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CA 2242996 C 2007/11/13

(11)(21) 2 242 996

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(22) Date de dépôt/Filing Date: 1998/07/13

(41) Mise à la disp. pub./Open to Public Insp.: 1999/03/26

(45) Date de délivrance/Issue Date: 2007/11/13

(30) Priorité/Priority: 1997/09/26 (EP97202957.3)

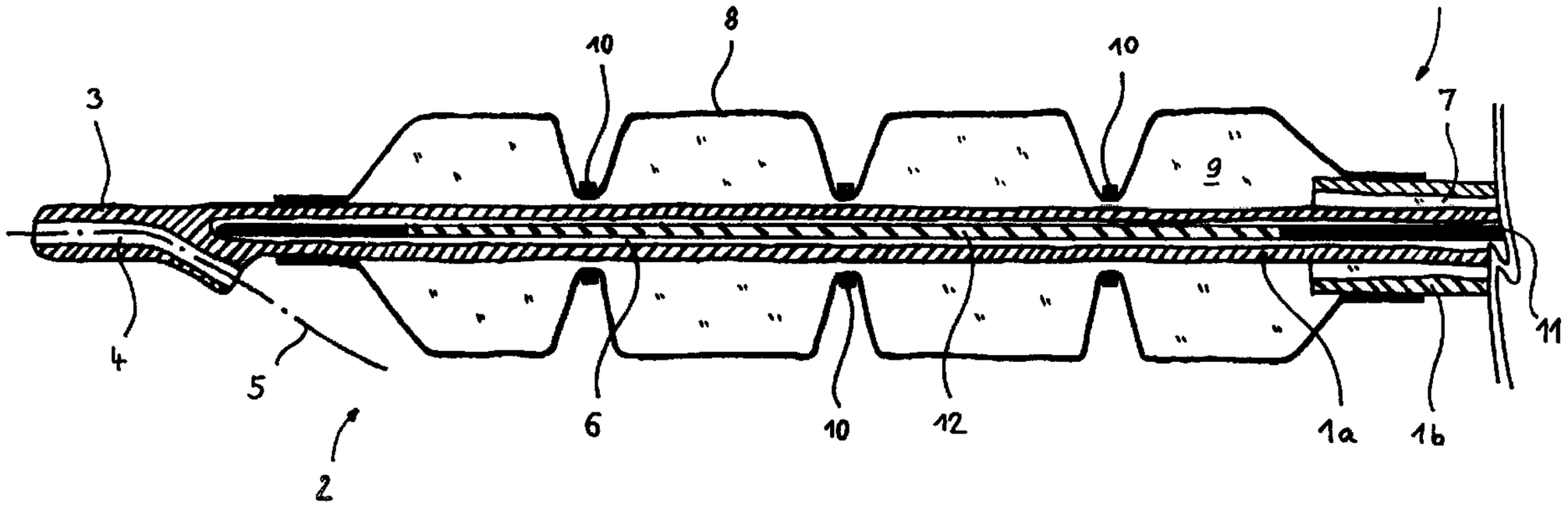
(51) Cl.Int./Int.Cl. *A61M 25/10* (2006.01), *A61N 5/10* (2006.01), *A61M 36/00* (2006.01)

(72) Inventeurs/Inventors:
SCHWAGER, MICHAEL, CH;
GHIELMETTI, CIRILLO, CH

(73) Propriétaire/Owner:
SCHNEIDER (EUROPE) GMBH, CH

(74) Agent: SMART & BIGGAR

(54) Titre : CATHETER PREPARE
(54) Title: PREPARED CATHETER



(57) Abrégé/Abstract:
In the case of a prepared catheter for intraluminal treatment of a vessel section with ionizing radiation, which catheter has an elongate shaft (1) with a proximal end and a distal end (2) as percutaneous transluminal access to the vessel section, an inflatable balloon (8) at the distal end (2) of the shaft (1), an inflation lumen (7) which runs through the shaft (1) and opens into the balloon (8), and a source (12) of ionizing radiation which can be positioned in the balloon (8), and which catheter is filled with an inflation medium (9) for applying pressure to the balloon (8), if the inflation medium (9) is a gas, only a comparatively small proportion of the ionizing radiation is absorbed and rendered ineffective as it passes through the gas. In this way, the intended dose of radiation can be administered within a short treatment time.

