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(54) Title: VENA CAVA FILTER FORMED FROM A TUBE

(57) Abstract: A filter formed from a tube is described herein. The filter may be formed from one or more tubes. The filter may include first and second filter members formed respectively from first and second tubes with the second filter member having a proximal end nested within the proximal end of the first filter member. The filter may include appendages including a tip section that terminates in a point. The proximal end of the filter may be defined by an opening configured to prevent relatively large emboli from passage through the filter.



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VENA CAVA FILTER FORMED FROM A TUBE

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 60/782,019, filed March 14, 2006, and U.S. Provisional Patent Application No. 60/831,705, filed July 18, 2006, each of which is incorporated by reference into this application as if fully set forth herein.

BACKGROUND

[0002] Inferior vena cava (IVC) filters are devices configured for insertion into a blood vessel to capture particles that may be present in the blood stream which, if transported to, for example, the lungs could result in serious complications and even death. Typically, IVC filters are utilized in patients who have a contraindication to anticoagulation or in patients developing clinically apparent deep vein thrombosis (DVT) and/or pulmonary embolism (PE). Patients who have recently suffered from trauma, have experienced a heart attack (myocardial infarction), or who have undergone major surgical procedure (e.g., surgical repair of a fractured hip, etc.) may develop clinically apparent DVT. When a thrombus clot loosens from the site of formation and travels to the lung, it may cause PE, a life-threatening condition. An IVC filter may be placed in the circulatory system to intercept one or more clots and prevent them from entering the lungs. IVC filters are either permanent or retrievable.

[0003] There are many different configurations for IVC filters, including those that include a central hub from which extend a plurality of struts that form filter baskets having a conical configuration, such as disclosed in U.S. Patent No. 6,258,026, which is incorporated by reference in its entirety into this application. Other IVC filter configurations utilize wires and/or frame members to form straining devices that permit flow of blood while trapping larger particles. IVC filters are generally configured for compression into a small size to facilitate delivery into the inferior vena cava and subsequent expansion into contact with the inner wall thereof. The IVC filter may later be retrieved from the deployed site by compressing the legs, frame members, etc., depending on the filter configuration. Typically, an IVC filter will include hooks or anchoring members for anchoring the filter in position within the inferior vena cava. The hooks may be more elastic than the legs or frame members to permit the hooks to straighten in response to withdrawal forces, which facilitate withdrawal from the endothelium layer of the blood vessel without risk of significant injury to the vessel wall.

[0004] The following references relate to filters: U.S. Patent No. 4,793,348; U.S. Patent No. 6,402,771; U.S. Patent No. 6,443,972, U.S. Patent No. 6,551,342; U.S. Patent Application Publication No. 2003/0195554; U.S. Patent Application Publication No. 2005/0080449; U.S. Patent Application Publication No. 2005/0165441; and U.S. Patent Application Publication No. 2005/0165442, each of which is incorporated by reference in its entirety into this application.

[0005] Applicants have recognized that it would be desirable to form an IVC filter from a tube, including removing portions from the tube to form various features of the IVC filter. Applicants have also recognized that it would be desirable to form an IVC filter from one or more tubes to increase the potential appendages and levels of filtration of the IVC filter. Thus, described herein are embodiments of an IVC filter formed from one or more tubes.

BRIEF SUMMARY OF THE INVENTION

[0006] Accordingly, implantable medical devices, including IVC filters, that are formed from one or more tubes are described herein.

[0007] In one embodiment, a method of making an implantable medical device includes providing a generally tubular structure having an inner diameter and a wall thickness, removing portions of the tubular structure along predetermined lines to form a plurality of appendages, weakening at least one section in one or more of the appendages near a distal end thereof, and bending the distal end of at least the appendages containing the section.

[0008] In another embodiment, a filter formed from a shape memory tube includes a plurality of legs having a distal end terminating in a pointed tip, a first section in the legs positioned adjacent the tip having a material strength less than a material strength of a second section proximal the first section, and a bent section distal the first section. In another embodiment, a filter includes a body and a plurality of legs formed from a generally tubular structure, a proximal end of the body being defined by the generally tubular structure, having an opening with a cross-sectional area less than a cross-sectional area of a dangerous migrating blood clot, the legs extending radially outward from the body along a longitudinal axis, one or more of the legs having a distal end terminating in a pointed tip and being formed into a hook.

[0009] In one embodiment, a method of making an implantable medical device, includes providing a first generally tubular structure having an inner diameter and a second generally tubular structure having an outer diameter less than the inner diameter of the first

tubular structure, removing portions of the first and second tubular structures along predetermined lines to form a plurality of first and second appendages, and nesting a proximal end of the second tubular structure within a proximal end of the first tubular structure.

[0010] In another embodiment, a filter formed from shape memory tubes includes a first filter member including a first proximal end defined by a first shape memory tube with an inner diameter, and a plurality of first appendages extending from the first proximal end, a distal end of at least one of the first appendages terminating in a pointed tip, and a second filter member including a second proximal end defined by a second shape memory tube with an outer diameter less than the inner diameter of the first shape memory tube, and a plurality of second appendages extending from the second proximal end, the second proximal end nested within the first proximal end and connected thereto.

[0011] In one embodiment, a method of filtering fluid includes flowing fluid, including particles of various cross-sectional areas, through a generally tubular member that simulates a blood vessel, positioning a filter in the tubular member about a central axis defined by the tubular member, and permitting particles having cross-sectional areas less than the cross-sectional area of a dangerous migrating blood clot to flow through the filter coincident with the central axis.

[0012] These and other embodiments, features and advantages will become more apparent to those skilled in the art when taken with reference to the following more detailed description of the invention in conjunction with the accompanying drawings that are first briefly described.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] FIG. 1 is a side perspective view of one embodiment of a filter formed from a tube, following removal of portions of the tube.

[0014] FIG. 2 is a side perspective view of the filter of FIG. 1, following a secondary procedure.

[0015] FIGS. 3A-3C are enlarged views of the distal end of a filter appendage, showing different potential tip structures.

[0016] FIG. 4 is a side perspective view of another embodiment of a filter formed from a tube.

[0017] FIG. 5 is a front perspective view of another embodiment of a filter formed from a tube.

[0018] FIG. 6 is a perspective view of an embodiment of a filter formed from a tube.

[0019] FIG. 6A is a cross-sectional view of FIG. 6 along line 6A-6A.

[0020] FIG. 7 is a perspective view of an embodiment of a filter formed from two tubes.

[0021] FIG. 7A is a cross-sectional view of FIG. 7 along line 7A-7A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0022] The following detailed description should be read with reference to the drawings, in which like elements in different drawings are identically numbered. The drawings, which are not necessarily to scale, depict selected embodiments and are not intended to limit the scope of the invention. The detailed description illustrates by way of example, not by way of limitation, the principles of the invention. This description will clearly enable one skilled in the art to make and use the invention, and describes several embodiments, adaptations, variations, alternatives and uses of the invention, including what is presently believed to be the best mode of carrying out the invention.

