of the occluding device. Hence, in this example, the occluding device compresses at a portion intermediate between the distal portion and the more proximal portions of the occluding device. When the pressure or force exerted by the user at the distal portion of the occluding device exceeds a threshold level that exceeds the frictional force preventing movement of the more proximal portions of the occluding device, the more proximal portions of the occluding device may move in a proximal direction responsive to the applied pressure or force. In this way, the occluding device may be repositioned proximally in the vessel.

[0065] In another example, the occluding device 100 may be repositioned in a blood vessel while the occluding device 100 is in a retracted state. FIG. 20 illustrates an example of the occluding device 100 in a retracted state. For example, negative pressure may be exerted at the occluding device 100 of FIG. 12 to cause the occluding device 100 to decrease in size as illustrated in FIG. 20. The occluding device 100 as illustrated in FIG. 20 is retracted and approximates the delivery device. FIG. 21 illustrates an example of repositioning the occluding device 100 while the occluding device is retracted. As FIG. 21 illustrates, the occluding device is moved in a distal direction. Similarly, the occluding device may also be repositioned in a proximal direction (not shown).

[0066] Also, deployment of the occluding device may be performed in parts. For example, the occluding device 100 may have a distal end and a proximal end. Deployment of the occluding device may include release of a distal end followed by release of the proximal end of the occluding device. Alternatively, deployment of the occluding device may include release of the proximal end followed by release of the distal end. Also, deployment of the occluding device may include release of the proximal end and the distal end of the occluding device 100 at approximately the same time.

[0067] FIG. 14 illustrates an example of release of the distal end of the occluding device 100 while the proximal end of the occluding device remains attached to the delivery device. As FIG. 14 shows, the distal end of the occluding device 100 is deployed and abuts the wall of the blood vessel. The proximal end of the occluding device 100 is still attached to the delivery device. Release of the proximal end of the occluding device may be accomplished in a variety of ways as described herein.

[0068] In addition, the partially deployed occluding device 100 as illustrated in FIG. 14 may be repositioned in the blood vessel. FIG. 15 illustrates an example of a partially deployed

occluding device 100 in which the distal end of the occluding device 100 has been released from the delivery device while the proximal end of the delivery device 100 remains attached and non-deployed to the delivery device. In addition, FIG. 15 demonstrates repositioning of the occluding device while partially deployed. As FIG. 15 shows, the delivery device and occluding device 100 has been moved proximally in the blood vessel. Also, FIG. 15 illustrates that the occluding device is partially deployed in the blood vessel such that the distal end of the occluding device is released from the delivery device while the proximal end of the occluding device 100 remains attached to the delivery device.

[0069] Alternatively, the proximal end of the occluding device may be released from the delivery device while the distal end of the occluding device remains attached to the delivery device. The distal end of the occluding device may then be deployed or released from the delivery device at a subsequent time. FIG. 16 illustrates an example of a partially deployed occluding device 100 in a blood vessel in which the proximal end of the occluding device 100 is released from the delivery device while the distal end of the occluding device remains attached to the delivery device. The proximal end of the occluding device 100 thus approximates the walls of the blood vessel.

[0070] FIG. 17 illustrates the example of FIG. 16 in which the occluding device 100 is repositioned proximally in the blood vessel. In this example, the occluding device is partially deployed such that the proximal end of the occluding device 100 is released from the delivery device while the distal end of the occluding device 100 is attached. The occluding device is then moved or repositioned to a more proximal location within the blood vessel. Alternatively, the occluding device may also be moved or repositioned to a more distal location within the blood vessel (not shown).

[0071] In an alternative embodiment, the bumper coil 60 and cap 62 can be eliminated and the proximal end of the occluding device 100 can be held in position relative to the protective coil 35 by a tapered section of the guidewire 21. In such an embodiment, the enlarged cross section of this tapered section can be used to retain the occluding device 100 in position along the length of the delivery guidewire 21 and prevent movement of the occluding device 100 in the direction of the proximal end 23.

