PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 25/00, 29/00, 37/00, A61N 1/30

A1

(11) International Publication Number: **WO 98/09678**

(43) International Publication Date: 12 March 1998 (12.03.98)

(21) International Application Number: PCT/US97/14236

(22) International Filing Date: 18 August 1997 (18.08.97)

(30) Priority Data:
119189 3 September 1996 (03.09.96) IL

(71) Applicant *(for TJ only)*: FRIEDMAN, Mark, M. [US/IL]; Alharizi 1, 43406 Raanana (IL).

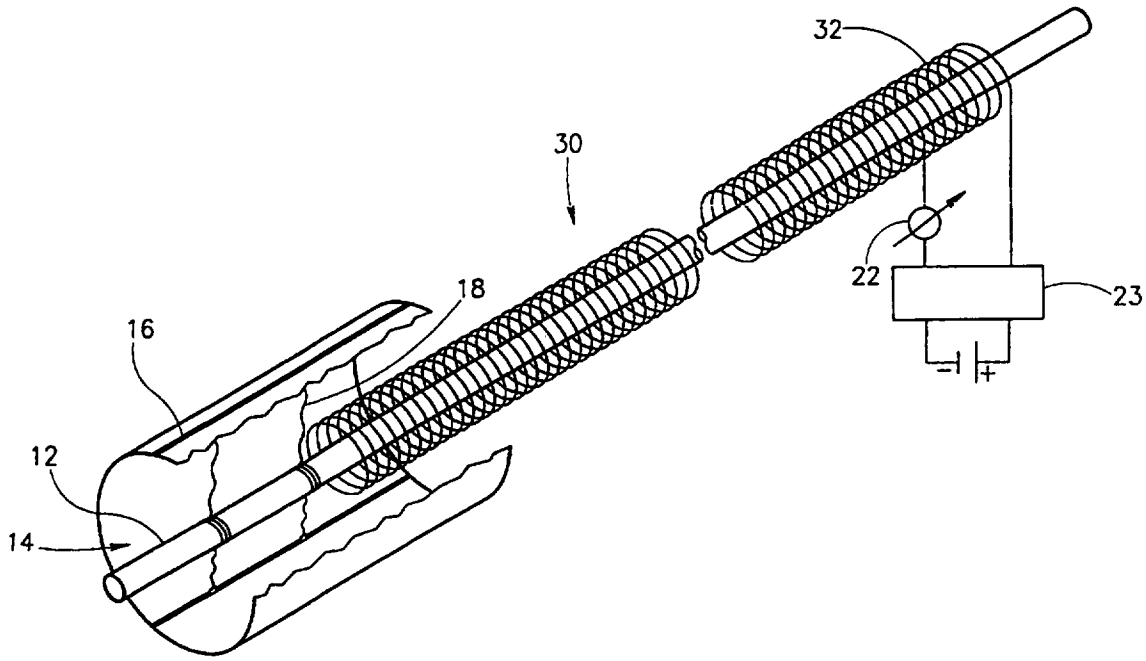
(71)(72) Applicant and Inventor: LEV, Shlomo [IL/IL]; Ahronowitz Street 25, 58445 Holon (IL).

(74) Common Representative: FRIEDMAN, Mark, M.; c/o Sheinbein, Robert, 2940 Birchtree Lane, Silver Spring, MD 20906 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: ANNULAR CATHETER



(57) Abstract

This invention is a catheter (10), including (a) an element (12); (b) an adjustable ring (14) attached to the element (12) such that at least a portion of the element (12) is substantially within the adjustable ring (14), the adjustable ring (14) having at least a first diameter and at least a second diameter, and the adjustable ring (14) being magnetizable; and (c) a magnetization unit (20, 22) located near a portion of the element, the magnetization unit (20, 22) determining when the adjustable ring (14) has the first diameter and when the adjustable ring (14) has the second diameter.

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.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

ANNULAR CATHETER

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a catheter intended to dilate biological ducts, such as occluded and narrowed blood vessels and, more particularly, to a catheter made of an elastic ring whose diameter and force of exertion is controlled by the application of a magnetic field. The elastic ring is able to expand while permitting substantially unchanged flow of fluid, such as blood through the catheter.

Cardiovascular disease is a growing problem in many countries. One of the hallmarks of this disease is the narrowing or occlusion of blood vessels, such as arteries and veins, by the deposition of fats and cholesterol on the walls of these vessels. Balloon catheters are well known in the art for broadening such narrowed or occluded blood vessels. Several types of such balloon catheters are known, all of which have a balloon located at one end of an elastomeric tubule and all of which operate by the same general principles. First, the catheter with the empty, flexible balloon is inserted into the narrowed or occluded blood vessel by using a wire guide. Next, the balloon, which can be ellipsoidal or spherical, is inflated and made rigid as a result of application of water pressure within the catheter. As the balloon is made rigid, it forcibly dilates the narrowed or occluded blood vessel, fractures the deposits of fats or cholesterol on the vessel walls and pushes them aside. This dilation stretches, and often tears, the tissues' fibers in the wall of the blood vessel. With the release of internal pressure within the balloon, it returns to its original diameter while the vessel walls remain laterally displaced and open to blood flow. The catheter, and the balloon at its end, are then removed from the blood vessel.

One important safety factor is the rate of dilation of the blood vessel. A slower rate of dilation is much safer since the tissues' fibers are less likely to tear,

and complications, such as a rupture of the blood vessel, are less likely to occur. Thus, a slow rate of dilation is strongly preferable.

Unfortunately, all of these balloon catheters have one major drawback: they substantially block the flow of blood through the blood vessel when the balloon is inflated and made rigid. Such a blockage deprives those tissues supplied by the blood vessel of blood, and hence of oxygen and nutrients, during the period when the balloon is inflated. This deprivation is particularly dangerous for sensitive tissues, which cannot tolerate an interruption in blood supply. Furthermore, such an interruption often causes significant patient discomfort which can even "feel like a heart attack".

In an attempt to solve this problem, a perfusion balloon catheter has been developed for use with blood vessels supplying sensitive tissues. This catheter has openings in the catheter wall before and after the balloon, connected by small tubes passing through the balloon internally, so that blood can perfuse through the catheter. Unfortunately, these openings only permit a small fraction of the blood to flow through the catheter, so that the blood flow is slow and significant patient discomfort is still present. Thus, even using such a perfusion balloon, the catheterization must be done extremely rapidly to avoid damage to sensitive tissues. Furthermore, extremely sensitive tissues, such as the brain, cannot even tolerate such a significant reduction in blood flow, so that blood vessels directly supplying the brain cannot be catheterized. Thus, the perfusion catheter does not adequately solve the problems of balloon catheters, such as the need for rapid dilation of the blood vessel.

However, as noted above, rapid dilation of the blood vessel is undesirable. Such rapid dilation can potentially lead to serious complications, such as rupture of the blood vessel, yet paradoxically, these serious complications must be risked during catheterization to avoid prolonged low blood flow through the vessel.

There is thus a widely recognized need for, and it would be highly advantageous to have, a catheter which can forcibly dilate an occluded or

narrowed blood vessel without a substantial reduction in blood flow through the vessel, so that dilation can occur relatively slowly even when the blood vessel is supplying a highly sensitive organ, such as the brain.

SUMMARY OF THE INVENTION

According to the present invention, there is provided a catheter, including: (a) an element for transferring a magnetic force; (b) an adjustable ring attached to the element such that at least a portion of the element is substantially within the adjustable ring, the adjustable ring having at least a first diameter and at least a second diameter, and the adjustable ring being magnetizable; and (c) a magnetization unit located near a portion of the element, the magnetization unit regulating the magnetic force transferred by the element for determining when the adjustable ring has the first diameter and when the adjustable ring has the second diameter. Preferably, the element is a rod formed of magnetizable metal, and the magnetization unit includes an induction coil wrapped substantially around at least a portion of the rod, such that when current is passed through the induction coil in one direction, the rod transfers the magnetic force with one direction of polarity, and when the current is passed through the induction coil in an opposing direction, the rod transfers the magnetic force with opposing polarity. Alternatively and preferably, the element is a rod formed of magnetizable metal, and the magnetization unit includes a permanent magnet, a distance of the magnet from the rod determining the magnetic force. Also preferably, the adjustable ring is magnetizable by a magnetic unit and the form of the magnetic unit is selected from the group consisting of powder, foil and chip.

According to another embodiment of the present invention, there is provided a method of catheterizing a biological duct of a subject, including the steps of: (a) inserting the catheter of claim 1 into the biological duct of the subject with the adjustable ring of the catheter having the first diameter such that the adjustable ring substantially does not contact the wall of the biological duct; (b)

regulating the magnetic force transferred by the element such that the adjustable ring has the second diameter, the second diameter being substantially larger than the first diameter; and (c) contacting the wall of the biological duct with the adjustable ring having the second diameter. Preferably, the wall of the biological duct is contacted more than once.

According to yet another embodiment of the present invention, there is provided a method of assembling a catheter, including the steps of: (a) preparing an adjustable ring from flexible and magnetizable material; (b) attaching the adjustable ring to an element for transferring a magnetic force; and (c) placing a magnetization unit near the element, such that the magnetization unit transmits the magnetic force. Preferably, the element is a rod and the magnetization unit is formed by wrapping an induction coil substantially around at least a portion of the rod. Alternatively and preferably, the magnetization unit is formed from a permanent magnet.

According to still another embodiment of the present invention, there is provided a repair catheter for repairing a wall of a biological duct, including: (a) an element for transferring a magnetic force; (b) a stent, at least a portion of the element being substantially within the stent, the stent having at least a first diameter and at least a second diameter, the stent being magnetizable and the stent containing activatable adhesive; and (c) a magnetization unit located near a portion of the element, the magnetization unit regulating the magnetic force transferred by the element for determining when the stent has the first diameter and when the stent has the second diameter, the activatable adhesive being activated when the stent has the second diameter such that the stent becomes substantially rigid.

