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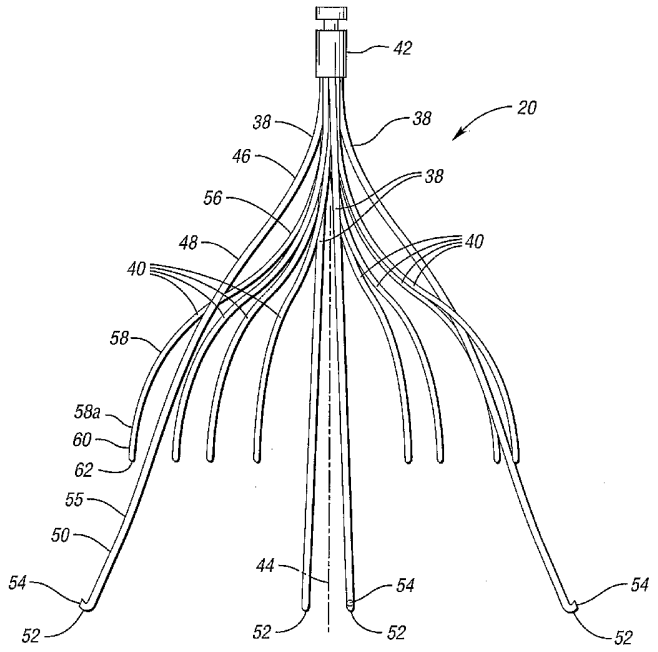
(54) Title: BLOOD CLOT FILTER CONFIGURED FOR A WIRE GUIDE



(57) Abstract: A filter (20) to capture blood clots includes a hub (42) with a passageway (43) through which a wire guide is received. The filter (20) also includes a plurality of primary struts (38) and a plurality of secondary struts (40) that extend from the hub (42). Each primary strut (38) terminates with a hook (52) to anchor the filter in the blood vessel when the filter is deployed in the blood vessel. The secondary struts (40) center the filter in the blood vessel as the secondary struts (40) engage the interior of the blood vessel during deployment of the filter (20) in the vessel.

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BLOOD CLOT FILTER CONFIGURED FOR A WIRE GUIDE

RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/625,900 filed November 8, 2004, the entire contents of which are incorporated herein by reference.

BACKGROUND

[0002] This invention relates to medical devices. More specifically, the invention relates to a removable vena cava clot filter.

[0003] Filtering devices that are percutaneously placed in the vena cava have been available for a number of years. A need for filtering devices arises in trauma patients, orthopedic surgery patients, neurosurgery patients, or in patients having medical conditions requiring bed rest or non-movement because of the likelihood of thrombosis in the peripheral vasculature of patients. The thrombi may break away from the vessel wall, and, depending on the size of the thrombi, pose a serious risk of pulmonary embolism when blood clots migrate from the peripheral vasculature through the heart and into the lungs.

[0004] A filtering device can be deployed in the vena cava of a patient when, for example, anticoagulant therapy is contraindicated or has failed. Typically, filtering devices are permanent implants even though the condition or medical problem that required the device has passed. Recently, filters have been employed or considered in preoperative patients and in patients predisposed to thrombosis, which, however, may increase the risk for pulmonary embolism in these patients.

[0005] Although the benefits of vena cava filters have been well established, improvements may be made. For example, filters generally have not been considered removable from a patient due to the likelihood of endotheliosis of the filter or fibrous reaction matter adherent to the endothelium during treatment. After deployment of a filter in a patient, proliferating intimal cells begin to accumulate around the filter struts that are in contact with the wall of the vessel. After a period of time, such ingrowth prevents removal of the filter without risk of trauma, requiring the filter to remain in the patient. As a result, there is a need for an effective filter that can be removed after the underlying medical condition has passed.

[0006] Although some filters have been designed to be removable from the vena cava, these filters commonly become off-centered or tilted with respect to the hub of the filter and the longitudinal axis of the vessel in which it has been inserted. As a result, these filters including the hub and the retrieval hook engage the vessel wall along their lengths and potentially become endothelialized within the vessel, making removal of the filters impossible or at least difficult.

SUMMARY

[0007] In a general aspect, the present invention provides a filter that includes a hub and a plurality of primary struts and a plurality of secondary struts that extend from the hub. Each primary strut terminates with a hook to anchor the filter in the blood vessel when the filter is deployed in the blood vessel. The secondary struts center the filter in the blood vessel as the secondary struts engage the interior of the blood vessel during deployment of the filter.

[0008] To guide the filter through a vessel, the hub is provided with a passageway through which a wire guide is received. Thus, the wire guide can be extended through a sheath so that the terminal end of the wire guide can be placed near the site of interest. A medical specialist, such as a physician, can then push the filter along the wire guide to the desired location. Once the filter is deployed, both the sheath and wire guide are removed from the patient. The hub may be provided with a groove that engages with a retrieval device to remove the filter from the vessel.

[0009] Each of the primary struts and the secondary struts includes a fixed end housed in the hub. These fixed ends are secured together in a bundle that defines a central axis extending through the passageway. The central axis is substantially parallel to a longitudinal axis extending through the blood vessel when the filter centers itself in the blood vessel.

[0010] In various embodiments, the filter has a collapsed configuration and an expanded configuration. The filter expands from the collapsed configuration to the expanded configuration as the filter is deployed in the blood vessel. The primary struts and secondary struts form a net when the filter is in the expanded configuration to capture blood clots.

[0011] The hooks may include barbs that engage the interior wall of the blood vessel. The primary struts and the secondary struts can be made of shape memory alloy.

[0012] In some embodiments, the primary struts are spaced apart angularly about the passageway such that the spacing between the primary struts are substantially equal. A pair of secondary struts may be positioned between each pair

of spaced apart primary struts, or a primary strut may be positioned between a respective pair of secondary struts.

[0013] In a particular embodiment, the filter includes four primary struts and eight secondary struts.

[0014] Further features and advantages of this invention will become readily apparent from the following description, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is an illustration of the anatomy the vena cava in which a filter is deployed in accordance with an embodiment of the invention.

[0016] FIG. 2 is a side perspective view of a vena cava filter in accordance with an embodiment of the invention.

[0017] FIG. 3 is a close-up view of a hub associated with filter shown in FIG. 2.

[0018] FIG. 4a is a cross-sectional view of the hub along the line 4-4 of FIG. 3.

[0019] FIG. 4b is a cross-sectional view of an alternative hub in accordance with the invention.

[0020] FIG. 5a is a cross-sectional view of a blood vessel showing the insertion of a wire guide.

[0021] FIG. 5b is a cross-sectional view of the blood vessel showing the insertion of a sheath and a vena cava filter over the wire guide.

[0022] FIG. 5c is a cross-sectional view of the blood vessel showing the vena cava filter partially deployed.

[0023] FIG. 6a is a cross-sectional view of the blood vessel showing the retraction of the sheath.

[0024] FIG. 6b is a cross-sectional view of the blood vessel showing the vena cava filter fully deployed.

[0025] FIG. 7 is a cross-sectional view of a blood vessel showing the vena cava filter of FIG. 2 deployed within the blood vessel.

[0026] FIG. 8 is a view of the blood vessel and filter of FIG. 7 taken along the line 8-8.

[0027] FIGs. 9a through 9e are interior views of the vena cava illustrating the removal of the vena cava filter.

DETAILED DESCRIPTION

[0028] Turning now to the drawings, FIG. 1 illustrates a vena cava filter 20 embodying the principles of the present invention. The vena cava filter 20 is shown implanted in a vena cava 22 after it has been inserted through an iliac vein 24 with the use of a sheath 26. Alternatively, the vena cava filter 20 can be inserted through a jugular vein. As described below in greater detail, once implanted, the vena cava filter 20 is able to self align itself within the vena cava 22 to minimize endotheliosis of the filter. The vena cava filter 20 captures or lyses thrombi (or clots) carried through the vena cava 22 from the iliac veins 24, 28 toward the heart and into the pulmonary arteries, where clots can cause embolization. Moreover, the vena cava filter 20 is configured to minimize obstruction of flood flow through the vena cava 22.

[0029] The iliac veins 24, 28 from the legs merge into the vena cava 22 at a juncture 30, and the renal veins 32 from the kidneys 34 join the vena cava 22 downstream of the juncture 30. The portion of the vena cava between the juncture

30 and the renal veins 32 defines an inferior vena cava 36. In the illustrated embodiment, the length of a vena cava filter 20 is shorter than the length of the inferior vena cava 36. Otherwise, if the lower part of the filter 20 extends into the iliac veins 24, 28, the filtering effectiveness of the filter 20 may be compromised.

