A distal embolic protection device for dedicated use in cerebral arterial blood vessels is described. The distal embolic protection device comprises a variable-thickness microguidewire and a collapsible filtering device mounted on the microguidewire over two mobile attachment points so that in its collapsed configuration, the thickness of the microguidewire and the filtering device at this region is less than or equal to 0.017 inch (0.432 mm) in thickness to be able to pass through existing conventional microcatheters. The mobile attachment points allow for rotatory and longitudinal mobility of the microguidewire while the filtering device is stable thereby decreasing the risk of trauma to the fragile cerebral arterial blood vessels. Preferably, the filtering device comprises an expansion assembly, e.g., a plurality of struts attached to a filter membrane that are in a folded position which self-expand to the desired dimensions within the cerebral blood vessels. Also described are methods of using the distal embolic protection devices of this invention.
VARIEABLE THICKNESS VASCULAR TREATMENT DEVICE SYSTEMS AND METHODS

INTEGRATION BY REFERENCE TO ANY PRIORITY APPLICATIONS

[0001] The present application is a continuation of U.S. patent application Ser. No. 11/859,272, filed Sep. 21, 2007 and issued as U.S. Pat. No. 9,034,007 on May 19, 2015. Any and all applications for which a foreign or domestic priority claim is identified in the Application Data Sheet as filed with the present application are hereby incorporated by reference under 37 C.F.R. §1.57.

FIELD OF INVENTION

[0002] This invention is related generally to the field of intravascular medical devices. Particularly a distal embolic protection device as well as methods for use of the device during neurovascular interventional procedures in the cerebral arterial blood vessels.

BACKGROUND OF INVENTION

[0003] Stroke is the leading cause of long term disability in the United States and the second leading cause of death worldwide with over 4.4 million deaths in a year (1999).1 There are over 700,000 new strokes every year in the United States.2 Around 85% of all strokes are acute ischemic strokes caused from a blockage in a blood vessel or a blood clot occluding a blood vessel.3 In 1996, the FDA approved a thrombolytic drug to dissolve blood clots called recombinant tissue plasminogen activator (r-tPA).4 Despite practice guidelines from multiple national organizations stating the intravenous r-tPA is the standard of care for patients with acute ischemic stroke within 3 hours from symptom onset,5 only 3-4% of patients with acute ischemic stroke received this drug in the United States.6 Unlike intravenous r-tPA, Intra-arterial infusion of thrombolytic agents can be used for up to 6 hours from acute ischemic stroke symptom onset and could benefit more people.7 Currently, intra-arterial infusion of thrombolytic agents are administered to a blood clot and the blood clot breaks up into smaller blood clots and travels downstream and potentially close up smaller cerebral blood vessels. With advances in regional stroke networks, there are more and more stroke patients who are getting access to intra-arterial thrombolysis and therapies, and are as high as 21.6%. However, there is no currently available distal embolic protection device that is dedicated to the cerebral blood vessels.

[0004] More than 8% of all acute ischemic strokes are from blockages in the cervical or neck carotid artery.2 Studies have shown that performing percutaneous balloon angioplasty and stenting on these blockages result in emboli or debris being dislodged downstream and could cause further strokes and therefore there have been large clinical trials of angioplasty and stenting of the carotid artery in the neck with distal embolic protection devices being used.8 In addition to blockages in the neck region of the carotid artery, more than 8% of all acute ischemic strokes are due to blockages in the cerebral arterial blood vessels called intracranial stenosis.2 Recently there has been a new device approved for intracranial angioplasty and stenting.9 Although the risks of small emboli or debris being dislodged during intracranial angioplasty and stenting is similar to the cervical carotid artery and rest of the body, there are no distal embolic protection devices in the market dedicated for cerebral arterial blood vessels. In addition, the distal embolic protection devices currently available for the cervical carotid artery are too bulky for use in the tortuous and fragile cerebral arterial blood vessels.

[0005] Embolic protection devices have been developed for the cervical carotid artery prior to carotid angioplasty and stenting.2 However, these devices do not have a small profile for use in the cerebral arterial blood vessels and will not be able to track and traverse the tortuous cerebral arterial blood vessels.

[0006] Barbut in U.S. Pat. No. 6,165,199 has described embolic protection devices that can be used for the cerebral arterial blood vessels. This is a proximal embolic protection device wherein the embolic protection device is before the clot or blockage comprising of a proximal balloon occlusion catheter to create flow arrest and an aspiration device to suction out the emboli or debris during the interventional procedure in the cervical and cerebral blood vessels. The drawbacks of a proximal protection device are that the flow arrest performed to decrease emboli or debris from traveling downstream can be detrimental in itself, since creating a flow arrest in an already ischemic blood vessel during the long neurovascular interventional procedures would itself worsen the cerebral ischemia and worsen the strokes. Dose et al in U.S. Pat. No. 6,669,721 describe thin-lumen distal embolic protection devices that can be potentially used in the cerebral blood vessels. The device has one or two rings and a thin-film filter that is attached to the guidewire. The drawbacks of this device is that during neurovascular interventional procedures, there is constant exchange of microcatheters, balloon catheters, and stent catheters over the guidewire or microguidewire, and a distal embolic protection device that is rigidly fixed to the guidewire or microguidewire would cause trauma to the cerebral arterial blood vessel wall as there will not be any mobility of the wire independent of the distal embolic protection device. Hopkins et al in U.S. Pat. No. 6,544,279 B1 describe distal embolic protection devices that do have mobility over a guidewire or microguidewire, however these guidewires or microguidewires are of uniform thickness and the mobile attachment point in these devices extend through the entire length of the device. Current microguidewires used in neurovascular interventional procedures to perform intracranial angioplasty and stenting among other procedures use microguidewires in the thickness of 0.014 inch (0.356 mm). Current microcatheters used for intracranial cerebral blood vessel catheterization for stroke as well as during intracranial angioplasty and stenting have an inner diameter of about 0.017 inch (0.432 mm). Having a distal embolic protection device mounted on a uniform thickness microguidewire of a thickness of 0.014 inch (0.356 mm) will not permit the distal embolic protection device in the collapsed form to have a thin enough or small enough profile to be compatible with existing microcatheters that are 0.017 inch (0.432 mm) in inner diameter. Having a distal embolic protection device mounted on a uniform thickness microguidewire with a mobile attachment point that extends through the entire length of the device will increase the overall thickness of the device in the collapsed configuration thereby limiting the trackability of the device and inhibiting access to the tortuous and narrow cerebral arterial blood vessels.

BRIEF SUMMARY OF INVENTION

[0007] The present invention provides a distal embolic protection device that can be used for neurovascular interven-
tional procedures including, but not limited to, intra-arterial thrombolytic or clot dissolving drug infusion for acute ischemic stroke, as well as percutaneous transluminal intracranial balloon angioplasty and stenting procedures for patients at risk for stroke so that the small emboli or debris that are dislodged during these procedures can be retrieved safely. The distal embolic protection device of this invention has a thin and small profile such that they are compatible with existing standard microcatheters. The distal embolic protection device of this invention is not attached to a balloon or stent. The present invention also addresses the limitations of all the prior art on embolic protection devices discussed above as well as those that have been referenced.

Another object of this invention is to have a distal embolic protection device that is dedicated to the cerebral arterial blood vessels and is suitable for use in cerebral arterial blood vessels of 1.5 mm to 4.5 mm in diameter. The definition of cerebral arterial blood vessels is described in the detailed description of Figs. 1, 2 and 3.

Another object of this invention is to have an embolic protection device that does not have to cause flow arrest to provide embolic protection. Devices that cause flow arrest have a risk of worsening a stroke. Therefore the embolic protection device of this invention is distal rather than proximal to the blockage or blood clot and not proximal to the blockage or blood clot.

Another object of this invention is to have a distal embolic protection device that can pass through the tortuous cerebral arterial blood vessels with no or little trauma to the vessels. Current embolic protection devices are transported or moved through catheters using a small steerable microcure. Due to the bulky nature of current embolic protection devices, it is very difficult to navigate through even in straight blood vessels leave alone tortuous blood vessels.

Another object of this invention is to have a distal embolic protection device comprising a collapsible filtering device that has a small thin profile so that in the collapsed configuration of the filtering device, the thickness of the distal embolic protection device is no more than about 0.017 inch (0.432 mm), preferably no more than about 0.014 inch (0.356 mm), and can be delivered and retrieved via a standard microcatheter (inner diameter of 0.017 inch, 0.432 mm), a balloon catheter or stent catheter that are used in neurovascular interventional procedures. The filtering device is not attached to a balloon or stent.

