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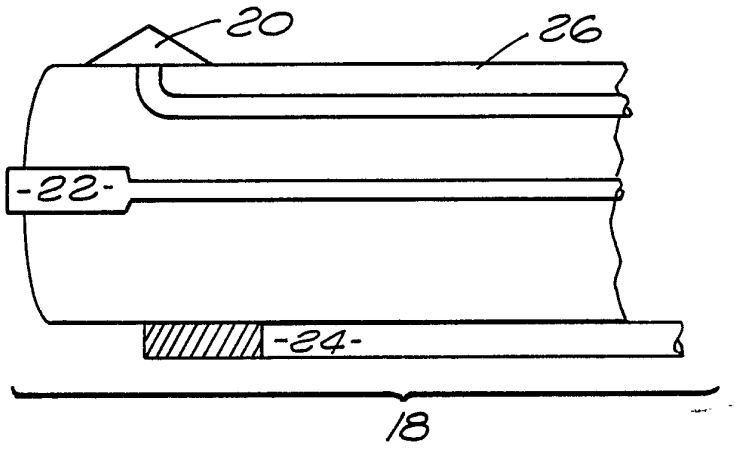

(57) Abstract

A multiprobe with thermal diffusion flow monitor (hereinafter known as "MPTDFM") that has improved reliabilit smaller overall size, simpler method of sensor positioning, better compatibility and capability to monitor blood flow, pressur and other critical physiological parameters is provided. The MPTDFM is formed by the combination of a thermal diffusion flo monitor (20), a pressure monitor (22), a multiple parameter monitor (24) and a support structure (26).

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MULTIPROBES WITH THERMAL DIFFUSION FLOW MONITOR

Background of the Invention

1. Field of the Invention.

The present invention relates to devices which measure tissue blood flow, particularly those based on the thermal diffusion flow concept, measure tissue pressure and can also assess the function of human tissue through the simultaneous monitoring of critical physiological parameters.

2. Description of the prior art.

The original reports using the thermal diffusion flow monitor concept appeared in the late 1960's. The work was done by Carter et al. (Carter L.P., Atkinson J.R. "Cortical blood flow in controlled hypotension as measured by thermal diffusion", J. Neurol. Neurosurg. Psychiatry, Vol. 36, pp. 906-913, 1973) using a Peltier stack. In order for the Peltier stack to be able to detect flow (as determined by the rate of cooling) the tissue of interest needed to be exposed and uniform contact between the sensor and the tissue surface was required. Although Peltier stacks are widely used, the system suffers from its relatively large size of the sensor and the variability of its output.

Later, in the 1980's, improvements including signal processing to stabilize the sensors output, simplified design of the sensor using a two-point system, where one point is a heat source and the other point a temperature sensor being positioned a short

distance away, were made. Still because of its large size , need for visual placement of the probe on the surface of the tissue and unreliable readings due to loose contact of the sensor tip with the surface of the tissue continue to limit its application.

Summary of the Invention

A multiprobe with thermal-diffusion flow monitor (hereinafter known as "MPTDFM") that has improved reliability, smaller overall size, simpler method of sensor positioning, better compatibility and capability to monitor blood flow, pressure and other critical physiological parameters is provided.

The MPTDFM of the present invention uses an anemometer and is to be placed into the substance of the tissue itself through a very small surgical opening and does not require visual positioning. The delivery system for the MPTDFM is one that is commonly used in medicine for the placement of various types of monitors, such as pressure monitors. It involves a small skin incision of approximately 1 cm, followed by opening of the connective tissue, such as by drilling a hole in bony coverings as would be required for access to the brain, and finally passage of the MPTDFM through this opening into the substance of the tissue. In this manner, the device can be placed quickly at the patient's bedside and a large operative procedure for visual positioning is not required.

In addition, the thermal diffusion flow monitor has better compatibility with pressure monitors as well as multiple parameter monitors in forming the MPTDFM for the detection and monitoring of biochemical substances.

Finally, use of an anemometer in the MPTDFM has the advantage of unexpected electrical properties. Specifically, the anemometer can be operated at a constant temperature mode with electrical current being supplied to the sensor. Thus, as the sensor tip of the anemometer is cooled by the blood flowing in the surrounding tissues, electricity will flow to the sensor to adjust it automatically. These changes in electrical current are then directly measured to produce a read-out. This direct measurement of the electrical current eliminates the need for additional circuitry that is required by other thermal monitoring designs which measure the temperature difference between a heat source and a temperature monitor.

Brief Description of the Drawings

The novel features which are believed to be characteristic of the invention are set forth with particularity in the appended claims. The invention itself, however both as to its organization and method of operation, may best be understood by reference to the following description taken in connection with the accompanying drawings, wherein similar character refer to similar elements throughout and in which:

FIGURE 1 illustrates a common thermal diffusion blood flow monitor mounted on a support structure;

FIGURE 2 illustrates an embodiment of the MPTDFM.

