(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 April 2001 (26.04.2001)

PCT

(10) International Publication Number
WO 01/28618 A2

(51) International Patent Classification[7]: A61M 25/10, A61B 17/22

(21) International Application Number: PCT/US00/41355

(22) International Filing Date: 20 October 2000 (20.10.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/161,124 22 October 1999 (22.10.1999) US
60/214,331 27 June 2000 (27.06.2000) US

(71) Applicant *(for all designated States except US)*: **REX MEDICAL, L.P.** [US/US]; 585 County Line Road, Radnor, PA 19087 (US).

(72) Inventor; and

(75) Inventor/Applicant *(for US only)*: **HINCHLIFFE, Peter, W., J.** [US/US]; 927 Brittney Terrace, Downingtown, PA 19335 (US).

(74) Agent: **QUINN, Charles, N.**; Saul Ewing LLP, Centre Square West, 1500 Market Street, 38th floor, Philadelphia, PA 19102-2186 (US).

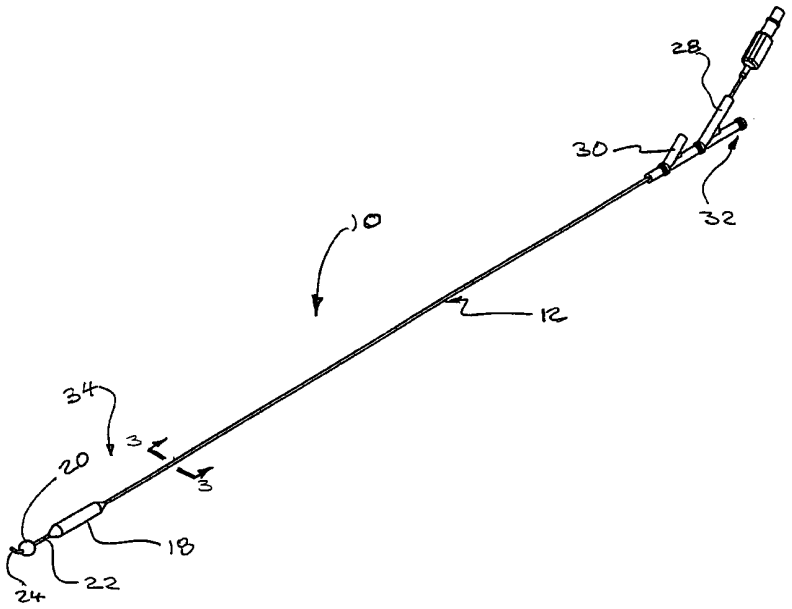
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

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.

(54) Title: DOUBLE BALLOON THROMBECTOMY CATHETER



(57) Abstract: Disposable apparatus for performing mechanical thrombectomy of dialysis grafts, comprising: (a) an axially elongated catheter; (b) a first balloon positioned along the exterior of said catheter; (c) a second balloon positioned along the exterior of said catheter; (d) said catheter including a pair of inflation ports respectively communicating with said second and third passageways proximate said second end of said catheter, adapted for connectable communication with a source of pressurized gas for selectably inflating said first and second balloons by supply of pressurized gas thereto via said second and third passageways in said catheter.

WO 01/28618 A2

DOUBLE BALLOON THROMBECTOMY CATHETER

Background of the Invention - Field of the Invention

This invention relates to thrombectomy apparatus and procedures of the type generally disclosed in published Patent Cooperation Treaty patent application PCT/US98/15156.

Summary of the Invention

In the course of a thrombectomy procedure, a clot is purged from the graft. Subsequently, the anastomosis are unplugged using two different types of balloons, preferably an angioplasty balloon for the venous side and a soft, "Fogarty," latex balloon for the arterial side. Both balloons are preferably positioned on a common catheter.

A catheter is used to deliver the wire for the dialysis thrombectomy procedure. The invention embraces the placement of the two balloons, namely the preferably angioplasty balloon for the venous side and preferably the soft, "Fogarty," style latex balloon for the arterial side, on the delivery catheter.