Another object of this invention is a distal embolic protection device comprising a variable thickness microguidewire and a collapsible filtering device, wherein the filtering device is rotatably mounted on the distal segment of the variable thickness microguidewire. The variable thickness microguidewire comprises a thinner segment bordered on both ends by thicker segments. The thinner segment is no more than about 0.010 inches in thickness and preferably about 0.008 to 0.010 inch (0.203 to 0.254 mm). The thicker segments, which make up the majority of the microguidewire, are thicker than the thinner segment and preferably no more than 0.017 inch (0.432 mm) in thickness, preferably no more than about 0.014 inch (0.356 mm). The variable thickness microguidewire may comprise a core microguidewire that extends throughout the entire length, or a portion of, of the microguidewire and a coating or covering or flexible hypotube or a combination thereof over the core microguidewire. The filtering device is mounted on the thinner segment, which is in the distal segment of the microguidewire to maintain a small thin profile so that tractability is maintained as well as compatibility with existing microcatheters, balloon catheters and stent catheters that are used in neurovascular interventional procedures. Preferably the small thin profile is no more than about 0.017 inch (0.432 mm) and preferably no more than about 0.014 inch (0.356 mm).

Another object of this invention is a distal embolic protection device comprising a variable thickness microguidewire and a filtering device, wherein the microguidewire and filtering device have rotational and longitudinal movement relative to and independently of each other, such that the filtering device can remain stable within the blood vessel while there is motion on the microguidewire both in the rotational as well as longitudinal directions relative to the filtering device so that there is no, or very limited, trauma to the fragile cerebral arterial blood vessels.

The filtering device of the distal embolic protection device of this invention may comprise mobile attachment points on its proximal and distal ends wherein the mobile attachment points attach the filtering device to the microguidewire. The mobile attachment points are of such a size that the thickness of the filtering device in the collapsed configuration is smaller than a cerebral arterial blood vessel and can pass through standard microcatheters that are used in neurovascular interventional procedures. Preferably the attachment points in conjunction with the filtering device in the collapsed configuration are no more than about 0.017 inch (0.432 mm), and more preferably not more than about 0.014 inch (0.356 mm) in thickness. Preferably the attachment points are short and abut, but do not cover, the thicker segments of the microguidewire.

In an embodiment of this invention, the distal embolic protection device comprises a filtering device rotatably mounted on the thinner segment of the microguidewire, and further comprises cylindrical coils that wind around the thinner segment of the microguidewire and connect the proximal and distal ends of the filtering device to the proximal and distal stops of the thicker segments of the microguidewire. The attached cylindrical coils decrease the shear stress on the thinner segment of the microguidewire during the retrieval of the distal embolic protection device.

Another object of this invention the distal embolic protection device comprises a radio-opaque portion that enables the device to be visualized during fluoroscopic neurovascular interventional procedures. For example, the thicker segments of the microguidewire, or the distal end of the microguidewire, or the filtering device itself may comprise radio-opaque sections so that the operator during a medical procedure can distinguish the filtering device and its position relative to the thicker and thinner segments of the microguidewire.

The distal embolic protection devices of this invention are dedicated to use in cerebral arterial blood vessels and their use in the treatment of existing stroke patients and patients that are at risk for strokes. The methods of this invention include e.g., crossing a vascular blockage or blood clot with a standard microcatheter and microwire. Then removing the microwire and once the microwire is removed, the distal embolic protection device is advanced via the microcatheter to the desired location. As the distal embolic protection device is not involved in navigation, it is able to pass the tortuous curves of the cerebral blood vessels due to the novel delivery system. The microguidewire is also designed to be compatible with existing microcatheters, balloon catheters
and stent catheters used in neurovascular interventions. In addition, the stops in the distal part of the microguidewire and the mobile attachment points on the filtering device allow for mobility of the microguidewire both in the rotary and longitudinal directions relative to the filtering device, wherein the filtering device is stable in the cerebral blood vessel thereby minimizing vessel trauma or dissections. The variable thickness of the distal part of the microguidewire also allows for the smaller overall profile of the device and improves its compatibility with existing microcatheters, balloon catheters, and stent catheters. The small profile also allows for easy retrieval of the distal embolic protection device of this invention using existing microcatheters, balloon catheters or stent catheters making the procedure shorter and safer.

[0018] The methods of this invention for collecting thrombo-embolic material, debris or clots released during percutaneous neurovascular interventional procedures specifically performed in the cerebral arterial blood vessels, comprises inserting the distal embolic protection device of this invention into a cerebral arterial blood vessel having an area of stenosis or a clot, deploying the filtering device distal to the area of blockage or clot and allowing the filtering device to expand to fill the diameter of the cerebral arterial blood vessel. The methods of this invention may further comprise advancing a standard microcatheter over a standard microwire across the area of stenosis or clot, positioning the microcatheter distal to the stenosis or clot, withdrawing the microwire, and advancing the distal embolic protection device through the standard microcatheter. The thickness of the thicker segments of the variable thickness microguidewire is no more than about 0.017 inch (0.432 mm) and preferably no more than about 0.014 inch (0.356 mm) such that it is compatible for use with standard microcatheters, which have an inner lumen diameter of about 0.017 inch (0.432 mm). In addition, the methods of this invention may further comprise withdrawing the microcatheter, while keeping the microguidewire in position distal to the stenosis or clot, unsheathing the distal embolic protection device and expanding the filtering device to the inside size of the cerebral arterial blood vessel, ranging from 1.5 mm to 4.5 mm, and wherein the expanded shape of the filter membrane is a hemispherical, helical or conical shape and spans the cerebral arterial blood vessel. The method may also comprise maintaining the microguidewire in position, exchanging the standard microcatheter for (1) a balloon catheter to perform balloon angioplasty of the cerebral arterial blood vessels, or (2) a stent catheter to perform stenting of the cerebral arterial blood vessels, and collecting any debris or clots that are dislodged during the balloon angioplasty and or stenting in the cerebral arterial blood vessels in the filter membrane. The methods of this invention also comprise maintaining the microguidewire in position and administering clot dissolving drugs or thrombolytics to a patient in need thereof through a standard microcatheter, such that any debris or clots that are dislodged will be collected by the filter membrane. The methods of this invention may comprise additional steps, e.g., recovering the distal embolic protection device by advancing a standard microcatheter, balloon catheter, or stent catheter over the variable thickness microguidewire, and withdrawing the distal embolic protection device and the standard microcatheter, balloon catheter or stent catheter.

Various embodiments of the present invention are shown in the figures and described in detail below.

BRIEF DESCRIPTION OF INVENTION/FIGURES

[0020] FIG. 1 is a schematic diagram illustrating the origin of the great vessels from the heart.

[0021] FIG. 2 is a schematic diagram illustrating the cervical and cerebral course of the internal carotid arteries and their branches.

[0022] FIG. 3 is a schematic diagram illustrating the cervical and cerebral course of the vertebral arteries and their branches.

[0023] FIG. 4 is a schematic diagram illustrating the Circle of Willis and the main collateral blood vessel pathways in the brain.

[0024] FIG. 5 illustrates the introducer system for delivery of the distal embolic protection device into the microcatheter.

[0025] FIG. 6 illustrates the introducer sheath and its components.

[0026] FIG. 7A illustrates a magnified cross-sectional view of an introducer sheath with the distal embolic protection device comprising the filtering device and variable thickness microguidewire. FIG. 7B illustrates a magnified view of the variable-thickness microguidewire with the filtering device mounted on it and shown in a collapsed configuration within the microcatheter.

[0027] FIGS. 8A and 8B illustrate the microguidewires in two lengths 300 cm and 190 cm respectively.

[0028] FIG. 9A is an illustration of the distal segment of the microguidewire (distal 30 cm). FIGS. 9B, 9C and 9D are magnified views of embodiments of the variable thickness microguidewire with different components of the distal segment of the microguidewire illustrated (distal 30 cm).

[0029] FIG. 10 is an illustration of one of the embodiments of the distal embolic protection device.

[0030] FIG. 11 is a schematic diagram illustrating the cross-sectional view of the distal embolic protection device described in FIG. 10.

[0031] FIG. 12 illustrates one of the embodiments of a distal embolic protection device in the expanded configuration showing the radio-opaque components under fluoroscopy.

[0032] FIG. 13 illustrates another embodiment of a distal embolic protection device over the variable thickness microguidewire.

