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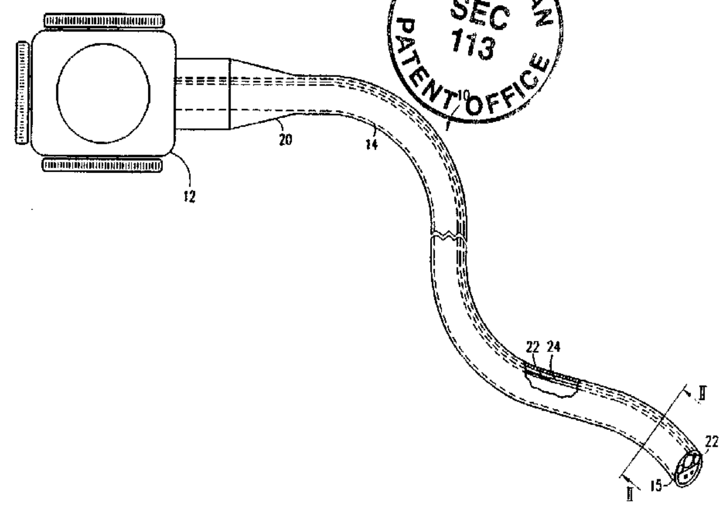
(54) Title: PRECISE POSITION DETERMINATION OF ENDOSCOPES



(57) Abstract

A locatable endoscope (14) attachment including an attachment (20) connectable to an insertion tube portion of an endoscope for determining the endoscope's (14) position; and one or more sensors (22), fixedly positioned with respect to the attachment (20), which are used for determining the positions of the one or more sensors (22). Preferably, when the attachment (20) is fixedly attached to the endoscope (14), the one or more sensors (22) are distanced from elements of the endoscope which interfere with determining the positions of the one or more sensors (22).

PRECISE POSITION DETERMINATION OF ENDOSCOPES

RELATED APPLICATIONS

This application is related to U.S. provisional application serial numbers 60/011,743, titled "Pointing Device Packages", filed on February 15, 1996 and 60/012,242, titled "Open-Lumen Passive Position Sensor", filed on February 26, 1996, the disclosures of which are incorporated herein by reference. This application is also related to the following PCT applications filed on even date as the instant application by applicant Biosense Inc.: A PCT application titled "Locatable Biopsy Needle", filed in the Israeli receiving office, a PCT application titled "Catheter with Lumen" and a PCT application titled "Medical Probes with Field Transducers", both filed in the U.S. receiving office, the disclosures of all of which are incorporated herein by reference. This application is a CIP of PCT application serial number PCT/IL97/00010, titled "Cardiac Electro-Mechanics" and filed in the Israeli receiving office by applicant Biosense LTD. on January 8, 1997, the disclosure of which is incorporated herein by reference. The above PCT applications designate, *inter alia*, the U.S.

FIELD OF THE INVENTION

The present invention relates generally to the field of endoscopy, and specifically to endoscope assemblies with position sensors.

BACKGROUND OF THE INVENTION

The use of endoscopes for diagnostic and therapeutic indications is rapidly expanding. There are now many types of specialized endoscopes, such as endoscopes for the upper esophagus, stomach, and duodenum; angioscopes for blood vessels; bronchoscopes for the bronchi; arthroscopes for joint spaces; colonscopes for the colon; and laparoscopes for the peritoneal cavity. The present invention applies to all types of endoscopes.

Typically, endoscopes have a long and flexible insertion tube with a diameter ranging between 15 - 25 millimeters. The insertion tube is inserted into a patient's body, along a selected path, during an endoscopic procedure. Multiple work channels usually extend along the length of the endoscope within the insertion tube. The work channels may allow, for example, air insufflation and water flow into the body. The work channels also allow inserting biopsy tools into and taking biopsies from the patient's body. Other mechanisms, which may be incorporated in the endoscope, are a visual imaging device, an illumination device, and a deflection mechanism. The proximal end of the endoscope usually has a handle in which the controls of the endoscope reside. Ordinarily, endoscopes are made of metallic, electrically conducting, materials. For example, U.S. Patent 4,869,238 whose disclosure is incorporated herein by reference, describes a standard three-layer wall for endoscopes, containing metal coils and wire mesh.

Cleaning and sterilizing endoscopes are expensive and tedious procedures. Endoscopes incorporate expensive and delicate apparatus which may be damaged during cleaning. Also, the long and narrow work channels in the insertion tube are difficult to clean.

