Innovation, Sciences et Développement économique Canada
Office de la Propriété Intellectuelle du Canada

Innovation, Science and Economic Development Canada
Canadian Intellectual Property Office

CA 2953211 C 2022/08/23

(11)(21) 2 953 211

(12) BREVET CANADIEN
CANADIAN PATENT

(13) C

(86) Date de dépôt PCT/PCT Filing Date: 2015/06/04
(87) Date publication PCT/PCT Publication Date: 2015/12/10
(45) Date de délivrance/Issue Date: 2022/08/23
(85) Entrée phase nationale/National Entry: 2016/12/02
(86) N° demande PCT/PCT Application No.: FR 2015/051488
(87) N° publication PCT/PCT Publication No.: 2015/185870
(30) Priorité/Priority: 2014/06/05 (FR1455144)

(51) Cl.Int./Int.Cl. *A61F 2/95* (2013.01)

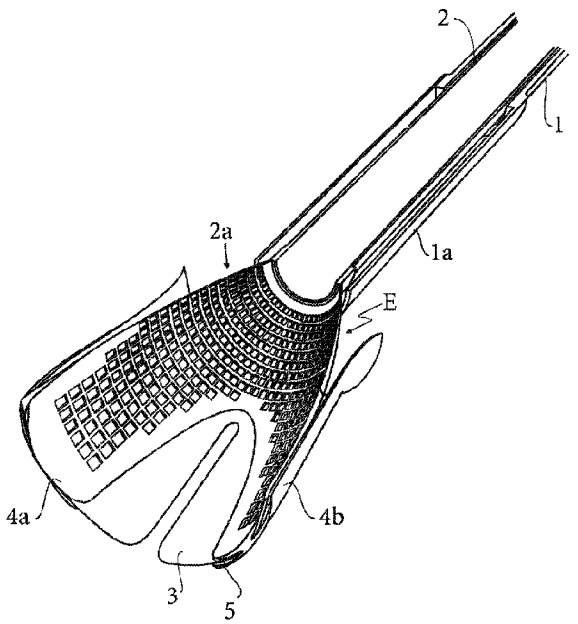
(72) Inventeurs/Inventors:
PAIN, BERNARD, FR;
VOLA, MARCO, FR;
PASQUINO, ENRICO, CH

(73) Propriétaires/Owners:
CENTRE HOSPITALIER UNIVERSITAIRE DE SAINT-ETIENNE, FR;
AORTICLAB S.R.L., IT

(74) Agent: ROBIC

(54) Titre : DISPOSITIF D'INTRODUCTION TRANSCATHETER DANS LA RACINE AORTIQUE AU NIVEAU DE LA JONCTION SINO TUBULAIRE

(54) Title: DEVICE FOR TRANSCATHETER INSERTION INTO THE AORTIC ROOT AT THE SINOTUBULAR JUNCTION



(57) Abrégé/Abstract:
There is provided a device for transcatheter insertion into an aortic root of an aorta at a sinotubular junction by means of a guide wire and a catheter with means for protecting surrounding tissues, wherein the device comprises an assembly serving as a valvular embolic filter, mounted with the ability to slide in a guided manner inside said catheter, said assembly having arrangements capable of forming, in the aortic root, a safety chamber ensuring a valve function and a protective function against embolic accidents.

Abstract

There is provided a device for transcatheter insertion into an aortic root of an aorta at a sinotubular junction by means of a guide wire and a catheter with means for protecting surrounding tissues, wherein the device comprises an assembly serving as a valvular embolic filter, mounted with the ability to slide in a guided manner inside said catheter, said assembly having arrangements capable of forming, in the aortic root, a safety chamber ensuring a valve function and a protective function against embolic accidents.

Date Reçue/Date Received 2020-07-02

DEVICE FOR TRANSCATHETER INSERTION INTO THE AORTIC ROOT AT THE SINOTUBULAR JUNCTION

The invention relates to the technical field of interventional cardiology and of endovascular and minimally invasive surgery and more particularly to an introducer device for intervention by a transcatheter approach.

The invention has an advantageous application, which must not however be considered as limiting, for any type of surgical intervention, for example for replacement of a valve or for valve implantation by a transcatheter approach, more generally known to a person skilled in the art by the acronym TAVI.

Any intervention performed by a transcatheter approach requires the operating surgeon to take very great care since, in a cardiac intervention for example, the blood circulation is not diverted, which is not the case, for example, in open-heart surgery, where there is an extracorporeal circulation of the blood.

The generation of debris from the aortic valve during the TAVI procedure may cause a post-operative coronary embolism, which leads to an infarction after the procedure, while a cerebral embolism may cause iatrogenic stroke.

It is also known that the implantation of an aortic valve by TAVI through a highly calcified native aortic valve often causes paravalvular leaks, which may endanger the patient's life in the medium term. This latter phenomenon is due to the irregularity of the calcifications, which produce imperfect adherence of the TAVI bioprostehsis with the aortic ring of the patient.

Date Reçue/Date Received 2020-07-02

In order to obtain better results with TAVI, it appeared important to place the valve on a surface that is as regular as possible in order to avoid a distortion susceptible of rendering the opening of the prosthesis incomplete and, similarly, to improve the contact between the native aortic ring and the bioprostehsis. This has the aim of minimizing the paravalvular leaks which affect the TAVI and which impact on the medium-term survival of the patients.

Proceeding from this prior art, and in order to obtain, for example, a remodeling of the implantation site ranging from medium transcatheter decalcification to complete removal of the native valve leaflets, and with the objective of allowing various procedures and interventions to be performed in complete safety by a transcatheter approach, it appeared important to be able to temporarily fit a device suitable for replacing the function of the native valve. One of the main problems arising in transcatheter decalcification of the aortic valve, with the heart beating and with no extracorporeal circulation, is that of avoiding migration of the calcium debris into the aortic root and downstream into the aortic arch. There is no doubt that this phenomenon is more evident in a transcatheter decalcification procedure than during a standard TAVI procedure, which is presently performed without the decalcification of the aortic valve.