[0023] While the examples provided herein are discussed with respect to IVC filters, it should be appreciated that the filter embodiments described herein could be used for filter applications that do not involve placing a filter device in the inferior vena cava. In other words, the filters described herein are not limited to IVC applications. Moreover, as used herein, the term "suture material" means a material that is, or could be, used as a suture thread by a surgeon, including, for example, synthetic polymers, polyglycolic acid (PGA), polylactic acid (PLA), polydioxanone (PDS), polyglactin, nylon, polypropylene (prolene), silk, catgut, non-absorbable/non-biodegradable materials, and combinations thereof. Included in this term are both monofilament and multifilament suture materials.

[0024] Further, as used herein the term "bio-resorbable" includes a suitable biocompatible material, mixture of various biocompatible materials or partial components of biocompatible material being altered into other materials by an agent present in the environment (e.g., a biodegradable material that degrades via a suitable mechanism such as hydrolysis when placed in biological tissue); such materials being removed by cellular activity or incorporated into the cellular structure (i.e., bioresorption, bioresorping, bioabsorption, or bioresorbable), such materials being degraded by bulk or surface degradation (i.e., bioerosion such as, for example, a water insoluble polymer that turns water-soluble in contact with biological tissue or fluid), or such materials being altered by a combination of one or more of biodegradable, bioerodable or bioresorbable activity when placed in contact with biological tissue or fluid.

[0025] Also, as used herein, the term “tip” or “tip section” means a member configured to engage a blood vessel wall, including a barb, hook, anchor, etc., examples of which are provided in U.S. Patent No. 6,258,026, which is incorporated by reference in its entirety into this application. As used herein, the phrase “weakening a section” means making the section thinner, heat treating the section, cutting grooves into the section, etc. Further, as used herein, the term “lower material strength” means either a lower modulus of elasticity or a lower ability to resist bending; however, the term “stiffness” does not imply a direct correlation with material strength in that a member or portion of a medical device with a relatively lower material strength may achieve a relatively higher stiffness based on its physical geometry. The term “dangerous migrating blood clot” is defined herein as a blood clot that is considered to be dangerous by a clinician skilled in the area of filter technology for a particular patient based on the patient's age, general state of health, cardiopulmonary reserve, etc. Finally, as used herein, the term “tube” means a generally tubular structure, having a lumen, an inner diameter, a wall thickness and a length.

[0026] Possible materials for the tube and filter described herein include a suitable biocompatible material such as, for example, stainless steel, noble metals and their alloys, shape memory metals, shape memory alloys, super elastic metal, linear elastic shape memory metal, metal alloys, shape memory polymers, polymers, bio-resorbable materials (e.g., metal alloys such as those shown and described in U.S. Patent No. 6,287,332; and U.S. Patent Application Publication No. 2002/0004060, each of which is incorporated by reference in its entirety into this application), and combinations thereof.

[0027] Where the filter is to be utilized with bio-active agents to control the formation of emboli, bio-active agents can be coated to a portion or the entirety of the filter for controlled release of the agents once the filter is implanted. The bio-active agents can include, but are not limited to, vasodilator, anti-coagulants, such as, for example, warfarin and heparin. Other bio-active agents can include, but are not limited to, agents such as, for example, anti-proliferative/antimitotic agents including natural products such as vinca alkaloids (i.e. vinblastine, vincristine, and vinorelbine), paclitaxel, epidipodophyllotoxins (i.e. etoposide, teniposide), antibiotics (dactinomycin (actinomycin D) daunorubicin, doxorubicin and idarubicin), anthracyclines, mitoxantrone, bleomycins, plicamycin (mithramycin) and mitomycin, enzymes (L-asparaginase which systemically metabolizes L-asparagine and deprives cells which do not have the capacity to synthesize their own asparagine); antiplatelet agents such as G(GP) II_b/III_a inhibitors and vitronectin receptor antagonists; anti-proliferative/antimitotic alkylating agents such as nitrogen mustards (mechlorethamine,

cyclophosphamide and analogs, melphalan, chlorambucil), ethylenimines and methylmelamines (hexamethylmelamine and thiotepa), alkyl sulfonates-busulfan, nirtosoureas (carmustine (BCNU) and analogs, streptozocin), trazenes - dacarbazine (DTIC); anti-proliferative/antimitotic antimetabolites such as folic acid analogs (methotrexate), pyrimidine analogs (fluorouracil, floxuridine, and cytarabine), purine analogs and related inhibitors (mercaptopurine, thioguanine, pentostatin and 2-chlorodeoxyadenosine {cladribine}); platinum coordination complexes (cisplatin, carboplatin), procarbazine, hydroxyurea, mitotane, aminogluthethimide; hormones (i.e. estrogen); anti-coagulants (heparin, synthetic heparin salts and other inhibitors of thrombin); fibrinolytic agents (such as tissue plasminogen activator, streptokinase and urokinase), aspirin, dipyridamole, ticlopidine, clopidogrel, abciximab; antimigratory; antisecretory (breveldin); anti-inflammatory: such as adrenocortical steroids (cortisol, cortisone, fludrocortisone, prednisone, prednisolone, 6 α -methylprednisolone, triamcinolone, betamethasone, and dexamethasone), non-steroidal agents (salicylic acid derivatives i.e. aspirin; para-aminophenol derivatives i.e. acetaminophen; indole and indene acetic acids (indomethacin, sulindac, and etodolac), heteroaryl acetic acids (tolmetin, diclofenac, and ketorolac), arylpropionic acids (ibuprofen and derivatives), anthranilic acids (mefenamic acid, and meclofenamic acid), enolic acids (piroxicam, tenoxicam, phenylbutazone, and oxyphenthatrazone), nabumetone, gold compounds (auranofin, aurothioglucose, gold sodium thiomalate); immunosuppressives: (cyclosporine, tacrolimus (FK-506), sirolimus (rapamycin), azathioprine, mycophenolate mofetil); angiogenic agents: vascular endothelial growth factor (VEGF), fibroblast growth factor (FGF); angiotensin receptor blockers; nitric oxide donors; anti-sense oligonucleotides and combinations thereof; cell cycle inhibitors, mTOR inhibitors, and growth factor receptor signal transduction kinase inhibitors; retinoids; cyclin/CDK inhibitors; HMG co-enzyme reductase inhibitors (statins); and protease inhibitors.

