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(71) **Applicant** *(for all designated States except US):* **C. R. BARD, INC.** [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).

(71) **Applicants and**
(72) Inventors: CHANDUSZKO, Andrzej, J. [US/US]; 311 N. Carriage Lane, Chandler, AZ 85224 (US). **SMALE, Joshua,** A. [US/US]; 1022 S. Una Avenue, Tempe, AZ 85281 (US).

(74) Agents: WIGHT, Todd, W. et al; Morrison & Foerster LLP, 19900 MacArthur Boulevard, Irvine, CA 92612-2445 (US).

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

(57) Abstract: A filter formed from a sheet is described herein. In one aspect of the invention, a filter is formed from a sheet of material and, following removal of portions of the sheet, the filter is folded into a shape for insertion into a blood vessel. In another aspect of the invention, features for a filter are formed from a sheet of material and incorporated into the filter.

VENA CAVA FILTER FORMED FROM A SHEET

PRIORITY

[0001] This application claims the benefit of priority to U.S. Provisional Patent Application No. 60/796,650, filed May 2, 2006, which is incorporated by reference into this application as if fully set forth herein.

BACKGROUND OF THE INVENTION

[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 blood vessel filters: U.S. Patent No. 3,540,431; U.S. Patent No. 4,793,348; U.S. Patent No. 6,506,205; U.S. Patent No. 6,551,342; U.S. Patent No. 6,712,834; U.S. Patent No. 6,783,538; U.S. Patent No. 6,881,218; U.S. Patent Application Publication No. 2004/0073252; U.S. Patent Application Publication No. 2004/0087999; and U.S. Patent Application Publication No. 2005/0080449, 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 sheet of material, including forming an IVC filter from a sheet and incorporating filter features formed from a sheet into an IVC filter. Thus, described herein are embodiments of an IVC filter formed from a sheet.

BRIEF SUMMARY OF THE INVENTION

[0006] Accordingly, implantable medical devices, including IVC filters that are formed from a sheet are described herein. In one embodiment, a filter for placement in a blood vessel includes a body defining a longitudinal axis, the body having a generally planar surface extending generally parallel to the longitudinal axis, and a plurality of appendages extending away from the longitudinal axis, at least one of the plurality of appendages having a generally planar surface.

[0007] In another embodiment, a filter includes a longitudinal body including a proximal section having a first cross-sectional area, a distal section having a second cross-sectional area, and a joining section positioned between the proximal and distal sections having a third cross-sectional area less than both the first and second cross-sectional areas, and a plurality of appendages haying a proximal end joined to a hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the hub including an opening configured for movement along a length of the joining section.

[0008] In yet another embodiment, a filter includes a longitudinal body having a first cross-sectional area, a first stop member spaced apart from a second stop member, the first and second stop members having a second cross-sectional area larger than the first cross-sectional area, and a plurality of appendages having a proximal end joined to a hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the hub including an opening configured for movement along a length of the body between the stop members.

[0009] In still another embodiment, a filter includes a longitudinal body including a proximal section, an intermediate section, and a distal section, a first joining section positioned between the proximal section and the intermediate section and a second joining

section positioned between the intermediate section and the distal section, the first and second joining sections each having a cross-sectional area less than a cross-sectional area of the proximal section, the intermediate section and the distal section, a first set of appendages having a proximal end joined to a first hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the first hub positioned along the first joining section and including an opening configured for movement along a length of the first joining section, and a second set of appendages having a proximal end joined to a second hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the second hub positioned along the second joining section and including an opening configured for movement along a length of the second joining section.

[0010] In yet another embodiment, a filter includes a longitudinal body having a first cross-sectional area, a first stop member spaced apart from a second stop member, the first and second stop members having a second cross-sectional area larger than the first cross-sectional area, a third stop member spaced apart from a fourth stop member, the third and fourth stop members having a third cross-sectional area larger than the first cross-sectional area, a first set of appendages having a proximal end joined to a first hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the first hub including an opening configured for movement along a length of the body between the first and second stop members, and a second set of appendages having a proximal end joined to a second hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the second hub including an opening configured for movement along a length of the body between the third and fourth stop members.

[0011] In one embodiment, a method of making a filter includes removing portions of a sheet of material along a first set of predetermined lines to form a plurality of arms, a plurality of legs and a body, folding the sheet of material along a second set of predetermined lines such that the arms and legs extend radially outward from the body along a longitudinal axis, and connecting a first joining section to a second joining section.

[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. 1A is a front view of a filter pattern following removal of portions of a sheet from which the filter was formed.

[0014] FIG. 1B is a perspective view of the filter pattern of FIG. 1 assembled into a filter for insertion into a blood vessel.

[0015] FIG. 2A is a perspective view of one embodiment of a filter.

[0016] FIG. 2B is an enlarged view of the section 2B-2B of FIG. 2A.

[0017] FIG. 2Ci is a side view of the filter of FIG. 2A being delivered to a vessel, while FIG. $2C_2$ is a side view of the filter of FIG. 2A being recovered from a vessel.

[0018] FIG. 2D is an enlarged view of one embodiment of a distal end of an appendage of FIG. 2A.

[0019] FIG. 2E is an enlarged view of another embodiment of a distal end of an appendage of FIG. 2A.

[0020] FIG. 2F is an enlarged view of yet another embodiment of a distal end of an appendage of FIG. 2A.

[0021] FIG. 2G is an enlarged view of still another embodiment of a distal end of an appendage of FIG. 2A.

[0022] FIG. 3A is a full perspective view of an embodiment of a filter.

[0023] FIG. 3B is a perspective view of the filter of FIG. 3A in a delivery configuration.

[0024] FIG. 4 is a perspective view of another embodiment of a filter.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0025] 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.

[0026] 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, and which material may be resorbable *in situ.* Such material may include, 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.

[0027] 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.

[0028] As used herein, the terms "weaken" and "weakening" mean making a section or sections of the filter thinner, heat treating the section or sections, cutting grooves into the section or sections, etc. Further, as used herein, the term "lower material strength" means either a lower modulus of elasticity or a lower ability to resist bending. Also, as used herein, the term "hook" means a member configured to engage a blood vessel wall, examples of which are provided in U.S. Patent No. 6,258,026, which is incorporated by reference in its entirety into this application. Possible materials for the sheet 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, super elastic shape memory materials, shape memory metal alloys, linear elastic shape memory metal, metal alloys, shape memory polymers, polymers, bio-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.

[0029] 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) Ilb/IIIa 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 - dacarbazinine (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, aminoglutethimide; 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, 6α-methylprednisolone, triamcinolone, betamethasone, and dexamethasone), non-steroidal agents (salicylic acid derivatives i.e. aspirin; para-aminophenol derivatives i.e. acetominophen; indole and indene acetic acids (indomethacin, sulindac, and etodalac), 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 (auranofm, 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; retenoids; cyclin/CDK inhibitors; HMG co-enzyme reductase inhibitors (statins); and protease inhibitors.

