PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 8/12, 17/34	A1	**(11) International Publication Number:** WO 91/08706 **(43) International Publication Date:** 27 June 1991 (27.06.91)

(21) International Application Number: PCT/GB90/01977

(22) International Filing Date: 18 December 1990 (18.12.90)

(30) Priority data:
8928533.2 18 December 1989 (18.12.89) GB
613,186 14 November 1990 (14.11.90) US

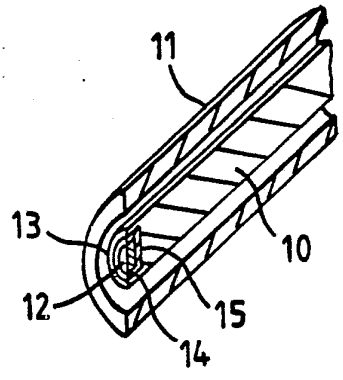
(71)(72) Applicants and Inventors: LESNY, Jan [GB/GB]; Tarrants, Stoborough, Wareham, Dorest BH20 5AJ (GB). AINDOW, Joseph, Douglas [GB/GB]; Precision Acoustic Limited, 5 Damers Road, Dorchester, Dorset DT1 2JX (GB).

(74) Agent: LUCKHURST, Anthony, Henry, William; Marks & Clerk, 57-60 Lincoln's Inn Fields, London WC2A 3LS (GB).

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

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

(54) Title: ULTRASONIC INSTRUMENT



(57) Abstract

An ultrasonic invasive instrument such as a biopsy needle has an ultrasonic transducer (12) mounted at one end. The transducer is electrically coupled to two conductors, such as a stylet (10) and cannula (11), to transmit signals indicating its position in an ultrasonic field transmitted by an imaging scanner. The transducer (12) is coupled to at least one of the conductors (10, 11) by an ohmic or capacitive coupling. In particular, body fluids can provide an electrical coupling between the transducer (12) and the cannula (11).

FOR THE PURPOSES OF INFORMATION ONLY

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

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	SD	Sudan
CF	Central African Republic	KP	Democratic People's Republic of Korea	SE	Sweden
CG	Congo			SN	Senegal
CH	Switzerland	KR	Republic of Korea	SU	Soviet Union
CI	Côte d'Ivoire	LI	Liechtenstein	TD	Chad
CM	Cameroon	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

ULTRASONIC INSTRUMENT

INTRODUCTION AND BACKGROUND

The present invention relates to an ultrasonic instrument for use in interventional procedures employed in surgical and medical investigations, treatment or diagnosis, in research and in related fields.

In procedures involving the insertion of an instrument into a human or animal body, it is often necessary for the position of the instrument to be known accurately. The use of ultrasonic instruments, in particular imaging scanners, to guide the insertion of surgical instruments such as puncture needles or catheters during invasive medical procedures is known. The imaging system usually relies on detection of passive echos from the instruments, but more recently techniques have been developed in which an ultrasonic transducer is located on the end of the instrument to provide an "active" detection system. The ultrasonic wave emitted by the imaging system is detected by the transducer, and an electrical signal is conveyed back to the imaging system, or the transducer emits an ultrasonic signal for

detection by the imaging system. For more general information reference can be made to US-A-3556079 and US-A-4249539. GB-A-2157828 describes an instrument in which the ultrasonic sensor is connected to a detection circuit by a pair of solid conductive paths. This requires quite complicated and accurate fabrication techniques.

OBJECTS AND SUMMARY OF THE INVENTION

It is an object of the present invention to provide an ultrasonic invasive instrument where the fabrication can be significantly less complicated and therefore less costly.

It has been found unexpectedly that it is not essential to have a conductive or very low resistance, connection to the transducer, but that satisfactory performance can be made if an ohmic or capacitive coupling is used.

According to the invention there is provided an ultrasonic invasive instrument comprising a device having an ultrasonic sensor secured at or near a first end of the device which is inserted into the body, and two electrically conductive paths extending from the sensor to a second end of the device for connection to the electronic circuitry, the sensor having first and

second electrode surfaces, at least one of which surfaces is electrically connected to a respective conductive path by an ohmic or capacitive coupling.

More particularly the invention is applied to a biopsy probe in which an electrically conductive stylet is arranged to be surrounded by an electrically conductive cannula. An electrically insulating barrier, such as an electrically non-conducting polymer film is positioned between the outer surface of the stylet and the inner surface of the cannula, and the ultrasonic sensor is mounted on the remote end of the stylet and, in use, is electrically coupled by body fluids or the like to the cannula so that signals generated by the sensor can be detected by an electronic circuit connected across the near ends of the stylet and the cannula.

The electrical connection between the stylet and sensor may be a capacitive and/or an ohmic coupling.

