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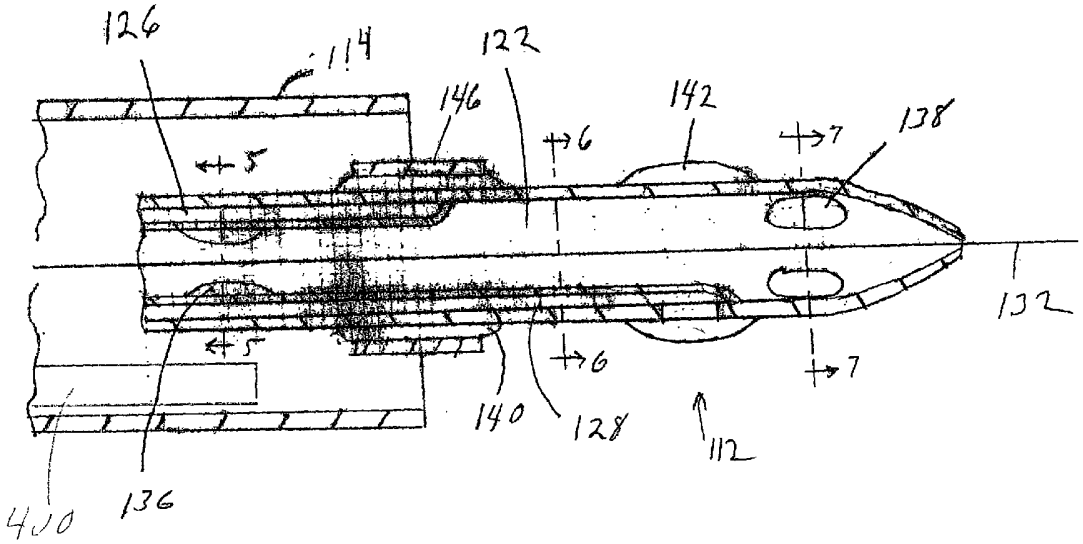
(54) Title: DISTAL PROTECTION DOUBLE BALLOON CATHETER



(57) Abstract: A system for performing a medical treatment in a blood vessel while providing downstream microcirculatory system protection, the system being composed of: a catheter (12), a central blood bypass flow lumen (22) extending along the longitudinal axis of the catheter and opening at the distal end, blood flow inlet (36) and outlet openings (38) extending from the lateral surface and communicating with the bypass flow lumen (22), and first and second inflation lumens (26, 28) extending to the lateral surface at respective first and second locations that are spaced apart along the longitudinal axis and that are between the inlet openings and the outlet openings; and first and second inflatable members (40, 42) secured to the lateral surface and each having an interior that communicates with a respective one of the first and second inflation lumens.

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TITLE OF THE INVENTION

DISTAL PROTECTION DOUBLE BALLOON CATHETER

[0001] This is a continuation-in-part of U.S. Application No. 10/118,332, filed April 9, 2002, the entire disclosure of which is incorporated herein by reference, which is itself a continuation-in-part U.S. Application No. 10/005,699, filed on December 7, 2001.

BACKGROUND OF THE INVENTION

[0002] The present invention relates to the treatment of obstructions in body passages, and particularly in arteries.

[0003] Treatments of this type typically produce debris that, if allowed to enter the microcirculatory system downstream of the treatment site, can cause damage to organs and tissues.

[0004] In the event of a heart attack caused by an arterial obstruction, there is reason to believe that the optimum treatment would be to immediately perform an angioplasty procedure, accompanied by removal of the resulting debris from the blood circulatory system. However, in order for such a treatment to be available when needed, suitable apparatus and knowledge of its use must be sufficiently widespread, and this would be more likely to occur if the apparatus is relatively inexpensive and easy to use.

BRIEF SUMMARY OF THE INVENTION

[0005] The present invention provides novel systems and methods that allow an angioplasty treatment, possibly with stenting or primary stenting, to be performed, while preventing the entry of debris resulting from such treatment into the distal microcirculatory system of a patient and assuring a continued supply of blood flow downstream of the obstruction during the angioplasty treatment and protection of organs and tissue downstream of the treatment site against damage that might be caused by debris resulting from the treatment.

[0006] One embodiment of a system according to the invention, for performing a medical treatment in blood vessels, is basically composed of: a catheter having a longitudinal axis, a distal end, an outer lateral surface, a central blood bypass flow lumen extending along the longitudinal axis and opening at the distal end, blood flow inlet and outlet openings extending from the lateral surface and communicating with the bypass flow lumen, and first and second inflation lumens extending to the lateral surface at respective first and second locations that are spaced apart along the longitudinal axis and that are between the inlet openings and the outlet openings; and first and second

inflatable members secured to the lateral surface and each having an interior that communicates with a respective one of the first and second inflation lumens, wherein the catheter has a thin outer wall enclosing a hollow interior that is completely occupied by the bypass flow lumen, except for the space occupied by the first and second inflation lumens.

[0007] The annular bypass lumen is formed adjacent the outer wall of the catheter. Therefore, the blood inlet and outlet openings in communication with the bypass flow lumen can be formed in a simple manner. In addition, these openings can be made relative large to assure an adequate blood flow, a flow of at least 30cc/min being considered necessary to maintain tissue viability.

[0008] Another embodiment of the invention for performing an angioplasty or stenting procedure in a blood vessel, comprises:

a catheter having a wall enclosing an axial lumen, the catheter having a distal end and the wall having a substantially circularly cylindrical inner surface and being provided with blood inlet openings spaced from the distal end and blood outlet openings in proximity to the distal end, the blood inlet openings and blood outlet openings communicating with the lumen and forming with the lumen a blood bypass flow path;

a blocking balloon carried by the catheter at a location between the blood inlet openings and the blood outlet openings; and

a guide wire insertable through the lumen and carrying a first structure dimensioned to be movable along the lumen but to substantially impede blood flow through the lumen when the first structure is positioned between the blood inlet openings and the blood outlet openings.

[0009] A further embodiment according to the invention is composed essentially of:

a double balloon catheter carrying a blocking balloon and an angioplasty balloon or sleeve and enclosing a blood bypass flow path through which blood can flow when one or both balloons are inflated;

a movable sheath surrounding the double balloon catheter; and

a guiding catheter surrounding the movable sheath.

BRIEF DESCRIPTION OF THE DRAWING

[0010] Figure 1 is a side elevational view, partly in cross section, of a first preferred embodiment of a catheter system according to the invention.

[0011] Figures 2 and 3 are cross-sectional views taken along lines 2-2 and 3-3, respectively, of Figure 1.

[0012] Figure 4 is a view similar to that of Figure 1 showing a second embodiment of the invention.

[0013] Figures 5, 6 and 7 are cross-sectional views taken along lines 5-5, 6-6 and 7-7, respectively, of Figure 1.

[0014] Figure 5' is a view similar to, and in the same plane as, Figure 5, showing a modified form of construction of the second embodiment.

[0015] Figure 8 is a side elevational view of a third embodiment of a catheter system according to the invention.

[0016] Figure 9 is a longitudinal, cross-sectional view of a fourth embodiment of the invention.

[0017] Figure 10 is a longitudinal view, partly in cross section, of a fifth embodiment of the invention.

[0018] Figure 11 is a longitudinal, cross-sectional view of a sixth embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

[0019] Referring to Figures 1-3, the system according to the first embodiment of the invention is composed essentially of a dilatation and embolic blocking catheter 12 and a surrounding, movable suction catheter 14, which may be in the form of a hypo tube.

