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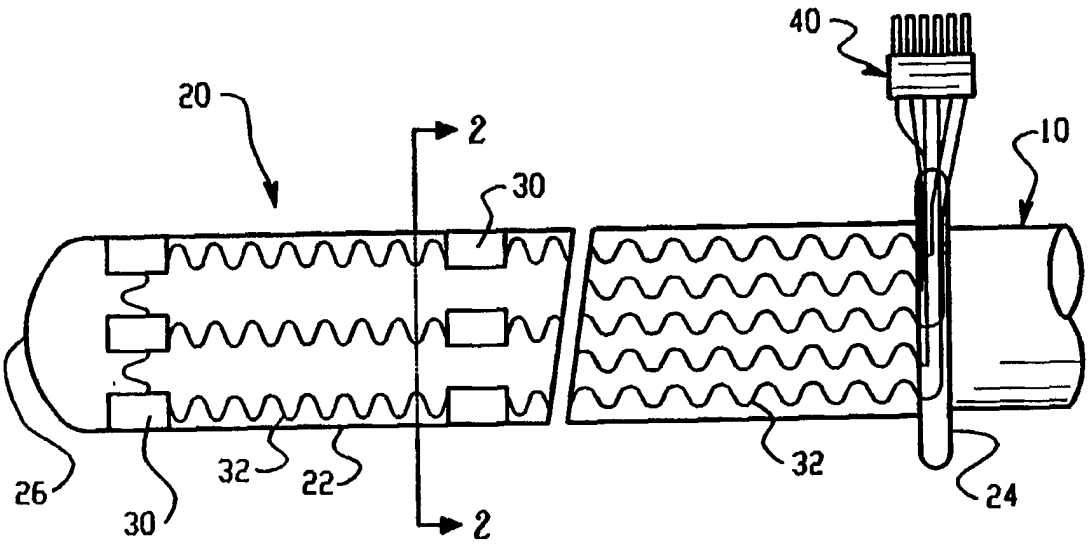

(57) Abstract

A tracking data sheath (20, 20', 100) arrangeable on a variety of different surgical instruments (e.g., catheters and probes) to provide the surgical instruments with 3–D tracking capability. The tracking data sheath (20, 20', 100) being generally elastomeric or rigid for convenient installation and removal, and having transducers (30) and conductors (32) embedded therein.

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TRACKING DATA SHEATH

Related Applications

The present application is a continuation-in-part (CIP) of co-pending International Application No. PCT/CA96/00194 filed March 24, 1996, which is a continuation-in-part (CIP) of U.S. Application Serial No. 08/411,959, filed March 28, 1995, now U.S. Patent No. 5,515,853. Both applications are incorporated herein by reference.

Field of the Invention

The present invention relates generally to a tracking device attachable to a surgical instrument, and more particularly to a tracking device in the form of a sheath attachable to a surgical instrument for tracking the position of same.

Background of the Invention

In medical procedures, such as catheterizations, intraluminal intraoperative ultrasound, endoscopic procedures and laparoscopic procedures, catheters, probes, needles, sensors and other instruments are introduced into a patient's body. In most cases, such as in the use of mapping and ablating catheters, these instruments are visualized inside the body using continuous fluoroscopy by creating a shadow of the instrument as the physician manipulates the instrument moving it within the body. In the case of intra operative ultrasound, transesophageal

ultrasound, intraluminal and laparoscopic ultrasound, an imaging head is inserted into the patient's body. The position of the imaging head is not known, and orienting and localizing is done only based on the image that is being generated by the imaging head. Some orienting, however, is possible from the length of the tube inserted into the patient, and the radial orientation of the device. The local orientation and location of the imaging head, however, are not typically available with existing systems.

