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(54) EMBOLI FILTRATION SYSTEM AND METHODS OF USE

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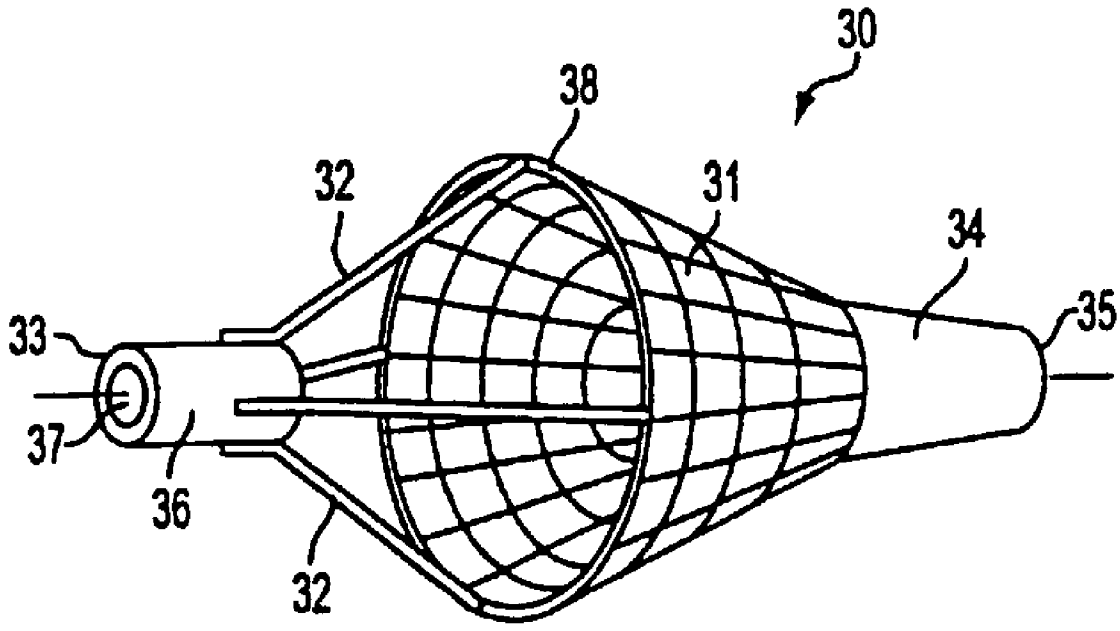
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(57) **ABSTRACT**

An emboli filtration apparatus is provided comprising a guide wire having a filter element captured thereon, so that the guide wire is free to rotate and translate while the filter element remains stationary. The apparatus allows for movement and rotation of the guide wire as devices are advanced over it to treat occlusive disease, substantially without dislodging the filter element. In a preferred embodiment, the guide wire comprises a proximal stop configured to reposition the filter element during a medical procedure without having to remove or insert additional interventional devices.



