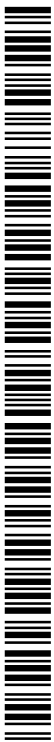




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(54) Title: MULTIFUNCTIONAL, ELECTROPHYSIOLOGICAL DIAGNOSTIC CATHETER FOR TREATMENTS IN ELECTROCARDIOLOGY



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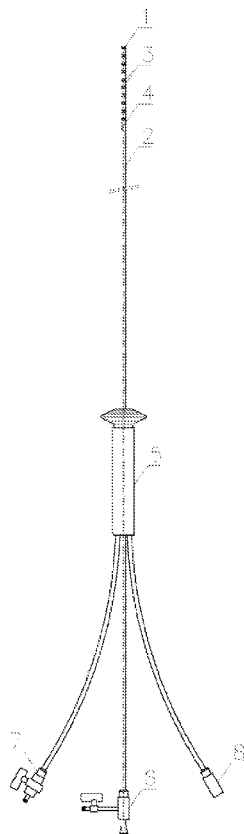


Fig. 3

(57) Abstract: The object of the invention is multifunctional, electrophysiological diagnostic catheter for electrocardiologic treatments comprising distal ending, diagnostic rings, balloon, main channel, manipulation handgrip, functional connection and internal channels characterised in that it comprises internally-located open central channel, wherein inlet/outlet of internal channel is located in distal ring; pumping channel for pumping up and pumping out of occlusion-stabilizing balloon is located after diagnostic rings; division of central channel on two branches in the region of catheter proximal end.



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MULTIFUNCTIONAL, ELECTROPHYSIOLOGICAL DIAGNOSTIC CATHETER FOR TREATMENTS IN ELECTROCARDIOLOGY

The object of the invention is multifunctional, electrophysiological diagnostic catheter used for treatments in electrocardiology consisting of stabilisation balloon, especially for stabilisation of catheter in coronary sinus.

Rapid diagnosis and fast treatment of potentially dangerous arrhythmia allows for significant reduction of patients' morbidity suffering from cardiac arrhythmia leading in most serious form to sudden cardiac death. One of diagnostic method used for cardiac arrhythmia diagnosis is invasive electrophysiological study (EPS) using diagnostic catheters. Reliable identification of cardiac arrhythmia substrate and continuous, precise monitoring of rhythm and catheter electrodes localised intracardiacly are essential.

Catheters equipped with balloon are known from the state of art. In application US3995623 there is the catheter described with flow balloon on its distal end passing through right vestibule, right ventricle to pulmonary artery. Clearance in tubule of catheter is open on distal end in order to monitor blood pressure in pulmonary artery or branch, or to obtain blood sample. A thermistor closer to the balloon enables measurement of blood temperature in this region, thus enables to identify cardiac output using termodilution technique. Second tubule comprises a gap, which is characteristically located in junction region of vena cava and right vestibule, in order to monitor pressure, infusion of liquid media and blood sampling. Besides two mentioned channels, third stream is used as a channel pumping balloon and fourth stream, which comprises thermistor wires, for distal and proximal electrodes.

Patent Nr. JP2893833 discloses endoscopic electrode comprising balloon, which is installed on the front end of tube made of synthetic resin, surrounding rim of front pipe ending in way to avoid gap closure, part of the front ending connecting with one tube clearance and recess are made by external surface of tube, and balloon can be communicated with one tube clearance delivering lateral gap to the tube interior or through excision of front tube part. Optical fibre is located in the clearance, and distance between fibre and inner surface of lumen is used as a passage for balloon expansion liquid. Balloon acts as a stabilizer, because even if saline is not used to fill balloon, catheter position is not changed and observation or diagnostics can be performed.

US2008097297 application describes medical product, which is able to penetrate blood vessels comprising at least one non-expandable piercing element fitted and configured for specific local activity in vivo e.g. diagnosis, sampling, energy therapy and drug administration. This device additionally comprises at least one inflatable balloon used for

local positioning, which is configured for safe placement of device around target tissue of human vessels or internal organs.