FIGURE 3 illustrates a typical conical hot film probe used in the MPTDFM;

FIGURE 4 illustrates one embodiment of the placement of multiple, single-point sensor tips onto a single probe;

FIGURES 5a-5c illustrate embodiments of temperature gradient monitoring by multiple single-point sensor tips in a single probe;

FIGURE 6a-6c illustrate embodiments to measure tissue pressure;

FIGURE 7 illustrates one embodiment of the positioning of the MPTDFM probe into the substance of brain tissue;

FIGURE 8 illustrates one embodiment of the MPTDFM with a side port placed on a catheter; and

FIGURE 9 illustrates an embodiment of the MPTDFM using an introducer.

Description of the Preferred Embodiment

Referring now to FIG. 1, a common thermal diffusion blood flow probe/pressure monitor 2 mounted on a flexible support structure 3 is shown. The monitor 2 is based on a two-point system where a point 4 is a heat source and another point 6 measures the temperature of the tissue. Together, these two points, 4 and 6, form the sensor tip 8. The sensor tip 8 is placed on the surface of the tissue to be monitored, with both points 4 and 6 requiring intimate contact. The heat source 4 is then activated to a set temperature, generally 41° C, which is higher than the ambient temperature of the underlying tissue. As blood flows past this region, it

cools the heated tissue. Thus, the temperature drop between the two points can be correlated with the rate of regional blood flow. For example, if the measured temperature is 41° C, there is little or no blood flow through the tissue, while a reading of 35° C means that there is significant blood flow with a high degree of cooling. Since the sensor tips are relatively large, so is the resulting thermal probe having dimensions typically 7 mm (width) by 5 mm (height), including the sensor tip, support structure and wiring. Generally, length of the probe is not of significance as the end of any probe must exit through the skin to be connected to a monitor by current connector 10.

The common thermal diffusion blood flow probe 2 described above can also be used to measure tissue pressure based on the transmission of pressure waves along a tube 12 filled with fluids. One end 14 of the tube 12 is positioned such that it is surrounded by the natural fluids of the tissue. Pressure changes from the tissue are transmitted through the natural fluids, which then are directly transmitted to the fluids at the end of the tube. High tissue pressure causes the natural fluids to flow into the end of the tube, while low tissue pressure will extract fluids out of the end of the tube. This pressure differential causes a displacement of the fluids in the tube, which is then transmitted along the entire length of the tube. By monitoring the opposite end 16 with a pressure transducer, or by measuring the changes in height of the fluid column, a direct pressure is determined. Measurements determined by this method, however, are subject to significant error if the measuring/monitoring end 14 is obstructed with tissue. This is because although solids transmit pressure waves very well, the volume of solid tissue remains fairly constant over a

wide range of pressures. Thus, despite wide variations in pressure there will be minimal displacement of fluids by tissue at the end 14 of the tube 12, leading to erroneous pressure determination at the monitoring end 16 of the tube. In contrast, the MPTDFM used in the present invention minimizes and/or eliminates completely this uncertainty in tissue pressure measurements and monitoring.

FIG. 2 shows an embodiment of the MPTDFM 18 of the present invention. The MPTDFM 18 is formed by the combination of a thermal diffusion flow monitor 20, a pressure monitor 22, a multiple parameter monitor 24 and a support structure 26.

The use of an anemometer to measure the rate of cooling of a solid has not been described before and the anemometer is generally used only when there is a continuous flow of material past the area of measurement (i.e., flowing fluid or stream of air). In addition, the combined use of an anemometer with different modalities in a single monitoring probe has not been commercially produced or experimentally described.

The thermal diffusion flow monitor 20 can be in the form of a conical hot film or hot wire probe 28 mounted on a catheter 30 with a diameter of 2 mm (FIG. 3). The probe 28 is a single-point sensor which acts as both a heat source and a temperature monitor. The single point design reduces the size of the sensor tip 32 and also permits multiple sensor tips to be placed onto a single probe (FIG. 4). The sensor 34 of the conical hot film probe is usually made of nickel or platinum deposited in a thin layer onto a backing material 36, such as quartz, and connected to the electronic package by leads 38 attached to the end of

the film. Double quartz protective coatings 40 are deposited over the thin film to prevent damage by abrasion or chemical reaction.

In another embodiment, shown in FIG. 4, a single probe 42 with support structure 44 is shown to have multiple sensor tips 46 to simultaneously monitor blood flow at different tissue sites. In addition, the array 48 of sensor tips 46 will more accurately reflect tissue blood flow by minimizing the sampling error associated with measurements made at a single site.

Referring to FIGS. 5a-c, embodiments are shown in which temperature gradients are monitored by periodically altering the function of the single-point sensor tips 46 in the array 48. In one embodiment (FIG. 5a), a single-point sensor tip 46 functions as a heat source. The remaining single-point sensor tips 50 then function as temperature monitors and are used to measure the temperature drop as distance d_1 increases from that heat source 46. In another embodiment (FIG. 5b), several single-point sensor tips 52-56 function as heat sources. The remaining sensors 58 are used to measure the temperature drop over the intervening distances d_2. In yet another embodiment (FIG. 5c), the entire array 48 of single-tip sensors are periodically heated. Thus, the array 48 functions as if it were a wire which is being heated and is capable of monitoring its own rate of cooling.

