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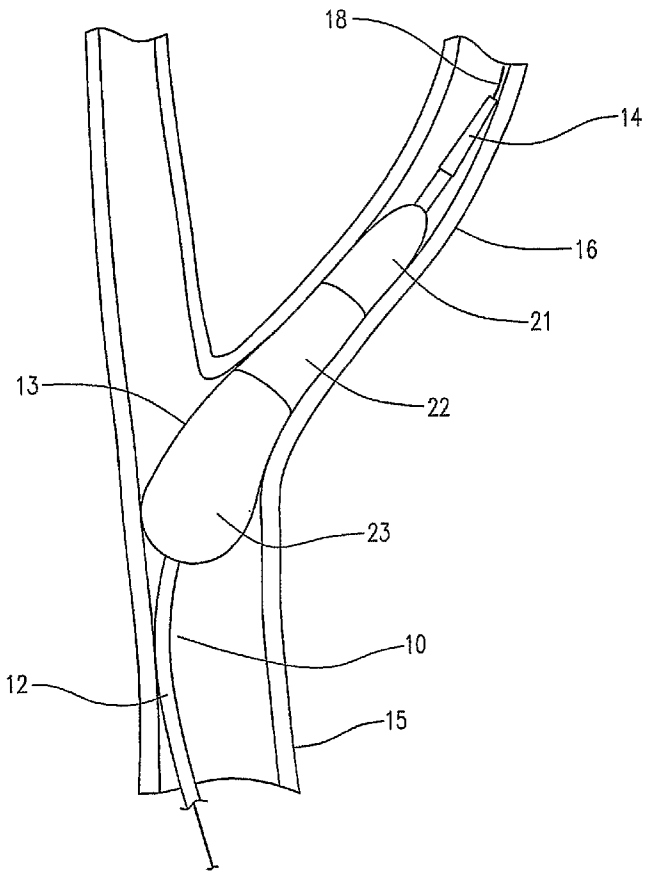
(54) Title: TAPERED MULTI-CHAMBER BALLOON



(57) Abstract: A catheter (10) for carotid artery dilatation that includes a multi-chamber balloon assembly (13) mounted at the distal end of the elongated tube that has at least two tandem chambers. Each chamber (21, 22, 23) communicates with a separate lumen and each separate lumen terminates at the proximal end at a lumen valve head. The chambers have an inflated configuration with a diameter that progressively tapers in a direction from proximal to distal, said taper extends substantially continuously from the proximal end of the balloon assembly to the distal end thereof.

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TAPERED MULTI-CHAMBER BALLOON

BACKGROUND OF THE INVENTION

Catheters having multiple or segmented balloons mounted thereon are known for a variety of uses. Some of these catheters the balloons communicate with a single inflation lumen, in others the different balloons or segments have separate lumens. Multiple balloons may be mounted on the catheter in tandem, concentrically or asymmetrically.

Certain applications to which catheters are applied present special problems. For instance, carotid artery stenosis has been treated using catheters for coronary angioplasty and/or for peripheral angioplasty, but have characteristic problems that create a need for specifically designed catheters. Carotid artery stenosis often originates in two common vessel areas of treatable significance. Primarily stenosis occurs at the bifurcation of the common carotid artery (CCA) and internal carotid artery (ICA). Secondarily, stenosis occurs in the ICA somewhat distal to the CCA and ICA bifurcation where the vessel size is substantially smaller.

Typically, those lesions found at the bifurcation of the CCA and CA are focal in nature, consist of large amounts of calcium and have a very heterogeneous surface morphology. When treating this kind of lesion set, a physician typically will pre and/or post dilate the lesion with a balloon. The pre-dilatation allows for ease of placement of the stent and the post-dilatation ensures the stent fully apposes the vessel contouring the stent to better conform to vessel configuration so that there is a well defined conduit for increased blood flow. The lesions found at the bifurcation of the CCA and CA make up approximately 80% of the world wide procedures that are treated with carotid artery stents. However, it would be useful if lesions in the internal carotid artery distal to the CCA and ICA bifurcation could also be treated at the same time with the same balloon catheter.

Documents describing some catheter systems and techniques for carotid artery surgery include US 6,086,548 (Chaisson et al); US 6,582,396 (Parodi); and US 6,905,490 (Parodi).

SUMMARY OF THE INVENTION

The present invention pertains to a tapered multi-chamber balloon catheter particularly suited to carotid artery stenosis. The catheter includes an interventional balloon with two or more chambered compartments. The compartments are each tapered so that the overall inflated diameter range allows for dilatation at an artery bifurcation and/or within an artery distal to the bifurcation where the vessel size has substantially reduced.

In some embodiments the catheter is provided with a valve that provides for successive inflation of the balloon compartments in a distal to proximal fashion. These embodiments allow the physician to pre- and/or post dilate a lesion set within a tapering vessel of distally small to proximally larger diameters such as found mostly at the CCA and ICA bifurcation. In most instances this system will serve as a post dilatation balloon working extremely well with deployed tapered and/or self-tapering stents. The chambered system allows the physician to regulate the diameter size of the balloon to fit the vessel appropriately as it tapers.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a schematic sectional view of a catheter located at a CCA-ICA bifurcation, with a tapered balloon of the invention in inflated state crossing the bifurcation.

Figure 2 is a longitudinal sectional view of the distal end of a catheter of the invention with the balloon in deflated state.

Figure 3 is a schematic sectional view of the proximal end of the catheter with the control valve in the first inflation position.

Figure 4 is a cross sectional view taken at 4-4 of Fig.3.

Figure 5 is a view as in Figure 2, but with the first chamber inflated.

Figure 6 is a view as in Figure 3, but with the control valve in the second inflation position.

Figure 7 is a view as in Figure 2, but with the first and second chambers both inflated.

Figure 8 is a view as in Figure 3, but with the control valve in the third inflation position.

Figure 9 is a view as in Figure 2, but with all chambers inflated.

0 is a view as in Figure 3 with the control valve in the "all" position.

Figure 11 is a view as in Figure 3 with the control valve in the "off" position.

DETAILED DESCRIPTION OF THE INVENTION

All published documents, including all US patent documents, mentioned anywhere in this application are hereby expressly incorporated herein by reference in their entirety. Any copending patent applications, mentioned anywhere in this application are also hereby expressly incorporated herein by reference in their entirety.

The invention is illustrated in the Figures for an embodiment of the invention adapted for treatment of lesions located at a bifurcation between common carotid artery 15 (CCA) and internal carotid artery 16 (ICA), and/or within the ICA above the bifurcation.

Referring to Figure 1, a catheter 10 is shown which includes a shaft 12, balloon 13 and distal end 14 is located at a bifurcation between common carotid artery 15 (CCA) and internal carotid artery 16 (ICA), the catheter shaft and balloon extend into internal carotid artery 16. Balloon 13 has three chambers 21, 22 and 23.

