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(54) Title: ABLATION AND MAPPING CATHETER FOR TREATMENTS IN ELECTROCARDIOLOGY

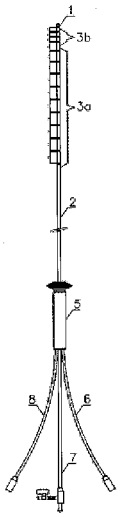


Fig1.

(57) Abstract: The object of the invention is an ablation and mapping catheter dedicated to treatments in electrocardiology and ablation of cardiac arrhythmias with the possibility of visualisation, comprising a distal tip, diagnostic rings, a main tube, a guiding handgrip, an electrical connector for a generator through which the diagnostic rings and a distal ring are connected to a system for three-dimensional electroanatomical mapping, characterised in that it comprises at least 8 (up to 14) diagnostic rings, wherein 4 diagnostic distal rings are connected to one generator and through it to the system for three-dimensional electroanatomical mapping and to an electrophysiological system, and subsequent 4 (up to 10) diagnostic proximal rings are connected to a second generator and/or to the system for three-dimensional electroanatomical mapping and to the electrophysiological system.

WO 2016/167673 A1

Ablation and mapping catheter for treatments in electrocardiology

The object of the invention is an ablation and mapping catheter used for treatments in electrocardiology, comprising at least 8 diagnostic rings, wherein all the mapping stimulating rings are connected via connectors to a generator (generators) and allow a non-fluoroscopic mapping in a three-dimensional electroanatomical system. The diagnostic rings are evenly distributed at the distal end of an electrode. The rings allow controlling the shape of the electrode in the area of its bending in three-dimensional electroanatomical systems for navigation without X-radiation.

An ablation catheter is known from the prior art US2004143254A, comprising a catheter tube which comprises proximal and distal parts, wherein the distal part is adapted to be placed in the body cavity, having tissues, to be ablated and is removed remotely from the said proximal part, wherein the distal part comprises flattened outer circumferential walls having an active area, wherein the said outer part has a cross-sectional shape along the active area, and in which this configuration is adapted to press the said active area against the tissue subjected to ablation. The catheter also comprises a lumen which is located in the active area, characterised in that at least one illuminator is located in the active area; and a porous tube is positioned within a duct and has at least one opening.

US2012035539A is also known, which relates to an electrode assembly of a catheter comprising an electrode tip which has further and closer end parts; and a multi-segment positioning magnet placed near the tip of an electrode. The electrode tip also comprises an ablation surface in the distal tip of the electrode.

Document US2004059327A relates to a contact detection system comprising: a catheter comprising a body having a closer end and a further end; an electrode comprising a tip and a base part; and an optical sensor, wherein the basic part of the electrode comprises an optically interactive surface; a part of the electrode is connected to the further end of the catheter; and the optical sensor is spaced from and operatively cooperates with the optically interactive surface. The optical sensor is configured to send and receive light energy or a signal based on light.

A known solution US2006247522A describes a magnetic mechanical navigation system for a catheter, comprising: a catheter comprising an elongated, flexible catheter body which has a distal end, at least a part which is adapted to be mechanically activated to adopt a curved geometry, a magnetically-responsive element realised at the distal end of the catheter; and an operating element at the distal end of the catheter. The magnetic navigation system is configured for applying a magnetic force of the magnetic element for deflecting the distal end of the catheter. The catheter comprises an operating element in the form of an ablation element. The operating element can be a diagnostic element.

A catheter known from US6171306 comprises a catheter body comprising a curved area shaped to at least partially enclose a tissue area, at least two spaced ablation electrodes in the curved area of the catheter body, positioned opposite each other, wherein the examined tissue is located between them, and any part of the electrode does not pass through the tissue; an indifferent electrode, a source of radio frequency energy in combination with ablation electrodes and an indifferent electrode, wherein respective sizes and arrangement of the at least two electrodes is such that a substantially continuous change is formed by the tissue area between the ablation electrodes in response to the simultaneous transmission from the ablation electrode to the tissue area to the indifferent electrode.

From WO1412423, a device is known which comprises an elongated tube comprising a closer end and a further end; an expandable system configured for transition from a radially folded state to a radially expanded state; a flexible printed circuit board (PCB flex); a number of electronic elements connected to PCB and configured to receive or transmit electrical signals.