[0033] FIG. 14A is an illustration of another embodiment of the distal embolic protection device.

[0034] FIG. 14B is a schematic diagram illustrating the cross-sectional view of the distal embolic protection device described in FIG. 14A.

[0035] FIG. 15A is an illustration of another embodiment of the distal embolic protection device.

[0036] FIG. 15B is a schematic diagram illustrating the cross-sectional view of the distal embolic protection device described in FIG. 15A.

[0037] FIG. 16 is a schematic diagram illustrating a significant blockage or stenosis 585 in the right middle cerebral artery 105.

[0038] FIG. 17 is a schematic diagram illustrating a microcatheter being advanced into the right middle cerebral artery over a microwire.

[0039] FIG. 18 is a schematic diagram illustrating the microcatheter has been carefully advanced across the blockage in the right middle cerebral artery over a microwire.
FIG. 19 is a schematic diagram illustrating the introducer sheath with the non-expanded distal embolic protection device and microguidewire are being advanced through the microcatheter.

FIG. 20 is a schematic diagram illustrating the distal embolic protection device in the appropriate location distal to the blockage and the microcatheter being withdrawn to deploy the device.

FIG. 21 is a schematic diagram illustrating the distal embolic protection device fully deployed.

FIG. 22 is a schematic diagram illustrating intracranial angioplasty being performed using the distal embolic protection device.

FIG. 23 is a schematic diagram illustrating intracranial stenting being performed using the distal embolic protection device.

FIG. 24 is a schematic diagram of a standard microcatheter used to recover the distal embolic protection device.

FIG. 25 is a schematic diagram illustrating the stent catheter or the tip of the standard microcatheter being advanced over the microguidewire to retrieve the distal embolic protection device.

FIG. 26 is a schematic diagram illustrating the distal embolic protection device being safely retrieved by either the stent catheter or a standard microcatheter.

FIG. 27 is a schematic diagram illustrating another use for this distal embolic protection device namely during intra-arterial thrombolysis for thrombus or blood clot causing acute ischemic stroke.

FIG. 28 is a schematic diagram illustrating a standard microcatheter being advanced across the thrombus or blood clot in the right middle cerebral artery over a microwire.

FIG. 29 is a schematic diagram illustrating a distal embolic protection device being deployed distal to the thrombus or blood clot causing the stroke and then the microcatheter is withdrawn back and intra-arterial thrombolysis is initiated.

FIG. 30 is a schematic diagram illustrating the retrieval of the distal embolic protection device with the standard microcatheter.

DETAILED DESCRIPTION OF INVENTION/FIGURES

FIG. 1 is a schematic diagram that illustrates the heart, the aorta and the supra-aortic vessels. The left ventricle is one of the chambers of the heart and pumps oxygenated blood to the rest of the body through the aorta. The innominate artery is one of the great vessels originating from the aorta and divides into two branches namely the right subclavian artery and the right common carotid artery. The right common carotid artery gives off the right internal carotid artery that continues intracranially to supply the anterior circulation or the front of the brain (see FIG. 2 for further details), and the left common carotid artery 55, which continues to supply the scalp, face and neck. This portion of the aorta 10 from which the left common carotid artery arises is also known as the aortic arch 60. The left subclavian artery 65 arises from the aortic arch and gives off several branches including the left vertebral artery which continues intracranially to supply the posterior circulation or the back of the brain (see FIG. 3 for further details). Subsequent to the origin of the left subclavian artery 65, the aortic arch curves inferiorly or downwards and is known as the descending aorta 75 which continues to supply the abdomen, spine and lower extremities.

FIG. 2 is a schematic diagram illustrating the cervical and intracranial course of the internal carotid arteries. The right common carotid artery divides into right external carotid artery and the right cervical internal carotid artery in the neck. The right internal carotid artery in the cervical or neck portion enters the base of skull and continues as the petrous portion of the right internal carotid artery. The petrous portion of the right internal carotid artery then continues as the tortuous cavernous portion of the right internal carotid artery. The right internal carotid artery then pierces the dura or covering layering of the brain to form the supraclinoid portion of the right internal carotid artery which also gives off the right posterior communicating artery which helps form the circle of Willis or the collateral pathway to other blood vessels in the brain (see FIG. 4 for further details). The supraclinoid portion of the right internal carotid artery then bifurcates into the right middle cerebral artery as well as the right anterior cerebral artery at the right internal carotid artery bifurcation. The right middle cerebral artery divides into several branches and the main ones being the right middle cerebral artery superior division and the right middle cerebral artery inferior division. The A1 segment of the right anterior cerebral artery further continues as the A2 segment of the right anterior cerebral artery and at the junction of the A1 and A2 segments gives off an important branch called the anterior communicating artery that communicates with the blood vessels from the left side of the brain to also form the circle of Willis.

The left common carotid artery divides into the left external carotid artery and the left cervical internal carotid artery in the neck. The left internal carotid artery in the cervical or neck portion enters the base of skull and continues as the petrous portion of the left internal carotid artery. The petrous portion of the left internal carotid artery then continues as the tortuous cavernous portion of the left internal carotid artery. The left internal carotid artery then pierces the dura or covering layering of the brain to form the supraclinoid portion of the left internal carotid artery which also gives off the left posterior communicating artery which helps form the circle of Willis or the collateral pathway to other blood vessels in the brain. The supraclinoid portion of the left internal carotid artery then bifurcates into the left middle cerebral artery as well as the left anterior cerebral artery at the left internal carotid artery bifurcation. The left middle cerebral artery divides into several branches and the main ones being the left middle cerebral artery superior division and the left middle cerebral artery inferior division. The A1 segment of the left anterior cerebral artery further continues as the A2 segment of the left anterior cerebral artery and at the junction of the A1 and A2 segments gives off an important branch called the anterior communicating artery.
communicates with the blood vessels from the right side of the brain to also form the circle of Willis.

In this invention, the internal carotid arteries from the petrous, cavernous and supraclinoid portions and their branches, along with the middle cerebral and anterior cerebral arteries and their branches are considered as cerebral arterial blood vessels (80 to 180).

FIG. 3 is a schematic diagram illustrating the course of the bilateral vertebral arteries and their branches. The right vertebral artery 40 is a branch of the right subclavian artery 20. The first portion of the right vertebral artery in the cervical or neck portion is called the V1 segment of the right vertebral artery 40. The right vertebral artery continues in the neck as the V2 segment of the right vertebral artery 185 and travels close to the base of brain. It makes a tortuous curve and is called the V3 segment of the right vertebral artery 190 and finally pierces the dura or outer covering layer of the brain and forms the V4 segment of the right vertebral artery 195. The V4 segment of the right vertebral artery 195 gives off an important branch to the right cerebellum called the right posterior-inferior cerebellar arteries 200 and then joins together with the V4 segment of the left vertebral artery 255 at the vertebro-basilar junction 205 to form the basilar artery 210. The basilar artery 210 gives off several branches including the bilateral anterior inferior cerebellar arteries 215 and 245, as well as the, the bilateral superior cerebellar arteries 220 and 240, and then bifurcates at the basilar apex 225 into the bilateral posterior cerebral arteries 230 and 235. The right posterior communicating artery 235 communicates with the right posterior cerebral artery 230 (see FIG. 4 for further details). The left posterior communicating artery 170 communicates with the left posterior cerebral artery 235 (see FIG. 4 for further details). The left vertebral artery 70 is a branch of the left subclavian artery 65. The first portion of the left vertebral artery in the cervical or neck portion is called the V1 segment of the left vertebral artery 70. The left vertebral artery continues in the neck as the V2 segment of the left vertebral artery 265 and travels close to the base of brain. It makes a tortuous curve and is called the V3 segment of the left vertebral artery 260 and finally pierces the dura or outer covering layer of the brain and forms the V4 segment of the left vertebral artery 255. The V4 segment of the left vertebral artery 255 gives off an important branch to the left cerebellum called the left posterior-inferior cerebellar arteries 250 and then joins together with the V4 segment of the right vertebral artery 195 at the vertebro-basilar junction 205 to form the basilar artery 210.

In this invention, the vertebral arteries from the V2, V3, and V4 segments and their branches, along with the basilar artery and the bilateral posterior cerebral arteries and their branches are also considered as cerebral arterial blood vessels (185 to 265).