[0030] Referring now to FIG. IA, a filter 110 is shown, following removal of portions of a sheet from which the filter 110 was formed but prior to the filter 110 being assembled into a device for deployment within a blood vessel. The filter 110 may be cut from a sheet of material by laser or other techniques known to one skilled in the art. The pattern for the filter 110 may be pre-programmed into a laser device or other cutting device, such that all features of the filter 110 are formed from the same sheet. Alternatively, select features of the filter (e.g., arms or other appendages) may be separately formed and attached to a filter framework formed from a sheet of material. The sheet of material utilized for forming the filter 110 may be any of the materials discussed above, but in one preferred embodiment, the material is Nitinol. The filter 110 includes arms 112 and legs 114 that are alternating from a first side 122 of the pre-assembled filter 110 to a second side 124, such that there are a total number of eleven appendages (six arms 112 and five legs 114). While it should be appreciated that any number of appendages is possible and within the scope of the invention, the preferred number of appendages is between 4 and 12.

[00311 Ir[1] the embodiment shown in FIG. IA, the method of making a filter includes removing portions of a sheet of material along a first set of predetermined lines to form a plurality of arms, a plurality of legs and a body, folding the sheet of material along a second set of predetermined lines such that the arms and legs extend radially outward from the body along a longitudinal axis, and connecting a first joining section to a second joining section. In particular, a central member or body 126 includes a leg 114 extending distally from a retrieval member 118, which is positioned at a proximal end of the filter 110. The configuration and number of the arms 112 and legs 114 extending from the central member 126 to the first side 122 are the same as the configuration and number of the arms 112 and legs 114 extending from the central member 126 to the second side 124; however, other embodiments may include non-symmetrical configurations. The central member 126 defines a longitudinal axis L of the filter 110 and has a generally planar surface 130 extending generally parallel to the longitudinal axis L. The arms 112 and legs 114 also have generally planar surfaces as filter 110 is formed from a sheet of material. In other embodiments, at least one of the appendages of the filter has a generally planar surface. The cross-section of the central member 126, the arms 112 and the legs 114 in filter 110 is generally rectangular, although in other embodiments, the cross-section may be generally square. Although each of the appendages of filter 110 is shown with similar cross-sections, in other embodiments, one

or more of the appendages and/or body may be constructed with different cross-sectional shapes. For example, by varying the width of the body, arms and/or legs, a sheet of material with uniform thickness could result in different cross-sectional shapes for the body and/or appendages. Alternatively, the widths of the body, arms and legs may be generally equivalent, such as in FIG. IA, but the sheet of material may have regions of varying thickness to produce different cross-sectional shapes for the body and/or appendages.

[0032] The legs 114 in filter 110 are configured with pointed tips 116 for formation of anchoring members, such as hooks, in a secondary procedure, while the arms 112 have blunt or rounded distal ends. In other embodiments, the arms 112 may include pointed tips. There are various possibilities for the configuration of the pointed tips 116, some of which are shown in FIGS. 2D-2G, discussed below. As indicated in FIG. IA, the filter 110 may include fold lines 128 that extend along pre-determined paths to delineate the arms 112 and legs 114. These fold lines may be etched onto the filter pattern or may otherwise be indicated. In one embodiment, a secondary procedure may be utilized to weaken the sheet of material along certain paths, such as the fold lines 128, in order to facilitate folding of the filter 110.

[0033] Once pre-programmed cuts have been made in a sheet of material, portions are removed so that a pre-determined filter configuration remains. Prior to, or following removal of, the portions of the sheet, 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 114 are formed with a pointed tip section 116 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. The bent tip section can form a hook for engagement of a blood vessel wall, such as shown in FIG. IB. Weakening procedures can also be performed on areas of the filter other than the tip section of an appendage. Another potential secondary procedure involves treating, such as heat setting, certain features of the filter to form the features into a desired configuration. 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, an anti-coagulant bio-active agent is disposed on a surface of the filter 112. 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. One technique for controlled release of bio-active agents can be achieved by dispersing the bio-active agents within a porous polymer medium for elution of the agents.

[0034] Referring to FIG. IB, the filter 110 has been assembled from a planar pattern shown in FIG. IA to a shape for implantation in a blood vessel. The filter 110 is folded along fold lines 128 and joined along select sections by methods known to one skilled in the art, including, for example, welding, adhesive bonding, solvent bonding, etc. In the embodiment of FIG. IB, the arms 112 and legs 116 are folded so that they extend radially outward from central member 126 in an expanded configuration; to aid in this formation, the arms 112 and legs 116 may be treated by one or more secondary processes, such as those discussed above. Following the preferred arrangement of the arms 112 and legs 116 with respect to central member 126, a joining section 120 is formed through welding. The joining section in the embodiment of FIG. IA includes proximal portions of opposing arms 112 adjacent the central member 128. Other joining sections may also be formed at different points along the filter 110. In one embodiment, a tube or solid tip may be utilized along with an attachment procedure, such as welding, in order to maintain the filter in its expanded configuration when subject to blood vessel pressures.

[0035] Also, as discussed above, the pointed tips 116 in FIG. IA may be formed into anchor members, such as hooks, configured for engagement with a blood vessel wall. Alternatively, legs 114 may be formed with ends configured for attachment of separately formed hooks. For example, the distal end of one or more legs may contain a notch or area formed to receive a proximal section of a separately formed hook. In such an embodiment, the hook(s) may be attached to the end of the one or more legs 114 in a secondary procedure by methods known to one skilled in the art (e.g., welding, adhesive bonding, solvent bonding, etc.). In one embodiment, the hook (whether separately formed or integral with the leg 114) 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 less 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 legs 114 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.

[0036] The filter **1**10 is illustrated in FIG. **IB** in an expanded configuration, defining an expanded perimeter. For delivery of the filter 110 to a blood vessel, the filter 110 is

compressed to a collapsed configuration, defining a collapsed perimeter smaller than the expanded perimeter. The filter 110 can be self-expanding due an intrinsic characteristic of the material of the sheet from which it is formed, 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 110 may be of the self-expanding variety, a separate expansion agent may also be utilized for deployment within a blood vessel. Retention members (e.g., hooks or barbs) may be provided on arms or legs such as the retention members shown and described in U.S. Patent Nos. 6,517,573 and 6,443,972, each of which is incorporated by reference in its entirety into this application. Arms 112 may be provided with additional bend to assist in centering the filter.

[0037] FIG. 2A illustrates filter 10, in which an appendage member 20 is formed from a sheet of material, while other portions of the filter, including body 11 are formed from a rod or structure with a lumen. Materials for the sheet, rod and structure with a lumen are described above with respect to the sheet and filter materials, but in a preferred embodiment the material for each is Nitinol. The body 11 includes a proximal section 12 and a distal section 14 joined by a joining section 16. These sections may be formed from one or more solid rods, hollow structures, or combinations thereof. In one embodiment, one or more portions of a solid rod or hollow structure may include a lumen, defined by a wall. The wall may be porous, including one or more openings, such that one or more bioactive agents disposed within the lumen may be released into the blood vessel into which the filter 10 is deployed.