According to still another embodiment of the present invention, there is provided a suction catheter for removing a deposit from a biological duct, the biological duct having a wall, the suction catheter including: (a) a rod for transferring a magnetic force, the rod being substantially hollow; (b) an

adjustable ring attached to the rod such that at least a portion of the rod is substantially within the adjustable ring, the adjustable ring having at least a first diameter and at least a second diameter, and the adjustable ring being magnetizable; (c) a magnetization unit located near a portion of the rod, the magnetization unit regulating the magnetic force transferred by the rod for determining when the adjustable ring has the first diameter and when the adjustable ring has the second diameter, such that when the adjustable ring has the second diameter, the adjustable ring contacts the wall of the biological duct; and (d) a suction device attached to a portion of the rod, the suction device exerting a vacuum force to remove the deposit from the biological duct when the adjustable ring contacts the wall of the biological duct.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

FIG. 1 is a view of one embodiment of the present invention;

FIGS. 2A and 2B are views of an adjustable ring according to the present invention;

FIG. 3 is a view of a second embodiment of the present invention, in which the induction coil is extended along substantially a majority of the element;

FIG. 4 is a view of a third embodiment of the present invention, in which the induction coil is replaced by a substantially permanent magnet;

FIG. 5 is a view of a fourth embodiment of the present invention, in which features of embodiments illustrated in Figures 1 or 3 and 4 are combined;

FIG. 6 is a view of a catheter and suction device according to the present invention;

FIGS. 7A, 7B and 7C are views of a stent for use with the present invention;

FIGS. 8A and 8B are views of a fifth embodiment of the present invention, in which the diameter of the ring is controlled by an external magnet;

FIG. 9 is a view of a sixth embodiment of the present invention, in which an induction coil is extended along the ring or rings; and

FIG. 10 is a view of a seventh embodiment of the present invention, in which the diameter of the ring is controlled by the insertion and removal of a magnetizable rod.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is of a catheter which can be used to forcibly dilate, and therefore clear, narrowed or occluded blood vessels. Specifically, the catheter includes an adjustable ring whose diameter is controlled by the application of a magnetic field. The adjustable ring is able to expand while permitting substantially unchanged flow of blood through the catheter. Preferably, the catheter is also used to apply a stent to a blood vessel wall to effect a repair of that wall. Also preferably, the catheter includes a suction pump to remove deposits on the walls of the occluded or narrowed blood vessel.

Although both the aforementioned and the following descriptions specifically describe a catheter for use with blood vessels, it should be understood that this is for clarity only and that the catheter can be inserted into any biological duct including, but not limited to, the gastrointestinal tract, urological ducts, gall bladder and passages of the lung.

It should be noted in passing that U.S. 5,089,006 to Stiles (hereinafter referred to as "Stiles") describes a biological duct liner and installation catheter which can use a magnetic field during the installation of the liner. However, the catheter disclosed by Stiles differs from that of the present invention in a number of ways. First, the catheter of Stiles is intended only for the installation of the liner, while the catheter of the present invention can also be used to forcibly dilate a biological duct and can then be removed. Second, the adjustable ring of the

present invention can be expanded and contracted to a variable diameter, while the liner of Stiles is only intended to expand to a predetermined diameter. Finally, the stent of the present invention includes an activatable adhesive, while the liner of Stiles does not.

The principles and operation of a catheter according to the present invention may be better understood with reference to the drawings and the accompanying description.

Referring now to the drawings, Figure 1 illustrates a catheter according to the present invention. Catheter **10** has an element **12** for transferring a magnetic force, preferably in the form of a rod and preferably made of magnetizable metal, most preferably of soft metal. Hereinafter, the term "magnetizable" is defined as either permanently or temporarily capable of transferring a magnetic force. Element **12** also preferably includes an annulus attached to element **12**, through which a wire guide can be threaded (not shown). At one portion **13** of element **12**, there is an adjustable ring **14**, shown partially cut-away in Figure 1 (see also Figure 2A below for a complete view). Hereinafter, the term "ring" includes both an annular ring and a cross-section of a cylinder. The ring can have one of three alternative forms. First, the ring can be a coil, preferably formed from a single, helically wound strip or wire. Second, alternatively and preferably, the ring can be an open weave net. Third, alternatively and most preferably, the ring is substantially continuous, such that the ring is a single piece of material without a beginning or an end. Adjustable ring **14** is magnetizable. Adjustable ring **14** preferably has at least one, and most preferably a plurality of, supporting ribs **16** attached to adjustable ring **14**. Ribs **16** act to stiffen adjustable ring **14**. Adjustable ring **14** is attached to element **12**, preferably by at least one, and most preferably a plurality of, fibers **18**. Hereinafter, "attached" is defined as connected to, or integrally formed with. Fibers **18** are preferably made from a strong, synthetic material such as polyamide.

At another portion of element **12**, there is an induction coil **20**. Induction coil **20** is wrapped substantially around element **12** and is then preferably attached to a rheostat **22**. Rheostat **22** regulates the flow of electricity from a source of electricity (not shown) through induction coil **20**. A switch **23** is preferably used to determine the direction of the flow of electricity. When electricity is permitted to flow through induction coil **20**, element **12** becomes magnetized. The polarity of element **12** depends upon the direction of the flow of electricity through induction coil **20**. Induction coil **20**, preferably together with rheostat **22**, forms a magnetization unit for regulating the magnetic force transferred by element **12**. Most preferably, electricity flowing through induction coil **20** is alternating current, so that the direction of flow is changeable, although direct current can be alternatively used.

Figures 2A and 2B are views of adjustable ring **14**. Figure 2A shows a perspective view of adjustable ring **14**. Ribs **16** can also be seen disposed around adjustable ring **14**. Figure 2B shows a cross-section of adjustable ring **14** through line B-B. A cross-section of a portion of a wall **24** of adjustable ring **14** can be seen. Adjustable ring **14** is preferably magnetizable as follows. Attached to wall **24**, and preferably embedded in wall **24**, is at least one, and preferably a plurality of, magnetic units **26**. If there is more than one magnetic unit **26**, at least a portion of said magnetic units **26** is arranged with the same pole **28** facing inward towards the interior of adjustable ring **14**. Pole **28** has fixed polarity, which can be either north or south. However, the polarity of portion **13** of element **12** alternates. Thus, depending upon the direction of the current through induction coil **20**, pole **28** alternately has the identical or the opposite polarity of portion **13** of element **12**. Each magnetic unit **26** can be any form of material, such as magnetizable metal, which causes adjustable ring **14** to be magnetizable including, but not limited to, powder either coated on wall **24** or embedded within wall **24**, or both, a chip or a thin section of foil either attached to wall **24** or

embedded within wall **24**, or both. If powder is used, preferably each magnetic unit **26** is arranged vertically in relation to element **12**.

The present invention can be operated in the following manner. Catheter **10** is inserted into a blood vessel of a subject via a standard catheter lead (not shown). Hereinafter, the term "subject" refers to a human or lower animal into whom catheter **10** is inserted. During this part of the procedure, the current does not flow through induction coil **20**, or alternatively passes through induction coil **20** in a direction which causes portion **13** of element **12** to have the opposite polarity as pole **28** of each magnetic unit **26**. Portion **13** thus attracts pole **28**. It should be noted that although element **12** is not magnetized by induction coil **20** when the current through induction coil **20** is substantially zero (i.e. -- does not flow), since element **12** is made from magnetizable metal, element **12**, or more specifically portion **13** of element **12**, still attracts pole **28**. At this point, adjustable ring **14** is collapsed (not shown) and therefore has a sufficiently small first diameter to permit the insertion of adjustable ring **14** into the blood vessel substantially without adjustable ring **14** contacting the walls of the blood vessel. It should be noted that in this embodiment, induction coil **20** remains substantially outside the subject's body (not shown).

When catheter **10**, and more specifically adjustable ring **14**, is located at the section of blood vessel to be dilated, rheostat **22** permits the flow of electricity through induction coil **20** in a direction which causes element **12** to become magnetized with opposite polarity to the previous polarity of element **12**, or alternatively permits electricity to start to flow through induction coil **20**, so that pole **28** of each magnetic unit **26** has the identical polarity as portion **13** of element **12**. Now each magnetic unit **26**, and hence wall **24**, is repelled away from element **12**. Adjustable ring **14** now expands to have a second, larger diameter, forcing the blood vessel to dilate (not shown). The rate of the expansion of adjustable ring **14**, and hence of the dilation of the blood vessel, is controlled by the flow of electricity through induction coil **20**. Such flow also

controls the extent of the expansion of adjustable ring **14**, since increasing the current also increases the repulsion between each magnetic unit **26** and element **12**. Such an increase in repulsion increases the diameter of adjustable ring **14**.

The maximum diameter of adjustable ring **14** is preferably at least partly determined by the length of fibers **18**, which attach adjustable ring **14** to element **12**. Fibers **18** act to maintain the position of adjustable ring **14** relative to element **12**.

During the dilation of adjustable ring **14**, it should be noted that the flow of blood through the blood vessel is substantially unaltered by catheter **10**. This is because adjustable ring **14** is substantially hollow, so that only element **12** presents any obstruction to the flow of blood. Thus, the supply of blood, and hence of oxygen and nutrients, to tissue fed by the blood vessel is substantially unimpaired. Furthermore, since the flow of blood is substantially unimpaired, the rate of dilation of the blood vessel can be relatively slow, enabling the fibers of the walls of the vessel to be slowly stretched, rather than torn as with a balloon catheter.

After the blood vessel has been dilated, the flow of current through induction coil **20** is again either reversed or stopped by rheostat **22**. Portion **13** of element **12** now has the opposite polarity as pole **28** of each magnetic unit **26**. Portion **13** thus attracts pole **28**. Wall **24** of adjustable ring **14** is now attracted towards element **12**, causing adjustable ring **14** to collapse back to the first diameter. Catheter **10** may now be safely withdrawn from the subject's body. It should be noted that adjustable ring **14** is preferably able to have a number of different diameters, rather than just the two diameters described herein for purposes of illustration.

As noted above, adjustable ring **14** preferably has at least one, and preferably a plurality of, supporting ribs **16** attached to adjustable ring **14**. Ribs **16** prevent buckling of adjustable ring **14**, or of its edges, when the current through induction coil **20** is such that wall **24** is attracted toward element **12**.

Ribs **16** are preferably formed of material which is not affected by the magnetic field, so that the expansion of adjustable ring **14** is not altered.

