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(54) **SINGLE-WIRE EXPANDABLE CAGES FOR EMBOLIC FILTERING DEVICES**

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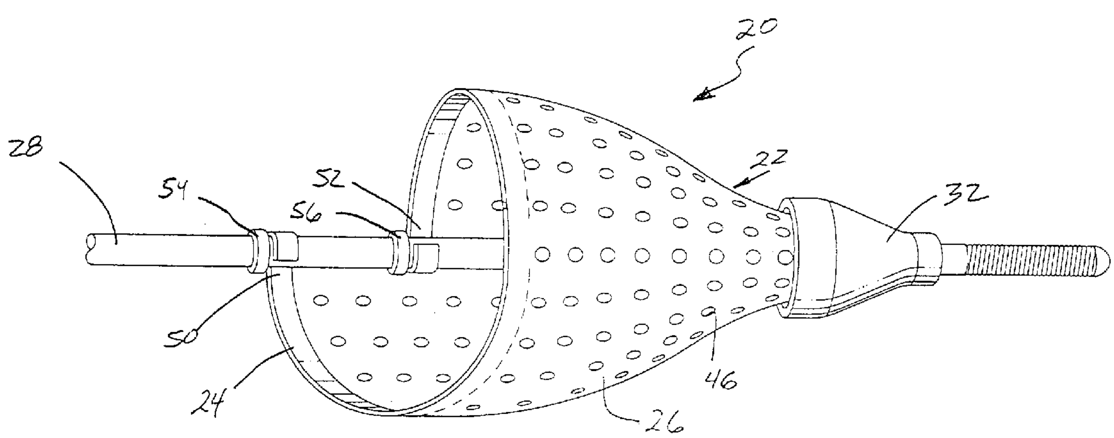
(57) **ABSTRACT**

A single-wire expandable cage for an embolic filtering device includes a single cage wire coupled to an elongated member, such as a guide wire, and adapted to expand from an unexpanded position to an expanded position in a patient's body vessel. The wire includes a first end and a second end which are coupled to the guide wire. A filter element is attached to the single-wire cage. The single-wire cage may be rotatably mounted to the guide wire or may be slidably disposed on the guide wire to allow the composite cage and filter element to be slid over the guide wire in an over-the-wire fashion once the guide wire is delivered to the target location in the patient's vasculature. One embodiment of the single-wire cage utilizes an offset arrangement in which the guide wire remains extended along the wall of the body vessel once the single-wire cage is deployed. Another embodiment of the device centers the guide wire within the body vessel.



