

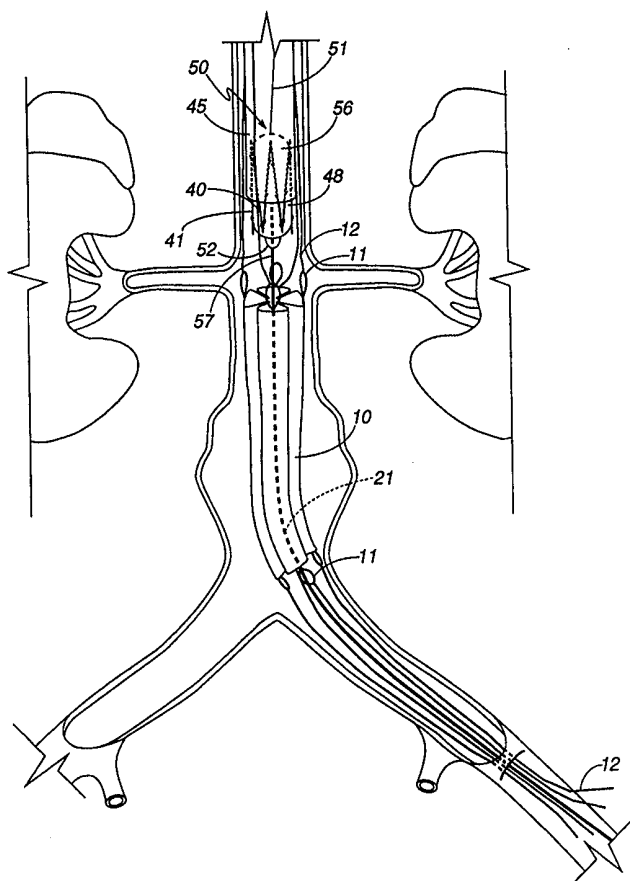


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(54) Title: MODULAR GRAFT ASSEMBLY**(57) Abstract**

An apparatus for engrafting a blood vessel comprising: a plurality of strings (12), a tubular graft (10) having a central lumen (25), wherein the plurality of strings (12) are removably attached to the tubular graft (10), the graft (10) is removably positioned at least partially within a restraining means, such as a sheath introducer (15), a guide wire (21) with an attachment means (22) for attachment of the plurality of strings (12), one or more stents (40) for deployment within the graft (10), and a means for deploying the stents (40) within the graft (10).



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MODULAR GRAFT ASSEMBLY

A. FIELD OF INVENTION

The present invention relates to a blood vessel engrafting system for repairing aneurysms and more particularly to a modular graft system for repairing aortic aneurysms by building a spring loaded graft within a blood vessel via percutaneous entry.

B. BACKGROUND OF THE INVENTION

An aortic aneurysm is a very common deteriorating disease typically manifested by a weakening and expansion of the aorta vessel wall at a region between the aorta-renal junction in the aorta-iliac junction. Aneurysm's affect the ability of the vessel lumen to conduct fluids, and may at times be life threatening, for instance, when rupture of the vessel wall occurs. A standard treatment for repairing an aneurysm is to surgically remove part or all of the aneurysm and implant a replacement prosthetic section into the vessel. Such surgery, however, is generally postponed until the aneurysm has grown to a diameter greater than five centimeters. With aneurysms over five centimeters in diameter, the risk of complications is greater than the risk inherent in surgical excision and grafting of the aneurysm. Consequently, aortic aneurysms measuring greater than five centimeters in diameter, and those showing rapid increase in size, are generally surgically engrafted as a matter of course, before rupture occurs.

The standard procedure for repairing an aortic aneurysm requires one or two days of preparing the large and small intestines prior to hospitalization. The operation itself generally takes one to three hours to perform, and necessitates several units of blood for transfusion. The patient commonly remains hospitalized for several days following surgery, and requires as much as three months recuperation time before returning to work.

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Moreover, there remains a significantly high rate of mortality and morbidity associated with the standard procedure. The mortality rate is as high as 8%, while the morbidity rate includes incident complications such as blood loss, respiratory tract infections, wound infections, graft infections, renal failure, and ischemia of the bleeding intestine. The mortality and morbidity rates for this type of major surgery are also often influenced by the fact that the typical aortic aneurysm patient is elderly and therefor less able to withstand major surgery, including anesthesia.

Other treatments for repairing an aneurysm involve deploying a graft device at the aneurysm site via a catheter traveling through a femoral artery. Conventional tubular aortic replacement sections, however, are generally considerably larger in diameter than the femoral artery and therefore cannot be inserted through the femoral artery lumen to the site of the aneurysm.

Even in the more advanced aortic graft assemblies which enable percutaneous deployment and placement of a spring loaded graft for a non-surgical correction of an aortic aneurysm, the required entry profiles require at least 10-12 FR. This is the case since these graft systems are comprised of graft material, two or more spring stents a balloon catheter, a sheath introducer, and plunger at a minimum, for deployment of the graft.

Thus, there exists a need for a treatment for aneurysms utilizing a system enabling deployment and placement of an aortic graft which is much smaller thus able to facilitate a much smaller entry profile.

C. SUMMARY OF THE INVENTION

The present invention is comprised of an apparatus for engrafting a blood vessel comprising: a plurality of strings, a tubular graft having a central lumen, wherein

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the plurality of strings are removably attached to the tubular graft, the graft is removably positioned at least partially within a restraining means, such as a sheath introducer, a guide wire with an attachment means
5 for attachment of the plurality of strings, one or more stents for deployment within the graft, and a means for deploying the stents within the graft.

D. BRIEF DESCRIPTION OF THE DRAWINGS

10 Figure 1A is a perspective view of the graft of the inventive assembly loaded within a sheath introducer;

Figure 1B is a perspective view of the graft of the inventive assembly loaded within a sheath introducer in a twisted position;

15 Figure 2A is a perspective view of the first embodiment of the guide wire of the present invention;

Figure 2B is a second embodiment of the guide wire of the present invention;

20 Figure 2C is a third embodiment of the guide wire of the present invention;

Figure 3A is a perspective view of the stent of the present invention;

Figure 3B is a perspective of the stent of the present invention;

25 Figure 4 is a perspective view of the guide wire of the present invention entering the brachial artery;

30 Figure 5 is a perspective view of the guide wire of the present invention passing between the brachial artery and the femoral artery and exiting the femoral artery;

Figure 6A is a perspective view of the first embodiment of the guide wire attached to the strings of the present invention;

35 Figure 6B is a perspective view of the second embodiment of the guide wire attached to the strings of the present invention;

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Figure 7 is a perspective view of the sheath introducer of the present invention and the graft exiting therefrom into the vessel in the region of the aneurysm;

5 Figure 8 is a perspective view of the graft of the present invention within the blood vessel and the stent deployment system being moved into position for stent deployment;

10 Figure 9 is a perspective view of a stent being deployed into the graft of the present invention;

Figure 10 is a perspective view of a stent being deployed into the graft of the present invention;

15 Figure 11 is a perspective view of the end cap of the present invention engaged with the graft, strings, and guide wire;

Figure 12 is a perspective view of the end cap of the present invention engaged with the graft, strings, and guide wire;

20 Figure 13 is a perspective view of the end cap of the present invention being removed from the graft;

Figure 14 is a perspective view of both end caps of the present invention engaged with the both graft ends, strings, and guide wire;

25 Figure 15 is a perspective view of both end caps of the present invention being removed from the graft.;

E. DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The nature and mode of operation of the present invention will now be more fully described in the following detailed description of a preferred embodiment and alternative embodiments to be read together with the accompanying drawing figures.

35 The term distal is used in this application. It refers to a position relative not to the heart, but the respective point of entry into the blood vessel. Furthermore, the terms proximal and proximate are used

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in this application. These terms refer to a position relative not to the heart, but to the respective point of entry. Thus, with respect to an apparatus, the end closer to the point of entry would be the proximate end, and the end farthest from the point of entry would be the distal end.

As shown in figure 1, the present invention is comprised of a graft 10, preferably Dacron, of a tubular shape when in an expanded position, and capable of being folded or twisted for loading into a sheath introducer 15. Graft 10 may have even end portions as shown in figures 1A, 1B, 6A, 6B, 7, 8, 9, and 10 or may have finger-like end portions as shown in the remaining graft drawings. Graft 10 is further comprised of a first end 16 and a second end 17, each end having a plurality of loops 11, preferably four loops on each side.

Sheath introducer 15 is comprised of a standard material such as plastic or any other substantially flexible material, and contains a distal end 18 and a proximal end 19 (not shown), each end containing an opening 20.

The present invention is further comprised of a plurality of strings 12 for temporary attachment to the loops 11 of graft 10. In particular, prior to loading of graft 10 into sheath introducer 15, strings 12 are temporarily attached to loops 11 by passing one end of each string 12 through a loop 11 pulling each end of each string upward and away from loops 11 such that a middle portion 13 of each string 12 is folded over each loop 11.