EA009756 B1 application discloses catheter comprising three elastic channels, wherein first, internal one delivers fluid for balloon filling, external is used as a support of balloon localization and lateral channel for lymph sampling. Annular-shaped elastic balloons are equipped with a threads for catheter installation in clearance of venous angle, where elliptically-shaped elastic balloon is equipped with trigger plate for a contact with lymph outlet. In case of lymph sampling, placement of catheter in operating position in venous angle depression is required, obtaining growth in volume through increasing of elastic balloon volume by injection of saline inside.

Also other solutions are known, which mention a possibility of blood flow blockade e.g. EP0363156 application refers to apparatus for volumetric blood measurement in vessel with walls characterised in that elastic catheter is adapted for placement in vessel and comprises ultrasound sensors. This apparatus is equipped with a device for pressure measurement in right atrium, pressure in pulmonary artery and wedge pressure, volumetric flow is determined using termodilution.

WO9806450 application discloses catheter-type device for haemorrhage control during closed surgery. In the end of catheter, inter alia balloon adapted for movement with elastic catheter along blood vessel, wherein pump-enabling channel is located, what makes possible fast balloon inflating (filling) and emptying, wherein when precise balloon location in surrounding of blood vessel is confirmed, balloon is located in the flow in order to close blood flow and prevent haemorrhage in designated region of surgical intervention and magnetic material is attached to the aforementioned balloon for magnetic coupling and balloon positioning by manipulation using magnet located outside of the blood vessel. Catheter can be equipped with a channel adapted for blood sampling and drug delivery.

In the state of art there are catheters known by which it is possible to take a blood sample.

US5607389A applications relates to a medical device comprising the probe and cover for probe and microdevice placement e.g. biopsy sampler for tissue sampling as a needle or sharp ending in order to facilitate sampler reach out to proper tissue or sampler with a shape similar to harpoon or as a jaws. Further embodiment includes knife sampler and electromagnetic transmitter for selective sample collection and electromagnetic ablative heating.

EP1145731 application discloses multilumenal, multipurpose catheter set comprising multiple axis channels, at least one channel supports other functionality than material delivery and material removal, which left after its delivery. Catheter can comprise at least two individual

channels parallel to middle catheter cylinder. Two channels are used for sampling of fluids from that body part, where catheter is placed.

Solutions known from the state of the art do not allow for universal connection of all diagnostic functions (measurement of heart potentials, localisation and navigation without fluoroscopy, selective blood sampling from suitable vessel or heart cavity localized using catheter ending, possibility of selective delivery of substance or contrast localized using catheter ending and catheter stabilization and blood flow blocking in blood vessel using balloon.)

In any of described solutions catheter stabilization in coronary cavity and blockade of fluid flow through coronary sinus was not mentioned. Objective solution based on connection of multiple functionalities utilized by one catheter-electrode, gives to the operator new and useful possibilities.

The subject matter of the invention is multifunctional, electrophysiological diagnostic catheter for treatment in electrocardiology comprising distal ending, diagnostic rings, balloon, main tube, manipulation handgrip, functional switches and internal channels

characterised in that it comprises:

- internally located open central channel, wherein inlet/outlet of central channel is located in distal ring;
- channel for pumping up and pumping out of occlusion-stabilizing balloon;
- occlusion-stabilizing balloon located after diagnostic rings;
- division of central channel in area of proximal catheter ending on two branches.

Preferably, central channel is unobstructed in both ways.

Preferably, inlet/outlet of central channel is round, wherein it is located in a recess, which is located centrally in distal ring.

Preferably, a recess has smooth, round, atraumatic edges.

Preferably, central channel is a flow channel for fluids.

Preferably, central channel is a transmission channel for introduction of microdevices and/or microelectrodes.