FIG. 4 is a schematic diagram illustrating the main collateral pathways and communications between the cerebral arterial blood vessels including the internal carotid artery system (90 to 170) as well as the vertebro-basilar artery system (205 to 245), and this is known as the Circle of Willis. The supraclinoid portion of the right internal carotid artery 90 gives off the right posterior communicating artery 95 which anastomoses or communicates with the right posterior cerebral artery 230 and helps form the posterior part of the circle of Willis. The supraclinoid portion of the right internal carotid artery 90 then bifurcates 100 into the right middle cerebral artery 105 as well as the right anterior cerebral artery 120 at the right internal carotid artery bifurcation 100. The A1 segment of the right anterior cerebral artery 120 further continues as the A2 segment of the right anterior cerebral artery 125 and at the junction of the A1 and A2 segments gives off an important branch called the anterior communicating artery 130 that anastomoses or communicates with the junction of the A1 segment 140 and A2 segments 135 of the left anterior cerebral artery and helps form the anterior part of the circle of Willis. The supraclinoid portion of the left internal carotid artery 165 gives off the left posterior communicating artery 170, which anastomoses or communicates with the left posterior cerebral artery 235 and helps form the posterior part of the circle of Willis. The supraclinoid portion of the left internal carotid artery 165 then bifurcates 145 into the left middle cerebral artery 150 as well as the left anterior cerebral artery 140 at the left internal carotid artery bifurcation 145. The A1 segment of the left anterior cerebral artery 140 further continues as the A2 segment of the left anterior cerebral artery 135 and at the junction of the A1 and A2 segments gives off an important branch called the anterior communicating artery 130 that communicates with the junction of the A1 segment 120 and A2 segments 125 of the right anterior cerebral artery and helps form the anterior part of the circle of Willis. The anterior 130 and posterior communicating arteries 95 and 170 help with the anastomoses or communication of the internal carotid artery system (90 to 170) with the vertebro-basilar arterial system (205 to 245) and helps maintain an adequate collateral pathway for blood supply in the brain (see FIG. 2 for further details on the course of the internal carotid arteries and see FIG. 3 for further details on the course of the vertebral arteries). There are numerous anatomic variations to this and can play an important role at the time of a stroke.

FIG. 5 illustrates an introducer system to deliver the distal embolic protection device into the microcatheter. The microguidewire 290 that contains the distal embolic protection device is housed in a protective spiral polymer case 270 to avoid kinks or bends in the microguidewire. The spiral loops of the protective polymer case are kept together by clasps 275. The proximal end of the microguidewire is at the inner end of the spiral polymer case. The distal end of the microguidewire with the distal embolic protection device are kept in an introducer sheath 305 that is made out of a polymer (such as Teflon) and the portion of the introducer sheath 310 directly overlying the distal embolic protection device and protecting it is shown in this figure. The proximal end of the introducer sheath has a hemostatic valve 295 and a port for attaching a saline flush syringe 300 to be able to saline flush the introducer sheath as well as the distal embolic protection device of any air. The distal end of the introducer sheath 315 is the part that helps feed the distal embolic protection device into the microcatheter. When the distal protection device needs to be loaded into the microcatheter, the introducer sheath is removed from the clasps, of the spiral polymer case 275 and the microguidewire is slowly pulled off the distal port of the spiral polymer case 285.

FIG. 6 illustrates the introducer sheath 305 as well as the portion of the distal end of the introducer sheath 310 directly overlying the distal embolic protection device and protecting it. When the saline syringe 325 is connected to port 300 of the introducer sheath and is flushed, then the hemostatic valve is locked at the proximal end 295, and saline drops 320 will be noted to arise from the tip of the introducer sheath 315 because of saline moving in the direction 330 of the tip of the introducer sheath 315 suggesting that the introducer sheath 305 and the portion of the distal end of the introducer
sheath 310 directly overlying the distal embolic protection device have been flushed of air.

[0061] FIG. 7A illustrates the distal embolic protection device comprising the filtering device in the collapsed configuration 350 that is back loaded into the introducer sheath 305 over the microguidewire. FIG. 7B illustrates a magnified view of the distal embolic protection device comprising the filtering device in a collapsed configuration mounted on the variable thickness micro-guidewire. The length of the micro-guidewire is sufficient for use in existing microcatheters during interventional neurovascular procedures and preferably ranges from 190 to 300 cm in length. The majority of the proximal 290 and distal 335 microguidewire are around 0.014 inch (0.356 mm) in thickness to be compatible with existing microcatheters, balloons, and stents that are used in neurovascular interventions. Part of the distal segment of the microguidewire 335, e.g., 135 cm, is shown in the figure. The distal segment of the microguidewire has a thinner segment 360 that is about 0.010 inch (0.254 mm) or less in thickness and this is in the location where the filtering device is mounted. The filtering device is depicted in a collapsed configuration 350. The thinner segment 360 of the microguidewire where the filtering device is located is much thinner than the rest of the microguidewire 335 and is no more than about 0.010 inch (0.254 mm) and preferably measures about 0.008 to 0.010 inch (0.203 mm to 0.254 mm) in thickness. This is to maintain a small thin profile of the filtering device in the collapsed or non-expanded configuration within the inner lumen of the introducer sheath 370 so that the overall thickness of the distal embolic protection device, comprising the microguidewire and filtering device in the collapsed configuration are kept to a thickness less than or equal to 0.017 inch (0.432 mm) to be compatible with existing microcatheters, balloons, and stents. The thinner segment 360 of the microguidewire meets the thicker segment of the microguidewire at the proximal stop 340 and distal stop 375. The proximal 340 and distal stops 375 are no more than about 0.017 inch (0.432 mm) and preferably range from 0.014 inch to 0.017 inch (0.356 mm to 0.432 mm). The filtering device 350 has proximal 345 and distal 355 attachment points that allow the filtering device to be mobile over the microguidewire in the rotatory and longitudinal directions, relative to the microguidewire. The movement of the filtering device relative to the microguidewire is limited to within the thinner segment of the microguidewire 360 by the proximal 340 and distal stops 375. The microguidewire distal 365 to the distal stop 375 comprises several components that are further described in FIG. 9 and includes a shapeable tip 395, preferably curved, to enable torqueability and to avoid wire perforation of a small vessel. The microguidewire may comprise a marker 380 at a predetermined location, e.g. at 135 cm from the distal tip of the microguidewire, to aid in determining when the distal embolic protection device is likely to emerge from the distal end of the microcatheter (normally 135 cm to 175 cm in length) and in determining the progress and location of the distal embolic protection device within the cerebral arterial blood vessel. Preferably the 135 cm marker is visually detectable by the operator so that fluoroscopy can be avoided till approximately 135 cm of the microguidewire has been advanced through the microcatheter.

[0062] FIGS. 8A and 8B illustrate the components of the microguidewire at two lengths namely an exchange length 300 cm (FIG. 8A) and a non-exchange length microguidewire length 190 cm respectively (FIG. 8B). The microguidewire is of variable thickness at the distal end, having a thinner segment to accommodate a distal embolic protection device. The majority of the microguidewire 335, other than the thinner segment, is of thickness no more than about 0.014 inch (0.356 mm) and is compatible for use with existing microcatheters, balloons, and stents used in neurovascular interventions. A marking 380 on the microguidewire indicates the 135 cm length so that fluoroscopy can be avoided till approximately 135 cm of the microguidewire has been advanced through the microcatheter. The distal segment of the microguidewire, where the filtering device is present, comprises a thinner segment 360 having a thickness that is no more than about 0.010 inch (0.254 mm) to accommodate the non-expanded filtering device and still maintain an overall low thickness profile of the distal embolic protection device. The microguidewire has a proximal 340 and distal 375 stop that will allow the filtering device to be stationary in a small cerebral arterial blood vessel despite rotatory and longitudinal motion of the microguidewire over a small distance. The proximal and distal stops have a thickness of no more than about 0.017 inch (0.432 mm) and preferably from 0.014 to 0.017 inch (0.356-0.432 mm). Part of the distal segment of the microguidewire 335 e.g. distal 30 cm comprises several components that are further described in detail in FIGS. 9A to 9D. The distal end includes a distal tip 365 which may comprise radio-opaque shapeable material to provide some trackability and to retain a curved shape to avoid small vessel perforation. FIG. 8A shows an exchange length microguidewire 300 cm in length. FIG. 8B shows a non-exchange length microguidewire 190 cm in length. The non-exchange length guidewire has a capability at its proximal end 385 to have an extension microguidewire 390 attached if it needs to be converted into an exchange length microguidewire.