[0028] Referring now to FIG. 1, a filter 10 is shown, formed from a tube 12. The tube 12 can be of any of the materials discussed above, but in a preferred embodiment, the tube 12 is made of Nitinol. The tube 12 has an inner diameter D_1 , a wall thickness T_1 and a length L_1 . In a preferred embodiment, the inner diameter D_1 is in the range of approximately less than 5 millimeters to approximately 20 millimeters, the wall thickness T_1 is in the range of approximately 100 microns to approximately 0.5 millimeters, and the length L_1 is in the range of approximately 30 millimeters to approximately 60 millimeters. The tube 12 is cut by a suitable technique, such as, for example, using chemical etching, photo etching, electrodischarge machining, or via a laser, along predetermined lines or patterns to form

features of the filter, such as appendages, retrieval members, etc. In FIG. 1, the predetermined lines or patterns outline legs 16 and an aperture 14 that forms a retrieval member. The legs 16 can be of potentially greater variation in size and shape, which is believed to be a benefit of forming a filter from a tube, due to the fact that problems inherent with the manufacture of different sizes of appendages and subsequent attachment to a hub or body are avoided. For example, in one embodiment, the appendages can have a greater thickness than width. Also, forming a filter from a tube is believed to facilitate manufacture of the filter because, for example, fewer steps may be necessary.

[0029] Once the pre-programmed cuts have been made in the tube 12, portions are removed so that the predetermined filter configuration remains, including legs 16 and body 18, as shown. Following removal of the portions of the tube, one or more secondary procedures may be implemented. One potential secondary procedure involves weakening a section of one or more of the appendages of a filter. For example, in the embodiment shown in FIG. 1, the legs 16 are formed with a pointed tip section at the distal end thereof. Thus, in one embodiment, a weakening procedure is performed in which a section proximal the tip section is thinned, removed, grooved, heated, etc. in order to lower material strength of the section such that bending the tip section is facilitated (see, e.g., FIGS. 3A-3C). The bent tip section can form a hook for engagement of a blood vessel wall, such as shown in FIG. 2. Weakening procedures can also be performed on areas of the filter other than the tip section of an appendage. One suitable technique may include the provision of sacrificial portions of the filter that can be removed prior to surface finishing the filter.

[0030] Another potential secondary procedure involves treating, such as heat setting, certain features of the filter to form the features into a desired configuration. For instance, in the embodiment shown in FIG. 2, the legs 16 are treated to extend radially outward from the body 18 along a longitudinal axis l_2 . Other potential secondary procedures include, for example, heat setting the filter in a collapsed or expanded configuration, heat treating sections of the filter, performing surface treatments on sections of the filter, performing chemical treatments on sections of the filter, and coating one or more surfaces of the filter with one or more bio-active agents. In one preferred embodiment, a bio-active agent is disposed on an inner surface of the filter. The bio-active agent may be an anti-coagulant or anti-proliferative agent. The anti-coagulant agent may be released into the blood stream via various mechanisms, as known to one skilled in the art, upon implantation and deployment of the filter in a blood vessel. Examples of suitable anti-coagulant agents are heparin, warafin

and their analogs. Examples of suitable anti-proliferative agents are rapamycin and its analogs.

[0031] As seen in FIG. 2, filter 10 has a proximal end defined by the tube 12 including opening 17, which in this embodiment has approximately the same inner diameter as the tube 12. The proximal end opening 17 permits passage of blood and relatively smaller emboli through the body 18 of the filter 10, but captures relatively larger emboli that may be considered by a clinician to be a dangerous migrating blood clot. By doing so, the filter 10 acts to reduce the size of the dangerous migrating blood clot through clot degradation, which can occur, for example, due to the erosive effect of the flow of blood thereover and/or the reductive effect produced by a bio-active agent coating on a surface of the filter. Thus, a significant advantage over filters with a central hub is realized as a central opening is provided to improve flow characteristics of the blood over and through the filter. Moreover, by forming the filter from a tube, improved performance characteristics may be realized, such as improved stress distribution, a smaller collapsed configuration for delivery (decreased profile), increased radial strength, increased migration resistance, and so on. It should also be noted that the appendages of a filter formed from a tube will have generally rectangular cross-sections as opposed to the circular cross-sections of appendages formed by wires or the like. However, appendages of generally circular cross-section can be formed via a surface shaping process such as, for example, grinding, polishing or electropolishing.

[0032] The filter 10 is illustrated in an expanded configuration, defining an expanded perimeter. For delivery of the filter 10 to a blood vessel, the filter 10 is compressed to a collapsed configuration, defining a collapsed perimeter smaller than the expanded perimeter. The filter 10 can be self-expanding due an intrinsic characteristic, in which case deployment may involve simply removal of a constraining force or exposing the filter to an elevated temperature (e.g., for a filter employing a temperature sensitive material), or alternatively can require a separate expansion agent (e.g., balloon) for expansion. It should be appreciated that while the filter 10 may be of the self-expanding variety, a separate expansion agent may also be utilized for deployment within a blood vessel.

[0033] FIGS. 3A-3C illustrate examples of possible tip sections for legs 16. FIG. 3A shows leg 16 with a shaft section 20 and a tip section 22 that tapers to a point. The leg 16 also includes a slit 24 cut through the leg 16 to facilitate bending the tip section distal the slit 24, as discussed above, in order to form an anchoring member or hook. FIG. 3B shows leg 16 with a tip section 23 that includes an aperture 26 which may provide certain advantages, including facilitation of bending with respect to the shaft section 20, also to provide an

anchoring member or hook. FIG. 3C shows a different embodiment, in which the tip section 25 includes a reduced width section 28 that tapers to a point, the reduced width section 28 having a proximal end attached to a distal end of the shaft section 20 such that a shoulder 27 is formed. Although the shoulder 27 is shown forming a 90 degree angle with respect to an edge of the shaft section 20, other embodiments of the shoulder 27 form an angle that is other than 90 degrees, such as, for example, an angled shoulder that connects an edge of the shaft section 20 to the reduced width section 28, an angled shoulder that connects the edges of the shaft section 20 to an intermediary shoulder, etc. Also, although the shoulders 27 on each side of the reduced width section 28 are shown to be generally similar, other embodiments may include dissimilar shoulders 27. In some embodiments, the reduced width section 28 may be angled with respect to the shaft section 20 to provide an anchoring member or hook for the filter. The weakening processes described in connection with FIGS. 3A-3C are believed to facilitate formation of hooks at the distal end of the legs 16, which are configured for engaging the wall of the blood vessel into which the filter 10 can be deployed. Removal from an IVC wall of a filter including hooks formed by one or more weakening procedure is believed to be facilitated and the IVC wall less prone to tearing.