In the course of practicing the method aspect of the invention and going forward with the thrombectomy procedure, the attending physician preferably proceeds to the venous side first, since blood endeavors to flow from the artery side to the vein side. Any blockage at the artery side means less blood flow through the graft thereby facilitating opening of blockage or unplugging of the venous side. Typically, plaque to be cleared at the venous side is stronger and tougher than any plaque at the artery side. Accordingly, a tough angioplasty balloon, typically formed of a synthetic material such as polyethylene teraphalate, is preferably used to unblock the venous side.

Plaque at the arterial side is generally not as hard, with a platelet plug often being encountered at the arterial side. The platelet plug is desirably pulled through the junction of the artery and the graft in order to unplug the arterial side.

In another aspect, this invention provides preferably disposable apparatus for performing mechanical thrombectomy cleansing of dialysis grafts where the apparatus preferably includes an axially elongated catheter preferably having at least three axially extending fluid communication passages therewithin, where a first one of the passages preferably has a rounded cross-section for free axial travel therealong of a guidewire inserted thereinto. In this aspect of the invention, the first balloon is desirably positioned along the exterior of the catheter proximate the first catheter end, with the interior of the first balloon being in fluid communication with a second one of the passageways. The first balloon, when inflated, is preferably generally spherical and positioned about the catheter so that the catheter defines an axis of the spherical balloon shape. The catheter desirably passes through the interior of the balloon when the first balloon is inflated.

In this aspect of the invention, a second balloon is desirably positioned along the exterior of the catheter inboard of the first balloon relative to the first catheter, with the interior of the second balloon being in fluid communication with a third passageway. The second balloon when inflated desirably has an axially elongated generally cylindrical central portion and generally conical end portions, with the cylindrical and conical portions of the balloon being symmetrically positioned about the catheter. The catheter desirably passes through the interior of the second balloon when the second balloon is inflated. The catheter

preferably further defines the axis of the cylindrical and conically shaped portions of the balloon.

In this aspect of the invention, the catheter desirably further includes a pair of inflation ports which respectively communicate with the second and third passageways proximate the second end of the catheter. The passageways are preferably adapted for individual connectable communication with the source of pressurized gas for selectably inflating the first and second balloons by supply of pressurized gas thereto via the second and third passageways in the catheter.

The first balloon is desirably latex. The second balloon is desirably terephalatic polyurethane or some other tough, puncture-resistant material.

The catheter exterior is desirably round but may be other shapes or asymmetrical.

The invention further embraces the inclusion of radiopaque markers, preferably in the form of bands, on the catheter to facilitate imaging during the thrombectomy cleansing of dialysis grafts. The radiopaque markers are preferably positioned on the catheter to be within the interior of the respective balloons when the balloons are inflated.

In another aspect of the invention, an angioplasty balloon may be used for the arterial side of the graft and a soft "Fogarty style" latex balloon used for the venous side. Both balloons are preferably used on the same catheter. A clot is purged from a dialysis graft and then the anastomosis are unplugged by using the balloons which are desirably of the two differing types.

Brief Description of the Drawings

Figure 1 is an isometric view in schematic form of a preferred double balloon thrombectomy catheter manifesting aspects of the invention.

Figure 2 is an enlarged schematic isometric view of the preferred double balloon thrombectomy catheter illustrated in Figure 1 showing the two balloons in larger form with radiopaque markers in place on the catheter to facilitate imaging.

Figure 3 is a sectional view of the tubular portion of the double balloon thrombectomy catheter illustrated in Figures 1 and 2 taken at lines and arrows 3-3 in Figure 1.

Figure 4 is a schematic sideview of another form of a double balloon thrombectomy catheter manifesting aspects of the invention.

Figure 5 is a sectional view of the double balloon thrombectomy catheter illustrated in Figure 4 taken at lines and arrows 5-5 in Figure 4.