An ultrasound based catheter guidance system as described in U.S. Patent No. 5,515,853 and incorporated herein by reference, can display the position and motion of catheters as a 3-D graphic. This system makes use of transit time ultrasound to measure the distance between an array of ultrasonic transducers. Using the time-of-flight principle of high frequency sound waves, it is possible to accurately measure distances within an aqueous medium, such as inside the body of a living being during a surgical procedure. High frequency sound, or ultrasound, is defined as vibrational energy that ranges in frequency from 100 kHz to 10 MHz. The device used to obtain three-dimensional measurements using sound waves is known as a sonomicrometer. Typically, a sonomicrometer consists of a pair of piezoelectric transducers, (i.e., one transducer acts as a transmitter while the other transducer acts as a receiver). The transducers are implanted into a medium, and connected to electronic circuitry. To measure the distance between the transducers, the transmitter is electrically energized to produce ultrasound. The resulting sound wave then propagates through the medium until it is detected by the receiver.

The transmitter typically takes the form of a piezoelectric crystal that is energized by a high voltage spike, or impulse function lasting under a microsecond. This causes the piezoelectric crystal to oscillate at its own characteristic resonant frequency. The envelope of the transmitter signal decays rapidly with time, usually producing a train of six or more cycles that propagate away from the transmitter through the aqueous medium. The sound energy also attenuates with every interface that it encounters.

The receiver also typically takes the form of a piezoelectric crystal (with similar characteristics to the transmitter piezoelectric crystal), that detects the sound energy produced by the transmitter and begins to vibrate in response thereto. This vibration produces an electronic signal in the order of millivolts, that can be amplified by appropriate receiver circuitry.

The propagation velocity of ultrasound in an aqueous medium is well documented. The distance traveled by a pulse of ultrasound can therefore be measured simply by recording the time delay between the instant the sound is transmitted and when it is received.

As indicated above, some of the transducers are mounted to the catheters (or other instrument) inserted into the body, and other transducers (i.e. reference transducers) are affixed to the patient at a fixed location, and provide external and/or internal reference frames. A large matrix of distances between many combinations of transducers is obtained many times per second, and then converted into x,y,z coordinates for each transducer. The motion of the catheter fitted with such ultrasonic

transducers can then be tracked in 3-D space, relative to the position of the external and/or internal reference transducers.

Catheters themselves are typically polymeric tubes with some diagnostic or therapeutic component incorporated into the distal segment of the catheter. To convert a conventional catheter into one that can be tracked has involved the remanufacture of the catheter such that it incorporates several ultrasonic transducers along its length to determine the position of the catheter relative to the reference transducers located elsewhere on or inside the patient. For low cost, disposable instruments, such as catheters, such integration is often appropriate, particularly, since the wires for interconnecting the transducers take up significant space and need to be integrated into the body of the catheter in an efficient way.

Other instruments inserted into the body, such as those incorporating ultrasound imaging elements, may be expensive and need to be sterilized and reused many times. There is also a very large number of variations in instrument configuration, particularly in those instruments that are used for laparoscopic surgery. Accordingly, it may not be feasible to incorporate localization and tracking transducers into all of these instruments during their manufacture. Moreover, ultrasonic transducers have a finite life span, and thus require periodic replacement. In view of the foregoing, it would be desirable if a whole range of instruments could be retrofitted with the ultrasonic transducers in a manner that does not require remanufacture, modification or permanent alteration thereof.

The present invention overcomes these and other drawbacks of prior art devices and provides a tracking data sheath for quickly and easily modifying an instrument to include tracking capabilities.

Summary of the Invention

According to the present invention there is provided a tracking data sheath which is attachable to a surgical or diagnostic instrument to allow the position of the instrument to be tracked. The sheath is generally elastomeric or rigid, and may be conveniently fitted to an instrument.

It is an object of the present invention to provide a tracking data sheath , which is easily attachable to a variety of different types of diagnostic and surgical instruments, including catheters, probes, sensors, needles, and the like.

It is another object of the present invention to provide a tracking data sheath which is easily removable from the instrument for convenient replacement and disposal.

It is still another object of the present invention to provide a tracking data sheath which may be pre-sterilized.

It is still another object of the present invention to provide a tracking data sheath which is easily fitted to a variety of instruments having various dimensions.

