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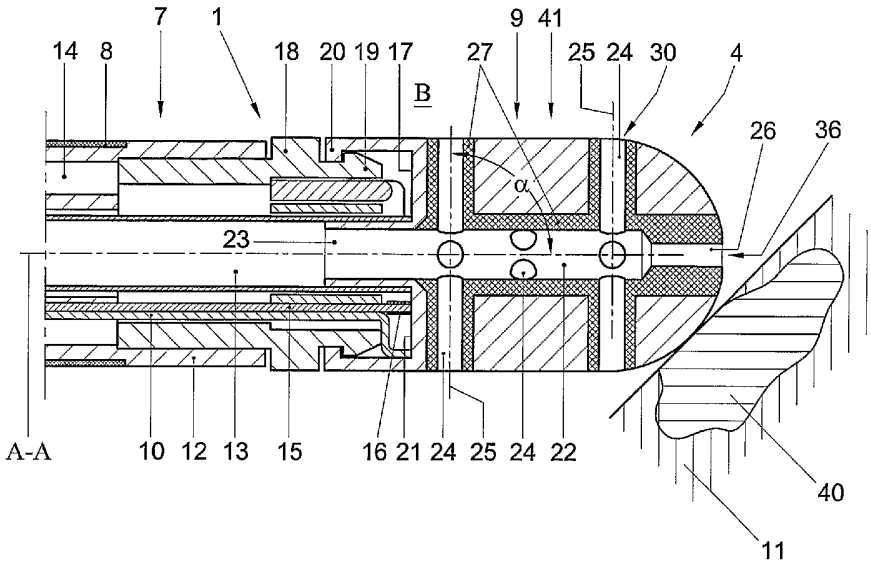
(54) **Title:** CATHETER AND METHOD, IN PARTICULAR FOR ABLATION AND LIKE TECHNIQUE



(57) **Abstract:** The invention relates to a catheter, provided with an elongated body with an electrically conductive first end, wherein through said body at least one live wire extends which is connected to said first end and a channel for feeding a cooling fluid through said body, which channel is provided, in or near said first end, with at least one outlet opening and wherein, in said first end, a temperature sensor has been arranged, while said channel is thermally insulated from said first end.

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Title: Catheter and method, in particular for ablation and like technique.

The invention relates to a catheter. The invention relates in particular to a catheter for ablation in body cavities such as blood vessels or organs such as a heart.

It is known to perform treatments in a human or animal body with the aid of catheters with an electrically conductive first end. This ablation electrode is typically present on the extremity of the catheter. Also, elaborations are known with several ablation electrodes one behind the other on the catheter which is inserted into the cavity mentioned. The patient is then laid on a conductive plate, for instance an earthed plate. Then, through the catheter, an electric current is passed which runs through the body. If the first end is held against or at a very short distance from a wall of the body cavity, this wall will be heated locally over a relatively small area, as a result of the electrical resistance of the wall. Consequently, in this area, ablation occurs. As a result thereof, part of the tissue of this wall dies. With this treatment, for instance heart rhythm disturbances can be treated and be prevented for the future.

During this treatment, known per se, it is of importance that the temperature of, in particular, the first part of the catheter can be controlled so that thus, the extent of heating of the target area can be examined and hence, on the basis of *inter alia* this temperature, the power which is to be supplied to this first end can be controlled. Moreover, prior to the actual treatment, with the aid of a relatively reduced power, the abutment of this first end against the wall can be examined, on the basis of the rise in temperature which is measured in this first end. The fact is that a poorer abutment will lead to a smaller temperature rise when the power supplied remains the same. Moreover, the temperature in the liquid, in particular blood, is to be prevented from rising too much around the first end because, as a result thereof, clogging can occur which can lead to dangerous situations in the body. Moreover, too

strong a heating of the first end of the catheter can lead to blistering, explosions due to boiling of entrapped liquid in the wall of the respective cavity such as the heart, which is dangerous to the health and, in extreme cases, can lead to openings in the heart wall, while, furthermore, the danger exists that undesirably large areas are affected, as a result of which damage to, for instance, an atrioventricular node can occur. In order to measure this temperature, it is known to include a temperature sensor such as a thermocouple in the first end.

In order to prevent the first end of the catheter from being heated too strongly, it has been proposed to cool this first end. To that end, Wittkampf (Journal of the American College of Cardiology 1988, 11, p. 17A) has described a catheter wherein a liquid channel is provided in the catheter terminating in outlet openings in the first end. A cooling fluid such as physiological salt solution can be urged through this channel and, during use, effects permanent cooling of the first end. Thus, the temperature thereof can be kept low. However, a drawback of this known catheter is that, in it, the actual temperature of the first end cannot be accurately measured.