[0020] Catheter 12 is provided with a central guidewire lumen 20 that is preferably coaxial with the longitudinal axis of catheter 12, a blood bypass flow lumen 22 that surrounds lumen 20 and is separated therefrom by a cylindrical wall 24, a proximal inflation lumen 26 and a distal inflation 28 lumen.

[0021] Lumen 20 extends the full length of catheter 12 and in open at the distal end thereof, which is the right-hand end in Figure 1. Lumen 20 is provided to receive a guidewire 32 that serves to guide catheter 12 to a desired treatment site.

[0022] Catheter 12 is provided with a plurality of blood flow inlet openings 36 and a plurality of blood flow outlet openings 38, each set of openings 36, 38 being distributed circumferentially around the outer lateral wall of catheter 12. Openings 36 and 38 extend through the lateral wall of catheter 12 into communication with lumen 22. Lumen 22 does not extend through the full length of catheter 12. The proximal end of lumen 22 extends to a point upstream of openings 36, while the distal end of lumen 22 extends downstream of openings 38. According to the present invention, all openings 36, 38 communicating with lumen 22 extend through the lateral wall of catheter 12.

[0023] Catheter 12 is completed by two inflatable members 40 and 42 carried on the outer wall of catheter 12 and each communicating with a respective one of inflation lumens 26 and

28. According to preferred embodiments of the invention, member 40 is a low compliance angioplasty balloon, or sleeve, or sheath, and member 42 is a high compliance blocking balloon. Balloons 40 and 42 are located between openings 36, 38. It is particularly important that the blood flow path defined by lumen 22 extend across balloon 42 because that balloon remains inflated for a longer period of time, of the order of several minutes, than does balloon 40, of the order of a few seconds. In further accordance with the invention, balloon 40 may carry a stent 46 that is to be expanded and deployed against the inner wall of a body passage to be treated.

[0024] Catheter 12 can also be provided with circular radiopaque bands adjacent to the proximal and distal edges of both balloons to assist in proper positioning of the catheter by conventional radiopaque fluoroscopic monitoring.

[0025] In practical embodiments of the invention, catheter 12 can have a size of 2-3 Fr (Fr is a notation indicating outside diameter; n Fr= n/3 mm), with a tapered tip, as shown, that helps to allow the catheter to traverse large obstructions.

[0026] The above-described device is manipulated to perform an angioplasty treatment in the following manner. Firstly, guidewire 32 is introduced into the blood vessel past the site

where a treatment is to be performed. This can be achieved by any conventional procedure that allows guidewire 32 to be advanced through the vessel in the direction of blood flow, *i.e.* so that the distal end of guidewire 32 points downstream. After the guidewire has been advanced to a point beyond the location of the obstruction to be treated, for example with the aid of conventional radiographic fluoroscopic monitoring, catheter 12 is placed over the guidewire so that the guidewire extends through lumen 20. Catheter 12 is then advanced over the guidewire to the site where the treatment is to be performed, specifically by bringing balloon 40 and stent 46, if provided, to a location opposite the obstruction. Then, tube 14 is inserted in the blood vessel around catheter 12 and brought to a location substantially as shown in Figure 1, upstream of the treatment site.

[0027] Then, balloon 42 is expanded by supplying a fluid at a suitable pressure, usually less than 1 atm, via lumen 28 to block the flow of blood between the outer wall of catheter 12 and the blood vessel wall. After balloon 42 has been thus inflated, blood continues to be supplied to the portion of the blood vessel downstream of catheter 12 by flowing through openings 36, lumen 22 and openings 38.

[0028] After balloon 42 has been inflated, balloon 40 is inflated by supplying a fluid at a suitable pressure via lumen

26 to press the obstruction outwardly and to expand and deploy stent 46. This operation generally results in the creation of debris consisting of material that has broken off from the obstruction. This debris will be prevented from flowing downstream of catheter 12 by inflated balloon 42 and will be trapped against the upstream side of balloon 42.

[0029] As soon as balloon 40 has been deflated, tube 14 is advanced in the downstream direction toward balloon 42 while suction is applied from an external suction source through tube 14. During this suctioning step, tube 14 can be moved back and forth along the axis of catheter 12 to aid the removal of debris. As a result, debris that has been trapped upstream of balloon 42 will be drawn into tube 14 and removed from the patient's body, where it can be inspected, possibly with the aid of a microscope. After suction has been performed for a sufficient time to assure removal of all debris, or at least all potentially dangerous debris, balloon 42 is deflated and tube 14 and catheter 12 are removed from the blood vessel.

[0030] A second embodiment of the a system according to the invention is shown in Figures 4-7 and is composed essentially of a dilatation and embolic blocking catheter 112 and a surrounding, movable suction catheter 114, which may be in the form of a hypo tube.

[0031] According to this embodiment, catheter 112 is a thin-walled body that is hollow, except for balloon inflation lumens, to be described below, to provide a blood bypass flow lumen 122 having a maximum cross section. Catheter 112 is provided with a proximal balloon inflation lumen 126 and a distal balloon inflation lumen 128. Lumens 126 and 128 are the only structures within catheter 112 and thus the only structures that reduce the cross section of lumen 122. Lumen 122 can, but need not, extend the full length of catheter 112 and has a small diameter opening at the distal end thereof for passage of a guidewire 132 that serves to guide catheter 112 to a desired treatment site. Preferably, the opening is made only slightly larger in diameter than guidewire 132 to allow more accurate guidance of catheter 112. If lumen 122 does not extend through the full length of catheter 112, the proximal end of lumen 122 may be located at a point upstream of openings 136, while the distal end of lumen 122 may be located downstream of openings 138, in the same manner as lumen 22 of Figures 1-3, while a guidewire lumen will be provided over the entire length of catheter 112, that is at least proximal, and possibly distal of lumen 122.

[0032] Catheter 112 is provided with a plurality of blood flow inlet openings 136 and a plurality of blood flow outlet openings 138, each set of openings 136, 138 being distributed

circumferentially around the outer lateral wall of catheter 112. All openings 136 and 138 extend through the lateral wall of catheter 112 into communication with lumen 122. A balloon, or a stent deployment sleeve or sheath, 140 and a balloon 142 are carried on the outer surface of catheter 112 at locations between openings 136 and 138. It is particularly important that the blood flow path defined by lumen 122 extend across balloon 142 because that balloon remains inflated for a longer period of time, of the order of several minutes, than does balloon 140, of the order of a few seconds.

[0033] Balloon or sleeve 140 communicates via openings in the wall of catheter 112 with inflation lumen 126 and balloon 142 communicates via other openings in the wall of catheter 112 with inflation lumen 128. According to preferred embodiments of the invention, balloon 140 is a low compliance angioplasty balloon, sheath, or sleeve, and balloon 142 is a high compliance blocking balloon. In further accordance with the invention, balloon 140 may carry a stent 146 that is to be expanded and deployed against the inner wall of a body passage to be treated.

[0034] Catheter 112 can also be provided with circular radiopaque bands adjacent to the proximal and distal edges of both balloons to assist in proper positioning of the catheter.

[0035] In practical embodiments of the invention, catheter 112 can have the following dimensions, identified in Figure 7:

a- an outer diameter of 1.0 mm (3 Fr.);

b- a wall thickness of 0.127 mm.

However, the diameter of the catheter can have other values, for example between about 2 Fr and 5Fr.

