

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
1 March 2007 (01.03.2007)

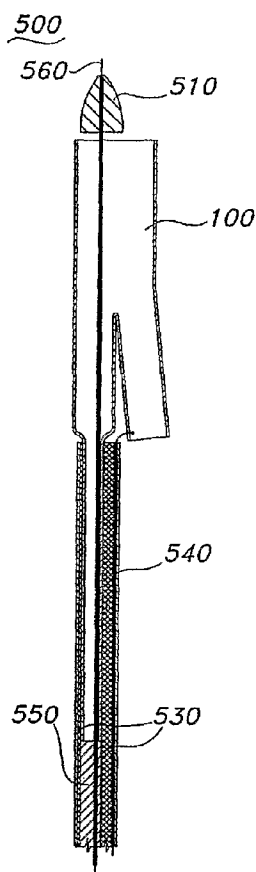
PCT

(10) International Publication Number
WO 2007/025101 A2

- (51) International Patent Classification: Not classified
- (21) International Application Number: PCT/US2006/033174
- (22) International Filing Date: 23 August 2006 (23.08.2006)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
11/211,895 25 August 2005 (25.08.2005) US
- (71) Applicant (for all designated States except US): **BOSTON SCIENTIFIC SCIMED, INC.** [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): **O'BRIEN, Mark, E.** [US/US]; 1 Boston Scientific Place, Natick, MA 01760 (US). **SHERRY, John, E.** [US/US]; 130 Birds Hill Avenue, Needham, MA 02492-4243 (US).
- (74) Agent: **COHEN, Joshua, L.**; RatnerPrestia, P.O. Box 980, Valley Forge, PA 19482 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LV, LY, MA, MD, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, SV, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, LV, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: ENDOLUMINAL PROSTHESIS ADAPTED TO DEPLOYMENT IN A DISTORTED BRANCHED BODY LUMEN AND METHOD OF DEPLOYING THE SAME



(57) Abstract: An endoluminal device adapted to be deployed in a branched body lumen is provided by intraluminal delivery from an access location remote from the location at which the device is to be deployed, i.e. by introduction through one of the branches of the branched body lumen. The device comprises an unbranched portion, a first branch portion and second branch portion in communication with the unbranched portion, and a distortion element removeably connected to the first branch portion for manipulating the geometry of the second branch portion. The distortion element extends along the first branch portion and back to the access location.



Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

ENDOLUMINAL PROSTHESIS ADAPTED TO DEPLOYMENT IN A DISTORTED BRANCHED
BODY LUMEN AND METHOD OF DEPLOYING THE SAME

BACKGROUND OF THE INVENTION

It is known to treat an abdominal aortic aneurysm (AAA) by
5 endoluminally implanting a bifurcated stent-graft in order to bypass the aneurysm.
Stent-grafts adapted for this use include a number of designs. A large class of these
designs incorporates a modular aspect that brings the benefits of reducing the size of
each individual sub-component to be implanted and facilitating a customized fit for
each patient. A downside of modular design is that it necessitates in situ assembly of
10 the sub-components. A common in situ assembly process of a two-piece device
includes an initial insertion of a bifurcated component whose branch portions are of
differing lengths; so called "long leg - short leg devices." The bifurcated component is
inserted from a remote location into and up an ipsilateral iliac artery and positioned in
the aortic neck so that the second branch portion directs luminal flow into the
15 contralateral iliac artery. Next, a leg extension component is engaged with the second
branch portion to extend the bifurcated device into the contralateral iliac artery. This
can be achieved by inserting a guidewire from a remote location into the contralateral
iliac artery and through the aperture of the second branch portion. The leg extension
component is then delivered along the guidewire and into engagement with the second
20 branch portion of the bifurcated component.

In patients with large saccular aneurysms, the aortic neck is typically
angularly offset significantly from the iliac arteries. The offset hinders insertion of the
leg extension component guidewire into the second branch portion aperture because
the guidewire approaches the aperture from an acute angle.

25 SUMMARY OF THE INVENTION

The present invention relates to a prosthetic device for facilitating
endoluminal assembly of a modular bifurcated endoluminal device in a branched body
lumen from a remote location. The invention is particularly advantageous in the
treatment of large saccular AAA's with a distorted aortic neck.