In order to solve this drawback, it has already been proposed to also include a thermocouple in the first end in such a catheter. However, as a result of the cooling this is inaccurate. Consequently, the temperature change of the end mentioned and, hence, of for instance the liquid, in particular the blood around this first end or the temperature of the wall, cannot be verified sufficiently accurately, so that clots can still occur, while, moreover, the extent of the temperature rise of the wall cannot be sufficiently controlled and verified. As the first end of this catheter remains relatively cool, no deposits of such clots will be detected on the outside, which entails the risk that it can be assumed, wrongfully, that during the treatment no clots have formed. The fact is that the liquid, in particular the blood around this first end and/or the wall, may very well have been heated such that coagulation has occurred, having clots as a result.

In an alternative embodiment, a catheter is provided with a closed channel extending through the first end, while the first end is cooled from the inside. Here, the same dangers arise as with the above-described catheter while, moreover, the great disadvantage occurs that the blood is not cooled at all.

The object of the invention is to provide a catheter with which, in a safe and accurate manner, treatments can be performed wherein in a body cavity, local heating of a wall, such as ablation, is to be obtained.

A further object of the invention is to provide such a catheter with which, during use, in a simple and accurate manner, abutment of a first end thereof against a wall can be examined.

A further object of the invention is to provide a catheter of which, during use, the first, leading end can be heated in a simple and accurate manner, in particular with the aid of current, while clots can be prevented in a simple manner.

The invention further contemplates providing such a catheter which is compatible with existing devices for ablation techniques.

A number of these and other objects is achieved with a catheter according to the invention.

With a catheter according to the invention, an elongated body is provided, through which a live wire extends, coupled to an electrically conductive first end. Moreover, through this elongated body, a channel extends terminating in or near a leading first end into at least one outlet opening. During use, liquid can be guided through this channel, which liquid can from this at least first outlet opening. In or near the first end, a temperature sensor has been arranged with which, during use, the temperature of this first end can be measured.

With a catheter according to the invention, a thermal separation is provided between the channel and the first end. This thermal separation has been arranged such that during use, liquid flowing through the channel

practically does not contact the first end before it flows from the at least one first outflow opening. Thus, during use, it is ensured that it is not the first end that is cooled by the liquid, at least not directly, but that it is the liquid extending therearound, in particular blood. With this, coagulation can be prevented while the temperature of the first end can be accurately measured.

In an advantageous embodiment, a catheter according to the invention is further characterized in that this channel has a longitudinal direction and is provided with a series of outlet openings, which outlet openings are positioned such that cooling fluid supplied, during use, through this channel flows through the outlet openings in an outflow direction including an angle with the longitudinal direction mentioned. This angle is for instance between 30° and 90°, more in particular between 45° and 90°, so that the outflow direction substantially faces away from the outside of the first end. Furthermore, also in the axially leading end of the first end, an outlet opening can be provided.

In an alternative embodiment, one or more outlet openings can be provided in a leading longitudinal edge of the body, such that during use, a flow is obtained substantially along the outside surface of this first end. To that end, the respective at least one outlet opening can be located adjacent the first end, viewed in front view. An advantage of such an embodiment can be, for instance, a simple construction, no channel extending through the respective first end and/or an advantageous outflow pattern.

In an advantageous embodiment, the or each outlet opening is designed such that a slightly turbulent flow is obtained around the first end, so that coagulation is prevented even better.

In a practical embodiment, at least in and/or adjacent the first end, the channel and/or the outlet openings are provided with a thermally insulating inside casing and/or designed in a thermally poorly conductive material. Herein, thermally poorly conductive is understood to at least include a heat transfer across the wall of the channel to the first end which is

considerably smaller, for instance 10% or more, more in particular 25% or more smaller than the heat transfer across the wall of a channel which would occur in such a catheter with similar dimensions without such thermally insulating features.

The temperature sensor, which can for instance be designed in a known manner as a thermocouple, is preferably included in the first end, at a distance from the interface between the first end and the body of the catheter, preferably adjacent the middle of the electrode. As a result, an accurate temperature measurement of this first end becomes possible. With automatically performed treatments, this sensor can also be used as a switch.

The first end can be manufactured from a thermally and electrically conductive material such as metal. Also, only an outer casing can be provided with metal, on, for instance, a plastic, ceramic or glass core, so that already a part of the desired thermal insulation can be obtained.

The invention further relates to a method for thermal treatment such as ablation, characterized by the features of claim 9.

With such a method, in a more accurate manner, the temperature of a first end of an ablation catheter can be checked and controlled, so that in an accurate and safe manner, ablations and other thermal treatments can be performed in body cavities such as blood vessels, a heart and the like. With a method according to the invention, the temperature of a wall part of a body cavity can be controlled particularly accurately, without the danger arising that coagulation occurs in blood flowing around this wall part. Coagulation of proteins in blood can lead to clot formation, which clots can become dislodged in the blood flow and can lead to, for instance, infarcts. In particular in the left ventricle and atrium of the heart, clots are to be avoided. With a method according to the invention, preferably, the temperature of the blood around this wall part is kept below the coagulation temperature, while the tip of the catheter used and/or the wall part to be treated can be heated to the desired, optionally higher, temperature. The or each electrode is then substantially

heated through the nearby wall, in which temperature increase occurs as a result of resistance. The extent of contact between the wall and the electrode will therefore be of influence to the heating of the electrode. This is a reason why a contact measurement can be important.