As displayed in figure 2a, the present invention is further comprised of a guide wire 21 for guiding string ends 14 from a point of entry 30 into the femoral artery 31 to a point of entry 32 in the brachial artery 33. Guide wire 21 is long enough to extend from point of entry 32 through point of entry 30 with plenty of room

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on each side for manipulation thereof. Guide wire 21 is comprised of a somewhat flexible material such as thin metal or plastic, having an attachment means 22 in a middle portion 23 thereof. In operation, string ends 14
5 are temporarily affixed to attachment means 22, preferably a ring, for passage from the femoral artery 31 to the brachial artery 33 and out guide wires' original point of entry 32.

Guide wire 21a is an alternative embodiment having
10 attachment means 22a at a distal end 23a thereof. Guide wire 24 is yet another embodiment and is comprised of a central lumen 25 in fluid communication with a tip balloon 26. In operation, tip balloon 26 is inflated within the second end 17 of graft 10 for temporary
15 attachment and passage from the femoral artery 31 through the point of entry of the brachial artery 32.

As shown in figures 3A, 3B, 8, 9, 10, the present invention is further comprised of a stent delivery system having one or more stents 40, a sheath introducer
20 45, and balloon catheter 50 and a plunger 60 (not shown).

A stent 40 is comprised of a wire formed in an endless series of straight sections joined by bends; a zig-zag configuration. Stent 40 is further comprised of
25 a plurality of spikes 41, for more securely affixing stent 40 within graft 10 and blood vessel 34. Spikes 41 line the outer surface of stent 40, or more particularly the surface of the stent which is in contact with graft 10 after deployment thereof. Spikes 41 are comprised of
30 a rigid material, such as metal or plastic, and are preferably cone shaped. Furthermore, stent 40 is comprised of a material such as metal which is deformable and capable of returning to its original shape; preferably a shape memory alloy having stress-
35 induced martensite characteristics, such as nitinol.

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Other materials may also be used such as stainless steel.

In operation, stent 40 is deformed either by inducing stress, or in the case of a shape memory alloy not having stress induced martensite characteristics, reducing temperature sufficiently to reach the temperature threshold for the metal's martensitic phase. After deformation of stent 40, it is loaded within sheath introducer 45. Sheath introducer 45 is of standard material, and is comprised of a distal end 46 and a proximal end (not shown), each end having an opening 48.

Stent 40 may also be passed over a balloon catheter 50 prior to deformation and pre-loading within sheath introducer 45, then loaded with balloon catheter 50. Balloon catheter 50 is comprised of a catheter 51 having a distal end 52 and a proximal end (not shown). In addition, catheter 51 is comprised of an opening at proximal end (not shown) and an opening into balloon (not shown) which is integral with distal end 52. Balloon catheter 50 is further comprised of an opening 57 at distal end 52 for passage of catheter 50 over guide wire 21.

Stent delivery system is further comprised of standard plunger having a central lumen for passage over catheter 51, and a head for contact with stent 40 at the head's substantially flat surface during stent deployment. Head is comprised of a standard substantially rigid material such as plastic or metal located at the forward most part of plunger for pushing force during deployment of stent 40.

In operation, the present invention is comprised of the following steps. First, strings 12 are temporarily attached to loops 11 of graft 10 by passing ends 14 through loops 11 and folding strings 12 over at middle portion 13 such that the string ends 14 are extending

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away from graft 10 at the same length. Graft 10 is then loaded into sheath introducer 15 such that string ends 14 are extending outward from each sheath opening 20. For loading of graft 10 into sheath introducer 15, graft
5 10 may be either twisted or folded so that the entry diameter is small.

Next, as depicted in Figures 4 and 5, guide wire 51 is inserted into the brachial artery 33 at point of entry 32, passed through the descending aorta 34, into
10 the femoral artery 31, and passed out of the vessel at point of entry 30. Guide wire 21 is then pulled from point of entry 30 until attachment means 22 emerges from the femoral artery 31.

String ends 14 at second end 17 of graft 10 are
15 attached temporarily to attachment means 22 of guide wire 21. Distal end 27 of guide wire 21 is passed through opening 20 of sheath introducer and through the central lumen (not shown) of graft 10. By virtue of the length of guide wire 21, distal end 27 will extend
20 through graft 10 and exit at the proximal opening 20a of sheath introducer 15.

After string ends 14 have been temporarily attached to attachment means 22, guide wire 21 may be withdrawn from point of entry 32 until attachment means 22 and
25 string ends 14 have been withdrawn completely from vessel 33 and may be manipulated by hand. Guide wire 21 may then be cut at a point distal attachment means 22 so that guide wire 21 may be used to guide stent deployment apparatus to the appropriate point in vessel 34.

30 String ends 14 may then be used to assist movement of sheath introducer 15 through the vessels to a point within vessel 34 of the aneurysm site using an image amplifier. The position of graft 10 can be verified, and sheath introducer 15 may then be withdrawn from
35 vessel, thus deploying graft 10 within vessel 34.

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String ends 14 may be used to hold graft 10 in position from both points of entry 32 and 30.

With graft 10 in position, stent deployment apparatus may be inserted into brachial artery 33, passed over guide wire 21 until its distal end 46 is within second end 17 of graft 10. At the appropriate position, sheath introducer 45 may be withdrawn, while at the same time applying pushing pressure to plunger for deployment of stent 40 within second end 17 of graft 10. After stent 40 is deployed and expanded within graft 10, balloon 56 of balloon catheter 50 may be expanded to secure the position of stent 40 within graft 10 and firmly affix spikes 41 within both graft 10 and vessel 34. After position of stent 40 is secure, balloon 56 of balloon catheter 50 may be deflated and the deployment apparatus removed from the vessel.

With guide wire 21 still in position, additional stents 40 may be deployed in the same manner within graft 10 until graft 10 is sufficiently secured to vessel wall 34. It is generally necessary to deploy at least two stents 40 within graft 10; one on each side of aneurysm 8. It is also valuable to deploy a stent into the middle of graft 10 to support the lumen thereof. If sufficient space is available for affixing stents 40 to graft 10 and vessel wall 34, three or more stent 40 may be used to secure graft 10 thereto. Since guide wire 21 extends from point of entry 30 to point of entry 32, the stent deployment apparatus may be used from either point of entry to deploy stents 40 within graft 10.

After stents 40 have been deployed within graft 10, and the stent deployment apparatus has been removed from the vessel, strings 12 may be removed by pulling one end 14 of each string until its opposing end is fully withdrawn from the vessel.

Entry sites may then be attended.

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As shown in Figures 11-15, an alternative embodiment provides an even smaller entry profile. End caps 70 may be used in place of sheath introducer 15 for restraining graft 10 during deployment thereof. Prior to insertion of graft 10 into a vessel, graft 10 is
5 twisted and each end is placed within an end cap 70.

End caps 70 are preferably comprised of silicon, and are of a cone shape with an opening 71 at the tip 72 thereof. Opening 71 enables end cap 70 to pass over
10 guide wire 21 through vessels. Opening 71 further enables passage of strings 12 through attachment means 22. In addition, end cap 70 is comprised of a cap ring 73 to facilitate the temporary attachment of string 12a thereto, just as strings 12 are attached to graft loops
15 11, and for the removal of end cap 70 after successful positioning of graft 10. After temporary attachment of string 12a to cap ring 73, string ends 14a are attached to attachment means 22 of guide wire 21, along with string ends 14, for passage through the vessels.

20 In operation after graft ends are loaded into end caps 70, and guide wire 21 is withdrawn sufficiently such that string ends 14 and 14a are removed from vessel at initial point of entry 30 of guide wire 21, graft 10 is inserted into vessel over guide wire 21, and pulled
25 through vessel to the aneurysm site by string ends 14. Care must be taken, however, not to prematurely tug on string ends 14a or end cap 70 will be prematurely removed from graft 10.

Graft 10 is pulled into the position for deployment
30 and verified with an image amplifier. When positioned, string ends 14a are pulled to remove end caps 70 from each side of graft 10. By continuing to pull on string ends 14a, end caps 70 may be removed from the vessels.

Stent delivery apparatus may then be used as
35 described hereinabove to deploy stents 40 within graft 10.

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F. CLAIMS

What is claimed is:

1. An apparatus for engrafting a blood vessel comprising:
 - 5 a plurality of strings;
 - a tubular graft having a central lumen; said plurality of strings removably attached to said tubular graft;
 - said graft removably positioned at least partially
 - 10 with a restraining means;
 - a guide wire having an attachment means for attachment of said plurality of strings;
 - one or more stents for deployment within said graft;
 - 15 a means for deploying said stents within said graft.
2. An apparatus according to Claim 1 wherein said restraining means is a sheath introducer.
- 20 3. An apparatus according to Claim 1 wherein said restraining means is an end cap.
4. An apparatus according to Claim 3 wherein said
- 25 end cap is cone shaped.
5. An apparatus according to Claim 3 wherein said end cap is comprised of a cap ring.
- 30 6. An apparatus according to Claim 1 wherein said graft further comprises a first end having a means for receiving said plurality of strings.
7. An apparatus according to Claim 1 wherein said
- 35 means for deploying said stents within said graft is

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comprised of a catheter and a plunger movably positioned within a lumen of said catheter.