To measure tissue pressure (see FIG. 6a), a pressure transducer 22 with a movable diaphragm/strain gauge 60 is placed in contact with the tissue. As pressure changes are transmitted through the tissue, they will cause a displacement of this diaphragm/strain

gauge 60 from its neutral position. The degree of change is then measured by one of two basic methods. In one method (FIG. 6b), a pneumatic circuit 62 which pumps air into the pressure transducer 22 is used to counterbalance the tissue pressure causing the diaphragm/strain gauge to return to its neutral position. The pressure used to obtain this equilibrium is measured and directly correlated to the tissue pressure. In the second method (FIG. 6c), a fiber optic cable 64 and a photodetector 66 are used. Initially, when the diaphragm/strain gauge system is in the neutral position, light 61 emitted from the end of fiber optic cable 65, after incidence on a reflective surface 63 connected to the diaphragm 60, is perfectly aligned with the photodetector 66. As tissue pressure changes, the diaphragm 60 is displaced, altering the alignment of the reflective surface 63 and thus the reflected light beam 67 with the photodetector 66. The change in the light intensity measured at the photodetector 66 is transmitted through the sensor cable 64 to a readout. The readout is directly related to tissue pressure. Thus, the thermal diffusion monitors of the present invention can be made fully compatible with various types of pressure monitor systems. For fluid filled cavities, such as ventricles of the brain, it may be advantageous to use a pressure monitor with a fluid filled column.

The multiple parameter monitors used in the present MPTDFM are well-known, and some modification thereof might be utilized without material effect upon the principle of the present invention. It should suffice to indicate that the types of multiple parameter monitor utilized in preferred embodiments of this invention include those temperature, oxygen and potential sensors (TOP Cat. No. M11199-19 probe)

produced by OttoSensors Corporation, 11000 Cedar Avenue, Cleveland, Ohio 44106.

The support structure 26 for the MPTDFM 18 must be flexible, thermally inert, of a small size while still supporting the placement of multiple sensors and nonallergenic to biological tissues. Materials for the fabrication of the support structure 26 are well-known and include various silicone based materials such as those used for medical catheters.

In operation in one embodiment as shown in FIG. 7, the MPTDFM probe 18 of the present invention is placed into the substance of the tissue (brain) 70 instead of onto the surface of the tissue. The tissues 72 covering the organ-brain are the skin and the bones of the skull. Hollow bolts 74 are used to hold the MPTDFM 18 in a stationary position in the tissue and permit exit of electrical wires 38 for attachment to external electrical components. In other embodiments involving only connective tissues, after the MPTDFM probe 18 is inserted, the tissue can be closed around the probe to provide anchoring instead of the use of bolts 74. Having the probe placed inside the tissue permits an easier method of sensor positioning and also dramatically reduces the chance of a poor contact between the thermal sensor tip 32 and the tissue 70, which is the major source of error with the earlier surface devices.

To provide more accurate readings, by eliminating chemical and thermal interferences from the support structure such as the catheter 30 and to permit the monitoring of a larger amount of tissue, a sensor tip 32 may be advanced through a side port 76 of a suitable catheter 30 (FIG. 8). In this design the

sensor tip 32 is in a measuring position, completely surrounded by tissue.

During insertion of the MPTDFM 18 into the tissue, tissue injury may occur as a result of the physical deformity which takes places as the MPTDFM 18 passes through the organ. This injury will cause the body to mount a localized increase in blood flow, which may lead to inaccurate blood flow determination. To minimize and possibly eliminate this potential error in measurement, an introducer 78 may be used (FIG. 9). The introducer 78 is essentially a cylindrical structure of greater diameter than the MPTDFM 18 itself. The introducer 78 is first inserted into the tissue. Once the introducer 78 is in position, the MPTDFM can be inserted through the center of the introducer. The introducer can then be removed and as the tissue returns to its original position, the MPTDFM sites on the probe will be surrounded.

Those skilled in the art will fully appreciate that the preferred embodiment shown and desirable to illustrate the present invention is exemplary only and that the same principles may be employed in providing a MPTDFM to monitor blood flow and simultaneously monitor pressure and critical physiological parameters. It will be further appreciated that various other modifications or changes, particularly with respect to probe construction, might be made without departing from the gist and essence of the invention. Accordingly, it should be further understood that the invention should be deemed limited only by the scope of the claims which follow and should be interpreted as encompassing all system constructions fairly regardable as functional equivalents of the subject matter to which claims are directed.

Having described our invention, what we claim and desire to secure by letters patent is:

1. A multiprobe system comprising:

a thermal diffusion flow monitor to monitor blood flow at tissue sites;

a pressure monitor to monitor tissue pressure;

a multiple parameter monitor to monitor critical physiological parameters of tissue; and

a support structure to support the placement of said thermal diffusion flow monitor, said pressure monitor and said multiple parameter monitor inside tissue.