[0038] The body 11 may have a circular or non-circular cross-section (e.g., square, rectangle, triangle, oval, etc.), but in a preferred embodiment the body 11 is generally tubular with a generally circular cross-section. Also, the different sections of the body may have different cross-sectional shapes and sizes. For example, the proximal section 12 may have a cross-sectional area smaller or larger than the cross-sectional area of the distal section 14, the joining section 16 could have a square cross-section while the proximal and distal sections 12, 14 have circular cross-sections, etc. However, in a preferred embodiment, the cross-sectional shapes of each of the proximal, distal and joining sections is circular; the cross-sectional areas of the proximal and distal sections are approximately equivalent; and the cross-sectional area of the joining section is less than the cross-sectional area of the proximal section and the distal section. Moreover, the proximal and distal sections may have

approximately the same length or different lengths. In one embodiment, the distal section 14 has a length greater than the length of the proximal section 12. Attached to the proximal section 12 (or integral therewith) is a retrieval member 18, shown exemplarily in a hook-like configuration. Attachment of retrieval member 18 to the proximal section 12 may be accomplished by methods known to one skilled in the art (e.g., welding, adhesive bonding, solvent bonding, etc.). In one embodiment, the proximal section 12, distal section 14, joining section 16 and retrieval member 18 are formed from a single generally tubular solid rod in the same manner as described above or alternatively, the joining section 16 is formed by removing portions of the rod and the retrieval member 18 is formed through heating and molding processes or via machining (e.g., EDM) and deburring/polishing. The retrieval member 18 can be pre-cut or attached to the filter and then bent into its final configuration.

[0039] The length of the joining section 16 is established based on the desired length for movement of the appendage member 20, which includes a set of appendages 22. In a preferred embodiment, the joining section 16 has a length between approximately 0.1 mm and approximately 40 mm, preferably between approximately 0.1 mm and approximately 3 mm. Each appendage 22 is attached at its proximal end to a hub 24, which can be configured for sliding movement along the length of the joining section 16 to relieve stress or strain on the filter. As shown in FIG. 2B, the hub 24 has an opening 26 that has a shape similar to that of the joining section 16 with a slightly larger size than the circumference of the joining section 16 to permit movement. In one embodiment, the opening 26 may be configured to have substantially the same cross-sectional area as the joining section 16 such that a friction fit between the two is established in order to prevent unimpeded movement of the hub 24 along the length of the joining section 16. In another embodiment, the opening 26 may be configured with a larger cross-sectional area than the joining section 16 to facilitate movement of the hub 24 along the length of the joining section 16. In either embodiment, the opening has a smaller cross-sectional area than both the proximal section 12 and distal section 14 such that movement outside of the length of the joining section 16 is prevented. In an embodiment where the proximal section and distal section are tubular, the opening has a diameter less than the diameter of the proximal and distal sections.

[0040] In a preferred embodiment, the appendages and hub are formed from a single sheet of material, having portions removed from a pre-determined pattern programmed into a cutting device, such as a laser device. The thickness of the sheet in a preferred embodiment is between approximately 0.1 mm and 0.4 mm. The appendages 22, thus, have opposing planar surfaces and lie in substantially the same plane in a non-stressed position. The

appendages lie in a plane approximately perpendicular and preferably in a plane generally oblique to the body 11 in a non-stressed position. Alternatively, the appendages can be heat treated and mechanically formed to form various angles. Although any number of appendages 22 is possible for the appendage member 20, in a preferred embodiment, the appendage member 20 includes between 4 and 12 appendages 22. The appendages 22 may be of varying thickness along their length, which may be produced by a sheet of material with varying thickness or through the utilization of secondary procedures. The appendages 22 may also be of varying width along their length (e.g., tapered from the proximal end to the distal end, shown in FIGS. 2D-2E). Moreover, the thickness or width of the appendages 22 may differ in a given set of appendages. For example, in one embodiment, alternating appendages in the set of appendages may have a similar thickness, which thickness is greater than adjacent appendages. In a preferred embodiment, the hub 24 can be connected to the body 16 by coupling the hub 24 onto the body 16 prior to the placement of the retrieval member 12. The coupling of the hub 24 can be achieved by a suitable coupling technique such as, for example, welding or screw threads.

[0041] The thickness and configuration of the appendages 22 in a preferred embodiment is such that the appendages are bendable in both a proximal and distal direction. More specifically, with reference to FIG. 2A, the appendages 22 can be fashioned with a flexibility in which the distal ends of the appendages 22 can bend in a direction toward and away from the retrieval member 18 such that at least the distal ends of the appendages 22 are generally parallel to the body 11. By imparting such flexibility to the appendages, recovery and delivery of the filter 10 can be accomplished using either a jugular access site or a femoral access site, as shown in FIG. 2Ci, which illustrates a filter delivery, and FIG. $2C_2$, which illustrates a filter recovery, thereby increasing the options available to a clinician. Thus, a force (e.g., catheter 100) contacting the appendages 22 directed in a distal direction from a proximal direction (i.e., from a jugular access site) will cause the appendages 22 to bend in a distal direction, while a force contacting the appendages 22 directed in a proximal direction from a distal direction (i.e., from a femoral access site) will cause the appendages 22 to bend in a proximal direction.

[0042] The distal ends of the appendages 22 can be orthogonal, as shown in FIG. 2A, or can be configured to terminate in a point. Examples of distal end sections for appendages 22 are shown in FIGS. 2D-2G. It should be appreciated that these examples are non-limiting and are non-exclusive to a particular set of appendages; that is, one set of appendages may include one or more of the distal end sections shown in FIGS. 2D-2G. Referring to FIGS.

2D-2E, the width of the appendage 22 tapers from a proximal portion of the appendage to the distal end as discussed above; however, the distal end of the appendage 22 in FIG. 2E terminates in a point 21, while the distal end of the appendage 22 in FIG. 2D is generally flat (i.e., the distal section is generally trapezoid in configured). FIG. 2F shows a distal end 23 that tapers to a point, although the sides of the majority of the length of the appendage 22 are parallel. Finally, FIG. 2G illustrates a hook 25 on the distal end of a tapered portion of the appendage 22, the hook 25 having a curved section 27 with a cross-sectional area less than a cross-sectional area of a shaft section 29. As discussed above, the hook may be formed by secondary procedures following formation of the appendage member 20. Also contemplated herein are distal ends of appendages that have rounded edges. The examples shown in FIGS. 2D-2G and described may be utilized with any of the appendages of the embodiments discussed herein. Retention members (e.g., hooks or barbs) may be provided on arms or legs such as the retention members shown and described in U.S. Patent Nos. 6,517,573 and 6,443,972, each of which is incorporated by reference in its entirety into this application.

