PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 :		(11) International Publication Number:
A61B 5/00	**A1**	**WO 95/10976**
		(43) International Publication Date: 27 April 1995 (27.04.95)

(21) International Application Number: PCT/US94/11661

(22) International Filing Date: 21 October 1994 (21.10.94)

(30) Priority Data:

08/141,280	22 October 1993 (22.10.93)	US
08/204,632	2 March 1994 (02.03.94)	US

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

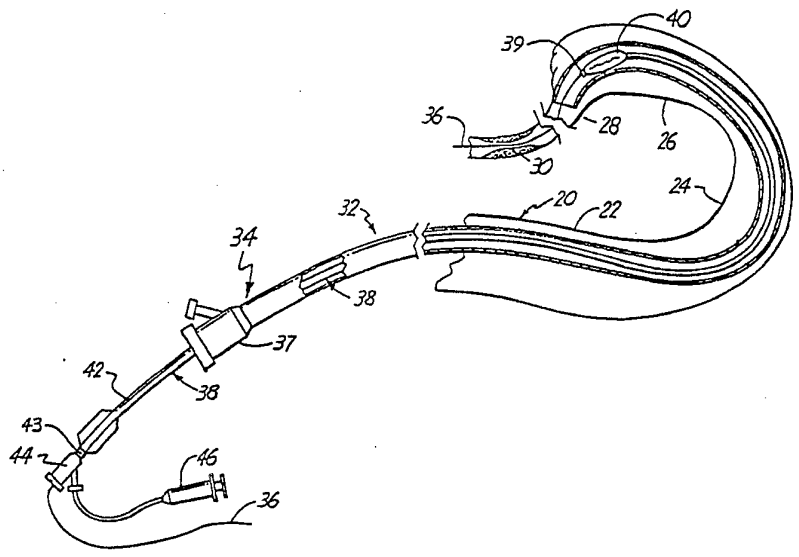
Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One SciMed Place, Maple Grove, MN 55311-1566 (US).

(72) Inventors: ELLIS, Louis; 3004 Armour Terrace, St. Anthony, MN 55418 (US). HASTINGS, Roger, N.; 1204 Circle High Drive, Burnsville, MN 55306 (US). HUMPHREY, John, W.; 17934 Liv Lane, Eden Prairie, MN 55346 (US).

(74) Agents: SEAGER, Glenn, M. et al.; Nawrocki, Rooney & Sivertson, P.A., Suite 401, Broadway Place East, 3433 Broadway Street Northeast, Minneapolis, MN 55413-3009 (US).

(54) Title: SHAFT MOVEMENT CONTROL APPARATUS AND METHOD



(57) Abstract

The present invention is a device and method for controlling longitudinal movement of a tube (34) relative to a shaft (36) slidably disposed within the tube, especially in the catheterization of a patient. An operative segment of the shaft cooperates with an ancillary tool to create a coupling force field between the shaft (36) and the tool (34). The tube can be moved over the shaft while the coupling force field operates through the tube to restrict movement of the shaft. In preferred embodiment, the shaft is a guide wire (36) and the tube is a catheter (34) with a lumen for slidably receiving the guide wire (36), while the coupling force is created magnetically.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	**GB**	United Kingdom	**MR**	Mauritania
AU	Australia	**GE**	Georgia	**MW**	Malawi
BB	Barbados	**GN**	Guinea	**NE**	Niger
BE	Belgium	**GR**	Greece	**NL**	Netherlands
BF	Burkina Faso	**HU**	Hungary	**NO**	Norway
BG	Bulgaria	**IE**	Ireland	**NZ**	New Zealand
BJ	Benin	**IT**	Italy	**PL**	Poland
BR	Brazil	**JP**	Japan	**PT**	Portugal
BY	Belarus	**KE**	Kenya	**RO**	Romania
CA	Canada	**KG**	Kyrgystan	**RU**	Russian Federation
CF	Central African Republic	**KP**	Democratic People's Republic of Korea	**SD**	Sudan
CG	Congo			**SE**	Sweden
CH	Switzerland	**KR**	Republic of Korea	**SI**	Slovenia
CI	Côte d'Ivoire	**KZ**	Kazakhstan	**SK**	Slovakia
CM	Cameroon	**LI**	Liechtenstein	**SN**	Senegal
CN	China	**LK**	Sri Lanka	**TD**	Chad
CS	Czechoslovakia	**LU**	Luxembourg	**TG**	Togo
CZ	Czech Republic	**LV**	Latvia	**TJ**	Tajikistan
DE	Germany	**MC**	Monaco	**TT**	Trinidad and Tobago
DK	Denmark	**MD**	Republic of Moldova	**UA**	Ukraine
ES	Spain	**MG**	Madagascar	**US**	United States of America
FI	Finland	**ML**	Mali	**UZ**	Uzbekistan
FR	France	**MN**	Mongolia	**VN**	Viet Nam
GA	Gabon				

SHAFT MOVEMENT CONTROL APPARATUS AND METHOD

Background of the Invention

The present invention relates to the field of medical devices, particularly catheters. In particular, the present invention relates to a method and device for controlling movement of an elongate shaft for use in the catheterization of a patient, where a portion of the shaft is inserted within the patient.

Angioplasty has gained wide acceptance in recent years as an efficient and effective method for treating types of vascular diseases. In particular, angioplasty is widely used for opening stenoses in the coronary arteries, although it is also used for treatment of stenoses in other parts of the vascular system.

The most widely used form of angioplasty makes use of a dilatation catheter which has an inflatable balloon at its distal end. Using fluoroscopy, the physician guides the dilatation catheter through the vascular system until the balloon is positioned across the stenosis. The balloon is then inflated by supplying a fluid under pressure through a inflation lumen to the balloon. The inflation of the balloon causes stretching of the artery and pressing the lesion into the artery wall to re-establish acceptable blood flow through the artery. In some angioplasty procedures, it may be

desirable to use a series of dilatation catheters having different sizes or balloon configurations.

One type of dilatation catheter has a guide lumen provided therein so that a guide wire can be used to establish the path through the stenosis. The dilatation catheter is then advanced over the guide wire until the balloon is positioned across the stenosis. The use of a guide wire enables the catheter to be advanced through the blood vessel relatively quickly, thereby reducing the time required for the procedure.

A "standard" guide wire for use in coronary angioplasty is about 175 cm long while a typical coronary angioplasty catheter is about 150 cm long. When the catheter is in place over the guide wire for use, a portion of the guide wire protrudes proximally from the catheter. The protruding portion enables the guide wire to be manipulated by a physician.

In some instances, it may be desirable to exchange one dilatation catheter (already on the guide wire) for a second dilatation catheter. It is usually preferred that the catheter be removed in a manner which enables the guide wire to remain in place in the blood vessel so that the succeeding catheter may be inserted into the blood vessel, over the guide wire already in place, and guided to the stenosis in the blood vessel. To maintain a guide wire in place while withdrawing the catheter, the

guide wire must be gripped at its proximal end to prevent it from being pulled out of the blood vessel with the catheter. The catheter, however, is longer than the proximal portion of the guide wire which protrudes out the patient. Thus, before the catheter is fully withdrawn, it completely covers the proximally extending portion of the guide wire. As a result, there was no means by which a standard guide wire can be held in place to prevent it from being withdrawn together with the catheter. To withdraw the catheter while leaving the guide wire in place, a guide wire with a longer effective length was required.

One means for addressing this difficulty is to use an exchange wire when performing a catheter exchange. An exchange wire may be used initially or may be exchanged for a standard guide wire already in place in the patient. An exchange wire typically is much longer (e.g., 300 cm) than the typical or standard guide wire. The additional length of the exchange wire results in a proximally protruding portion which is longer than the length of the catheter to be removed. When a catheter is removed, some part of the proximally protruding portion of the exchange wire is always exposed to provide a means by which the exchange wire can be gripped and its position in the blood vessel maintained. The succeeding

catheter is then inserted into the patient over the exchange wire.

It is generally recognized as undesirable to insert, advance and withdraw a series of guide wires during these types of procedures. Repeated guide wire insertions increase the risk of injury to the patient and also increase the time required for the procedure. It also requires exposure of the patient to additional radiation because of the additional fluoroscopy which is required to properly place the successive guide wires across the stenosis. In addition, long exchange wires are cumbersome and difficult to handle while maintaining the guide wire in place across the stenosis.

Techniques to eliminate the need to change guide wires have been proposed. One solution is the use of a guide wire extension which is attached to the proximal end of the guide wire while the guide wire remains in place in the patient. The guide wire extension effectively increases the length of the guide wire to that of an exchange guide wire. While the technique substantially shortens the duration of the procedure because the extension can be attached at the proximal end of the guide wire much faster than an exchange of guide wires can be performed, the extended guide wire is still cumbersome as the physician is required to handle an

extended length of a guide wire outside of the patient during at least a portion of the procedure.

One means for catheter exchange without lengthening the guide wire is by use of a balloon catheter with a guide wire lumen located only adjacent the distal end of the catheter. With this configuration, the guide wire is external to the balloon catheter except adjacent the distal end of the balloon catheter. This catheter arrangement allows the catheter to be withdrawn over the guide wire without requiring the physician to completely release the guide wire until the distal end of the catheter is outside of the patient's body. The guide wire lumen on the catheter is shorter than the length of exposed guide wire, which allows at least some portion of the proximal end of the guide wire to be exposed at all times so that it can be grasped and its position relative to the stenosis can be maintained during removal of the catheter.

Another means for exchanging a catheter without the use of an extended guide wire is to engage the guide wire at a point distally of the catheter and hold it in place relative to the stenosis. This has been done by providing an inflatable guide wire holding balloon which is adapted to be inflated only within a guide catheter. In this arrangement, the dilatation catheter in the patient is withdrawn over the guide wire and inside of

the guide catheter a short distance. The guide wire holding balloon is aligned distally relative to the dilatation catheter and is then inflated, thereby "trapping" the guide wire against an inner wall of the guide catheter (and constraining the guide wire from longitudinal movement relative to the guide catheter). The dilatation catheter is then withdrawn over the guide wire (the proximal end of the guide wire can be released) and a second dilatation catheter is placed on the guide wire and advanced along the guide wire to the point where the guide wire is trapped against the guide catheter wall. The guide wire holding balloon is then deflated and the physician advances the second dilatation catheter along the guide wire to the stenosis to continue the procedure. It also has been disclosed that mechanical means such as a wire snare be used within a guide catheter to secure the guide wire thereto, instead of a balloon.

While arrangements have been proposed to facilitate catheter exchanges in guide wire catheter systems without the need for a long guide wire length, they require a modified catheter (no full-length guide wire lumen) or additional components within the patient (e.g., balloon for trapping guide wire within guide catheter). It is desired to devise an arrangement which allows catheter exchanges over a standard length guide wire using a

catheter having a full-length guide wire lumen. It is also desired to provide a measurement of the distance the guide wire has moved thus determining the situs of the wire.

Summary of the Invention

The present invention is a method and device for controlling movement of a shaft for use in the catheterization of a patient where a distal portion of the shaft is inserted within the patient. The present invention is also useful for facilitating movement of a tube relative to a shaft extending through the tube, where distal portions of both the tube and the shaft are inserted within a patient, as well as measuring movement of the tube and shaft to determine their situs within the patient.

The device of the present invention includes two pieces used in conjunction with each other. The first piece is an operative segment on the shaft. The second piece is an ancillary tool which, when positioned adjacent the operative segment on the shaft, cooperates with the operative segment to create a coupling force field between the operative segment and the tool, thus coupling the tool and the shaft together. The force created between the two pieces is strong enough to maintain the position of the shaft relative to the tool

when the tube is aligned over the operative segment of the shaft. A third piece is used in cooperation with the operative segment to couple therewith in a manner to provide signals indicative of the movement of the shaft.

In one preferred embodiment, the present invention is used to facilitate catheter exchanges in a guide wire catheter system without the need for a long guide wire length. In this preferred embodiment, the shaft is a guide wire, and the tube is a catheter with a lumen for slidably receiving the guide wire. The coupling force field between the operative segment on the guide wire and the tool is created by magnetism and is strong enough to maintain the tool and the guide wire in a coupled relation when the catheter is aligned over the operative segment on the guide wire and the catheter is moved longitudinally relative to the guide wire. The materials used to create the magnetic coupling force may be permanent magnets or magnetically permeable material.

The present invention is ideally suited for facilitating catheter exchanges without the need for a long guide wire length or a modified catheter. When a guide wire catheter system utilizing the present invention is pre-inserted within the vessel of a patient, the original catheter may be exchanged for a second catheter by simply aligning the operative segment on the guide wire with the tool to create the coupling force

field; withdrawing the original catheter proximally past the tool and over the guide wire (which is held stationary relative to the tool) until the catheter is free of the guide wire; aligning the second catheter over the guide wire; and advancing the second catheter past the tool and over the guide wire until the second catheter is properly positioned. A handle, which couples fixedly to the tool and slidably to the catheter assembly, provides for ease of operation. The handle may preferably have an adjustable length. The catheter assembly is stabilized within the tool through the use of a geometrically configured catheter receiving notch.