Abstract

In the case of a prepared catheter for intraluminal treatment of a vessel section with ionizing radiation, which catheter has an elongate shaft (1) with a proximal end and a distal end (2) as percutaneous transluminal access to the vessel section, an inflatable balloon (8) at the distal end (2) of the shaft (1), an inflation lumen (7) which runs through the shaft (1) and opens into the balloon (8), and a source (12) of ionizing radiation which can be positioned in the balloon (8), and which catheter is filled with an inflation medium (9) for applying pressure to the balloon (8), if the inflation medium (9) is a gas, only a comparatively small proportion of the ionizing radiation is absorbed and rendered ineffective as it passes through the gas. In this way, the intended dose of radiation can be administered within a short treatment time.

FIG. 1

Pa 97/19 CO_2 Balloon

Description

The invention relates to a prepared catheter for intraluminal treatment of a vessel section with ionizing radiation, which catheter has an elongate shaft with a proximal end and a distal end as percutaneous transluminal access to the vessel section, an inflatable balloon at the distal end of the shaft, an inflation lumen which runs through the shaft and opens into the balloon, and a source of ionizing radiation which can be positioned in the balloon, and which catheter is filled with an inflation medium for applying pressure to the balloon.

Catheters of the type mentioned in the introduction are used, for example, during or after percutaneous transluminal angioplasty, such as balloon dilation or atherectomy of a stenosed blood vessel section, in order to prevent restenosis of this section. This is based on the fact that application of a defined dose of radiation can check an excessive cell proliferation triggered by the angioplasty and that by this means a restenosis of the treated vessel section can be avoided. A catheter of the generic type can, however, also be used for radiation treatment of other body cavities, such as the oesophagus or trachea or for treating the prostate.

A catheter of the type mentioned in the introduction is known from EP 0 633 041 A1, in which a guide wire is arranged to be longitudinally displaceable in a central guide-wire lumen of a two-lumen balloon catheter. An emitter of radioactive radiation in the form of a filament is incorporated into the tip of the guide wire. The second lumen serves as inflation lumen for the balloon, by means of whose inflation the radiation emitter positioned in the guide-wire lumen is centred radially in the vessel section that is to be treated. In this way, a radiation dose distribution is obtained uniformly about the circumference of the vessel wall. For applying pressure to the balloon, a normal physiological solution for balloon dilations is used. The radiation source preferably used is yttrium- 90, an easily screenable beta emitter with a half-life of 2.7 days, a mean electron energy of 0.942 MeV, and a maximum electron energy of 2.28 MeV.

Over the greater part of its course from the emitter positioned in the balloon to the vessel wall to be treated, the radioactive radiation has to pass through inflation medium, in which process - as in any matter - radiation energy is absorbed. Thus, the energy dose available at the surface of the vessel wall, and the depth of penetration of the radiation into the vascular tissue at the wall, depend on the initial activity of the source, on the coefficient of absorption of the inflation medium, and on the length of travel of the radiation through the inflation medium. With physiological saline solution or contrast medium, inflation media are normally used which do not have too negligible a coefficient of absorption. Thus, known catheters of the type mentioned in the introduction suffer the drawback of long irradiation times and, consequently, treatment times. Because of the necessary centering of the emitter in an inflated balloon, the flow of blood in the treated vessel has to be interrupted during this treatment. A high rate of absorption also places stringent demands on the radial centering of the source for generating a uniform radiation dose distribution.

The invention is therefore based on the object of providing a catheter of the type mentioned in the introduction, in which as small a proportion as possible of the ionizing radiation is absorbed on its travel from the source through the inflated balloon to the vessel section that is to be treated.

The invention provides prepared catheter for intraluminal treatment of a vessel section with ionizing radiation, which catheter has an elongate shaft with a proximal end and a distal end as percutaneous transluminal access to the vessel section, an inflatable balloon at the distal end of the shaft, an inflation lumen which runs through the shaft and opens into the balloon, and a source of ionizing radiation which can be positioned in the balloon, and which catheter is filled with an inflation medium for applying pressure to the balloon, characterized in that the inflation medium is a gas. When the inflation medium is a gas, the radiation passes through a medium with a comparatively low coefficient of absorption, since the latter is generally higher for liquids than it is for gases. Therefore, the radiation attenuates only slightly as it passes through the inflation medium, so that a sufficient radiation dose can be delivered to the vessel section within a short time. In addition, the radiation intensity is less dependent on the source distance, as a result of which inaccuracies in the centering of the source have only slight effects on the uniformity of the dose distribution. Furthermore, gas-filled balloons have up to about three times shorter deflation times compared to balloons which have been inflated with liquid, a fact which is attributable to the lower viscosity of gases compared to liquids. The advantage of this is, for example, that when providing treatment using a

balloon which interrupts the flow of blood, it is possible to respond quickly to an ischaemic reaction on the part of the patient by deflating the balloon.

