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- as to the identity of the inventor (Rule 4.17(i))
- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
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(54) Title: BALLOON CATHETER

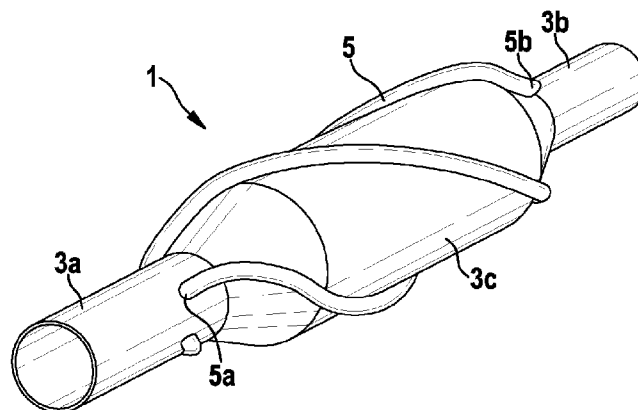


FIG. 1

(57) Abstract: The invention relates to a balloon catheter with a catheter shaft (3a) and an expandable balloon portion (3c) and with working means (5) for working on vascular deposits, wherein the working means comprise at least one proximally open and distally closed attachment tube (5) laid on the periphery of the balloon portion (3c).



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Balloon catheter

The invention relates to a balloon catheter comprising at least a catheter shaft and an expandable balloon portion, and comprising working means for working on vascular
10 deposits.

Balloon catheters and balloon catheter-stent devices have long been known and are used in a clinical setting in their hundreds of thousands for the treatment of vasoconstrictions (stenoses) of blood vessels. The long-known treatment by expansion (dilatation) by means
15 of a balloon catheter is supplemented in devices of this kind by a stabilisation of the expanded vessel portion by means of a support element, that is to say the stent expanded by means of the balloon and left behind at the location of the stenosis following the deflation of the balloon and the withdrawal of the balloon catheter (stenting). Reference is made, purely by way of example, to DE 10 2004 059 523 A1 in respect of devices of this
20 kind, said document describing a new stage of development of these devices.

In many cases an at least partial removal of deposits on the vessel wall is desirable in addition to the expansion and stabilisation of the stenosis portion. For this purpose, balloon catheters having what are known as cutting balloons with cutting blades on the balloon
25 surface and more recently also stents having scoring elements for cutting vascular deposits have been developed and are also used already in a clinical setting.

Document WO 2009/046206 A1 presents a balloon catheter with attached scoring elements. Here, there are helically extending metal wires or comparable plastic elements
30 attached to the balloon portion of the balloon catheter. Document US 8,348,987 B2 presents a balloon catheter-stent device with scoring elements attached to the stent structure.

It has been found that both solutions have significant disadvantages.

Cutting balloons are relatively rigid on account of the attached cutting elements and can only be introduced with difficulty into complex lesions, and there is a significant risk of perforation here as well. In addition, the minimum (deflated) balloon diameter is larger than in comparable balloons without cutting elements. Lastly, cutting balloons put up a relatively high resistance as the device is advanced through the vessel system, which hinders precise handling.

In stents with scoring elements there is the risk, *inter alia*, that the scoring elements, which also protrude in the insertion state, might cause tissue damage. On the other hand, the effects actually attained at the intended site of insertion have not proven to be satisfactory in clinical studies.

The object of the invention is therefore to provide an improved balloon catheter of the aforementioned type which can be handled easily and reliably and which can be configured in a versatile manner in accordance with different user requirements.

The invention includes the concept of equipping the balloon catheter with working means which in the starting state with deflated balloon, that is to say during the insertion of the balloon catheter, have a different physical characteristic than in the end state with inflated balloon, in which they are intended to be suitable for working on a stenosis. In particular, in the starting state they should have a low rigidity and should also protrude to the smallest possible extent beyond the peripheral surface of the (as yet uninflated) balloon portion, whereas in the end state they should protrude beyond the balloons surface to an extent sufficient for working and should be sufficiently rigid.

