(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 April 2015 (02.04.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/047094 A1

(51) International Patent Classification:
*A61F 2/07* (2013.01) *A61F 2/966* (2013.01)
*A61F 2/954* (2013.01)

(21) International Application Number:
PCT/NL2014/050663

(22) International Filing Date:
26 September 2014 (26.09.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/882,709 26 September 2013 (26.09.2013) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

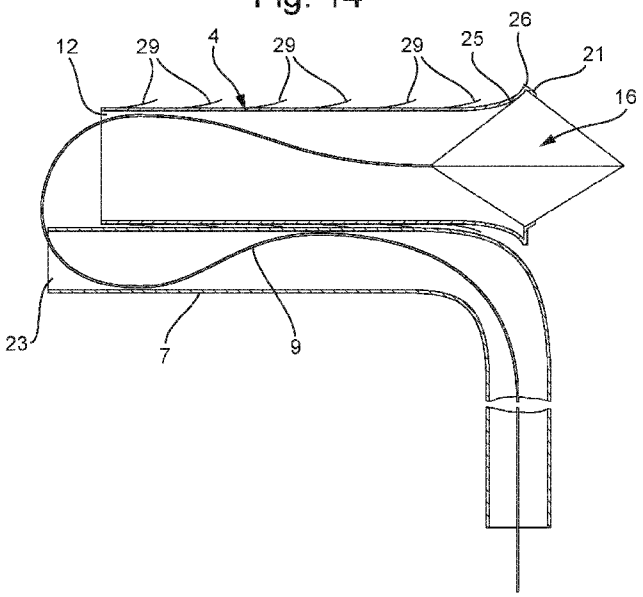
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

**Published**:

— *with international search report (Art. 21(3))*

(54) Title: METHOD AND STENT GRAFT FOR USE IN TREATMENT OF A THORACOABDOMINAL ANEURYSM

Fig. 14




(57) Abstract: A stent graft (4) for positioning in a side branch of a human aorta. The stent graft is expandable from a delivery configuration to an expanded configuration in which the stent has an end (25) that is flared and/or provided with a flange (26), for seating in a hole in a wall of a stent graft positioned in the human aorta. A method for treatment of a thoracoabdominal aneurysm is also described. A side branch stent graft is positioned in a side branch of a human aorta, then a main stent graft is positioned in the human aorta in a position bridging the side branch, then a hole is made in a wall of the main stent graft, and the side branch stent graft is connected to the hole with an end seated in the hole, such that it forms a side branch duct branching off from the main stent graft.

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TITLE: Method and stent graft for use in treatment of a thoracoabdominal aneurysm

## FIELD AND BACKGROUND OF THE INVENTION

The invention relates to a method and stent graft for use in treatment of a thoracoabdominal aneurysm.

Most thoracoabdominal aortic aneurysms are treated with a minimally invasive intervention called endovascular stent-graft repair, instead of by conventional surgery. This treatment includes using a catheter to insert and guide a stent graft (a tubular device comprising a fabric and/or film supported by a support structure - usually a metal mesh) into the aorta to the site of the aneurysm. The procedure begins by making a small incision in the groin and inserting the stent-graft into the femoral artery (which descends directly from the aorta). Using fluoroscopy and transesophageal echocardiography (TEE), the stent-graft is guided through the aorta to the aneurysm. With the stent-graft in place, blood flows through the stent-graft instead of through the aneurysm, eliminating the risk of rupture. The theory behind the procedure is that once in place inside the aorta, the stent graft acts as a false lumen through which blood can travel, instead of flowing into the aneurysm sack. The stent graft shields the aneurysm from the circulation and thereby prevents the aneurism from rupturing.

Because in the thoracoabdominal region arteries (the Celiac, Superior Mesenteric, Renal and Inferior Mesenteric Arteries) branch off from the aorta, provisions are necessary to allow blood flow through the wall of the aortic stent graft into these side arteries. For this purpose, stent grafts with side braches, fenestrations and scallops have been used. A problem of using such stents is that locations and dimensions of the side arteries vary, so that there are many critical measurements on which the dimensions of the stent graft have to match the dimensions of the section of the aorta be treated. In practice matching such a wide variety of dimensions can only be achieved by using

tailor made stent grafts. To manufacture such a tailor made stent graft, the exact geometry of the stent graft is determined from a 3D CT scan of the section of the aorta to be treated. This involves high costs and a long manufacturing time, usually more than six weeks.

Even though the stent graft is tailor made, its implantation is often cumbersome. Problems encountered before proper positioning of the stent graft is achieved often result in a significant time of ischemia of target organs like the kidneys and intestines.

## SUMMARY OF THE INVENTION

It is an object of the present invention to provide a solution that avoids the need of tailor made manufacturing a stent graft for each individual patient to dimensions measured from the section of the aorta to be treated of that individual patient and that reduces the risk of delays during implantation entailing significant ischemia of target organs like the kidneys and intestines.

According to the invention, this object is achieved by providing a stent graft according to claim 1. The invention can also be embodied in method according to claim 6.

Because a side branch stent graft is positioned in the or each side branch that is covered after the main stent graft of a straight tube design without side ports is positioned in the section of the aorta to be treated (bridging the aneurism from a healthy section upstream of the aneurism to a healthy section downstream of the aneurism), subsequently a hole is made in the wall of the main stent graft in line with the or each side branch in which a side branch stent graft has been positioned and an end of the or each side branch stent graft is seated in the corresponding hole in the wall of the main stent graft, flow through the or each side branch is restored very quickly. In particular, during the positioning of a side branch stent graft, blood flow through the side branch is impaired only to a small extent, because this

intervention is performed prior to insertion of the main stent graft. Since the connections of the side branch stent grafts to the main stent grafts are made in-situ at the locations where the respective side branches branch off from the aorta, the need of manufacturing a tailor made stent graft and the need of positioning the main stent graft with great precision is avoided. In particular, relatively wide tolerances can be allowed regarding the axial positioning of the main stent graft and the orientation of the main stent graft about its longitudinal center line is of no relevance.

Particular elaborations and embodiments of the invention are set forth in the dependent claims.

Further features, effects and details of the invention appear from the detailed description and the drawings.

## BRIEF DESCRIPTION OF THE DRAWINGS

Figs. 1-9 are schematic cut-away views of successive stages of placement of an example of a stent graft according to the invention in combination with a stent graft covering an thoracoabdominal aneurysm;

Fig. 10 is a more detailed schematic cut-away view of an example of a stent graft assembly according to the invention prior to insertion to a positions as shown in Fig. 2;

Fig. 11 is a schematic rear end view of the stent graft assembly according to Fig. 10 in a condition generally corresponding to the stage shown in Figs. 3 and 4;

Fig. 12 is a side view in cross section along a plane XII-XII in Figs. 11 and 13;

Fig. 13 is a schematic front end view of the stent graft as shown in Figs. 11 and 12;

Fig. 14 is a side view in cross section along a midplane of the stent graft assembly according to Figs. 10-13 in an expanded condition generally corresponding to the stage shown in Fig. 7;

Fig. 15 is a front end view of the stent graft as shown in Fig. 14; and

Fig. 16 is a side view in cross section along a midplane of the stent graft assembly according to Figs. 10-15 in an expanded condition generally corresponding to the stage shown in Fig. 8.

