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— *of inventorship (Rule 4.17(iv))*

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(54) **Title**: ABLATION BALLOON CATHETER

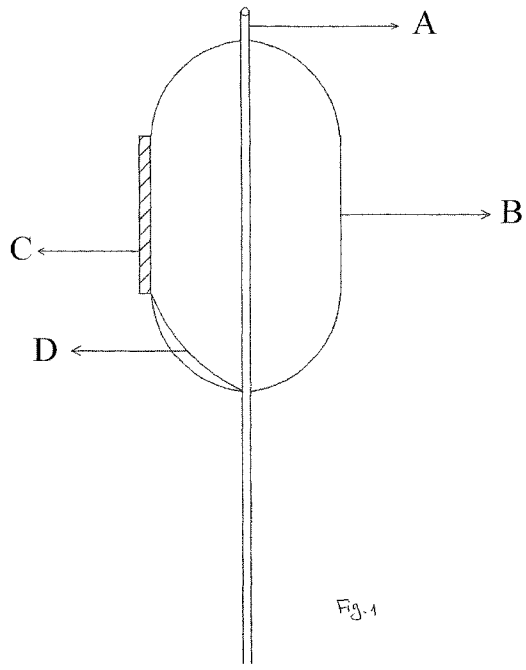

Fig.1

(57) **Abstract**: The invention relates to balloon catheters (A), in particular to balloon catheters (A) for the treatment of stenotic lesions. The object of the invention is to provide an improved device and an improved method for the dilation of narrowed vessels, valves or other portions of bodies, in particular human bodies. An inventive balloon catheter (A) comprises at least one inflatable element (B) for dilating valves or vessels, wherein the catheter (A) further comprises a conductive surface (C) being designed to ablate related surfaces through heat, coldness or direct transmission of electric current.

Ablation Balloon Catheter

Technical Field:

Medicine

Background Art:

The invention relates to balloon catheters, in particular to balloon catheters for the treatment of stenotic lesions. In general stenotic lesions such as narrowed valves, vessel or other parts of a body are treated by dilating those parts by balloon catheters. Therefore a known balloon catheter comprising for example a cylindrical inflatable element with a diameter wider than the opening to be dilated is inserted through an aperture of a body, inflated in order to dilate the narrowed part and removed afterwards.

Since many valves and vessels are generally composed of inelastic tissues it is a problem that they tend to tear at the weakest point, this being sometimes unpredictable, with a resultant permanent dilatation.

In case of muscular stenosis or elastic tissues (subpulmonic, subaortic stenosis), it might be necessary to make use of alternative methods. For example, instead of using balloon catheters it is possible to carry out an open surgery or to use cutting blade catheters.

An open surgery (e.g cardiac) is carried out to dissect any muscular, dysplastic narrowing like the one subvalvular (e.g. in case of subaortic stenosis) with the inherent disadvantages, complications, risks of the operation. Open heart surgeries are not advisable for some patients, e.g. in case of instability or small size.

Cutting blade catheters are used in particular in coronary arteries and peripheral pulmonary arteries.

Open surgery and the use of cutting blade catheters are not suitable for many patients because of their inherent risks or because of patients factors like their weight, age or other reasons. Furthermore the costs and the mortality rate of these methods are high, the patients have to stay in hospital for about one week, and there is a significant incidence of recurrences.

Disclosure Of Invention :

The object of the invention is to provide an improved device and an improved method for the dilation of narrowed vessels, valves or other portions of bodies, in particular human bodies.

The problem is solved by a balloon catheter according to claim 1 and by a method according to claim 8.

According to the invention a balloon catheter comprises at least one inflatable element for dilating valves or vessels, characterized in that the catheter comprises a conductive surface being designed to ablate related surfaces through heat, coldness or direct transmission of electric current.