Disposable endoscopic sheaths have been developed, to avoid the need for cleaning and sterilizing endoscopes. These sheaths substantially isolate the endoscope from the patient, and thus prevent the endoscope from being contaminated. Some of these sheaths have thick walls containing work channels within them, leaving only part of their cross-section for a lumen which receives the insertion tube of the endoscope. The walls of the work channels and the areas between the work channels usually comprise the same material as the outer wall.

A sheath with thick walls is described, for example, in PCT publication WO 94/28782, whose disclosure is incorporated herein by reference. WO 94/28782 describes a disposable sheath which may include work channels. The sheath removably receives a cylindrical insertion tube which contains controls and other delicate apparatus of the endoscope. Another disposable sheath is described in U.S. Patent 5,483,951, whose disclosure is incorporated herein by reference. This disposable sheath comprises a thin outer wall, inner work channels, and a lumen with a "D" shaped cross-section. The lumen is adapted to receive and substantially isolate a non-disposable insertion tube of an endoscope, which is accordingly "D" shaped.

Many endoscopic procedures involve irreversible actions such as taking tissue samples and ablation at the distal end of the insertion tube of the endoscope. Performing these actions at an incorrect position can damage important blood vessels or nerves, puncture the intestine, or otherwise cause severe damage to the patient. Therefore it is useful to have a method of determining the position and/or orientation of the distal end of the endoscope.

Through a visual imaging device the user can observe images transmitted from the distal end of the endoscope. From these images and from knowledge of the path the endoscope has followed, the user can ordinarily determine the position of the endoscope. However, there are organs of the human body in which the images and knowledge of the path do not suffice to determine the position of the endoscope to sufficient accuracy. Some organs, such as the brain, have a homogenous appearance in which it is very hard or even impossible to find a specific point based only on the images from the imaging device. In addition, determining the position of the endoscope from the images could be very time consuming. In many endoscopic procedures, such as endoscopic bypass surgery, the amount of time a patient can endure the endoscopic procedure is limited.

In some procedures, the endoscope is used to map a section of an organ. The map is produced by systematically bringing the distal end of the endoscope in contact with a plurality of points within the organ and registering the positions of the points. To confirm that the entire section of the organ has been mapped, a sufficient density of points must be registered within the section. To insure use of a sufficient density of points it is necessary to have unique position identification for every point.

Another problem which arises, for example, in colonscope procedures, is formation of loops in the long and narrow tube of the colonscope. Such loops may arise when the insertion tube encounters an obstacle, or gets stuck in a narrow passage. Instead of progressing, the tube forms loops within the patient. In an attempt to proceed in insertion of the colonscope, excess force may be exerted, damaging delicate tissue in the patient's body. The user may proceed with the attempted insertion of the endoscope without realizing there is a problem. The ability to see the configuration of the endoscopic insertion tube within the patient's body, allows early discovery of the existence of loops and makes straightening them simpler.

One method used in the art to determine the configuration of the insertion tube is x-ray imaging. Another method used is magnetic field positioning, which avoids the x-ray exposure to the patient and the operator. PCT application PCT/GB93/01736, whose disclosure is incorporated herein by reference, describes a method of magnetic field position determination using low frequency magnetic fields to determine the position of a miniature sensor embedded within a colonscope tube. Based on the position of the sensor at sequential time periods, an image of the configuration of the colonscope tube is produced.

In tests mentioned in PCT/GB93/01736 it was found that there were some distortions in the image due to the metallic construction of the colonscope. The metallic construction of the colonscope reacts with the sensing magnetic field in that currents are induced in the colonscope by the magnetic field. These currents, called eddy currents, generate a disturbing magnetic field which is overlaid on the sensing magnetic field. Thus, the amplitude and/or phase of the magnetic field used by the position determining system are changed in proximity of metallic substances. The magnitude and effect of the eddy currents depend on the size and geometry of the metallic substances. For example, large metal rings change the magnetic field substantially in their proximity. Conversely, small metal objects and objects with a relatively high resistance, within which substantially no eddy currents are formed, does not substantially affect the magnetic field.