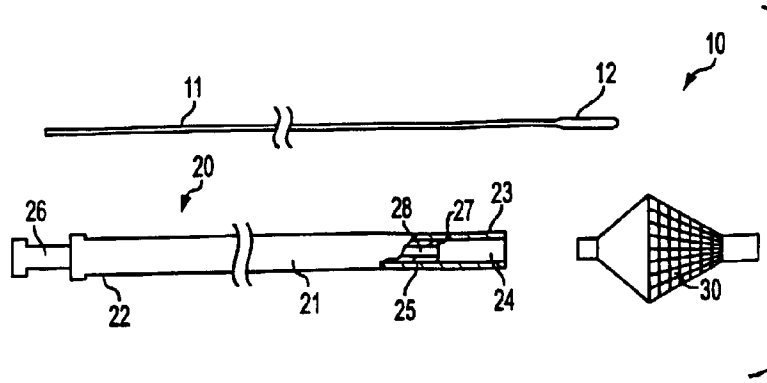


FIG. 1

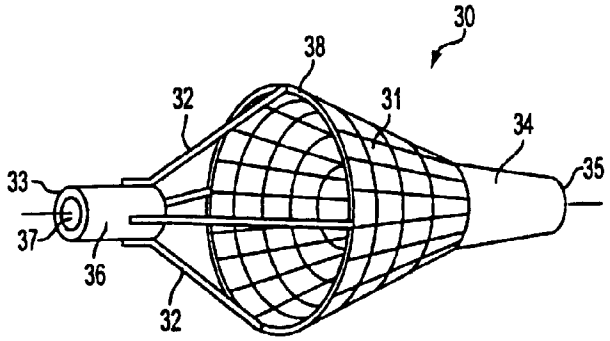


FIG. 2A

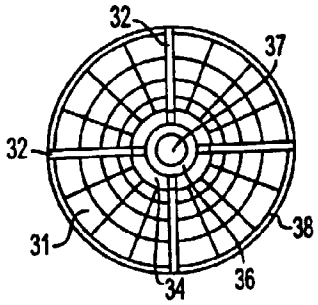


FIG. 2B

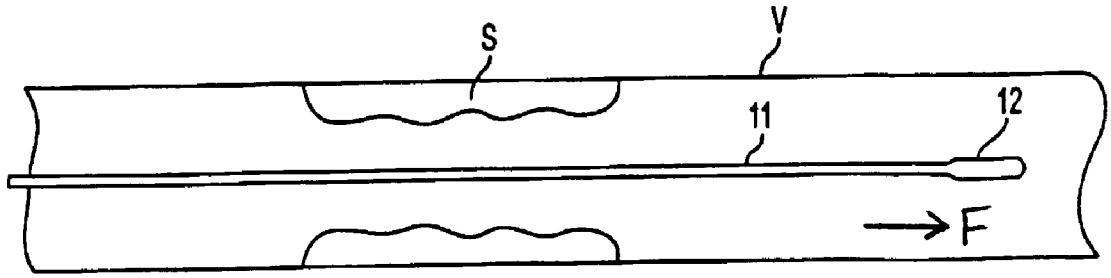


FIG. 3A

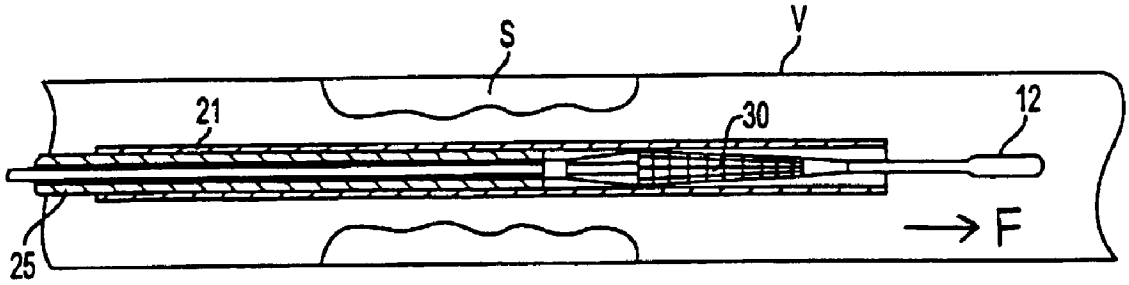


FIG. 3B

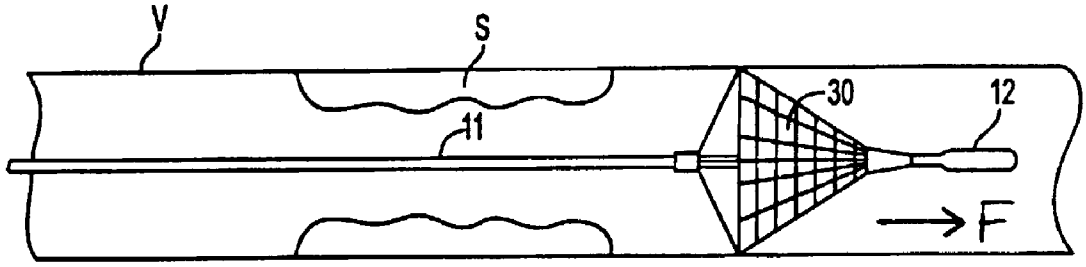


FIG. 3C

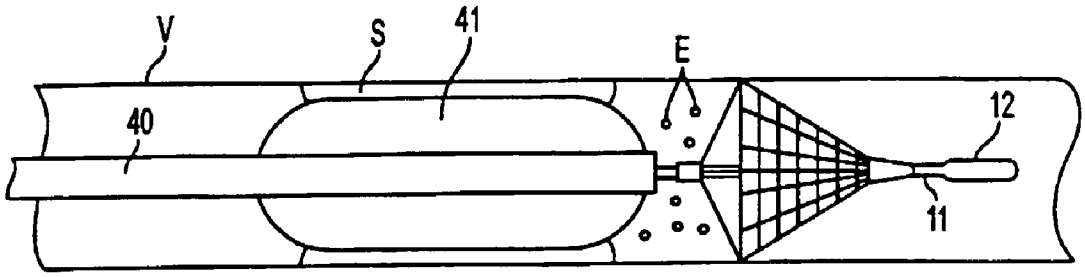


FIG. 3D

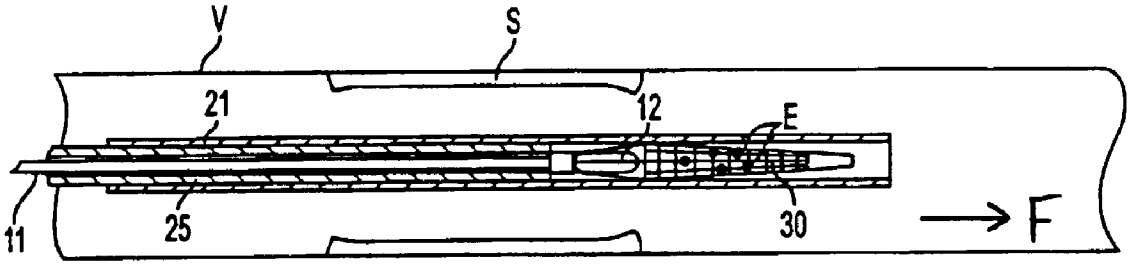


FIG. 3E

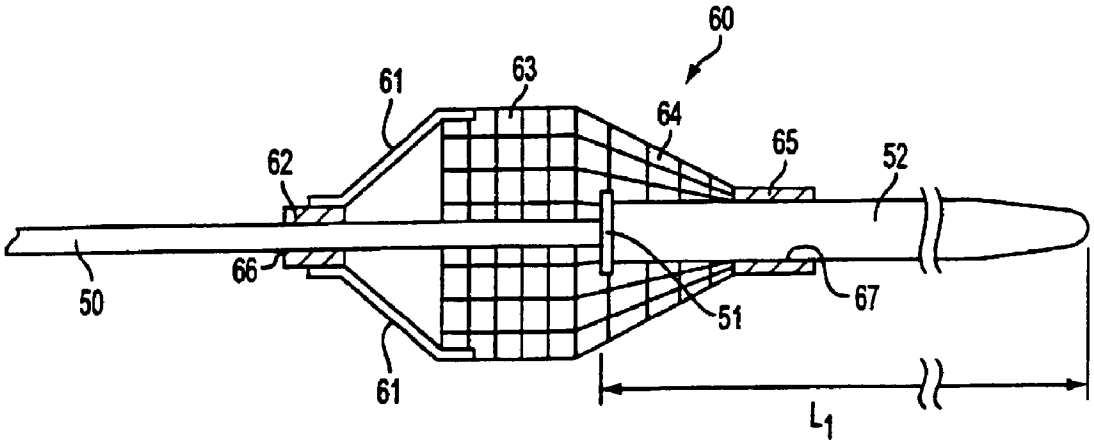


FIG. 4A

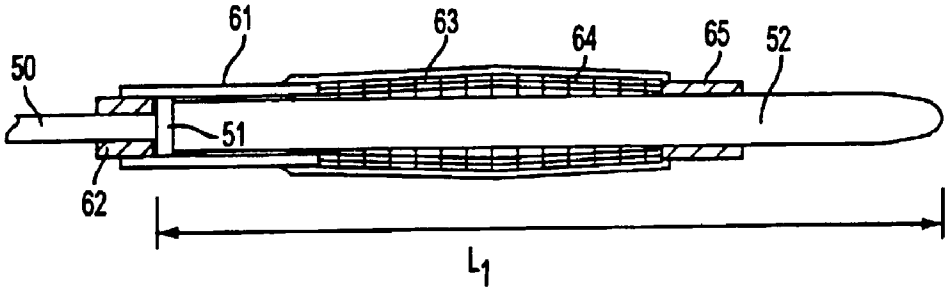


FIG. 4B

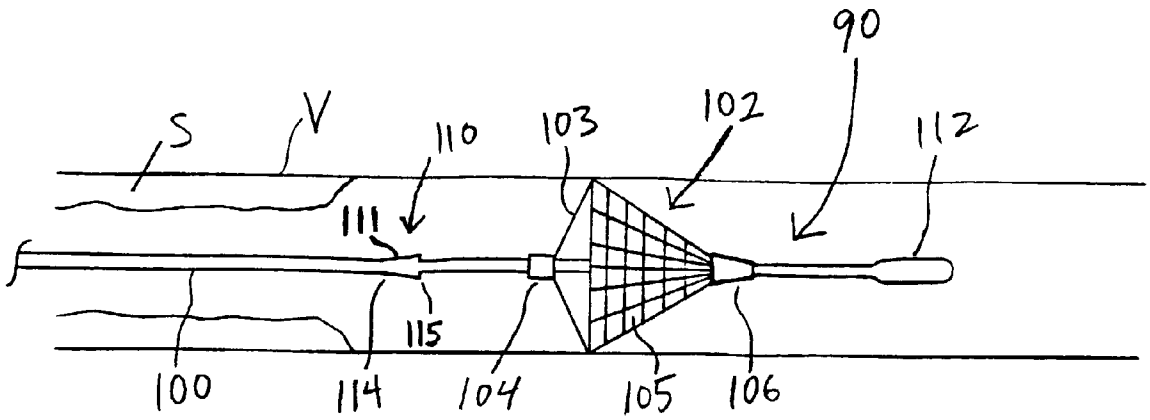

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FIG. 5A

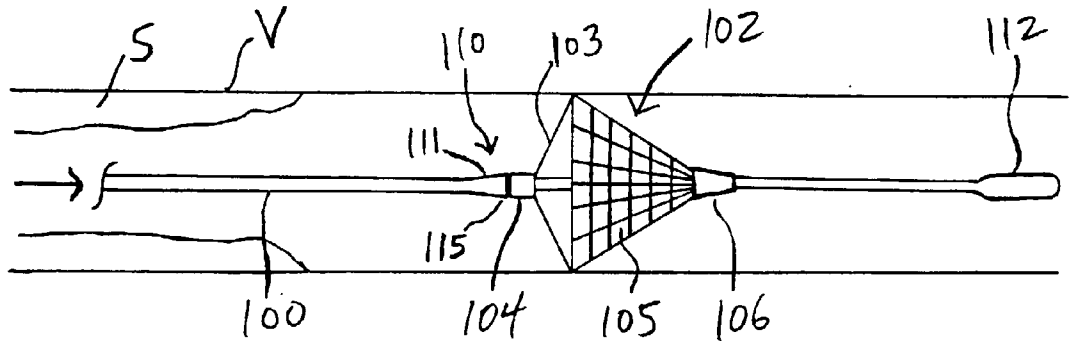

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FIG. 5B

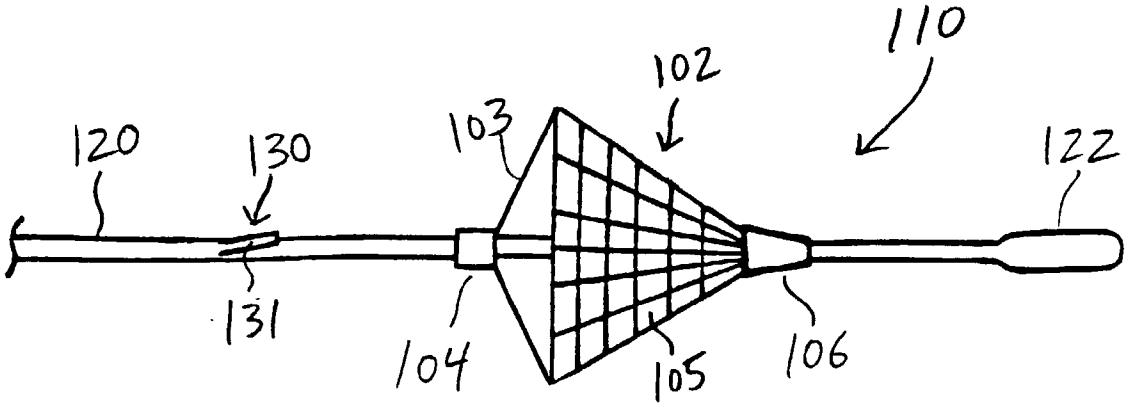


FIG. 6A

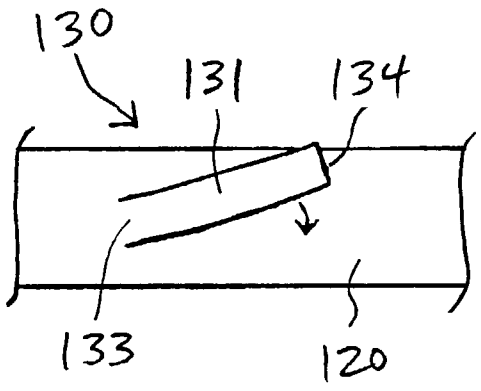


FIG. 6B

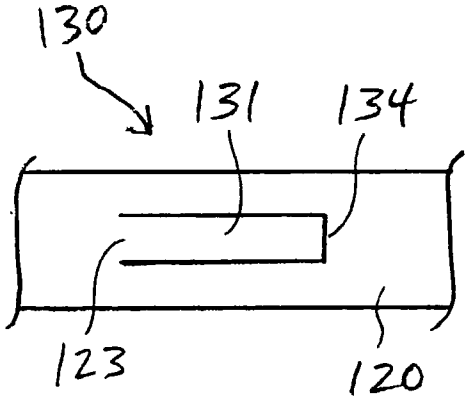


FIG. 6C

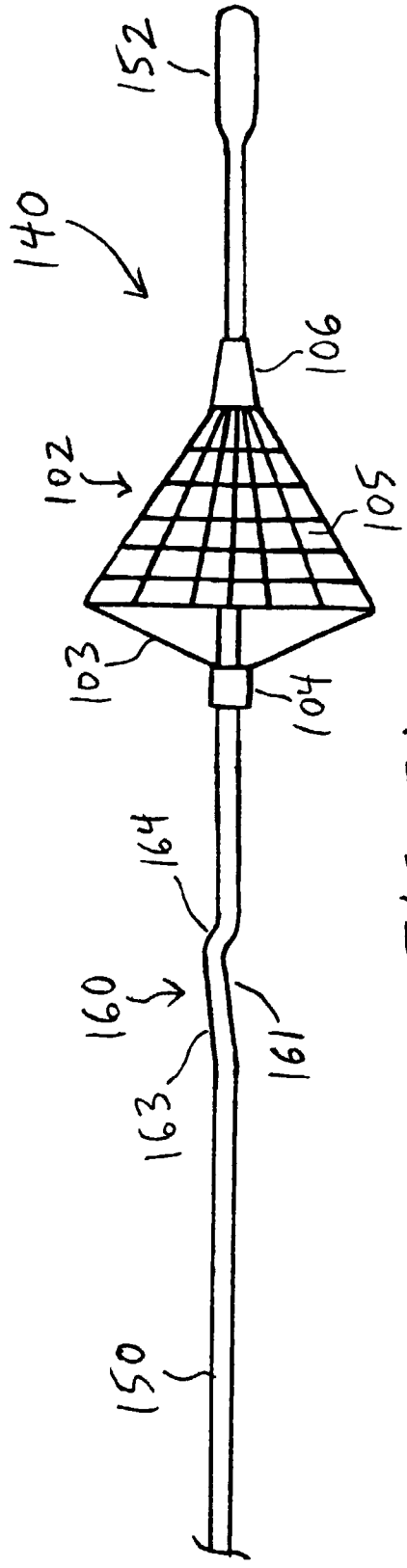

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FIG. 7A

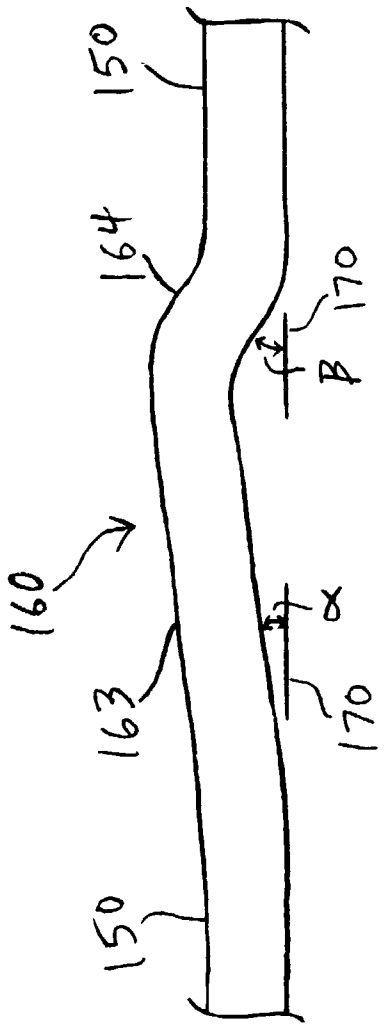

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FIG. 7B

EMBOLI FILTRATION SYSTEM AND METHODS OF USE

REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a continuation-in-part of U.S. patent application Ser. No. 09/774,197, filed Jan. 29, 2001, which is a continuation-in-part of U.S. patent application Ser. No. 09/354,897, filed Jul. 16, 1999, now U.S. Pat. No. 6,179,859.

FIELD OF THE INVENTION

[0002] The present invention relates to apparatus and methods for removing emboli from the blood stream that are generated during treatment of vascular disease, such as angioplasty, atherectomy or stenting. More particularly, an emboli filtration device and methods are provided having a captured filter that enables movement of a guide wire associated with the filter without displacing the filter.

BACKGROUND OF THE INVENTION

[0003] Atherosclerosis and other vascular occlusive diseases are becoming prevalent today in many developed countries. In such diseases, the flow areas of blood vessels become narrowed or occluded by the buildup of plaque on the walls of the vessels, leading to ischemia, and depending upon the location of the vessel, damage to the organ or limb. A number of surgical and percutaneous procedures have been developed for treating stenosis in the coronary arteries and carotid arteries, including endarterectomy, angioplasty, atherectomy and stenting.

[0004] One problem frequently encountered during such procedures is that pieces of plaque ("emboli") often are dislodged from the stenosis or the vessel wall. Such emboli may travel into smaller diameter regions of the vasculature, blocking blood vessels and causing ischemic injury. This problem is especially severe where the emboli are permitted to travel into the coronary arteries and carotid arteries, and can result in infarction, stroke and even death.