## DETAILED DESCRIPTION

In the schematic drawings to which the present detailed description refers, the structure of the human body and embodiments of the disclosed devices are not shown to scale and relative positions of some parts may differ from practice to allow all relevant parts, in particular wires, to be depicted in a clearly distinguishable manner.

In Figs. 1-9 a thoracoabdominal section of an aorta 1 with an aneurism 2 is shown. The aneurism 2 is located generally opposite of a side branch 3 of the aorta 1, which side branch 3 may for instance be a Celiac Artery, a Superior Mesenteric Artery, a Renal Artery or an Inferior Mesenteric Artery. In this portion of a human body, successive stages of an embodiment of a method according to the invention including delivery of an example of a side branch stent graft 4 according to the invention and in-situ assembly to a stent graft assembly according to the invention are shown. Figs. 10-16 constitute more detailed representations of the example of the side branch stent graft 4 in various stages shown in Figs. 1-9.

A first stage of the shown embodiment of a method according to the invention is the placement of a base stent 5 in the side branch 3. The purpose of the base stent 5 is to protect the inner surface of the side branch 3 from being damaged by axial displacements of the side branch stent graft 4 within the side branch 3.

Next, a guidewire 6 is navigated via the aorta 1 into the side branch 3 into a position extending through the base stent 5. A sheath 7 containing a side branch stent graft 4 is advanced over the guidewire 6 in the direction of an arrow 8 until a position in the base stent 6 has been reached, for instance as is illustrated in Fig. 2. Next, the guidewire 6 may be retracted out of the body of the patient.

The arrangement of the side branch stent graft 4 in the sheath 7 is shown in more detail in Fig. 10. To the side branch stent graft 4, a retraction string 9, an advancing string 10 and a deployment string 11 are connected. The strings may for instance be provided in the form of metal and/or plastic wire and/or one or more of the strings 9-11 may be in the form of a thread each composed of a plurality filaments. The strings 9-11 may also be of a composite construction of wire and thread and/or be provided with an outer layer, for instance for lowering friction and or improving biocompatibility.

The retraction string 9 is connected to an expandable piercing member 16 with a sharp point at its distal end projecting from a front end of the side branch stent graft 4 and extends through the side branch stent graft 4 in it delivery configuration such that after expanding, the string 9 extends through the lumen of the side branch stent graft 4 and out of the rear end 12 of the stent graft (cf. Figs. 15 and 16).

The advancing string 10 is anchored to the rear end 12 of the side branch stent graft 4 and extends between lobes of the side branch stent graft 4 such that after expanding of the side branch stent graft 4 the advancing string 10 is on the outside of the side branch stent graft 4 (cf. Figs. 6, 11 and 13) and the advancing string 10 disengages from the side branch stent graft 4. Approximately half way between the front and rear end of the side branch stent graft 4 (preferably in the middle half of the side branch stent graft 4) the advancing wire projects from the side branch stent graft 4 in its delivery configuration.

In the present example, the side branch stent graft 4 is of a self expanding type. Self expanding stents grafts are known as such. The deployment string 11 projects from the side branch stent graft 4 at its front end and extends through the side branch stent graft 4 in its delivery configuration along a trajectory for keeping the side branch stent graft 4 in its delivery configuration. Such deployment strings are known as such in the field of self expanding stent grafts.

Next, the sheath 7 is retracted in the antegrade direction 13 indicated in Fig. 3, while leaving the side branch stent graft 4 and the strings 9-11 attached thereto in the side branch 3 within the lumen of the base stent 5 so that a configuration as shown in more detail in Figs. 11-13 is reached.

Then, a main stent graft 14 is delivered into the aorta 1 in a retrograde direction 15 and deployed in a position extending from a healthy section of the aorta 1 above the aneurism 2 to a healthy section of the aorta 1 below the aneurism 2 as shown in Fig. 4. In the present example, this entails blocking the entry of the side branch 3 from the aorta 1, so that blood circulation towards the organs connected to the side branch 3 is blocked. To avoid ischemia, blood flow through the side branch 3 should be restored as quickly as possible.

In the present example, this is achieved at least to a significant extent by advancing the side branch stent graft 4 towards the main stent graft 14 such that the sharp point of the piercing member 16 pierces a hole in the wall of the main stent graft 14, so that blood flow through the side branch is at least partially restored very quickly. Advancing of the side branch stent graft 4 for piercing the wall of the main stent graft 14 is achieved by pulling the advancing string 10 in the direction 17 is attached to the side branch stent graft 4 in a position spaced from its front end where the piercing member 16 is located, the advancing string 10 can deflect from a front portion of the side branch stent graft 4 as it is pulled, thereby exerting a force on the side branch stent graft 4 urging it generally in axial direction thereof while the advancing

string is pulled along and guided by the base stent 5. In the present example the advancing string 10 projects from the side branch stent graft 4 approximately in the middle thereof. This allows the side branch stent graft 4 to be pulled forward until approximately in the middle of the side branch stent graft 4 reaches an end of the base stent 5.

Next, the side branch stent graft 4 is deployed by pulling the deployment string 11 as indicated by arrow 18 in Fig. 6. This causes the hole in the wall of the main stent graft 14 to be enlarged, so that blood flow into the side branch 3 is further restored very quickly after the main stent graft 14 has been deployed. The deployment string 11 is then pulled completely out of the patient as indicated by arrow 19. Deployment of the side branch stent graft 4 also causes the advancing string 10 to become disengaged from the side branch stent graft 4. This advancing string 10 is then also pulled out of the patient, which leaves only the retraction string engaged to the piercing member 16 extending through the sheath 7. Thus, a configuration as shown in more detail in Figs. 14 and 15 is achieved.

As the side branch stent graft 4 is deployed, also wings 20 of the piercing member unfold and remain engaged with the front end of the side branch stent graft 4 by means of hooks 21. Then the sheath 7 is again advanced along the retraction string 9 (arrow 22) until its distal end 23 is located distally of the side branch stent graft 4. Then the retraction string 9, which has thus been brought in a position looped through the distal end 23 of the sheath 7, is pulled (arrow 24), which causes the side branch stent graft 4, that is engaged by the hooks 26 of the piercing member 16, to be retracted into the side branch 3, so that a flared end portion 25 of the side branch stent graft 4 (having a diameter gradually increasing towards the front end of the side branch stent graft 4) with a flange 26 is seated in the hole in the wall of the main stent graft 14. Also, the flared distal end portion 25 and the flange 26 pull the main stent graft 14 against the orifice of the side branch 3. Thus, the front end of the side branch stent graft 4 is seated in the hole in the wall of the

main stent graft 14 sufficiently tightly to avoid clinically significant leakage of blood through the seating.

