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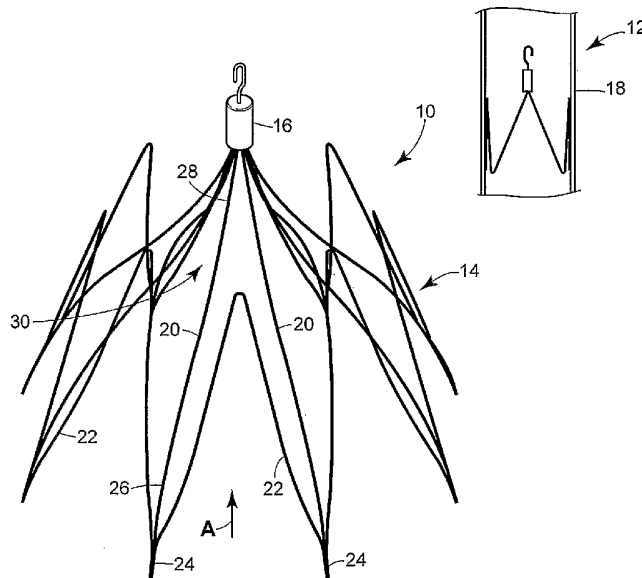
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(54) Title: REMOVABLE FILTER HEAD



(57) Abstract: A filter (10) for use within the lumen of a blood vessel that includes a plurality of interconnected intraluminal filter elements (14) adapted to flexibility convert between a filter configuration and an open configuration. The filter further includes a removable filter head (16) having a retainer (50) and a stopper (70) movable between a first position and a second position. The retainer and the stopper cooperate at the first position to secure the plurality of interconnected intraluminal filter elements into the filter configuration and the movement of the stopper to the second position releases the plurality of interconnected intraluminal filter elements to the open configuration.

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## REMOVABLE FILTER HEAD

### CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent claims benefit under 35 U.S.C. § 119(e) to United States Provisional Patent Application Serial Number 60/668,036 filed April 4, 2005, the disclosure of which is hereby expressly incorporated herein by reference.

### TECHNICAL FIELD

[0002] This patent generally relates to filters for use in the treatment of vascular diseases, and more specifically to filters that include a removable filter head adapted to convert, in vivo, the filter from a filter configuration to an open, stent-like configuration.

### BACKGROUND

[0003] Convertible filters for treating vascular disease are known from the present inventor's own U.S. Patent Nos. 6,267,776 and 6,517,559, the disclosures of which are hereby expressly incorporated herein by reference. These patents disclose numerous embodiments of convertible filters and particularly convertible filters suitable for treatment of vascular disease such as atherosclerotic and embolismic disease.

[0004] Generally, convertible filters include a filter structure having a plurality of filter legs arranged to form a single or double cone filter basket within the vessel lumen to trap blood borne clots or plaque with the vessel. A release member releasable secures the legs or filtering elements of the filter structure such that the filter may have two distinct configurations: filter or open/stent-like. The conversion is affected by release of the release member

from the filter legs allowing the spring action of the filter legs themselves or of an externally applied opening force, such the force of a spring coupled to the filter legs, to open the filter legs from the filter configuration to the stent-like configuration. The release member may be a biodegradable material that deteriorates over time to release the filter legs to move to the stent-like configuration.

[0005] In another convertible filter, the release member is a mechanical retainer that includes a hook or similar grasping structure to allow the release member to be physically separated from the filter structure. Removal of the release member involves engaging the grasping structure with a snare and forcing the separation of the release member from the filter structure. The filter structure, which is typically attached to the wall by endothelial tissue, resists the applied force. The release member needs to be releasable from the filter legs with a minimum of force so that the reaction force exerted by the filter legs on the vessel wall does cause detrimental damage to the integrity of the wall. A well-designed release member will facilitate release of the member from the filter legs without transferring significant forces through the filter structure into the vessel wall.

[0006] Upon separation of the release member from the filter legs, the filter structure opens to assume the stent-like configuration along the wall of the blood vessel.

**BRIEF DESCRIPTION OF THE DRAWINGS**

[0007] For a more complete understanding of the invention, reference should be made to the following detailed description and accompanying drawings wherein:

[0008] FIG. 1 illustrates a side view of an exemplary convertible filter assembly constructed in accordance with the teachings of the present invention;

[0009] FIG. 2 illustrates the convertible filter assembly of FIG. 1 aligned with a grasping device;

[0010] FIG. 3 illustrates an enlarged view of a removable filter head portion of the convertible filter assembly cooperating with the grasping device in a retracted state;

[0011] FIG. 4 illustrates an enlarged cross-sectional view of the removable filter head and grasping device of FIG. 3.

[0012] FIG. 5 illustrates a cross-sectional view of the removable filter head taken along the line 5-5;

[0013] FIG. 6 illustrates the enlarged cross-sectional view of the removable filter head and grasping device of FIG. 4 shown in an unsecured position;

[0014] FIG. 7 illustrates the enlarged cross-sectional view of the removable filter head and grasping device of FIG. 6 after the release of the unsecured filter elements;

[0015] FIG. 7a illustrates the enlarged cross-sectional view of an alternative construction of the removable filter head and grasping device of FIG. 6 after the release of the unsecured filter elements; and

[0016] FIG. 8 illustrates a perspective view of the convertible filter assembly after separation of the removable filter head.

#### DETAILED DESCRIPTION

[0017] The removable filter head including a release mechanism constructed in accordance with the teachings of the present invention provides a safe system for converting, in vivo, a convertible filter, such as a vena cava filter, from a closed, filter configuration to an open, stent-like configuration.

[0018] The removable filter head incorporates the release mechanism to releasably secure a plurality of interconnected intraluminal filter elements (filter elements) in a single or double cone filter structure or filter basket. The release mechanism includes a retainer adapted to receive the plurality of filter elements and a stopper movable, relative to the removable filter head and the retainer, between a secured position and an unsecured position. In operation, the filter elements are positioned within the retainer and held in position by, for example, the friction between the retainer, the filter elements and the stopper, when the stopper is in the secured position.

[0019] Movement of the stopper, relative to the removable filter head and the retainer, from the secured position adjacent to the retainer to the unsecured position, releases the filter elements while maintaining the position of the removable filter head relative to the filter elements and the wall of the

blood vessel. Subsequently, the released filter elements can convert or expand from the filter configuration to the stent-like configuration when the removable filter head is physically separated from the filter elements.