[0043] Referring now to FIG. 3A, a filter 30 is illustrated, including a body 31, a first appendage member 50 and a second appendage member 60. Both first and second appendage members 50, 60 may be configured according to any of the embodiments discussed above in connection with appendage member 20 of FIG. 2A. Body 31 includes a proximal section 32, an intermediate section 34 and a distal section 36. Proximal section 32 is connected to intermediate section 34 by a first joining section 42 and intermediate section 34 is connected to distal section 36 by a second joining section 44. Attached to (or integral with) proximal section 32 and distal section 36, respectively, are first retrieval member 38 and second retrieval member 40. First appendage member 50 includes a first set of appendages 52 attached at their proximal end to a first hub 54, while second appendage member 60 includes a second set of appendages 62 attached at their proximal end to a second hub 64. As with the embodiment of FIG. 2A, the first and second hubs 54, 64 are configured to move along the length of first and second joining sections 42, 44, respectively. Filter 30, by including retrieval members at each end of thereof, facilitates recovery or delivery thererof because either a jugular or femoral approach may be utilized with a snare. The snare is movable through a retrieval catheter and is configured to engage the retrieval members 38, 40 such that either approach may be employed by a clinician to recover the filter 30 from a blood vessel in which it is deployed. As described above, the appendages 52 and 62 may be configured to flexibly bend when contacted with a force during recovery, such that the

appendages 52 and 62 bend in the same direction as the contacting force of the catheter as shown in FIG. $2C_2$.

[0044] FIG. 3B shows one potential configuration of appendages 52 and 62, following a secondary procedure, e.g., a loading or a deployed configuration. In particular, each of the first and second appendage members 50, 60 are arranged so that they form a conical shape by methods known to one skilled in the art, such as annealing. As shown, the first set of appendages 52 have distal ends directed toward the retrieval member 38 positioned at the proximal end of the filter 30, while the second set of appendages 62 have distal ends directed toward the retrieval member 40 positioned at the distal end of the filter 40. Thus, the first and second appendage members 50, 60 form conical baskets directed in generally opposite directions. In another embodiment, the first and second appendage members 50, 60 are directed in the same direction (either toward the proximal or distal end). With respect to materials, in the preferred embodiments, the entire filter can be resorbed or portions of the filter can be resorbed over time. Retention members (e.g., hooks or barbs) may be provided on arms or legs such as the retention members shown and described in U.S. Patent Nos. 6,517,573 and 6,443,972, each of which is incorporated by reference in its entirety into this application.

[0045] FIG. 4 illustrates filter 70 including a body 72 and an appendage member 80. Appendage member 80 includes a set of appendages 82 attached at their proximal end to a hub 84. In this embodiment, hub 84 is limited in its movement by first and second stop members 74, 76 attached to the body 72. The first and second stop members 74, 76 have a greater cross-sectional area than the opening of the hub 84 to prevent movement of the hub beyond the length between the first and second stop members 74, 76, which in a preferred embodiment is between approximately 0.5 mm and approximately 40 mm. The body 72 may have any cross-sectional shape, as discussed above, but in a preferred embodiment is circular. Instead of two stop members, one stop member (74 or 76) may be utilized in combination with a body 72 having a smaller cross-sectional area proximate the stop member and a larger cross-sectional area to provide for, in effect, a second stop with the body 72. The body may be solid or may contain a lumen over a length thereof, the lumen being defined by a wall having one or more openings therein for release of a bio-active agent from the lumen. The body 72 has a retrieval member 78 positioned at a proximal end thereof, the retrieval member 78 either being attached to the body 72 or formed thereon. In one embodiment, a second retrieval member is positioned at a distal end of the body 72 and a second set of appendages

are spaced from the appendages 82, limited in movement along the body by third and fourth stop members.

[0046] 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 for placement in a blood vessel, the filter comprising:

a body defining a longitudinal axis, the body having a generally planar surface extending generally parallel to the longitudinal axis; and

a plurality of appendages extending away from the longitudinal axis, at least one of the plurality of appendages having a generally planar surface.

2. The filter of claim 1, wherein the at least one of the plurality of appendages comprises a cross-section selected from a group consisting essentially of generally rectangular and square cross-sections and combinations thereof.

3. The filter of claim 2, wherein each of the plurality of appendages comprise a cross-section selected from a group consisting essentially of generally rectangular and square cross-sections, and combinations thereof.

4. The filter of claim 3, wherein at least one of the appendages comprises an anchor member.

5. The filter of claim 4, wherein the anchor member comprises a hook.

6. A filter, comprising:

a longitudinal body including a proximal section having a first cross-sectional area, a distal section having a second cross-sectional area, and a joining section positioned between the proximal and distal sections having a third cross-sectional area less than both the first and second cross-sectional areas; and

a plurality of appendages having a proximal end joined to a hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the hub including an opening configured for movement along a length of the joining section.

7. The filter according to claim 6, wherein the proximal section and distal section of the body are generally tubular.

8. The filter according to claim 7, wherein the first cross-sectional area is approximately equivalent to the second cross-sectional area.

9. The filter according to claim 7, wherein the joining section is generally tubular, and wherein the opening has a diameter less than the diameter of the proximal section and distal section.

10. The filter according to claim 6, wherein the joining section has a length between approximately 0.5 mm and approximately 40 mm.

11. The filter according to claim 6, wherein at least one of the proximal section and distal section have a non-circular cross-sectional shape.

12. The filter according to claim 6, wherein the appendages are formed from a single sheet of material having a thickness.

13. The filter according to claim 12, wherein the thickness of the sheet is between approximately 0.1 mm and approximately 0.4 mm.

14. The filter according to claim 12, wherein the sheet comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, shape memory metal alloys, metal alloys, linear elastic shape memory alloy, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

15. The filter according to claim 6, wherein the appendages are configured to bend toward the proximal section when a force contacts the appendages from the distal direction and to bend toward the distal section when a force contacts the appendages from a proximal direction.

16. The filter according to claim 6, wherein one or more of the appendages includes a width that decreases in a direction away from the body.

17. The filter according to claim 6, wherein one or more of the appendages includes a distal end that terminates in a point.

18. The filter according to claim 6, wherein one or more of the appendages includes a hook.

19. The filter according to claim 18, wherein the hook comprises a generally curved profile having a cross-sectional area less than a cross-sectional area of a shaft section.

20. The filter according to claim 6, further comprising a retrieval member connected to the proximal section of the body.

21. The filter according to claim 6, wherein the appendages are stressed in a generally curved configuration to extend generally in either a proximal or distal direction.

22. The filter according to claim 6, wherein at least a portion of the body includes a length with a lumen, a wall of the body along the length of the lumen including a plurality of pores in fluid communication with the lumen.

23. A filter, comprising:

a longitudinal body having a first cross-sectional area;

a first stop member spaced apart from a second stop member, the first and second stop members having a second cross-sectional area larger than the first cross-sectional area; and

a plurality of appendages having a proximal end joined to a hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the hub including an opening configured for movement along a length of the body between the stop members.

24. The filter according to claim 23, wherein the body is generally tubular.

25. The filter according to claim 23, wherein the appendages are formed from a single sheet of material having a thickness.

26. The filter according to claim 25, wherein the thickness of the sheet is between approximately 0.1 mm and approximately 0.4 mm.

27. The filter according to claim 25, wherein the sheet comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, shape memory metal alloys, metal alloys, linear elastic shape memory alloy, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

28. The filter according to claim 23, wherein the appendages are configured to bend toward the proximal section when a force contacts the appendages from the distal direction and to bend toward the distal section when a force contacts the appendages from a proximal direction.

29. The filter according to claim 23, wherein one or more of the appendages includes a width that decreases in a direction away from the body.

30. The filter according to claim 23, wherein one or more of the appendages includes a distal end that terminates in a point.

