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(54) **METHOD AND APPARATUS FOR EMBOLI CONTAINMENT**

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Related U.S. Application Data

(63) Continuation of application No. 09/790,220, filed on Feb. 21, 2001, which is a continuation of application No. 08/813,023, filed on Mar. 6, 1997, now patented, which is a continuation-in-part of application No. 08/650,464, filed on May 20, 1996, now abandoned.

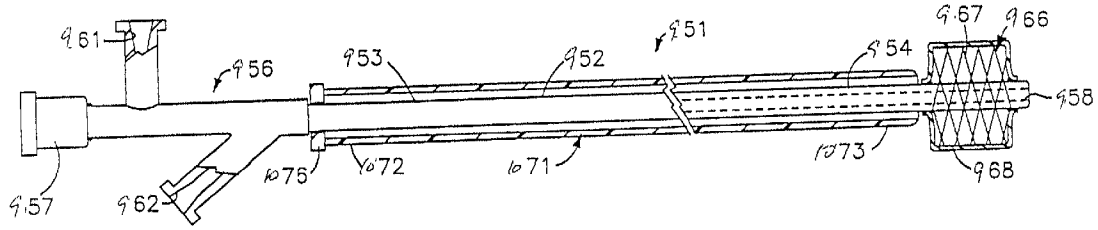
Publication Classification

(51) **Int. Cl.**[7] **A61M 29/00**; A61F 2/06

(52) **U.S. Cl.** **623/1.2**

(57) **ABSTRACT**

Disclosed herein is a catheter for use in an emboli containment system. In one embodiment, the catheter includes a flexible elongate member having self-expanding sealing means mounted on its distal extremity. This self-expanding sealing means can take any suitable form, such as a braided structure formed of a suitable shape memory material such as a nickel titanium alloy. In order to prevent abrasion of a vessel, it is desirable to cover the braided structure with a covering of a suitable material such as a polymer which extends over the braided structure and which moves with the braided structure as it expands and contracts.