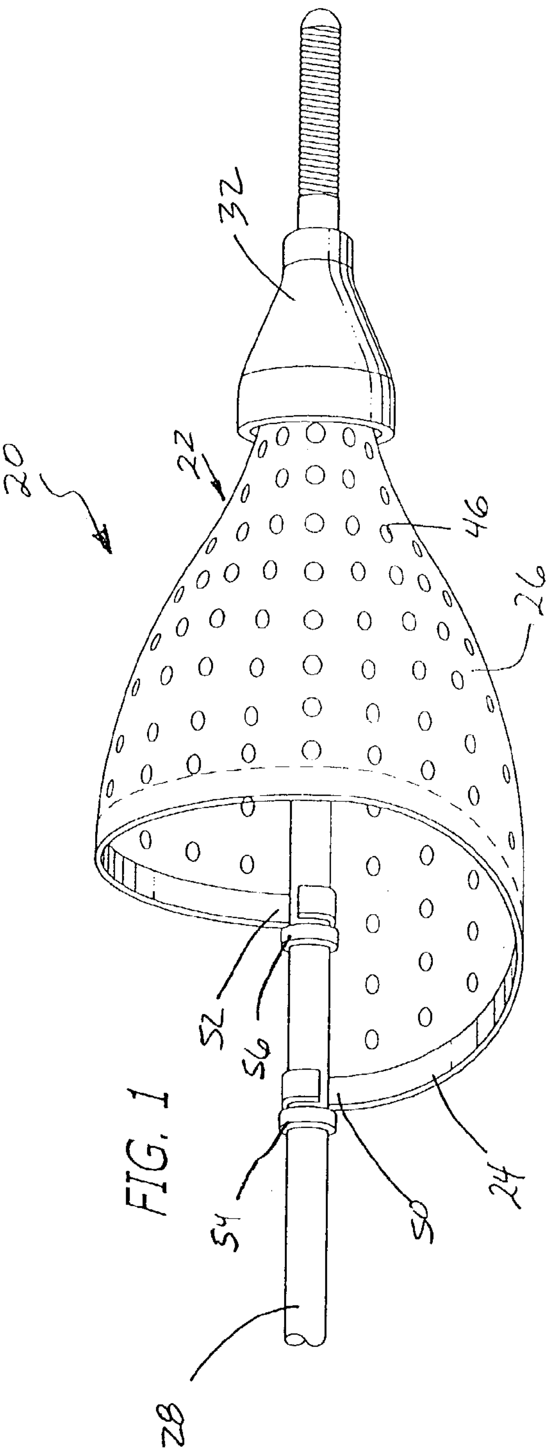


FIG. 1

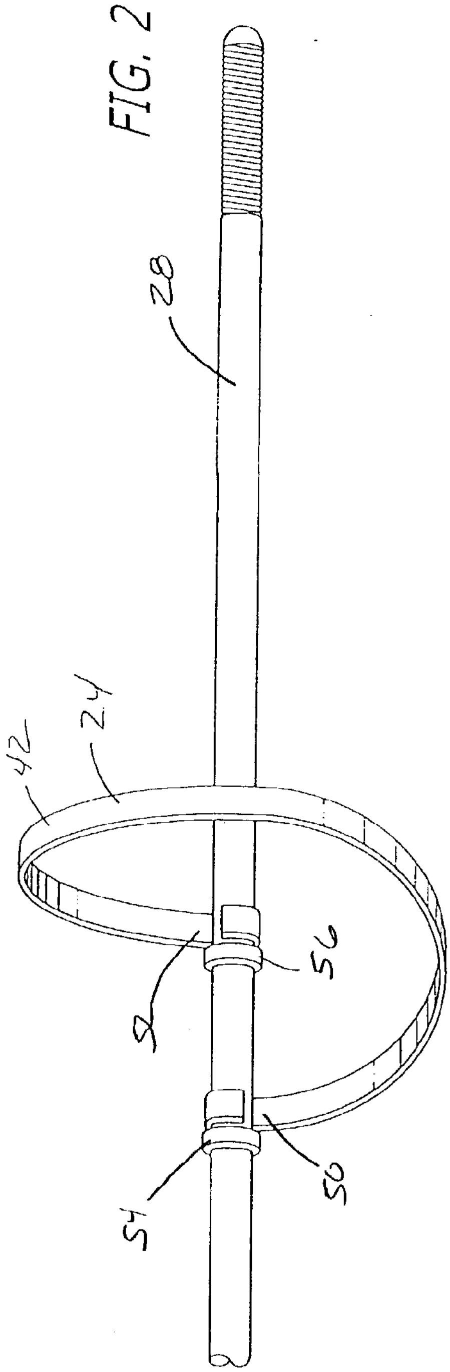


FIG. 2

FIG. 3

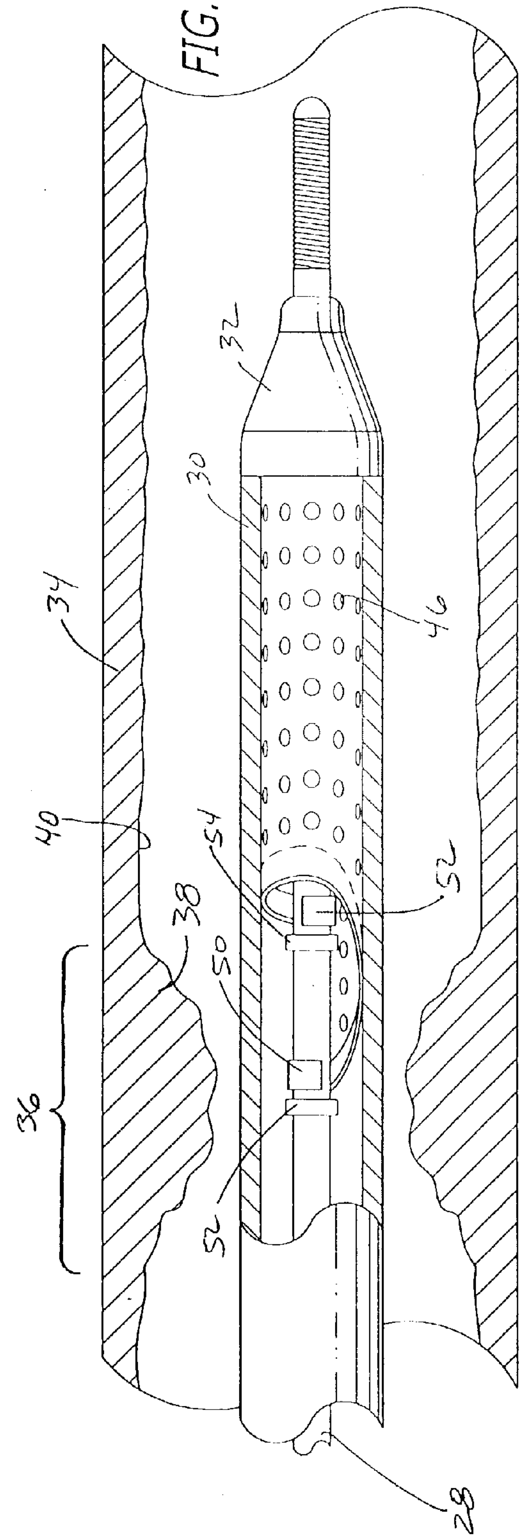

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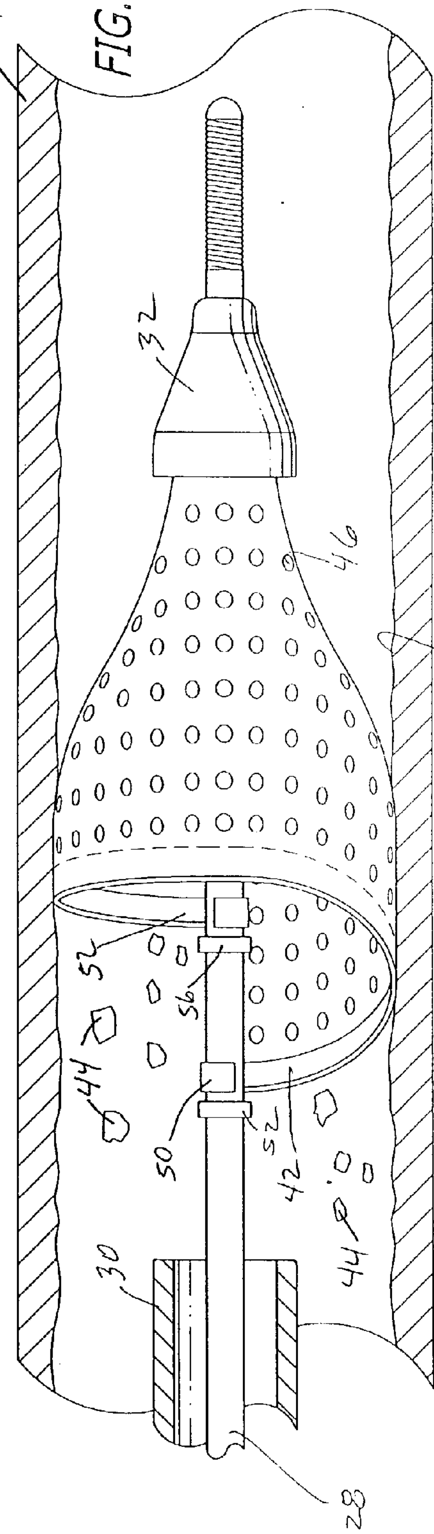
FIG. 4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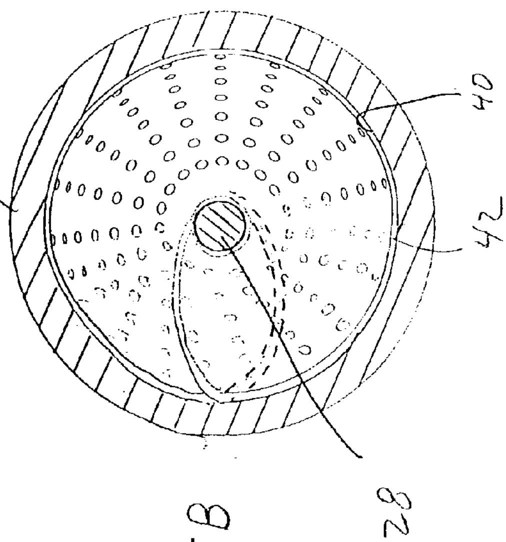