Description of the Preferred Embodiments and Best Mode Known for Practicing the Invention

When a dialysis graft is to be cleaned, blood flows through the dialysis graft from the arterial side to the vein side. Typically, the graft fills with clotting material as time passes and must be cleaned periodically in order for subsequent dialysis procedures to be completed successfully.

When dialysis grafts are cleaned, the loosened clotting material is desirably broken up at a location well upstream of that at which loosened particles of clotting material would flow downstream to the lungs. Accordingly, once the graft itself is cleaned, for example using the approach and apparatus disclosed in the published PCT patent application referenced above, the juncture of the graft with the vein is desirably cleaned prior to cleaning the juncture of the graft with the artery. This is desirable because if the artery side were to be

cleaned initially, this would increase the risk of loosened particles of clotting matter being released into the artery, flowing further into the associated body extremity and possibly causing problems in the extremity of the body limb in which the graft is implanted. If the artery side were cleaned first, once the artery side was clean, blood would tend to flow through the graft directly to the vein side, reducing the desirable likelihood of loosened residual particles flowing through the artery to which the graft is connected and on into arteries of successfully decreasing size and downwardly into the treated extremity of the limb in which the graft is implanted.

When the arterial anastomosis shows signs of narrowing, a physician or other attending health professional might opt to perform angioplasty on the artery side. However, normally in accordance with the invention, an angioplasty balloon is used to unplug juncture of the graft and the vein. Material gathering at the juncture of the graft and the vein tends to be plaque-like and is difficult to remove. Hence, a high-strength angioplasty balloon is preferably used for the graft-vein juncture cleaning procedure.

When the cleaning procedure is done at the juncture of the artery and the graft, in practicing the invention most often the physician or attending health care professional preferably uses a latex or other soft balloon. This is desirably accomplished by inserting a wire through the clotting material at the artery-graft juncture. The clotting material at the artery-graft juncture consists mostly of platelets. Once the wire is inserted, from the graft through the platelets and into the artery, the latex balloon is inflated. The platelet plug is then pulled out of position at the juncture of the artery and the graft. This is accomplished by inflating the latex balloon positioned within the artery and then pulling the balloon against the

platelet plug and into the graft; this is performed after the balloon has passed through the platelet plug in an uninflated condition. As a result, the platelet plug and clotting material are removed at the same time, sometimes permitting the clotting material and the platelet plug to be removed from the graft without an incision.

Referring to the drawings, a double balloon thrombectomy catheter manifesting the preferred embodiment of the invention is designated generally 10 and includes a catheter designated generally 12. Within catheter 12 are a major internal conduit designated generally 14 and secondary and tertiary internal conduits designated 16 and 26 respectfully, for supply of gas to the angioplasty and latex balloons respectively.

An angioplasty balloon designated generally 18 is mounted on the exterior of catheter 10. The interior of angioplasty balloon 18 communicates in a gas-tight relationship with secondary internal conduit 16 within catheter 12 in order that angioplasty balloon 18 may be inflated by supply of pressurized gas thereto via secondary internal conduit 16.

Double balloon thrombectomy catheter 10 further includes a preferably latex balloon 20 positioned as illustrated in the drawings on the exterior of catheter 12. Similarly to angioplasty balloon 18, latex balloon 20 is positioned to communicate with the interior of tertiary internal conduit 26 in order that pressurized gas may flow through tertiary internal conduit 26 and inflate latex balloon 20.

A rotatable thrombectomy wire 22 preferably having a j-shaped tip designated generally 24 is slidably resident within major internal conduit 14. Wire 22 may be advanced out of a distal end 32 of major internal conduit 14 within catheter 12 to perform thrombectomy

procedures as described in published Patent Cooperation Treaty patent application PCT/US98/15156 identified above.

A connection port 28 is provided facilitating supply of pressurized gas to secondary internal conduit 16. Similarly, another connection port 30 is supplied for furnishing pressurized gas to tertiary internal conduit 26. Connection ports 28, 30 are preferably at the proximate end 34 of catheter 12 which is opposite distal end 32 of catheter 12 from which wire 22 emerges to perform the thrombectomy procedure.

