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(54) Title: A CATHETER ASSEMBLY WITH SELECTABLE ELECTRODES

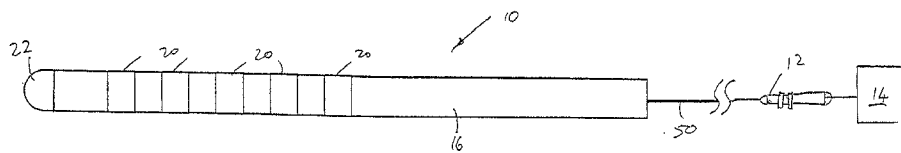


FIG. 1

(57) Abstract: A catheter assembly (10) with selectable electrodes (20) includes an elongate electrode sheath (16) defining a lumen (18). A plurality of electrodes (20) are carried by the electrode sheath (16), each of at least some of the electrodes (20) having a conductive member (26) arranged to be accessible via the lumen (18) of the electrode sheath (16). A stylet (24) is displaceably received in the lumen (18) of the electrode sheath (16), the stylet 24 carrying at least one conductive element (40) for engaging the conductive member (26) of at least one selected electrode (20) to place the at least one selected electrode (20) in communication with equipment to which the catheter assembly (10) is connected, in use.



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"A catheter assembly with selectable electrodes"**Cross-Reference to Related Applications**

The present application claims priority from United States of America Provisional Patent Application No 61/012,164 filed on 7 December 2007, the contents
5 of which are incorporated herein by reference.

Field

The present disclosure relates, generally, to the field of catheters and, more particularly, to a catheter assembly with selectable electrodes.

10

Background

Catheters carrying electrodes are used in various medical applications. These applications include treatment of cardiac abnormalities as well as neurological applications. The range of applications includes sensing electrical impulses from the
15 patient's body, stimulating nerves in a patient's body, treating pain management, for example, using heat treatment, and treating cardiac abnormalities using ablation techniques.

In many situations, it is desirable that a particular electrode of the catheter be selected for the required purpose. This also may include selecting more than one
20 electrode at a time.

A convenient method of selecting the electrode while the catheter is *in situ* would be useful. In this regard, it will also be appreciated that, in certain circumstances, some catheters are permanently implanted into a patient's body and it may be necessary to switch from one electrode to another where the catheter has been
25 fibrosed to facilitate more effective treatment.

Summary

According to the invention, there is provided a catheter assembly with selectable electrodes, the assembly including
30 an elongate electrode sheath defining a lumen;
a plurality of electrodes carried by the electrode sheath, each of at least some of the electrodes having a conductive member arranged to be accessible via the lumen of the electrode sheath; and
a stylet displaceably received in the lumen of the electrode sheath, the stylet
35 carrying at least one conductive element for engaging the conductive member of at

least one selected electrode to place the at least one selected electrode in communication with equipment to which the catheter assembly is connected, in use.

The conductive member may be electrically engaged by the conductive element of the stylet to place the selected electrode/s in electrical communication with the
5 electrical equipment. However, in some applications it may be desired to determine the temperature of tissue at a site of the patient's body. Thus, in addition, or instead, the conductive element may be brought into thermal contact with the conductive member of the selected electrode/s to enable the temperature at the selected electrode/s to be communicated to the electrical equipment.

10 The electrical equipment may be dependent on the application of the catheter assembly. In applications where the catheter assembly is used to sense electrical impulses in a patient's body, the electrical equipment may include a device for displaying and/or storing data relating to the electrical impulses. Where the catheter
15 assembly is used for pain management, such as by heat treatment, or where the catheter assembly is used for stimulation, the electrical equipment may include an energy source.

The conductive member of each electrode of the at least some electrodes may protrude into the lumen. Each electrode may communicate with its associated conductive member by means of an opening formed through a wall of the electrode
20 sheath, the opening containing a conductive filler.

In an embodiment, at least one of the at least one conductive element of the stylet and the conductive member of each electrode may include a detent mechanism so that a force is required to obtain contact, or latching, between the conductive element and the conductive member. The detent mechanism may be defined by the conductive
25 element standing proud of an outer surface of the stylet.

A first force may be required to cause the conductive element and the conductive member to make contact with each other and a second, greater force may be required to cause the conductive element and the conductive member to part.

One of the conductive member and the conductive element may carry a current
30 carrying contact element to facilitate electrical contact between the conductive member and the conductive element. The current carrying contact element may be a resiliently flexible device and may be in the form of a coil spring arranged in an annular configuration. The current carrying contact element may, for example, be a BalContact™ spring available from Bal Seal Engineering, Inc. of 19650 Pauling,
35 Foothill Ranch, CA, 92610-2610, USA. It will be appreciated that, in certain

circumstances, the current carrying contact element, due to its resilient flexibility may, itself, constitute the detent mechanism.