The balloon catheter according to the invention thus allows to mechanically dilate a vessel, valve or other portion of a human body and to treat the related surfaces through heat, coldness or direct transmission of electric current. This catheter has in particular the following advantages. It allows to safely position the catheter first and to combine the effects of a mechanical dilatation with the effects of an ablation through a conductive surface through heat, coldness or the direct transmission of electric current. The presence of an inflatable element allows stability during the ablation procedure inside tubular structures. It stents the surrounding surface

allowing stability for both the catheter and the vessel, valve or other portion of a body. In addition, it ensures an excellent contact between the ablating surface and the vessel ablated.

Further advantages are the following:

- Synergistic effects by the combination of mechanical balloon dilatation with the ablation effect of energy (heat, cold, electric current)
- Achieving the dilatation of narrow vessels with an interventional procedure without the need for surgery
- Avoiding the inherent risks and complications of surgery including open heart surgery
- Possible application for patients unsuitable for surgery (unstable patients, small weight etc.)
- Avoidance of scars on the surface of the body.
- Less duration of hospital stay
- Less cost.
- Possibility of assessment of the dilatation process during the same procedure.
- Improved success rates in dilatation.
- Directing the site of the tear to the intended site to avoid any unpredictable tears.
- Confirming the optimum site of dilatation or ablation electrically through the recorded electrical potential from the conductive surface adjacent to the surface before dilatation.
- The energy delivered through the ablating surface avoids bleeding from the cut surfaces, a possible side effect of using blades.

The inventive method of dilating a vessel or another portion of a body comprises the following steps:

a) introducing a balloon catheter with at least one inflatable element into a body,

b) dilating the inflatable element in order to retain the balloon catheter on a desired position within a vessel or another portion of the body,

c) utilizing a conductive surface in order to ablate related surfaces through heat, coldness or direct transmission of electric current.

One advantage of the inventive method is that testing the efficiency of the dilatation process is possible while carrying out the intervention (e.g cardiac catheterization, urethral catheterization) under live conditions. This allows a redilatation or another treatment of the same area if necessary. The shape, depth and length of the ablated surface is controllable.

The inventive balloon catheter and the inventive method may be applied inside vessels whether blood vessels, cardiac passages, gastrointestinal passages, urinary tract and other body vessels.

Conductive surfaces may be positioned on one or more sides of the inflatable element or the catheter. It may have different shapes, e.g. longitudinal, transverse, circular or a complex geometry. It may also vary in its size so that heat, coldness or electric current can be transmitted to the catheter surface during the process of dilatation. It is chosen as to ablate the muscular, elastic or tough surface that narrows the vessel, valve or other portion of the body. The invention allows to easily perform ablation cuts longitudinal in a manner similar to those done during surgery even those done during open heart surgery, as the shape and size of the conductive

surface on the side(s) of the balloon or catheter is controllable and may be modified.

The ablation surface may be composed of multiple poles, when a recording of the surface in needed. The ablating surface may be classically composed of the multiple poles (4-mm or 8-mm tips with 4mm in between) but any variation in size and shape according to the expected ablation area is feasible.

The inflatable element may be easily filled with radio-opaque dye during the inflation facilitating the visualisation and positioning step by step.

The balloon catheter may be positioned along a previously positioned guidewire through its lumen allowing easier and more rapid positioning of the catheter at the desired place.

The inventive balloon catheter and the inventive method offer a better stability (balloon, guidewire stabilizes position), better mapping of the site (both imaging and electrical mapping of the site), easier technique of insertion (no need for protective long sheaths to guard against the blade), safety (minimal risk of unintended injury because of the previous factors) and an easier retrieval (like a regular catheter). For the aforementioned reasons, the catheter size and consequently the sheath size may be reduced resulting in a reduced injury risk for the patient.

According to another aspect of the invention the size and/or shape of the conductive surface is modifiable. For example, if the conductive element is applied to the inflatable element, the size of the (effective) conductive element may be varied by varying the inflation pressure of the inflatable element.

