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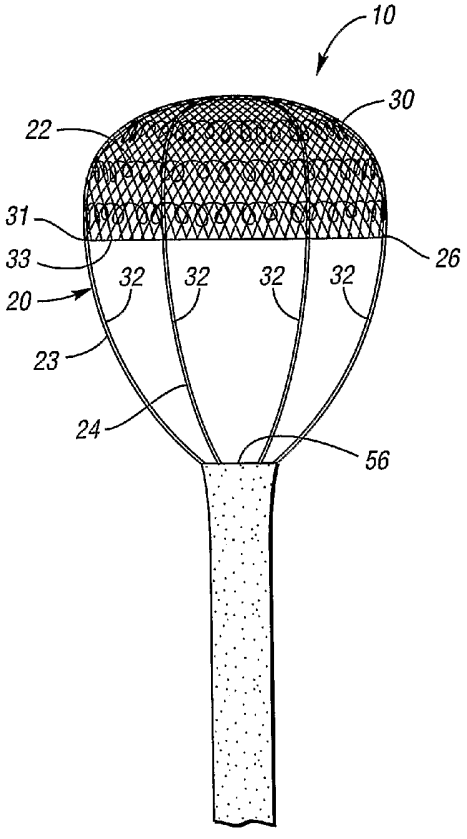
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(54) Title: EMBOLI CAPTURING DEVICE HAVING A COIL AND METHOD FOR CAPTURING EMBOLI



(57) Abstract: An embolic capturing device for capturing emboli within a body lumen is disclosed. The embolic capturing device (10) comprises a filtering basket (20) and at least one coil (22) attached to the basket. The filtering basket includes a frame (23) and a filtering body (30) disposed on the frame. The at least one coil is attached to the filtering body for filtering emboli in the body lumen.

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EMBOLI CAPTURING DEVICE HAVING A COIL AND METHOD FOR CAPTURING EMBOLI

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application serial no. 60/616,577, filed on October 6, 2004, entitled "EMBOLI CAPTURING DEVICE AND METHOD FOR CAPTURING EMBOLI," the entire contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to medical devices. More particularly, the present invention relates to emboli capturing devices and methods for capturing emboli within a body vessel.

[0003] Distal protection devices that are percutaneously placed in a body vessel have been available for years. Currently, there are a number of approaches for distal protection to prevent emboli from traveling to create an undesirable embolism, e.g., pulmonary embolism. For example, vena cava filters are more commonly being used for trapping emboli in the vena cava filter to prevent pulmonary embolism. Also, anti-platelet agents and anticoagulants may be used to breakdown blood clots. Moreover, snares and baskets (e.g., stone retrieval baskets) are more commonly used for retrieving urinary calculi. Additionally, coils are commonly used to occlude aneurysms and accumulate thrombi in a body vessel.

[0004] Treatments for a stenotic lesion provide a potential in releasing blood clots and other thrombi plaque in the vasculature of the patient. One example is the treatment for a carotid artery stenosis. Generally, carotid artery stenosis is the narrowing of the carotid arteries, the main arteries in the neck that supply blood to

the brain. Carotid artery stenosis (also called carotid artery disease) is a relatively high risk factor for ischemic stroke. The narrowing is usually caused by plaque build-up in the carotid artery. Plaque forms when cholesterol, fat and other substances form in the inner lining of an artery. This formation process is called atherosclerosis.

[0005] Depending on the degree of stenosis and the patient's overall condition, carotid artery stenosis has been treated with surgery. The procedure (with its inherent risks) is called carotid endarterectomy, which removes the plaque from the arterial walls. Carotid endarterectomy has proven to benefit patients with arteries substantially narrowed, e.g., by about 70% or more. For people with less narrowed arteries, e.g., less than about 50%, an anti-clotting drug may be prescribed to reduce the risk of ischemic stroke. Examples of these drugs are anti-platelet agents and anticoagulants.

[0006] Carotid angioplasty is a more recently developed treatment for carotid artery stenosis. This treatment uses balloons and/or stents to open a narrowed artery. Carotid angioplasty is a procedure that can be performed via a standard percutaneous transfemoral approach with the patient anesthetized using light intravenous sedation. At the stenosis area, an angioplasty balloon is delivered to predilate the stenosis in preparation for stent placement. The balloon may then be removed and exchanged via catheter for a stent delivery device. Once in position, a stent may then be deployed across the stenotic area. If needed, an additional balloon can be placed inside the deployed stent for post-dilation to make sure the struts of the stent are pressed firmly against the inner surface of the vessel wall.

During the stenosis procedure however, there is a risk of such blood clots and thrombi being undesirably released into the blood flow within the vasculature.

[0007] Thus, there is a need to provide a device and method for distally protecting and capturing emboli within a body lumen during a stenosis procedure.

BRIEF SUMMARY OF THE INVENTION

[0008] In one embodiment, the present invention provides an embolic capturing device for capturing emboli within a body lumen. The device comprises a basket including a frame and a filtering body disposed on the frame configured to have an expanded state and a collapsed state. The frame has first and second portions. The filtering body has a lip disposed on the second portion of the frame to define an opening of the filtering body when the basket is in the expanded state for capturing emboli. The filtering body extends from the lip to a filter end. The device further comprises at least one coil attached to one of the basket and the filtering body for filtering emboli in a body lumen.

[0009] Another embodiment of the present invention provides an embolic capturing apparatus for capturing emboli within a body vessel. In this embodiment, the apparatus comprises the embolic capturing device including a tubular shaft having proximal and distal ends. The distal end of the tubular shaft is connected to the first portion of the frame. The apparatus further comprises an inner catheter in which the device is disposed for deployment in the body vessel, and an introducer sheath through which the inner catheter is advanced for percutaneous insertion into the body vessel. The introducer sheath is configured to allow the inner catheter to be disposed therethrough for positioning of the device in the body vessel. The apparatus further comprises an outer catheter co-axially disposed about the inner

catheter and within the introducer sheath to collapse and expand the embolic capturing device for delivery and retrieval thereof.

[0010] Yet another embodiment of the present invention is a method for capturing emboli within a body vessel. The method comprises percutaneously introducing the embolic capturing device for capturing emboli during a stenosis procedure at a stenotic area, and disposing the embolic capturing device through the stenotic area. The method further comprises deploying the embolic capturing device in the body vessel downstream of the stenotic area to capture emboli during the stenosis procedure.

[0011] Further objects, features, and advantages of the present invention will become apparent from consideration of the following description and the appended claims when taken in connection with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Figure 1 is a side environmental view of an embolic capturing device disposed in a body vessel during a stenosis procedure in accordance with one embodiment of the present invention;

[0013] Figure 2 is a side view of the embolic capturing device of Figure 1;

[0014] Figure 3a is a side view of a primary coil body of one of the coils in Figure 2;

[0015] Figure 3b is a cross sectional view of the primary coil body in Figure 2b taken along line 3b – 3b;

[0016] Figure 3c is a side view of one of the coils depicting a secondary coil body;

[0017] Figure 3d is a cross sectional view of the coil of Figure 3c taken along line 3d – 3d;

[0018] Figure 4a is an exploded view of an embolic capturing apparatus for capturing emboli in a body vessel in accordance with one embodiment of the present invention;

[0019] Figure 4b is a side view of the embolic capturing apparatus in Figure 4a;

[0020] Figure 4c is a break-away side view of the device of the distal protection apparatus for delivery from a balloon angioplasty catheter;

[0021] Figure 4d is an enlarged view of the device in Figure 4c in circle 4d;

[0022] Figure 5 is a flow chart depicting one method of capturing emboli in a body vessel caused by a stenosis procedure.