[0030] Referring now to FIGs. 2, 3, and 4, the filter 20 includes four primary struts 38 and eight secondary struts 40, each of which extends from a respective fixed end housed in a hub 42. To attach the fixed ends of the struts to the hub 42, the fixed ends are crimped together in a compact bundle about an opening or passageway 43, thereby defining a central or longitudinal axis 44. The diameter of this bundle is minimized to accommodate the size of the wires used to form the struts. The hub 42 is provided with a groove 45, which, as described below, engages with a retrieval device for removing the vena cava filter 20.

[0031] Each primary strut 38 is formed with a first curved section 46 that bends away form the central axis 44 and a second curved section 48 that bends away from the hub 42. A substantially straight section 50 extends from the second curved section 48 and terminates in an anchoring hook 52 with a barb 54. The section 50 may also have an additional curved section 55 that further flares the anchoring hooks 52 away from the central axis 44. Each primary strut 38 maintains a non-parallel relationship with the central axis 44 when the filter 20 is in its deployed configuration.

[0032] When the filter 20 is deployed in the blood vessel (see, for example, FIG. 7), the anchoring hooks 52 engage with the interior of the blood vessel in a first axial plane 57 aligned substantially perpendicular to the longitudinal axis of the blood vessel. The diameter of this plane of engagement 57 is about 30 mm or less.

[0033] The primary struts 38 have sufficient spring strength to move the hooks 52 to the interior wall, where the hooks 52, in particular, the barbs 54, anchor into the interior wall of the blood vessel to prevent the filter 20 from migrating from the delivery location of the filter in the blood vessel. In various embodiments, the primary struts 38 are formed from superelastic material, stainless steel wire, MP35N, Nitinol, elgiloy, chronichrome, cobalt chrome alloy or any other suitable material that will result in a self-opening or self-expanding filter. In certain embodiments, the primary struts 38 are formed from wire with a round or near round cross section with a diameter of at least about 0.015 inch. In other embodiments, the primary struts do not have a round cross-section. For example, the primary struts 38 can take on any shape with rounded edges to maintain non-turbulent blood flow. Rather than forming the struts from wire, they can be cut from a tube of any appropriate material by laser cutting, electrical discharge machining, or any other suitable process. Subsequently, the struts can be finished, for example, with an electropolishing process so that the resulting struts are substantially rounded.

[0034] A pair of secondary struts 40 is positioned between adjacent primary struts 38 as shown in FIG. 4a, or, alternatively, a primary strut 38 is positioned between a pair of secondary struts 40 as shown in FIG. 4b. Each secondary strut 40 has a first curved section 56 that bends away from the central axis 44, a second curved or converging section 58 that bends toward the central axis 44, and an end section 60 that terminates in a tip 62 pointing toward the central axis 44. The tips 62 are located longitudinally between the hub 42 and the anchoring hooks 54 of the primary struts 38. To minimize the trauma to the vena cava caused by removing the filter 20, the free ends 60 of the secondary struts 40 do not have anchoring hooks.

[0035] When the filter 20 is in its deployed configuration, the outer regions 58a of the converging section 58 of each secondary strut 40 engage with the wall of the blood vessel. The radial force created between the secondary struts 40 and the wall of the blood vessel serves to align the filter 20 about the center of the blood vessel so that the central axis 44 is substantially parallel to the axis of the blood vessel.

[0036] When the filter 20 is deployed within the vessel, the outer regions 58a of the secondary struts 40 engage with the interior of the blood vessel in a second axial plane 65 (FIG. 7) that is substantially parallel to the first axial plane 57. The diameter of the second axial plane of engagement is also about 30 mm or less. As a result, the filter 20 has two layers or planes of struts longitudinally engaging the vessel wall. Note that the length of the primary struts 38 defines the length of the filter 20, since the secondary struts 40 do not extend further upstream than the primary struts 38. That is, the secondary struts 40 do not add to the overall length of the filter. In some embodiments, the length of the filter 20 is between about 3 cm and 7 cm. In a particular embodiment, the length of the filter is about 5cm.

[0037] The secondary struts 40 can be made from the same type of material as the primary struts 38 and can be formed by the same process used to form the primary struts. However, the secondary struts may have round or near round cross section with a smaller diameter than the primary struts. In a particular embodiment, the diameter of the secondary struts is at least about 0.01 inch. The hub 42 can be made of any suitable material. For example, the hub 42 can be made from the same material as the primary struts and secondary struts to minimize the possibility of galvanic corrosion.

[0038] FIGs. 5 and 6 illustrate the deployment of the filter 20 in the vena cava 36, as performed, for example, by a medical specialist such as a physician. Referring in particular to FIG. 5a, the medical specialist insets a wire guide 66 through one of the iliac veins 24 or 28, using, for example, the Seldinger technique, until the distal end of the wire guide 66 is advanced beyond the inferior vena cava 36 to insure seating of the wire guide 66.

[0039] Then, as shown in FIG. 5b, the specialist inserts a delivery sheath 26 holding the filter 20 over the wire guide 66 through the puncture site of the patient into the iliac vein 24 and advances the sheath 26 and filter 20 to the deployment site. Note that neither the sheath 26 nor the filter 20 scrape or puncture the inner wall of the blood vessel because they follow the path of the wire guide 66. As such, the sheath 26 is deployed over the wire guide 66 so that the distal end of wire guide 66 extends beyond the distal end of the sheath 26 and the proximal end of the wire guide extends beyond the proximal end of the sheath. Referring to FIG. 5c, the specialist then pushes the filter 20 out of the distal end of the delivery sheath 26 with the free ends of the primary struts 38 held, for example, by a filter retainer member. The filter retainer member may be connected to a pusher member, such as a cannula, that is fed through the proximal end of the delivery sheath 26 until the filter reaches the terminal end of the delivery sheath 26. For a more complete disclosure of the filter delivery system that may be adapted to deliver the filter 20 to a desired location, reference may be made to U.S. Patent No. 5,324,304.

[0040] As the filter 20 emerges from the delivery sheath 26, the secondary struts 40 expand to an expanded state to stabilize the attitude of the filter 20 about the center of the blood vessel 36. The specialist pulls the sheath 26 back until the

filter 20 is fully deployed in the vena cava 36, as shown in FIG. 6a, and then pulls the wire guide 66 away from the filter, as shown in FIG. 6b, when the specialist is satisfied with the placement of the of the filter 20. The sheath 26 and the wire guide 66 are subsequently removed from the patient.

[0041] When fully deployed, the free ends of the primary struts 38 along with the converging section of the secondary struts 40 engage with the vessel wall. The anchoring hooks 52 (FIG. 7) of the primary struts 38 anchor the filter 20 at the location of deployment, preventing the filter 20 from moving with the blood flow (BF) through the vessel. Specifically, as the sheath 26 is pulled back, the barbs 54 are oriented in the direction BF, which along with the outward spring bias of the primary struts 38 causes the anchoring hooks 52 to engage the vessel wall and anchor the filter at the location of deployment. As a result, the filter 20 is supported by the two sets of struts 38, 40 at respective planes of engagement 57, 65 spaced axially along the length of the filter. Moreover, the struts 38, 40 avoid engaging the vessel wall along their lengths to minimize endothelialization in the vessel wall.

[0042] With further reference to FIG. 7, the filter 20 is shown fully expanded after being deployed in the inferior vena cava 36. In particular, the anchoring hooks 52 at the ends of the primary struts 38 are shown as being anchored in the inner lining of the inferior vena cava 36. As mentioned above, after deployment of the filter 20, the pressure of the blood flow on the filter 20 contributes in maintaining the barbs 54 anchored in the inner lining of the blood vessel such as the inferior vena cava 36. Also, as noted previously, the converging section 58 of the secondary struts 40 are spring biased to engage with the vessel wall. The engagement of the converging section 58 with the vessel wall functions both initially and after full

deployment of the filter to stabilize the attitude of filter 20 about the center of the blood vessel.

[0043] Referring also to FIG. 8 there is shown a netting pattern ("net") formed by the primary struts 38 and the secondary struts 40 extending from the hub 42. This net catches thrombi carried in the blood stream to prevent the thrombi from reaching the heart and lungs, where the thrombi could cause pulmonary embolism. The size of the net is designed to catch and stop thrombi that are of a size that are undesirable in the vasculature of the patient.

[0044] As illustrated in FIG. 8, the struts 38, 40 have substantially equal angular spacing between them. Alternatively, the secondary struts alone may have substantially equal angular spacing between adjacent secondary struts, for example, when the primary struts 38 are employed as the anchoring struts and the secondary struts are employed as the filtering struts. In this alternative implementation, the angle between the primary struts and the adjacent secondary struts is smaller than the angle between adjacent secondary struts.