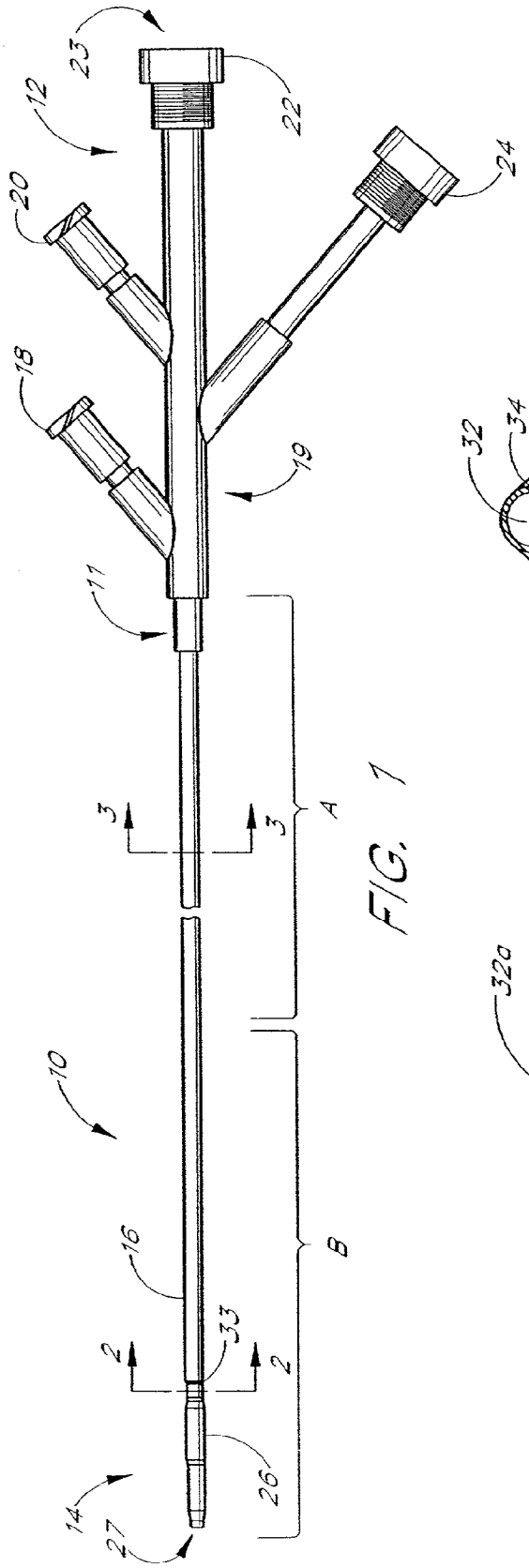


FIG. 1

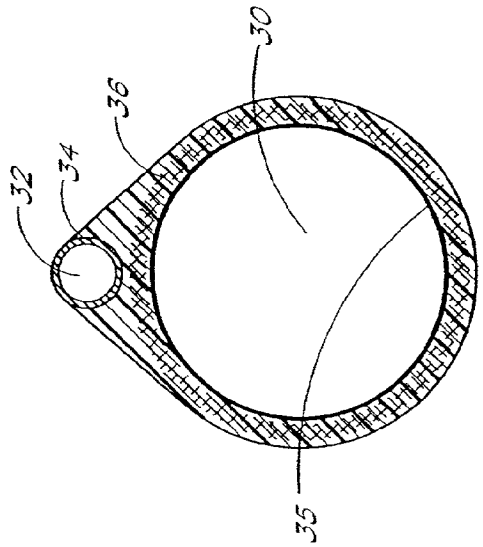


FIG. 3

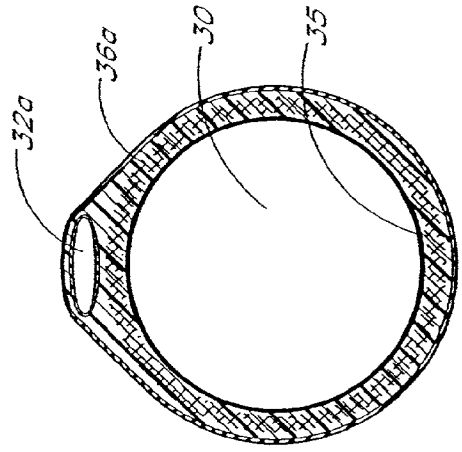


FIG. 2

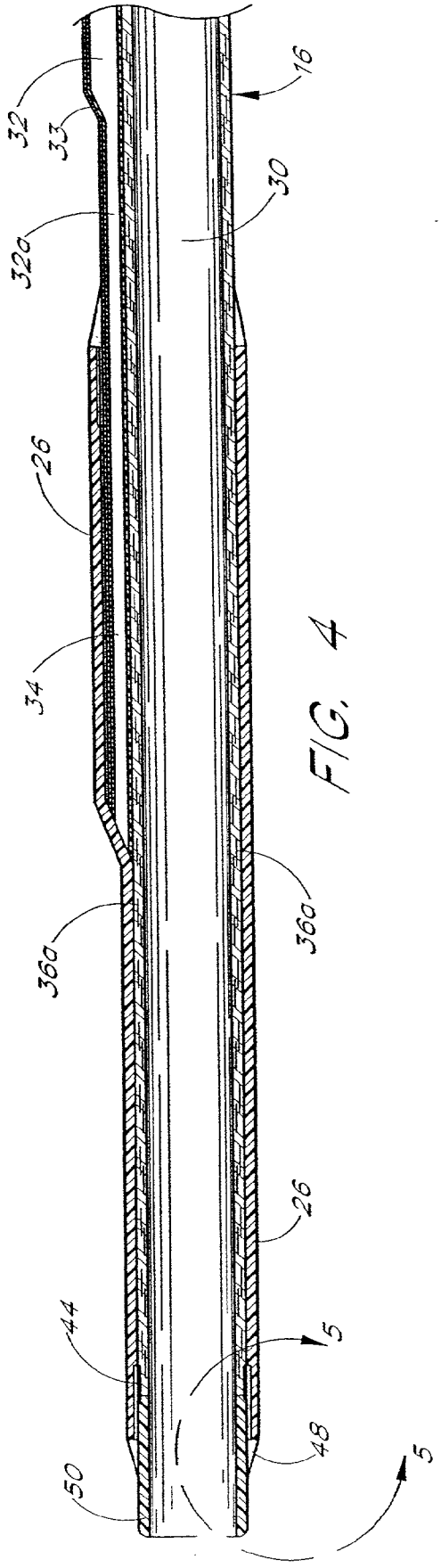


FIG. 4

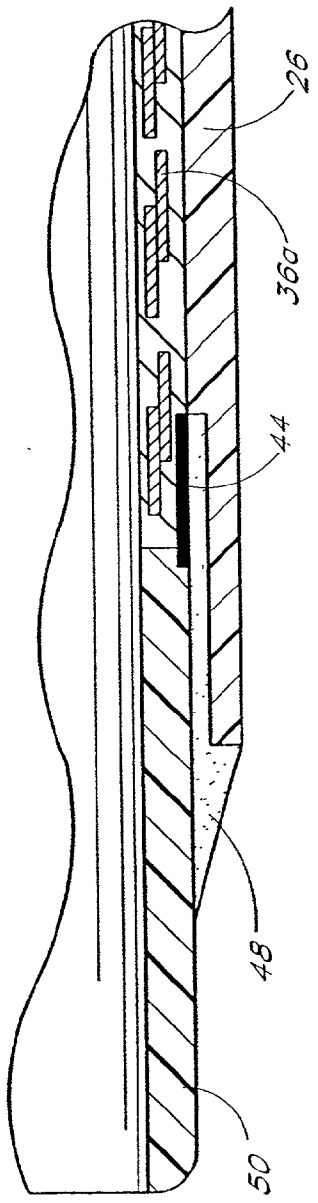


FIG. 5

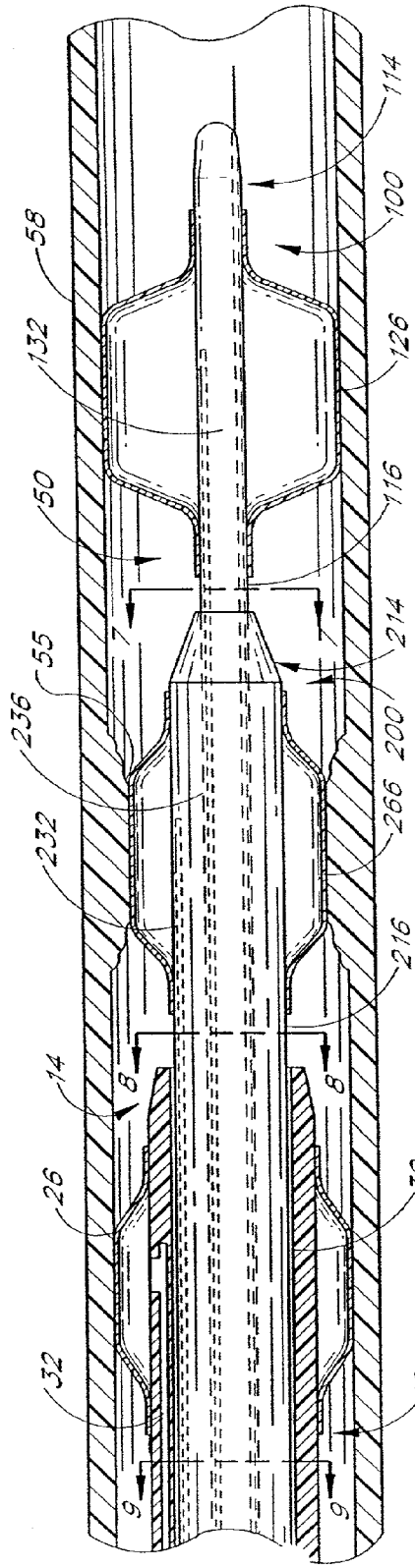


FIG. 6

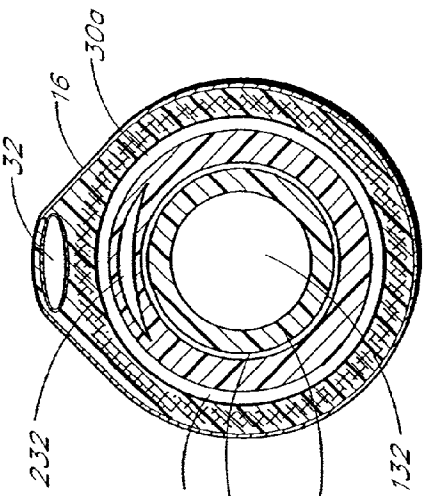


FIG. 9

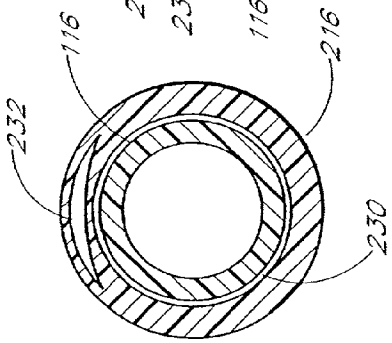


FIG. 8

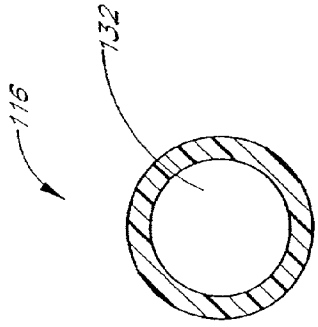


FIG. 7

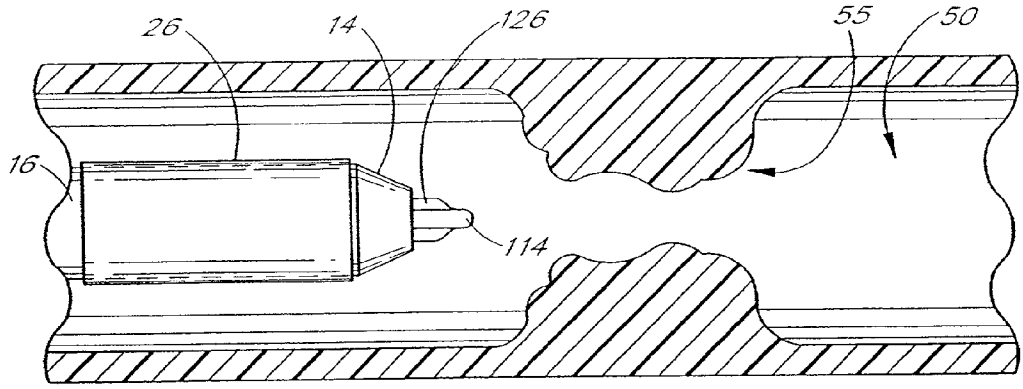


FIG. 10A

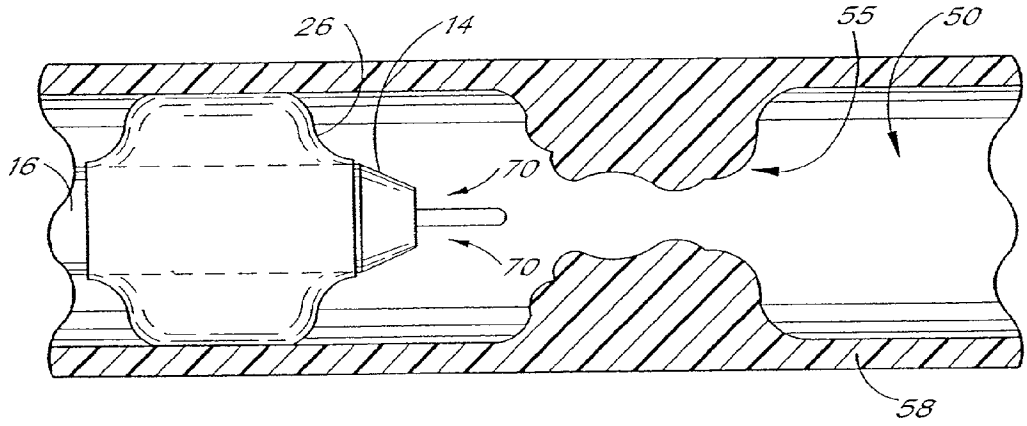


FIG. 10B

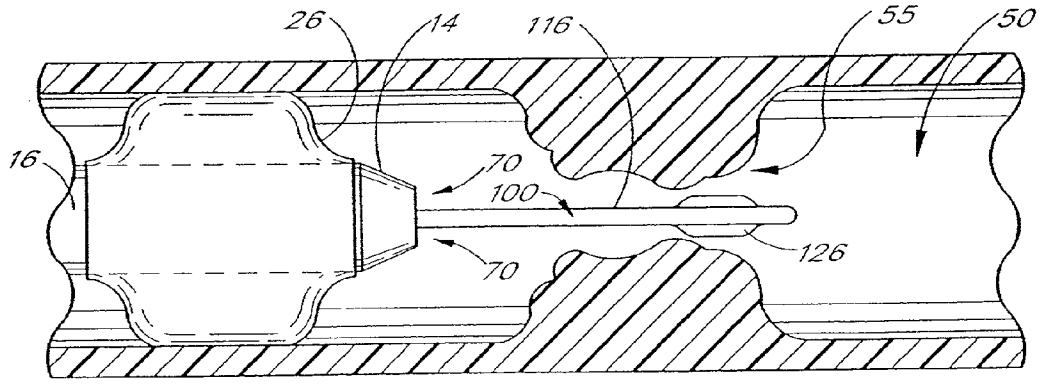


FIG. 10C

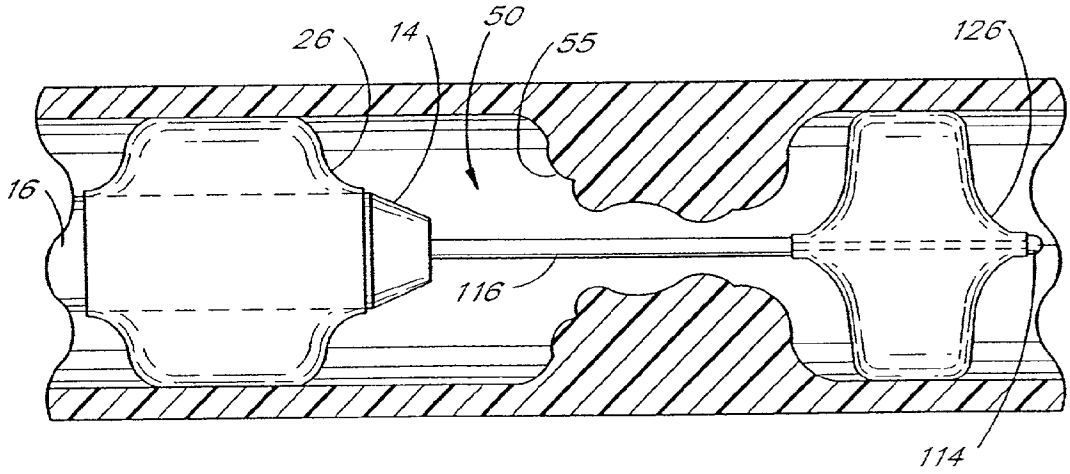


FIG. 10D

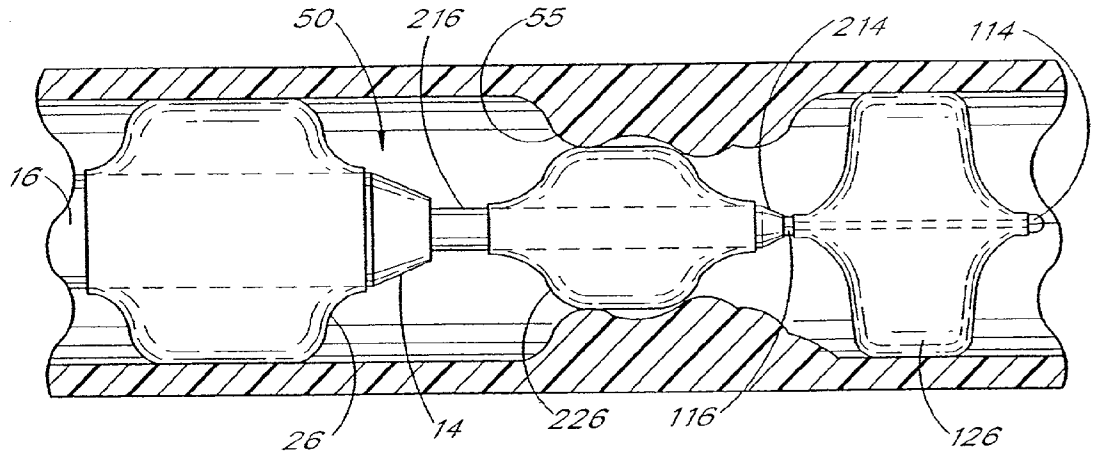


FIG. 10E

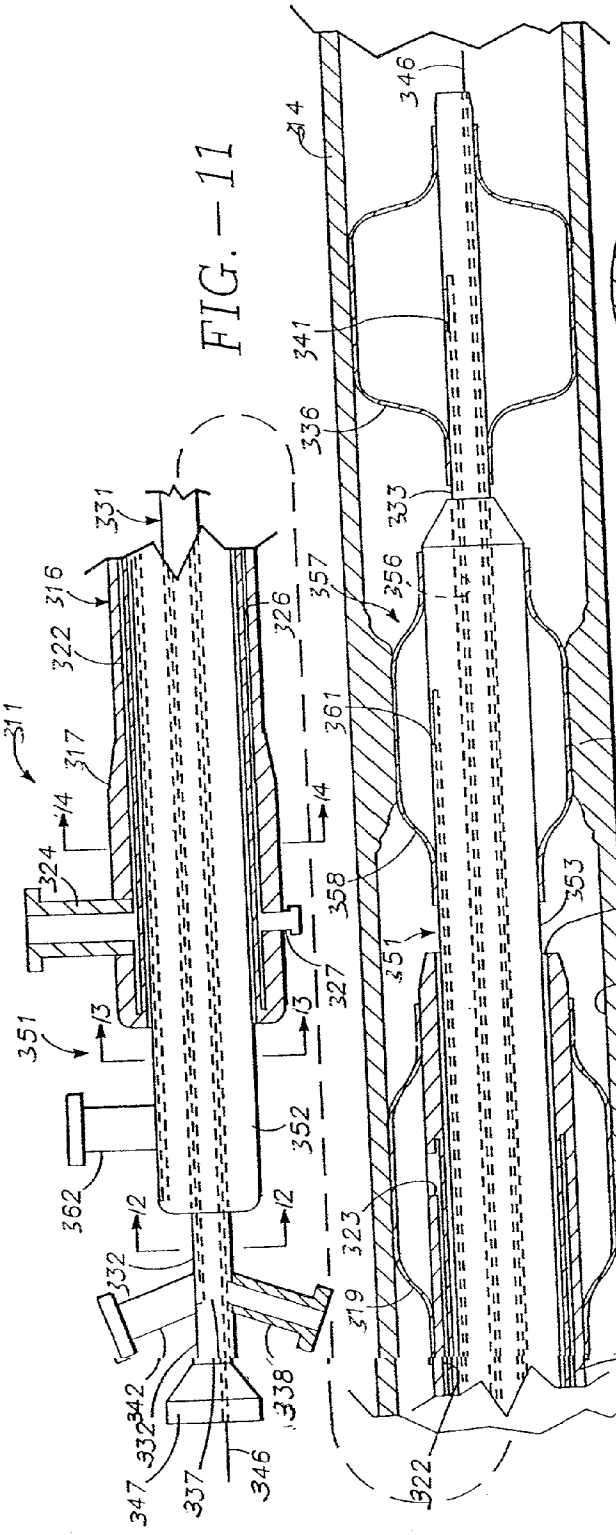


FIG. -11

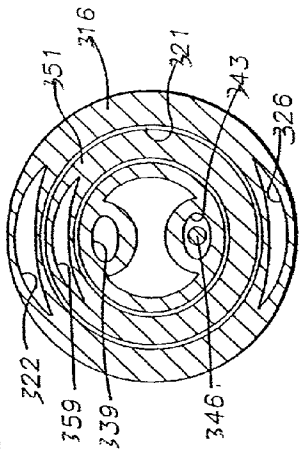


FIG. -14

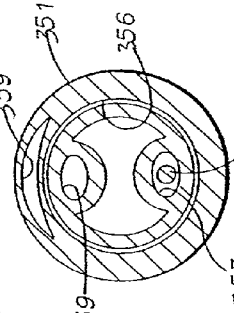


FIG. -13

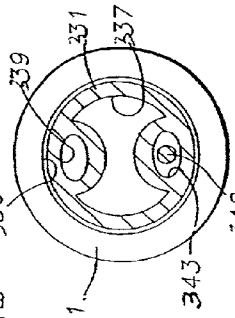


FIG. -12

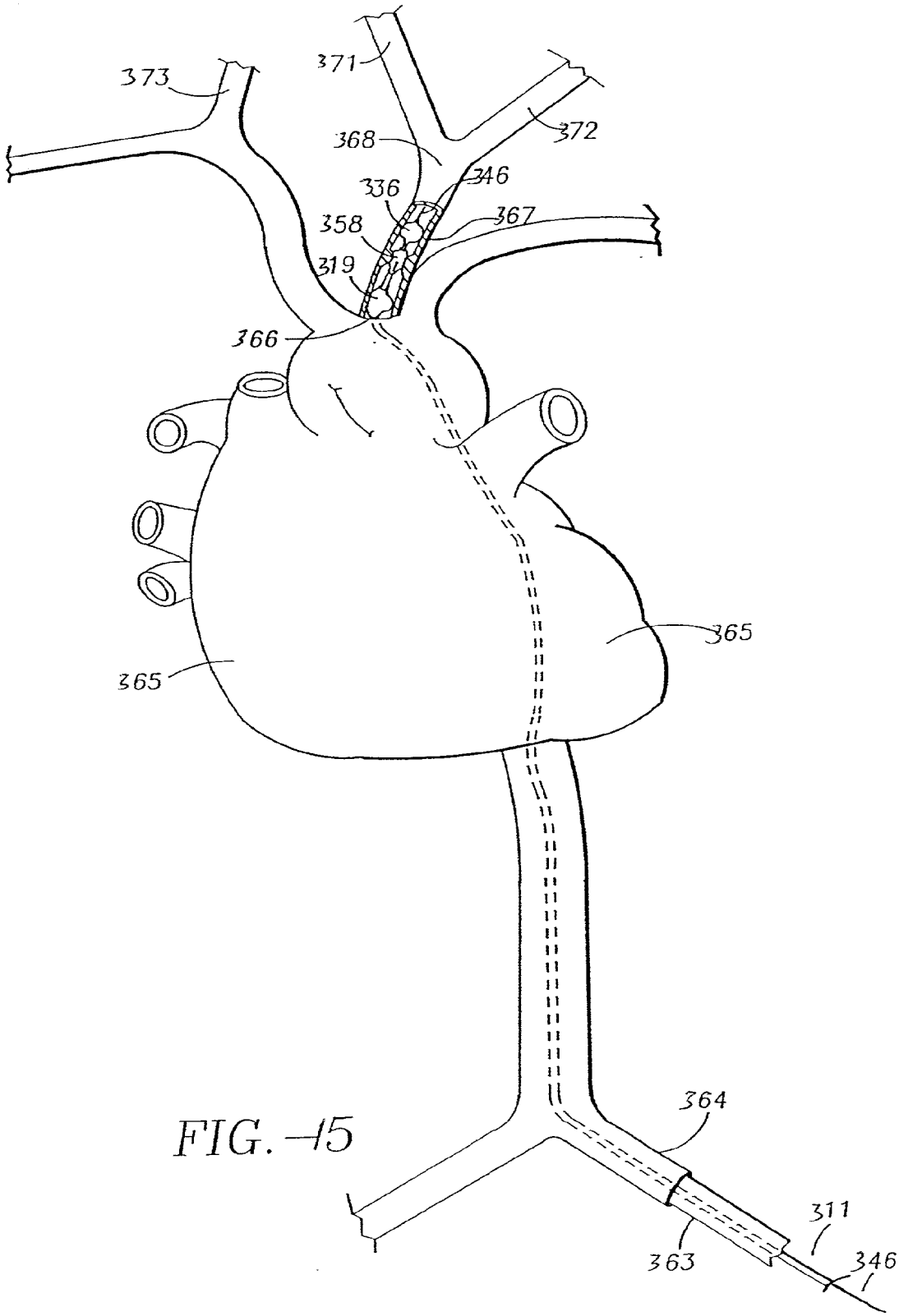


FIG. -15

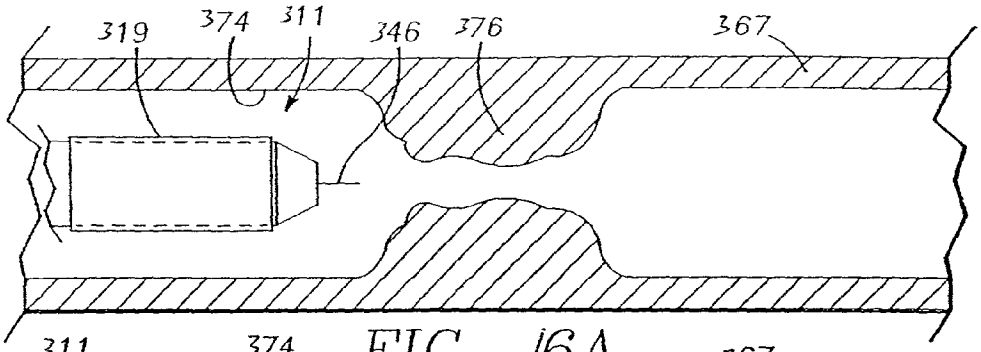


FIG. -16A

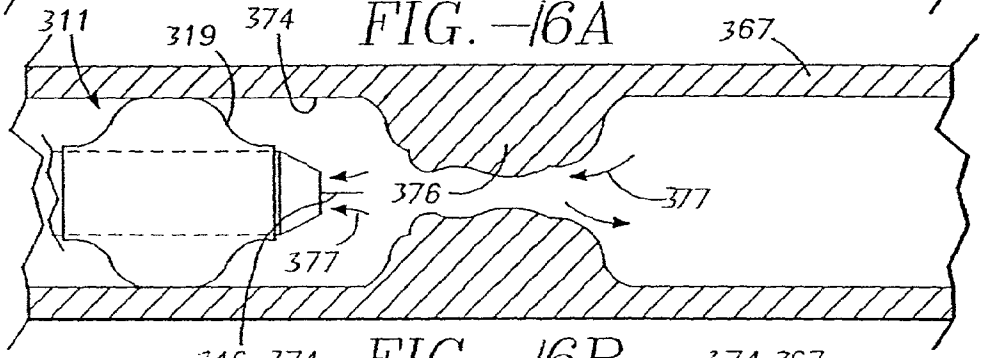


FIG. -16B

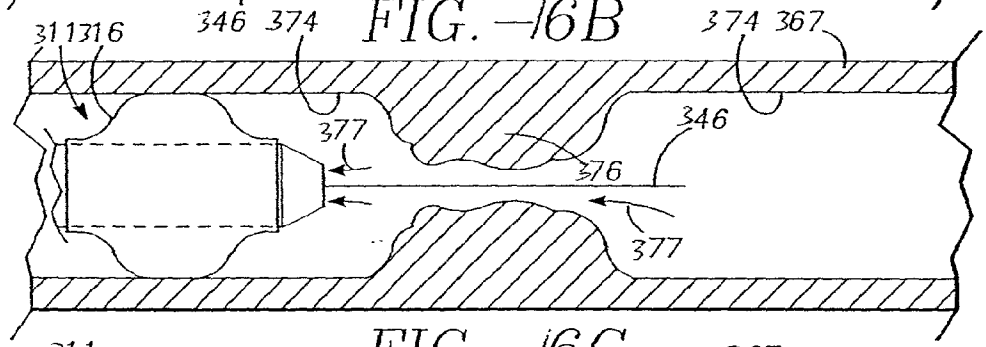


FIG. -16C

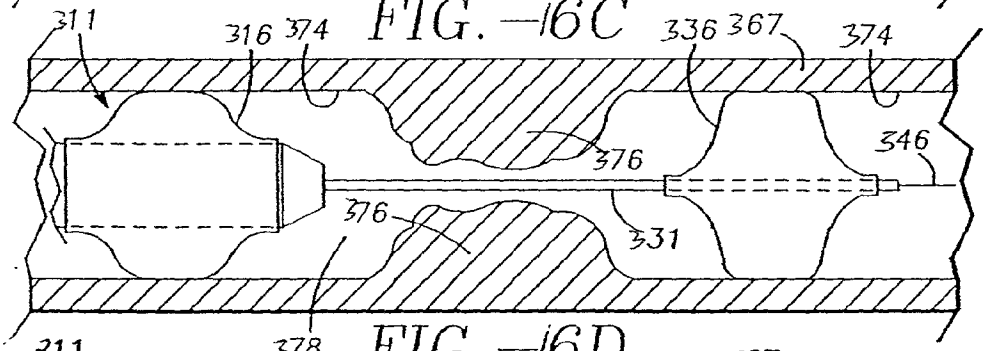


FIG. -16D

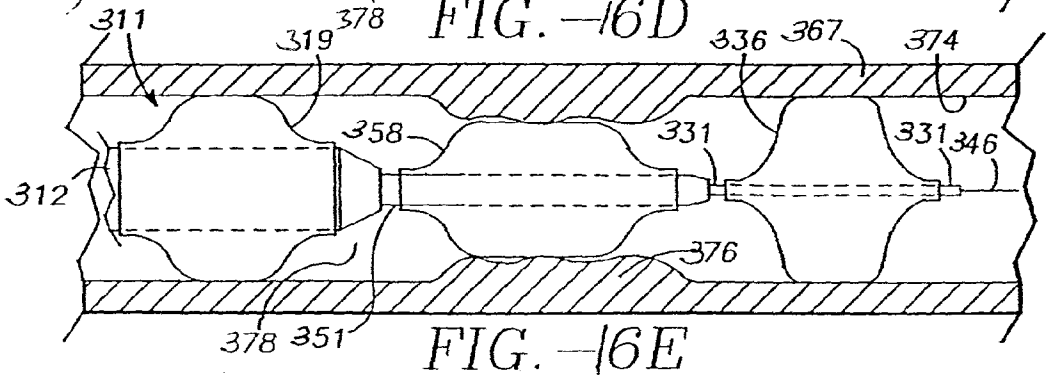


FIG. -16E

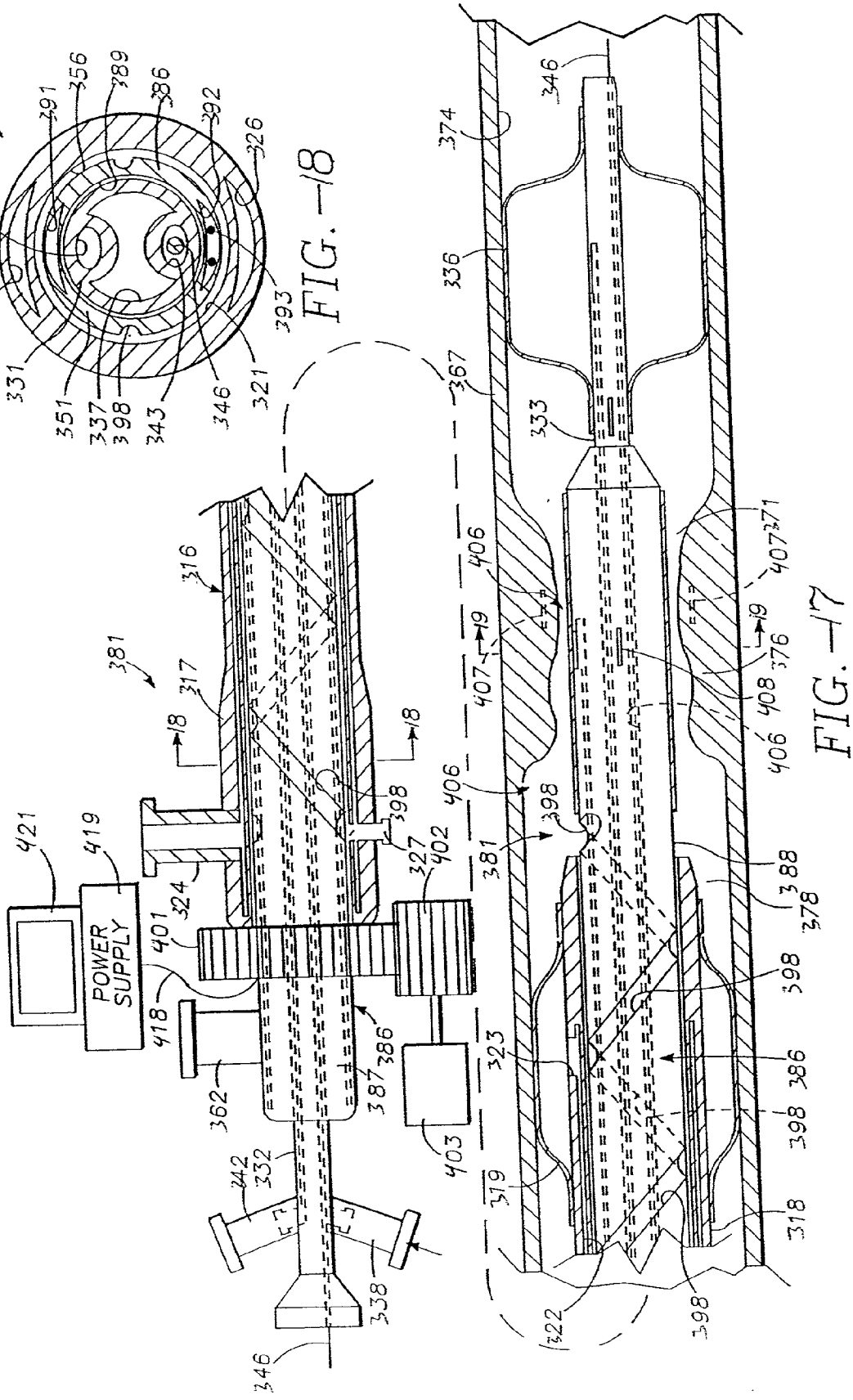


FIG. -17

FIG. -18

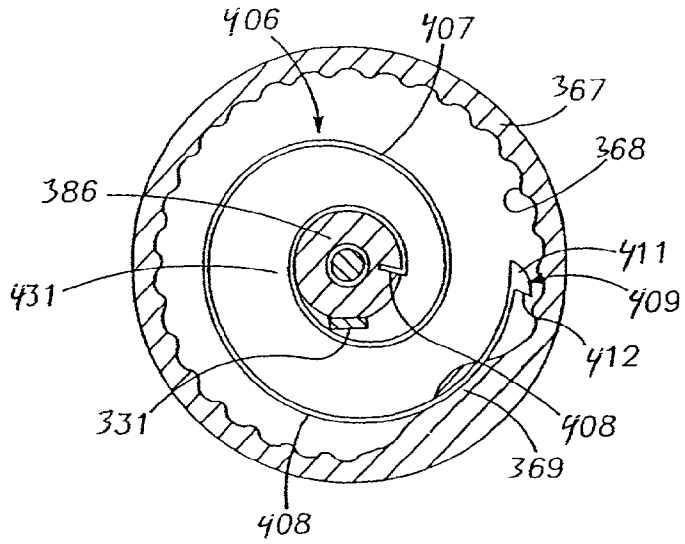


FIG. -19

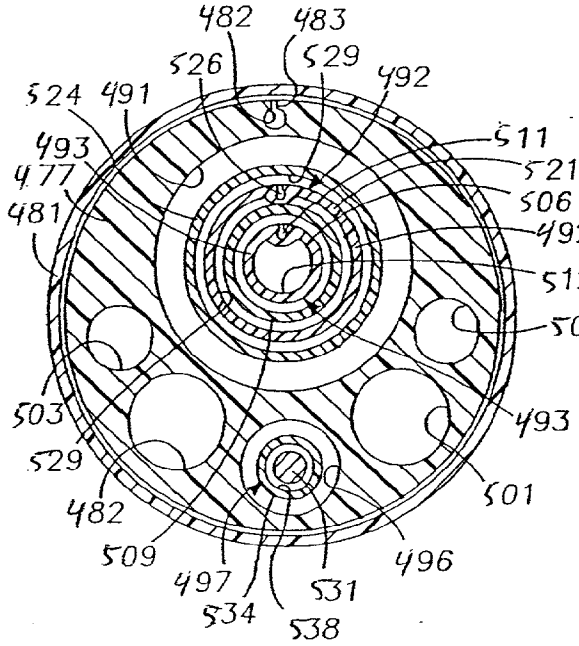


FIG. -23

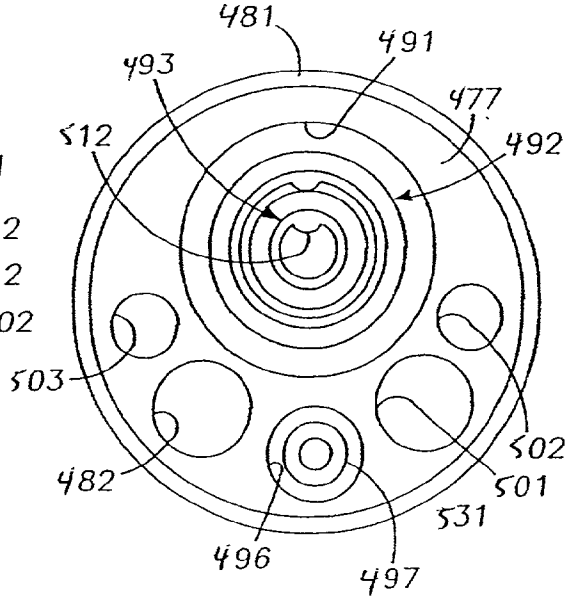


FIG. -24

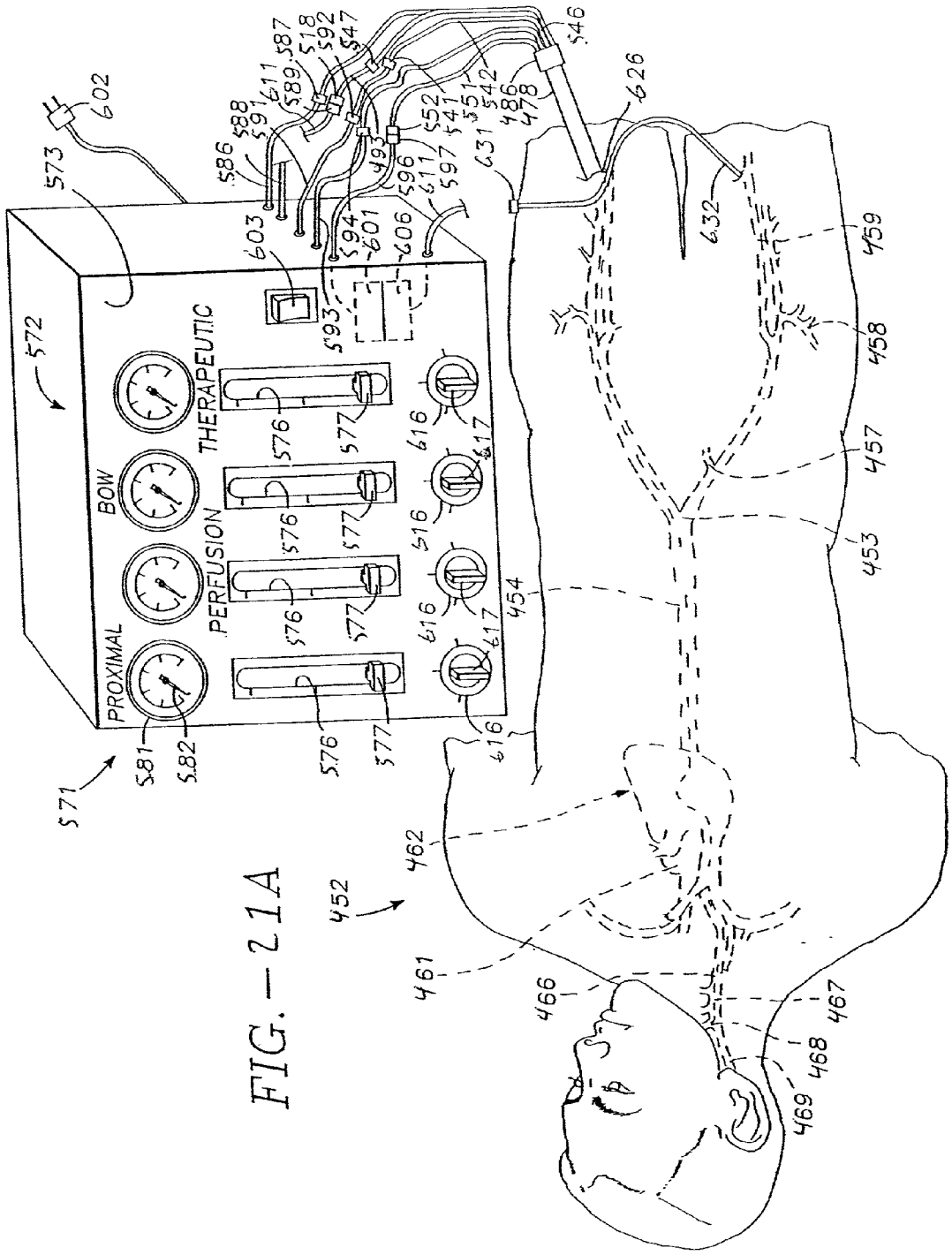

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FIG. — 21A

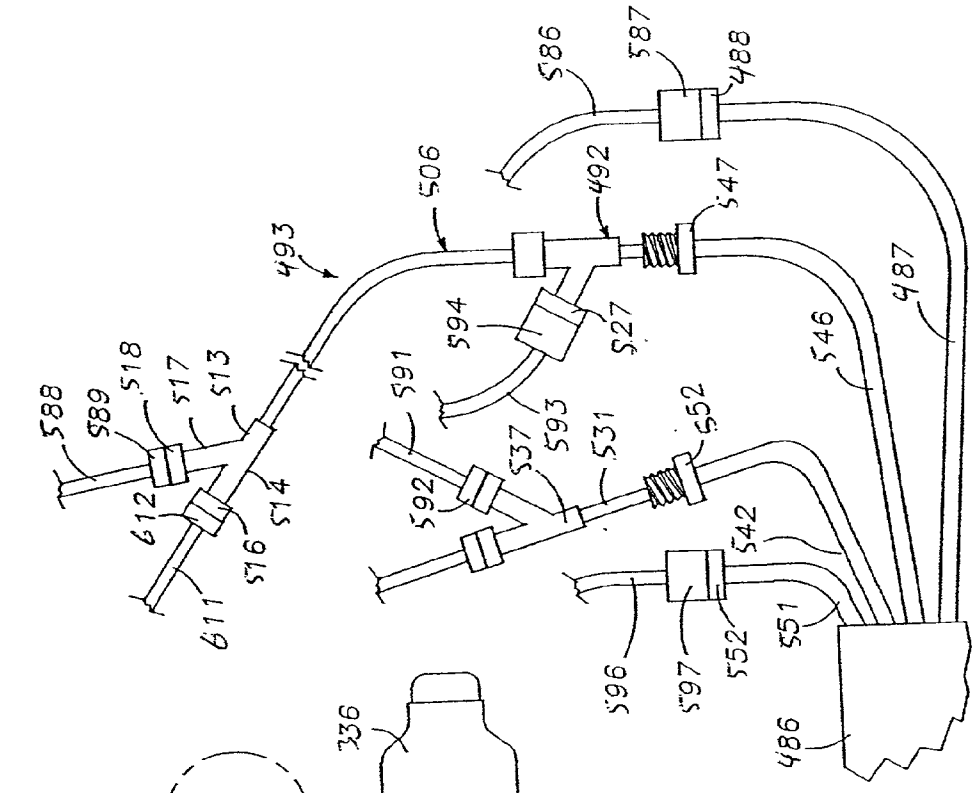

FIG. – 21B

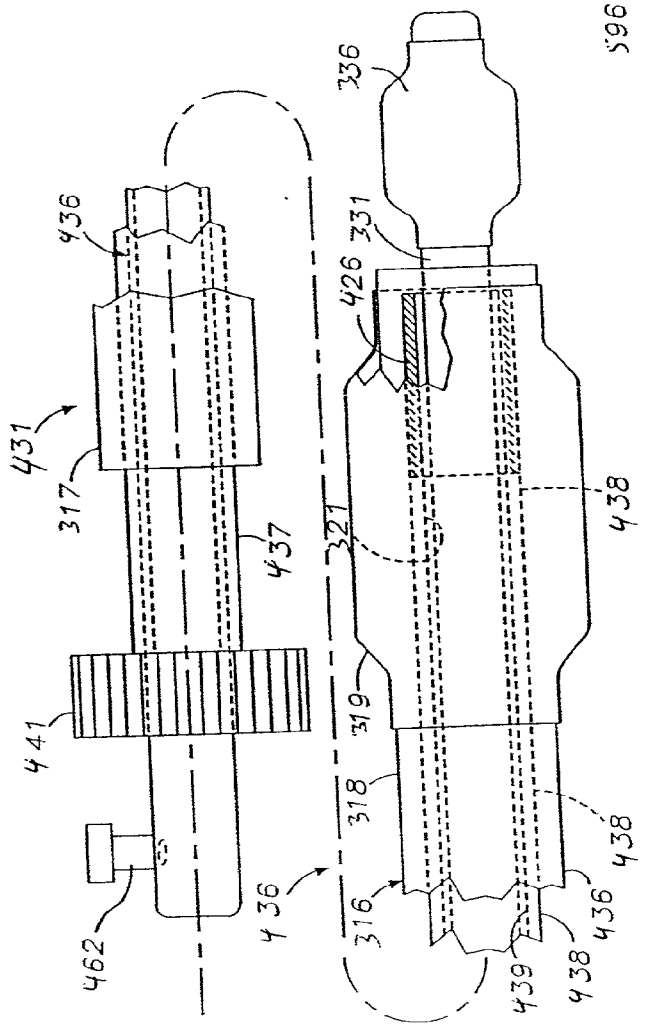

FIG. – 20

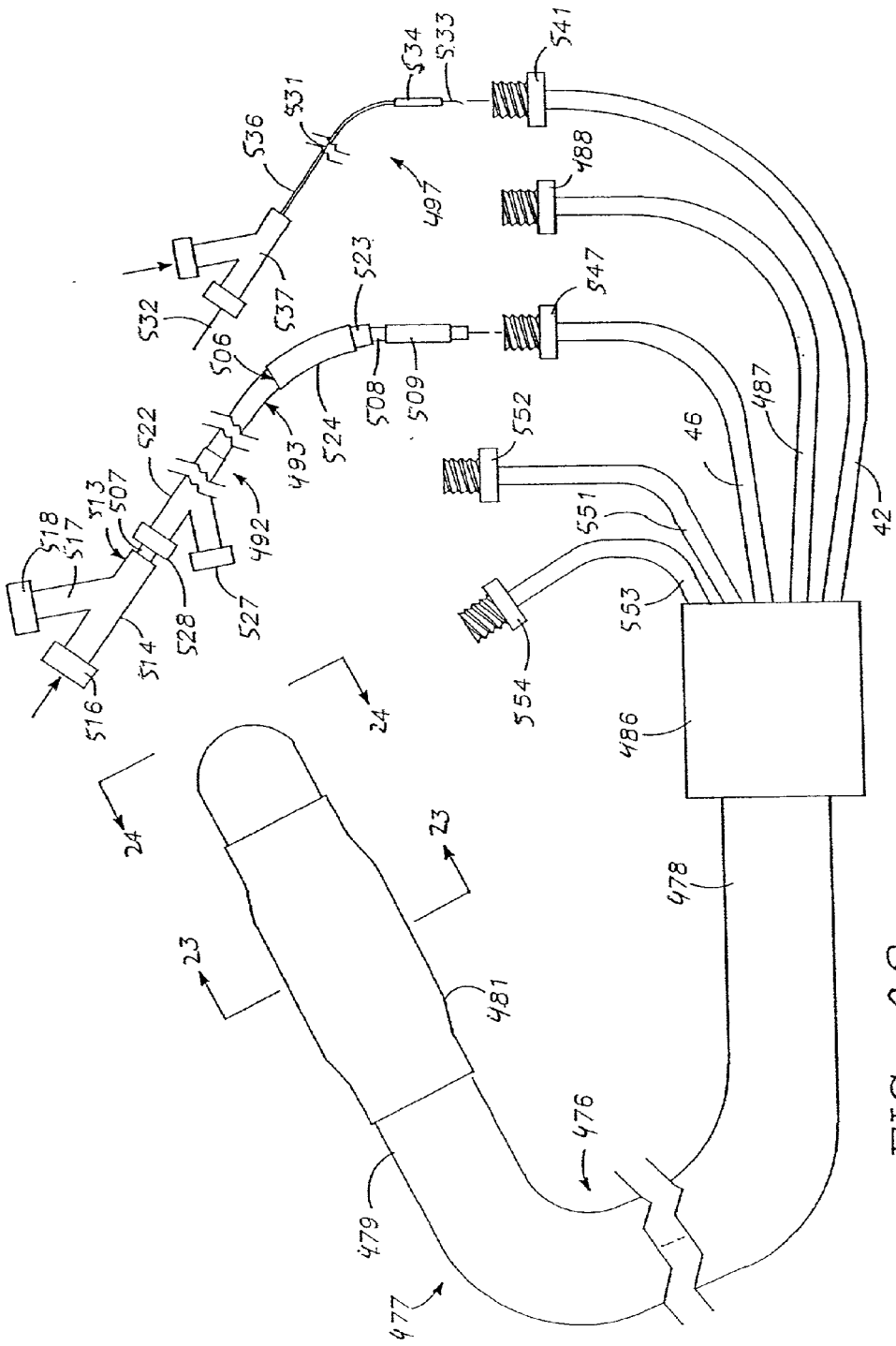
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FIG. -22