[0005] Emboli filtration devices are known in which filter elements are deployed against the walls of a vessel distal of a stenosis. Such filters typically comprise a polymer or wire sac mounted on a distal region of a guide wire or angioplasty catheter, and permit blood to flow through the filter while trapping emboli. Once treatment of the stenosis is completed, the filter containing the captured emboli is contracted and withdrawn from the vessel.

[0006] For example, U.S. Pat. No. 5,814,064 to Daniel et al. (Daniel) describes an emboli capturing system having a radially expandable mesh filter disposed on the distal end of a guide wire. The filter is deployed distal of a region of stenosis, and any interventional devices, such as an angioplasty balloon or stent delivery system are advanced along the guide wire. The filter is designed to capture emboli generated during treatment of the stenosis while permitting blood to flow through the filter.

[0007] U.S. Pat. No. 4,723,549 to Wholey et al. (Wholey) describes an angioplasty catheter having a filter element disposed on its distal end. The filter is supported on a plurality of circumferential struts, and is expanded against an interior wall of a vessel, distal of a stenosis, by an inflation balloon. An angioplasty balloon is disposed on the catheter proximal of the filter for dilating the stenosis. The filter captures emboli dislodged during the dilatation procedure, and then is contracted and removed from the vessel with the angioplasty catheter.

[0008] A key disadvantage of previously known emboli filtration systems, such as described in the foregoing patents, is that the filters in those devices are fixedly attached to the guide wire or angioplasty catheter, respectively. If the catheter or guide wire is rotated, bumped or moved after the filter has been deployed, there is a substantial risk that the filter will become temporarily dislodged or skewed, thereby permitting emboli to escape past the filter. Such motion is especially likely to occur when other devices such as an angioplasty balloon catheter are deployed along the guide wire after the filter is deployed, as in the Daniel patent.

[0009] U.S. Pat. No. 6,336,934 to Gilson et al. (Gilson) describes an embolic protection device having a collapsible filter element that is mounted on a tubular sleeve, wherein the tubular sleeve is slidable and rotatable on a guide wire between proximal and distal stops. The filter element on the tubular sleeve is delivered in a collapsed state within a catheter and self-deploys when the catheter is retracted. In the deployed state, the tubular sleeve facilitates some manipulation of the guide wire while potentially reducing disruption of the filter element.

[0010] One drawback associated with the device described in the Gilson patent is that the guide wire is delivered into the patient's vessel with the filter element disposed in a collapsed state between the proximal and distal stops near the distal end of the guide wire. The placement of the filter element near the distal end of the guide wire during delivery may make it difficult for the guide wire to negotiate tortuous anatomy during delivery. It would be advantageous to deliver the guide wire in an unencumbered manner to the site of the occlusion, then subsequently deliver other interventional devices including the filter element.

[0011] In view of these drawbacks of previously known devices, it would be desirable to provide emboli filtration apparatus and methods having a filter element that remains stationary once deployed.

[0012] It also would be desirable to provide emboli filtration apparatus and methods having a filter that may be deployed along a guide wire, but is configured so that subsequent displacements or rotation of the guide wire will not dislodge the filter.

[0013] It further would be desirable to provide emboli filtration apparatus and methods that reduce the risk of emboli escaping from a filter element.

[0014] It still further would be desirable to provide emboli filtration apparatus and methods that reduce the risk of trauma to vessel endothelium resulting from movement transferred to the emboli filtration apparatus.

[0015] It still further would be desirable to provide emboli filtration apparatus and methods that enable a filter element to be repositioned during a medical procedure without having to remove or insert additional interventional devices.

SUMMARY OF THE INVENTION

[0016] In view of the foregoing, it is an object of the present invention to provide emboli filtration apparatus and methods having a filter element that remains stationary once deployed.

[0017] It is another object of the present invention to provide emboli filtration apparatus and methods having a filter that may be deployed along a guide wire, but is configured so that subsequent displacements or rotation of the guide wire will not dislodge the filter.

[0018] It is also an object of this invention to provide emboli filtration apparatus and methods that reduce the risk of emboli escaping from a filter element.

[0019] It is a further object of the present invention to provide emboli filtration apparatus and methods that reduce the risk of trauma to vessel endothelium resulting from movement transferred to the emboli filtration apparatus.

[0020] It is still a further object of the present invention to provide emboli filtration apparatus and methods that enable a filter element to be repositioned during a medical procedure without having to remove or insert additional interventional devices.

[0021] These and other objects of the present invention are accomplished by providing emboli filtration apparatus comprising a guide wire having a filter element captured thereon, so that the guide wire is free to rotate and translate while the filter element remains stationary. The apparatus thus allows for movement and rotation of the guide wire as devices are advanced over it to treat a stenosis, substantially without dislodging the filter element. Accordingly, the risk of permitting emboli to escape during temporary displacement or skewing of the filter element is reduced, as well as movement-induced trauma of the vessel endothelium.

[0022] In a preferred embodiment, the apparatus comprises a guide wire having a filter element captured for rotation and translation on a distal end thereof. The filter element preferably comprises a wire or polymer sac affixed to a plurality of self-expanding struts. The filter element has a contracted state, suitable for transluminal insertion disposed inside a retractable sheath, and a deployed state, wherein an outer perimeter of the filter element engages the walls of a vessel when the sheath is retracted proximally.

[0023] The filter element includes a proximal capture ring having a diameter that is larger than the diameter of the guide wire, but smaller than the diameter of the distal tip of the guide wire. The capture ring allows the guide wire to move freely relative to the filter element over a limited range, so that movement or rotation of the guide wire does not cause the filter to move or to scrape against the walls of the vessel. When it is desired to retract the filter element, the guide wire is pulled proximally so that the distal tip of the guide wire engages the capture ring and pulls the filter element back into a sheath to its contracted state.

[0024] Optionally, the filter element may include a cylindrical sleeve that ensures that the filter forms an adequate seal against the walls of the vessel in the deployed state, thus preventing bypass flow around the filter. The sleeve also assists in orienting the axis of the filter element parallel to the axis of the vessel.

[0025] In a further alternative embodiment of the present invention, the guide wire further comprises a proximal stop disposed proximal of the distal tip. The proximal stop is configured so that a filter element having an elastomeric capture ring may be advanced distally over the proximal stop during delivery of the filter element and locked distal of the proximal stop. As a further alternative, the proximal stop may be configured to permit the capture ring to pass distally over it, but prevent proximal passage.

[0026] During a medical procedure, the filter element is advanced to a central position between the proximal stop and distal tip. Advantageously, if it becomes necessary to advance the filter element distally during the medical procedure, the guide wire may be advanced distally to cause the proximal stop to abut the capture ring and urge the filter element distally. Using the proximal stop of the guide wire, it is not necessary to remove interventional devices or insert a push tube over the guide wire to reposition the filter element.

[0027] Methods of using the apparatus of the present invention to remove emboli during a surgical or percutaneous transluminal procedure also are provided.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028] Further features of the invention, its nature and various advantages will be apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

[0029] **FIG. 1** is a side view of the components of a first embodiment of apparatus constructed in accordance with the principles of the present invention;

[0030] FIGS. **2A-2B** are, respectively, a perspective view and end view of the filter element of **FIG. 1**;

[0031] FIGS. **3A-3E** are side sectional views showing deployment, use and removal of the apparatus of **FIG. 1** in accordance with the methods of the present invention;

[0032] FIGS. **4A-4B** are, respectively, side sectional views of an alternative embodiment of the apparatus of the present invention in deployed and contracted states;

[0033] FIGS. **5A-5B** are side sectional views depicting use of an alternative embodiment of the present invention having a proximal stop disposed on a guide wire;

[0034] FIGS. **6A-6C** are, respectively, a side view of an alternative embodiment of the proximal stop of FIGS. **5A-5B**, and enlarged views of the proximal stop in relaxed and contracted states; and

[0035] FIGS. **7A-7B** are side views of a further alternative embodiment of a proximal stop provided in accordance with principles of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0036] The present invention is directed to an emboli filtration system and methods that filter out emboli generated during surgical or percutaneous interventional procedures. In accordance with the principles of the present invention, a filter element is captured on a guide wire so that the guide wire is capable of rotation and translation, without disturbing the placement of the filter element. Because the filter element is captured on the guide wire, however, the filter element is readily removed by retracting the guide wire into a sheath.