30 Generally, an endoluminal device is adapted to be deployed in a
branched body lumen, from an access location remote from the location at which the
device is to be deployed, by introduction through one of the branches of the branched
body lumen. The device comprises an unbranched portion and at least two branch
portions in communication with said unbranched portion. The branch portions
35 comprise a first branch portion adapted to be deployed in one branch of the body lumen

and a second branch portion adapted to be directed toward a second branch of the body lumen. The device further comprises a distortion element removeably connected to the second branch portion for manipulating the geometry of the second branch portion. The distortion element extends along the first branch portion to the access
5 location. The distortion element can be an elongated filament such as a wire, a yarn, or a cable. The removable connection can be a slipknot, a ring, or an eyelet.

Optionally, the present invention also includes: a second endoluminal device adapted to be mated with the second branch portion of the first device; the methods for using and inserting those devices, and apparatus therefore.

10 BRIEF DESCRIPTION OF THE DRAWINGS

The invention is best understood from the following detailed description when read in connection with the accompanying drawings. It is emphasized that, according to common practice, the various features of the drawings are not to scale. On the contrary, the dimensions of the various features may be arbitrarily expanded or
15 reduced for clarity. Included in the drawings are the following Figures:

Figure 1 illustrates a typical large saccular aneurysm having an offset neck;

Figure 2A illustrates a prior art bifurcated endoluminal device having a long leg and a second branch portion;

20 Figure 2B illustrates use of the prior art device depicted in Figure 2A in a distorted aneurysm;

Figure 3A illustrates a first device embodiment of the present invention;

Figure 3B illustrates the device of Figure 3A in use in a distorted aneurysm;

25 Figure 3C illustrates the device of figure 3A in use in a distorted aneurysm showing attachment of an optional leg extension;

Figure 4A illustrates a second device embodiment of the present invention;

30 Figure 4B illustrates the device of Figure 4A in use in a distorted aneurysm;

Figure 4C illustrates the device of figure 4A in use in a distorted aneurysm showing attachment of an optional leg extension;

Figure 5A illustrates an introducer embodiment according to the present invention showing the loaded endoluminal device fully collapsed within the introducer;

Figure 5B illustrates the introducer of Figure 5A with the loaded endoluminal device partially deployed;

5 Figure 5C illustrates the introducer of Figure 5A with the loaded endoluminal device deployed;

Figures 6A-C are cross-sectional views of the loaded introducer shown in Figure 5A at the respective cross-section planes 6A-6A, 6B-6B, and 6C-6C;

10 Figure 7 illustrates an exemplary second introducer for deployment of a leg-extending second device;

Figure 8A illustrates an optional embodiment of the device including an everted leg in use in a distorted aneurysm; and

Figure 8B illustrates the everted leg embodiment of Figure 8A with the everted leg deployed.

15 DETAILED DESCRIPTION OF THE INVENTION

The invention will next be illustrated with reference to the figures wherein the same numbers indicate similar elements in all figures. Such figures are intended to be illustrative rather than limiting and are included herewith to facilitate the explanation of the apparatus of the present invention.

20 Figure 1 illustrates an exemplary AAA having a large saccular portion 15 and a tortuous neck 10 distorted from its natural vertical alignment. Ipsilateral iliac artery 20 and contralateral iliac artery 30 are also indicated. Figure 2A depicts a bifurcated "long leg - second branch portion" prosthetic device used in the prior art to treat AAA's. Figure 2B illustrates the difficulties in an exemplary prior art device being
25 implanted in a large saccular AAA having a tortuous neck.

As proposed herein and as shown in Figure 3A, an embodiment of the present invention is a bifurcated endoluminal device 100 that includes a distortion element 140 removeably connected to second branch portion 130. Distortion element 140 can take the form of any elongated filament that is capable of translating a pulling
30 force from a remote location to the second branch portion 130. Examples of a suitable elongated filament are a wire, yarn, or cable. Distortion element 140 is connected to second branch portion 130 by a removable connection means 150 such as a slipknot, ring, or eyelet by which distortion element 140 can be detached following its use.