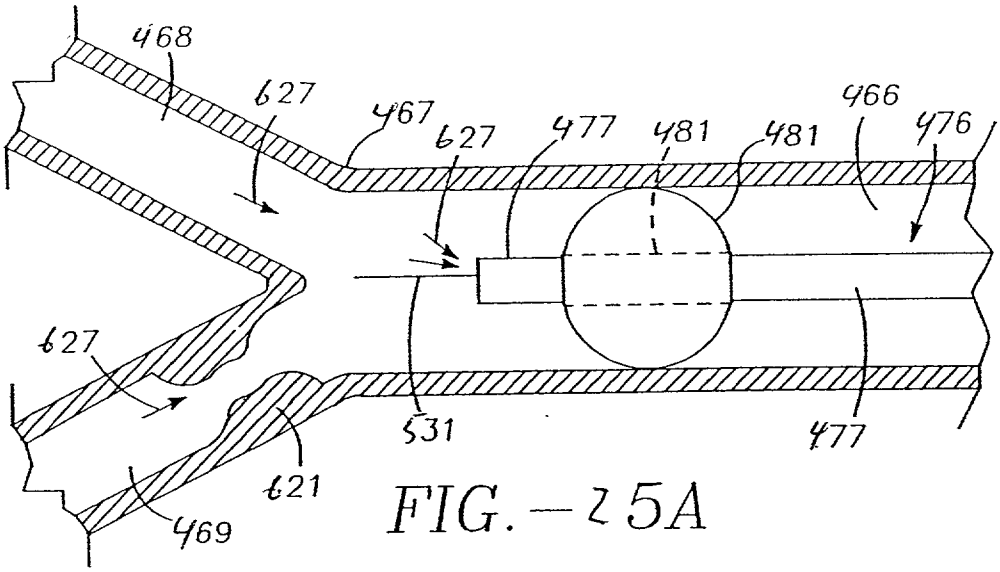

FIG.—25A

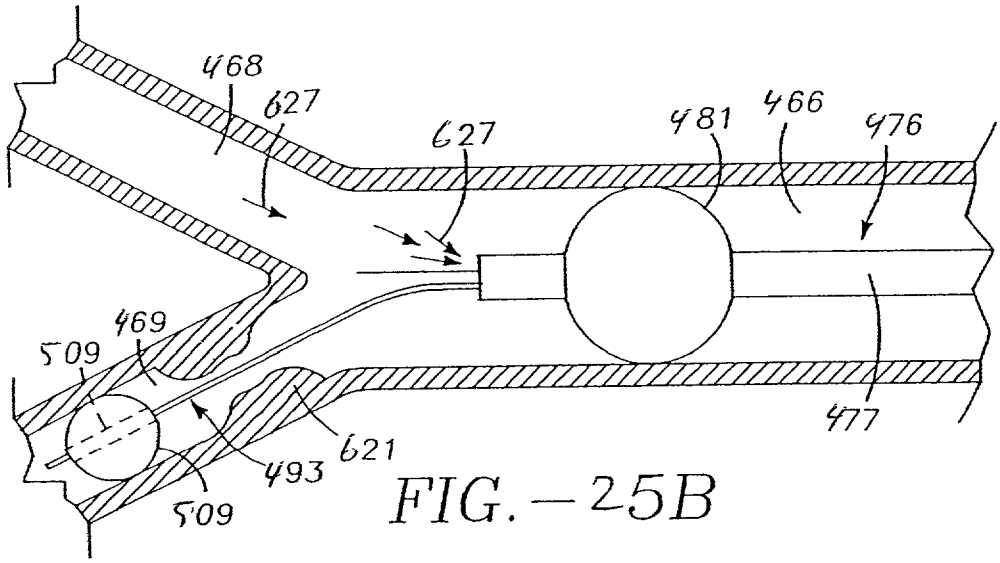

FIG.—25B

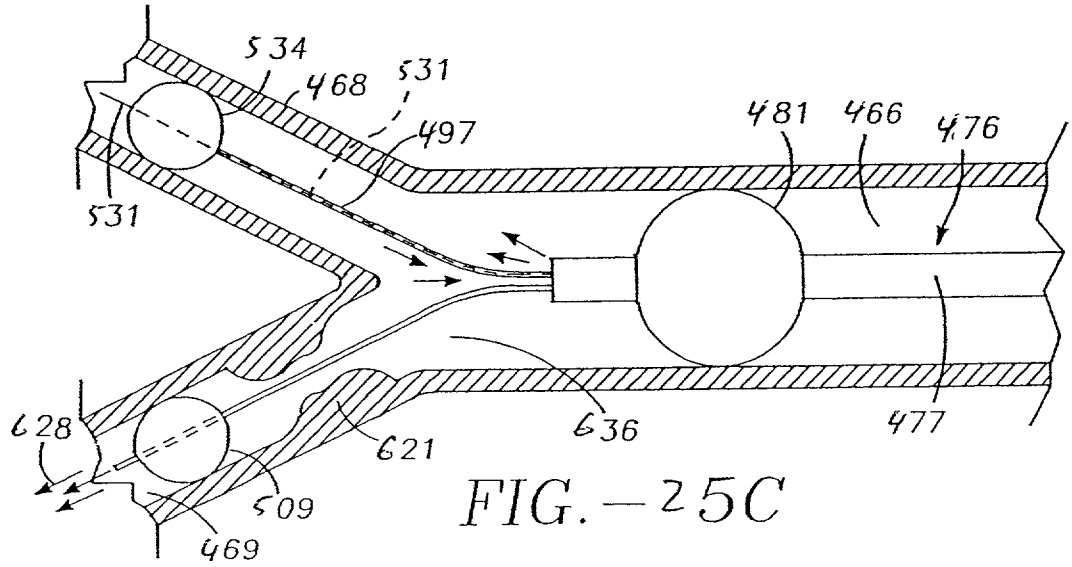

FIG.—25C

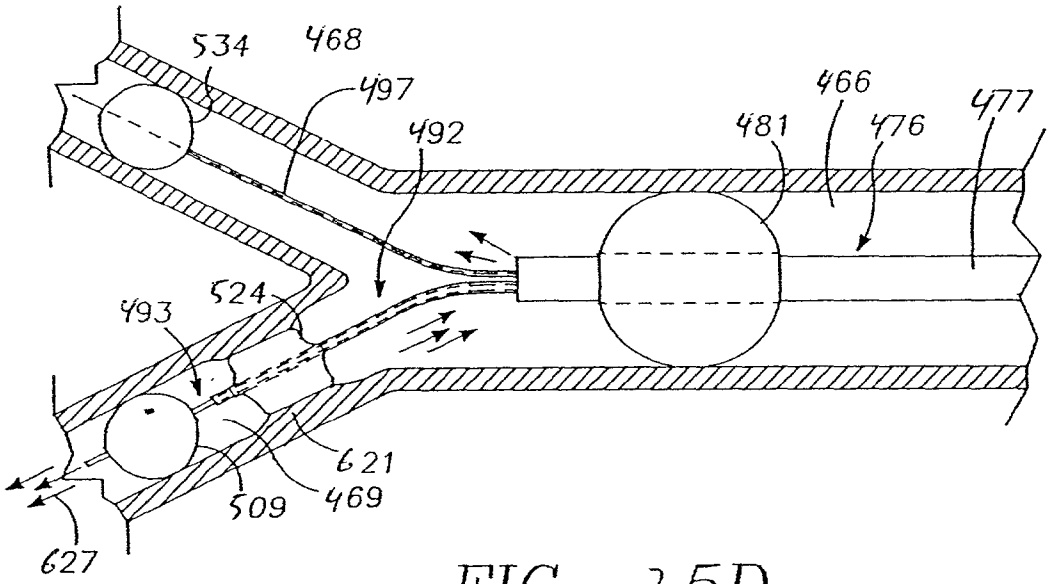

FIG. —25D

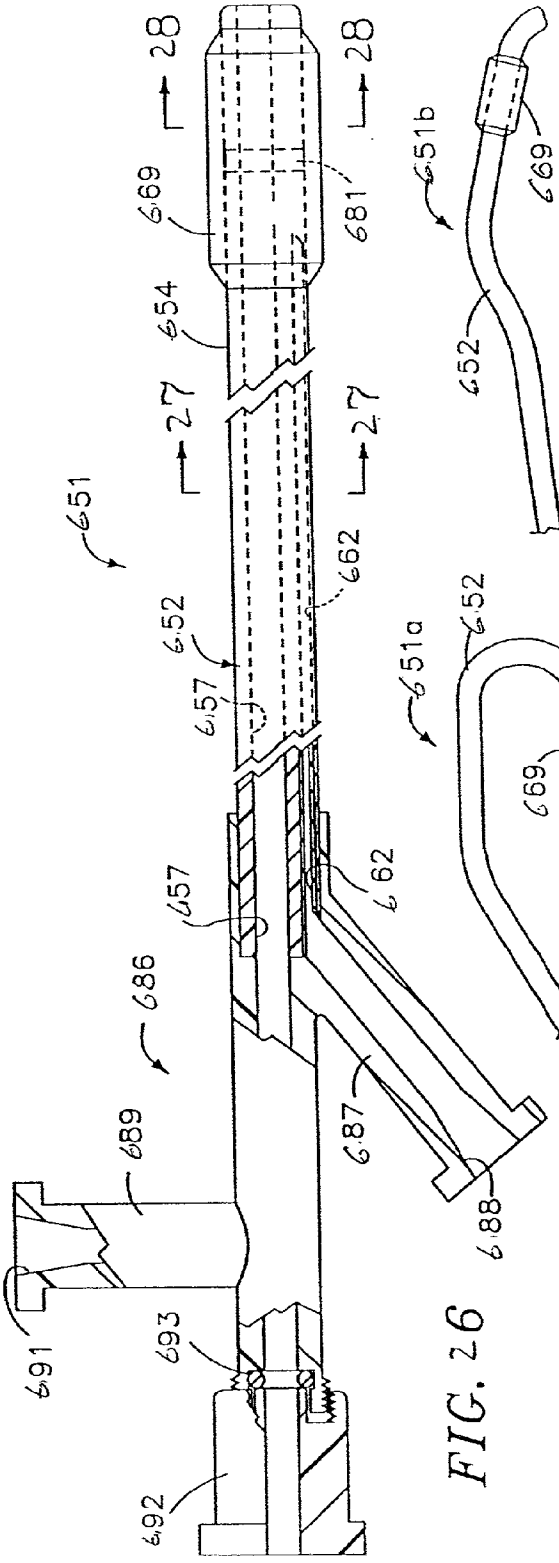

FIG. 26

FIG. 26B

FIG. 26A

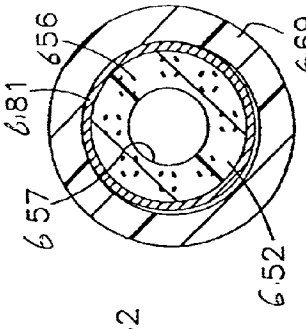

FIG. 28

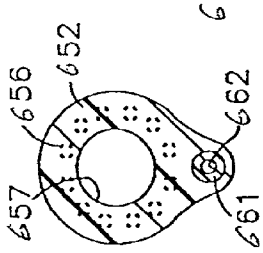

FIG. 27

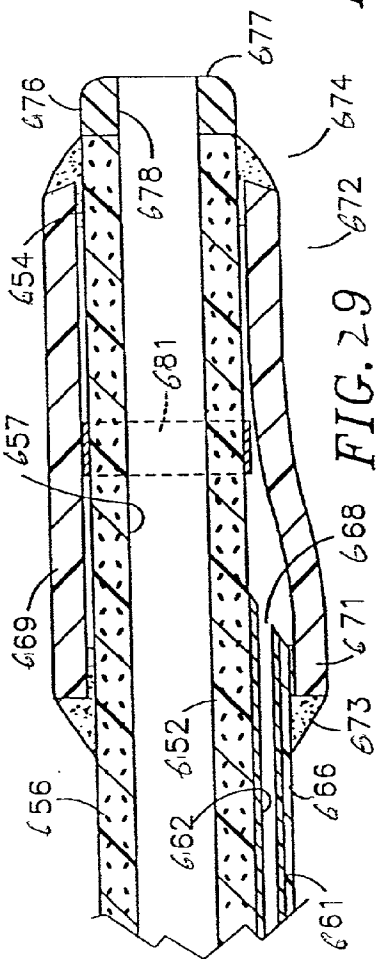

FIG. 29

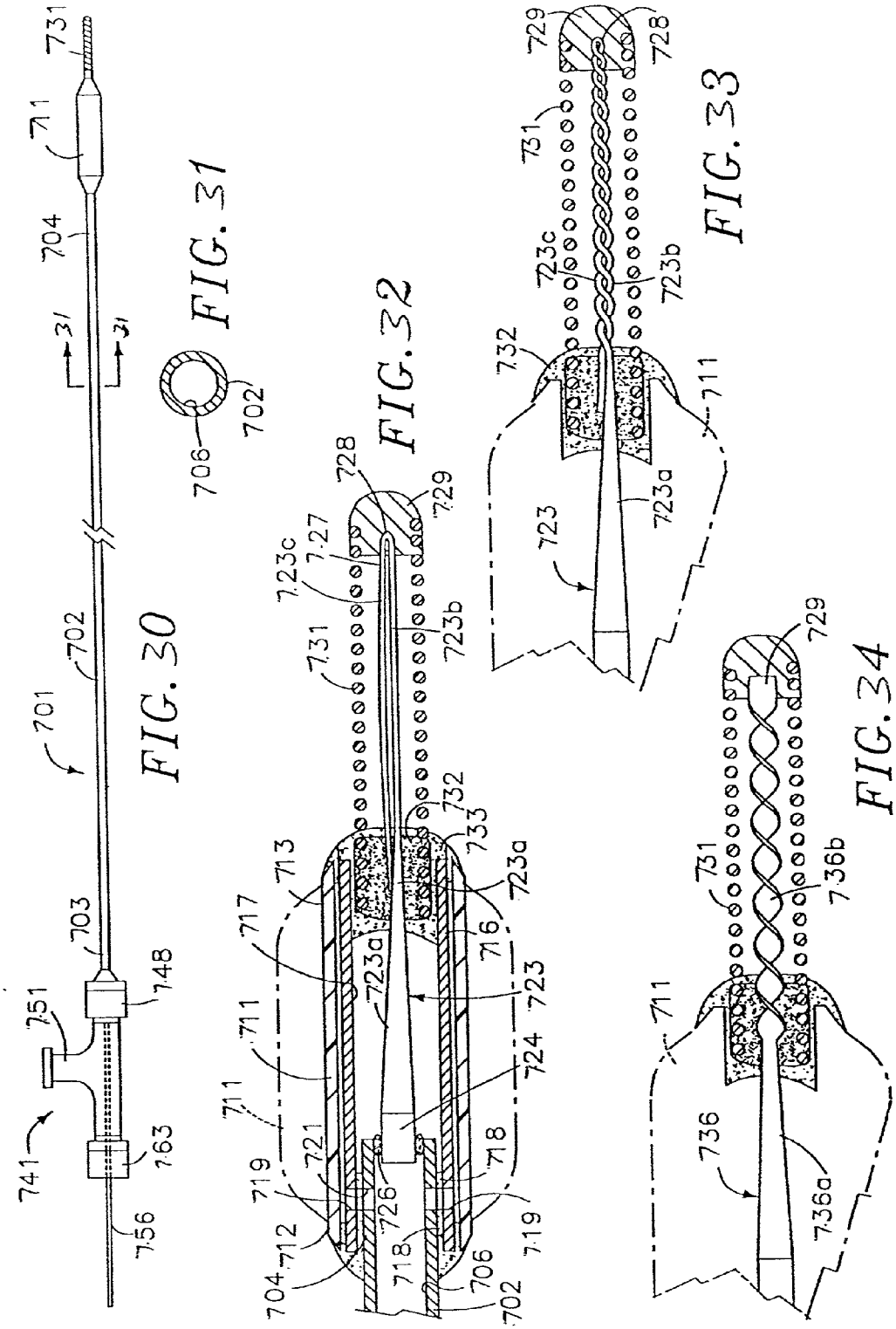

FIG. 30

FIG. 31

FIG. 32

FIG. 33

FIG. 34

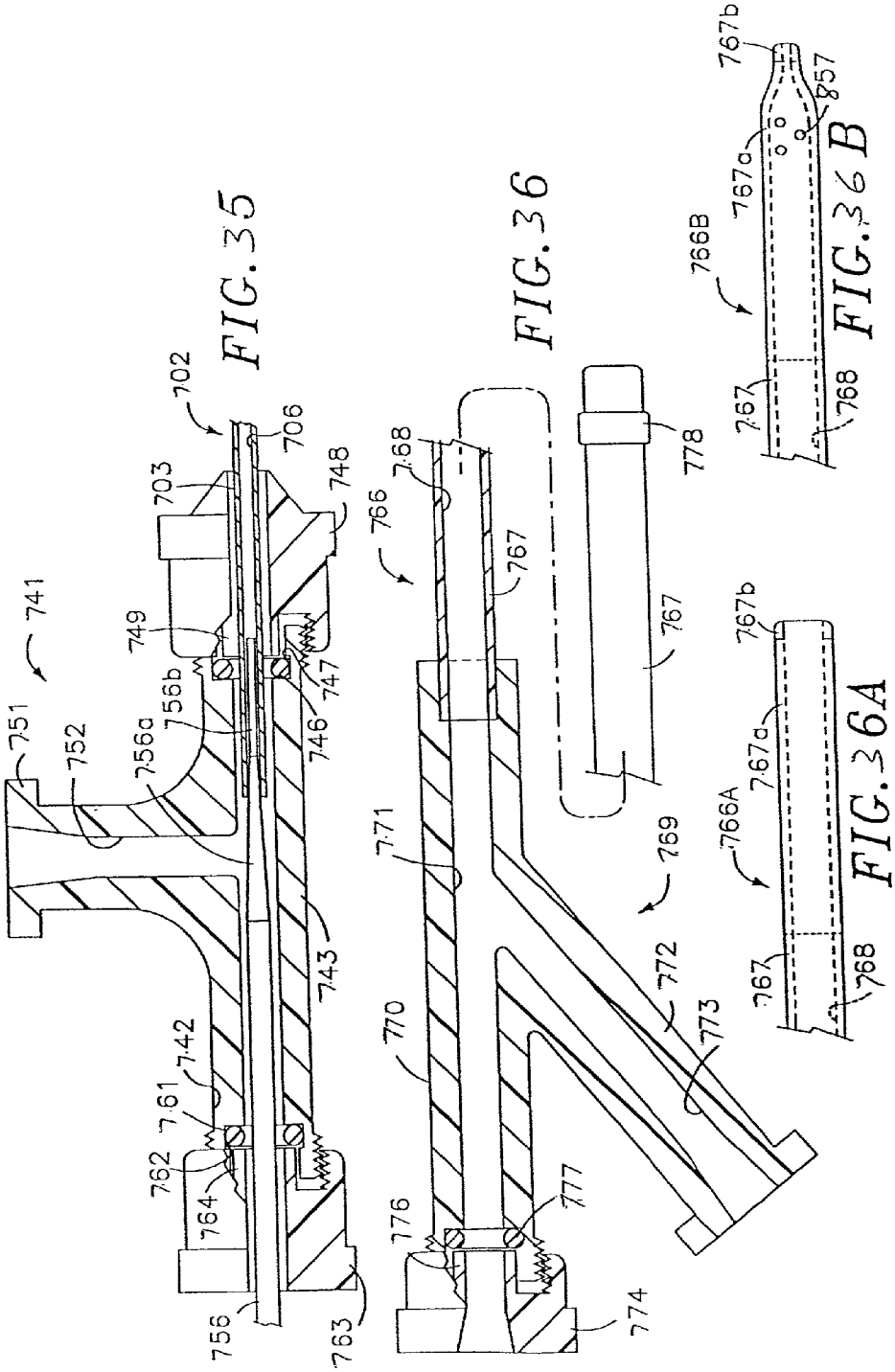

FIG. 35

FIG. 36

FIG. 36A

FIG. 36B

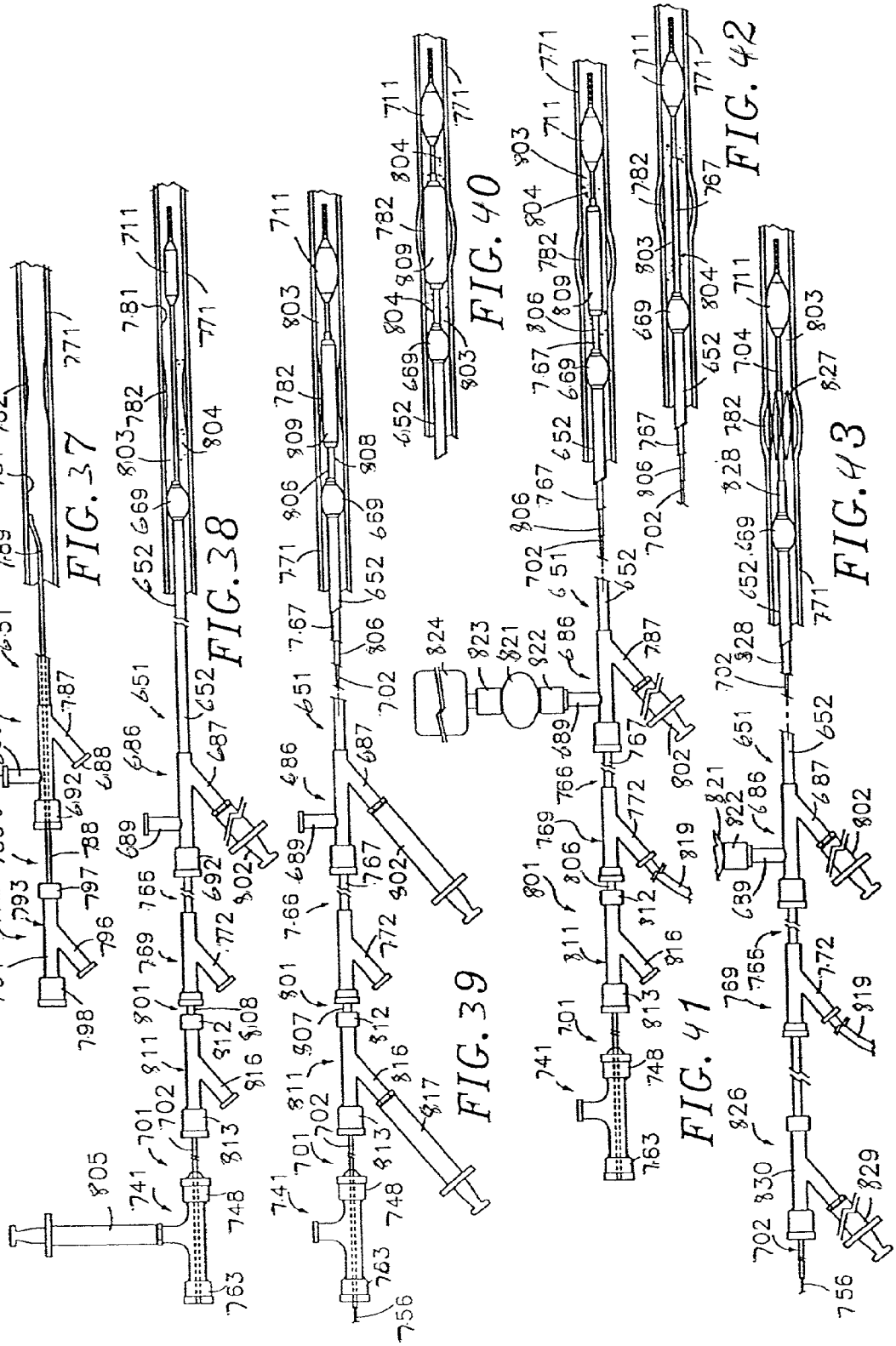

FIG. 37

FIG. 38

FIG. 39

FIG. 40

FIG. 41

FIG. 42

FIG. 43

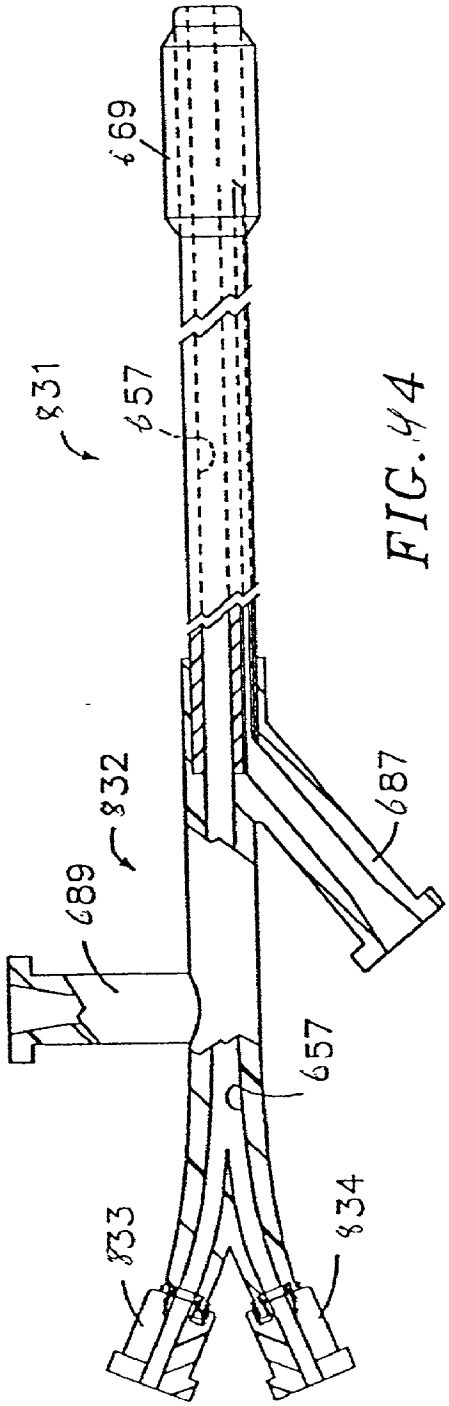
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FIG. 44

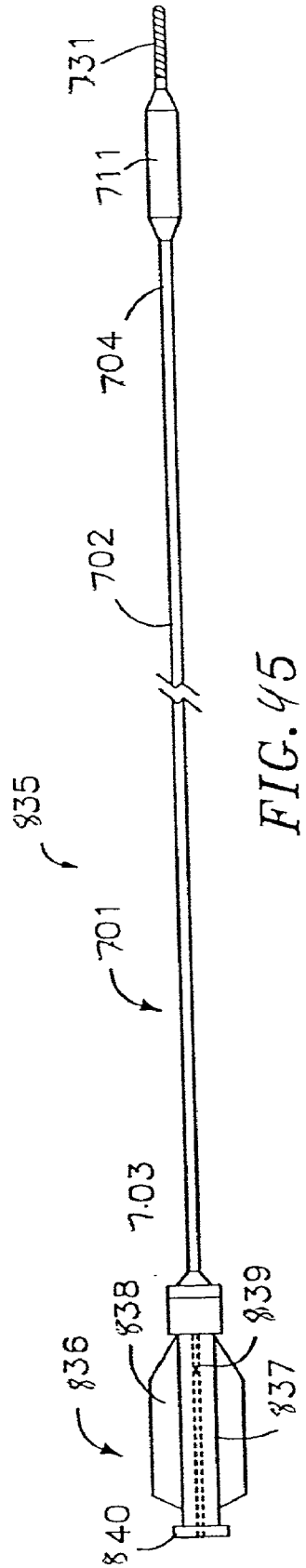
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FIG. 45