FIG. 5B

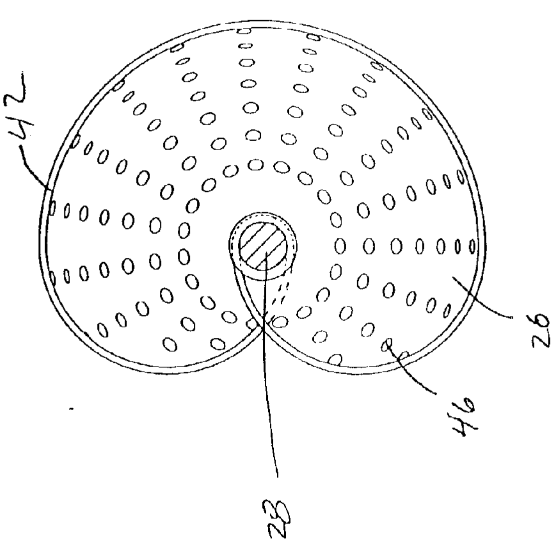

FIG. 5A

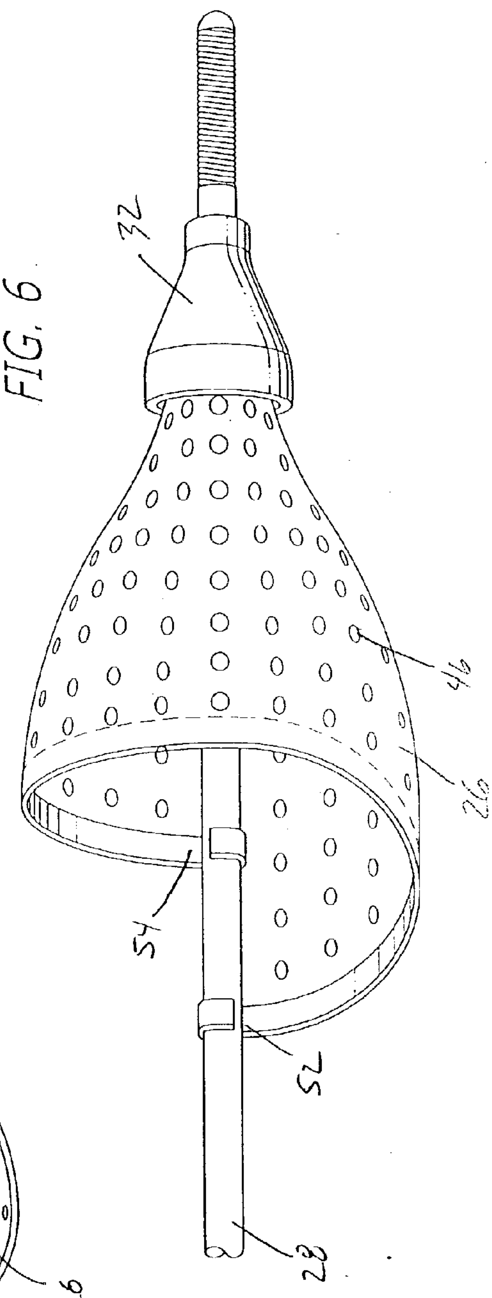

FIG. 6

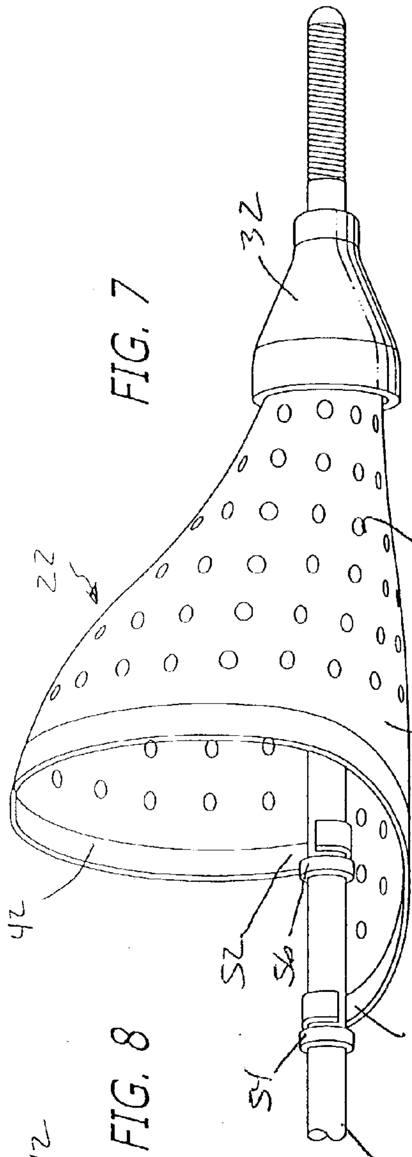

FIG. 7

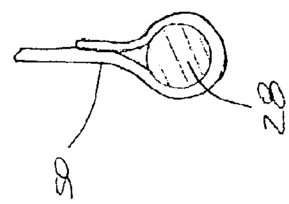

FIG. 10

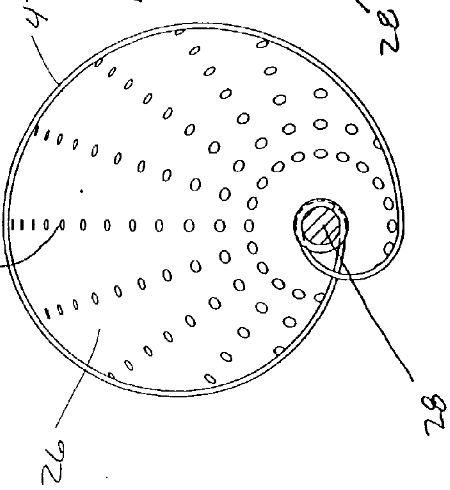

FIG. 8

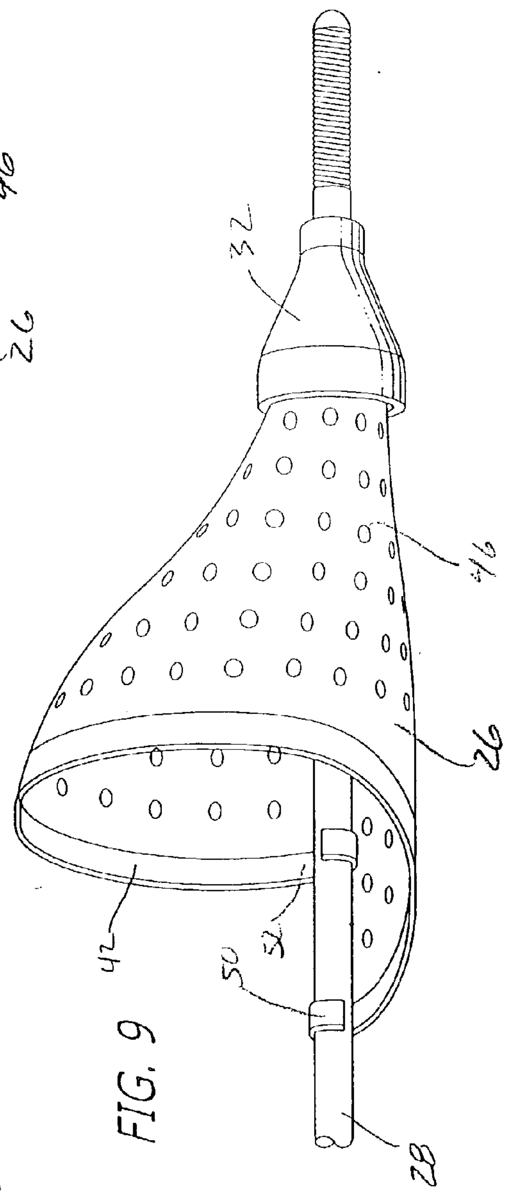

FIG. 9

SINGLE-WIRE EXPANDABLE CAGES FOR EMBOLIC FILTERING DEVICES

BACKGROUND OF THE INVENTION

[0001] The present invention relates generally to filtering devices used when an interventional procedure is being performed in a stenosed or occluded region of a body vessel to capture embolic material that may be created and released into the vessel during the procedure. The present invention is more particularly directed to an embolic filtering device having an expandable cage or basket made from a single wire that possesses good flexibility and bendability during delivery.