Catheter **10**, as illustrated in Figures 1, 2A and 2B, can be assembled as follows. First, induction coil **20** is wrapped substantially around element **12**. Induction coil **20** is then preferably connected to rheostat **22**, which is eventually connected to a source of electricity (not shown). Rheostat **22** does not need to be connected to the source of electricity until catheter **10** is to be operated.

Next, adjustable ring **14** is made from flexible and magnetizable material, preferably by attaching, and most preferably embedding, at least one, and preferably a plurality of, magnetic units **26** in flexible material. Poles **28** of magnetic units **26** should be oriented as described above, so that at least a portion of magnetic units **26** have the same pole **28** facing toward the interior of adjustable ring **14**, if there is more than one magnetic unit **26**. Preferably, at least one, and preferably a plurality of, supporting ribs **16** are then attached to adjustable ring **14**. Finally, adjustable ring **14** is attached to portion **13** of element **12**, preferably by at least one, and most preferably a plurality of, fibers **18**.

Figure 3 is a view of a second embodiment of the present invention. In this embodiment, a catheter **30** is very similar to catheter **10** of Figure 1, with one exception. An induction coil **32** of catheter **30** extends along substantially a majority of element **12** and makes a loop. Also, induction coil **32** preferably extends substantially inside the body of the subject during normal operation. Preferably, induction coil **32** extends from one portion of element **12** substantially near adjustable ring **14**, and most preferably extends within adjustable ring **14**. Catheter **30** has a substantially similar mode of operation as catheter **10** of Figure 1. Catheter **30** is also similarly assembled, except that induction coil **32** is placed on element **12** so as to extend along substantially a majority of element **12** and then to return along element **12**, preferably extending inside the body of the subject during normal operation.

Figure 4 is a view of a third embodiment of the present invention, in which the induction coil is replaced by a substantially permanent magnet. In this embodiment, a catheter **34** is again substantially similar to catheter **10** of Figure 1, with one exception. Catheter **34** does not have an induction coil. Instead, a permanent magnet **36** is located at one portion of element **12**. A sleeve **38** preferably then extends from permanent magnet **36** along element **12**. The degree of expansion, and hence the diameter, of adjustable ring **14** is controlled by the strength of permanent magnet **36**. At least permanent magnet **36**, and preferably permanent magnet **36** and sleeve **38**, form a magnetization unit for catheter **34**. The magnetization of element **12** is controlled by the placement of the magnetization unit relative to element **12**, such that when the magnetization unit is near element **12**, element **12** is magnetized; and when the magnetization unit is not near element **12**, element **12** is not magnetized.

Catheter **34** is assembled in a substantially similar manner as catheter **10**, except that no induction coil **20** is wrapped around element **12** and no rheostat **22** is used. Instead, sleeve **38** is attached to permanent magnet **36**. Sleeve **38** is then slipped over element **12**, so that element **12** is substantially inside sleeve **38**.

Figure 5 is a view of a fourth embodiment of the present invention, in which features of embodiments illustrated in Figures 1 or 3 and 4 are combined. A catheter **40** has both an induction coil **42**, like catheter **10** of Figure 1 or alternatively like catheter **30** of Figure 3, depending upon the length of induction coil **42**, and a permanent magnet **44** shown partially cut-away, like catheter **34** of Figure 4. A sleeve **46** extends from permanent magnet **44** along element **12**. When current flows through induction coil **42** in one direction, the magnetization of element **12** in the polarity of permanent magnet **44** is augmented and adjustable ring **14** expands. When current either flows through induction coil **42** in the opposite direction or does not flow, the magnetization of element **12** has the opposite polarity of permanent magnet **44** and adjustable ring **14** collapses (not shown).

In this case, at least permanent magnet **44** and induction coil **42**, and preferably permanent magnet **44** and sleeve **46**, and induction coil **42** and rheostat **22**, form a magnetization unit for catheter **34**.

Catheter **40** is assembled in a substantially similar manner as catheters **10** and **34**. Catheter **40** is assembled as for catheter **10**. Next, sleeve **46** is attached to permanent magnet **44**. Sleeve **46** is then slipped over element **12**, so that element **12** is substantially inside sleeve **46**.

Preferably, element **12** in any of the embodiments of Figures 1-6 is hollow. Also preferably, element **12** and adjustable ring **14** are both coated with a material which rejects adhesion by blood, cholesterol or other tissue components. Most preferably, the material is polytetrafluoro-ethylene. Alternatively and preferably, rather than being made from magnetizable metal, element **12** is made from material which is permanently magnetic. In this case, the magnetization of element **12** will be neutralized by induction coil **20** or **42**, depending on which embodiment is desired.

Figure 6 is a view of a catheter with a suction device according to the present invention. Catheter **10** is shown with a suction device **48**, which can be a pump, for example. Element **12** is preferably hollow in this embodiment, although element **12** can alternatively be substantially solid and an extra hollow tube **49** present as shown. In the first case, element **12** alone is a suction element, while in the second case, element **12** and tube **49** together form the suction element. The suction element also preferably includes at least one, and preferably a plurality of, suction tubes **50** connected to the suction element. The opening of each suction tube **50** should be placed at or near a least one, and preferably a plurality of openings **53** in adjustable ring **14**, which permits suction device **48** to exert a vacuum force through adjustable ring **14**. Catheter **10** can be used with induction coil **20** or alternatively, with induction coil **32**.

Catheter **10** is operated in a similar fashion as described above for Figure 1, at least until adjustable ring **14** is in position within the blood vessel. After

adjustable ring **14** is at the desired location within the blood vessel, adjustable ring **14** is expanded at least once, causing the blood vessel to be forcibly dilated. Now the force exerted by suction device **48** through suction tube **50** can remove at least a portion of the deposit or deposits on the wall of the blood vessel. Preferably, adjustable ring **14** is rapidly and repeatedly expanded and contracted in order to more efficiently loosen these deposits from the walls of the blood vessel. This is accomplished by using alternating current through oscillation controller **51**, so that adjustable ring **14** can oscillate. In this configuration, the diameter, force and frequency of oscillation can be controlled for maximum efficiency.

One further advantage of this configuration is that the deposits are not left on the wall of the blood vessel and any dislodged debris does not remain in the blood vessel. The likelihood of an embolism occurring can potentially be substantially reduced by removing this debris.

Figures 7A, 7B and 7C are views of a stent for repairing a damaged blood vessel wall, which is intended for use with the present invention. Stent **52** alone is shown in Figure 7A, and reference should also be made to Figures 2A, 2B and 6 for the description of operation of stent **52**. Stent **52** is made of flexible material and is preferably substantially continuous, such that stent **52** is a single piece of material without a beginning or an end. Stent **52** has a wall **54**. Wall **54** can have one of two different configurations, shown in Figures 7B and 7C.

Figure 7B shows a cross-sectional view of stent **52** through line A-A, showing the preferred features of a cell **56** and a cell **58**. Each cell **56**, of which there is preferably a plurality, contains component "A" of an adhesive. Each cell **58**, again of which there is preferably a plurality, contains component "B" of an adhesive. Neither component "A" nor component "B" alone has any adhesive quality. However, when component "A" and component "B" are mixed, the adhesive becomes activated. This mixing takes place when the walls of cells **56**

and **58** are ruptured and adjustable ring **14** is oscillated, during the following procedure.

Stent **52** is placed over adjustable ring **14**, so that adjustable ring **14** is substantially inside stent **52** (not shown) and stent **52** expands when adjustable ring **14** expands. Next, catheter **10** is placed at the portion of the blood vessel to be repaired, by a substantially similar method to that described for catheter **10** of Figure 6. Once catheter **10** is in place, adjustable ring **14**, and by extension stent **52**, is expanded by reversing the direction of current flowing through induction coil **20** or alternatively by allowing current to begin to flow through induction coil **20**, so that element **12** now repels adjustable ring **14**. The expansion of stent **52** causes cells **56** and **58** to rupture, so that components "A" and "B" can come in contact. As stent **52** is oscillated, or rhythmically expanded and contracted, by the oscillation of adjustable ring **14**, components "A" and "B" of the adhesive mix and the adhesive is activated. The adhesive causes stent **52** to become rigid and maintain the extended state of stent **52**. After the adhesive is cured, the current can be shut off, or the direction of flow of current reversed, and catheter **10** withdrawn from the subject. Stent **52** remains within the blood vessel because stent **52** maintains the expanded state relative to the diameter of the blood vessel (not shown).

Figure 7C shows the same cross-sectional view of wall **54**, except that the structure of wall **54** has been changed. Now, wall **54** includes at least one, and preferably a plurality of magnetic units **60**, so that stent **52** is magnetizable. Each magnetic unit **60** is attached to wall **54**, and preferably embedded in wall **54**. If there is more than one magnetic unit **60**, at least a portion of said magnetic units **60** is arranged with the same pole **28** facing inward towards the interior of stent **52**. Each magnetic unit **60** can be any form of material, such as magnetizable metal, which causes stent **52** to be magnetizable including, but not limited to, powder either coated on wall **54** or embedded within wall **54**, or both, a chip or a thin section of foil either attached to wall **54** or embedded within wall **54**, or both.

If powder is used, preferably each magnetic unit **60** is arranged vertically in relation to element **12**.

The operation of stent **52** in this embodiment is similar to that described above, except that since stent **52** is directly magnetizable, the magnetic force acts on stent **52** directly, without adjustable ring **14**. Furthermore, stent **52** also includes at least one, and preferably a plurality of fibers (not shown), similar to fiber **18**. Each fiber attaches stent **52** to element **12**, until stent **52** is in place and the adhesive is cured. At that point, each fiber is cut, so that catheter **10** can be withdrawn from the subject, leaving stent **52** behind.

Although the operation of stent **52** has been described using catheter **10** of Figure 6, it should be understood that the catheters shown in Figures 1, 3, 5 or 8-10 can be also be used with stent **52**, if the electrical current flowing through the induction coil is alternating current. If alternating current is used, any of these catheters, in combination with stent **52**, can be described as a "repair catheter".