Figure 3B shows the device in use whereby distortion element 140 enables the surgeon to effectively pull second branch portion 130 toward first branch portion 120 by applying tension or otherwise manipulating distortion element 140. Thus, the surgeon is able to facilitate the location of open end 160 of second branch portion 130 with guidewire 610. Using guidewire 610, the surgeon can optionally
5 deploy and mate a second device (200) to second branch portion (130) using second introducer 600 (an example of which is illustrated at Figure 7) as needed to extend second branch portion (130) as shown in Figure 3C. When distortion element 140 is no longer needed it can be detached from second branch portion 130 by detaching
10 removeable connection means 150 and pulling it through the ipsilateral iliac 30. Preferably, removal is performed through introducer 500 (discussed further below) by which device 100 was originally introduced. For example, where connection means 150 is a slipknot, simply pulling on the slipknot to untie it and then pulling distortion element 140 through introducer 500. Likewise, where connection means 150 is a slip
15 ring, pulling one end of distortion element 140 through the slip ring and then pulling distortion element 140 through introducer 500.

As further proposed herein and as shown in Figure 4A, another embodiment of the present invention is a bifurcated endoluminal device 300. Bifurcated device 300 includes the features of bifurcated device 100 and further
20 incorporates a removeable pivot point means 310 positioned on first branch portion 120 of device 300. Pivot point means 310 serves as an axis around which pulling force exerted by the surgeon can be re-directed laterally towards second branch portion 130. Pivot point means 310 may be any structure capable of performing this redirection such as a ring, hook, button, or nipple. Figure 4B illustrates use of pivot means 310 in
25 combination with distortion element 140 and connection means 150 to orient second branch portion 130 to facilitate insertion of guidewire 610. Using guidewire 610, the surgeon can optionally deploy and mate a second device (200) to second branch portion (200) using second introducer (600) as needed to extend second branch portion (130) as shown in Figure 4C.

30 While the invention may be introduced in any number of ways which may be devised by those skilled in the art, one way of doing so is by the deployment apparatus illustrated in Figures 5A, 5B, 5C and 6A, 6B, and 6C.

More specifically, in Figure 5A and in Figures 6A, 6B, and 6C there is shown bifurcated endoluminal device 100 compressed for endoluminal placement in an
35 outer sheath 520 and mounted on guidewire tube 570 through which extends guidewire 560, extending from the external access point, where the delivery apparatus enters the

vasculature, to a nose cone 510 just distal (with respect to the access point) of device 100. An inner sheath 530 terminates just proximal of the proximal end of second branch portion 130 and a pusher element 550 is disposed just proximal of first branch portion 10. Distortion element 140, attached to second branch portion 130 by
5 removeable connection means 150, includes a return length or lengths extending within outer sheath 520 in a distortion element channel 540 to the external access point.

It will be noted that inner sheath 530 generally occupies the space within outer sheath 520 not otherwise occupied by pusher element 550 except for distortion element channel 540 which permits passage of distortion element 140.

10 Figure 5B illustrates deployment of bifurcated endoluminal device 100 as outer sheath 520 is retracted to the point where second branch portion 130, unbranched portion 110, and a portion of first branch portion 120 are expanded, in this case by the self expansion characteristics of their elasticity or memory metal composition. At this stage, tension can be applied to distortion element 140 (or
15 otherwise manipulating distortion element 140), thereby constraining second branch portion 130 to a limited angular separation from first branch portion 120 and thus second branch portion 130 can be better aligned with contralateral iliac 30 (as seen in Figure 3B).

Sequentially, Figure 5C shows the final deployment stage of bifurcated
20 endoluminal device 100 when outer sheath 520 and inner sheath 530 are both withdrawn to the point where the remainder of first branch portion 120 is deployed. As shown in Figure 3B, with distortion element 140 effecting some control over the angular disposition of second branch portion 130, capture of bifurcated endoluminal device 100 from contralateral iliac 30 can then be performed by passing guidewire/snag wire 610
25 from contralateral iliac 30 into open end 160. Thereafter, guidewire/snagwire 610 can be used, for example, to guide second introducer 600 for deploying and mating a leg-extending second device 200 to second branch portion 130.

As shown in Figure 8, an optional embodiment of bifurcated device 100 alternatively provides for the second branched portion as an everted leg (800). This
30 optional embodiment is deployed in the same manner as previous embodiments. However, to provide an extended second branch portion the surgeon inserts snagline 620 into open end (810) of the everted leg. As above, distortion element 140 can be used to orient open end (810) to facilitate insertion of snagline 620. Using snagline 620, the surgeon can then pull everted leg 800 down and into contralateral iliac artery
35 30. An advantage of this embodiment has an advantage in that in many applications would required no further leg extension of the second branch portion.