[0002] Numerous procedures have been developed for treating occluded blood vessels to allow blood to flow without obstruction. Such procedures usually involve the percutaneous introduction of an interventional device into the lumen of the artery, usually by a catheter. One widely known and medically accepted procedure is balloon angioplasty in which an inflatable balloon is introduced within the stenosed region of the blood vessel to dilate the occluded vessel. The balloon dilatation catheter is initially inserted into the patient's arterial system and is advanced and manipulated into the area of stenosis in the artery. The balloon is inflated to compress the plaque and press the vessel wall radially outward to increase the diameter of the blood vessel, resulting in increased blood flow. The balloon is then deflated to a small profile so that the dilatation catheter can be withdrawn from the patient's vasculature and the blood flow resumed through the dilated artery. As should be appreciated by those skilled in the art, while the above-described procedure is typical, it is not the only method used in angioplasty.

[0003] Another procedure is laser angioplasty which utilizes a laser to ablate the stenosis by super heating and vaporizing the deposited plaque. Atherectomy is yet another method of treating a stenosed body vessel in which cutting blades are rotated to shave the deposited plaque from the arterial wall. A vacuum catheter is usually used to capture the shaved plaque or thrombus from the blood stream during this procedure.

[0004] In the procedures of the kind referenced above, abrupt reclosure may occur or restenosis of the artery may develop over time, which may require another angioplasty procedure, a surgical bypass operation, or some other method of repairing or strengthening the area. To reduce the likelihood of the occurrence of abrupt reclosure and to strengthen the area, a physician can implant an intravascular prosthesis for maintaining vascular patency, commonly known as a stent, inside the artery across the lesion. The stent can be crimped tightly onto the balloon portion of the catheter and transported in its delivery diameter through the patient's vasculature. At the deployment site, the stent is expanded to a larger diameter, often by inflating the balloon portion of the catheter.

[0005] The above non-surgical interventional procedures, when successful, avoid the necessity of major surgical operations. However, there is one common problem which can become associated with all of these non-surgical procedures, namely, the potential release of embolic debris into the bloodstream that can occlude distal vasculature and cause significant health problems to the patient. For example, during deployment of a stent, it is possible that the metal struts of the stent can cut into the stenosis and shear off pieces of plaque that can travel downstream and lodge somewhere in the patient's vascular system. Pieces of plaque material are sometimes generated during a balloon angioplasty procedure and become released into the bloodstream. Additionally, while complete vaporization of plaque is the intended goal during laser angioplasty, sometimes particles are not fully vaporized and enter the bloodstream. Likewise, not all of the emboli created during an atherectomy procedure may be drawn into the vacuum catheter and, as a result, enter the bloodstream as well.

[0006] When any of the above-described procedures are performed in the carotid arteries, the release of emboli into the circulatory system can be extremely dangerous and sometimes fatal to the patient. Debris carried by the bloodstream to distal vessels of the brain can cause cerebral vessels to occlude, resulting in a stroke, and in some cases, death. Therefore, although cerebral percutaneous transluminal angioplasty has been performed in the past, the number of procedures performed has been somewhat limited due to the justifiable fear of an embolic stroke occurring should embolic debris enter the bloodstream and block vital downstream blood passages.

[0007] Medical devices have been developed to attempt to deal with the problem created when debris or fragments enter the circulatory system following vessel treatment utilizing any one of the above-identified procedures. One approach which has been attempted is the cutting of any debris into minute sizes which pose little chance of becoming occluded in major vessels within the patient's vasculature. However, it is often difficult to control the size of the fragments which are formed, and the potential risk of vessel occlusion still exists, making such a procedure in the carotid arteries a high-risk proposition.

[0008] Other techniques include the use of catheters with a vacuum source which provides temporary suction to remove embolic debris from the bloodstream. However, as mentioned above, there can be complications associated with such systems if the catheter does not remove all of the embolic material from the bloodstream. Also, a powerful suction could cause trauma to the patient's vasculature.

[0009] Another technique which has had some success utilizes a filter or trap downstream from the treatment site to capture embolic debris before it reaches the smaller blood vessels downstream. The placement of a filter in the patient's vasculature during treatment of the vascular lesion can reduce the presence of the embolic debris in the bloodstream. Such embolic filters are usually delivered in a collapsed position through the patient's vasculature and then expanded to trap the embolic debris. Some of these embolic filters are self expanding and utilize a restraining sheath which maintains the expandable filter in a collapsed position until it is ready to be expanded within the patient's vasculature. The physician can retract the proximal end of the restraining sheath to expose the expandable filter, causing the filter to expand at the desired location. Once the procedure is completed, the filter can be collapsed, and the filter (with the trapped embolic debris) can then be removed from the vessel. While a filter can be effective in capturing embolic material, the filter still needs to be collapsed and removed from the vessel. During this step, there is a possibility that trapped embolic debris can backflow through the inlet opening of the filter and enter the bloodstream as the filtering system is being collapsed and removed from the patient. Therefore, it is important that any captured embolic debris remain trapped within this filter so that particles are not released back into the body vessel.

[0010] Some prior art expandable filters vessel are attached to the distal end of a guide wire or guide wire-like member which allows the filtering device to be steered in the patient's vasculature as the guide wire is positioned by the physician. Once the guide wire is in proper position in the vasculature, the embolic filter can be deployed to capture embolic debris. The guide wire can then be used by the physician to deliver interventional devices, such as a balloon angioplasty dilatation catheter or a stent delivery catheter, to perform the interventional procedure in the area of treatment. After the procedure is completed, a recovery sheath can be delivered over the guide wire using over-the-wire techniques to collapse the expanded filter for removal from the patient's vasculature.

[0011] When a combination of an expandable filter and guide wire is utilized, it is important that the expandable filter portion remains flexible in order to negotiate the often tortuous anatomy through which it is being delivered. An expandable filter which is too stiff could prevent the device from reaching the desired deployment position within the patient's vasculature. As a result, there is a need to increase the flexibility of the expandable filter without compromising its structural integrity once in position within the patient's body vessel. Also, while it is beneficial if the area of treatment is located in a substantially straight portion of the patient's vasculature, sometimes the area of treatment is at a curved portion of the body vessel which can be problematic to the physician when implanting the expandable filter. If the expandable filter portion is too stiff, it is possible that the filter may not fully deploy within the curved portion of the body vessel. As a result, gaps between the filter and vessel wall can be formed which may permit some embolic debris to pass therethrough. Therefore, the filtering device should be sufficiently flexible to be deployed in, and to conform to, a tortuous section of the patient's vasculature, when needed.

[0012] Another problem presented to a physician utilizing an embolic filtering device is the possible undesired collection of embolic debris on the struts or ribs that form the cage onto which the filter is attached. The exposed surface of proximally located struts provide a potential area where embolic debris can stick, never reaching the filter positioned downstream from these struts. As the embolic filtering device is being collapsed for removal from the patient, it is possible for embolic debris which has become stuck to these struts to become dislodged and enter the blood stream. As a result, the design of the embolic filtering device itself may pose a danger if too many struts are located proximal to the filter since increased surface area will be exposed to the embolic particles. Therefore, it may be beneficial to use thin struts in the proximal region of the filtering device or to reduce the number of struts forming the self-expanding cage.