31. The filter according to claim 23, wherein one or more of the appendages includes a hook.

32. The filter according to claim 31, wherein the hook comprises a generally curved profile having a cross-sectional area less than a cross-sectional area of a shaft section.

33. The filter according to claim 23, further comprising a retrieval member connected to the proximal section of the body.

34. The filter according to claim 23, wherein the appendages are stressed in a generally curved configuration to extend generally in either a proximal or distal direction.

35. The filter according to claim 23, wherein at least a portion of the body includes a length with a lumen, a wall of the body along the length of the lumen including a plurality of pores in fluid communication with the lumen.

36. The filter according to claim 23, wherein the length of the body between the first and second stop members is between approximately 0.5 mm and approximately 40 mm.

37. A filter, comprising:

a longitudinal body including a proximal section, an intermediate section, and a distal section;

a first joining section positioned between the proximal section and the intermediate section and a second joining section positioned between the intermediate section and the distal section, the first and second joining sections each having a cross-sectional area less than a cross-sectional area of the proximal section, the intermediate section and the distal section;

a first set of appendages having a proximal end joined to a first hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the first hub positioned along the first joining section and including an opening configured for movement along a length of the first joining section; and

a second set of appendages having a proximal end joined to a second hub such that the appendages in a non-stressed position lie in a plane generally oblique to the

longitudinal body, the second hub positioned along the second joining section and including an opening configured for movement along a length of the second joining section.

38. The filter according to claim 37, wherein the proximal section, the intermediate section, and the distal section are generally tubular.

39. The filter according to claim 38, wherein the first and second joining sections are generally tubular, and wherein the openings thereof have a diameter less than the diameter of the proximal section, intermediate section and distal section.

40. The filter according to claim 37, wherein the first and second joining sections have a length between approximately 0.5 mm and approximately 40 mm.

41. The filter according to claim 37, wherein at least one of the first and second set of appendages are formed from a single sheet of material having a thickness.

42. The filter according to claim 41, wherein the thickness of the sheet is between approximately 0.1 mm and approximately 0.4 mm.

43. The filter according to claim 41, wherein the sheet comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, shape memory metal alloys, metal alloys, linear elastic shape memory alloy, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

44. The filter according to claim 37, wherein the first and second set of appendages are configured to bend toward the proximal section when a force contacts the appendages from the distal direction and to bend toward the distal section when a force contacts the appendages from a proximal direction.

45. The filter according to claim 37, wherein at least a portion of the body includes a length with a lumen, a wall of the body along the length of the lumen including a plurality of pores in fluid communication with the lumen.

46. The filter according to claim 37, wherein one of the first and second set of appendages is made of a bio-resorbable material.

47. The filter according to claim 37, further comprising a first retrieval member connected to the proximal section of the body and a second retrieval member connected to the distal section of the body.

48. A method of retrieving the filter according to claim 47 from either a jugular access site or a femoral access site, comprising:

inserting a catheter through one of the access sites and positioning the catheter adjacent the filter;

coupling a snare to one of the first retrieval member and second retrieval member; and

pulling the snare in a direction toward the access site until the first and second set of appendages are substantially within the catheter.

49. A filter, comprising:

a longitudinal body having a first cross-sectional area;

a first stop member spaced apart from a second stop member, the first and second stop members having a second cross-sectional area larger than the first cross-sectional area;

a third stop member spaced apart from a fourth stop member, the third and fourth stop members having a third cross-sectional area larger than the first cross-sectional area;

a first set of appendages having a proximal end joined to a first hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the first hub including an opening configured for movement along a length of the body between the first and second stop members; and

a second set of appendages having a proximal end joined to a second hub such that the appendages in a non-stressed position lie in a plane generally oblique to the longitudinal body, the second hub including an opening configured for movement along a length of the body between the third and fourth stop members.

50. The filter according to claim 49, wherein the body is generally tubular.

51. The filter according to claim 49, wherein at least one of the first and second set of appendages are formed from a single sheet of material having a thickness.

52. The filter according to claim 51, wherein the thickness of the sheet is between approximately 0.1 mm and approximately 0.4 mm.

53. The filter according to claim 51, wherein the sheet comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, shape memory metal alloys, metal alloys, linear elastic shape memory alloy, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

54. The filter according to claim 49, wherein the first and second set of appendages are configured to bend toward the proximal section when a force contacts the appendages from the distal direction and to bend toward the distal section when a force contacts the appendages from a proximal direction.

55. The filter according to claim 49, further comprising a first retrieval member connected to a proximal section of the body and a second retrieval member connected to a distal section of the body.

56. The filter according to claim 49, wherein at least a portion of the body includes a length with a lumen, a wall of the body along the length of the lumen including a plurality of pores in fluid communication with the lumen.

57. The filter according to claim 49, wherein the length of the body between the first and second stop members and between the third and fourth stop members is between approximately 0.5 mm and approximately 40 mm.

58. The filter according to claim 49, wherein one of the first and second set of appendages is made of a bio-resorbable material.

59. A method of making a filter, comprising:

removing portions of a sheet of material along a first set of predetermined lines to form a plurality of arms, a plurality of legs and a body;

folding the sheet of material along a second set of predetermined lines such that the arms and legs extend radially outward from the body along a longitudinal axis; and

connecting a first joining section to a second joining section.

60. The method according to claim 59, wherein the sheet comprises a material selected from the group consisting essentially of stainless steel, shape memory metals, shape memory alloys, shape memory metal alloys, metal alloys, linear elastic shape memory alloy, shape memory polymers, polymers, bio-resorbable materials and combinations thereof.

61. The method according to claim 60, wherein the sheet comprises Nitinol.

62. The method according to claim 59, wherein the cutting comprises forming a pointed tip section at the distal end of one or more of the legs.