[0034] Alternatively, hooks may be separately formed and attached to the end of legs 16 in a secondary procedure by any attachment method known to one skilled in the art (e.g., welding, adhesive bonding, solvent bonding, etc.). In one embodiment, the hook contains a linear portion connected to an arcuate portion that terminates in a point, as shown and described in U.S. Patent No. 6,258,026. In one embodiment, the arcuate member has a cross-sectional area smaller than the cross-sectional area of the linear portion, as shown and described in U.S. Patent No. 6,258,026. Details of potential hooks for attachment to legs 16 are shown and described in U.S. Patent Application No. 11/429,975, filed May 9, 2006, claiming priority to U.S. Provisional Patent Application No. 60/680,601, filed May 12, 2005, each of which is incorporated by reference in its entirety into this application.

[0035] Referring to FIG. 4, another embodiment of a filter formed from a tube is illustrated. Filter 30 includes appendages (i.e., legs 32 and arms 34) extending from a body 36, having an opening 38 at a proximal end thereof. The legs 32 include a shaft section 40 and a tip section 42, which may be configured according to the embodiments discussed herein (for example, the embodiments illustrated in FIGS. 3A-3C). The legs 32 and arms 34 can be of varying shapes and sizes or of substantially the same shape and size. As shown in FIG. 4, the legs 32 and arms 34 are processed in a secondary procedure to extend the appendages radially outward from the body along a longitudinal axis l_4 . This is the expanded

configuration of filter 30, which defines an expanded perimeter thereof. For delivery to a blood vessel, the filter 30 is compressed to a collapsed configuration defining a collapsed perimeter smaller than the expanded perimeter.

[0036] The arms 34 in this embodiment are shorter in length than the legs 32 (but do not have to be) and extend first outwardly with respect to a longitudinal axis l_4 and then distally with respect to the proximal opening 38. The arms 34 may provide a centering function to the filter 30 and, although shown in this embodiment without hooks or vessel-engaging members on their distal ends, may include hooks in other embodiments. The legs 32 of the filter 30 extend angularly or arcuately with respect to the longitudinal axis l_4 and include a junction near a distal end thereof at which point the legs 32 diverge at a greater angle from the longitudinal axis l_4 , terminating in a pointed tip section 42 that may be formed into a hook. In other embodiments, less than all the legs 32 may terminate in a pointed tip section. The lengths of the legs 32 and arms 34 may be approximately the same as one another or may have different lengths, although generally the arms 34 will have a shorter length than the legs 32. The number of legs 32 and arms 34 can be wide-ranging (e.g., 2, 3, 4, 6, 12, etc.), but in a preferred embodiment, the filter 30 contains six legs 32 and six arms 34. As mentioned, one or more of the legs 32 and one or more of the arms 34 may include a hook at a distal end thereof. A hook may also be positioned along the length of one or more of the legs 32, and/or one or more of the arms 34 to provide an engaging member for engaging the wall of a blood vessel. These hooks along the length of the legs 32 and/or arms 34 may either be included in the original pattern for the filter 30 (formed from a tube and integral with the appendages) or may be attached in a secondary procedure.

[0037] Referring to FIG. 5, another embodiment of a filter formed from a tube is illustrated. In the embodiment shown in FIG. 5, rather than a proximal opening defined by the tube, filter 50 includes a retrieval member 56 that can be either formed from the tube or attached in a secondary procedure by methods known to one skilled in the art. Filter 50 also includes a first level of filtration formed by legs 52 and a second level of filtration formed by arms 54. The first and second levels of filtration are formed by removing portions of a tube, such as portions whose excision results in openings 53. The legs 52 and arms 54 forming the first and second levels of filtration, respectively, are shown with hooks 58 that can be formed through secondary processing, either through a weakening process coupled with a bending process or by separate attachment, as discussed above. The retrieval member 56 has a hook-like configuration in this embodiment, but could alternatively be embodied by an aperture in a side of a proximal section of the filter 50, as discussed in connection with FIGS. 1-2. To

recover the filter 50, a recovery device engages the retrieval member 56 and pulls the filter 50 into a recovery catheter, whereby the recovery catheter forces the appendages to compress to a filter collapsed configuration. In certain embodiments, this retraction of the filter 50 forces the hooks 58 to distort toward a straightened configuration, allowing for separation of the hooks 58 from the blood vessel wall.

[0038] FIGS. 6-7 illustrate an embodiment of a filter formed from two tubes. In this embodiment, a first filter member 60 is formed from a first tube, as shown in FIG. 6, the first filter member 60 including appendages 62 terminating in pointed tip sections 64 and a proximal end 66 defined by the tube from which it is formed, having a proximal opening 68, as shown in FIG. 6A. The pointed tip sections 64 can be formed into hooks as described herein in a secondary process. In other embodiments, one or more appendages may include non-pointed tip sections and/or tip sections that are initially formed into a desired configuration. Referring to FIG. 7, a filter 80 includes the first filter member 60 and a second filter member 70. The second filter member 70 includes appendages 72 with tip sections 74, shown here in a pointed configuration. However, in other embodiments, one or more of the appendages of the second filter member 70 are blunt or non-pointed in configuration. The second filter member 70 also includes a proximal end 76 that is defined by the tube from which it is formed, having a proximal opening 78, as shown in FIG. 7A. In one embodiment, the combined thickness of the first and second tubes is in the range of approximately 0.1 millimeters to approximately 2 millimeters.

[0039] The proximal end 76 of the second filter member 70 is nested within the proximal end 66 of the first filter member 60 and attached thereto by methods known to one skilled in the art (e.g., adhesive bonding, solvent bonding, mechanical connection, welding, brazing, crimping, etc.). The outer diameter of the second filter member proximal end 76 is less than the inner diameter of the first filter member proximal end 66 to permit the nesting; however, the outer diameter of the proximal end 76 may be only slightly less than the inner diameter of the proximal end 66 in order to provide a tight fit between the first and second filter members. In one embodiment the inner diameter of the proximal end 76 is approximately 0.5 millimeters, the inner diameter of the proximal end 66 is approximately 1.25 millimeters and the outer diameter of the proximal end 66 is approximately 2 millimeters. The proximal end 82 of the filter 80 (including proximal end 76 nested within proximal end 66 in this embodiment) may include an aperture that forms a retrieval member, such as aperture 14 in FIG. 1, or may include a different type of retrieval member positioned proximal of the appendages 62, 72.

[0040] In the embodiment shown in FIG. 7, the appendages 62 of the first filter member 60 are longer than the appendages 72 of the second filter member 70 such that the first filter member appendages 62 form a first level of filtration and the second filter member appendages 72 form a second level of filtration at a position along the filter 80 different from the first level of filtration. Alternatively, or in addition, to the different levels of filtration, one of the first or second filter member appendages 62, 72 may provide the filter 80 with a self-centering capability. In other embodiments, the appendages 62, 72 may be similar in length or the appendages 72 may be longer than the appendages 62. The appendages 62, 72 are formed by removing portions of a first and second tube and can be further formed into hooks through secondary processing, such as that described above. The filter 80, due to the nested configuration, includes a greater number of appendages or struts than is possible in a single filter member formed from a tube. This permits additional levels of filtering and/or centering as discussed, and provides a smaller filter diameter than a filter with a similar number of appendages, as an increase in the diameter of the tube is necessary to increase the number of appendages. As is appreciated by one skilled in the art, a smaller profile facilitates delivery of the filter to a blood vessel. Although FIG. 7 illustrates a preferred embodiment of two nested filter members, in other embodiments three or more filter members could be nested to form a filter.