[0045] The filter 20 may be removed percutaneously from the vena cava. To remove the filter 20, the hub 42 is typically grasped about the groove 45 (see FIG. 3) by a retrieval device that is introduced percutaneously in the vena cava.

[0046] FIGs. 9a through 9e illustrate part of a retrieval device 68 being used, for example, by a medical specialist, for removing the filter 20 from the inferior vena cava 36. The retrieval device 68 includes a removal sheath 70 (FIGs. 9d and 9e) and a snare 74 with a loop 75 inserted through a catheter 72.

[0047] Referring to FIG. 9a, the specialist places the catheter 72 into the inferior vena cava 36 and advances the loop portion 75 of the snare 74 out of the

distal end of the catheter 72. Then, as shown in FIG. 9b, the specialist positions the loop 75 over the hub 42. The specialist manipulates the snare 74 by any suitable means from the proximal end of the snare 74 such that the loop 75 engages with the groove 45. Once the loop 75 is engaged with the groove 45, the specialist advances the catheter 72 to tighten the loop 75 about the groove 45 as shown in FIG. 9c.

[0048] Next, as shown in FIG. 9d, the specialist inserts the sheath 70 into the superior vena cava through the patient's jugular vein and then advances the sheath 70 over the catheter 72. As counter traction is used by pulling the catheter 72 and the snare 74 while pushing the sheath 70, the sheath 70 passes over the filter 20. As the sheath 70 passes over the filter 20, the primary struts 38 and then the secondary struts 40 engage the edge of the end of the sheath 70, causing the struts to pivot at the hub 42 and collapse towards the central axis 44 of the filter 20 (FIG. 9e). This pivoting movement toward the central axis 44 causes the anchoring ends 52 of the primary struts 38 and the converging section 58 of the secondary struts 40 to retract from the inner wall of the vessel 36. In this way, only small point lesions 76 where the anchoring hooks 54 of the primary struts 38 anchored to the vessel wall and surface lesions where the converging section 58 (see FIG. 2) of the secondary struts 48 engaged the vessel wall remain after the removal procedure. It should be noted that removal of the filter 20 from the patient is not limited to the procedure shown in FIG. 9. Other suitable procedures may be employed. For example, the filter 20 may be removed through a femoral vein of the patient.

CLAIMS

What is claimed is:

1. A filter (20) for capturing blood clots in a blood vessel comprising:

a hub (42) with a passageway (43) through which a wire guide is received;

a plurality of primary struts (38) that extend from the hub (42) and terminate with respective hooks (52) to anchor the filter (20) in the blood vessel when the filter (20) is deployed in the blood vessel; and

a plurality of secondary struts (40) that extend from the hub (42), the secondary struts (40) centering the filter (40) in the blood vessel as the secondary struts (40) engage the interior of the blood vessel during deployment of the filter (20) in the blood vessel.

2. The filter of claim 1 wherein each of the primary struts (38) and the secondary struts (40) includes a fixed end housed in the hub (42), the fixed ends of the primary and secondary struts being secured together in a bundle that defines a central axis (44) extending through the passageway (43), the central axis (44) being substantially parallel to a longitudinal axis extending through the blood vessel when the filter (20) centers itself in the blood vessel.

3. The filter of claim 1 wherein the filter (20) has a collapsed configuration and an expanded configuration, the filter (20) expanding from the collapsed configuration to the expanded configuration as the filter is deployed in the blood vessel, the

secondary struts (40) centering the filter as the filter expands to its expanded configuration.

4. The filter of claim 2 wherein the primary struts (38) and secondary struts (40) form a net when the filter is in the expanded configuration to capture blood clots.

5. The filter of claim 1 wherein the hooks (52) are provided with barbs (54) that engage the interior wall of the blood vessel.

6. The filter of claim 1 wherein the primary struts (38) are made of shape memory alloy.

7. The filter of claim 1 wherein the secondary struts (40) are made of shape memory alloy.

8. The filter of claim 1 wherein the primary struts (38) are spaced apart angularly about the passageway, the spacing between the primary struts being substantially equal.

9. The filter of claim 8 wherein a pair of secondary struts (40) is positioned angularly between each pair of spaced apart primary struts.

10. The filter of claim 8 wherein a primary strut (38) is positioned between a respective pair of secondary struts.

11. The filter of claim 1 wherein the plurality of primary struts (38) is four primary struts.

12. The filter of claim 1 wherein the plurality of secondary struts (40) is eight secondary struts.

13. The filter of claim 1 wherein the hub is provided with a groove (45) for retrieving the filter from the blood vessel.

14. A method of deploying the filter (20) of claim 1 in a blood vessel for capturing blood clots comprising:

inserting a wire guide (66) into the blood vessel, the wire guide (66) having a proximal end and a distal end, the proximal end being external to the vessel and the distal end being near the deployment location for the filter (20);

deploying a sheath (26) over the wire guide, the sheath (26) having a proximal end and a distal end;

inserting the filter (20) into the proximal end of the sheath (26); and

pushing the filter (20) through the sheath (26) until the filter (20) exits the distal end of the sheath (26) and expands to an expanded configuration, the secondary struts (40) centering the filter (20) in the blood vessel as the secondary struts (40) expand to the expanded configuration and engage the interior of the blood vessel, the primary struts (38) expanding to the expanded configuration upon exiting the distal end of the sheath (26), and the hooks (52) anchoring the filter in the blood vessel.

15. The method of claim 14 further comprising removing the wire guide (66) from the sheath (26).

16. The method of claim 14 further comprising removing the sheath (26) from the vessel.

17. The method of claim 14 wherein each of the primary struts (38) and the secondary struts (40) includes a fixed end, the fixed ends of the primary and secondary struts (38,40) being secured together in a bundle that defines a central axis (44) extending through the passageway (43), the central axis (44) being substantially parallel to a longitudinal axis extending through the blood vessel when the filter (20) centers itself in the blood vessel.

18. The method of claim 14 wherein the primary and secondary struts (38,40) form a net when the filter (20) is in the expanded configuration to capture blood clots.

19. The method of claim 14 wherein the hub (42) is provided with a groove (45) for retrieving the filter (20) from the vessel.

20. The method of claim 19 further comprising introducing a retrieval device (68) into the vessel, the retrieval device (68) including a snare (74) that engages with the groove (45), and pulling the snare(74) and the filter (20) into a retrieval sheath (70) to remove the filter (20) from the vessel.