In another embodiment, the stylet may carry at least two axially spaced conductive elements for enabling at least two electrodes to be selected simultaneously.

5 The stylet may be tubular to define a passage.

The, or each, conductive element may have an electrical conductor associated with it for electrically connecting the, or each, conductive element to the electrical equipment, in use. The, or each, electrical conductor may extend through the passage.

10 In an embodiment, the assembly may include a steering control device received in the passage of the stylet for effecting steering and deflection of at least a distal region of the electrode sheath. In this embodiment, the electrical conductors may be embedded in material, i.e., the wall, of the stylet. The stylet may therefore be manufactured in accordance with the teachings of the Applicant's International Patent Application No. PCT/AU01/01339 dated 19 October 2001 and entitled "An electrical
15 lead".

Brief Description of Drawings

Fig. 1 shows a side view of a first embodiment of a distal part of a catheter assembly with selectable electrodes;

20 Fig. 2 shows a sectional side view of the distal part of the catheter assembly of Fig. 1;

Fig. 3 shows, on an enlarged scale, a sectional side view of the part of the catheter assembly encircled by Circle 'A' in Fig. 2;

25 Fig. 4 shows a sectional side view of a distal part of a component of the catheter assembly;

Fig. 5 shows, on an enlarged scale, a sectional side view of the part of the component encircled by Circle 'B' in Fig. 4;

Fig. 6 shows a three dimensional view of a second embodiment of a distal part of a catheter assembly with selectable electrodes;

30 Fig. 7 shows a sectional side view of the distal part of the catheter assembly of Fig. 6;

Fig. 8 shows, on an enlarged scale, a sectional side view of the part of the catheter assembly encircled by Circle 'C' in Fig. 7;

35 Fig. 9 shows a sectional side view of a distal part of a first component of the catheter assembly of Fig. 6;

Fig. 10 shows, on an enlarged scale, a sectional side view of the part of the first component encircled by Circle 'D' in Fig. 9;

Fig. 11 shows a sectional side view of a distal part of a first version of a second component of the catheter assembly of Fig. 6; and

5 Fig. 12 shows a sectional side view of a distal part of a second version of the second component of the catheter assembly of Fig. 6.

Detailed Description of Exemplary Embodiments

Referring initially to Figs. 1-5 of the drawings reference numeral 10 generally
10 designates a first embodiment of a catheter assembly with selectable electrodes. What is illustrated in the drawings represents a distal part of the catheter assembly 10. As illustrated schematically in Fig. 1 of the drawings, the catheter assembly 10 is connected via a catheter handle 12 to electrical equipment 14.

The catheter assembly 10 includes an elongate electrode sheath 16 defining a
15 lumen 18 (Fig. 2). The electrode sheath 16 carries a plurality of electrodes 20 in axially spaced relationship on an external surface of a distal region of the electrode sheath 16. If desired, the electrode sheath 16 terminates, at its distal end, in an end electrode 22.

A stylet 24 (Fig. 2) is displaceably received in the lumen 18 of the electrode sheath 16. Referring in greater detail to Figs. 2 and 3 of the drawings, it is to be noted
20 that each electrode 20 has a conductive member 26 projecting into the lumen 18 of the electrode sheath 16. As illustrated more clearly in Fig. 3 of the drawings, each conductive member 26 is a substantially channel shaped device defining a radially inwardly facing channel 28. An electrical conductor 30, which may conveniently be in the form of a canted, coil spring arranged in an annular formation is received in the
25 channel 28 of each conductive member 26. As indicated above, the electrical conductor 30 is, for example, a BalContact™ spring.

Each conductive member 26 communicates with its associated electrode 20 via a conductive filler material 32 received in an opening 34 formed through a wall 36 of the electrode sheath 16.

30 The stylet 24 carries a conductive element in the form of a conductive collar 40 inwardly of its distal end 42 as shown in Figs. 4 and 5 of the drawings. The collar 40 defines a radially outwardly facing channel 44 which mates with the conductor 30, in use, as will be described in greater detail below. In addition, as illustrated more clearly in Fig. 5 of the drawings, the collar 40 is dimensioned so that its outer diameter is
35 greater than the outer diameter of the stylet 24. The collar 40 thus stands proud of an outer surface 46 of a wall 48 of the stylet 24 and acts as a detent mechanism so that a

force is required to make and break electrical, mechanical and/or thermal contact between the collar 40 and the relevant conductive member 26. This ensure that, when any electrode 20 is selected by bringing the collar 40 into mating engagement with the conductive member 26 of the selected electrode 20, a predetermined force is required to
5 cause engagement between the conductive member 26, the collar 40 and the conductor 30 to ensure good electrical contact (and/or thermal contact, if applicable) and mechanical purchase between the stylet 24 and the selected electrode 20.