Magnetic field position determining systems typically determine positions according to the magnetic field's amplitude and/or its phase. Changes in the amplitude and/or phase due to eddy currents cause inaccuracies in determined positions and interfere with precise determination of positions. Interference can also arise from ferro-magnetic materials in the endoscope, which concentrate the magnetic field in their proximity. Thus, ferro-magnetic materials cause distortions in the magnetic field, changing the amplitude and phase of the field at measured points.

The interference is dependent on the frequency of a drive signal which generates the magnetic field. A high drive signal frequency is preferred in order to enhance sensor sensitivity, but must be limited so as not to intensify the interference to the position determining system. Therefore, the PCT/GB93/01736 system makes a compromise in its choice of the frequency used. If a different method to minimize the interference is used, it would be possible to enjoy the advantages of a higher drive signal frequency.

Existing catheters have a metal coil (for structural purposes) within them. The coil extends along the length of the catheter except for a small part of the distal end of the catheter. A sensor coupled with a magnetic field position determining system is embedded within the distal end of the catheter.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide accurate positioning of an endoscope using a magnetic field position determining system.

Accordingly, the invention provides a position determining system for an endoscope comprising:

an attachment connectable to a portion of an endoscope;

one or more sensors within said attachment, said one or more sensors capable of transmitting and receiving magnetic fields; and

a sheath for covering said attachment.

Preferably, the position determining system includes an endoscope.

In a further preferred embodiment the one or more sensors are embedded within the attachment.

Preferably markings are provided on the outside of the attachment which indicate the positions of the one or more sensors.

In a preferred embodiment the attachment comprises a tube.

The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an endoscopic sheath installed over a colonscope, in accordance with a preferred embodiment of the present invention;

Fig. 2 is an enlarged cross-sectional view of the endoscopic sheath of Fig. 1, taken along line II-II toward the distal end of the endoscopic sheath, not showing the colonscope's insertion tube;

Fig. 3 is a side cross-sectional view of a further preferred embodiment of the present invention;

Fig. 4 is a cross-sectional view of another preferred embodiment of the present invention;

Fig. 5 is a perspective view of an endoscope with sensor attachments in accordance with a preferred embodiment of the present invention;

Fig. 6 is a cross-sectional view of yet another preferred embodiment of the present invention; and

Fig. 7 is a side cross-sectional view of an endoscope in accordance with another preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Reference is made to Fig. 1 which shows a flexible endoscopic sheath 20, installed over an endoscopic insertion tube 14 of a colonscope. Colonscope 10, comprises a control unit 12 and insertion tube 14 which has a distal end 15. Colonscope 10 is placed in a flexible endoscopic sheath 20, which is adapted to tightly receive tube 14. Insertion tube 14 and sheath 20 are inserted together into a patient's body, such that tube 14 is essentially isolated from the patient's body. One or more sensors 22 are embedded along sheath 20 as described below. A position determining system (not shown) determines the position in space of sensors 22, preferably, according to magnetic fields transmitted to and/or from sensors 22.

Insertion tube 14 is a long and narrow flexible tube with durable walls, and preferably has a "D" shaped cross-section. A deflection mechanism, a visual imaging device, and possibly other apparatus are located within tube 14. Wires serving the apparatus within the colonscope, run along insertion tube 14 from its distal end 15 to control unit 12. Ordinarily, tube 14 is a non-disposable elongate tube, which comprises electrical conducting materials.

Flexible endoscopic sheath 20 is an elongate disposable tube which generally comprises materials which do not interfere with the operation of the position determining system. Interfering materials include electrically conducting materials, and ferro-magnetic materials. Preferably, sheath 20 comprises polyethylene or polyvinylchloride ("PVC"), but can comprise any durable lubricious material. It is noted that in some prior art descriptions sheath 20 also comprises a metal spring or other electrically conducting part. In the present invention, where such sheaths are used, measurements are preferably made, in the design stage, to determine the interference induced by the conducting part. The influence of the conducting part of the sheath may be ignored if the interference it induces is small relative to the interference induced by materials within the colonscope. Alternatively, in accordance with the present invention, a similar sheath may be used in which the conducting part is replaced by a functionally equivalent part, comprising non-conducting materials.