Although the invention is illustrated and described herein with reference to specific embodiments, the invention is not intended to be limited to the details shown. Rather, the claims which follow are intended to be construed to encompass any modifications which may be made by those skilled in the art to which this invention
5 pertains that nevertheless lie within the spirit and scope of this invention.

What is claimed:

1 1. An endoluminal device adapted to be deployed in a branched body
2 lumen, from an access location remote from the location at which the device is to be
3 deployed, by introduction through one of the branches of the branched body lumen,
4 said device comprising:

5 (a) an unbranched portion;

6 (b) at least two branch portions in communication with said unbranched portion,
7 comprising

8 (i) a first branch portion adapted to be deployed in one branch of the
9 body lumen and

10 (ii) a second branch portion adapted to be directed toward a second
11 branch of the body lumen; and

12 (c) a distortion element removably connected to said second branch portion for
13 manipulating the geometry of the second branch portion, said distortion element
14 extending along the first branch portion to said access location.

1 2. An endoluminal device, as recited in claim 1, wherein said branched
2 body lumen is the lower aorta and the branches thereof are the iliac arteries, and the
3 endoluminal device is a stent graft.

1 3. The device of claim 1 wherein said endoluminal device is a first device
2 and further comprising:

3 (d) a second device adapted to be endoluminally deployed, from a second
4 access location in a second branch lumen, said second device also adapted to be mated
5 with the second branch portion of the first device.

1 4. The device of claim 1 wherein the distortion element comprises an
2 elongated filament.

1 5. The device of claim 4 wherein the elongated filament is one of a wire,
2 a yarn, and a cable.

1 6. The device of claim 1 wherein the distortion element is removably
2 connected to said second branch portion by a removable connection means comprising
3 one of a slipknot, a ring, and an eyelet.

1 7. An endoluminal device as recited in claim 1 wherein said second
2 branch portion comprises:

3 an at least partially everted portion folded within said unbranched portion
4 and adapted to be extended into the second branch of the body lumen by unfolding
5 said everted portion.

1 8. An introducer adapted to deliver the device of claim 1 in a body
2 lumen, said introducer comprising:

3 (a) a tubular outer sheath having a proximal end, a distal end, and a length
4 extending therebetween;

5 (b) a tubular inner sheath disposed within said outer sheath;

6 (c) a channel disposed between the outer sheath and the inner sheath, said
7 channel adapted to communicate said distortion element from said second branch
8 portion of said endoluminal device to said access location for manipulation of the
9 second branch portion.

1 9. A system for deploying the device of claim 1, said system comprising:
2 an introducer adapted to deliver said device; and
3 said device loaded into said introducer.

1 10. A system for deploying the device of claim 4, said system
2 comprising:

3 a first introducer adapted to deliver said first device;

4 said first device loaded into said first introducer;

5 a second introducer adapted to deliver said second device; and

6 said second device loaded into said second introducer.