8. An apparatus of Claim 1 further comprising an
5 entry sheath for maintaining the patency of a point of entry into a blood vessel.

9. An apparatus according to Claim 1 wherein said
guide wire is comprised of a middle portion, and said
10 attachment means is comprised of a ring located at said middle portion of said guide wire.

10. An apparatus according to Claim 1 wherein said
guide wire is comprised of an attachment end and said
15 attachment means is a ring positioned at said attachment end.

11. An apparatus according to Claim 1 wherein said
guide wire is less than .38 millimeters in diameter.
20

12. An apparatus according to Claim 1 wherein said
attachment means is comprised of a balloon at an
attachment end of said guide wire, wherein said balloon
is in fluid communication with a central lumen of said
25 guide wire.

13. An apparatus according to Claim 1 wherein said
tubular graft is comprised of one or more graft loops.

14. An apparatus according to Claim 13 wherein
30 said graft loops are positioned at a first end of said graft.

15. A method for engrafting a blood vessel
35 comprising the following steps:

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- a. preloading a graft within a sheath introducer;
- b. temporarily attaching a plurality of strings to said graft;
- 5 c. inserting arterial sheaths into the brachial and femoral arteries percutaneously;
- d. passing a guide wire into the brachial artery under an image amplifier;
- e. retrieving a first end of said guide wire
10 from the groin and attaching each end of said plurality of strings to the said guide wire;
- f. pulling said guide wire into said femoral artery and withdrawing said guide wire from the brachial artery;
- 15 g. removing said strings from said guide wire;
- h. inserting said sheath introducer into femoral arterial sheath and passing said sheath introducer to the position within the aorta where
20 deployment will take place;
- i. holding said plurality of string ends in position while withdrawing sheath introducer from the vessel thus holding graft in position within said blood vessel;
- 25 j. passing a preloaded stent catheter over said guide wire into a lumen of said graft;
- k. deploying a stent within said graft;
- l. withdrawing said stent catheter from said vessel and deploying another stent within said graft by
30 the method of step k;
- m. removing said guide wire, said stent catheter, said brachial arterial sheath, and said femoral arterial sheath from the vessel and attending to entry sites.

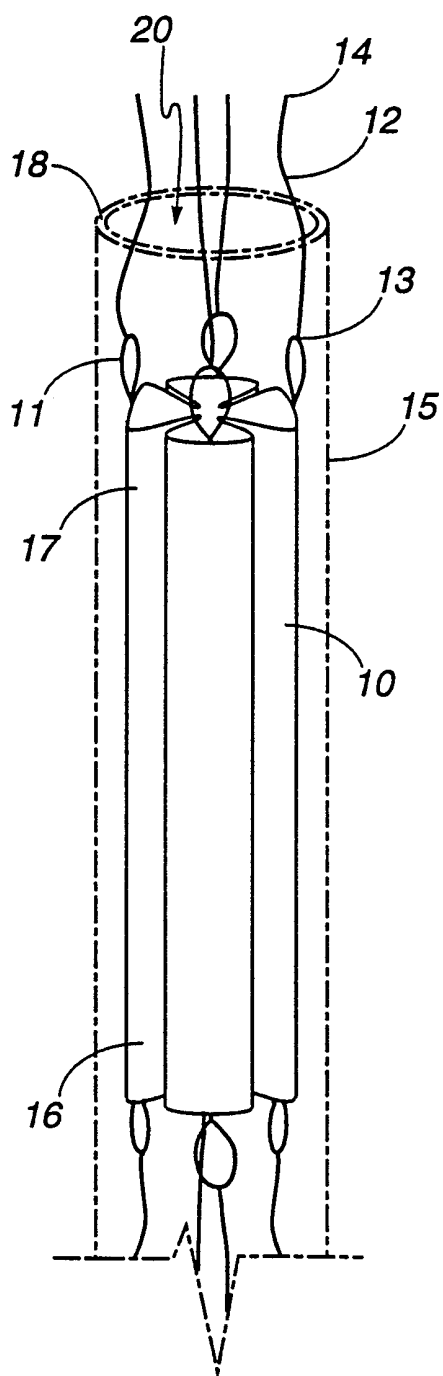


FIG. 1A

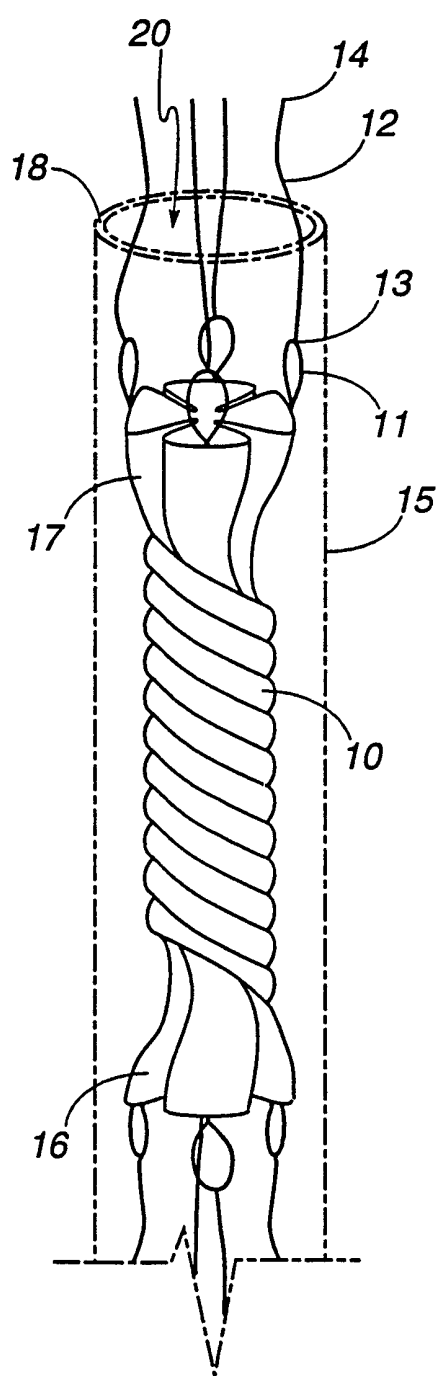


FIG. 1B

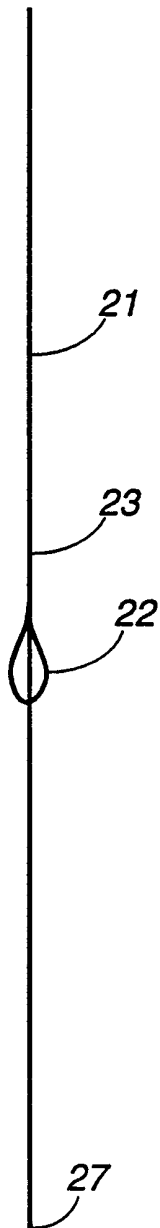


FIG. 2A



FIG. 2B

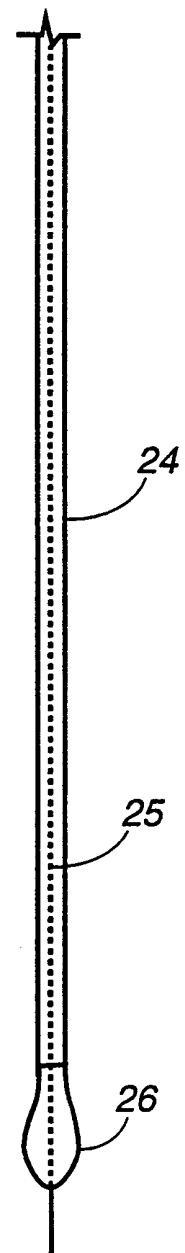


FIG. 2C

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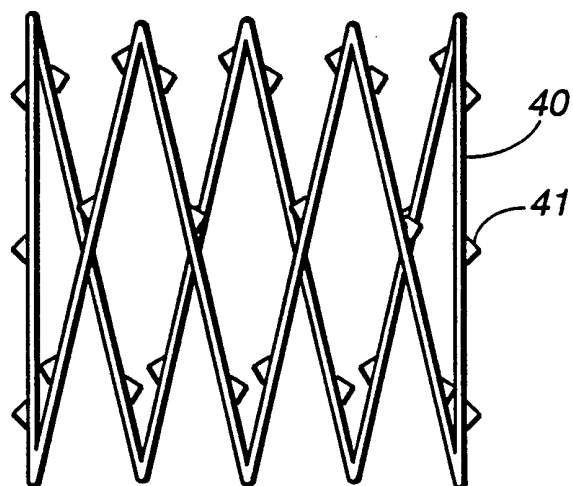