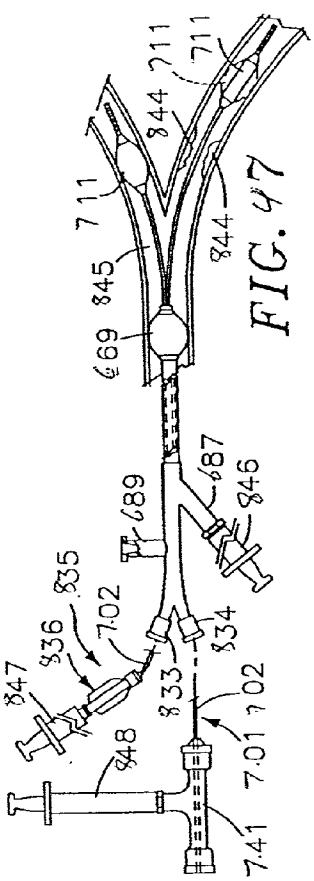

FIG. 47

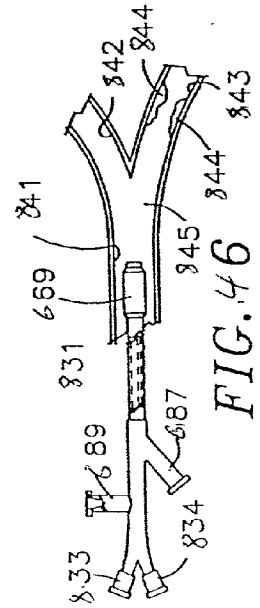

FIG. 46

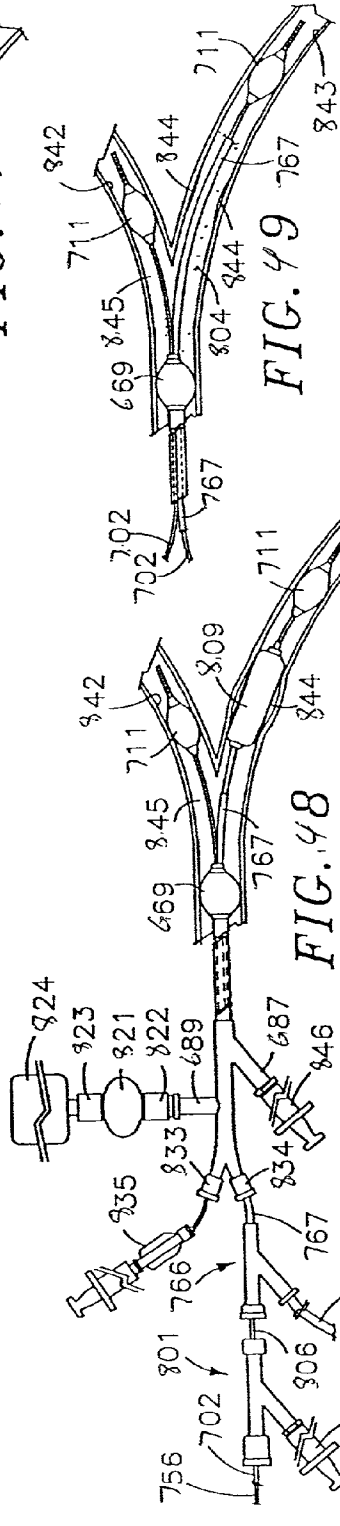

FIG. 49

FIG. 48

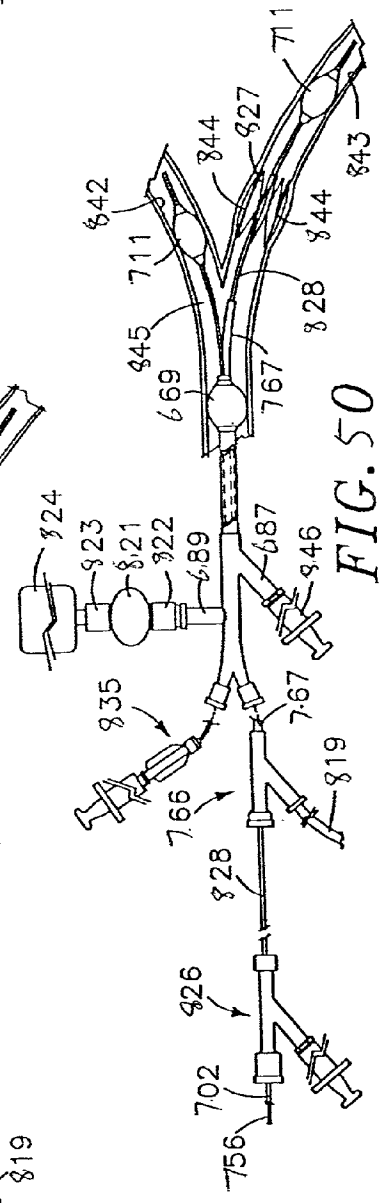

FIG. 50

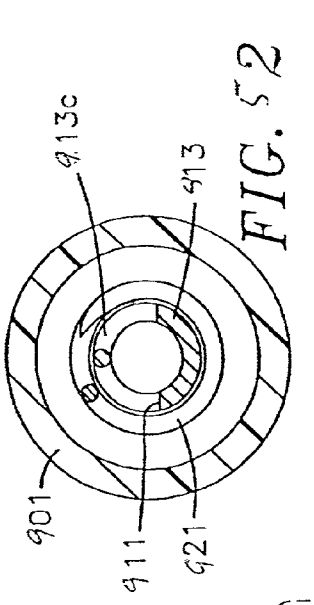
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FIG. 52

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906c
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756a

FIG. 51

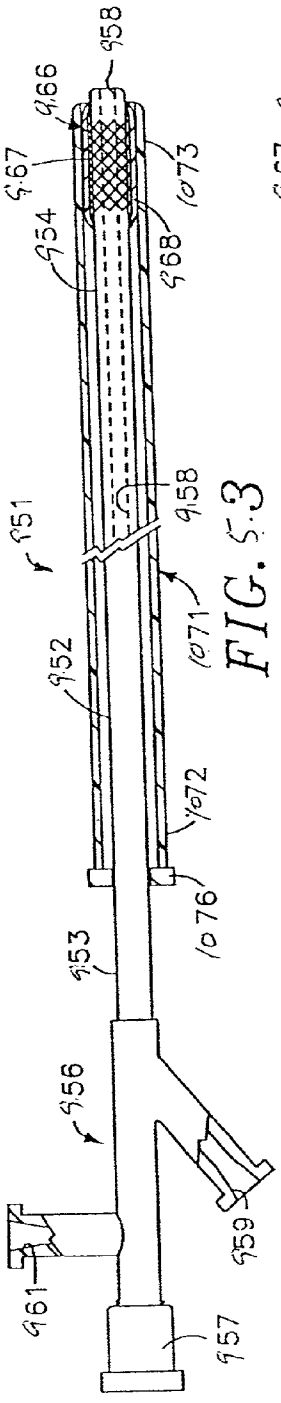

FIG. 53

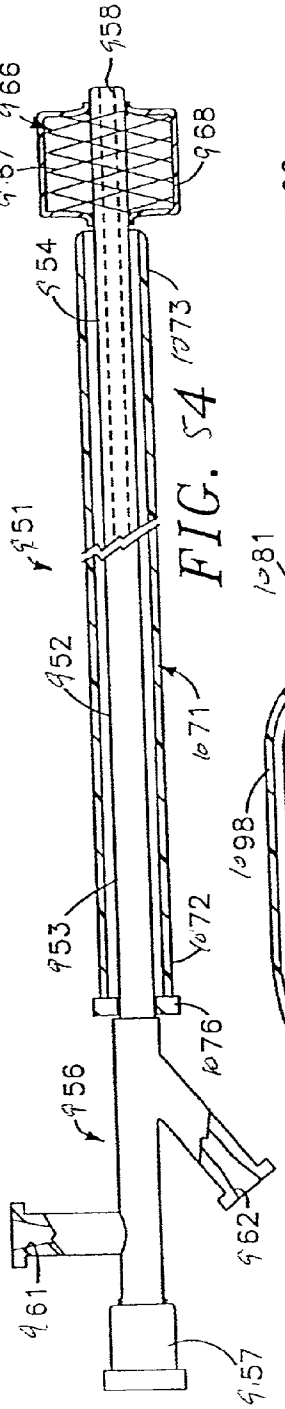

FIG. 54

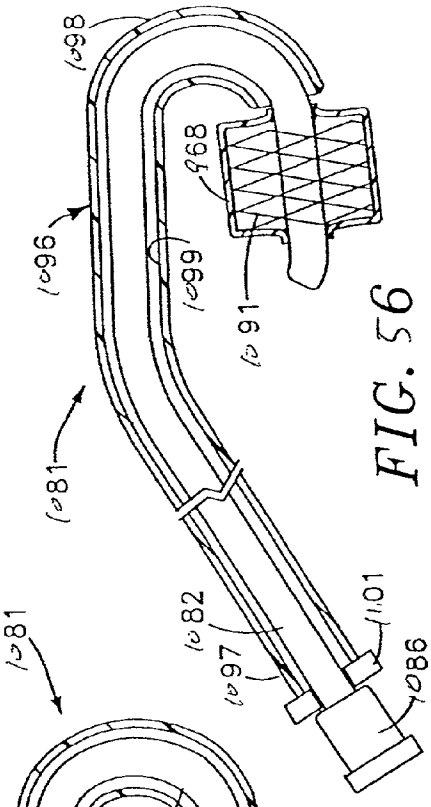

FIG. 56

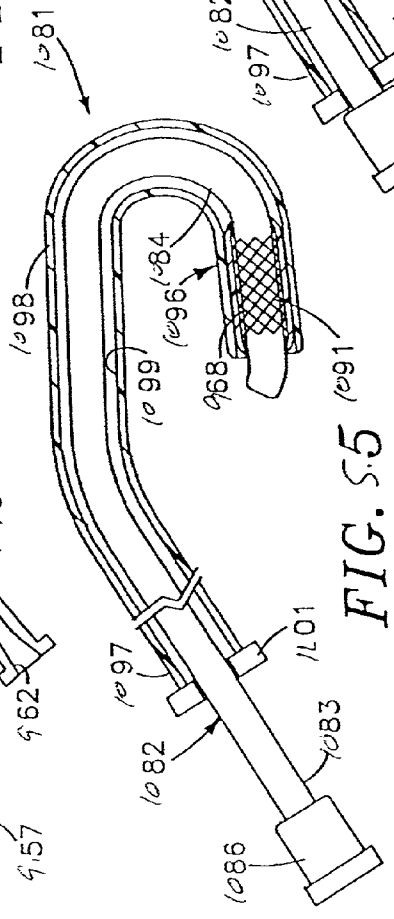

FIG. 55

METHOD AND APPARATUS FOR EMBOLI CONTAINMENT

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of application Ser. No. 09/790,220, filed on Feb. 21, 2001, which is a continuation of application Ser. No. 08/813,023, filed on Mar. 6, 1997, now U.S. Pat. No. 6,270,477, which is a continuation-in-part of application Ser. No. 08/650,464 filed on May 20, 1996, now abandoned, the entirety of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0002] The present invention generally relates to medical devices, and in particular, to catheters which can be used in an emboli containment system. This invention also relates to an apparatus and method for treating occluded vessels in living bodies and more particularly balloon catheters and balloon guide wires for treating occlusions in vessels in human bodies, as for example carotid arteries.

[0003] Balloon angioplasty, and other transluminal medical treatments, are well-known, and have been proven efficacious in the treatment of stenotic lesions in blood vessels. The application of such medical procedures to certain blood vessels, however, has been limited, due to the risks associated with creation of emboli during the procedure. For example, angioplasty is not the currently preferred treatment for lesions in the carotid artery, because of the possibility of dislodging plaque from the lesion, which can enter the various arterial vessels of the brain and cause permanent brain damage. Instead, surgical procedures are currently used, but these procedures present substantial risks.

[0004] One solution to this problem is the use of a multi-catheter emboli containment system, as disclosed in the above-referenced application Ser. No. 08/650,464. As disclosed therein, a treatment chamber within a blood vessel is formed by two occlusion balloons on opposite sides of a stenotic lesion, thereby preventing emboli migration during the treatment procedure. The chamber is created by two occlusion balloon catheters which are slidably disposed with respect to one another.

[0005] Emboli containment procedures of this type are advantageous, because they permit the clinician to utilize the benefits of transluminal treatment in a wider variety of blood vessels. However, the procedures require the complex coordination of multiple catheters. Consequently, it is desirable to have catheters which make it easier for the clinician to utilize an emboli containment system. It is also desirable that the catheters used in the emboli containment system have a high degree of flexibility, to navigate tortuous blood vessel networks.

[0006] Consequently, there exists a need for improved emboli containment catheters. This is especially true in the context of the "main" catheter, through which other catheters are inserted and controlled to form the emboli containment system. There is also a need for new and improved apparatus and methods which make it possible to treat occluded vessels without endangering the patient.

SUMMARY OF THE INVENTION

[0007] The present invention advantageously provides as a main catheter an occlusive device adapted for use in a multi-catheter emboli containment system. In one aspect of the present invention, there is provided a catheter, comprising an elongate flexible tubular body having a proximal end and a distal end. The tubular body incorporates a metallic member, which may comprise a braid or a coil. A main lumen and an inflation lumen extend through the tubular body, and are in a side-by-side configuration. The main lumen is sized to receive a therapeutic and/or diagnostic device such as a balloon angioplasty catheter or an atherectomy catheter. The tubular body is provided with a manifold. The manifold has an aspiration port which is in fluid communication with the main lumen. The distal end of the tubular body also has a tip formed of a more flexible material than that used to form the tubular body.

[0008] In one preferred embodiment, an inflatable balloon is mounted on the distal end of the tubular body. An inflation port is also provided on the manifold in this embodiment. The inflation port is in fluid communication with the inflation lumen. In this embodiment, the inflatable balloon is formed of a block copolymer of styrene-ethylene-butylene-styrene.

[0009] In another preferred embodiment, the metallic braid or coil is formed of a metal selected from the group consisting of 304, 316, or 400 series stainless steel, nitinol, platinum, gold, Elgiloy (™), or combinations thereof. Where a metallic braid is used, it may optionally have a braid density at a first point on the tubular body that is greater than the braid density of the metallic braid at a second point on the tubular body by at least 20 picks per inch. Similarly, where a metallic coil is used, it may optionally have a coil density at a first point on the tubular body that is greater than the coil density at a second point on the tubular body.

[0010] In another aspect of the present invention, there is provided a catheter comprising an elongate flexible tubular body having a proximal end and a distal end. Alternatively, there may be provided a circular cross-sectional configuration at the proximal end which is continuous with a distal end having a reduced internal and outer tubular body diameters. A first and second lumen extend through the tubular body from the proximal end to the distal end in a side-by-side configuration. The first lumen has a generally circular cross-sectional configuration at the proximal end and a generally oval cross-sectional configuration at the distal end. The second lumen has a diameter no smaller than 0.05 inches, preferably no smaller than 0.08 inches, and is adapted to slidably accommodate a therapeutic or diagnostic device.

[0011] In one preferred embodiment, an inflatable balloon is mounted on the distal end of the tubular body. The inflatable balloon is in fluid communication with the first lumen, such that fluid passing through the first lumen may be used to inflate or deflate the inflatable balloon. The second lumen size may vary in certain embodiments, such that in one embodiment, the second lumen has a diameter no smaller than about 0.05 inches, and is preferably no less than 0.080 inches.

[0012] In another aspect of the present invention, there is provided a catheter with variable stiffness, comprising a tubular body having a proximal end and a distal end. A metallic braid or metallic coil is within the tubular body. In one embodiment, the proximal end of the tubular body has

a lower braid or coil density than the distal end. In another embodiment, the braid or coil density is kept constant along the length of the tubular body, and the tubular body is formed of materials with greater stiffness at the proximal end. In another embodiment, a combination of braids and coils of varying density can be used at various points along the tubular body, to create a catheter tubular body having a more flexible distal end.

[0013] In another aspect of the present invention, there is provided a method of making a catheter tubular body. The method comprises providing a first polymeric tube formed of a first material having a first melting point. The first polymeric tube is then inserted into a second polymeric tube to form a combined tube. The second polymeric tube is formed of a second material having a second melting point which is less than the first melting point. The combined tube is then placed adjacent to a third tube. The third tube is formed in part of the second material. The tubes are then heated to a temperature greater than the second melting point but less than the first melting point, such that the combined tube melt fuses with third tube to form a catheter tubular body having two lumen extending therethrough in a side-by-side configuration. The first material may be selected from the group comprising polyimide, polyamide, PET and PEEK, blends thereof and the second material may be selected from the group comprising Pebax (™), polyethylene, nylon, or Hytrel (™) or blends thereof. Preferably, the temperature of the heating step is from about 250° to 600° F. It is also preferred that the third tube incorporate a metallic member, such as a braid or coil.

[0014] In general, it is an objection of the present invention to provide an apparatus or an assembly and method which can be used with approved diagnostic and therapeutic devices while minimizing the opportunities for emboli to migrate downstream.

[0015] Another object of the present invention to provide an apparatus or assembly and method of the above character which makes it possible to perform therapeutic procedures without using perfusion.

[0016] Another object of the invention is to provide an apparatus or assembly and method of the above character in which the proximal balloon utilized is a balloon carried by a guide wire.

[0017] Another object of the invention is to provide an apparatus or assembly and method of the above characters in which the inflation fitting carried by the proximal extremity of the balloon-on-a-wire is removable so that catheters can be slid over the wire without removal of the wire from the site in which it is disposed.

[0018] Another object of the present invention is to provide an apparatus or assembly and method for treating occluded vessels of the above character which makes it possible to prevent downstream flow of debris or emboli.

[0019] Another object of the invention is to provide an apparatus and method which makes it possible to reverse the flow of blood in an occluded vessel during the time that a stenosis is being crossed.

[0020] Another object of the invention is to provide an apparatus and method of the above character in which a negative pressure is created within the vessel to reverse the flow of blood in the vessel.

[0021] Another object of the invention is to provide an apparatus and method of the above character in which it is only necessary to stop the flow of blood in a vessel of a patient for a very short period of time.

[0022] Another object of the invention is to provide an apparatus and method in which a working space is provided in the vessel free of blood for treatment of the stenosis.

[0023] Another object of the invention is to provide an apparatus and method of the above character in which material which is dislodged during the treatment of the occlusion or stenosis is removed by suction.

[0024] Another object of the invention is to provide an apparatus and method of the above character in which blood is shunted around the working space.

[0025] Another object of the invention is to provide an apparatus and method in which a cutting device is utilized for treatment of the stenosis or atheroma in the vessel and in which the material removed from the stenosis or atheroma is aspirated out of the operating space.

[0026] Another object of the invention is to provide an apparatus and method of the above character in which the amount of material removed from the stenosis or atheroma can be precisely controlled.

[0027] Another object of the invention is to provide an apparatus and method of the above character which makes it possible to treat stenoses or occlusion in the vessel which are normally not accessible for surgical procedures.

[0028] Another object of the invention is to provide an apparatus and method of the above character which utilizes two spaced apart balloons to create the working space in the vessel.

[0029] Another object of the invention is to provide an apparatus and method of the above character that can be utilized to create a working space in a vessel having a bifurcation therein and in which the working space includes the bifurcation.

[0030] Another object of the invention is to provide an apparatus and method of the above character which utilizes three spaced apart balloons to create the working space in the vessel having a bifurcation therein.

[0031] Another object of the invention is to provide an apparatus and method of the above character which includes a control console for controlling the inflation of the blood flow pump.

[0032] Another object of the invention is to provide an apparatus and method of the above character which is particularly adapted for use with the carotid vessels.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] **FIG. 1** is a side view of an embodiment of the catheter of the present invention.

[0034] **FIG. 2** is a cross-sectional view of catheter of **FIG. 1** along lines **2-2**.

[0035] **FIG. 3** is a cross-sectional view of the catheter of **FIG. 1** along lines **3-3**.

[0036] **FIG. 4** is a longitudinal cross-sectional view of the distal end of the catheter of **FIG. 1**.

[0037] **FIG. 5** is an enlargement of the region circumscribed by lines **5-5** of the catheter of **FIG. 4**.

[0038] **FIG. 6** is an illustration of the catheter of the present invention as used in an emboli containment system.

[0039] **FIG. 7** is a cross-sectional view of the emboli containment system of **FIG. 6** along lines **7-7**.

[0040] **FIG. 8** is a cross-sectional view of the emboli containment system of **FIG. 6** along lines **8-8**.

[0041] **FIG. 9** is a cross-sectional view of the emboli containment system of **FIG. 6** along lines **9-9**.

[0042] FIGS. **10A-E** illustrate the use of an embodiment of the catheter of the present invention in an emboli containment treatment procedure.

[0043] **FIG. 11** is a side-elevational view partially in section showing the catheter apparatus or assembly of the present invention for treating occluded vessels.

[0044] **FIG. 12** is a cross-sectional view taken along the line **12-12** of **FIG. 11**.

[0045] **FIG. 13** is a cross-sectional view taken along the line **13-13** of **FIG. 11**.

[0046] **FIG. 14** is a cross-sectional view taken along the line **14-14** of **FIG. 11**.

[0047] **FIG. 15** is a schematic illustration of how the catheter apparatus shown in **FIG. 11** is deployed in a carotid artery.

[0048] FIGS. **16A-16E** are illustrations showing the various steps utilized in deployment of the catheter apparatus in performing the method of the present invention in a vessel where a bifurcation is not present.

[0049] **FIG. 17** is a side-elevational view partially in section of another embodiment of a catheter apparatus or assembly incorporating the present invention for treating occluded vessels using an atherectomy device.

[0050] **FIG. 18** is a cross-sectional view taken along the line **18-18** of **FIG. 17**.

[0051] **FIG. 19** is a cross-sectional view taken along the line **19-19** of **FIG. 17**.

[0052] **FIG. 20** is a side-elevational view in section of the distal extremity of another embodiment of a catheter apparatus incorporating the present invention and utilized for delivering an expandable stent to a stenosis.

[0053] **FIG. 21A** is a schematic illustration showing the manner in which the apparatus of the present invention is utilized in connection with vessels of a patient in performing the method of the present invention.

[0054] **FIG. 21B** is an additional partial schematic illustration showing interconnections in the catheter apparatus shown in **FIG. 21A**.

[0055] **FIG. 22** is a plan view of another embodiment of a catheter apparatus incorporating the present invention.

[0056] **FIG. 23** is a cross-sectional view taken along the line **23-23** of **FIG. 22**.

[0057] **FIG. 24** is an end elevational view looking down the line **24-24** of **FIG. 22**.

[0058] **FIGS. 25A, B**, C, and D are illustrations or cartoons showing the method of the present invention being utilized with the apparatus shown in **FIG. 21** in a vessel having a bifurcation therein.

[0059] **FIG. 26** is a side-elevational view of a main catheter incorporating the present invention.

[0060] **FIGS. 26A and 26B** are partial side-elevational views of the distal extremities showing alternative embodiments of the main catheter of the present invention incorporating, respectively, Judkins left shape and Judkins right shape in their distal extremities.

[0061] **FIG. 27** is a cross-sectional view taken along the line **27-27** of **FIG. 26**.

[0062] **FIG. 28** is a cross-sectional view taken along the line **28-28** of **FIG. 26**.

[0063] **FIG. 29** is an enlarged partial cross-sectional view of the distal extremity of the catheter shown in **FIG. 26**.

[0064] **FIG. 30** is a side-elevational view of the balloon-on-a-wire construction incorporating the present invention.

[0065] **FIG. 31** is a cross-sectional view taken along the line **31-31** of **FIG. 30**.

[0066] **FIG. 32** is an enlarged cross-sectional view of the distal extremity of the construction in **FIG. 30**.

[0067] **FIG. 33** is a cross-sectional view similar to **FIG. 32** but showing a different embodiment utilizing a twisted dual core.

[0068] **FIG. 34** is a cross-sectional view similar to **FIG. 32** but showing the use of a twisted core.

[0069] **FIG. 35** is a cross-sectional view of the proximal removable fitting of the construction shown in **FIG. 30**.

[0070] **FIG. 36** is a side-elevational view partially in cross section of an irrigation catheter incorporation the present invention.

[0071] **FIGS. 36A and 36B** are side-elevational views of the distal extremities of additional embodiments of irrigation catheters incorporating the present invention.

[0072] FIGS. **37-43** are cartoons showing the manner in which the apparatus of the present invention shown in FIGS. **26-36** is used performing a therapeutic procedure in accordance with the present invention.

[0073] **FIG. 44** is a side-elevational view partially in cross-section of another embodiment of a main catheter incorporating the present invention.

[0074] **FIG. 45** is a side-elevational view partially in cross-section showing another embodiment of an irrigation catheter incorporating the present invention.

[0075] FIGS. **46-50** are cartoons showing the manner in which a therapeutic carotid procedure is performed in accordance with the present invention where there is a bifurcation.

[0076] **FIG. 51** is a side-elevational view partially in section of another embodiment of a balloon-on-a-wire incorporating the present invention.

[0077] **FIG. 52** is a cross-sectional view taken along the line **52-52** of **FIG. 51**.

[0078] **FIG. 53** is a side-elevational view in section of another embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels.

[0079] **FIG. 54** is a side-elevational view in section similar to **FIG. 53** but showing the apparatus in **FIG. 53** with the self-expandable sealing means deployed.

[0080] **FIG. 55** is a side-elevational view in section of another embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels.

[0081] **FIG. 56** is a view similar to **FIG. 55** but showing the self-expandable sealing means deployed.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0082] Referring to **FIG. 1**, there is depicted an embodiment of the balloon catheter of the present invention. Although illustrated and described below in the context of an emboli containment system featuring balloon dilatation treatment of a stenotic lesion, it is to be understood that the present invention can be easily adapted to a variety of emboli containment treatment applications. For example, the present inventors contemplate that the catheter of the present invention can be used in emboli containment treatment procedures which include atherectomy, stent implantation, drug delivery, as well as other applications. Furthermore, although depicted and described as a two lumen catheter, it should be appreciated that the present invention may also be adapted to catheters having more than two lumen. The manner of adapting the present invention to these various treatments and structures will become readily apparent to those of skill in the art in view of the description which follows.

[0083] Catheter **10** generally comprises an elongate flexible tubular body **16** extending between a proximal control end **12** and a distal functional end **14**. Tubular body **16** has a main lumen **30** which extends between ends **12** and **14**. Main lumen **30** terminates in a proximal opening **23** and a distal opening **27**. A smaller inflation lumen **32**, configured in a side-by-side relationship with main lumen **30**, extends along the length of tubular body **16** and may terminate within or near an occlusion balloon **26** mounted on the distal end **14** of catheter **10**, as described below. Inflation lumen **32** is in fluid communication with balloon **26**, such that fluid passing through inflation lumen **32** may be used to inflate or deflate balloon **26**. In some embodiments, the inflation lumen may originate at a point distal to the proximal end **12**, and extend distally from that point in a side-by-side configuration with main lumen **30**.

[0084] In some embodiments, instead of an occlusion balloon **26**, distal end **14** is provided with a mechanical occlusive device such as a pull-wire activated braid which filters all particles larger than **12** microns. Alternatively, other occlusive filtering devices may also be used, as is known by those of skill in the art.

[0085] A control manifold **19** is provided at the proximal end **12** of catheter **10**. Control manifold **19** is generally provided with a number of ports to provide access to the catheter lumen. For example, for the embodiment depicted in **FIG. 1**, control manifold **19** is provided with a catheter end-access port **22** and a catheter side-access port **24**, to provide an introduction point for the insertion of other catheters into lumen **30**. Ports **22** and **24** are preferably provided with standard Tough Borst connectors, although other sealing type connectors, such as a hemostasis valve, may be used. Manifold **19** is also provided with an aspiration port **20** which is in fluid communication with lumen **30**, for attachment of devices to aspirate fluid into opening **27**, through lumen **30**, and out port **20**. An inflation port **18**, in fluid communication with lumen **32**, is further provided on manifold **18** for attachment of devices to inflate or deflate balloon **26**. In one preferred embodiment, ports **18** and **20** are provided with standard luer connectors, to facilitate attachment of standard inflation or aspiration apparatus, respectively, to ports **18** and **20**. Other embodiments of catheter **10** may feature more or less ports, depending upon the number of lumen in the catheter and the desired functionalities of the catheter.

[0086] Manifold **19** is preferably formed out of hard polymers or metals, which possess the requisite structural integrity to provide a functional access port to the catheter lumen, such as for balloon inflation or fluid aspiration. In one preferred embodiment, manifold **19** is integrally formed out of medical grade polycarbonate. Other suitable materials may be used to form manifold **19**, such as polyvinyl chloride, acrylics, acrylonitrile butadiene styrene (ABS), nylon, and the like.

[0087] Manifold **19** is attached to tubular body **16** so that the various ports are placed in communication with the appropriate lumen, as described above in connection with **FIG. 1**. Preferably, a strain relieving connector **11** is used to join manifold **19** to tubular body **16**. For the embodiment depicted in **FIG. 1**, strain relieving connector **11** consists of a length of flexible polymeric tubing, such as 40 durometer (D) Pebax (™), or other polyether block amides, and other similar materials. Tubular body **16** is inserted in one end of strain relieving connector **11**, and the other end of strain relieving connector **11** is inserted into manifold **19**. Suitable adhesives, such as a cyanoacrylate, epoxies, or uv curable adhesives, may be used to bond manifold **19** to strain relieving connector **11**. Alternately, manifold **19** may also be insert molded with the tubular body **16**, as is known by those of skill in the art. Adhesives may also be used to bond the strain relieving connector **11** to tubular body **16**, or alternately, conventional heat bonding, as known to those of skill in the art, may be used to attach tubular body **16** to strain relieving connector **11**.

[0088] The length of tubular body **16** may be varied considerably depending upon the desired application. For example, where catheter **10** is to be used as part of an emboli containment system for treatment of carotid artery disease, with catheter **10** being introduced at the groin, the length of tubular body **16** may range from 80 to 110 centimeters, and is preferably 95 cm. Other treatment procedures, requiring a longer or shorter tubular body **16**, are easily accommodated by the present invention, by forming a tubular body **16** of the desired length during the manufacturing process.