Alternatively, the inflatable element may comprise different chambers that may be opened or closed by valves or other means. By selecting which chambers are to be inflated, it is possible to influence the shape of the inflated element and thus the (effective) conductive element.
Alternatively, the balloon catheter may comprise a modular system to exchange one or more conductive elements. Thus, it may be possible to combine one or several inflatable elements with different forms and sizes with one or more conductive elements with different forms and sizes. Thereby, the form and size of the inflatable element and the form and size of the conductive element may be chosen dependent on the vessel, valve or other body part and dependent on the lesion to be treated. Thus, the duration of a treatment may be reduced.
If the conductive surface is insulated from the inflatable element, it may be achieved that the inflatable element (balloon) is not affected itself during the inflation procedure.
An exemplary use of the inventive balloon catheter is described. The proposed balloon catheter may be introduced in the deflated state to the proposed stenosed area. Once positioned, the balloon is inflated with either CO2 or other gas or fluid. As already mentioned, it is possible to use radio-opaque dye. The position of the balloon may be confirmed by a known imaging method, such as ultrasound, X-ray, fluoroscopy, MRI, or CT imaging. The position can be further confirmed by endovessel electrical mapping recording from the available electrodes surface of the catheter. After confirmation, applied energy (electrical, radiofrequency or cryo) is connected to the catheter producing the desired ablation lesion in combination with the mechanical effect of the balloon dilatation. The process may be repeated endlessly by disconnecting the energy source,

deflating the balloon and repositioning of the catheter at another location or same location with different angulations.

The size and shape of the ablating and recording surface of the catheter is variable according to the expected stenosed segment. It might be devised as multiple electrodes with the classic 4 mm or 8 mm tip surface set in a linear position or different position with different size, spacing or shape e.g. circular, irregular according to the expected surface to be dilated (shape and characteristics). At the end of the procedure, the balloon is deflated and retrieved easily similar to regular catheters. The balloon catheter may comprise a steering wire.

The ablation surface may even involve the tip of the catheter to allow perforation of solid tissue before its dilatation whenever needed.

The proposed catheter has at least one lumen connected to the balloon, one lumen connected to the open tip of the catheter allowing the use of guidewires for easy positioning.

The inventive balloon ablation catheter may be produced by any company in the field of balloon catheters and radiofrequency ablation catheters. The conductive element may be manufactured of copper, iron, aluminum, steel or any other appropriate material.

The inventive balloon catheter and the inventive method may be applied in particular as follows:

- Dilating stenosed vessels, namely intracardiac, extracardiac and elsewhere in the body as a primary procedure or where the lesions did not or might not respond to simple balloon dilatation technique
- Dilating a restrictive atrial septal defect or a patent foramen ovale
- Dilating a restrictive VSD in complex heart lesions while particularly avoiding injury of the conductive system of the heart

- Dilating coronary arterial stenosis
- Dilating venous stenosis, e.g pulmonary vein stenosis.
- Dilating pulmonary artery stenosis origin or peripheral.
- Dilating right or left ventricular outflow tract obstruction not amenable to regular balloon and necessitating surgery
- Dilating urinary passage particularly those resistant or having regular balloon failure, dilating prostatic hypertrophy.
- Dilating gastrointestinal passage particularly those resistant or having regular balloon failure.
- Dilating stenotic valves (specially the dysplactic ones)

Brief Description of Drawings :

Further aspects of the inventions are shown in the figures and mentioned in the following part of the description:

Figure 1: shows a first example of an inventive balloon catheter in a side view.

Figure 2: shows the balloon catheter of figure 1 in a top view.

Figure 3: shows a second example of an inventive balloon catheter in a top view.

Figure 4: shows a third example of an inventive balloon catheter in a side view.

The inventive balloon catheter shown in figures 1-4 comprise a catheter tube A, an inflatable element B, namely an inflatable balloon and a conductive element C. In figures 1 and 2 the inflatable element B has a cylindrical shape and the conductive element C is attached to the outer surface of the inflatable balloon B, thereby being disposed at a certain

distance of the catheter tube A. In order to conduct heat, coldness or electric current from the catheter tube to the conductive element C, the inflatable balloon B is partially made of a conductive medium D. Alternatively, the inflatable balloon B may be equipped with an inner or outer layer of a conductive medium D.