FIG. 3A

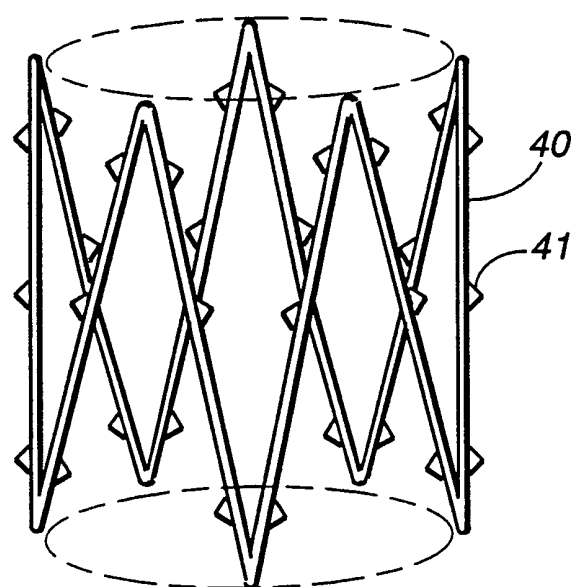


FIG. 3B

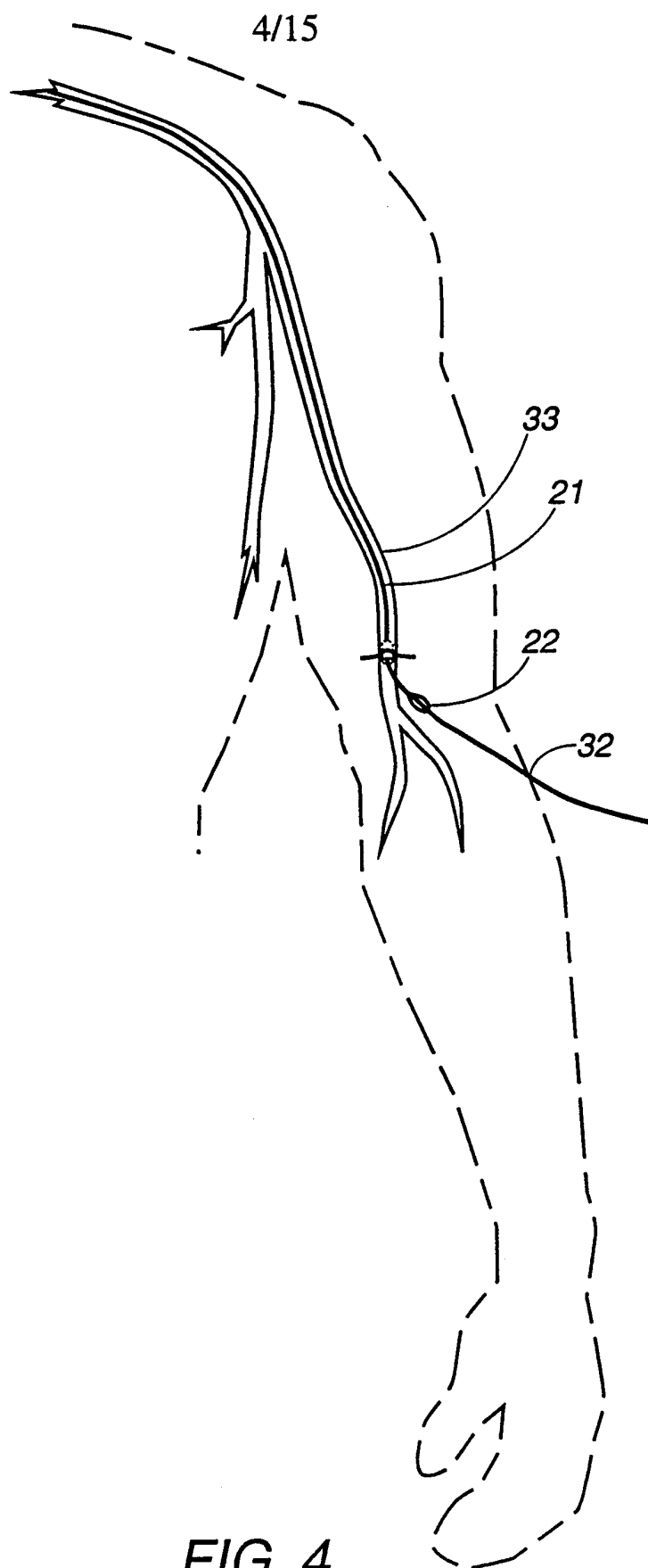


FIG. 4

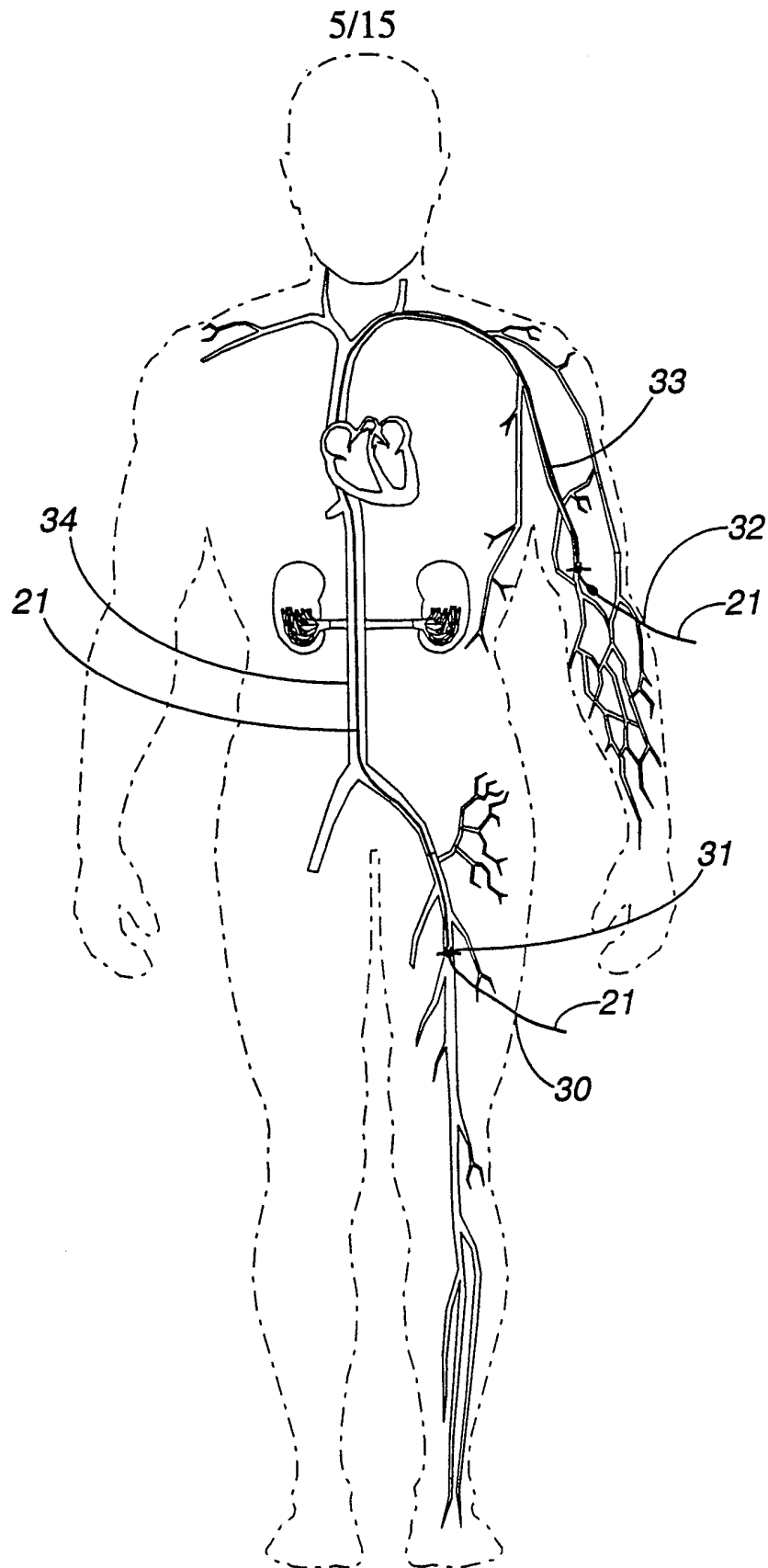