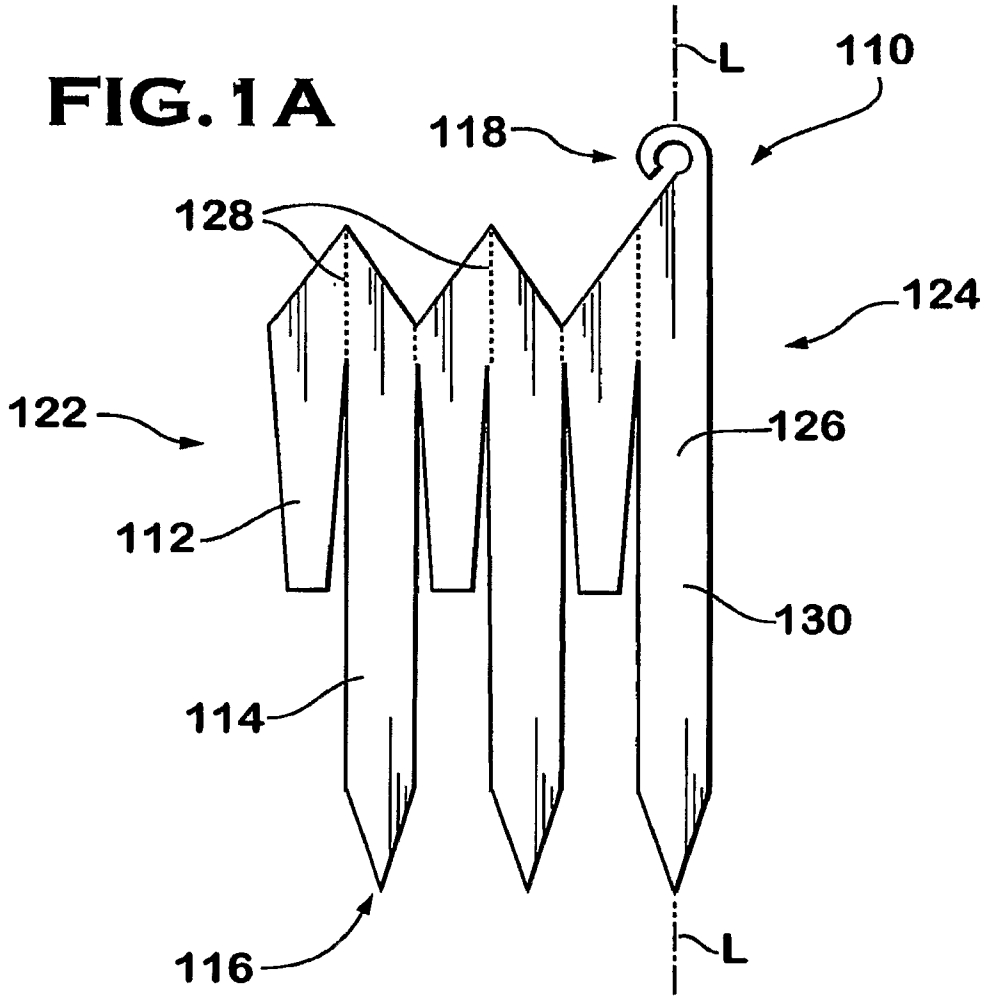
63. The method according to claim 62, further comprising bending the tip section to form a hook.

64. The method according to claim 63, wherein the hook comprises a generally curved profile having a cross-sectional area less than a cross-sectional area of a shaft section.

65. The method according to claim 59, wherein the first set of predetermined lines includes a retrieval member at a proximal end of the body.

66. The method according to claim 59, wherein connecting comprises welding the first joining section to the second joining section.

FIG. 1A



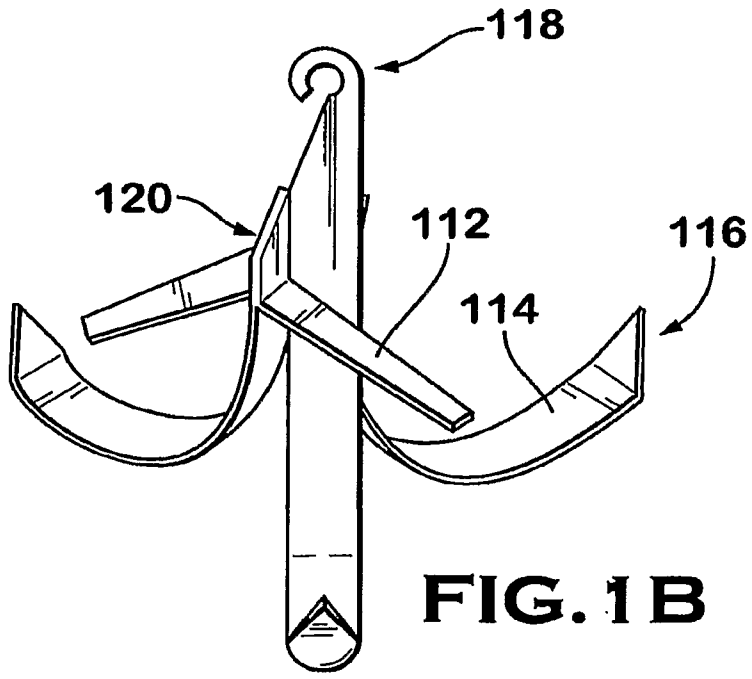
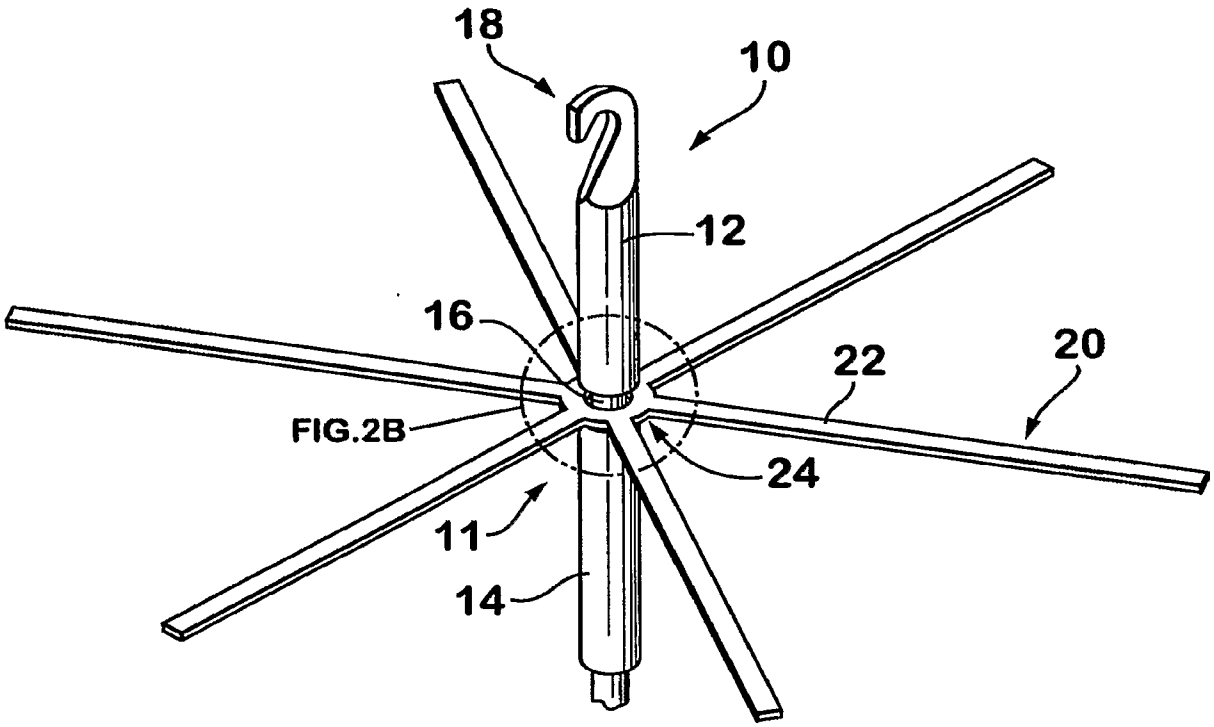