[0089] The outer diameter of tubular body **16** may also be varied considerably, and in most cases, will depend upon the intended treatment procedure for which catheter **10** will be used. That is, the outer diameter of tubular body **16** must be large enough to be capable of forming a main lumen **30** which can slidably accommodate the other catheters used in the emboli containment system, as described in detail below.

However, the outer diameter of tubular body **16** must also be smaller than the internal diameter of smallest blood vessel through which catheter **10** passes during the selected treatment procedure. In general, the diameter of main lumen **30** may range from at least about 0.05 inches to about 0.12 inches, and be capable of accommodating many types of catheters to be used therein, while still maintaining a low profile for the diameter of tubular body **16**.

[**0090**] For many treatment applications, it has been found that a tubular body having an outside diameter of no more than about 0.135 inches (10 French) is preferred. Advantageously, with an outer diameter of this size, main lumen **30** may have an internal diameter of about 0.10 inches, making lumen **30** capable of accommodating a wide variety of treatment catheters, or catheters used for diagnostic purposes. Of course, as will be appreciated by those of skill in the art, where the catheters intended to be inserted into lumen **30** are known to have outer diameters significantly smaller than 0.10 inches, such that lumen **30** may be smaller than 0.10 inches and still accommodate them, a tubular body **16** having an outer diameter of less than 0.135 inches may be selected.

[**0091**] Although not required, the interior surface of lumen **30** may be provided with a liner **35** formed of a lubricous material, to reduce the frictional forces between the lumen surface and the catheters which are inserted into lumen **30**. In one preferred embodiment, liner **35** is formed out of polytetrafluoroethylene (PTFE). Lubricous materials other than PTFE, which are biocompatible, fairly flexible, and easily mounted to other polymeric materials of the type used to form catheter tubular bodies, may also be used to form liner **35**. Examples of such materials include polyethylene, Pebax (™), nylon, and the like. Where increased flexibility of the distal end **14** of catheter **10** is desired, Pebax (™) may be used in place of PTFE along a selected portion of distal end **14**, such as the distal most 15-20 cm of end **14**.

[**0092**] To minimize the outer diameter of tubular body **16**, it is preferable that inflation lumen **32** be as small as possible in accordance with its function. That is, inflation lumen **32** is preferably no larger than required to provide sufficient fluid to balloon **26** for rapid inflation, or so that fluid may be quickly withdrawn from balloon **26** during deflation. For compliant expansion balloons of the type described below, inflation lumen diameters of from about 0.008 inches to about 0.018 inches are satisfactory, with a diameter of about 0.014 inches being preferred for some applications.

[**0093**] Furthermore, in one embodiment, as illustrated in FIGS. **1-3**, the outer diameter of tubular body **16** just proximal to balloon **26** is minimized by providing an inflation lumen **32***a* with an oval cross-sectional configuration, as illustrated in **FIG. 3**. Preferably, inflation lumen **32***a* has an oval cross-sectional configuration which extends proximally from the proximal edge balloon **26** by a distance of at least 0.1 cm, more preferably 1 cm, and optimally by a distance equal to the length of tubular body **16**. For ease of manufacturing, the cross-sectional configuration of lumen **32** at points further proximal to balloon **26** may be generally circular, as illustrated in **FIG. 2**. Where the lumen configuration differs from proximal to distal end, as illustrated in **FIGS. 2 and 3**, a region of transition **33** is provided wherein the lumen configuration changes from circular to oval.

[**0094**] It will be appreciated by those of skill in the art that other cross-sectional configurations of lumen **32***a* may be provided and still function to reduce the profile of tubular body **16**. For example, triangular, rectangular, or other non-oval cross sectional configurations are easily adapted to lumen **32***a,* and the manner of incorporating such alternative cross-sectional configurations will be readily apparent to those of skill in the art in view of the description which follows.

[**0095**] A variety of different manufacturing methods may be used to alter the cross-sectional configuration of lumen **32**, as will be appreciated by those of skill in the art. In one preferred method, lumen **32** is formed of a polymeric tube, such as a polyimide tube, which has been compressed at one end so that it has the desired oval shape. The polyimide tube is then inserted into a second tube formed of a material having a lower melting point than polyimide, such as 72D Pebax (™). The combination is then heat bonded to another tube defining main lumen **30**, such as a braided Pebax (™) tube, as described below. The heat bonding takes place at a temperature greater than the melting temperature of Pebax (™), but less than the melting temperature of polyimide, so that the Pebax (™) tubes melt fuse to form the two lumen tubular body.

[**0096**] Alternately, the cross-sectional configuration, as well as the cross-sectional area of lumen **32**, may also be altered by joining two separate polymeric tubes together to form a continuous inflation lumen **32**. One of the tubes, corresponding to the proximal end of catheter **10** as shown in **FIG. 3**, may have a circular cross-sectional configuration. The second tube, corresponding to the distal end of catheter **10** as shown in **FIG. 2**, has an oval configuration. One end of a mandrel may be inserted into each of the tubes, and conventional heat bonding may be used to create the cross-sectional configuration transition. As before, the combined tube may then be heat bonded to a second tube defining main lumen **30** to form tubular body **16**.

[**0097**] As illustrated in **FIG. 1**, an inflatable balloon **26** is mounted on the distal end **14** of catheter **10**. In most applications where catheter **10** is to be used in an emboli containment treatment procedure, inflatable balloon **26** will function as an occlusion balloon, to prevent blood from passing through the blood vessel distal of balloon **26**. Thus, inflatable balloon **26** is preferably able to expand to fit a variety of different blood vessel diameters. Accordingly, it is preferred that inflatable balloon **26** have a compliant expansion profile, tending to increase in radial diameter with increasing inflation pressure. To achieve this, balloon **26** may be made out of materials which impart such expansion characteristics, including elastomeric materials such as latex or silicone. In one preferred embodiment, inflatable balloon **26** is formed out of a material comprising a block copolymer of styrene-ethylene-butylene-styrene, sold under the trade name C-Flex (™). Further details as to balloons of this type are disclosed in our copending application entitled PRE-STRETCHED CATHETER BALLOON, Ser. No. 08/812,139, filed Mar. 6, 1997, now abandoned, the entirety of which is incorporated by reference.

[**0098**] Inflatable balloon **26** may be placed in fluid communication with lumen **32***a* via a fill hole (not shown) extending through tubular body **16** within balloon **26**, such that fluid may be introduced into lumen **32** through inflation port **18** to inflate balloon **26**. Alternately, lumen **32***a* may terminate within balloon **26**, to provide the requisite fluid

communication. Balloon **26** may be attached to tubular body **16** by any suitable manner known to those of skill in the art, such as adhesives or heat bonding.

[**0099**] Tubular body **16** must have sufficient structural integrity, or "stiffness," to permit catheter **10** to be advanced through vasculature to distal arterial locations without buckling or undesirable bending of tubular body **16**. However, it is also desirable for tubular body **16** to be fairly flexible near distal end **14**, so that tubular body **16** may be navigated through tortuous blood vessel networks. Thus, in one preferred embodiment, tubular body **16** is made to have variable stiffness along its length, with the proximal portion of tubular body **16** being less flexible than the distal portion of tubular body **16**. Advantageously, a tubular body **16** of this construction enables a clinician to more easily insert tubular body **16** into blood vessel networks difficult to reach by a tubular bodies having uniform stiffness. This is because the stiffer proximal portion provides the requisite structural integrity needed to advance tubular body **16** without buckling, while the more flexible distal region is more easily advanced into and through tortuous blood vessel passageways.

[**0100**] In one preferred embodiment, variable stiffness along the length of tubular body **16** is achieved by forming a polymeric tubular body **16** which incorporates along its length a variable stiffness metallic member. The metallic member may comprise a braid or coil, and may have varying braid density or coil pitch at different points along the catheter tubular body. For example, as shown in **FIGS. 2 and 3**, tubular body **16** may be provided with a braid **36** incorporated into the wall structure of tubular body **16**. Referring to **FIG. 1**, to achieve variable stiffness, proximal region A of catheter **10** is provided with a metallic braid **36** having a lower braid density than that present in the metallic braid **36**a of distal region B. The lower braid density of proximal region A permits polymer flow in between the braids during the formation of the tubular body. Because the polymer is relatively stiffer than the braid, the lower braid density results in proximal region A being less flexible, or "stiffer", than distal region B. In one preferred embodiment, the braid density of proximal region A varies from 60 to 80 picks per inch, while that of region B varies from 90 to 110 picks per inch.

[**0101**] As will be appreciated by those of skill in the art, metallic members other than braids may be incorporated into tubular body **16** to create variable stiffness. For example, a metallic coil may be introduced into tubular body **16**. The coil may have different pitch along the length of tubular body **16**, such that region A is provided with a coil having a lower pitch than that present in region B. The manner of adapting a coil, and other metallic members, to the catheter tubular body in place of a braid will become readily apparent to those of skill in the art in view of the description which follows.

[**0102**] The precise density of the braiding provided to regions A and B can be varied considerably at the point of manufacture, such that catheters having a variety of different flexibility profiles may be created. Moreover, the braid density may be varied within catheter regions A and B as well, by providing a metallic braid which has a braid density gradient along its length. For example, the most proximal part of region A may be provided with a metallic braid **36** having a braid density of about 60 picks per inch, with the braid density increasing distally at a certain rate so that the final pick count is not more than 110 picks per inch at the distal end.

[**0103**] A variety of different metals, known to be ductile and shapeable into fine wires and flat ribbons, having a diameter of about 0.0005 inches to about 0.005 inches for wires, or the same thickness for a ribbon, may be used to form the metallic braids **36** and **36***a* or metallic coils. For example, stainless steel, platinum, gold and nitinol, or combinations thereof are all suitable metals. In one preferred embodiment, braid **36** is formed of stainless steel, and has a braid density which varies from 70 picks per inch at the most proximal part of region A, to 100 picks per inch at the most distal part of region B.

[**0104**] Metallic braids **36** may be introduced into the structure of tubular body **16** through conventional catheter forming techniques. For example, tubular body **16** may be formed by braiding over a 72D Pebax (™) tube that has a removable core mandrel in the internal diameter supporting the Pebax (™) tube, and then inserting the braided tube into a 72D Pebax (™) outer tube at the proximal region A and a 35D Pebax (™) tube at the distal region B, so that the braid is sandwiched between the inner and outer tubes. A stainless steel support mandrel may be inserted into the removable core mandrel as additional support. A shaping container such as a fluorinated ethylene propylene (FEP) shrink tube is inserted over the outer Pebax (™) tube, and the entire apparatus may then be placed in a hot box or oven kept at a temperature slightly greater than the melting temperature of the Pebax (™) tubes. The Pebax (™) tubes will melt and fuse together, and once cooled, will form a tubular body incorporating the metallic braid. The shaping container and mandrels may then be removed and discarded.

[**0105**] In another embodiment, variable stiffness of tubular body **16** may be achieved by forming regions A and B of tubular body **16** out of polymeric materials having differing degrees of stiffness. For example, one half of an inner tube of 72D Pebax (™) may be inserted into an outer tube of 35D Pebax (™), and the other half of the inner tube may be inserted into a 72D Pebax (™) outer tube. The combination may then be heat fused, as described above. The 35D/72D Pebax (™) combination forms a more flexible tubular body than the region 72D/72D Pebax combination. More or less flexible materials may be used as desired to alter the flexibility of the resulting tubular body. Furthermore, the flexibility of the various regions of a tubular body formed in this manner may be varied further by incorporating a metallic member having either a uniform density, or a varying density, into the tubular body, as described above.

[**0106**] In another preferred embodiment, variable stiffness along the length of the tubular body may be achieved by using different metallic members in regions A and B. For example, proximal region A may be provided with a multilayer coil, while distal region B may be provided with a braid. Alternately, proximal region A may be provided with a metallic braid, while distal region B may be provided with a single layer coil. As discussed above, the densities of the metallic members in the respective sections may be varied considerably to select for a desired variable stiffness profile, as will be appreciated by those of skill in the art.

[**0107**] In one preferred embodiment, variable stiffness along the length of the tubular body is achieved by keeping

the braid density constant along the length of tubular body **16** and then forming the proximal and distal portions of tubular body **16** of polymeric materials of differing stiffness. For example, braid density may be uniform and range from 60-80 picks/inch, more preferably be about 70 picks/inch, with region A being formed of 72D Pebax (™) and region B being formed of 25-50D Pebax (™). Alternately, region A can be formed of high density polyethylene and region B of low density polyethylene.

[**0108**] Moreover, any of a variety of different polymeric materials known by those of skill in the art to be suitable for catheter body manufacture may be used to form tubular body **16**. For example, tubular body **16** may be formed out of Pebax (™), blends of Pebax (™), and nylons, polyetheretherketone (PEEK), polyethylenes, and Hytrel (™), and the like. Different materials might also be combined or blended to select for desirable flexibility properties.

[**0109**] Also, although tubular body **16** has been described in the context of having two regions of differing flexibility, it will be readily appreciated by those of skill in the art that three or more regions of differing flexibility may easily be provided, by adapting the teachings contained herein.

[**0110**] In the above-discussed embodiments, and all other embodiments of the present invention, it may be preferred to provide main lumen **30** and the outer surface of tubular body **16** with a hydrophillic coating, a hydrophobic coating, or combinations thereof. For example, main lumen **30** may be provided with a hydrophobic coating, such as silicone, while tubular body **16** is provided with a hydrophillic coating, such as polyvinyl pyrrolidone (PVP), polyurethane blends, copolymers of acrylonitrile, and the like. Other hydrophobic and hydrophillic coatings, as known to those of skill in the art, may also be used. In addition, any of a variety of antithrombogenic coatings, such as heparin, may also be applied to the catheter of the present invention, alone or in combination with other coating types.

[**0111**] Referring to **FIGS. 4 and 5**, there is illustrated a cross-sectional view of the distal end **14** of catheter **10**. Distal end **14** is provided with a soft distal tip **50**, which is not pre-formed with tubular body **16**, but is instead attached to tubular body **16** as a tube post manufacturing step. Distal tip **50** is preferably soft enough and flexible enough, so as to minimize trauma to body vessels as catheter **10** is advanced, and also to facilitate navigation of catheter **10** in tortuous vessels. In one preferred embodiment, distal tip **50** is formed as a 0.5 cm sleeve of 25-40D Pebax (™), and is bonded to tubular body **16** by heat fusing. Alternately, distal tip **50** may be attached to tubular body **16** by adhesives, or by insert molding, as is known to those of skill in the art. Preferably, distal tip **50** is in alignment with tubular body **16**, and does not bend or curve, such that the radial axis of distal tip **50** is substantially the same as that of tubular body **16**.

[**0112**] The distal end **14** of catheter **10** is also preferably provided with a radiopaque material **44**. Advantageously, radiopaque material **44** serves as a marker to help the clinician position catheter **10** during a medical procedure. Various well-known radiopaque materials may be used in distal end **14**, such as platinum, gold, and platinum-iridium blends. The full length, or part of the length of the tubular body, may also be radiopaque by blending radiopaque materials in the polymeric materials used to form the body. Furthermore, radiopacity of the tip can also be achieved by loading (i.e., comparing) the distal tip **50** with a sufficient amount of barium sulfate. Alternatively, bismuth subcarbonate, bismuth trioxide or bismuth oxychloride may be used as a radiopaque filler. Also, radiopacity may be achieved by using radiopaque wire or flat ribbon to make the braid or coil.

[**0113**] Illustrated in FIGS. **6-9**, there is an emboli containment system utilizing catheter **10** of the present invention. Catheter **10** of the present invention is used in the treatment of a stenosis **55** in a lumen **50** in a blood-carrying vessel **58** in which the stenosis **55** at least partially occludes the lumen **50**. The emboli containment system depicted in **FIG. 6** comprises a catheter **10**, as described above, as well as catheters **100** and **200**.

[**0114**] Catheter **100** comprises an elongate flexible tubular body **116** having proximal end and distal end **114**. An inflatable balloon **126** of the same type as inflatable balloon **26** is coaxially mounted on tubular body **116** on the end **114** of catheter **100**. The tubular body **116** has centrally disposed inflation lumen **132** in fluid communication with balloon **126**, such that fluid passing through lumen **132** may be used to inflate balloon **126**. Alternatively, fluid may be withdrawn from lumen **132** to deflate balloon **126**. As shown in **FIG. 6**, catheter **100** is disposed within main lumen **30** of catheter **10** and is slidably and coaxially mounted therein for variable displacement of balloon **126** with respect to the first balloon **26**, as hereinafter described. One preferred embodiment of a catheter **100** is disclosed in our co-pending application, entitled HOLLOW MEDICAL WIRES AND METHODS OF CONSTRUCTING SAME, Ser. No. 08/812,876, filed Mar. 6, 1997, now U.S. Pat. No. 6,068,623, the entirety of which is incorporated by reference.

[**0115**] The emboli containment system also comprises catheter **200** comprising an elongate flexible tubular body **216** having proximal end and distal end **214**. Catheter **200** is also provided with a generally centrally disposed lumen **230** extending from the proximal end to the distal end of catheter **200**, and through which catheter **100** is coaxially and slidably mounted.

[**0116**] The distal end **214** of catheter **200** is provided with means for performing a medical procedure, such as an apparatus for treating stenotic lesion **55**. In the embodiment of the invention shown in **FIG. 6**, this means comprises a dilatation balloon **226**, which is preferably a non-compliant inflatable balloon which is coaxially mounted on the distal end **214** of catheter **200**. Balloon **226** may also be attached to tubular body **216** in the same manner as balloons **26** and **126** hereinbefore described. Tubular body **216** is provided with a balloon inflation lumen **232** which is in fluid communication with balloon **226**, such that balloon **226** may be inflated by the passage of fluid through lumen **232**.

[**0117**] The operation and use of the emboli containment system utilizing the catheter of the present invention for treating occluded vessels may now be briefly described in connection with an occlusion formed by a stenosis in a carotid artery, as illustrated in FIGS. **10**A-E.

[**0118**] Catheter **100** is inserted into an incision into a femoral artery of a patient and is advanced through that artery into the aorta of the patient and into the ostium of the carotid artery to be treated. After catheter **100** has been introduced, catheters **10** and **200**, with balloons **26** and **226**

completely deflated, are introduced over catheter **100** and are advanced into the ostium of the carotid artery and into the lumen or passageway of the vessel as shown in FIGS. **10**A-E.

[**0119**] The emboli containment system is advanced until catheter **10** is proximal of a stenosis **55** in the vessel lumen **50** to be treated. Balloon **26** is then inflated by introducing a suitable inflation medium such as a radiopaque liquid into port **18** to cause it to pass through the balloon inflation lumen **32** to inflate balloon **26**, as shown in **FIG. 10B**. Balloon **26** is progressively inflated until it engages the side wall **58** of the vessel to occlude the lumen **50**.

[**0120**] Catheter **100** is then advanced through stenosis **55** as shown in **FIG. 10C**. Catheter **100** with deflated balloon **126** thereon is advanced through stenosis **55** until the balloon **26** is distal of stenosis **55** as shown in **FIG. 10D**. Balloon **126** is then inflated by passing an inflation medium through lumen **132** to the interior of the balloon **126** to inflate the balloon **126** until it engages the sidewall **58** of the vessel lumen **50**. As soon as the balloon **126** has been inflated, a working space is provided between balloons **26** and **126**, so that medical procedures can be undertaken to remove or reduce the stenosis **55** in the space between second balloons **26** and **126**, without risk of unwanted particles or emboli escaping into the blood stream.

[**0121**] For emboli containment systems featuring balloon dilatation treatment, it is desired to compress the plaque or material forming the stenosis to provide a larger vessel. Thus, catheter **200** is advanced over catheter **100** to cause distal end **214** with balloon **226** thereon to be advanced into the working space. As soon as balloon **226** has been properly positioned within stenosis **55**, balloon **226** is inflated with a suitable inflation medium, as for example a radiopaque liquid. Balloon **226** can be inflated to the desired pressure to cause compression of the plaque of the stenosis **55** against the sidewall **58** of lumen **50** by the application of appropriate inflation pressure. As in conventional angioplasty procedures, balloon **226** can be formed of a non-elastic relatively non-compliant material so that appropriate pressures, such as 10-15 atmospheres, can be used within balloon **226** to apply compressive forces to the vessel without danger of rupturing the vessel. It should be appreciated that the non-elastic capabilities can also be achieved by a composite elastic material.

[**0122**] Once the clinician is satisfied that the occlusion forming stenosis **55** has been sufficiently compressed, balloon **226** can be deflated. After the appropriate dilation of stenosis **55** has been accomplished, catheter **200** can be removed from the stenosis. Moreover, in one preferred method, catheter **200** is completely withdrawn from the emboli containment system, and an irrigation catheter is inserted over catheter **100** and through lumen **30**, as described in our copending application entitled METHOD FOR EMBOLI CONTAINMENT, Ser. No. 08/812,875, filed Mar. 6, 1997, now U.S. Pat. No. 5,833,644, the entirety of which is incorporated by reference. Fluid introduced into the working space may be removed by supplying a negative pressure or suction to aspiration port **20**. This creates a negative pressure within space **30***a* defined by the interior surface of lumen **30** and outer tubular body **216**, to suck or aspirate blood or other fluids in lumen **50** into space **30***a* and out of aspiration port **20**. In this manner, irrigation and aspiration of the working space may take place so that any plaque coming off the occlusion forming the stenosis **55** can be aspirated out of the vessel. Subsequently, balloon **26** and balloon **126** can be deflated to permit normal blood flow through the vessel lumen **50**. The entire catheter assembly can then be removed and a suture applied to the incision created to obtain access to the femoral artery.

[**0123**] In general, the catheter apparatus is for treatment of a stenosis in a lumen in a blood carrying vessel. It is comprised of a main catheter and a balloon-on-a-wire device. The main catheter is comprised of a first flexible elongate tubular member having proximal and distal extremities. A first inflatable elastic balloon having an interior is coaxially mounted on the distal extremity of the first flexible elongate tubular member. The first flexible elongate tubular member has a balloon inflation lumen therein in communication with the interior of the first balloon. The first elongate tubular member has a main lumen therein extending from the proximal extremity to the distal extremity and exiting through the distal extremity. An adapter is mounted on the proximal extremity of the first flexible elongate tubular member and has a balloon inflation port in communication with the balloon inflation lumen, a therapeutic catheter port and an aspiration port in communication with the main lumen. The balloon-on-a-wire device is comprised of a guide wire having proximal and distal extremities.

[**0124**] A second inflatable elastic balloon has an interior and is coaxially mounted on the distal extremity of the guide wire. The guide wire has a balloon inflation lumen therein in communication with the interior of the second balloon. The balloon-on-a-wire device is slidably mounted in the therapeutic catheter port and in the main lumen of the first elongate tubular member with the proximal extremity of the guide wire being disposed outside of the main lumen. Removable valve means is carried by the proximal extremity of the guide wire and has the capability of forming a fluid-tight seal with respect to the guide wire while permitting relative axial movement of the guide wire and the first flexible elongate tubular member with respect to each other whereby the first balloon can be moved so that it is proximal of the stenosis and the second balloon so that it is distal of the stenosis. The removable valve means includes an inflation port in communication with the balloon inflation lumen and the guide wire. The apparatus is also comprised of means coupled to the balloon inflation port of the first flexible elongate tubular member for inflating the first balloon and means coupled to the balloon inflation port of the removable valve means for inflating the second balloon to create a working space which brackets the stenosis.

[**0125**] More particularly as shown in FIGS. **11-14**, the catheter apparatus **311** of the present invention is for use in the treatment of a stenosis **312** in a lumen **313** in a blood-carrying vessel **314** in which the stenosis **312** has a length and a width or thickness which at least partially occludes the lumen **313**. The apparatus consists of a first elongate flexible tubular member **316** formed of a suitable plastic material which is provided with proximal and distal extremities **317** and **318**. A first balloon **319** is mounted on the distal extremity **318** and preferably is a compliant balloon formed of a suitable elastic material such as a latex or a very low radiation polyethylene so that it can be inflated to the size of the vessel **314** in which it is to be disposed. Thus, the balloon **319** should be capable of expanding to various diameters

depending on the size of the vessel. The first balloon **319** can be formed as a separate balloon separate from the elongate tubular member **316** as shown and adhered thereto by suitable means such as an adhesive (not shown), or it can be formed integral with the tubular member **16** in a manner well known to those skilled in the art.

[**0126**] The tubular member **316** is provided with a large centrally disposed or main lumen **321** extending from the proximal extremity **317** to the distal extremity **318**. It is also provided with a balloon inflation lumen **322** which has a distal extremity in communication with the interior of the first balloon **319** through a port **323**. The proximal extremity of the balloon inflation lumen **322** is in communication with a balloon inflation fitting **324** mounted on the proximal extremity **317** of the tubular member **316**. The fitting **324** can be of a conventional type as for example a Luer-type fitting which is adapted to be connected to a balloon inflation device (not shown) for inflating and deflating the first balloon **319**.

[**0127**] The first tubular member **316** is also provided with an aspiration lumen **326** which exits through the distal extremity **318** and the proximal extremity **317** of the tubular member **316**. A Luer-type fitting **327** is mounted on the proximal extremity **317** and is in communication with the aspiration lumen **326**. The fitting **327** is adapted to be connected to a suitable aspiration or suction source (not shown) of a conventional type such as a syringe or rubber bulb for aspiration purposes as hereinafter described.

[**0128**] The catheter assembly or apparatus **311** also consists of a second elongate flexible tubular member **331** having proximal and distal extremities **332** and **333**. A second inflatable balloon **336** of the same type as the first inflatable balloon is coaxially mounted on the distal extremity **333** in a conventional manner. The tubular member **331** is provided with a large generally centrally disposed arterial blood flow lumen **337** which opens through the distal extremity **333** and is in communication with a Luer-type fitting **338** which as hereinafter described is adapted to be connected to a supply of arterial blood from the patient which for example can be taken from another femoral artery of the patient by the use of a blood pump.

[**0129**] The second tubular member **331** is also provided with a balloon inflation lumen **339** which is in communication with the interior of the second inflatable balloon **336** through a port **341**. The proximal extremity of the lumen **339** is in communication with the Luer-type fitting **342** mounted on the proximal extremity **332** of the second tubular member **31** and as with the balloon inflation fitting **324** is adapted to be connected to a balloon inflation-deflation device (not shown) of a conventional type. The second tubular member **331** is also provided with a lumen **343** which also can be used as a guide wire and/or for introducing a saline solution extending from the proximal extremity to the distal extremity. The lumen **343** is sized so that it is adapted to receive a conventional guide wire **346** as for example a 0.014" or 0.018" guide wire and extends from the proximal extremity to the distal extremity so that the guide wire **346** can extend beyond the distal extremity of the second tubular member **331**. A fitting **347** is provided on the proximal extremity **332** in communication with the lumen **343** for introducing the saline solution.

[**0130**] As shown in **FIG. 11**, the second tubular member **331** is disposed within the central lumen **321** of the first tubular member **316** and is slidably and coaxially mounted therein for displacement of the second balloon **336** with respect to the first balloon **319** as hereinafter described.

[**0131**] The catheter assembly or apparatus **311** also consists of a third elongate flexible tubular member **351** having proximal and distal extremities **352** and **353**. It is provided with a centrally disposed lumen **356** extending from the proximal extremity **352** to the distal extremity **353** and through which the second tubular member **331** is coaxially and slidably mounted.

[**0132**] Means **357** is provided on the distal extremity **353** of the third tubular member **351** for performing a medical procedure. In the embodiment of the invention shown in **FIG. 11**, this means **357** consists of a third balloon **358** which can be non-compliant coaxially mounted on the distal extremity of the third tubular member **351**. The third balloon **358** can be attached in the same manner as the first and second balloons **319** and **336** hereinbefore described. The third tubular member **351** is provided with a balloon inflation lumen **359** which has its distal extremity in communication with the interior of the balloon **358** through a port **361**. The proximal extremity of the balloon inflation **359** is in communication with a Luer-type fitting **362** provided on the proximal extremity **352** and adapted to be connected to a conventional inflation deflation device (not shown) for inflating and deflating the third balloon **358**.