[0063] FIG. 9A is an illustration of an embodiment of the distal segment of the microguidewire e.g. distal 30 cm described in FIG. 8. FIGS. 9B, 9C and 9D are magnified views of the various components of the distal segment of the variable thickness microguidewire e.g. distal 30 cm. The microguidewire is of variable thickness at the distal segment to accommodate a filtering device at its distal end. The majority of the microguidewire 335 is no more than about 0.014 inch (0.356 mm) in thickness, and is compatible with existing microcatheters, balloons, and stents used in neurovascular interventions. The microguidewire 335 comprises various components including a core microguidewire 334 that runs the entire length of the microguidewire and provides support and trackability that is needed for catheterization of the small cerebral arterial blood vessels. The core microguidewire comprises of a metal e.g. stainless steel or an alloy e.g. nickel-titanium. The core microguidewire 334 is no more than about 0.014 inch (0.356 mm) in majority of its length in the proximal segment and is tapered to no more than about 0.010 inch (0.254 mm) in the distal segment of the microguidewire e.g. distal 30 cm. The distal segment of the microguidewire e.g. distal 30 cm comprises a core microguidewire 334 depicted in FIG. 9B-D that is no more than about 0.010 inch (0.254 mm) in thickness forming the thinner segment of the microguidewire 360 of FIGS. 9C-D, and comprises thicker segments proximal to the proximal stop 340 as well as distal to the distal stop 375, where the core may be coated or covered by another layer or layers, e.g., a coil made up of a radio-opaque material or metal or alloy such as platinum as shown in FIG. 9C forming the shapeable tip of the microguidewire 395, or a flexible hypotube 336 of FIG. 9D covering the core microgu-
idewire 334 or a combination of both as shown in FIG. 9D. The coating, or covering, may provide more support as well as trackability that is need for catheterization of the small cerebral arterial blood vessels. The coated core microguide wire is no more than about 0.014 inch (0.356 mm) in thickness in the majority of its length. The various components of this distal segment of the microguide wire are illustrated in more detail in FIGS. 9B to 9D. The thinner segment of the microguide wire 360 is no more than about 0.010 inch (0.254 mm) to accommodate the filtering device in its non-expanded state and still maintain an overall low thickness profile of the distal embolic protection device. In this thinner segment of the microguide wire where the filtering device is mounted 360, the components of the microguide wire are predominantly just the core microguide wire 334 as previously described. The distal end of the microguide wire 365 comprises several components that include a core microguide wire 334 as previously described, and a shapeable tip comprising a radio opaque material, metal or alloy, e.g., platinum, that is shapeable to provide some trackability and to retain a curved shape to avoid small vessel perforation. In addition the shapeable tip of the distal end of the microguide wire 365 may also include a coating or covering layer, such as a flexible hypotube 336, covering the core microguide wire 334 to give it more support and strength and is no more than about 0.014 inch (0.356 mm) in the majority of its length. The microguide wire has proximal 340 and distal 375 stops that allow the filtering device to be stationary in a small cerebral blood vessel despite rotatory and longitudinal motion of the microguide wire relative to the filtering device between the proximal and distal stops. The thickness of the stops is no more than about 0.017 inch (0.432 mm) and preferably from 0.014 to 0.017 inch (0.356-0.432 mm).

Various components of the variable thickness microguide wire may be made up of materials that are biocompatible or surface treated to produce biocompatibility. Suitable materials include, e.g., stainless steel, platinum, titanium and its alloys including nickel-titanium, etc. Suitable materials also include a combination of metals and alloys such that the core of the microguide wire 334 forming the thinner segment 360 could be made from metals or alloys such as stainless steel or nickel-titanium, etc. In order to provide a shapeable tip that has some trackability, and that has the capacity to retain a curved shape to avoid small vessel perforation, as well as be visible during neurovascular interventional procedures, the distal end of the core microguide wire 334 is preferably covered by a coating of a radio-opaque material or metal or alloy, e.g., platinum. To provide more support to the core microguide wire to be able to advance the microguide wire along with the filtering device through a microcatheter, the core microguide wire 334 may have a coating or covering layer, e.g., a flexible hypotube, and made of metals or alloys, e.g., nickel, titanium, platinum, tungsten etc. In the areas where the microguide wire needs to be visible namely the parts of the distal segment of the microguide wire 335 e.g. distal 30 cm and the distal tip of the microguide wire 365 including the two stops 340 and 375, the coating or covering layer over the core microguide wire, or the flexible hypotube, or the core microguide wire itself, comprise or are coated with radio-opaque materials, metals or alloys, including but not limited to platinum, tantalum, gold, palladium, tungsten, tin, silver, titanium, nickel, zirconium, rhenium, bismuth, molybdenum, or combinations of the above etc to enable visibility during neurovascular interventional procedures.

FIG. 10 is an illustration of one of the embodiments of the distal embolic protection device comprising the filtering device and the microguide wire. The filtering device has a proximal 345 and distal 355 attachment points that are also the sliding or mobile components of the filtering device. These mobile attachment points have a capacity to allow the microguide wire to rotate 430 as well as move back and forth in the longitudinal direction 435 between the two stops in the microguide wire (340, 375) while keeping the filtering device stationary in a small cerebral blood vessel and thereby decrease friction and trauma on the cerebral blood vessel walls.

The filtering device of the distal embolic protection device of this invention may comprise a filter membrane and an expansion assembly capable of assuming an expanded configuration and a collapsed configuration. Preferably the expansion assembly comprises a plurality of struts (400, 405, 410) that connect the proximal attachment point 345 to the distal attachment point 355. The filter membrane may be attached to the struts and the distal attachment point, and in the expanded configuration the filter membrane has a hemispherical shape covering the struts.

The struts comprise a biocompatible material or materials that are surface treated for biocompatibility. The materials are preferably self-expanding. Suitable materials include but are not limited to stainless steel, titanium and its alloys, cobalt-chromium alloy, carbon fiber and its composites, and various biomedical polymers, e.g., polyurethane, polyethylene, polyester, polypropylene, polytetrafluoroethylene, polyamides, polycarbonate or polyethylene-terephthalate. A shape memory or super-elastic material such as nickel-titanium alloy is also suitable. The number of struts will depend on the size of expansion needed for the diameter of the cerebral blood vessel. The distal embolic protection device will be suitable for use in cerebral blood vessels from vessel diameters of 1.5 mm to 4.5 mm.

In addition to the two stops in the microguide wire 340 and 375, as well as the two mobile attachment points in the filtering device 345 and 355, various portions of the distal embolic protection device including parts of the struts 400 to 410, or parts of the filter membrane 415 may be radio-opaque. Radio-opaque materials are understood as materials that are visible on a fluoroscopy screen during neurovascular interventional procedures. This allows the operator to determine the location of the device during neurovascular interventions. Radio-opaque materials include, e.g., metals or alloys including but are not limited to platinum, tantalum, gold, palladium, tungsten, tin, silver, titanium, nickel, zirconium, rhenium, bismuth, molybdenum, or combinations of the above etc. The struts may comprise metals or alloys that are radio-opaque, e.g., platinum or the others listed above. Alternatively the struts may comprise shape-elastic alloys such as nickel-titanium, which are not significantly radio-opaque but small portions of radio-opaque metals or alloys, e.g., tantalum, can be attached to non-radio-opaque struts by suturing the filter membrane to the struts with tantalum wires or other suitable radio-opaque material.

The filtering device also comprises a filter membrane 415 for collecting emboli or debris that might be released during the neurovascular intervention. The filter membrane may comprise a biomedical polymer, e.g., poly-
urethane (BioSpan™ made by Polymer Technology Group and Chronoflex™ made by CardioTech International), poly-
ethylene (Rexell™ made by Huntsman), polypropylene (In-
spire™ made by Dow), polyester (Hytril™ made by Dupont),
poly tetra fluoro-ethylene (Teflon™ made by Dupont), poly-
mides (Durethan™ made by Bayer), polycarbonate (Core-
thane™ made by Corvita Corp), or polyethylene-terephthal-
ate (Dacron™ made by Dupont). The filter membrane may fur-
ther comprise a radio-opaque material, e.g., particles of
tantalum, particles of gold, other radio-opaque agents, e.g.,
barium sulfate, tungsten powder, bismuth subcarbonate, bism-
uth oxychloride, iodine containing agents such as iohexol
(Omnipaque™ made by Amersham Health). The filter mem-
brane comprises pores 420 that are of the dimensions small
enough to trap emboli or debris but large enough to allow the
free passage of blood and its components such as blood cells
preferably the pores are of 50 microns to 150 microns. The
arrows 425 indicate the direction of blood flow within the
blood vessel.