[0072] As shown in FIG. 4, the guidewire assembly 20 includes a support 70 for the occluding device 100. In a first embodiment, the support 70 can include an outer surface of the delivery guidewire 21 that is sized to contact the inner surface of the occluding device 100 when the occluding device 100 is loaded on the guidewire assembly 20. In this embodiment, the outer surface of the delivery guidewire 21 supports the occluding device 100 and maintains it in a ready to deploy state. In another embodiment, illustrated in the Figures, the support 70 comprises a mid-coil 70 that extends from a location proximate the protective coil 35 rearward toward the bumper coil 60. The mid-coil 70 extends under the occluding device 100 and over the delivery guidewire 21, as shown in FIG. 1. The mid-coil 70 can be coextensive with one or more sections of the delivery guidewire 21. For example, the mid-coil 70 could be coextensive with only the second section 24 of the delivery guidewire 21 or it could extend along portions of both the third section 26 and the second section 24 of the delivery guidewire 21.

[0073] The mid-coil 70 provides the guidewire assembly 20 with an outwardly extending surface that is sized to contact

the inner surface of the occluding device **100** in order to assist in supporting the occluding device and maintaining the occluding device **100** in a ready to deploy state. Like the other coils discussed herein and illustrated in the figures, the coiled form of the mid-coil **70** permits the mid-coil **70** to flex with the delivery guidewire **21** as the delivery guidewire **21** is advanced through the vasculature of the patient. The mid-coil **70** provides a constant diameter along a length of the delivery guidewire **21** that is covered by the occluding device **100** regardless of the taper of the delivery guidewire **21** beneath the occluding device **100**. The mid-coil **70** permits the delivery guidewire **21** to be tapered so it can achieve the needed flexibility to follow the path of the vasculature without compromising the support provided to the occluding device **100**. The mid-coil **70** provides the occluding device **100** with constant support regardless of the taper of the delivery guidewire **21** prior to the occluding device **100** being deployed. The smallest diameter of the occluding device **100** when in its compressed state is also controlled by the size of the mid-coil **70**. Additionally, the diameter of the mid-coil **70** can be chosen so that the proper spacing, including no spacing, is established between the occluding device **100** and the inner wall of the micro-catheter **1** prior to deployment of the occluding device **100**. The mid-coil **70** can also be used to bias the occluding device **100** away from the delivery guidewire **21** during its deployment.

[0074] In either embodiment, the support **70** can have an outer diameter D_3 of about 0.010 inch to about 0.018 inch. In an embodiment, the outer diameter D_3 is about 0.014 inch. The support **70** can also have a length L_3 of about 2.0 cm to about 30 cm. In an embodiment, the length L_3 of the support **70** is about 7 cm.

[0075] The occluding device **100** may also be placed on the mid-coil **70** between an optional pair of radio-opaque marker bands located along the length of the guidewire assembly **20**. Alternatively, the protective coil **35**, bumper coil **60** and/or mid-coil **70** can include radio-opaque markers. In an alternative embodiment, the guidewire assembly **20** may include only a single radio-opaque marker. The use of radio-opaque markers allows for the visualization of the guidewire assembly **20** and the occluding device **100** during placement within the vasculature. Such visualization techniques may include conventional methods such as fluoroscopy, radiography, ultra-sonography, magnetic resonance imaging, etc.

[0076] The occluding device **100** can be delivered and deployed at the site of an aneurysm according to the following method and variations thereof. The delivery of the occluding device **100** includes introducing the micro-catheter **1** into the vasculature until it reaches a site that requires treatment. The micro-catheter **1** is introduced into the vasculature using a conventional technique such as being advanced over or simultaneously with a conventional vascular guidewire (not shown). The positioning of the micro-catheter **1** can occur before it receives the guidewire assembly **20** or while it contains the guidewire assembly **20**. The position of the micro-catheter **1** within the vasculature can be determined by identifying radio-opaque markers positioned on or in the micro-catheter **1**.