Finally, as shown in Fig. 8, the sheath 7 is advanced further along the retraction string 9 (arrow 27) into the lumen of the side branch stent graft 4 and over the piercing member 16. The piercing member wings 20 have tapering proximal so that the wings 20 fold back to generally the deployment configuration, disengage from the front end of the side branch stent graft 4 and can be retracted through or together with the sheath 7 as is shown in more detail in Fig. 16.

Then, the sheath 7 extending along the outside of the main stent graft 14, between the outside of the side branch stent graft 4 and the base stent 5 and into the lumen of the side branch stent graft 4 can be pulled out of the patient (arrow 28) with the retraction string 9 with the piercing member 16 held therein, so that only a stent graft assembly composed of the base stent 5, the side branch stent graft 4 and the main stent graft 14 is left in the patient, providing protection against rupture of the aneurism 2 (Fig. 9).

As is best seen in Figs 14 and 16, the side branch stent graft 4 has barbs 29 pointing obliquely away from the outer circumference of the side branch stent graft 4. When the side branch stent graft 4 is retracted into the side branch 3, the barbs 29 engage the inner wall of the side branch and/or the base stent 5, so that the side branch stent graft 4 is reliably retained in its retracted position.

Within the framework of the invention, many other embodiments are conceivable. For instance advancing and retracting the side branch stent graft may be achieved using a Bowden cable type arrangement extending into the lumen of the base stent.

As an alternative for making the hole in the main stent graft another device such as a catheter tool inserted into the lumen of the main stent graft may be used.

The side branch stent graft may be delivered and optionally expanded using a catheter inserted into the lumen of the main stent graft, without prior placement of a base stent in the side branch.

Also in such situations, in-situ formation of a hole in the wall properly positioned in line with the location of a side branch is achieved and seating of the flared end portion and/or flange of the side branch stent graft is achieved in-situ.

Claims

1. A stent graft for positioning in a side branch of a human aorta closely adjacent to the aorta, the stent graft comprising a tubular barrier for conducting blood flow through the stent graft, said stent graft being expandable from a delivery configuration to an expanded configuration having larger outer and inner cross-sections than in the delivery configuration, wherein in the expanded configuration, the stent has an end that is flared and/or provided with a flange, for seating in a hole in a wall of another stent graft positioned in the human aorta.

2. A stent graft according to claim 1, wherein one single end is flared and/or provided with a flange.

3. A stent according to claim 1, further comprising a piercing member for piercing the hole in the wall of the other stent graft positioned in the human aorta.

4. A stent graft system comprising a stent graft according to claim 1, further comprising an advancing string and a retraction string attached thereto, the advancing string being attached to be automatically released upon expanding of the stent graft and the retraction string being detachable from the stent graft after expanding the stent graft.

5. A stent graft system according to claim 4, further comprising a sheath through which the advancing string and the retraction string extend, the sheath being insertable into a lumen of the stent graft in expanded condition for disengaging the retraction string from the stent graft.

6. A method for treatment of a thoracoabdominal aneurysm, comprising:

positioning a side branch stent graft in a side branch of a human aorta closely adjacent to the aorta, the stent graft comprising a tubular barrier for conducting blood flow through the stent graft,

subsequently positioning a main stent graft in the human aorta in a position bridging the side branch,

subsequently making a hole in a wall of the main stent graft in a position in line with the side branch, and

subsequently connecting the side branch stent graft to the hole with an end of the side branch stent graft seated in a hole in the wall of the main stent graft, such that the side branch stent graft forms a side branch duct communicating with and branching off from a main duct formed by the main stent graft.

7. A method according to claim 6, wherein the side branch stent graft is expanded from a delivery configuration prior after introduction of an end of the side branch stent graft into the hole in the wall of the main stent graft.