FIG. 5

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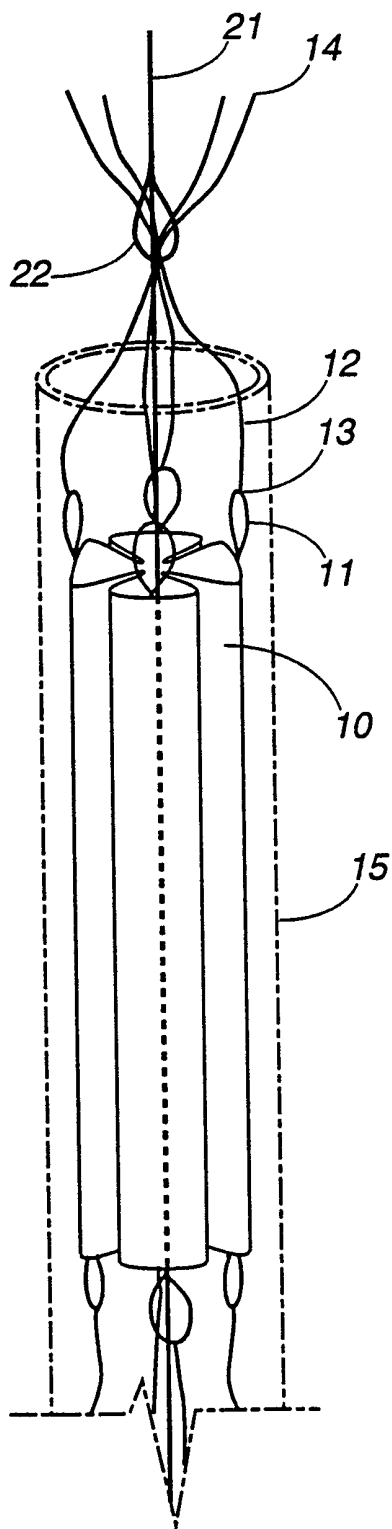


FIG. 6A

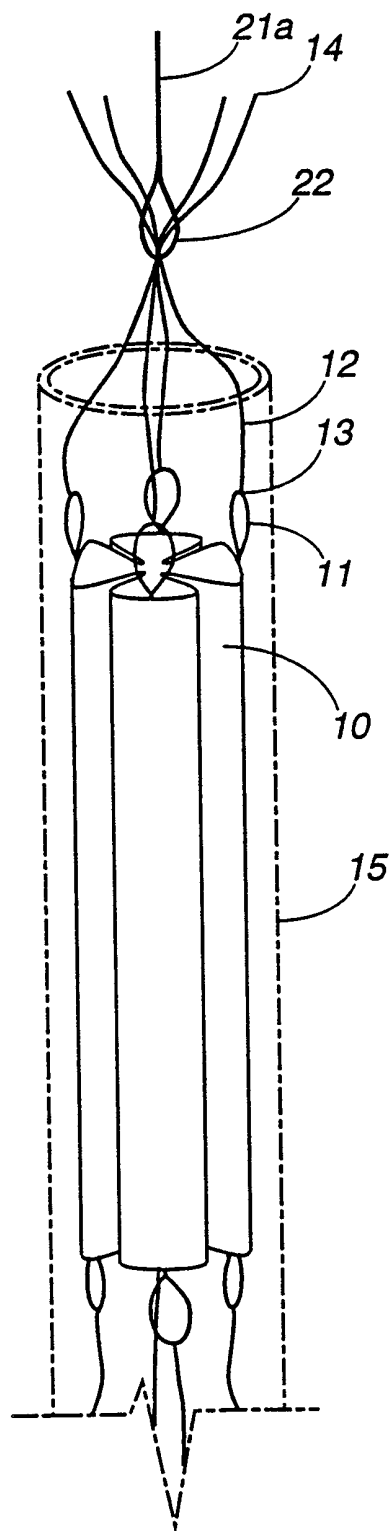