[0070] The microguidewire is thinner between the two
radio-opaque stops 340 and 375 and in this thin segment 360,
the microguidewire thickness is no more than about 0.010
inch (0.254 mm). This is to allow for the thickness of the
filtering device comprising the struts that in its non-
expanded state the distal embolic protection device overall is
no more than about 0.017 inch (0.432 mm). This is to enable
the distal embolic protection device to be delivered through
standard microcatheters that are commercially available
(such as Echelon™ microcatheter, ev3 Inc: Excelsior™
microcatheter, Boston Scientific Corp: Prowler™ microcath-
eter, Cordis Neurovascular etc) that have an internal diameter
of about 0.017 inch (0.432 mm).

[0071] FIG. 11 is a schematic diagram illustrating the
cross-sectional view of the distal embolic protection device
described in FIG. 10. Some of the struts 400 and 405 are
shown in an expanded configuration, wherein the filter mem-
brane 415 is depicted with a hemispherical shape covering the
struts. The microguidewire 360 passing through the center of
the filtering device as well as the distal attachment point 355
of the filtering device are also shown.

[0072] FIG. 12 is an illustration showing the distal embolic
protection device described in FIG. 10 in an expanded con-
figuration showing the radio-opaque components under fluo-
roscopy. The distal segment of the microguidewire 335 e.g.
distal 30 cm is radio-opaque along with the proximal stop 340
and are made of radio-opaque metals or alloys, e.g., platinum,
as mentioned in description of FIGS. 8A, 83 and 10. The
microguidewire in the thinner segment 360 is not radio-
opaque and is made up of a metal or alloy, e.g., nickel-
titanium or stainless steel. The distal stop 375 as well as the
distal end of the microguidewire 365 including the shapeable
tip 395 are also made of a radio-opaque metal or alloy such as
platinum as described in detail in FIGS. 8A, 83, and 10.
Portions of the struts 400 to 410 of the distal embolic protec-
tion device described in FIG. 10 are also made of a radio-
opaque metal or alloy, e.g., platinum, or have a covering with
a radio-opaque material, e.g., tantalum as described in FIG.
10 in detail. This enables the operator performing the neu-
rovascular interventional procedure to clearly visualize the
deployed distal embolic protection device as well as the posi-
tion of the microguidewire.

[0073] FIG. 13 is an illustration of another embodiment of
a distal embolic protection device of this invention compris-
ing a filtering device rotatably mounted on a variable-thick-
ness microguidewire. The filtering device has proximal 345
and distal 355 attachment regions that are also the sliding or
mobile components of the distal embolic protection device.
These mobile attachment points have a capacity to allow the
microguidewire to rotate 430 as well as move back and forth
in the longitudinal direction 435 between the two stops in the
microguidewire (340, 375) while keeping the distal embolic
protection device stationary in a small cerebral blood vessel
and thereby help decrease friction and trauma on the cerebral
blood vessel walls. The distal embolic protection device in this
embodiment comprises an expansion assembly comprising
a plurality of struts (400, 405, 410) that connect the proximal attachment point 345 to the distal attachment point
355 and are capable of assuming an expanded configuration
and a collapsed configuration. The expanded configuration is
the plurality of struts and the filter membrane having a hemi-
pherical shape is depicted. The distal embolic protection
device further comprises two cylindrical coils 436 and 437.
Cylindrical coil 436 connects the proximal stop 340 to the
proximal attachment point 345 of the filtering device. Cyl-
indrical coil 437 connects the distal attachment point 355 of the
filtering device to the distal stop 375 of the microguidewire.
The cylindrical coils allow for rotatory 430 as well as longi-
tudinal movement 435 of the filtering device relative to the
microguidewire in the thinner segment of the microguidewire
360. The cylindrical coils decrease the shear stress on the
thinner segment of the microguidewire 360 when the distal
embolic protection device is recovered with a microcatheter,
ballon catheter or stent catheter. The coils provide added
support to the thinner segment of the microguidewire 360 and
reduce fracture or stretching of the microguidewire at the
region of the proximal stop 340 or distal stop 375. The cylin-
drical coils may be made of a biocompatible material, or a
material that is surface treated to be biocompatible and may
comprise radio-opaque metals or alloys, e.g., platinum, as
described in detail in FIG. 10.

[0074] FIG. 14A is an illustration of another of the embodi-
ments of the filtering device attached to the microguidewire.
The filtering device comprises proximal 455 and distal 460
attachment points that are also the sliding or mobile compo-
nents of the distal embolic protection device. These mobile
attachment points have a capacity to allow the microgui-
dewire to rotate 490 as well as move longitudinal direction
495 between the two proximal and distal stops of the micro-
guidewire (340, 375) while the filtering device remains sta-
nary in the small cerebral blood vessel and thereby help to
decrease friction and trauma on the cerebral blood vessel
walls. The distal embolic protection device in this embed-
ment comprises a filter membrane attached to the distal end of
the filtering device and an expansion assembly comprising a
plurality of struts 465, 470, 475 that connect the proximal
attachment point 455 of the filtering device to the distal
attachment point of the filtering device 460. The plurality of
struts in the expanded configuration and the filter membrane
having a helical or conical shape and covering the struts is
also depicted.