It is yet another object of the present invention to provide a tracking data sheath which is durable and can withstand considerable force.

These and other objects will become apparent from the following description of the preferred embodiment taken together with the accompanying drawings and the appended claims.

Brief Description of the Drawings

The invention may take physical form in certain parts and arrangements of parts, a preferred embodiment and method of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

Fig. 1 is a side perspective view of the tracking data sheath according to a preferred embodiment of the present invention;

Fig. 2 is a sectional view taking along lines 2-2 of Fig. 1; and,

Figs. 3 and 4 are side perspective views of a tracking data sheath according to an alternative embodiment of the present invention; and

Fig. 5 is a side perspective view of a tracking data sheath according to a second alternative embodiment of the present invention.

Detailed Description of the Preferred Embodiment

Referring now to the drawings wherein the showings are for the purposes of illustrating a preferred embodiment of the invention only and not for purposes of limiting same, Fig. 1 shows a tracking data sheath 20 arranged on an

instrument 10. It should be noted that instrument 10 may take the form of various type of instruments including catheters, ultrasound probes and endoscopes.

Tracking data sheath 20 includes an elongated body portion 22 having a proximal end 24 and a distal end 26. In the embodiment shown in Fig. 1, distal end 26 is closed. However, in many cases, distal end 26 will be open to enable diagnostic or therapeutic components located at the distal end of instrument 10 to remain active and unobstructed.

Body portion 22 has an inner wall 28A and an outer wall 28B, as shown in Fig. 2. Transducers 30 and conductors 32 are preferably cast, imbedded, or laminated between walls 28A and 28B. Accordingly, there is no remaining void between wall 28A and 28B. Transducers 30 are preferably piezoelectric transducer crystals consisting of PZT or PVDF material. Conductors 32 preferably take the form of very thin and flexible wires that are cast, imbedded, or laminated into body portion 22 in a wavy or tortuous coiled fashion, so as to stretch with sheath 20 appropriately during rolling, unrolling and other manipulations, as will be explained below.

Conductors 32 connect transducers 30 to each other and with a connector 40 at the proximal end 24. Conductors 32 are used to carry electrical signals for "firing" a transmitter transducer, and to carry electrical signals generated by a receiver transducer when it receives a sound wave from a transmitter transducer. It should be understood that the term "firing" refers to the action of energizing a transducer to oscillate by sending a voltage spike or impulse function to the transducer. Transducers 30 are preferably interconnected together in a plurality of

"rings" within walls 28A and 28B to enable several individual transducers 30 to be "fired" in unison as a ring. The electrical signals and sound waves described above are collectively referred to as tracking signals.

Connector 40 connects sheath 20 to a 3-D tracking and imaging system. Accordingly, conductors 32 communicates electrical signals to and from transducers 30 and the 3-D tracking and imaging system.

In a first embodiment of the present invention, body portion 22 is preferably constructed from an appropriate elastomeric material, to form a rubberized polymeric tubular housing, resembling a sleeve or sock. Body portion 22 is preferably as thin as possible to facilitate rolling off and unrolling onto instrument 10, as will be explained below. Accordingly, sheath 20 will be elastic to enable body portion 22 to easily fit over of instrument 10, and also to prevent any constraint on the flexibility of instrument 10, if it is intended to flex.

It should be appreciated that sheath 20 may have various lengths and diameters to facilitate use on a wide range of instrument configurations, while maintaining sufficient tightness to prevent movement of transducers 30 relative to instrument 10. In addition, a temporary adhesive such as tape may be used to ensure that the segment of sheath 20 containing transducers 30 does not slide up or down on instrument 10, thus compromising the 3-D registration of the position of instrument 10 relative to a tracking environment.

Turning now to Figs. 3 and 4, there is shown an alternative embodiment of the present invention. In this respect, a tracking data sheath 20' is

shown having an open distal end 26. The other elements of tracking data sheath 20' are the same as tracking data sheath 20, shown in Figs. 1 and 2. Because distal end 26 is open, any diagnostic or therapeutic components located at the distal end of instrument 10 can remain active and unobstructed.