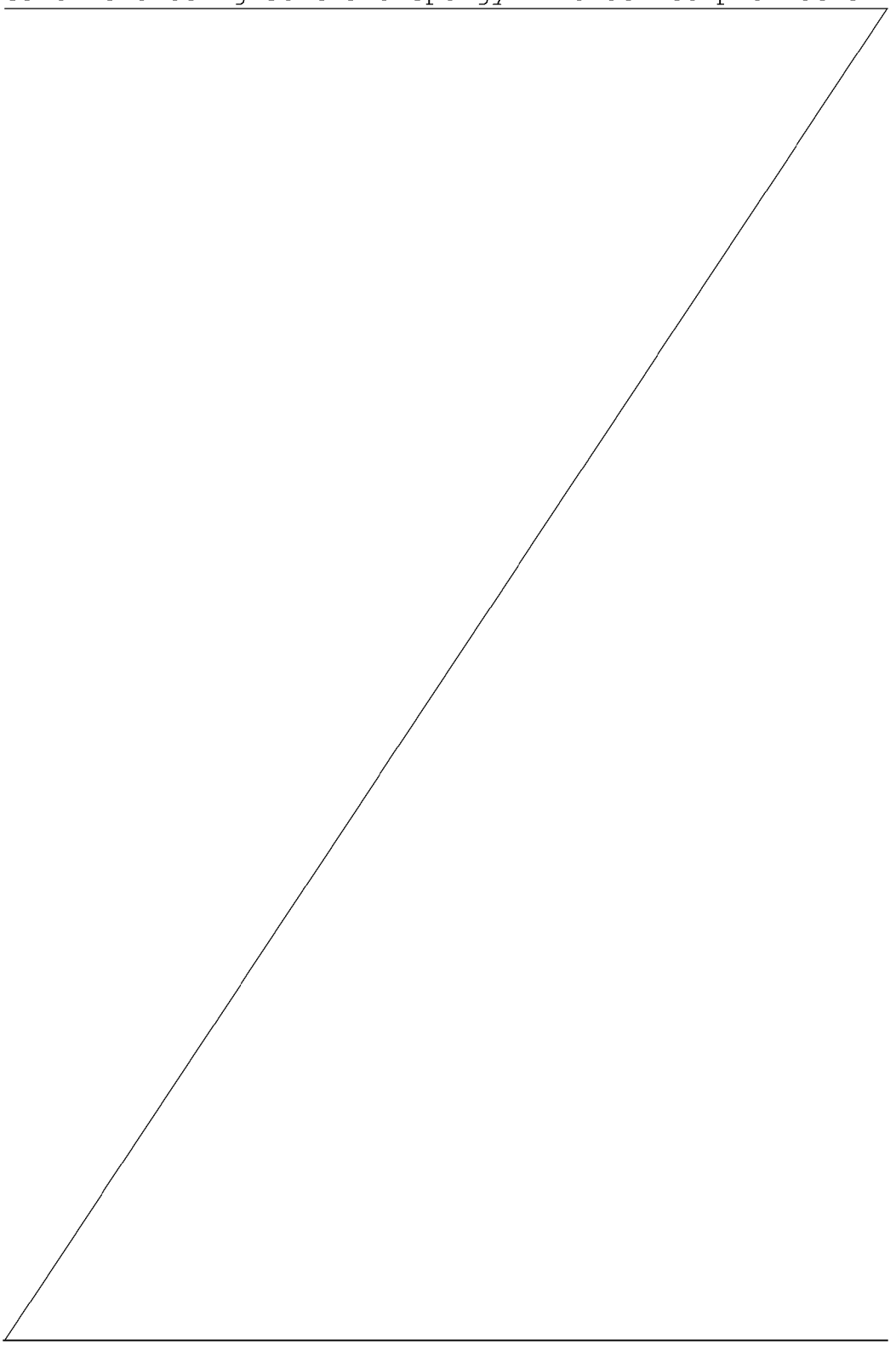
To address this problem, a device has been conceived and developed that is introduced by a transcatheter approach into the aortic root at the sinotubular junction by means of a guide wire and a catheter, with means for protecting the surrounding tissues during placement of said catheter.

Date Reçue/Date Received 2020-07-02

According to a general aspect of the invention, there is provided a device for transcatheter insertion into an aortic root of an aorta at a sinotubular junction by means of a guide wire and a catheter with means for protecting surrounding tissues, wherein the device comprises an assembly serving as a valvular embolic filter, said assembly being slidably mounted in a guided manner inside said catheter, said assembly having arrangements designed for forming, in the aortic root, a safety chamber ensuring a valve function and a protective function against embolic accidents, said arrangements comprising a tubular body with ends, the tubular body being secured at one of said ends to a part which is, as and when required, either deployable outside the catheter or retractable inside the catheter, said part having filtration arrangements combined with means designed for reproducing a temporary valve function corresponding to opening during a systolic phase and to closing during a diastolic phase, in order to prevent any regurgitation of blood in a deployed position of said part for covering a native aortic valve with a seat secured in the aortic root at sinuses of Valsalva without obstructing blood flow, in which device said part has a general conical shape and has angularly offset shells with contours enveloping commissures of the native aortice valve, said shells being mounted in combination with a filtering membrane, the filtering membrane comprising a lower layer composed of a mesh network with a porosity suitable for blocking tissue debris while allowing passage of the blood flow, the filtering membrane further comprising an upper layer made of a soft and extensible polymer material for acting as a temporary valve, by simple deformation; wherein said lower and upper layers are fixed together via a weld at a base of the

Date reçue/date received 2021-10-19

conical shape of the part and on a perimeter thereof, said weld being soft and spongy in order to provide an



Date reçue/date received 2021-10-19

optimal seat for a valve filter on a base of the aortic root and in order to allow an end of said conical shape to be able to be closed progressively, until retraction inside the catheter, over the polymer material, by sliding the catheter in order to clear the debris captured when the catheter is slid downward between the polymer material of the membrane and the polymer filter until reaching said end of said conical shape.

Other possible aspect(s), object(s), embodiment(s), variant(s) and/or advantage(s) of the present invention, all being preferred and/or optional, are briefly summarized hereinbelow.

For example, the device comprises an assembly serving as a valvular embolic filter, mounted with the ability to slide in a guided manner inside said catheter, said assembly having arrangements capable of forming, in the aortic root, a safety chamber performing a valve function and a protective function against embolic accidents.

As a result of these features, the device makes it possible to perform various interventions by a transcatheter approach, for example removing the calcified tissue and vegetation from within and above the flaps of the aortic valve, fitting any given type of valve in place, etc., the intervention being carried out under the conditions of a physiological circulation and not using an extracorporeal circulation.

To solve the problem of creating this safety chamber, the arrangements of the assembly serving as a valvular embolic filter comprise a tubular body secured, at one of its ends, to a part capable, as and when required, of being either deployed outside the catheter or retracted

Date Reçue/Date Received 2020-07-02

advantageously an inflatable balloon filled with a sterile radiopaque solution.