The coupling between the sensor and the needle may be a capacitive and/or an ohmic coupling, the latter being provided by the medium present in use adjacent the sensor.

Thus the invention provides a construction for an invasive ultrasonic instrument which is easier to

manufacture than the instrument of, for example, GB-A-2157828.

The invention is applicable to a wide range of instruments used in surgical and medical investigations, diagnosis, treatment and associated research, for example puncture needles, catheters and endoscopes, used for example for aspiration of liquids, taking histological and cytological biopsy samples, chorionic villus sampling, umbilical cord blood sampling, amniocentesis, in vivo fertilisation, positioning capsules for taking small bowel biopsies, ductography, selective arteriography, phlebography, embolisation, drug administration, radioactive source implantation and cardiac catheterisation.

Other aspects, preferred features and advantages of the invention will be apparent from the following description and the accompanying claims.

DESCRIPTION OF THE DRAWINGS

The invention will be further described by way of example with reference to the accompanying drawings, in which: -

Figure 1 shows an ultrasonic invasive instrument forming

a first embodiment of the invention;

Figure 2 shows an end of the instrument of Figure 1 on enlarged scale;

Figure 3 shows a biopsy needle forming a particularly preferred embodiment of the invention; and

Figure 4 shows another particularly preferred embodiment of the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, in Figures 1 and 2 a metallic stylet 10 has an electrically insulating outer polymer coating and is surrounded by a hollow metallic cannula or needle 11. A preferred coating is parylene by Union Carbide which has FDA approval, but other medically approved coatings may be used. Alternatively, or as well, the inner surface of the cannula may be coated. An ultrasonic sensor 12 (see Figure 2) is bonded to the end surface 13 of the stylet 1, or it may be bonded on the side a short way from the end face. The bonding is achieved by a thin layer 15 of a conventional medically-inert adhesive, but very preferably biocompatible. The adhesive need not be electrically conductive, since it is sufficient to provide an ohmic

or capacitive coupling.

The sensor is preferably a PVDF (polyvinylidene difluoride) film, which is typically 52 microns thick. Other sensors, such as lead zirconate titanate might be used. Usually, the material has a conductive metallic coating on its two major surfaces to form electrodes. However, it has been found that it is not necessary to provide these coatings and it is particularly preferred that uncoated material be used. One advantage which this gives is that the uncoated material is transparent and so more easily positioned by eye on the stylet tip. Also, the polarity of the connection of the material (i.e. which face is electrically connected to which conductor) has been found not to be important.

The solid stylet 10 forms a first conductor and the surrounding cannula 11 forms a second conductor for feeding signals from the sensor 12. The sensor 12 is electrically coupled to the cannula 11 by body fluids which will surround and enter the end of the cannula 11 adjacent the sensor 12. In the alternative a conductive fluid, such as saline, may be fed into the cannula 11, the fluids providing an ohmic or capacitive electrical coupling.

An outer sheath 18 and inner core 19 of a co-axial cable 16, which fits on a housing 17, are electrically

connected to the near ends of the stylet 10 and the needle 11. The stylet 10 and housing 17 are removeable to allow fluids etc. to be sucked into the cannula 11. A twisted pair two-core cable may be used with a surrounding grounded sheath for improved signal to noise ratio, the wires of the twisted pair being connected respectively to the stylet 10 and cannula 11. Signals generated by the transducer 12 are transmitted along the stylet 10 and the needle 11 to be measured in effect across the near ends of the stylet 10 and the needle 11. The sensor 12 couples electrically with the stylet 10 either ohmically or capacitively, as explained above, and also couples with the needle 11 ohmically and/or capacitively. Although the signals generated by the transducer are small, the apparently poor electrical connections for the sensor 12 are in fact found to be satisfactory in practice.

The device of Figures 1 and 2 is typically for cytological use or a shaped end may be provided on the cannula 11 for histology.

Figure 3, shows a biopsy needle, the particular design shown being similar to the "Tru-Cut" needle marketed by Travenol Laboratories, Inc. The stylet 10 has a recess 20 near its end 21. The recess 20 cooperates with a cutting edge 22 on the end of the cannula 11 to take a

tissue sample as the stylet 10 moves back into the cannula 11, as is well known. The ultrasonic sensor may be positioned in the recess 20, but preferably is positioned on the end surface 23 as in the embodiment of Figs. 1 and 2. In the recess 20, the sensor is better protected from damage and, in use, ultrasonic waves impinging on the remote end of the stylet 10 may be acoustically conducted up the stylet to the sensor at 16. Although this introduces a short acoustic delay, which may cause a registration error in the image, this may be clinically insignificant. If required this delay may be corrected for by a suitable signal processing method in the associated electronic detection and display circuitry. A greater problem arises when the probe is positioned in the body with the stylet 10 withdrawn into the cannula 11. Body fluids are needed to electrically couple the sensor 12 to the cannula 11, and these might not penetrate past the end 23. Saline could be injected in the probe to reduce this difficulty, but it is particularly preferred that the sensor be mounted on the end surface 23.
The stylet 10 and cannula 11 are electrically connected to the monitoring instrumentation (not shown) by a twisted pair cable 27.