In another preferred embodiment, a pair of electrical coils are positioned around magnetic nodes on the guide wire magnetic segment to couple therewith for providing signals in the coils which can be used to determine the distance the guide wire has moved, and in what direction.

Brief Description of the Drawings

The invention will be further described with reference to the accompanying drawings where like numbers refer to like parts in several views and wherein:

Figure 1 is a diagrammatic view of an angioplasty catheter system in the vascular system of a patient.

Figure 2 is an enlarged view in side elevation of one embodiment of the present invention which shows guide wire captivation.

Figure 3 is a sectional view of the captivation tool in Figure 2.

Figure 4 is a detail sectional view of an operative segment of a guide wire which is one preferred embodiment of the present invention.

Figure 5 is a view in end elevation showing one preferred embodiment of the present invention.

Figure 6 is a view in side elevation along line 6-6 in Figure 5.

Figure 7 is an enlarged fragmentary detail of portion A in Figure 5 illustrating the placement of a catheter assembly, shown in section, into the tool housing.

Figures 8-13 depict a preferred method of use for the present invention.

Figure 8 shows the catheter and guide wire pre-inserted in a vessel of a patient, with the operative segment on the guide wire disposed within the proximal end of the dilatation catheter.

Figure 9 shows the tool being placed over the operative segment of the guide wire.

Figure 10 shows the dilatation catheter being withdrawn over the guide wire and past the tool.

Figure 11 shows the dilatation catheter external from the patient's body with the tool adjacent the operative segment on the guide wire.

Figure 12 shows the dilatation catheter external to the patient's body with the tool removed from adjacent the guide wire.

Figure 13 shows the guide wire remaining in place in the vessel of the patient with the tool and dilatation catheter removed.

Figure 14 is a detail sectional view of an operative segment of a guide wire which is another preferred embodiment of the present invention.

Figure 15 is a detail sectional view of an operative segment of a guide wire which is another preferred embodiment of the present invention.

Figure 16 is a schematic illustration of a guide wire extension containing an operative segment.

Figure 17 is a schematic illustration of a tool which includes an electromagnet.

Figure 18 is an exploded view of the three major components of the tool of an alternative embodiment.

Figure 19 is an isometric view of the operation of the alternative embodiment of Figure 18.

Figure 20 is a close up view of the catheter receiving notch of the alternative embodiment.

Figure 21 is a longitudinally sectioned view of the proximal end of the guide wire of the preferred embodiment.

Figure 22 is a diagrammatic and schematic view of the guide wire movement measuring embodiment of this invention.

Figure 23 is a graph indicating the form of display provided by the embodiment of Figure 22.

Figure 24 is a diagrammatic view of another feature of the movement measuring embodiment of this invention.

Figure 25 is an isometric view of a tool similar to Figure 18 with an adjustable length handle.

Figure 26 is an isometric view of the magnetic block portion of Figure 18 and of a movable cover for connection to the block.

While the above identified drawing features set forth preferred embodiments, other embodiments of the present invention are also contemplated, as noted in the discussion. This disclosure presents illustrative embodiments of the present invention by way of representation and not limitation. It should be understood that numerous other modifications and embodiments can be devised by those skilled in the art which fall within the scope and spirit of the principles of this invention. It should be noted that the figures

have not been drawn to scale as it has been necessary to enlarge certain portions for clarity.

Detailed Description of the Preferred Embodiments

The present invention is a method and device for controlling movement of an elongated shaft in the catheterization of a patient, where a portion of the shaft is inserted within the patient. More precisely, the present invention is a method and device for controlling the movement of an elongated shaft extending through an elongated tube, wherein a portion of both the tube and shaft are inserted within the patient. In one preferred embodiment, the shaft is a guide wire and the tube is a catheter with a lumen for slidably receiving the guide wire.

A vascular system 20 and an angioplasty catheter system 32 are shown in Figure 1. In an angioplasty procedure, entry into the vascular system 20 is typically through the femoral artery in the thigh (as schematically shown at 21 in Figures 2 and 8). A distal portion of the vascular system 20 includes a descending aorta 22, an aortic arch 24, and an ascending aorta 26. Extending from the ascending aorta 26 is a coronary artery 28, in which a stenosis 30 is formed.

The angioplasty catheter system 32 includes a guide catheter 34, a guide wire 36 extending through the guide

catheter 34, and a dilatation catheter 38 with an inflatable balloon 40 mounted at a distal end 39 of a main tubular shaft 42 of the dilatation catheter 38. The dilatation catheter 38 is designed for use in conjunction with a guide wire, and has a guide wire lumen 45 (Figures 2, 3 and 7) extending along its entire length. The dilatation catheter 38 also has an inflation lumen 47 extending therethrough. The dilatation catheter 38 may be a dual lumen or coaxial lumen structure. In a coaxial arrangement (as shown), the inflation lumen 47 is provided between the outer main shaft 42 and an inner tubular shaft 41 disposed coaxially within the outer shaft 42. The guide wire lumen 45 is thus defined by the interior of the inner tubular shaft 41.

As illustrated in Figure 1, a proximal portion of the guide wire 36 protrudes proximally out of a proximal end 43 of the dilatation catheter 38 and a proximal portion of the dilatation catheter 38 protrudes proximally out of a Y-adaptor 37 connected to a proximal end of the guide catheter 34. An inflation manifold 44 is connected to the proximal end 43 of the dilatation catheter 38 for facilitating inflation of the balloon 40. An inflation device 46 for inflating the balloon 40 is in fluid communication with the balloon 40 via the inflation manifold 44 and the inflation lumen 47.

The basic angioplasty procedure consists of inserting the guide catheter 34 into the vascular system 20 at the femoral artery. The guide catheter 34 is advanced through the vascular system 20 until a distal end of the guide catheter 34 is adjacent the mouth of the coronary artery 28 as shown in Figure 1. Next, the distal end 39 of the dilatation catheter 38 is loaded onto and over a proximal end of the guide wire 36 and advanced over the guide wire 36 until the distal end 39 of the dilatation catheter 38 is adjacent a distal end of the guide wire 36. Then, the assembled combination of the guide wire 36 and the dilatation catheter 38 is inserted into the proximal end of the guide catheter 34 and advanced distally therethrough, retracing the already established path of the guide catheter 34 through the patient's vascular system 20. The guide wire 36 and the dilatation catheter 38 combination typically is advanced distally until adjacent the distal end of the guide catheter 34. The distal tip of the guide wire 36 is then advanced separately and manipulated into the artery tree to and across the stenosed artery. The dilatation catheter 38 is then advanced over the guide wire 36 to position the balloon 40 across the stenosis 30. The balloon 40 is inflated to dilate the stenosis 30 to re-establish acceptable blood flow through the artery.

However, sometimes the dilatation catheter 38 must be exchanged for another dilatation catheter to complete the angioplasty procedure. When exchanging the dilatation catheter 38 for another catheter, it is desirable to hold the guide wire 36 in place across the stenosis 30 during withdrawal of the dilatation catheter 38 (and advancement of the next catheter) to eliminate the need to re-establish the position of the guide wire 36 by retracing the tortuous path to the stenosis 30 after the dilatation catheter 38 is exchanged. Maintaining the guide wire 36 in place after an initial dilatation also provides the physician with a path through the stenosis 30 in case of an abrupt closure of the vessel.

The present invention facilitates holding the guide wire 36 in place across the stenosis 30 without requiring an exchange wire, an extension wire or additional intravascular devices to accomplish the dilatation catheter exchange over the guide wire 36. In one form of the present invention, means are provided proximally of the guide catheter Y-adaptor 37 to cooperate with the guide wire 36 for maintaining the position of the guide wire 36 across the stenosis 30. One preferred embodiment of the present invention, as shown in Figures 2-7, employs a captivation tool 50 which cooperates with an operative segment 52 of the guide wire 36 to create a

coupling force field between the tool 50 and the operative segment 52. The coupling force field is defined by an energy field (such as a magnetic field). The force generated by the field is strong enough to maintain the position of the guide wire 36 relative to the tool 50 when the dilatation catheter 38 is aligned over the operative segment 52 of the guide wire 36, and particularly when the dilatation catheter 38 is moved over the guide wire 36. As shown in Figure 2, the operative segment 52 of the guide wire 36 is located on a proximal portion of the guide wire 36 and is positioned so that the operative segment 52 is located some distance beyond the proximal end of the guide catheter Y-adaptor 37.

As seen in Figure 3, the operative segment 52 of the guide wire 36 includes a plurality of magnetically permeable segments 54 secured on the guide wire 36 at locations along the guide wire 36. (Examples of suitable magnetically permeable materials are Rodar, manufactured by T.N. Wilbur B. Driver Company and available in tube form from Uniform Tubes of Collegeville, PA; Hiperco Alloy 50, manufactured by Carpenter Steel of Reading, PA; Permendur or 2V Permendur, listed as high permeable magnetic materials having large saturation flux densities in the CRC Handbook of Chemistry and Physics, 47th ed.; or any other material with a suitably large residual

induction). In this embodiment, as seen in Figures 3 and 4, the operative segment 52 includes a plurality of magnetically permeable segments 54 secured about a reduced diameter portion 57 of guide wire 36. Non-magnetically permeable segments 53 are disposed between and about each of the magnetically permeable segments 54, respectively. In all embodiments of the operative segment 52 on the guide wire 36, the outside diameter of the operative segment 52 stays essentially the same as the outside diameter of the guide wire 36, and the transitions between magnetically permeable and non-magnetically permeable materials are smooth.

As seen in Figures 5-7, the captivation tool 50 includes a housing member 56. The housing member 56 includes a longitudinal slot 60 defined by a pair of side slot surfaces 62 and 64, and a bottom slot surface 66. The slot 60 provides a space with sufficient size to slidably receive the dilatation catheter 38 and allow the dilatation catheter 38 to longitudinally pass freely through the slot 60, yet still restrict lateral movement of the dilatation catheter 38 between the slot surfaces 62, 64, and 66.

The housing member 56 also includes a plurality of rectangular-shaped magnetic sections 72 (shown in phantom in Figure 5) which have exposed surfaces at bottom slot surface 66. As best seen in Figure 6, the magnetic

sections 72 are provided at longitudinally spaced locations along the housing member 56 corresponding to the spacing of the magnetically permeable sections 54 on the guide wire 36. The magnetically permeable sections 54 on the guide wire 36 and the magnetic sections 72 in the housing member 56 are spaced such that they can be aligned across from each other as shown in Figure 3. Although the material of the bottom slot surface 66 alternates between the housing member 56 and the magnetic sections 72, the bottom slot surface 66 is smooth. The magnetic sections 72 are preferably made from a strong magnetic material with a large cohesive force (such as neodymium boron iron) that can hold a magnetization through a relatively thin section.

The size and spacing of the magnetic sections 72, as well as the size and spacing of the magnetically permeable sections 54 of the operative segment 52 on the guide wire 36, are chosen to maximize the longitudinal attractive force on the guide wire 36 while minimizing the radial attractive force on the guide wire 36. The net force for maintaining the position of the guide wire 36 relative to the tool 50 is governed by the equation:

$$F_{net} = F_L - \mu F_R$$

where

F_{net} is the net force available to maintain the position of the guide wire 36,

F_L is the longitudinal force of attraction between the tool 50 and the operative segment 52 on the guide wire 36,

F_R is the radial force of attraction between the tool 50 and the operative segment 52, and

μ is the friction coefficient between the guide wire 36 and the dilatation catheter 38. Thus, to obtain optimum performance from the device, it is desirable to maximize the force F_L and minimize the force F_R and the friction coefficient μ. The friction coefficient μ may be reduced through the use of lubricous coatings and materials, and the attractive forces F_L and F_R may be optimized through the use of mathematical modeling techniques known in the art. For example, positioning the magnetic sections 72 in the tool 50 such that the polarity of the magnetic sections 72 alternates between magnetic sections 72 reduces the radial attractive force F_R. Such alternation increases the total effective magnetic field, thereby increasing the longitudinal holding force. The total coupling force between the operative segment 52 and the tool 50 is proportional to the number of magnetic sections 72 in the tool 50.

In one preferred embodiment, the guide wire 36 has an outside diameter of 0.018 inches. The operative segment 52 has a length of approximately 10 inches with approximately 50 magnetically permeable sections 54, each

having a length of 0.1 inch, separated by non-magnetically permeable sections 53 with a length of 0.1 inch. A non-operative segment approximately 2 inches long is attached to the proximal end of the operative segment 52. The tool 50 is approximately 4.0 inches long, 1.0 inch high, and 1.0 inch wide, with 20 magnetic sections (magnets) 72 spaced 0.2 inches apart. The magnetic sections 72 are 0.04 inches thick and 0.75 inches high, with a width of 0.75 inches. The height and width of the magnetic sections 72 are determined as a function of the thickness of the magnetic sections 72. The magnetic poles of the magnetic sections 72 are alternated so that like poles of the spaced magnetic alternated so that like poles of the spaced magnetic sections 72 are facing each other. The slot 60 for receiving the dilatation catheter 38 is 0.10 inch wide and 0.10 inch deep. The holes 68 centered under each of the magnetic sections 72 (for gluing magnetic sections 72 in place during assembly) are approximately 0.04 inches in diameter.