The invention is explained in more detail below with reference to the figures of the attached drawings, in which:

- Figure 1 is a partial and perspective view showing in particular the assembly serving as a valvular embolic filter,

- Figure 2 is a view corresponding to Figure 1 in partial cross section,

- Figures 3 to 20 show the main steps of a transcatheter intervention using the device according to the invention, in an application to an aortic valve, which application must not be regarded as strictly limiting the invention.

The device according to the invention comprises an assembly (E) serving as a valvular embolic filter, mounted with the ability to slide in a guided manner inside a catheter (1). As will be indicated in the description below, the catheter (1) is equipped with the assembly (E) introduced into the aortic root (RA) by means of a guide wire (g), as is the current practice for this type of intervention.

The filtering assembly (E) has arrangements capable of producing, in the aortic root (RA), a safety chamber performing a valve function and a protective function against embolic accidents. This assembly (E) comprises a body (2) mounted so as to slide freely inside the catheter (1). Of course, the catheter (1) and the body (2) are made of a soft material.

Date reçue/date received 2021-10-19

The tubular body (2) is secured, at one of its ends, to a part (2a) which is in the general shape of a cone and is capable of producing the safety chamber as such. This part (2a) is capable, as and when required, of either being deployed outside the catheter (1) or retracted inside the catheter (1). This part (2a) has filtration arrangements combined with means capable of reproducing the temporary valve function corresponding to opening during the systolic phase and to closing 10 during the diastolic phase.

The aim sought is therefore to to prevent any regurgitation of blood in a deployed position of this part (2a) which constitutes the safety chamber, the objective being to cover the native aortic valve with a seat secured in the aortic root and, more precisely, at the junction between the ring and the origin of the sinuses of Valsalva without obstructing the blood flow.

As the figures of the drawings show, in particular Figures 1 and 2, the part (2a) of the embolic filter is in the general shape of a cone and has angularly offset shells (3). For example, these shells are offset by 120° in order to reproduce the position of the commissures of the native valve. The base of the conical part formed by the shells (3) is able, for example, to position itself on the floor of the aortic root, to move under the coronary ostium and, at the same time, go round the three commissures of the native valve. It will be noted that, in the case of a bicuspid aortic valve, the conical general shape may be adapted and have only two shells.

These features permit correct positioning of the valvular embolic filter, which is important.

The shells (3) are mounted in combination with a filtering membrane (4). This filtering membrane (4)

Date reçue/date received 2021-10-19

comprises a layer (4a) designated as lower layer, composed of a mesh network with a porosity suitable for blocking any tissue debris while allowing the passage of the blood flow. Moreover, this filtering membrane (4) has another layer (4b), designated as upper layer, made of a soft and extensible thin polymer material in order to act as a temporary valve, by simple deformation.

The layers (4a), (4b) are fixed together at the base of the conical part formed by the shells (3). Advantageously, this fixing is done by welding (5) on the perimeter of the base of the conical part (2a). The weld is soft and spongy in order to provide an optimal seat for the valvular filter at the base of the aortic root.

The meshed lower layer (4a) is fixed to the end of the body (2) and in a continuation thereof by any known and suitable means. For example, this fixing can likewise be done by welding. Consequently, the upper layer (4b) serving as valve is free and remains open at the top of the conical shape.

The catheter (1) has a radiopaque end able to protect the surrounding tissue during its introduction and its navigation in the aorta. As will be indicated in the description below, the end is retractable inside the assembly serving as embolic filter and, consequently, retractable inside the body (2) of the latter and the catheter (1). Advantageously, this end is formed by an inflatable balloon (6) filled with a sterile radiopaque solution.

Reference is made to Figures 3 to 20 showing the different sequences for placement of an aortic valve, noting that the device can be used for other cardiac valves such as tricuspid valves, mitral valves and

Date reçue/date received 2021-10-19

pulmonary valves, but also for the introduction of instruments such as a decalcifying instrument in order to achieve a remodeling of the implantation site.

Figure 3 shows the aortic root, while Figure 4 shows the same root after placement of the guide wire (g) which is engaged, in a known manner, to pass through the stenosed aortic valve.

The whole of the introducer device, including the catheter (1) equipped with the assembly (E) serving as valvular embolic filter and the balloon (6), is introduced into the descending aorta by means of the guide wire (g) (Figure 5). It will be noted that the whole of the device can be introduced directly into the aortic root with a direct juncture of the ascending aorta following trans-aortic access through a small thoracotomy or by means of an endoscopy trocar or alternatively by a transcatheter approach via the femoral artery or through oter peripheral vessels such as the subclavian arteries or axillary arteries.

The whole of the introducer catheter is positioned at the sinotubular junction (Figure 6). When the device is in position, the end of the balloon is deflated (Figure 7), in such a way that its diameter is smaller than the internai diameter of the introducer device, especially of the tubular body (2) (Figure 7). The balloon (6) is then completely withdrawn from the device (Figure 8).

The device is then advanced to the aortic root (Figure 9).

The catheter (1) is then withdrawn (arrow F in Figure 35 10), in such a way that the part of the end forming the sheath (1a) covering the assembly (E) of the valvular filter releases the latter, which is partially deployed (Figure 10). The tubular body (2) is then pushed from

Date reçue/date received 2021-10-19

the aortic root until the filter assembly, by way of its outer part resulting from the soft weld, cornes to bear in the sinuses of Valsalva near the coronary ostium without obstructing the coronary flow (Figure 11).

The upper layer (4b) of the membrane made of a soft and extensible polymer material acts as a valve ensuring a complete valve function (Figure 12), while the mesh network of the lower layer (4a) blocks the tissue debris. As indicated, the shells (3) conform to the commissures of the native valve, thereby permitting good sealing and complete seating of the device on the floor of the aortic root.

As is shown in Figure 13, the opening the valvular conical filter can be modified by acting on the catheter (1), of which the end (1a) forms a sheath cooperating with said filter in order to modify the opening of the filter restrictively (Figure 13).

Having verified the stable position of the catheter (1), it is possible, by way of the catheter, to introduce the chosen medical device, for example a valve (V) (Figure 14). If necessary, prior to the placement of the valve, it is possible to carry out decalcification by any known and suitable means.

It will be noted that if the tissue of the leaflets to be removed has been limited and regurgitation is medium to moderate, the introducer device can be removed and the transcatheter valve can be implanted.