With this method, preferably in a known manner, a cooling fluid such as a physiological salt solution is supplied through a channel extending through the catheter, which cooling fluid is directly introduced into the respective body cavity. In a method according to the invention, preferably, this cooling fluid is thermally insulated to a high extent from the material of the first end of the catheter leading during use, so that the blood around this first end is cooled more than the first end itself. Preferably, the temperature of the first end is then measured accurately so that the temperature of the wall against which or at which the catheter is held can be accurately controlled.

With the aid of the cooling fluid, the temperature of the blood around this first end is preferably kept lower than approximately 55°C. The temperature or the outside of the first end is then preferably kept below approximately 65°C.

With the aid of the cooling fluid, turbulence is preferably generated in the blood around the first end, so that clot formation in the blood is prevented even better.

In the further subclaims, further advantageous embodiments of the invention are described. In clarification of the invention, embodiments of the invention will be further described with reference to the drawing. In the drawing:

Fig. 1 schematically shows a catheter according to the invention with a first end in a heart ventricle;

Fig. 2 schematically shows a number of catheters in a heart, for treatment of heart rhythm disturbances;

Fig. 3 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a first embodiment;

Fig. 4 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a second embodiment;

Fig. 5 schematically shows, greatly enlarged, in cross section, a forward end of a catheter according to the invention, in a third embodiment; and

Fig. 5A shows a cross section along the line VA-VA in Fig. 5.

In this description, identical or corresponding parts have identical or corresponding reference numerals. The embodiments shown are only given by way of example and should not be construed as being limitative in any manner. In particular, combinations of parts of the embodiments shown are also understood to be described herein. Herein, a body cavity is understood to include at least each part of a human or animal body which can be reached by a forward end of a catheter.

In Fig. 1 it is schematically shown how a catheter 1 has been inserted into a heart 2 of a patient 3. A forward end 4 of a catheter 1A is inserted into a ventricle 5, in particular a right ventricle of the heart, while the corresponding forward end 4 of the second catheter 1B is inserted into the right atrium of the heart 2. This is merely shown as an illustration of possible positions. The catheter(s) has/have or has/have been inserted into the heart 2 from, for instance, the groin of the patient 3, which is a method known per se and will therefore not be described further, no more than the known method and device for controlling these catheters and the works thereto in the catheter.

In Fig. 2, in cross section, a heart 2 is shown, with left and right ventricle 5A, 5B and left and right atrium 6a, 6B. Into this heart 2, four catheters 1 have been inserted. During, for instance, a measurement and/or treatment of heart rhythm disturbances, one or more catheters 1 can be inserted into the heart 2, in order to obtain a clear picture of the electric currents in the heart. Each of the catheters 1 shown has a body 7 which is elongated and can be guided through the vascular system of the patient. The

body 7 has a forward end 4, further to be called the first end 4 which is inserted as far as into the heart 2. In, at least adjacent the first end, a number of electrodes 8 is provided in the form of metal rings, for instance three, which are separated from each other by electrically insulating material of the body and each can be connected, via a conductive wire through the body 7 to electronic equipment, so that, in a manner known per se, measurements can be carried out, for instance an electrogram can be made.

The first end 4 is further provided with a tip 9 manufactured from an electrically conductive material such as metal, which tip, via an electrically conductive wire 10 (Figs. 3 – 6), can be connected to electronic equipment (mentioned but not shown) with which, via the wire 10, current can be fed to this tip 9. During the measurement and/or the treatment, the patient lies on an electrically conductive underground, for instance on a earthed plate (not shown). For performing the treatment, for instance an ablation, the tip 9 of the catheter 1 is pressed against the wall 11 of the heart 2, so that a current will start to run through this wall 11. As a result of electrical resistance of the tissue of the wall, heat development will occur adjacent the tip 9, so that tissue can be treated, in particular heart muscle cells can be killed, so that undesired conduction pathways in the heart 2 or undesired sources of heart rhythm disturbances can be blocked. This is a known treatment, called ablation technique, for preventing heart rhythm disturbances. For a further description of these techniques, reference is made to the publication mentioned in the introduction and relevant manuals.

It is known to use a cooling fluid in a catheter 1 for use in for instance ablation techniques. This liquid is brought through a channel in the catheter to the forward end of the catheter and from there it is either introduced into the blood stream or returned through the catheter. At the inside of the catheter, the cooling fluid is then brought into intimate contact with the electrode to be cooled such as the tip of the catheter, in order to cool this electrode and thus prevent deposition of proteins on the outside. Such a

catheter is for instance described in EP 0 856 292. However, such catheters have the drawback that the temperature of the respective electrode, such as the tip, no longer yields a good picture of the heat development in the wall 11 and/or in the blood B around this electrode.