[0041] Each of the filter embodiments discussed herein can also include one or more filaments attached thereto. In one embodiment, the filaments are made of suture material, although in other embodiments, the filaments are made of a bio-resorbable material or any of the materials discussed above with respect to possible materials for the filter. The filaments could be attached to the body, one or more of the appendages of the filter, or a combination thereof. The filaments may be attached to the filter by wrapping the filament one or more times around an attachment location on the filter, tying the filament to an attachment location on the filter, heating the filament adjacent to an attachment location on the filter to create a bond therebetween, applying an adhesive to the filament and/or an attachment location on the filter, applying a solvent to the filament and/or an attachment location on the filter, etc. Of course, other possibilities for attaching the filament to an attachment location on a filter known to one skilled in the art are also within the scope of this invention.

[0042] This invention has been described and specific examples of the invention have been portrayed. While the invention has been described in terms of particular variations and illustrative figures, those of ordinary skill in the art will recognize that the invention is not limited to the variations or figures described. In addition, where methods and steps described

above indicate certain events occurring in certain order, those of ordinary skill in the art will recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Therefore, to the extent there are variations of the invention, which are within the spirit of the disclosure or equivalent to the inventions found in the claims, it is the intent that this patent will cover those variations as well. Finally, all publications and patent applications cited in this specification are herein incorporated by reference in their entirety as if each individual publication or patent application were specifically and individually put forth herein.

CLAIMS

What is claimed is:

1. A filter formed from a shape memory tube, comprising:
a plurality of legs having a distal end terminating in a pointed tip;
a first section in the legs positioned adjacent the tip having a material strength less than a material strength of a second section proximal the first section; and
a bent section distal the first section.
2. The filter according to claim 1, wherein the first section comprises an aperture formed in the distal end.
3. The filter according to claim 1, wherein the first section comprises a reduced width section.
4. The filter according to claim 1, further comprising a plurality of arms having a length different than a length of the legs.
5. The filter according to claim 4, wherein one or more of the arms has a distal end terminating in a pointed tip.
6. The filter according to claim 1, further comprising a retrieval member positioned at a proximal end of the filter.
7. The filter according to claim 6, wherein the retrieval member comprises an aperture formed in a side of the shape memory tube.
8. The filter according to claim 6, wherein the retrieval member comprises a hook.
9. The filter according to claim 1, wherein the plurality of legs extend radially outward from a body along a longitudinal axis.
10. The filter according to claim 9, further comprising a plurality of arms extending radially outward from the body along the longitudinal axis.
11. The filter according to claim 10, wherein one or more of the arms have a blunt distal end.

12. The filter according to claim 1, wherein the bent section comprises a generally curved profile having a cross-sectional area smaller than a cross-sectional area of the second section.
13. The filter according to claim 1, comprising a proximal section defined by the shape memory tube, having an opening with a cross-sectional area less than a cross-sectional area of a dangerous migrating blood clot.
14. The filter according to claim 1, comprising a bioactive agent disposed on an inner surface of the shape memory tube.
15. The filter according to claim 1, wherein the shape memory tube comprises Nitinol.
16. A method of making an implantable medical device, comprising:
providing a generally tubular structure having an inner diameter and a wall thickness;
removing portions of the tubular structure along predetermined lines to form a plurality of appendages;
weakening at least one section in one or more of the appendages near a distal end thereof; and
bending the distal end of at least the appendages containing the section.
17. The method according to claim 16, wherein the tubular structure comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, super elastic metal, metal alloys, linear elastic shape memory metal, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.
18. The method according to claim 17, wherein the tubular structure comprises Nitinol.
19. The method according to claim 16, wherein the cutting comprises forming a pointed tip section at the distal end of one or more of the appendages.
20. The method according to claim 19, wherein the bending comprises forming the tip section into a hook.
21. The method according to claim 20, wherein the hook comprises a generally curved profile having a cross-sectional area smaller than a cross-sectional area of a shaft section.

22. The method according to claim 19, wherein the tip section includes a proximal end and a distal end, the proximal end being connected to a shaft section and having a width less than a width of the shaft section.
23. The method according to claim 19, further comprising forming an aperture in the tip section.
24. The method according to claim 16, wherein the cutting comprises forming an aperture in a side of the tubular structure adjacent a proximal end thereof.
25. The method according to claim 16, wherein the appendages comprise a plurality of legs formed to extend radially outward from a body along a longitudinal axis.
26. The method according to claim 25, wherein the appendages further comprise a plurality of arms formed to extend radially outward from the body along the longitudinal axis.
27. The method according to claim 26, wherein one or more of the legs are formed with a pointed tip at the distal end, and wherein one or more of the arms are formed with a blunt distal end.
28. The method according to claim 16, wherein the inner diameter is in the range of approximately 3 millimeters to approximately 20 millimeters.
29. The method according to claim 16, wherein the wall thickness is in the range of approximately 100 microns to approximately 0.5 millimeters.
30. The method according to claim 16, wherein the plurality of appendages comprise a first level of filtration spaced apart from a second level of filtration.
31. The method according to claim 30, wherein one or more of the appendages forming the first level of filtration are formed with a pointed tip section.
32. The method according to claim 31, wherein one or more of the appendages forming the second level of filtration are formed with a pointed tip section.

33. The method according to claim 30, wherein the appendages forming the first level of filtration have a first length, and wherein the appendages forming the second level of filtration have a second length different from the first length.
34. The method according to claim 30, further comprising forming a retrieval member from a portion of the tubular structure proximal the appendages.
35. A method of filtering fluid, comprising:
flowing fluid, including particles of various cross-sectional areas, through a generally tubular member that simulates a blood vessel;
positioning a filter in the tubular member about a central axis defined by the tubular member; and
permitting particles having cross-sectional areas less than the cross-sectional area of a dangerous migrating blood clot to flow through the filter coincident with the central axis.
36. The method according to claim 35, further comprising releasing one or more bio-active agents from a surface of the filter.
37. The method according to claim 35, further comprising releasing one or more anti-coagulants from a surface of the filter.
38. A filter, comprising a body and a plurality of legs formed from a generally tubular structure, a proximal end of the body being defined by the generally tubular structure, having an opening with a cross-sectional area less than a cross-sectional area of a dangerous migrating blood clot, the legs extending radially outward from the body along a longitudinal axis, one or more of the legs having a distal end terminating in a pointed tip and being formed into a hook.
39. The filter according to claim 38, wherein the distal end of one or more of the legs comprises a weakened section.
40. The filter according to claim 39, wherein the weakened section comprises an aperture in the distal end.
41. The filter according to claim 38, further comprising a plurality of arms, wherein one or more of the arms have a blunt distal end.