Angioplasty balloon 18 is preferably configured with a cylindrical central portion designated generally 36 and respective conical end portions each designated 38 as illustrated in the drawings.

While the invention has been described with reference to use of a latex balloon to remove the platelet plug anastomosis at the artery-graft juncture, the balloon may alternatively be made of other similar soft materials such as polyisoprene, which is a synthetic latex substitute and is well tolerated by persons who are latex-intolerant.

Desirably, the angioplasty balloon is a polyethylene terpthalate material capable of withstanding up to twenty (20) atmospheres of pressure. Hence, the angioplasty balloon can be inflated to a very high pressure and significant force may be generated when the balloon is inflated to press against the plaque material and thereby open a passageway through the plaque material at the graft-vein juncture.

The angioplasty balloon desirably has a "rewrap" characteristic, so that the balloon rewraps tightly about itself when deflated, to ease insertion and removal of the balloon through introductory sheaths.

Optionally and desirably radiopaque markers, most desirably in the form of marker bands 21, 31, may be provided preferably on the exterior of catheter 10. These radiopaque markers are desirably provided positioned on catheter 10 so that the marker bands 21, 31 are within the interior of the latex and angioplasty balloons respectively when those balloons are inflated in the manner illustrated in Figure 2. However, positioning of the radiopaque markers is not limited to that illustrated in Figure 2, the radiopaque markers need not be within one or both of the balloons when the balloons are inflated. So long as the attending physician knows the location of the radiopaque markers vis-à-vis that of the balloons, the angioplasty procedure may go forward with the balloon-carrying catheter being guided radiographically.

While the invention has been described as preferably embracing an angioplasty balloon and a softer latex balloon preferably mounted on a common catheter, the position of the balloons may be reversed from that illustrated in Figure 2, the balloons may be differently configured from what is illustrated in Figure 2, two balloons of the same type may be used on the catheter, and the like.

Claims

1. Disposable apparatus for performing mechanical thrombectomy of dialysis grafts, comprising:

(a) an axially elongated catheter having at least three axially elongated non-communicating passages therewithin extending substantially the axial length of said catheter;

i. a first one of said passages as being of rounded cross-section for free axial travel therealong of a guide wire when inserted thereinto;

(b) a first balloon positioned along the exterior of said catheter proximate a first catheter end, with the interior of said first balloon being in fluid communication with a second one of said passageways, said first balloon when inflated being generally spherical and positioned about said catheter so that said catheter defines an axis of said spherical balloon shape;

(c) a second balloon positioned along the exterior of said catheter inboard of the first balloon relative to the first catheter end, with the interior of said second balloon being in fluid communication with a third one of said passageways, said second balloon when inflated having an axially elongated generally cylindrical central portion and generally conical end portions, with said cylindrical and conical portions of said balloon being symmetrically positioned about said catheter;

(d) said catheter including a pair of inflation ports respectively communicating with said second and third passageways proximate said second end of said catheter, adapted for connectable communication with a source of pressurized gas for selectably inflating said first and second balloons by supply of pressurized gas thereto via said second and third passageways in said catheter.

2. Apparatus of claim 1 wherein said first balloon is latex.

3. Apparatus of claim 1 wherein said second balloon is terephalatic polyurethane.

4. Apparatus of claim 1 wherein said catheter exterior is round.

5. Apparatus of claim 1 wherein said catheter exterior is asymmetrical.

6. Apparatus of claim 1 further comprising radiographically detectable means on said catheter located at a predetermined position for detection by x-ray or other radiographic imaging apparatus to permit guidance of the catheter by an attending physician during the performance of a medical procedure.

7. Apparatus of claim 6 wherein said radiographically is in band form.

8. Apparatus of claim 7 wherein at least one of said bands is within at least one of said balloons when said balloon is inflated.