With a catheter 1 according to the invention, these drawbacks have been solved in that, during use, the electrode such as the tip 9, is not cooled, at least not directly, but that the blood B *is*, so that, in the blood, no coagulation occurs and clots are prevented. As a result, the temperature of the respective electrode such as the tip 9 can be accurately measured and controlled, while, from it, an estimate can be made of the temperature of the wall 11.

Hereinafter, a number of examples of catheters 1 according to the invention is described.

In Fig. 3, a first embodiment of a forward end of a catheter 1 according to the invention is shown, in cross-sectional side view.

This catheter 1 comprises an elongated body 7 with a first end 4, formed by a tip 9 made of an electrically and thermally conductive material, in particular metal such as platinum. The body has a longitudinal axis A-A and comprises a substantially cylindrical wall 12 through which a channel 13 extends. Between the wall 12 and the channel 13, there is an annular space 14 through which extends, for instance, the electrically conductive wire 10, the different connecting points for the electrodes 8 and control means known per se (not shown) for control of the end 4. Moreover, through the annular space 14 a second electrically conductive wire 15 extends which is connected to a thermocouple 16.

In the embodiment shown in Fig. 3, the tip 9 is coupled to the body 7 by means of a coupling part 18 which is attached, for instance glued, by a first side within the wall 12, and, on the other side, fitted in a compatible second snap edge 20 of the tip 9 via a snap edge 19. In this embodiment, the thermocouple 16 has been arranged in or against the interface 17 between the

body 7 and the tip 9, at least on the end surface 21 of the tip 9 proximal to the body 7 and the coupling part 18.

In the first end 4, in particular in the tip 9, a channel part 22 is provided extending in line with the axis A-A and connected to the channel 13, for instance in that a sleeve 23 extends from the end surface 21 in the channel 13 and is fitted therein. From an outside 41 of the tip 9, first bores 24 are provided reaching as far as in the channel part 22 and extending substantially radially. These first bores 24 all have a longitudinal axis 25 including an angle α with the longitudinal axis A – A of the body 7, for instance approximately 90°. A second bore 26 is provided in line with the channel 13, at least with the axis A – A, which bore 26 terminates in the apex 36 of the tip 9. In each bore 24, 26, as well as around the channel part 22, a thermally insulating casing 27 is provided such, that during use a cooling fluid, in particular physiological salt solution, can be passed through the channel 13, the channel part 22 and the bores 24, 26 without direct contact occurring between the cooling fluid and the (inside of) the tip 9. Thus, direct cooling of the tip 9 by the cooling fluid is prevented for the larger part. In the elaboration of Fig. 3, the sleeve 23 is not thermally insulated.

In Fig. 4, a first, more advantageous alternative embodiment of a first end 4 of a catheter 1 according to the invention is shown, distinguished from the one according to Fig. 3 in that here, also the sleeve 13 is thermally insulated, while, moreover, the thermocouple 16 is arranged closer to the apex 36 of the tip 9, so that an even more accurate temperature measurement of, in particular, the heart wall can be performed.

In Fig. 5, a further alternative embodiment is shown, with only tip 9 in cross-sectional side view, which, as to built-up, largely corresponds to the one of the elaborations of Figs. 3 and 4. However, here, a tip 9 is provided having a core 28, manufactured from a material with a low thermal and/or electrical conductivity, for instance glass, ceramics or plastic, and a casing 29 with, relative thereto, a good heat conductivity and/or electrical conductivity.

Here, only in the casing 29 the bores 24, 26 have been provided with a thermal inside casing, at least formed as part of the core 28, so that in a simple manner the desired thermal insulation is obtained. In this embodiment, the longitudinal axes 25 extend approximately tangentially relative to the channel part 22 (Fig. 5A) and include an angle α with the longitudinal axis A – A which angle deviates from 90°, for instance approximately 75° to 80°, such that the outflow direction is slightly in the direction of the apex 36, at least in the direction of the wall 11. Thus, the cooling of the blood around the tip 9 and adjacent the wall 11 can be even more improved. A thermocouple 16 has been provided against the casing 29.

In the embodiments according to the Figs. 3 – 5, each time, the extremity of each bore 24, 26 forms an outflow opening 30 for cooling fluid. These outflow openings 30 can for instance be formed such that during use a turbulent flow is generated in blood flowing by. Means that can be used to that end are known from hydrodynamics. In the embodiments shown, for instance thirteen outflow openings have been provided but it will be clear that any number of outflow openings 30 can be provided.

Optionally, near the electrode, in particular near the interface 17 between body 7 and tip 9, one or more outlet openings can be provided, so that a part of the cooling fluid is directed along the tip 9, at least along the outer surface of the electrode, for direct cooling of the blood and/or generating turbulence.

