PATENT ASSIGNMENT

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SUBMISSION TYPE:	NEW ASSIGNMENT
NATURE OF CONVEYANCE:	ASSIGNMENT

CONVEYING PARTY DATA

Name	Execution Date
Hiroshi Nakagawa	08/21/2007

RECEIVING PARTY DATA

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Internal Address:	Room 201
City:	Norman
State/Country:	OKLAHOMA
Postal Code:	73019

PROPERTY NUMBERS Total: 1

Property Type	Number
Application Number:	13210090

OP $40.00 13210090

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NAME OF SUBMITTER:	Emily A. Vogt

Total Attachments: 27
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CONFIRMATORY ASSIGNMENT

WHEREAS I, Dr. Hiroshi Nakagawa of 1216 North West 195th Street, Edmond, Oklahoma 73003, hereinafter ASSIGNOR, by University of Oklahoma Proprietary Information Invention Disclosure No. 04HSC045 dated 8 March 2004 (hereinafter said Prior Assignment), have assigned my entire right, title, and interest in, to, and under said inventions and patent application in the Netherlands included in said Prior Assignment (Exhibit A attached hereto), including my entire right, title, and interest in, to, and under any and all patents to be obtained therefor throughout the world, for use in any and all goods or services used or useful in, or related to, catheter and method, in particular for ablation and like technique, together with the right to sue and recover for, and the right to profits or damages due or accrued arising out of or in connection with, any and all past, present, or future infringements of any patent or patents issuing with respect thereto;

AND WHEREAS said inventions and patent application included in said Prior Assignment (Exhibit A) are more fully identified in Exhibit I attached hereto, said Exhibit I including, for example, application number and filing date information, that was unavailable on 8 March 2004;

NOW, THEREFORE, for and in consideration of good and valuable consideration to me in hand paid by ASSIGNEE, the receipt of which is hereby acknowledged, I hereby confirm that I have sold, assigned, and transferred unto the University of Oklahoma, a university previously organized and existing under the laws of the State of Oklahoma, and having an address at 660 Parrington Oval, Room 201, Norman, OK 73019 (hereinafter ASSIGNEE), its successors and assigns, my entire right, title, and interest in, to, and under said inventions and said applications, set forth in Exhibit I, and all divisions, continuations, continuations-in-part, reissues, or renewals thereof, and all patents, both foreign and domestic, that may or shall issue therefor, including all of my entire rights under any and all international conventions, for use in any and all goods or services used or useful in, or related to, the medical device industry, together with the right to sue and recover for, and the right to profits or damages due or accrued arising out of or in connection with, any and all past, present, or future infringements of any patent or patents issuing with respect thereto;

AND I HEREBY confirm that I have authorized ASSIGNEE, its successors and assigns, or anyone it has properly designated, to apply for patents, in its own name if desired, in any and all foreign countries, and additionally to claim the filing date of any aforesaid application, and otherwise take advantage of the provisions of any and all international conventions;

AND I HEREBY confirm that I have authorized and requested any official of any State whose duty consists of issuing patents, or other evidence or forms of any industrial property protection on any aforesaid application, to issue same to ASSIGNEE, its successors and assigns, in accordance herewith;

AND I HEREBY covenant and agree with ASSIGNEE, its successors and assigns, that I had the full right to convey the entire interest assigned in said Prior Assignment and confirmed herein, and that I have not executed, and will not execute, any agreement in conflict herewith, and that I will not do any other act whatsoever conflicting with these presents, and that I or my

successors, assigns, executors, or administrators will at any time upon request, without further or additional consideration, but at the expense of ASSIGNEE, its successors and assigns, communicate to ASSIGNEE, its successors and assigns, any facts known to ASSIGNOR respecting said invention, and testify in any legal proceedings, sign any lawful papers, execute any original, divisional, continuation, continuation-in-part, and reissue applications, make any rightful oaths, and generally do such additional acts as ASSIGNEE, its successors and assigns, may deem necessary or desirable to obtain and enforce proper protection for said inventions throughout the world;

AND I HEREBY FURTHER covenant and agree that this Confirmatory Assignment is effective as of 8 March 2004 when I executed said Prior Assignment, and I hereby confirm title in the ASSIGNEE as of 8 March 2004.

IN TESTIMONY WHEREOF, ASSIGNOR hereunto sets his hand on the under-mentioned day and year, and delivers this Confirmatory Assignment.

August 21, 2007
(Date)

Dr. Hiroshi Nakagawa

Before me on this 21 day of August 2007, personally appeared Dr. Hiroshi Nakagawa, known to me to be the person whose name is subscribed to the above and foregoing Confirmatory Assignment and acknowledged that he executed the same as his free and voluntary act for the uses and purposes contained therein.

IN WITNESS WHEREOF, I have hereunto set my signature.