The device of the present invention for facilitating a dilatation catheter exchange while maintaining a guide wire in place within a vessel is employed in the following manner. Of course, performing such an exchange requires that the angioplasty catheter system 32 already be in place in the vascular system 20 of the patient as

previously described. As such, the proximal end of the guide wire 36 and the proximal end 43 of the dilatation catheter 38 protrude proximally outside the patient as seen in Figure 8, with the proximal end of the guide wire 36 extending proximally beyond the proximal end 43 of the dilatation catheter 38. Recall that the operative segment 52 of the guide wire 36 (identified schematically by the "xxx's" in Figures 8-13) is located near the proximal portion of the guide wire 36 and is disposed within the proximal end 43 of dilatation catheter 38. To begin the exchange, the physician grasps the proximal end of the guide wire 36 to maintain its distal end in place across the stenosis 30. The physician then places a proximal portion of the dilatation catheter 38 (having the operative segment 52 extending therein) into the slot 60 of the housing member 56 (see Figures 7 and 9) and aligns the operative segment 52 with the tool 50.

The alignment of the operative segment 52 with the tool 50 is relatively simple because the operative segment 52 is longer than the slot 60 in the tool 50, and the distance between the magnetically permeable sections 54 on the guide wire 36 and the corresponding magnetic sections 72 on the tool 50 is relatively small. The result is that when the operative segment 52 is positioned within the slot 60 of the tool 50 only a small amount of movement (less than half the distance between

the magnetic sections 72 on the tool 50) is required to align the magnetically active portions of the operative segment 52 and the tool 50. As the spacing between the magnetic sections 72 becomes smaller, less movement is required to align the tool 50 and the operative segment 50. At the given dimensions, the tool 50 and the operative segment 52 effectively become self-aligning, and simply positioning the operative segment 52 within the slot 60 of the tool 50 ensures proper alignment.

Once the operative segment 52 on the guide wire 36 is properly aligned with the magnetic sections 72 of the captivation tool 50, the guide wire 36 is attracted to the captivation tool 50 by the resultant magnetic field created therebetween (see Figures 2, 3, and 7). This results in the guide wire 36 being pulled (along with the dilatation catheter shafts 41 and 42) against the bottom slot surface 66 of the housing member 56 as seen in Figures 3 and 7. The drawings are exaggerated for clarity in this regard.

Once the guide wire and tool 50 have been so coupled, the physician releases the guide wire 36 proximal to the tool 50 and then grasps the proximal end 43 of the dilatation catheter 38 proximally of the tool 50. The dilatation catheter 38 is pulled proximally over the guide wire 36 and past the tool 50 while holding the tool 50 (and thus the guide wire 36) in a stationary

position relative to the patient (see Figure 10). The physician may choose to hold the tool 50 in his hand, or alternately the physician may place the tool 50 on the table to hold the tool 50 stationary. The longitudinal magnetic attraction between the guide wire 36 and the captivation tool 50 is greater than the friction between the guide wire 36 and the inner catheter shaft 41. Accordingly, the dilatation catheter 38 may be pulled over the guide wire 36 while maintaining the guide wire 36 in the same position relative to the captivation tool 50. This ultimately maintains the guide wire 36 in position across the stenosis 30 during this maneuver, as long as the tool 50 is held generally stationary with respect to the patient.

The catheter 38 is withdrawn until the distal end of the dilatation catheter 38 is exposed outside of the patient's body as seen in Figure 11. As such, a portion of the guide wire 36 will be exposed between the distal end of the catheter 38 and the proximal end of the guide catheter 34, which protrudes outside the patient's body. The physician then grasps this exposed portion of the guide wire 36 distal to the tool 50 and the distal end of the dilatation catheter 38 as at 76. The physician then laterally separates the catheter 38 and the guide wire 36 therein from the tool 50 by overcoming the radial magnetic forces between the guide wire operative segment

52 and the tool 50. The physician then completely withdraws the first balloon catheter 38 proximally off of the guide wire 36. The guide wire 36 has thus been held in a generally stationary position during the entire catheter removal procedure in a very simple and elegant manner, which can be managed by the physician without the need for extra persons to hold or manipulate additional catheter or guide wire components.

Next, while still maintaining the guide wire 36 in place by grasping at 76, a second dilatation catheter is placed on the proximal end of the guide wire 36 and moved distally over the guide wire 36 until the operative segment 52 of the guide wire 36 is positioned within a distal end of the second dilatation catheter (preferably within the second catheter at a point proximal to the balloon thereon). The operative segment 52 of the guide wire 36 and the tool 50 are positioned together (as previously described) until the operative segment 52 is magnetically aligned with the magnetic sections 72 of the captivation tool 50. The physician then releases the guide wire 36 distally of the tool 50 as at 76, grasps the second dilatation catheter, and distally advances the second dilatation catheter over the guide wire 36 longitudinally relative to tool 50 and the guide wire 36 to distally advance the second catheter through the guide catheter 34. During dilatation catheter advancement, the

captivation tool 50 is held stationary relative to the patient to ultimately maintain the distal end of the guide wire 36 in place across the stenosis 30. The second dilatation catheter is advanced distally over the guide wire 36 until the proximal end of the guide wire 36 extends beyond a proximal end of the second dilatation catheter. The physician then grasps the guide wire 36 proximal to the tool 50 and dilatation catheter manifold 44, and separates the second dilatation catheter and the guide wire 36 therein from the tool 50. The second dilatation catheter is then further advanced distally over the guide wire 36 until the balloon of the second dilatation catheter is across the stenosis 30 for dilatation. The dilatation catheter exchange procedure using the captivation tool 50 and operative segment 52 can thus be repeated in this manner as necessary.

During the dilatation catheter removal and insertion procedure, the position of the guide wire 36 is maintained relative to the guide catheter 34, and more importantly, relative to the stenosis 30. The present invention is ideally suited for facilitating catheter exchanges without the need for a long exchange guide wire, a modified catheter, or additional intravascular devices such as a guide wire holding balloon for "trapping" the guide wire against a wall of the guide catheter. The present invention allows catheter

exchanges over a standard length guide wire using a catheter having a full length guide wire lumen. Additionally, the procedure may be performed by a single physician and without the prolonged use of X-ray fluoroscopy used to observe the position of the guide wire, since the guide wire is held stationary by use of the present invention and thus its position need not be continuously observed.

The utility of the present invention is not limited to catheter exchange procedures. The present invention may be used as a "third hand" during a catheterization procedure. Typically during a catheterization procedure, the physician is required to simultaneously manipulate the guide wire 36, the dilatation catheter 38, and the guide catheter 34. The simultaneous manipulation often requires the use of additional medical personnel, which increases the cost and complexity of the procedure. By placing the operative segment 52 adjacent the tool 50 and securing the tool 50 itself in a stationary position, the present invention eliminates the need for the physician (or a second person) to continually hold the guide wire 36 during the procedure. The operative segment 52 provided on the guide wire 36 can be made long enough to allow the use of more than one tool 50 during a catheterization procedure. For example, when the physician is withdrawing the dilatation catheter 38 from

the patient and is required to grasp the guide wire 36 before completely removing the dilatation catheter 38 from the guide wire 36 (e.g., when the physician grasps the guide wire 36 at 76 before completely withdrawing the dilatation catheter 38 of the guide wire 36, as seen in Figures 11 and 12 and as previously described), a second tool 50 may be used in place of the physician actually grasping the guide wire 36.

In alternate embodiments, the operative segment 52 on the guide wire 36 may take a number of forms including those shown in Figures 14, 15 and 21. In Figure 14, each of a plurality of non-magnetically permeable segments 58 are secured about reduced diameter portions 55 of the guide wire 36A. The guide wire 36A is made of a magnetically permeable material, and segments 58 are a non-magnetically permeable material such as plastics or non-magnetic metals. As seen in Figure 15, the operative segment 52 may include an elongate non-magnetically permeable tubular member 51 with a plurality of solid cylindrically-shaped magnetically permeable segments 54A secured within member 51. The tubular member 51 is connected to a reduced diameter portion 59 of the guide wire 36. Another embodiment of the operative segment 52 is a guide wire segment made of a single material which can exist in either a magnetic or non-magnetic state (such as martensite of austenite steel) depending upon

the heat treatment of the material. Alternating sections of the wire are heat treated locally to form alternating magnetic and non-magnetic sections on the guide wire. In each embodiment of the operative segment 52, the magnetically permeable material may be replaced with permanent magnets.

The operative segment 52 may be provided on a short guide wire extension 74 (e.g., about 12 inches long) for a standard guide wire. As shown schematically in Figure 16, this short extension 74 would connect to the proximal end of the standard guide wire 76 in a conventional manner, such as shown, e.g., in U.S. Patents Gambale et al. 4,922,923; Messner et al. 4,875,489; Crittenden et al. 5,035,686; or Palmer et al. 5,117,838. The short extension 74 is selectively attachable to the standard guide wire 76 and can be connected and disconnected multiple times during a single procedure. Use of the short guide wire extension 74 with an operative segment 52 allows the physician to perform a catheter exchange using the present invention even if the catheterization procedure was started using a standard guide wire 76. The use of the short extension 74 in a catheter exchange merely requires the additional acts of attaching the extension 74 to the guide wire 76 and withdrawing the original catheter proximally far enough to cover the operative segment 52 on the short extension 74 before

positioning the dilatation catheter 38 relative to the tool 50 for magnetic coupling of the extended guide wire and the tool 50. Otherwise, the use of such a short guide wire extension 74, either for holding the wire/catheter assembly during the procedure or to facilitate a catheter exchange over a stationary wire, is essentially the same as described herein.

The tool 50 may be adapted to fit over the guide catheter 34 (as in a 2-piece "clam shell" design), may be made in the form of a guide catheter extension, or may be incorporated directly into the guide catheter Y-adaptor 37, for example. Additionally, the tool 50 may be designed such that the magnetic sections 72 in the tool 50 are moved within the housing member 57 and away from the slot 60 in the housing member 56. With this feature, the attraction between the tool 50 and the operative segment 52 on the guide wire 36 is effectively "turned off" when the magnetic sections 72 are moved sufficiently laterally away from the slot 60 in the housing member 56 and the operative segment 52 of the guide wire 36 therein to break the magnetic attraction therebetween.

The three major components of an alternative embodiment of the tool are shown in exploded view 100 in Figure 18. Magnet fixture block 108 receives permanent magnets (not shown) in magnet receiving slots 104 as described above. Preferably, the magnets are placed with

alternating polarity to increase the effective axial holding force and decrease the effective normal force which reduces longitudinal friction. Magnet fixture block 108 is preferably molded of a polycarbonate, with General Electric Lexan HP2X-42046 being the recommended material.

Bottom block 102 is molded of a similar but clear material, such as General Electric Lexan HP2X-111, and engages with magnet fixture block 108, through receiving channel 101. In operation, magnet fixture block 108 is held within receiving channel 101 by the engagement of longitudinal protrusions 116 and 114 of magnetic fixture block 108 within longitudinal channels 115 and 117 of bottom block 102, respectively. Configured catheter receiving notch 118 stabilizes the position of the catheter assembly as discussed in greater detail below.

Operator handle 111 is molded of Lexan HP2X-111 (clear) material. It has a catheter receiving element 112 and a configured engagement latch 110, which is fixedly engaged within receiving notch 103 of bottom block 102 and receiving notch 105 of magnet fixture block 108.

Figure 19 is a isometric composite view of the alternative embodiment of Figure 18 in operation. Catheter receiving element 112 slidably engages y-adapter 113 of catheter assembly 119 as shown. Catheter assembly

119 is stabilized within configured catheter receiving notch 118. The operator conveniently grasps the entire assembly using handle 111.

A cross sectional view of the assembled tool is shown in Figure 20. Inclines 120 and 122 direct catheter assembly 119 into catheter stabilization channel 118, which is configured to hold catheter assembly 119 within the above described magnetic field. Permanent magnet 127 is shown held in place by contact with molded spikes 129a, 129b, and 129c.

An alternative embodiment of the proximal end of guide wire active area 126 is shown in longitudinal sectioned view 21. The inner core 132 of the assembly is preferably a wire of Hyperco 50B, which is an alloy of 48.5% cobalt, 48.5% iron, and 3% vanadium. It is commercially available as explained above and has a diameter of about .011 inch.

Inner core 132 is circumferentially ground to produce a reduced diameter of about .0045 inch for a distance of about .075 inch at areas 136 and 140, which are separated by distance 138, also about .075 inch. Proximal distance 134 is about 10.075 inches, and distance 142 is about .5 inch. The proximal end of a standard spring coil guide (not shown for clarity) is butt welded to distal end 144 of inner core 132.