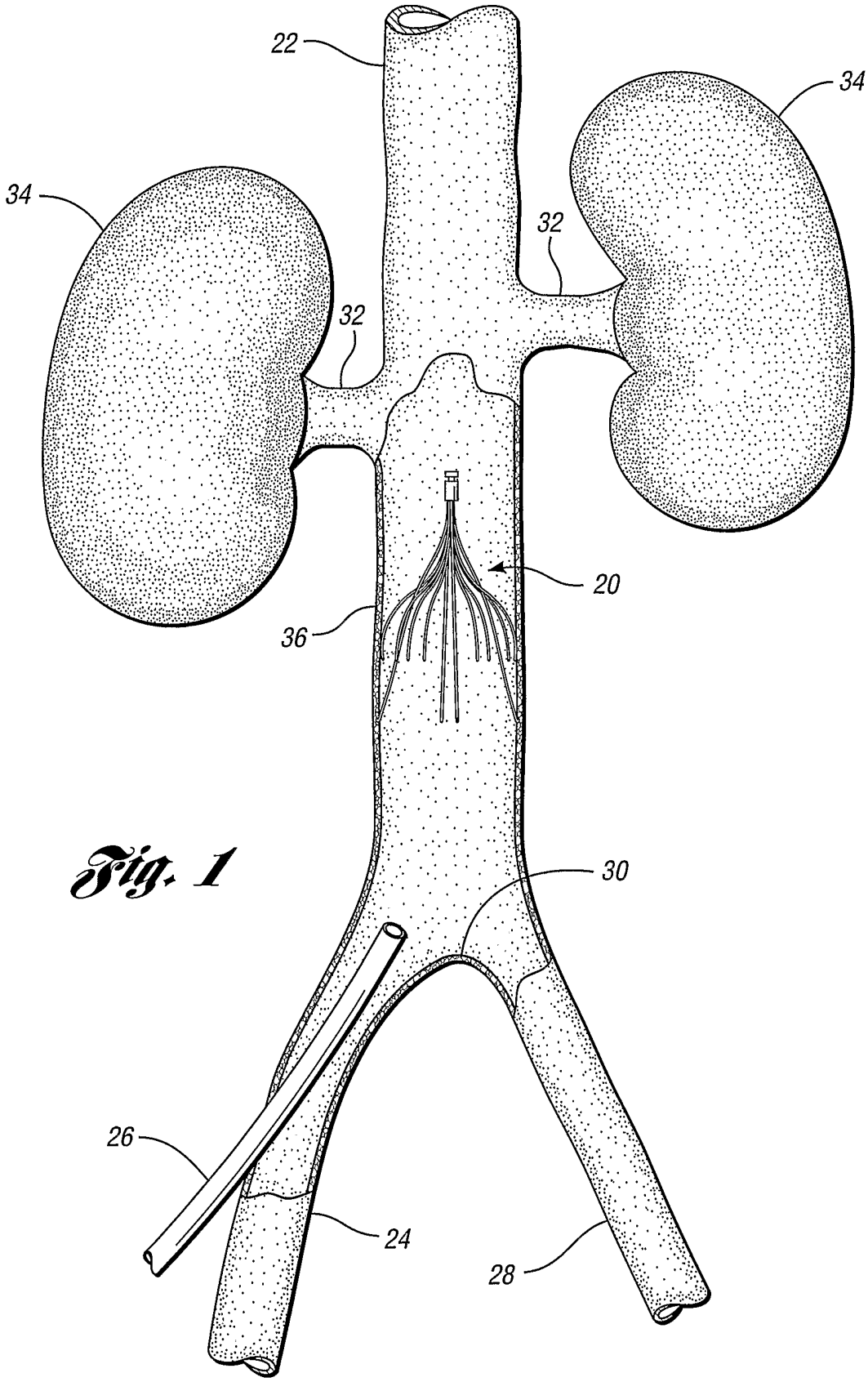
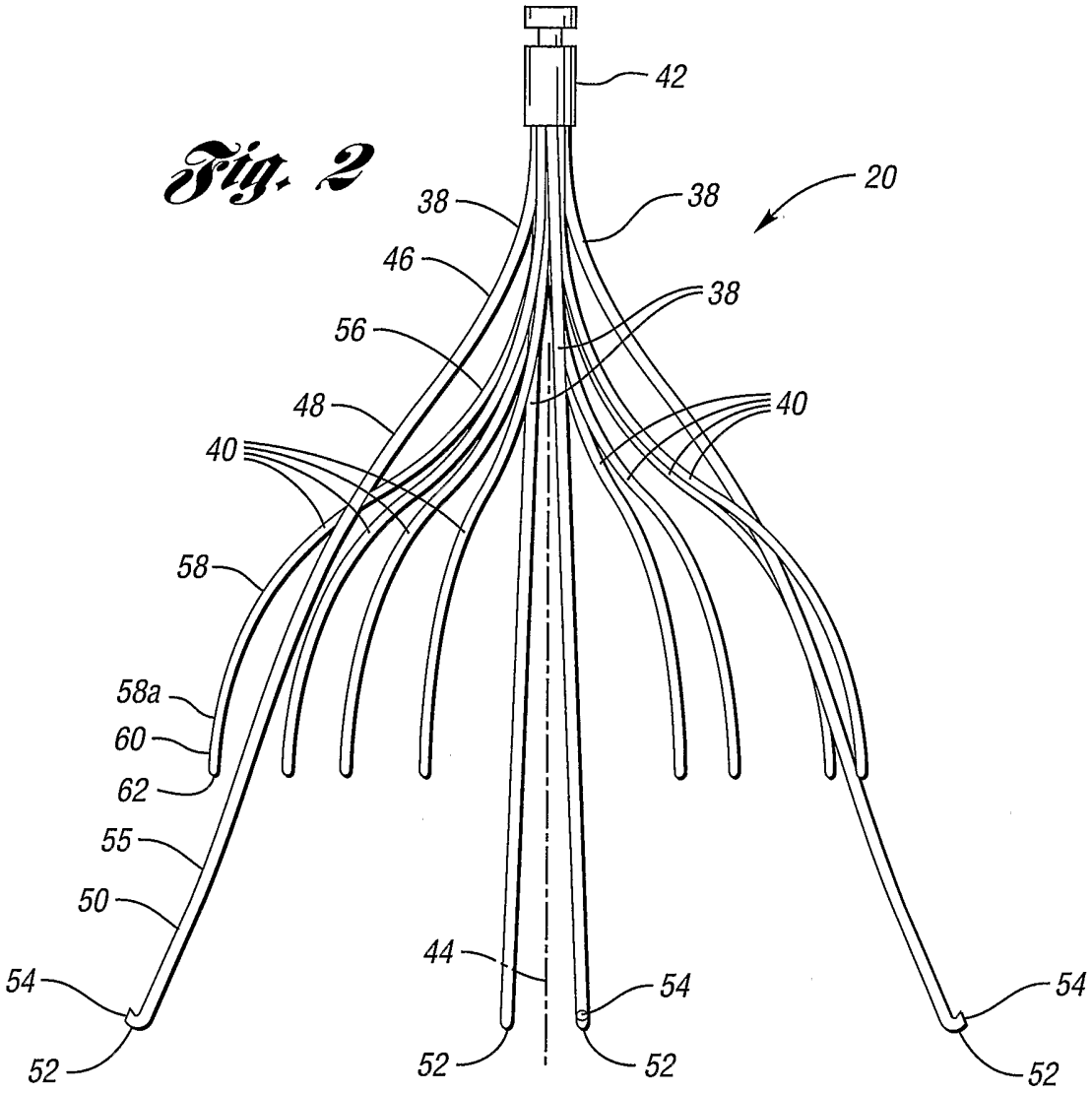