**[0020]** FIGS. 1-3 generally illustrate a convertible filter assembly 10 deployed in a filter configuration within the lumen of a blood vessel 12. The convertible filter assembly 10 includes a plurality of intraluminal filter elements (filter elements) 14 secured in the filter configuration by a removable filter head 16, as shown in FIG. 1. The term "filter configuration" as used herein refers to the convertible filter assembly 10 when positioned within the blood vessel 12 for the treatment of vascular diseases. Similarly, the terms "open configuration" or "stent-like configuration" refer to the convertible filter assembly 10 with the removable filter head 16 separated from the filter elements 14, and the unrestrained filter elements 14 extended along a wall 18 of the blood vessel 12.

**[0021]** The filter elements 14 in this exemplary embodiment are arranged in a single cone configuration and aligned within the blood vessel 12 in the direction of the blood flow indicated by the arrow A to trap matter carried within the blood flow, for example, dislodged blood clots or plaque. The filter elements 14 each include a filter leg 20 flexibly attached to an orientation member 22 at a flexure point 24. In operation, deployment of the convertible filter assembly 10 within the blood vessel 16 allows the orientation members 22 to engage the wall 18 of the blood vessel 12 and align the entire convertible filter assembly 10 with the blood flow. However, it is noted that the particular configuration of the convertible filter, single cone, dual cone,

basket, stabilizing members or no stabilizing members, etc., is not critical, and the herein described removable filter head is adaptable to virtually any such structure.

**[0022]** The filter legs 20 include an inferior end 26 and a superior end 28 aligned along the wall 18 of the blood vessel 12 by the orientation member 22. In particular, the inferior end 26 is an unsecured portion of the filter leg 20 positioned upstream from the superior end 28. The superior end 28 is, in turn, bundled and secured together by the removable filter head 16 to form a filter basket generally indicated by the reference numeral 30. As used herein to assist the reader, the terms superior and inferior indicate the orientation of the convertible filter assembly 10 within the blood vessel 12 and relative to the direction of the blood flow (indicated by the arrow A). For example, the term inferior indicates a downstream position and the term superior indicates an upstream position relative to the direction of blood flow within the blood vessel 12.

**[0023]** The convertible filter assembly 10 including the removable filter head 16, the filter legs 20 and the orientation members 22 may be manufactured from a radiopaque and non-ferromagnetic metal that has been certified for use in medical devices by the International Standards Organization (ISO). The filter legs 20 and the orientation members 22 may be manufactured from metallic wires having, for example, a round, flat or any suitable cross-sectional shape. The convertible filter assembly 10 may be further drug-coated.

[0024] The wires may be a high cobalt, low ferrous alloy, such as the alloys sold under the registered trademark ELGILOY® which is also referred to as PHYNOX. The composition of these alloys may, by weight percent, be: cobalt 42%, chromium 21.5%, nickel 18%, iron 8.85%, molybdenum 7.5%, manganese 2% with the balance made up of carbon and beryllium having a maximum of 0.15% carbon and 0.001% beryllium. The wires may also be composed of 316L stainless steel or other alloys of nickel and titanium known to be shape-memory metals which are sold and manufactured under the registered trademark NITINOL® or an alloy of tantalum (Ta). Convertible filter assemblies 10 constructed from these metals will be non-thrombogenic and preferably withstand twelve million respiratory cycles without mechanical failure.

[0025] FIGS. 2 and 3 generally illustrate the convertible filter assembly 10 deployed within the blood vessel 12 and aligned with a snare catheter 32. In particular, FIGS. 2 and 3 illustrate the alignment and capture of the removable filter head 16 by the snare catheter 32. The snare catheter 32, or any other suitable gripping device, can be inserted into the lumen of the blood vessel by any known method of insertion and deployment, and maneuvered through the patient's circulatory system to a position adjacent to the removable filter head 16 and the superior end 28 of the filter legs 20. The snare catheter 32 may include a sheath 34 and a snare 36 such as, for example, a gooseneck snare or a hook, slideable relative to the sheath 34. Similarly, the removable filter head 16 may include a catch 38 or hook adapted to be engaged by the snare 34.



[0026] FIG. 3 illustrates an enlarged view the removable filter head 16 deployed within the blood vessel 12 and engaged by the snare catheter 32. In particular, FIG. 3 shows the snare catheter 32 maneuvered, via a patient's circulatory or cardiovascular system, to a position adjacent to the removable filter head 16. From this position, the snare 36 can loop around or otherwise grasp the catch 38 to slideably secure the snare catheter 32 and sheath 34 to the removable filter head 16. By increasing the tension in the direction indicated by the arrow T, the snare 36 can be retracted into the sheath 34 while simultaneously sliding the sheath 34 towards the removable filter head 16. It will be understood that the applied tension T will be sufficient to withdraw the snare 36 into the sheath 24, but not great enough to shift or disturb the overall position of the convertible filter assembly 10 relative to the wall 18 of the blood vessel wall 12.

[0027] FIG. 4 illustrates an enlarged cross-sectional view of the snare catheter 32 in an abutting relationship with removable filter head 16. Specifically, the snare catheter 32 includes a tip 40, defined as the terminal end of the sheath 34, in an abutting relationship with the removable filter head 16. As shown, the tip 40 is firmly seated against the removable filter head 16 and the snare 36 and catch 38 are retracted into the hollow interior 42.

[0028] The removable filter head 16 is a roughly cylindrical body 44 that includes an open first end 46 and a second end 48 that includes a retainer 50 formed integrally therein. The open first end 46 accepts an end cap 52 sized to close and/or seal the roughly cylindrical body 44. The end cap 52 includes a lip 56 which can be seated against a top edge 60 of the cylindrical body 44,

and a cylindrical wall 58 sized to cooperate with the interior surface of the cylindrical body 44 such that the lip 56 and a top edge 60 of the cylindrical body 44 are in an abutting relationship. The cylindrical wall 58 and the cylindrical body 44 may be held together in a press-fit or friction arrangement, may include male and female threads and be rotatably joined and may be glued, welded or otherwise secured together in any desired manner. The end cap may further include an external, flat surface 54 arranged to bear against and/or bias the tip 40 of the sheath 34 when the snare 36 and catch 38 are retracted into the hollow interior 42. The flat surface 54 provides a firm contact between the two components, the removable filter head 16 and the snare catheter 32, and allows the transmission of forces therebetween.

[0029] The end cap 52 further includes an orifice 62 sized to slideably accept a rod portion 64 connected to the catch 38. The rod portion 64 extends through the orifice 62 into an interior 66 of the cylindrical body 44 to engage a stopper 70 having a contiguously formed shaft 68. The stopper 70, as shown in this exemplary embodiment, is a roughly cylindrical component sized to releasably engage the retainer 50 formed at the second end 48 of the cylindrical body 44. In operation, the stopper 70 is movable within the interior 66 of the cylindrical body 44 between a secured position adjacent to the retainer 50, and an unsecured position adjacent to the end cap 54.