Preferably, central channel is a compartment for selective drug administration or contrast agent or saline or blood sampling.

Preferably, multi-purpose catheter performs measurement of blood pressure.

Preferably, occlusion-stabilizing balloon with modifiable diameter assumes a shape from spherical to ellipsoidal.

Preferably, occlusion-stabilizing balloon is filled with air or saline.

Preferably, multi-purpose catheter is guided and monitored using system for electroanatomical mapping.

Preferably, in manipulation handgrip of multifunctional catheter there is placed:

- inlet/outlet for electric connections,
- inlet/outlet for central channel,
- inlet/outlet for pumping/draining channel of occlusion-stabilizing channel.

Preferably, proximal end of central channel comprises tee dividing proximal end of central channel on two branches, wherein one is ended with diaphragm, while second comprises opening/closing valve and ending for connection of pumping device, preferably syringe.

Preferably, proximal end of pumping channel comprises ending for connection of pumping device, preferably syringe.

Multifunctional catheter is a universal reference, stimulating, diagnostic and enabling to sample blood e.g. from coronary sinus, peripheral and venous vessels type of catheter. In one catheter there are few diagnostic features combined usually available in combination of two or three catheters (haemodynamic catheter, diagnostic, electrophysiological catheter, catheter with balloon).

The advantage of multifunctional catheter is a very precise blood sampling depending on location of catheter ending, and also the fact, that it can be used for blood sampling from vein or peripheral vessels from other organs e.g. cerebral circulation.

The advantage is also the use of balloon for occlusion-stabilizing of catheter in coronary sinus or closing examined venous vessel. Thanks to the catheter according to the invention there is a possibility for precise, selective blood sampling from venous or peripheral vessels depending on catheter placement. Occlusion-stabilizing balloon prevents mixing of blood from coronary sinus outflow (blood from heart muscle) with blood localised in right atrium (blood from body peripheries). Through inlet/outlet of central channel it is possible to administrate contrast or blood sampling, it is also possible to administrate additional drug, perform pressure measurement or introduce other microdevices with diagnostic-therapeutic capabilities. Therefore catheter (its central channel) can be the transmission channel for atraumatic and selective introduction of microdevices and/or microelectrodes, which dimension and structure enable navigation and precise atraumatic introduction through venous system e.g. to cardiac cavities or coronary sinus.

The advantage is also introduction of channel division outgoing from manipulation handgrip. Channel division enables practical separation of catheter function on electrophysiological ending for central channel and ending for filling system and draining of stabilization balloon.

It selectively divides functions for operator service. From division spot also electrical connections come out, joining with electric socket plugged to the connector which is transmitting electroanatomical and electrophysiological system parameters. Additionally handgrip comprises a system controlling catheter distal ending, which is not a subject of the invention.

Multifunctional catheter according to the invention was described in more details in exemplary embodiments and on the drawing, wherein fig. 1 shows side view of main channel, covering distal ring, diagnostic rings and balloon, fig. 2 shows cross-section of main channel of multifunctional catheter, fig. 3 shows side view on multifunctional diagnostic catheter with the manipulation handgrip and functional connections.

Multifunctional catheter comprises manipulation handgrip 5, main channel 2, distal ring 1, occluding-stimulation balloon 4, diagnostic rings 3, and three connections: liquid connection 6 - for contrast administration or blood sampling from coronary sinus or introduction of microdevices, pumping connection 7 - for pumping up and pumping out of balloon and electric connection 8 for electrical wires connecting diagnostic rings 3 and distal ring 1 with electrophysiological system.

Multifunctional catheter comprises two channels. Channel B is centrally located flow channel for liquids, which opens through distal atraumatic ending 1, as shown in fig. 1. Pumping channel A is a channel used for filling and draining of occlusion-stabilizing balloon 4 through pumping connection 6 for liquid or gas pumping/draining from balloon. Balloon 4 is an expandable balloon made of elastic material.