While the tip electrode 22 has been shown as not being connectable to the stylet 24, it will be appreciated that, if desired, the tip electrode could be connected to a
10 similar conductive member 26 to be engaged by the collar 40 of the stylet 24.

Depending on the application of the catheter assembly 10, the force required to cause mechanical and electrical engagement between the conductive member 26 and the collar 40 is of the order of 20g. It will, however, be appreciated that this is subject to the application of the catheter assembly 10 and may be more or less than 20g but
15 may be at least 10g.

In addition, to inhibit damage being caused to surrounding tissue by use of the catheter assembly 10, it may be required that electrical and mechanical engagement between the conductive member and the collar 40 breaks when a force exceeding a predetermined amount, greater than that of the engaging force, occurs. Once again,
20 depending on the application of the catheter assembly 10, the force is of the order of 40g but could be greater or less than this.

The collar 40 communicates electrically with the electrical equipment 14 by means of an electrical conductor 50. In the embodiment illustrated, the stylet 24 is hollow and defines a passage 52. The electrical conductor 50 extends through the
25 passage 52 and through the catheter handle 12 and is connected to the electrical equipment 14.

As indicated above, the catheter assembly 10 could be used in numerous applications, including permanent implantation in a patient's body. In the case of permanent implantation, the conductor 50, instead of extending through the passage 52
30 of the stylet 24, could be embedded in the wall 48 of the stylet 24. The stylet 24 could therefore be manufactured in accordance with the teachings of the Applicants International Patent Application No. PCT/AU01/01339 dated 19 October 2001 and entitled "An electrical lead".

In one embodiment, the catheter assembly 10 could be used for cardiac purposes
35 for diagnosing and treating cardiac abnormalities. Thus, the electrodes 20 could be used for sensing irregular impulses in the heart wall. These impulses are detected by

the relevant, selected electrode 20 and are passed, via the collar 40, through the electrical conductor 50 to the electrical equipment 14 where the impulses can be displayed and/or recorded. In another cardiac application, the electrodes 20 can be used for ablation therapy in which case the electrical equipment 14 is a source of
5 ablation energy such as radiofrequency (RF) energy which is transmitted through the conductor 50 to the selected electrode 20 to enable ablation of heart tissue to occur. It will be appreciated that, in this embodiment, additional conductors (not shown) for temperature sensing equipment associated with the electrodes 20, such as thermocouples or thermistors (not shown), will extend through the passage 52 of the
10 stylet 24 to the relevant electrode 20. Instead, these additional conductors could be embedded in the wall 36 of the electrode sheath 16 to extend through the handle 12 to the electrical equipment 14.

In still a further application, the catheter assembly 10 could be used in neurological applications such as sensing neurological impulses and, once again, the
15 electrical equipment 14 in that case would be a device for displaying and/or recording those neurological impulses.

In still a further application, the catheter assembly 10 could be used to stimulate nerves, for example, in functional electrical stimulation (FES) devices. In that case, the electrical equipment 14 could be a control unit for controlling stimulation of the
20 patient's nerves via the electrodes 20 of the catheter assembly 10.

It will be appreciated that the examples set out above are not intended to be exhaustive and other applications will be readily apparent to persons skilled in the art.

Referring again to Fig. 3 of the drawings, another version of this embodiment is shown. In this embodiment, the assembly 10 includes a steering control device in the
25 form of a further stylet 54 receivable in the passage 52 of the stylet 24. In this embodiment, the stylet 24 is of a flexible material and may not be sufficiently rigid for steering and/or manipulating the catheter assembly 10. In such circumstances, the further stylet 54 is used for steering the catheter assembly 10 to the desired location in a patient's body and/or deflecting a distal part of the electrode sheath 16 of the catheter
30 assembly 10.

To accommodate the stylet 54 within the passage 52 of the stylet 24, the electrical conductor 50, instead of extending through the passage 52, is embedded in the wall of the stylet 24 as shown in dotted lines at 56 in Fig. 3 of the drawings. Thus, the stylet 24, in this version, may be manufactured in accordance with the teachings of
35 the applicant's International Patent Application No. PCT/AU01/01339 referenced above. While the conductor 56 has been illustrated as extending axially along the stylet

24, this is for illustrative purposes only. In practice, it is more likely that the conductor 56 will be helically wound within the wall of the stylet 24.

Referring now to Figs. 6-12 of the drawings, a second embodiment of a catheter assembly 10 is illustrated. With reference to the previous embodiment, like reference numerals refer to like parts, unless otherwise specified.

In this embodiment, the stylet 24 includes two axially spaced collars 40. Thus, the stylet 24 can be used for engaging two electrodes 20 simultaneously, both mechanically and electrically as well as thermally, if required. While, in the illustrated embodiment, the collars 40 have been indicated as being spaced apart sufficiently so that adjacent electrodes 20 are latched simultaneously, it will be appreciated that this need not be the case and the spacing between the collars 40 can be greater than the spacing between adjacent electrodes 20. It will also be appreciated that, if desired, the stylet 24 could carry more than two collars 40 so that more than two electrodes 20 can be latched simultaneously.