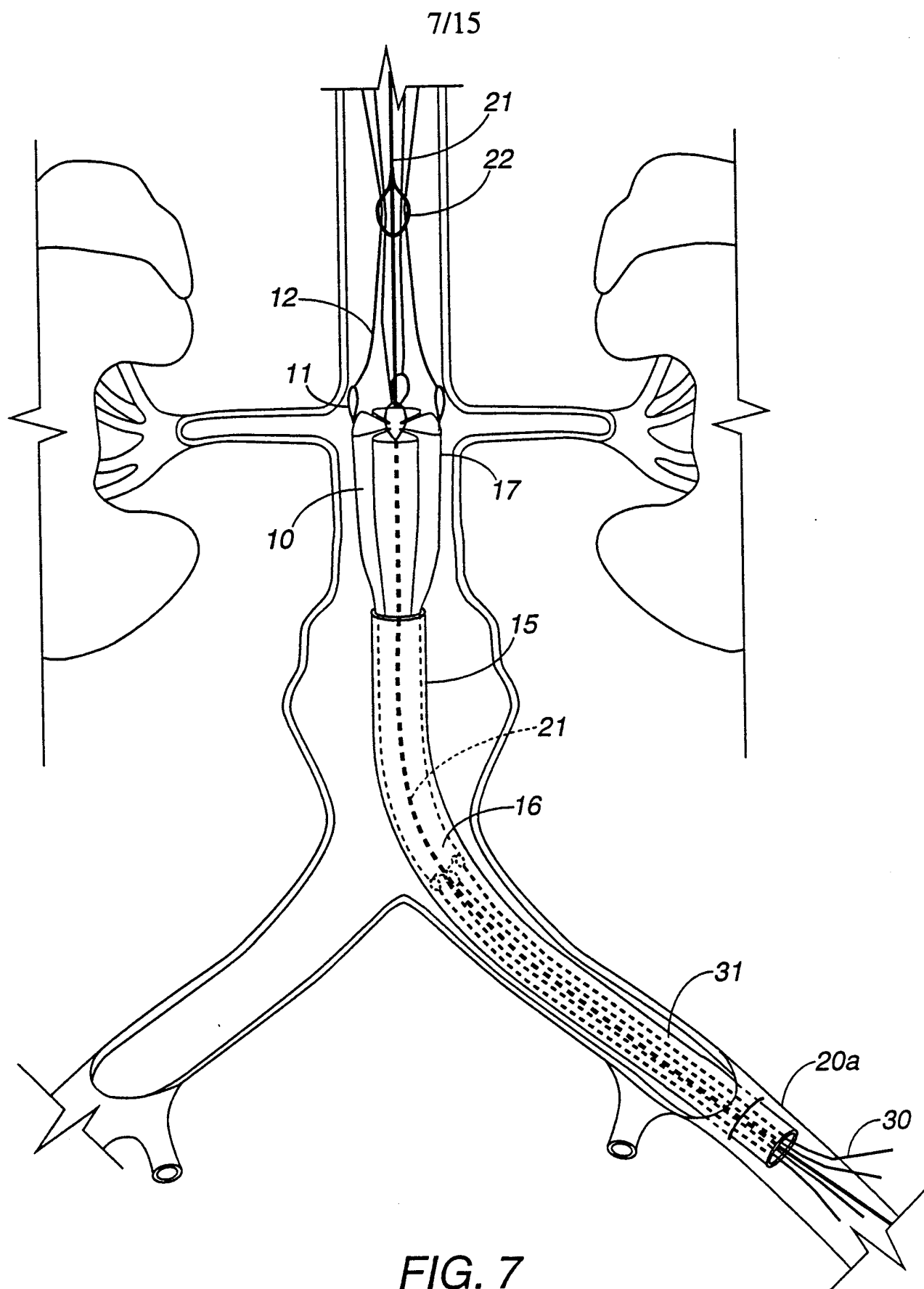
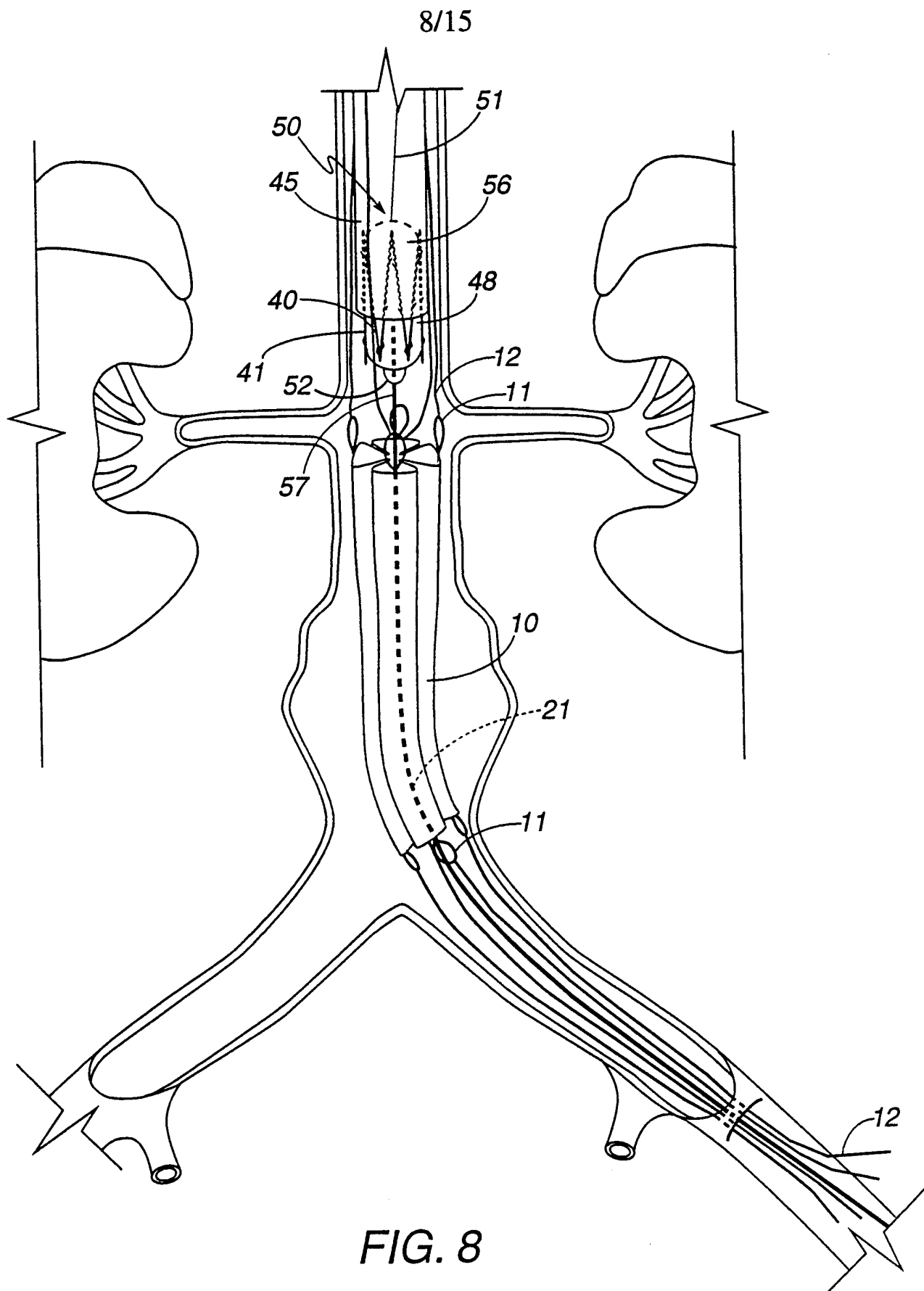
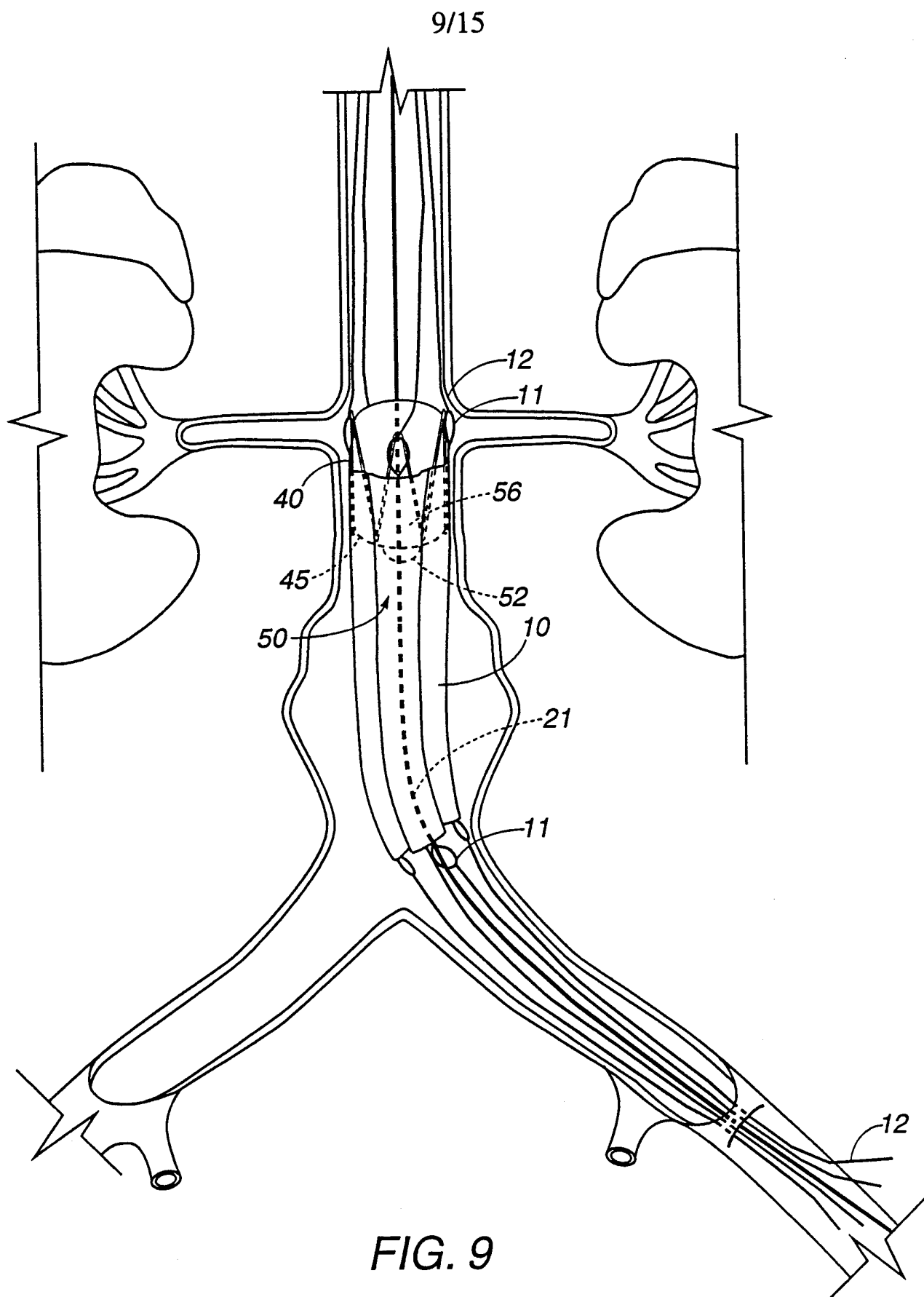