[0013] What has been needed is an expandable filter assembly having high flexibility and bendability with sufficient strength to be successfully deployed within a patient's vasculature to collect embolic debris which may be released into the patient's vasculature. Moreover, it would be beneficial if the design of the filtering device reduces the chances of embolic debris becoming stuck to the struts of the device, rather than being trapped within the filter. The present invention disclosed herein satisfies these and other needs.

SUMMARY OF THE NVENTION

[0014] The present invention provides a flexible, single-wire cage for use with an embolic filtering device designed for capturing, for example, embolic debris created during the performance of a therapeutic interventional procedure, such as a balloon angioplasty or stenting procedure, within a body vessel. The present invention provides the physician with an embolic filtering device having good flexibility to be steered through tortuous anatomy while possessing sufficient strength to hold open a filtering element against the wall of the body vessel for capturing embolic debris. An embolic filtering device made in accordance with the present invention is relatively easy to deploy and is easily conformable to the patient's anatomy.

[0015] An embolic filtering device made in accordance with the present invention utilizes a single wire to create an expandable cage. The single-wire cage can be made from a self-expanding material, for example, nickel-titanium (NiTi), and is capable of expanding from a collapsed position or configuration having a first delivery diameter to an expanded or deployed position or configuration having a second implanted diameter. A filter element made from an embolic-capturing material is attached to the single-wire cage to move between the unexpanded position and a deployed position.

[0016] In one aspect of the present invention, the cage wire is coupled to the distal end of an elongated member, such as a guide wire, and is adapted to expand and conform to the size and shape of the body vessel in which it is deployed. The cage wire has one end which is coupled to the guide wire and a second end that is likewise coupled to the guide wire. In one particular aspect of the invention, the first and second ends of the cage can be rotatably mounted to the guide wire. The first end and second end of the cage wire are positioned longitudinally away from each other a certain distance to allow a spiral configuration to be formed as the wire unfurls into the expanded position. The spiral created by the cage wire is adapted to conform within the body vessel of the patient. A filter element is, in turn, attached to the single-wire cage and will contact the wall of the body vessel wall once deployed within the patient. The cage wire can be extremely thin wire, or alternately, a wire ribbon having an expanded width that provides additional surface area onto which the filter member can be attached. The filter member can be attached to the single-wire cage, for example, by bonding or other attachment techniques well-known in the art.

[0017] In another aspect of the present invention, the single-wire cage is not only rotatably mounted onto the guide wire, but has one end fixed between a pair of stop fittings that limit the longitudinal travel of the single-wire cage on the guide wire itself. In this regard, the single-wire cage will be both rotatably mounted onto the guide wire and will have a limited range of longitudinal motion along the guide wire as well. In this regard, if the proximal end of the guide wire is moved or rotated by the physician, the deployed single-wire cage and filter should remain stationary within the body vessel and should not move with the guide wire.

[0018] In another aspect of the present invention, the single-wire cage is mounted onto the guide wire such that the guide wire remains substantially centered within the body vessel once the cage is deployed. In yet another aspect of the present invention, the single-wire cage remains offset from the center of the body vessel when deployed. The cage is said to be "offset" in that the guide wire extends substantially along the vessel wall of the patient, rather than being "centered" in the body vessel when the single-wire cage is expanded. In this offset position, there is little cage structure directly in front of the filter member once deployed in the open vessel, resulting in a virtually unobstructed opening for the filter element. The first and second ends of the single-wire cage can be rotatably connected to the guide wire in this offset cage arrangement such that the cage wire spirals when expanded to provide and maintain a satisfactory opening for the filter member. In this arrangement, the single-wire cage will still conform to the particular size and shape of the body vessel once implanted.

[0019] The single-wire cage can be "set" to remain in the expanded, deployed position until an external force is placed over the cage wire to collapse and move the cage wire to a collapsed position. One way of accomplishing this is through the use of a restraining sheath, for example, which can be placed over the filtering device in a coaxial fashion to contact the single-wire cage and move the cage into the collapsed position. The guide wire and filtering assembly, with the restraining sheath placed over the filter assembly, can be delivered through the patient's vasculature to the target location. Once the physician properly manipulates the guide wire into the target area, the restraining sheath can be retracted to deploy the single-wire cage into the expanded position. This can be easily performed by the physician by simply retracting the proximal end of the restraining sheath. Once the restraining sheath is retracted, the self-expanding properties of the single-wire cage cause the cage wire to move in an outward, radial fashion away from the guide wire to contact the wall of the body vessel. As the cage wire expands radially, so does the filter element which will now be maintained pressed against the vessel wall to collect embolic debris that may be released into the bloodstream as the physician performs the interventional procedure. The guide wire can be used by the physician to deliver the necessary interventional device into the area of treatment. The deployed filter element captures embolic debris created and released into the body vessel during the interventional procedure. A retrieval sheath can be delivered over the guide wire to collapse the filter assembly for removal from the patient.

[0020] In another aspect of the present invention, the single-wire cage has a "windsock" type of filter design that possesses good flexibility and bendability, yet possesses sufficient radial strength to maintain the filtering element in an open position once deployed in the body vessel.

[0021] In another aspect of the present invention, the filtering assembly, which includes the single-wire cage and filter element, is moveable in a coaxial fashion over the guide wire so as to permit the guide wire to be first steered into the target area by the physician, with the filtering assembly being delivered later to the desired location along the guide wire in an over-the-wire fashion. In this regard, the filtering assembly is maintained in a collapsed delivery position by a restraining sheath or other restraining device so that it may be delivered over the guide wire to the exact location where the filtering capabilities of the device is needed. This over-the-wire feature can be implemented with the embodiment of the single-wire cage in which the guide wire is centered within the body lumen once the cage is deployed or the offset version in which the guide wire remains at an offset location near the side wall of the body lumen.

[0022] It is to be understood that the present invention is not limited by the embodiments described herein. The present invention can be used in arteries, veins, and other body vessels. Other features and advantages of the present invention will become more apparent from the following detailed description of the invention, when taken in conjunction with the accompanying exemplary drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] **FIG. 1** is a side elevational view of an embolic filtering device having a single-wire cage embodying features of the present invention.

[0024] **FIG. 2** is a side elevational view of the single-wire cage of **FIG. 1** in its expanded configuration with the filter element removed to better show the single-wire cage.

[0025] **FIG. 3** is an elevational view, partially in cross section, of the embolic filtering device of **FIG. 1** as it is being delivered within a body vessel to a location downstream from an area to be treated.

[0026] **FIG. 4** is an elevational view, partially in cross section, similar to that shown in **FIG. 3**, wherein the embolic filtering device is deployed in its expanded position within the body vessel for filtering purposes.

[0027] **FIG. 5A** is an end view of the single-wire cage of **FIG. 1** in its fully expanded position.