Fig. 1

Fig. 2



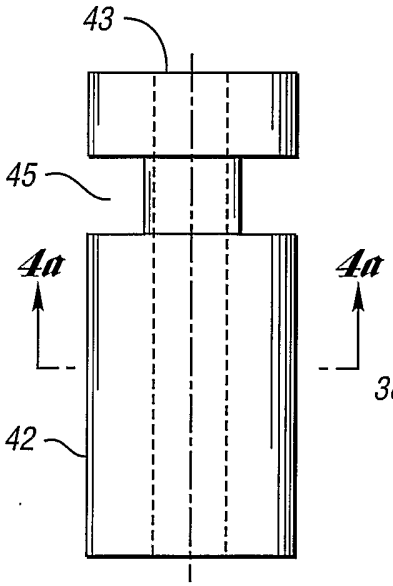


Fig. 3

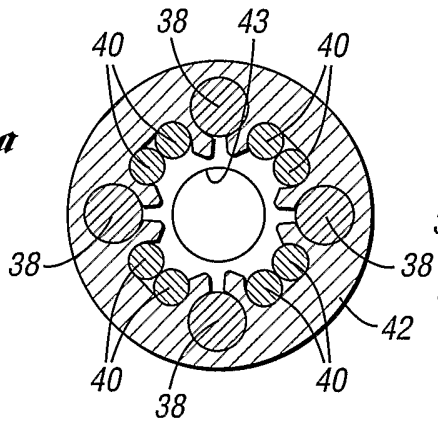


Fig. 4a

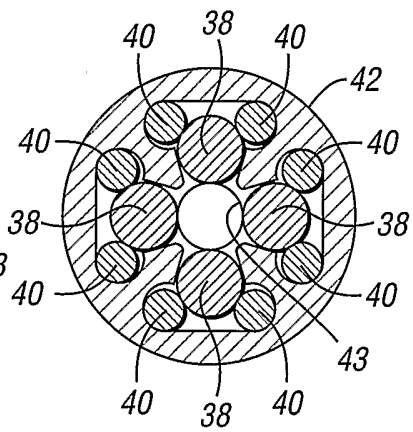


Fig. 4b

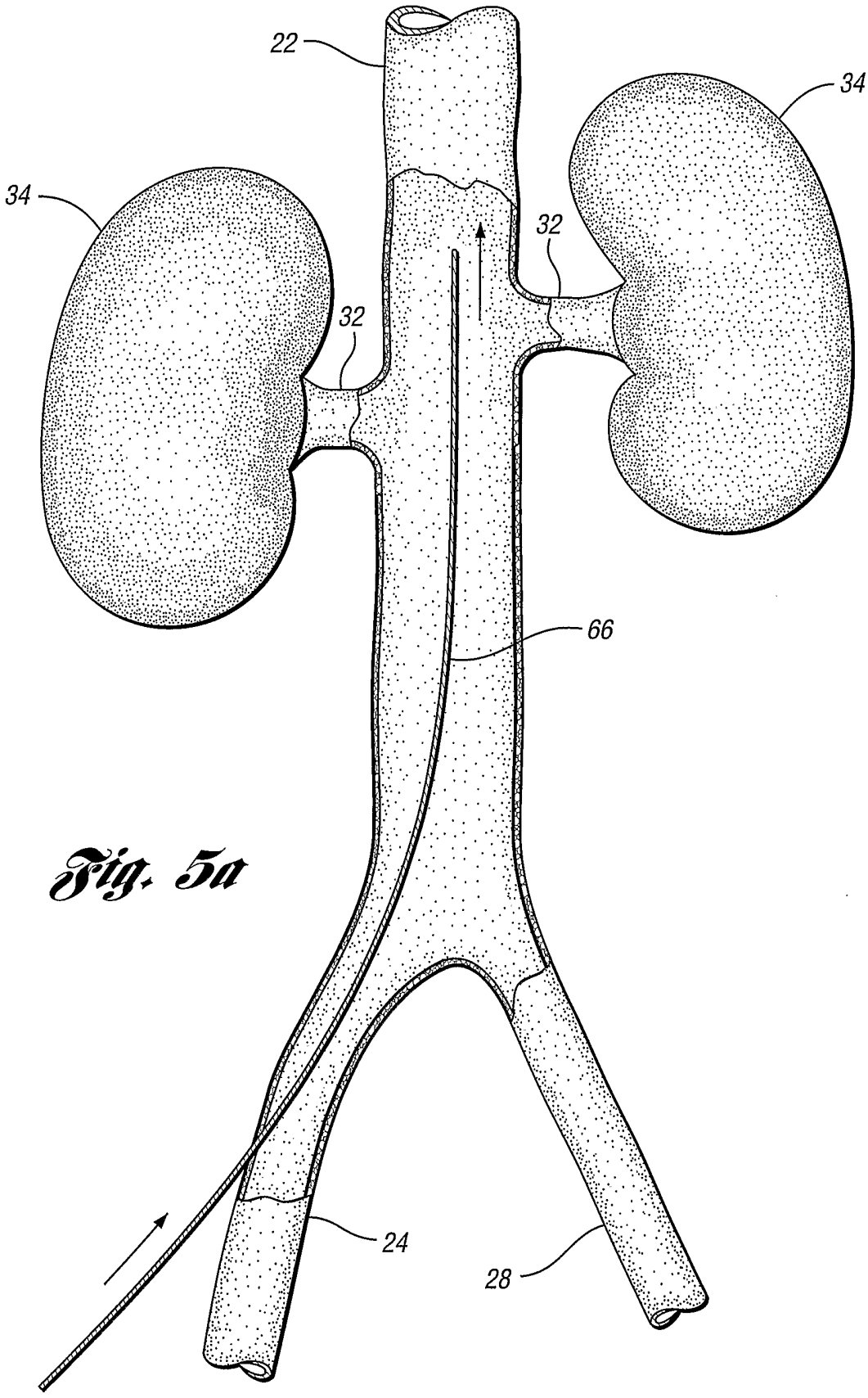


Fig. 5a

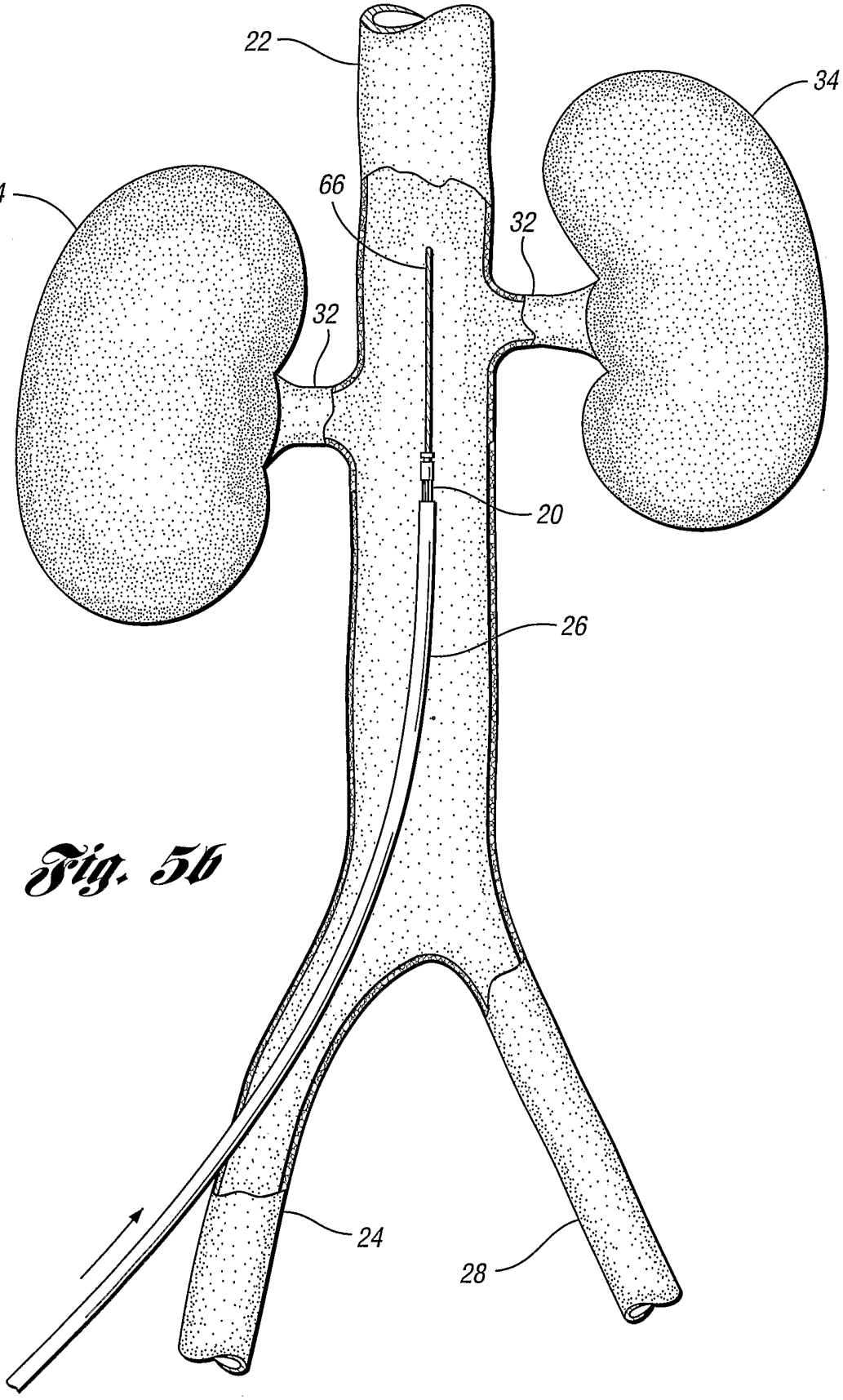


Fig. 5b