[**0133**] The operation and use of the catheter assembly or apparatus **311** in the method of the present invention for treating occluded vessels may now be briefly described in connection with an occlusion formed by a stenosis in a vessel not having a bifurcation therein as for example in saphenous graft or in one of the right and left carotid arteries, also called internal and external carotid arteries, of a patient in connection with the illustrations shown in **FIGS. 15 and 16**A-16E. A guiding catheter **363 (FIG. 15)** of a conventional type is inserted into an incision into a femoral artery **364** of a patient and is advanced through that artery into the aorta of the heart **365** of the patient and into the ostium **366** of the selected carotid artery or vessel as for example the left carotid **367**.

[**0134**] After the guiding catheter has been appropriately positioned, the guide wire **346** is introduced separately into the guiding catheter or along with the catheter assembly **311**. The distal extremity of the catheter apparatus or assembly **311** with all of the first, second and third balloons **319**, **336** and **358** completely deflated, is introduced into the guiding catheter **363** along with or over the guide wire **346** and is advanced through the guiding catheter **363** into the ostium **366** of the carotid artery or vessel **367** and into the lumen or passageway **368** of the vessel as shown in **FIGS. 15 and 16**B.

[**0135**] The distal extremity of the catheter assembly **311** is advanced until it is just proximal of a stenosis **369** in the carotid artery **367** to be treated. The balloon **319** is then inflated by introducing a suitable inflation medium such as a radiopaque liquid into the fitting **324** to cause it to pass through the balloon inflation lumen **322** through the port **323** and into the interior of the first balloon **319** to inflate the same as shown in **FIG. 16B**. The balloon **319** is progressively inflated until it engages the side wall of the vessel **367** to occlude the vessel **367**. At the time that this is occurring, a negative pressure or suction is applied to the aspiration

fitting **327** to supply a negative pressure through the balloon inflation lumen **322** to suck or aspirate blood in the vessel **367** distal of the first balloon **319** into the aspiration lumen **326** and out the aspiration fitting **327** to thereby reverse the flow of blood through the stenosis as shown by the arrows **371** in **FIG. 16B**.

[**0136**] While a reverse flow of blood is occurring in the vessel **367**, the guide wire **346** is advanced through the stenosis **369** as shown in **FIG. 16C**. In the event that any pieces or particles of plaque are knocked off of the occlusion formed by the stenosis **369** by movement of the guide wire **346** through the same, such pieces of plaque or emboli will be drawn out with the reverse flow of blood into the aspiration lumen **326** and out of the aspiration fitting **327**. During the time that the guide wire **346** is being advanced through the stenosis **369** it may be desirable at the same time to introduce a saline solution through the guide wire lumen **343** of the second elongate flexible tubular member **331** to exit through the distal extremity of the second elongate flexible tubular member **331** into the space immediately proximal of the stenosis **369**. This introduced saline solution aids the flow of particulate or other particles dislodged from the stenosis **369** during advancement of the guide wire **346** through the same and carries them back with the mixed saline blood solution through the aspiration lumen **326** in a manner hereinbefore described.

[**0137**] With the guide wire **346** remaining in position, the second elongate flexible tubular member **331** with the second balloon **336** thereon in a deflated condition is advanced over the guide wire **346** through the stenosis **369** until the second balloon **336** is distal of the stenosis **369** as shown in **FIG. 16D** after which the second balloon **336** is inflated by introducing an inflation medium as for example a radiopaque liquid through the inflation fitting **342** into the lumen **339** through the port **341** to the interior of the second balloon **336** to inflate the second balloon **336** until it engages the sidewall of the vessel **367**.

[**0138**] Prior to, during or after inflation of the second balloon **336**, the guide wire **346** can be removed. However, it is preferable to remove the guide wire **346** as soon as the second balloon **336** has been advanced so that it is beyond the stenosis **369**. At this time, and certainly prior to complete inflation of the second balloon **336**, blood is shunted across the stenosis **369** and into the lumen **368** distal of the second balloon **336** by introducing blood through the fitting **338** and into the centrally disposed blood flow lumen **337** in the second tubular member **331** so that it exits out the central lumen **337** distal of the second balloon **336**. The blood which is supplied to the fitting **337** can be taken from another femoral artery of the patient and pumped into the fitting **338**. In addition, if desired, the blood which is aspirated in the space distal of the first balloon **319** can be appropriately filtered and also supplied to the fitting **338**. By shunting blood past the stenosis **369** in this manner it can be seen that blood is being continuously supplied to the carotid artery of the patient during the time that the second balloon **336** is inflated and occludes the lumen **368** in the vessel **367**.

[**0139**] As soon as the second balloon **336** has been inflated, it can be seen that there is provided a working space **376** (**FIG. 16D**) between the first and second balloons **319** and **336** so that medical procedures can be undertaken to remove or reduce the stenosis **369** in the space between the first and second balloons **319** and **336**.

[**0140**] Assuming that it is desired to compress the plaque or material forming the stenosis **369** to provide a larger lumen, opening or passageway through the stenosis **369** the third tubular member **51** can be advanced by grasping the proximal extremity **352** to cause the distal extremity with the third balloon **358** thereon to be advanced into the working space **376**. As soon as the balloon **358** has been properly positioned within the stenosis **369**, the balloon **358** also can be inflated with a suitable inflation medium as for example a radiopaque liquid. The balloon **358** can be inflated to the desired pressure to cause compression of the plaque of the occlusion against the sidewall of the vessel **367** by the application of appropriate pressure. As in conventional angioplasty procedures, the third balloon **358** can be formed of a non-elastic relatively non-compliant material so that high pressures as for example 10-15 atmospheres can be used within the balloon to apply compressive forces to the vessel without danger of rupturing the vessel. It should be appreciated that the non-elastic capabilities can also be achieved by a composite elastic material.

[**0141**] Since the blood flow has been restored to the vessel **367** by the shunt hereinbefore described, the compression of the occlusion forming the stenosis **369** can be carried out for an extended period of time, as for example after a few minutes, if desired to help ensure that a large lumen or passageway is formed through the stenosis **369** as shown in **FIG. 16E**. If it is believed that the occlusion forming the stenosis **369** has been sufficiently compressed, the third balloon **358** can be deflated. In the event an inelastic balloon is utilized for the third balloon **358**, and it is desired to utilize a larger third balloon, this can be accomplished by removing the third tubular member **351** with the deflated balloon **358** thereon and introducing a third tubular member **351** having a larger size balloon thereon over the second tubular member **331** and advancing it into the stenosis **369** and inflating the larger size balloon to create a still larger passage through the stenosis **369**.

[**0142**] After the appropriate dilation the stenosis **369** has been accomplished the third balloon can be removed from the stenosis while aspiration of the working space **376** is still ongoing so that any plaque coming off the occlusion forming the stenosis **369** can be aspirated out of the vessel. After the third balloon **358** has been removed from the stenosis, the second balloon **336** and the first balloon **319** can be deflated to permit normal blood flow through the vessel **367** after which the arterial blood flow supply to the fitting **338** can be terminated. The entire catheter assembly **311** can then be removed from the guiding catheter **363** after which the guiding catheter **363** can be removed and a suture applied to the incision created to obtain access to the femoral artery.

[**0143**] In place of the third balloon **358** for causing compression of the occlusion forming the stenosis **367** to create a larger passageway therethrough, an atherectomy device **381** (see **FIG. 17**) can be utilized for operating in the working space **376** to remove the plaque of the occlusion forming the stenosis. This can be accomplished with a catheter assembly or apparatus **381** which in many respects is similar to the apparatus **311** shown in **FIG. 11** and consists of a first tubular member **316** with a first balloon **319** and a second tubular **331** with a second balloon **336** thereon. In place of the third flexible elongate tubular member **351** there is provided a third flexible elongate tubular member **386** which is provided with proximal and distal extremities **387**

and **388**. The flexible elongate tubular member **386** is slidably and rotatably mounted in the central lumen **321** of the flexible elongate member **316** and is provided with a central or main lumen **389** through which the second flexible elongate tubular member **331** extends. It is also provided with a lumen **391** extending from the proximal extremity to the distal extremity through which a saline solution can be introduced for saline irrigation as hereinafter described. It is also provided with another lumen **392** which is adapted to receive a plurality of electrical conductors **393** for performing electrical functions as hereinafter described. The lumen **392** is connected to a conventional Luer-type fitting **396** serving as a fluid irrigation fitting mounted on the proximal extremity first tubular member **312** and is in communication with an annular recess **397** which is in communication with the lumen **391** provided in the tubular member **386** for supplying a saline irrigation liquid through the flexible elongate tubular member **386** and into the working space **376** provided between the first and second balloons **316** and **336**. In order to aid aspiration of the saline irrigation liquid from the working space **376**, the outer surface of the flexible elongate tubular member **386** is provided with a helical groove **398** therein which has one end which opens into the working space **376** and which has the other end in communication with the aspiration fitting **327**.

[**0144**] Means is provided for rotating the second tubular member **386** and consists of suitable means such as a spur gear **401** mounted on the proximal extremity **387** of the tubular member **386**. The spur gear **401** is driven in a suitable manner as for example by another smaller spur gear **402** which is of greater width than spur gear **401** so as to provide a splined gear connection between the gears **401** and **402**. This accommodates the desired longitudinal movement for the tubular member **386** so that the distal extremity **388** of the tubular member **386** can be advanced and retracted in the working space **376** as hereinbefore described. An electrical drive motor **403** is provided for driving the gear **402**.

[**0145**] Atherectomy means **406** is provided on the distal extremity **388** of the flexible elongate tubular member **386**. As shown in **FIGS. 17 and 19**, the atherectomy means **406** consists of a flexible elongate member **407** formed of a suitable material such as stainless steel or preferably a superelastic Nitinol. The flexible elongate member **407** is wound into a helix as shown in **FIG. 19** onto the distal extremity of the tubular member **386**. The flexible elongate member **407** can be formed of a ribbon having a thickness of 0.003" and a width of 0.060". One end of the flexible elongate member **407** can be secured to the tubular member **386**, as for example by inserting the same into a slit **408** and additionally by the use of adhesive (not shown). The flexible elongate member **407** is wrapped into a helix in a direction opposite to the direction of normal rotation of the tubular member **386** and can be provided with a special tip **409** on its free end with the tip having an arcuate surface **411** that is inclined rearwardly to terminate at a cutting edge **412** (see **FIG. 19**) which is adapted to engage the plaque or the stenosis **369**.

[**0146**] When the distal extremity **388** of the flexible elongate tubular member **386** has been introduced into the working space **376**, the end or tip **409** of the flexible elongate member **407** of the atherectomy means **406** is free. A saline solution is introduced into the fitting **357**. Thereafter the motor **403** can be energized to cause rotation of the tubular member **386** and to thereby cause rotation of the helically wound flexible elongate member **407** to cause its free end or tip **409** to be moved outwardly radially under centrifugal force to bring the cutting edge **412** into engagement with the plaque **369** in the stenosis **369** to cause progressive removal of the plaque forming the stenosis **369** to enlarge the passageway extending through the stenosis. Because of the rounded configuration of the tip **409**, the tip **409** will not dig into the vessel wall but will only remove plaque which is engaged by the cutting edge **412**. As the plaque is being removed, the saline solution introduced through the fitting **396** into the space **376** picks up the plaque particles or emboli as they are being removed. The saline solution with the plaque or emboli therein is removed through the spiral groove **398** and through the aspiration port **327**. The flexible elongate tubular member **386** can be moved back and forth so that the cutting tip **409** engages the length of the stenosis **369** so that substantially all of the stenosis **369** can be removed.

[**0147**] Means is provided to sense when sufficient plaque has been removed from the stenosis **369** and to ensure that cutting edge **412** does not cut into the vessel wall. An ultrasonic sensor **416** (see **FIG. 17**) is mounted in the distal extremity of the tubular member **386** and is connected by conductors **393** (see **FIG. 18**) extending through the lumen **392** and connected to a cable **418** which is connected to an ultrasonic power supply **419** and a video monitor **421**. By using the Doppler effect, ultrasonic energy can be utilized in connection with the transducer **416** to ascertain the depth of cut being made by the flexible elongate member **407** as it is being rotated.

[**0148**] As soon as a desired amount of plaque has been removed from the stenosis **369** to provide the desired passage through the stenosis, rotation of the tubular member **386** is terminated after which the tubular member **386** can be withdrawn followed by deflation of the second balloon **336** and withdrawing it. Deflation of the first balloon **316** then occurs after which it is withdrawn from the vessel **367**. Thereafter, the guiding catheter **363** can be removed and the incision closed as hereinbefore described.

[**0149**] In order to ensure that restenosis will not take place, it may be desirable to place a cylindrical stent **426** in the stenosis **369**. Such a stent **426** can be a self-expanding stent formed of a suitable material such as a superelastic Nitinol and movable between unexpanded and expanded conditions. Such a stent **426** can be placed by a suitable catheter apparatus **431** of the type shown in **FIG. 20**. The stent **426** which is cylindrical in form is pushed over the proximal extremity of the second elongate flexible tubular member **331** into the main or central lumen **321** so that it is retained in the unexpanded position. It is then pushed forwardly toward the distal extremity of the first flexible elongate tubular member **316** by means of a flexible elongate tubular member **436** having proximal and distal extremities **437** and **438** and having a flow passage **439** extending from the proximal extremity **437** to the distal extremity **438**. The proximal extremity **437** is provided with a knurled collar **441** which is adapted to be engaged by the hand to facilitate pushing of the flexible elongate tubular member **436** so that its distal extremity is in engagement with the stent **426**. Thus, when desired the stent **426** may be discharged or dislodged from the distal extremity of the

second tubular member **331** and pushed into the working space **376** created between the first balloon **319** and the second balloon **336**.

[**0150**] After the stent **426** has been discharged out of the end of the first flexible elongate tubular member **316**, the stent **426** will self expand toward its expanded condition until it is in engagement with the wall of the vessel in the vicinity of the occlusion forming the stenosis **369** to frictionally retain the stent in engagement with the vessel wall. As soon as the stent **426** is in engagement with the vessel wall, the second balloon **336** can be deflated as can the first balloon **319**. The first deflated balloon **336** can then be withdrawn through the interior of the cylindrical stent **426**. This can be followed by deflation of the first balloon **319** and the removal of the flexible elongate tubular member **316** with its first balloon **319** and the flexible tubular member **331** with its second balloon **336**, along with the flexible elongate member **436** until the entire catheter assembly or apparatus **431** has been removed from the guiding catheter **363**. Thereafter the guiding catheter **363** can be removed and the incision sutured as hereinbefore described.

[**0151**] In **FIG. 21**, there is shown another embodiment of an apparatus **451** incorporating the present invention which is particularly adapted for use treating a stenosis at or near a bifurcation appearing in an arterial vessel. The apparatus **451** is shown being used on a human being **452** showing the principal arteries and pulmonary veins of the human body. Thus there as shown, the abdominal aorta **453** branches into the common iliac **454** which branches into the external iliac **456** and the internal iliac **457**. The external iliac branches into the deep femoral artery **458** and into the femoral artery **459**. The abdominal aorta **453** extending in the opposite direction passes through the aortic arch **461** of the heart **462**. The aortic arch **461** is connected to the common carotid **466** which extends into a bifurcation **467** branching into the external carotid **468** and the internal carotid **469**. Similar bifurcations appear in the basilar artery which is an artery which is particularly inaccessible for surgical treatment.

[**0152**] As hereinafter explained, the apparatus **451** shown in **FIGS. 21, 22** and **23** consists of a proximal occlusion balloon catheter **476** which can be considered to be a first catheter. The catheter **476** is formed of a flexible elongate tubular member **477** having proximal and distal extremities **478** and **479**. The tubular member **477** is formed of a suitable material such as plastic and can have a suitable size ranging from 5 to 14 French and preferably 9 to 10 French. A balloon **481** is provided on the distal extremity **479** and is formed of a suitable elastic material. It is generally cylindrical in form and has its proximal and distal extremities secured to the tubular member **477** by suitable means such as an adhesive (not shown). The tubular member **477** is provided with a plurality of lumens therein. One lumen **482** serves as a balloon inflation lumen and extends from the proximal extremity **478**. It can have a suitable size such as 0.024" and has port **483** in communication with the interior of the balloon **481**. A manifold **486** formed of a suitable material such as plastic is mounted on the proximal extremity **478**. A tubular member **487** is mounted in the manifold **486** and is in communication with the inflation lumen **482**.

[**0153**] The tubular member **477** is also provided with a large lumen **491** having a suitable size as for example 0.045" which is adapted to slidably receive therein a therapeutic balloon catheter **492** and a perfusion balloon catheter **493**. It is also provided with another lumen **496** having a suitable size as for example 0.026" which is adapted to receive a balloon-on-a-wire catheter **497**. It is also provided with an aspiration lumen **501** having a suitable size as for example 0.025" and an irrigation lumen **502** having a suitable size as for example 0.015". There is also provided another lumen **503** which can be used for other purposes.

[**0154**] The therapeutic balloon catheter **492** and the perfusion balloon catheter **493** are constructed in a manner similar to the balloon catheters hereinbefore described. Thus the perfusion balloon catheter **493** is provided with a flexible elongate tubular member **506** having proximal and distal extremities **507** and **508**. A balloon **509** formed of an elastic material is secured to the distal extremity **508** by suitable means such as an adhesive (not shown) and is adapted to be inflated through a port **510** in communication with a balloon inflation lumen **511**. The tubular member **506** is also provided with a blood perfusion lumen **512** which is centrally disposed therein. The proximal extremity **507** of the tubular member **506** is connected to a Y adapter or fitting **513** of which the central arm **514** is in communication with the blood perfusion lumen **512** and is provided with a Luer-type fitting **516**. The side arm **517** of the fitting **513** is in communication with the balloon inflation lumen **511** and is provided with a Luer-type fitting **518** adapted to be connected to a source of pressure as hereinafter described.

[**0155**] The therapeutic balloon catheter **492** consists of a tubular member **521** having a proximal and distal extremities **522** and **523**. A balloon **524** formed of a non-elastic material is secured to the distal extremity **523** by suitable means such as an adhesive. A port (not shown) is in communication with the interior of the balloon **524** and is in communication with a balloon inflation lumen **526**. A Luer-type fitting **527** is mounted on the proximal extremity **522** and is in communication with the balloon inflation lumen **526**. Another fitting **528** is mounted on the proximal extremity **522** and is in communication with a large centrally disposed lumen **529** which can receive the perfusion balloon catheter **493** for slidable movement as hereinafter described.

[**0156**] The balloon-on-a-wire catheter **497** is slidably mounted in the lumen **496** and consists of a guide wire **531** of a conventional construction having a suitable diameter as for example 0.018" and having a proximal and distal extremities **532** and **533**. A balloon **534** formed of a non-elastic material is mounted on the distal extremity **533** and is secured thereto by suitable means such as an adhesive (not shown). The proximal extremity of the balloon **534** is secured to the distal extremity of a tubular member **536** formed of a suitable material such as plastic and which is coaxially disposed on the guide wire **531**. The tubular member **536** extends the length of the guide wire to the proximal extremity and is connected to a Luer-type wye fitting **537** and is in communication with an annular lumen **538** disposed between the tubular member **536** and the exterior surface of the guide wire **531**. The lumen **538** is in communication with the interior of the balloon **534** for inflating and deflating the balloon **534**. The balloon-on-a-wire catheter **497** is adapted to be introduced through a fitting **541** carried by a tube **542** mounted in the manifold **486** and in communication with the lumen **496** in the multi-lumen elongate tubular member **477**.

[0157] A tube **546** is mounted in the manifold **486** and is in communication with the large lumen **491** and is provided with a fitting **547** which is adapted to receive the perfusion balloon catheter **493** and the therapeutic balloon catheter **492** as hereinafter described. Another tube **551** is provided in the manifold **486** and is in communication with the aspiration lumen **501**. It is provided with the fitting **552**. Another tube fitting **553** is mounted in the manifold **486** and is in communication with the irrigation lumen **502** and is provided with a fitting **554**.

[0158] The various fittings for the catheter as hereinbefore described are adapted to be connected into a control console **571**. The control console **571** consists of a rectangular case **572** which is provided with a front panel **573**.

[0159] A plurality of balloon inflation deflation devices **576** of a conventional type typically called endoflaters are mounted within the case **572** and have control handles **577** extending through vertically disposed slots **578** provided in the front panel. These endoflaters **576** are labeled as shown in **FIG. 21** and are connected by tubing (not shown) through pressure gauges **581** mounted in the front panel **573** and are provided with needle indicators **582** to indicate the pressure being applied by the endoflater to the tubing. The tubing is connected in such a manner so that the endoflater **576** and the associated pressure gauge **581** are connected to a tube **586** which is provided with a mating fitting **587** adapted to mate with a fitting **488** so that it is in communication with the inflation lumen **482** of the proximal occlusion balloon catheter **476**. In a similar manner, the tubing **588** is provided with a fitting **589** which mates with a fitting **518** of the balloon inflation lumen **511** of the perfusion balloon catheter **493** for inflating balloon **509**. Similarly, tube **591** with its mating fitting **592** is adapted to mate with the fitting **537** for inflating the balloon **534**. Similarly, the tube **593** with its fitting **594** mates with the fitting **527** in communication with the balloon inflation lumen **526** for inflating the balloon **524** of the therapeutic catheter **492**. Another tube **596** which is provided with its fitting **597** mates with the fitting **552** that is in communication with the aspiration lumen **501**. The tube **596** is in communication with the inlet of a blood pump **601** of a suitable type as for example a roller pump well known to those skilled in the art which is mounted within the case **572** and which is connected to a source of electrical power through electrical plug **602** connected into the case **572**. The roller pump **601** is provided with an on/off switch **603** mounted on the front panel **573**. After it passes through the pump **601**, blood is supplied to a blood filter **606** of a conventional type and then is supplied through a tube **611** having a fitting **612** adapted to mate with the fitting **516** of the perfusion balloon catheter which is in communication with the perfusion lumen **512**.

[0160] A three-way valve **616** is associated with each of the endoflaters **576** and has a control knob **617** extending through the front panel **573** and is adaptable to be moved between three positions with a center off position and an aspiration position in a counter-clockwise direction and a pressurized position in a clockwise position as viewed in **FIG. 24**.

[0161] Operation and use of the apparatus **451** may now be briefly described as follows. Let it be assumed that it is desired to treat a stenosis occurring in a bifurcation in a carotid artery as depicted by the illustrations shown in **FIGS. 25A through 25D**. As shown in the illustration in **FIG. 25A**, let it be assumed that a stenosis is present adjacent the bifurcation **467** and in the external carotid **468** and that it is desired to treat this stenosis in accordance with the apparatus **451** of the present invention in performing the method of the present invention. The proximal occlusion balloon catheter **476** is loaded with the therapeutic balloon catheter **492** slidably mounted over the perfusion balloon catheter **493** and both are slidably mounted in the main lumen **491**. The balloon-on-a-wire catheter **497** is slidably mounted in the lumen. While the patient is being prepared for the procedure, all of the lumens in the catheters of the apparatus are flushed with saline to remove all air from the lumens. They are then connected to the control console **571** in the manner hereinbefore described and as shown in **FIG. 21**. An incision **626** (see **FIG. 21A**) is made in the femoral artery in the left leg of the patient and a guiding catheter (not shown) similar to the type utilized in angioplasty is introduced through the femoral artery **459**. This guiding catheter is advanced until it is near the aorta arch **461**. Thereafter, the first or proximal occlusion balloon catheter **476** has its distal extremity **479** introduced into the guiding catheter and advanced in the guiding catheter. It is advanced so that its distal extremity **479** enters the common carotid and is near the bifurcation **467**. The balloon **481** is inflated by operating the control handle **577** associated with the proximal occlusion balloon **481** as shown in **FIG. 25A** to create the desired pressure within and to inflate the elastic balloon **481** so that it occludes the common carotid just proximal of the stenosis **624**. As soon as this occurs, the roller pump **601** is turned on by operating the on/off switch **603** to create a negative pressure on the distal side of the balloon **481** to cause blood to flow in a reverse direction as shown by arrows **627** to thereby change the directional flow of blood from the internal and external carotids away from the brain rather than to the brain. The blood travels into the aspiration lumen **501** as indicated by the arrows **627** and into the tube **551** through fittings **552** and **597** and tube **596** to the roller pump **603**. The blood after passing through the roller pump **603** passes through a blood filter **606** and then passes into the tube **611** and the fitting **612** and connected to the fitting **589** of the perfusion catheter **493**. Alternatively, the fitting **612** can be which is connected to another fitting **631** mounted on a tube **632** introduced into the venous side of the circulatory system of the patient's body, as for example into the vein in the right leg of the patient **452** as shown in **FIG. 21**. Any debris or emboli in the aspirated blood being pumped will be filtered out by the blood filter **606**.

[0162] As soon as or during the time this retrograde circulation of blood is established through the roller pump **601**, the perfusion balloon catheter **493** extending proximally from the fitting **547** is advanced into the internal carotid **469** past the stenosis **621** at the bifurcation **467**. If necessary, a guide wire can be utilized which can be introduced through the perfusion lumen **512** to aide in advancing the perfusion balloon catheter **493** into the internal carotid **469**. Any emboli or debris dislodged from the stenosis **621** by crossing the same either by the guide wire or by the distal extremity of the catheter **493** will be picked up by the retrograde flow of blood which is being aspirated through the proximal occlusion balloon catheter **476** to thereby prevent any emboli or debris from entering the brain of the patient. The elastic perfusion balloon **509** is then inflated as shown in **FIG. 25B** using the appropriate end-

oflater to inflate the balloon to the desired pressure while watching the associated pressure gauge. As soon as occlusion occurs, perfusion of blood can be started as hereinafter described.

[0163] Prior to or after the balloon **509** of perfusion catheter **493** has been inflated, the balloon-on-a-wire catheter **497** extending proximally of the fitting **541** is advanced into the external carotid **469** as shown in **FIG. 25C**. The balloon **534** is then expanded by use of the appropriate endoflater to supply an inflating medium through the fitting **537** to occlude the external carotid **469**. As soon as occlusion has been accomplished in both the external and internal carotids, retrograde flow of blood is terminated by shutting off the roller pump **601**. It should be appreciated that if desired, automatic controls can be provided whereby when a certain pressure is reached in each of the balloons **509** and **534** the roller pump would automatically be shut off to stop retrograde flow. By this procedure, it can be seen that the lesion of stenosis **621** has been bracketed by the balloons **481**, **509** and **534**. Prior to that occurring, retrograde flow of blood is established to prevent any emboli or debris from moving towards the brain.

[0164] As soon as retrograde flow of blood has been terminated, perfusion of blood is started. This can be accomplished by connecting a cannula (not shown) to the fitting **516** of the perfusion catheter **506** and to obtain a supply of blood from the femoral artery in the other leg of the patient. Alternatively, an outside blood supply can be used. Thus fresh blood will be supplied from the femoral artery of the patient directly into the perfusion balloon so that it is discharged distally of the perfusion balloon **509** as shown by the arrows **628** to continue to supply blood to the carotid artery. It has been found that it is unnecessary to a supply perfusion of blood to the external carotid artery because there is sufficient auxiliary circulation in that carotid artery during the time the procedure is taking place.

[0165] In the event there is inadequate pressure on the arterial blood being perfused to overcome the resistance in the lumen **469**, the roller pump **601** can be utilized by merely operating the same in a reverse direction and connecting it between the cannula and the perfusion catheter.