1/7

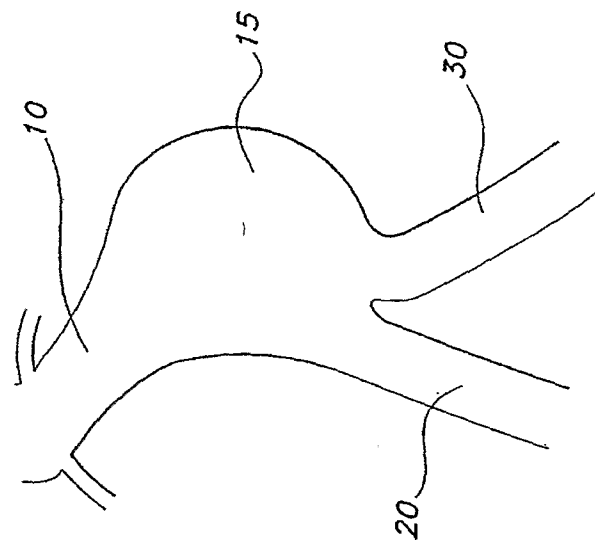


FIG. 1

2/7

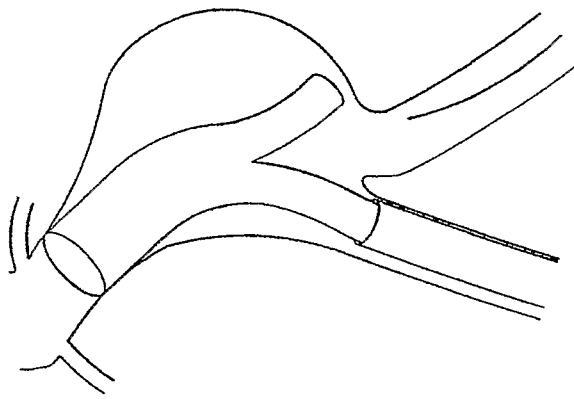


FIG. 2B
(PRIOR ART)

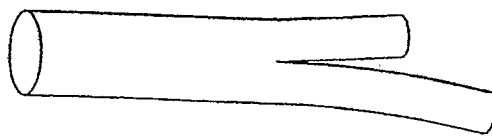


FIG. 2A
(PRIOR ART)

3/7

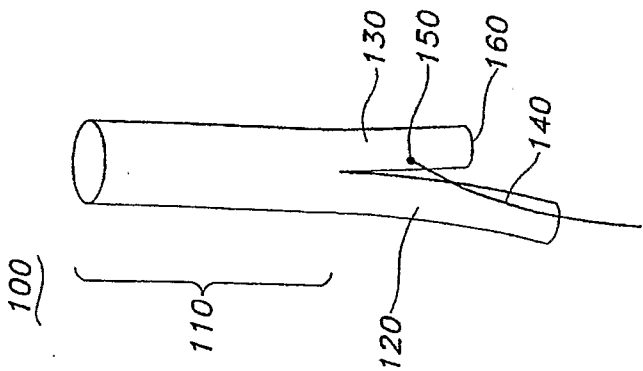
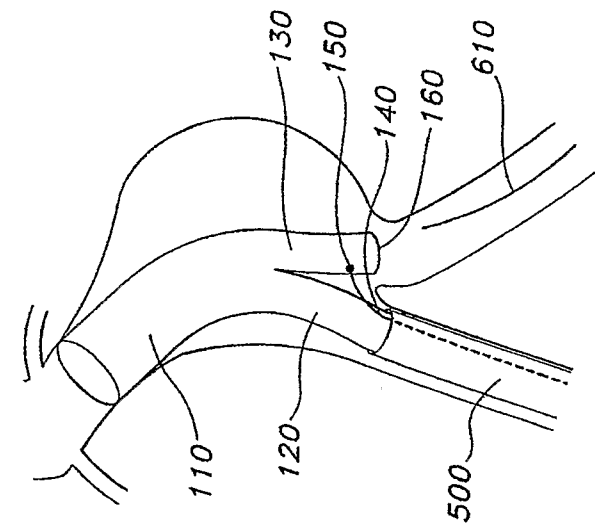
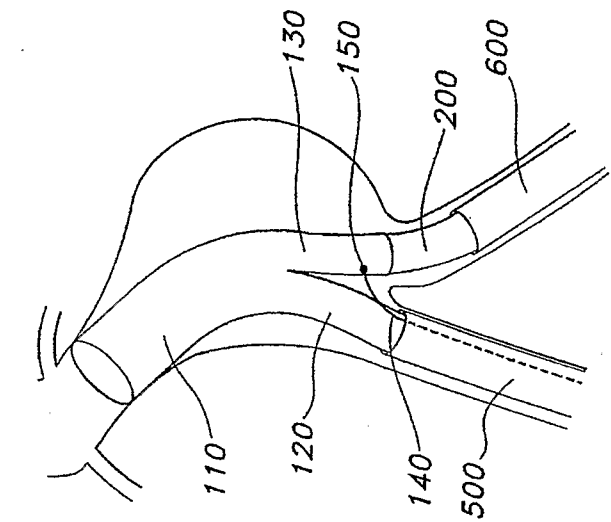