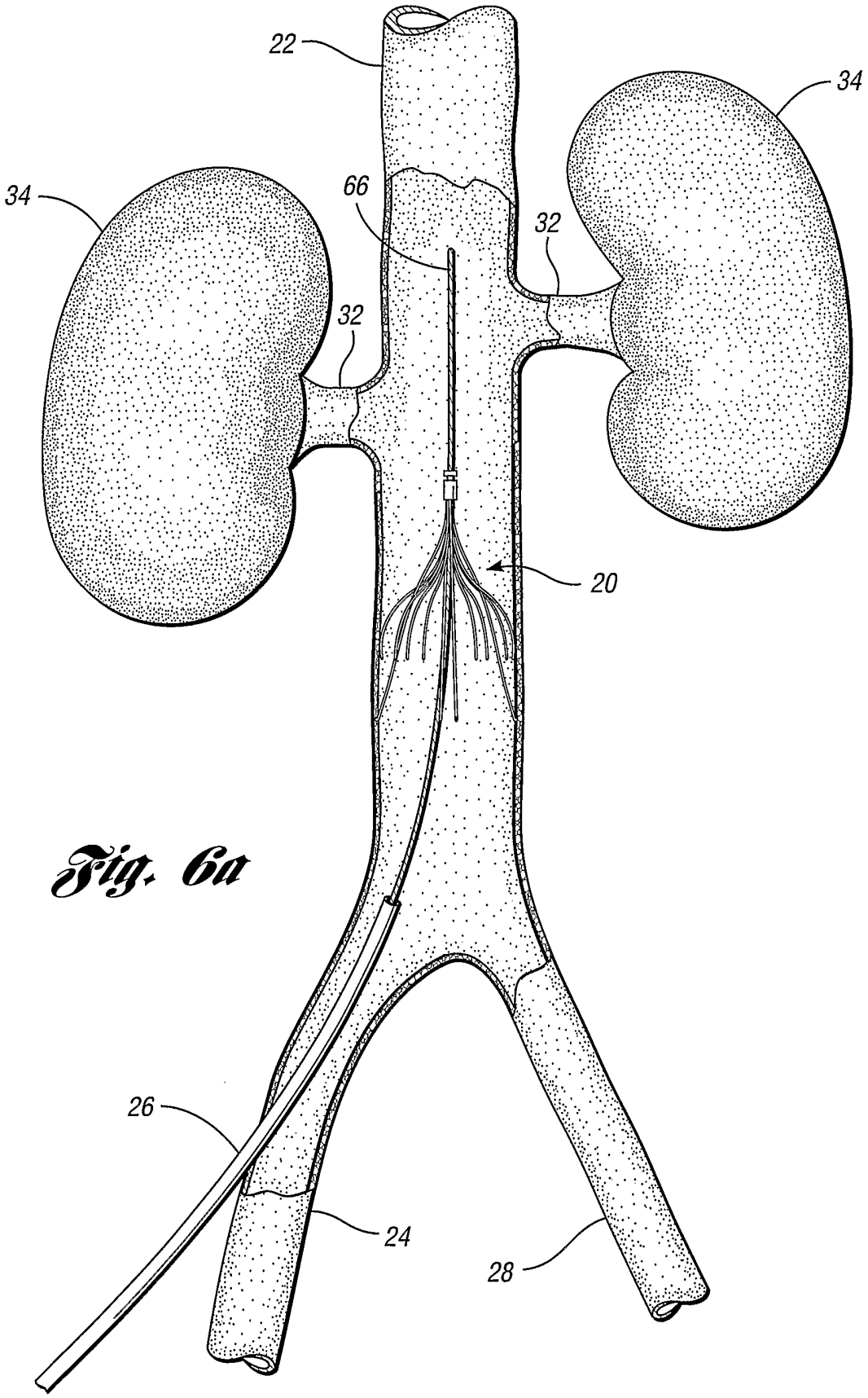


Fig. 6a

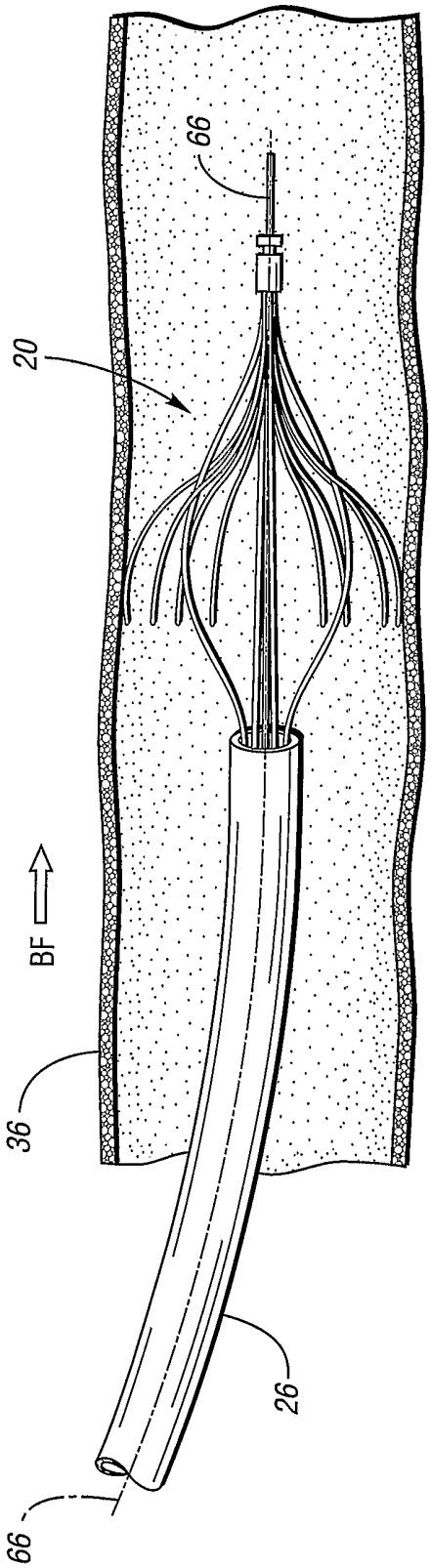


Fig. 5A

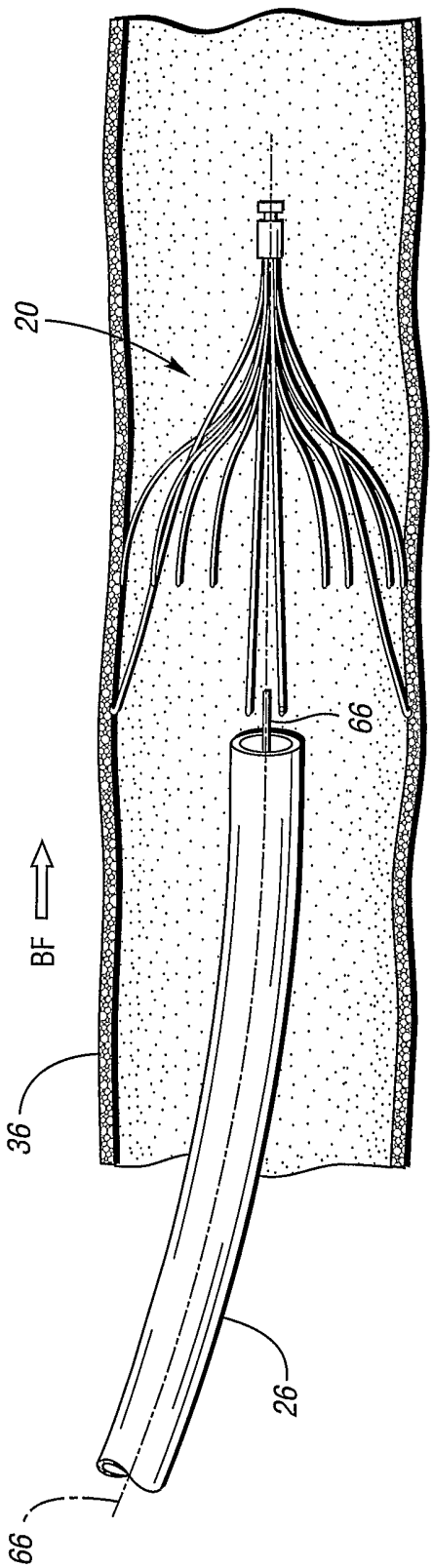


Fig. 6A

Fig. 7

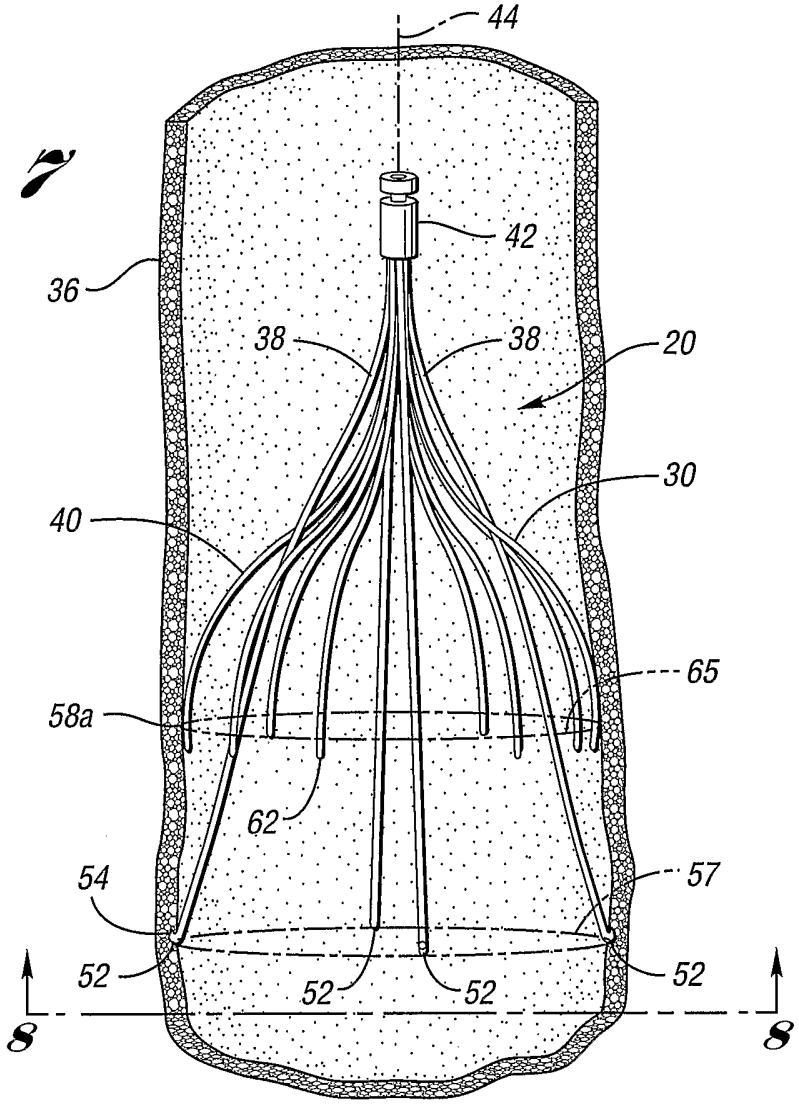

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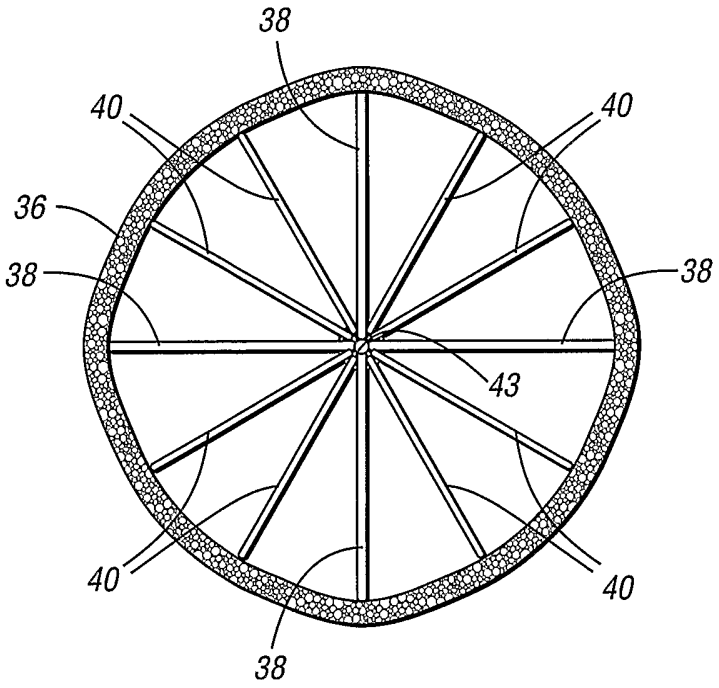