Kathy Bright

Printed name: Kathy Bright

KATHY BRIGHT
NOTARY
07005063
EXP. 06/04/11
PUBLIC
STATE OF OKLAHOMA

Assignor's initials

Exhibit I

Application No./ Patent No.	Country	Filing Date	Title
1024658	Netherlands	29-Oct-2003	Catheter and method, in particular for ablation and like technique
PCT/NL2004/000741	WO	20-Oct-2004	Catheter and method, in particular for ablation and like technique
2004290563	Australia	24-Apr-2006	Catheter and method, in particular for ablation and like technique
P10415696-0	Brazil	28-Apr-2006	Catheter and method, in particular for ablation and like technique
2,543,524	Canada	25-Apr-2006	Catheter and method, in particular for ablation and like technique
200480039067.0	China	19-Jun-2006	Catheter and method, in particular for ablation and like technique
04793666.1	Europe	23-May-2006	Catheter and method, in particular for ablation and like technique
2006-537907	Japan	28-Apr-2006	Catheter and method, in particular for ablation and like technique
10-2006-7010319	Korea	26-May-2006	Catheter and method, in particular for ablation and like technique
2006/118345	Russia	26-May-2006	Catheter and method, in particular for ablation and like technique
10/595,608	US	28-Apr-2006	Catheter and method, in particular for ablation and like technique

NON-CONFIDENTIAL

OTD DISCLOSURE NO: 04HSC045 DATE RECEIVED OTD: 3/5/04

UNIVERSITY OF OKLAHOMA
PROPRIETARY INFORMATION/INVENTION DISCLOSURE

NOTE: This statement shall be treated as confidential information except for specific sections as noted. Except for individuals engaged in the evaluation and approval process, the information will not be divulged to others without proper confidentiality agreements in place, except as required by law. The objective of the form is to obtain the information necessary to determine whether to pursue patent protection for your invention.

SECTION I
NONCONFIDENTIAL INFORMATION

1. Nonconfidential title of the work:

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

2. Nonconfidential lay abstract of invention:

During radiofrequency catheter ablation, heart tissue is ablated by tissue heating via an ablation electrode in contact with the heart wall. Lesion formation is monitored via measurement of electrode temperature rise. Heating of blood in the vicinity of the electrode may create protein aggregation and so called thrombus formation that effectively limits the ablation process. Cooling of blood by saline irrigation through the ablation electrode enhances patient safety by preventing thrombus formation and also enables higher energy delivery and larger lesions. Present open flush, irrigated ablation catheters cool surrounding blood, but also the electrode itself. Electrode cooling however impedes measurement of electrode temperature rise and monitoring of lesion formation. The current invention describes the thermal insulation between the metal electrode and its internal irrigation channels. This insulation enables electrode temperature rise during ablation and monitoring of lesion formation while preventing protein aggregation in the blood pool.

3. Nature of work: Machine ☐ Process ☒ Utility ☒ Software ☐

If Software: Have proper copyright markings been utilized? Yes ☐ No ☐

OFFICE OF TECHNOLOGY DEVELOPMENT
660 Parrington Oval, Room 201
Norman, Oklahoma 73019
Telephone (405) 325-3800
Fax (405) 325-7162

Exhibit A

CONFIDENTIAL

4. Please list all submitters below:

Submitters	Office Mailing Address	% of Contribution*	Office Phone No.	Citizenship
a. Hiroshi Nakagawa	1200 Everett Drive ET 6E-103 Oklahoma City, OK 73104	100	(405) 271-9696	Japan
b. Frederick Wittkampf, PfD	University Medical Center Utrecht P.O. Box 85500, 3508 GA, Utrecht, The Netherlands	0	(31)(31) 2506171	Netherlands
c.			( )	
d.			( )	
e.			( )	

*NOTE: This % of contribution is an estimate providing for the division of proceeds, and not an assessment of legal inventorship. If this column is blank, submitters will share equally any revenues generated based on information contained in this disclosure.

5. If you have any other affiliations (i.e. received salary from another party, housed in other facilities besides university facilities), please list below: N/A

Submitters	Other Affiliations	% of Salary Other Affiliation Paid
a.		
b.		
c.		
d.		
e.		

6. Has a Conflict of Interest form been filed with the Provost's office? Yes ☐ No ☒

7. List specific University research support as well as external funding. List all sources, including matching funds.

   a. Name of sponsoring agency, company, or internal funding
   Cardiac Arrhythmia Research Institute at the University of Oklahoma Health Sciences Center

   b. Principal Investigator
   Hiroshi Nakagawa, MD, PhD

   c. Co-Investigators; Consultants
   Frederic Wittkampf, PhD University of Utrecht Netherlands

   d. Grant or Project Number
   N/A

   e. University Account Code

   f. Attach copy of Grant or Contract Document.
   N/A

Has a biological, chemical or physical material or substance obtained from others been used in the creation of this invention? Yes ☐ No ☒

If Yes, was a Materials Transfer Agreement or similar document used to obtain the material or substance? Yes ☐ No ☐

If Yes, attach a copy of the agreement.