2. The multiprobe system of claim 1, wherein said thermal diffusion flow monitor is a conical hot film probe.

3. The multiprobe system of claim 1, wherein said thermal diffusion flow monitor is a single probe with multiple sensor tips to simultaneously monitor blood flow at different tissue sites.

4. The multiprobe system of claim 3, wherein further a single-point sensor tip of said single probe functions as a heat source and remaining sensor tips function as temperature monitors to measure temperature drop at distance d_1 from said heat source.

5. The multiprobe system of claim 3, wherein further a multiple of said sensor tips function as heat sources, and remaining sensor tips function as temperature monitors to measure temperature drops at intervening distances d_2 from said heat sources.

6. The multiprobe system of claim 3, wherein further all of said sensor tips are periodically heated to monitor its own rate of cooling.

7. The multiprobe system of claim 2 wherein further said conical hot film probe is made of metal deposited in a thin layer onto a backing material.

8. The multiprobe system of claim 7, wherein further said conical hot film probe has double quartz protective coating deposited over said thin metal layer.

9. The multiprobe system of claim 1, wherein further said pressure monitor is a pressure transducer with a movable diaphragm/strain gauge to measure pressure change in the tissue.

10. The multiprobe system of claim 9, wherein further a pneumatic circuit is used to measure pressure change in the tissue.

11. The multiprobe system of claim 9, wherein further a fiber optic photodetector system is used to measure pressure change in the tissue.

12. The multiprobe system of claim 1, wherein further said multiple parameter monitor measures the oxygen content, temperature, potential and electrical conductivity of the tissue.

13. The multiprobe system of claim 1, wherein further said support structure is constructed of silicone based material.

14. The multiprobe system of claim 13, wherein further said support structure is a medical catheter.

15. The multiprobe system of claim 1, wherein further said multiprobe system is placed into the tissue by cutting a skin incision of about 1 cm, followed by making an opening of about 1 cm in the protective tissue layers which cover an organ that is to be monitored.

16. The multiprobe system of claim 1, wherein further said thermal diffusion flow monitor is advanced through a side port of a catheter into the tissue to be monitored.

17. The multiprobe system of claim 1, wherein further an introducer is used to introduce said multiprobe system into the tissue to be monitored.

18. A thermal diffusion flow monitor to monitor blood flow at tissue sites comprising a conical hot film probe.

19. The thermal diffusion flow monitor of claim 18, wherein further said probe has multiple sensor tips to simultaneously monitor blood flow at different tissue sites.

20. The thermal diffusion flow monitor of claim 19, wherein further a single-point sensor tip of said single probe functions as a heat source and remaining sensor tips function as temperature monitors to measure temperature drop at distance d_1 from said heat source.

21. The thermal diffusion flow monitor of claim 19, wherein further a multiple of said sensor tips function as heat sources, and remaining sensor tips

function as temperature monitors to measure temperature drops at intervening distances d_2 from said heat sources.

22. The thermal diffusion flow monitor of claim 19, wherein further all of said sensor tips are periodically heated to monitor its own rate of cooling.

23. The thermal diffusion flow monitor of claim 18, wherein further said conical hot film probe is made of metal deposited in a thin layer onto a backing material.

24. The thermal diffusion flow monitor of claim 18, wherein further said conical hot film probe has double quartz protective coating deposited over said thin metal layer.

AMENDED CLAIMS

[received by the International Bureau
on 12 July 1991 (12.07.91);
original claims 6-8,15,22-24 cancelled; claims 1 and 2 amended;
claims 9-14 and 16-17 renumbered as claims 6-11 and 12-13;
claim 18 amended and renumbered as claim 14; claims 19-21
renumbered as claims 15-17; new claims 18-20 added; other claims
unchanged (4 pages)]

Having described our invention, what we claim and desire to secure by letters patent is:

1. A multiprobe system comprising a support structure having means for housing a plurality of elements inside tissue, wherein said plurality of elements further comprises:

thermal diffusion means to monitor blood flow at tissue sites;

pressure monitor means to monitor tissue pressure; and

multiple parameter means to monitor critical physiological parameters of tissue.

2. The multiprobe system of claim 1, wherein said thermal diffusion means further comprises a conical hot film probe made of metal deposited in a thin layer onto a backing material and having a double quartz protective coating deposited over said thin metal layer.

3. The multiprobe system of claim 1, wherein said thermal diffusion flow monitor is a single probe with multiple sensor tips to simultaneously monitor blood flow at different tissue sites.

4. The multiprobe system of claim 3, wherein further a single-point sensor tip of said single probe functions as a heat source and remaining sensor tips function as temperature monitors to measure temperature drop at distance d_1 from said heat source.

5. The multiprobe system of claim 3, wherein further a multiple of said sensor tips function as heat sources, and remaining sensor tips function as temperature monitors to measure temperature drops at intervening distances d_2 from said heat sources.

6. The multiprobe system of claim 1, wherein further said pressure monitor is a pressure transducer with a movable diaphragm/strain gauge to measure pressure change in the tissue.