[0077] After the micro-catheter **1** is positioned at the desired location, the guidewire is removed and the distal end of the introducer sheath **10** is inserted into the proximal end of the micro-catheter **1**, as shown in FIG. 1. In an embodiment, the distal end of the introducer sheath **10** is introduced through the hub **2** at the proximal end of the micro-catheter **1**.

The introducer sheath **10** is advanced within the micro-catheter **1** until a distal tip of the introducer sheath **10** is wedged within the micro-catheter **1**. At this position, the introducer sheath **10** cannot be advanced further within the micro-catheter **1**. The introducer sheath **10** is then securely held while the delivery guidewire assembly **20** carrying the occluding device **100** is advanced through the introducer sheath **10** until the occluding device **100** is advanced out of the introducer sheath **10** and into the micro-catheter **1**.

[0078] The guidewire assembly **20** and the occluding device **100** are advanced through the micro-catheter **1** until the tip coil **29** is proximate the distal end of the micro-catheter **1**. At this point, the position of the micro-catheter **1** and guidewire assembly **20** can be confirmed. The guidewire assembly **20** is then advanced out of the micro-catheter **1** and into the vasculature of the patient so that the proximal end **107** of the occluding device **100** is positioned outside the distal end of the micro-catheter **1** and adjacent the area to be treated. At any point during these steps, the position of the occluding device **100** can be checked to determine that it will be deployed correctly and at the desired location. This can be accomplished by using the radio-opaque markers discussed above.

[0079] When the distal end **102** of the occluding device **100** is positioned outside the micro-catheter **1**, the proximal end **107** will begin to expand, in the direction of the arrows shown in FIG. 7, within the vasculature while the distal end **102** remains covered by the protective coil **35**. When the occluding device **100** is in the proper position, the delivery guidewire **21** is rotated (See FIG. 8) until the distal end **102** of the occluding device **100** moves away from the protective coil **35** and expands within the vasculature at the desired location. The delivery guidewire **21** can be rotated either clockwise or counter clockwise as needed to deploy the occluding device **100**. In an embodiment, the delivery guidewire **21** may be rotated, for example, between two and ten turns in either or both directions. In another example, the occluding device may be deployed by rotating the delivery guidewire **21** clockwise for less than five turns, for example, three to five turns. After the occluding device **100** has been deployed, the delivery guidewire **21** can be retracted into the micro-catheter **100** and removed from the body.

[0080] In one alternative or additional deployment method, the distal end **102** of the occluding device **100** may be passed outside of the micro-catheter **1**. The occluding device **100** may be further advanced so that the proximal end **107** of the occluding device **100** passes outside of the micro-catheter. However, in this example, the proximal end **107** of the occluding device **100** expands responsive to the application of pressure to the inner surfaces of the occluding device **100**. The applied pressure may be from any source. Examples of pressure exerted in the occluding device **100** include, but are not limited to, infusion of fluid or air into the lumen of the occluding device.

[0081] The increase in pressure in the occluding device may cause the occluding device **100** to expand. Expansion of the occluding device **100** may cause a disconnection of the proximal end **107** of the occluding device **100** and/or the distal end **102** of the occluding device **100** such that the occluding device may substantially fill the lumen of the vessel. Alternatively, the increase in pressure in the occluding device may expand the occluding device **100** without detachment of either the proximal end **107** or the distal end **102** of the occluding device **100**. In this example, the occluding

device **100** may be expanded without detaching the occluding device **100** from the delivery system. The expanded occluding device **100** may be adjusted and moved within the vessel in the expanded state while connected to the delivery system. When the occluding device **100** is at a desired location in the vessel, the occluding device **100** may be released from the delivery system. Release of the occluding device **100** from the delivery system may be accomplished in a variety of ways as described herein.

[0082] In addition, the coverage of the occluding device **100** may be adjusted while the occluding device is expanded and connected to the delivery system. For example, the occluding device **100** may be unsheathed from the micro-catheter **1** and expanded under pressure (e.g., from fluid or air) such that the occluding device **100** is expanded in the vessel. The position of the occluding device **100** may be further adjusted. Also, the pressure applied within the occluding device **100** may be adjusted to increase the size of the expanded occluding device **100** in the vessel. Relative adjustments of the size of the expanded occluding device **100** (i.e., by adjusting the amount of pressure applied to the occluding device **100**) and of the position or location of the occluding device **100** permit control of coverage of the occluding device when placed in the vessel.