[0075] The struts, preferably made of a biocompatible
material or a material that is surface treated to be biocom-
patible and preferably made of a self-expanding material, are
detailed in the embodiment described in FIG. 10. Suitable
materials include but are not limited to stainless steel, tita-
nium and its alloys, cobalt-chromium alloy, carbon fiber and
its composites, and various polymers. A shape memory or
super-elastic material such as nickel-titanium alloy is also
suitable. The number of struts will depend on the size of expansion needed for the diameter of the cerebral blood vessel. The distal embolic protection device will be suitable for use in cerebral blood vessels from vessel diameters 1.5 mm to 4.5 mm. [0076] In addition to the two stops in the microguidewire 340 and 375, as well as the two mobile attachment points in the filtering device 455 and 460, various portions of the distal embolic protection devices of this invention including parts of the struts 505 and 510, or parts of the filter membrane 480 may be radio-opaque. Radio-opaque materials are understood to be materials that are visible on a fluoroscopy screen during neurovascular interventional procedures. This allows the operator to determine the location of the device during neurovascular interventions. Radio-opaque materials include metals or alloys including but are not limited to platinum, tantalum, gold, palladium, tungsten, tin, silver, titanium, nickel, zirconium, rhenium, bismuth, molybdenum, or combinations of the above. The struts can be made of metals or alloys that are radio-opaque, e.g., platinum or the others listed above. Alternatively the struts are made of shape-elastic alloys such as nickel-titanium, which are not significantly radio-opaque, and may further comprise small portions of radio-opaque metals or alloys such as tantalum, that can be attached to the non-radio-opaque struts by suturing the filter membrane to the struts with a radio-opaque material, e.g., tantalum wires, etc. [0077] The filtering device comprises a filter membrane 480 to capture emboli or debris that might be released during the neurovascular intervention. The filter membrane is preferably a biomedical polymer, e.g., polyurethane (BioSpan™ made by Polymer Technology Group and Chronoflex™ made by CardioTech International), polyethylene (Rexell™ made by Huntsman), polyplyrene (Inspire™ made by Dow), polyester (Hytril™ made by Dupont), poly tetra fluoro ethylene (Teflon™ made by Dupont), polyamides (Durethan™ made by Bayer), polycarbonate (Corvita™ made by Corvita Corp), or polyethylene-terephthalate (Dacron™ made by Dupont). The filter membrane may further comprise a radio-opaque material, e.g., particles of tantalum, particles of gold, other radio-opaque agents such as barium sulfate, tungsten powder, bismuth subcarbonate, bismuth oxychloride, iodine containing agents such as Omnipoise™. The filter has pores 485 that are small enough to trap emboli or debris but large enough to allow the free passage of blood and its components such as blood cells, preferably the pores are 50 microns to 150 microns in diameter. The arrows 500 indicate the direction of blood flow within the cerebral blood vessel. [0078] The microguidewire is thinner between the two radio-opaque stops 340 and 375 and in this thinner segment 360, the microguidewire thickness is no more than about 0.010 inch (0.254 mm). This is to accommodate the filtering device such that in its non-expanded configuration the thickness of the filtering device is less than or equal to 0.017 inch (0.432 mm). This is to enable the distal embolic protection device to be delivered through standard microcatheters that are commercially available (such as Echelon™ microcatheter, ev3 Inc; Excelsior™ microcatheter, Boston Scientific Corp; Prowler™ microcatheter, Cordis Neurovascular etc) that have an internal diameter of about 0.017 inch (0.432 mm). [0079] FIG. 14B is a schematic diagram illustrating the cross-sectional view of the distal embolic protection device described in FIG. 14A. The struts 465 to 475 are depicted in an expanded configuration, providing the filtering device with a helical or conical shape. The filter membrane 480 is depicted as covering the struts 465, 470, 475. The microguidewire 360 passing through the center of the filtering device as well as the distal attachment point 460 of the filtering device are shown. [0080] FIG. 15A is an illustration of another embodiment of the distal embolic protection device. The filtering device has proximal 535 and distal 530 attachment points that are also the sliding or mobile components of the filtering device. These mobile attachment points have a capacity to allow the microguidewire to rotate 565 as well as move back and forth in the longitudinal direction 570 relative to the filtering device between the two stops in the microguidewire 340, 375 while keeping the filtering device stationary in a small cerebral blood vessel and thereby decrease friction and trauma on the cerebral blood vessel walls. The filtering device in this embodiment comprises a filter membrane 555 and a ring 525. The filter membrane is attached to the ring and the ring is connected to the proximal attachment point 535. The ring in turn comprises a plurality of struts 540, 545, 550 that connect the ring 525 to the distal attachment point 530. The ring and if present the plurality of struts when expanded can provide the filtering device with a conical shape. [0081] The ring, and if present the plurality of struts, are made of biocompatible materials or materials that are surface treated such that they are bioincompatible. The materials are preferably self-expanding as described in FIG. 10. Suitable materials include but are not limited to stainless steel, titanium and its alloys, cobalt-chromium alloy, carbon fiber and its composites, and various polymers. A shape memory or super-elastic material such as nickel-titanium alloy is also suitable. The number of struts will depend on the size of expansion needed for the diameter of the cerebral blood vessel to be treated. The distal embolic protection devices of this invention are suitable for use in cerebral blood vessels from vessel diameters 1.5 mm to 4.5 mm. [0082] In addition to the two stops in the microguidewire 340 and 375, as well as the two mobile attachment points in the device 535 and 530, various portions of the distal embolic protection device including the ring 525, or parts of the filter membrane 555 may further comprise a radio-opaque material. Radio-opaque materials are understood as materials that are visible on a fluoroscopy screen during neurovascular interventional procedures. This allows the operator to determine the location of the device during neurovascular interventions. Radio-opaque materials can include metals or alloys, including but not limited to platinum, tantalum, gold, palladium, tungsten, tin, silver, titanium, nickel, zirconium, rhenium, bismuth, molybdenum, or combinations of the above etc. The struts can be made up of metals or alloys that are radio-opaque such as platinum or the others listed above. Alternatively the struts may be made of shape-elastic alloys such as nickel-titanium, which are not significantly radio-opaque, but may be made radio-opaque by attaching small portions of radio-opaque metals or alloys, e.g., tantalum, to the non-radio-opaque struts by suture the filter membrane to the struts with a radio-opaque material, e.g., tantalum wires etc. [0083] The filtering device comprises a filter membrane 555 that extends from the ring 525 to the distal attachment point 530, and acts as a filter for emboli or debris that might be released during the neurovascular intervention. The filter membrane can cover the struts. Materials for this filter
include but are not limited to biomedical polymers such as, e.g., polyurethane (BioSpan™ made by Polymer Technology Group and ChronoFlex™ made by CardioTech International), polyethylene (Rezel™ made by Huntsman), polypropylene (Inspire™ made by Dow), polyester (Hytril™ made by DuPont), poly tetra fluoro ethylene (Teflon™ made by DuPont), polyamides (Durethan™ made by Bayer), polycarbonate (Corethane™ made by Corvita Corp.), or polyethylene-terephthalate (Duoron™ made by DuPont). The filter has pores 560 that are small enough to trap emboli or debris but large enough to allow the free passage of blood and its components such as blood cells. Preferably the pores are 50 microns to 150 microns. The arrows 575 indicate the direction of blood flow with the cerebral blood vessel. The filter membrane may further comprise radio-opaque materials, e.g., as particles of tantalum, particles of gold, other radio-opaque agents, e.g., barium sulfate, tungsten powder, bismuth subcarbonate, bismuth oxychloride, iodine containing agents such as Omnipaque™.

[0084] The microguidewire is thinner between the two radio-opaque stops 340 and 375 and in this thinner segment 360, the microguidewire thickness is no more than about 0.010 inch (0.254 mm). This is to allow for the thickness of the distal embolic protection device, the ring and the struts if present such that in the non-expanded state the ring of the distal embolic protection device is no more than about 0.017 inch (0.432 mm). This is to enable the distal embolic protection device to be delivered through standard microcatheters that are commercially available (such as Echelon™ microcatheter, ev3 Inc.; Excelsior™ microcatheter, Boston Scientific Corp; ProWorx™ microcatheter, Cordis Neurovascular etc) that have an internal diameter of about 0.017 inch (0.432 mm).

[0085] FIG. 15B is a schematic diagram illustrating the cross-sectional view of the distal embolic protection device described in FIG. 15A. The radio-opaque ring is shown 525 and is attached to a filter membrane 555 connecting the ring to the distal attachment point 530. The filter membrane has micro-pores 560. In one of the embodiments of this device, there is also a plurality of struts 540 to 550 connecting the ring 525 to the distal attachment point. The microguidewire 360 passing through the side of the filtering device as well as the proximal 515 and distal attachment points 530 of the filtering device are shown.

[0086] FIG. 16 is a schematic diagram illustrating a significant blockage or stenosis 585 in the right middle cerebral artery 105 that is causing mini-strokes and is refractory to medical therapy. A guide catheter (6 French or larger) 580 has been advanced into the right internal carotid artery 30 so that intracranial balloon angioplasty and stenting can be performed.

[0087] FIG. 17 is a schematic diagram illustrating that through the guide catheter in the right internal carotid artery, a microcatheter 590 is being advanced in the right internal carotid artery into the right middle cerebral artery over a microwire 600. The microwire is carefully advanced across the blockage in the right middle cerebral artery 585. The microcatheter is then advanced over the microwire.

[0088] FIG. 18 is a schematic diagram illustrating that the microcatheter 590 has been carefully advanced across the blockage in the right middle cerebral artery 585 over a microwire. The microwire has been removed once the microcatheter is distal to the blockage 585 in the right middle cerebral artery. Prior to exchanging the microcatheter for a balloon catheter, a distal embolic protection device is decided to be advanced to the right middle cerebral artery through the microcatheter.

[0089] FIG. 19 is a schematic diagram illustrating the introducer sheath 305 with the non-expanded distal embolic protection device 310 comprising microguidewire 290 are being advanced through the microcatheter 590. The hemostatic valve 295 at the proximal end of the introducer sheath is released so that the microguidewire 290 can be advanced. Once the distal embolic protection device 310 has entered the microcatheter 590 and guide catheter 580, the introducer sheath 305 can be removed. The guide catheter 580 is connected to a rotating hemostatic valve 595 to prevent back-bleeding. The microcatheter 590 passes through the rotating hemostatic valve 595 and then into the guide catheter 580.

[0090] FIG. 20 is a schematic diagram illustrating the distal embolic protection device 350 in the non-expanded state in the appropriate location distal to the blockage 585 in the right middle cerebral artery. With the microguidewire 365 in position and fixed, the microcatheter 590 is being withdrawn to deploy the filtering device. The tip of the microguidewire 395 is shaped to avoid perforating a small vessel. The distal stop 375 in the microguidewire acts as the radio-opaque marker.

[0091] FIG. 21 is a schematic diagram illustrating the distal embolic protection device fully deployed in the right middle cerebral artery distal to the blockage 585. The radio-opaque distal part of the microguidewire 365 along with the shapeable tip 395 are noted. The radio-opaque stops of the microguidewire 340 and 375 are noted. The filtering device with the plurality of struts 405 and 410 between the two attachment points 345 and 355 are noted. The filter membrane 415 is noted. With the microguidewire fixed in position, the microcatheter 590 is being exchanged for a balloon catheter so that intracranial balloon angioplasty can be performed.