Channel A and channel B are surrounded by electric wires connecting diagnostic rings 3 and distal ring 1 with manipulation handgrip 5 and transmitting electrophysiological parameters of electrophysiological system.

Additionally in main channel 2 there are wires placed controlling distal end of catheter.

Proximal end of main channel 2 while connecting with manipulation handgrip 5 divides on two channels and cluster of electric wires. There are emerging branches coming out from manipulation handgrip 5 to liquid connection 6 of central channel B, pumping connection 7 for filling and draining of occlusion-stabilizing balloon and to the electric connection 8.

Liquid connection 6 ends with tee from which:

- one branch is an extension of central channel and creates proximal ending of central channel and is equipped with diaphragm enabling introduction of microdevices without liquid leakage.
- Second branch is equipped with a valve and an ending for syringe.

Pumping connection 7 is equipped with a valve and an ending for syringe, which is used for balloon pumping up and pumping out 4.

Electric connection 8 creates electric socket, which is connected with electrophysiological system through connector.

Inlet/outlet of central channel B is located in distal ring of catheter and is shaped atraumatically, what means that the edges are smooth and curved as shown in fig. 2, and besides gap is placed below external walls. Sharp edges could break the blood vessels continuity and increase perforation risk.

Multifunctional diagnostic catheter comprises diagnostic rings 3 present in amount of 4 to 20 (default 10) for analysis of electric parameters of heart and vessels evenly distributed on length of 6 to 14 cm. These rings are located in the vicinity of distal and of catheter. In preferred embodiment diagnostic rings are used as a rings visible under X-ray or in system of non-fluoroscopic navigation and mapping.

On distal end of the catheter there is also occlusion-stabilizing balloon 4 present, which is placed after diagnostic rings 3 and enables selective blockage of blood flow in intubated vessel.

In vicinity of main channel of proximal end there is a manipulation handgrip present, where channel division occurs. Division of catheter channels and electric wires enables interchangeable usage of liquid dosing device in case of drug administration, contrast agent, or suction device in case of blood sampling. Channel division enables easy separation of main channel component functions and its redirection to connections going out of proximal part of handgrip. Multifunctional catheter is made of elastic material enabling its easy bending, and distal end is equipped with a control system localised in catheter handgrip and connected with a proper ties.

Catheter is finally positioned using X-rays, analysis of electric potentials or using non-fluoroscopic three dimensional electroanatomical system. Subsequently, occlusion-stabilizing balloon 4 is pumped up in order to stabilize catheter position in vessel - in proximal end of coronary sinus. To the central channel B blood sample is taken, sucked using low-pressure suction device (syringe) and after passage through distributor and disconnection of suction device is poured to the test-tube. In case when there is a need to administrate drug, contrast or other medical agent to a specific heart region or vessels, liquid connection 6 is connected to the pumping device (syringe) and through distributor and next through the central channel B medical agent is administered. Between activities described above there is a need of central channel B flushing using saline solution.

Through central channel B there is a possibility of microdevice introduction e.g. MicroCosinus electrode for ultrasonography, to the heart regions, which can be used for blood vessels diagnostics with a small diameter.

In a preferred embodiment it is possible to measure blood pressure in a chosen region of heart or vessels based on connection to the liquid connection 6.

Catheter with occlusion-stabilizing balloon 4 in drained state is introduced to the patient's peripheral vein vessels (femoral vein, subclavian vein) and is further passed through main vessels to right cardiac cavities. Control system enables bending of catheter distal ending, what permits localization of coronary sinus outflow. Navigation and localisation of catheter position can be performed based on catheter translucency in X-rays or based on analysis of potentials and electrophysiological parameters by three-dimensional system and non-fluoroscopic navigation (without X-rays). Catheter thanks to diagnostic rings 3 enables continuous registration of potentials and construction of virtual electroanatomical map giving an image of examined vessels and cardiac cavities. When operator reaches his goal, so when he gets to his desirable location, occlusion-stabilizing balloon 4 is pumped up and can become an electrode-stabilizing system in coronary sinus (reducing risk of electrode falling out during patient's heart or breathing movement). Additionally stable electrode localisation enables stable and precise building of cardiac cavities contours and use of intracardial electrode as a marker/reference point for other points in created virtual map of heart. Additionally balloon can in precise manner prevent blood mixing from coronary sinus with blood coming from right vestibule, that enables reliable and selective bloods sampling from catheter end.