Fig. 8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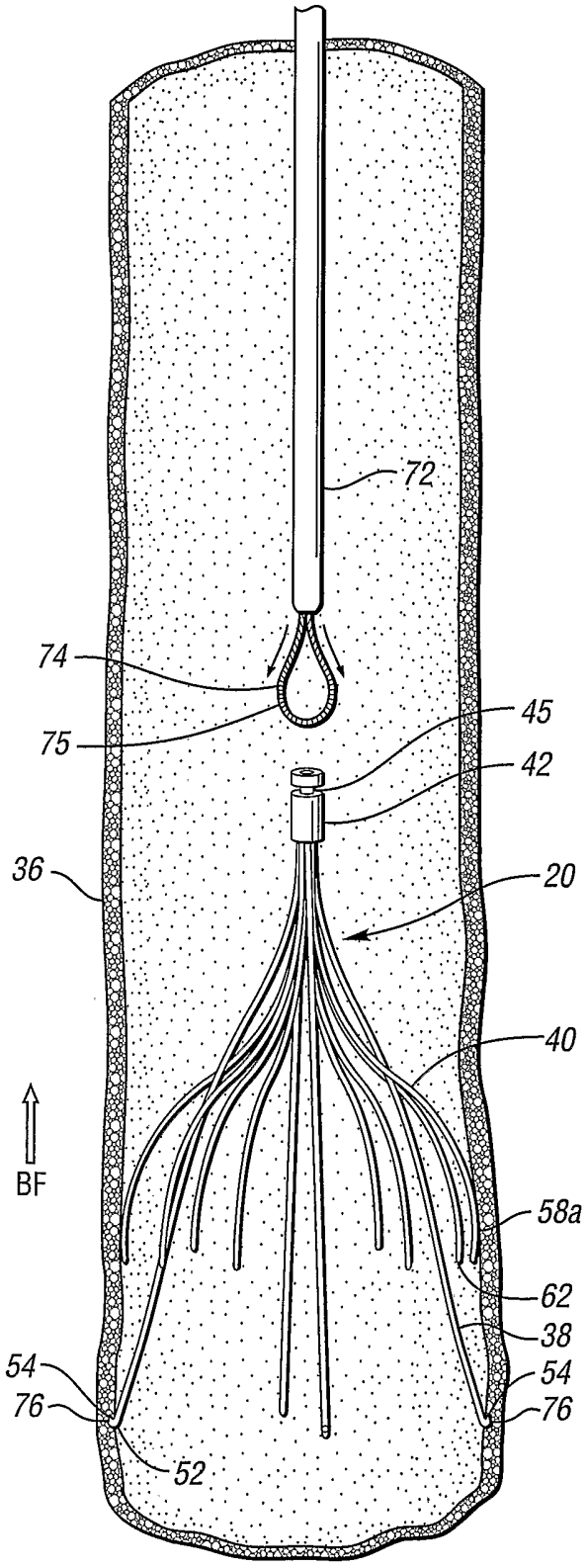
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Fig. 9a

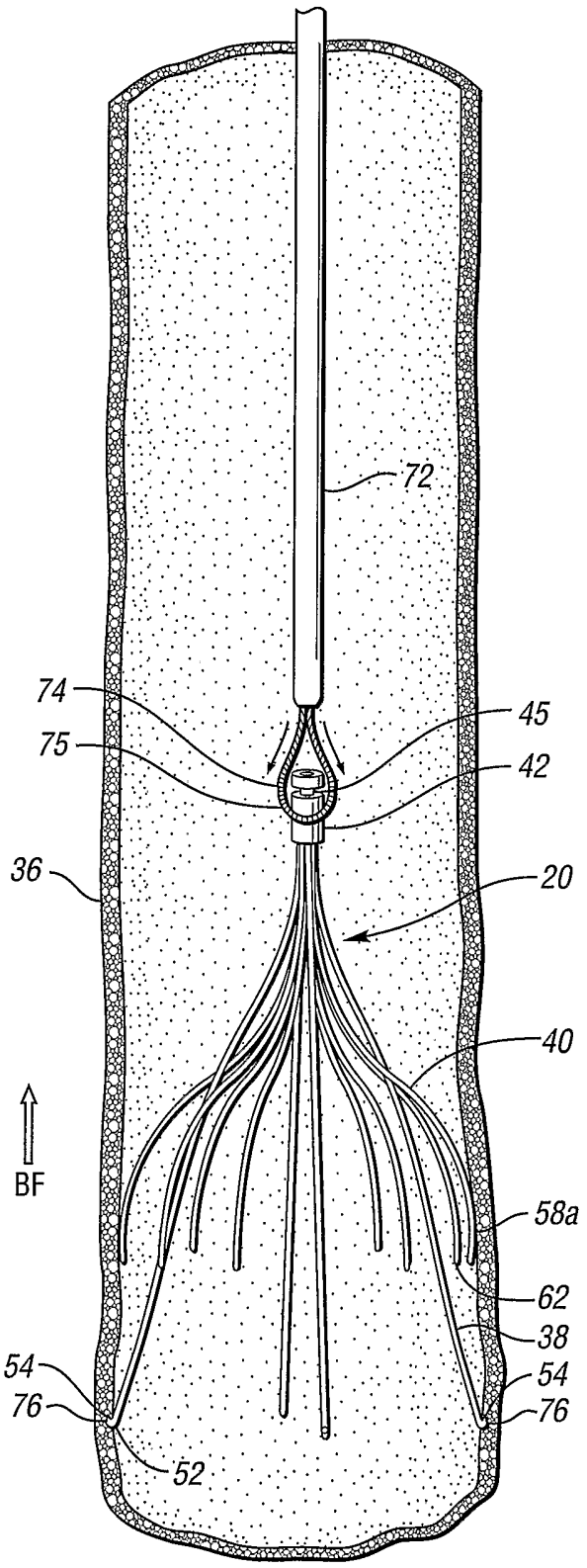
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Fig. 9b