[0023] Figure 6 is a side view of an embolic capturing device in accordance with another embodiment of the present invention;

[0024] Figure 7 is a side view of an embolic capturing device in accordance with yet another embodiment of the present invention; and

[0025] Figure 8 is a side view of an embolic capturing device in accordance with another embodiment of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0026] Embodiments of the present invention generally provide embolic capturing devices, embolic capturing apparatus, and methods for capturing emboli in a body vessel during angioplasty for treatment of a stenosis. One particular stenosis is a carotid artery stenosis. The embodiments solve the concerns of current stenosis treatments, such as the relatively high risks of surgery and the potential

release of emboli into the vasculature during the stenosis procedure. Embodiments of the present invention provide a relatively low risk approach to capturing emboli released during a stenosis procedure, e.g., balloon angioplasty.

[0027] Figure 1 illustrates an embolic capturing device 10 percutaneously deployed in a body vessel 12, e.g., the carotid artery, of a patient during balloon angioplasty or vascular stenting. As shown, device 10 is percutaneously deployed at a deployment location 14 downstream from a stenotic area 16 in the body vessel 12. For example, device 10 may be used during a percutaneous transluminal coronary angioplasty at the carotid artery. As shown, the stenotic area 16 is an area in the body vessel 12 whereat a relatively large amount of plaque build-up has occurred. As known, a common treatable cause of acute stroke is atheromatous narrowing at the carotid artery. It is generally believed that in this situation ischemic stroke commonly occurs from local thrombus formation that develops as a consequence of plaque build-up, ulceration, and laminar flow disturbances in and around the stenotic area. The local thrombus formation serves as a source for eventual arterial thrombo-embolism downstream into the intracranial circulation, commonly to the middle cerebral artery territory.

[0028] The embolic capturing device 10 is configured to be compressed or collapsed in a loaded state for delivery through a catheter to a deployment location 14 within the body vessel 12. At the deployment location 14, the embolic capturing device 10 is configured to be deployed and expanded in an expanded state within the body vessel 12. As mentioned in greater detail below, embodiments of a delivery apparatus are configured to dispose the embolic capturing device 10 at the deployment location 14 downstream from the stenotic area 16 to capture emboli.

[0029] Figure 2 depicts the embolic capturing device 10 for capturing emboli in a body vessel 12 for a stenosis procedure in accordance with one embodiment of the present invention. As shown, embolic capturing device 10 comprises a basket 20 and at least one coil 22 attached to the basket 20 for capturing emboli in the body vessel 12. In this embodiment, the basket 20 includes a frame 23 having first and second portions 24 and 26. The basket 20 further includes a filtering body 30 disposed on the frame 23. In this embodiment, the first portion 24 is a proximal portion and the second portion 26 is a distal portion of the frame 23. As shown, the frame 23 is defined by a plurality of struts 32 extending from the first portion 24 to the second portion 26. In this embodiment, the struts 32 extend from the first portion 24 to the second portion 26. The struts may be attached to the distal end 556 of the tubular shaft or may extend proximally to the proximal end of the delivery apparatus.

[0030] Preferably, the filtering body 30 is disposed on the second portion 26 of the frame 23, which is configured to have an expanded state and a collapsed state. As shown, the filtering body 30 has a lip 31 disposed on the second portion 26 of the basket 20 to define an opening 33 of the filtering body 30 when the basket 20 is in the expanded state for capturing emboli. The filtering body 30 extends from the lip 31 to a filter end 35.

[0031] The filtering body 30 is preferably a woven mesh or net configuration disposed on the frame 23. However, the filtering body 30 may be any other suitable filtering mechanism such as a filtering membrane without falling beyond the scope of spirit of the present invention. The filtering body 30 may be made of any suitable material, such as super-elastic material (e.g. Nitinol), connective tissue material, shape memory alloy, aluminum, platinum, metal alloy, mesh/net cloth, nylon,

polymeric material, polytetrafluoroethylene (PTFE), or woven mixtures thereof without falling beyond the scope or spirit of the present invention.

[0032] In one embodiment, the filtering body 30 is made of connective tissue material for capturing emboli. In this embodiment, the connective tissue comprises extracellular matrix (ECM). As known, ECM is a complex structural entity surrounding and supporting cells that are found within mammalian tissues. More specifically, ECM comprises structural proteins (e.g., collagen and elastin), specialized protein (e.g., fibrillin, fibronectin, and laminin), and proteoglycans, a protein core to which are attached are long chains of repeating disaccharide units termed of glycosaminoglycans.

[0033] Most preferably, the extracellular matrix is comprised of small intestinal submucosa (SIS). As known, SIS is a resorbable, acellular, naturally occurring tissue matrix composed of ECM proteins and various growth factors. SIS is derived from the porcine jejunum and functions as a remodeling bioscaffold for tissue repair. SIS has characteristics of an ideal tissue engineered biomaterial and can act as a bioscaffold for remodeling of many body tissues including skin, body wall, musculoskeletal structure, urinary bladder, and also supports new blood vessel growth. In many aspects, SIS is used to induce site-specific remodeling of both organs and tissues depending on the site of implantation. In theory, host cells are stimulated to proliferate and differentiate into site-specific connective tissue structures, which have been shown to completely replace the SIS material in time.

[0034] In this embodiment, SIS is used to temporarily adhere the filtering body 30 to the walls of a body vessel in which the device 10 is deployed. SIS has a natural adherence or wettability to body fluids and connective cells comprising the

connective tissue of a body vessel wall. Due to the temporary nature of the duration in which the device 10 is deployed in the body vessel, host cells of the wall will adhere to the filtering body 30 but not differentiate, allowing for retrieval of the device 10 from the body vessel.

[0035] The filtering body 30 may be disposed on the frame 23 by any suitable means, such as by thermal bonding, sonic welding, or adhesive bonding. Preferably, the filtering body 30 is disposed on the frame 23. In use, the filtering body 30 preferably is self-expandable such that when the frame 23 radially expands during deployment, the filtering body expands consistently with negligible resistance, if any.

[0036] In this embodiment, a plurality of coils 22 is attached to the basket 20. Preferably, each coil is attached to a strut 32 and radially extends across the basket 20 to attach to another strut 32. Preferably, a plurality of coils 22 are attached to the frame 23 for filtering emboli in the body vessel 12. The coils may be attached to the struts 32 by any suitable means such as by thermal bonding or sonic welding.