Inner core 132 is coated with an adhesive, which is preferably Hysol 9412 to fill the ground areas 136 and 140 to an overall depth at the unground areas of about .001 inch. The resulting structure has a uniform outside diameter of about .011 inch, which is covered before curing is completed by hypotubing 128 of 304 stainless steel. The wall thickness of hypotubing 128 is chosen to provide a standard finished outside diameter, such as .018 or .014 inch. Hypotubing 128 extends distally of distal end 144 of inner core 132 by at least .5 inch along area 146 to provide strain relief to the butt weld at distal end 144. Proximal end 130 is ground to a smooth hemispherical shape.

Another way to selectively apply a magnetic field between the operative segment of the guide wire and the tool is to form the magnet on the tool as an electromagnet. As illustrated diagrammatically in Figure 17, a guide wire (or guide wire extension) 86 includes an operative segment 52 (as previously described) and the guide wire 86 is, in use, inserted within a lumen of a catheter 88. A tool 90 in this embodiment includes an electromagnet 92 which has selectively activated sections therein aligned to cooperate within the operative segment 52, and which is connected to a current source 94 through an on/off switch 96. Operation of the switch 96 thus controls the application of current to the electromagnet

92 and the creation of a magnetic field thereby. The selectively activated sections within the tool 90 may be energized by wall current (AC) or rectified wall current (DC), either of which can be turned off by switch 96 to break the holding force between the tool 90 and the guide wire 86.

Figure 22 shows another embodiment of this invention by which the movement and direction of the guide wire can be measured, thus giving the operator information of the situs of the guide wire within the body of the patient. A segment 212 of a guide wire 210 is shown in longitudinal cross-section as including a length of magnetic material 214, which provides a series of magnetic nodes in segment 212. Material 214 may be the same Hyperco 50B as described above in the discussion of Figure 20, for example.

In Figure 22 a pair of electrical coils 222 and 224 are shown placed around segment 212 in spaced relation. Preferably, coils 222 and 224 are spaced to provide a 90 degree phase shift in relation to the nodes of material 214. Coil 222 is connected to an electrical circuit 226 and coil 224 is connected to an electrical circuit 228. In Figure 22, arm 203 has been selected to be a male member to cooperate with female member 201 to provide the desired variability in the length of handle 111. A generator of approximately a 500 kilohertz signal is

connected to coils 222 and 224. As shown in Figure 22 the generator would be a portion of electrical circuits 226 and 228, though preferably a single generator would be used.

As guide wire 210 is moved longitudinally, magnetic material 214 will couple with coils 222 and 224 to create signals therein. The use of such a friction device 210 will thus provide for selection of a number of lengths of handle 111 limited only by the lengths of male member 203 and female member 201. These signals are presented to circuits 226 and 228, where they are amplified, filtered and preferably off-set to zero; the processed signals may then be displayed in the manner shown in Figure 23. If preferred, button 210 could instead actuate a detent member (not shown) through the aperture in tube 201, which member would cooperate with one of a plurality of detent apertures (not shown) in arm 203 to thus provide a finite number of present lengths of handle 111. Alternatively, the processed signals from circuits 226 and 228 may be presented to another electrical circuit 230. It has been found in practice that a desired number of preset lengths would be three, with the distance between block 102 and the Yconnector such as 113 in Figure 19 selectable at 1.5, 2.75 and 4.00 inches. Circuit 230, which preferably is a digital circuit, takes

the signals from circuits 226 and 228 and displays them in digital form.

Figure 23 shows a graph of guide wire position versus inductance. A first sine wave 252 is based on the signals induced in coil 222 and a second sine wave 254, shown in dotted lines, is based on the signals induced in coil 224. Because of the 90 degree phase shift the viewer of the display of Figure 23 can see in which longitudinal direction segment 212 is being moved, and because the distance between nodes of magnetic material 214 is known, the viewer of the display of Figure 23 can also see how far segment 212 and thus guide wire 210 have bee moved longitudinally.

Figure 24 depicts another preferred embodiment of the measuring apparatus of this invention. A catheter 310 is shown connected to one end of a Y-adapter 312. Another catheter 315 is slidably mounted on its distal side through Y-adapter 312 and into catheter 310. Catheter 315 passes through the center of a coil fixture 320 to where the proximal end of catheter 315 is connected to a catheter manifold 314. A guide wire 316 is shown slidably mounted through manifold 314 and Y-adapter 312 as well as through both of catheters 310 and 315. Catheter 316 has a magnetic segment at its proximal end (not shown) the same or similar to segment 212 of Figure 22, which will magnetically couple with electrical

coils (not shown) mounted in fixture 320 in the manner described above with regard to Figures 22 and 23.

The coils in fixture 320 are connected to electrical cables 322 and 324, which cables are adapted to be connected to electrical circuitry such as circuits 226 and 228 of Figure 22 for the purpose of providing a display such as that of Figure 23 in the manner described above. In Figure 24 fixture 320 is shown as being longitudinally moveable. When moved to be connected to manifold 314, fixture 320 will be fixed relative to guide wire 316 and the display will be of the movement of wire 316 along its longitudinal path. When moved to be connected to Y-adapter 312, fixture 320 will be fixed relative to catheter 315 and the resultant display will be of the longitudinal movement of catheter 315 with its internal guide wire 316.

Another preferred embodiment of the tool of Figures 18 and 19 is shown in Figure 25. Here there is again depicted a basic block 102 which carries magnet block 108 having receiving notch 118, as well as a catheter receiving element or holder 112. Block 102 and holder 112 are again shown as joined by a handle indicated generally as 111. In this embodiment of Figure 25, handle 111 is of an adjustable or variable length and comprises a pair of arms 402 and 403 connected to another element 401. In this embodiment, arm 402 is shown molded

to tube 401, while arm 403 is telescopically or slidably mounted within tube 401. It will be recognized that either or both of arms 402 and 403 could be mounted for relative movement with regard to element 401 to achieve the desired lengthening or shortening of handle 111. In Figure 25, arm 403 has been selected to be a male member to cooperate with female member 401 to provide the desired variability in the length of handle 111.

Also shown in Figure 25 is a push button or switch 410. Switch 410 is operable through an aperture (not shown) in member 401 to provide a friction against slidably mounted arm 403 when it is desired to lock arm 403 against further movement within tube 401. The use of such a friction device 410 will thus provide for selection of a number of lengths of handle 111 limited only by the lengths of male member 403 and female member 401. If preferred, button 410 could instead actuate a detent member (not shown) through the aperture in tube 401, which member would cooperate with one of a plurality of detent apertures (not shown) in arm 403 to thus provide a finite number of present lengths of handle 111. It has been found in practice that a desired number of preset lengths would be three, with the distance between block 102 and the Y-connector such as 113 in Figure 19 selectable at 1.5, 2.75 and 4.00 inches.

In Figure 26, there is shown an exploded view of block 102 and a cover 420 adapted to receive block 102 in a manner such that receiving notch 118 is left open to receive a guide wire such as 119 depicted in Figure 19. Cover 420 is rotatably mounted on block 102 so that after guide wire 119 has been placed in notch 118 cover 420 can be rotated to cover notch 118 and thus retain wire 119 against undesired removal.

It is contemplated that other forms of connection than those shown in the figures of the drawings could be used to connect handle 111 to the respective of block 102 or element 112. For example, either or both of block 102 and element 112 could be connected to handle 111 through a swivel device, thus providing further freedom of movement of the apparatus of this invention by the operator of the tool of this invention.

It is also contemplated that alternate forms of coupling forces may be used in the present invention. For instance, instead of using permanent magnets or electromagnets, the coupling force field between the guide wire and the captivation tool may be generated by the use of electrostatic or electric fields. In each case, the coupling force between the tool and the guide wire can operate through the catheter body, and there is no contact required between the tool and the guide wire.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is:

1. A device for use in measuring longitudinal relative movement between a guide wire and a catheter member, the catheter member having longitudinal lumen for slidable reception of the guide wire, the device comprising:

a magnetically active segment on the guide wire; and

electrical coil means positioned around the magnetically active segment on the guide wire such that a magnetic force therebetween couples the coil means and the guide wire together for providing signals indicative of the relative position and movement between the guide wire and the catheter member.

2. The device of claim 1, wherein the electrical coil means comprises at least a pair of spaced coils.

3. The device of claim 2, wherein the magnetically active segment on the guide wire includes a linear series of magnetic nodes.

4. The device of claim 3, wherein the spacing between the pair of coils comprises a phase shift

therebetween of 90 degrees relative to the magnetic nodes on the guide wire.

5. The device of claim 1 including an electrical circuit connected to the coil means for displaying the signals.

6. The device of claim 5, wherein the guide wire has a distal section and a proximal section, the magnetically active segment being on the proximal section and the proximal section being selectively securable to the distal section.

7. The device of claim 6 wherein the magnetically active segment on the guide wire includes at least one magnet.

8. The device of claim 6 wherein the magnetically active segment on the guide wire includes magnetically permeable material.

9. In a catheter tool including a catheter receiving element, a housing including a guide wire retaining portion, and a handle connected between the element and the housing, the improvement comprising:

a. handle adjustment means selectively operable to adjust the length of the handle for varying the distance between the element and the housing.

10. The improvement of claim 9 in which the handle adjustment means comprises at least a pair of telescoping arms.

11. The improvement of claim 10 including friction adjustment apparatus connected to the telescoping arms for selectively applying friction to prevent telescoping movement between the pair of arms.

12. The improvement of claim 10 including detent apparatus connected to the telescoping arms including a plurality of detent positions for selective actuation at any one of the plurality of detent positions to prevent telescoping movement between the pair of arms.

13. The improvement of claim 9 including a guide wire cover mounted on the housing and operable to cover the guide wire retaining portion when a guide wire is present in the portion.

14. The tool of claim 9 including a guide wire cover movably mounted on the housing and moveable to cover the guide wire retaining portion when a guide wire is present in the portion.