[0083] Also, a negative pressure may be applied (e.g., air suction or removal of fluid from within the occluding device **100**) to cause the occluding device to retract. The retracted occluding device **100** may further be placed back into the micro-catheter **1**. In one example, the occluding device **100** may be expanded and retracted as desired for movement or placement of the occluding device **100** within the vessel.

[0084] In an alternative or additional deployment step shown in FIG. 9, friction between the occluding device **100** and inner surface of the micro-catheter **1** cause the distal end of the occluding device **100** to separate from the protective coil **35**. The friction can be created by the opening of the occluding device **100** and/or the mid-coil **70** biasing the occluding device **100** toward the inner surface of the micro-catheter **1**. The friction between the micro-catheter **1** and the occluding device **100** will assist in the deployment of the occluding device **100**. In those instances when the occluding device **100** does not open and separate from the protective coil **35** during deployment, the friction between occluding device **100** and the inner surface of the micro-catheter **1** will cause the occluding device **100** to move away from the protective coil **35** as the delivery guidewire **21** and the micro-catheter **1** move relative to each other. The delivery guidewire **21** can then be rotated and the occluding device **100** deployed within the vessel.

[0085] In an alternative or additional deployment method, as shown in FIG. 22, the guidewire assembly **20** is released from the occluding device **100**. The guidewire assembly **20** may be released from the occluding device **100** in various methods, including those previously discussed. For example, the guidewire **21** may be hydraulically pressurized to move the guidewire assembly **20**. Another possibility is the guidewire assembly **20** contains a spring or spring like mechanism to slidably move the guidewire assembly **20** away from the occluding device **100**. An assembly **20** for supporting and deploying an occluding device **100** is provided such that an assembly **20** includes a guidewire **21** having an occluding device retaining member **35**, such as a coil for receiving of the occluding device **100**, a proximally positioned retaining member **60** for engaging a second end of the

occluding device **100**. The flexibility of the guidewire **21** allows the guidewire assembly **20** to bend and conform to the curvature of the vasculature as needed for positional movement of the occluding device **100** within the vasculature.

[0086] When the guidewire assembly **20** is releasing or deploying the occluding device **100**, the guidewire **21** may curl or otherwise locate position in a non-rectilinear free manner, such as 360 degrees about the longitudinal axis of guidewire **21**. In one embodiment, this feature provides for an atraumatic aspect of assembly **21** in a blood vessel lumen. In one embodiment, the atraumatic aspect enables improved control for repositioning of the occluding device **100** within the vasculature. In one embodiment, the first end of the occluding device **100** and the second end of the occluding device **100** may move longitudinally in relation to each other as the occluding device **100** is deployed into the blood vessel lumen of the body, such being positioned to the weakened part of the blood vessel. In one aspect the guidewire **21** is configured to curl when the first end of the occluding device **100** and the second end of the occluding device **100** move in relation to each other.

[0087] The guidewire **21** may have a portion that curls in various manners, such as into a coil-like shape, as shown in FIG. 23. The guidewire **21** may continue to curl while the occluding device **100** expands, as shown in FIG. 24. In one embodiment, the occluding device **100** may be self-expanding as discussed previously. A portion of the guidewire **21** may curl within the interior void of the occluding device **100**. When the occluding device **100** is fully expanded, as shown in FIG. 25, a portion of the curled guidewire **21** may still reside within the occluding device **100** interior space.

[0088] In one embodiment, the guidewire assembly **20** does not move forward during deployment of the occluding device **100**, causing the proximal end **107** and the distal end **102** to move in relation to towards each other, and curling the guidewire **21** to form a coil feature as a result. This may occur, for example, when the guidewire assembly **20** abuts a vessel and stops movement. While the guidewire assembly **20** is stationary, the occluding device **100** continues to move in a forward direction. While the guidewire assembly **20** is stationary and the occluding device **100** is moving, the guidewire **21** curls. A portion of the guidewire **21** may curl within interior void of the occluding device.