Each collar 40 has an electrical conductor 50 associated with it, the conductors 50 extending through the passage 50 of the stylet 24, through the handle 12 of the catheter assembly 10 to the electrical equipment 14. However, as described above with reference to the first embodiment, it will be appreciated that, in certain circumstances, the assembly 10 could include the further stylet 54 for steering and/or deflecting the distal part of the electrode sheath 16. In that case, the conductors 50 associated with each collar 40 would be embedded in the wall of the stylet 24.

In the version of the stylet 24 shown in Fig. 11 of the drawings, the conductor 30 is carried by the conductive member 26 of each electrode 20. Conversely, in the version of the stylet shown in Fig. 12 of the drawings, each collar 40 carries a conductor 30.

While the embodiments have been described with reference to the stylet being placed in electrical contact with the selected electrode/s, the assembly 10 can also be used to feed temperature information from the selected electrode/s 20 to the electrical equipment 14. Thus, the stylet 24 could carry a copper/Constantin pair of wires which are placed in thermal contact with the selected electrode/s 20 via the collar 40 of the stylet 24. The copper wire may be spaced 180° from the Constantin wire so that a more accurate determination of the temperature of the selected electrode/s 20 can be made.

It is an advantage of the invention that a catheter assembly 10 is provided which renders electrodes 20 carried by the assembly 10 easily selectable by a clinician. This improves the versatility of the catheter assembly 10. In addition, a plurality of electrodes 20 can be selected simultaneously or, instead, electrodes 20 can be energised

sequentially. Once again, this improves the versatility of the assembly 10 as it is a simple procedure for the clinician to select a desired electrode.

Still further, because it is not necessary for the electrode sheath 16 to carry conductors for the electrodes 20, a thinner electrode sheath 16 can be made which is
5 easier to manipulate and navigate through a patient's body.

Where there are a greater number of electrodes to be selected, the handle 14 may include a motor so that the stylet 24 can be displaced electromechanically for improving speed of selection of the electrodes.

Even in the situation where a cathode assembly 10 is permanently implanted in a
10 patient, it is a simple procedure for a clinician to select a different electrode for any purpose simply by moving the stylet 24 so that its collar 40 engages the desired electrode/s 20.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific
15 embodiments without departing from the scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS:

1. A catheter assembly with selectable electrodes, the assembly including
an elongate electrode sheath defining a lumen;
a plurality of electrodes carried by the electrode sheath, each of at least some of
5 the electrodes having a conductive member arranged to be accessible via the lumen of
the electrode sheath; and
a stylet displaceably received in the lumen of the electrode sheath, the stylet
carrying at least one conductive element for engaging the conductive member of at
least one selected electrode to place the at least one selected electrode in
10 communication with equipment to which the catheter assembly is connected, in use.
2. The assembly of claim 1 in which the conductive member of each electrode of
the at least some electrodes protrudes into the lumen.
- 15 3. The assembly of claim 2 in which each electrode communicates with its
associated conductive member by means of an opening formed through a wall of the
electrode sheath, the opening containing a conductive filler.
4. The assembly of any one of the preceding claims in which at least one of the at
20 least one conductive element of the stylet and the conductive member of each electrode
includes a detent mechanism so that a force is required to obtain contact between the
conductive element and the conductive member.
5. The assembly of claim 4 in which a first force is required to cause the
25 conductive element and the conductive member to make contact with each other and a
second, greater force is required to cause the conductive element and the conductive
member to part.
6. The assembly of claim 4 or claim 5 in which one of the conductive member and
30 the conductive element carries a current carrying contact element to facilitate contact
between the conductive member and the conductive element.
7. The assembly of any one of the preceding claims in which the stylet carries at
least two axially spaced conductive elements for enabling at least two electrodes to be
35 selected simultaneously.

8. The assembly of any one of the preceding claims in which the stylet is tubular to define a passage.
9. The assembly of claim 8 in which the, or each, conductive element has an
5 electrical conductor associated with it for electrically connecting the, or each, conductive element to the electrical equipment, in use.
10. The assembly of claim 9 in which the, or each, electrical conductor extends through the passage.
- 10 11. The assembly of any one of claims 1 to 9 which includes a steering control device received in the passage of the stylet for effecting steering and deflection of at least a distal region of the electrode sheath.
- 15 12. The assembly of claim 11 in which the, or each, electrical conductor is embedded in material of the electrical sheath.