Figures 8A and 8B are views of a catheter in which the diameter of the ring is controlled by an external magnet. Figure 8A shows catheter **10** with an element **62**. Element **62** is made of substantially non-magnetizable material. Adjustable ring **14** is substantially similar as shown in Figures 1 and 2. However, the magnetic force controlling the diameter of adjustable ring **14** is now supplied outside the body of a subject **64**, as shown in Figure 8B. Subject **64** is shown schematically. At least one, and preferably a plurality of, magnetization units **66** are disposed substantially near subject **64**. Each magnetization unit **66** is formed from an induction coil **68** and a conductor **70**, preferably with at least one rheostat **72**. Induction coil **68** can be a single wire, or alternatively and preferably, induction coil **68** is a plurality of separate wires. In the latter case, each wire of induction coil **68** can be connected together with only one wire directly connected to rheostat **72**. Alternatively and preferably, each wire of induction coil **68** can be directly connected to each of a plurality of rheostats **72**,

so that the flow of electricity, and hence the magnetic force, can be substantially separately regulated for each magnetization unit **66**.

Induction coil **68** is wrapped substantially around conductor **70** and is then preferably attached to rheostat **72**. Rheostat **72** regulates the flow of electricity from a source of electricity **73** through induction coil **68**. A switch (not shown) is preferably used to determine the direction of the flow of electricity. Also preferably, an oscillation controller **75** is also used to permit adjustable ring **14** to be rapidly and repeatedly expanded and contracted in order to more efficiently loosen deposits from the walls of the blood vessel. However, alternating current must be used with oscillation controller **75**. In this configuration, the diameter, force and frequency of oscillation can be controlled for maximum efficiency.

When electricity is permitted to flow through induction coil **68**, conductor **70** becomes magnetized. The polarity of conductor **70** depends upon the direction of the flow of electricity through induction coil **68**. Electricity flowing through induction coil **68** is preferably alternating current, so that the direction of flow is changeable, although direct current can also be used as described for the catheter of Figures 1 and 2.

The operation of catheter **10**, as depicted in Figures 8A and 8B, is substantially similar to that of the catheter of Figures 1 and 2, with one exception. Since the magnetic power is now being supplied outside subject **64** and element **62** is made of substantially non-magnetizable material, the diameter of adjustable ring **14** is now only controlled either by allowing electricity to flow through induction coil **68**, or alternatively by changing the direction of electricity flowing through induction coil **68**. In the first case, when electricity flows through induction coil **68**, adjustable ring **14** expands, and when electricity does not flow through induction coil **68**, adjustable ring **14** collapses.

In the second case, when electricity is flowing substantially in one direction, adjustable ring **14** has a first diameter and when electricity is flowing substantially in an opposing direction, adjustable ring **14** has a second diameter.

For example, in the first direction, conductor **70** attracts adjustable ring **14**, so that adjustable ring **14** expands. Then in the second direction, conductor **70** repels adjustable ring **14**, so that adjustable ring **14** contracts. Preferably, a plurality of magnetization units **66** are disposed relatively evenly around subject **64**, so that the magnetic force is substantially evenly distributed around subject **64**.

Figure 9 is a view of a catheter in which each induction coil is extended along each adjustable ring. Figure 9 shows catheter **10** which is substantially similar to the catheter shown in Figures 1 and 2, except that the structure of an adjustable ring **72** is different. Preferably, there is a plurality of adjustable rings **72**. Each adjustable ring **72** is made of magnetizable metal and is preferably divided into at least two sections **74**, and most preferably into more than two sections **74**. Each section **74** has an induction coil **76** wrapped substantially around section **74**. Induction coil **76** is then preferably attached to rheostat **78**. Rheostat **78** regulates the flow of electricity from a source of electricity (not shown) through induction coil **76**. A switch (not shown) is preferably used to determine the direction of the flow of electricity. Induction coil **76** and adjustable ring **72** together form a magnetization unit **80**, preferably with rheostat **78**.

When electricity is permitted to flow through induction coil **76**, each adjustable ring **72** becomes magnetized. The polarity of each part **74** of each adjustable ring **72** depends either upon the actual flow of electricity through induction coil **76**, or alternatively and preferably, upon the direction of the flow of electricity through induction coil **76**. Preferably, electricity flowing through induction coil **76** is alternating current, so that the direction of flow is changeable, although direct current can also be used.

The operation of catheter **10**, as depicted in Figure 9, is substantially similar to that of the catheter of Figures 1 and 2, with one exception. The diameter of adjustable ring **72** is now directly controlled either by the actual flow of electricity through induction coil **76**, or alternatively and preferably, by the

preferably, by the direction of electricity flowing through induction coil **76**. In the first case, when electricity flows through induction coil **76**, adjustable ring **72** expands, and when electricity does not flow through induction coil **76**, adjustable ring **72** collapses.

In the second case, when electricity is flowing substantially in one direction, adjustable ring **72** has a first diameter and when electricity is flowing substantially in an opposing direction, adjustable ring **72** has a second diameter. For example, in the first direction, adjustable ring **72** is repelled from element **12**, so that adjustable ring **72** expands. Then in the second direction, adjustable ring **72** is attracted to element **12**, so that adjustable ring **72** contracts. One particular advantage of this configuration is that a plurality of adjustable rings **72** can be located along element **12**, but controlled individually, so that each adjustable ring **72** can have a different diameter. Furthermore, the horizontal location of each adjustable ring **72** can be adjusted with respect to another adjustable ring **72**, by controlling the polarity of rings **72** at one edge so that both adjustable rings **72** repel one another.

Figure 10 shows a catheter in which the magnetic force is controlled by the relative position of an inserted magnetic element. A catheter **80** has an element **82**. Element **82** includes a substantially non-magnetizable sheath **84** and a magnetic rod **86**. Catheter **80** also has adjustable ring **14**. The operation of catheter **80** is as follows. When catheter **80** is inserted into a blood vessel (not shown), adjustable ring **14** has a first diameter. At the appropriate location within the blood vessel, rod **86** is removed, causing adjustable ring **14** to expand to a second, substantially larger diameter (not shown). Alternatively and preferably, rod **86** is not present within sheath **84** when catheter **80** is inserted into the blood vessel. Rod **86** is then inserted into sheath **84** at the appropriate location within the blood vessel, causing adjustable ring **14** to expand. The appropriate behavior of adjustable ring **14** relative to the location of rod **86** depends upon the correct position of the poles of the various magnets, as described above.

While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications and other applications of the invention may be made.

WHAT IS CLAIMED IS:

1. A catheter, comprising:

(a) an element;

(b) at least one adjustable ring attached to said element such that at least a portion of said element is substantially within said at least one adjustable ring, said at least one adjustable ring having at least a first diameter and at least a second diameter, and said at least one adjustable ring being magnetizable; and

(c) a magnetization unit located near a portion of said at least one adjustable ring, said magnetization unit determining when said at least one adjustable ring has said first diameter and when said at least one adjustable ring has said second diameter.

2. The catheter of claim 1, wherein said magnetization unit includes an induction coil wrapped substantially around said at least one adjustable ring.

3. The catheter of claim 1, wherein said magnetization unit includes an induction coil wrapped substantially around a conductor.

4. The catheter of claim 1, wherein said at least one adjustable ring features a plurality of sections and a diameter of each of said sections is substantially separately adjustable.

5. The catheter of claim 1, wherein said element features a magnetic rod, a location of said rod relative to said at least one adjustable ring substantially determining said diameter of said at least one adjustable ring.

6. The catheter of claim 1, further comprising a stent, at least a portion of said at least one adjustable ring being substantially within said stent, said stent having at least a first diameter and at least a second diameter, said stent being magnetizable and said stent containing activatable adhesive, said activatable adhesive being activated when said stent has said second diameter such that said stent becomes substantially rigid.

7. The catheter of claim 1, wherein said at least one adjustable ring is a stent, said stent containing activatable adhesive, said activatable adhesive being activated when said stent has said second diameter such that said stent becomes substantially rigid.

8. A method of catheterizing a biological duct of a subject, the biological duct having a wall, the method comprising the steps of:

(a) inserting the catheter of claim 1 into the biological duct of the subject with said at least one adjustable ring of the catheter having said first diameter such that said at least one adjustable ring substantially does not contact the wall of the biological duct;

(b) causing said at least one adjustable ring to have said second diameter, said second diameter being substantially larger than said first diameter; and

(c) contacting the wall of the biological duct with said at least one adjustable ring having said second diameter.

9. The method of claim 8, wherein the wall of the biological duct is contacted more than once with said at least one adjustable ring.

10. The method of claim 8, further comprising the steps of:

(d) causing said at least one adjustable ring to substantially return to having said first diameter; and

(e) withdrawing said catheter from said biological duct.

11. The method of claim 8, wherein said catheter further comprises a plurality of adjustable rings and each of said adjustable rings has a substantially different diameter relative to others of said adjustable rings.

12. The method of claim 8, wherein said element features a magnetic rod, a location of said rod relative to said at least one adjustable ring substantially determining said diameter of said at least one adjustable ring.