Fig. 1

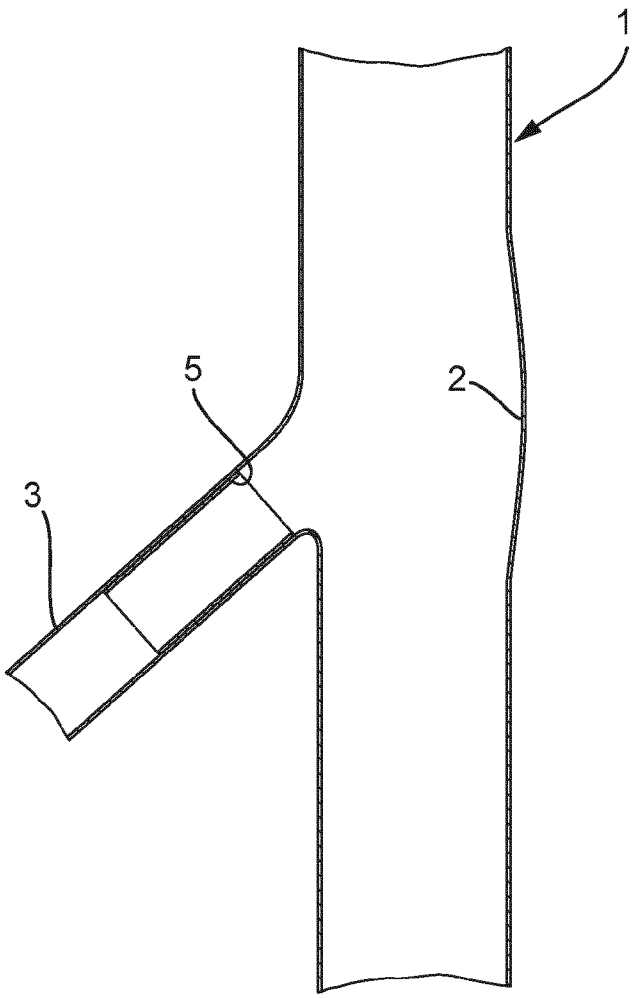



Fig. 2

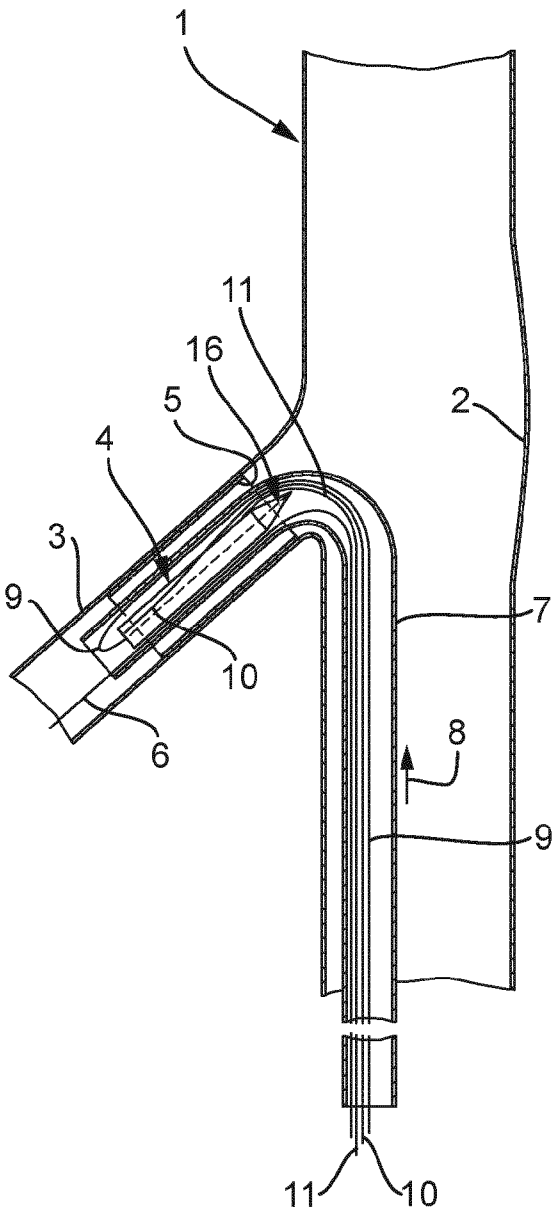


Fig. 3

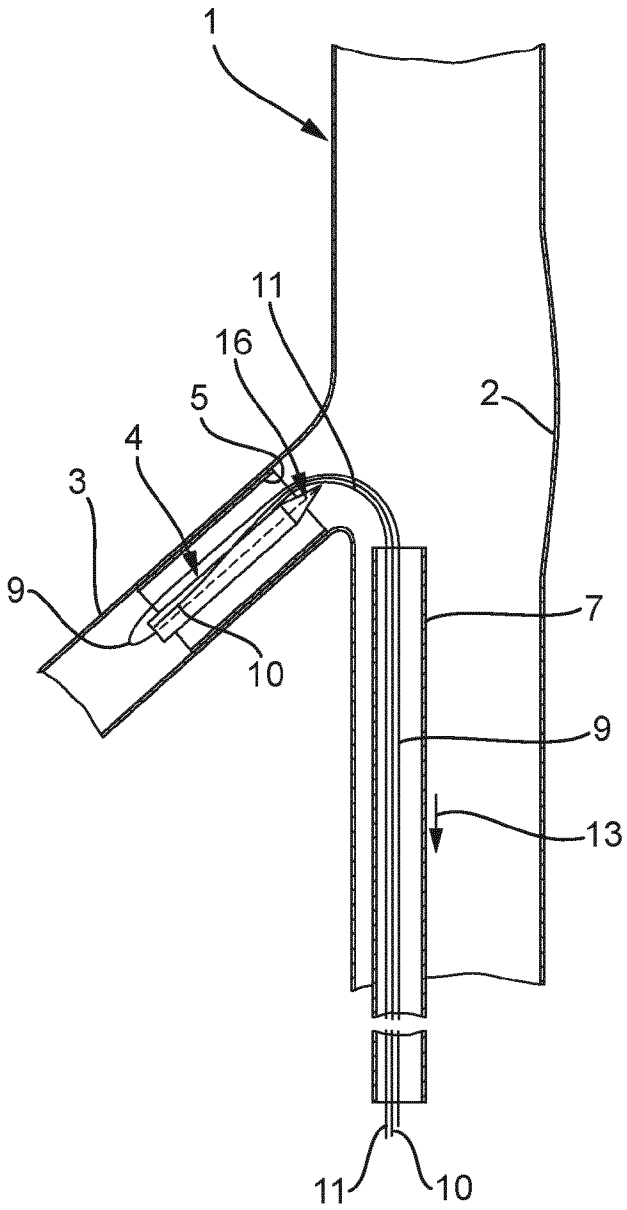


Fig. 4

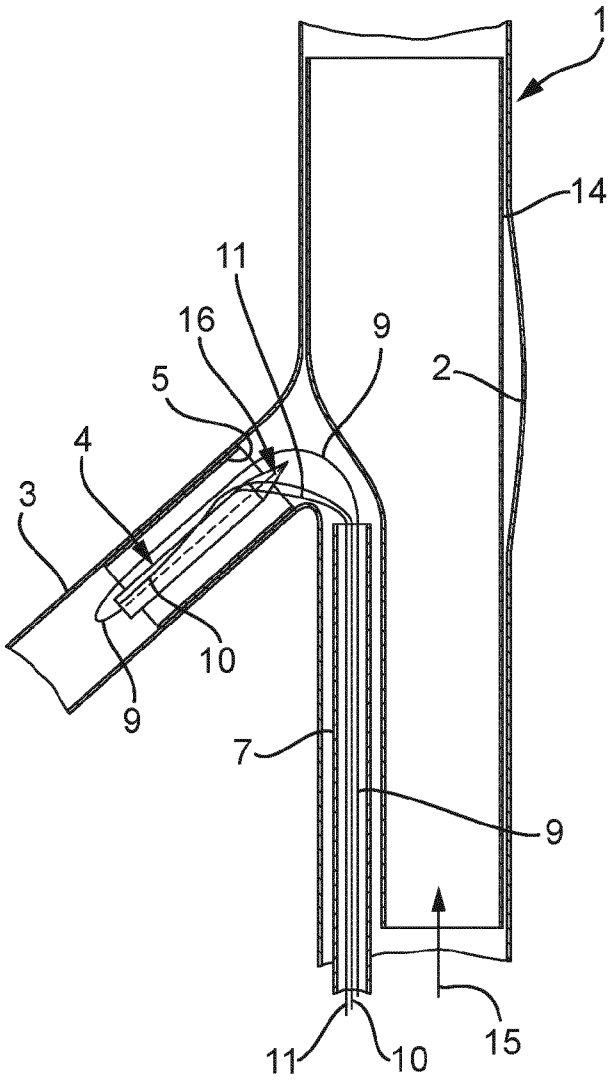



Fig. 5

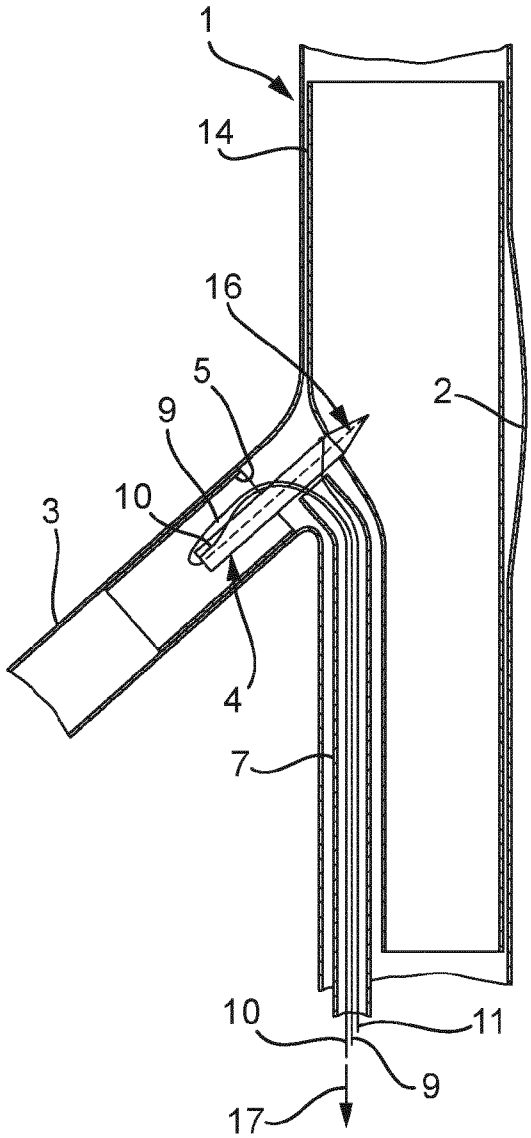


Fig. 6

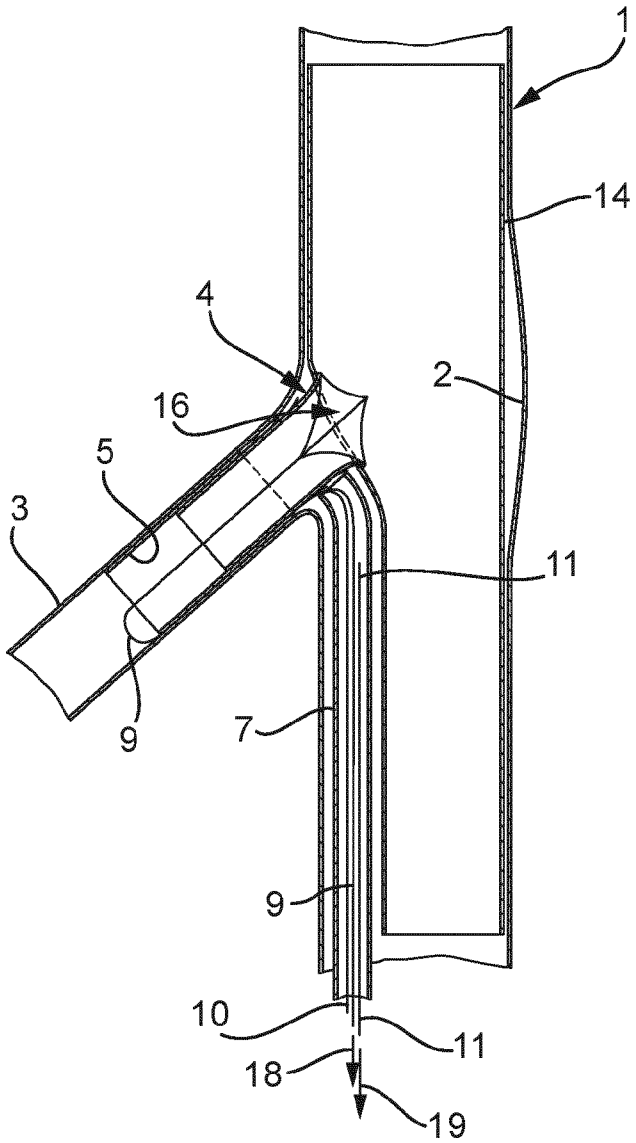


Fig. 7

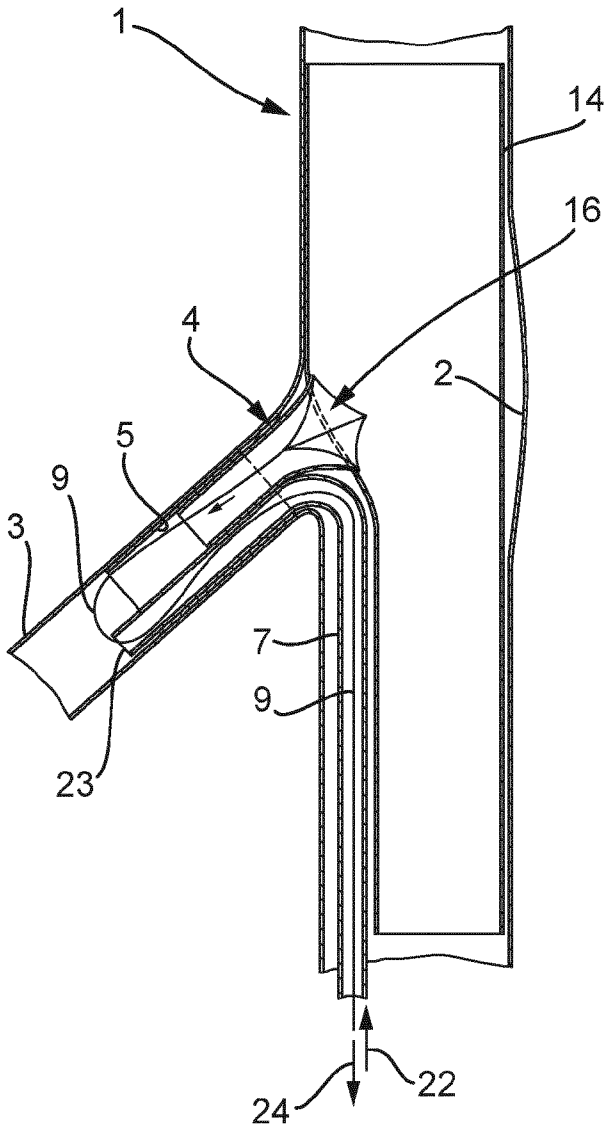



Fig. 8

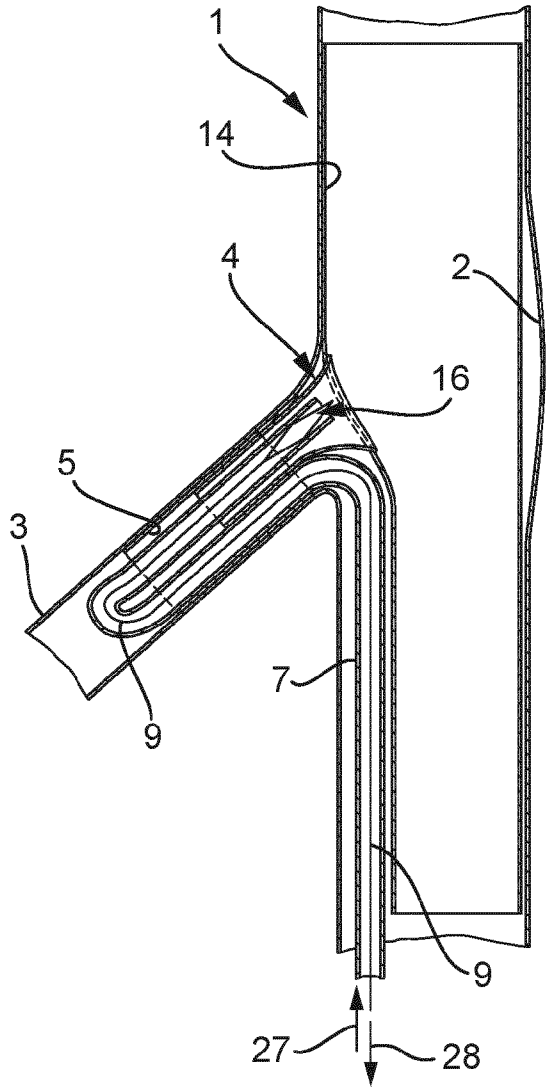


Fig. 9

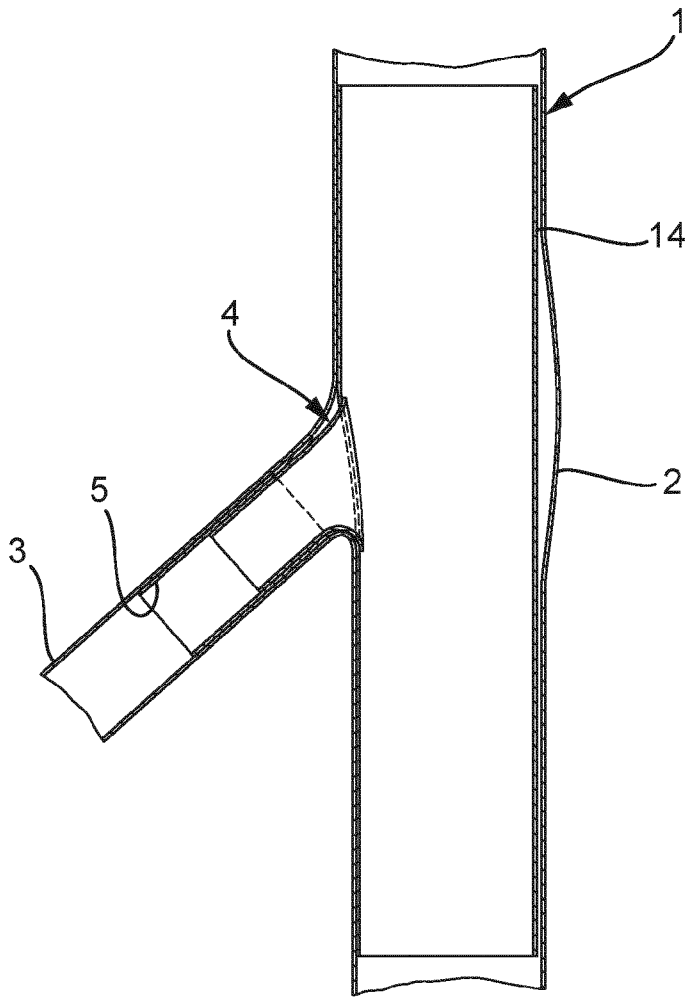


Fig. 10

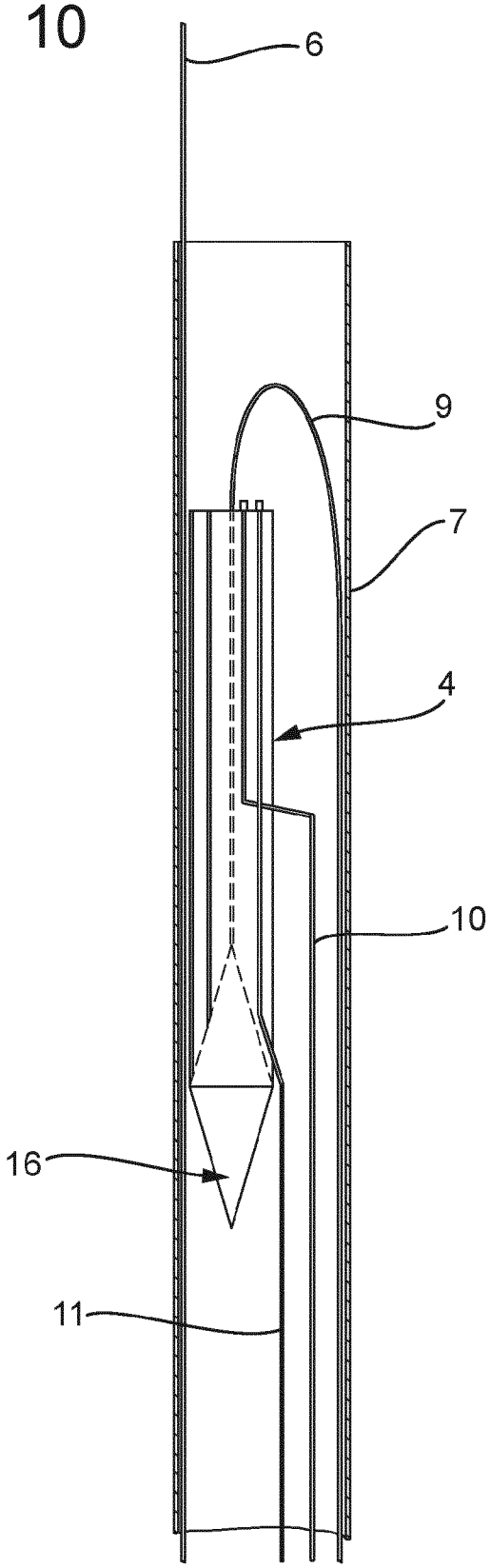