[0036] According to another feature of the invention, dimension b can vary along the length of the catheter and can, for example, have a greater value in a region aligned with balloon 140 than in a region between balloon 140 and the distal end of the catheter. A greater thickness in the region aligned with balloon 140 will help to keep the catheter from being compressed radially by the forces generated by balloon 140 during artery wall dilation, while a lesser thickness in the region between balloon 140 and the distal end of the catheter will give lumen 122 a larger cross section.

[0037] The provision of a tapered distal end, as shown, helps to allow the catheter to traverse large obstructions.

[0038] A modified version of the second embodiment is shown in Figure 5'. This version differs from the embodiment of Figures 5-7 only in that one inflation lumen, such as, for example, lumen 128 of figures 4-7, is replaced by a lumen 128' that extends outwardly from the outer lateral wall of catheter

112. This serves to enlarge the flow path provided by lumen 122.

[0039] A third embodiment of the invention is illustrated in Figure 8. This embodiment differs from those previously described in two basic respects: balloons 140 and 142 are mounted directly adjacent to one another; and the outer diameter of catheter 212 changes along its length, having a larger value, d_1, at least in the region aligned with balloon 140 and a smaller diameter, d_2, over all or a part of its length between balloon 140 and the distal end of the catheter. This configuration will act as a sump that increases blood flow through lumen 122. In addition, as described above with respect to the embodiment of Figures 4-7, the wall thickness of catheter 212 in the region between balloon 140 and the distal end can be smaller than in the region aligned with balloon 140. In practical embodiments of the catheter of Figure 8, d_1 can have a value between 3 and 5Fr and d_2 can have a value between 2 and 4Fr, with d_1 always being greater than d_2.

[0040] By placing balloon 142 directly adjacent balloon 140, it becomes possible to better prevent the escape of debris at locations that are directly adjacent to a side branch of the artery being treated. Balloon 140 and 142 can be mounted so that their facing edges abut one another.

[0041] According to other possibilities, the catheter system can be constructed so that balloons 140 and 142 are movable longitudinally relative to one another, for example as disclosed in issued U.S. patent No. 5,342,306. According to another possibility, balloon 142 can be spaced from balloon 140 and can be constructed in a manner to expand parallel to the axis of the catheter in a direction toward balloon 140, as disclosed in U.S. patent No. 5,380,284. The contents of these patents are incorporated herein by reference. Both of these alternatives allow the practitioner to better deal with situations in which the region in which an angioplasty treatment is to be performed is located directly adjacent a side branch of the artery being treated.

[0042] Embodiments of the invention can possess one or both of the features described above with reference to Figure 8 The above-described device is manipulated to perform an angioplasty treatment in the same manner as described earlier herein with respect to the embodiment shown in Figures 1-3.

[0043] A fourth embodiment of the invention is shown in Figure 9, which is a longitudinal, cross-sectional view showing two portions of a catheter 150, with a segment between the two portions broken away. Catheter 150 is preferably a thin-walled element that encloses a central lumen 160 that extends along the entire length of catheter 150 and opens at

the distal end thereof. The internal surface of the wall of catheter 150 is preferably circularly cylindrical.

[0044] The wall of catheter 150 is provided with a proximal balloon inflation lumen 162 for supplying inflation fluid to balloon, or sleeve, 40, and a distal balloon inflation lumen 164 for supplying inflation fluid to balloon 42. Preferably, lumens 162 and 164 are made as small as permitted to meet balloon, or sleeve, inflation and deflation requirements so as to leave as much space as possible for lumen 160.

[0045] Lumen 160 is a blood bypass flow lumen that extends between blood inlet openings 166 proximal to balloon 40 and blood outlet openings 168 distal to balloon 42. Openings 166 and 168, and the opening at the distal end of catheter 150, are dimensioned to provide a blood flow passage having a suitably large cross section to assure an adequate bypass blood flow when one or both of balloons 40 and 42 are inflated and lumen 160 is unobstructed.

[0046] When an angioplasty or stenting procedure is to be performed, a special guide wire 170 is inserted onto lumen 160, in place of a conventional guide wire that will normally have previously been present. Guide wire 170 carries two structures that form enlargements of wire 170. These structures may be beads 172 and 174, each of which may be spherical or cylindrical.

[0047] Bead 172 is dimensioned to substantially completely block lumen 160, while being just small enough to slide along lumen 160 in order to allow introduction and positioning of wire 170. Bead 174 is made smaller than bead 172, but larger in diameter than the opening at the distal end of catheter 150 and serves as an abutment to define a distal end position of guide wire 170 in catheter 150.

[0048] Before the start of an angioplasty or stenting procedure, guide wire 170 is withdrawn from catheter 150, or is at least in a retracted position, relative to the position shown in Figure 9, so that bead 172 is upstream of blood inlet openings 166. At some point after the start of dilatation of the blood vessel, or of the obstruction to be treated, guide wire 170 is advanced to bring bead 172 to a location between blood inlet openings 166 and blood outlet openings 168, thereby substantially blocking blood flow, and the flow of debris, through the blood bypass flow path. Proper positioning of guide wire 170 is aided by engagement of bead 174 against the wall of catheter 150 at the distal end thereof.

[0049] An angioplasty or stenting procedure with the device shown in Figure 9 will be performed in the manner described earlier herein, with the device of Figure 9 provided in place of catheter 12, 112, or 212.

[0050] Figure 10 shows the components of a fifth embodiment of the invention. The innermost component is a double balloon catheter 150, which could be identical to catheter 12, 112, 212, or 150, as shown in Figures 1-9. Catheter 150 carries a blocking balloon 42, and an angioplasty balloon, or sleeve, 40. A movable sheath, or hypotube, 240 is dimensioned to surround catheter 150. Sheath 240 is an imperforate tube that is open at both ends. The proximal end of sheath 240 is connected to a source 260 of flushing liquid, such as saline solution. Preferably, the inner diameter of sheath 30 is only slightly larger than the outer diameter of deflated balloon or sleeve 40.

[0051] A guiding catheter 250 is dimensioned to surround sheath 240. Guiding catheter 250 is composed of an imperforate tube that is open at both ends. The proximal end of catheter 250 is connected to a suction source 270.

[0052] The above-described appliance will be used in the following manner.

[0053] As the first step, a guide wire 32 is inserted into the blood vessel, most commonly a coronary artery, in the downstream direction, i.e. in the direction of blood flow in the vessel, to extend past the location of the obstruction to be removed, which will consist of plaque, clot, or a combination thereof.

[0054] Then, catheter 150 is advanced over guide wire 32 to bring balloon or sleeve 40 opposite the obstruction. Sheath 240 and guiding catheter 250 can be introduced and positioned in the blood vessel at any medically appropriate point in time.

[0055] Catheter 150 may be provided with radiopaque markers, possibly at locations immediately adjacent both ends of balloon 40, which can be observed radiographically in order to help bring balloon 40 to the proper position opposite the obstruction.

[0056] Guiding catheter 250 is introduced into the blood vessel around sheath 240 to a point at which the distal end of catheter 250, like the distal end of sheath 240, is located upstream of the obstruction that is to be treated.

[0057] Blocking balloon 42 can then be inflated to block the flow of blood through the vessel around catheter 150. At this time, an adequate blood flow is maintained through the blood passages constituted by lumen 160, inlet openings 166 and outlet openings 168 and the opening at the distal end of catheter 150.