FIG. 1B

FIG.2A



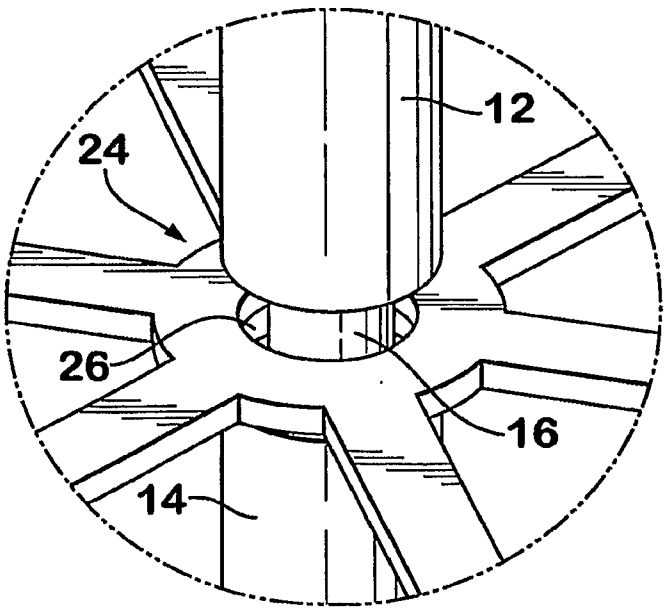


FIG.2B

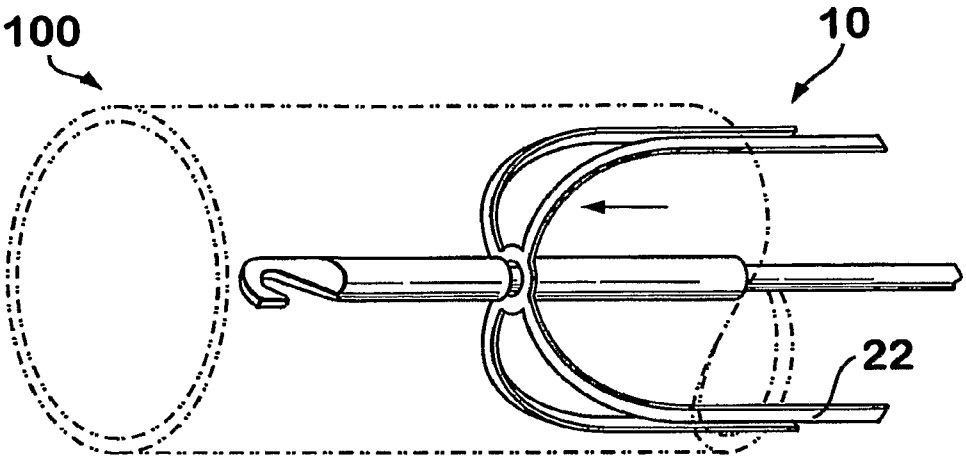


FIG.2C1

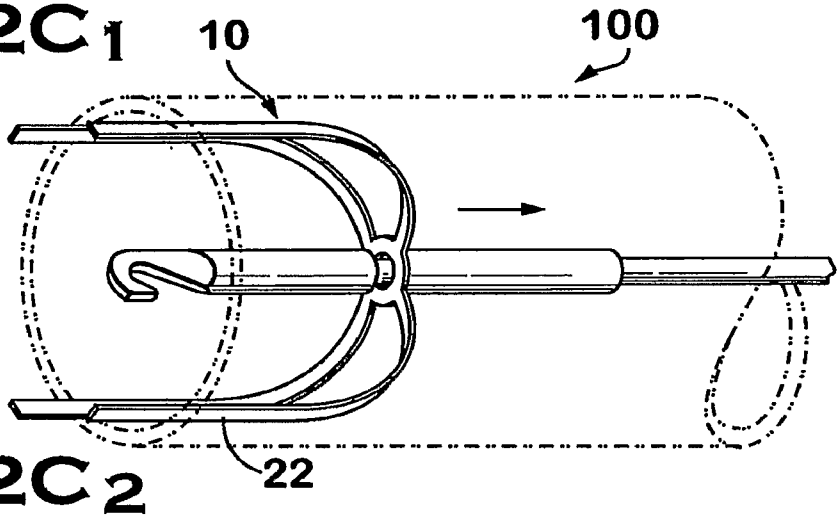


FIG.2C2

FIG.2D

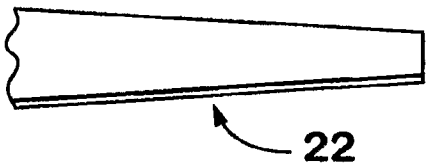
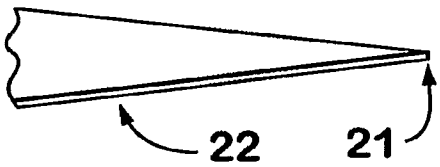