Blood is sampled using syringe connected to the liquid connection 7 protected by a valve. Gap in liquid connection 7 for substance administration or blood sampling can be also used for drug administration, pressure measurement. Gap on the proximal end of central channel B is ended with a gate (diaphragm), which enables introduction of microdevices with an additional diagnostic-therapeutic functions e.g. MicroCosinus electrode with a diameter below 2 mm for electrophysiological diagnostics of vessel with a very small diameter. Pressure measurement can be registered using liquid connection 6 or using microdevice for pressure measurement introduced through gap on proximal end of central channel.

Diagnostic rings 3 distributed in distance 6 to 14 cm from distal ring 1 of catheter enables registration of electrophysiological parameters (shape and amplitude of mono- and bipolar electric potential, impedance), selective stimulation using external stimulator or non-fluoroscopic navigation using three-dimensional system.

Occlusion-stabilizing balloon 4 is filled using saline solution and performs stabilizing and blocking functions for flow in coronary sinus.

Claims

1. Multifunctional, electrophysiological diagnostic catheter for treatment in electrocardiology comprising distal ending, diagnostic rings, balloon, main tube, manipulation handgrip, functional switch and internal channels
characterised in that it comprises:
 - internally located open central channel (B), wherein inlet/outlet of central channel is located in distal ring (1);
 - pumping channel (A) for pumping up and pumping out of occlusion-stabilizing balloon (4);
 - occlusion-stabilizing balloon (4) located after diagnostic rings (3);
 - division of central channel (B) in area of proximal catheter ending on two branches.
2. Multifunctional catheter according to claim 1, characterised in that the central channel (B) is unobstructed in both ways.
3. Multifunctional catheter according to claim 1 or 2 characterised in that the inlet/outlet of central channel (B) is round, wherein it is located in a recess, which is located centrally in distal ring (1).
4. Multifunctional catheter according to claim 1 or 2 or 3, characterised in that the recess has smooth, round, atraumatic edges.
5. Multifunctional catheter according to any of the preceding claims, characterised in that the central channel (B) is a flow channel for liquids.
6. Multifunctional catheter according to any of the preceding claims, characterised in that the central channel (B) is a transmission channel for introduction of microdevices and/or electrodes.
7. Multifunctional catheter according to any of the preceding claims, characterised in that the central channel (B) is compartment for selective drug administration or contrast agent or saline or blood sampling.
8. Multifunctional catheter according to any of the preceding claims, characterised in that it performs a blood pressure measurement.

9. Multifunctional catheter according to claim 1 characterised in that the occlusion-stabilizing balloon (4) with modifiable diameter assumes a shape from spherical to ellipsoidal.
10. Multifunctional catheter according to claim 1 or 9 characterised in that the occlusion-stabilizing balloon (4) is filled with air or saline.
11. Multifunctional catheter according to claim 1 characterised in that it is guided and monitored using system for electroanatomic mapping.
12. Multifunctional catheter according to claim 1, characterised in that in manipulation handgrip (5) there are placed:
 - inlet/outlet to the manipulation handgrip (5) and electric connections,
 - inlet/outlet to central channel (B),
 - inlet/outlet to pumping/draining channel (A) of occlusion-stabilizing channel (4).
13. Multifunctional catheter according to any of the preceding claims, characterised in that the proximal end of central channel (B) comprises tee dividing proximal end of central channel (B) on two branches, wherein one is ended with diaphragm, while second comprises an opening/closing valve and an ending for connections of pumping device, preferably syringe.
14. Multifunctional catheter according to any of the preceding claims, characterised in that the proximal ending of pumping channel (A) comprises an ending for connection of pumping device, preferably syringe.