When using a catheter 1 according to the invention in a treatment of, for instance, heart rhythm disturbances or the like, wherein ablation technique is used in a body cavity flown-through with blood such as a ventricle or atrium of a heart or an artery or a vein, preferably, the current intensity and the supply of cooling fluid is regulated such, that the temperature of the blood around the tip 9 is kept below the coagulation temperature. In practice, this means below approximately 55°C, so that no coagulation occurs. Preferably , the temperature of the tip 9 is regulated such that it does not

exceed 65°C. In practice, this has appeared to be a reasonably safe limit. With larger electrodes (of a length of, for instance, 8 mm instead of 4 mm) relatively more cooling will occur to blood flowing around so that there is a larger difference between the tissue and electrode temperature. With an 8 mm tip, 50 to 55° is a good target value, at least with existing electrodes. The electrode will clearly remain cooler than the heated tissue of the wall, which is kept below 100°C in order to prevent the earlier-mentioned explosions. In Fig. 3, schematically, in the wall 11 an area 40 is indicated in which heat development occurs as a result of the current passed through the wall 11, as described earlier. Naturally, as to dimension and shape, this area of influence 40 depends on the current intensity used, and duration of the treatment and is only given by way of indication.

The invention is not limited in any manner to the exemplary embodiments given in the description and the drawing. Many variations thereon are possible within the framework of the invention as outlined by the claims.

For instance, different materials can be used for the different parts, and outflow openings can be provided in different manners, as long as, at least substantially, the tip 9 is prevented from being cooled from the inside by cooling fluid flowing therethrough. The leading end of the catheter can have any desired shape and can also be used on different locations than the heart, for instance also for fighting tumors and such aberrations of for providing scar tissue in a controlled manner. A catheter according to the invention can also be provided with several electrodes, at least one of which being provided with a cooling device according to the invention, with insulated outflow opening. Also, only one electrode can be provided at a distance of the end.

These and many comparable variations are understood to fall within the framework of the invention as outlined by the claims.

Claims

1. A catheter, provided with an elongated body with an electrically conductive first end, wherein through said body at least one live wire extends which is connected to said first end and a channel for feeding a cooling fluid through said body, which channel is provided, in or near said first end, with at least one outlet opening and wherein, in said first end, a temperature sensor has been arranged, while said channel is thermally insulated from said first end.

2. A catheter according to claim 1, wherein said at least one outflow opening is provided in said first end.

3. A catheter according to claim 1 or 2, wherein said channel has a longitudinal direction and is provided with a series of outlet openings, which outlet openings are arranged such that during use, cooling fluid supplied through said channel flows out through said outlet openings in an outflow direction which included an angle with said longitudinal direction.

4. A catheter according to claim 1 or 2, wherein the outlet openings are provided with a thermally insulating inside casing.

5. A catheter according to any one of the preceding claims, wherein at least one said outlet opening is provided in said body, adjacent said first end.

6. A catheter according to any one of the preceding claims, wherein said first end is attached to said body, wherein said temperature sensor is provided in said first end, at a distance from an interface formed between said body and said first end.

7. A catheter according to any one of the preceding claims, wherein the outlet openings are designed such that cooling fluid flowing therefrom during use flows away from said first end.

8. A catheter according to any one of the preceding claims, wherein said first end has at least one metal outside.

9. A method for thermal treatment, in particular ablation, wherein a catheter with an electrically conductive first end is provided in a body cavity, with said first end near or, preferably, against a wall of said body cavity, while at a distance from said first end a complementary electrically conductive element is arranged, preferably outside the body in which said cavity is located, whereupon an electric current is generated between said first end and said conductive element, such that said wall is heated, whereupon, adjacent said first end, a cooling fluid is dispensed, while the temperature of said first end is measured and is regulated, while direct cooling of said first end from the inside thereof by said cooling fluid is prevented.

10. A method according to claim 9, wherein said cooling fluid, through a channel in said catheter, is supplied and dispensed in said protein containing liquid, while said cooling fluid in said catheter is separated from at least said first end through thermal insulation.

11. A method according to claim 9 or 10, wherein the cooling fluid is dispensed in a protein containing liquid such as blood around said first end such that said protein containing liquid is cooled with the aid of said cooling fluid adjacent an interface between said protein containing liquid and said wall and near the outside of said first end and is kept at a temperature below the coagulation temperature of said protein containing liquid.

12. A method according to any one of claims 9 – 11, wherein said ablation is performed in a body cavity wherein as liquid, blood is present, while the temperature of said blood is kept at a temperature below approximately 55°C and the temperature of said first end is regulated such that it remains below approximately 65°C.

13. A method according to any one of claim 9 – 12, wherein as cooling fluid a physiological salt solution is used, which is introduced into said protein containing liquid such that around said first end, turbulence occurs in said protein containing liquid.