If No, identify source and explain.

GENERAL PATENT INFORMATION

In order to obtain patent protection, your invention must demonstrate the following:

1. New (or novel): The invention must be new, that is, it has not been previously used, sold or described publicly.
2. Useful: The invention must have an actual use and not be just a subject for additional research.
3. Non-obvious: The invention must not be obvious at the time of conception to another person having ordinary skill in the art.

The patent laws set forth those classes of inventions eligible for patenting as follows:

1. Machines
2. Processes
3. Compositions of Matter
4. Manufacture

CONFIDENTIAL

SECTION II
PROPRIETARY INFORMATION
DOCUMENTATION

OBJECTIVE: To define the nature, purpose and operation of the invention, a practical presentation is preferable to highly theoretical material.

EVENTS	DATE	SUPPORTING DOCUMENTATION
1. Initial Idea		
2. First oral or written description of information. (Please provide copy of witnessed lab notebook showing date of discovery.)		
3. Level of testing completed (Lab scale, prototype, etc.)		
4. Prototype completed		
5. First written or oral publication date (include date of printed abstracts, any oral presentations, or electronic publication dates of journals, poster presentations, presentations to industry etc.) Attach copies.	Dec, 2003 May 22, 2004	Printed for NASPE Abstracts NASPE-Heart Rhythm Society Conference
6. Other external oral or written disclosures.		

7. Provide a full description of the proprietary information. This information should be in such detail as to "teach" the invention and to provide the basis for a patent application. Someone skilled in the art

should be able to reproduce the invention within a reasonable period of time based on the information supplied here.

a. Complete detailed description of invention (attach separate sheets if necessary):

b. Provide a complete description of the State of the Art prior to your invention. Include a list of any literature references, patent applications, or issued patents you are aware of. Cite source of literature or patent search information. (Attach separate sheets if necessary.)

c. Describe the advantages, improvements and technical impact of your invention over existing practice (novel or unusual features):

d. List the areas of applications of invention indicating the problem solved in the area by your invention:

e. List the main advantages of the invention (list in the order as the advantages would relate to the list of applications in item d. above):

f. List any known disadvantages using the same format as above:

8. Describe the state of development of your invention? Is there a prototype or samples of materials available for viewing or testing? Include any test results available.

9. Outline the further research and development, if any, that would greatly enhance the state of development of the invention.

10. List any funded or submitted proposals that have been submitted previously based on this invention. Were proprietary markings affixed to the proposal?

11. Attach any pertinent tables or drawings describing the invention.

12. Provide any other comments you may have regarding your proprietary information.

13. Provide the date and description of all planned publications, oral presentations, poster sessions, abstracts, preprints, or other public dissemination of the invention. (Check to see if the journal publishes electronically and provide OTD with the earliest of the dates.)

DATE	DESCRIPTION

14. Submitter's signatures (this disclosure is submitted under the University of Oklahoma Intellectual Property Policy, Patents, Paragraph 1.1.)

In consideration of employment or a consulting relationship, and subject to any prior agreements with The University of Oklahoma Board of Regents, this invention/discovery is hereby assigned to The University of Oklahoma Board of Regents, together with all patents covering said invention/discovery.

Signature	3-8-04 Date	1216 N. W. 195th Street Home Address Edmond, OK 73003 City, State, Zip
Signature	Date	Home Address City, State, Zip
Signature	Date	Home Address City, State, Zip
Signature	Date	Home Address City, State, Zip
Signature	Date	Home Address City, State, Zip

15. Invention Disclosed to and Understood By (Witness):

Signature Date

16. Office of Technology Development

Signature Date

 CONFIDENTIAL

SECTION III
COMMERCIAL POTENTIAL

NOTE: The information contained in this section will not be distributed to anyone outside of the University of Oklahoma, except as required by law.

1. Where would your idea have commercial value?

U.S.	☒	South America	☒	Africa	☒
Canada	☒	Japan	☒	Australia	☒
Europe	☒	Asia	☒	Other	☐

2. In your judgment, does the proprietary information require copyright or patent protection in order to be successfully marketed:

a. Patent protection ☒
b. Copyright protection ☐
c. Know-How could be licensed ☐

3. List any companies, and individuals within those companies, that you feel may have a commercial interest in licensing the invention. (Indicate by special note those companies that have contacted you regarding the invention.)

NOTE: If you need to add additional information, please begin a new page to enter information. Thank you.

P66372NL00

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.

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

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.