[0058] Then, balloon, or sleeve, 40 is expanded in order to dilate the obstruction, and possibly also the blood vessel. Balloon 40 may, in accordance with current practice in the art, be provided with stent 46, which will be expanded against

the obstruction in order to permanently establish an open blood flow passage in the blood vessel at the location of the obstruction.

[0059] At or before this point in the procedure, guide wire 170 can be introduced to block blood flow through lumen 160 of catheter 150. A similar blocking arrangement could be used with catheter 112, or 212.

[0060] Then, balloon 40 is deflated and sheath 240 is advanced in the downstream direction, preferably, but not necessarily, by a distance sufficient to cover openings 166. These two operations, the deflation of balloon 40 and the advancing of sheath 240, can be performed in any order, or simultaneously. Preferably, sheath 240 is advanced as soon as possible after completion of the angioplasty step.

[0061] Movement of sheath 240 over openings 166 along with a flow of flushing liquid from source 260 reduces any blood flow between the region where the angioplasty step has been performed and inlet openings 166, thereby minimizing the danger of any debris entering lumen 160 and then flowing downstream of the catheter. This possibility is further reduced by dimensioning catheter 150 and sheath 240 so that only a very small gap exists therebetween. Of course, when catheter 150 and guide wire 170 are used, the danger of any

debris entering lumen 160 and then flowing downstream of the catheter is already minimal or nonexistent.

[0062] To facilitate and accelerate the removal of debris, and further prevent the escape of debris into lumen 160, a saline solution is caused to flow from source 260 through sheath 240 and around catheter 150 in the downstream direction, while suction is applied by suction source 270 through guiding catheter 250. Saline solution introduced via sheath 240 and natural blood flow around catheter 250 are drawn into catheter 250 along with debris from the angioplasty or stenting step. This allows essentially all of the debris to be removed in a short period time.

[0063] After this suction operation has been performed for a sufficient period of time, balloon 42 is deflated and the entire appliance may be withdrawn from the blood vessel.

[0064] Thus, an assembly according to the invention can perform an angioplasty or stenting operation while allowing a bypass blood flow through the catheter and enabling thorough and speedy removal of embolic debris.

[0065] Figure 11 shows the components of a sixth embodiment of the invention. In this embodiment, the innermost component is a single balloon catheter 312 that carries an angioplasty balloon, or sleeve, 40. Moveable sheath, or hypotube, 240 is dimensioned to surround catheter 312 and guiding catheter 250

is dimensioned to surround sheath 240. Sheath 240 and guiding catheter 250 are identical in structure and function to sheath 240 and guiding catheter 250 described in connection with Figure 10.

[0066] As in the embodiments previously described herein, balloon 40 may carry a stent 46 that is to be expanded and deployed against the inner wall of a body passage to be treated.

[0067] Catheter 312 is preferably a thin-walled element enclosing a central lumen 360 that extends along the entire length of catheter 312 and opens at the distal end thereof. The wall of catheter 312 is provided with a balloon inflation lumen 364 for supplying inflation fluid to balloon, or sleeve, 40. Preferably, lumen 364 is made as small as permitted to meet the inflation and deflation requirements of balloon, or sleeve, 40 so as to leave as much space as possible for lumen 360. Lumen 360 performs the same functions as lumen 160 described in connection with Figure 9. Openings 366 and 368, and the opening at the distal end of catheter 312, correspond in structure and function to the openings 166 and 168, and the opening at the distal end of catheter 150, respectively, described with reference to Figure 9. Because catheter 312 has only the one balloon inflation lumen 364, in addition to central lumen 360, central lumen 360 can be given a larger

cross-sectional area than lumen 160 of the embodiment of Figure 9, thereby permitting increased bypass blood flow.

[0068] Catheter 312 is further provided with a component for trapping debris when an obstruction is being dilated by expansion of balloon 40 and stent 46, if the stent is provided. The debris trapping component is composed of an annular sheet 380 of flexible, porous material secured at its distal end to catheter 312 and at its proximal end to a ring 384 of a resiliently deformable material, such as a memory metal. The device further includes a plurality of filaments, or wires, 388 connected between ring 384 and catheter 312, the connection to catheter 312 being, as shown, at a location between ring 384 and balloon 40. Filaments or wires 388 can be made of a polymer material or a memory metal and any number of filaments 388 may be provided. Filaments or wires 388 may be secured to catheter 312 with the aid of a further ring 392 made of plastic or metal.

[0069] Sheet 380 is made of a material having a porosity sufficient to retain potentially harmful debris particles while allowing blood to pass therethrough. For this purpose, sheet 380 preferably has pores with a diameter of 50-100 microns.

[0070] Sheet 380 and ring 384 are dimensioned so that ring 384 will extend fully across a body passage when the apparatus is in use.

[0071] Since it is preferable to not displace the apparatus relative to the body passage when the debris trapping device is fully deployed, which is the configuration shown in Figure 11, the debris trapping device is preferably fully or partially collapsed by hypotube 240. For the purpose, tube 240 is advanced in the direction of the distal end of catheter 312, while catheter 312 itself is held stationary, so that filaments 388 will first enter tube 240, causing ring 384 to begin to contract radially. This movement can continue until the entire debris trapping component has been retracted into tube 240, or at least until ring 384 has collapsed by a sufficient amount to be out of contact with the walls of the body passage while catheter 312 is being moved. Thus, preferably, the debris trapping component will be fully or at least partially retracted into tube 240 whenever catheter 312 is being moved into position prior to a treatment and whenever catheter 312 is withdrawn from the body passage at the completion of treatment.

[0072] When balloon 40, and possibly also stent 46, are being expanded to dilate an obstruction, the debris resulting from this operation will flow into, and be trapped in, sheet

380, while blood is permitted to pass through the sheet. In addition, a flow of blood continues through openings 366, lumen 360 and openings 368. Since catheter 312 contains only a single inflation lumen 364, substantially all of the region enclosed by the wall of catheter 312, which wall is preferably as thin as possible, is constituted by lumen 360. Thus, openings 366, lumen 360 and openings 368 provide a blood bypass flow passage having a substantial effective cross-section and upon deflation of balloon 40, the pores in sheet 30 provide an additional blood flow passage before the debris trapping device is retracted into tube 240.

[0073] Except for the limitations discussed above with regard to the procedure for placing the debris trapping component in a retracted condition during any movement of catheter 312, the apparatus shown in Figure 11 is used in the manner described above with respect to the apparatus of Figure 10.

[0074] The basic elements of one practical example of the embodiments shown in Figure 11 can have the following diameters:

catheter 312-3Fr;

tube 240-4Fr; and

tube 250-7Fr

[0075] According to alternative embodiments of the invention, devices such as shown in Figures 4-11 could be supplemented with a separate suction tube that is movable relative to the catheter and is connected to suction source 270. One example is suction tube 400, shown in Figure 4. The suction tube could have a diameter of 3Fr and could be used in place of hypotube 240.

[0076] The foregoing description of the specific embodiments will so fully reveal the general nature of the invention that others can, by applying current knowledge, readily modify and/or adapt for various applications such specific embodiments without undue experimentation and without departing from the generic concept, and, therefore, such adaptations and modifications should and are intended to be comprehended within the meaning and range of equivalents of the disclosed embodiments. It is to be understood that the phraseology or terminology employed herein is for the purpose of description and not of limitation. The means, materials, and steps for carrying out various disclosed functions may take a variety of alternative forms without departing from the invention.