FIG. 3A

FIG. 3B

FIG. 3C

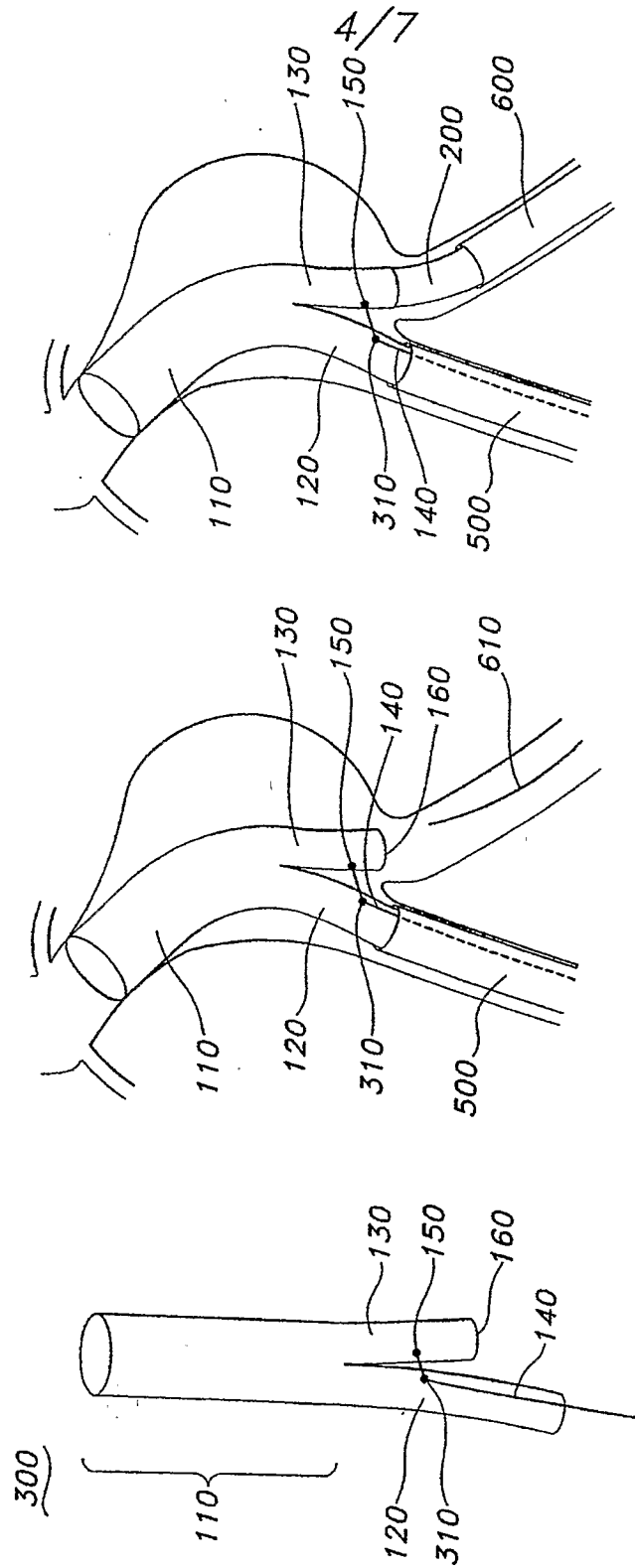


FIG. 4A

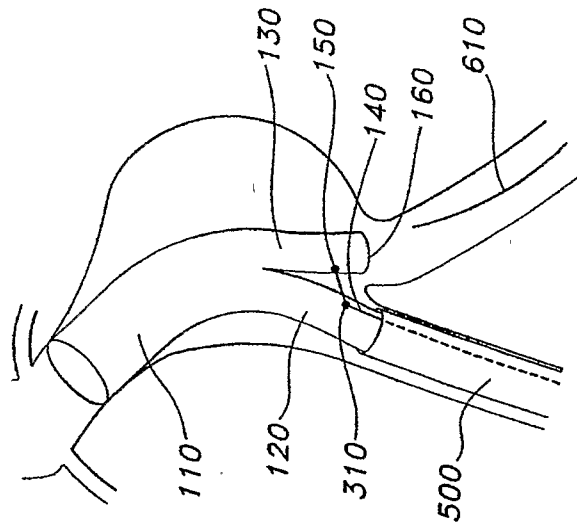


FIG. 4B

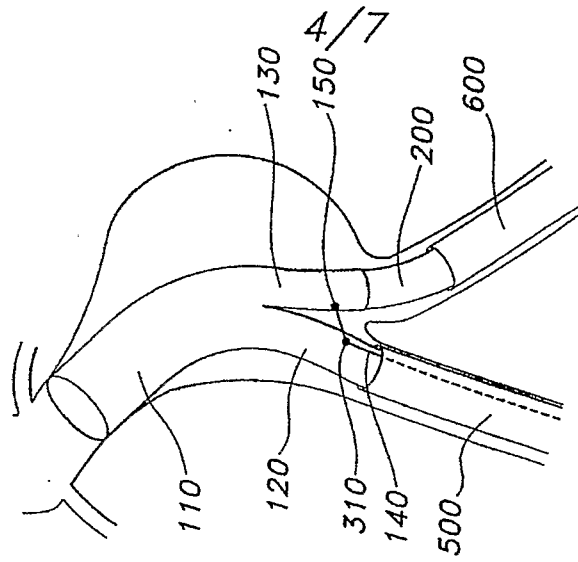