Conversely, if the tissue ablation has been completed with total removal of the flaps, it is important to keep the introducer device in place in order to ensure the temporary valve function to prevent aortic

Date reçue/date received 2021-10-19

insufficiency, which could pose a threat to the life of the patient during the surgical intervention.

When the valve function of the conical filter is terminated, the device can be withdrawn.

The withdrawal of the device involves the closure of the filter membrane, ensuring that the trapped debris is not embolized. The valvular filter is gently withdrawn from the root of the aortic valve (Figure 15) and is progressively reintroduced into the catheter. The sheath (1a) of the catheter (1) is slid down between the polymer material of the membrane and the polymer filter (Figures 16, 17 and 18) until reaching the end of the conical part, closing it up gradually to tilt the shells (3), which are retracted inside the catheter (1) over the polymer material by sliding in order to clear the debris trapped in the filter.

When the withdrawal procedure has been completed and the valvular filter has been fully closed, the device can be withdrawn in complete safety from the aorta (Figure 19). It is then a simple matter of removing the guide wire (Figure 20).

The advantages are clear from the description.

Date reçue/date received 2021-10-19

CLAIMS

1. A device for transcatheter insertion into an aortic root of an aorta at a sinotubular junction by means of a guide wire and a catheter with means for protecting surrounding tissues, wherein the device comprises an assembly serving as a valvular embolic filter, said assembly being slidably mounted in a guided manner inside said catheter, said assembly having arrangements designed for forming, in the aortic root, a safety chamber ensuring a valve function and a protective function against embolic accidents, said arrangements comprising a tubular body with ends, the tubular body being secured at one of said ends to a part which is, as and when required, either deployable outside the catheter or retractable inside the catheter, said part having filtration arrangements combined with means designed for reproducing a temporary valve function corresponding to opening during a systolic phase and to closing during a diastolic phase, in order to prevent any regurgitation of blood in a deployed position of said part for covering a native aortic valve with a seat secured in the aortic root at sinuses of Valsalva without obstructing blood flow, in which device said part has a general conical shape and has angularly offset shells with contours enveloping commissures of the native aortice valve, said shells being mounted in combination with a filtering membrane, the filtering membrane comprising a lower layer composed of a mesh network with a porosity suitable for blocking tissue debris while allowing passage of the blood flow, the filtering membrane further comprising an upper layer

Date reçue/date received 2021-10-19

made of a soft and extensible polymer material for acting as a temporary valve, by simple deformation; wherein said lower and upper layers are fixed together via a weld at a base of the conical shape of the part and on a perimeter thereof, said weld being soft and spongy in order to provide an optimal seat for a valve filter on a base of the aortic root and in order to allow an end of said conical shape to be able to be closed progressively, until retraction inside the catheter, over the polymer material, by sliding the catheter in order to clear the debris captured when the catheter is slid downward between the polymer material of the membrane and the polymer filter until reaching said end of said conical shape.

2. The device as claimed in claim 1, wherein the lower layer composed of the mesh network is fixed to said one of said ends of the tubular body and in a continuation thereof, while the upper layer serving as the temporary valve is free and remains open at a top of the conical shape.

3. The device as claimed in claim 1 or 2, wherein the catheter has a radiopaque end designed for protecting the surrounding tissues during an introduction and a navigation through the aorta.

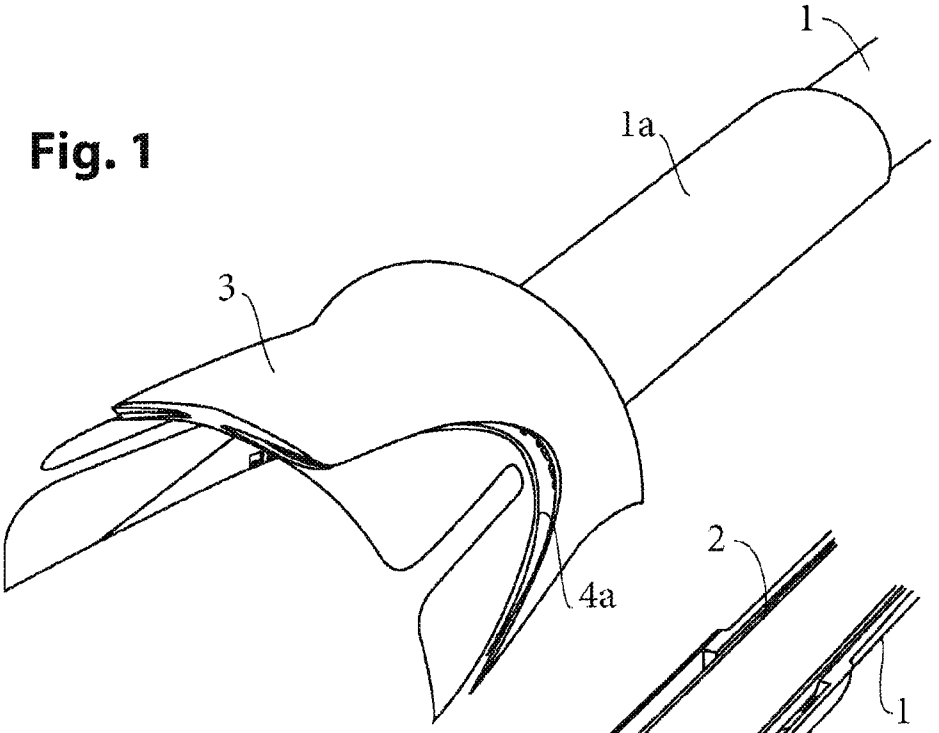
4. The device as claimed in claim 3, wherein the radiopaque end is retractable inside the tubular body of the assembly serving as the valvular embolic filter.

Date reçue/date received 2021-10-19

5. The device as claimed in claim 4, wherein the radiopaque end is an inflatable balloon filled with sterile radiopaque solution.