[0037] In this embodiment, the embolic capturing device 10 further comprises a tubular shaft 53 having proximal and distal ends 54 and 56. In one example, the first portion 24 of the frame 23 may be connected to the distal end 56 of the tubular shaft 53 or may proximally extend to the proximal end of the delivery apparatus. For example, the plurality of struts 32 may be bonded to the distal end of the tubular shaft 53. In another example, each of the struts 32 may distally extend from the proximal end of the tubular shaft or delivery apparatus through the distal end of the tubular shaft and curve back proximally, defining the basket, to the proximal end of the tubular shaft. As discussed below, the plurality of struts 32 may be comprised of

a super-elastic material or a shape memory alloy, such as Nitinol. The struts 32 may be bonded to the distal portion of the tubular shaft 53 by any suitable means such as by thermal bonding or sonic welding.

[0038] In one embodiment shown in Figures 3a to 3d, each of the coils may comprise a primary coil body 34 formed in a secondary coil body 36. Preferably, the primary coil body 34 is formed to define a primary structure 40. As shown, the primary structure 40 is wound, preferably by a coil winding machine, to a helical shape to define the secondary coil body 36. As shown in Figures 3c and 3d, the secondary coil body 36 includes a series of loops 42 having a first end 44 and a second end 46. The series of loops 42 define a cross sectional lumen 50 formed axially along the coil. Preferably, each coil further includes fibers 52 attached to the primary coil body 34 by the initial tension thereof (discussed below).

[0039] Preferably, each coil is comprised of platinum or any other suitable metal, composition, or alloy having a predetermined magnitude of tensile strength, e.g., between about 40,000 and 400,000 pounds per square inch. In this embodiment, the primary coil body 34 includes a predetermined initial tension, e.g., between about 5 and 100 grams of weight. Initial tension may be defined to be the amount of force required to cause a 4 centimeter length of coil to begin to elongate. The initial tension may also be defined by the amount of force required to cause a coil to begin elongating at a ratio of between about 1.25 to 15 grams per centimeter. Moreover, each primary coil body 34 may have a length of between about 5 and 15 centimeters, and may have an outer diameter ranging between about 5 and 15 millimeters. Preferably, the strands 52 have a length extending from the coil of

between about 5 to 10 millimeters and have an outer diameter of about 0.00050 to 0.00100 inch.

[0040] Figures 4a to 4d depict an embolic capturing apparatus 110 which implements the embolic capturing device 10 for capturing thrombi in a body vessel in accordance with one embodiment of the present invention. As shown, the apparatus 110 includes an inner catheter 114 defining a catheter lumen and preferably made of a soft, flexible material such as a silicone or any other suitable material. Generally, the inner catheter 114 has a proximal end 122, a distal end 124, and a plastic adapter or hub 116 to receive apparatus to be advanced therethrough. In this embodiment, the inside diameter of the inner catheter may range between 0.014 and 0.027 inch. The apparatus 110 further includes a wire guide 120 which provides an introducer sheath 118 (discussed in greater detail below) a path during insertion of the introducer sheath 118 within a body vessel. The size of the wire guide is based on the inside diameter of the introducer sheath.

[0041] As mentioned above, the apparatus 110 further includes a polytetrafluoroethylene (PTFE) introducer sheath 118 for percutaneously introducing the inner catheter 114 in a body vessel. Of course, any other suitable material may be used without falling beyond the scope or spirit of the present invention. The sheath 118 may have a size of about 4-French to 8-French and allows the inner catheter 114 to be inserted therethrough to the deployment location in the body vessel. The sheath 118 receives the inner catheter 114 and provides stability of the inner catheter 114 at the deployment location. When the distal end 124 of the inner catheter 114 is at the deployment location in the body vessel, the tubular shaft and

the capturing device are advanced through the inner catheter and the device is deployed through the distal end 124.

[0042] The apparatus 110 may further include an outer catheter 123 disposed co-axially about the inner catheter within the introducer sheath. The outer catheter 123 is advanced with the inner catheter 114 to the deployment location. As the device 10 is deployed through the inner catheter 114, the outer catheter facilitates deployment in the body vessel as it is restricted relative to inner catheter 114.

[0043] In one embodiment, the outer catheter may have an expandable balloon 125, as shown in Figure 4c, disposed radially thereon to allow for balloon angioplasty and vascular stenting. During the stenosis procedure, the balloon of the outer catheter is positioned at the stenotic area via fluoroscopy. As the outer catheter is maintained its position within the vasculature, the inner catheter may be distally advanced relative to the apparatus toward the deployment location downstream from the stenotic area. Thus, during balloon angioplasty and vascular stenting, the embolic capturing device is deployed at the deployment location to capture emboli that have detached from the stenotic area.

[0044] It is to be understood that the apparatus 110 described above is merely one example of an apparatus that may be used to deploy the capturing device in a body vessel. Of course, other apparatus, assemblies, and systems may be used to deploy any embodiment of the capturing device without falling beyond the scope or spirit of the present invention.

[0045] Figure 5 illustrates an example of one method 210 of capturing emboli within a body vessel during angioplasty. In this embodiment, the introducer sheath is percutaneously introduced into the body vessel of a patient and the outer catheter

is then guided through the introducer sheath and the balloon is positioned at the stenotic area via the wire guide. The embolic capturing device is compressed to its loaded state, and loaded at the proximal end of the inner catheter. The inner catheter is advanced through the outer catheter and the device is advanced to the deployment location in step 212. In step 214, the device is deployed at the deployment location in the body vessel. This may be accomplished by maintaining the position of the outer catheter such that the balloon maintain their position at the stenotic area while advancing the inner catheter to the deployment location downstream from the stenotic area. As a result, the basket will deploy and expand the device within the body vessel.

[0046] In step 216, the location of the device in the body vessel is ascertained by any suitable means, such as by fluoroscopy. If the device is at the deployment location in the body vessel, then the inner catheter is retracted therefrom in step 218. Preferably, the device is deployed by moving the distal end of the inner catheter along the lumen of the body vessel.

[0047] Figure 6 illustrates an embolic capturing device 310 in accordance with another embodiment of the present invention. In the example shown in Figure 6, the plurality of struts 332 of the basket 320 may be formed integrally with the tubular shaft. For example, the basket 320 may be formed of a malecot configuration, wherein the tubular shaft 353 has slits 321 longitudinally formed thereon defining the frame 323. In this embodiment, the tubular shaft has a shaft body extending to a distal portion 325 thereof. As shown, the second portion 326 of the frame is integral with the distal portion 325 of the frame and the first portion 324 is integral with the shaft body 355 to define the malecot configuration.

[0048] Upon axial pressure to the malecot configuration, the struts 332 (defined by the slits 321) radially expand to form the basket 320 for capturing emboli. In this embodiment, the filtering body is disposed on the frame 323 and is self-expandable so that when the frame 323 expands, the filtering body expands consistently as well with negligible resistance, if any. The malecot configuration provides a more simplified deployment and a retrieval of the basket 320 from the body vessel. In this embodiment, the struts 332, basket 320, and tubular shaft 353 are made of a PTFE.