The invention also includes the concept of bringing about this "state transition" in a manner similar to that implemented in the case of the catheter balloon itself, specifically by filling with a suitable liquid. Lastly, the invention comprises the concept that the working means have at least one additional tube with a closed end, which tube is attached with a

suitable profile to the balloon portion of the catheter and will be referred to hereinafter as an attachment tube.

Within the scope of this application, a balloon catheter is understood to mean a catheter which is suitable for being introduced into a bodily vessel or lumen of a patient, in particular into a lumen of the bloodstream. A balloon catheter of this kind comprises at least one catheter shaft and an expandable balloon portion, referred to as a balloon for short. The expansion (inflation) of the balloon is implemented by acting on said balloon with a fluid via a lumen of the catheter shaft.

In expedient embodiments of the invention a plurality of attachment tubes of this kind, in particular 3 to 5 attachment tubes, is provided. Improved working effects can be achieved hereby compared with an individual attachment tube.

In particular, the attachment tube or the attachment tubes lies/lie helically on the balloon portion, wherein it/they describes/describe in particular at least a half turn about the longitudinal axis of the balloon portion between the proximal balloon neck and the distal balloon neck. The angular range of a helical course between proximal and distal balloon neck of the attachment tube or the attachment tubes will be determined by a person skilled in the art in accordance with the specific configuration, in particular in respect of the length of the balloon portion, the number of attached tubes, and requirements of the specific application. In particular if a plurality of attachment tubes are provided, it is also possible in principle to lay said attachment tubes parallel to the longitudinal axis of the balloon portion.

In an embodiment of the invention currently considered to be expedient, the attachment tube or each attachment tube is welded or glued at least over the majority of its length to the balloon portion. Alternatively, it is possible that the attachment tube is fixedly connected, in particular welded or adhesively bonded, to the catheter shaft substantially only at the proximal balloon neck. In the latter variant it would appear to be advantageous if the attachment tube or each attachment tube is also welded or glued therebetween at specific points to the balloon portion so as to prevent undesirable tangential and/or axial

displacements of the tube or the tubes relative to the balloon and associated deteriorations of the working effect.

In a further embodiment the catheter shaft comprises an inner shaft and an outer shaft, and
5 the open proximal end of the attachment tube or each attachment tube is connected fluidically to the lumen of the outer shaft. The attachment tube or the attachment tubes is/are pressurised at this moment, that is to say simultaneously with the catheter balloon, which makes the structure of the catheter as a whole and also handling thereof particularly simple. In another catheter construction known per se, the catheter shaft has a first lumen
10 for a guide wire and a second lumen for introducing a fluid for expanding the balloon portion, and the open proximal end of the attachment tube or each attachment tube is fluidically connected to the second lumen.

Alternatively, it is provided that the open proximal end of the attachment tube or each
15 attachment tube opens out into a separate proximal fluid connection of the balloon catheter. This offers the possibility of controlling the characteristic of the working means independently of the inflation of the balloon, but requires a separate fluid line extending as far as the proximal catheter end or an additional lumen in the catheter body and a separate connection of the catheter.

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Here, it is possible on the one hand that the open proximal end of the attachment tube or each attachment tube is connected via an additional lumen in the catheter shaft to the dedicated fluid connection. Alternatively, as a modification of known catheter configurations, the proximal end of the attachment tube or each outer tube can be
25 connected to the separate fluid connection via a working fluid tube laid externally on the catheter shaft.

In a further embodiment of the invention the balloon catheter has a working means protective sleeve displaceable along the catheter shaft. This protective sleeve is advanced
30 as far as the distal balloon neck before and during insertion of the catheter and covers the outer tube or the outer tubes, and is withdrawn as far as at least the proximal balloon neck after the insertion, so as to expose the outer tube or the outer tubes for implementation of

its/their working purpose. It goes without saying that in a construction of this kind an additional actuation element is required for the working means protective sleeve, and the handling of the catheter of this kind is slightly more complex.