Date reçue/date received 2021-10-19

Fig. 1



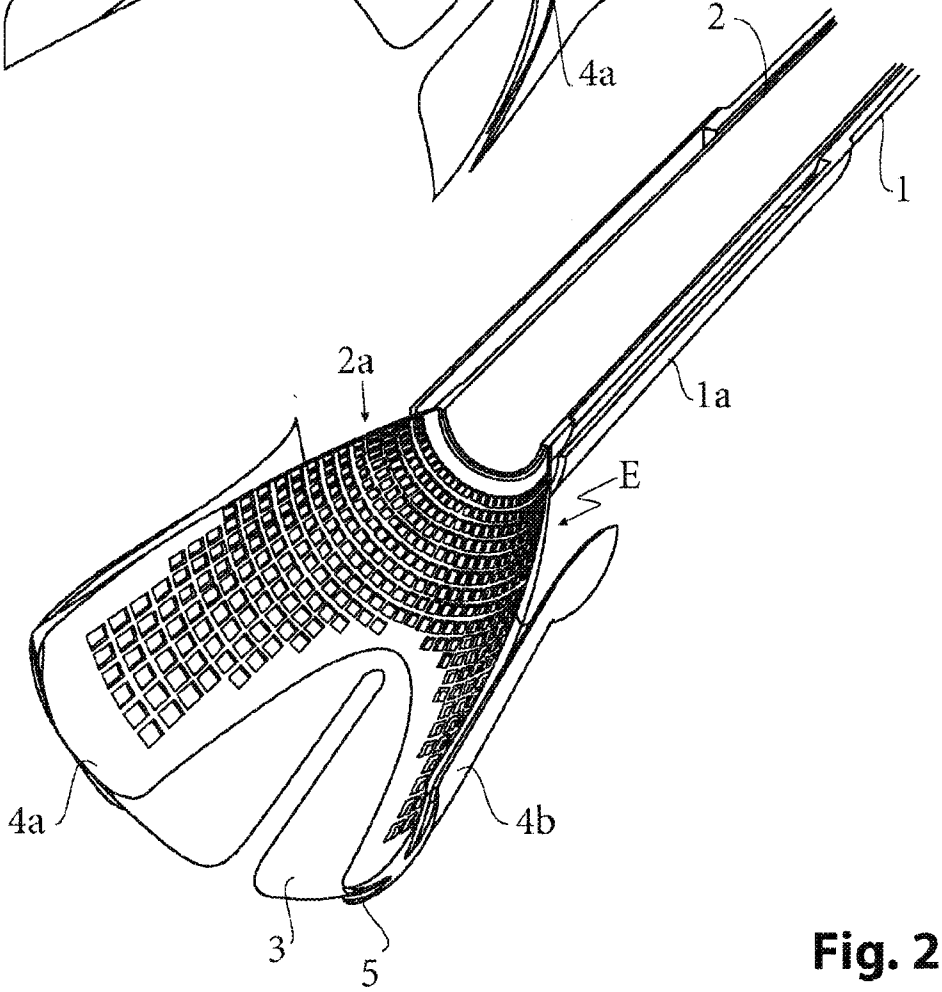


Fig. 2