[0028] **FIG. 5B** is a cross-sectional end view of the single-wire cage of **FIG. 1** in its deployed, expanded position within a body vessel.

[0029] **FIG. 6** is a side elevational view of another embodiment of an embolic filtering device having a single-wire cage which embodies features of the present invention.

[0030] **FIG. 7** is a side elevational view of an embodiment of an embolic filtering device having an offset, single-wire cage which embodies features of the present invention.

[0031] **FIG. 8** is an end view of the single-wire cage of **FIG. 7** in its fully expanded position.

[0032] **FIG. 9** is a side elevational view of yet another embodiment of an embolic filtering device having an offset, single-wire cage which embodies features of the present invention.

[0033] **FIG. 10** is cross-sectional view of the guide wire and one end of the single-wire cage as it is securely fastened to the guide wire.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0034] Turning now to the drawings, in which like reference numerals represent like or corresponding elements in the drawings, **FIGS. 1 and 2** illustrate one particular embodiment of an embolic filtering device **20** incorporating features of the present invention. This embolic filtering device **20** is designed to capture embolic debris which may be created and released into a body vessel during an interventional procedure. The embolic filtering device **20** includes an expandable filter assembly **22** having a self-expanding, single-wire cage **24** and a filter element **26** attached thereto. In this particular embodiment, the expandable filter assembly **22** is rotatably mounted on the distal end of an elongated (solid or hollow) cylindrical tubular shaft, such as a guide wire **28**. The expandable filter assembly also could be attached directly onto the guide wire, so as not to rotate independently of the guide wire. The guide wire has a proximal end (not shown) which extends outside the patient and is manipulated by the physician to deliver the filter assembly into the target area in the patient's vasculature. A restraining or delivery sheath **30 (FIG. 3)** extends coaxially along the guide wire **28** in order to maintain the expandable filter assembly **22** in its collapsed position until it is ready to be deployed within the patient's vasculature. The expandable filter assembly **22** can be deployed by the physician by simply retracting the restraining sheath **30** proximally to expose the expandable filter assembly. Once the restraining sheath is retracted, the single-wire cage **24** immediately begins to expand within the body vessel (see **FIG. 4**), causing the filter element **26** to expand as well.

[**0035**] An obturator **32** affixed to the distal end of the filter assembly **32** can be implemented to prevent possible "snowplowing" of the embolic filtering device as it is being delivered through the vasculature. The obturator can be made from a soft polymeric material, such as Pebax 40D, and has a smooth surface to help the embolic filtering device travel through the vasculature and cross lesions while preventing the distal end of the restraining sheath **30** from "digging" or "snowplowing" into the wall of the body vessel.

[**0036**] In **FIGS. 3 and 4**, the embolic filtering device **20** is shown as it is being delivered within an artery **34** or other body vessel of the patient. Since the embolic filtering device made in accordance with the present invention possesses excellent bendability and flexibility, it will conform well to the shape of the vasculature while allowing the filter assembly to more easily negotiate a curved radius in the patient's vasculature.

[**0037**] Referring specifically now to **FIG. 4**, the embolic filtering device **20** is shown in its expanded position within the patient's artery **34**. This portion of the artery **(FIG. 3)** has an area of treatment **36** in which atherosclerotic plaque **38** has built up against the inside wall **40** of the artery **34**. The filter assembly **22** is to be placed distal to, and downstream from, the area of treatment **36**. For example, the therapeutic interventional procedure may comprise the implantation of a stent (not shown) to increase the diameter of an occluded artery and increase the flow of blood therethrough. It should be appreciated that the embodiments of the embolic filtering device described herein are illustrated and described by way of example only and not by way of limitation. Also, while the present invention is described in detail as applied to an artery of the patient, those skilled in the art will appreciate that it can also be used in other body vessels, such as the coronary arteries, carotid arteries, renal arteries, saphenous vein grafts and other peripheral arteries. Additionally, the present invention can be utilized when a physician performs any one of a number of interventional procedures, such as balloon angioplasty, laser angioplasty or atherectomy which generally require an embolic filtering device to capture embolic debris created during the procedure.

[**0038**] The cage **24** includes a single cage wire **42** which, upon release from the restraining sheath **30**, expands the filter element **26** into its deployed position within the artery **(FIG. 4)**. Embolic particles **44** created during the interventional procedure and released into the bloodstream are captured within the deployed filter element **26**. The filter may include perfusion openings **46**, or other suitable perfusion means, for allowing blood flow through the filter element **26**. The filter element will capture embolic particles which are larger than the perfusion openings while allowing some blood to perfuse downstream to vital organs. Although not shown, a balloon angioplasty catheter could be initially introduced within the patient's vasculature in a conventional SELDINGER technique through a guiding catheter (not shown). The guide wire **28** is disposed through the area of treatment and the dilatation catheter can be advanced over the guide wire **28** within the artery **34** until the balloon portion is directly in the area of treatment **36**. The balloon of the dilatation catheter can be expanded, expanding the plaque **38** against the wall **40** of the artery **34** to expand the artery and reduce the blockage in the vessel at the position of the plaque **38**. After the dilatation catheter is removed from the patient's vasculature, a stent (not shown) could be implanted in the area of treatment **36** using over-the-wire or rapid exchange techniques to help hold and maintain this portion of the artery **34** and help prevent restenosis from occurring in the area of treatment. The stent could be delivered to the area of treatment on a stent delivery catheter (not shown) which is advanced from the proximal end of the guide wire to the area of treatment. Any embolic debris created during the interventional procedure will be released into the bloodstream and should enter the filter **26**. Once the procedure is completed, the interventional device may be removed from the guide wire. The filter assembly **22** can also be collapsed and removed from the artery **34**, taking with it any embolic debris trapped within the filter element **26**. A recovery sheath (not shown) can be delivered over the guide wire **28** to collapse the filter assembly **22** for removal from the patient's vasculature.

[**0039**] Referring again to **FIGS. 1 and 2**, the single-wire cage **24** is made from a single-cage wire **42** which has a first end **50** and a second end **52** attached to the guide wire **28**. The cage wire **42** is shown as a ribbon wire which has additional width that provides an additional bonding area for attaching the filter element **26** thereto. It should be appreciated that the size of the width of this cage wire **42** can vary from a very thin width to a width which is even greater than that shown in **FIGS. 1 and 2**. The size and width of the cage wire **42** can accordingly vary as is needed for a particular application. Additionally, the size and width, and even thickness of the cage wire **42**, can be varied depending upon the particular material which is utilized in manufacturing of the wire.