Catheter 10 is shown as an over-the-wire catheter that is deployed along a guide wire 18, but it should be understood that other catheter configurations, for instance rapid exchange catheter configurations may be employed without departing from the invention hereof.

In Figure 2 the distal end of catheter 10 is shown with the balloon 13 in deflated condition. Separate inflation lumens 31, 32, 33 are provided in shaft 12 which open respectively into the chambers 21, 22 and 23.

Referring to Figure 3, at the proximal end of the system the control valve body is suitably designed to inflate each chamber sequentially in an incremental mode by way of a control valve 24 having a selection knob 25 thereon. In the incremental inflation mode the operation inflates chambers 21, 22, and 23 in that order to coordinate the distal to proximal inflation of the three balloon chambers.

Figures 3, 6 and 8 depict various selection knob positions that are provided for the operator. A single inflation port 34 is provided for use with all three chambers. An incremental inflation sequence is desirably employed, so that the ICA is occluded distally first (Figure 3) by rotating the selection knob 25 to position 1; the intermediate chamber 22 is inflated next by rotating the selection knob 25 further to position 2 (Figure

6); and the largest chamber 23 is inflated by rotating the selection knob 25 to position 3 (Figure 8). By inflating in sequence the most distally engagable surface of the ICA is encountered first and engagement therewith serves to secure the catheter against backing out of ICA when the balloon is employed to dilate a lesion more proximally in the ICA or at the ICA-CCA bifurcation. Also the chambered and tapered configuration of the balloon allows for most necessary dilations to be performed without inflation of all three chambers.

Optionally, a fourth position, the "all" position depicted in Figure 10, is also provided wherein all three chambers may be inflated at the same time. Safety stops 28, which engage post 29 to limit rotation of the selection knob, may be provided on the selection knob to prevent the user from turning the knob to make an unintended lumen connection with port 34.

Figure 11 illustrates an intermediate position "off" of the valve where no lumen connection is provided. Suitably a procedure is initiated from this position by rotating the valve knob clockwise or counterclockwise

For an application at a CCA/ICA bifurcation, the taper (taken at nominal inflation of about 2 atm) suitably ranges in diameter from 4 mm at the most distal end of the balloon to 10 mm at the most proximal end. The catheter shaft may have a size of about 5 F. Each chamber may have a length in the range of from about 0.75 to about 1.75 cm, with a total length of the balloon assembly being in the range of about 3.5-4.5 cm.

Referring to Figures 5, 7 and 9, the chamber sizes of balloon 13 are selected to provide substantially the entire range of dilatation sizes in progressively increasing diameter range that can be encountered in this artery system. For instance, chamber 21, which is the most distal chamber on the shaft, suitably may have a diameter range of 4-6 mm and a length of approximately 1.25 - 1.75 cm. In incremental inflation mode chamber 21 will always inflate first as depicted in Figure 5. This chamber will ensure that no matter how large/or small the vessel is, it will inflate to the typically smallest diameter found in carotid arteries. In some instances, this portion of the system may be the only portion inflated to pre and/or post dilate the lesion as it may be used with short and/or focal lesions.

Chamber 22 is the middle chamber of balloon 13. Chamber 22 suitably may have a diameter range of 6-8 mm and a length of approximately 1.25 - 1.50 cm. Also suitably, the total length of chambers 21 and 22 will be about 30 mm, which represents

approximately 75% of the lesions found in the carotids today. As shown in Figure 7, in the incremental mode of inflation this chamber serves as the next chamber that will inflate after the chamber 21 has been inflated and the selection knob is moved to the second position. Inflation of chamber 22 will continue the dilatation of the vessel in the wider more proximal region of the ICA. Chamber 21 remains inflated when the valve is moved from the first to the second position.

Chamber 23 is the most proximal balloon on the shaft. Suitably chamber 23 may have a diameter range of 8-10 mm and a length of approximately 1 cm. This is the final chamber that is inflated in incremental inflation mode. Suitably the total system has a length of about 4 cm, which will provide appropriate coverage of 100% of the lesion sets found at the carotid bifurcation. Chambers 21 and 22 remain inflated when the valve is moved from the second to the third position.

While the invention has been described for a three-chambered balloon assembly, it should be understood that in some embodiments the invention the balloon assembly may have only two chambers and that in other embodiments more than three chambers may be employed.

Cylindrical tandem balloons, and techniques for mounting such balloons on catheters, are described in US 4,763,654 (Jang). The same or similar techniques may be employed to mount the tapered multi-chambered balloons of the invention on catheters.

The balloon chambers may be formed of any polymer material having physical properties suitable for medical device dilatation or stent placement balloons. The polymers may be homopolymers, random copolymers, block copolymers or alternating copolymers. As used herein, the term copolymer refers to any polymer formed from more than one monomer. Blends of more than one polymer may also be employed or a mixture of a polymer and a modifier such as a plasticizer may be employed.

The balloon chambers may be formed of a single layer or of multiple layers of the same or different polymers or polymer blends. Reinforcing fibers may be provided on a macroscopic scale as a weave, braid or the like of the fiber, optionally entrained in a polymer matrix or as over the balloon, or on a microscopic scale as oriented fibers that are produced by phase separation from a blend during extrusion.

Examples of polymers that may be used to form the balloon chambers include polyesters such as polyethyleneterephthalate (PET), polybutylene terephthalate (PBT), polyethylene terephthalate/isophthalate copolymers and polyethylene naphthalate (PEN),

polyethylene terephthalate/naphthalate copolymers; polyamides including nylon 12, nylon 11, nylon 10, nylon 610, nylon 6 and nylon 66; polyurethanes; block copolymers incorporating a polyester, polyamide, polyurethane and/or polyether segment; polycarbonates including polyesterpolycarbonates; any copolymers thereof; or blends comprising such polymers. Specific examples include polyamide/polyether/polyester block copolymers such as PEBAX® resins, in particular PEBAX 6333, 7033 and 7233, polyester/polyether block copolymers such as ARNITEL® EM 740 from DSM Engineering Plastics and polyurethanes such as ISOPLAST® 301 and PELLETHANE® 2363-75D from Dow Chemical Company.

Suitably the balloon distension profile is semi-compliant, nominally providing distension from about 2 atm to burst of about 10-25%. Polymers that can be employed to provide such a distension profile include the PEBAX®, ARNITEL® and PELLETHANE® resins previously mentioned.

In some embodiments of the invention the balloon material is the same for each chamber. In other embodiments the balloon material may be different from one chamber to the next. This may be desirable if it is desired to operate the catheter in a mode that provides different inflation pressures to the different chambers. Use of different inflation pressures between the chambers may be desirable, for instance because at a given inflation pressure, the force applied per unit of balloon area decreases. To counter this effect in the tapered multi-chamber balloon system of the present invention the balloon pressure may be increased as the inflation is successively incremented from the smallest to the largest chamber. The valve design accommodates such an operating mode since each inflated chamber is successively isolated from the pressure source once the next chamber is selected, when the incremental inflation mode is employed.