[0077] Thus the expressions "means to..." and "means for...", or any method step language, as may be found in the specification above and/or in the claims below, followed by a

functional statement, are intended to define and cover whatever structural, physical, chemical or electrical element or structure, or whatever method step, which may now or in the future exist which carries out the recited function, whether or not precisely equivalent to the embodiment or embodiments disclosed in the specification above, i.e., other means or steps for carrying out the same functions can be used; and it is intended that such expressions be given their broadest interpretation.

CLAIMS

What is claimed is:

1. An assembly for performing an angioplasty or stenting procedure in a blood vessel, comprising:

a catheter having a wall enclosing an axial lumen, said catheter having a distal end and said wall having a substantially circularly cylindrical inner surface and being provided with blood inlet openings spaced from said distal end and blood outlet openings in proximity to said distal end, said blood inlet openings and blood outlet openings communicating with said lumen and forming with said lumen a blood bypass flow path;

a blocking balloon carried by said catheter at a location between said blood inlet openings and said blood outlet openings; and

a guide wire insertable through said lumen and carrying a first structure dimensioned to be movable along said lumen but to substantially impede blood flow through said lumen when said first structure is positioned between said blood inlet openings and said blood outlet openings.

2. The assembly of claim 1, wherein said catheter has an opening at said distal end that communicates with said axial lumen, and said guide wire carries a second structure

dimensioned and located to abut against said wall of said catheter at said opening at said distal end when said first structure is in position to impede blood flow through said lumen.

3. The assembly of claim 2, further comprising an expandable blood vessel dilation device carried by said catheter at a location between said blood inlet openings and said blocking balloon.

4. The assembly of claim 3, wherein each of said structures constitutes a cylindrical or spherical enlargement of said guide wire.

5. An assembly for performing an angioplasty or stenting procedure in a blood vessel, comprising:

a double balloon catheter carrying a blocking balloon and an angioplasty balloon or sleeve, said catheter enclosing a blood bypass flow path through which blood can flow when one or both balloons are inflated;

a movable sheath surrounding said double balloon catheter; and

a guiding catheter surrounding said movable sheath.

6. The assembly of claim 5, further comprising: a source of flushing fluid coupled to said sheath for delivering flushing fluid into said sheath; and a suction source coupled to said guiding catheter for creating a suction force within said guiding catheter.

7. A method for performing an angioplasty or stenting procedure in a blood vessel containing an obstruction with the assembly of claim 6, comprising:

introducing the balloon catheter into the blood vessel to a location at which the angioplasty balloon or sleeve faces the obstruction and the blocking balloon is downstream of the obstruction;

expanding the blocking balloon and the angioplasty balloon or sleeve to dilate the obstruction;

contracting the angioplasty balloon or sleeve and introducing a flushing liquid through the sheath from the source of flushing fluid to a region between the angioplasty balloon or sleeve and the blocking balloon; and

applying a suction force to the region between the angioplasty balloon or sleeve and the blocking balloon through the guide catheter from the suction source.

8. A device for treating obstructions in a body passage, comprising:

a catheter having a distal end and provided with a bypass flow passage constituted by at least one inlet opening remote from said distal end, at least one outlet opening close to said distal end and a longitudinally extending lumen extending between, and communicating with, said inlet and outlet openings:

a dilation component carried by said catheter at a location between said inlet opening and said outlet opening and operable to dilate an obstruction in the body passage; and

a debris trapping component carried by said catheter at a location between said distal end and said dilation component, said debris trapping component comprising a flexible sheet that is expandable to obturate the body passage and that is porous to allow passage of liquid while blocking passage of debris resulting from dilation of the obstruction,

wherein said catheter encloses only said bypass flow passage and a lumen for supplying fluid to said dilation component.

9. The device of claim 8 wherein said flexible sheet surrounds said catheter and has a distal end that is

secured to said catheter and a proximal end that is dimensioned to contact the wall of the body passage so that said sheet forms, a receptacle that is open toward said dilation component.

10. The device of claim 9 wherein said debris trapping component further comprises: a ring attached to said proximal end of said sheet, said ring being normally in a configuration to contact the wall of the body passage and being resiliently deformable into a radially contracted configuration by external forces; and a plurality of strips of flexible material connected to said ring and to said catheter at a location between said ring and said dilation component.

11. The device of claim 10 further comprising a first hollow tube surrounding said catheter and a second hollow tube surrounding said first hollow tube, each of said hollow tubes being movable relative to said catheter.