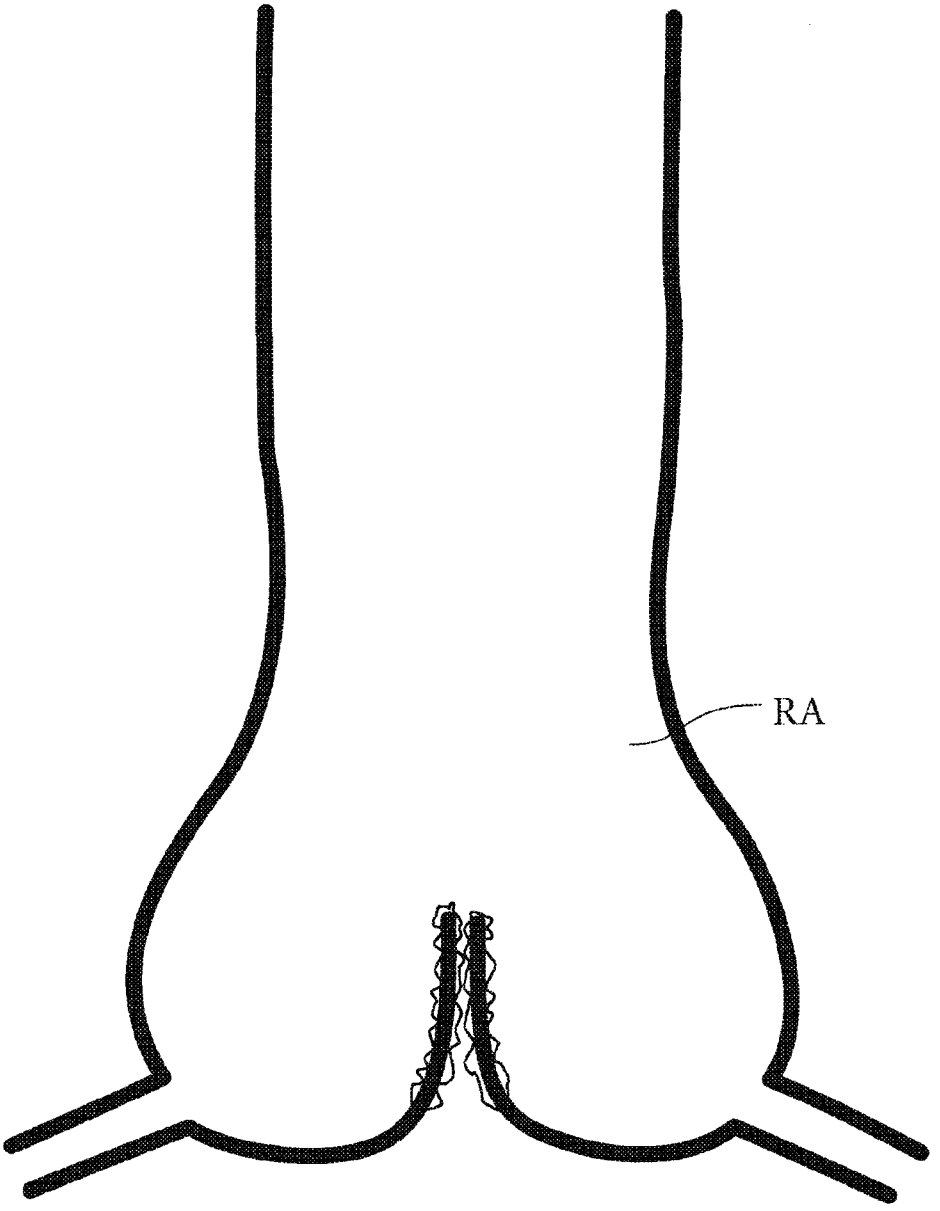


Fig. 3

Date reçue/date received 2021-10-19

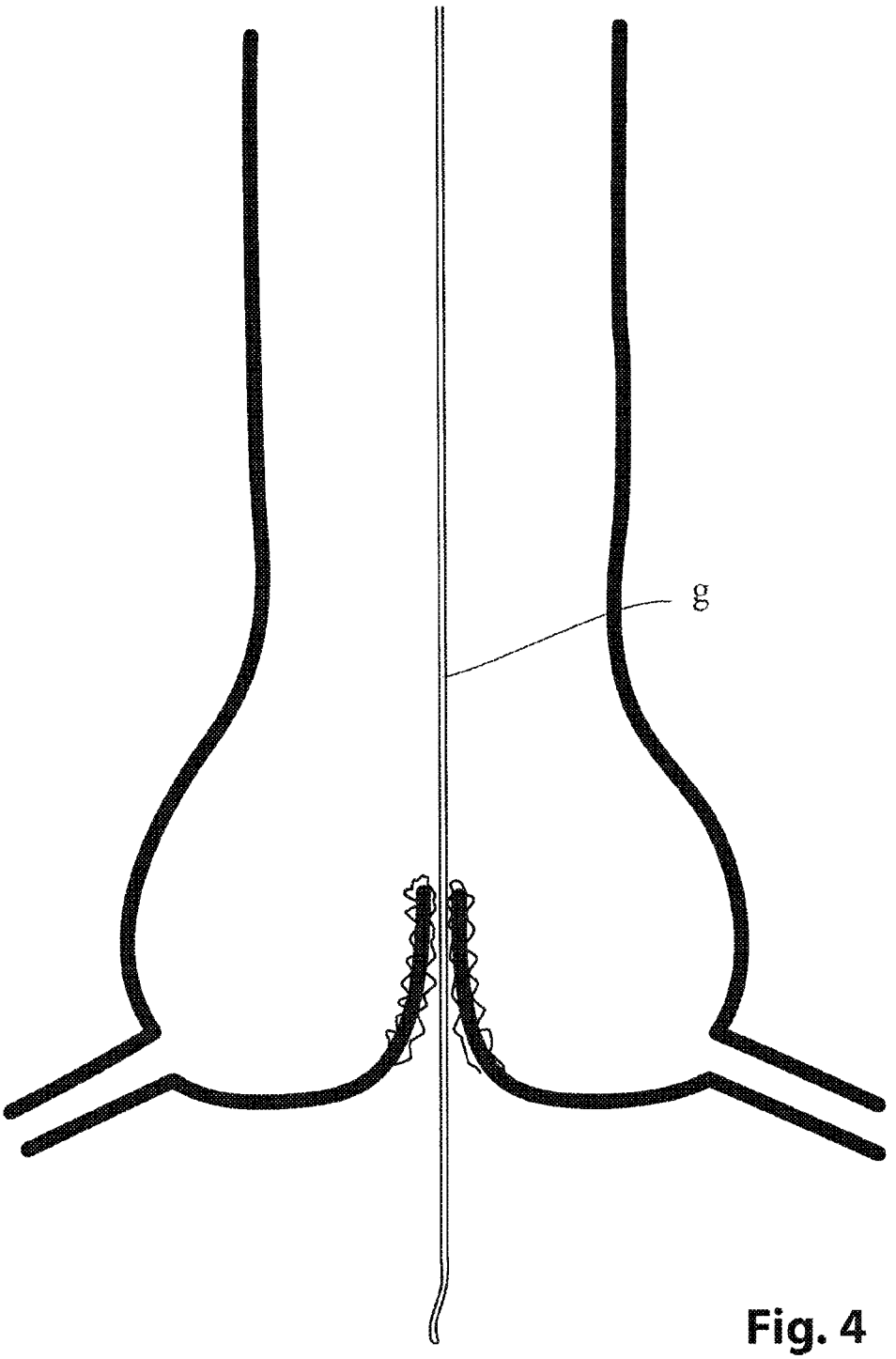