The above examples and disclosure are intended to be illustrative and not exhaustive. These examples and description will suggest many variations and alternatives to one of ordinary skill in this art. All these alternatives and variations are intended to be included within the scope of the claims, where the term "comprising" means "including, but not limited to". Those familiar with the art may recognize other equivalents to the specific embodiments described herein which equivalents are also intended to be encompassed by the claims. Further, the particular features presented in the dependent claims can be combined with each other in other manners within the scope of the invention such that the invention should be recognized as also specifically directed

to other embodiments having any other possible combination of the features of the dependent claims. For instance, for purposes of claim publication, any dependent claim which follows should be taken as alternatively written in a multiple dependent form from all claims which possess all antecedents referenced in such dependent claim if such multiple dependent format is an accepted format within the jurisdiction. In jurisdictions where multiple dependent claim formats are restricted, the following dependent claims should each be also taken as alternatively written in each singly dependent claim format which creates a dependency from an antecedent-possessing claim other than the specific claim listed in such dependent claim.

CLAIMS

1. A catheter comprising

an elongated tube having proximal and distal ends and a plurality of lumens therethrough;

a multi-chamber balloon assembly mounted at the distal end of the elongated tube comprising at least two tandem chambers, each chamber communicating with a separate lumen and each separate lumen terminating at the proximal end at a lumen valve;

each chamber having an inflated configuration with a diameter that progressively tapers in a direction from proximal to distal, said taper extending substantially continuously from the proximal end of the balloon assembly to the distal end thereof.

2. A catheter as in claim 1 further comprising a lumen valve control for the lumen valve that provides the operator at least an inflation sequence wherein the balloon chambers are sequentially inflated from the chamber located most distally on the catheter to the chamber located most proximally on the catheter.

3. A catheter as in claim 1 wherein the multi-chamber balloon assembly has at least three tandem chambers.

4. A catheter as in claim 1 wherein the multi-chamber balloon assembly has three tandem chambers and each chamber has a length in the range of from about 0.75 to about 1.75 cm.

5. A catheter as in claim 4 wherein the balloon assembly tapers from a greatest diameter of about 10 mm at the proximal end of the most proximal chamber to a least diameter of about 4 mm at the distal end of the most distal chamber.

6 A catheter as in claim 1 wherein the balloon material employed to form each of the chambers is the same.

7. A catheter as in claim 6 wherein the balloon material is a semi-compliant plastic material.

8. A method of dilating a carotid artery near a bifurcation between a common carotid artery 15 (CCA) and internal carotid artery, the method comprising

deploying a balloon catheter having proximal and distal ends and a plurality of lumens therethrough through the common carotid artery and into the internal carotid artery, wherein

the catheter comprises a multi-chamber balloon assembly mounted at the distal end of the elongated tube comprising at least two tandem chambers, each chamber communicating with a separate lumen and each separate lumen terminating at the proximal end at a lumen valve head, and each chamber has an inflated configuration with a diameter that progressively tapers in a direction from proximal to distal, said taper extending substantially continuously from the proximal end of the balloon assembly to the distal end thereof,

so that balloon assembly most proximal chamber of the balloon assembly crosses the bifurcation between the common carotid artery and the internal carotid artery, and

inflating the chambers sequentially from the most distal chamber and then proceeding proximally until the desired dilation has been achieved.

9 A method as in claim 8 wherein the multi-chamber balloon assembly has at least three tandem chambers.

10. A method as in claim 9 wherein the dilatation is completed without inflation of at least the most proximal chamber of the balloon assembly.

11. A method as in claim 8 wherein the multi-chamber balloon assembly has three tandem chambers and each chamber has a length in the range of from about 0.75 to about 1.75 cm.

12. A method as in claim 11 wherein the balloon assembly tapers from a greatest diameter of about 10 mm at the proximal end of the most proximal chamber to a least diameter of about 4 mm at the distal end of the most distal chamber.