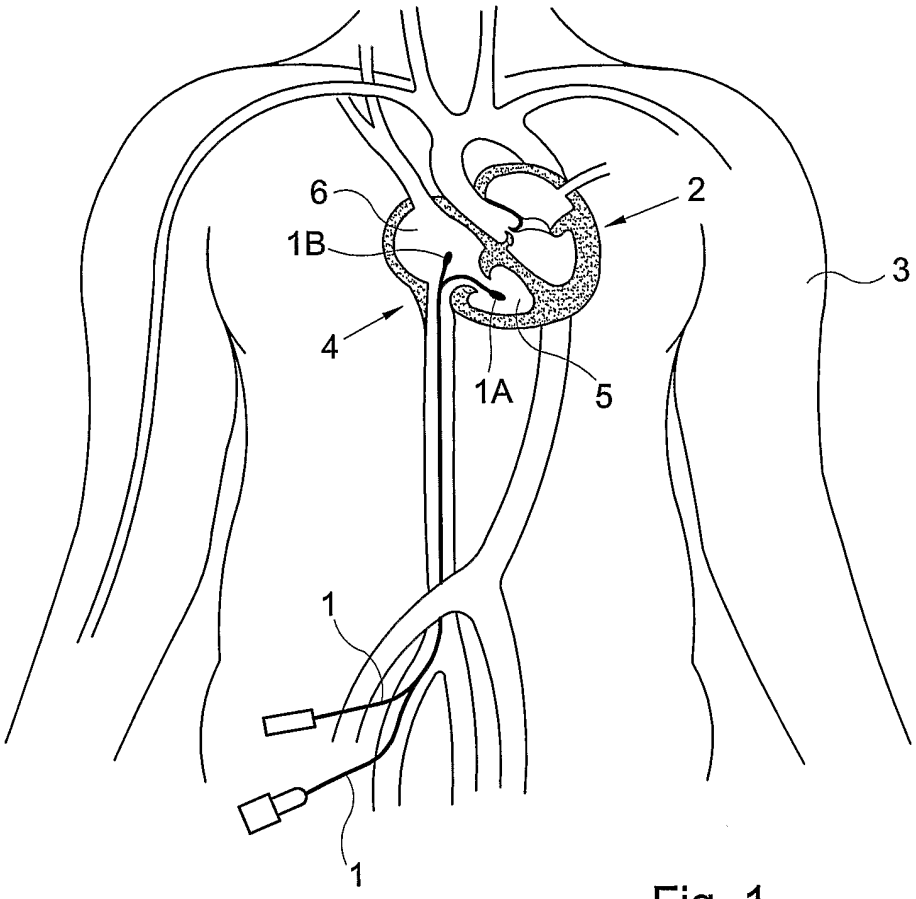

Fig. 1

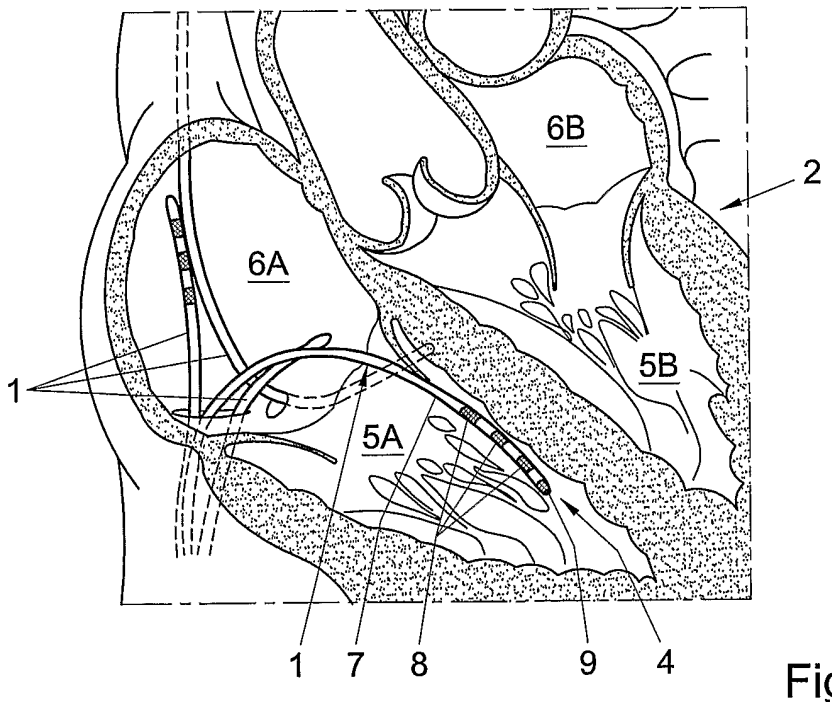

Fig. 2

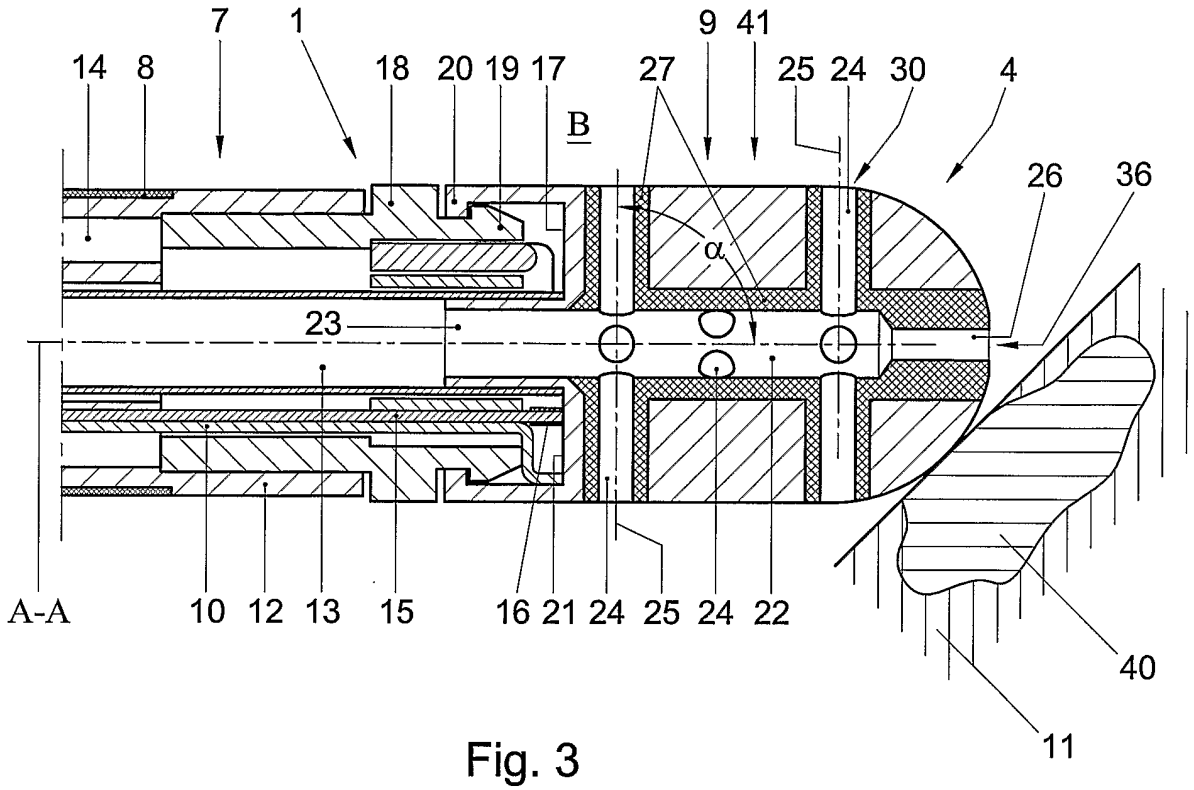