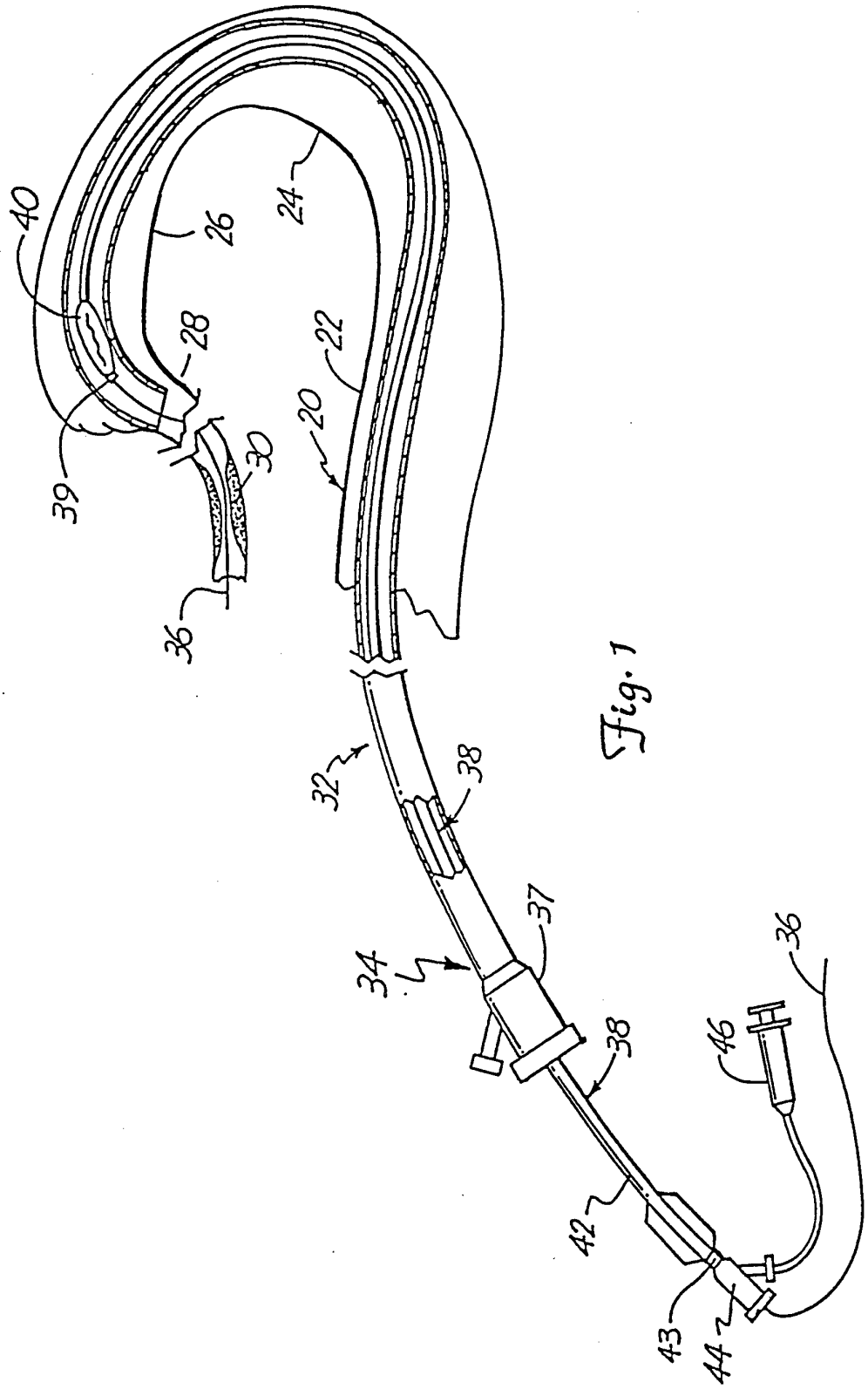


Fig. 1

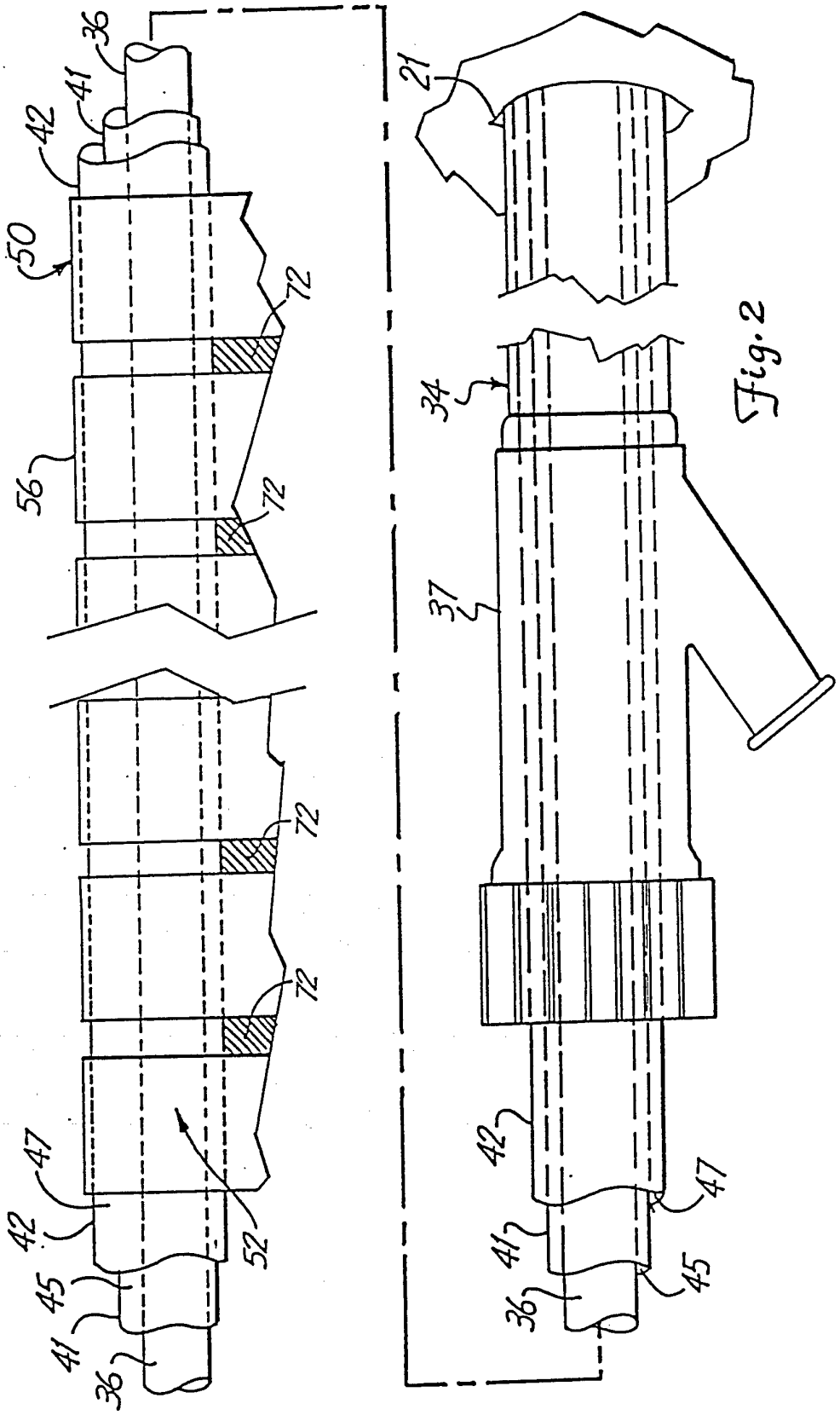


Fig. 2

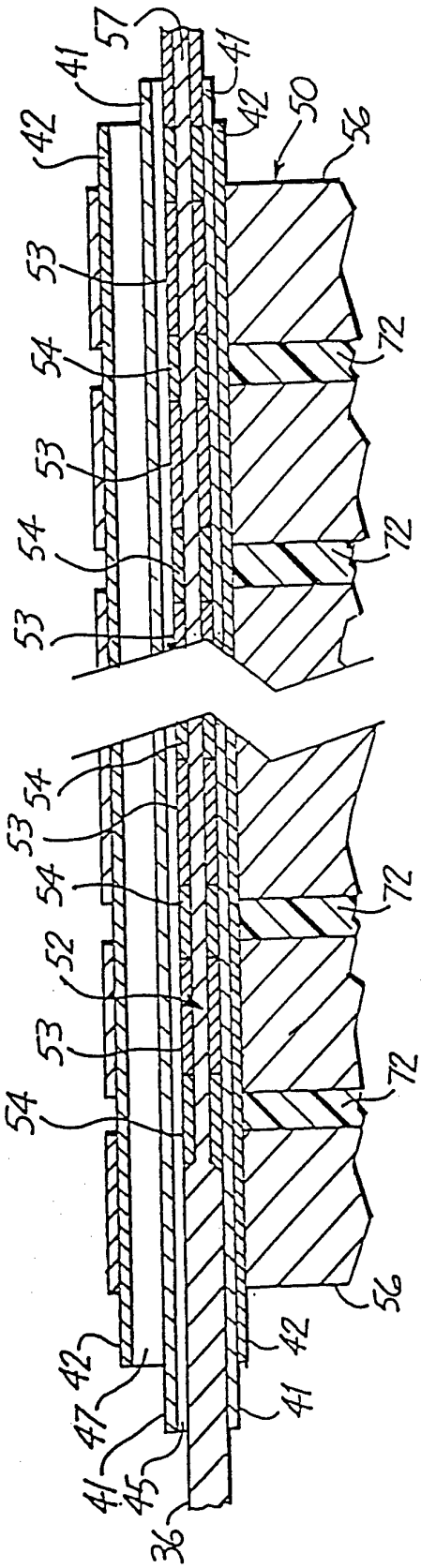

57
41
41
42
42
50
56
53
54
72
53
54
72
53
54
53
54
52
53
72
54
72
56
42
42
47
41
41
45
36