[0049] Figure 7 depicts an embolic capturing device 410 in accordance with yet another embodiment of the present invention. As shown, the device 410 includes a plurality of struts 432, each strut 432 being an elongate member attached proximally to a hub 433 of a push wire 431. In this embodiment, the struts 432 and push wire 431 are configured to be passed through an inner catheter 435 of a delivery apparatus. The push wire 431 allows for the struts 432 to be deployed and retrieved from the body vessel by pushing or retracting the embolic capturing device 410 relative to the delivery apparatus.

[0050] In this embodiment, each of the coils 422 includes a tether 425 proximally extending therefrom to provide for an easier and simplified way of retrieving the coils 422 from deployment. In this embodiment, each tether 425 proximally extends from the basket through the catheter lumen to a common joint for delivery and retrieval. A practitioner is able to retrieve and push the coil through the catheter lumen from the proximal end of the push wire.

[0051] The struts mentioned above, e.g. struts 32 of Figures 1 and 2, may be comprised of any suitable material such as a superelastic material, stainless steel

wire, cobalt-chromium-nickel-molybdenum-iron alloy, or cobalt-chrome alloy. It is understood that the struts may be formed of any other suitable material that will result in a self-opening or self-expanding basket, such as shape memory alloys. Super-elastic, shape memory alloys have a property of becoming rigid, that is, returning to a remembered state, when heated above a transition temperature. A shape memory alloy suitable for the present invention may comprise Ni-Ti available under the more commonly known name Nitinol. When this material is heated above the transition temperature, the material undergoes a phase transformation from martensite to austenic, such that material returns to its remembered state. The transition temperature is dependent on the relative proportions of the alloying elements Ni and Ti and the optional inclusion of alloying additives.

[0052] In one alternate embodiment, the struts, e.g., the struts 32 of Figures 1 and 2, may be made from Nitinol with a transition temperature that is slightly below normal body temperature of humans, which is about 98.6°F. Although not necessarily a preferred embodiment, when the struts 32 is deployed in a body vessel and exposed to normal body temperature, the alloy of the struts 32 will transform to austenite, that is, the remembered state, which for one embodiment of the present invention is the expanded configuration when the struts 32 is deployed in the body vessel. To remove the basket, the struts 32 are cooled to transform the material to martensite which is more ductile than austenite, making the struts 32 more malleable. As such, the basket can be more easily collapsed and pulled into a lumen of a catheter for removal.

[0053] In another alternate embodiment, the struts 32 may be made from Nitinol with a transition temperature that is above normal body temperature of

humans, which is about 98.6° F. Although not necessarily a preferred embodiment, when the struts 32 is deployed in a body vessel and exposed to normal body temperature, the struts 32 is in the martensitic state so that the struts 32 is sufficiently ductile to bend or form into a desired shape, which for the present invention is an expanded configuration. To remove the basket, the struts 32 are heated to transform the alloy to austenite so that the struts 32 becomes rigid and returns to a remembered state, which for the struts 32 in a collapsed configuration.

[0054] Figure 8 depicts the embolic capturing device 510 for capturing emboli in a body vessel for an endoluminal procedure in accordance with another embodiment of the present invention. As shown, embolic capturing device 510 comprises a basket 520 and at least one coil 522 attached to the basket 520 for capturing emboli in a body vessel. In this embodiment, the basket 520 includes a frame 523 having first and second portions 524 and 526. In this embodiment, the first portion 524 is a proximal portion and the second portion 526 is a distal portion of the frame 523. As shown, the frame 523 is defined by a plurality of struts 532 extending from the first portion 524 to the second portion 526. In this embodiment, the struts 532 extend from the first portion 524 to the second portion 526. The struts 523 preferably extend proximally to the proximal end of the delivery apparatus. The struts may be attached to the distal end 556 of the tubular shaft or may extend proximally to the proximal end of the delivery apparatus.

[0055] While the present invention has been described in terms of preferred embodiments, it will be understood, of course, that the invention is not limited thereto since modifications may be made to those skilled in the art, particularly in light of the foregoing teachings.

CLAIMS

1. An embolic capturing device for capturing emboli within a body lumen, the device comprising:

a basket including a frame and a filtering body disposed on the frame configured to have an expanded state and a collapsed state, the frame having first and second portions, the filtering body having a lip disposed on the second portion of the frame to define an opening of the filtering body when the basket is in the expanded state for capturing emboli, the filtering body extending from the lip to a filter end; and

at least one coil attached to the basket.

2. The device of claim 1 wherein the filtering body is disposed on the second portion of the frame.

3. The device of claim 1 wherein the at least one coil comprises a plurality of coils.

4. The device of claim 1 wherein each coil is longitudinally attached to the filtering body.

5. The device of claim 1 wherein the coil is attached to the filtering body across the cross section of the frame.

6. The device of claim 1 further comprising a tubular shaft having a shaft body extending to a distal portion, the shaft body having slits formed longitudinally therethrough to the distal portion, the slits define a plurality of struts forming the frame of the basket.

7. The device of claim 6 wherein the tubular shaft is formed of a malecot configuration, the second portion of the frame being integral with the distal portion of

the frame and the first portion being integral with the shaft body to define the malecot configuration.

8. The device of claim 1 further comprising a tubular shaft having proximal and distal ends, the distal end being connected to the first portion of the frame for delivery and retrieval of the device.

9. The device of claim 8 wherein the frame includes a plurality of struts defining the frame, each pair of opposed struts being integrally formed, each pair of struts being configured to distally extend from the proximal end of the tubular shaft to the second portion and further extend oppositely to the proximal end, defining the basket.

10. The device according to any of the preceding claims wherein the filtering body comprises super-elastic material, connective tissue material, shape memory alloy, aluminum, platinum, metal alloy, nylon, polymeric material, polytetrafluoroethylene, or a mixture thereof.

11. A distal protection apparatus for capturing emboli within a body vessel, the apparatus comprising:

an embolic capturing device comprising:

a tubular shaft having proximal and distal ends;

a basket including a plurality of struts and a filtering body disposed on the struts, each of the struts having first and second portions, the first portion being proximally attached to the distal end of the tubular shaft and extending to the second portion to which the filtering body is attached, the filtering body having a lip disposed on the second portion to define an opening of the filtering body when the basket is in the expanded state for capturing emboli, the filtering body extending from the lip to a filter end;

at least one coil attached to the basket for filtering emboli in the body lumen; and

an inner catheter in which the device is disposed for deployment in the body vessel;

an introducer sheath through which the inner catheter is advanced for percutaneous insertion into the body vessel, the introducer sheath being configured to allow the inner catheter to be disposed therethrough for positioning of the device in the body vessel; and

an outer catheter co-axially disposed about the inner catheter and within the introducer sheath to collapse and expand the embolic capturing device for delivery and retrieval thereof.

12. The device of claim 11 wherein the filtering body is disposed on the second portions.

13. The apparatus of claim 11 wherein the at least one coil comprises a plurality of coils.

14. The apparatus of claim 11 wherein each coil is longitudinally attached to the filtering body.

15. The apparatus of claim 11 wherein each coil is attached to the filtering body across the cross section of the filtering body.

16. The apparatus of claim 11 wherein the outer catheter further includes a balloon formed thereon for stenosis procedure.

17. The apparatus according to any of the preceding claims wherein the filtering body comprises super-elastic material, connective tissue material, shape memory alloy, aluminum, platinum, metal alloy, nylon, polymeric material, polytetrafluoroethylene, or a mixture thereof.