As can best be seen in Fig. 2, which is a cross-sectional view of endoscopic sheath 20 of Fig. 1, without the colonscope's insertion tube, sheath 20 preferably has a circular external cross-section. Within sheath 20 there is a lumen 17, shaped and sized to tightly receive insertion tube 14. The rest of the cross-section of sheath 20 contains several work channels 25, 26 and 27 running substantially parallel to the longitudinal axis of sheath 20. Work channels

25, 26 and 27 are used to pass materials and apparatus in and out of the patient's body, such materials as air, water and also biopsy taking apparatus. In an exemplary embodiment channel 25 is an air channel, channel 26 is a water channel, and channel 27 is used for passing biopsy taking apparatus into the patient and is called a biopsy channel. It is noted that occasionally, electrically conducting apparatus, which induces interference, is passed through biopsy channel 27. Ordinarily, substantially no interference to the operation of the position determining system is caused by such apparatus, because of the small size of the apparatus, and the distance between the apparatus and sensors 22. However, preferably, work channels near sensors 22 are allocated tasks which do not include passing interfering materials through them. Accordingly, sensors 22 are embedded farthest from biopsy channel 27. In other words, the channel farthest from sensors 22 is used for biopsy apparatus.

As mentioned above, along sheath 20 there are one or more miniature sensors 22, which are used in conjunction with the position determining system. In a preferred embodiment of the invention the sensors sense the amplitude and/or phase of the magnetic field in their proximity. The position determining system uses the amplitude and/or phase to determine positions within the endoscope. Each of sensors 22 measures at least three coordinates. Preferably, each sensor 22 allows determination of the six coordinates of position and orientation. Alternatively, a few sensors which measure only two coordinates, may be used, if the sensors are fixedly positioned relative to each other. The sensors are, preferably, miniature coils such as described, for example, in PCT/GB93/01736, U.S. Patent 5,391,199, PCT publication WO95/04938, PCT publication WO96/05768, or U.S. Provisional Patent application no. 60/011,724, filed February 15, 1996, which is assigned to the assignee of the present application, all of which patents, publications and applications are incorporated herein by reference. Sensors 22 are located on the inner side of sheath 20 near its circumference, spaced from interfering materials by an amount sufficient to avoid interference to the operation of the position determining system. In a preferred embodiment of the invention, the sensors are diametrically opposite lumen 17. As can best be seen in Fig. 1, wires 24, running along sheath 20, connect sensors 22 to the position determining system (not shown). Wires 24 are thin enough so as to take up minimal space of the interior of sheath 20, and also so as not to interfere with the operation of the position determining system. Alternatively, sensors 22 are wireless. In a preferred embodiment of the invention, at least one sensor 22 is coupled with a transmitter on an integrated circuit.

Before insertion of tube 14 into a patient, it is tightly placed and precisely oriented within sheath 20. In addition, distal end 15 of tube 14 is preferably brought to a re-locatable depth within sheath 20. Thus, precise positional co-ordination between sensors 22 and insertion tube 14, is achieved.

One method of tightly attaching a sheath to an endoscope is to shrink the sheath around the endoscope using chemical or heat methods. Preferably, such a sheath includes a "rip cord", such as a Kevlar® cable running along the inside of the sheath, to facilitate removal of the sheath after usage. Pulling such a rip cord, perpendicular to the endoscope, rips the sheath so that it may be easily removed from the endoscope. Such a cord is especially important if the cross-section of the endoscope is not constant, such as due to attachments.

Sensors 22 are precisely fixed, relative to sheath 20 and hence to insertion tube 14, so that the position determining system will be able to determine the position of any point along sheath 20 and insertion tube 14. In addition, sensors 22 are preferably embedded within sheath 20 to protect sensors 22 from the surroundings.

In some preferred embodiments of the invention the position determining system uses DC currents. In these embodiments, conducting materials do not interfere with the operation of the position determining system. Therefore the sensors are distanced only from ferro-magnetic materials. In these systems, the decision of where to place the sensors is performed according to the locations of ferro-magnetic materials within the insertion tube.

Reference is now made to Fig. 3 which shows an endoscopic sheath in accordance with a preferred embodiment of the present invention. In some embodiments of the present invention, sheath 20 has a distal end 28 which extends beyond distal end 15 of tube 14. Distal end 28 preferably isolates distal end 15 from the patient's body. Sheath 20 preferably has a transparent window 30 on its distal end 28, allowing an imaging device within tube 14 an unobstructed field of view. Window 30 preferably comprises a clear transparent optical grade plastic, as described, for example, in U.S. Patent 5,402,768, which is incorporated herein by reference. In accordance with the present invention, distal end 28 is substantially free of substances interference causing to the operation of the position determining system. Therefore, substantially no interference is induced on a sensor 22 embedded within distal end 28. Preferably, distal end 28 is thick enough to contain at least one sensor 22 in such a way that does not obscure the view through window 30. In a preferred embodiment of the present invention, the interference to the position determining system at different points within distal end 28 is measured, and sensor 22 is embedded at a point which has the least interference.