Fig. 3

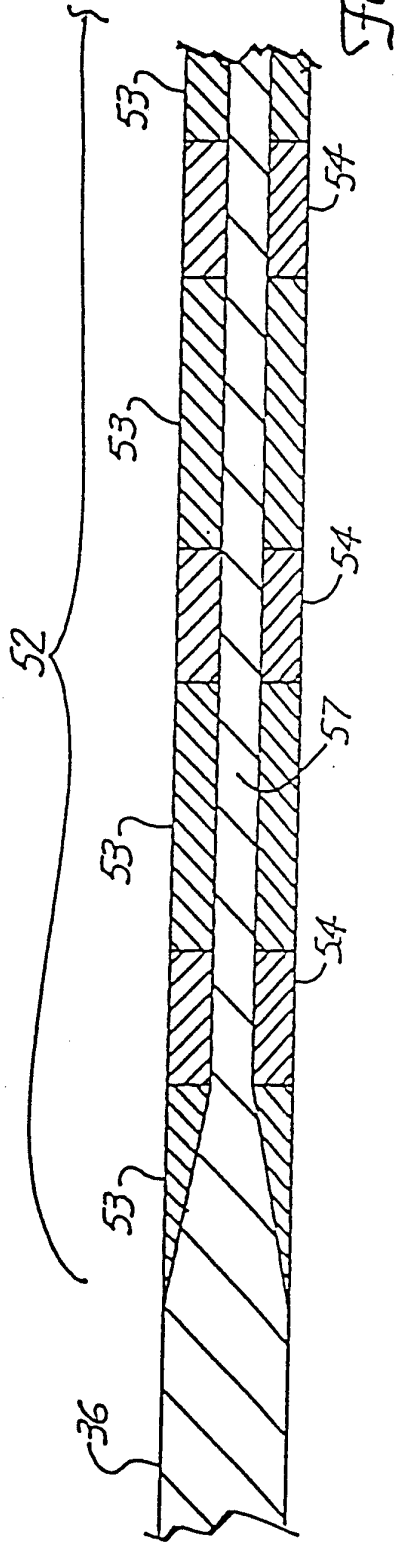


Fig. 4

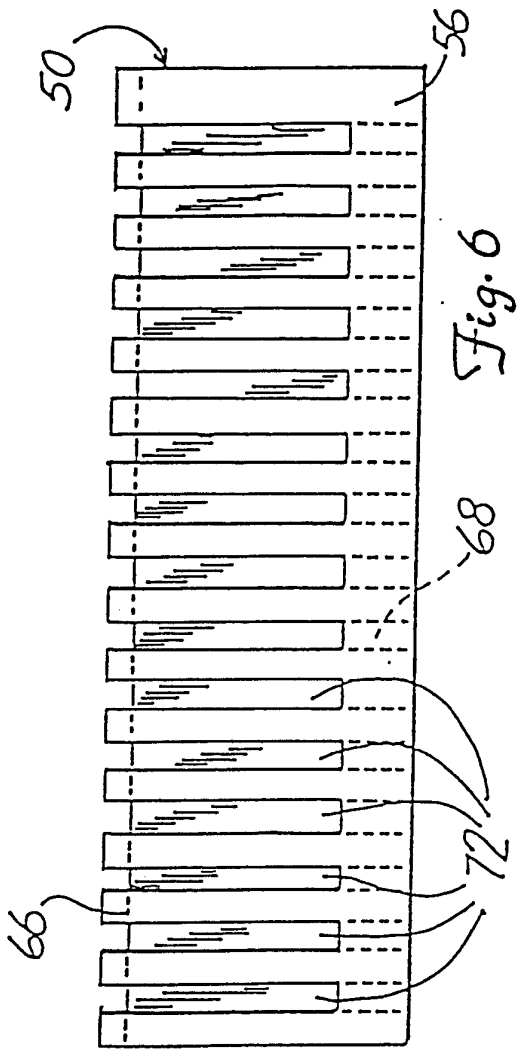


Fig. 6

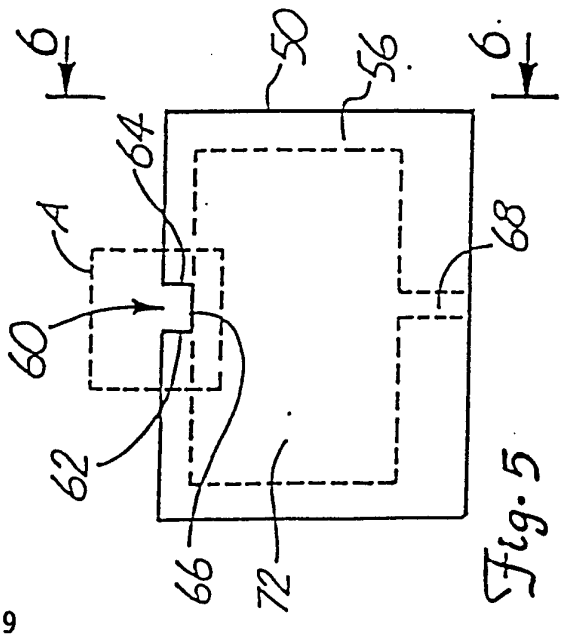


Fig. 5

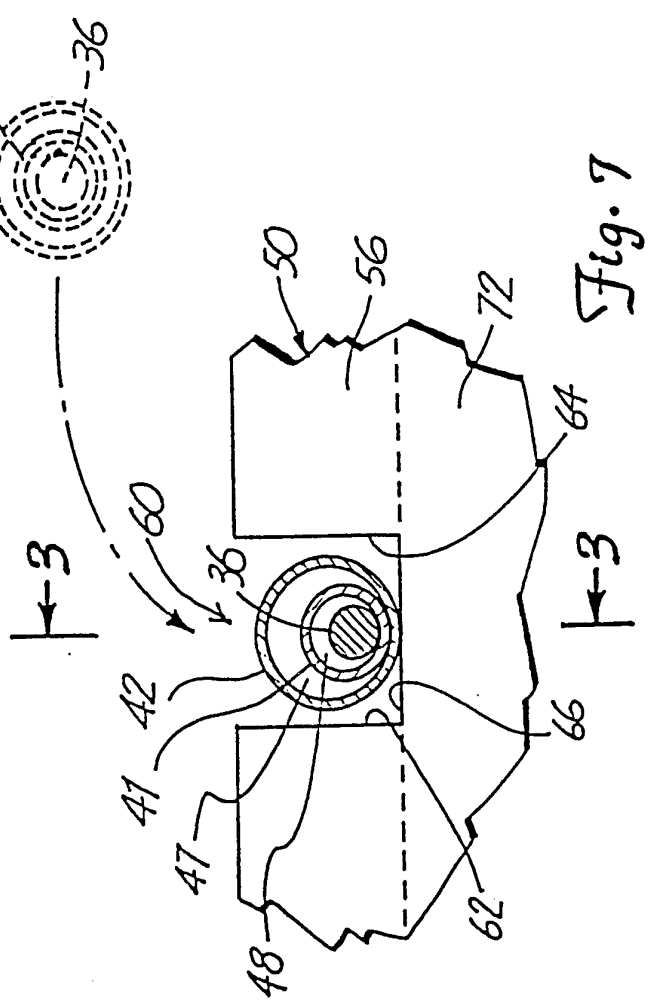


Fig. 7

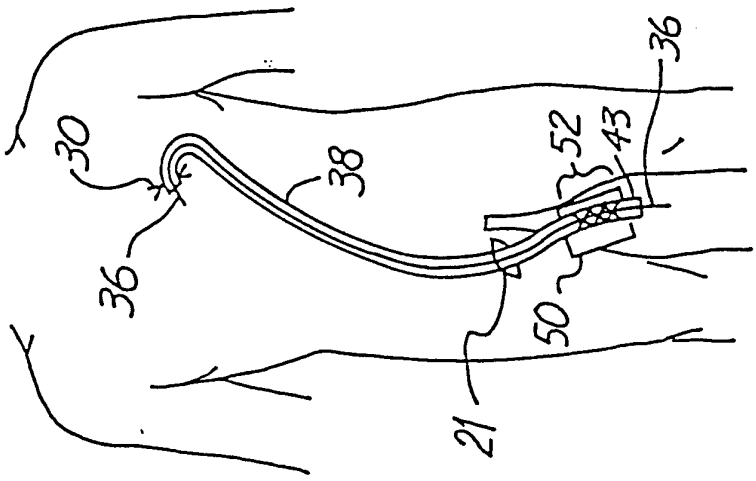


Fig. 9

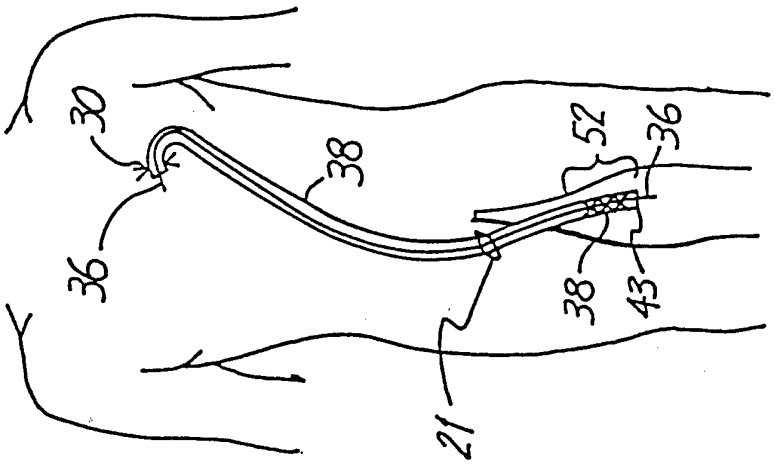


Fig. 8

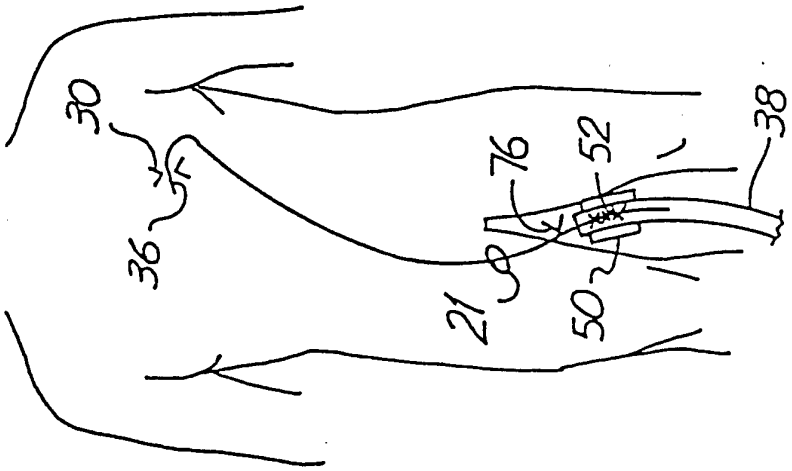


Fig. 11

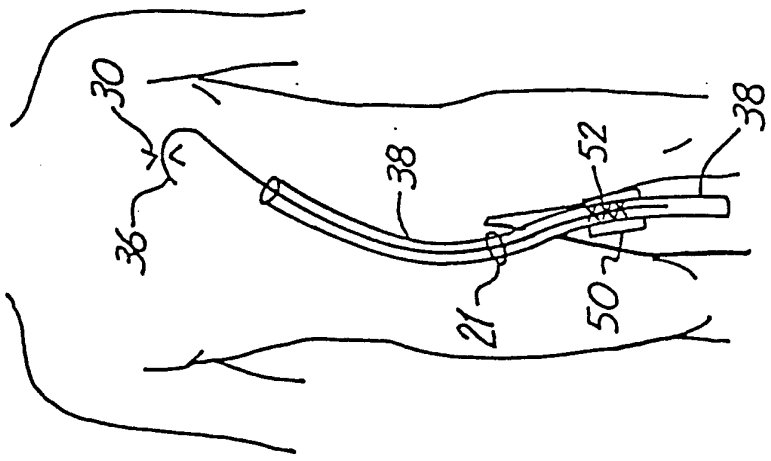


Fig. 10

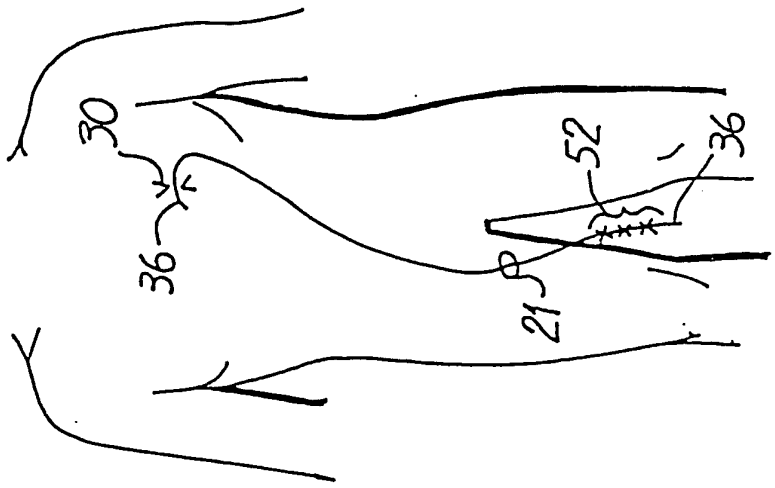


Fig. 13

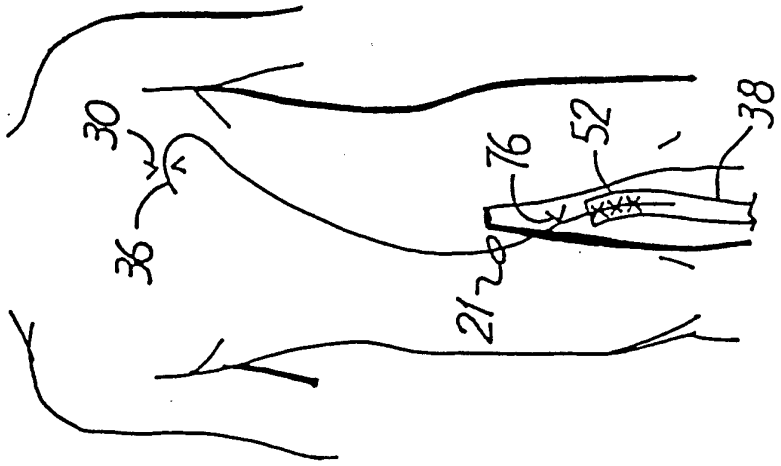


Fig. 12

Fig. 14

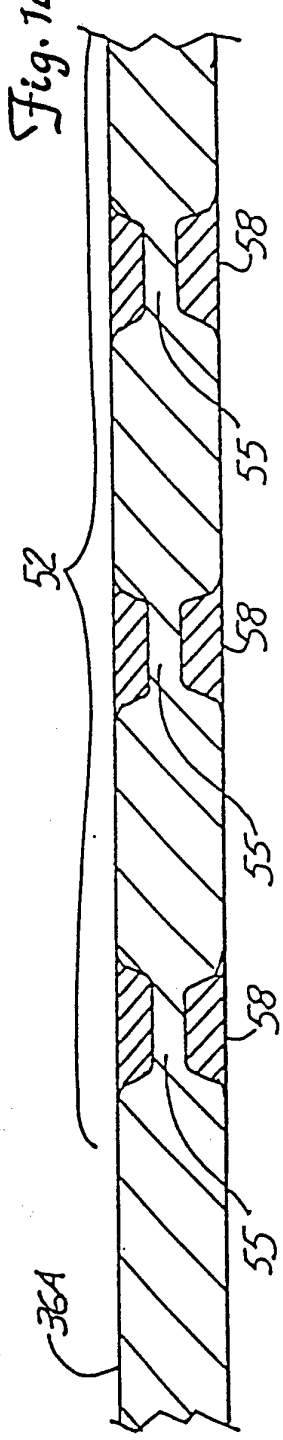
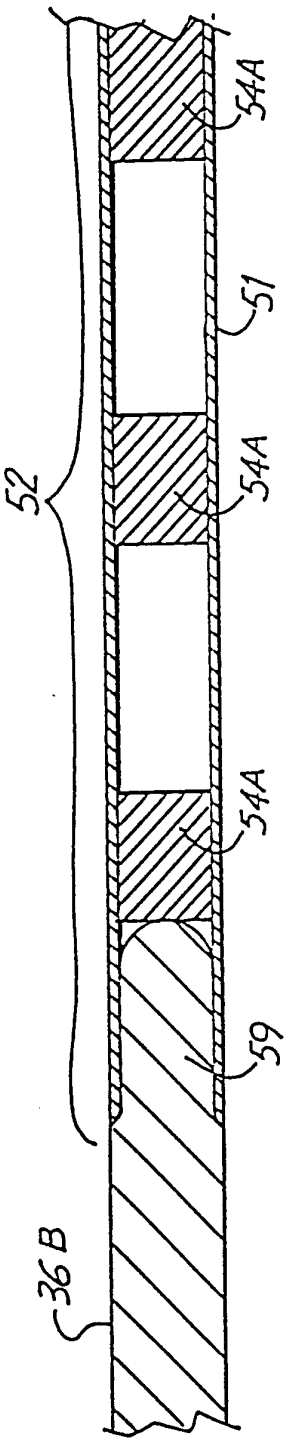


Fig. 15



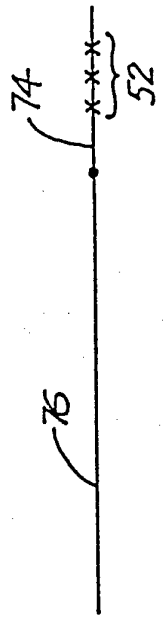
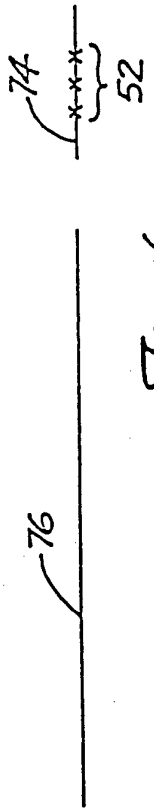