The outer surface of the stylet 10 is electrically insulated from the cannula 11 by a polymer coating.

Also, as indicated above, it is possible to insulate the inner surface of the needle 11 to provide the insulating barrier between the stylet 10 and the needle 11 or a separately formed insulating sleeve could also be used in the embodiments of Figures 1 and 2 and Figure 3.

Figure 4 illustrates another embodiment, in which the probe 30 has a hollow metallic body 31, typically of stainless steel, and a copper wire 32 is carried within the hollow core 33. The wire 32 is electrically insulated from the body 31 by epoxy resin 34. A PVDF sensor 35 is bonded to the wire 32 by a U-V cured adhesive 36. As before the sensor does not need a metallic coating on its surface and the adhesive 36 need not be electrically conductive. The sensor 35 is spaced from the body 31 and its outer surface (electrode) 37 makes electrical contact with the body 31 by a capacitive or ohmic coupling, such as by body fluids. A twisted wire pair is connected to the near ends (not shown) of the body 31 and wire 32. The probe 30 may be part of a body tissue sampling device, such as the device of Figures 1 and 2.

Various modifications may be made to the described embodiments and it is desired to include all such modifications as fall within the scope of the accompanying claims.

CLAIMS

1. An ultrasonic invasive instrument comprising a device having an ultrasonic sensor secured at or near a first end of the device which is inserted into the body, and two electrically conductive paths extending from the sensor to a second end of the device for connection to electronic circuitry, the sensor having first and second electrode surfaces, at least one of which surfaces is electrically connected to a respective conductive path by an ohmic or capacitive coupling.

2. An instrument as claimed in claim 1, in which the sensor is a PVDF film ultrasonic transducer.

3. An instrument as claimed in claim 2, in which the PVDF is not provided with a metallic coating on one or both of its faces.

4. An instrument as claimed in claim 1, 2 or 3 in which the sensor is glued in position on the device with an electrically non-conducting adhesive.

5. An instrument as claimed in any one of claims 1 to 4, in which one of the electrically conductive paths is provided by a wall of the device and, in use, the sensor is ohmically or capacitively coupled to the wall.

6. An instrument as claimed in claim 5, in which the sensor is electrically coupled to the wall by body fluids.

7. An instrument as claimed in any one of claims 1 to 6, wherein the sensor is mounted on a cylindrical stylet and is electrically coupled to a condutor passing through the centre of the stylet, and to the cylindrical stylet wall.

8. An instrument as claimed in any one of claims 1 to 6, wherein the sensor is mounted on a stylet which provides a first of the conductive paths and the second is provided by a cannula surrounding the stylet and through which the stylet moves.