As shown in figures 3 and 4, the conductive element C may also be located on or near the catheter tube. The inflatable element B in figure 3 has a cylindrical shape, while the catheter tube A is located at the circumference of the inflatable element B.

In figure 4, the inflatable element B has a half-cylindrical shape. The catheter tube A and the conductive element C are disposed to the planar section of the half cylinder.

Reference Signs:

A catheter tube

B inflatable element (balloon)

C ablating (conductive) surface

D conductive medium

Claims

1. Balloon catheter comprising at least one inflatable element (B) for dilating valves or vessels, characterized in that the catheter comprises a conductive surface (C) being designed to ablate related surfaces through heat, coldness or direct transmission of electric current.
2. Balloon catheter according to claim 1, characterized in that the conductive surface (C) is positioned on the surface of the inflatable element (B) or on a catheter tube (A).
3. Balloon catheter according to one of the preceding claims, characterized in that the size and/or shape of the conductive surface (C) is modifiable.
4. Balloon catheter according to one of the preceding claims, characterized in that the inflatable element (B) has a cylindrical or half-cylindrical shape.
5. Balloon catheter according to one of the preceding claims, characterized in that the conductive surface (C) comprises multiple poles.
6. Balloon catheter according to one of the preceding claims, characterized in that it comprises two or more conductive surfaces (C) being positioned on different sides of the catheter or inflatable element (B).

7. Balloon catheter according to one of the preceding claims, characterized in that the inflatable element (B) is made of a material being resistant to heat and/or coldness.

8. Balloon catheter according to one of the preceding claims, characterized in that the conductive surface (C) is insulated from the inflatable element.

9. Method of dilating a vessel or another portion of a body characterized by the following steps:

A) introducing a balloon catheter (A) with at least one inflatable element (B), in particular a balloon catheter (A) according to one of the aforementioned claims, into a body,

B) dilating the inflatable element (B) in order to retain the balloon catheter (A) on a desired position within a vessel or another portion of the body,

C) utilizing a conductive surface (C) in order to ablate related surfaces through heat, coldness or direct transmission of electric current.

10. Method according to claim 9, characterized in that the balloon catheter (A) is used to mechanically dilate the vessel or other portion of the body before, during or after the utilization of the conductive surface (C).

11. Method according to claims 9 or 10, characterized in that the shape or size of the conductive surface (C) is modified.