Fig. 16



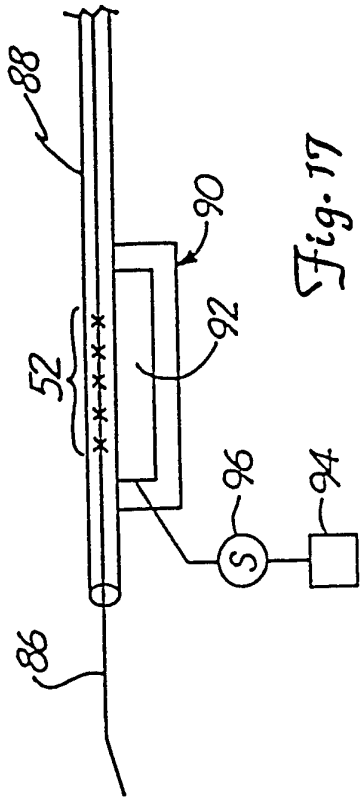


Fig. 17

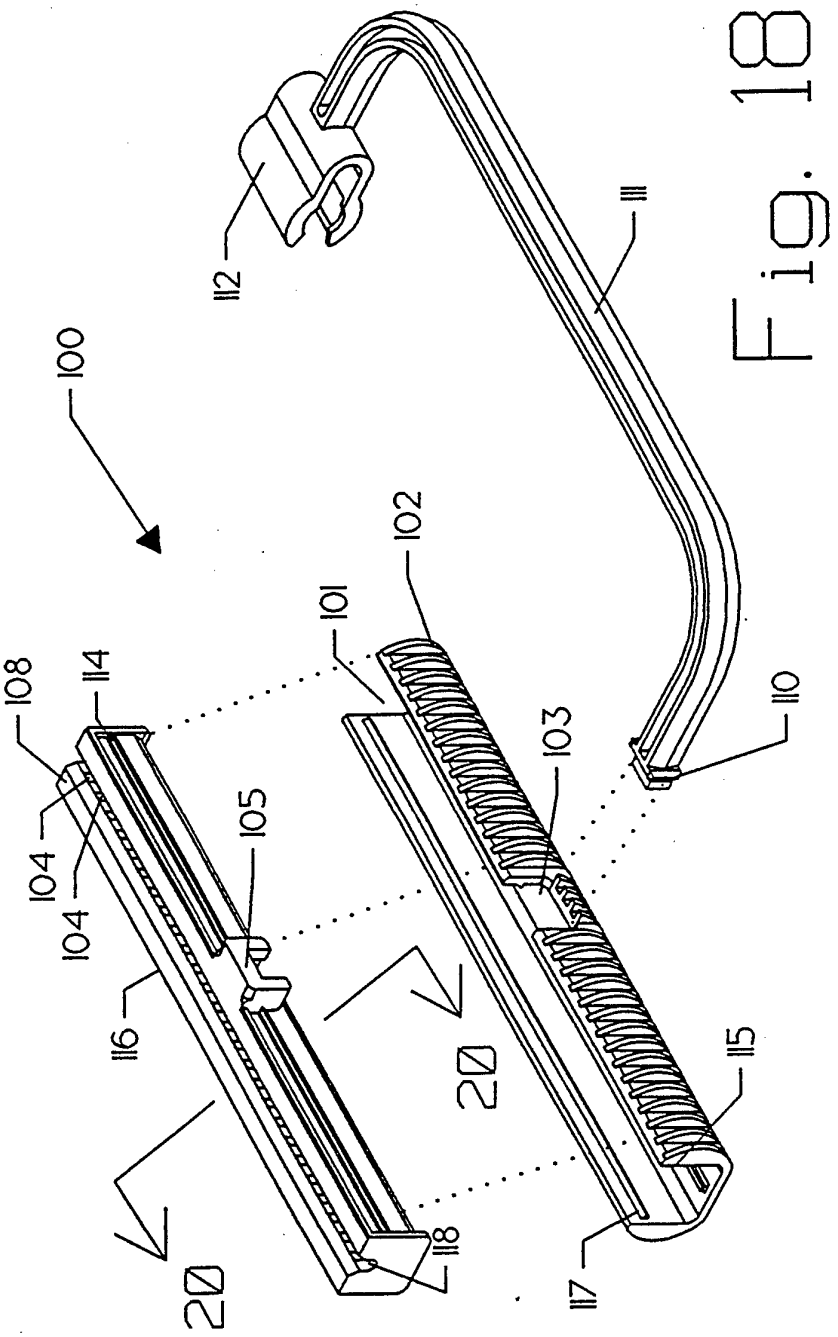

100
101
102
103
104
104
105
108
110
111
112
114
115
116
117
118
20
20

Fig. 18

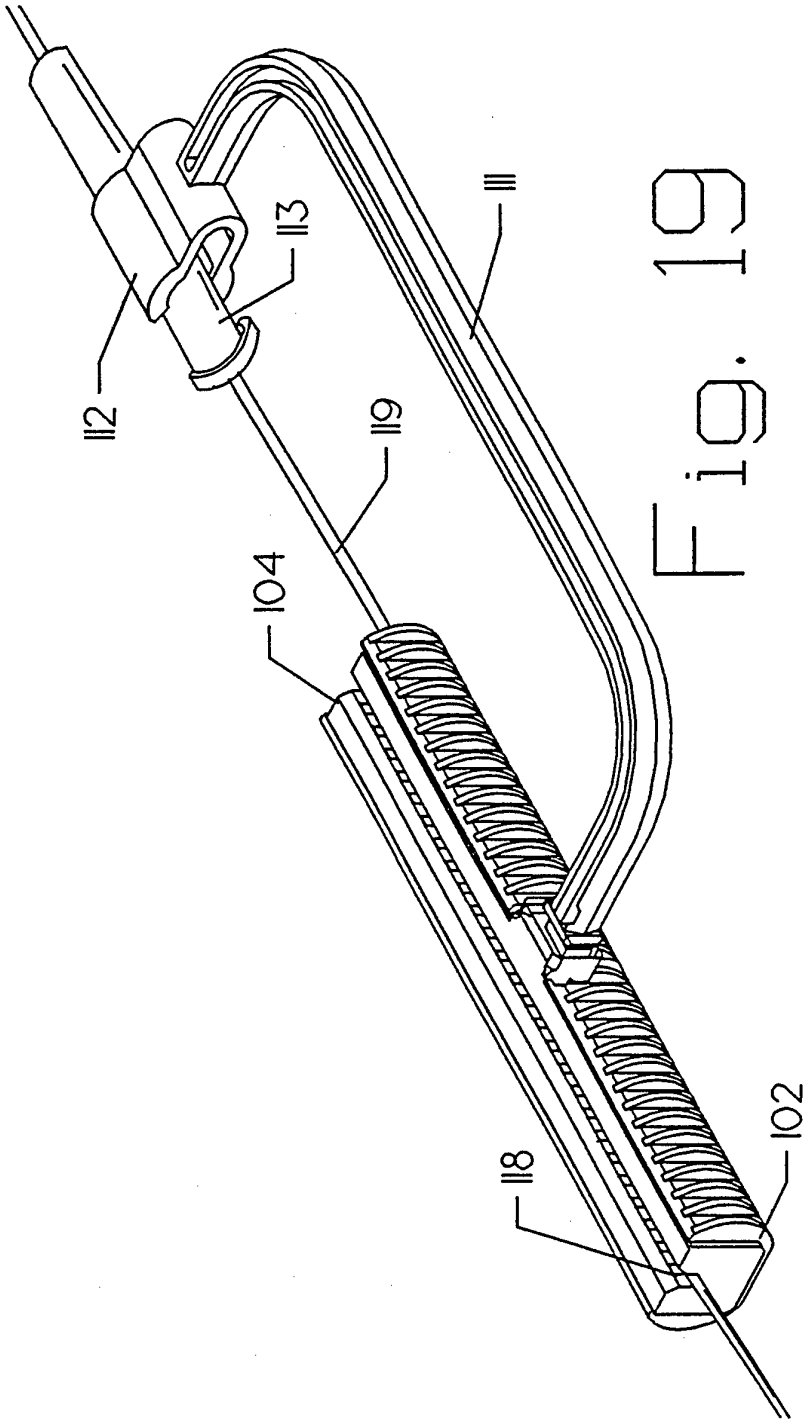


Fig. 19

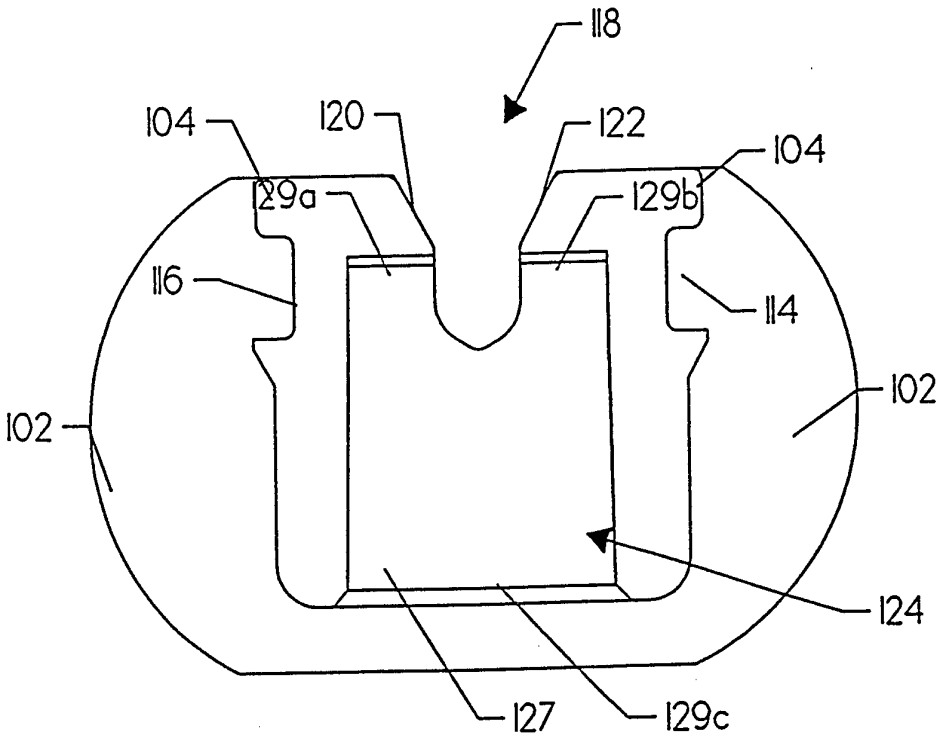


Fig. 20

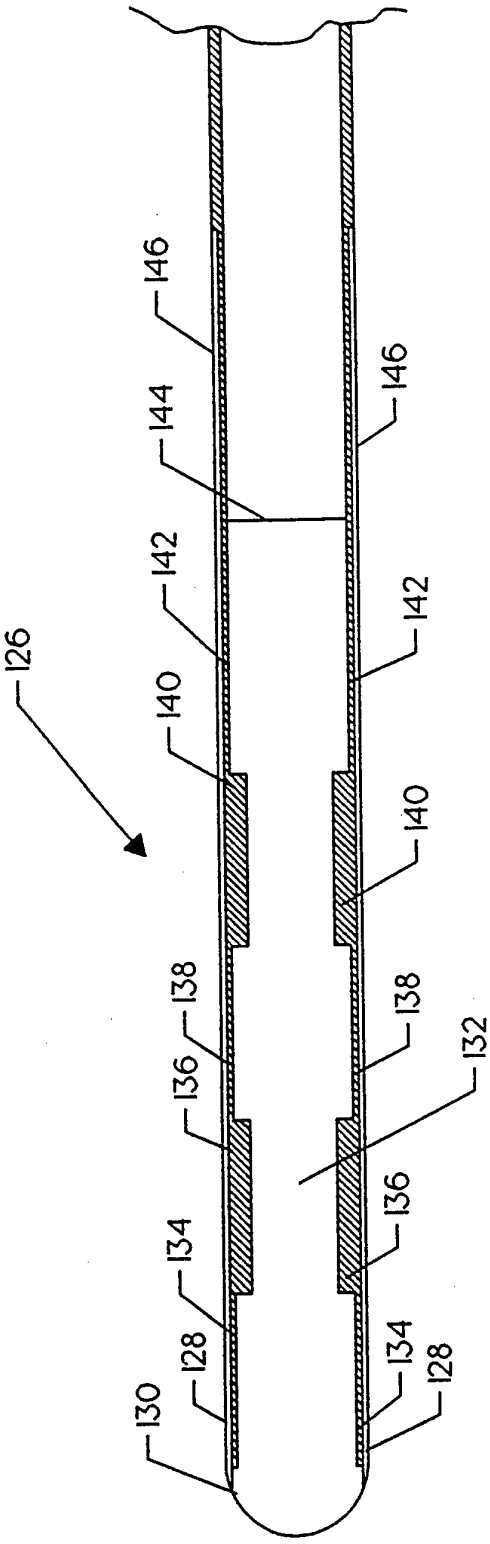


Fig. 21

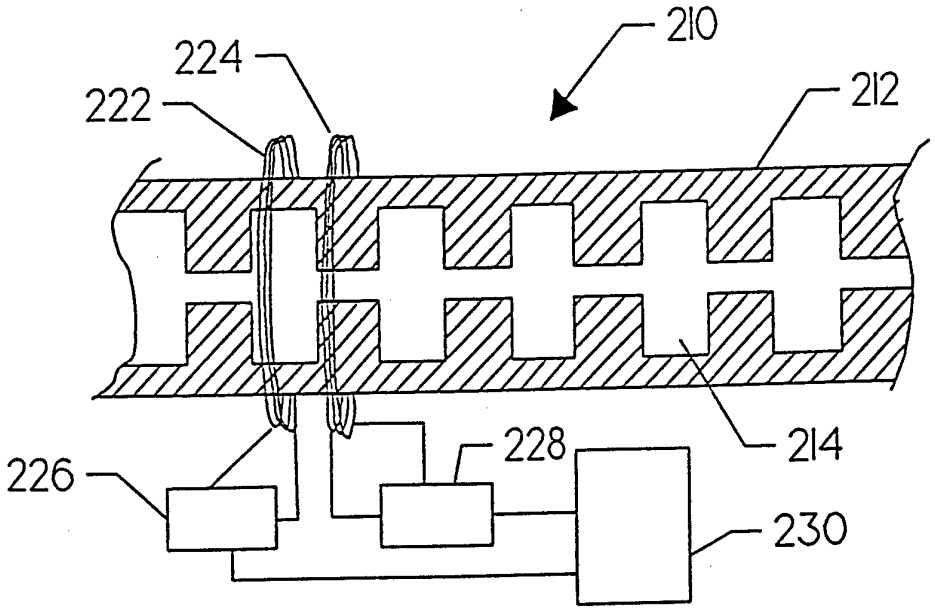


Fig. 22

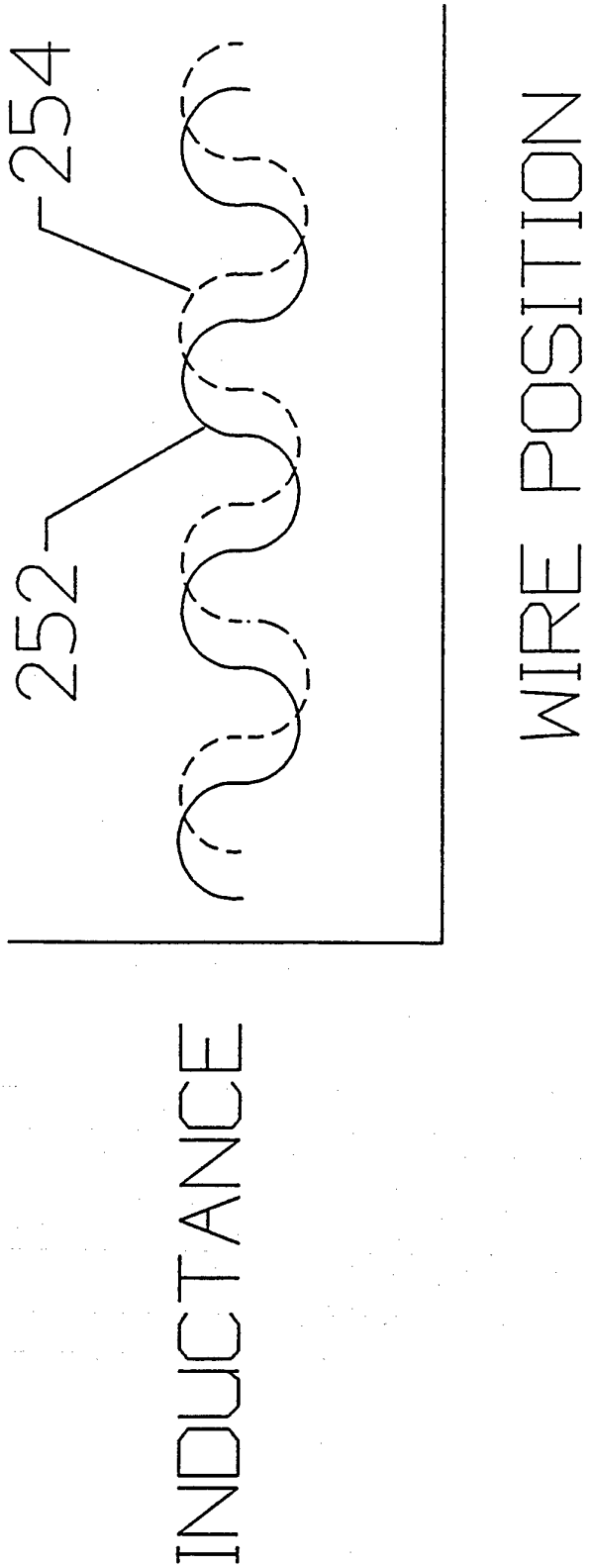


Fig. 23

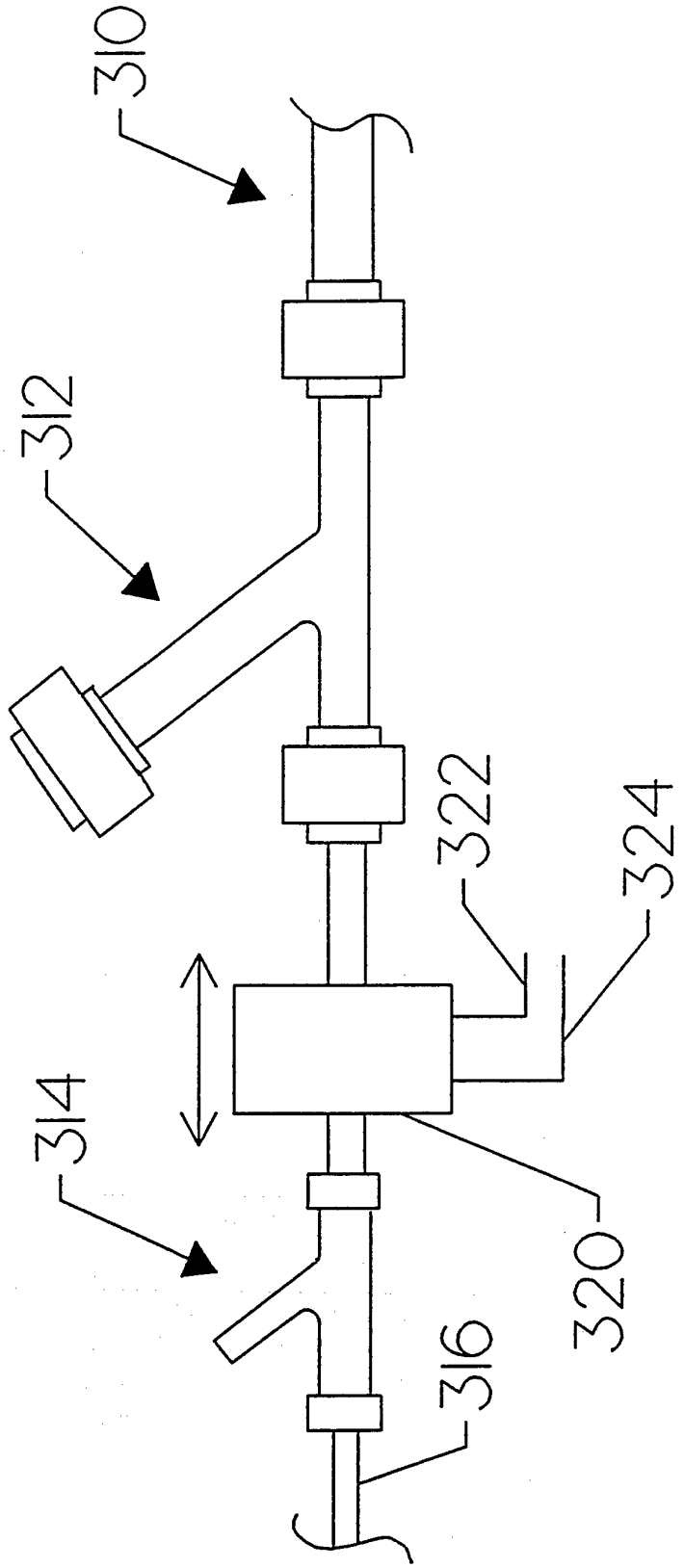


Fig. 24

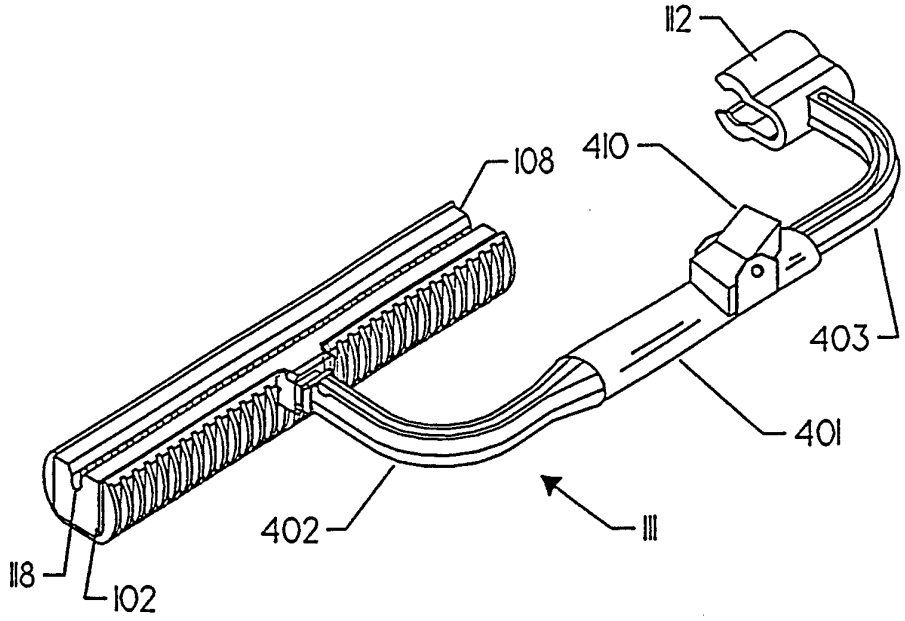


Fig. 25

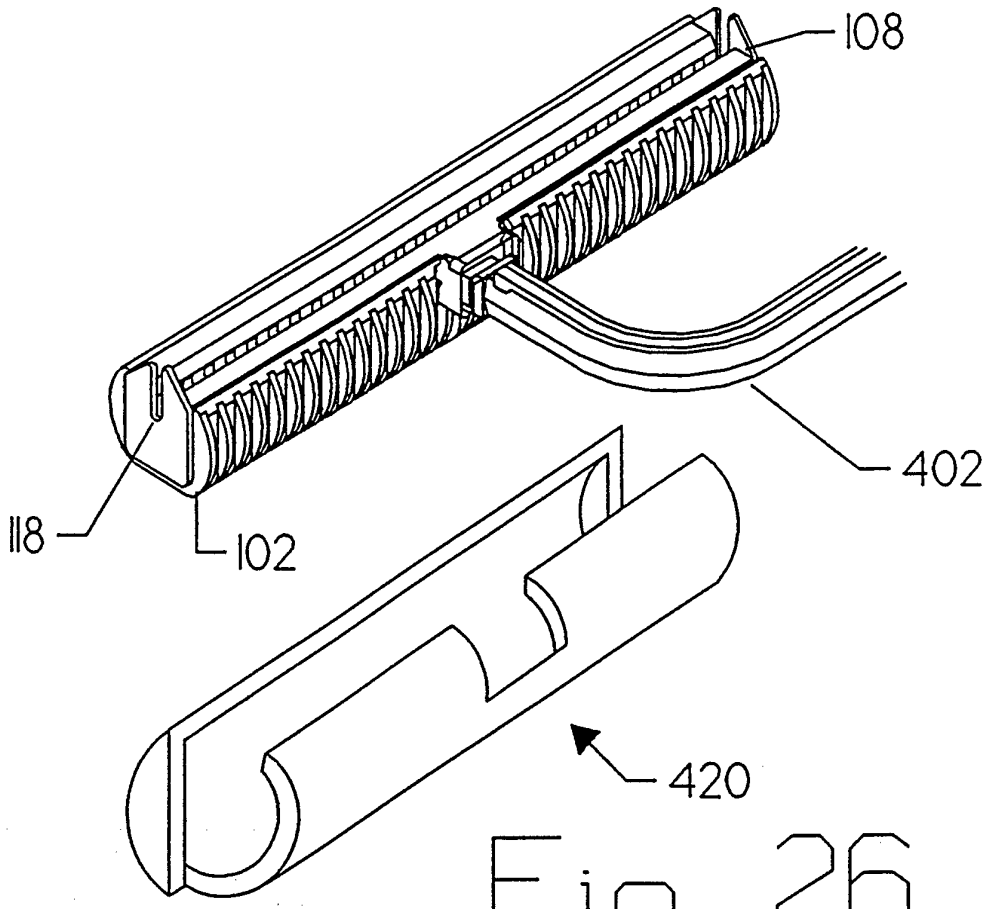


Fig. 26

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US94/11661

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/00
US CL : 128/772

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/772,657,658 ; 604/95,280-283

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

none

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

none

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A, 3,674,014 (Tillander) 04 July 1972	1-14
A	US,A, 4,244,362 (Anderson) 13 January 1981	1-14
A	US,A, 5,234,407 (Teirstein et al.) 10 August 1993	1-14
A	US,A, 4,726,369 (Mar) 23 February 1988	1-14
A	US,A, 5,161,534 (Berthiaume) 10 November 1992	1-14

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

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 02 MARCH 1995	Date of mailing of the international search report 17 MAR 1995
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer Max Hindenburg Telephone No. (703) 308-3130

Form PCT/ISA/210 (second sheet)(July 1992)★