13. A method as in claim 8 wherein the balloon has a semi-compliant inflation profile.

FIG. 1

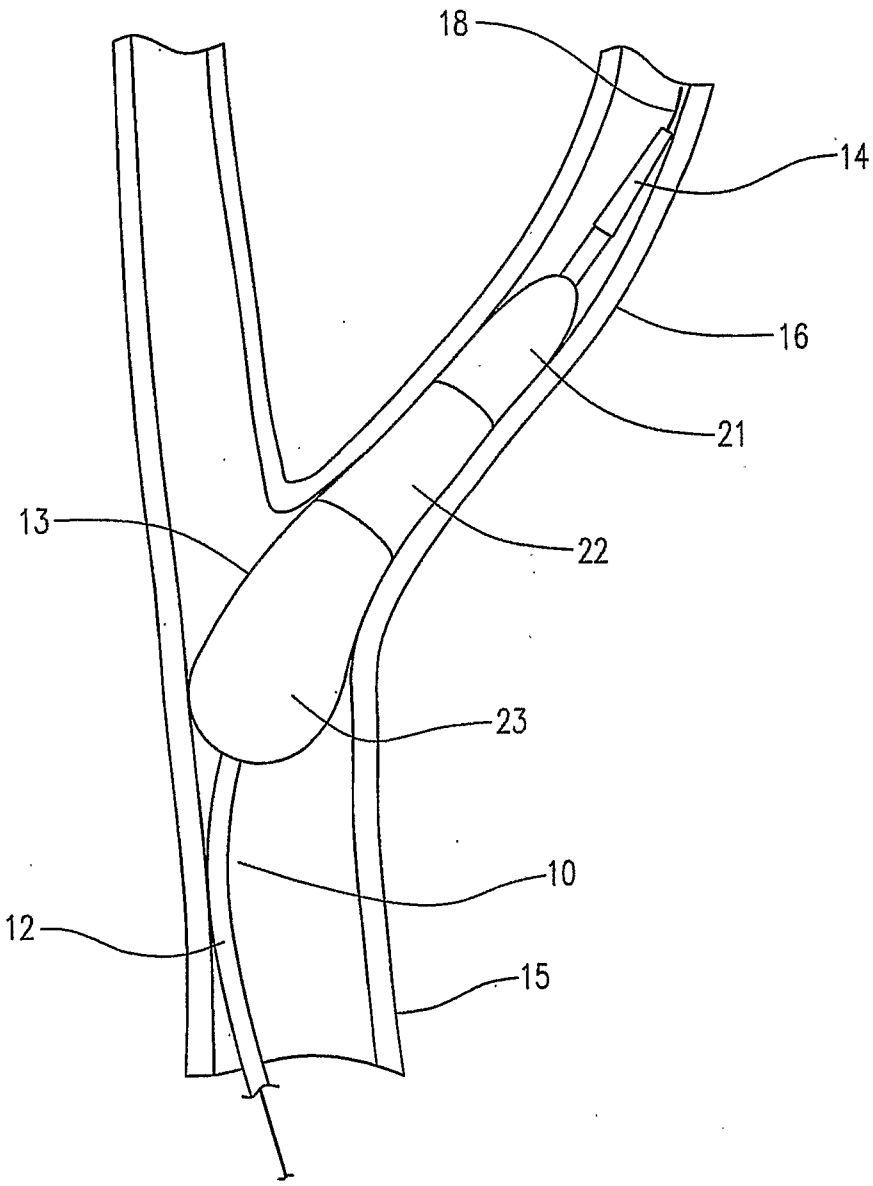


FIG. 2

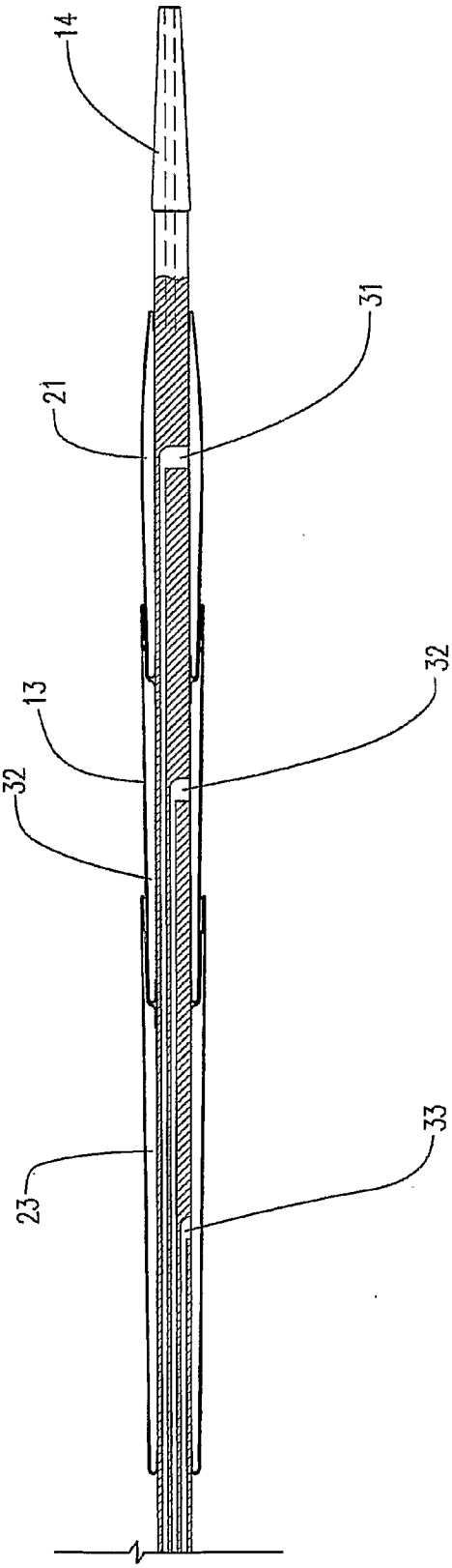


FIG. 3

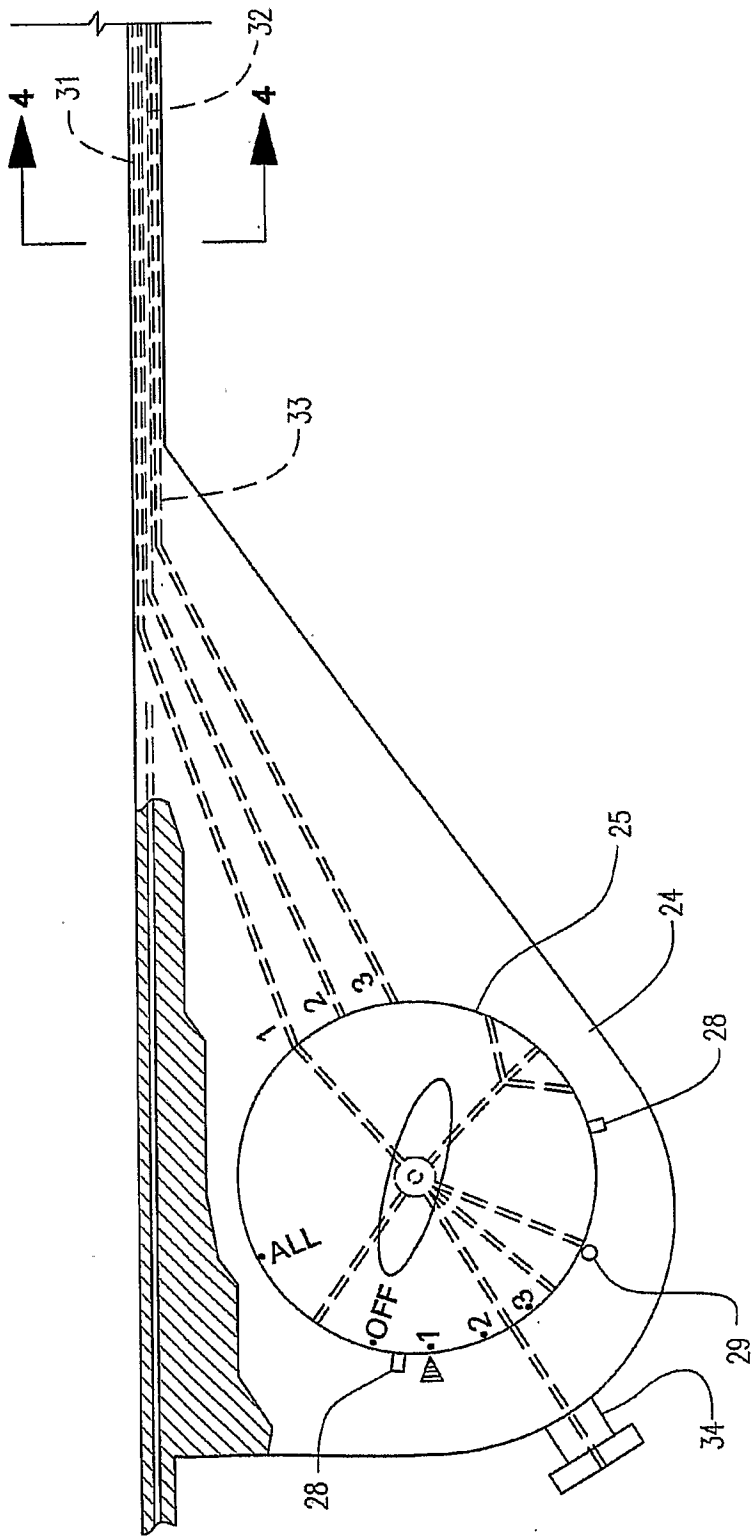


FIG. 4

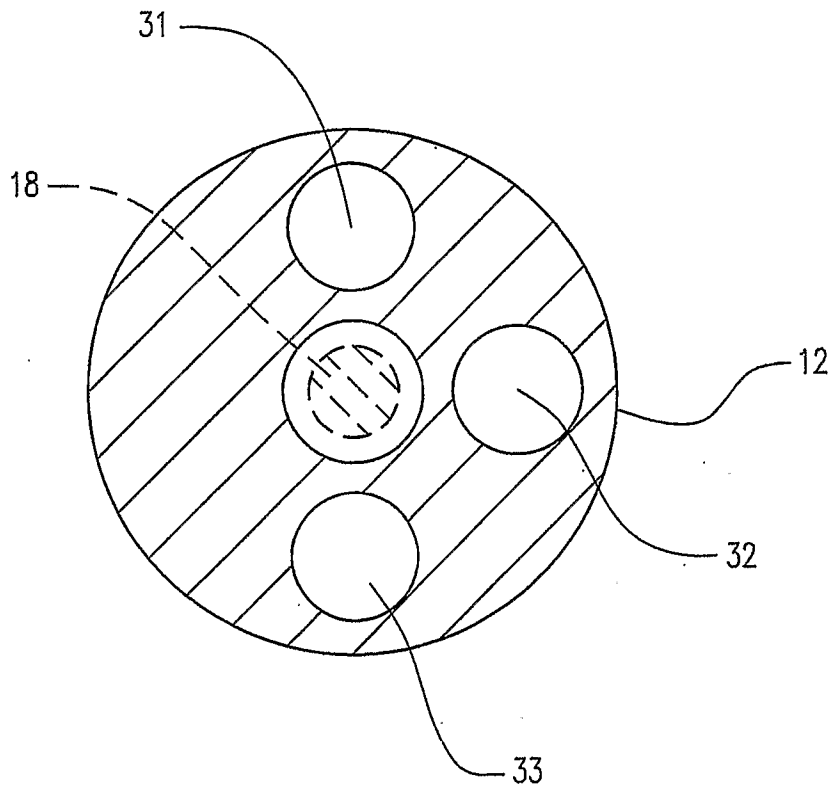


FIG. 5

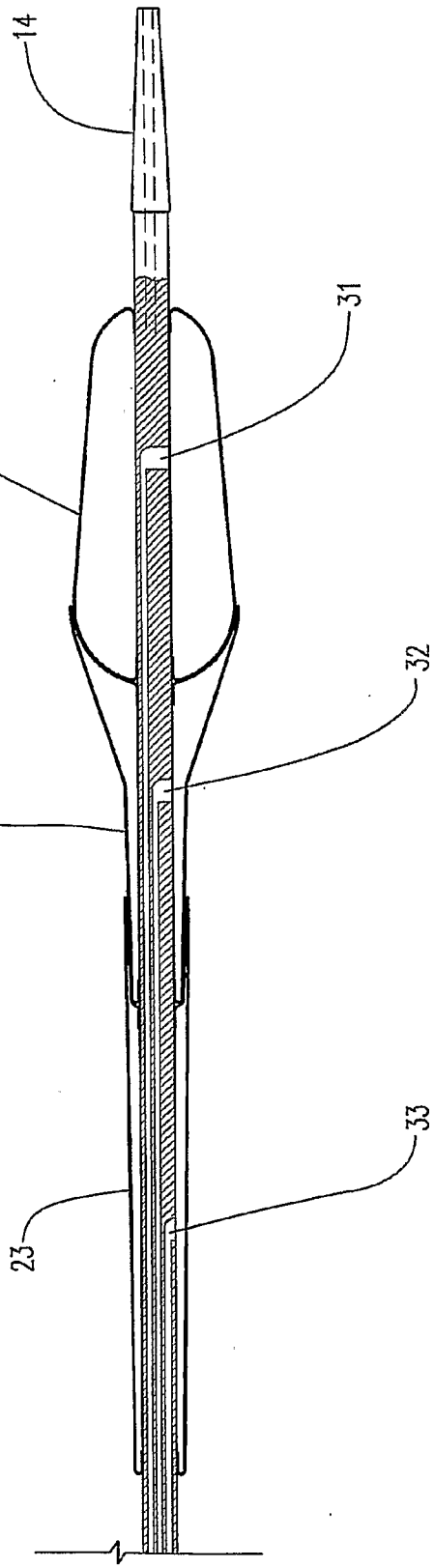


FIG. 6

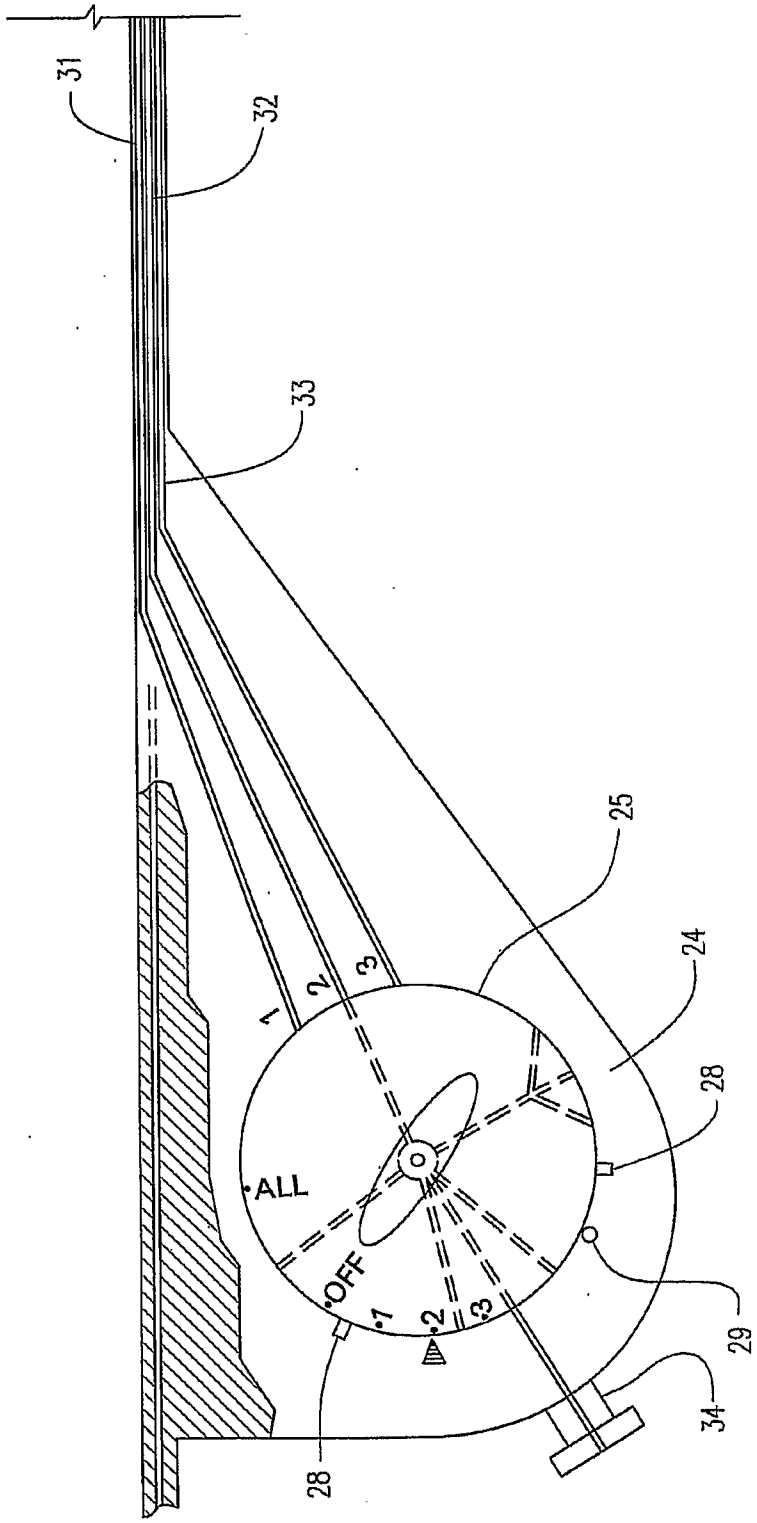


FIG. 7

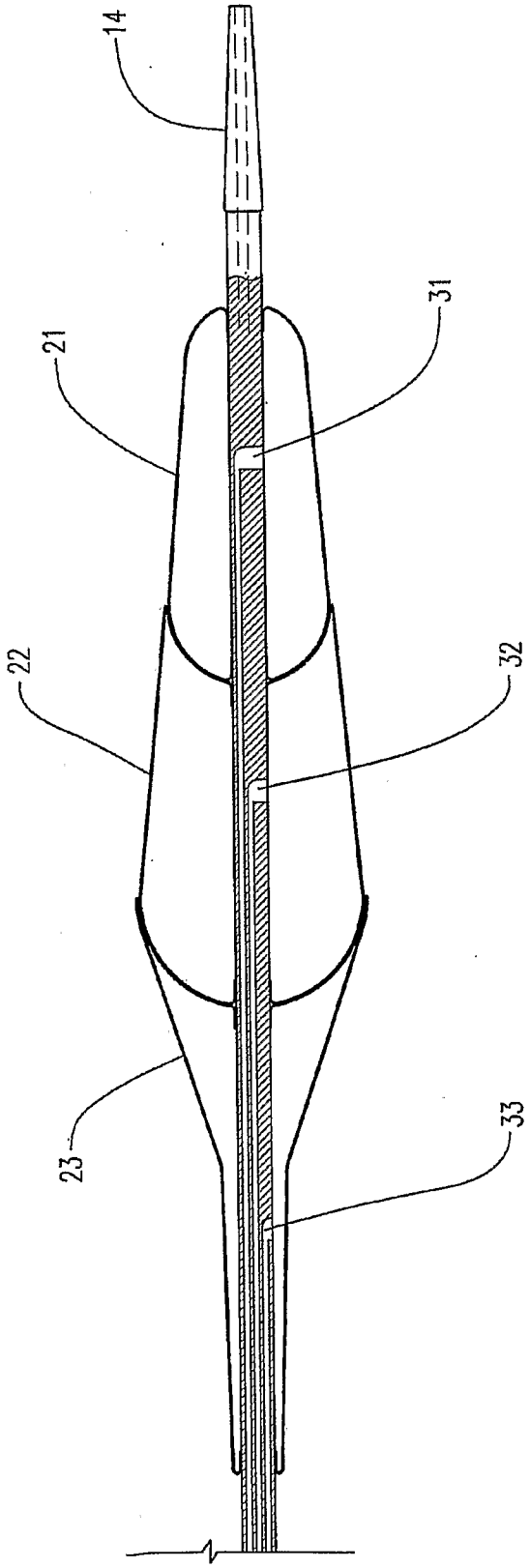


FIG. 8

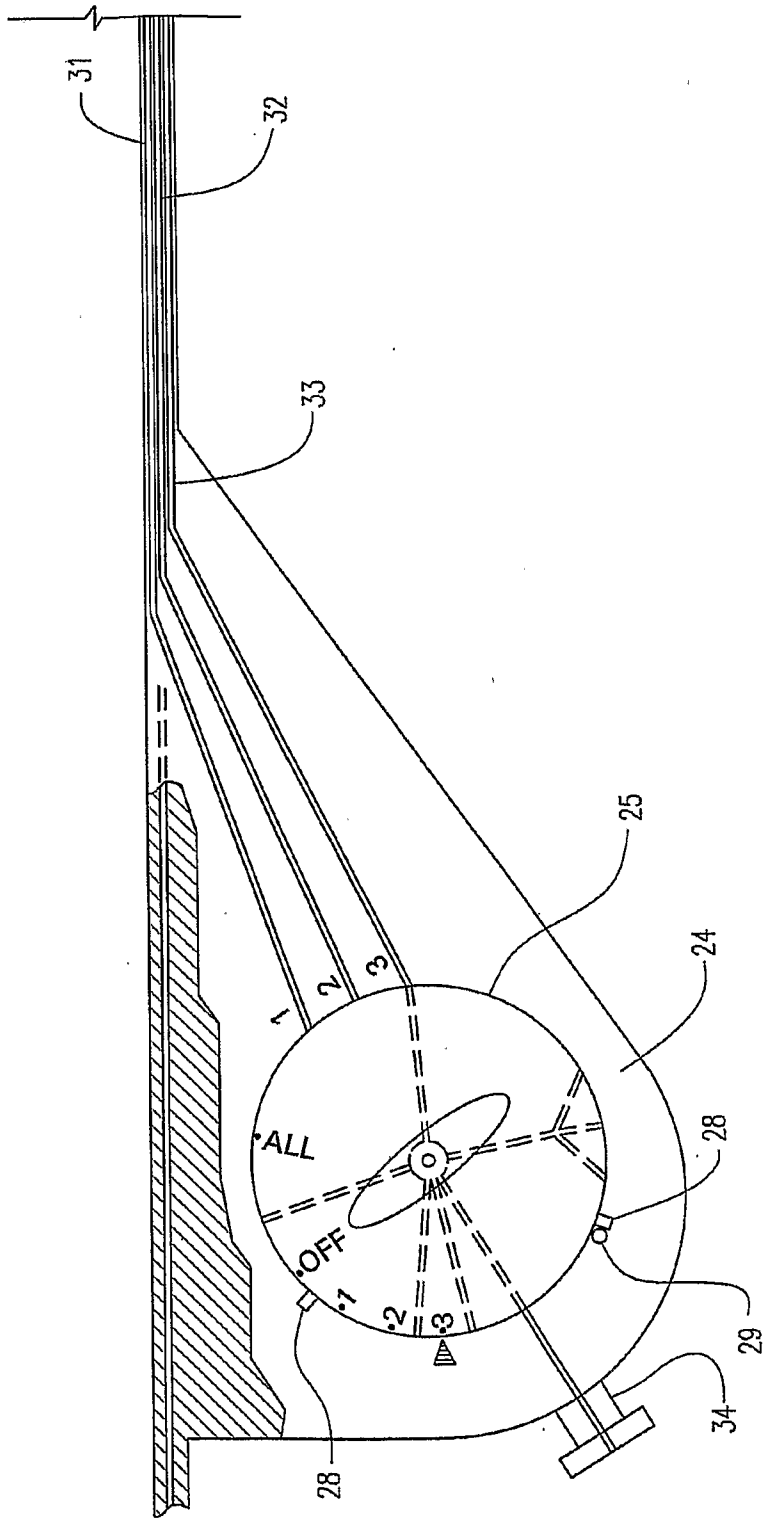


FIG. 9

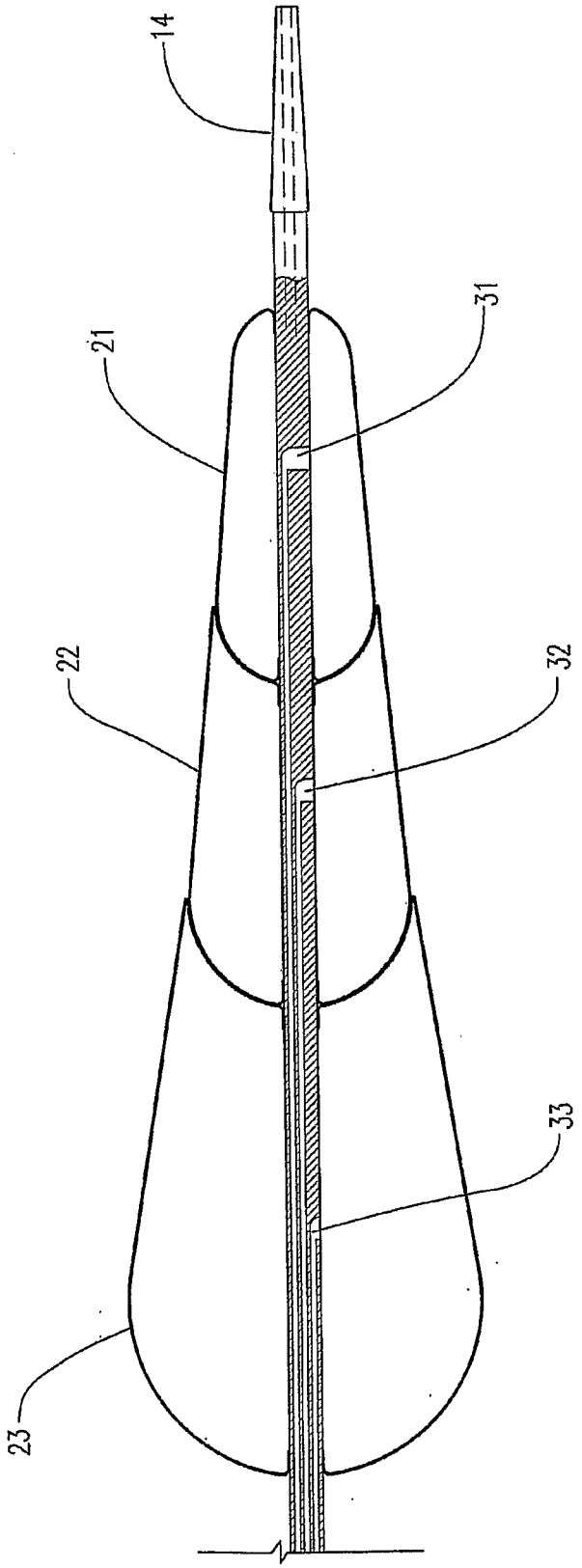