[0030] The stopper 70 includes varying diameter portions that define a flange 72 and plug 74. The flange 74 and plug 74, of this present embodiment, are integral elements which are aligned coaxially with the shaft 68 and the rod portion 64. Physically, the flange 72 is a radially extending

disc that compliments the interior 66 of the cylindrical body 44 and the plug 74 has a reduced diameter, relative to the flange 72, sized to cooperate with the retainer 50 when the stopper 70 is in the secured position. The shaft 68, as shown, may include a blind bore 76 sized to securely accept the rod portion 64 in, for example, a threaded or press fit arrangement. The removable filter head 16 may further include a push nut 78 positioned adjacent to the cylindrical wall 58 of the end cap 52 to hold the stopper 70, via the shaft 68 and flange 72, in secure contact with the retainer 50.

**[0031]** A force applied through the catch 38 and rod portion 62 in the direction indicated by the arrow T allows the shaft 68 to elastically deform the push nut 78 and move the stopper 70 to the unsecured position adjacent 48 to the cylindrical wall 58 of the end cap 52. The cylindrical wall 58 and push nut 78 cooperate with the flange 72 to limit the overall movement of the stopper 70 to the unsecured position adjacent to the end cap 52. The shaft 68 further includes a reduced diameter portion 80 adjacent to the flange 72 and arranged to cooperate with the push nut 78 to, upon movement to the unsecured position at the open first end 46, prevent the stopper 70 and plug from reengaging the retainer 50.

**[0032]** The plug 74 and the retainer 50 cooperate to compressively engage and retain the superior ends 28 of the filter legs 20 when the stopper 70 is in the secured position. The superior end 28 of the filter legs 20 may be aligned within a plurality of grooves 82 (see FIG. 5) formed within the retainer 50 at the second end 48 of the cylindrical body 44. The aligned filter legs 20 may, in turn, be held in position by inserting the plug 74 into the retainer 50

and creating an interference fit therebetween. Moreover, the flange 72 may be sized and arranged to compressively engage the aligned superior ends of the filter legs 20 against the retainer 50. In this way, the superior ends 28 of the filter legs 20 are aligned and secured within the cylindrical body 44 of the removable filter head 16 to thereby create the filter basket 30.

**[0033]** FIG. 6 illustrates an enlarged cross-sectional view of the removable filter head 16 in an abutting relationship with the tip 40 of the snare catheter 32. In particular, the catch 38 and the snare 36 are withdrawn into the sheath 34 such that the tip 40 is firmly seated against the flat surface 54. Moreover, the application of tension through the snare 26 and the catch 38, in the direction indicated by the arrow T, forces the stopper 70 to move towards the unsecured position adjacent to the end cap 52.

**[0034]** The movement of the stopper 70, in turn, causes the shaft 68 to bear against and elastically deform the push nut 78. In particular, the stopper movement elastically deforms the fingers, indicated by the numerals 78a and 78b, of the push nut 78. The elastically deformed fingers 78a, 78b ride along the shaft 68 and engage a reduced diameter portion 80 to prevent the stopper 70 from returning to the secured position adjacent to the retainer 50. Similarly, the flange 72 engages the cylindrical wall 58 and prevents additional movement or over-travel in the direction of the end cap 52. In this way, the stopper 70 is locked into the unsecured position away from the retainer 50 and between the end cap 52 and the retainer 50. The reduced diameter portion 80 may further act as a detent such that as the stopper 70 arrives at the unsecured position, it is engaged by the reduced diameter portion to retain

it in the unsecured position. The action of the fingers sliding from the shaft 68 to the reduced diameter portion may also provide a haptic snap or click indication through the catheter, allowing the medical professional to know that the stopper 70 is fully retracted to the unsecured position.

[0035] The tension applied to retract the stopper 70 and elastically deform the push nut 78, can cause the entire convertible filter assembly 10 to move in order to react forces against the blood vessel wall 18. In order to limit force transfer to the vessel wall, the tension applied through the snare 36 is counteracted and balanced by an equal and opposite force applied to the flat surface 54 through the sheath 34. In this way, while the catch 38 and the attached stopper 70 are forced to disengage from the retainer 50, the counterforce applied through the sheath 34 maintains the position of the removable filter head 16 and attached filter elements 14, relative to the blood vessel wall 18.

[0036] As shown in FIG. 6, upon disengagement of the plug 74 from the retainer 50, the stopper 70 remains secured adjacent to the end cap 52 by the cooperation of the reduced diameter portion 80 and the fingers 78a, 78b of the push nut 78. The superior ends 28 of the filter legs 20 will typically remain aligned within the grooves 82 of the retainer 50, but will be unfettered and ready for release. This arrangement allows convertible filter assembly 10 to be transitioned from the filter configuration to the open or stent-like configuration by releasing the superior ends 28 of the filter legs 20 from the retainer 50.

**[0037]** As outlined above, the process of transitioning the convertible filter assembly 10 begins with maneuvering and aligning the snare catheter 32 and the snare 36 with the removable filter head 16 and the catch 38. The aligned snare 36 engages the catch 38, and the sheath 34 is positioned in contact with the flat surface 54 of the end cap 52. In this way, the tip 40 of the snare catheter 32 abuts the removable filter head 16 (through contact with the end cap 52) and the sheath 34 encloses both the snare 36 and the catch 38.

**[0038]** Application of tension in the direction of the arrow T to the free end of the snare 36, e.g., the end of the snare 36 which is outside of the patient's body, pulls the catch 38 deeper into the sheath 34 and forces the attached stopper 70 to disengage from the retainer 50. It will be understood that unless the tension is greater than the force generated by the fingers 78a, 78b of the push nut 78 and the friction between the plug 74 and the retainer 50, the stopper 70 cannot be disengaged. Simultaneously, a counterforce can be applied to the removable filter head 16 through the sheath 34 in order to balance and counteract the effects of the tension applied through the snare 36. In other words, as the snare 36 is pulled to release the plug 74 from the retainer 50, the sheath 34 is pushed to engage the removable filter head 16 through the flat surface 54 of the end cap 52 and prevent movement relative to the blood vessel wall 18.