[**0040**] The single-wire cage **24** of the present invention is shown rotatably mounted to the distal end of the guide wire **28** to allow the entire filter assembly **22** to remain stationary once deployed in the body vessel. In this regard, the first end **50** and second end **52** are shown rotatably mounted to the guide wire **28**. This feature prevents the filtering assembly from rotating against the wall of the body vessel in the event that the proximal end of the guide wire should be rotated by the physician during use. As a result, the possibility that movement of the proximal end of the guide wire could translate to the deployed filter assembly **22** is prevented. Therefore, trauma to the wall of the body vessel is minimized. Referring again to **FIGS. 1 and 2**, a pair of stop fittings **54** and **56** are placed on the guide wire to maintain the first end **50**, and hence the proximal end of the single-wire cage **24**, rotatably fixed to the guide wire **28**. These stop fittings **54** and **56** allow the cage **24** to spin on the guide wire while restricting the longitudinal movement of the cage on the guide wire. As can be seen in **FIG. 1**, the first end **50** of the cage wire **42** can move between the stop fittings **54** and **56** to allow the cage to have at least some longitudinal movement on the guide wire. Alternatively, stop fitting **56** can be moved proximally on the guide wire to prevent longitudinal motion of the first end **50**, while still permitting rotation. It should be appreciated that the second end **52** of the cage wire **42** is also movable in the longitudinal direction of the guide wire in order to move between the expanded and unexpanded positions. Stop fittings could also be used to limit, or prevent, longitudinal travel of the second end **52** along the guide wire as well. Accordingly, it may be preferred to have the obturator **32** slidably disposed along the guide wire as well to allow it to rotate and move longitidinally along the guide wire when moving between the unexpanded and expanded positions. This particular mechanism is just one way in which the single-wire cage **24** can be mounted to the guide wire **28**. Other embodiments disclosed herein can use similar stop fittings as those described above. Alternatively, the expandable cage can be attached directly onto the guide wire so as not to rotate independently.

[**0041**] Referring now to **FIGS. 5A and 5B**, an end view of the opening of the filter element **26** is shown. Referring particularly to **FIG. 5**A, the end view shows the single-wire cage **24** as it extends in its most radially expanded position outside of a body lumen. As can be seen in **FIG. 5**A, the opening created by the single-wire cage **24** is not perfectly round, but has a somewhat elliptical shape. However, once implanted within the body lumen, as is schematically shown in **FIG. 5**B, the single-wire cage adapts to the size of the body lumen such that the single-wire cage becomes more circular to ensure that there are no gaps formed between the filter element and the wall of the body lumen. In this regard, the first and second ends of the cage wire **42** rotate on the guide wire which allows the single-wire cage to assume a more circular shape once implanted in the body lumen. As a result, there is little chance of gaps being formed between the filter element and the wall of the body vessel.

[**0042**] Referring now to **FIG. 6**, an alternative embodiment of the filtering device **20** is shown. In this particular embodiment, the single-wire cage **24** is shown again rotatably mounted to the guide wire **28**, however, this particular embodiment lacks the pair of stop fittings which were used on the previously described embodiment shown in FIGS. **1-4**. This will allow the entire filter assembly **22** to move along the length of the guide wire and in fact can be delivered over the guide wire as a separate filtering element after the guide wire is initially positioned within the patient's vasculature. In such an arrangement, the guide wire is first steered into the target area and then the filter assembly can be delivered over the guide wire as it is maintained in its unexpanded, delivery position by a delivery sheath or other restraining device. The distal end of the filter assembly would have to come in contact with a stop fittings or fastener (not shown) which could be located at the distal end of the guide wire which contacts the filter assembly to prevent it from being delivered past the distal end of the guide wire. In such an arrangement, an over-the-wire filtering system can be utilized. It should also be appreciated that the first and second ends of the single-wire cage could also be permanently attached to the guide wire **26** to create a permanent filter/guide wire assembly.

[**0043**] Referring now to FIGS. **7-9**, several alternative embodiments of the filtering device **20** are shown. Referring initially to **FIG. 7**, the filtering device **20** is shown as an offset assembly in which the guide wire **28** will remain close to the wall of the body vessel once implanted within the patient. This particular embodiment differs from the one shown in FIGS. **1-6** in that the guide wire **28** would not be centered in the body vessel when implanted. Rather, it would again remain closer to the side wall of the body vessel. This particular embodiment has some advantages in that the opening of the filter element **26** is unimpeded by any portion of the expandable cage since the expandable cage also remains extended along the periphery of the vessel wall once implanted. Reference should be given to **FIG. 8** which shows the expanded single-wire cage in its fully expanded position. As can be seen in **FIG. 8**, there is virtually no portion of the single-wire cage that would block the opening of the filter element. **FIG. 8** is similar to **FIG. 5A** in that the single-wire cage **24** is shown in its fully expanded position. It should be appreciated that once implanted into a smaller diameter body vessel, the single-wire cage will conform to the wall of the vessel in a manner which is similar to that shown in **FIG. 5B**.

[**0044**] **FIG. 9** shows another embodiment of the offset filter assembly of **FIG. 7** except that the stop fittings have been removed from the guide wire to allow the filter assembly to be slidably disposed on the guide wire. This particular embodiment of the filtering assembly is again similar to that shown in **FIG. 6** in that the filter assembly could either be permanently attached to the guide wire or could be slid and delivered across the guide wire in a coaxial fashion after the guide wire has been steered into the desired area of the patient's vasculature. This particular embodiment, as shown in **FIG. 9**, provides the benefits of an offset cage with the ability to slide the entire filter assembly over the guide wire in an over-the-wire fashion.

[**0045**] Referring now to **FIG. 10**, the first end **50** of the cage wire **42** is shown as it is attached to the guide wire **28**. In this particular figure, the first end **50** is shown as it extends around the guide wire **28** and is looped and attached back onto itself, via a bonding, soldering, braising, or other fastening technique, to help prevent the end of the cage wire from being accidentally removed from the guide wire. The previous embodiments of the filtering assembly show the first and second ends of the cage wire attached to the guide wire in a loop fashion which helps to maintain the single-wire cage on the guide wire. The particular arrangement of the end of the cage wire, as shown in **FIG. 10**, helps to prevent the wire from being accidentally removed from the wire during use. Such a particular arrangement is particularly useful in the event that the filter assembly is being slid over the guide wire in a coaxial fashion when used in accordance with the embodiments shown in **FIGS. 6 and 9**. Again, this is just one way in which the ends of the cage wire can be physically attached to the guide wire.

[**0046**] The expandable cage of the present invention can be made in many ways. One particular method of making the cage is to cut a thin-walled tubular member, such as nickel-titanium hypotube, to remove portions of the tubing in the desired pattern, leaving relatively untouched the portions of the tubing which form the single-wire structure. The tubing may be cut into the desired pattern by means of a machine-controlled laser. The tubing used to make the cage could possible be made of suitable biocompatible material, such as spring steel. Elgiloy is another material which could possibly be used to manufacture the cage. Also, very elastic polymers possibly could be used to manufacture the single-wire cage.

[**0047**] The thickness of the wire is often very small, so the tubing from which the single-wire cage is made may have a small diameter. Typically, the tubing has an outer diameter on the order of about 0.020-0.040 inches in the unexpanded condition. Also, the cage can be cut from large diameter tubing. Fittings are attached to both ends of the lased tube to form the final cage geometry. The wall thickness of the tubing is usually about 0.076 mm (0.001-0.010 inches). As can be appreciated, the strut width and/or depth at the bending points will be less. For cages deployed in body lumens, such as PTA applications, the dimensions of the tubing may be correspondingly larger. While it is preferred that the cage be made from laser cut tubing, those skilled in the art will realize that the cage can be laser cut from a flat sheet and then rolled up in a cylindrical configuration to form the spiral shape of the cage wire. The single-wire cage can also be used by just setting a piece of wire, or wire ribbon, with the desired spiral shape that the wire makes when attached to the guide wire. In this regard, the final expanded diameter could be set into the material.