In a preferred embodiment of the invention, the inflation medium is carbon dioxide. In the treatment of blood vessels, it is possible, in the event of a leaking or defective balloon, for the blood to absorb a certain amount of carbon dioxide without harming the patient. Since carbon dioxide is transported anyway in the blood, its biological tolerability in humans is not in question.

In a further advantageous embodiment of the invention, the inflation lumen has, along the greater part of its length lying within the patient's body during treatment, a cross-sectional area of at most 0.300 mm^2, or at most 0.200 mm^2. The cross-sectional area of the inflation lumen can also be defined as a function of the balloon volume, for example when expressed in mm^2, not greater than a maximum use volume of the balloon in mm^3 divided by 1200, or 1600. By reducing the cross-sectional area of the inflation lumen, the overall profile of the catheter can be made smaller, as a result of which a catheter according to the invention is suitable for minimally invasive percutaneous trans-luminal treatments via small puncture openings and guide catheters. In addition, the catheter can also be used in correspondingly narrower vessels, in which case the time for the balloon to empty still remains small compared to known catheters with liquid inflation media.

According to one aspect of the present invention, there is provided a prepared balloon catheter for intraluminal ionizing radiation treatment of a vessel section within a patient's body, the catheter having an elongate shaft with a gas-filled inflation lumen extending therethrough, and a balloon disposed on a distal end of the shaft, the balloon having a maximum inflated volume, wherein the inflation lumen extending through the shaft has a cross-sectional area having a value in mm not greater than the maximum inflated volume of the balloon in mm^3 divided by 1200.

According to another aspect of the present invention, there is provided a prepared balloon catheter for intraluminal ionizing radiation treatment of a vessel section within a patient's body, the catheter having an elongate shaft with a proximal end and a distal end, a balloon arranged at the distal end of the shaft, the balloon having a maximum inflated volume, and an inflation lumen having a length which runs through the shaft and opens into the balloon, wherein the catheter is filled with an inflation medium having a viscosity lower than that of water for applying pressure to the balloon, and wherein the inflation lumen has, along the greater part of the length lying within the patient's body during treatment, a cross-sectional area having a value in mm^2 not greater than the maximum inflated volume of the balloon in mm^3 divided by 1200.

Further advantages of a catheter according to the invention will become apparent from a preferred illustrative embodiment which is described in detail hereinbelow with reference to the drawing, in which:

FIG. 1 shows, in a longitudinal cutaway, the distal section of a catheter according to the invention.

According to FIG. 1, a catheter according to the invention for intraluminal treatment of a vessel section with ionizing radiation has a three-lumen shaft 1 which has a proximal end (not shown) and a distal end 2, and serves as transluminal access to the vessel section. The shaft 1 is made up of an outer shaft 1b and an inner shaft 1a which runs coaxially inside the latter and projects distally from it. In a tip 3 of the inner shaft 1b there is a short guide-wire lumen 4 for receiving a guide wire (not

shown, course indicated by dot-and-dash line 5), onto which the catheter is threaded in order to be advanced through the vessel system. During the insertion of the catheter, a central lumen 6 which is closed distally is used for receiving a stiffening wire (not shown) which transmits axial thrust to the tip 3 as the shaft 1 is being advanced. An annular inflation lumen 7 running between inner shaft 1a and outer shaft 1b opens into a balloon 8 arranged at the distal end 2 of the shaft 1, which balloon 8 is filled, via the inflation lumen 7, with an inflation medium 9, for example carbon dioxide, and is thereby inflated. With approximately the same emptying time for the balloon 8, the use of carbon dioxide as inflation medium permits a reduction in the cross-sectional area of the inflation lumen 7, for example to values of less than 0.300 mm^2, although cross-sectional areas of less than 0.200 mm^2 have already been produced. The achievable ratio between the maximum use volume of the balloon and the cross-sectional area of the inflation lumen, with tolerable emptying times, is approximately 1200:1. In order to obtain a thin outer shaft 1b, the emptying times evolving from a ratio of 1600:1 have also been accepted in some cases. The inflated balloon 8 is subdivided into a plurality of balloon segments by constrictions which are formed by ring elements 10, as a result of which the central lumen 6 is radially centred even in the event of deformation of the inner shaft 1a. When the balloon catheter has been positioned, the stiffening wire is removed from the central lumen 6 and replaced by a source wire 11 into which a source 12 of ionizing radiation is incorporated distally. The source 12 is, for example, a filament of yttrium-90, which is positioned in the balloon in such a way that the emitted beta radiation substantially passes through the inflation medium 9 on its travel to the vessel wall.