FIG. 4C

5/7

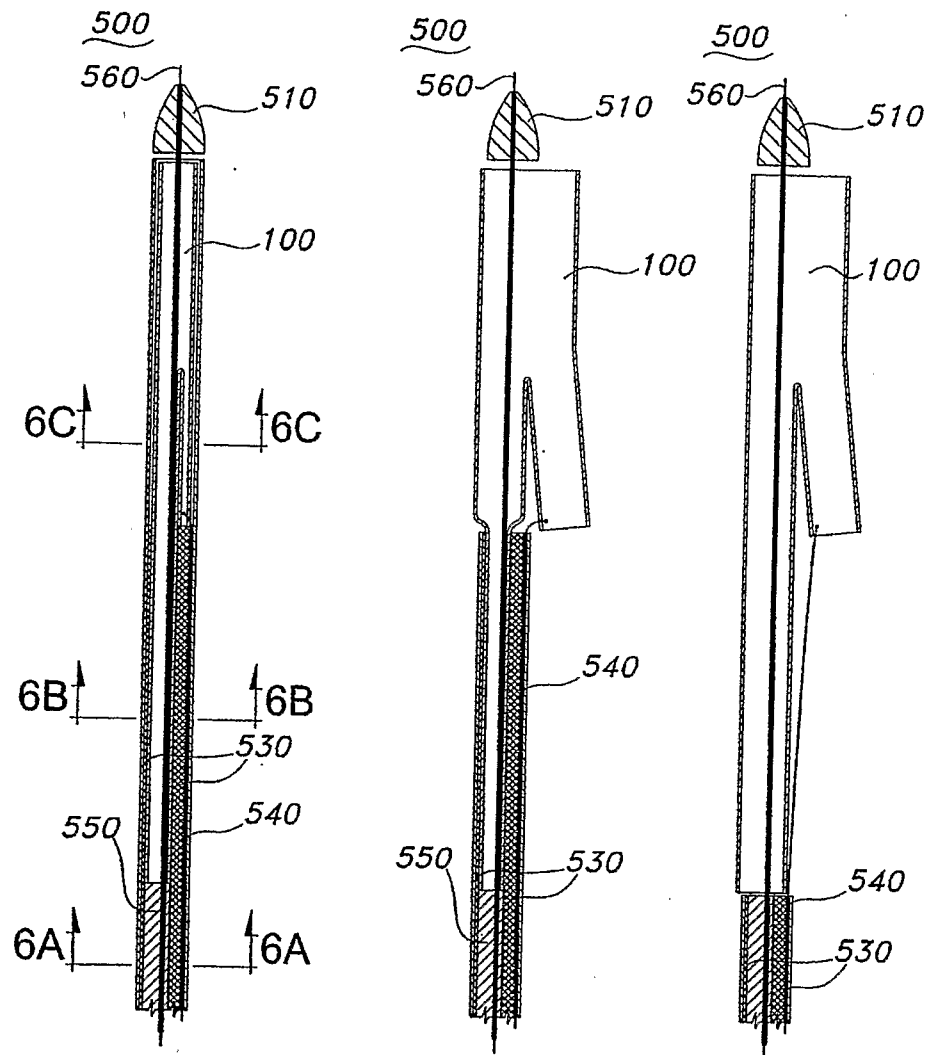


FIG. 5A

FIG. 5B

FIG. 5C

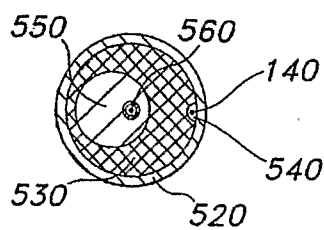


FIG. 6A

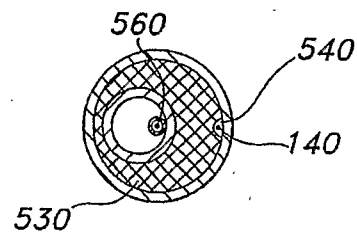