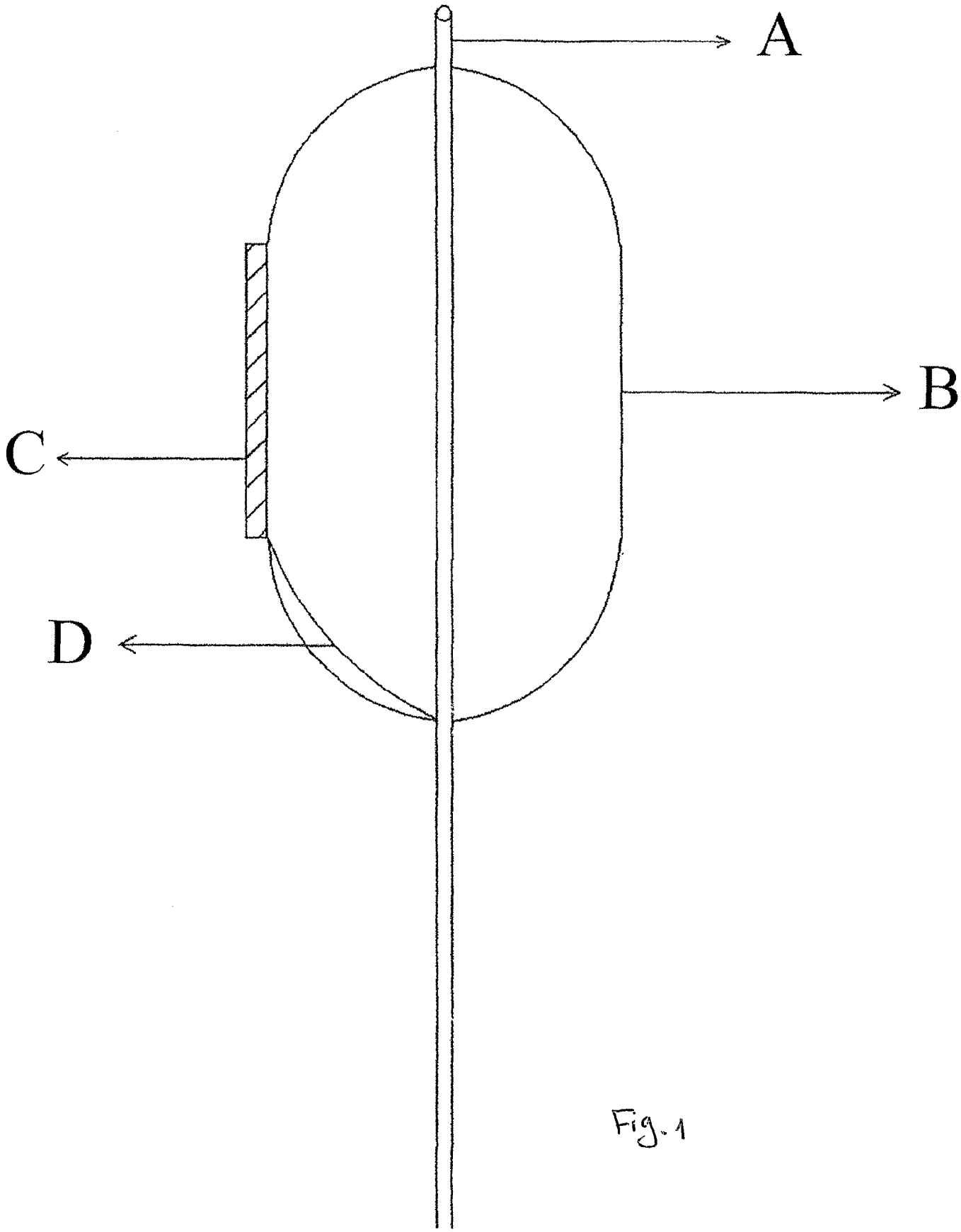

Fig. 1

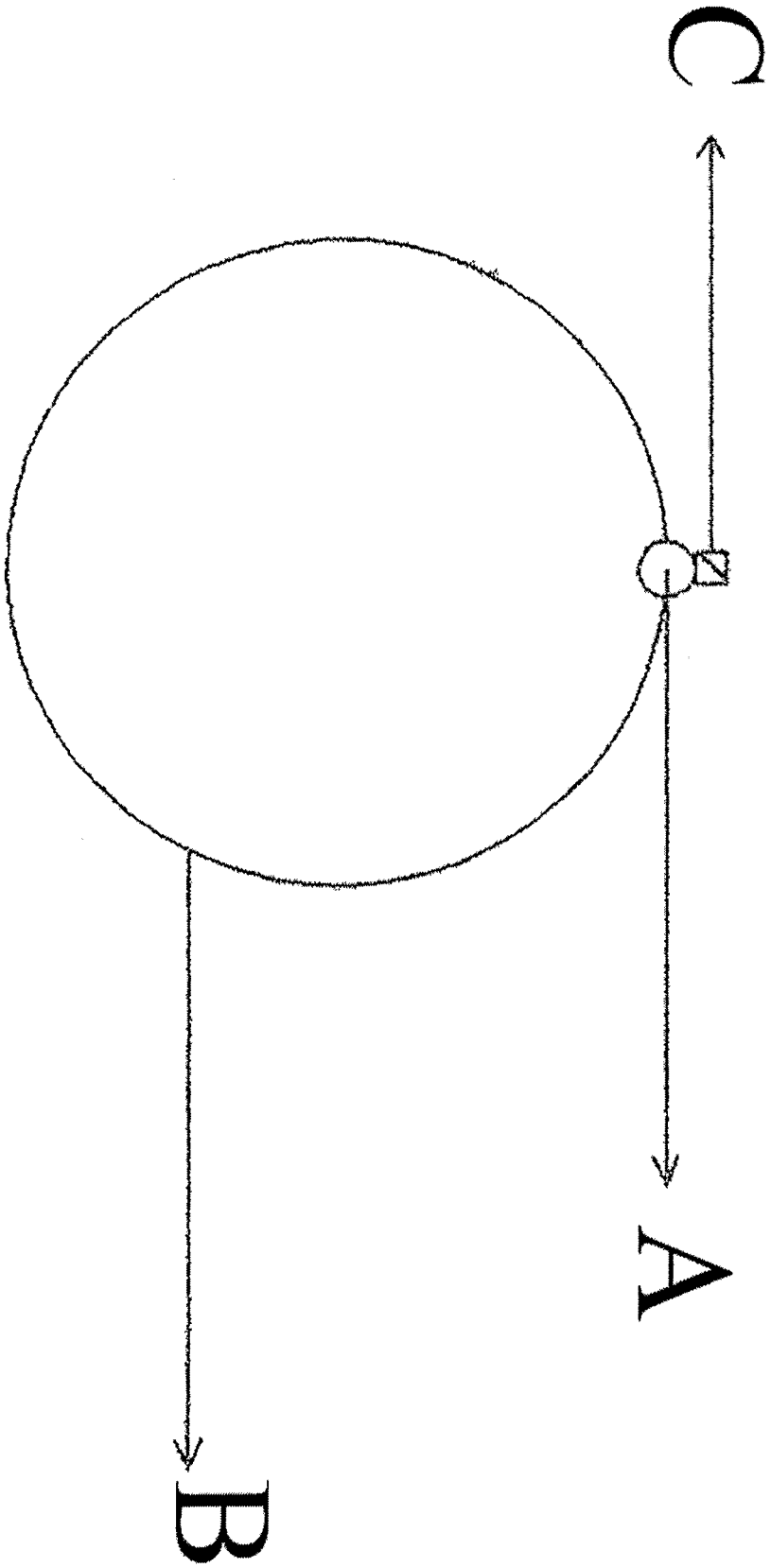

Fig-2

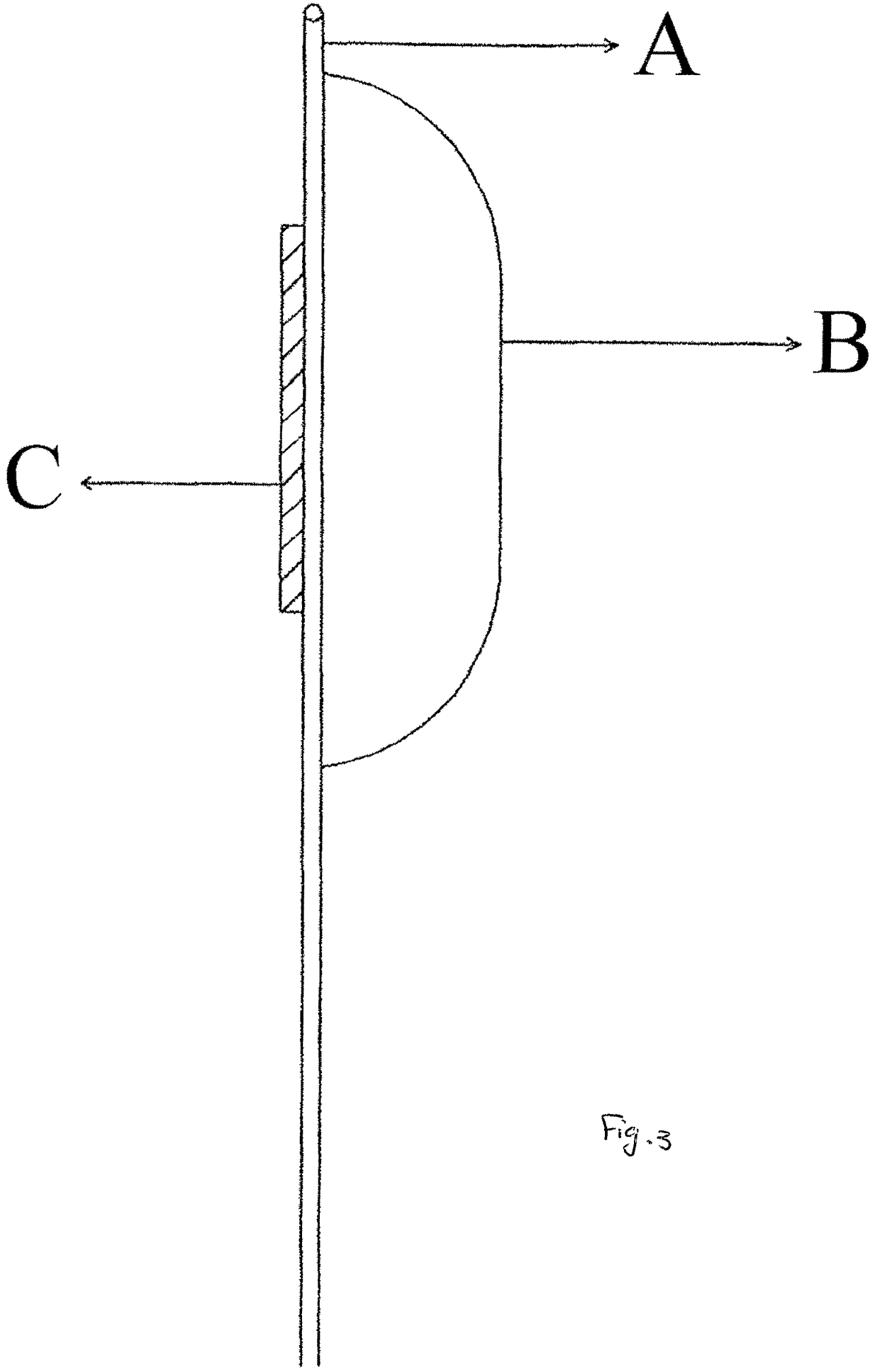

Fig. 3

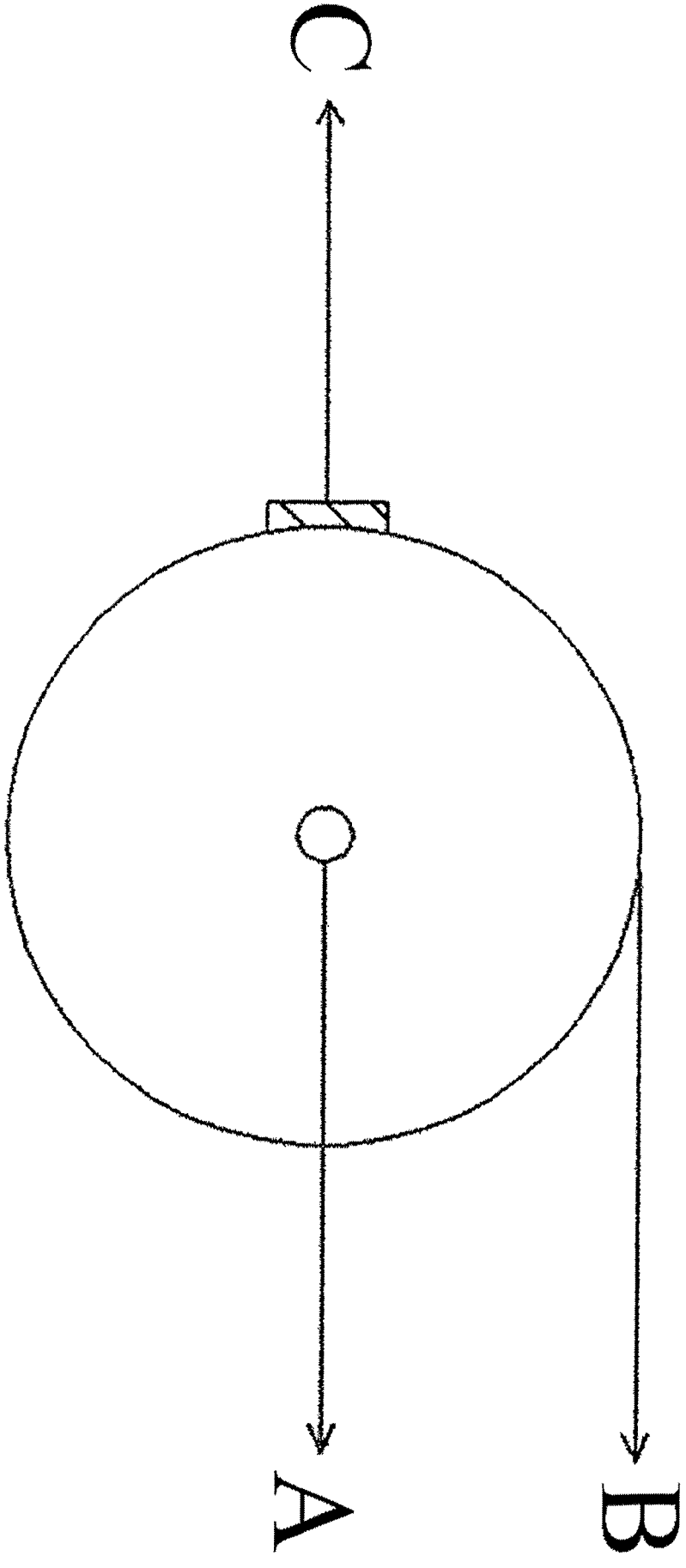

Fig. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EG 2009/000033

A. CLASSIFICATION OF SUBJECT MATTER
IPC[8]: ***A61B 18/02*** (2006.01); ***A61B 18/04*** (2006.01); ***A61M 25/10*** (2006.01)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC[8]: 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)
EPODOC, WPI

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5035694 A (KASPRZYK ET AL.) 30 July 1991 (30.07.1991) *Entire document* --	1-11