Fig. 11

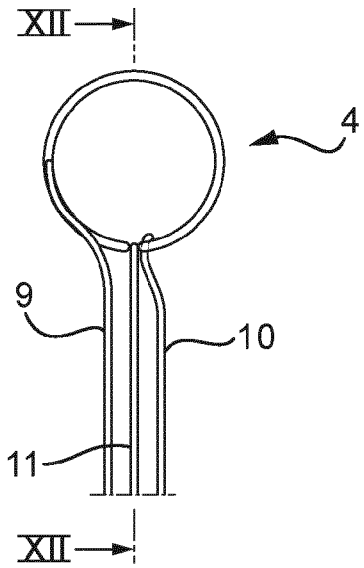



Fig. 13

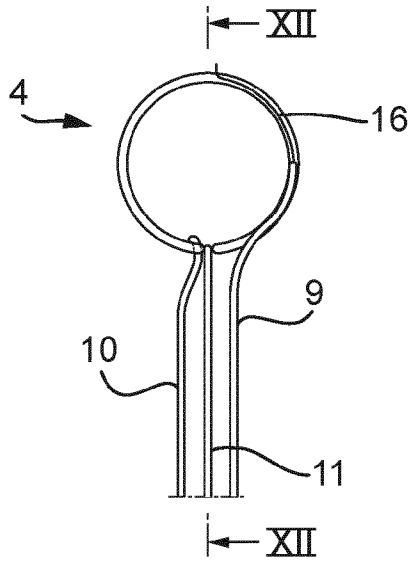



Fig. 12

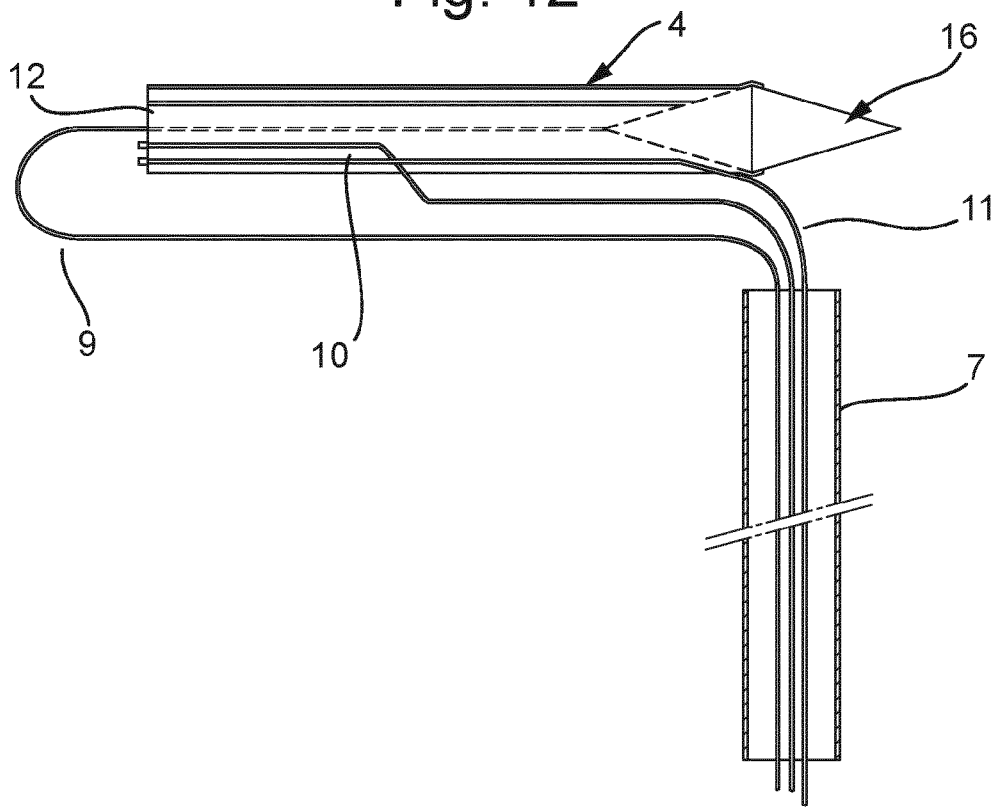


Fig. 14

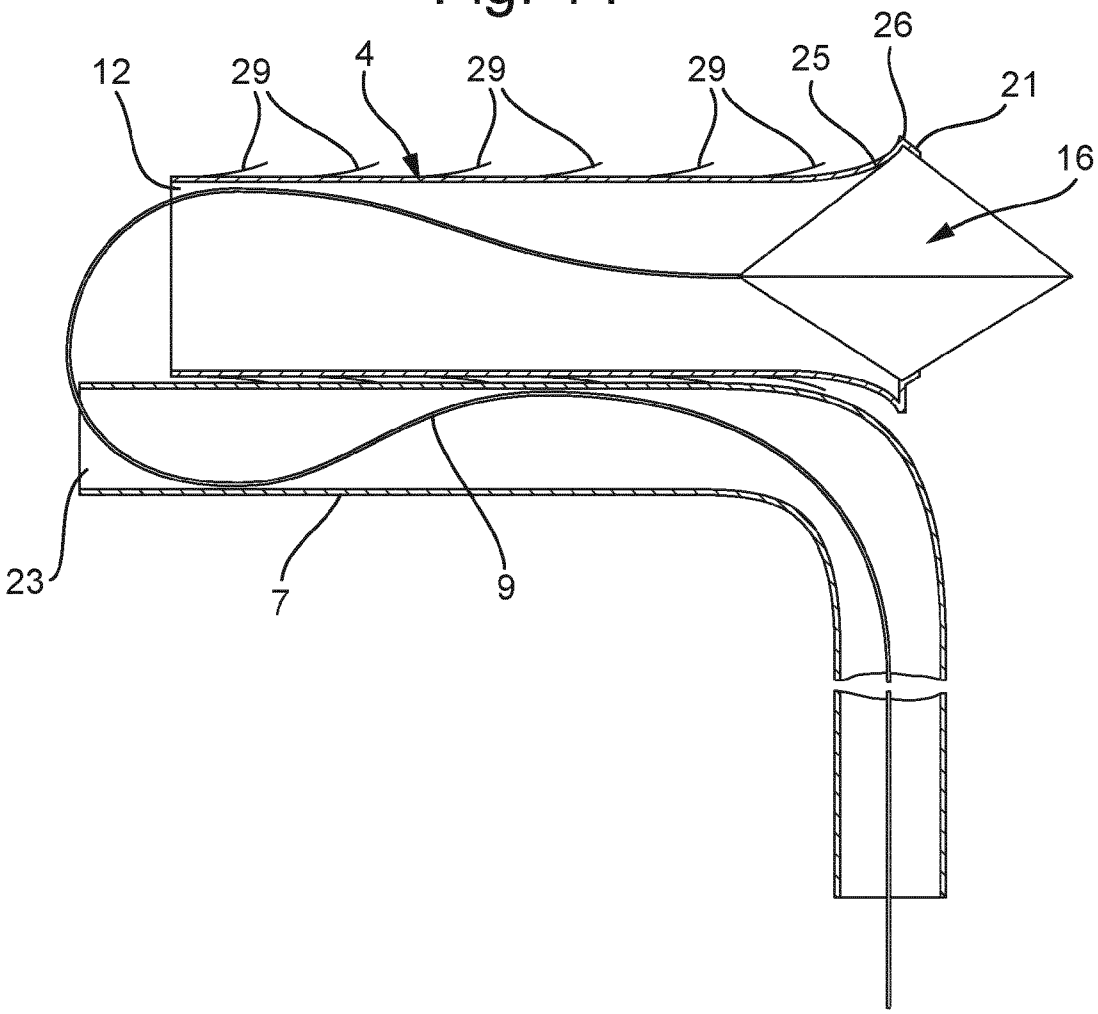



Fig. 15

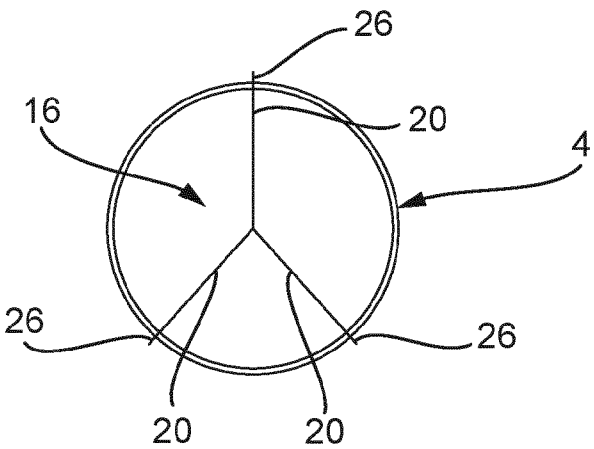
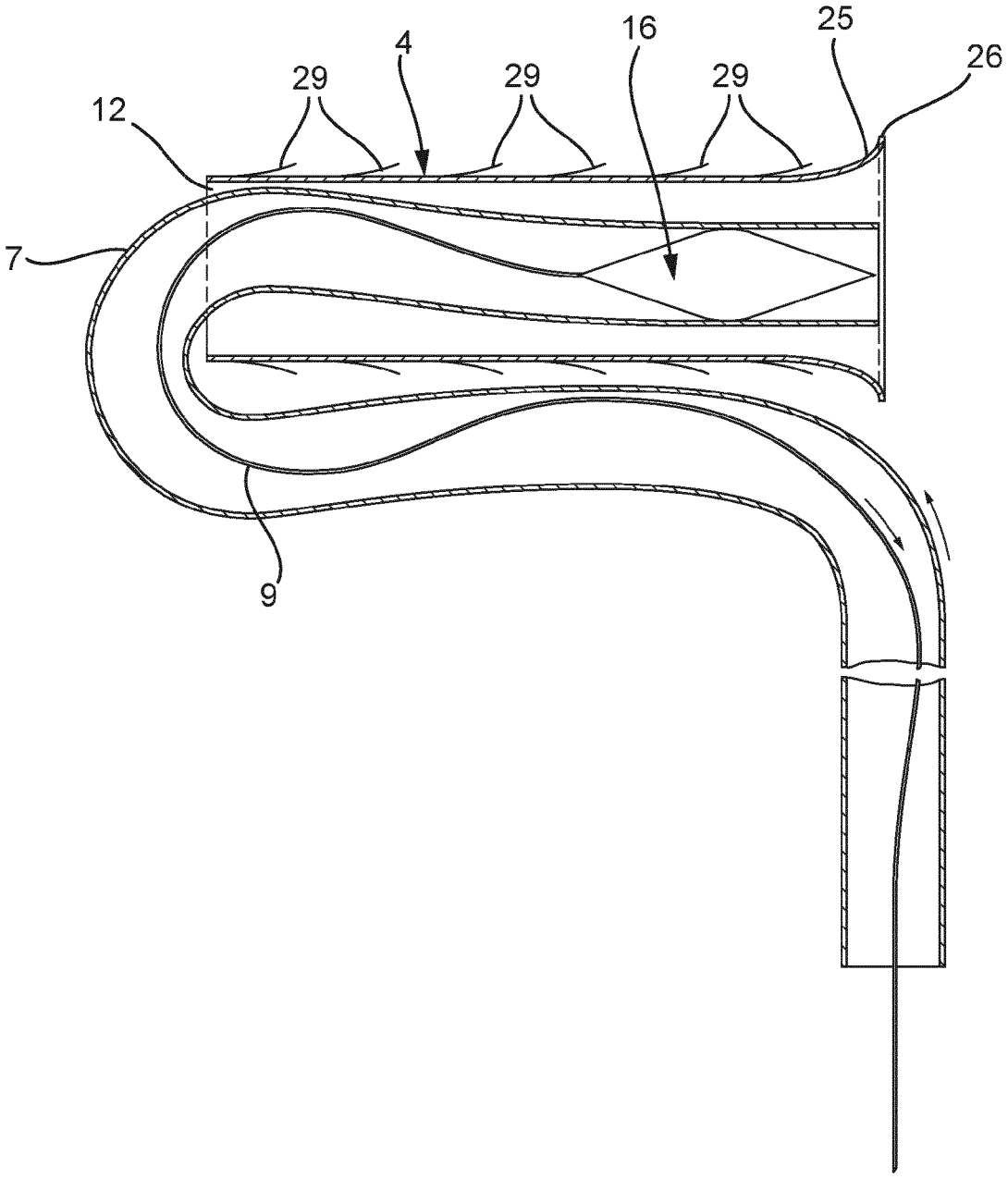


Fig. 16



# INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2014/050663

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/07 A61F2/954 A61F2/966