FIG. 6B

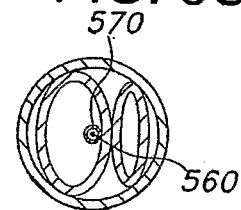


FIG. 6C

6/7

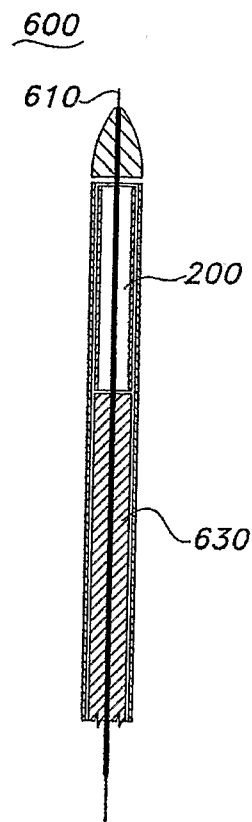


FIG. 7

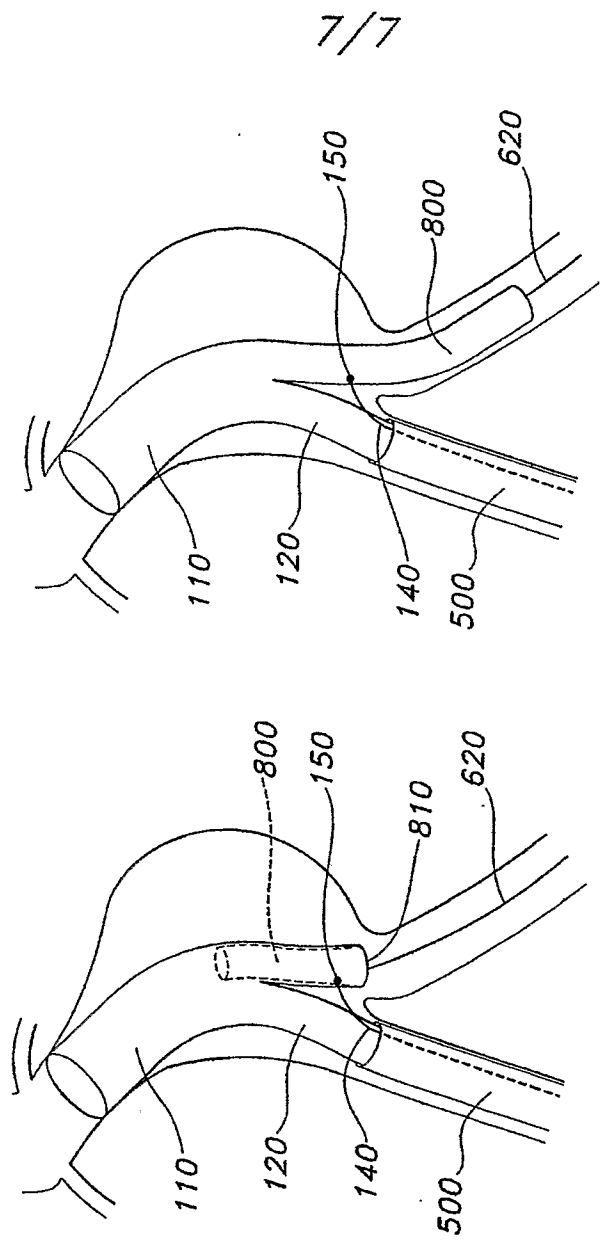


FIG. 8B

FIG. 8A