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Fig. 3

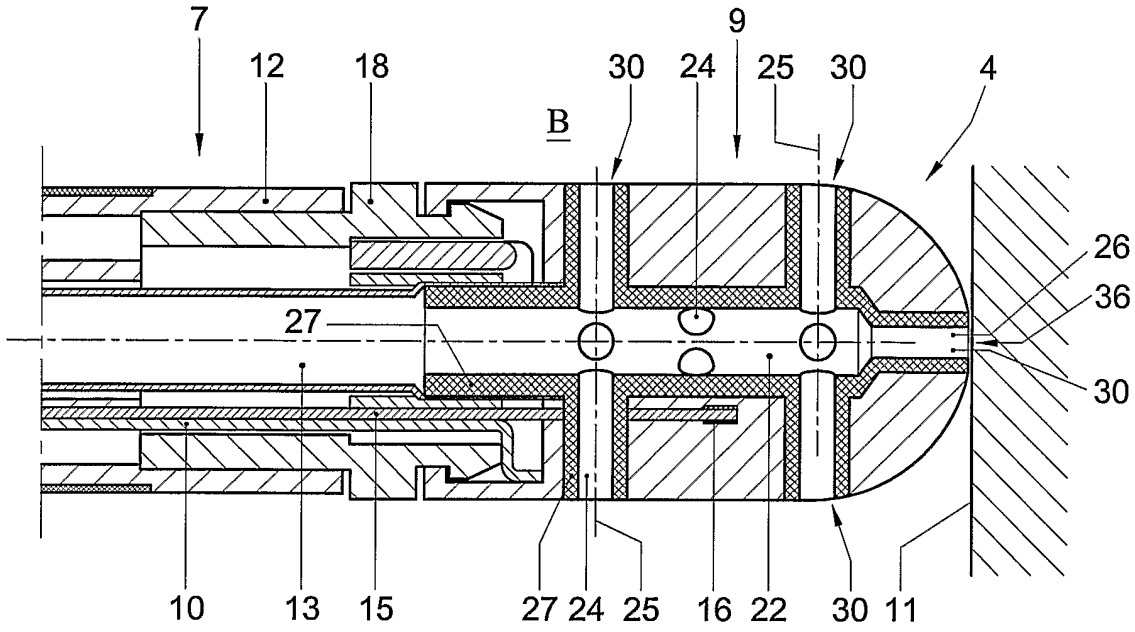
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Fig. 4