The carbon dioxide used as inflation medium is, for example, kept ready in gas bottles at a pressure of 11 bar, for example. The gas pressure can be reduced via a reducing valve, so that an inflation syringe can also be filled with carbon dioxide in the sterile area of a catheter laboratory. Air is removed from the balloon and inflation lumen of the catheter in a customary manner, for instance with a syringe creating a vacuum. The balloon can thereafter be inflated with the carbon dioxide taken up by the inflation syringe.

List of references

1 Shaft

1a Inner shaft

1b Outer shaft

2 Distal end

3 Tip

4 Guide-wire lumen

5 Guide-wire course

6 Central lumen

7 Inflation lumen

8 Balloon

9 Inflation medium, carbon dioxide

10 Ring element

11 Source wire

12 Source

CLAIMS:

1. A prepared balloon catheter for intraluminal ionizing radiation treatment of a vessel section within a patient's body, the catheter having an elongate shaft with a gas-filled inflation lumen extending therethrough, and a balloon disposed on a distal end of the shaft, the balloon having a maximum inflated volume, wherein the inflation lumen extending through the shaft has a cross-sectional area having a value in mm^2 not greater than the maximum inflated volume of the balloon in mm^3 divided by 1200.

2. A prepared balloon catheter for intraluminal ionizing radiation treatment of a vessel section within a patient's body, the catheter having an elongate shaft with a proximal end and a distal end, a balloon arranged at the distal end of the shaft, the balloon having a maximum inflated volume, and an inflation lumen having a length which runs through the shaft and opens into the balloon, wherein the catheter is filled with an inflation medium having a viscosity lower than that of water for applying pressure to the balloon, and wherein the inflation lumen has, along the greater part of the length lying within the patient's body during treatment, a cross-sectional area having a value in mm^2 not greater than the maximum inflated volume of the balloon in mm^3 divided by 1200.

3. The catheter of claim 2, wherein the inflation lumen has, along the greater part of the length lying within the patient's body during treatment, a cross-sectional area having a value in mm^2 not greater than the maximum inflated volume of the balloon in mm^3 divided by 1600.

4. The catheter of claim 2, wherein the inflation lumen has, along the greater part of the length lying within

the patient's body during treatment, a cross-sectional area of at most 0.300 mm^2.

5. The catheter of claim 4, wherein the inflation lumen has, along the greater part of the length lying within the patient's body during treatment, a cross-sectional area of at most 0.200 mm^2.