Fig. 4

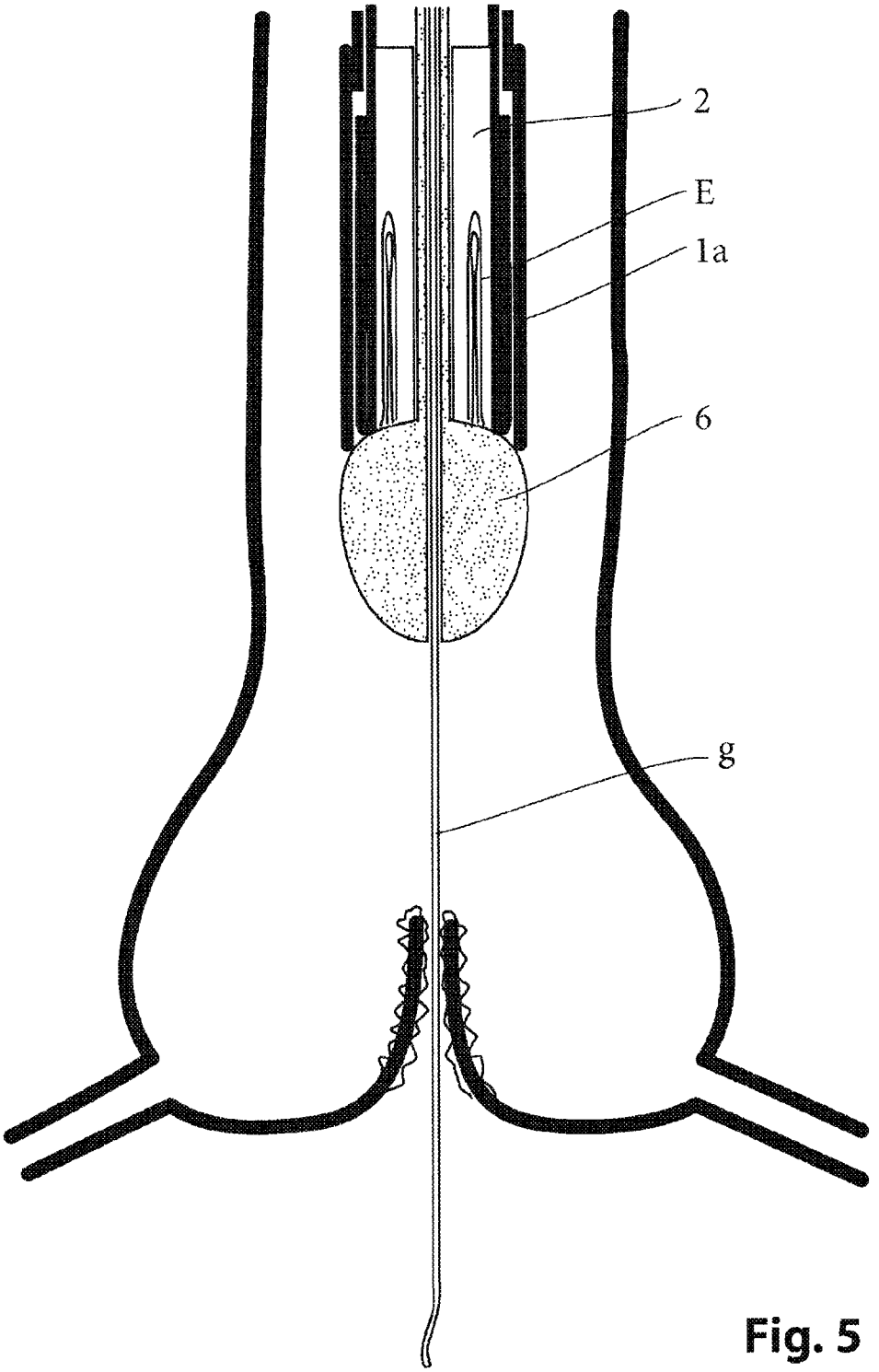


Fig. 5

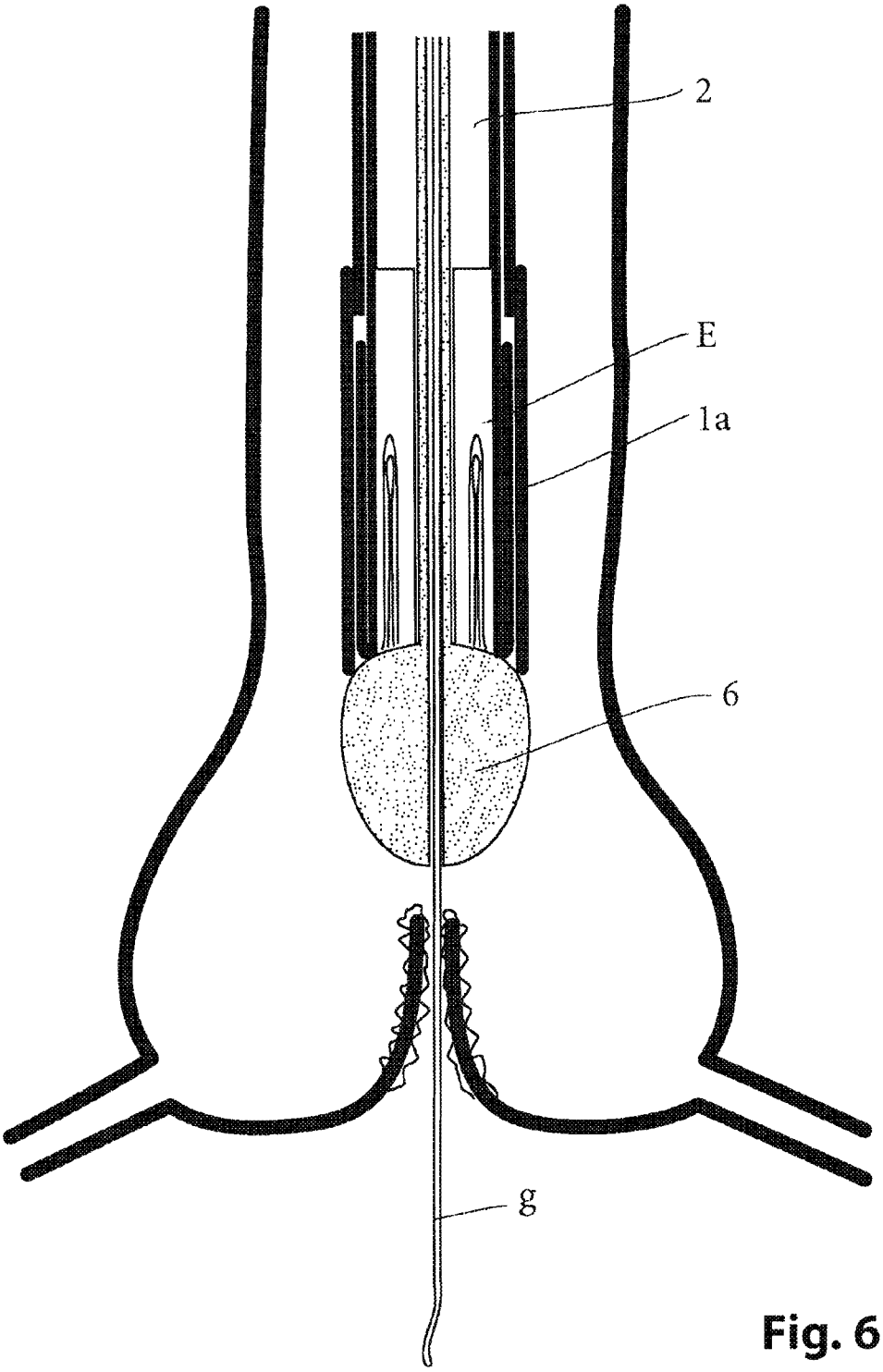