7. The multiprobe system of claim 6, wherein further a pneumatic circuit is used to measure pressure change in the tissue.

8. The multiprobe system of claim 6, wherein further a fiber optic photodetector system is used to measure pressure change in the tissue.

9. The multiprobe system of claim 1, wherein further said multiple parameter monitor measures the oxygen content, temperature, potential and electrical conductivity of the tissue.

10. The multiprobe system of claim 1, wherein further said support structure is constructed of silicone based material.

11. The multiprobe system of claim 10, wherein further said support structure is a medical catheter.

12. The multiprobe system of claim 1, wherein further said thermal diffusion flow monitor is advanced through a side port of a catheter into the tissue to be monitored.

13. The multiprobe system of claim 1, wherein further an introducer is used to introduce said multiprobe system into the tissue to be monitored.

14. A thermal diffusion flow monitor to monitor blood flow at tissue sites comprising a conical hot film probe made of metal deposited in a thin layer

onto a backing material and having a double quartz protective coating deposited over said thin metal layer.

15. The thermal diffusion flow monitor of claim 14, wherein further said probe has multiple sensor tips to simultaneously monitor blood flow at different tissue sites.

16. The thermal diffusion flow monitor of claim 15, wherein further a single-point sensor tip of said single probe functions as a heat source and remaining sensor tips function as temperature monitors to measure temperature drop at distance d_1 from said heat source.

17. The thermal diffusion flow monitor of claim 15, wherein further a multiple of said sensor tips function as heat sources, and remaining sensor tips function as temperature monitors to measure temperature drops at intervening distances d_2 from said heat sources.

18. A method of monitoring blood flow at tissue sites comprising the steps of:

inserting a multiprobe system of claim 3 into the tissue and heating all of said sensor tips periodically to monitor each sensor tip's rate of cooling.

19. A method of monitoring blood flow at tissue sites comprising the steps of:

cutting a skin incision of about 1 cm into tissue, opening about 1 cm in the protective tissue layer which covers an organ to be monitored; and

placing a multiprobe system of claim 1 into said tissue.

20. A method of monitoring blood flow simultaneously at different tissue sites comprising the steps of:

inserting a multiprobe system of claim 15 into the tissue; and

heating of said sensor tips periodically to monitor each sensor tip's rate of cooling.

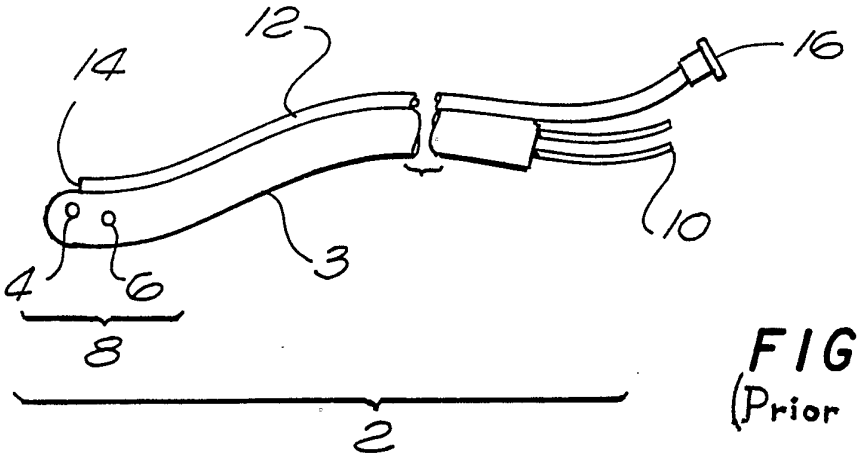

FIG. 1
(Prior Art)