18. A method for capturing emboli within a body vessel, the method comprising:

percutaneously introducing an embolic capturing device for capturing emboli during a stenosis procedure at a stenotic area, the embolic capturing device including:

a basket including a frame and a filtering body attached within the frame, the frame having first and second portions; and

at least one coil attached to the basket for filtering emboli in a body lumen;

disposing the embolic capturing device through the stenotic area; and

deploying the embolic capturing device in the body vessel to capture emboli.

19. An embolic capturing device for capturing emboli within a body lumen, the device comprising:

a basket including a frame configured to have an expanded state and a collapsed state; and

at least one coil attached to the frame for capturing emboli.

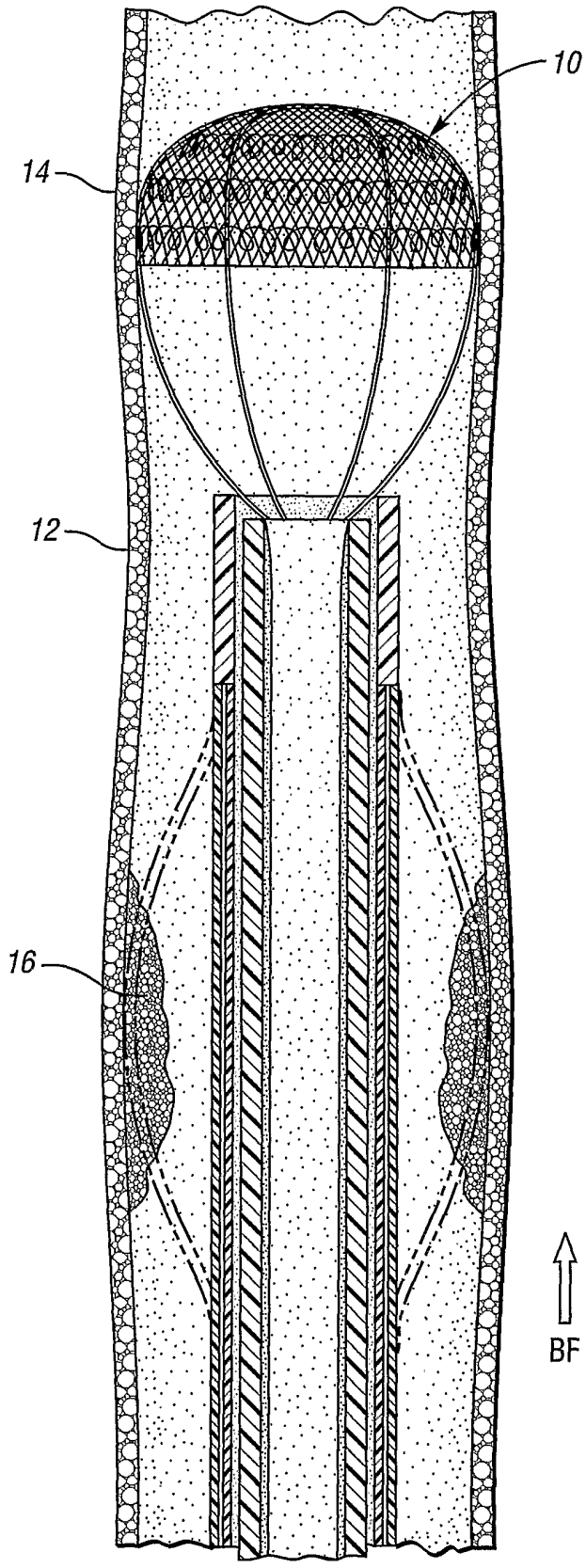


Fig. 1

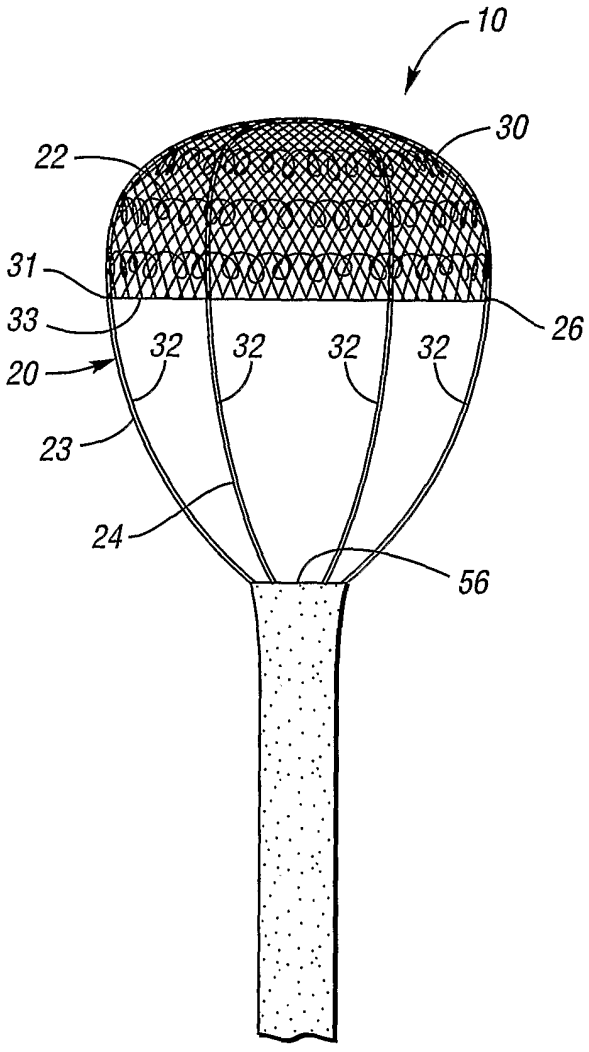


Fig. 2

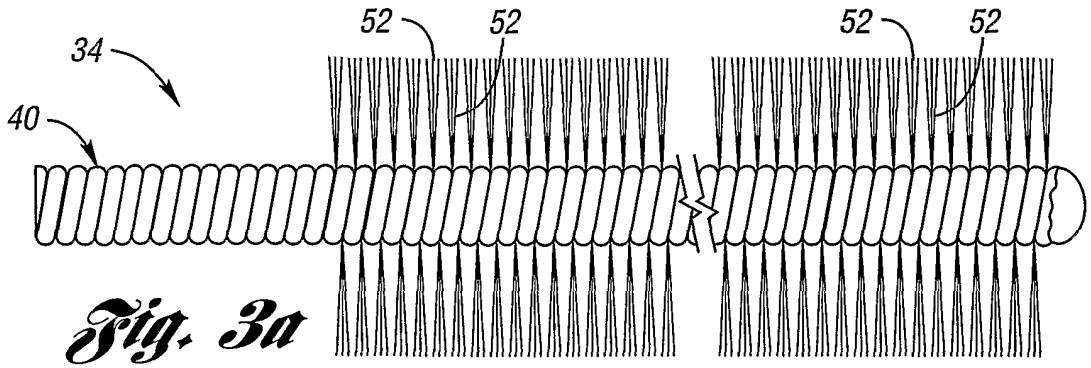