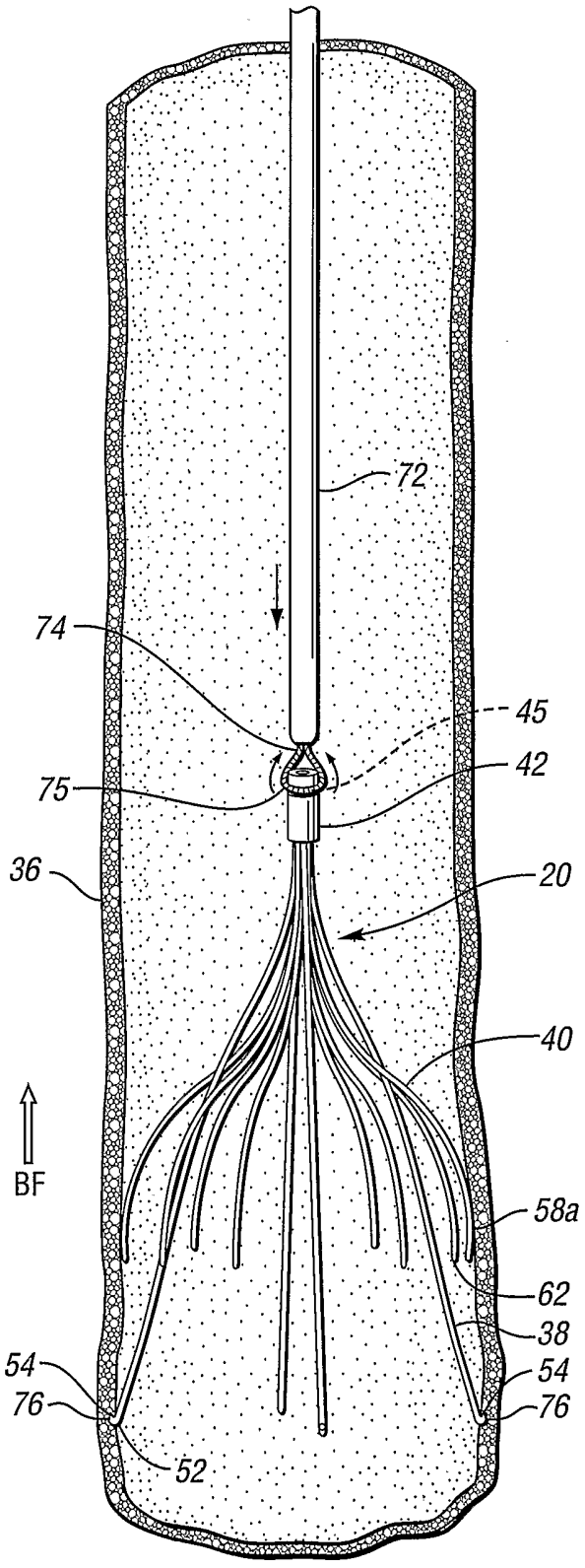

Fig. 9c

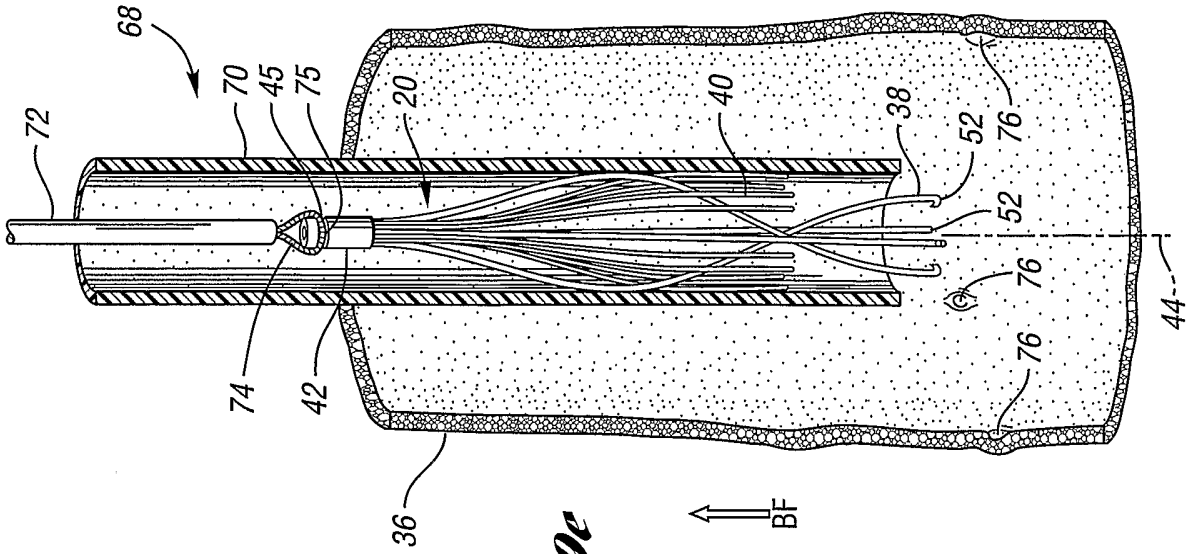
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Fig. 9c

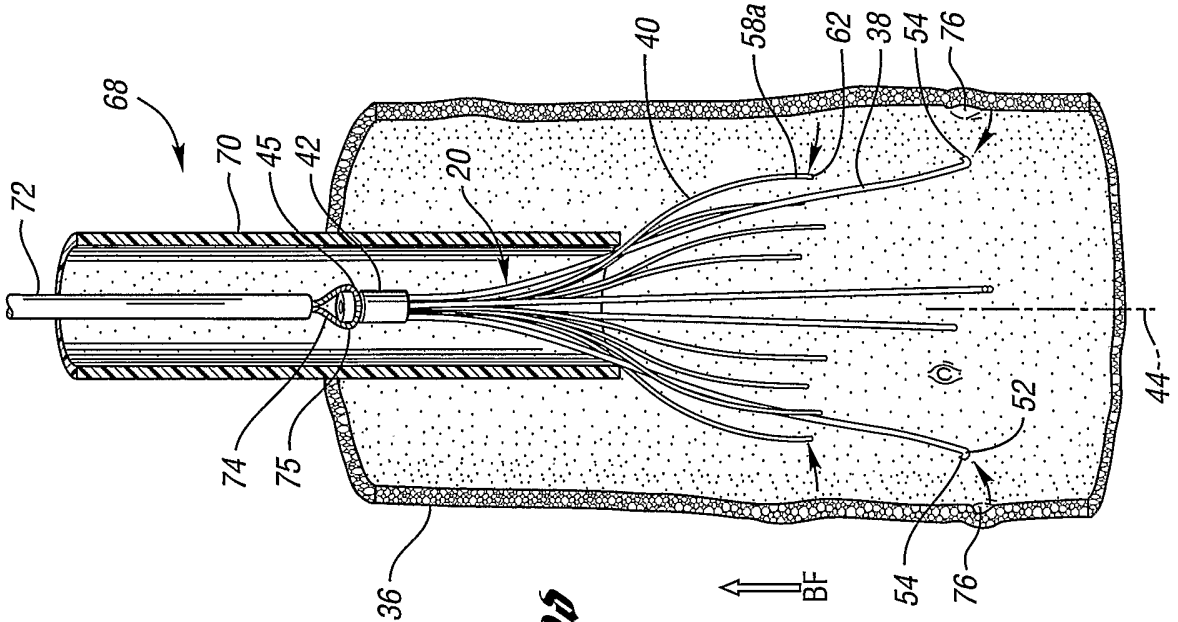
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Fig. 9b

INTERNATIONAL SEARCH REPORT

Ir tional application No
I /US2005/040299

A. CLASSIFICATION OF SUBJECT MATTER
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.
Y	US 6 007 558 A (RAVENSCROFT ET AL) 28 December 1999 (1999-12-28) column 3, line 51 - column 4, line 47 column 5, line 16 - line 19 figures 1,9	1-8, 10-13
Y	US 5 242 462 A (EL-NOUNOU ET AL) 7 September 1993 (1993-09-07) column 4, line 51 - line 57 column 5, line 24 - line 35 figure 8	1-8, 10-12
Y	US 5 147 379 A (SABBAGHIAN ET AL) 15 September 1992 (1992-09-15) column 4, line 36 - line 40	13
A	US 5 634 942 A (CHEVILLON ET AL) 3 June 1997 (1997-06-03) column 6, line 25 - line 48	1,8,11

☐ 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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 February 2006	06/03/2006

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Amaro, H

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

ernational application No.
PCT/US2005/040299

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. [X] Claims Nos.: 14-20
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
/US2005/040299

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