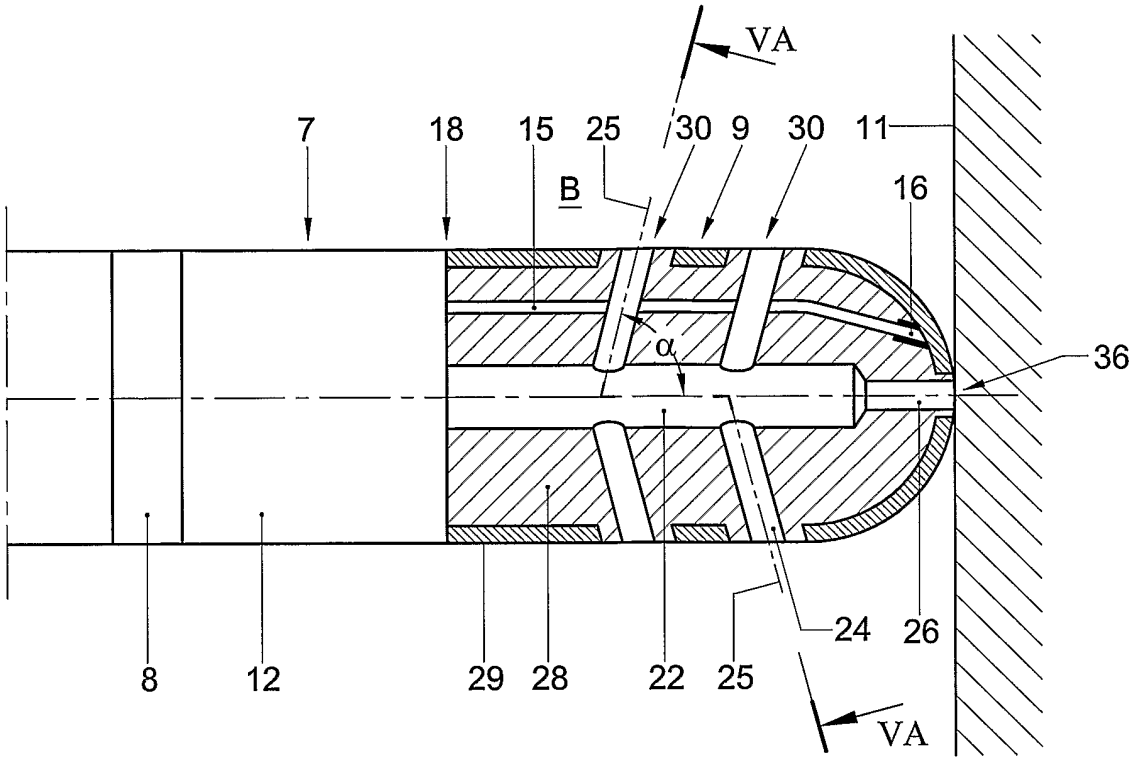
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Fig. 5

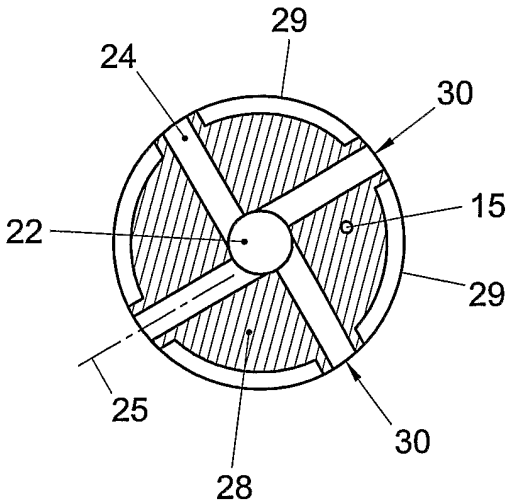
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Fig. 5A

INTERNATIONAL SEARCH REPORT

Inte al Application No
PCT/NL2004/000741

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/14

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 7 A61B

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)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 96/36860 A (EP TECHNOLOGIES) 21 November 1996 (1996-11-21) page 34, line 22 - page 35, line 30; figure 10	1
A	EP 0 856 292 A (MEDTRONIC INC) 5 August 1998 (1998-08-05) cited in the application abstract	1
A	US 6 500 175 B1 (GOUGH EDWARD J ET AL) 31 December 2002 (2002-12-31) column 3, line 66 - column 4, line 17	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"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 when the document is taken alone

"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

Date of the actual completion of the international search	Date of mailing of the international search report
14 January 2005	24/01/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Mayer-Martenson, E

INTERNATIONAL SEARCH REPORT

ational application No.
PCT/NL2004/000741

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 9-13
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
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, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

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.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] 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 claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

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