Document US2002002329A describes a recording and ablation catheter for electrically recording or mapping and creating lesions of linear ablations in the ventricle, comprising: a hollow vascular catheter or a casing, having a lumen for placing within the catheter: a guiding element for assisting in the navigation of the said catheter or casing into the vascular system of the patient: a flexible internal catheter which comprises a catheter operating point, having closer and further ends adapted to assume an arched shape, capable of contacting the inner surface of the ventricle, when used from the main catheter or casing through an internal duct on which there is the said operating part of the catheter and a number of spaced electrodes connected in series on the said operating section of the catheter.

None of the known solutions indicates the need for better visibility of the catheter position in the human body, and especially the one realised by means of diagnostic rings arranged on a distal section of the catheter, longer than usual, limited to 3 - 4 cm.

The existing ablation catheters have standard 4 diagnostic rings connected to a generator and through additional connections therefrom to an electrophysiological system and/or a three-dimensional electroanatomical system. The first distal ring is also an ablation ring, and its width and structure depends on the manufacturer and the type of electrode. By default, generators do not comprise connectors for more than 4 rings of the point ablation electrode. Introduction of additional rings allows for the reception of signals from the distal part, i.e. about 4 cm, as well as from an electrode part distant from the distal end at a distance of above 4 - 10 cm. This allows for the reception of signals from two areas of the heart simultaneously – e.g. from the right ventricle, the His-bundle area and the right atrium. This will allow for simplified diagnostics with one electrode analysing simultaneously atrio-ventricular and ventriculo-atrial conductions and the His-bundle area. The additional rings can be used for specialised differentiating stimulations and stimulations on demand while performing mapping or ablation from the distal ring of the catheter. The additional rings will be visible in three-dimensional electroanatomical systems, in particular in the range of the electrode bending, which will allow for the visualisation of the electrode curvature and its shape at a distance of above 8-10 cm, and not only about 4 cm.

The present solution consists in placing, in the area of the distal tip of the catheter, an additional quantity of diagnostic rings allowing, above all, the navigation by means of a system for three-dimensional electroanatomical mapping, the faster collection of potentials for creating virtual maps of heart cavities, and the catheter visibility in the area of its bending in the treatments without or with very significant reduction of the need to use X-radiation.

The present solution provides the operator with new and useful capabilities.

Modern standards for treating arrhythmia assume an early qualification of children and adults with recurrent arrhythmia resistant to pharmacological treatment for ablation, as well as treatments for the prevention of occurrence of another attack of arrhythmia or removal of additional atrio-ventricular pathways. An invasive diagnostic method performed before and after the ablation treatment is an invasive electrophysiology study using diagnostic catheters. It consists in the analysis of parameters of stimulus formation, conduction and intracardiac potentials in the atria, the conduction system and in the ventricles. Modern electrophysiology aims at reducing the invasiveness and the complexity of treatments with the reduction of the number of electrodes, vascular punctures, and patient and medical personnel exposure to adverse effects of X-radiation (risk of cancer, encumbrance of outfits and discomfort of radiological protection).

The essence of the invention is an ablation and mapping catheter for treatments in electrocardiology, comprising a distal tip, diagnostic rings, a main tube, a guiding handgrip, an electrical connector for a generator through which the diagnostic rings and a distal ring are connected to a system for three-dimensional electroanatomical mapping and to an electrophysiological system, characterised in that it comprises at least 8 diagnostic rings, wherein 4 diagnostic distal rings (3b) are connected to one generator and through it to the system for three-dimensional electroanatomical mapping, and subsequent at least 4 (up to 10) diagnostic proximal rings (3a) are connected to a second generator and/or to the system for three-dimensional electroanatomical mapping.

Preferably, the ablation and mapping catheter comprises up to 14 diagnostic rings, wherein 4 rings are constituted by the diagnostic distal rings (3b), and at least 4 (up to 10) rings are constituted by the diagnostic proximal rings (3a).

Preferably, the main tube (2) is terminated by the distal ring (1).

Preferably, the distal ring (1) has smooth, rounded, atraumatic edges.

Preferably, the ablation and mapping catheter can be guided and monitored by the system for three-dimensional electroanatomical mapping with visualisation of the shape of the distal part of the catheter tip with the area of its bending.

Preferably, the main tube (2) in the guiding handgrip (5) is separated into two wiring harnesses (6 and 8) and a harness (7) for cooling the distal ablation ring of the catheter.