Reference is made to Fig. 4 which shows the cross-section of a sheath 120 in accordance with another embodiment of the invention. Sheath 120 comprises a cylindrical lumen 117 which is preferably, axially centered within sheath 120. Lumen 117 is shaped to tightly receive an endoscopic insertion tube. Several work channels run parallel to lumen 117, within sheath 120, radially surrounding lumen 117. Preferably, there are three channels, for example, for air 125, for water 126 and for biopsy apparatus 127. One or more sensors 22 are embedded along sheath 120, preferably, on the outer circumference of sheath 120, as far as possible from lumen 117. Preferably, sensors 22 are embedded near air channel 125, and water channel 126, so as to keep them away from any metal apparatus passing through biopsy channel 127.

On the insertion tube, there is preferably a marking indicating the correct orientation of the insertion tube within the lumen. In a preferred embodiment of the invention, the insertion tube has a key, and the lumen has a corresponding slot. Thus, the insertion tube can be inserted into the lumen only in the correct orientation. In addition, the distal end of the insertion tube contacts the inner surface of the distal end of the lumen. Thus, the position determining system can precisely register the location and orientation of the insertion tube according to the position of sensors 22.

In some preferred embodiments of the present invention, the sensors are embedded within attachments to the endoscope. Reference is now made to Fig. 5 which shows an endoscope with sensors in accordance with a preferred embodiment of the invention. As shown in Fig. 5, an endoscope 90 has one or more attachments 94 which incorporate sensors 22. Preferably, endoscope 90 has a groove 96 along at least part of its length. Attachments 94 are, preferably, situated within groove 96 and are preferably shaped to smoothly fit in groove 96 without protruding from it. Attachments 94 are comprised substantially of non-interference causing materials and are preferably thick enough so as to substantially separate between sensors 22 and interference causing structures within the endoscope. Preferably, an adhesive connects attachments 94 to endoscope 90. Alternatively, or additionally, attachments 94 are connected to endoscope 90 using any connection method known in the art. Sensors 22 are preferably embedded within attachments 94 in the portion of attachment 94 farthest from endoscope 90. Thus, most of each attachment 94 separates its associated sensor 22 from interference causing structures within endoscope 90.

In a preferred embodiment of the invention, a thin sheath 92 covers endoscope 90 and attachments 94, and thus isolates endoscope 90 from the patient's body and also keeps attachments 94 in fixed positions on endoscope 94. Before insertion of endoscope 90 into the patient, endoscope 90 is preferably brought to an external reference calibration point and the position determining system registers the positions of the sensors relative to endoscope 90.

In a preferred embodiment of the invention, one or more sensors are situated within one long attachment which is placed along the endoscope. Reference is now made to Fig. 6, which shows a cross-section of an endoscopic assembly, in accordance with another embodiment of the present invention. As shown in Fig. 6, a disposable sheath 150 isolates an endoscope 147 from the patient's body. A groove 142 runs along the length of endoscope 147. A disposable tube 144 is laid along endoscope 147 within groove 142, such that sheath 150 covers endoscope 147 and tube 144. Endoscope 147 and tube 144 can be, for example, as described in U.S. Patent 4,646,722, whose disclosure is incorporated herein by reference. In accordance with the present invention, one or more sensors 22 are fixed along disposable tube 144, and preferably are embedded within its wall. Sensors 22 are embedded substantially along a straight line parallel to the longitudinal axis of tube 144. On the outer side of tube 144, this straight line is preferably marked to identify where sensors 22 are embedded. The marking helps the user lay tube 144 in groove 142 such that sensors 22 are adjacent to sheath 150, and therefore are distanced from interference causing structures within endoscope 147. Also, the position of the sensors in relation to endoscope 147 is thus accurately established.