**[0039]** By overcoming the friction between the plug 74 and the retainer 50, the shaft 68 elastically deforms the fingers 78a, 78b of the push nut 78 and allows the stopper 70 to move away from the retainer 70 and to the unsecured position adjacent to the end cap 52. The fingers 78a, 78b, in turn,

engage the reduced diameter portion 80 and lock or otherwise prevent the stopper 70 from reengaging the retainer 50. The movement of the stopper 70 is further limited, by the interference between the flange 72 and the cylindrical wall 58 of the end cap 52. This release mechanism within the removable filter head 16 allows the stopper 70 to be disengaged from the retainer 50 and prevents unwanted reengagement of the components.

[0040] FIG. 7 illustrates the removable filter head 16 after the stopper 70 and plug 74 have been disengaged from the retainer 50. The unrestrained superior ends 28 of the filter legs 20 have been released from the grooves 82, and have flexed or expanded to the open or stent-like configuration.

Generally, in order to disengage the removable filter head 16 and release the superior ends 28 of the filter legs 20, the entire removable filter head 16 is pulled, via the snare catheter 32, away from the filter elements 14 lodged or encapsulated in the wall 18 of the blood vessel 12. In this way, the removable filter head 16 and the snare catheter 32 are separated from the filter elements 14 for extraction through the patient's circulatory system. The filter elements 14 remain secured to the wall 18 of the blood vessel 12 in the open or stent-like configuration.

[0041] FIG. 7a illustrates an alternative construction of the removable filter head 16 after the stopper and plug 74 have been disengaged from the retainer 50. Like reference numerals designate like elements. The retainer 50 is formed with a smooth bore that receives the superior ends 28 of the filter legs. The stopper and plug 74 are formed with grooves 82' that engage and align the filter legs with the stopper and plug 74 in the secured position, and,

as shown in FIG. 7a, release the filter legs when in an unsecured position. Alternative arrangements wherein grooves 82/82' are formed in one or both of the retainer 50 or plug 74 may be used.

**[0042]** FIG. 8 illustrates the released intraluminal filter elements 14 expanded and extended along the wall 18 of the blood vessel 12. In this open or stent-like configuration, the filter basket 30 is open and allows blood to flow freely through the blood vessel 12.

**[0043]** Although certain embodiments have been described in accordance with the teachings of the present disclosure, the scope and coverage of this patent is not limited thereto. For instance, while the removable filter 14 has been illustrated and describes as having a cylindrical body, it will be understood that any desired shape or configuration may be employed. Further, while a specific embodiment of the intraluminal filter elements 14 has been described herein, many other single or double cone arrangements may be employed. This patent is intended to cover all embodiments of the teachings of the disclosure that fairly fall within the scope of the permissible equivalents.



## CLAIMS

What is claimed is:

1. A filter for use within the lumen of a blood vessel that includes a plurality of interconnected intraluminal filter elements adapted to flexibly convert between a filter configuration and an open configuration, the filter comprising:
  - 5 a removable filter head including,
    - a retainer; and
    - a stopper movable between a first position and a second position;
  - 10 wherein the retainer and the stopper cooperate at the first position to secure the plurality of interconnected intraluminal filter elements into the filter configuration and wherein the movement of the stopper to the second position releases the plurality of interconnected intraluminal filter elements to the open configuration.
- 15 2. The filter of claim 1 further comprising a catch fixedly attached to the stopper and adapted to mechanically release the stopper from the retainer in response to a releasing force.
3. The filter of claim 2, wherein the releasing force is provided by a snare catheter positioned adjacent to the catch and the removable filter head.
- 20 4. The filter of claim 2, wherein the catch is a hook adapted to cooperate with a snare portion of the snare catheter to mechanically release the stopper from the retainer.

5. The filter of claim 1, wherein the removable filter head includes a push nut arranged to limit the travel of the stopper relative to the retainer.
6. The filter of claim 5, wherein the push nut includes a plurality of elastically deformable fingers adapted to secure the stopper in the  
5 second position.
7. The filter of claim 1, wherein the retainer includes a plurality of grooves adapted to receive the plurality of interconnected intraluminal filter elements
8. A removable filter head adapted to secure a plurality of interconnected  
10 intraluminal filter elements in a filter configuration, the removable filter head comprising:  
a retainer sized to accept the plurality of interconnected intraluminal filter elements; and  
a stopper movable between a first position and a second position  
15 relative to the retainer, wherein the stopper is sized to engage the plurality of interconnected intraluminal filter elements and the retainer, and wherein the movement of the stopper from the first position to the second position releases the plurality of interconnected intraluminal filter elements.
- 20 9. The removable filter head of claim 8, further comprising a catch fixedly attached to the stopper and arranged to move the stopper from the first position to the second position in response to a releasing force.

10. The removable filter head of claim 9, further comprising a flat surface arranged to bias the releasing force and prevent movement of the retainer relative to the plurality of interconnected intraluminal filter elements.
- 5 11. The removable filter head of claim 10, wherein the releasing force is transmitted by a catheter having a snare, and wherein the catheter is arranged to abut the flat surface and the snare is arranged to engage the catch.
12. The removable filter head of claim 9, wherein the catch is a hook  
10 fixedly attached the stopper and sized to cooperate with a snare catheter to move the stopper to the second position.
13. The removable filter head of claim 8, wherein the retainer body includes a push nut arranged to limit the movement of the stopper.
14. The removable filter head of claim 8, wherein the stopper includes a  
15 flange sized to compressively engage the plurality of interconnected intraluminal filter elements.
15. A method of converting a filter including a plurality of interconnected intraluminal filter elements positioned within the lumen of a blood vessel to an open configuration, the method comprising:  
20 inserting a snare catheter having a first end into the lumen of the blood vessel;  
positioning the snare catheter adjacent to a removable filter head having a retainer and a release mechanism, wherein the release mechanism is adapted to releasably secure the plurality of  
25 interconnected intraluminal filter elements;

engaging the release mechanism with snare catheter;  
shifting the release mechanism relative to the removable filter head  
and the retainer to thereby release the plurality of  
interconnected intraluminal filter elements.