The ablation and mapping catheter is a universal type of catheter for ablation, stimulation, diagnosis and which allows for navigation without the use of X-ray fluoroscopy in the three-dimensional electroanatomical system. It comprises at least 8-14 diagnostic rings allowing for visualisation of the distal section having over a dozen centimetres of the catheter and of its bending.

An advantage of the catheter according to the invention is an increased number of diagnostic rings present behind the distal area of 4 cm and beyond the distal bending of the electrode, allowing for visualisation of the distal section of the electrode, having 8 to 14 cm, in the three-dimensional electroanatomical system. This allows the analysis of the shape of the distal end of the electrode, of deformations of the distal bending, and of the risk assessment for the looping of the distal end of the electrode when passing through vessels and cardiac cavities.

Another advantage is the use of dimensions (diameter width) of 4 to 8F allowing for the production of the catheter of very small sizes of diameter, useful in the treatment of children and young people and those with low body weight (Size of the catheter is given in French (F)

scale which specifies the perimeter of the catheter in millimetres. Conversion of this size to the diameter of the catheter is as follows 1F = 0.33 mm).

An advantage of the catheter is the possibility of using, from one ablation catheter, stimulation, recording of potentials and navigation without the use of X-ray fluoroscopy from more than 4 rings. This allows, when using one electrode, for performing simultaneous and improved mapping, stimulation, analysis of potentials and formation of electroanatomical maps from at least 2 heart cavities and to reduce the need to use additional diagnostic catheters and additional punctures. Increasing the number of rings by additional 4-10 ones on the distal section of the catherer, including its bending, is a unique solution and allows for visualisation of a substantially longer section in a three-dimensional electroanatomical system for non-fluoroscopic mapping and navigation (without X-radiation), which will ensure a constant monitoring of not only the catherer tip (4cm), but also the distal part of the catherer and its bending distanced by 4-10 cm from the catherer end. This will allow for an accurate estimation of the catheter position, its deformations and curvature, which may improve efficiency and precision in the navigation of the catheter. The project of the catheter was created based on experiences and demand of electrophysiologists conducting ablation treatments in the three-dimensional non-fluoroscopic system and on limitations in introducing the protocol of non-fluoroscopic navigation, visualisation and ablation of arrhythmia in children and adolescents.

From the handgrip, two electrical connections extend which connect to an electrical outlet connectable to a connector for transmitting parameters to the electroanatomical and electrophysiological systems. From the handgrip, when using a system for cooling the electrode tip, a connector extends which is used for cooling the distal tip and the distal ring implementing current applications, the said connector not being a part of the invention. In addition, the handgrip comprises a system for guiding the distal tip of the catherer, which is not part of the invention either.

The ablation and mapping catherer according to the invention has been further described in embodiments and in the drawing in which Fig. 1 shows a top view of the ablation and mapping catheter together with a guiding handgrip and functional connectors, Fig. 2 shows a top view of a main tube including a distal ring, diagnostic rings, and Fig. 3 shows a cross section through the main tube of the ablation and mapping catherer.

The ablation and mapping catherer comprises a guiding handgrip 5, a main tube 2, a distal ring 1, diagnostic rings, including distal 3b and proximal 3a ones and two electrical connectors 6 and 8 for electric wires connecting the diagnostic rings 3a and 3b and the distal ring 1 to an electrophysiological system. Furthermore, the catherer comprises a connector for a cooling duct 7, which is not an object of the invention.

The ablation and mapping catherer comprises at least 8 diagnostic rings, wherein 4 rings are connected to one generator and through it to a three-dimensional system, and subsequent 4-10 ones are connected to a second generator and/or further through it to the three-dimensional system.

In addition, in the main tube 2, there are wires 4 for guiding the distal end of the catherer and a duct for liquid for cooling the distal ring of the ablation catherer, wherein they are not an object of the invention.

The proximal end of the main tube, when connecting to the guiding handgrip, is separated into two wiring harnesses and a harness which is provided with a tap and a tip for cooling the distal ablation ring of the catherer.

The distal ring of the catherer has an atraumatic shape, which means it has a smooth, rounded tip with openings allowing for cooling of the electrode. Sharp edges would disrupt the continuity of vessels and increase the risk of perforations.