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)
A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | DE 102 13 055 A1 (PEROUSE BORNEL LAB [FR])<br>26 September 2002 (2002-09-26) | 1-3 |
| Y | paragraphs [0021] - [0028]; figure 1<br>paragraphs [0063] - [0065] | 4,5 |
| | --- | |
| X | WO 2013/026585 A1 (CT HOSPITALIER UNIVERSITAIRE NIMES [FR]; BRANCHERAU PASCAL [FR]; ALRIC)<br>28 February 2013 (2013-02-28)<br>page 6, line 24 - page 9, line 15; figure 1<br>page 15, line 8 - page 18, line 16 | 1-3 |
| | --- | |
| Y | WO 2006/047520 A2 (ALVEOLUS INC [US]; SATASIYA PANKAJ [US]; ALEXANDER TONY [US])<br>4 May 2006 (2006-05-04)<br>page 7, line 29 - page 10, line 21; figures 7-9 | 4,5 |
| | --- | |

☐ 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 | Date of mailing of the international search report |
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| 10 December 2014 | 18/12/2014 |

| Name and mailing address of the ISA/ | Authorized officer |
|---|---|
| European Patent Office, P.B. 5818 Patentlaan 2<br>NL - 2280 HV Rijswijk<br>Tel. (+31-70) 340-2040,<br>Fax: (+31-70) 340-3016 | Skorovs, Peteris |

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# INTERNATIONAL SEARCH REPORT

International application No.
PCT/NL2014/050663

**Box 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:

1. [X] Claims Nos.: 6, 7
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)**

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/NL2014/050663

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