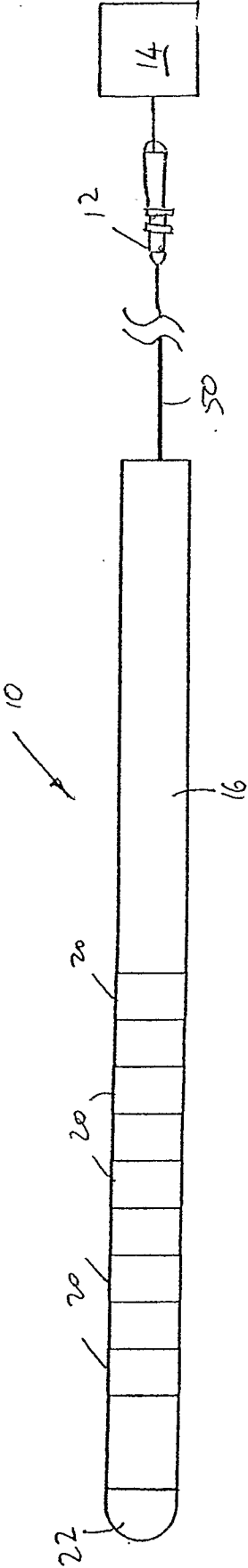


FIG. 1

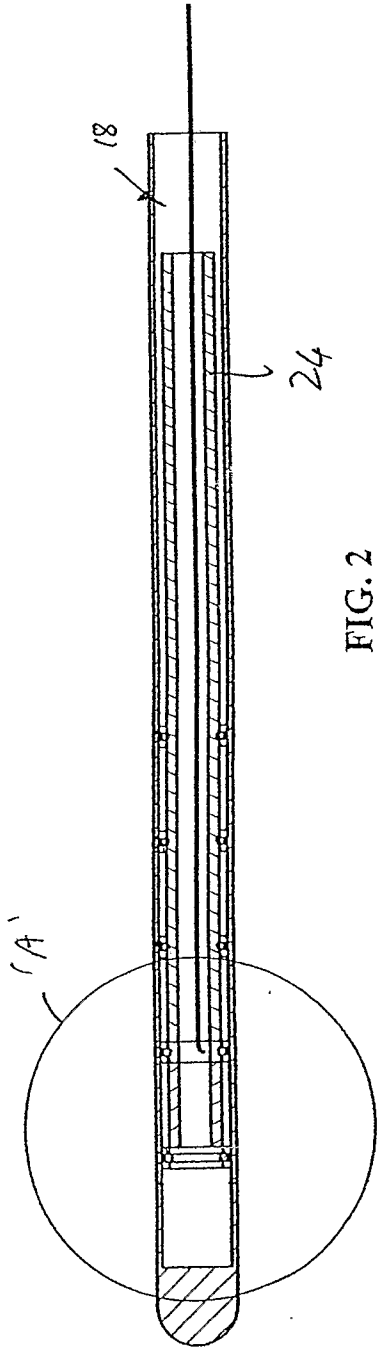
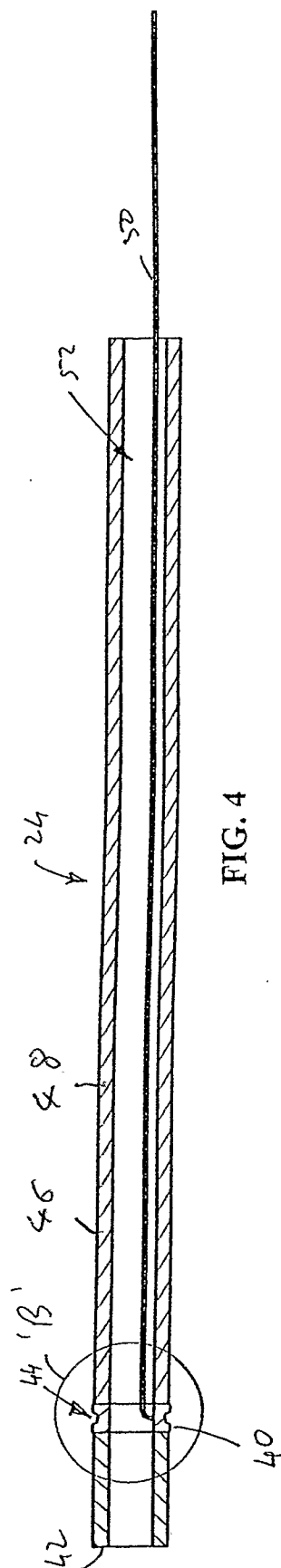
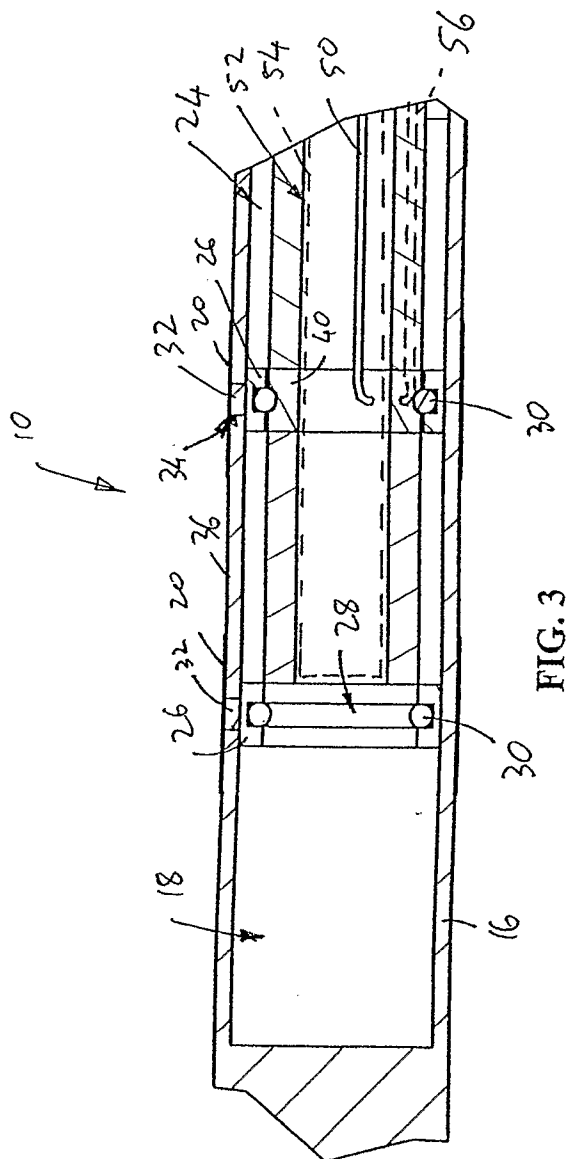