[0089] In an alternate embodiment, the guidewire assembly **20**, while releasing the occluding device **100**, moves at a slower rate than the occluding device **100**, curling the guidewire **21**. The guidewire **21** may curl in the shape of a coil. Alternatively, the curling of the guidewire **21** need not take a discernable shape of a coil.

[0090] In at least one embodiment, the outer surface of the occluding device **100** is a lattice structure. The distal end **102** of the occluding device **100** and the proximal end **107** of the occluding device **100** may move in relation to each other, causing the lattice structure to compress and pack the occluding device **100**. In at least one embodiment, the guidewire assembly **20** may include a tip **28** and a flexible tip coil **29** secured to the distal end **27** of the delivery guidewire **21**, as shown in FIGS. 4 and 5.

[0091] After the occluding device **100** radially self-expands into gentle, but secure, contact with the walls of the vessel so as to occlude the neck of the aneurysm **A**, the micro-catheter **1** may be removed entirely from the body of the patient. Alternatively, the micro-catheter **1** may be left in

position within vasculature to allow for the insertion of additional tools or the application of drugs near the treatment site.

[0092] In one embodiment, a method for introducing and deploying an occluding device within a vessel, the method includes introducing a guidewire assembly **20** into a microcatheter; positioning an end of the microcatheter proximate a weakened wall portion of a blood vessel; advancing at least a portion of the guidewire assembly **20** out of the microcatheter so that the guidewire **21** moves longitudinally and radially that a first end of the occluding device moves longitudinally in relation to a second end of the occluding device **100**, while deploying the occluding device **100** at the weakened portion.

[0093] In one embodiment, a method includes a step of confirming the position of the occluding device prior to deploying the occluding device. In one embodiment, the user may reposition the occluding device **100** after deploying at least a portion of the occluding device **100**. In another embodiment, the user may compress and pack the occluding device along the longitudinal axis of the guidewire **21** by the movement of the guidewire **21** and coiling feature. The tip **28** of the assembly **21** may stay stationary against the wall of the vessel and proximal to distal movement of the guidewire **21** causes the curling feature to compress while compressing the occluding device (e.g., moving the proximal end of occluding device **100** towards the distal end of the device **100**). The occluding device **100** may be compressed or retracted by a negative pressure. The negative pressure may be applied via the micro-catheter **1** or the introducer sheath **10** and may cause the occluding device **100** to retract or decrease in size. In one example, a negative pressure is exerted at the occluding device **100** after the occluding device **100** is passed out of the micro-catheter **1** and expanded in the vessel. The negative pressure causes the occluding device **100** to retract. Upon retraction, the occluding device **100** may be reduced in size. In another example, the occluding device **100** may be replaced back into the microcatheter **1** after retraction. The negative pressure may be applied in a variety of ways. For example, the negative pressure may be applied by suction of air from the micro-catheter **1** or by removal or suction of fluid from the micro-catheter **1**. In one embodiment, by movement of the guidewire **21**, there is curling at least a portion of the guidewire in the shape of a coil within the occluding device.

[0094] Known materials can be used in the present invention. One common material that can be used with the occluding device **100** and the guidewire **21** is Nitinol, a nickel-titanium shape memory alloy, which can be formed and annealed, deformed at a low temperature, and recalled to its original shape with heating, such as when deployed at body temperature in the body. The radio-opaque markers can be formed of radio-opaque materials including metals, such as platinum, or doped plastics including bismuth or tungsten to aid in visualization.

[0095] The apparatus and methods discussed herein are not limited to the deployment and use within the vascular system but may include any number of further treatment applications. Other treatment sites may include areas or regions of the body such as organ bodies. Modification of each of the above-described apparatus and methods for carrying out the invention, and variations of aspects of the invention that are obvious to those of skill in the art are intended to be within the scope of the claims. Furthermore, no element, component or method step is intended to be dedicated to the public regardless of whether the element, component or method step is explicitly recited in the claims.