FIG. 1

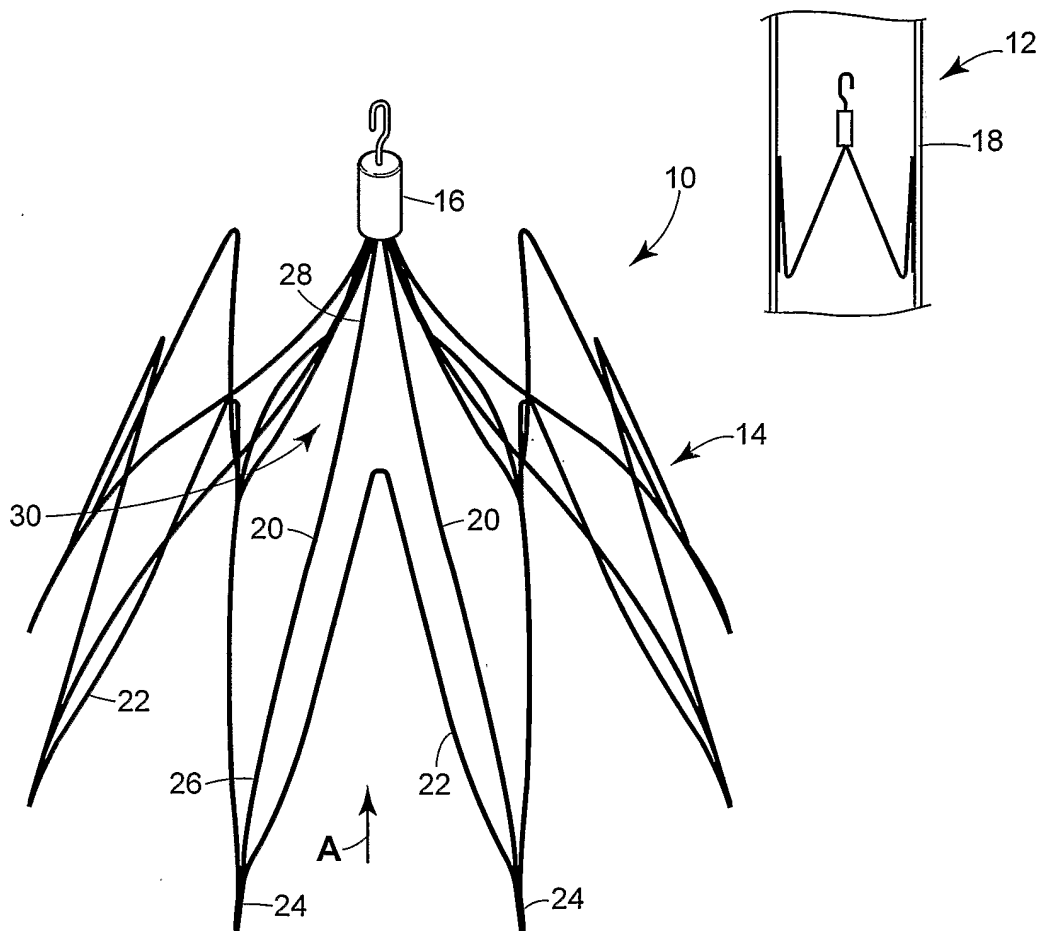


FIG. 2

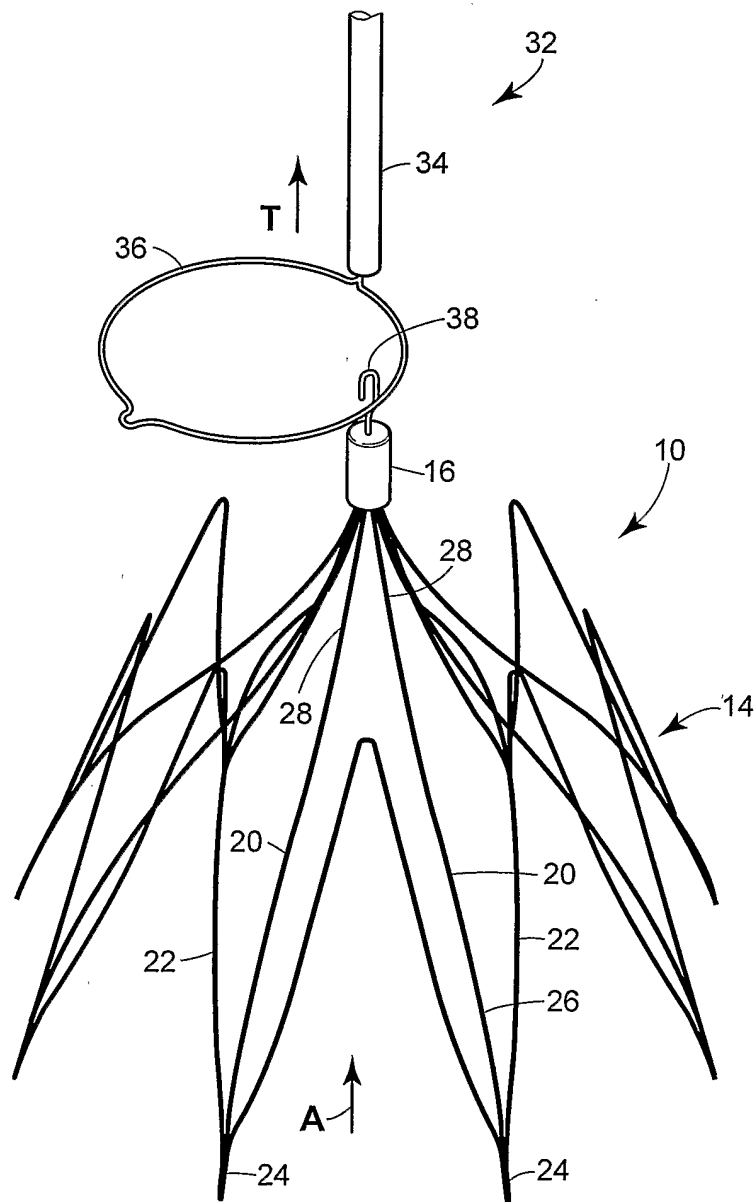
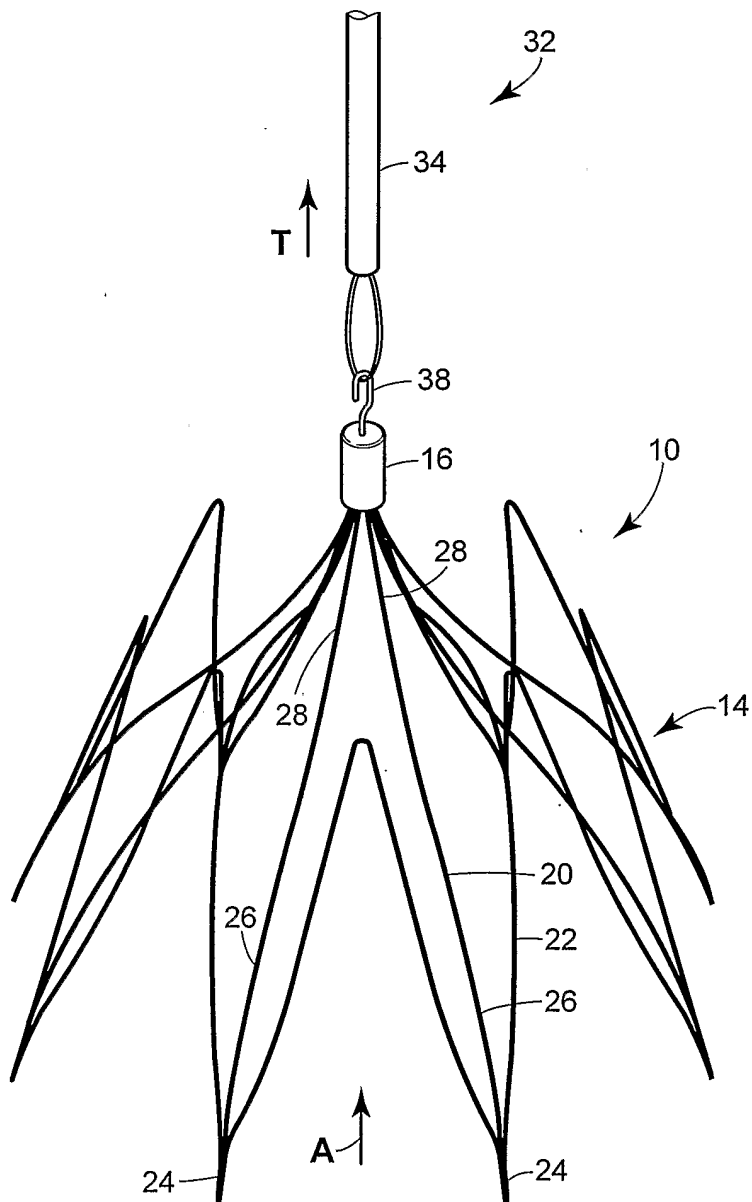
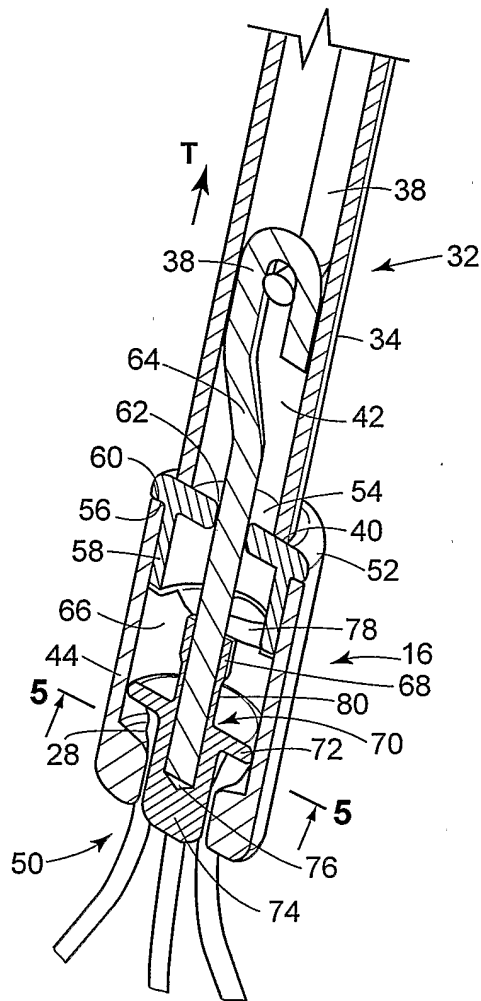