[0037] Referring to **FIG. 1**, apparatus **10** of a first embodiment of the present invention comprises guide wire **11**,

delivery sheath **20** and filter element **30**. In accordance with the principles of the present invention, guide wire **11** includes enlarged diameter distal region **12**. Guide wire **11** may be constructed of material commonly used in guide wire construction, such as stainless steel or a high strength polymer. Distal region **12**, which acts as a distal stop to limit travel of filter element **30** in the distal direction, comprises a soft metal or metal alloy coil or may be formed from a flexible polymer, such as polyethylene or nylon, molded onto the distal region of the guide wire. Alternatively, guide wire **11** and distal region **12** may comprise a mechanism, such as are known in the art, for steering distal region **12** through a patient's vasculature. Illustratively, guide wire **11** may have a diameter of about 0.018 inches (0.46 mm) and the diameter of distal region **12** may be about 0.022 inches (0.56 mm).

[**0038**] Delivery sheath **20** comprises flexible catheter **21** having proximal end **22**, distal end **23**, and interior lumen **24**. Push tube **25** is disposed within lumen **24**, and includes proximal end **26**, distal end **27** and guide wire lumen **28**, to permit catheter **21** and push tube **25** to be advanced along guide wire **11**. Proximal end **26** of push tube **25** extends through proximal end **22** of catheter **21**, so that push tube **25** may be translated in the distal and proximal directions relative to catheter **21**. Catheter **21** and push tube **25** preferably comprise flexible materials such as are commonly used in catheter construction, for example, polyethylene, polyurethane or nylon. Delivery sheath **20** preferably has an outer diameter of about 4 Fr.

[**0039**] Referring now to **FIGS. 2A and 2B**, filter element **30** comprises funnel-shaped filter sac **31** coupled to plurality of self-expanding struts **32** at proximal end **33** and soft elastomeric cone **34** at distal end **35**. Struts **32** are affixed to capture ring **36**, and self-expand from a contracted state, when filter element is disposed in lumen **24** of catheter **21**, and a deployed state, when filter element is ejected from delivery sheath **20**. In the deployed state, struts **32** extend outward to urge the perimeter of sac **31** into engagement with the walls of a vessel.

[**0040**] Struts **32** may comprise a resilient metal or metal alloy, such as stainless steel or nickel-titanium, or a resilient polymer. It is expected that at least three struts **32** spaced equidistant apart around the perimeter of sac **31** should be employed to provide adequate expansion and control of the sac, although a greater number may be used. Alternatively, struts **31** may comprise flexible strands, and expansion of sac **31** may be accomplished by adding a flexible and resilient self-expanding nickel-titanium hoop along perimeter **38** of the sac.

[**0041**] Particulate matter, such as emboli, pass through struts **32** and are trapped against sac **31**, which permits blood to pass freely through. The size of emboli trapped by sac **31** is determined by the pore size of the sac, and preferably is about 0.0012 inches (30 microns). Sac **31** may comprise a polymer sleeve affixed to struts **32** or a self-expanding wire mesh constructed from a resilient metal alloy, for example, nickel-titanium.

[**0042**] Capture ring **36** has bore **37** with an inner diameter greater than the diameter of guide wire **11**, but smaller than the diameter of distal region **12**. This allows guide wire **11** to be rotated or translated distally relative to filter element **30**, without imposing a force on the filter element that might temporarily dislodge the filter element. Accordingly, various devices, such as angioplasty catheters, atherectomy devices or stent delivery systems may be exchanged on guide wire **11** without disturbing filter element **30** or causing it to scrape against the walls of the vessel. As will of course be understood, capture ring **36** need not be a tubular member, but may have any suitable shape that allows guide wire **11** to pass freely through it.

[**0043**] Elastomeric cone **34** is coupled to the distal end of sac **31** and includes a tapered central lumen that permits guide wire **11** to freely pass through cone **34** with minimal clearance. Elastomeric cone **34** preferably comprises a non-stick or slick surface, such as polytetrafluoroethylene, and is designed so that emboli trapped in sac **31** are prevented from passing out of the filter element through the space between guide wire **11** and the lumen of elastomeric cone **34**. Cone **34** is sufficiently soft and flexible so that its lumen can expand to permit distal region **12** of guide wire **11** to be pulled proximally through the cone, and then the lumen will seal itself to prevent emboli from escaping through the lumen, as described hereinafter.

[**0044**] Referring now to FIGS. **3**, preferred methods of using the apparatus of **FIG. 1** are described. In **FIG. 3**A, guide wire **11** first is percutaneously and transluminally inserted into vessel V, such as a coronary artery or common carotid artery, so that distal region **12** is disposed distal of stenosis S in the direction of blood flow (indicated by arrow F).

[**0045**] In **FIG. 3**B, delivery sheath **20** with filter element **30** loaded in lumen **24** in the contracted state is advanced along guide wire **11** until the filter element is disposed at a desired location distal of the stenosis, as determined, for example, by fluoroscopy. Proximal end **26** of push tube **25** is then held stationary while catheter **21** is retracted in the proximal direction.

[**0046**] As catheter **21** is retracted, struts **32** of filter element **30** expand outward to urge the perimeter of sac **31** into engagement with the walls of vessel V, as depicted in **FIG. 3C**. Delivery sheath **20** then is withdrawn proximally and removed from guide wire **11**. Guide wire **11** then may be advanced a short distal distally, so that any incidental movement of the guide wire associated with exchanging interventional instruments along guide wire **11** will not cause distal region **12** to contact filter element **30**.

[**0047**] In **FIG. 3**D, angioplasty catheter **40** is illustratively advanced along guide wire **11** until balloon **41** is disposed across the stenosis. Balloon **41** then is inflated and deflated for one or several cycles, as in conventional, to dilate and disrupt the plaque comprising stenosis S and increase the diameter of vessel V. During this dilatation procedure, particles of plaque or emboli E are generated. These emboli are carried by blood flow in direction F into sac **31** of filter element **30**, where they become trapped.

[**0048**] Insertion and advancement of angioplasty catheter **40** along guide wire **11** may cause the guide wire to be translated over a short range or rotated. Because filter element **30** is not affixed to guide wire **11**, however, such motion of the guide wire is not transferred to the filter element. Instead, filter element **30** remains stationary even though the guide wire rotates or translates relative to the filter element.

[0049] Once balloon **41** has dilated stenosis S, angioplasty catheter **40** is withdrawn along guide wire **11** while leaving the guide wire in place. If desired, a stent delivery system (not shown) may be advanced along guide wire **11** and one or more stents deployed across the dilated stenosis to retain the patency of the dilated vessel.

[0050] When treatment of the stenosis is completed, delivery sheath **20** (with push tube **25** removed) may again be advanced along guide wire **11** to a position just proximal of filter element **30**. Guide wire **11** then is pulled proximally so that distal region **12** passes through elastomeric cone **34** and bears against capture ring **36**. The lumen in cone **34** seals itself after distal region **12** passes through it so that emboli trapped in sac **31** do not escape through the lumen of cone **34**.

[0051] When guide wire **11** is pulled further in the proximal direction, with catheter **21** held stationary, struts **32** are forced radially inward by the distal edge of the catheter. This in turn causes sac **31** to disengage the vessel walls. As the guide wire continues to be pulled proximally, struts **32** cause sac **31** to collapse inward to its contracted position and the filter element is retracted into lumen **24** of catheter **21**. Emboli E are trapped and retained in filter element **30** throughout treatment of the stenosis, and are withdrawn from the vessel when the filter element is retracted within catheter **21**. Catheter **21** then is removed from the vessel.