What is claimed:

1. A method for delivering a self-expanding device within a vessel, the method comprising:

introducing an assembly and a self-expanding device into a lumen of an elongate member, the assembly comprising an innermost delivery wire extending through a lumen of the device, the delivery wire having a distal retaining member for receiving a first end of the device and a proximally positioned retaining member for engaging a second end of the device when the device is axially positioned against said proximally positioned retaining member; the delivery wire having an expandable portion with a radially compressed state and a radially expanded state, wherein the expandable portion is radially constrained in the radially compressed state by the elongate member and the device as the device and the expandable portion remain within the elongate member;

positioning an end of the elongate member proximate a weakened wall of a vessel;

advancing at least a portion of the assembly out of the elongate member, so that the expandable portion forms a non-rectilinear shape when transitioning from the radially compressed state to the radially expanded state and as the device expands radially and engages the vessel wall;

wherein the device foreshortens longitudinally as the device expands; and

wherein the expandable portion foreshortens longitudinally, while releasing the device, at a slower rate than does the device.

2. The method according to claim **1**, further comprising confirming the position of the device prior to expanding the device.

3. The method according to claim **1**, further comprising repositioning the device after expanding at least a portion of the device.

4. The method according to claim **1**, further comprising replacing the device into the elongate member.

5. The method according to claim **1**, wherein advancing at least a portion of the assembly out of the elongate member further comprises changing a shape of the expandable portion into a coil shape within the expanded device.

6. The method of claim **1**, wherein the expandable portion forms a coil-shaped portion.

7. The method of claim **1**, wherein the expandable portion forms a coil within an interior void of the device.

8. The method of claim **1**, wherein an outer surface of the device is a lattice structure.

9. The method of claim **8**, wherein a lattice density of the lattice structure changes when the first end of the device and the second end of the device move towards each other.

10. The method of claim **1**, wherein at least a portion of the assembly is stationary relative to the vessel while advancing the at least a portion of the assembly out of the elongate member.

11. A method for delivering a self-expanding device within a vessel, the method comprising:

introducing an assembly and a self-expanding device into a lumen of an elongate member, the assembly comprising an innermost delivery wire extending through a lumen of the device, the delivery wire having a device retaining member for receiving a first end of the device and a proximally positioned retaining member for engaging a second end of the device when the device is positioned

against said proximally positioned retaining member; the delivery wire having an expandable portion with a radially compressed state and a radially expanded state, wherein the expandable portion is radially constrained by the elongate member and the device as the device and the expandable portion remain within the elongate member;

positioning an end of the elongate member proximate a weakened wall of a vessel;

advancing at least a portion of the assembly out of the elongate member, so that the expandable portion forms a pattern of peaks when the first end of the device and the second end of the device move in relation to each other along a length of the assembly as the device is expanded; wherein the first end of the device and the second end of the device move relative to each other along a length of the assembly at a first rate; and

wherein the device retaining member and the proximally positioned retaining member move relative to each other along the length of the assembly at a second rate, slower than the first rate.

12. The method according to claim **11**, further comprising confirming the position of the device prior to expanding the device.

13. The method according to claim **11**, further comprising repositioning the device after expanding at least a portion of the device.

14. The method according to claim **11**, further comprising replacing the device into the elongate member.

15. The method according to claim **11**, wherein advancing at least a portion of the assembly out of the elongate member further comprises changing a shape of the expandable portion into a coil shape within the expanded device.

16. The method of claim **11**, wherein the expandable portion forms a coil-shaped portion.

17. The method of claim **11**, wherein the expandable portion forms a coil within an interior void of the device.

18. The method of claim **11**, wherein an outer surface of the device is a lattice structure.

19. The method of claim **18**, wherein a lattice density of the lattice structure changes when the first end of the device and the second end of the device move towards each other.

20. The method of claim **11**, wherein at least a portion of the assembly is stationary relative to the vessel while advancing the at least a portion of the assembly out of the elongate member.

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