FIG. 10

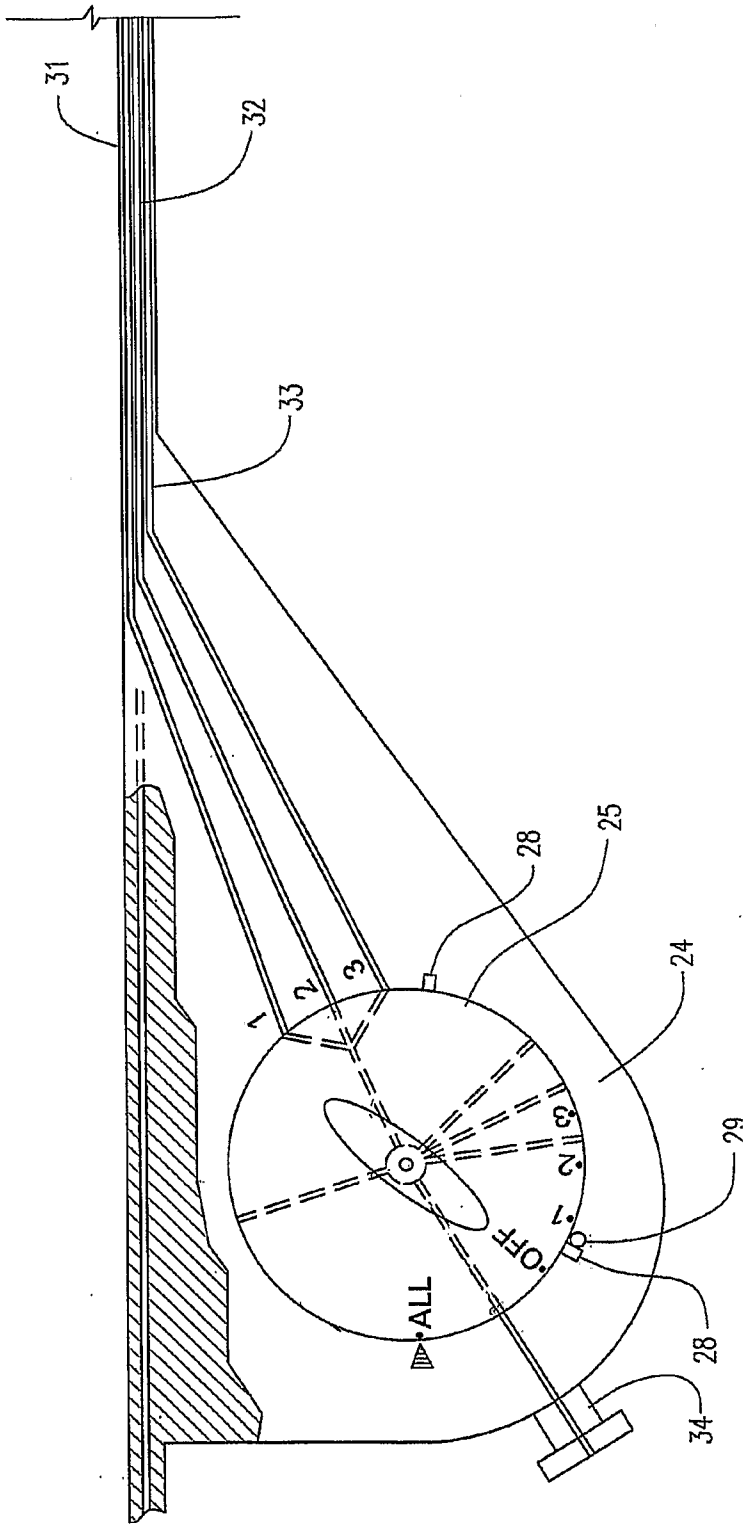
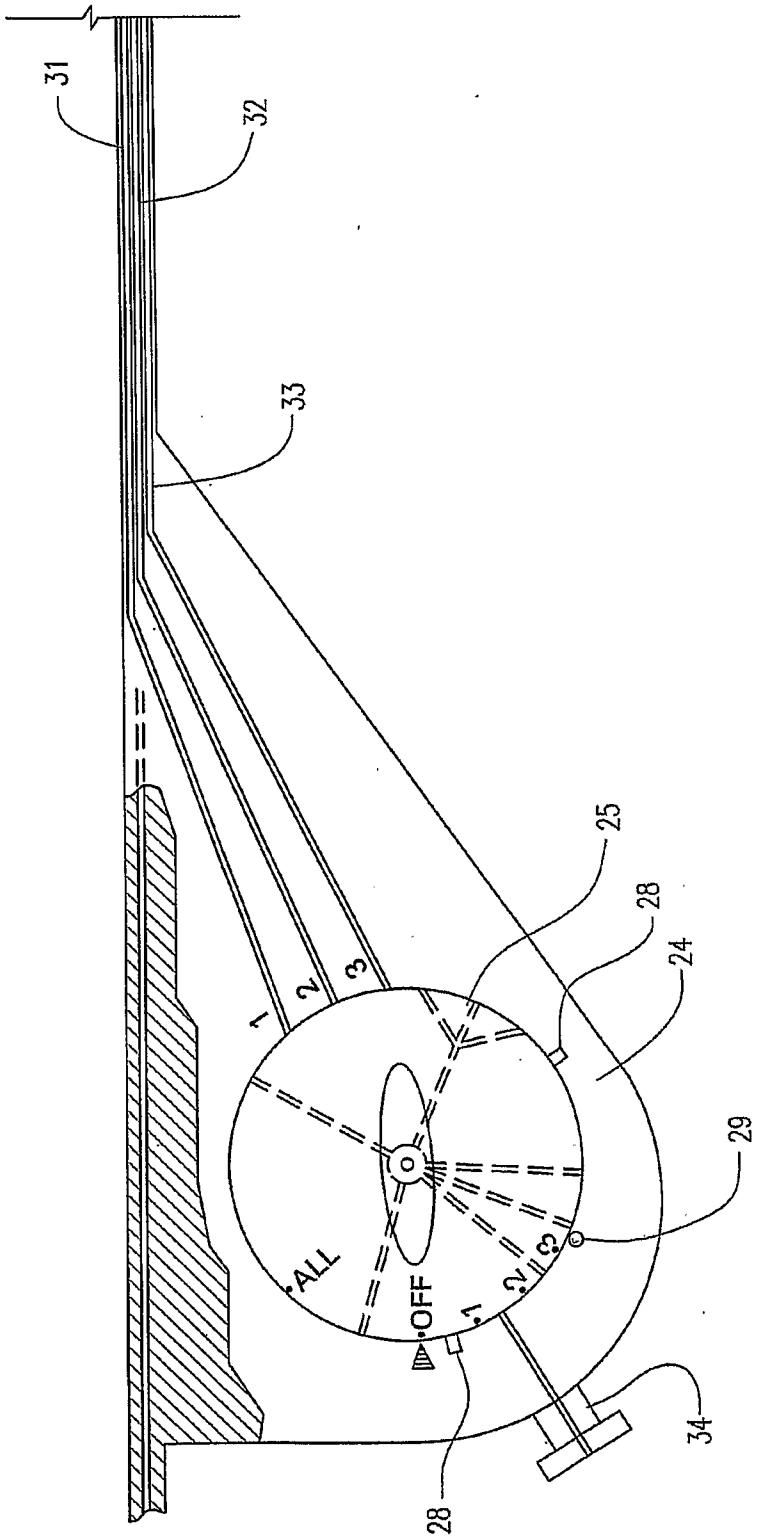


FIG. 11



INTERNATIONAL SEARCH REPORT

International application No
PCT/US2006/031125

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/10

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)
A61M

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4 763 654 A (JANG G DAVID [US]) 16 August 1988 (1988-08-16) cited in the application column 9, line 10 - column 11, line 15; figures 1-5 column 15, lines 29-48 column 21, lines 20-56; figure 21	1-7