[**0048**] The single-wire cage can be laser cut much like a stent is laser cut. Details on how the tubing can be cut by a laser are found in U.S. Pat. No. 5,759,192 (Saunders), U.S. Pat. No. 5,780,807 (Saunders) and U.S. Pat. No. 6,131,266 (Saunders) which have been assigned to Advanced Cardiovascular Systems, Inc.

[**0049**] Nickel-titanium alloy is yet another material which can be used to from the single-wire cage due to the self-expanding properties such a material possesses. A suitable composition of nickel-titanium which can be used to manufacture the single-wire cage of the present invention is approximately 55% nickel and 45% titanium (by weight) with trace amounts of other elements making up about 0.5% of the composition. The austenite transformation temperature is between about 0° C. and 20° C. in order to achieve superelasticity at human body temperature. The austenite temperature is measured by the bend and free recovery tangent method. The upper plateau strength is about a minimum of 60,000 psi with an ultimate tensile strength of a minimum of about 155,000 psi. The permanent set (after applying 8% strain and unloading), is less than approximately 0.5%. The breaking elongation is a minimum of 10%. It should be appreciated that other compositions of nickel-titanium can be utilized, as can other self-expanding alloys, to obtain the same features of a self-expanding cage made in accordance with the present invention.

[**0050**] In one example, the cage of the present invention can be laser cut from a tube of nickel-titanium (Nitinol) whose transformation temperature is below body temperature. After the wire pattern is cut into the hypotube, the tubing is expanded and heat treated to be stable at the desired final diameter. The heat treatment also controls the transformation temperature of the cage such that it is super elastic at body temperature. The transformation temperature is at or below body temperature so that the cage is superelastic at body temperature. The cage is usually implanted into the target vessel which is smaller than the diameter of the cage in its fully expanded position so that the single-wire cage can apply a force to the vessel wall to maintain the cage and filter element in its expanded position. It should be appreciated that the single-wire cage can be made from either super-elastic, stress-induced martensite NiTi or shape-memory NiTi.

[**0051**] The cage also could be manufactured by laser cutting a large diameter tubing of nickel-titanium which would create the cage in its expanded position. Thereafter, the formed cage could be placed in its unexpanded position by backloading the cage into a restraining sheath which will keep the device in the unexpanded position until it is ready for use. If the cage is formed in this manner, there would be no need to heat treat the tubing to achieve the final desired diameter. This process of forming the cage could be implemented when using superelastic or linear-elastic nickel-titanium.

[**0052**] The polymeric material which can be utilized to create the filtering element include, but is not limited to, polyurethane and Gortex, a commercially available material. Other possible suitable materials include ePTFE. The material can be elastic or non-elastic. The wall thickness of the filtering element can be about 0.00050-0.0050 inches. The wall thickness may vary depending on the particular material selected. The material can be made into a cone or similarly sized shape utilizing blow-mold technology or dip molding technology. The openings can be any different shape or size. A laser, a heated rod or other process can be utilized to create to perfusion openings in the filter material. The holes, would of course be properly sized to catch the particular size of embolic debris of interest. Holes can be lazed in a spinal pattern with some similar pattern which will aid in the re-wrapping of the media during closure of the device. Additionally, the filter material can have a "set" put in it much like the "set" used in dilatation balloons to make the filter element rewrap more easily when placed in the collapsed position.

[**0053**] The materials which can be utilized for the restraining sheath can be made from polymeric material such as cross-linked HDPE. This sheath can alternatively be made from a material such as polyolifin which has sufficient strength to hold the compressed strut assembly and has relatively low frictional characteristics to minimize any friction between the filtering assembly and the sheath. Friction can be further reduced by applying a coat of silicone lubricant, such as Microglide®, to the inside surface of the restraining sheath before the sheaths are placed over the filtering assembly.

[**0054**] Further modifications and improvements may additionally be made to the device and method disclosed herein without departing from the scope of the present invention.

Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. An embolic filtering device used to capture embolic debris in a body vessel, comprising:

a filter assembly including an expandable cage adapted to move between an unexpanded position and an expanded position and a filter element attached to the expandable cage, the cage forming an structure capable of opening the filter element and maintaining the filter element open until the cage is placed in the unexpanded position; and

an elongated member having a distal end and a proximal end, the expandable cage being coupled to the guide wire near the distal end, wherein the cage is made from a continuous wire having a first end coupled to the guide wire and a second end coupled to the guide wire, the first end and second end being spaced apart along the longitudinal axis of the guide wire.

2. The filtering device of claim 1, wherein the cage forms a spiral shape when placed in the expanded position.

3. The filtering device of claim 1, wherein the elongated member is a steerable guide wire.

4. The filtering device of claim 1, wherein the wire is made from a material which is self expanding.

5. The filtering device of claim 1, wherein the first end and second end of the expandable cage are rotatably mounted to the elongated member.

6. The filtering device of claim 1, further including a pair of stop fittings mounted onto the elongated member, the first end of the expandable cage being mounted between the pair of stop fittings.

7. The filtering device of claim 6, wherein the pair of stop fittings are positioned on the guide wire to allow the first end of the expandable cage to move longitudinally between the pair of stop fittings.

8. The filtering device of claim 1, wherein the elongated member is centered in the body vessel when the expandable cage is deployed into the expanded position.

9. The filtering device of claim 1, wherein the elongated member is deployed near the wall of the body vessel when the expandable cage is deployed.

10. The filtering device of claim 1, wherein the wire forming the expandable basket is a wire ribbon.

11. The filtering device of claim 10, wherein the wire ribbon is made from a nickel-titanium alloy.

12. The filtering device of claim 11, wherein the expandable cage forms a spiral when placed in the expanded position.

13. The filtering device of claim 1, wherein the expandable cage is slidably mounted to the elongated member to allow the filtering assembly to be moved along the length of the elongated member.

14. The filtering device of claim 1, further including an obturator attached to the filtering element.

15. The filtering device of claim 1, wherein the second elongated member is a tubular member.

16. The filtering device of claim 1, wherein the expandable cage is movable between its expanded and unexpanded positions through relative longitudinal movement between the first elongated member and second elongated member.

17. The filtering device of claim 1, wherein the cage forms a spiral shape when placed in the expanded position.

18. The filtering device of claim 1, wherein the elongated member is a steerable guide wire.

19. The filtering device of claim 1, wherein the wire is made from a material which is self expanding.

20. The filtering device of claim 1, wherein the second elongated member is a tubular member.

21. The filtering device of claim 6, wherein the expandable cage is movable between its expanded and unexpanded positions through relative longitudinal movement between the first elongated member and second elongated member.

22. The filtering device of claim 1, further including a pair of stop fittings mounted onto the elongated member, the second end of the expandable cage being mounted between the pair of stop fittings.

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