FIG. 3



**FIG. 4**



**FIG. 5**

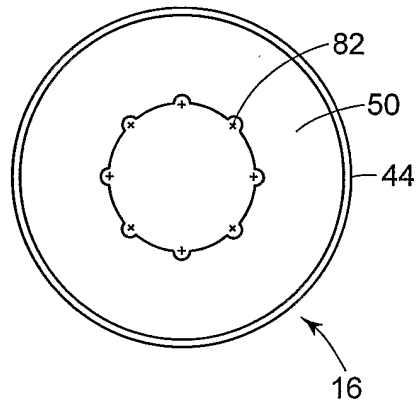




FIG. 6

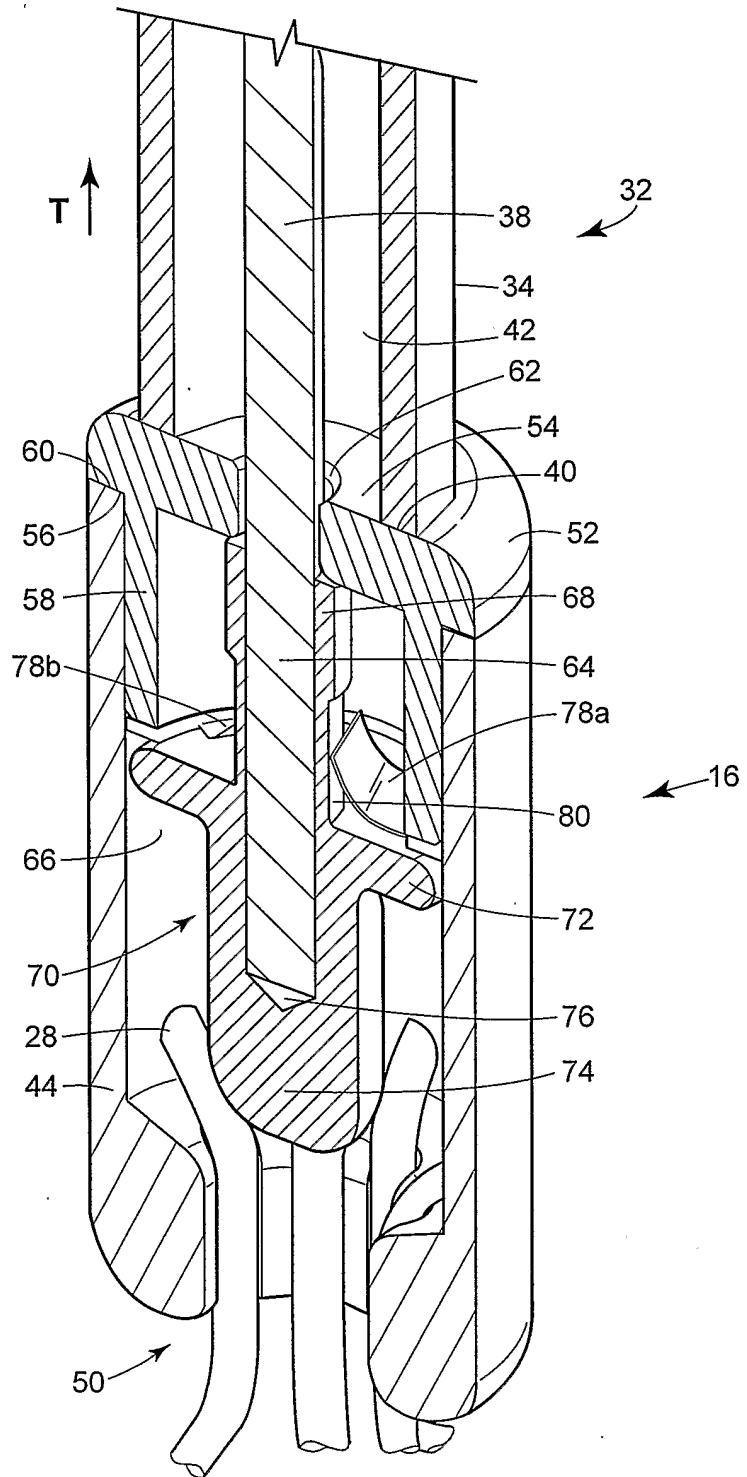