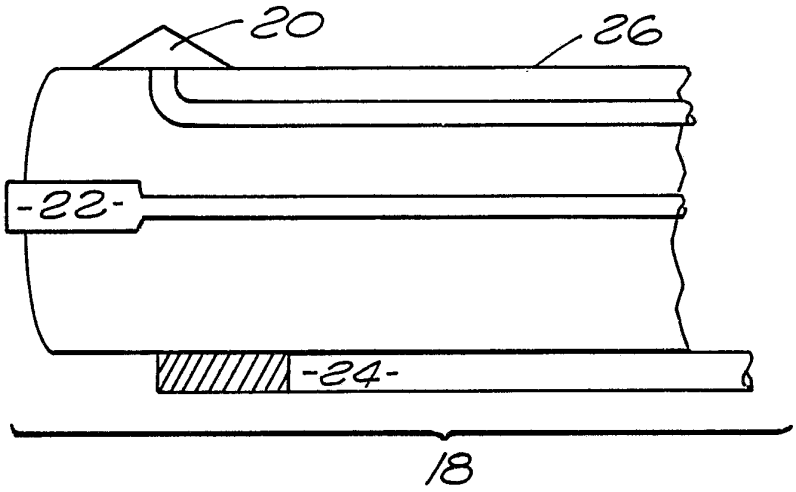

FIG. 2

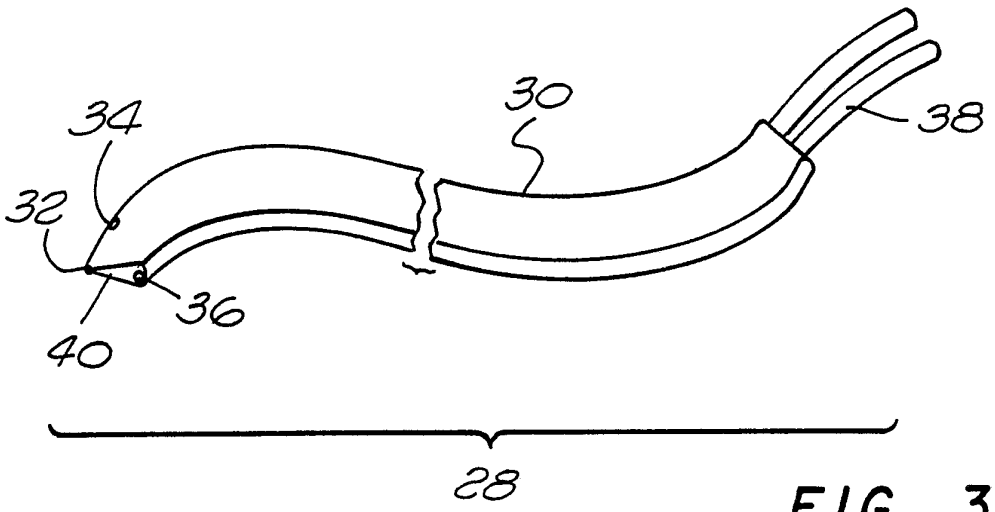

FIG. 3

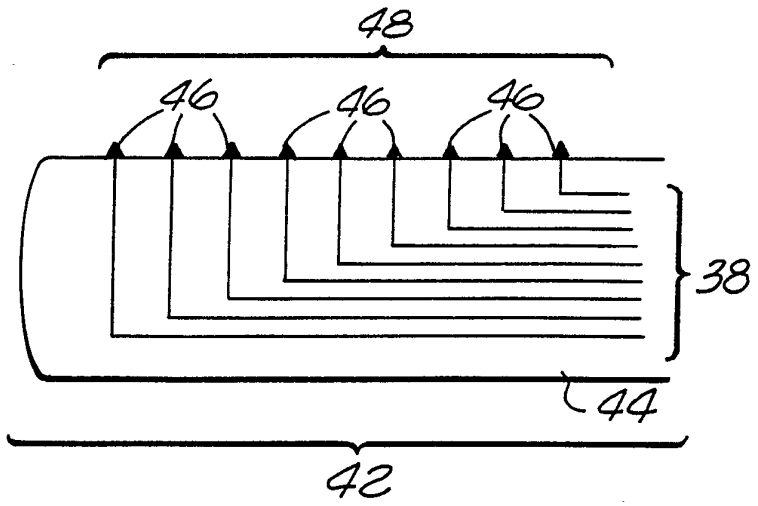

FIG. 4

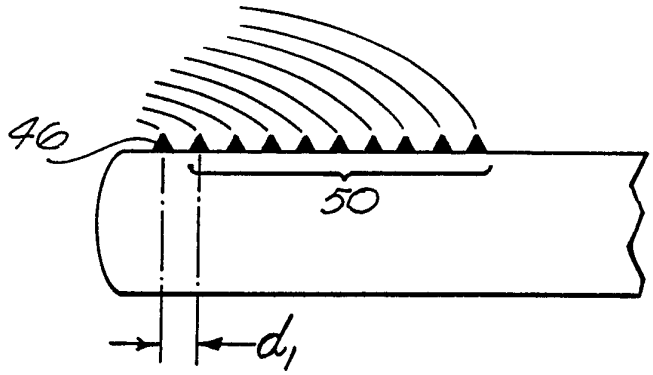

FIG. 5A

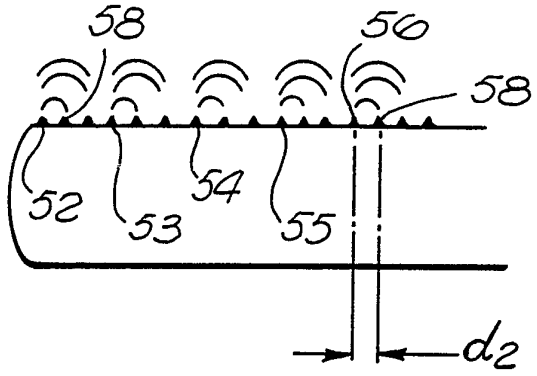

FIG. 5B

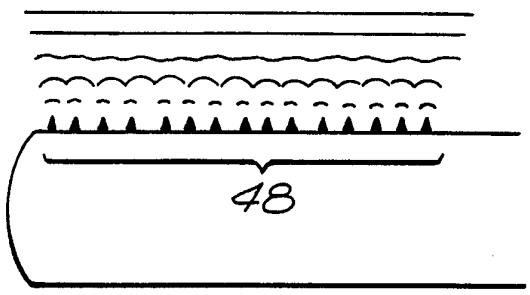

FIG. 5C

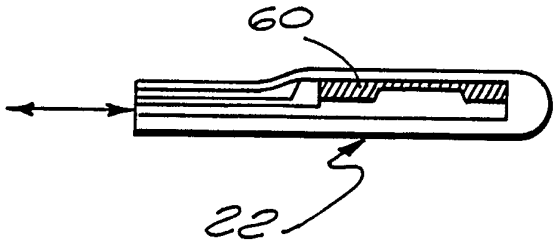

FIG. 6A

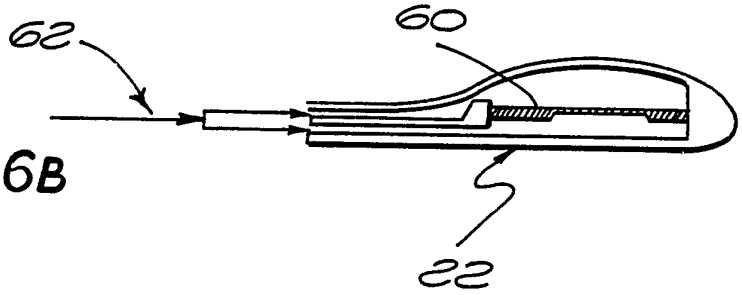

FIG. 6B

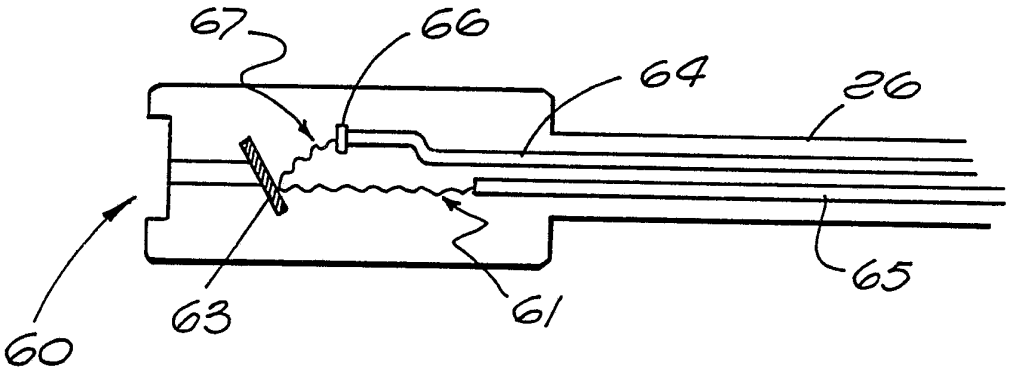

FIG. 6C

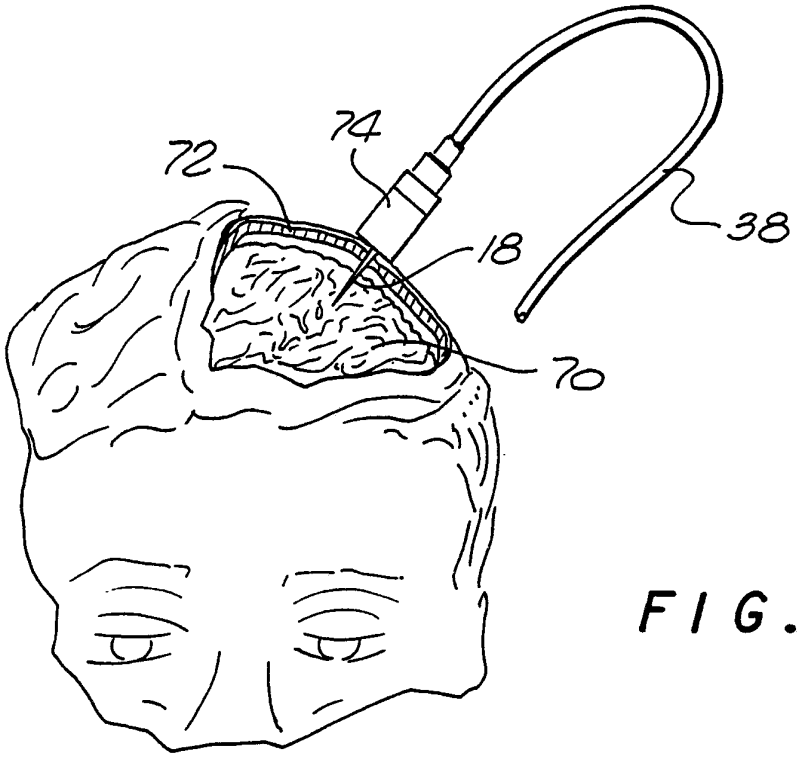

FIG. 7

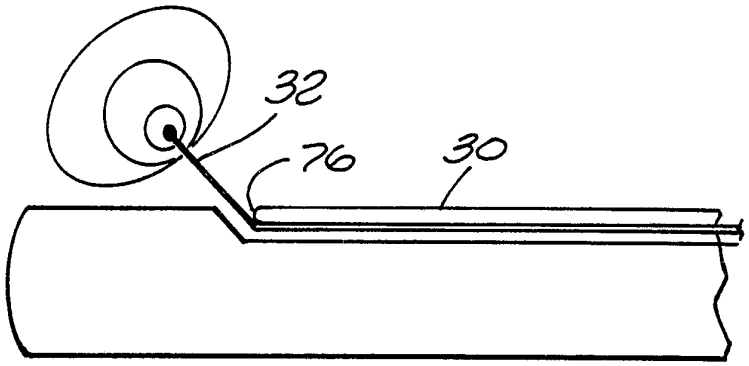

FIG. 8

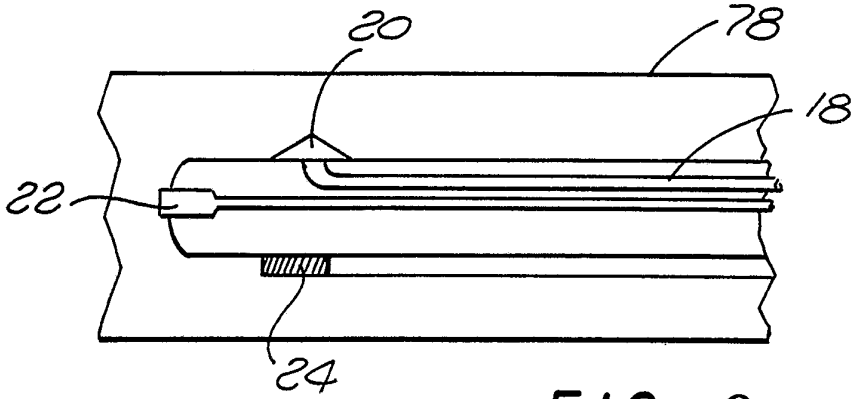

FIG. 9

INTERNATIONAL SEARCH REPORT

International Application No PCT/US91/00322

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC(5) A61B 5/00
US CL 128/670

II. FIELDS SEARCHED

Minimum Documentation Searched 4

Classification System	Classification Symbols
US CL	128/670,673,675,692,736

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 5

III. DOCUMENTS CONSIDERED TO BE RELEVANT 14

Category *	Citation of Document, 16 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No. 18
X Y	US, A, 4,850,358 (MILLAR) 25 JULY 1989, SEE ENTIRE DOCUMENT.	1,3,6,9-10 12,and 14-17 9,11,13
Y	US, A, 4,803,992, (LEMELSON) 14 FEBRUARY 1989 SEE ENTIRE DOCUMENT.	9,11