Fig. 4 illustrates the fitting of tracking data sheath 20' to instrument 10. It should be noted that the following fitting procedure also applies to sheath 20 described above. Sheath 20 is mounted to instrument 10 and unrolled over instrument 10. It should be noted that it may be desirable to supply sheath 20' pre-sterilized. Accordingly, sheath 20' may be rolled up along its longitudinal axis for convenient storage and to facilitate the insertion of instrument 10 into sheath 20', and the unrolling of sheath 20' over the length of instrument 10.

Referring now to Fig. 5, there is shown another embodiment of the present invention. In this embodiment, tracking data sheath 100 has an elongated body portion 122 having a proximal end 124 and a distal end 126. In the embodiment shown in Fig. 5, both ends 124 and 126 are open. Importantly, body portion 122 is a generally rigid member, preferably formed of a plastic material. Body portion 122 has an inner surface 128A and an outer surface 128B. Transducers 30 and conductors 32 are preferably cast, embedded or laminated into body portion 122. It should be appreciated that since body portion 122 is a generally rigid member, conductors 32 need not be arranged in a wavy or coiled fashion. A connector 40 located at the proximal end 124 connects to a 3-D tracking and imaging system.

It should be appreciated that transducers 30 may take the form of a ring-shaped array of crystals (Fig. 5), or a segmented or unsegmented cylindrical single crystal. This configuration enables ultrasound energy to radiate at a large angle away from perpendicular to the axis of the cylinder, such that the crystal array functions as a line source of ultrasound energy, or as a collection of point sources, each radiating ultrasound energy in a fan substantially away from the plane of the cylinder.

Tracking data sheath 100 may be inserted into a bodily structure (e.g., an organ) under 3-D tracking. Subsequently, an instrument (e.g., ablation probe) is inserted inside of sheath 100. In this manner, sheath 100 facilitates positioning of the instrument to the desired location, without the need to permanently attach a tracking system to the instrument. After the instrument is located at the desired position, sheath can be slid upwards along the shaft of the instrument, and out of the way of the treatment area.

The foregoing is a description of the specific embodiment of the present invention. It should be appreciated that this embodiment is described for purposes of illustration only and that numerous alterations and modifications may be practiced by those skilled in the art without departing from the spirit and scope of the invention. For instance, while a preferred embodiment of the present invention has been described with reference to a system using ultrasonic sound waves to determine position, electromagnetic waves are suitable substitutes. Accordingly, the ultrasonic transducers can be suitably replaced by electromagnetic transducers. It is intended

that all such modifications and alterations be included insofar as they come within the scope of the invention as claimed or the equivalents thereof.

Having thus described the invention, it is now claimed:

1. A tracking data sheath attachable to an instrument means comprising:

an elongated body member having an outer portion and an inner portion;

a plurality of transducer means for generating tracking signals, the transducer means arranged between the outer and inner portions;

conductor means for communicating tracking signals to and from the plurality of transducer means; and

connector means for connecting the tracking data sheath to a tracking system, the connector means connected to said conductor means.

2. A tracking data sheath according to claim 1, wherein said connector means is located external to said body member.

3. A tracking data sheath according to claim 1, wherein said plurality of transducer means are arranged annularly about said elongated body member.

4. A tracking data sheath according to claim 1, wherein said plurality of transducer means are piezoelectric transducer crystals.

5. A tracking data sheath according to claim 1, wherein said plurality of transducer means are electromagnetic transducers.

6. A tracking data sheath according to claim 1, wherein said body member is formed of an elastomeric material.

7. A tracking data sheath according to claim 1, wherein said body member is formed of a rigid material.

8. A tracking data sheath according to claim 1, wherein said plurality of transducer means are cast, imbedded, or laminated between said outer and inner portions.

9. A tracking data sheath according to claim 1, wherein said conductor means are wavy wires.

10. A tracking data sheath according to claim 1, wherein said sheath further comprises:

adhesive means for adhering said body member to said instrument means.