9. A method for opening dialysis grafts clogged by thrombolytic material, comprising:

(a) introducing a catheter-shielded wire into a dialysis graft;

(b) extending said wire out of said catheter within said graft;

(c) rotating said wire while moving said wire along the length of said graft to loosen thrombolytic material within said graft;

(d) withdrawing said wire into said catheter;

(e) inserting said catheter into a vein communicating with said graft sufficiently far to position an angioplasty balloon carried by said catheter within the junction of said vein and said graft;

(f) inflating said angioplasty balloon by introduction of pressurized gas thereinto, to enlarge juncture of said vein and said graft;

(g) withdrawing said catheter and said angioplasty balloon from said juncture of said vein and said graft;

(h) inserting said catheter into an artery communicating with said graft sufficiently far to position a soft balloon carried by said catheter in said artery with junction of said artery and said graft being between said balloon and a point of entry of said catheter into said graft;

(i) inflating said soft balloon by introduction of gas thereinto;

(j) withdrawing said catheter from said artery-graft juncture sufficiently to pull thrombolytic material encountered by said soft balloon in the neighborhood of said artery-graft juncture into said graft.

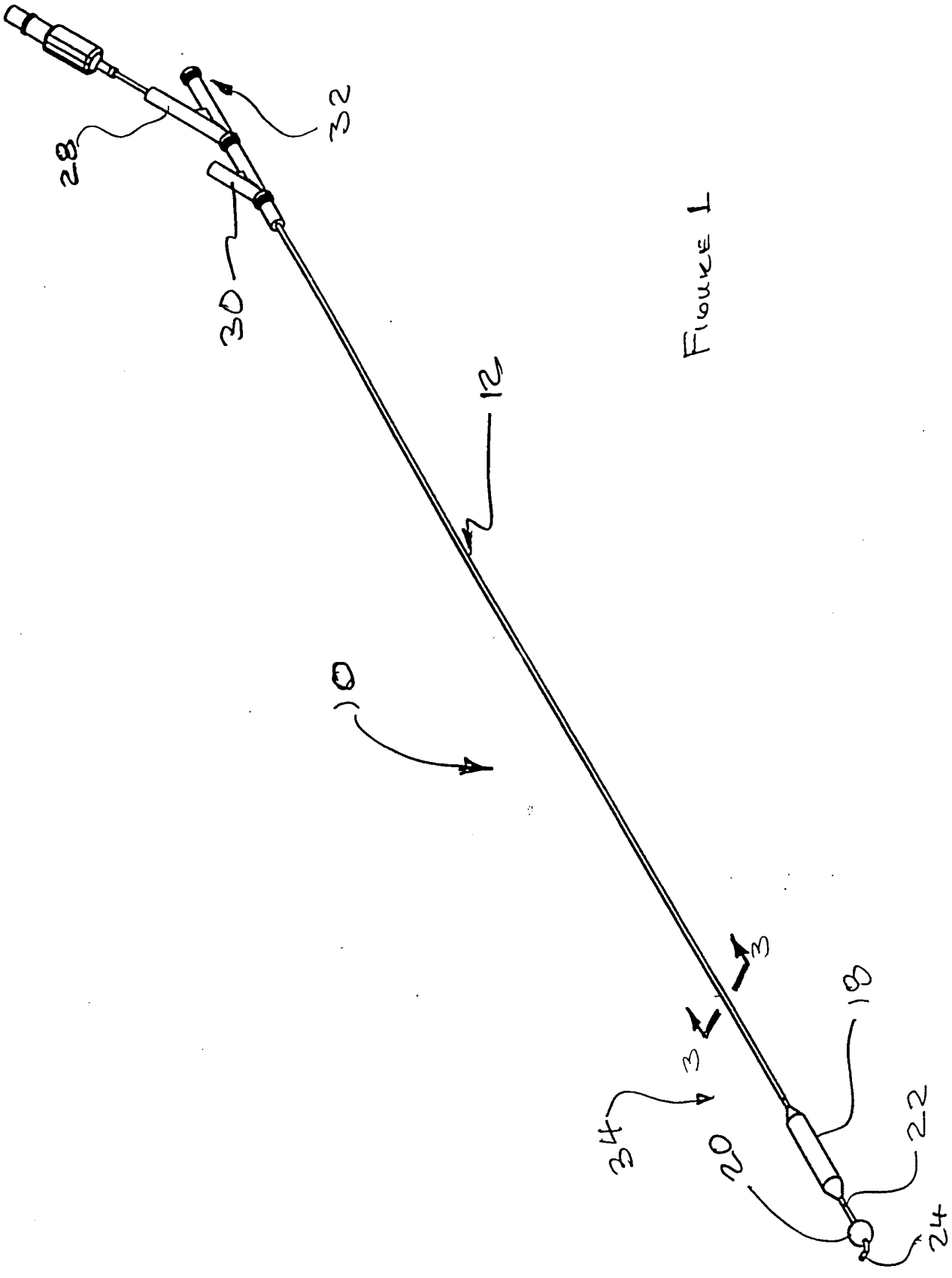


Figure 1

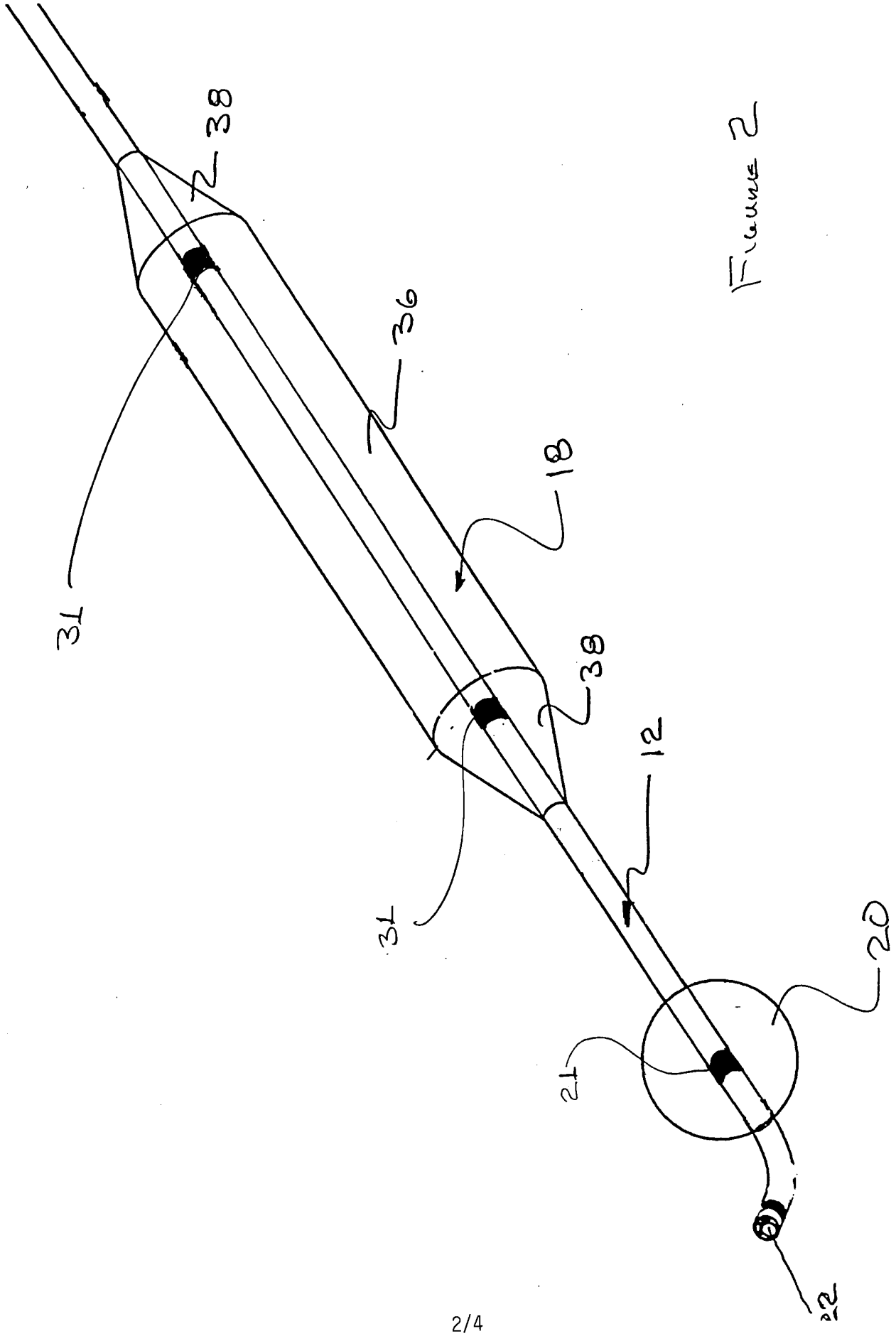


Figure 2

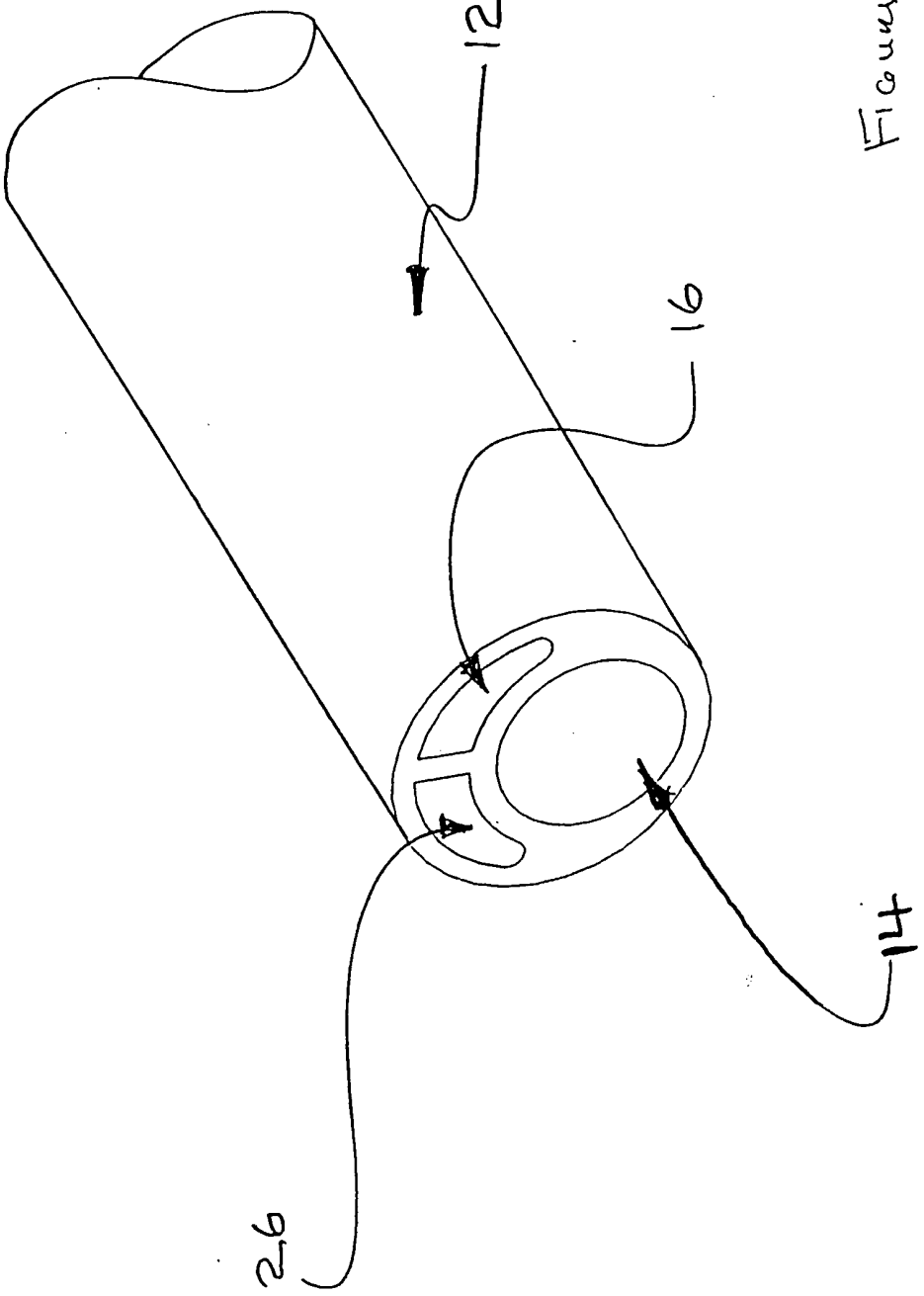


Figure 3

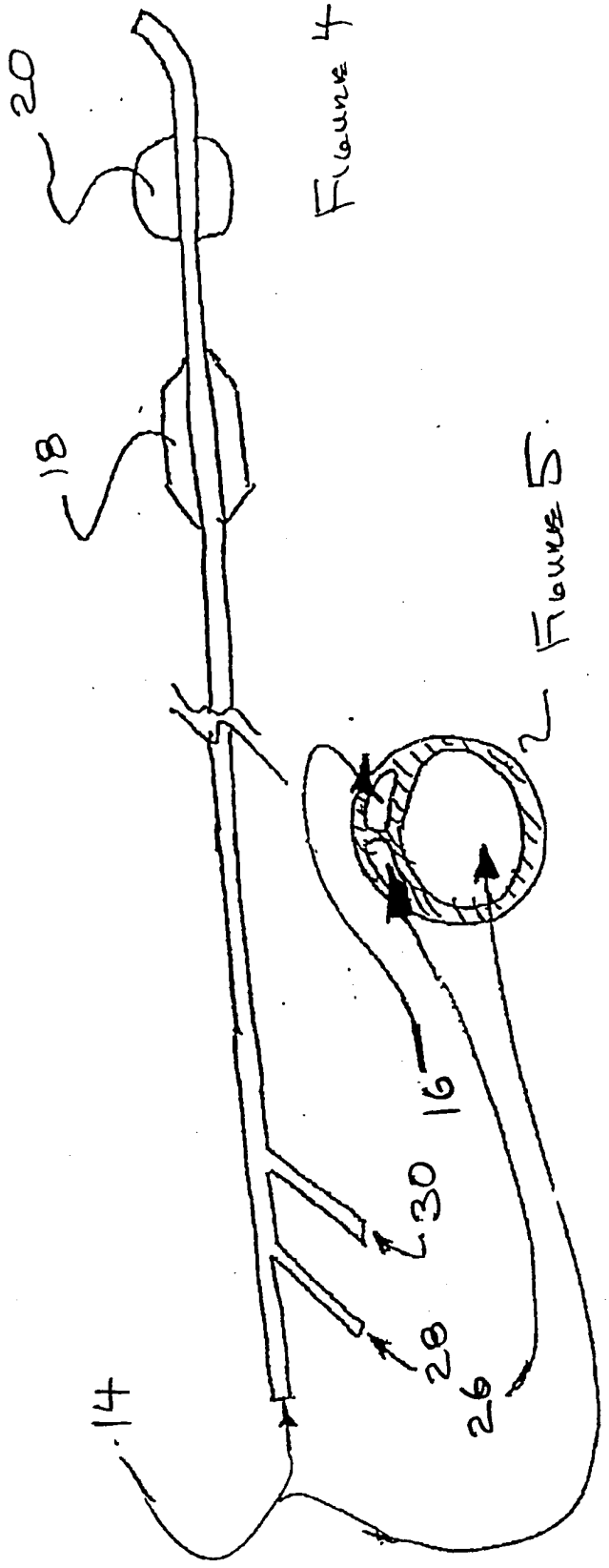


Figure 4

Figure 5