FIG.2E



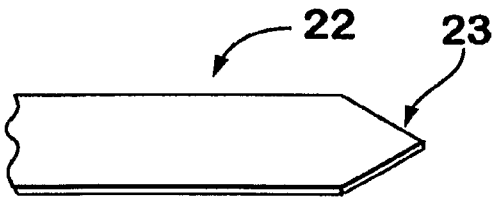


FIG.2F

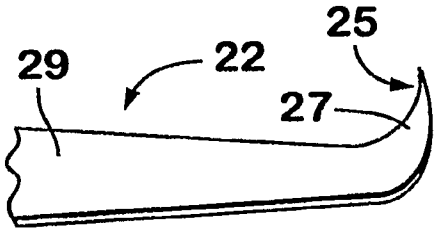


FIG.2G

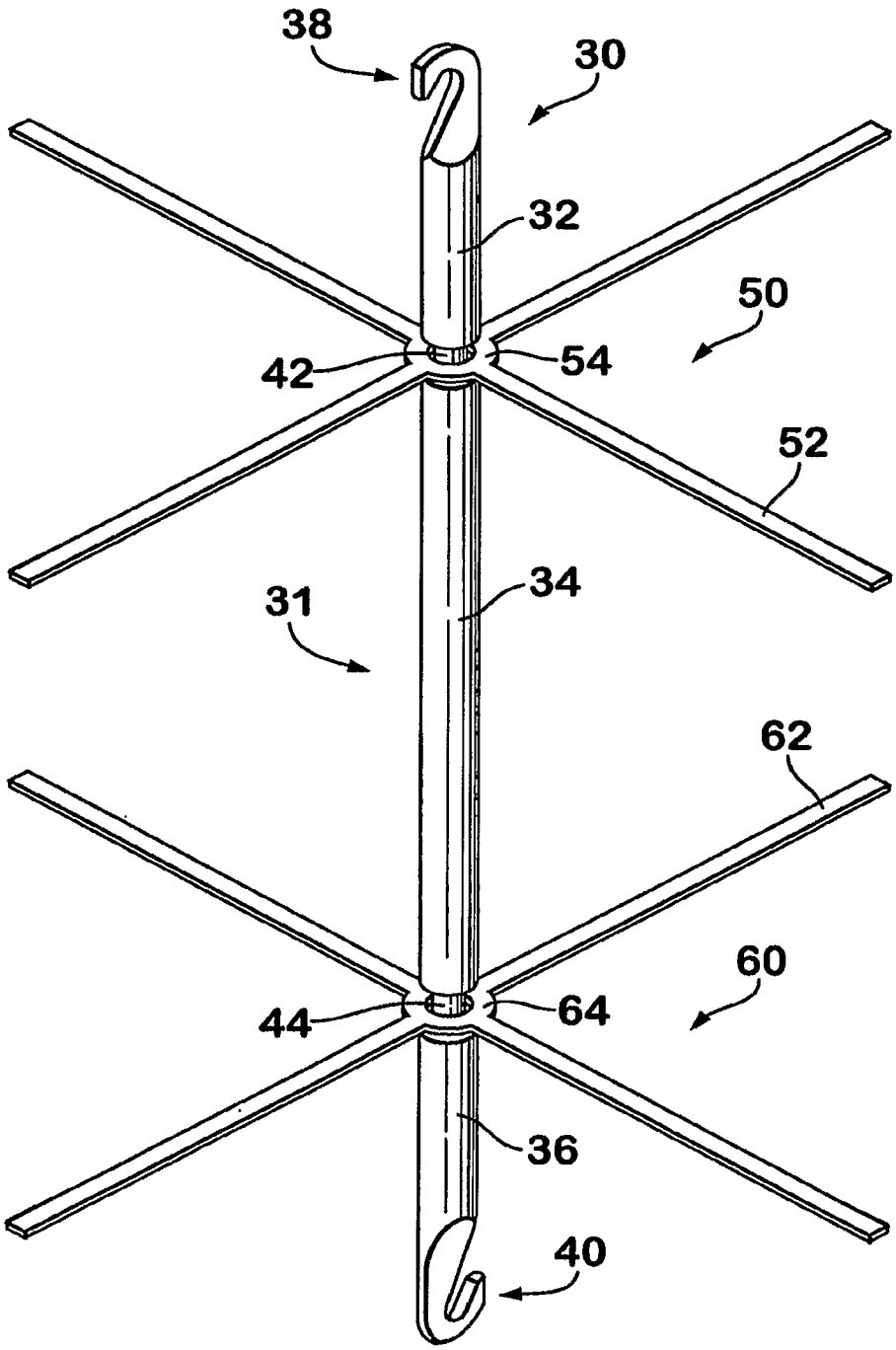


FIG.3A

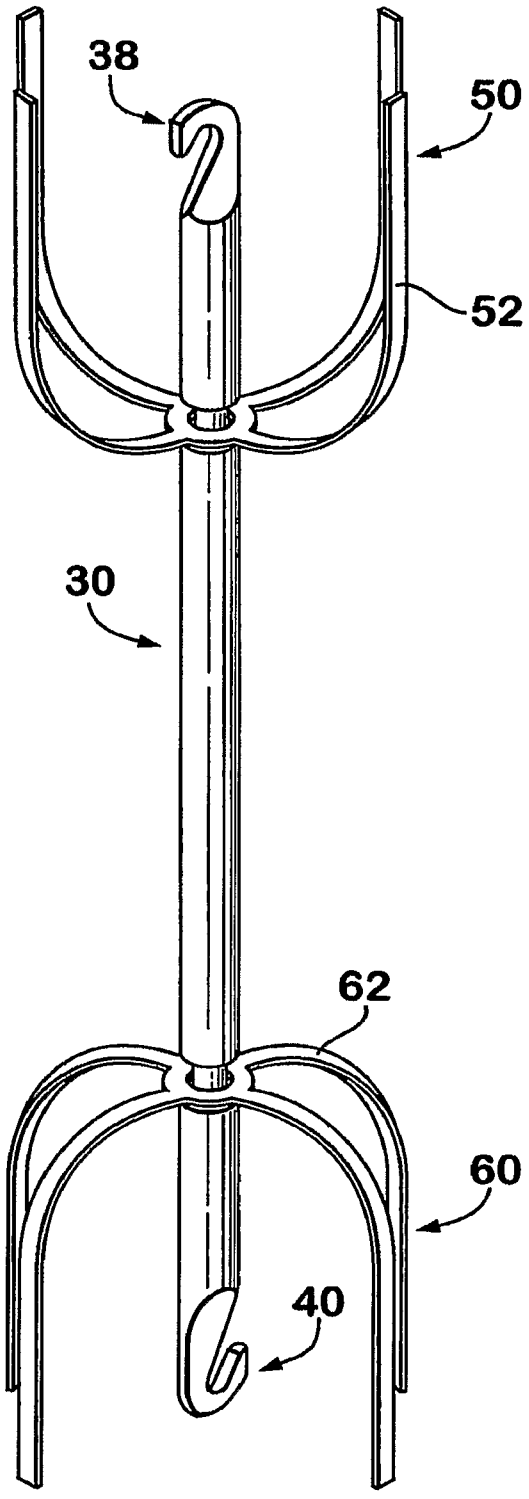


FIG.3B

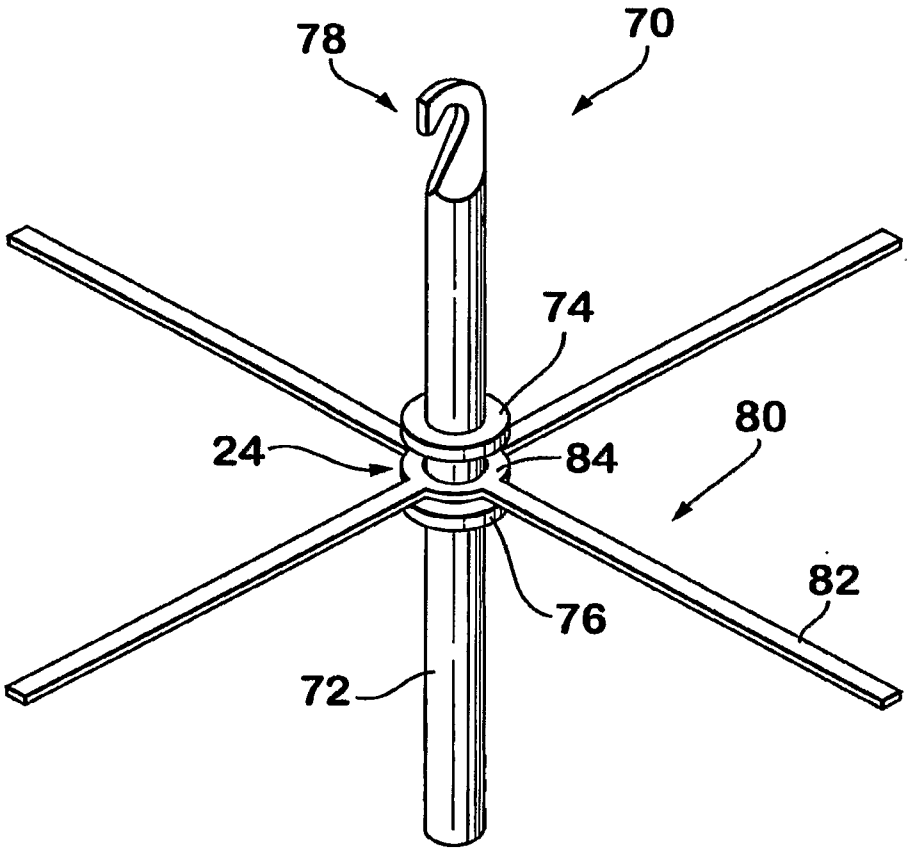


FIG.4