11. A method for configuring a surgical instrument with a position tracking sheath including a generally elastomeric body member having at least one open end, and position indicating means for indicating the position of the position tracking sheath, the method comprising:

rolling the sheath along the longitudinal axis thereof into a rolled-up position;

inserting the surgical instrument into the open end of the sheath over the surgical instrument;

unrolling the sheath from the rolled-up position onto the surgical instrument; and

connecting the position indicating means with a position tracking system.

12. A method for configuring a surgical instrument with a position tracking sheath according to claim 11, wherein said position indicating means include a plurality of transducer means located in said elastomeric body member, the plurality of transducer means fired individually by said position tracking system.

13. A method for configuring a surgical instrument with a position tracking sheath according to claim 11, wherein said position indicating means include a plurality of transducer means located in said elastomeric body member, the pluality of transducer means fired in unison by said position tracking system.

14. A method for configuring a surgical instrument with a position tracking sheath including a generally rigid body member having at least one open end, and position indicating means for indicating the position of the position tracking sheath , the method comprising:

inserting the surgical instrument into the sheath ; and

connecting the position indicating means with a position tracking system.

15. A method for configuring a surgical instrument with a position tracking sheath according to claim 14, wherein said position indicating means include a plurality of transducer means located on said body member, the plurality of transducer means fired individually by said position tracking system.

16. A method for configuring a surgical instrument with a position tracking sheath according to claim 14, wherein said position indicating means includes a plurality of transducer means located on said body member, the plurality of transducer means fired in unison by said position tracking system.

17. A tracking data sheath attachable to an instrument means comprising:

an elongated body member;

a plurality of transducer means for generating tracking signals;

conductor means for communicating tracking signals to and from the plurality of transducer means; and

connector means for connecting the tracking data sheath to a position tracking system.