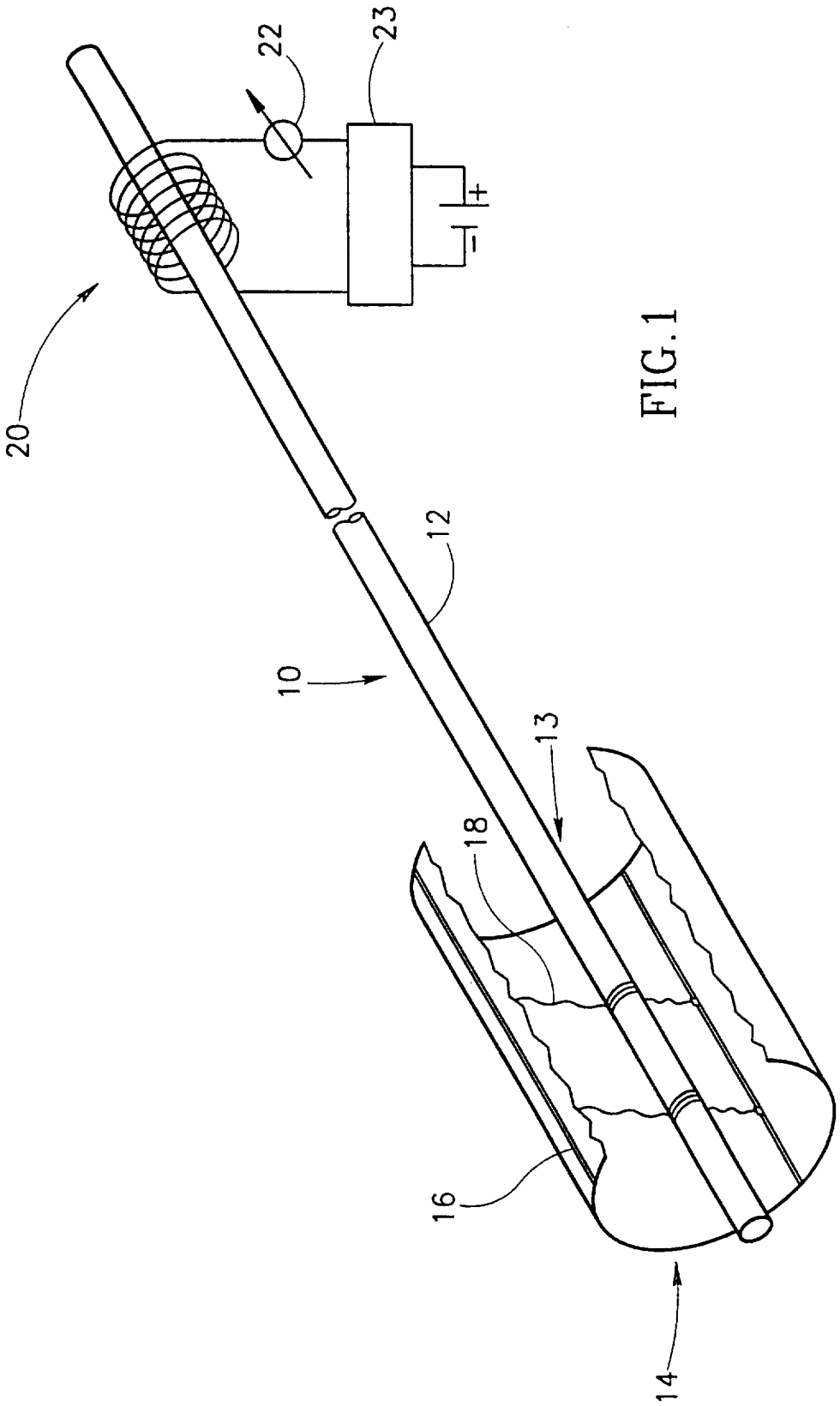


FIG. 1

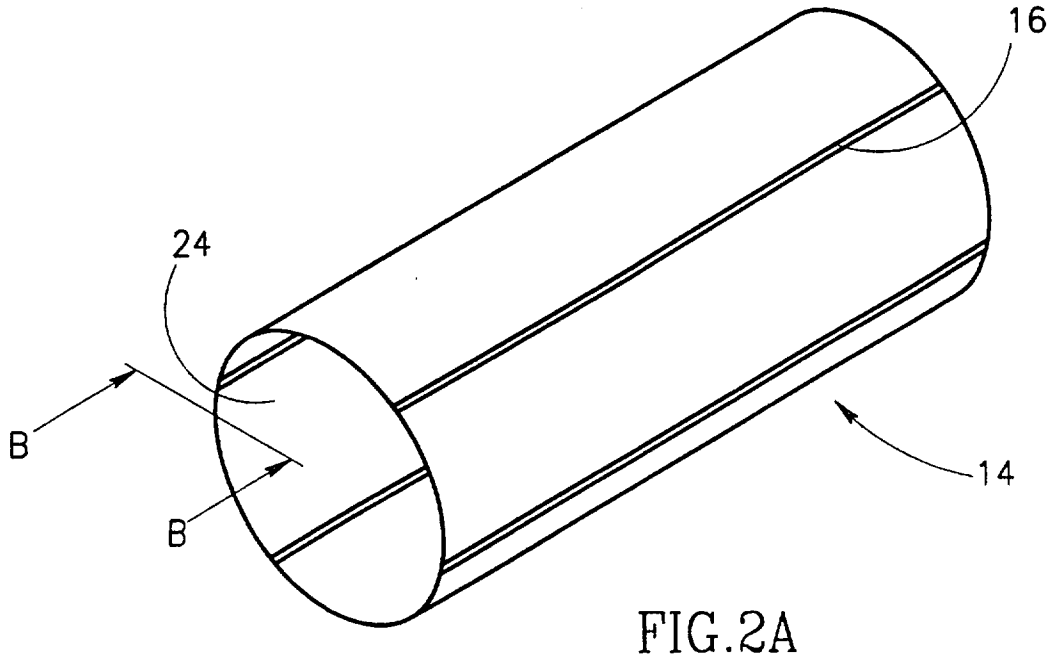


FIG.2A

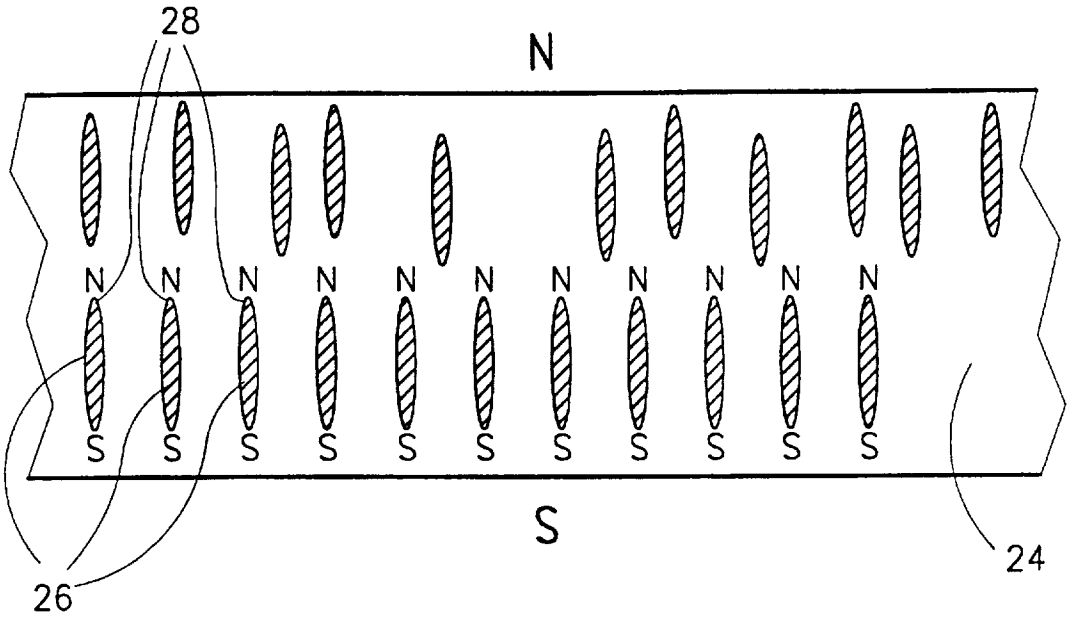


FIG.2B

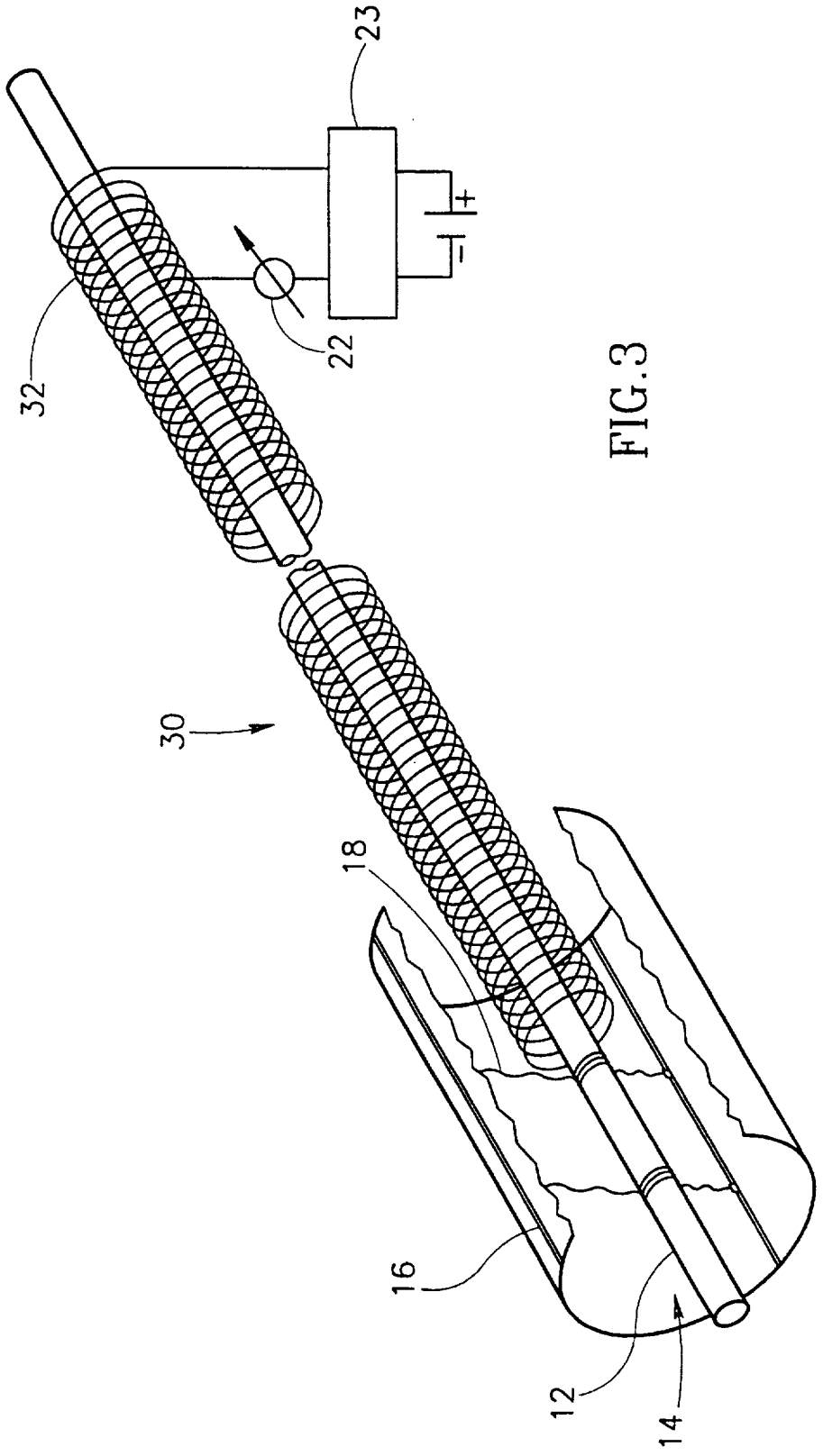


FIG.3

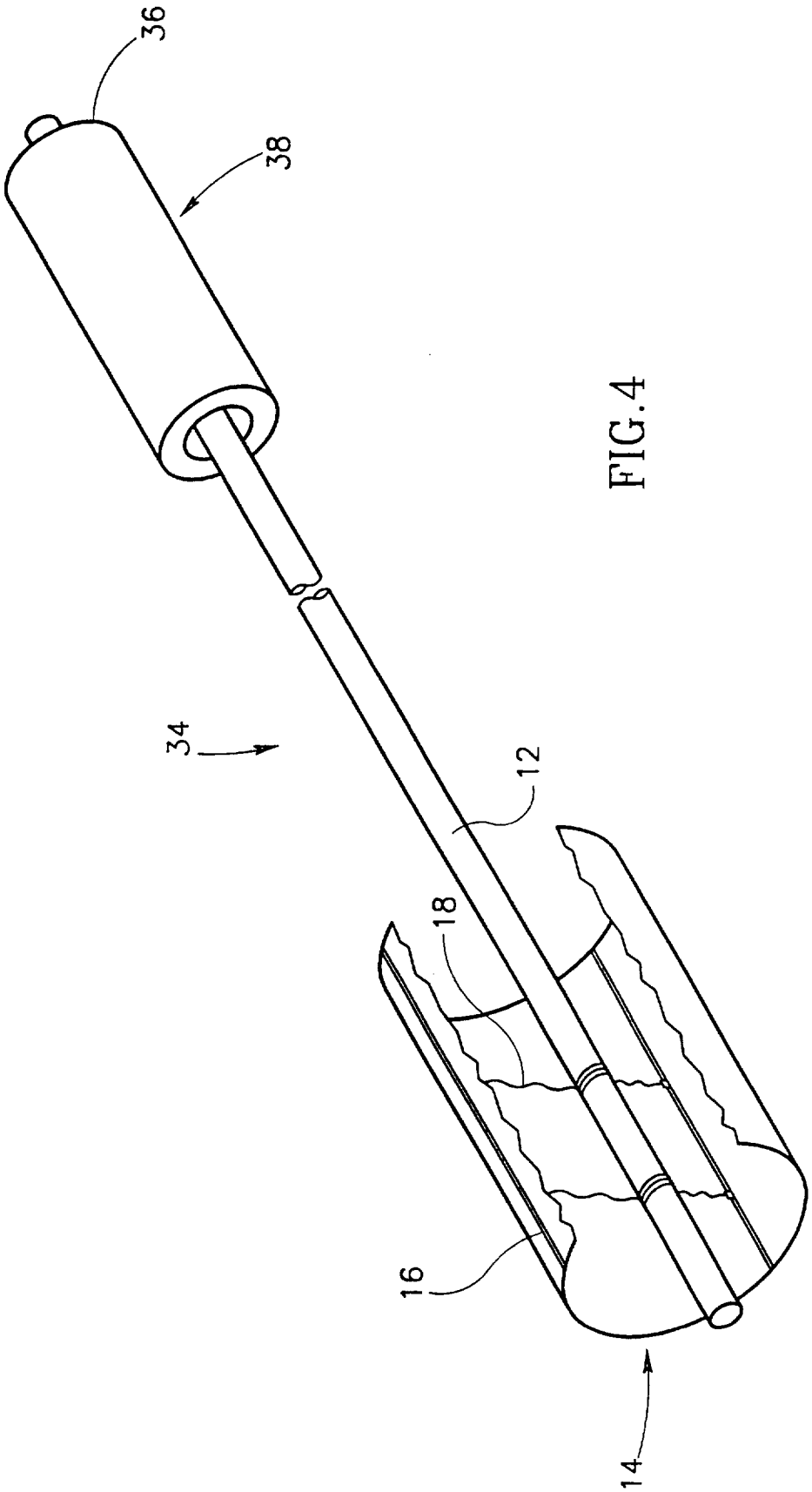


FIG.4

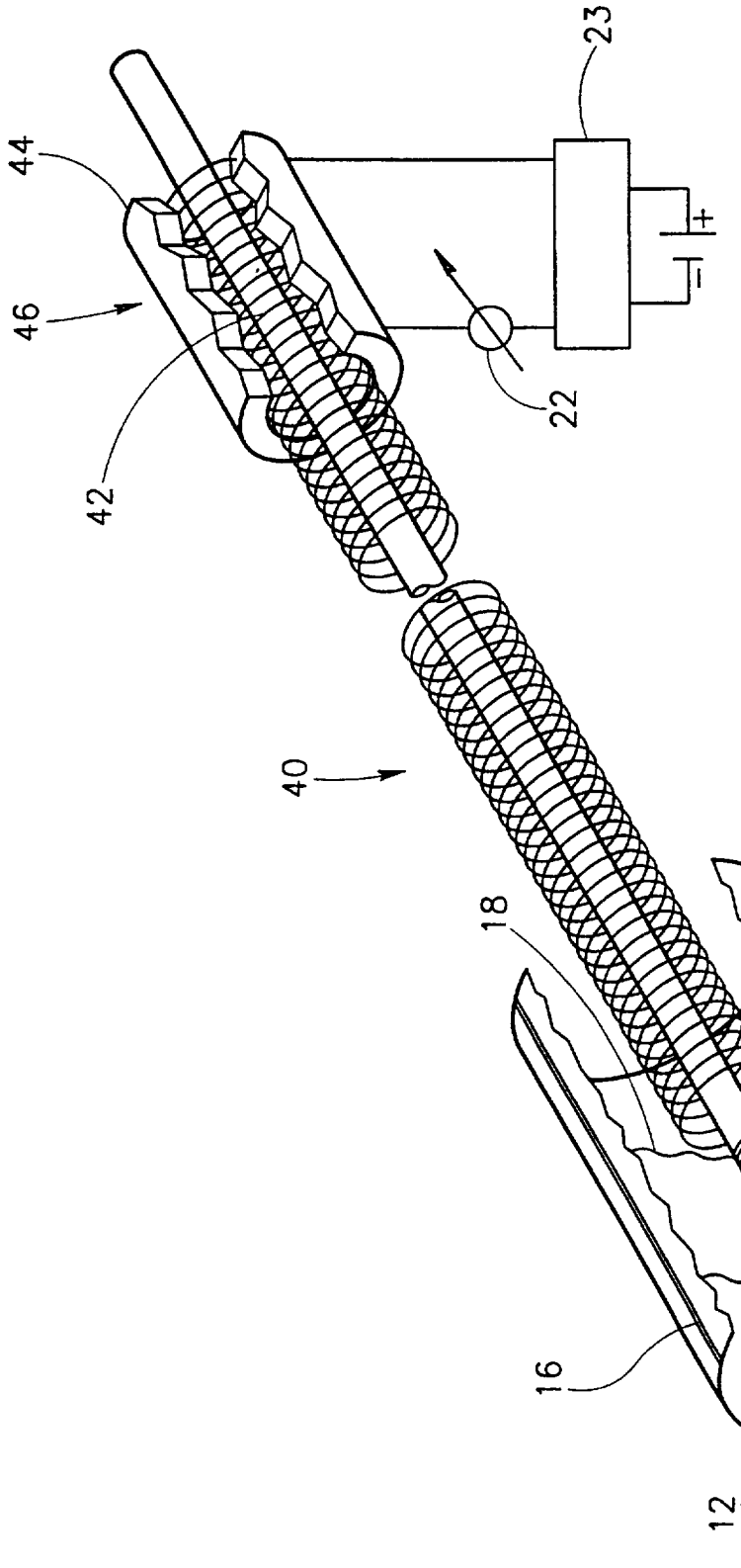


FIG.5

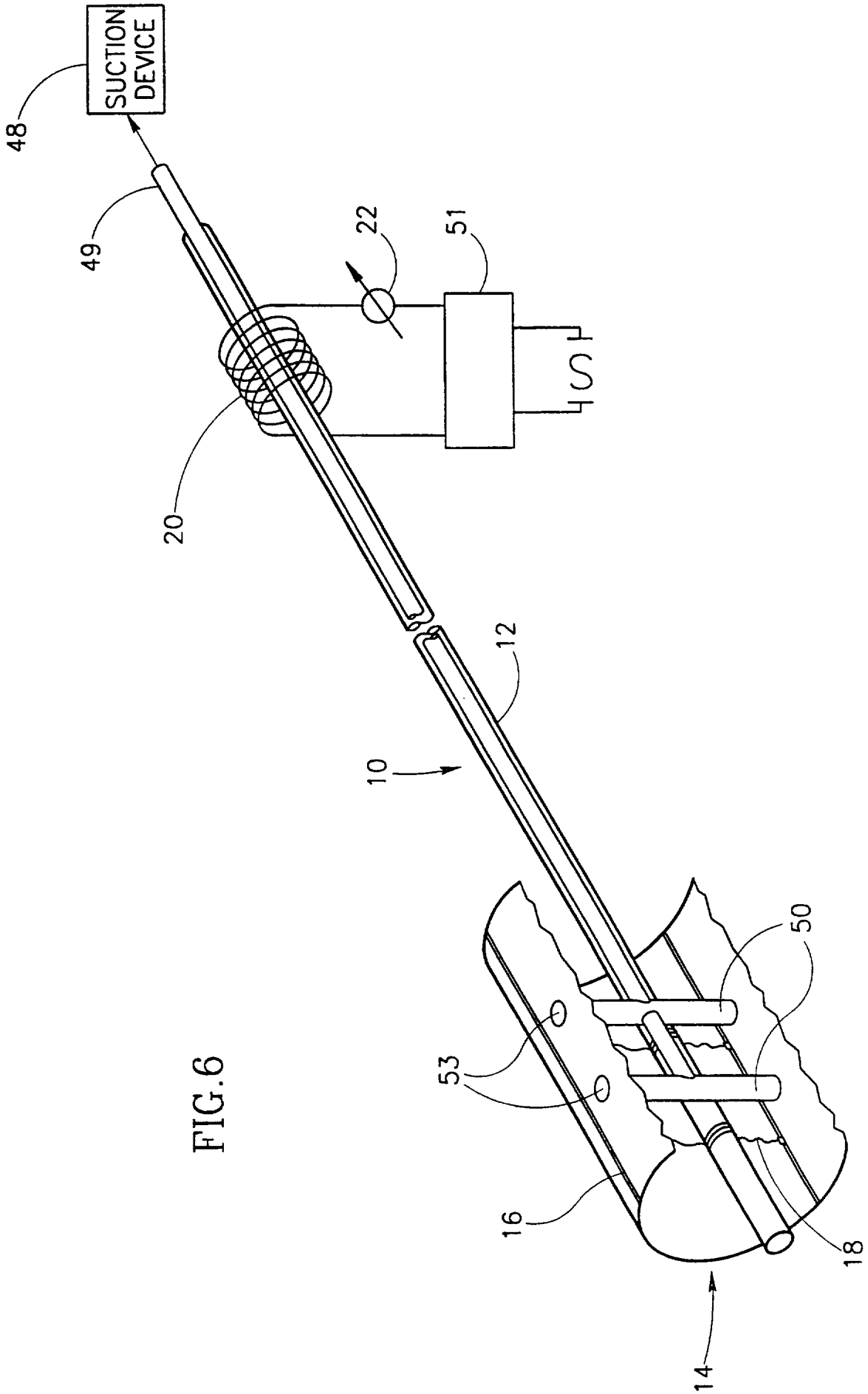


FIG.6

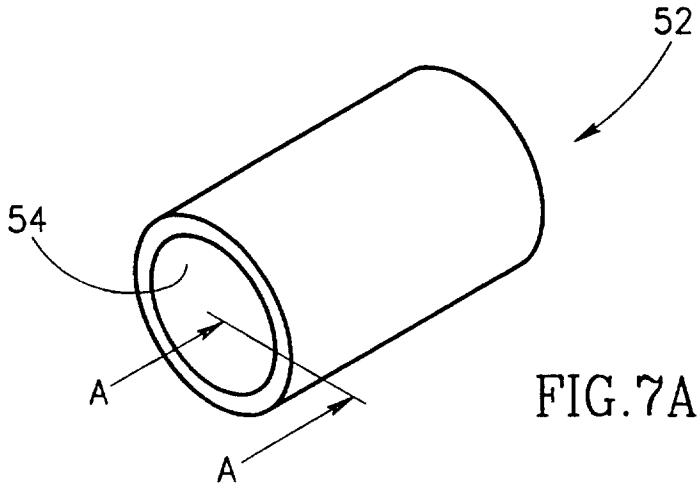


FIG.7A

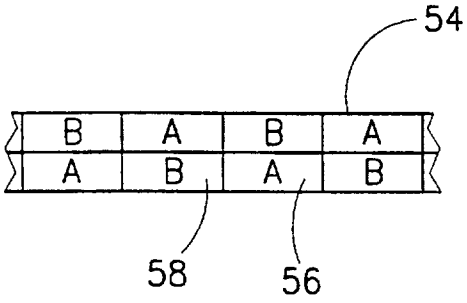


FIG.7B

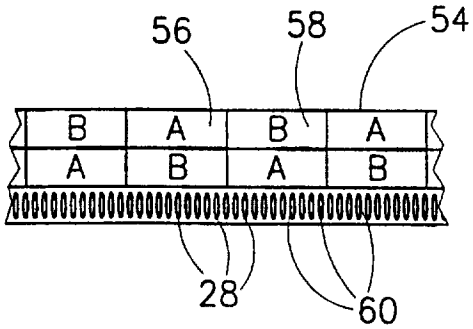


FIG.7C

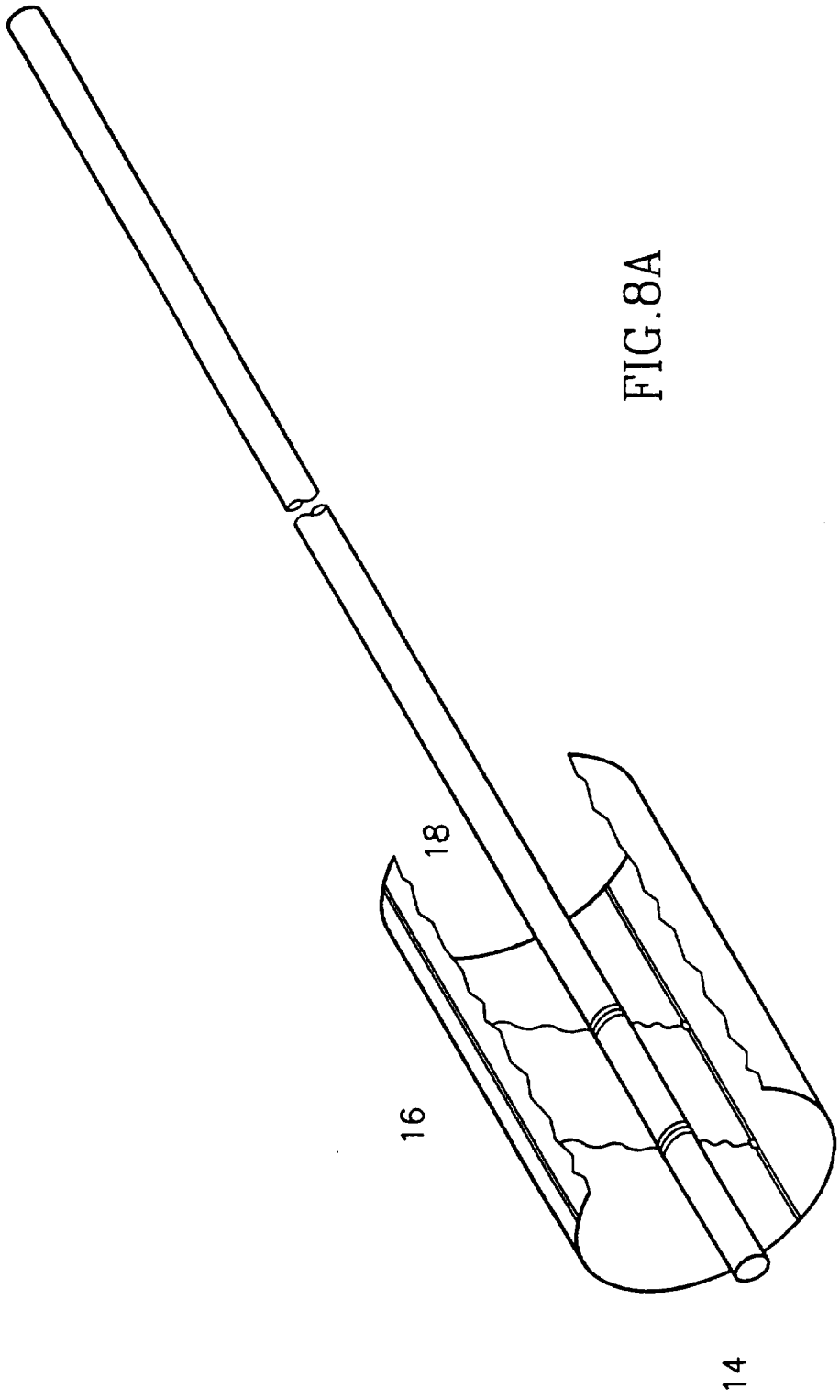


FIG.8A

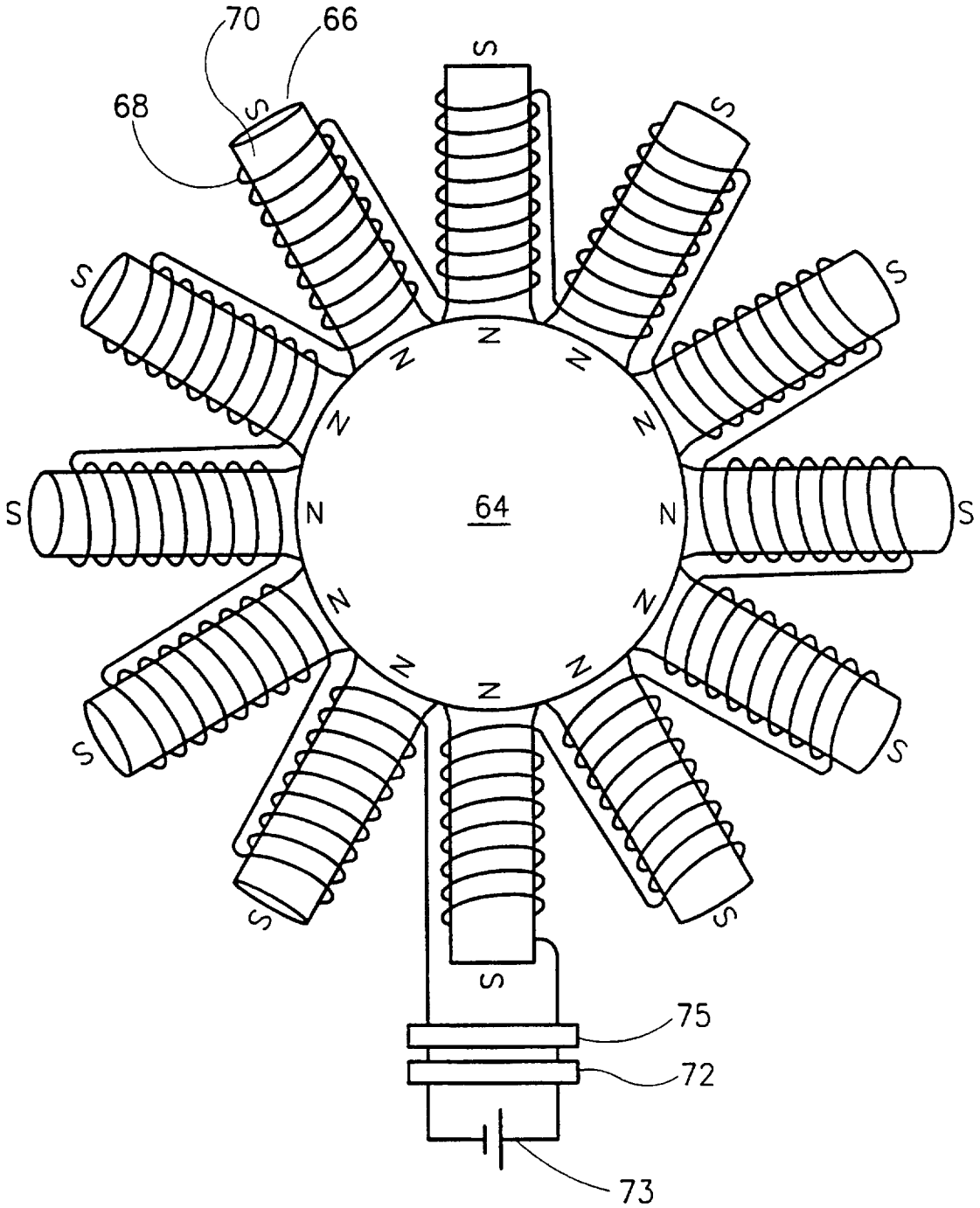