The ablation and mapping catherer comprises diagnostic rings for the analysis of electrical parameters of the heart and vessels, present in an amount of 8 to 14 units (3a and 3b - 4 by default) distributed evenly over the length of 4 to 14 cm. These rings are located near the distal end of the catherer. In a preferred embodiment, the diagnostic rings serve as rings visible under X-rays and in the system for non-fluoroscopic navigation and mapping. The diagnostic rings are located before, on and behind the distal tip of the catherer. In the known point ablation catheters, (ablation from one ring) rings were not placed in the area behind the bending of the distal part of the catheter and at a considerable distance from the distal ring. In addition, for point ablations, not more than 4 rings were used for connecting to a power generator of radio frequency.

In the area of the proximal end of the main tube, there is the guiding handgrip within which electrical wires are being separated. The separation of the electrical wires allows, apart from a standard connector for 4 diagnostic distal rings (3b), the use of an additional connection for subsequent diagnostic proximal rings (3a).

The ablation and mapping catheter is made of an elastic material allowing it to be easily bent, and the distal end is provided with a guiding system located in the handgrip of the catherer and connected with appropriate bands.
The catherer is ultimately positioned by the non-fluoroscopic three-dimensional electroanatomical system or/and by means of the navigation with the use of X-radiation.

The ablation and mapping catheter is introduced into venous or arterial peripheral vessels (femoral vein/artery) of the patient and is then guided through main vessels into right and left cavities of the heart. The guiding system allows for bending the distal tip of the catherer. Navigation and localisation of the catherer position can be conducted based on the catheter translucency under X-radiation or based on analysis of potentials and electrophysiological parameters through the three-dimensional system and the non-fluoroscopic navigaton (without X-radiation). The catherer, thanks to all the diagnostic rings (1, 3a, 3b), allows a continuous recording of potentials and of the construction of virtual electroanatomical map forming an image of the examined veins, arteries and heart cavities. At the time when the operator reaches his goal, i.e. reaches the desired location in which an ablation treatment from the distal ring 1 is to be conducted, application of radio frequency current is conducted with the use of a system for cooling the electrode tip.
The diagnostic rings (1, 3a i 3b) allow for the recording of electrophysiological parameters (shape and amplitude of unipolar and bipolar electric potential, impedance), the selective stimulation with an external stimulator, and the non-fluoroscopic navigation using the three-dimensional system. The operator, thanks to additional proximal rings 3a, has the ability to quickly and simultaneously record potentials and to stimulate from places distant from the distal ring 1 and is able to assess the shape of bending, looping and deformations of the distal part of the catherer. The operator, thanks to additional proximal rings 3a, has the ability, without changing the position of the distal tip of the electrode, to conduct control stimulations and monitoring from distant areas or other cavities of the heart without changing the position of the catheter. After mapping, stimulation of the ablation, the catherer in its entirety is removed by a sheath passage (introducer). The sheath passage is removed according to the adopted protocol depending on the degree of anticoagulation in the patient during the treatment.

Claims

1. An ablation and mapping catheter for treatments in electrocardiology, comprising a distal tip, diagnostic rings, a main tube, a guiding handgrip, an electrical connector for a generator through which the diagnostic rings and a distal ring are connected to a system for three-dimensional electroanatomical mapping and to an electrophysiological system, characterised in that it comprises at least 8 diagnostic rings, wherein 4 diagnostic distal rings (3b) are connected to one generator and through it to the system for three-dimensional electroanatomical mapping, and at least 4 (up to 10) subsequent diagnostic proximal rings (3a) are connected to a second generator and/or to the system for three-dimensional electroanatomical mapping.
2. The ablation and mapping catheter according to claim 1, characterised in that it comprises up to 14 diagnostic rings, wherein 4 rings are constituted by the diagnostic distal rings (3b), and at least 4 (up to 10) rings are constituted by the diagnostic proximal rings (3a).
3. The ablation and mapping catheter according to claim 1, characterised in that the main tube (2) is terminated by the distal ring (1).
4. The ablation and mapping catheter according to claim 1, characterised in that the distal ring (1) has smooth, rounded, atraumatic edges.
5. The ablation and mapping catheter according to claim 1, characterised in that it can be guided and monitored by the system for three-dimensional electroanatomical mapping with visualisation of the shape of the distal part of the catheter tip with the area of its bending.
6. The ablation and mapping catheter according to claim 1, characterised in that the main tube (2) in the guiding handgrip (5) is separated into two wiring harnesses (6 and 8) and a harness (7) for cooling the distal ablation ring of the catheter.