FIG. 1

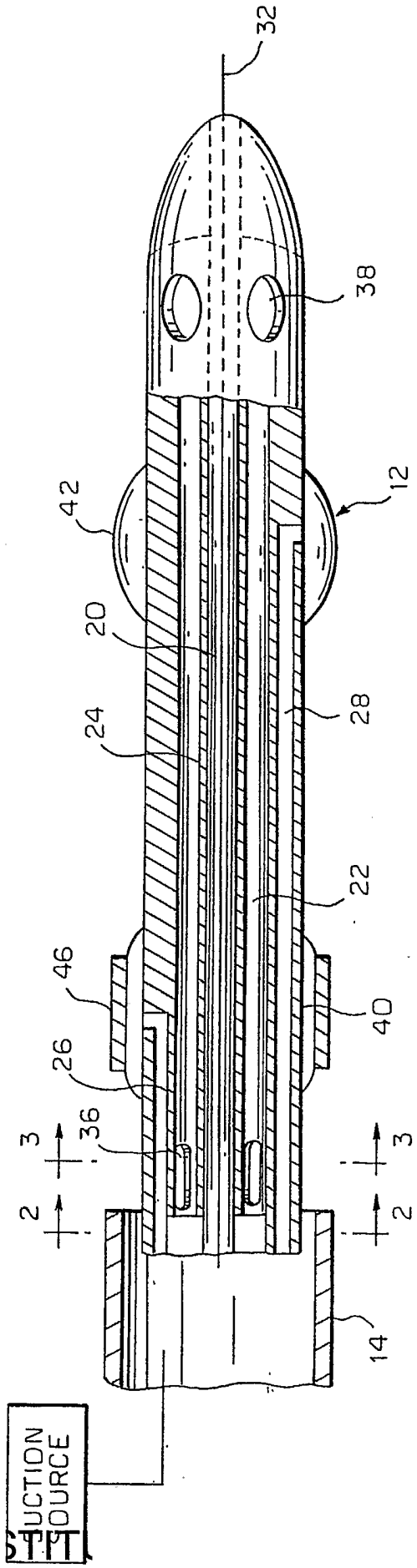


FIG. 2

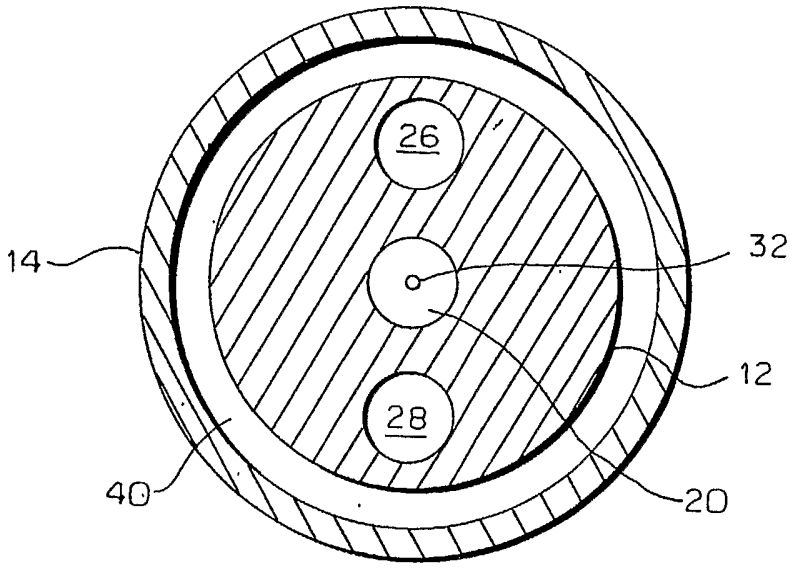


FIG. 3

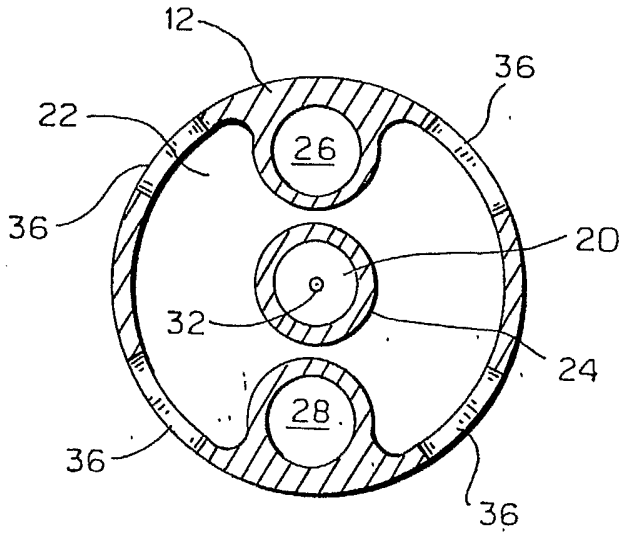


FIG. 4

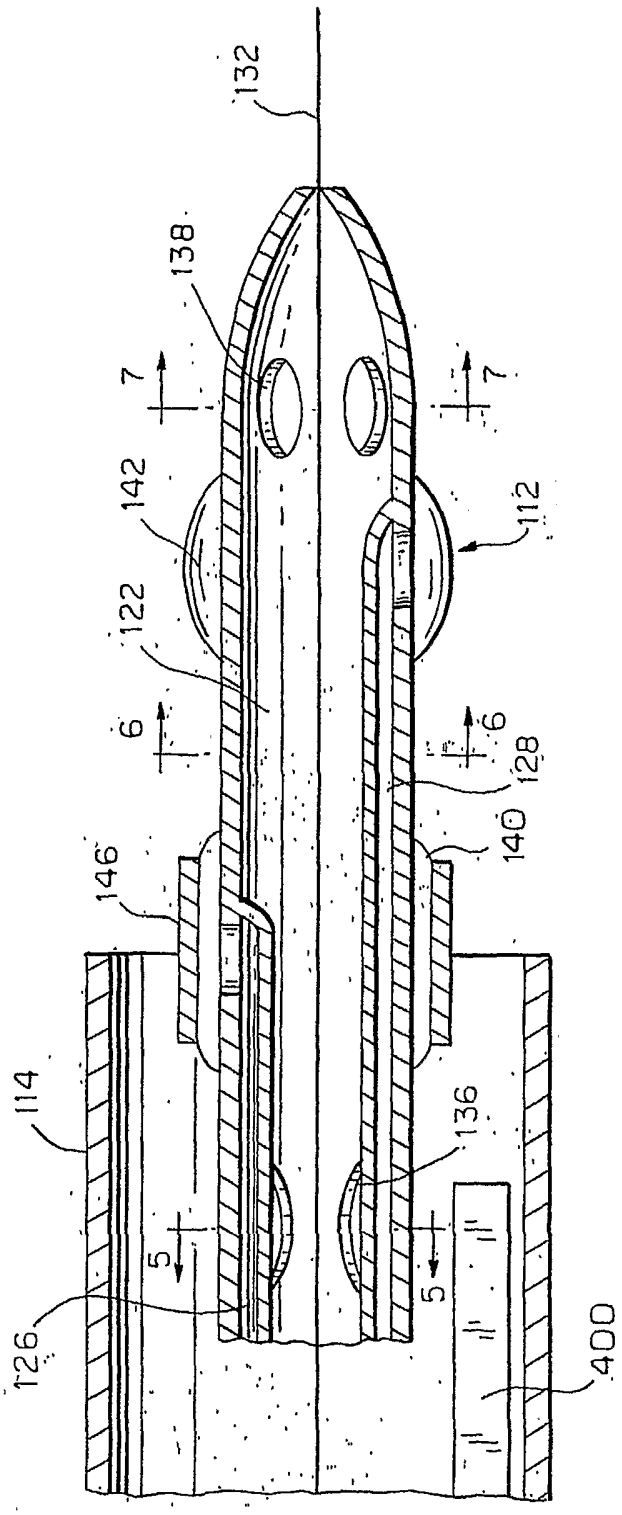


FIG. 5

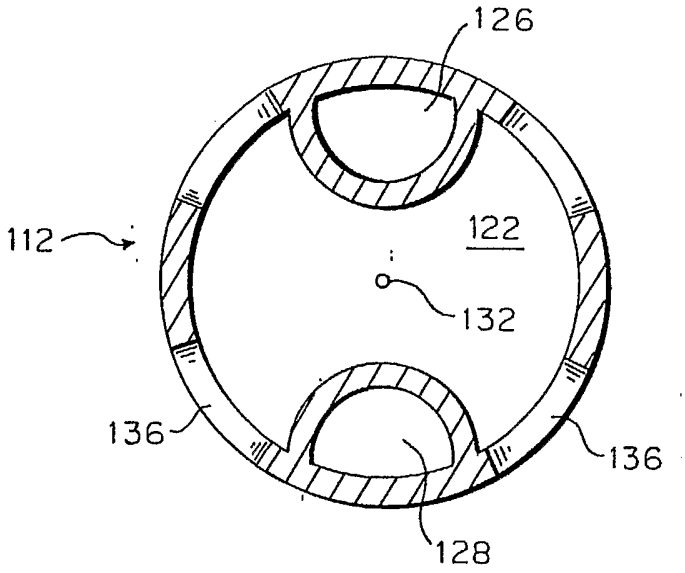


FIG. 5'