Y	US, A, 4,809,704 (SOGAWA) 07 MARCH 1989, SEE ENTIRE DOCUMENT.	13
A,P	US, A, 4,960,109 (LELE) 02 OCTOBER 1990, SEE ENTIRE DOCUMENT.	1-24
A,P	US, A, 4,955,380 (EDELL) 11 SEPTEMBER 1990, SEE ENTIRE DOCUMENT.	1-24
A	US,A, 4,883,062 (NICHOLSON) 28 NOVEMBER 1989 SEE ENTIRE DOCUMENT.	1-24
A	US, A, 4,841,981 (TANABE) 27 JUNE 1989, SEE ENTIRE DOCUMENT.	1-24

* Special categories of cited documents: 15

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"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)

"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

"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

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"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.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 2	Date of Mailing of this International Search Report 2
03 APRIL 1991	24 APR 1991
International Searching Authority 1	**Signature of Authorized Officer 20**
RO/US	KRISTA M. PFAFFLE

Form PCT/ISA/210 (second sheet) (May 1986)

FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

CONTINUED ON NEXT PAGE

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE [1]

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers ____ because they relate to subject matter [2] not required to be searched by this Authority, namely:

2. ☐ Claim numbers ____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out [3], specifically:

3. ☐ Claim numbers ____, because they are dependent claims not drafted in accordance with the second and third sentences of [illegible]

VI. ☐ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING [4]

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.

2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:

3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:

4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

☐ The additional search fees were accompanied by applicant's protest.

☐ No protest accompanied the payment of additional search fees.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category *	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No [13]
A	US, A, 4,815,471 (STOBIE) 28 MARCH 1989, SEE ENTIRE DOCUMENT.	1-24
A	US, A, 4,688,577 (BRO) 25 AUGUST 1987, SEE ENTIRE DOCUMENT.	1-24
A	US, A, 4,660,562 (HOUSE, SR.) 28 APRIL 1987, SEE ENTIRE DOCUMENT.	1-24
A	US, A, 4,554,927 (FUSSELL) 26 NOVEMBER 1985, SEE ENTIRE DOCUMENT.	1-24
A	US, A, 4,473,081 (DIOGUARDI) 25 SEPTEMBER 1984, SEE ENTIRE DOCUMENT.	1-24