It is noted, that although in the above embodiments the sheath is separate from the insertion tube of the endoscope, the sheath can also be a non-separable part of the insertion tube. In such embodiments, there is no separable sheath, but rather there is one endoscopic insertion tube with two parts. One part contains the circumference of the insertion tube and the work channels and is substantially free of interference causing structures, and the other part is the core of the insertion tube which contains interference causing structures. In accordance with preferred embodiments of the invention, the sensors are embedded in the part which is free of interference causing structures.

Reference is now made to Fig. 7 which shows an endoscopic insertion tube 160 with a combined lengthwise and widthwise division in accordance with a preferred embodiment of the invention. As shown in Fig. 7, insertion tube 160 has an axial metal core 162, and sections 164 which contain various apparatus of insertion tube 160. The apparatus in sections 164 are parts of a deflection system or other systems such as a visual imaging system, and contain interference causing structures. Other sections 168, which do not contain interference causing structures, have embedded within them one or more sensors 22. Axial core 162 is preferably thin and contains wires which connect the device within insertion tube 160 with the proximal end of insertion tube 160. Preferably, also wires 170, which connect sensors 22 to a position determining system outside of the endoscope, run within axial core 162.

It is noted, that although the invention has been described in conjunction with a magnetic field position determining system, it can also be used with other position determining systems, such as, acoustic position determining systems. When using acoustic position determining, hard substances within the insertion tube reflect acoustic waves and therefore interfere with the operation determining positions. Therefore, in accordance with the present invention, the sensors, which are ordinarily transducers, are distanced from hard substances within the insertion tube. The distancing is performed in a manner similar to the described above distancing of magnetic field sensors from conducting and ferro-magnetic materials.

It is also noted, that although the invention has been described in conjunction with an endoscope, it can also be used with any other medical instrument for which position determination is desired. In particular, the invention can be used with invasive tools such as catheters and feeding tubes.

It will be appreciated that the preferred embodiments described above are cited by way of example, and the full scope of the invention is limited only by the claims.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. a position determining system for an endoscope comprising:

an attachment connectable to a portion of an endoscope;

one or more sensors within said attachment, said one or more sensors capable of transmitting and receiving magnetic fields; and

a sheath for covering said attachment.

2. The position determining system of claim 1 including an endoscope.

3. The position determining system of claim 1, wherein the one or more sensors are embedded within the attachment.

4. The attachment of claim 1, wherein determining the positions of the one or more sensors is performed by transmitting and receiving magnetic fields.

5. The attachment of claim 1, comprising markings on the outside of the attachment which indicate the positions of the one or more sensors.

6. The attachment of claim 1, wherein the attachment comprises a tube.

7. A position determining system for an endoscope substantially as hereinbefore described with reference to the accompanying drawings.

DATED: 16 July 1999

CARTER SMITH & BEADLE
Patent Attorneys for the Applicant:

BIOSENSE, INC.