X	EP 0315982 A2 (SOLZBACH) 17 May 1989 (17.05.1989) *Entire document* --	1-11
X	US 2003/229340 A1 (SHERRY ET AL.) 11 December 2003 (11.12.2003) *Entire document* --	1-11

☒ 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
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 April 2010 (21.04.2010)	11 May 2010 (11.05.2010)
Name and mailing address of the ISA/ AT **Austrian Patent Office** Dresdner Straße 87, A-1200 Vienna Facsimile No. +43 / 1 / 534 24 / 535	Authorized officer KÖNIG H. Telephone No. +43 / 1 / 534 24 / 339

Continuation of first sheet

Continuation No. II:

Observations where certain claims were found unsearchable

(Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

Claims Nos.: 9-11 because they relate to subject matter not required to be searched by this Authority, namely:

Although claims 9-11 are directed to a therapeutic method of treatment of the human/animal body (Rule 67.1 (iv) PCT), the search has been carried out on the complete set of claims.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EG 2009/000033

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6123718 A (TU ET AL.) 26 September 2000 (26.09.2000) *Entire document*	1-11
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X	US 2005/070888 A1 (DIMATTEO ET AL.) 31 March 2005 (31.03.2005) *Entire document*	1-11

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/EG 2009/000033

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US A 5035694		JP A 2002011101	2002-01-15
		WO A1 9014046	1990-11-29
		JP T 4505569T	1992-10-01
		EP A1 0474734	1992-03-18
		CA A1 2057924	1990-11-16
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US A 2003229340		US A1 2003229340	2003-12-11
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US A 2005070888		WO A1 2006050134	2006-05-11
		US A1 2005070888	2005-03-31