5 In expedient embodiments the attachment tube or each attachment tube comprises a material from the group of polyamides, polyimides, polyesters, polyethers, polyolefins and copolymers thereof. Materials which are compatible with the material of the catheter balloon such that light welding or adhesive bonding is possible are particularly preferred.

10 In further embodiments of the invention the diameter of the attachment tube or each attachment tube lies in the range between 2% and 8%, preferably between 2% and 4%, of the diameter of the balloon. The specific determination of the attachment tube geometry will be made by a person skilled in the art as a matter of routine, in particular under consideration of the structure of the balloon catheter per se and the specific situation of
15 application.

In further embodiments it is provided that the attachment tube or at least part of the attachment tubes comprises a cutting or sawing edge for abrasive working on vascular deposits. The cutting or sawing edge(s) can be adhesively bonded or welded to the
20 attachment tube proximally, distally and/or over the entire length. Alternatively, the cutting or sawing edge(s) can also be produced directly with the forming of the attachment tube. Materials that are suitable for the cutting or sawing edge are in particular metals (for example stainless steel) or polymers, such as polyamides, polyimides, polyesters, polyethers, polyolefins and copolymers thereof. The diameter of an attachment tube (or
25 maximum radial extent thereof) is advantageously between 4% and 8% of the balloon diameter. This is advantageous in particular for applications in which the balloon catheter should not only break through calcareous deposits, but should also separate and/or remove them in layers. It goes without saying that the provision of cutting or sawing edges can slightly hamper the handling of the balloon catheter during the insertion process; this
30 disadvantage, however, is outweighed in certain application situations by the advantages of an embodiment of this kind.

The following advantages, inter alia, can be attained with the invention at least in certain embodiments:

Advantages and expedient features of the invention will also become clear from the following description of an exemplary embodiment with reference to the drawings, in which:

Fig. 1 shows a schematic perspective view of a balloon catheter in accordance with a first embodiment of the invention,

Fig. 2 shows a schematic perspective view of a balloon catheter in accordance with a further embodiment of the invention,

Fig. 3 shows a schematic perspective view of a balloon catheter in accordance with a further embodiment of the invention,

Fig. 4 shows a schematic longitudinal sectional view of the main structure of a balloon catheter,

Fig. 5 shows a schematic longitudinal sectional view of a second main structure of a balloon catheter,

Fig. 6 shows a schematic longitudinal sectional view of a balloon catheter in accordance with a further embodiment of the invention.

Fig. 1 shows a sketch of a balloon catheter 1 which comprises an outer shaft 3a, an inner shaft 3b, and a balloon portion 3c (shown in the inflated state in the drawing), and also three attachment tubes 5 laid on the balloon portion 3c. The attachment tubes 5 laid helically at equal angular distances over the peripheral surface of the balloon portion 3c each have a proximal open end. They are connected there fluidically at mouth points 5a to the inner lumen of the catheter shaft 3a, that is to say are subjected to fluid pressure simultaneously with the inflation of the balloon 3c and in the same way as the balloon

portion. At their distal ends 5b, the attachment tubes 5 are closed in a fluid-tight manner. The attachment tubes can be welded, adhesively bonded or otherwise fixedly connected over their entire surface or also only at specific points, for example at the neck portions of the balloon 3c, to the balloon 3c and/or the adjoining shaft portions.

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Fig. 2 shows a modification of the structure shown in Fig. 1, wherein the same reference numerals are provided for matching or functionally similar parts, and those parts will not be described further here. The main difference of the balloon catheter 1' from the balloon catheter 1 according to Fig. 2 lies in a modified embodiment of the attachment tubes 5' at the proximal ends thereof. Here, these attachment tubes specifically do not open out into the catheter shaft 3a, but instead are connected to one another via a branch piece 5a' and are connected to a separate fluid line (not shown) leading to the proximal catheter end. In this embodiment the attachment tubes 5' are placed under fluid pressure via the separate fluid line, independently of the inflation of the balloon portion 3c.