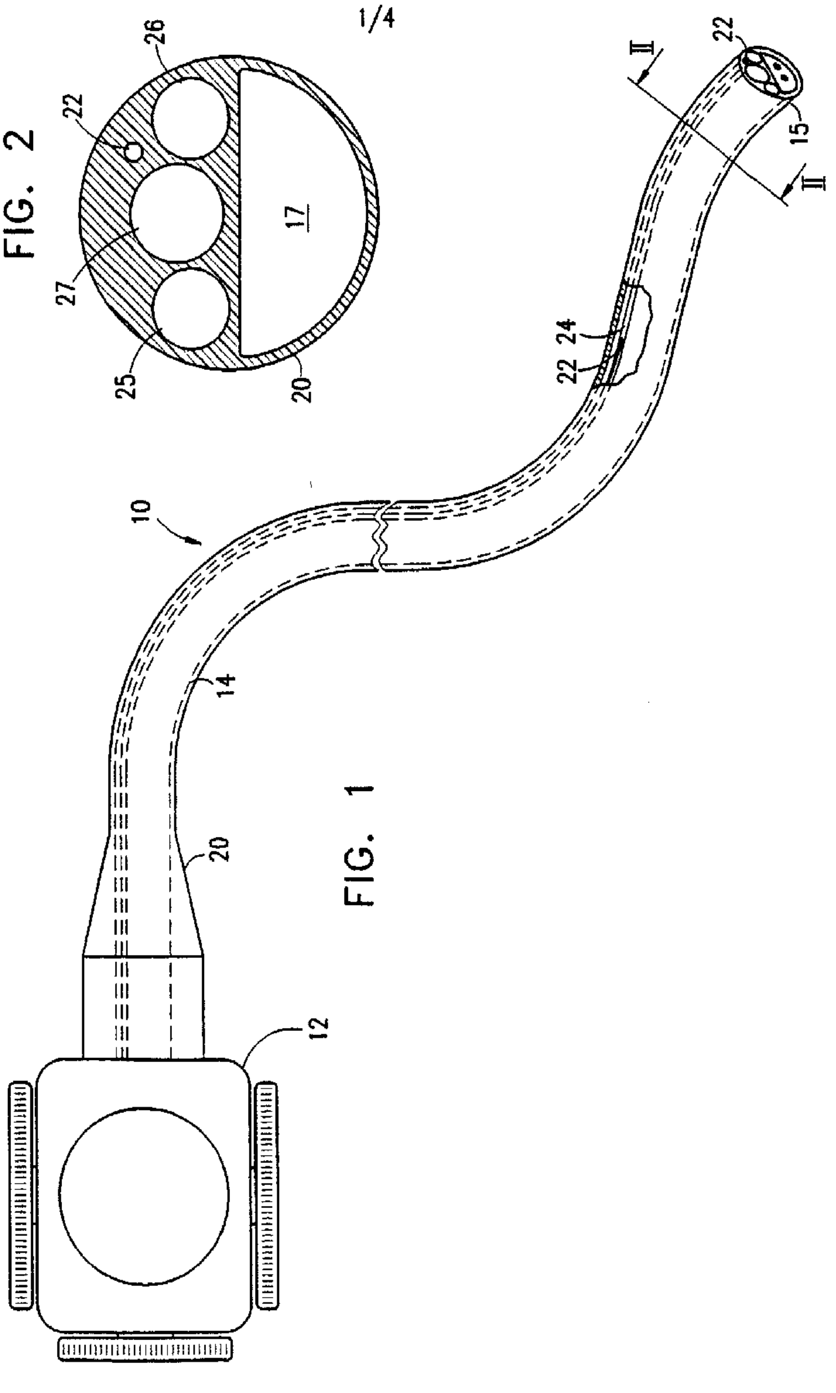


FIG. 2

FIG. 1

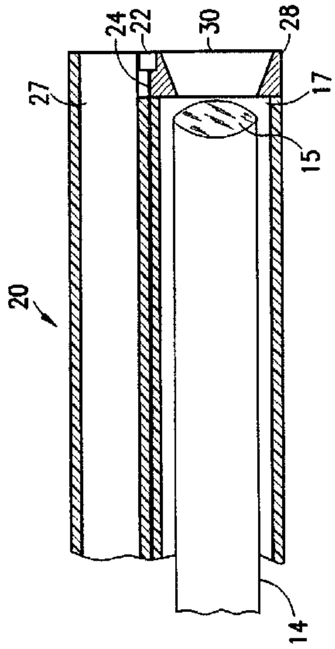


FIG. 3

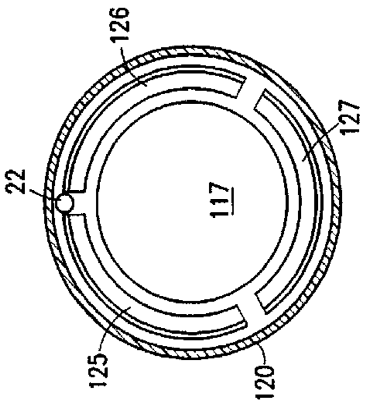