FIG. 7

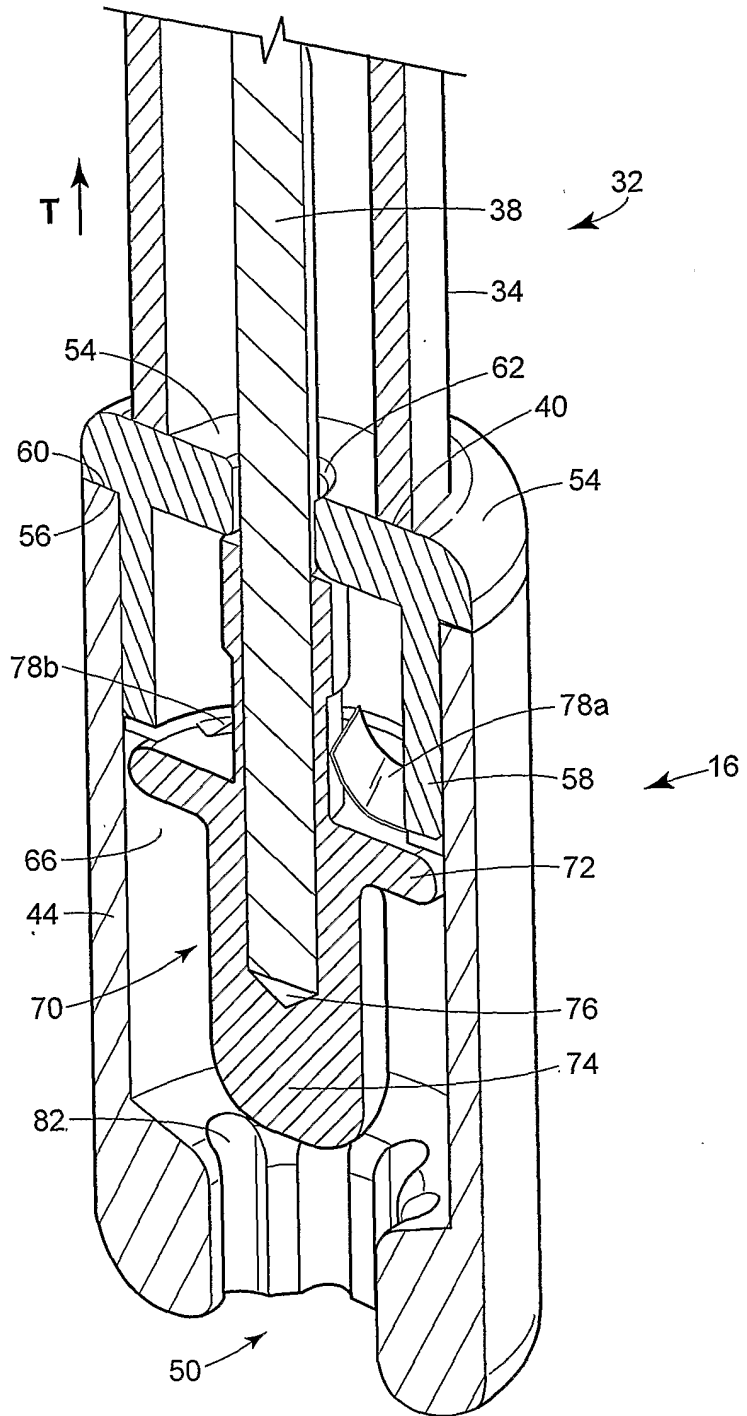
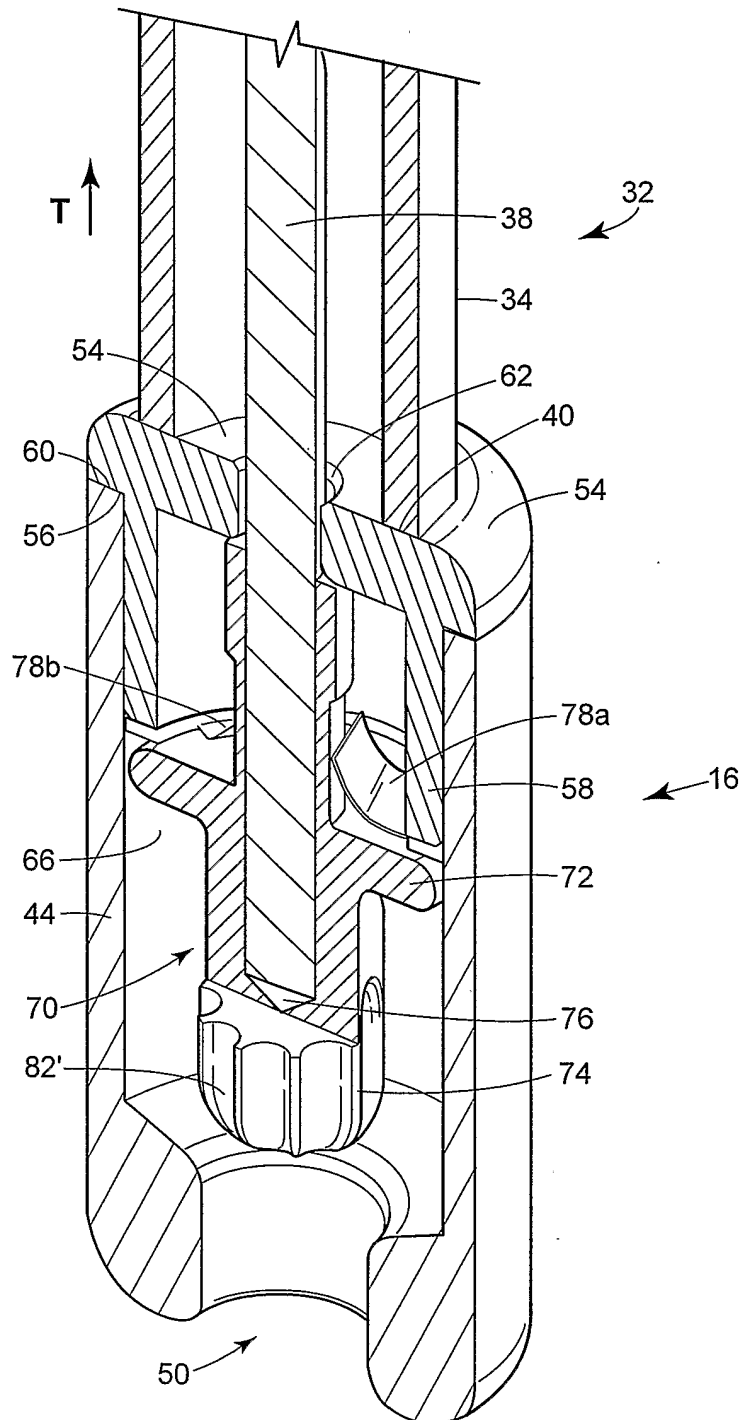
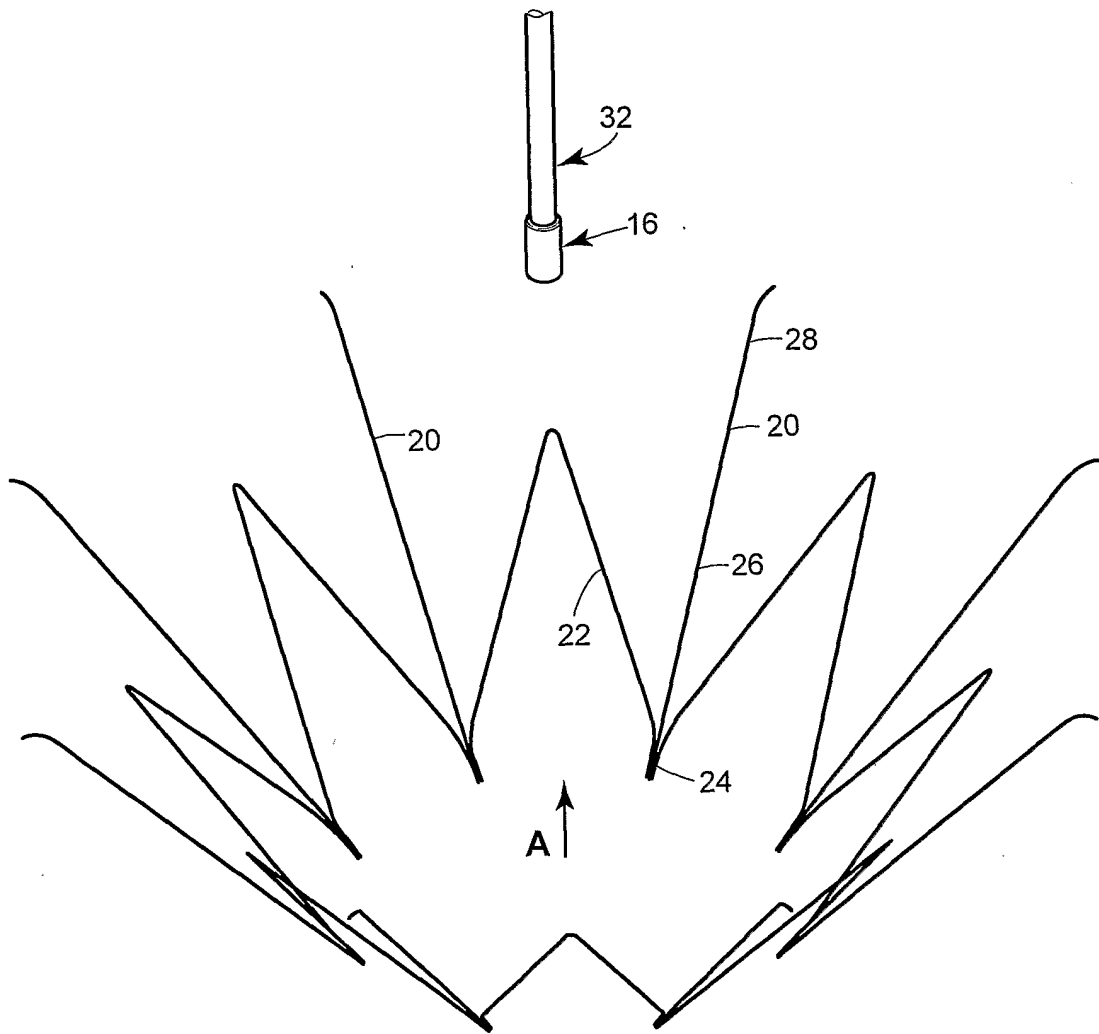