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Fig. 3 shows a further balloon catheter 1'', which is derived from the balloon catheter 1 according to Fig. 1 by way of a modification. The main difference here lies in the fact that a sawtooth structure is formed on the attachment tubes 5'' and enables abrasive working on vascular deposits at the site of use of the balloon catheter.

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Fig. 4 schematically shows, in the form of a longitudinal sectional view, a first variant of the inner structure of a balloon catheter 10 according to the invention with a substantially coaxial structure. The catheter shaft (not referenced separately here) comprises an inner shaft 12, in which a guide wire 11 is received, and an outer shaft 13. A balloon portion 14 is welded to the inner shaft 12 at a distal balloon neck 14a and to the outer shaft 13 at a proximal balloon neck 14b. The balloon portion 14 is shown here in the expanded state. In order to produce this state, a lumen 13a for feeding a fluid into the balloon portion 14 is provided in the outer shaft 13, whereas an inner shaft lumen 12a coaxial with the lumen 13a receives the guide wire 11 longitudinally displaceably in the inner shaft 12. An attachment tube 15 as working means of the balloon catheter 10 is fluidically connected at the proximal balloon neck 14b to the outer shaft lumen 13a. The attachment tube 15 is thus inflated simultaneously with the balloon portion 14.

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Fig. 5 shows a further balloon catheter 10' with a different structure, wherein like or functionally comparable parts are denoted by the same numbers as in Fig. 4 and will not be described here again. In contrast to the balloon catheter 10 according to Fig. 4, the balloon catheter 10' has a one-piece catheter shaft 12', in which two lumens 12a (for the guide wire 11) and 12b (as fluid channel) are incorporated parallel to one another. The catheter shaft 12' is welded to the balloon portion 14' both at the distal balloon neck 14a and at the proximal balloon neck 14b. The balloon portion 14' is filled via passages 12c from the fluid channel 12b into the interior of the balloon portion 14' with a fluid fed from the proximal catheter and is expanded hereby. A further passage 12d connects the fluid channel 12b to the attachment tube 15'. Fluid in the lumen 12b thus again places the attachment tube under fluid pressure simultaneously with the balloon portion 14' and expands said tube. Alternatively to the shown configuration, the attachment tube 15' can also run externally on the catheter shaft 12' to the proximal catheter end.

A further alternative to the configurations shown in Fig. 4 and Fig. 5 lies in that an additional lumen is provided within the outer catheter in the arrangement according to Fig. 4 or within the catheter shaft in the arrangement according to Fig. 5, which additional lumen is used exclusively to supply fluid to the attachment tube or the attachment tubes. This variant is shown schematically in Fig. 6, more specifically together with a further modification of the configuration according to Fig. 4. This lies in that a working means protective sleeve 16 is associated with the actual balloon catheter C2'. This protective sleeve covers the attachment tubes 15.1 and 15.2 (and any further attachment tubes; not shown here) in the insertion state and is withdrawn proximally after insertion, when the balloon catheter is placed in operation with its attachment tubes serving as working means.

Otherwise, the invention can also be embodied in a large number of modifications of the examples shown here and aspects of the invention described further above.

Claims

1. A balloon catheter (1; 1', 1''; 10; 10'; 10'') with a catheter shaft (12'; 12/13) and an expandable balloon portion (3c; 14; 14'), and with working means for working on
5 vascular deposits,
wherein the working means comprise at least one proximally open and distally closed attachment tube (5; 5', 5''; 15; 15'; 15.1, 15.2) laid on the periphery of the balloon portion.
- 10 2. The balloon catheter according to claim 1, wherein the working means comprise a plurality of attachment tubes (5; 5', 5''; 15; 15'; 15.1, 15.2), in particular three to five attachment tubes.
- 15 3. The balloon catheter according to claim 1 or 2, wherein the attachment tube or the attachment tubes (5; 5', 5''; 15; 15'; 15.1, 15.2) is/are laid helically on the balloon portion (3c 14; 14'), wherein it/they describes/describe in particular at least one half turn about the longitudinal axis of the balloon portion between the proximal balloon neck (14b) and the distal balloon neck (14a).
- 20 4. The balloon catheter according to any one of the preceding claims, wherein the attachment tube or each attachment tube (5; 5', 5''; 15; 15'; 15.1, 15.2) is welded or glued at least over the majority of its length to the balloon portion.
- 25 5. The balloon catheter according to any one of claims 1 to 3, wherein the attachment tube or each attachment tube (5; 5', 5''; 15; 15'; 15.1, 15.2) is securely fixed, in particular welded or adhesively bonded, to the catheter shaft (12'; 12/13) substantially only at the proximal balloon neck (14b) and at the distal balloon neck (14a).
- 30 6. The balloon catheter according to claim 5, wherein the attachment tube or each attachment tube (5; 5', 5''; 15; 15'; 15.1, 15.2) is welded or glued at specific points