FIG. 2



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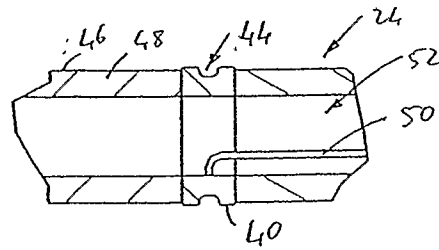


FIG. 5

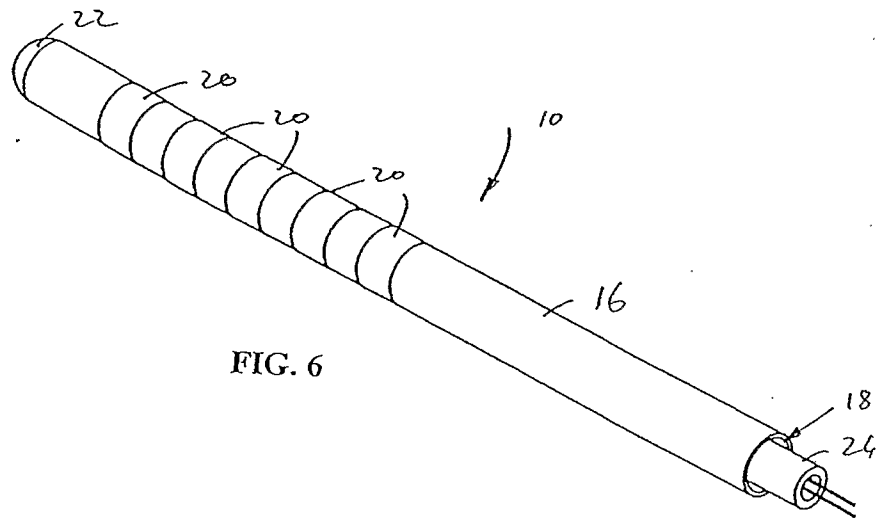


FIG. 6

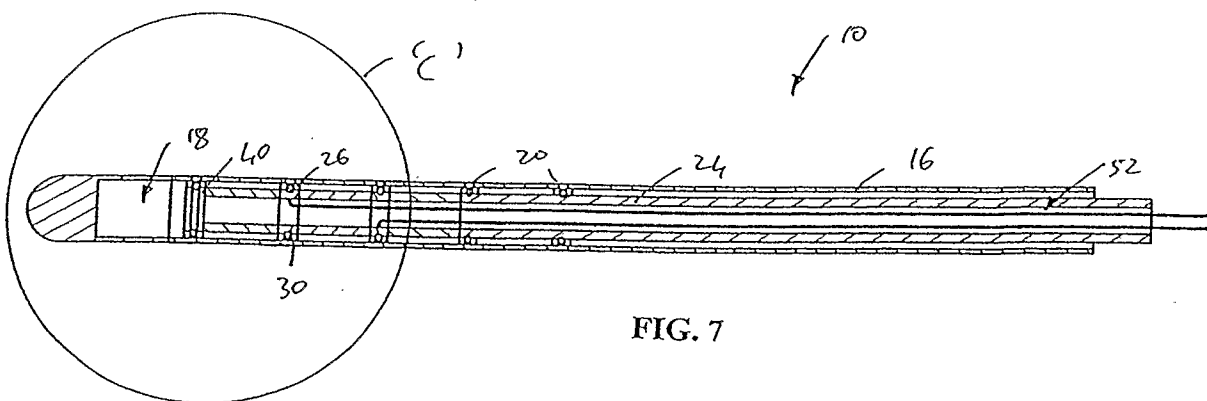


FIG. 7

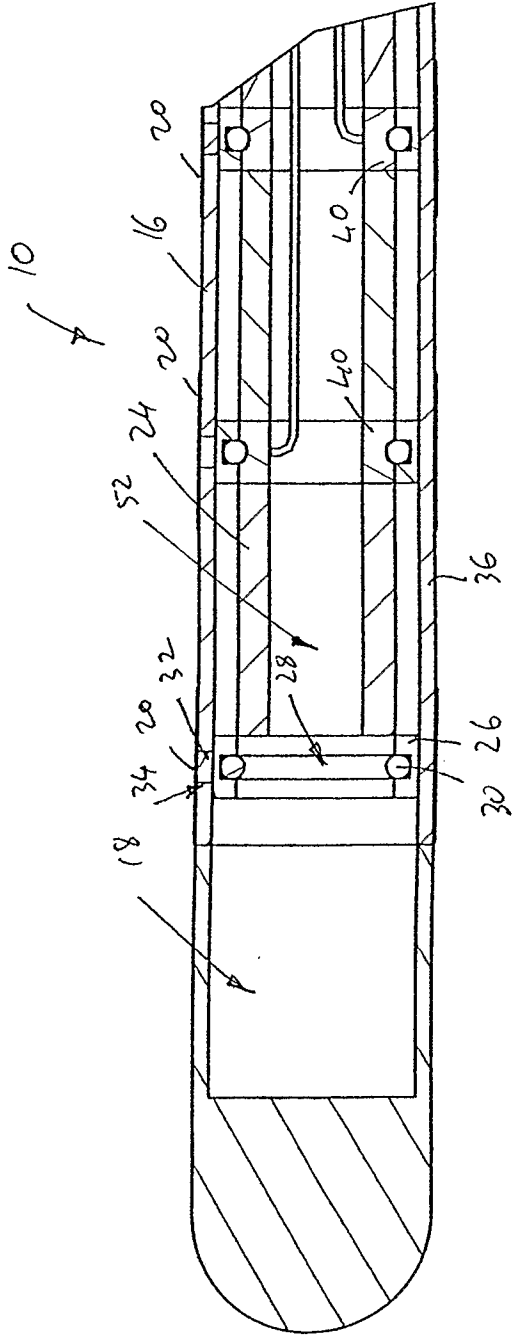


FIG. 8

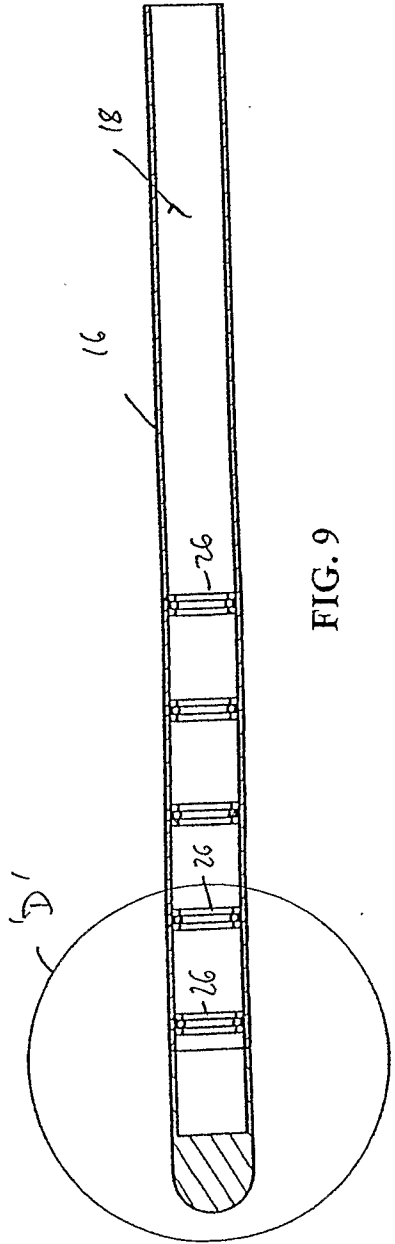
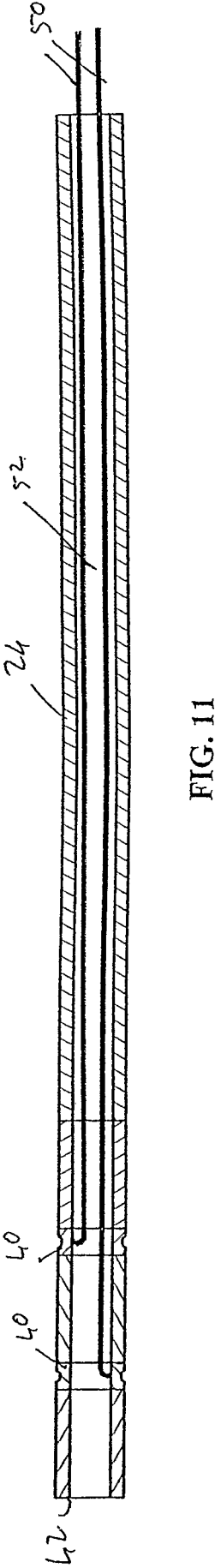
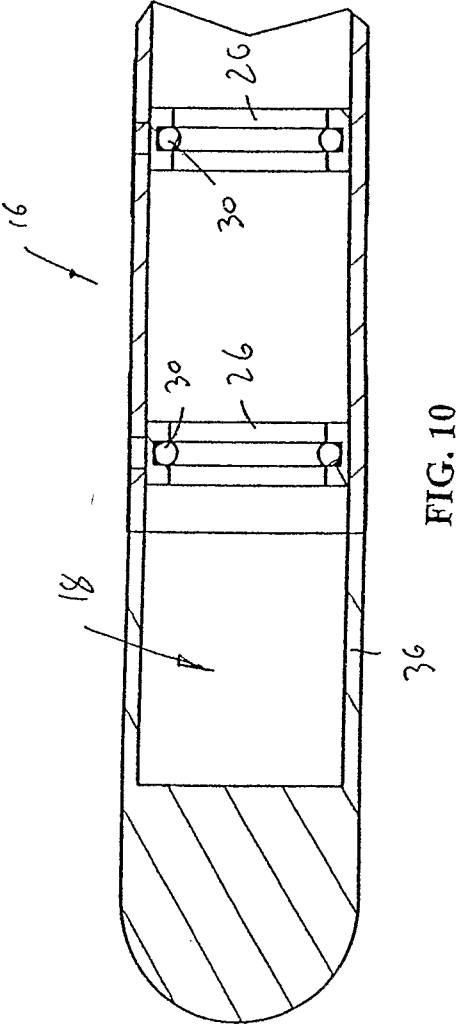


FIG. 9



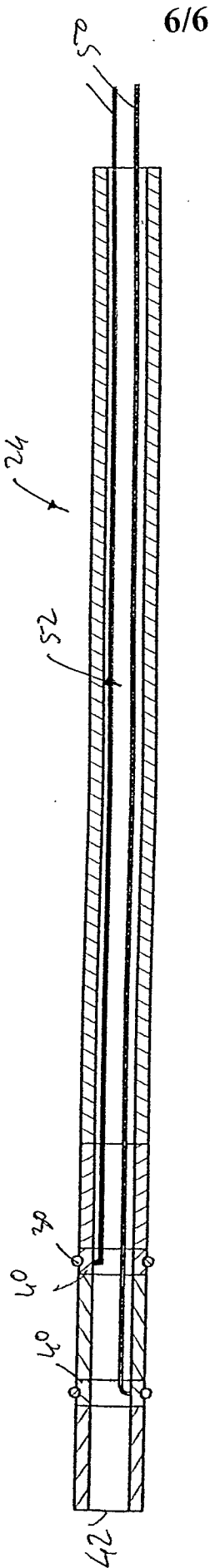


FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2008/001788

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61B 18/14 (2006.01) *A61B 5/145* (2006.01) *A61M 25/00* (2006.01)

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)

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 practicable, search terms used)
EPODOC, WPI IPC A61B 5, A61M 25/00 & KEYWORDS CATHETER, CANNULA, SELECT, CHOOSE, SWITCH, ELECTRODE, MOVE, DISPLACE, SLIDE, SHIFT & OTHERS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO1998019611A1 (CORDIS WEBSTER INC) 14 May 1998 see page 3 line 22–page 6 line 13 & figures 1-5	1-12
A	EP1803410A1 (BIOSENSE WEBSTER INC) 4 July 2007 see column 6 paragraph 22–column 7 paragraph 24 & figures 1, 2 & 2A	1-12
A	WO1994026186A1 (VIDAMED INC) 24 November 1994 see abstract & figures 1-3	1-12
A	WO1994004220A1 (VIDAMED INC) 3 March 1994 see abstract & figures 1-4	1-12



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:

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Date of the actual completion of the international search
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Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU2008/001788

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian 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		Patent Family Member					
WO	9819611	CA	2270235	EP	0951244	US	5893885
EP	1803410	JP	2007185505	US	2007156128		
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		AU	19895/97	AU	20475/95	AU	20708/97
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Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

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