[0052] Referring now to **FIGS. 4A and 4B**, an alternative embodiment of the filter element and guide wire of the present invention is described. Guide wire **50** is similar in construction to guide wire **11** described with respect to **FIG. 1**, except that it includes flange **51** on enlarged diameter distal region **52** of guide wire **50**, and enlarged distal region **52** has length L_1 that is longer than the length of the filter element **60** in the contracted state.

[0053] Distal region **52** may be formed from a malleable material, a coil spring, or a pliable thermoplastic material molded onto guide wire **50**, and preferably is covered with a smooth hydrophilic coating to facilitate movement of filter element **60** as described hereinafter. Alternatively, guide wire **50** and distal region **52** may comprise a mechanism, such as are known in the art, for steering distal region **52** through a patient's vasculature. Distal region **52** also may comprise a radiopaque material or may include a radiopaque band (not shown) to assist in visualization and placement of the guide wire.

[0054] Filter element **60** comprises self-expanding struts **61** coupled to capture ring **62** and tubular sleeve **63**. Sleeve **63** is affixed at its distal end to funnel-shaped filter sac **64**, which in turn is coupled to distal ring **65**. Capture ring **62** has bore **66** with an inner diameter larger than the diameter of guide wire **50**, but smaller than the diameter of distal region **52**. Accordingly, guide wire **50** may freely translate and rotate through bore **66** of capture ring **62** while the filter element remains stationary.

[0055] Distal ring **65** has bore **67** with a diameter slightly larger than the diameter of distal region **52**. This enables distal ring **65** to slide or rotate freely over distal region **52**, but with minimal clearance for emboli to escape from sac **64** through the annulus between distal ring **65** and distal region **52**. Distal region **52** includes flange **51**, which has a diameter that is larger than the diameter of bore **66** of capture ring **62**. Thus, filter element **60** is captured on guide wire **50** proximally by distal ring **65** abutting against flange **51**, and distally by capture ring **62** abutting against flange **51**.

[0056] Sleeve **63** and sac **64** filter blood passing through the vessel, and preferably have a pore size selected to filter out particles having a diameter greater than 0.0012 inches (30 microns). Sleeve **63** and sac **64** preferably comprise a flexible woven metal alloy, polymer tube, or perforated fabric, and are expanded to the deployed state, as shown in **FIG. 4A**, by struts **61**. Advantageously, sleeve **63** is designed so that its perimeter conforms to the inner diameter of the vessel to seal against bypass flow, even in curved vessels. In addition, sleeve **63** tends to prevent skewing of the filter element and ensures that the filter is properly oriented parallel to the axis of the vessel when the filter element is deployed.

[0057] Filter element **60** is suitable for delivery percutaneously and transluminally to a desired location in a vessel using delivery sheath **20** of **FIG. 1**. In particular, struts **61** may be radially compressed to collapse sleeve **63** and sac **64**, as shown in **FIG. 4B**, thereby permitting the filter element to be loaded into lumen **24** of catheter **21** so that capture ring **62** abuts against distal end **27** of push tube **25**.

[0058] Deployment of filter element **60** is similar to the method described with respect to **FIGS. 3B and 3C**. Specifically, delivery sheath **20** is advanced through a vessel with distal region **52** extending beyond distal end **23** of catheter **21**. Once distal region **52** has crossed the stenosis, as confirmed by fluoroscopy, push tube **25** is held place and catheter **21** is retracted proximally. Alternatively, push tube **25** may be omitted and guide wire **50** may be held stationary with filter element **60** held in position by flange **51**. Retraction of catheter **21** uncovers filter element **60**, allowing struts **61** to expand outward and urge the perimeter of sleeve **63** and sac **64** into engagement with the walls of the vessel.

[0059] Delivery sheath **20** then is removed, and one or more interventional devices may be serially employed on guide wire **50**. Like the embodiment of **FIG. 1**, motion imparted to guide wire **50** during exchange of instruments along the guide wire causes the guide wire to slide through filter element **60** without causing skewing or displacement of the filter element. Advantageously, this prevents emboli from escaping sac **64** or damage to the endothelium caused by scraping of the filter element.

[0060] Once treatment of the stenosis is completed, the treatment device (e.g., angioplasty catheter, etc.) is removed, and delivery sheath **20** is again advanced along guide wire **50**. When distal end **23** of catheter **21** is disposed adjacent to capture ring **62**, guide wire **50** is pulled proximally. As a result of this motion, distal region **52** passes through filter element **60** until flange **51** abuts against capture ring **62**. Further proximal movement of guide wire **50** causes struts **61** to be urged inward, collapsing sleeve **63** and sac **64** so that they can be drawn into lumen **24** of catheter **21**.

[0061] Unlike the embodiment of **FIG. 1**, where the distal region passes through cone **34**, length L_1 is sufficiently long so that distal ring **65** is still disposed over the enlarged diameter of distal region **52** when the filter element is in the contracted state. Accordingly, when filter element **60** is contracted for removal, emboli cannot escape through bore **67** of distal ring **65**, since the bore continues to be substan-

tially blocked by distal region **52** of guide wire **50**. Delivery sheath **20**, guide wire **50** and filter element **60** then are removed from the vessel with any emboli trapped within the contracted filter element.

[**0062**] In a preferred embodiment of the apparatus of FIGS. **4**, guide wire **50** has a suitable length for transluminal percutaneous applications and a diameter in a range of about 0.006 to 0.025 inches , and more preferably 0.012 inches. Distal region **52** of guide wire **50** has a diameter larger than the diameter of guide wire **50**, and preferably in a range of about 0.010 to 0.038 inches, more preferably 0.018 inches.

[**0063**] While filter element **60** may comprise any length suitable for an intended application, in one preferred embodiment, filter element **60** has a deployed length of 3.5 cm and a maximum deployed diameter of 12 mm. For this embodiment, length L_1 of distal region **52** preferably is 5.0 cm. For a guide wire having a diameter of 0.012 inches and distal region having a diameter of 0.018 inches, capture ring **62** preferably has an inner diameter of 0.014 inches and an outer diameter of 0.018 inches. In this case distal ring **65** preferably has an inner diameter of 0.0181 inches and an outer diameter of 0.024 inches.

[**0064**] Referring now to FIGS. **5**, apparatus **90** of an alternative embodiment of the present invention comprises guide wire **100** and filter element **102**. Filter element **102** preferably is constructed in accordance with filter element **30** of FIGS. **1-3**. Specifically, filter element **102** comprises funnel-shaped filter sac **105** coupled to plurality of self-expanding struts **103** at a proximal end and elastomeric cone **106** at a distal end. Struts **103** are affixed to capture ring **104**, as described in detail hereinabove with respect to **FIGS. 2**. Optionally, filter element **102** also may comprise cylindrical sleeve **63**, as described hereinabove with respect to FIGS. **4**, disposed between struts **103** and sac **105**.

[**0065**] Guide wire **100** comprises proximal stop **110** and distal region **112**. Distal region **112** serves as a distal stop that limits the distal movement of filter element **102** along guide wire **100**, as described hereinabove. Proximal stop **110** has proximal and distal ends **114** and **115** and taper **111** disposed therebetween, as shown in **FIG. 5A**. Taper **111** of guide wire **110** spans from proximal end **114**, which preferably has a guide wire diameter of about 0.018 inches, to distal end **115**, which preferably has an enlarged diameter of about 0.022 inches. Proximal stop **110** and distal region **112** are spaced apart such a distance that filter element **102**, when deployed therebetween, will not be disturbed by incidental longitudinal movements of guide wire **100**.