[0166] After the lesion or stenosis **621** has been bracketed as hereinbefore described and a working space **636** formed adjacent the stenosis or lesion **621**, a therapeutic procedure can be employed. By way of example this can consist of advancing the therapeutic balloon catheter **492** over and axially of the perfusion catheter **493** to bring its balloon **524** into registration with the stenosis **621** as shown in **FIG. 25D**. Thereafter, the balloon **524** can be inflated by use of the appropriate endoflater as hereinbefore described to cause the inelastic balloon to be pressurized to a pressure of 10 to 15 atmospheres to compress the stenosis **621**. Prior to or during this procedure it may be desirable to introduce a saline or heparin solution or a radiopaque contrast liquid into the working space **636**. This can be accomplished by introducing this liquid through the injection lumen **502**. If desired, this can be accomplished prior to terminating the aspiration procedure hereinbefore described. Also it should be appreciated that if desired a small endoscope can be inserted through one of the lumens to view the area within the working space. Alternatively, if desired an ultrasonic probe can be utilized to view the area in which the lesion is disposed.

[0167] As hereinbefore described with a previous embodiment, in place of the therapeutic balloon catheter, other types of catheters can be utilized as for example one incorporating an atherectomy device of the type hereinbefore described to facilitate removal of the stenosis. It is readily apparent that during these procedures if it is necessary to supply a saline solution or a heparinized solution into the working space that the working space can also be continued to be aspirated to remove any debris or emboli which occur during the procedure.

[0168] Let it be assumed that the desired therapeutic actions have been undertaken and that the stenosis **621** has been reduced and substantially eliminated so that there is adequate flow through the internal carotid. If it can be seen that there also is a stenosis in the external carotid, the balloon-on-a-wire catheter **497** and the perfusion catheter **493** can be withdrawn and moved so that they enter the opposite carotid to permit therapeutic treatment of a stenosis occurring in the other carotid.

[0169] When all the desired therapeutic procedures have been accomplished, the supply of saline or contrast solution can be terminated and the therapeutic balloon **524** deflated. The balloon **534** of the balloon-on-a-wire catheter can be deflated as well as the perfusion balloon **509**. Perfusion of blood through the perfusion catheter can be terminated. The perfusion balloon catheter **493** and the balloon-on-a-wire catheter **497** can be retracted into the main multi-lumen tubular member **477** of the proximal occlusion balloon catheter after which the perfusion balloon catheter can be withdrawn carrying with it the other catheters disposed therein. Thereafter, the guiding catheter can be removed and a suture applied to the incision made to gain access to the femoral artery.

[0170] It is readily apparent that similar procedures can be carried out with respect to other vessels in the body, such as saphenous vein grafts in the heart, and particularly with respect to vessels in the brain where it is difficult if not impossible to employ surgical procedures as for example with respect to the basilar arteries in which bifurcations appear.

[0171] As also herein before explained, the catheter apparatus of the present invention can be utilized for deploying stents. Where that is desirable the apparatus of the present invention, perfusion can be accomplished during employment of the stent.

[0172] From the foregoing it can be seen that an apparatus and method has been provided for treating occluded vessels and particularly for treating carotid arteries. The apparatus and method of the present invention is particularly advantageous for the carotid arteries because it permits access to portions of the carotid arteries which are not accessible by surgery.

[0173] The catheter apparatus assembly and method of the present invention are also particularly useful for treating other occluded vessels but particularly the carotid arteries because it makes possible the removal of plaque without endangering the patient. An operating or working space is provided while shunting blood around the working space so that there is continued blood flow in the vessel to support the functions which are normally supported by the vessel. As also pointed out above, the apparatus and method of the

present invention are particularly useful in connection with vessels having bifurcations therein and in which the stenosis occurs at or near the bifurcation. From the foregoing it can be seen with the apparatus and method of the present invention, retrograde flow of blood is accomplished during deployment of the device to prevent undesired travel of emboli. Occlusion of the vessels is provided to obtain a working space by bracketing the working space with balloons while at the same time maintaining perfusion of blood making it possible to utilize a substantial period of time for undertaking therapeutic procedures with respect to the bracketed stenosis.

[0174] In connection with the present apparatus and method for treating occluded vessels, it has been found that it is possible to utilize the apparatus and method without perfusion and other procedures involving the carotid arteries and saphenous vein grafts for periods of time extending over five minutes and greater which has made it possible to simplify the apparatus and the method utilized in conjunction therewith.

[0175] With respect to an apparatus or assembly which does not require the use of perfusion, a main catheter **651** utilized as a part of the apparatus is shown in **FIGS. 26, 27, 28** and **29** consists of a flexible elongate tubular member **652** formed of a suitable material such as plastic of the type hereinbefore described and which has proximal and distal extremities **653** and **654**. The tubular flexible elongate tubular member **652** can be of various sizes as for example for a saphenous vein graft catheter it can be 8 to 9.5 French in balloon profile with a length ranging from 80 cm to 120 cm. The flexible elongate tubular member **652** can be formed of a suitable material such as PEBAX, Nylon, Hytrel, polyurethane or polyethylene. A flexible braid **656** (see **FIGS. 27, 28** and **29**) formed of a suitable material such as stainless steel is embedded within the wall of the flexible elongate tubular member **652** as shown and extends from the proximal extremity **653** to the distal extremity **654**. The braid **656** can be formed of a suitable stainless steel such as a wire or ribbon having a thickness of 0.001". The braid **656** provides additional torquability and also inhibits the kinking of the flexible elongate tubular member **652** when it must extend over a tight radius. The flexible elongate tubular member **652** is provided with a large central lumen **657** having a suitable diameter such as 0.065 or greater" extending from the proximal extremity to the distal extremity.

[0176] If it is desired to provide a flexible elongate member **652** which has a greater flexibility at the distal extremity, a different material can be used in the distal extremity **654**. For example, the distalmost 5-15 centimeters can be formed of a material such as PEBAX having a Shore D hardness of 35-50 with the remainder of the flexible elongate member **652** having a Shore D hardness of 65-75.

[0177] A supplemental flexible elongate tubular member **661** is provided which has incorporated therein a balloon inflation lumen **662**. The supplemental flexible elongate tubular member **661** can be of a suitable size as for example an I.D. of 0.014" and an O.D. of 0.018" and formed of a suitable material such as a polyimide. The supplemental flexible elongate tubular member has a length which is almost as long as the flexible elongate tubular member **652** and overlies the outside wall of the flexible elongate tubular member **652** and extends from the proximal extremity to near the distal extremity as shown in **FIGS. 26 and 29**. A tube **663** of a suitable material such as Pebax extends over the length of the polyimide tubing **661** and is secured to the flexible elongate tubular member **652** by a shrink tube **666** extending from the proximal extremity **653** to the distal extremity **654**, after which the shrink tube **663** is subjected to heat. The shrink tube **666** is then subjected to a hot melt process of a temperature around 350° F. for a period of time until the Pebax tube **663** melts, after which the shrink tubing **666** can be stripped off so that there remains a relatively uniform mass formed of Pebax that surrounds the braid **657** and the polyimide tube **661** which forms the supplemental flexible elongate tubular member **661**. The polyimide tube which forms the supplemental flexible elongate tubular member **661** thus provides an inflation lumen **667** extending from the proximal extremity and to the distal extremity and opens through an opening **668** into the interior of an occlusion balloon **669** which is bonded to and coaxially mounted on the distal extremity of the flexible elongate member **652** in the manner shown in **FIG. 29**. The polyimide tubing is provided to give the balloon inflation lumen shaft **361** greater strength than that which is provided by the Pebax itself.

[0178] As can be seen from **FIG. 29**, the supplemental flexible elongate tubular member **661** is terminated short of the distalmost extremity of the flexible elongate tubular member **652** by approximately 1 cm. The occlusion balloon **669** is formed of various compliant or non-compliant materials. Suitable compliant materials include elastomers such as C-Flex latex, silicones and polyurethanes. Suitable non-compliant materials would be polyethylene, PET and Nylon. A composite material can also be used such as a combination of PET and an elastomer. The occlusion balloon **669** should have a strength so that it can readily accommodate any pressure of one atmosphere and as high as four atmospheres, or approximately 60 psi. The occlusion balloon **669** is cylindrical and is provided with proximal and distal extremities **671** and **672** which are secured by a suitable medical grade adhesive. Alternatively, fuse bonding may be used. Thus a seal **673** formed of this adhesive bonds the proximal extremity **671** of the occlusion balloon **669** over the outer surface of the distal extremity of the flexible elongate tubular member **652** and the supplemental flexible elongate tubular member **661**. Similarly, a seal **674** bonds the distal extremity **672** to the distal extremity of the flexible elongate tubular member **652** to provide an air-tight space within the balloon accessible through the opening **668**. A soft cylindrical tip **676** formed of suitable material such as Pebax is bonded to the distal extremity of the flexible elongate tubular member **652** and is provided with a rounded surface **677** which extends forwardly and has a passage **678** therein in communication with the lumen **657** and the flexible elongate tubular member **652**. A cylindrical radiopaque marker **681** formed of a suitable material such as platinum, platinum-iridium or gold is mounted on the distal extremity of the flexible elongate tubular member **652** in a position so it is substantially equidistant of the ends of the occlusion balloon **669**.

[0179] A main adapter or fitting **686** formed of a suitable material such as plastic is mounted on the proximal extremity **653** of the flexible elongate tubular member **652**. It is provided with a first Luer fitting **687** which provides a balloon inflation port **688** in communication with the balloon inflation lumen **662**. It is also provided with another

Luer fitting **689** which is provided with an aspiration port **691** in communication with the main central lumen **657**. The main adapter **686** is also provided with a Tuohy-Borst fitting **692** which is in communication with the central lumen **657**. The Tuohy-Borst fitting **692** is adapted to receive therapeutic devices, as for example a balloon-on-a-wire device as hereinafter described and is adapted to form a liquid-tight seal therewith by an o-ring **693**.

[**0180**] A balloon-on-a-wire device **701** incorporating the present invention is shown in **FIGS. 30 and 31**. The device **701** consists of a guide wire **702** formed of a suitable material such as stainless steel and having a suitable diameter as for example ranging from 0.010" to 0.032" but preferably a diameter ranging from 0.014" to 0.018". It is preferable that the guide wire **702** be formed of a nickel titanium alloy typically called Nitinol which has the advantage that it is more flexible and has greater kink resistance characteristics than another suitable material such as stainless steel.

[**0181**] It has a suitable length as for example 150 cm. The guide wire **702** is provided with proximal and distal extremities **703** and **704** and is provided with a central lumen **706** extending from the proximal extremity to the distal extremity. The lumen can be of a suitable size as for example 0.010" I.D. for an 0.014" O.D. guide wire.

[**0182**] An occlusion balloon **711** is coaxially mounted on the distal extremity **704** of the guide wire **702**. The occlusion balloon **711** is preferably formed of the same material as the occlusion balloon **669** on the main catheter **651**. The occlusion balloon **711** has proximal and distal extremities **712** and **713**. A tube **716** formed of a suitable material such as a polyimide is disposed within the occlusion balloon **711** and has a bore **717** extending therethrough which is sized so that it is slightly larger than the outside diameter of the guide wire **702** so that its proximal extremity can be slipped over the distal extremity **704** of the guide wire **702** and then bonded thereto by suitable means such as an adhesive **718**. A plurality of circumferentially spaced apart radially extending inflation holes **719** are provided in the proximal extremity of the tube **716** and are in alignment with similarly spaced holes **721** provided in the distal extremity **704** of the guide wire **702** so that they are in communication with the central lumen **706** of the guide wire **702**. The inflation holes **719** as shown are in communication with the interior of the occlusion balloon **711** so that fluid passing from the passage **706** can be utilized for inflating the occlusion balloon **711**.

[**0183**] A solid core wire **723** formed of a suitable material such as stainless steel is provided with a proximal tapered extremity **724**. The core wire **723** is sized so it is adapted to fit within the lumen **706** of the guide wire **702** and is secured therein by suitable means such as an adhesive **726** or alternatively a weld. The core wire **723** has a tapered portion **723***a* which commences at the proximal extremity **724** and which is tapered so that the cross-sectional diameter progressively decreases to the distal extremity of the occlusion balloon **711**. The core wire **723** is also provided with additional portions **723***b* and **723***c* which can be of substantially constant diameter as for example 0.003". The portion **723** is folded over with respect to the portion **723***b* so that the portions **723***b* and **723***c* lie in a plane to facilitate shaping of the distal extremity of the guide wire **702** during use of the same. The core wire **723** is provided with a distal extremity **727** in which a bend **728** is formed between the two portions **723***b* and **723***c*. The bend **728** is secured within a hemispherical solder bump or protrusion **729** which is carried by the distal extremity of a coil **731** formed of a suitable radiopaque material such as platinum or a platinum alloy. The platinum coil **731** can have a suitable outside diameter as for example 0.014" corresponding to the diameter of the guide wire **702** and can have a suitable length ranging from 1 to 3 cm. The proximal extremity of the coil **731** is secured to the distal extremity of the polyimide tube **716** by suitable means such as an adhesive **732** which can be the same adhesive or a different adhesive **733** utilized for securing the distal extremity **713** of the balloon to the polyimide tube **716** to form a fluid-tight seal between the distal extremity of the occlusion balloon **711** and the distal extremity of the polyimide **716**. From this construction it can be seen that the portions **723***b* and **723***c* of the core wire **723** in addition to serving as a shaping ribbon are also utilized as a safety ribbon to ensure that the tip **728** and the spring **731** cannot be separated from the guide wire **702**. The proximal extremity **712** of the balloon **711** is also secured to the proximal extremity of the polyimide tube **716** and also to the distal extremity **704** of the guide wire **702** to form a fluid-tight seal with respect to the occlusion balloon **711** so that the occlusion balloon **711** can be inflated and deflated through the inflation holes **719** and **721**.

[**0184**] Alternative constructions for the distal extremity of the core wire **723** are shown in **FIGS. 33 and 34**. In **FIG. 23** it can be seen that the portions **723***b* and **723***c* have been twisted to in effect provide a twisted pair serving as a safety ribbon and as a shaping ribbon. In the embodiment shown in **FIG. 34**, the core wire **736** is provided with a tapered portion **736***a* which is the same as the tapered portions of **723***a* hereinbefore described. However, the core wire **736** has been provided with a distal portion **736***b* which has been flattened to a suitable thickness as for example a width of 0.006" and a thickness of 0.003" and then twisted to form a helix as shown in which the distal extremity is embedded within the solder **729**. Such a helix **736** can serve as a safety ribbon and also can be shaped to some extent.

[**0185**] A removable inflation fitting **741** or valve attachment **741** is mounted on the proximal extremity of the guide wire **702** and forms a part of the balloon-on-a-wire device **701**. The fitting or attachment **741** is formed of a suitable material such as a polycarbonate and is provided with a central bore **742**. The attachment or fitting is slid externally over the proximal extremity **703** of the guide wire **702**. Means is provided for forming a fluid-tight seal between the proximal extremity **703** of the guide wire **702** and a body **743** of the fitting **741** and consists of an o-ring **746** (see **FIG. 35**) seated in a well **747**. A thumb screw **748** is threadedly mounted on the body **743** and is provided with an inwardly extending circular protrusion **749** that is adapted to engage the o-ring **746** and to compress the same to form a fluid-tight seal when the protrusion **749** is moved inwardly toward the o-ring **746** as the thumb screw **748** is rotated in a clockwise direction. The o-ring **746** decompresses or springs back when released upon rotation of the thumb screw **748** in a counterclockwise direction so that the fitting **741** can be removed from the distal extremity **703** of the guide wire **702**. The body **742** also includes a Luer fitting **751** which provides an inflation port **752** that is in communication with the bore **742** in the body **743** and which is also in commu-

nication with the open proximal extremity of the guide wire **702** and the lumen **706** therein.

[**0186**] Means is provided for plugging the bore **706** when the removable attachment or fitting **741** is removed and consists of a plug mandrel **756** formed of a suitable material such as 0.014" stainless steel solid rod. It is necessary that this rod have a diameter which is greater than the diameter of the lumen **706** and the guide wire **702**. The plug mandrel **756** is provided with a progressive portion **756***a* that tapers down from as, for example from 0.014" to a suitable diameter as for example 0.008" to a cylindrical portion **756***b*.

[**0187**] Means is provided for forming a fluid-tight seal between the plug mandrel **756** which forms a plug mandrel and the body **743** of the attachment or fitting **741** and consists of an o-ring **766** providing suitable sealing means seated within a well **762** provided in the body **743**. A thumb screw **763** threadedly engages the body **743** and is provided with a cylindrical protrusion **764** which engages the o-ring and compresses it to form a fluid-tight seal with respect to the plug mandrel **756** by rotation in a clockwise direction of the thumb screw **763**. The plug mandrel **756** can be released by a counterclockwise rotation of the thumb screw **763** permitting decompression of the o-ring **761**.

[**0188**] An irrigation catheter **766** incorporating the present invention is shown in **FIG. 36** and consists of a flexible elongate tube **767** formed of a suitable material such as polyethylene, PEBAX, Hytrel or Teflon having a suitable size as for example an outside diameter of 0.066" and an inside diameter of 0.058" and having a length of approximately 150 cm. A lumen **768** is provided therein and extends from the proximal extremity to the distal extremity and is in communication with an adapter **769** provided on the proximal extremity of the tube **767**. The adapter **769** is provided with a body **770** formed of a suitable material such as plastic and is provided with a bore **771** extending therethrough. The adapter **769** is provided with a side arm **772** which carries a conventional Luer-type connection and provides an irrigation port **773** in communication with the bore **771**. A thumb screw **774** threadedly mounted on the body **770** carries a cylindrical protrusion **776** adapted to compress an o-ring **777** carried by the body **770** into engagement with a therapeutic catheter of the type hereinafter described. A radiopaque tip marker **778** of a suitable type, as for example one formed as a platinum-iridium band **778** is provided on the distal extremity of the flexible elongate element **767** to facilitate positioning of the irrigation catheter as hereinafter described.

[**0189**] Operation of the apparatus shown in **FIGS. 26 through 36** in performing the method of the present invention for treating occluded vessels may now be briefly described as follows utilizing the cartoons which are shown in FIGS. **37-43**. Let it be assumed that it is desired to treat a vessel **781** in the human body as for example a saphenous vein graft having at least a partial occlusion or stenosis **782** which is formed by plaque in the vessel. The main catheter **651** is introduced into the body through a conventional procedure such as for example by making an incision into the femoral artery in a leg of the patient.

[**0190**] Thereafter the main catheter **651** can be introduced into the femoral artery by use of a large conventional guiding catheter because the main catheter **651** is of a relatively large size, as for example 8 to 9.5 French. In order to eliminate the need for such a large guiding catheter, a smaller conventional guiding catheter **786** of the type shown in **FIG. 37** can be utilized which can be introduced through the main catheter **651**. Utilizing such a catheter, the main catheter **651** can be inserted independently through a conventional sheath (not shown) in the femoral artery and thereafter the guiding catheter **786** is introduced through the main catheter **651** so that its distal extremity **789** is in the vessel. Alternatively, the guiding catheter **786** can be deployed into the main catheter **651** and the guiding catheter **786** introduced at the same time into the femoral artery.

[**0191**] The guiding catheter **786** is conventional and thus will not be described in detail. It consists of a flexible elongate tubular member **787** (see **FIG. 37**) formed of a suitable material such as plastic having proximal and distal extremities **788** and **789**. The distal extremity **789** is provided with a preformed bend as shown. An adapter **792** is mounted on the proximal extremity **788** and consists of a body **793** in the form a wye in which the central leg **794** is provided with a flow passage (not shown) therein in communication with the central lumen (not shown) extending from the proximal extremity **788** to the distal extremity **789** of the flexible elongate tubular member **787**. The body **793** is provided with a side leg **796** which also is in communication with a lumen (not shown) extending from the proximal extremity **788** to the distal extremity **789**. A knob **797** carrying an o-ring (not shown) secures the adapter **792** to the proximal extremity **788** with a fluid-tight seal. Another knob **798** is provided which is carried by the central leg **794** of the body **793** and is provided with an o-ring (not shown) which can be moved to close the flow passage in the central leg **794**, or alternatively it can be opened to receive a guide wire which can be utilized for advancing the guide catheter **786** if that be necessary and then forming a fluid-tight seal with respect to the guide wire.

[**0192**] Assuming that the guiding catheter **786** has been inserted into the main catheter **651** before insertion of the main catheter **651** into the femoral artery, both catheters can be inserted in unison while advancing the distal extremity of the guide catheter **786** so that it precedes the distal extremity of the main catheter **651** and serves to guide the main catheter **651** into the vessel of interest, as for example the vessel **781** having the stenosis **782** therein. The main catheter **651** is then advanced so that its distal extremity is at the proximal side of the stenosis **782**. By way of example, the main catheter **651** can be advanced through the aortic arch of the heart and thence into a saphenous vein graft so that the occlusion balloon **669** on its distal extremity is positioned proximal of the stenosis **782**. As soon as this has been accomplished, the guiding catheter **786** can be removed.

[**0193**] As soon as the distal extremity of the main catheter **651** has been deployed so that it is just proximal of the stenosis **782** to be treated, an assembly shown in **FIG. 38** is introduced into the main catheter **651**. This assembly can be provided by preloading the irrigation catheter **766** onto the therapeutic catheter **801** by inserting the distal tip of the therapeutic catheter **801** through the fitting **769** of the irrigation catheter **766** and advancing the therapeutic catheter **801** until its therapeutic balloon **809** exits from the irrigation catheter **766**. The balloon-on-a-wire catheter **701** also is preloaded by removing the valve attachment **746** and then inserting the proximal end **703** into the guide wire lumen at the distal tip of the therapeutic catheter **801** and

then advanced proximally until the proximal end protrudes out of the proximal end of the therapeutic catheter. The valve attachment **741** is then reattached to the proximal end **703**. The preassembled irrigation catheter **766**, the therapeutic catheter **801** and the balloon-on-a-wire catheter **701** are then introduced in unison as an assembly into the main catheter **651**. The balloon-on-a-wire device **701** is then advanced until the distal extremity is near the distal extremity of the main catheter **651** but before the distal extremity has been advanced through the stenosis **782**.

[**0194**] Let it be assumed that it is now desired to inflate the occlusion balloon **669** carried by the main catheter **651**. This can be accomplished in a suitable manner such as with an inflation-deflation device represented schematically by a syringe **802** secured to the fitting **687** (see **FIG. 38**) and supplying a balloon inflation fluid through the balloon inflation lumen **662** to inflate the occlusion balloon **669** to an occlusion pressure ranging from 1 to 3.9 atmospheres and preferably approximately one to two atmospheres to engage the side wall forming the vessel **781** to occlude the vessel **781** and to prevent further blood flow through the vessel and to thereby provide a working space **803** distal of the occlusion balloon **669**. As soon as the occlusion balloon **669** has been inflated, the balloon-on-a-wire device **701** can be advanced across the lesion or stenosis **782** until the deflated occlusion balloon **711** carried thereby is distal of the stenosis **782**. It is safe to cross the stenosis **782** because the flow of blood through the stenosis **782** has been occluded by the occlusion balloon **669**. Thus if any of the plaque forming the stenosis is dislodged by the occlusion balloon **711** on the balloon-on-a-wire device **701** as the occlusion balloon **711** is crossing the stenosis **782**, the plaque particles or emboli **804** will not be carried off by blood. The positive pressure of blood in secondary collaterals or vasculature will prevent emboli from traveling downstream into the secondary vasculature. If desired, aspiration can be supplied to the working space **803** encompassing the stenosis **782** by placing a suitable vacuum connected to the fitting **689** of the main catheter.

[**0195**] The occlusion balloon **711** can then be readily inflated by use of a syringe **805** secured to the fitting **751** of the removable valve fitting or attachment **741** of the balloon-on-a-wire device **701** proximal of the fitting **686** and accessible outside the body of the patient. The occlusion balloon **711** is inflated (see **FIG. 39**) to at least approximately one to two atmospheres to bracket the stenosis and to determine the size of the working space **803** to provide a chamber. It should be appreciated that the size of this working space or chamber **803** can be adjusted by changing the position of the occlusion balloon **711** in the vessel **781**. If desired, this can be accomplished while the occlusion balloon **711** is inflated.

[**0196**] Now let it be assumed that the occlusion balloon **711** has been inflated with the appropriate working space **803** and that it is desired to introduce a therapeutic balloon catheter **801** into the working space **803** to treat the stenosis **782**. If the therapeutic catheter **801** is not in the main catheter **651** as hereinbefore described, this can be readily accomplished in the present invention by inserting a plug mandrel **756** into the open end of the lumen **706** of the guide wire **702**. After the plug mandrel **756** has been inserted, the syringe **805** can be removed after which the thumb screws **748** and **763** can be loosened to permit the o-rings therein to become decompressed and to release the guide wire **702** and the plug mandrel **756** to permit the fitting or valve attachment **741** to be slipped off to provide a proximal end on the guide wire **702** which is free of obstructions. During removal of the valve attachment or fitting **741**, the occlusion balloon **711** remains inflated and continues to be disposed distally of the stenosis **782**. The occlusion balloon **669** also remains inflated because the syringe **802** remains attached to the fitting **686** and is disposed proximal of the stenosis **782**.

[**0197**] The conventional therapeutic catheter **801** then can be delivered over the guide wire **702** if it is not already present. The therapeutic catheter **801** is provided with a flexible elongate tubular member **806** having proximal and distal extremities **807** and **808** with a central flow passage (not shown) extending between the same. A therapeutic balloon **809** on its distal extremity is adapted to be inflated to therapeutic pressures ranging from 4-20 atmospheres through a balloon inflation lumen (not shown) carried by the flexible elongate tubular member **806** through an adapter **811** mounted on the proximal extremity **807**. The therapeutic balloon **809** can be considered to be means for performing work carried by the distal extremity **808** of the flexible elongate tubular member **806**. The adapter **811** can be removable of the type hereinbefore described or alternatively can be permanently attached thereto. Assuming that it is a removable adapter, the removable adapter **811** is provided with knobs **812** and **813** carrying o-rings (not shown) adapted to establish fluid-tight seals with the flexible elongate member **806** and the plug mandrel **756**, respectively. It is also provided with an inflation port **816** similar to those hereinbefore described which is in communication with the inflation lumen (not shown) provided in the flexible elongate tubular member **806** for inflating the therapeutic balloon **809**.

[**0198**] After the balloon catheter **801** has been positioned by the use of radiopaque markers (not shown) conventionally employed in such devices, the therapeutic balloon **809** is disposed so that it is in general alignment with the stenosis **782** as shown in **FIG. 39**. The therapeutic balloon **809** is then inflated in a conventional manner to perform work by use of an inflation-deflation device schematically represented by the syringe **817** attached to the inflation port **816** to the desired pressure to compress the plaque forming the stenosis **782** as shown in **FIG. 40** to increase the size of the opening through the stenosis **782** in the vessel **781**.

[**0199**] Let it be assumed that during the compression of the plaque forming the stenosis **782**, additional emboli **804** are formed as shown in **FIG. 41** by pieces of plaque becoming dislodged from the plaque **782** within the vessel **781**. Let it also be assumed that it is desired to remove these emboli before deflation of the occlusion balloons **669** and **711** disposed proximally and distally of the stenosis **782**. To accomplish this, the therapeutic balloon **809** is deflated by use of the syringe **817**. As soon as this has been accomplished, a saline solution can be introduced through the irrigation catheter **766** by connecting a tube **819** carrying the saline solution from a suitable source as for example a free or pressurized saline bag (not shown) and delivered through the irrigation port or side arm **772** where it is carried through the large central lumen of the irrigation catheter **766** so that the saline solution is discharged into the working space **803** disposed between the occlusion balloons **711** and **669** as shown in **FIG. 41**. At the same time suitable aspiration means is connected to the aspiration port **689** of the adapter

686 and as shown can consist of a hand operated bulb **821** which has a one way check valve **822** therein connected to the fitting **689**.