42. The filter according to claim 38, wherein the proximal end of the body has an inner diameter in the range of approximately 2 millimeters to approximately 40 millimeters and a wall thickness in the range of approximately 100 microns to approximately 0.5 millimeters.
43. The filter according to claim 38, further comprising an aperture in a side of a proximal section of the body.
44. The filter according to claim 38, further comprising a plurality of filaments attached to one of the body and the legs.
45. The filter according to claim 44, wherein the filaments comprise a resorbable material.
46. The filter according to claim 44, wherein the filaments comprise suture material.
47. A filter formed from shape memory tubes, comprising:
a first filter member including a first proximal end defined by a first shape memory tube with an inner diameter, and a plurality of first appendages extending from the first proximal end, a distal end of at least one of the first appendages terminating in a pointed tip; and
a second filter member including a second proximal end defined by a second shape memory tube with an outer diameter less than the inner diameter of the first shape memory tube, and a plurality of second appendages extending from the second proximal end, the second proximal end nested within the first proximal end and connected thereto.
48. The filter according to claim 47, wherein at least one of the second appendages includes a distal end terminating in a pointed tip.
49. The filter according to claim 47, wherein each of the first appendages includes a distal end terminating in a pointed tip.
50. The filter according to claim 47, wherein the first appendages have a length different than the length of the second appendages.
51. The filter according to claim 47, wherein the length of the first appendages is longer than the length of the second appendages.

52. The filter according to claim 51, wherein each of the plurality of first appendages comprises a first section in the appendages positioned adjacent the tip having a material strength less than a material strength of a second section proximal the first section.
53. The filter according to claim 52, further comprising a bent section distal the first section.
54. The filter according to claim 53, wherein the bent section comprises a generally curved profile having a cross-sectional area smaller than a cross-sectional area of the second section.
55. The filter according to claim 52, wherein the first section comprises an aperture formed in the distal end.
56. The filter according to claim 52, wherein the first section comprises a reduced width section.
57. The filter according to claim 51, wherein each of the plurality of first appendages comprises a first section in the appendages positioned adjacent the tip having a stiffness less than a stiffness of a second section proximal the first section.
58. The filter according to claim 47, wherein the first proximal end comprises a retrieval member.
59. The filter according to claim 58, wherein the retrieval member comprises an aperture formed in a side of the first and second proximal ends.
60. The filter according to claim 58, wherein the retrieval member comprises a hook.
61. The filter according to claim 47, wherein the first and second appendages comprise a plurality of first and second legs extending radially outward from the first and second proximal ends, respectively, along a longitudinal axis.
62. The filter according to claim 61, wherein one or more of the second appendages includes a blunt distal end.

63. The filter according to claim 47, wherein the second proximal end has a proximal opening defined by an inner diameter thereof with a cross-sectional area less than a cross-sectional area of a dangerous migrating blood clot.
64. The filter according to claim 47, further comprising a bioactive agent disposed on an inner surface of at least one of the first and second shape memory tubes.
65. The filter according to claim 47, wherein the first and second shape memory tubes comprise a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, super elastic metal, metal alloys, linear elastic shape memory metal, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.
66. The filter according to claim 65, wherein the first and second shape memory tubes comprise Nitinol.
67. The filter according to claim 47, wherein the inner diameter of the second shape memory tube is in the range of approximately 0.5 millimeters to approximately 3 millimeters.
68. The filter according to claim 47, wherein the inner diameter of the second shape memory tube is in the range of approximately 3 millimeters to approximately 20 millimeters.
69. The filter according to claim 47, wherein a combined wall thickness of the first and second shape memory tubes is in the range of approximately 0.1 millimeters to approximately 2 millimeters.
70. The filter according to claim 47, wherein the first appendages comprise a first level of filtration and the second appendages comprise a second level of filtration at a position along the filter different than the first level of filtration.
71. A method of making an implantable medical device, comprising:
providing a first generally tubular structure having an inner diameter and a second generally tubular structure having an outer diameter less than the inner diameter of the first tubular structure;
removing portions of the first and second tubular structures along predetermined lines to form a plurality of first and second appendages; and

nesting a proximal end of the second tubular structure within a proximal end of the first tubular structure.

72. The method according to claim 71, further comprising attaching the second tubular structure to the first tubular structure.

73. The method according to claim 72, wherein the attaching is selected from the group consisting of adhesive bonding, solvent bonding, mechanical connection, welding, brazing, crimping and combinations thereof.

74. The method according to claim 71, wherein the first and second tubular structures comprise a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, super elastic metal, metal alloys, linear elastic shape memory metal, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

75. The method according to claim 74, wherein the first and second tubular structures comprise Nitinol.

76. The method according to claim 71, further comprising weakening at least one section in one or more of the first appendages near a distal end thereof and bending the distal end of at least the appendages containing the section.

77. The method according to claim 76, wherein the bending comprises forming the tip section into a hook.

78. The method according to claim 77, wherein the hook comprises a generally curved profile having a cross-sectional area smaller than a cross-sectional area of a shaft section.

79. The method according to claim 71, wherein the removing comprises forming a pointed tip section at the distal end of one or more of the first appendages.

80. The method according to claim 79, wherein the tip section includes a proximal end and a distal end, the proximal end being connected to a shaft section and having a width less than a width of the shaft section.

81. The method according to claim 79, further comprising forming an aperture in the tip section.

82. The method according to claim 71, further comprising forming a retrieval member in at least one of the first and second tubular structures at a proximal end thereof.
83. The method according to claim 71, further comprising attaching a retrieval member proximal the first and second appendages.
84. The method according to claim 71, wherein the first appendages comprise a plurality of first legs formed to extend radially outward from the proximal end of the first tubular structure along a longitudinal axis.
85. The method according to claim 84, wherein the second appendages comprise a plurality of second legs formed to extend radially outward from the proximal end of the second tubular structure along a longitudinal axis, the second legs having a shorter length than the first legs.
86. The method according to claim 85, wherein one or more of the first legs are formed with a pointed tip at the distal end, and wherein one or more of the second legs are formed with a blunt distal end.