to the balloon portion (3c; 14, 14') between the proximal and distal balloon neck (14b, 14a).

- 5 7. The balloon catheter according to any one of the preceding claims, wherein the catheter shaft comprises an inner shaft (3b; 12) and an outer shaft (3a; 13), and the open proximal end (5a) of the attachment tube or each attachment tube (5; 15) is fluidically connected to the lumen of the outer catheter (3a; 13).
- 10 8. The balloon catheter according to any one of claims 1 to 6, wherein the catheter shaft (12'; 12/13) comprises a first lumen (12a) for a guide wire (11) and a second lumen (12b'; 13a) for introducing a fluid for expanding the balloon portion, and the open proximal end of the attachment tube or each attachment tube is fluidically connected to the second lumen (12b; 13a).
- 15 9. The balloon catheter according to any one of claims 1 to 6, wherein the open proximal end (5a') of the attachment tube or each attachment tube (5'; 15.1, 15.2) opens out into a dedicated proximal fluid connection of the balloon catheter (1'; 10'').
- 20 10. The balloon catheter according to claim 9, wherein the open proximal end of the attachment tube or each attachment tube is connected to the dedicated fluid connection via an additional lumen in the catheter shaft.
- 25 11. The balloon catheter according to claim 9, wherein the open proximal end of the attachment tube or each attachment tube (15.1, 15.2) is connected to the dedicated fluid connection via a working fluid tube laid externally on the catheter shaft (12/13).
12. The balloon catheter according to any one of the preceding claims, with a working means protective sleeve (16) displaceable along the catheter shaft (12/13).
- 30 13. The balloon catheter according to any one of the preceding claims, wherein the attachment tube or each attachment tube (5; 5', 5''; 15, 15'; 15.1, 15.2) comprises a

material from the group of polyamides, polyimides, polyesters, polyethers, polyolefins and copolymers thereof.

14. The balloon catheter according to any one of the preceding claims, wherein the
5 diameter of the attachment tube or each attachment tube (5; 5', 5''; 15, 15'; 15.1, 15.2) lies in the range between 2% and 8%, preferably between 2% and 4%, of the diameter of the balloon.
15. The balloon catheter (1'') according to any one of the preceding claims, wherein the
10 attachment tube or at least part of the attachment tubes (5'') has a cutting or sawing edge for abrasive working on vascular deposits.