Fig. 3a

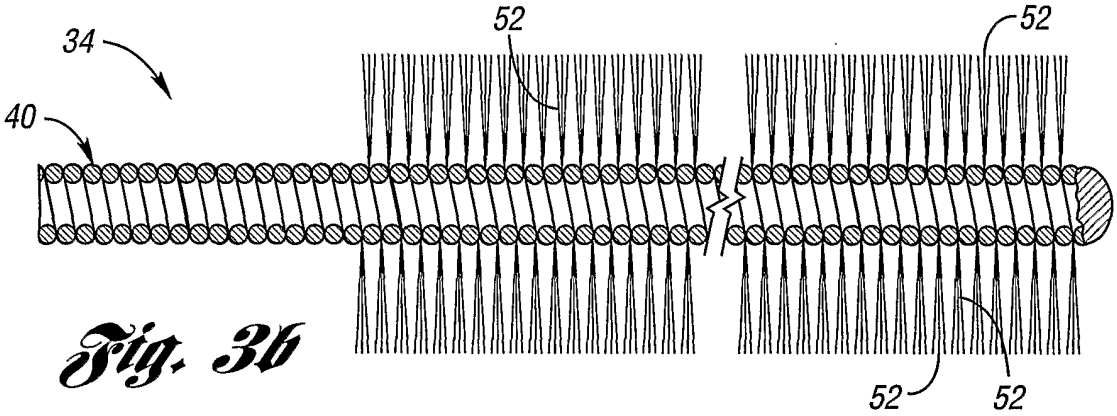


Fig. 3b

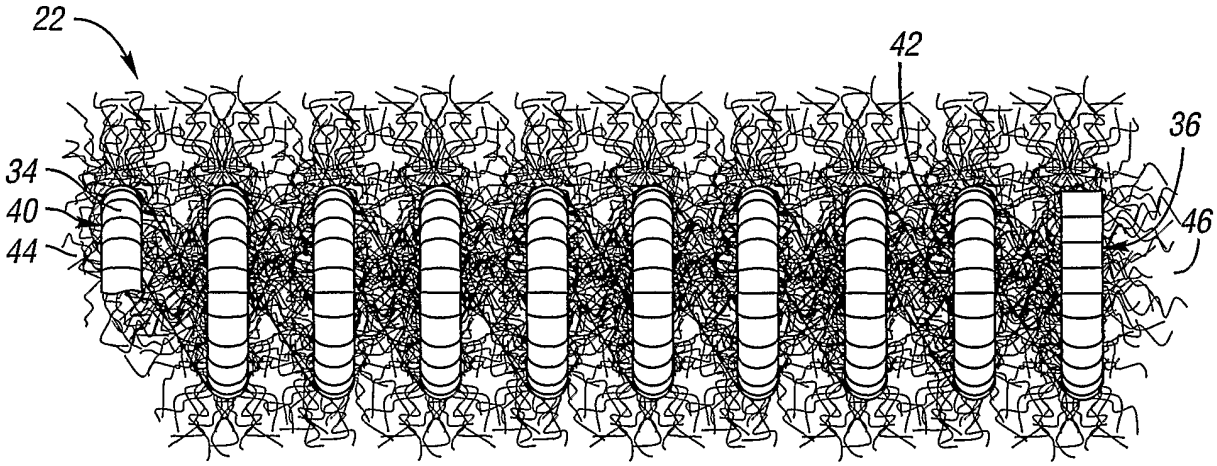


Fig. 3c

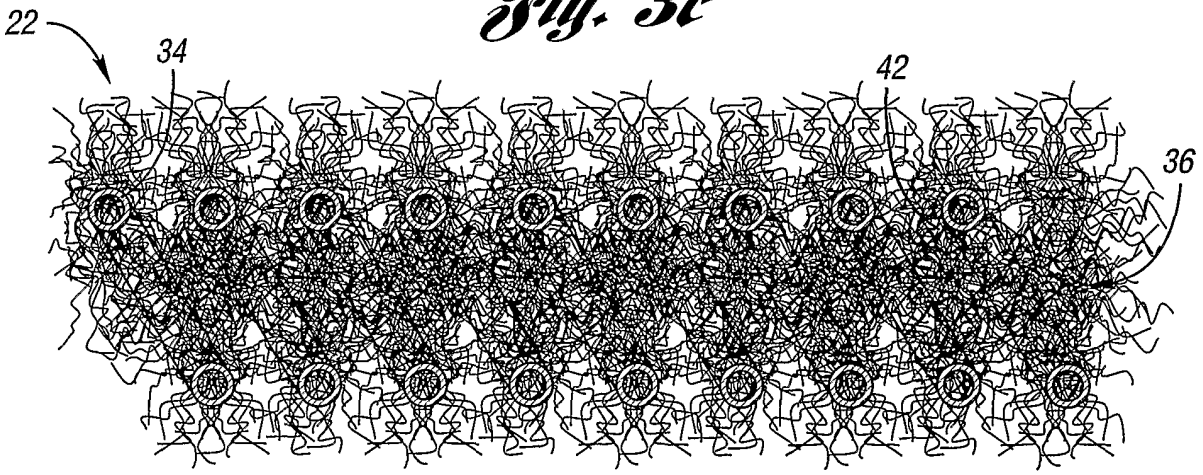


Fig. 3d

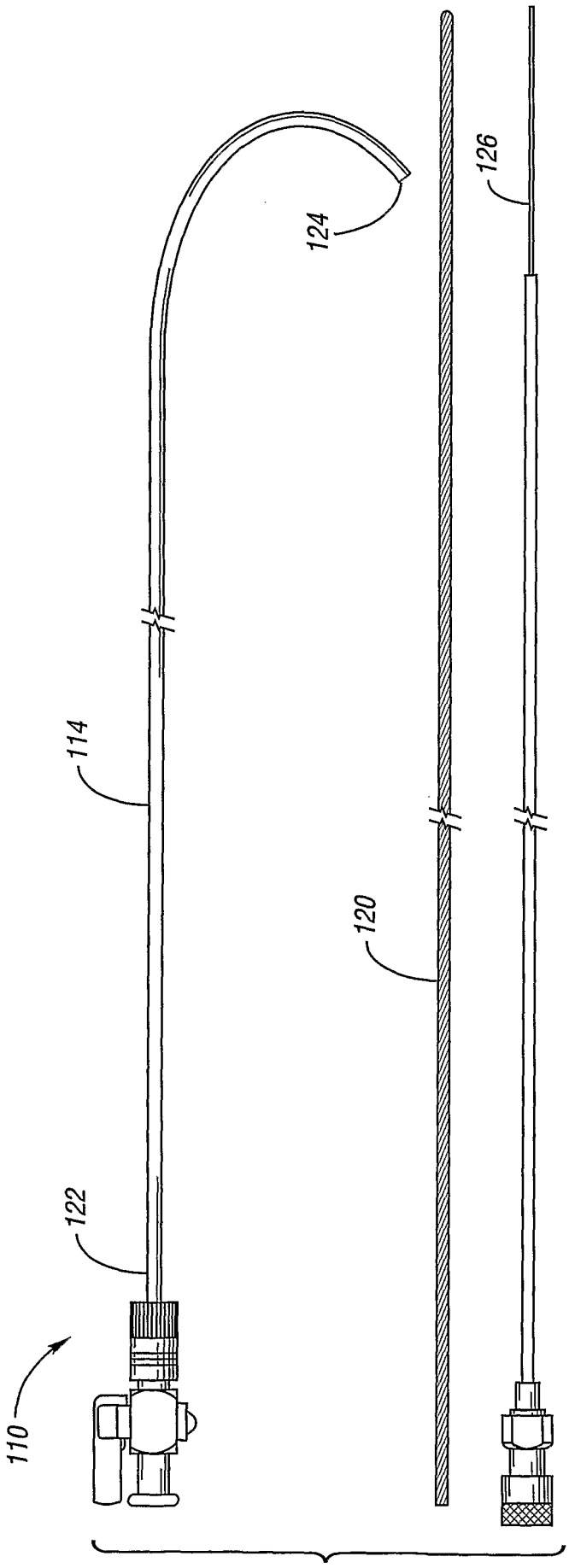


Fig. 4a

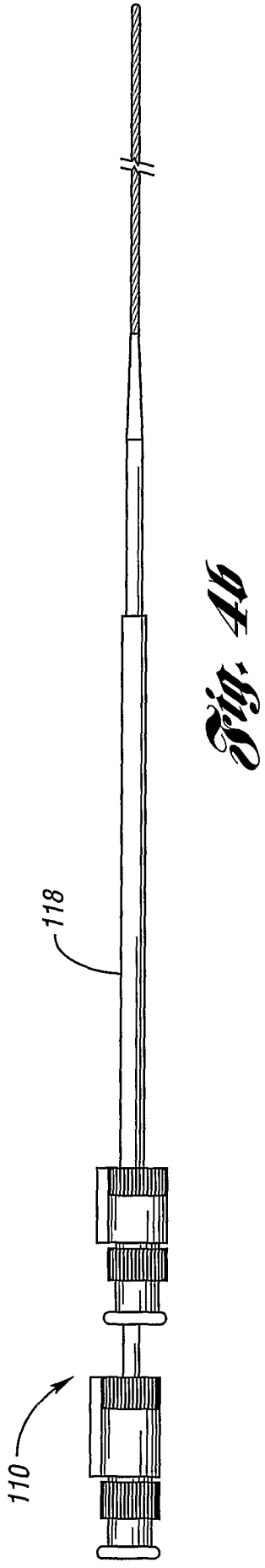


Fig. 4b

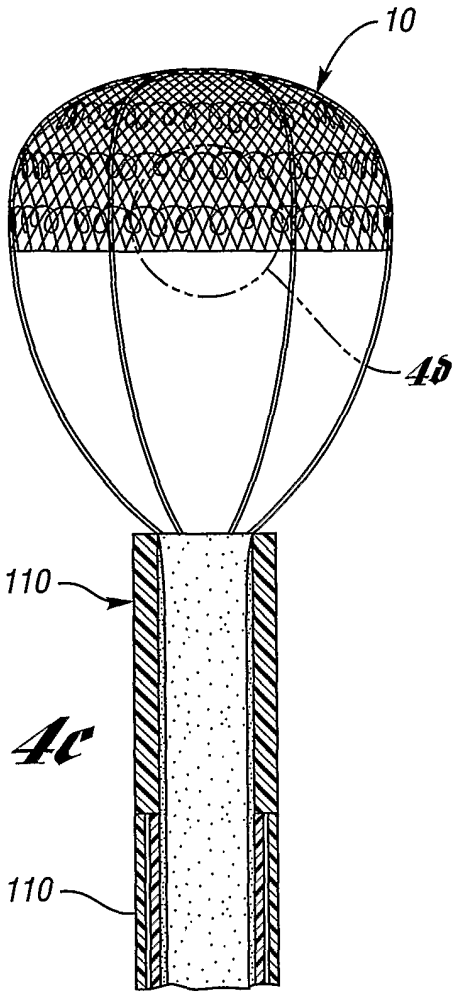


Fig. 4c

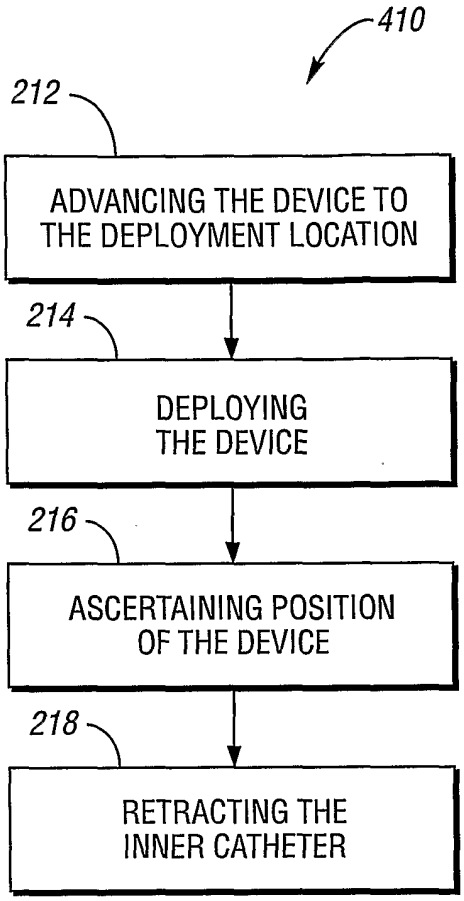


Fig. 5

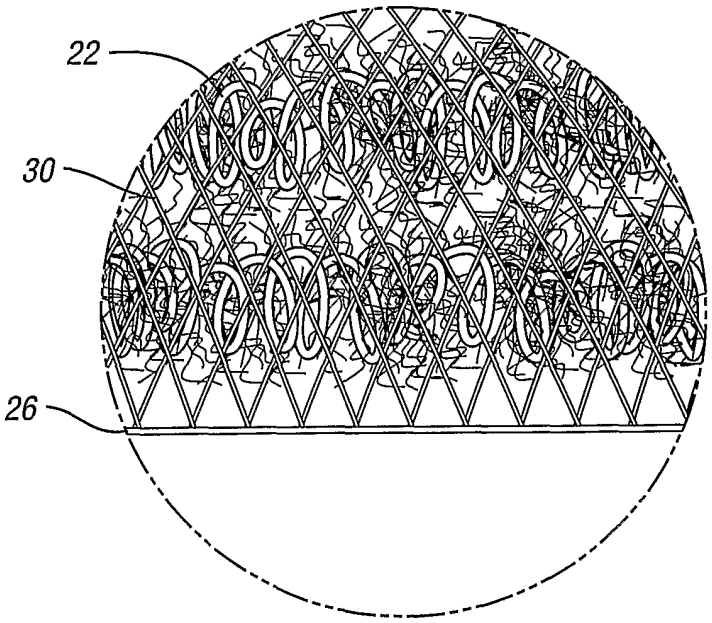
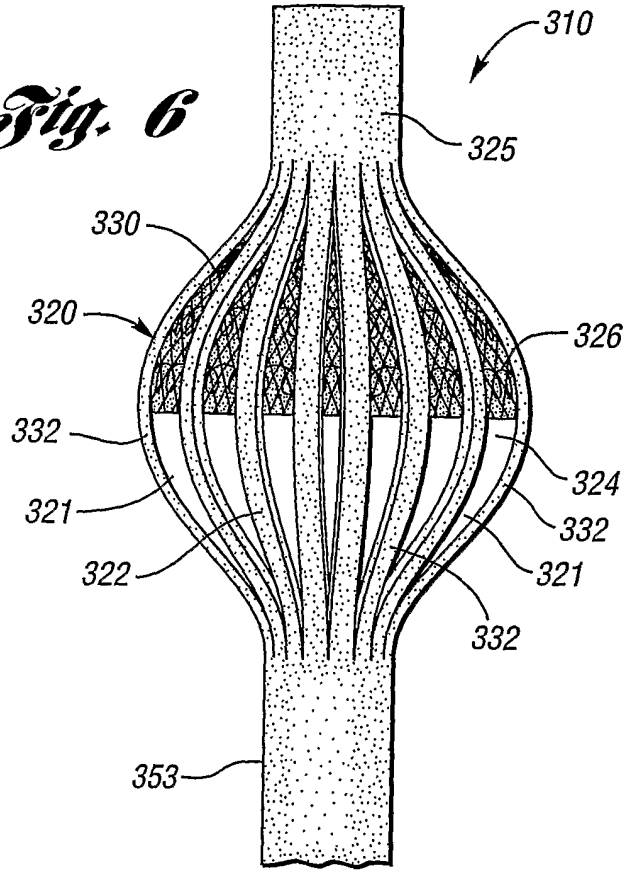


Fig. 4b

Fig. 6



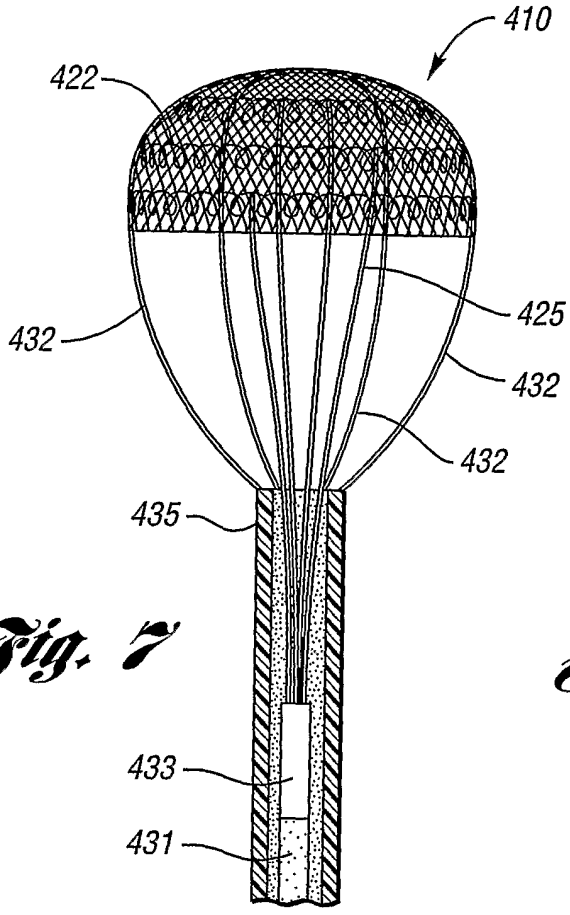


Fig. 7

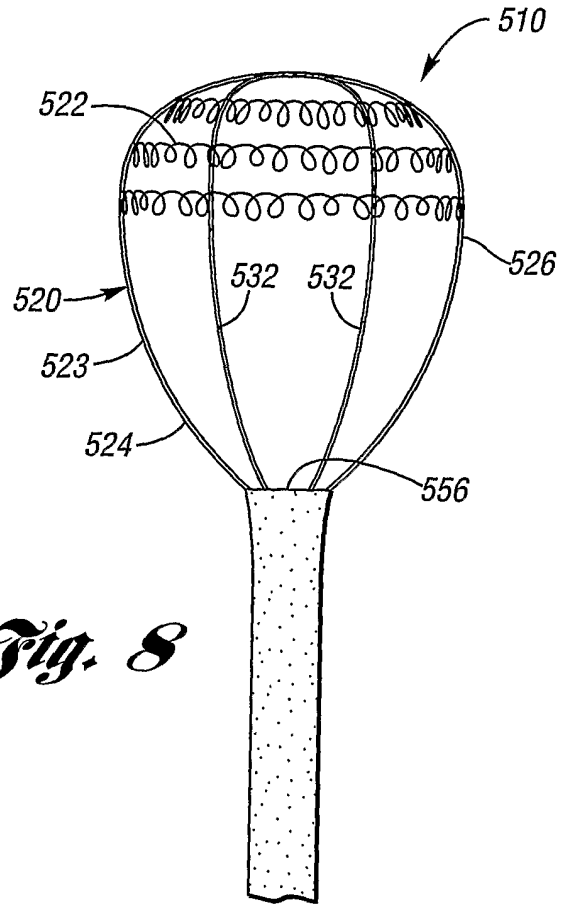


Fig. 8

INTERNATIONAL SEARCH REPORT

ıtional application No
/US2005/036164

A. CLASSIFICATION OF SUBJECT MATTER
A61F2/01

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)
A61F

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 01/45590 A (PERCUSURGE, INC) 28 June 2001 (2001-06-28)	1-4, 6-14,17, 19
Y		16
A		5,15
	figure 29a	

Y	WO 01/08743 A (INCEPT LLC) 8 February 2001 (2001-02-08) figure 5c	16