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FIG. 1

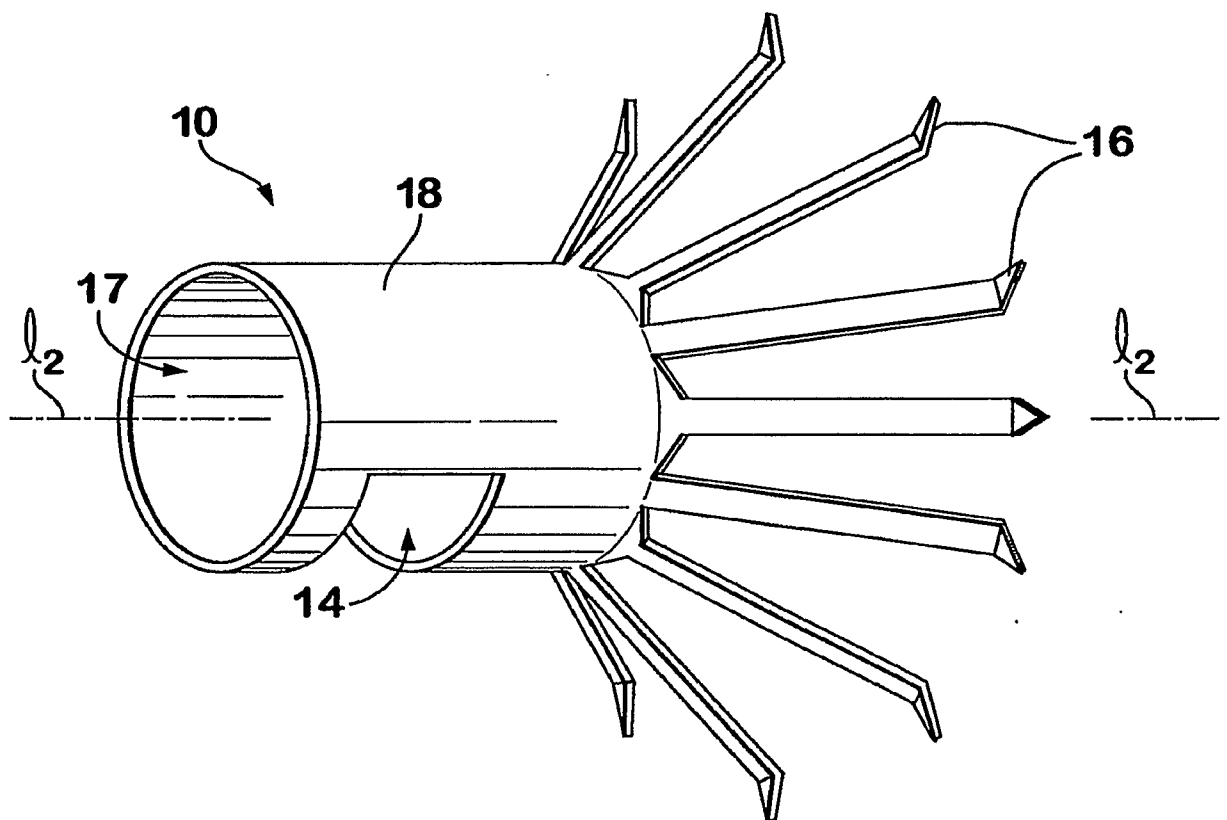
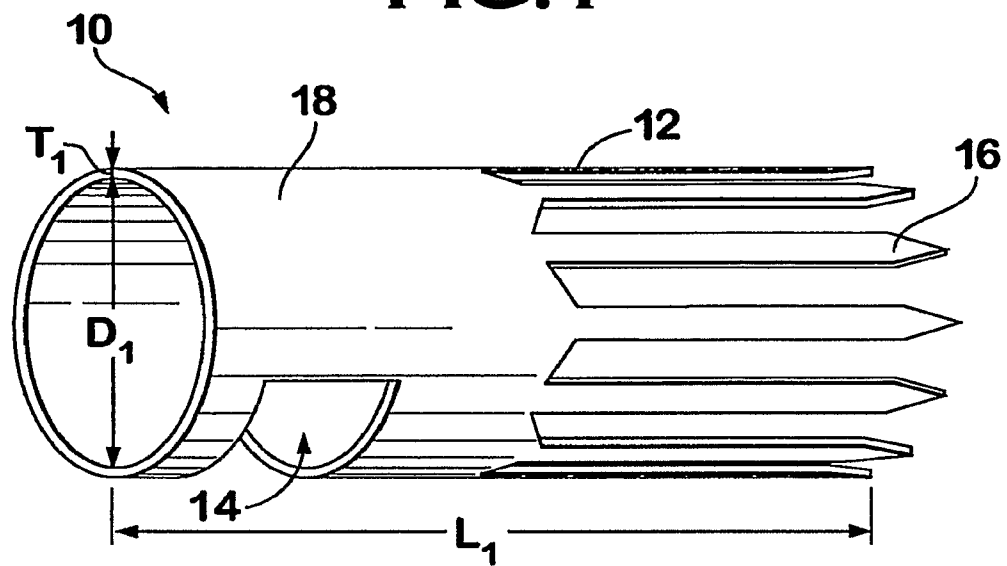