[**0200**] The bulb **821** is provided with another one-way check valve **823** which is connected to a flexible collection bag **824**. The bulb **821** makes it possible to generate a vacuum corresponding approximately to 3-30" of mercury. Thus, by compressing the bulb **821** by hand, it is possible to create suction within the chamber or space **803** formed in the vessel between the occlusion balloons **669** and **711** each time the bulb **821** is compressed and released. Alternatively, the aspiration can be accomplished by use of a syringe in place of the bulb **821** and the collection bag **824**. Saline liquid supplied through the irrigation catheter **766** carrying the emboli **818** is aspirated through the central lumen **657** of the main catheter **651**. The aspirated liquid in each cycle of operation created by pressing the bulb **821** is delivered to the collection bag **824**. With such a procedure it has been found that it is possible to aspirate emboli as large as 600 μm. Such removal can be assured by observing when clear liquid exits outside the body from the aspiration port **691**. A chamber having a length ranging from 3 cm to 15 cm can be totally cleared of emboli within a short period of time ranging from 5 to 30 seconds. Alternatively, irrigation can be accomplished by removing the therapeutic catheter **801** after deflating the therapeutic balloon **809**. The irrigation catheter can be advanced over the balloon-on-a-wire device **701** until the distal tip is just proximal of the occlusion balloon **711** as shown in **FIG. 42** to provide a greater flow of saline and faster aspiration.

[**0201**] After all of the emboli **804** have been removed, introduction of saline through the tube **819** is halted. It should be appreciated that the ports for irrigation and aspiration can be reversed in function if desired. Thereafter, the occlusion balloon **711** is deflated by removing the plug **756** and utilizing a syringe **805**, after which the occlusion balloon **669** is deflated permitting blood flow to be reestablished in the vessel **781**. Alternatively, the occlusion balloon **669** can be first deflated and aspiration commenced at that time, permitting emboli trapped distally of the occlusion balloon **669** by blood flowing from the proximal side of the occlusion balloon **669** to be aspirated through the central lumen **657**. In order to prevent excessive expansion of the vessel **781** being treated, the pressure of the irrigation liquid is typically maintained under 30 psi. This pressure preferably should be below the occlusion balloon pressure.

[**0202**] If it is desired to deliver a stent to the site of the stenosis formed by the plaque **782**, this can be readily accomplished during the same procedure. Typically it is desirable to permit the blood to flow normally for a period of several minutes after which the occlusion balloon **669** can be reinflated by the syringe **805** and the occlusion balloon **711** can be reinflated by inserting the removable valve attachment **741** if it has been removed of the balloon-on-a-wire device **701** and utilizing the syringe **803** to reinflate the occlusion balloon **711**. The plug mandrel **756** can be inserted to keep the occlusion balloon **711** inflated after which the valve attachment **741** can be removed.

[**0203**] A conventional stent delivery catheter **826** carrying a stent **827** on its flexible shaft **828** is introduced over the balloon-on-a-wire device **701** and delivered to the site of the dilated stenosis **782** (see **FIG. 43**). The stent **827** can be of the self-expanding type or of the type which can be expanded by a balloon (not shown) carried by the catheter **826** by connecting a syringe **829** to an adapter **830** of the type hereinbefore described of the stent delivery catheter **826**. After the stent **827** has been deployed in the dilated stenosis **782**, the stent delivery catheter **826** can be removed after which the occlusion balloon **711** can be deflated followed by deflation of the proximal balloon **661** in the manner hereinbefore described. Also it should be appreciated that if desired in connection with the deployment of the stent delivery catheter **826** before it is removed but after deflation of its balloon (not shown), it may be desirable to again flush the working space or chamber **803** between the occlusion balloons **669** and **711** of emboli which may be dislodged during the delivery and deployment of the stent. The irrigation catheter **766** can be deployed in the same manner as hereinbefore described with a saline irrigation solution supplied to the working space **803** in the manner hereinbefore described and liquid aspirated therefrom by the use of the bulb **821** in the manner hereinbefore described.

[**0204**] Heretofore the apparatus of the present invention has been utilized for performing a procedure on a saphenous vein graft where there are no branches to be dealt with. An apparatus incorporating the present invention also can be useful in connection with vessels in a human being having branches therein, as for example the carotids. For this purpose, a main catheter **831** (see **FIG. 44**) is provided which is very similar to the main catheter **651** with the exception that the adapter **832** provided on the proximal extremity is provided with catheter ports **833** and **834** which are in communication with the large central lumen **657** extending the length of the main catheter. The catheter ports **833** and **834** have a construction similar to the exchange catheter and therapeutic catheter port **692** hereinbefore described in connection with the main catheter **651**. These two catheter ports **833** and **834** are necessary because in a carotid procedure, two balloon-on-a-wire devices are utilized. The main catheter should be larger, as for example as large as 12 French, to provide a larger central lumen to accommodate the two balloon-on-a-wire devices.

[**0205**] One of the balloon-on-a-wire devices can be substantially identical to the balloon-on-a-wire device **701** described. The other balloon-on-a-wire device **835** as shown in **FIG. 45** differs from the device **701** shown in **FIG. 30** in that in place of the removable valve attachment **741** there is provided a fixed adapter **836** which consists of a body **837** provided with diametrically extending wings **838** to facilitate grasping of the adapter **836**. The body **837** is provided with a bore **839** which is in communication with the lumen **706** in the guide wire **702**. The adapter is provided with a Luer-type fitting **840** to provide a balloon inflation port.

[**0206**] Operation and use of the apparatus of the present invention in performing a procedure in a carotid artery is shown in the cartoons in FIGS. **46-50**. Let it be assumed that it is desired to perform a procedure with the apparatus of the present invention on a carotid artery in a patient, as for example common carotid **841** which branches into an external carotid **842** and an internal carotid **843** and that there is a narrowing or a stenosis **844** in the internal carotid **843** near the bifurcation into the external and internal carotids **842** and **843**. The main catheter **831** can be introduced in the manner hereinbefore described with respect to a saphenous vein graft. For example it can be introduced through the

femoral artery in the leg and then advanced into the aortic arch up into the common carotid **841** until the occlusion balloon **669** carried thereby is near the bifurcation as shown in **FIG. 46**. The occlusion balloon **669** is then inflated to at least one atmosphere as shown in **FIG. 47** to form a seal to occlude the common carotid **841** and to temporarily stop the flow of blood to the face and brain of the patient through the common carotid **841** and to provide a working space **845** distal of the occlusion balloon **669**. The inflation is accomplished by suitable means as for example a syringe **846** secured to the balloon inflation fitting **687**. Thereafter, a balloon-on-a-wire device **831** of the type shown in **FIG. 45** is introduced through the catheter port **833** and advanced through the central lumen **657** of the main catheter **831** after which the distal extremity is guided into the external carotid **842** so it is disposed beyond the bifurcation. The occlusion balloon **711** carried by the distal extremity is then inflated by suitable means such as a syringe **847** secured to the attachment **836** to occlude the external carotid. As hereinbefore pointed out, the balloon **711** is an occlusion balloon that typically is inflated to a suitable occlusion pressure as for example one to two atmospheres.

[**0207**] Another balloon-on-a-wire device such as the balloon-on-a-wire device **701** is then introduced through the catheter port **834** and advanced through the central passage or lumen **657** until it exits from the main catheter **831** after which it is guided into the internal carotid **843** past the stenosis **844** so that the occlusion balloon **711** is distal of the stenosis **844**. The occlusion balloon **711** is then inflated as shown by the dotted lines in **FIG. 47** by the use of a syringe **848** secured to the inflation port carried by the removable valve attachment **741**. Thus, the limits of the working space or chamber **845** are defined by the occlusion balloons **669** and **711**. As soon as the balloon **711** has been inflated, the balloon inflation lumen can be plugged in the manner hereinbefore described by the use of a plug mandrel **756** (see **FIG. 48**). It should be appreciated even though the guide wire **702** and the occlusion balloon **711** carried thereby may dislodge particles from the plaque forming the stenosis **844**, the dislodged particles will not travel to the brain because the common carotid supplying blood to the internal carotid **843** has been occluded by the occlusion balloon **669**.

[**0208**] The removable valve attachment **741** can then be removed in the manner hereinbefore described so that the proximal extremity of the guide wire **702** is free of obstructions as shown in **FIG. 68**. Thereafter the irrigation catheter **766** can be introduced over the guide wire **702** and thence into the port **834** until its distal extremity extends beyond the distal extremity of the main catheter **831**. A therapeutic balloon catheter **801** of the same type as hereinbefore described can then be introduced through the irrigation catheter **766**. It should be appreciated that if desired, the therapeutic balloon catheter can be preloaded into the irrigation catheter **766** and the irrigation catheter **766** and the therapeutic balloon catheter **801** can be introduced in unison. Assuming that the irrigation catheter **766** has been introduced first, the therapeutic balloon catheter **801** is introduced through the irrigation catheter **766** until it extends beyond the distal extremity of the irrigation catheter **766** and is moved into the working space **845** until the therapeutic balloon **809** carried by the distal extremity thereof is in registration with the stenosis **844**. The therapeutic balloon **809** is then inflated as shown in **FIG. 48** by the use of an inflation/deflation device **851** represented schematically by a syringe to a suitable therapeutic pressure to compress the plaque forming the stenosis **844** to dilate the stenosis to increase the size of the flow passage through the stenosis **844**. The therapeutic balloon **809** can then be deflated. In the event emboli **804** are created as hereinbefore described by the passage of the therapeutic balloon **809** through the stenosis, these emboli **804** can be removed as shown in **FIG. 49** by introducing a saline solution through the tube **819** and into the irrigation port **773** of the irrigation catheter **766** to cause a saline solution to be discharged into the space formed between the two occlusion balloons **711** and **669**. To achieve a more effective aspiration, the distal tip of the irrigation catheter **766** can be moved through the stenosis **844** to just proximal of the occlusion balloon **711**. Aspirate is removed through the aspiration port **689** through the use of the bulb **821** and the collection bag **824** to remove the saline solution carrying with it the emboli **804** which may have been created and deposit the same in the collection bag **824**. This irrigation and aspiration can be carried on for a suitable period of time as for example 5 to 30 seconds after which the occlusion balloons **711** in both of the branches **842** and **843** can be deflated and the devices **701** and **835** can be removed along with the catheter **801** carrying the therapeutic balloon **809**. Similarly, the occlusion balloon **669** can be deflated to permit blood to flow into the common carotid **841** and the external and internal carotids **842** and **843**. Alternatively, the sequence of deflation of the balloons can be carried out in the manner hereinbefore described in connection with a vessel without a bifurcation.

[**0209**] In the event it is desired to deliver a stent into the dilated stenosis **844**, this can be accomplished by reinflating the occlusion balloon **669** and then reinflating the occlusion balloons **711** in both of the branches after which a balloon stent delivery catheter **826** of the type hereinbefore described can be delivered over the guide wire **702** in the same manner as the therapeutic balloon catheter **766** and delivered into the desired location and then deployed in the dilated stenosis **844**. After the stent **827** has been deposited and the balloon of the stent delivery catheter **826** is deflated, the irrigation and aspiration procedures hereinbefore described can be repeated to remove any emboli within the space formed between the occlusion balloons **711** and **669**. The stent delivery catheter **826** can be removed. After a suitable period of irrigation and aspiration, as for example 5 to 30 seconds, the occlusion balloon **711** can be deflated after which the occlusion balloon **669** can be deflated and the balloon-on-a-wire devices **701** and **835** removed along with the main catheter **652**.

[**0210**] From the foregoing it can be seen that there has been provided a new and improved apparatus and a method for utilization of the same which makes it possible to carry out such stenosis opening procedures without the perfusion of blood. Complete stenosis procedures can be carried out in a period of time which is less than six minutes for each complete procedure. Even though blood flow is occluded during this period of time, this period of time is much less than the period of time, as for example 30 minutes, required for a conventional endoatherectomy. Thus, the procedures of the present invention can be carried out without endangering the patient, as for example the brain or the heart of the patient.

[**0211**] The desire to eliminate the use of a large guiding catheter for use with the main catheter **651** was hereinbefore

discussed. Also, it was hereinbefore disclosed that the main catheter **651** can be inserted independently through a conventional sheath (not shown) in the femoral artery and thereafter a smaller conventional guiding catheter **786** is introduced through the main catheter so that its distal extremity **789** is in the vessel. In other procedures it may be desirable to carry this concept still further, i.e., eliminating the need for a large guiding catheter and also the need for a smaller guiding catheter to be advanced through the main catheter. To do this, it may be desirable to provide a distal extremity on the main catheter **651** which is shaped in a predetermined manner. For example, in the main catheter **651***a* shown in **FIG. 26A** there is provided in the distal extremity a conventional Judkins left shape and in the main catheter **651***b* shown in **FIG. 26B** there is provided in the distal extremity a conventional Judkins right shape. Other than the shaping of the distal extremities as hereinbefore described, the main catheters **651***a* and **651***b* are constructed in a manner very similar to the catheter **651** and are provided with occlusion balloons **669** as shown.

[**0212**] Since the main catheters **651***a* and **651***b* are relatively flexible, they can be inserted into the femoral artery and have their distal extremities guided into the desired locations with the catheter being selected for the appropriate bend to reach the desired location. With the main catheter having such capabilities, it is possible in connection with the present invention to advance the main catheter **651** into the desired location by the use of a balloon-on-a-wire device of the type hereinbefore described, or alternatively over a conventional guide wire. This makes it possible to eliminate the use of a guiding catheter and therefore substantially simplify the procedures of the present invention and reduce the costs of such procedures.

[**0213**] In connection with the irrigation catheter **766** hereinbefore described in **FIG. 36**, it should be appreciated as shown in **FIGS. 36A and 36B** that irrigation catheters **766***a* and **766***b* can be provided which have soft distal extremities to provide additional flexibility and trackability and thereby reduce trauma in vessels through which they are introduced. Thus in the irrigation catheter **766***a* shown in **FIG. 36A**, the main portion of the flexible elongate tubular member **767** which can be considered to be the shaft can have a greater stiffness than the distal portion **767***a* of the distal extremity. This can be readily accomplished by utilizing a plastic such as Pebax and Hytrel of various desired durometers. For example, the main shaft **767** can have a durometer ranging from 80-100 whereas the distal portion **767***a* can have a durometer ranging from 50-70. The cylindrical tip **767***c* with a rounded forward edge as shown is provided with a still lower durometer as for example 35-55 durometer. Thus it can be seen that there has been provided an irrigation catheter which has a very soft tip and which has a distal portion in the distal extremity which is very flexible to permit tracking and to reduce trauma.

[**0214**] In the irrigation catheter **766***b* shown in **FIG. 36**, the shaft **767** can have a durometer ranging from 80-100 whereas the portion **767***a* can have a durometer ranging from 60-70 and which has a portion **767***b* formed of the same durometer material that is inclined inwardly and distally to reduce the size of the opening for the passage or lumen **768** as shown. The tip **767** which can be formed of a low durometer as for example 35-55 durometer is mounted on the distal extremity **767***b*. In order to enhance the flow of irrigation fluid from the lumen **768** a plurality of holes **857** is circumferentially distributed around the portion **767***a* to augment the flow of irrigation fluid other than through the passage **856**. The use of the embodiments **766***a* and **766***b* of the irrigation catheter is very similar to that hereinbefore described with the irrigation catheter **766** shown in **FIG. 36**. It should be appreciated that if differing stiffnesses are desired for the main catheters **651** and **831**, the same concepts as disclosed for the irrigation catheter **766** can be utilized by selecting materials having desired durometers for various portions of the catheters.

[**0215**] Another embodiment of the balloon-on-a-wire device is shown in **FIGS. 51 and 52** in which the balloon-on-a wire device **901** is in many respects very similar to the balloon-on-a-wire device **701** shown in **FIG. 30** as hereinbefore described. The balloon-on-a-wire device **901** consists of a flexible elongate member in the form of a guide wire **702** having proximal and distal extremities **703** and **704** with a lumen **706** extending therethrough. A removable valve attachment or fitting **741** is provided on the proximal extremity **907**. A plug mandrel **756** is carried by the removable valve attachment **741** for use in plugging the bore **706** when necessary. An elastomeric balloon **906** is provided on the distal extremity **704** and is provided with proximal and distal extremities **907** and **908**. The balloon **906** has a suitable length as for example 10 millimeters and a suitable diameter when collapsed or deflated of 1 mm. In order that the balloon **906** assume a generally rectangular shape as viewed in cross-section as shown in **FIG. 51** with generally right angle corners, the balloon **906** is provided with spaced-apart cylindrical regions **906***a* and **906***b* of greater thickness than an intermediate portion **906***c*. For example, portions **906***a* and **906***b* can have a thickness of 0.006" to 0.010" and portion **906***c* of 0.003" wall thickness. Such a balloon when inflated will have a squareness as illustrated by the dotted lines in **FIG. 51**. This squareness of the balloon corners helps to assure that emboli will not become entrapped between the balloon and the vessel wall and thereby will not roll by the balloon as it is moved in the vessel.

[**0216**] An elongate slot **911** is ground into the distal extremity of the guide wire **702** to a suitable depth which is in excess of one half of the diameter of the guide wire **702**. The slot **911** is in communication with the lumen **706** and opens into the interior of the balloon **906**. A tapered core wire **913** is mounted in the distal extremity **704** of the guide wire **702**. The core wire **913** is provided with a portion **913***a* which has a progressive decrease in diameter extending from the proximal extremity to a portion **913***b* which is generally of a uniform diameter of a suitable size, as for example 0.003" and is formed into a bend **916** and extends proximally along the slot **916** and proximally thereof where it is secured to the guide wire **702** by suitable means such as an adhesive **918**. A coil spring **921** formed of a suitable material such as stainless steel or platinum extends over the slot **911** and proximally and distally of the slot **911** and is secured thereto by suitable means as solder **922**. Positioned in this manner, the coil **921** generally circumscribes the inner circumference of the balloon **906** and serves to protect the balloon **906** from any sharp edges as for example sharp edges formed by the slot **911** in the coil wire **702**. A tip coil **926** formed of a suitable radiopaque material such as a platinum or a platinum alloy is mounted over the distal extremity of the guide wire **702** and secured thereto by suitable means such as solder **927**. The distal extremity of

the tip coil **926** which may have a suitable length, as for example 3 mm, is bonded to the core wire **913***b* by a solder **928** which encloses the bend **916** and provides a rounded forwardly protruding surface **929**. The distal extremity **908** of the balloon **906** is secured to the coils **921** and **926** by an adhesive **931**. Similarly, the proximal extremity **907** of the balloon **906** is secured to the guide wire **702** and the portion **913***b* by an adhesive **932**.

[**0217**] The balloon-on-a-wire device **901** can be utilized in the same manner as the balloon-on-a-wire device **701** hereinbefore described. It is believed that the balloon-on-a-wire device **901** has several desirable features. For example the balloon **906** is protected from any sharp edges by the coil spring **921**. The slot **911**, in addition to providing a means for inflating the balloon, also serves to provide a progressive weakening of the distal extremity of the guide wire **702** to impart additional flexibility to the distal extremity of the device.

[**0218**] By utilizing a balloon-on-a-wire constructions herein disclosed, it is possible to reduce the overall size of the apparatus for the procedures. In view of the fact that guide wires having a size of 0.014" to 0.018" are utilized in the present invention, many conventional therapeutic balloon devices can be utilized by advancing the same over such size guide wires. By the provision of removable valve attachments for the balloon-on-a-wire devices, it is possible to use such devices for providing the one or more balloons necessary for a procedure while at the same time making it possible to utilize such devices as guide wires after removing the removable valve attachments on the proximal extremities. This makes it possible to utilize conventional stent delivery catheters, ultrasound catheters and the like by advancing them over the already in place guide wires.

[**0219**] It should be appreciated that it may be possible to eliminate the use of the occlusion balloons **711** which are distal of the proximal balloon carried by the main catheter and distal of the stenosis, since blood flow is occluded during the time that the occlusion balloon **669** is inflated.

[**0220**] Another embodiment of a catheter apparatus incorporating the present invention for treating occluded vessels is shown in **FIGS. 53 and 54**. As shown therein, the catheter apparatus **951** consists of a flexible elongate member **952** similar to those hereinbefore described which is provided with proximal and distal extremities **953** and **954**. A conventional adapter **956** is mounted on the proximal extremity and is provided with a Tuohy-Borst fitting **957** which is in communication with a large central lumen **958** extending from the proximal extremity **953** to the distal extremity **954**. An aspiration fitting **961** is provided on the adapter **956** as well as an irrigation fitting **962**, both of which are in communication with the central lumen **958**. However, it should be appreciated that if desired separate lumens can be provided in the flexible elongate member **952** for both of the fittings **961** and **962**.

[**0221**] Self-expanding sealing means **966** is mounted on the distal extremity **954**. This self-expanding sealing means **966** can take any suitable form. For example, as shown it can consist of a braided structure **967** formed of a suitable shape memory material such as a nickel titanium alloy that will attempt to expand to a predetermined shape memory. Other than shape memory materials, other materials such as stainless steel, titanium or other materials can be utilized in the braid **967** as long as they have the capability of expanding when the self-expanding seal means is released. Also it should be appreciated that the self-expanding seal means **966** can be comprised of an absorbent material which when it absorbs saline or blood expands to form a seal. Such seals can be readily accomplished because it is only necessary to form a seal of approximately one atmosphere to prevent small particles from moving downstream.

[**0222**] In order to prevent abrasion of a vessel, it is desirable to cover the braided structure **967** with a covering **968** of a suitable material such as a polymer which extends over the braided structure **967** and which moves with the braided structure **967** as it expands and contracts. The polymer can be of a suitable material such as silicone, C-flex, polyethylene or PET which would form a good sealing engagement with the wall of the artery.

[**0223**] Means is provided for compressing the self-expanding sealing means **966** so that the apparatus can be inserted into the vessel **781** and consists of an elongate sleeve **1071** having proximal and distal extremities **1072** and **1073** and a bore **1074** extending from the proximal extremity **1072** to the distal extremity **1073**. A collar **1076** is mounted on the proximal extremity **1072** of the sleeve **1071** and is positioned near the adapter **956**. The collar **1076** serves as means for retracting the sleeve as shown in **FIG. 54** to uncover the self-expanding sealing means **966** after the catheter has been deployed to permit the self-expanding sealing means **966** to expand and form a seal with the arterial vessel adjacent the stenosis to be treated.

[**0224**] Another embodiment of a catheter apparatus for treating occluded vessels incorporating the present invention is shown in **FIGS. 55 and 56**. As shown therein, the apparatus **1081** consists of a guiding catheter **1082** having proximal and distal extremities **1083** and **1084**. As shown, the distal extremity **1083** is provided with a preformed bend of a conventional type. A conventional attachment **1086** is mounted on the proximal extremity **1083**. Self-expanding seal means **1091** is mounted on the distal extremity **1084** and is of the type hereinbefore described in connection with the embodiments shown in **FIGS. 53 and 54**. A sleeve **1096** similar to the sleeve **1071** of the previous embodiment is provided in the present embodiment for encasing the self-expanding seal means **1091** and for releasing the same after it has been disposed in an appropriate position within a vessel adjacent the occlusion to be treated. Thus a sleeve **1096** is provided having proximal and distal extremities **1097** and **1098** and having a bore **1099** extending from the proximal extremity to the distal extremity which is sized so that it can receive the guide catheter **1082**. It is provided with a collar **1101** on its proximal extremity which is adapted to be disposed outside the patient and which is adapted to be grasped by the physician for pulling the sleeve **1096** proximally to uncover the self-expanding seal **1091** after the apparatus has been deployed to permit the self-expansion of the sealing means **1091** to form a seal with the vessel wall is shown in **FIG. 56**.

[**0225**] In accordance with the hereinbefore described descriptions, it is apparent that the apparatus can be readily deployed and serve the same function as the main catheter. To accomplish this, the assembly **1081** can be introduced into the femoral artery and the distal extremity advanced into the desired location in the arterial vessel. After it has

been properly positioned, the physician can retract the sleeve **1096** to permit the self-expanding seal means **1091** to expand and to form a seal with the wall of the arterial vessel to occlude the arterial vessel and interrupt the flow of blood in the vessel to provide a working space distal of the occlusion formed. This prevents small particles which may thereafter be dislodged from moving downstream. Since a central lumen is available, the therapeutic procedures hereinbefore described can be employed with the catheter apparatus shown in **FIGS. 53, 54, 55** and **56**.

[**0226**] Thus it can be seen that it has been possible to substantially reduce the complexity of the apparatus utilized in such procedures. This reduces the cost of the apparatus used therein as well as reducing the time required for performing such procedures making the procedures less costly.

[**0227**] It will be appreciated that certain variations of the present invention may suggest themselves to those skilled in the art. The foregoing detailed description is to be clearly understood as given by way of illustration, the spirit and scope of this invention being limited solely by the appended claims.

What is claimed is:

1. An apparatus for occlusion of a vessel, the apparatus comprising:

a flexible elongate member having a distal extremity; and

an expandable and contractible metallic braided structure having first and second ends, both the first and second ends being mounted on the distal extremity, the braided structure having a covering thereon, the covering being movable with the braided structure during expansion thereof and being capable of substantial sealing engagement with a wall of the vessel to interrupt fluid flow there through.

2. The apparatus of claim 1, wherein the braided structure is self-expanding.

3. The apparatus of claim 2, further comprising an elongate sleeve, the sleeve being slidable over the braided structure for contraction thereof.

4. The apparatus of claim 1, wherein the elongate member has a lumen extending there through.

5. The apparatus of claim 1, wherein the covering is movable with the braided structure during expansion and contraction thereof.

6. An apparatus for temporary occlusion of a blood vessel, the apparatus comprising:

a flexible elongate member having a distal extremity;

a structure having first and second ends mounted on the distal extremity and having contracted and expanded configurations; and

a covering on the structure, the covering being movable with the structure during expansion thereof and being capable of substantial sealing engagement with a wall of the blood vessel to interrupt blood flow there through, the structure and the covering being non-inflatable between the contracted and expanded configurations.

7. The apparatus of claim 6, wherein the structure comprises a braid.

8. The apparatus of claim 7, wherein the braid comprises a metal.

9. The apparatus of claim 6, wherein the structure is self-expanding.

10. The apparatus of claim 9, further comprising an elongate sleeve, the sleeve being slidably disposed over the structure for contraction thereof.

11. The apparatus of claim 6, wherein the covering is moveable with the structure during expansion and contraction thereof.

12. The apparatus of claim 6, wherein the covering expands and contracts with the structure.

13. An apparatus for occlusion of a vessel, the apparatus comprising:

a flexible elongate member having a distal extremity;

a braided structure having first and second ends, both the first and second ends being mounted about the distal extremity, the structure being movable between a contracted shape and an expanded shape; and

a covering being located on and movable with the braided structure such that, when the braided structure is in the expanded shape, the covering substantially seals against a wall of the vessel to interrupt fluid flow there through, the braided structure and the covering being non-inflatable between the contracted and expanded shapes.

14. The apparatus of claim 13, wherein the braided structure has a shape memory.

15. The apparatus of claim 14, wherein the shape memory is the expanded shape.

16. The apparatus of claim 15, further comprising an elongate sleeve, the sleeve being slidably disposed over the braided structure for encasing the braided structure in the contracted shape.

17. The apparatus of claim 13, wherein the braided structure comprises a material selected from the group consisting of shape memory metal, nickel titanium alloy, stainless steel and titanium.

18. The apparatus of claim 13, wherein the covering comprises a material selected from the group consisting of silicone, C-Flex, polyethylene and PET.

19. An apparatus for occlusion of a blood vessel, the apparatus comprising:

a flexible elongate member having a distal extremity; and

means for sealing having first and second ends, both the first and second ends being mounted on the distal extremity, the means for sealing being capable of self-expansion into sealing engagement with a wall of the blood vessel to interrupt blood flow there through.

20. The apparatus of claim 19, wherein the means for sealing comprises an expandable and contractible braided structure with a covering thereon, the covering being movable with the braided structure during expansion and contraction thereof.

21. The apparatus of claim 19, wherein the means for sealing comprises an absorbent material which, when it absorbs blood, expands to form a seal with a wall of the blood vessel.

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