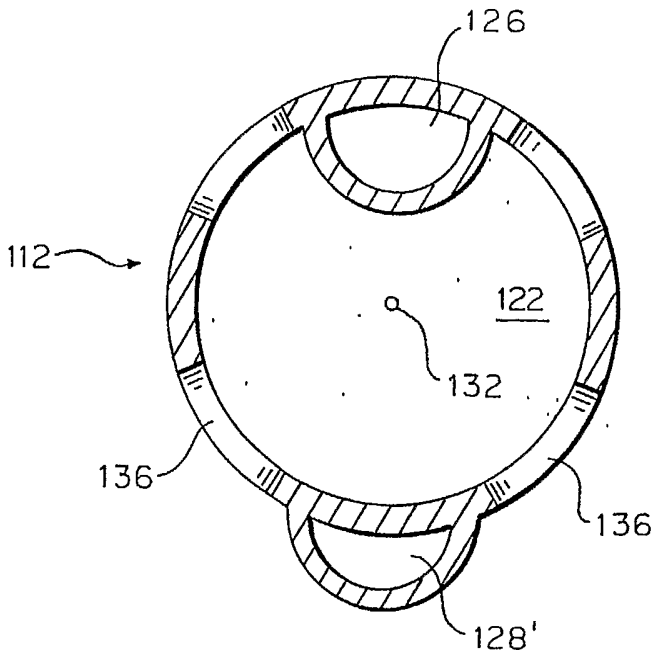


FIG. 6

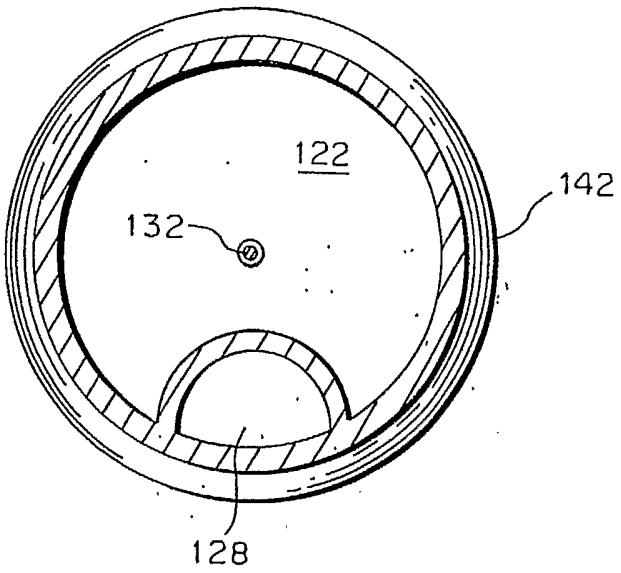


FIG. 7

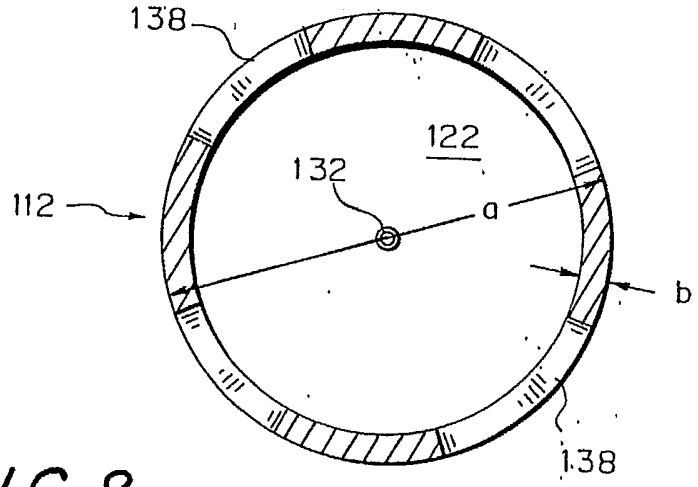
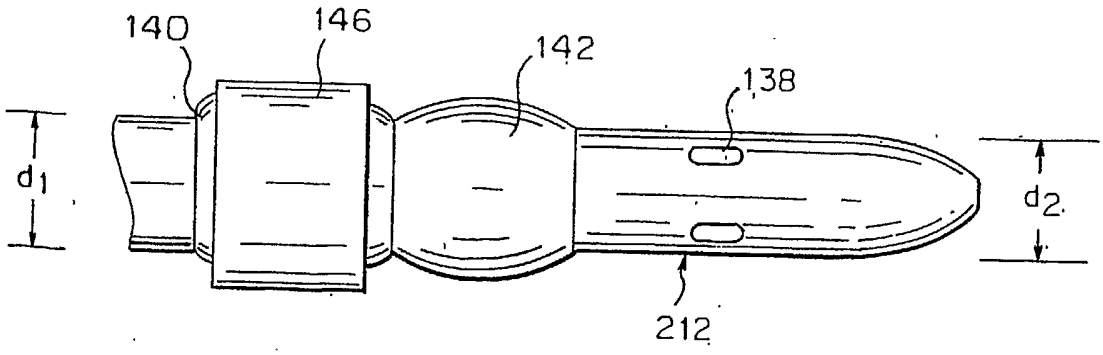