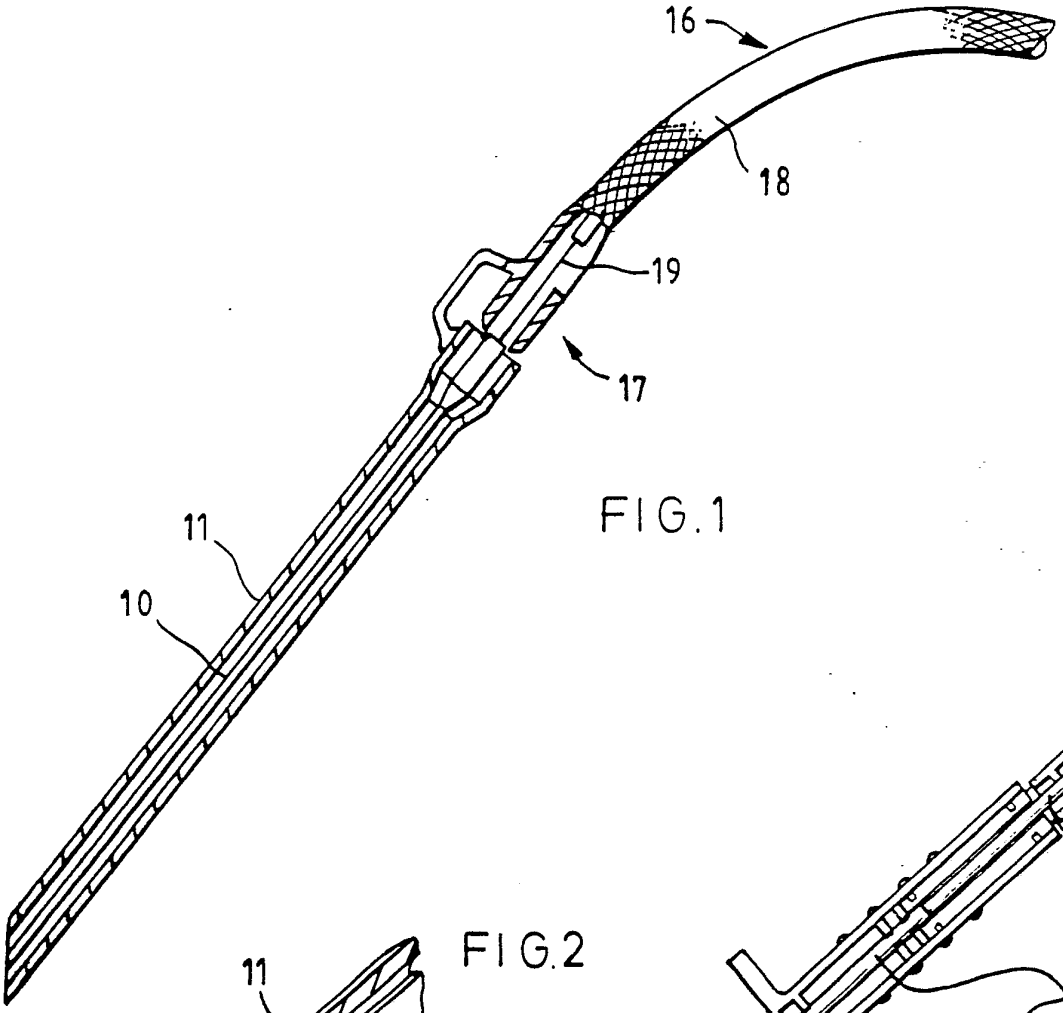
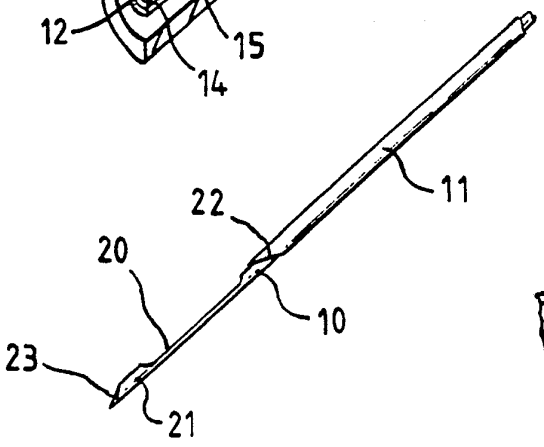


FIG.1

FIG.2

FIG.3



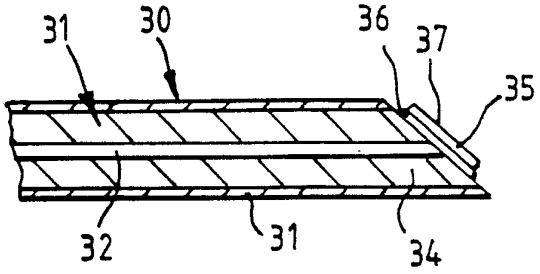


FIG.4

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 90/01977

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

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

Int.Cl. 5 A61B8/12 ; A61B17/34

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X Y	GB,A,2157828 (J.LESNY ET AL.) 30 October 1985 see the whole document (cited in the application)	1, 2, 8 3-5, 7
P,Y	US,A,4911172 (T.BUI ET AL.) 27 March 1990 see column 2, line 66 - column 3, line 51; figures 1-6	3-5
Y	US,A,2507770 (H.H.CLAASSEN) 16 May 1950 see column 1, line 35 - column 2, line 6; figure 1	3
X Y	EP,A,260953 (P.G.YOCK ET AL.) 23 March 1988 see the whole document	1 4, 5, 7
A	US,A,4706681 (B.BREYER ET AL.) 17 November 1987 see abstract; figures 1-7	1

-/--

° Special categories of cited documents : [10]

"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	Date of Mailing of this International Search Report
25 MARCH 1991	19 APR 1991
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	HUNT B.W.

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

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	DE,A,3718604 (SIEMENS AG) 22 December 1988 see the whole document ---	1, 6

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. PCT/GB90/01977 SA 42934

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 25/03/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
GB-A-2157828	30-10-85	None	
US-A-4911172	27-03-90	None	
US-A-2507770		None	
EP-A-260953	23-03-88	AU-A- 7847487	04-02-88
		JP-A- 63177866	22-07-88
		US-A- 4887606	19-12-89
US-A-4706681	17-11-87	None	
DE-A-3718604	22-12-88	None	