18. A tracking data sheath according to claim 17, wherein said body member is generally elastomeric.

19. A tracking data sheath according to claim 17, wherein said body member is generally rigid.

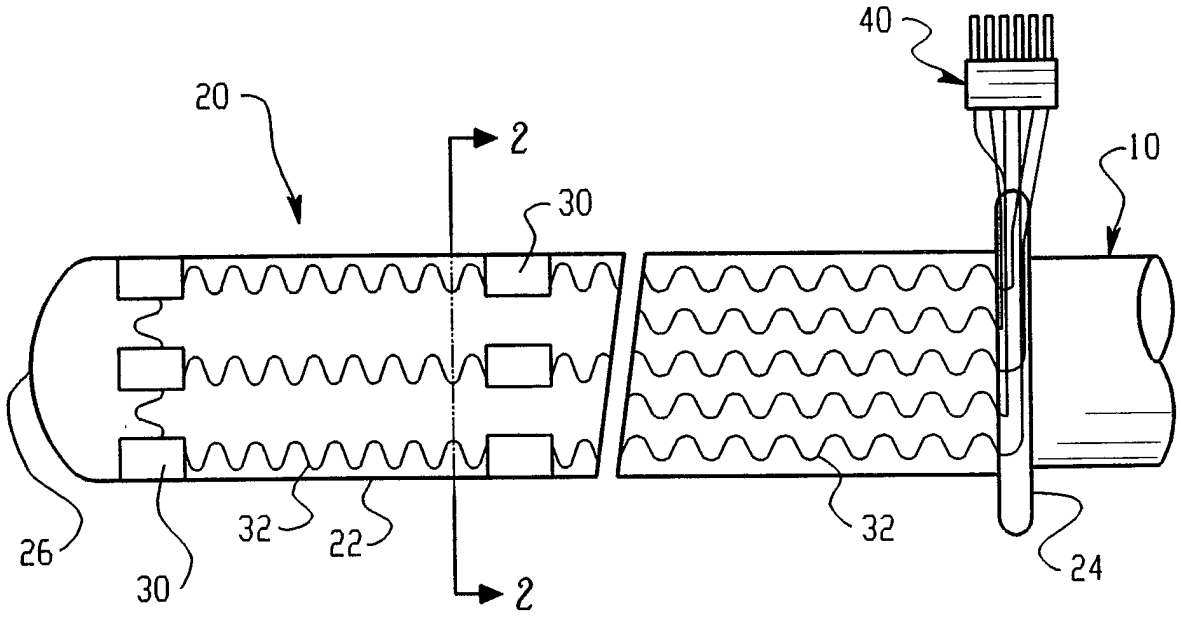

Fig. 1

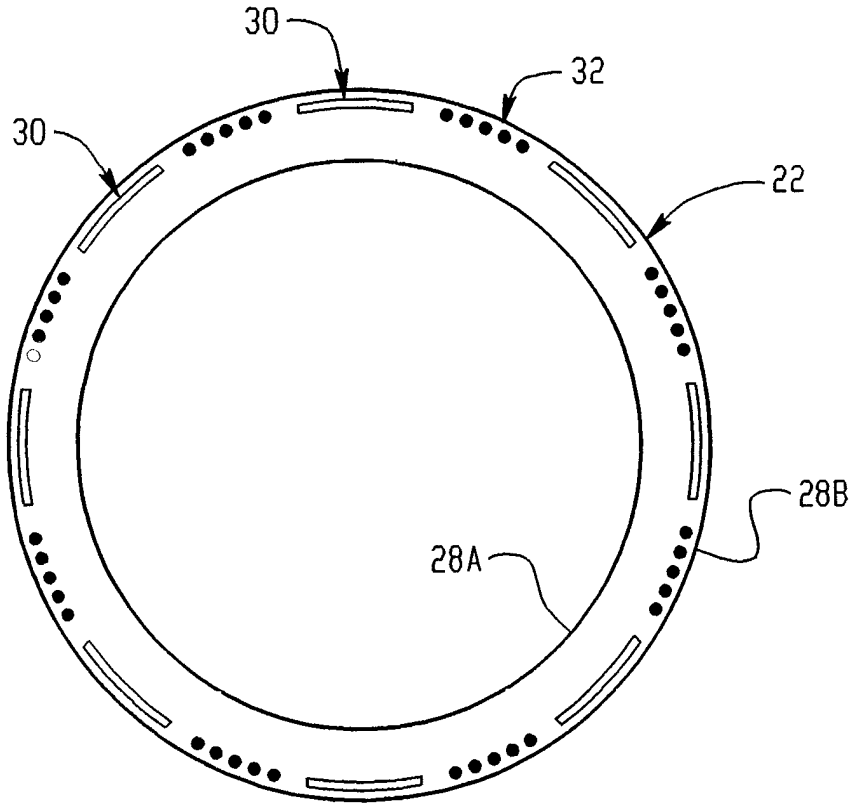

Fig. 2

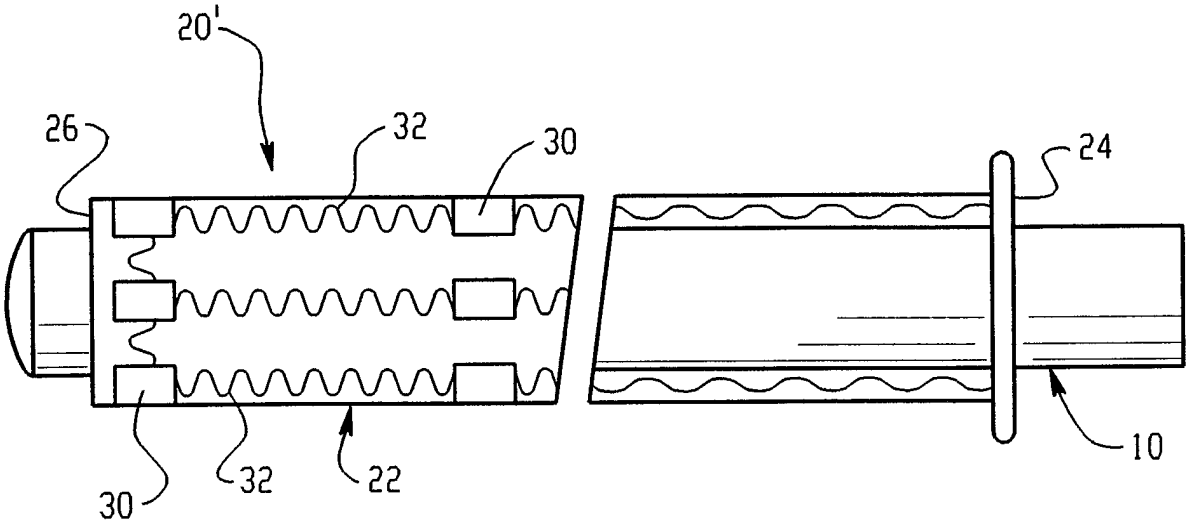

Fig. 3

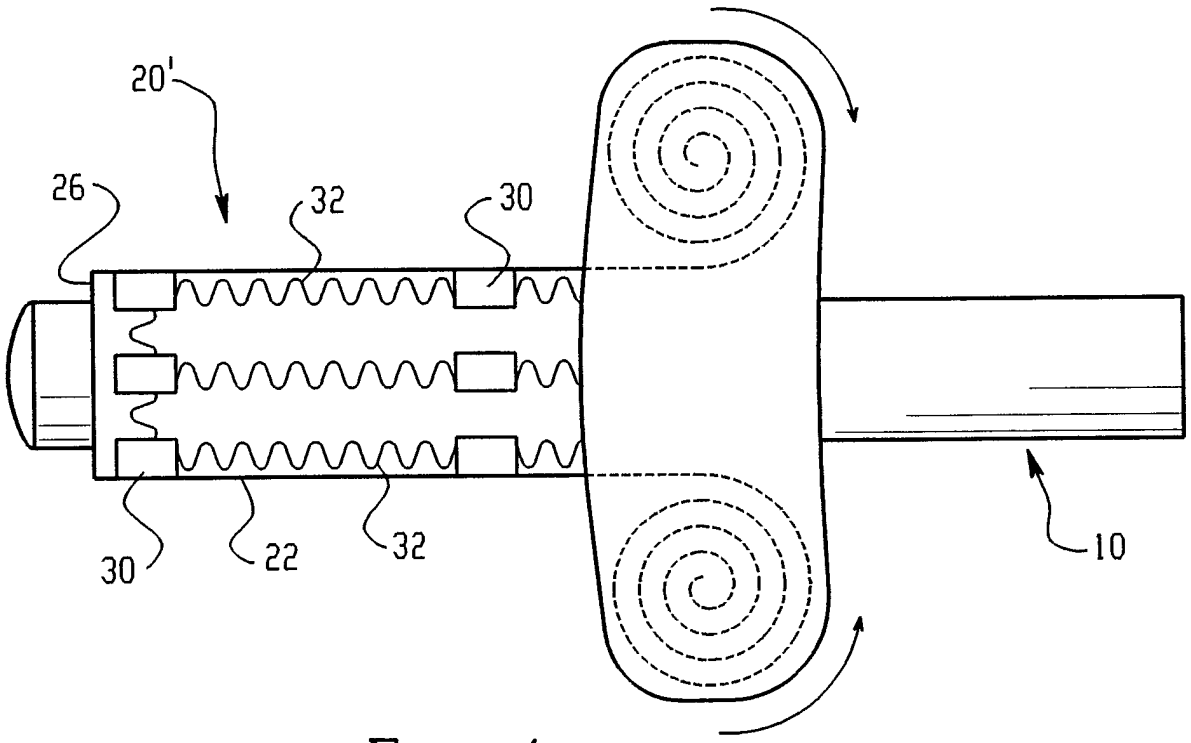

Fig. 4

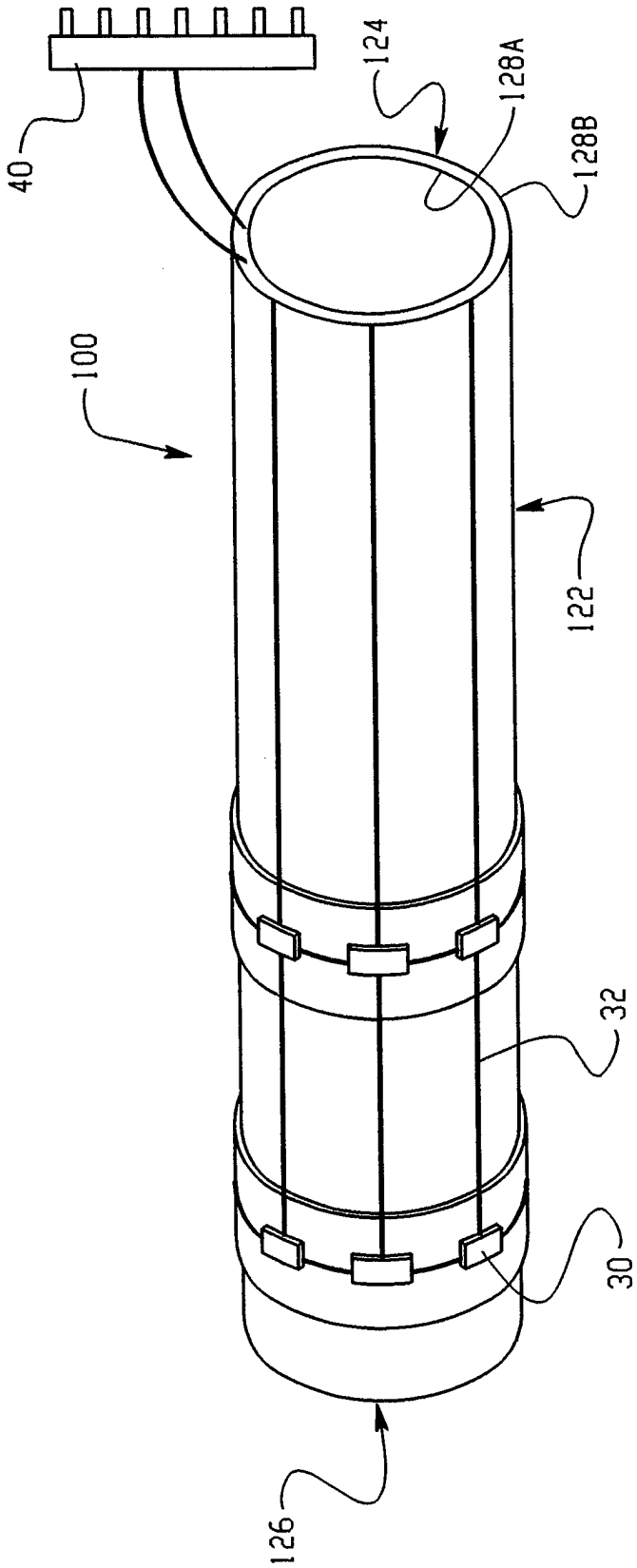

Fig. 5

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01S15/89 A61B8/12

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)
IPC 6 A61B G01S

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5 240 004 A (WALINSKY PAUL ET AL) 31 August 1993 see the whole document	1-4,6,7, 10,11, 14,17-19
Y	US 5 135 001 A (SINOFSKY EDWARD L ET AL) 4 August 1992 see the whole document see figures 1-4	1-4,6,7, 10,11, 14,17-19
A	EP 0 671 221 A (INTRAVASCULAR RES LTD) 13 September 1995 see the whole document	1-19
A	US 5 335 663 A (OAKLEY CLYDE G ET AL) 9 August 1994 see column 4, line 9 - column 7, line 10	1-19

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15 July 1998	23/07/1998

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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 4 317 369 A (JOHNSON STEVEN A) 2 March 1982 see the whole document see figures 2-4 -----	1-19

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte .ional Application No
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