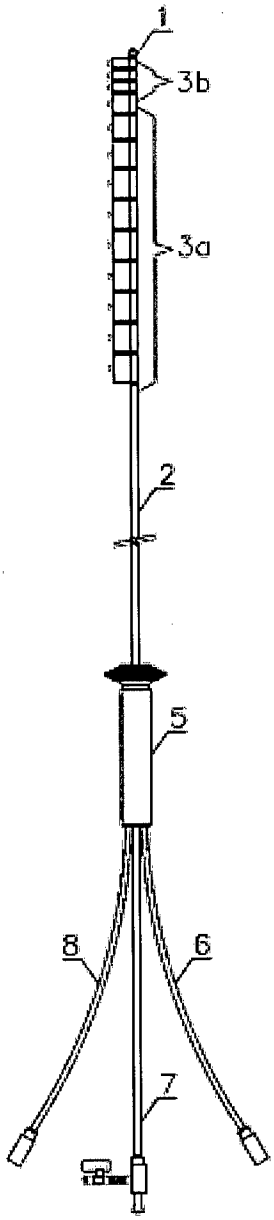


Fig1.

Fig. 1

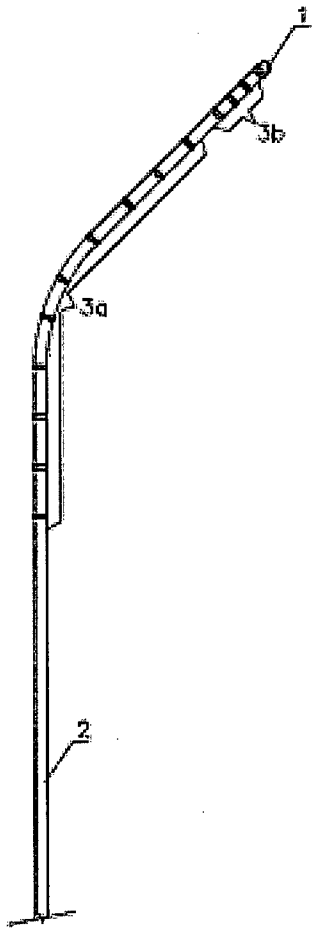


Fig 1.

Fig. 2

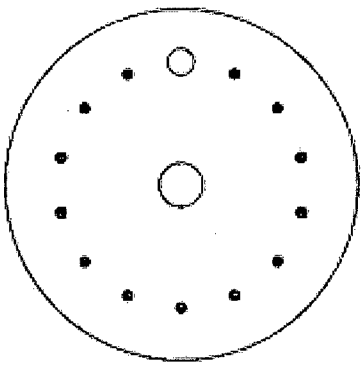


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No
PCT/PL2015/000106

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B18/14 A61B19/00 A61B5/042 A61B5/00 A61B18/12
A61B18/00
ADD.
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)
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 practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 5 577 509 A (PANESCU DORIN N [US] ET AL) 26 November 1996 (1996-11-26) column 2, line 19 - line 30; figures 1-30 column 6, line 1 - column 7, line 62 column 10, line 28 - column 14, line 6 column 15, line 40 - line 42	1,2,4,5 3,6
Y	US 2010/057072 A1 (ROMAN RICARDO D [US] ET AL) 4 March 2010 (2010-03-04) paragraphs [0012], [0075], [0078], [0081], [0089], [0098], [0123]; figures 1-20B	3,6
A	EP 1 112 720 A1 (STOCKERT RUEDIGER [DE]) 4 July 2001 (2001-07-04) paragraphs [0009], [0013], [0015], [0019], [0026], [0041], [0048], [0049]; figures 1,2	1-6

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2015	04/12/2015

Name and mailing address of the ISA/	Authorized officer
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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/PL2015/000106

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2009/209950 A1 (STARKSEN NIEL F [US]) 20 August 2009 (2009-08-20) paragraphs [0107], [0108], [0112], [0113], [0115], [0116], [0120], [0121], [0124], [0126], [0132] - [0134]; figures 20,32,33	1-6

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INTERNATIONAL SEARCH REPORT

Information on patent family members

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