FIG. 7A



**FIG. 8**



**INTERNATIONAL SEARCH REPORT**

International application No  
PCT/US2006/012453

**A. CLASSIFICATION OF SUBJECT MATTER**  
INV. A61F2/01

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)  
EPO-Internal

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category* | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|-----------|---|-----------------------|
| X         | US 6 241 746 B1 (BOSMA GJALT ET AL)<br>5 June 2001 (2001-06-05)<br>the whole document                                       | 1-4,8,9,<br>12        |
| A         | EP 1 258 228 A (B. BRAUN MEDICAL SAS)<br>20 November 2002 (2002-11-20)<br>the whole document                                | 1,8                   |
| A         | US 6 267 776 B1 (O'CONNELL PAUL T)<br>31 July 2001 (2001-07-31)<br>the whole document                                       | 1-14                  |
| A         | WO 01/62184 A (SCIMED LIFE SYSTEMS, INC;<br>BOSTON SCIENTIFIC LIMITED)<br>30 August 2001 (2001-08-30)<br>the whole document | 1-14                  |

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

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|---|--|
| Date of the actual completion of the international search<br><br>3 August 2006  | Date of mailing of the international search report<br><br>23/08/2006 |
| Name and mailing address of the ISA/<br>European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,<br>Fax: (+31-70) 340-3016 | Authorized officer<br><br>Steiner, B                                 |

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2006/012453

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 15  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

|   |
|---|
| International application No<br>PCT/US2006/012453 |
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| Patent document cited in search report |    | Publication date |    | Patent family member(s) | Publication date |
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