[**0066**] Apparatus **90** of FIGS. **5** preferably is deployed in the manner described hereinabove with respect to apparatus **10** of FIGS. **1-3**, except as noted below. In a first step, guide wire **100** is percutaneously and transluminally inserted into treatment vessel V under fluoroscopy, with proximal stop **110** preferably being disposed just distal of stenosis S. In a next step, filter element **102** is advanced along guide wire **100** in a contracted state, preferably being contracted within lumen **24** of catheter **21**, as described hereinabove with respect to **FIG. 3B**. Push tube **25** of **FIG. 3B** then is advanced distally so that a distal end of push tube **25** abuts capture ring **104** and advances filter element **102** distally over guide wire **100**.

[**0067**] As push tube **25** advances filter element **102**, elastomeric cone **106** is pushed distally over proximal stop **110** of guide wire **100**. Elastomeric cone **106** is configured to be flexible enough to radially expand over the enlarged diameter of distal end **115** of proximal stop **110**. After being advanced over distal end **115**, elastomeric cone **106** then substantially seals itself about guide wire **100** to prevent emboli from subsequently escaping when a medical procedure is performed.

[**0068**] As push tube **25** further is advanced, capture ring **104** then is advanced over proximal stop **110**. Capture ring **104** also is compliant enough to expand over the enlarged diameter of distal end **115** when advanced distally, and then substantially seals itself about guide wire **100** after it passes over proximal stop **110**. Once filter element **102** is disposed between proximal stop **110** and distal region **112**, filter element **102** is deployed, e.g., by proximally retracting catheter **21** while holding push tube **25** stationary. The catheter and push tube then may be removed from the patient's vessel.

[**0069**] Once deployed, filter element **102** preferably is provided in a central position between proximal stop **110** and distal region **112**, as depicted in **FIG. 5A**, either by proximally retracting or distally advancing guide wire **100** under fluoroscopy. In this central position, incidental movements of guide wire **100** will not substantially disturb filter element **102**.

[**0070**] If it becomes necessary to advance filter element **102** distally during the medical procedure, guide wire **100** may be advanced distally by a physician until distal end **115** of proximal stop **110** abuts capture ring **104** and gently urges filter element **102** distally, as shown in **FIG. 5B**. Advantageously, this enables filter element **102** to be advanced distally without having to remove angioplasty or stenting apparatus, then having to advance a push tube over then length of guide wire **100**. Upon repositioning of filter element **102**, guide wire **100** preferably is repositioned to the central position depicted in **FIG. 5A**, so that incidental movements of guide wire **100** do not disturb filter element **102**.

[**0071**] When treatment of the stenosis is completed and any emboli are captured within sac **105** of filter element **102**, delivery sheath **20** (with push tube **25** removed) may be advanced to a location just proximal of filter element **102**. Guide wire **100** then is retracted proximally so that distal region **112** passes through elastomeric cone **106** and bears against capture ring **104**, as described hereinabove with respect to **FIG. 3E**. A lumen of cone **106** seals itself after distal region **112** passes through to prevent emboli from escaping downstream. Distal region **112** then abuts capture ring **104** and pulls filter element **102** in a proximal direction. With the catheter held stationary, struts **103** are forced radially inward by the distal edge of the catheter to cause filter element **102** and any emboli captured therein to be removed via the catheter.

[**0072**] Advantageously, the one-way stop feature of proximal stop **110** allows guide wire **100** to be advanced through a patient's vasculature without having filter element **102** disposed on the guide wire. This facilitates advancement of guide wire **100** through a patient's tortuous vasculature. Then, when guide wire **100** is properly positioned in a vessel unencumbered, filter element **102** may be advanced distally over proximal stop **110**, and securely positioned between proximal stop **110** and distal region **112** during the medical procedure.

[0073] Referring now to FIGS. **6**, an alternative embodiment of proximal stop **110** of the embodiment of FIGS. **5** is described. In **FIG. 6**A, guide wire **120** preferably is provided substantially in accordance with guide wire **11** of **FIG. 1**, and comprises enlarged diameter distal region **122**, which acts as a distal stop to limit travel of filter element **102** in the distal direction, as described hereinabove. Guide wire **120** further comprises proximal stop **130**, which includes at least one depressible tab **131** having proximal end **133** and distal end **134**, as shown in FIGS. **6**B-**6**C.

[0074] Proximal end **133** of depressible tab **131** is affixed to guide wire **120**, e.g., using a solder, while distal end **134** is biased to extend slightly radially outward from guide wire **120** in a relaxed state, as shown in **FIG. 6B**. Depressible tab **131** may comprise a slight concave curvature to cause distal end **134** to be biased radially outward or, alternatively, proximal end **133** may be affixed to guide wire **120** in such a manner that allows distal end **134** to be biased radially outward in the relaxed state.

[0075] Depressible tab **131** is flexible so that it may be transformed between the relaxed state, shown in **FIG. 6**B, and a contracted state, as shown in **FIG. 6C**. In the contracted state, external compressive forces cause depressible tab **131** to be substantially flush with an exterior surface of guide wire **120**. Guide wire **120** optionally may comprise a shallow slot (not shown) disposed in a lateral surface that is adapted to receive depressible tab **131** in the contracted state. When depressible tab **131** is contracted, as shown in **FIG. 6**C, the shallow slot serves to ensure that depressible tab **131** does not extend radially beyond guide wire **120**.

[0076] Apparatus **110** of FIGS. **6** preferably is deployed in the manner described hereinabove with respect to apparatus **10** of FIGS. **1-3**, except as noted below. In a first step, guide wire **120** is percutaneously and transluminally inserted until proximal stop **130** is disposed just distal of a stenosis. In a next step, filter element **102** is advanced along guide wire **120** in a contracted state, preferably being contracted within lumen **24** of catheter **21**, as described hereinabove with respect to **FIG. 3B**. Push tube **25** of **FIG. 3B** then is advanced distally so that a distal end of push tube **25** abuts capture ring **104** and advances filter element **102** distally.

[0077] As push tube **25** advances filter element **102**, elastomeric cone **106** is pushed distally over proximal stop **130**. Depressible tab **131** assumes the contracted state, depicted in **FIG. 6**C, as filter element **102** is advanced distally to facilitate advancement of elastomeric cone **106** over proximal stop **130**. Elastomeric cone **106** also may radially expand over proximal stop **130**, if necessary, and then substantially seal itself about guide wire **120** after it passes over proximal stop **130**. As push tube **25** further is advanced, capture ring **104** then is advanced over proximal stop **130** in the same manner as elastomeric cone **106**.

[0078] After elastomeric cone **106** and capture ring **104** are advanced distally over proximal stop **130**, depressible tab **131** returns to the relaxed state, depicted in **FIG. 6B**. Filter element **102** then is deployed between proximal stop **130** and distal region **122**, e.g., by proximally retracting catheter **21** while holding push tube **25** stationary. The catheter and push tube then may be removed from the patient's vessel.

[0079] Once deployed, filter element **102** preferably is provided in a central position between proximal stop **130** and distal region **122** by proximally retracting or distally advancing guide wire **120** under fluoroscopy. If it becomes necessary to advance filter element **102** distally during a medical procedure, guide wire **120** may be advanced distally to cause distal end **134** of depressible tab **131** to abut capture ring **104** and gently urge filter element **102** distally. Upon completion of the medical procedure, catheter **21** may be advanced distally over guide wire **120** to cause filter element **102** and any emboli captured therein to be removed via the catheter, as described in detail hereinabove with respect to **FIG. 3E**.

[0080] Referring now to **FIGS. 7, a** further alternative embodiment of the present invention is described, whereby guide wire **11** of **FIG. 1** is slightly bent to comprise a one-way proximal stop mechanism. Guide wire **150** of **FIG. 7A** comprises enlarged diameter distal region **152**, which acts as a distal stop to limit travel of filter element **102** in the distal direction. Guide wire **150** further comprises proximal stop **160**, which includes bent section **161** of guide wire **150** having proximal taper **163** and distal taper **164**. Proximal taper **163** comprises angle a with respect to longitudinal axis **170** of guide wire **150**, while distal taper **164** comprises angle β with respect to longitudinal axis **170**, as depicted in **FIG. 7B**.