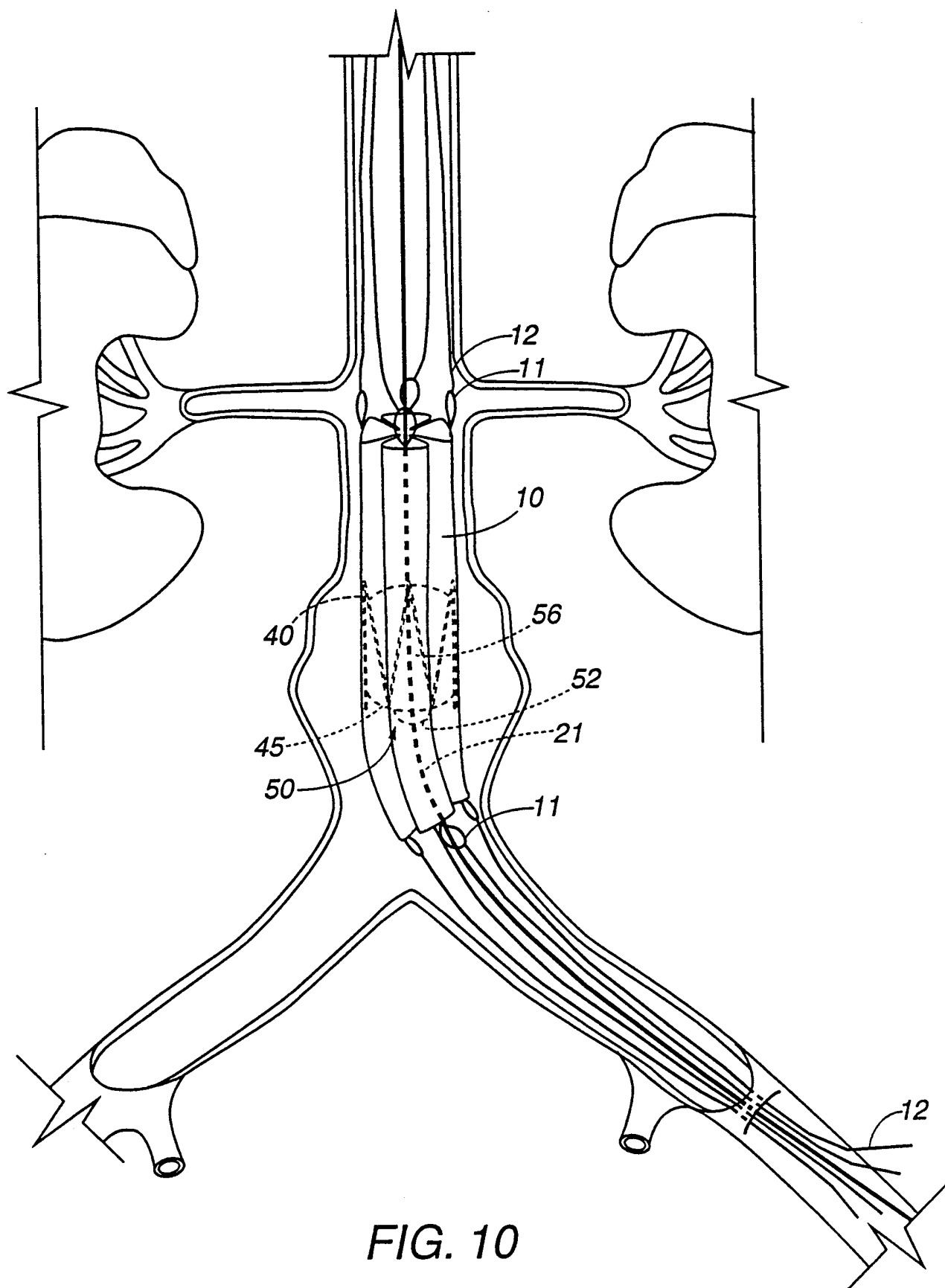
FIG. 6B



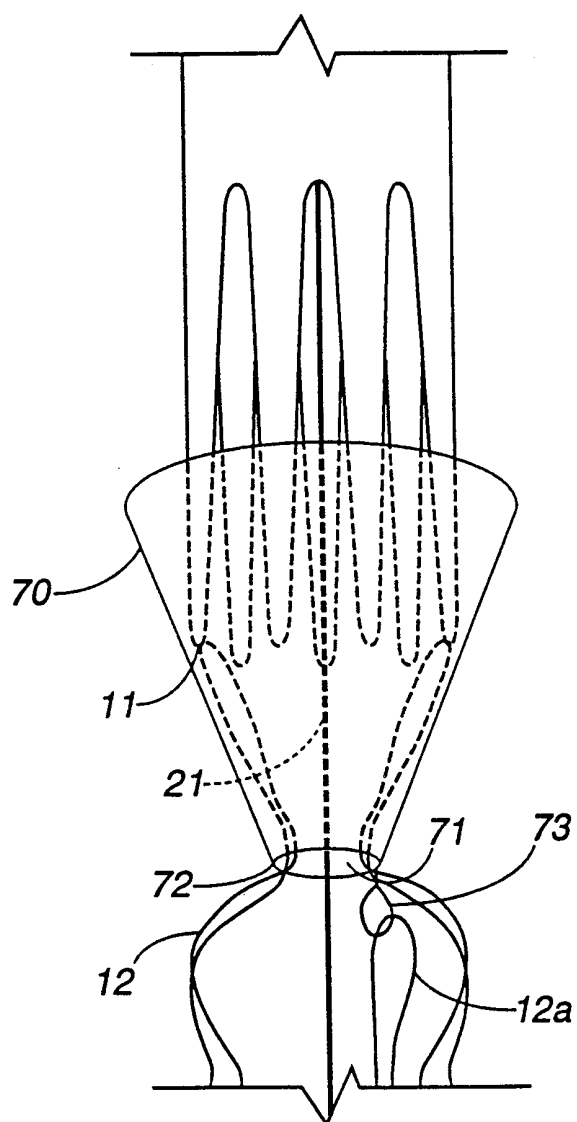




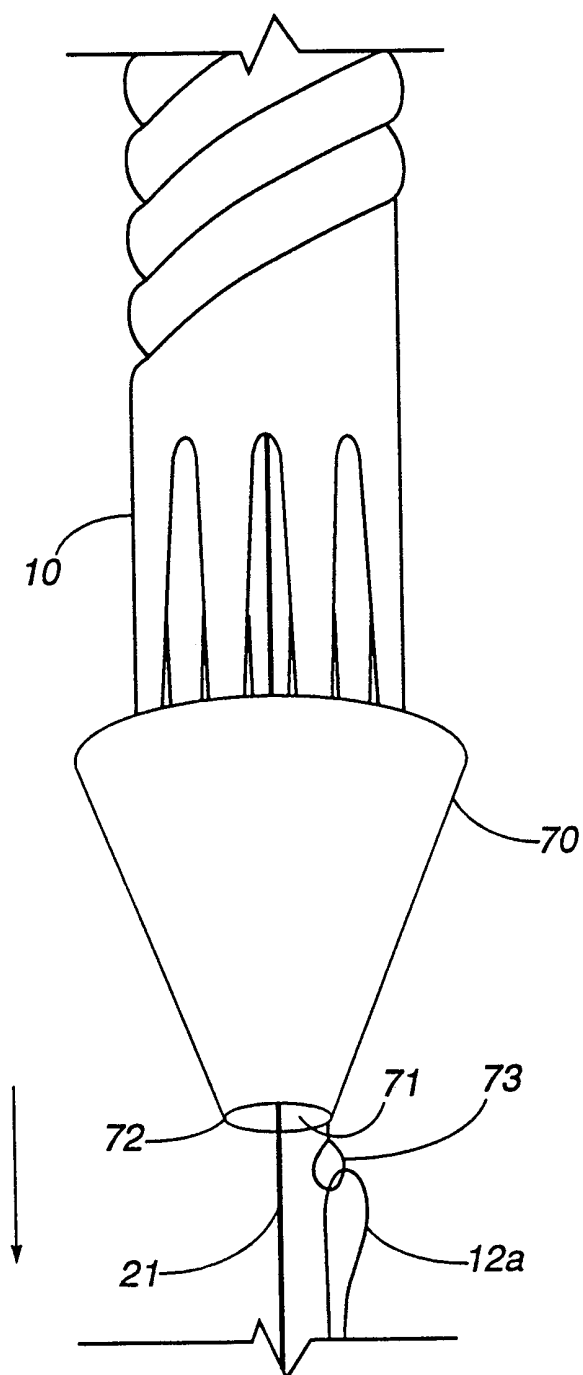
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**FIG. 11**