FIG.8B

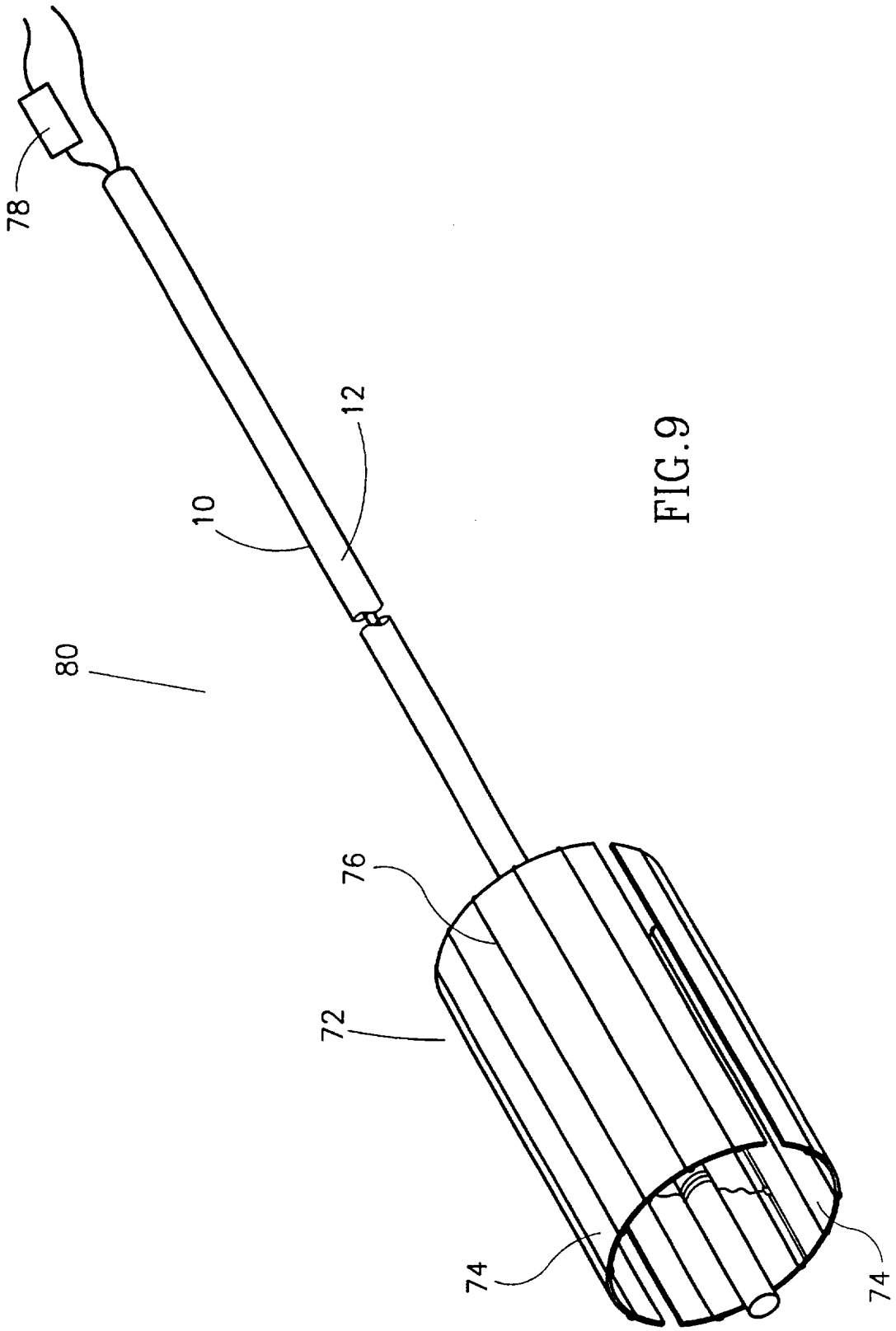


FIG.9

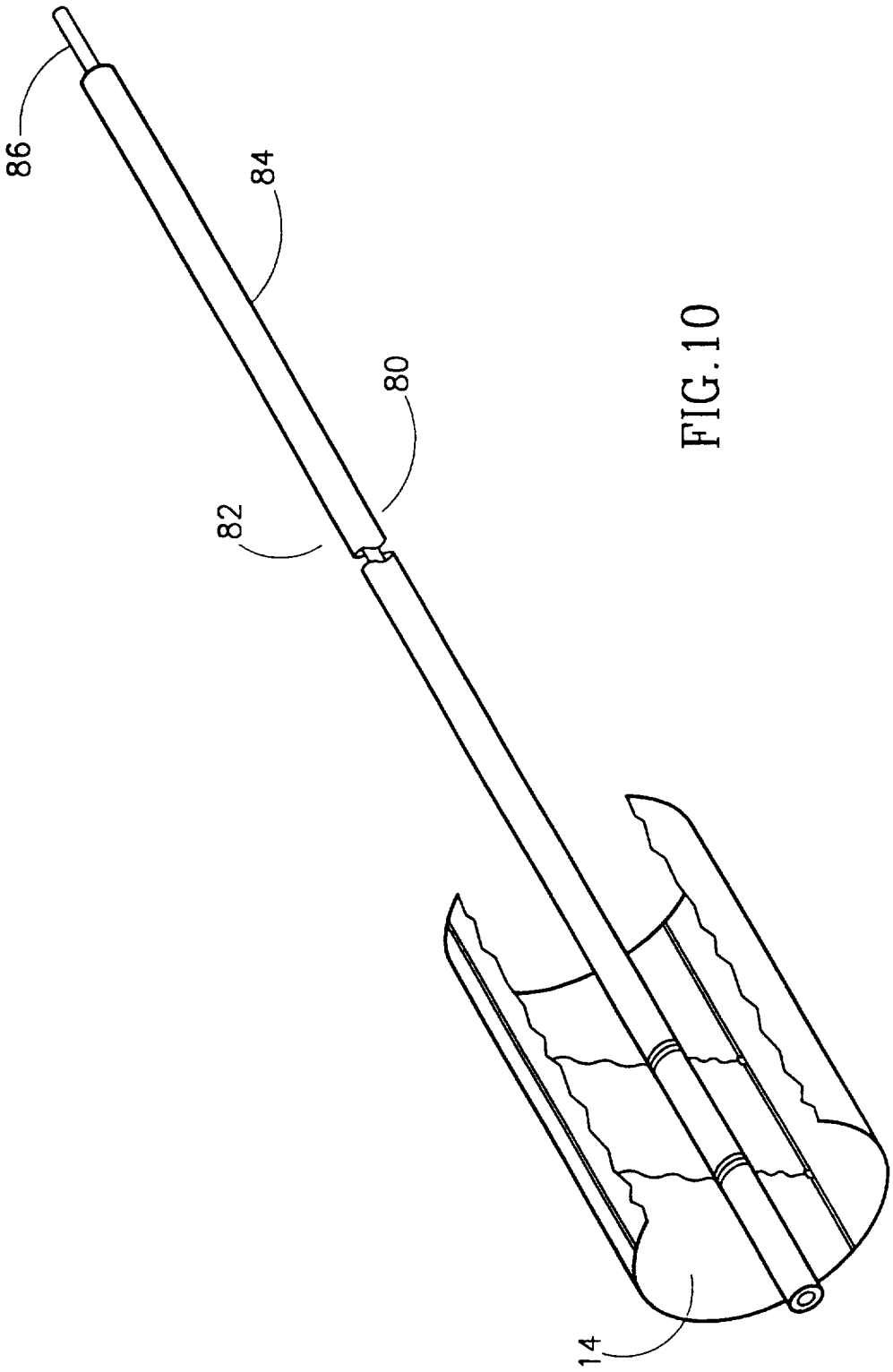


FIG.10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/14236

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/00, 29/00, 37/00; A61N 1/30
US CL :600/12; 604/21, 104, 282; 606/198
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. : 600/12; 604/21, 93, 104, 107-109, 281, 282; 606/191-194, 198

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)

APS
Search Terms: catheter, expand or dilate, magnet?, stent or implant

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 5,571,135 A (FRASER et al) 05 November 1996, discloses magnetic retaining means external to body mating with magnetic means on inserted catheter.	1-12
A	US 5,540,712 A (KLESHINKSI et al) 30 July 1996, discloses the use of applied magnetic field to orient the shape memory alloy used to form an expandable vascular stent.	1-12
A	US 5,445,646 A (EUTENEUER et al) 29 August 1995, discloses magnetic securing means.	1-12
Y	US 5,409,460 A (KRUMME) 25 April 1995, discloses expandable shape memory alloy stent deployable by the application of magnetic field, col. 5 lines 49-65.	1-12

[X] 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 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 12 SEPTEMBER 1997	Date of mailing of the international search report 14 OCT 1997
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer CHALIN SMITH Telephone No. (703) 308-2988

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/14236

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,812,841 A (ISAACSON) 28 May 1974, discloses magnetically activated valve mechanism.	1-12
A	US 4,315,509 A (SMIT) 16 February 1982, discloses magnetically driven peristaltic mechanism.	1-12