FIG. 2

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FIG.3A

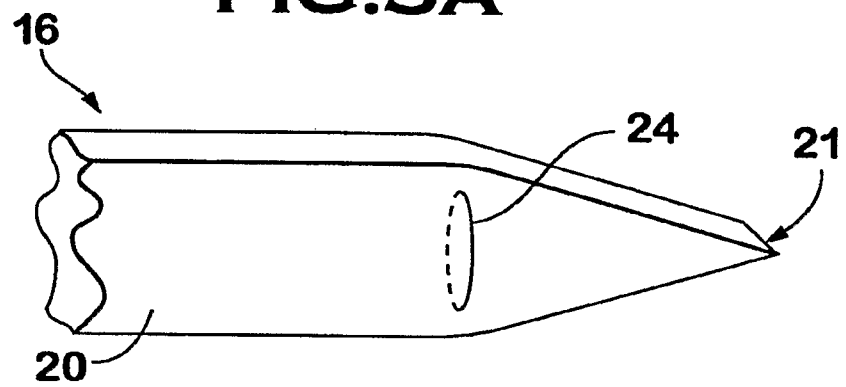


FIG.3B

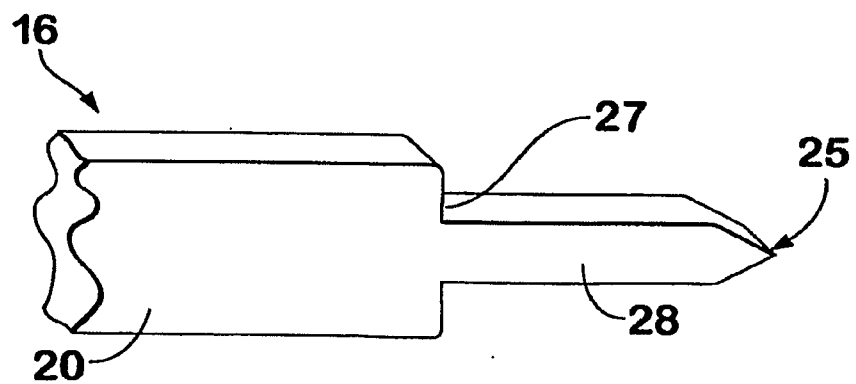
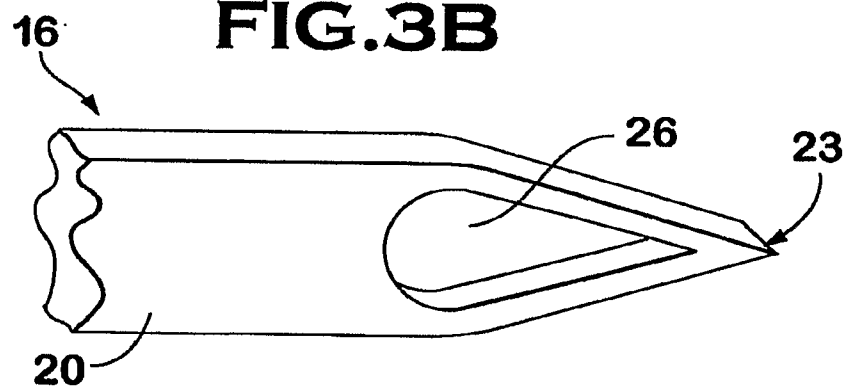


FIG.3C

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FIG. 4

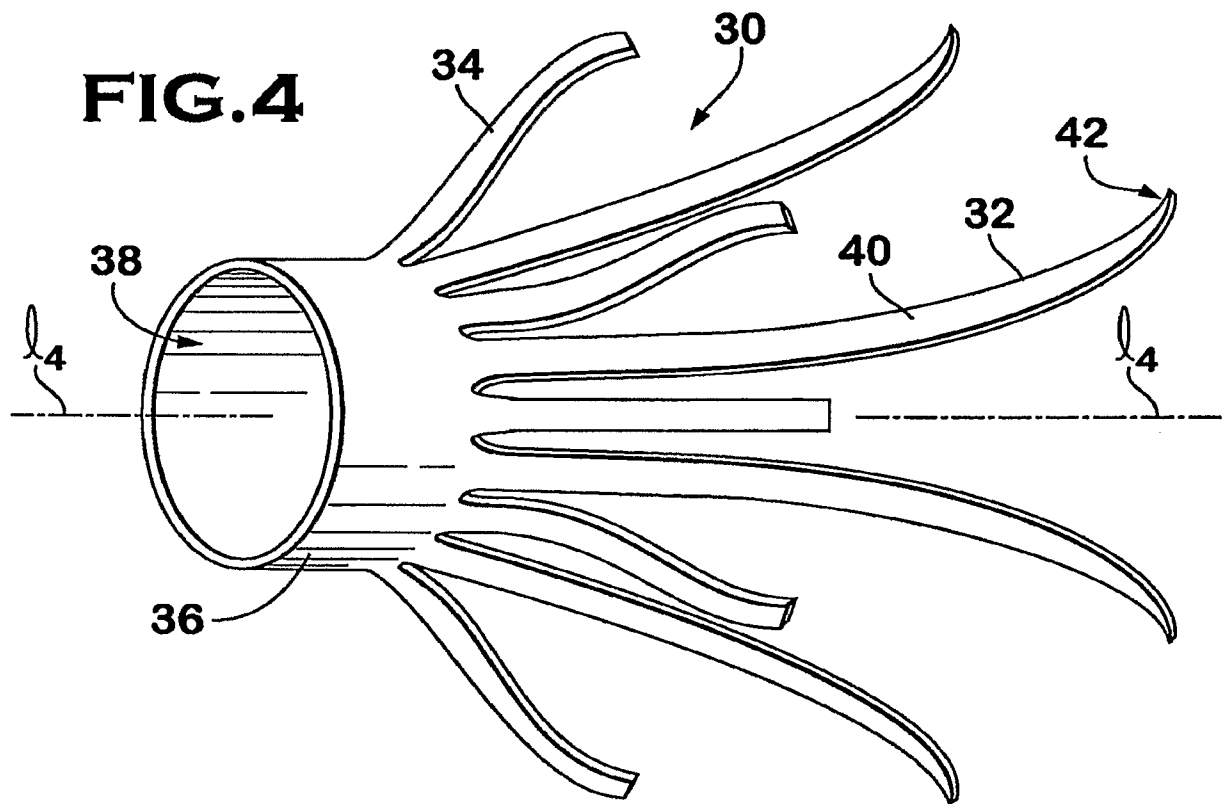
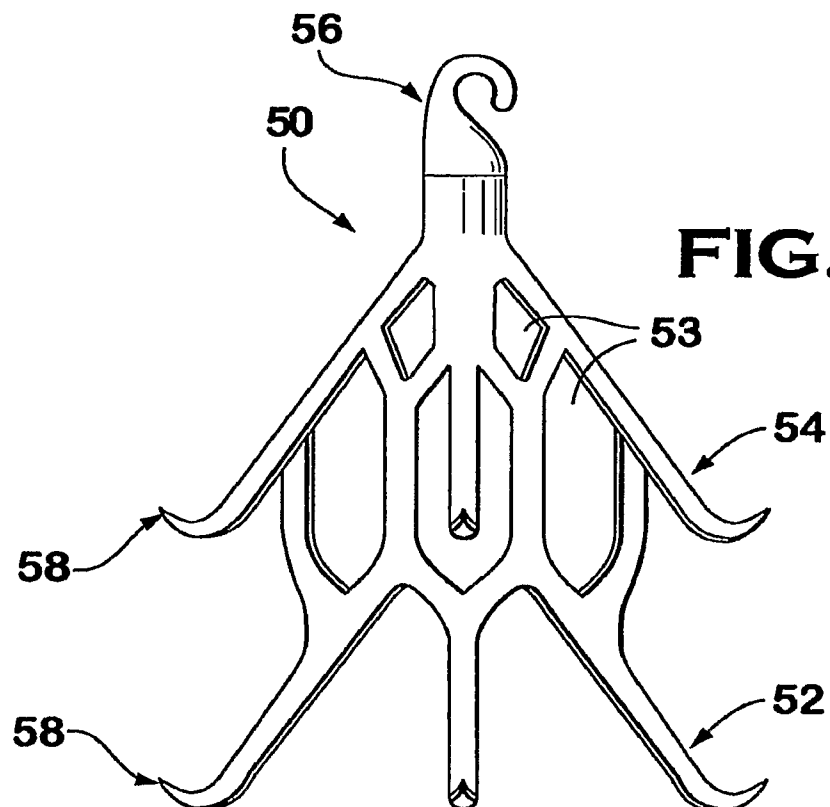


FIG. 5



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