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*FIG. 12*

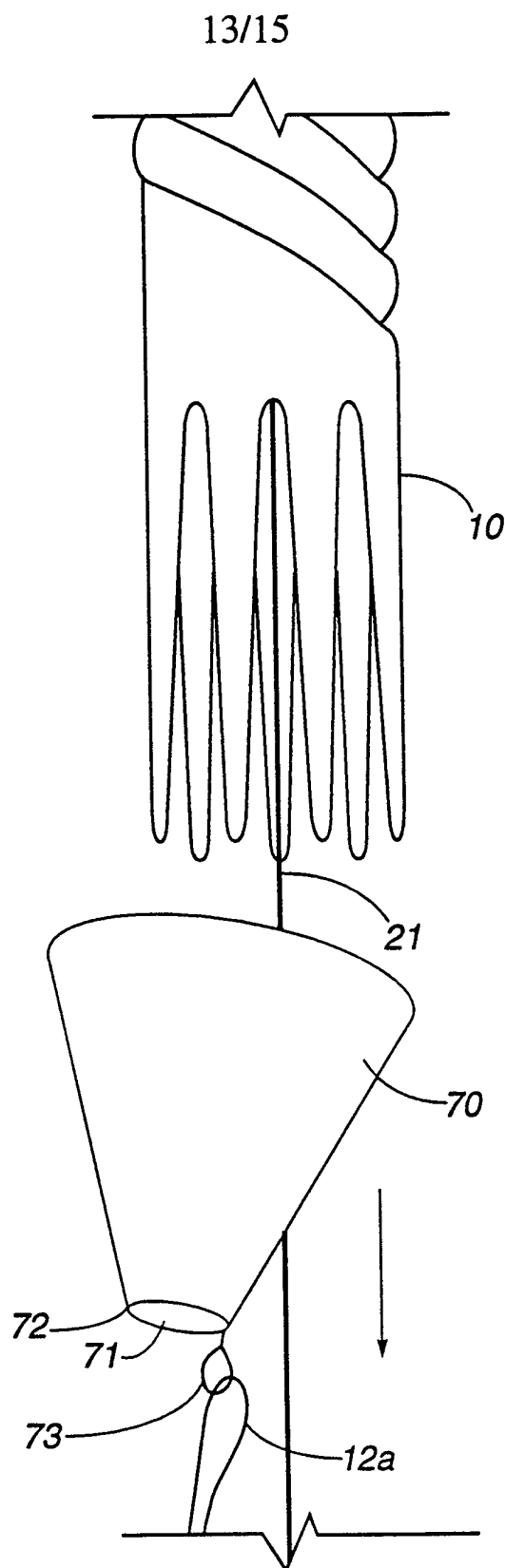
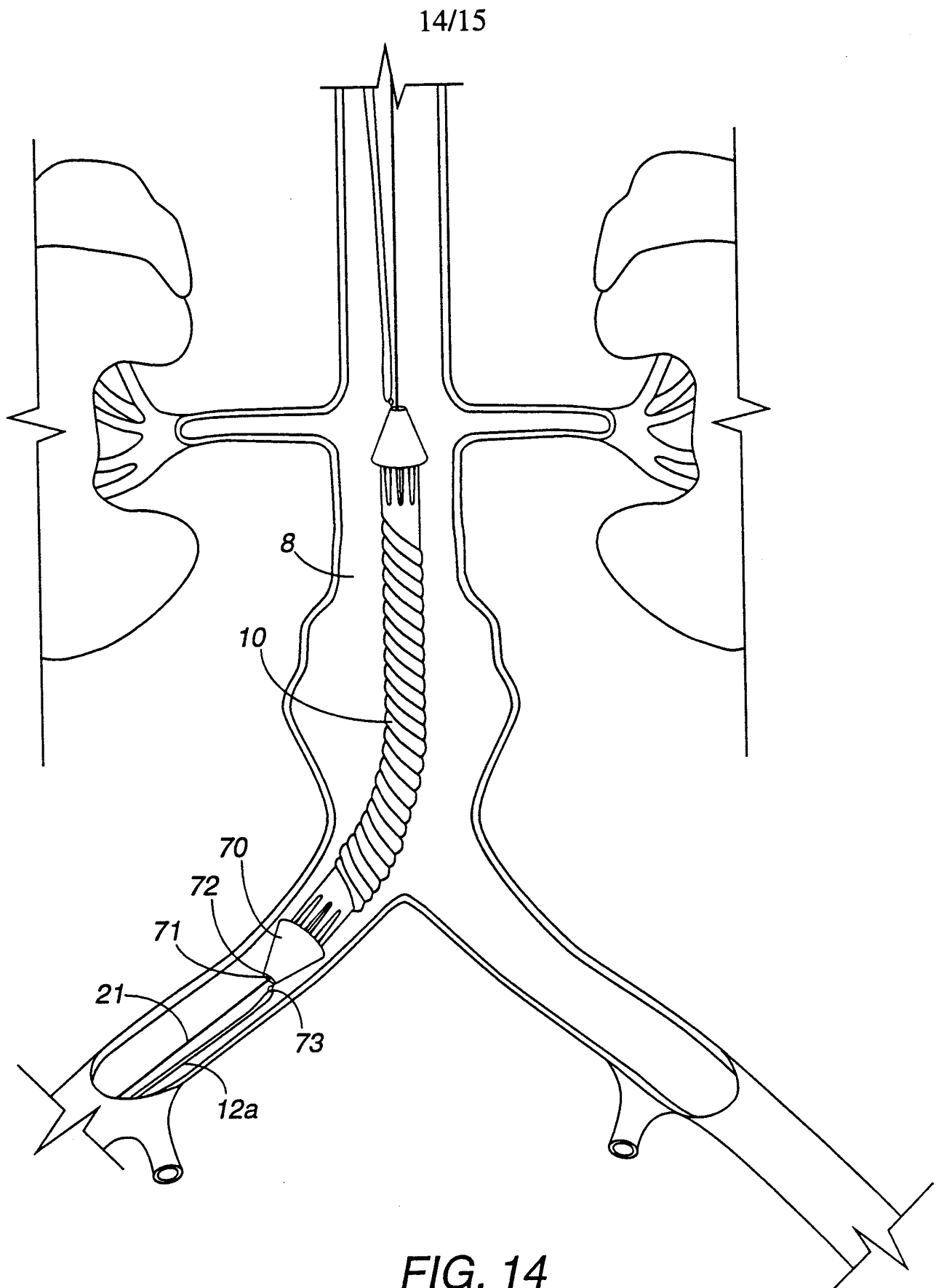
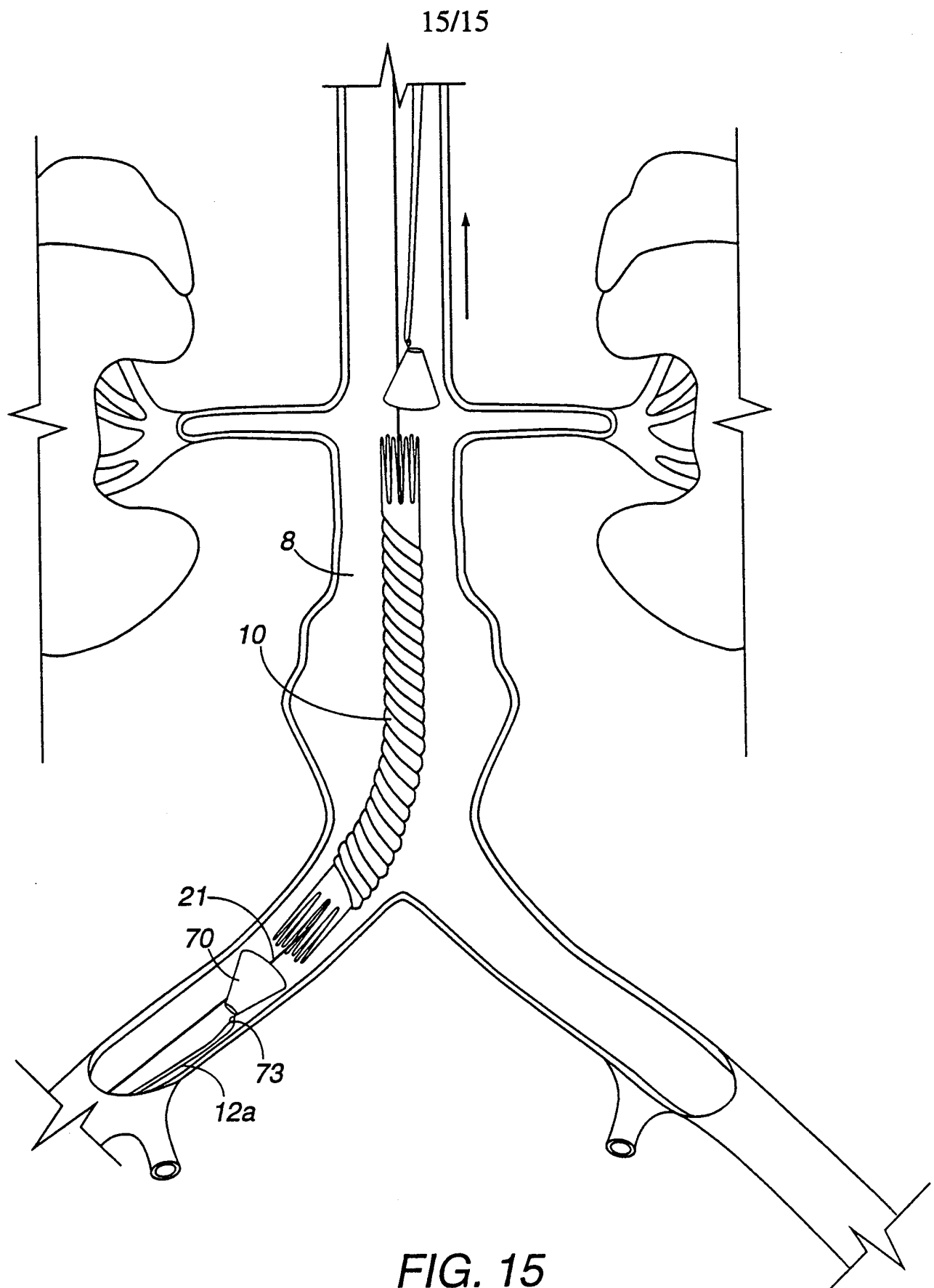


FIG. 13





INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/21373

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 2/06

US CL : 606/194, 195, 198; 623/1, 11, 12

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)

U.S. : 606/194, 195, 198; 623/1, 11, 12

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 practicable, search terms used)
APS, MEDLINE, EMBASE, BIOSIS, WPIDS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- , P Y	US 5,800,521 A (ORTH) 01 September 1998, col. 2 line 62- col. 3 line 6; col. 3 lines 8-17; Fig. 1; and col. 5 lines 1-11.	1, 2, 6-10, 12-15 ----- 3-5, 11
Y,E	US 5,843,162 A (INOUE) 01 December 1998, col. 7 lines 31-42; and Figs. 10, 22 and 27.	3-5
A	US 5,456,694 A (MARIN et al) 10 October 1995, col. 8 lines 27-58.	2, 7, 8, 11, 12

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	"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
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"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

01 FEBRUARY 1999

Date of mailing of the international search report

24 MAR 1999

Name and mailing address of the ISA/US
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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/21373

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

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

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

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 II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

Please See Extra Sheet.

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

International application No.
PCT/US98/21373

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION WAS LACKING

This ISA found multiple inventions as follows:

Group I, claim(s) 1-14, drawn to an apparatus.

Group II, claim(s) 15, drawn to a method.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack Unity of Invention because they are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for more than one species to be searched, the appropriate additional search fees must be paid. The species are as follows:

Species A: A sheath introducer restraining means (Figures 1, 6-10)

Species B: An end cap restraining means (Figures 11-15)

The inventions listed as Groups I and II do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The product as claimed can be used in a materially different process of using that product, i.e. in the instant case, the product can be used as a genitourinary filter.