FIG. 4

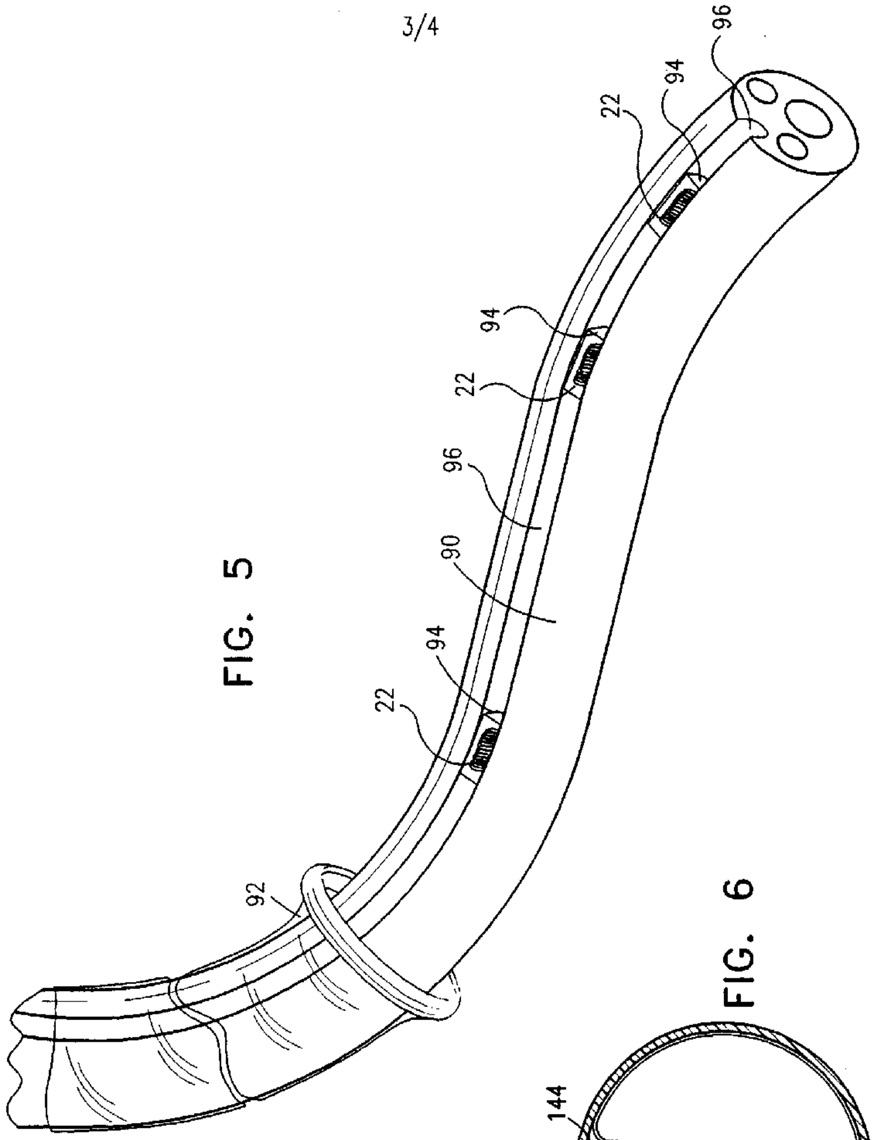


FIG. 5

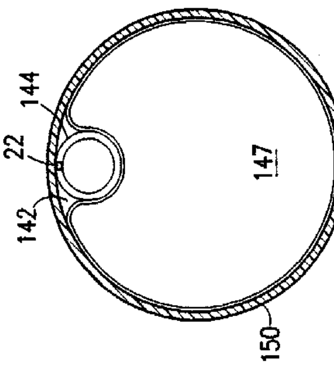


FIG. 6

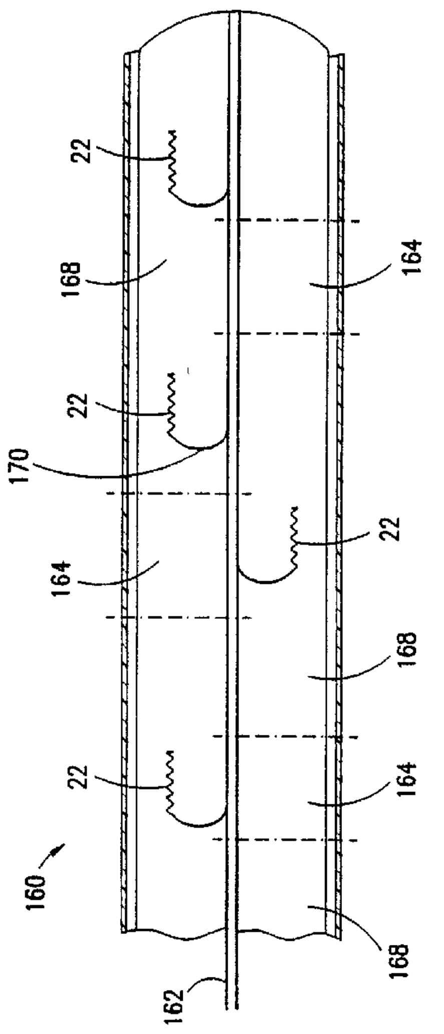


FIG. 7