[0081] Proximal stop **160** is configured to facilitate distal advancement of filter element **102** over bent section **161** of guide wire **150** via proximal taper **163**, while inhibiting movement of filter element **102** in a proximal direction over bent section **161** via distal taper **164**. In a preferred embodiment, angle β is greater than angle α, as illustratively shown in **FIG. 7**B, to permit advancement of filter element **102** in a distal direction only.

[0082] Proximal stop **160** of guide wire **150** is flexible enough so that proximal and distal tapers **163** and **164** may assume substantially flat configurations, i.e., substantially parallel to longitudinal axis **170** of guide wire **150**, when elastomeric cone **106** and capture ring **104** are advanced distally over bent region **161**. Once filter element **102** is advanced distally over proximal stop **160**, proximal and distal tapers **163** and **164** return to the bent configurations depicted in **FIG. 7A**.

[0083] Apparatus **140** of FIGS. **7** preferably is deployed in the manner described hereinabove with respect to apparatus **10** of FIGS. **1-3**, except as noted below. In a first step, guide wire **150** is percutaneously and transluminally inserted until proximal stop **160** is disposed just distal of a stenosis. In a next step, filter element **102** is advanced along guide wire **150** in a contracted state, preferably being contracted within lumen **24** of catheter **21**, as described hereinabove with respect to **FIG. 3B**. Push tube **25** of **FIG. 3B** then is advanced distally so that a distal end of push tube **25** abuts capture ring **104** and advances filter element **102** distally.

[0084] As push tube **25** advances filter element **102**, elastomeric cone **106** is pushed distally over proximal taper **163** of guide wire **150**. Proximal and distal tapers **163** and **164** may assume substantially flat configurations, i.e., substantially parallel to longitudinal axis **170**, to facilitate distal advancement of elastomeric cone **106**. As push tube **25** further is advanced distally, capture ring **104** then is advanced over proximal stop **160** in the same manner as elastomeric cone **106**.

[0085] Once filter element **102** is disposed between proximal stop **160** and distal region **152**, filter element **102** is

deployed, as described hereinabove. Filter element **102** preferably is provided in a central position between proximal stop **160** and distal region **152**, as shown in **FIG. 7**A, by proximally retracting or distally advancing guide wire **150** under fluoroscopy. If it becomes necessary to advance filter element **102** distally during a medical procedure, guide wire **150** may be advanced distally until distal taper **164** of proximal stop **160** abuts capture ring **104** and gently urges filter element **102** distally. Proximal stop **160** of guide wire **150** is configured to retain the bent shape depicted in FIGS. **7** as distal taper **164** urges filter element **102** distally. Upon completion of the medical procedure, catheter **21** may be advanced distally over guide wire **150** to cause filter element **102** and any emboli captured therein to be removed via the catheter, as described in detail hereinabove with respect to **FIG. 3E**.

[**0086**] While preferred illustrative embodiments of the invention are described above, it will be apparent to one skilled in the art that various changes and modifications may be made. The appended claims are intended to cover all such changes and modifications that fall within the true spirit and scope of the invention.

1. Apparatus for filtering emboli from blood flowing through a vessel, the apparatus comprising:

a guide wire having proximal and distal regions, and proximal and distal stops on the distal region; and

a filter element configured to rotate and translate on the guide wire between the proximal and distal stops,

wherein the filter element and the proximal stop are configured to permit advancement of the filter element from the proximal region by passing in vivo over the proximal stop, the proximal stop thereafter prohibiting proximal retraction of the filter element over the proximal stop.

2. The apparatus of claim 1 wherein the distal stop limits translation of the filter element in a distal direction.

3. The apparatus of claim 1 wherein the proximal stop has proximal and distal ends and a taper disposed therebetween.

4. The apparatus of claim 3 wherein the proximal end has a first diameter that is less than a second diameter of the distal end.

5. The apparatus of claim 3 wherein the filter element comprises a compliant member configured to pass over the proximal stop.

6. The apparatus of claim 1 wherein the proximal stop and distal stop are spaced apart such a distance that the filter element, when deployed therebetween, will not be disturbed by incidental longitudinal movements of the guide wire.

7. The apparatus of claim 1 wherein the proximal stop is configured to abut against a proximal portion of the filter element, after the filter element is moved to the distal region, when the guide wire is advanced.

8. The apparatus of claim 1 further comprising a plurality of self-expanding struts coupled between a capture ring and a filter sac.

9. The apparatus of claim 1 wherein the proximal stop comprises at least one depressible tab having proximal and distal ends, wherein the proximal end is affixed to the guide wire.

10. The apparatus of claim 9 wherein the distal end of the depressible tab is biased radially outward from the guide wire in a relaxed state.

11. The apparatus of claim 10 wherein the distal end of the depressible tab is configured to abut against the filter element once the filter element is moved to the distal region.

12. The apparatus of claim 10 wherein the depressible tab further comprises a contracted state in which the distal end is substantially flush with an exterior surface of the guide wire.

13. The apparatus of claim 9 wherein the depressible tab is configured to facilitate distal advancement of the filter element over the proximal stop in the contracted state.

14. The apparatus of claim 1 wherein the proximal stop includes a bent section of the guide wire, the bent section including a proximal taper and a distal taper.

15. The apparatus of claim 14 wherein the proximal taper comprises a first angle with respect to a longitudinal axis of the guide wire and the distal taper comprises a second angle with respect to the longitudinal axis, wherein the first angle is less than the second angle.

16. A method for filtering emboli from blood flowing through a vessel, the method comprising:

providing apparatus comprising a guide wire having a distal region including a distal stop, a proximal stop disposed proximal of the distal stop, and a filter element disposed for-translation on the guide wire;

transluminally inserting the guide wire into a vessel;

distally advancing the filter element in a contracted state over the proximal stop; and

deploying the filter element, distal of the proximal stop and proximal of the distal stop, to engage a wall of the vessel and filter emboli out of blood flowing through the vessel.

17. The method of claim 16 further comprising advancing a treatment device along the guide wire to treat a portion of the vessel proximal of the location of the filter element, wherein incidental rotation or translation of the guide wire relative to the filter element does not displace the filter element.

18. The method of claim 17 further comprising a step of, after use of the treatment device is completed, pulling the guide wire proximally so that the distal stop engages the filter element and causes the filter element to return to the contracted state.

19. The method of claim 16 further comprising:

distally advancing the guide wire; and

causing the proximal stop to abut and urge the filter element distally.

20. The method of claim 16 wherein providing apparatus comprising a proximal stop comprises providing a taper on the guide wire, the method further comprising:

distally advancing the filter element in the contracted state over the taper; and

causing a distal end of the taper to abut and reposition the filter element when the guide wire is advanced distally by a physician.

21. The method of claim 16 wherein providing apparatus comprising a proximal stop comprises providing a bent section of the guide wire having proximal and distal tapers, the method further comprising:

distally advancing the filter element in the contracted state over the proximal and distal tapers; and

causing the distal taper to abut and reposition the filter element when the guide wire is advanced distally by a physician.

22. The method of claim 16 wherein providing apparatus comprising a proximal stop comprises providing at least one depressible tab having a proximal end affixed to the guide wire and a distal end, the method further comprising:

providing the depressible tab in a relaxed state wherein the distal end is biased radially outward from an exterior surface of the guide wire;

distally advancing the filter element over the depressible tab to cause the distal end of the depressible tab to be substantially flush with the exterior surface of the guide wire; and

returning the depressible tab to the relaxed state after the filter element is advanced distal of the proximal stop.

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