6. The catheter of claim 2, wherein the inflation medium is a gas.

7. The catheter of claim 6, wherein the inflation medium is carbon dioxide.

SMART & BIGGAR
PATENT AGENTS
OTTAWA, CANADA

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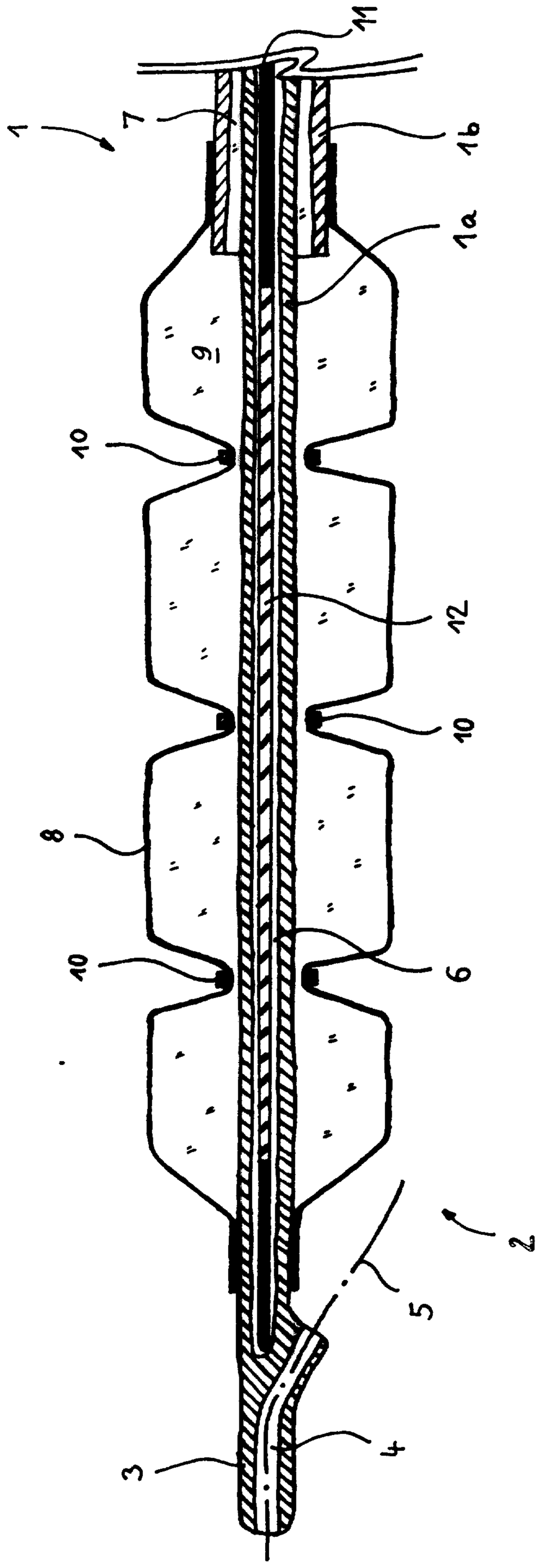

FIG. 1

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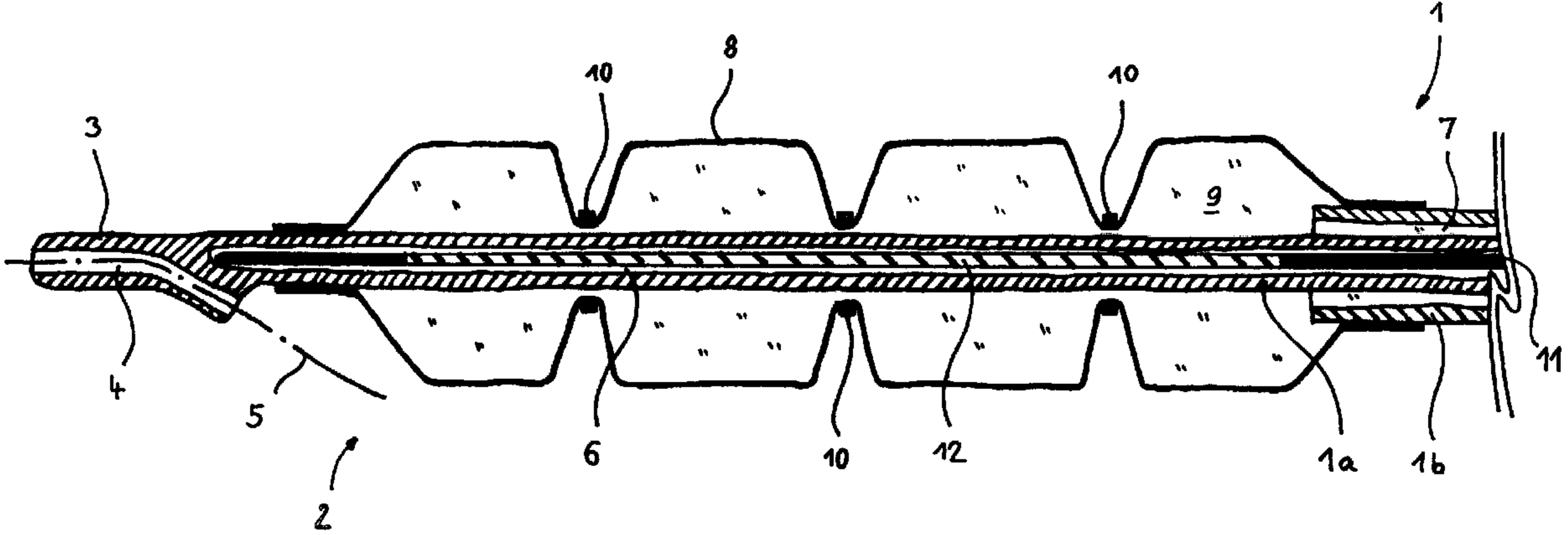
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