X	US 6 066 149 A (SAMSON ET AL) 23 May 2000 (2000-05-23) figures 2a,5a	1,19

X	US 2002/123766 A1 (SEGUIN JACQUES ET AL) 5 September 2002 (2002-09-05) figure 10	1,19

	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
3 February 2006	13/02/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Franz, V

2

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INTERNATIONAL SEARCH REPORT

ational application No
'/US2005/036164

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/153117 A1 (CLUBB THOMAS L ET AL) 5 August 2004 (2004-08-05) figures 1a,1b,6a-6f	1,19
X	US 2002/065507 A1 (ZADNO-AZIZI GHOLAM-REZA) 30 May 2002 (2002-05-30) figures 43,44	1,19
A	US 2002/151926 A1 (WALLACE MICHAEL P ET AL) 17 October 2002 (2002-10-17) figure 5	1-17,19
A	EP 0 865 772 A (SARCOS, INC; PRECISION VASCULAR SYSTEMS, INC) 23 September 1998 (1998-09-23) figure 3	1-17,19

INTERNATIONAL SEARCH REPORT

ıational application No.
PCT/US2005/036164

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

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

1. [X] Claims Nos.: 18
because they relate to subject matter not required to be searched by this Authority, namely:

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

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

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

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

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

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

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

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

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

Remark on Protest

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

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

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

ational application No
/US2005/036164

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