[0092] FIG. 22 is a schematic diagram illustrating the filtering device is in place distal to the blockage 585 in the right middle cerebral artery. With the microguidewire in position, the microcatheter is exchanging for a balloon catheter 605. The mobile attachment points 345 and 355 of the filtering device allow for the filtering device to be stationary even if there is minimal movement of the microguidewire 335 during the microcatheter exchange. When the balloon 610 is across the blockage 585 in the right middle cerebral artery, intracranial balloon angioplasty is performed. During intracranial balloon angioplasty, emboli or debris are released 615 and are collected in the distal embolic protection device by the filter 415.

[0093] FIG. 23 is a schematic diagram illustrating that after intracranial angioplasty, the balloon 610 shown in FIG. 22 is deflated and the balloon catheter 605 is exchanged for an intracranial stent catheter 620 over the microguidewire. When the stent is in position across the area of blockage 630 in the right middle cerebral artery where balloon angioplasty was performed, the stent is deployed. During intracranial stenting, small emboli or debris are released 615 and are collected in the filter 415 of the distal embolic protection device. After stenting is performed, the distal embolic protection device can be retrieved using the stent catheter 620 by advancing it over the microguidewire till the radio-opaque markers in struts of the distal embolic protection device suggest that the filter has closed so that the device can be safely removed.

[0094] FIG. 24 is a schematic diagram illustrating a standard microcatheter, which can be alternatively used to
retrieve the distal embolic protection device. In this case, the stent catheter 620 shown in FIG. 23 is exchanged for a standard catheter 590 over the microguidewire 335. The standard microcatheter has a proximal 640 and distal end 645. Standard microcatheters that are commercially available (such as Echelon™ microcatheter, ev3 Inc; Excelsior™ microcatheter, Boston Scientific Corp; Prowler™ microcatheter, Cordis Neurovascular etc) can be used and their inner lumen diameter range from 0.017 to 0.021 inch (0.432 mm to 0.533 mm) and are usually 135 to 175 cm in length.

[0095] FIG. 25 is a schematic diagram illustrating the tip of the standard microcatheter 645 being advanced over the microguidewire such that the filtering device 350 closes to the collapsed configuration to prevent spillage of the emboli or debris collected during the procedure. The stent is noted to be in good position 625 across the angioplastied area 630.

[0096] FIG. 26 is a schematic diagram illustrating the filtering device 350 in the closed non-expanded state being carefully withdrawn into the guide catheter 580. The microcatheter tip 645 is closely approximated to the struts of the filtering device to prevent spillage of the contents of the distal embolic protection device namely emboli or debris. The stent is noted to be in good position 625 across the angioplastied area 630.

[0097] FIG. 27 is a schematic diagram illustrating another use for this distal embolic protection device. This figure illustrates a thrombus or blood clot 650 in the right middle cerebral artery and is occluding this right middle cerebral artery and causing an acute ischemic stroke. The patient presents after 3 hours from symptom onset and is a candidate for immediate neurovascular interventional therapy with intra-arterial thrombolytic infusion. A guide catheter 580 (6 French or greater) is advanced into the right internal carotid artery.

[0098] FIG. 28 is a schematic diagram illustrating a standard microcatheter 590 being advanced across the thrombus or blood clot 650 in the right middle cerebral artery over a microwire 600. Once the microcatheter is across the thrombus or blood clot, the microwire will be removed and a microcatheter angiogram may be performed to identify if the cerebral blood vessels distal to the thrombus or blood clot are patent.

[0099] FIG. 29 is a schematic diagram illustrating a distal embolic protection device is advanced through the microcatheter 590 into a position distal to the thrombus or blood clot 650 and then the microcatheter is withdrawn to the proximal part of the right middle cerebral artery to deploy the distal embolic protection device. The radio-opaque stops 340 and 375 in the microguidewire, as well as, the radio-opaque attachment points 455 and 460 of the distal embolic protection device are well visualized. Also the distal radio-opaque microguidewire segment 365 and the shapeable tip 395 are well visualized. Intra-arterial thrombolytic infusion is initiated through the microcatheter with the microguidewire in position 335. The thrombus or blood clot is broken down 655 into smaller emboli or debris 660, which are collected in the filter membrane 480 of the distal protection device. The struts 470 of the distal embolic protection device are in the expanded position to maintain the shape of the filter membrane.

[0100] FIG. 30 is a schematic diagram illustrating after intra-arterial thrombolysis, the microcatheter 590 is advanced over the microguidewire such that the filtering device 350 closes to the collapsed configuration to prevent spillage of the emboli or debris collected during the procedure. The filtering device 350 in the closed non-expanded state is then carefully withdrawn into the guide catheter 580. All through the process, the microcatheter tip 645 is closely approximated to the struts of the distal embolic protection device to prevent spillage of the contents of the distal embolic protection device namely emboli or debris.

[0101] While the invention is susceptible to various modifications, and alternative forms, specific examples thereof have been shown and are herein described in detail. It should be understood, however, that the invention is not to be limited to the particular forms or methods disclosed, but to the contrary, the invention is to cover all modifications, equivalents and alternatives falling within the spirit and scope of the appended claims.

CITED REFERENCES

1. (canceled)
2. A method of treating vasculature, the method comprising:

tracking a treatment device through a catheter from a proximal end of the catheter to a distal end of the catheter, the treatment device comprising:

an elongate element comprising:

a proximal segment including a proximal hypotube around a first portion of core, a distal segment including a distal hypotube around a second portion of the core, and a third segment comprising a third portion of the core, the third segment longitudinally between the proximal segment and the distal segment, and a treatment tool around the third segment; and deploying the treatment tool out of the catheter.
3. The method of claim 2, wherein the treatment tool comprises a balloon.
4. The method of claim 2, wherein the treatment tool comprises a stent.
5. The method of claim 2, wherein the treatment tool comprises a filtering device.
6. The method of claim 5, comprising collecting thromboembolic material.
7. The method of claim 6, further comprising at least one of performing an angioplasty procedure and positioning a stent, wherein the at least one of performing the angioplasty procedure and positioning the stent dislodges the thromboembolic material.
8. The method of claim 6, further comprising:
advancing a guidewire across the thromboembolic material;
tracking the catheter over the guidewire and across the thromboembolic material; and
before tracking the device through the catheter, withdrawing the guidewire from the catheter.
9. A vascular treatment system comprising:
a core;
a first hypotube around a first portion of the core;
a second hypotube around a second portion of the core;
a third hypotube around a third portion of the core, the third hypotube longitudinally between the first hypotube and the second hypotube, the third hypotube transformable between a collapsed configuration and an expanded configuration, the third hypotube comprising:
a proximal attachment point,
a distal attachment point, the third hypotube rotatable around the third portion of the core, and
a plurality of struts connecting the proximal attachment point and the distal attachment point, the third hypotube longitudinally movable along the third portion of the core in the expanded configuration; and
a filter membrane coupled to the third hypotube.
10. The system of claim 9, wherein, when the third hypotube is in the expanded configuration, the filter membrane has a hemispherical, helical, or conical shape.
11. The system of claim 9, wherein the catheter comprises a balloon catheter.
12. A vascular treatment system comprising:
a treatment device comprising:
a proximal hypotube around a first portion of a core;
a distal hypotube around a second portion of the core, the distal hypotube longitudinally spaced from the proximal hypotube by a segment comprising a third portion of the core;
a treatment tool in a collapsed configuration around the segment and between the proximal hypotube and the distal hypotube.
the treatment tool transformable between the collapsed configuration and an expanded configuration.
13. The system of claim 12, wherein the treatment tool comprises a balloon.
14. The system of claim 12, wherein the treatment tool comprises a stent.
15. The system of claim 12, wherein the treatment tool comprises a filtering device.
16. The system of claim 15, wherein the filtering device comprises:
a proximal attachment point;
a distal attachment point;
a plurality of struts connecting the proximal attachment point and the distal attachment point, the struts configured to self-expand from the collapsed configuration to an expanded configuration; and
a filter membrane coupled to the at least one of the struts and the distal attachment point, wherein the filtering device is rotationally and longitudinally movable relative to the core.
17. The system of claim 12, further comprising a catheter.
18. The system of claim 17, wherein the treatment tool is trackable uncovered through the catheter from a proximal end of the catheter to a distal end of the catheter.
19. The system of claim 17, wherein the catheter comprises a balloon catheter.
20. The system of claim 17, wherein the catheter comprises a stent catheter.
21. The system of claim 17, wherein the catheter has an inner diameter that is no more than 0.017 inches.

* * * * *