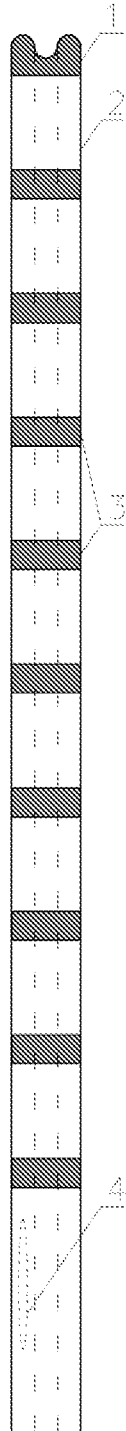


Fig. 1

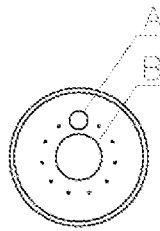


Fig. 2

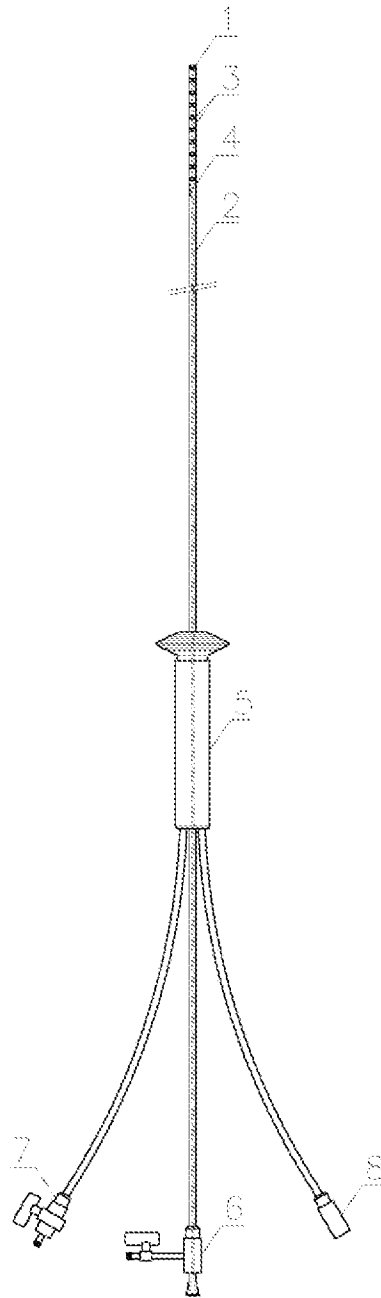


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No PCT/IB2015/051815

A. CLASSIFICATION OF SUBJECT MATTER
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 ADD. A61B5/0215 A61B5/15

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 A61M

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	EP 1 011 437 B1 (CARDIMA INC [US]) 31 May 2006 (2006-05-31) paragraphs [0001], [0022], [0023], [0025], [0030]; figures 1,2,11,12 -----	1-14
X	US 2010/198040 A1 (FRIEDMAN PAUL [US] ET AL) 5 August 2010 (2010-08-05) paragraphs [0010], [0185], [0191] - [0194], [0214] - [0216], [0235]; figures 2,42,49 -----	1-14
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Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance	"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
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"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 16 June 2015	Date of mailing of the international search report 22/06/2015
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Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer Mecking, Nikolai
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INTERNATIONAL SEARCH REPORT

International application No
PCT/IB2015/051815

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 363 156 A2 (CARDIOMETRICS INC [US]) 11 April 1990 (1990-04-11) cited in the application page 4, line 10 - page 6, line 12; figures 1,2 -----	1-14

INTERNATIONAL SEARCH REPORT

Information on patent family members

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