FIG. 8



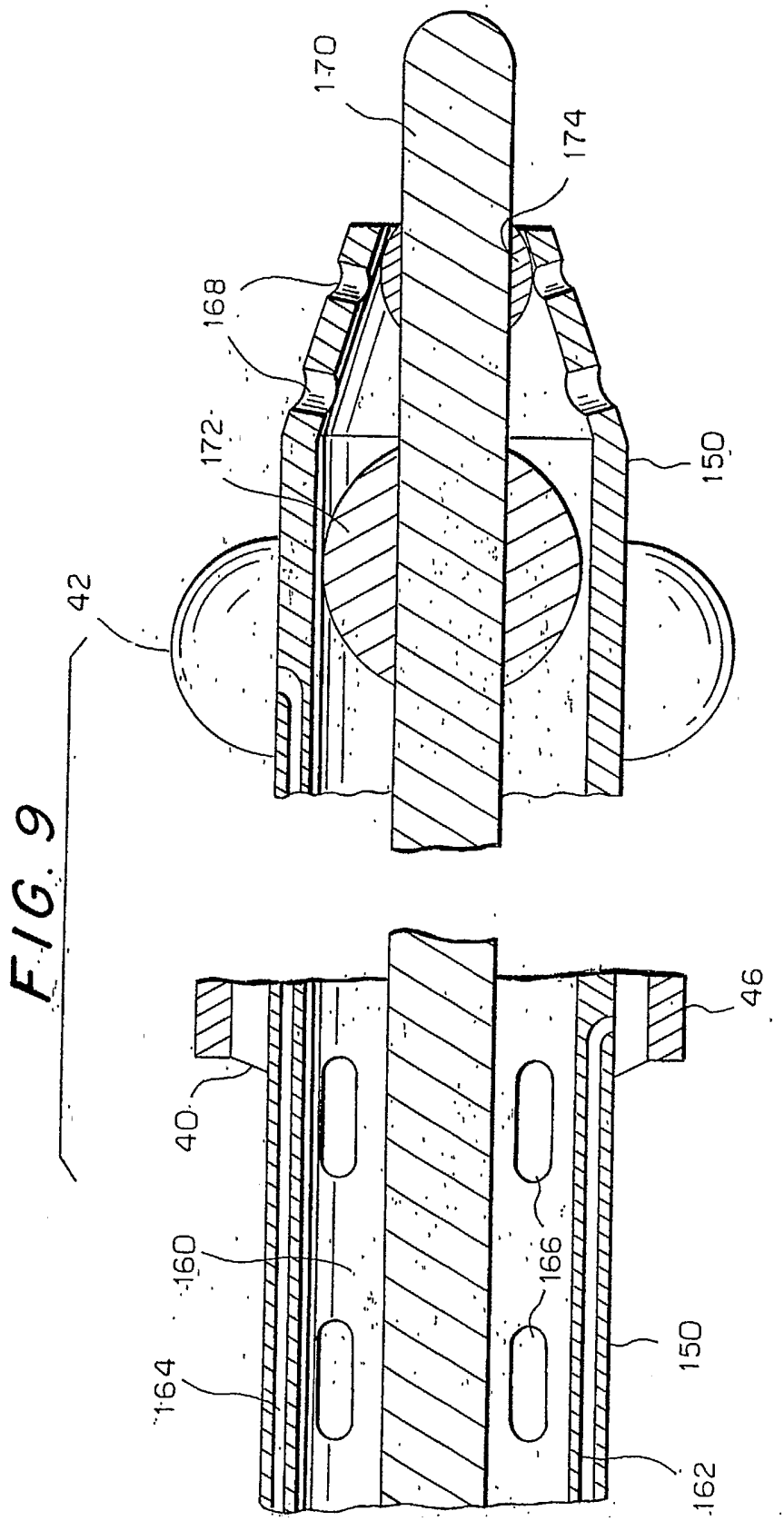


FIG. 9

FIG. 10

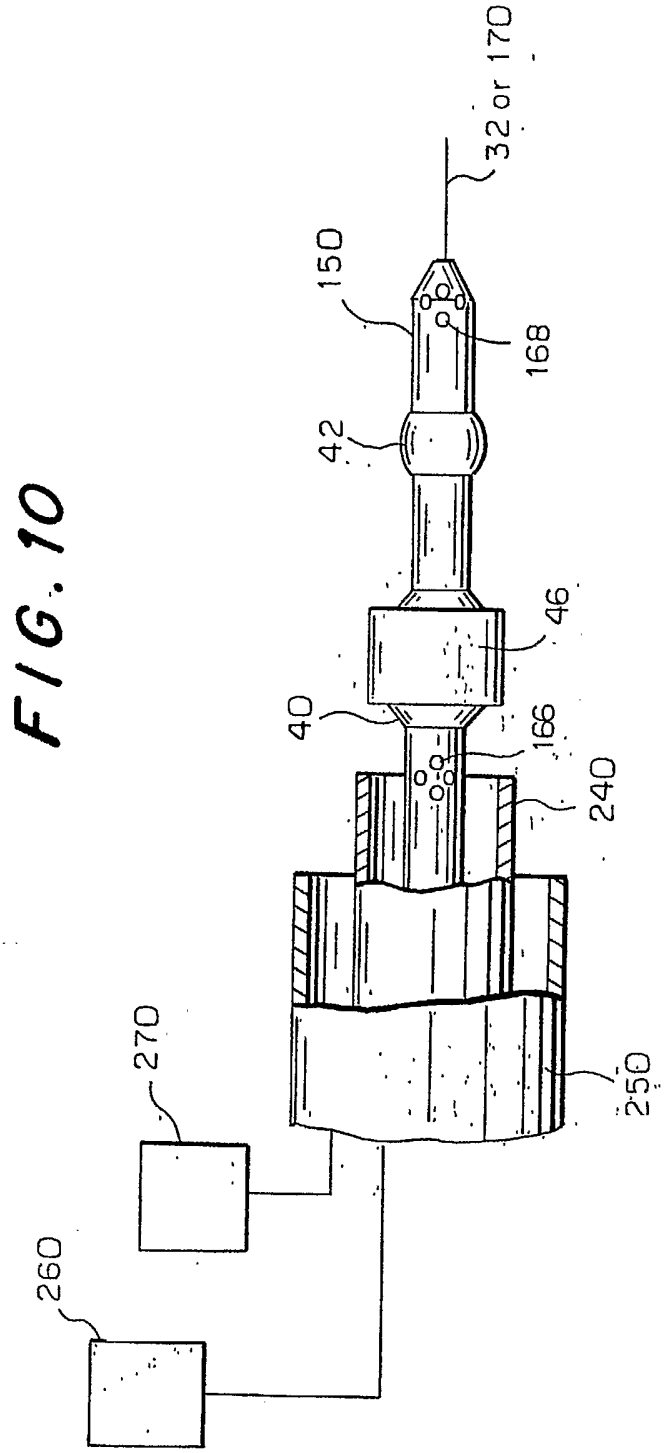
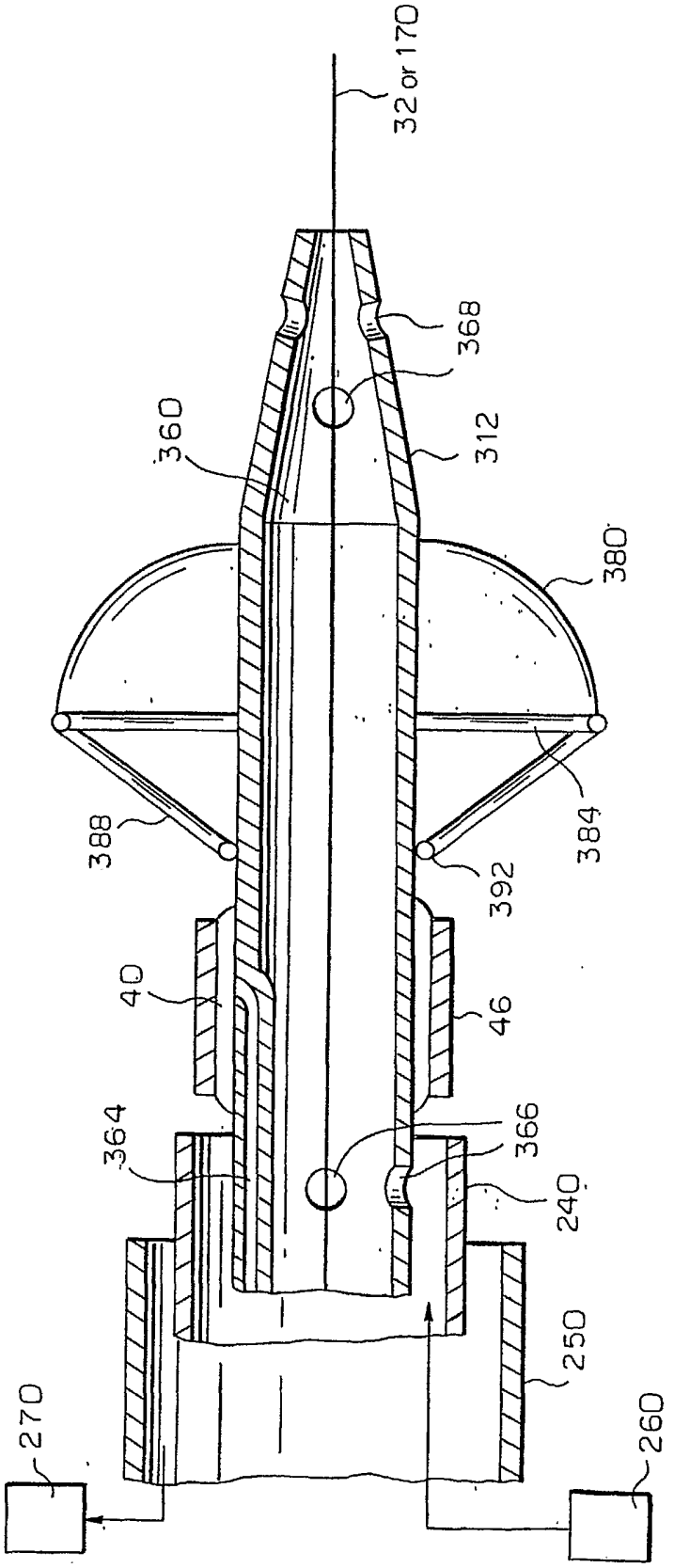


FIG. 11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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/10732

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61M 29/00
US CL : 606/194; 604/101.05

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, 200; 604/101.05, 101.03, 102.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
None

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,478,309 A (SWEEZER et al.) 26 December 1995, (26.12.1995), see figures 8-14.	1-7
A, P	US 6,485,500 B1 (KOKISH et al.) 26 November 2002 (26.11.2002), see figures 13 and 25.	8-11

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

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"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

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2003 (28.07.2003)	04 SEP 2003
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703)305-3230	Authorized officer (Jackie) Tan-Uyen T. Ho Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet) (July 1998)