Y	US 6 488 653 B1 (LOMBARDO GIUSEPPE [US]) 3 December 2002 (2002-12-03) the whole document	1-7
A	US 5 002 532 A (GAISER JOHN W [US] ET AL) 26 March 1991 (1991-03-26) the whole document	1-7

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[X] Further documents are listed in the continuation of Box C.

[X] 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
21 November 2006	30/11/2006

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	Jameson, Patricia

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2005/084745 A (MEDILATOR [IL]; CONDREA ALEXANDER [IL]; VADASZ ARIE [IL]; CHIEL ELIRAN) 15 September 2005 (2005-09-15) page 14, line 28 - page 16, line 5; figures 10a-c	1
A	US 6 527 739 B1 (BIGUS STEVE [US] ET AL) 4 March 2003 (2003-03-04) column 5, line 49 - column 6, line 10; figure 7	1
A	WO 97/17101 A (HEMODYNAMICS INC [US]) 15 May 1997 (1997-05-15) page 3, line 16 - page 7, line 7; figures 1-8	1
A	US 2003/109909 A1 (LEDESMA MICHELLE N [US] ET AL) 12 June 2003 (2003-06-12) paragraphs [0021] - [0027]; figure 1	1
A	US 550 238 A (H.R ALLEN JR) 26 November 1895 (1895-11-26) the whole document	1,2
A	US 6 022 359 A (FRANTZEN JOHN J [US]) 8 February 2000 (2000-02-08) column 10, lines 8-58; figures 12-14	1

3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2006/031125

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.: 8-13
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
PCT/US2006/031125

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4763654 A	16-08-1988	AU 599137 B2	12-07-1990
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