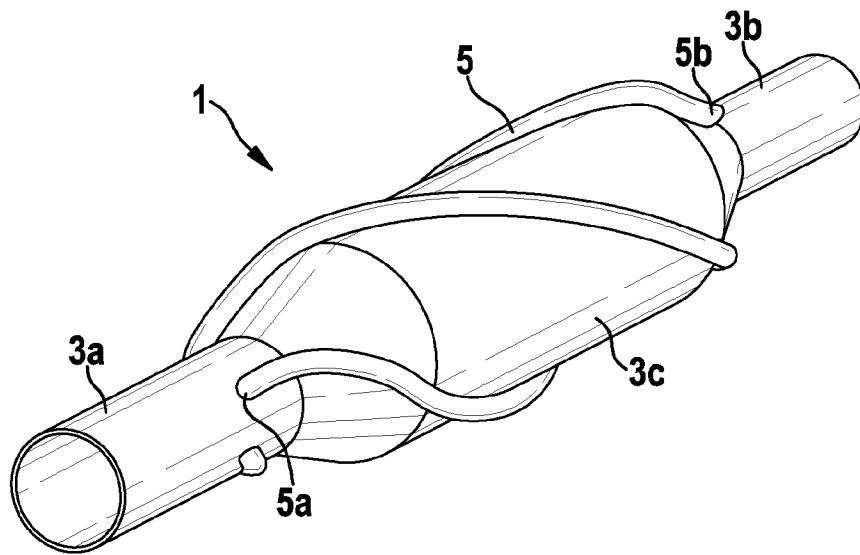


FIG. 1

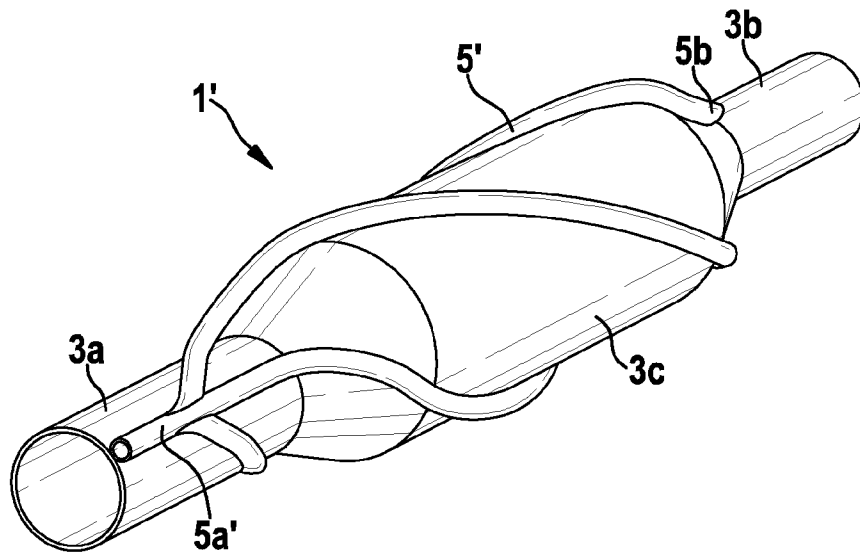


FIG. 2

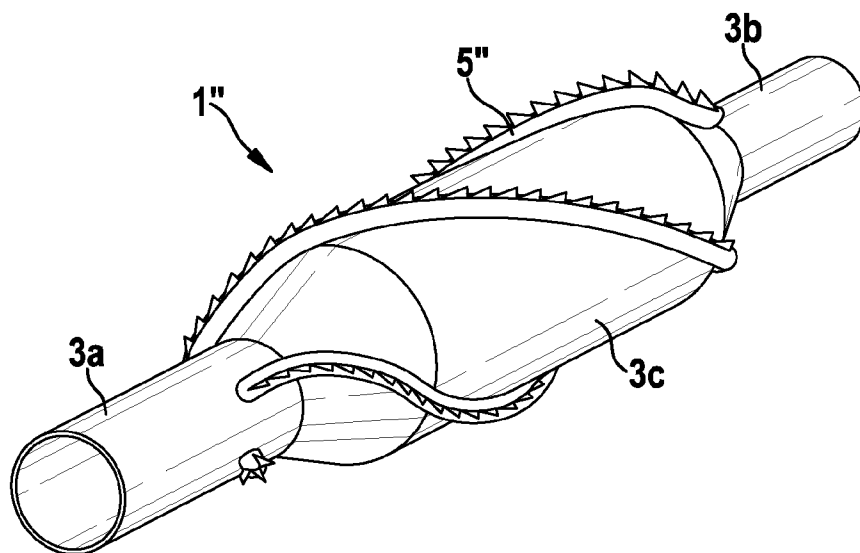


FIG. 3

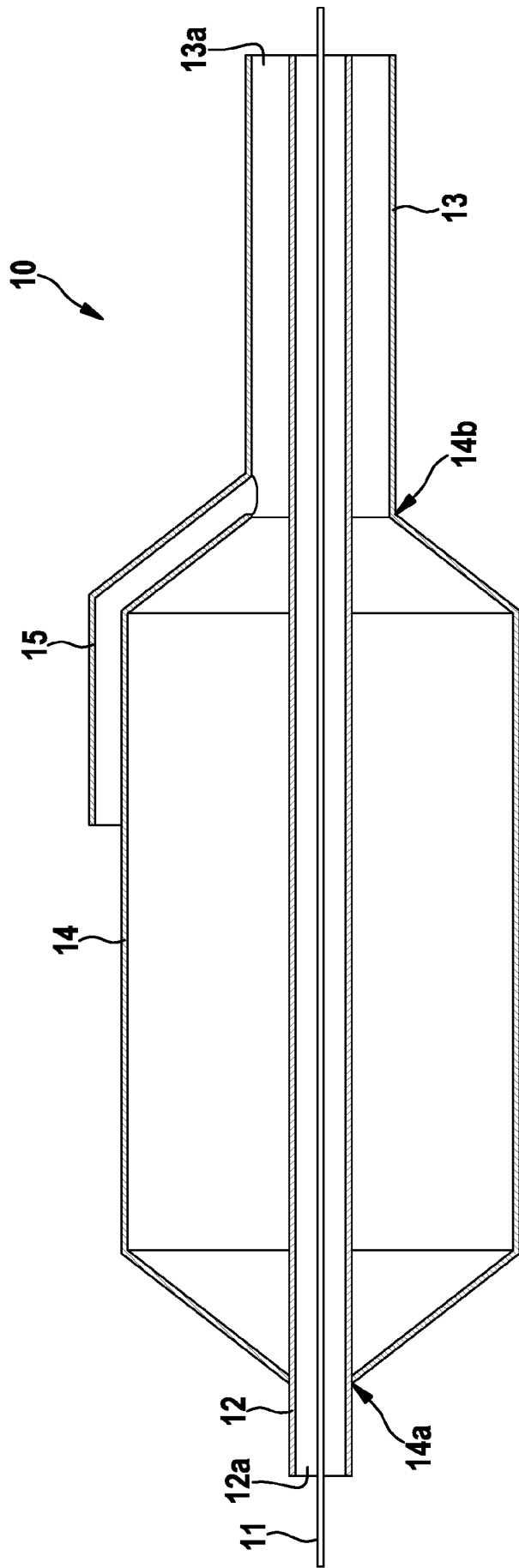


FIG. 4

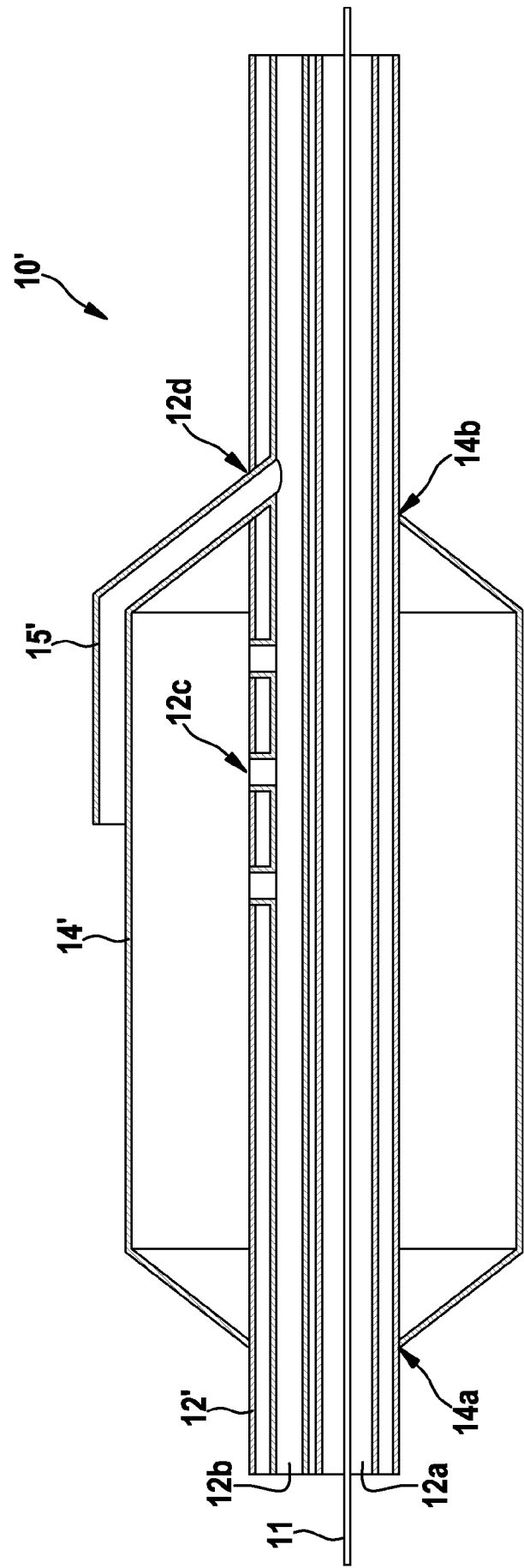


FIG. 5

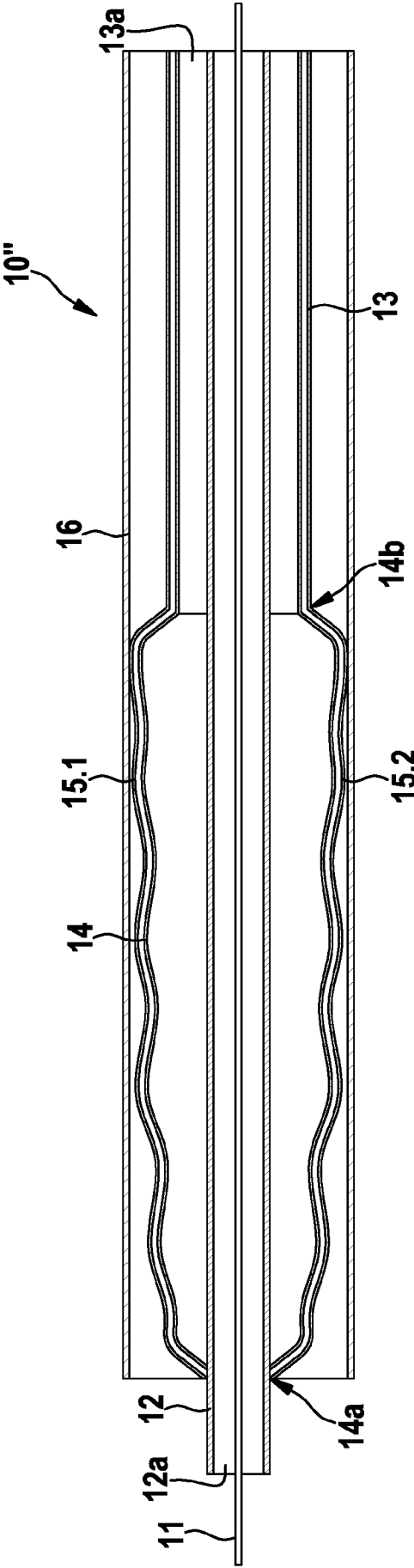


FIG. 6

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/075042

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B17/3207 A61B17/22 A61M25/10
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 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.
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X	US 2002/045852 A1 (SAAB MARK A [US]) 18 April 2002 (2002-04-18) paragraph [0058] - paragraph [0059]; figure 6 -----	1,3,9-11
A	US 2013/060127 A1 (BURTON DAVID G [US] ET AL) 7 March 2013 (2013-03-07) paragraph [0032] - paragraph [0039]; figures 2a,b, 3 ----- -/--	1



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

22 November 2018

Date of mailing of the international search report

30/11/2018

Name and mailing address of the ISA/

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Moers, Roelof

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/075042

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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