Fig. 6

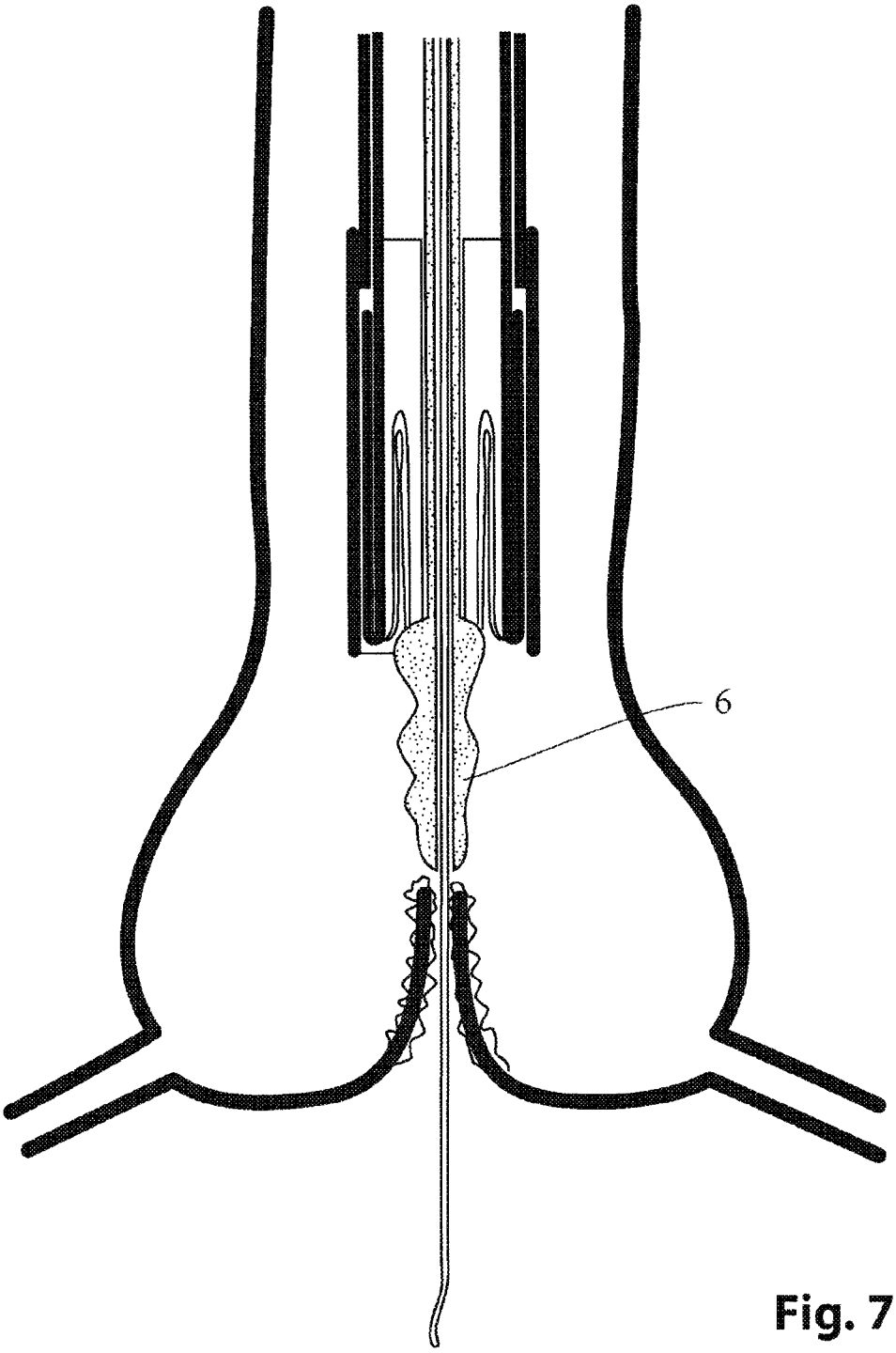


Fig. 7

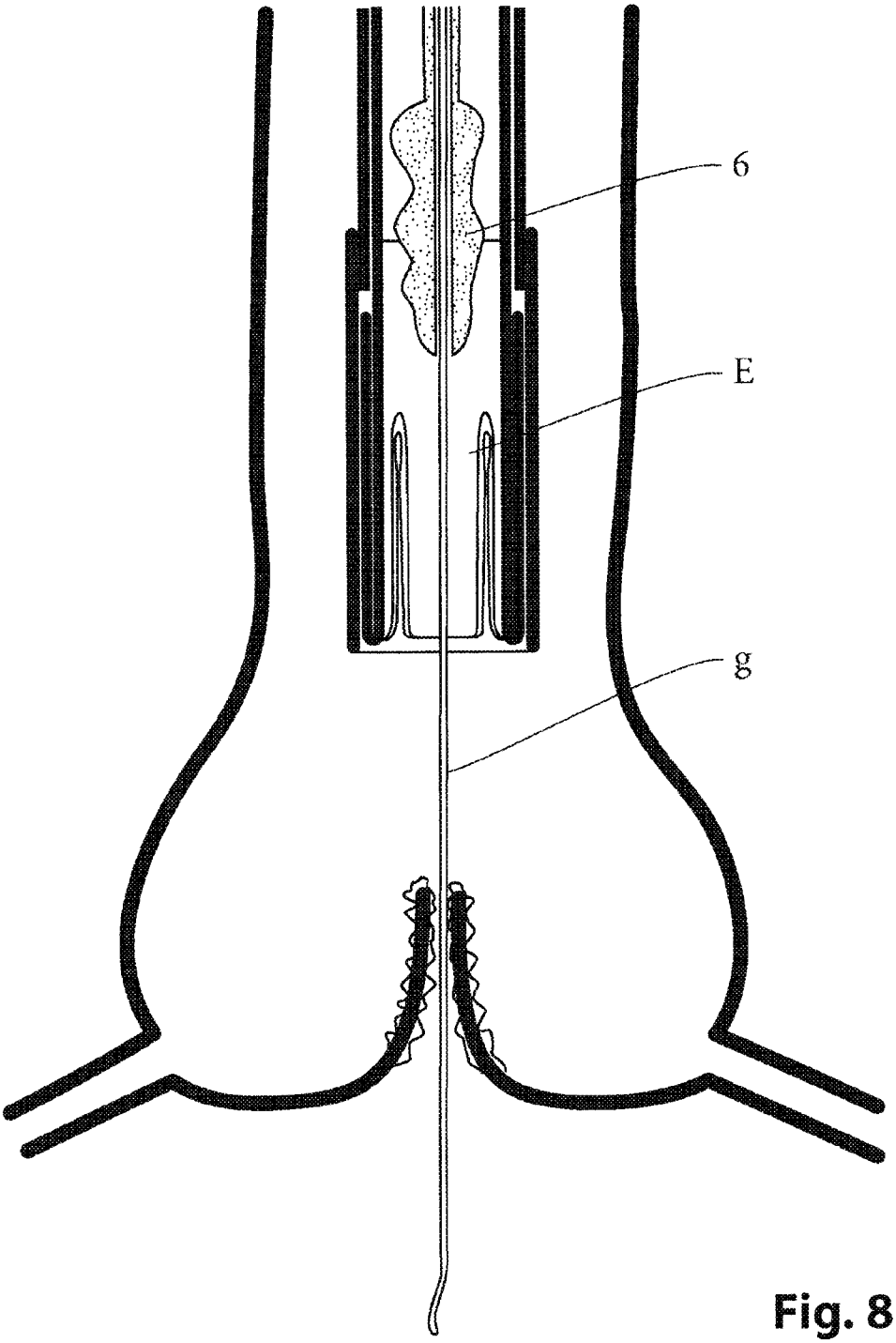


Fig. 8

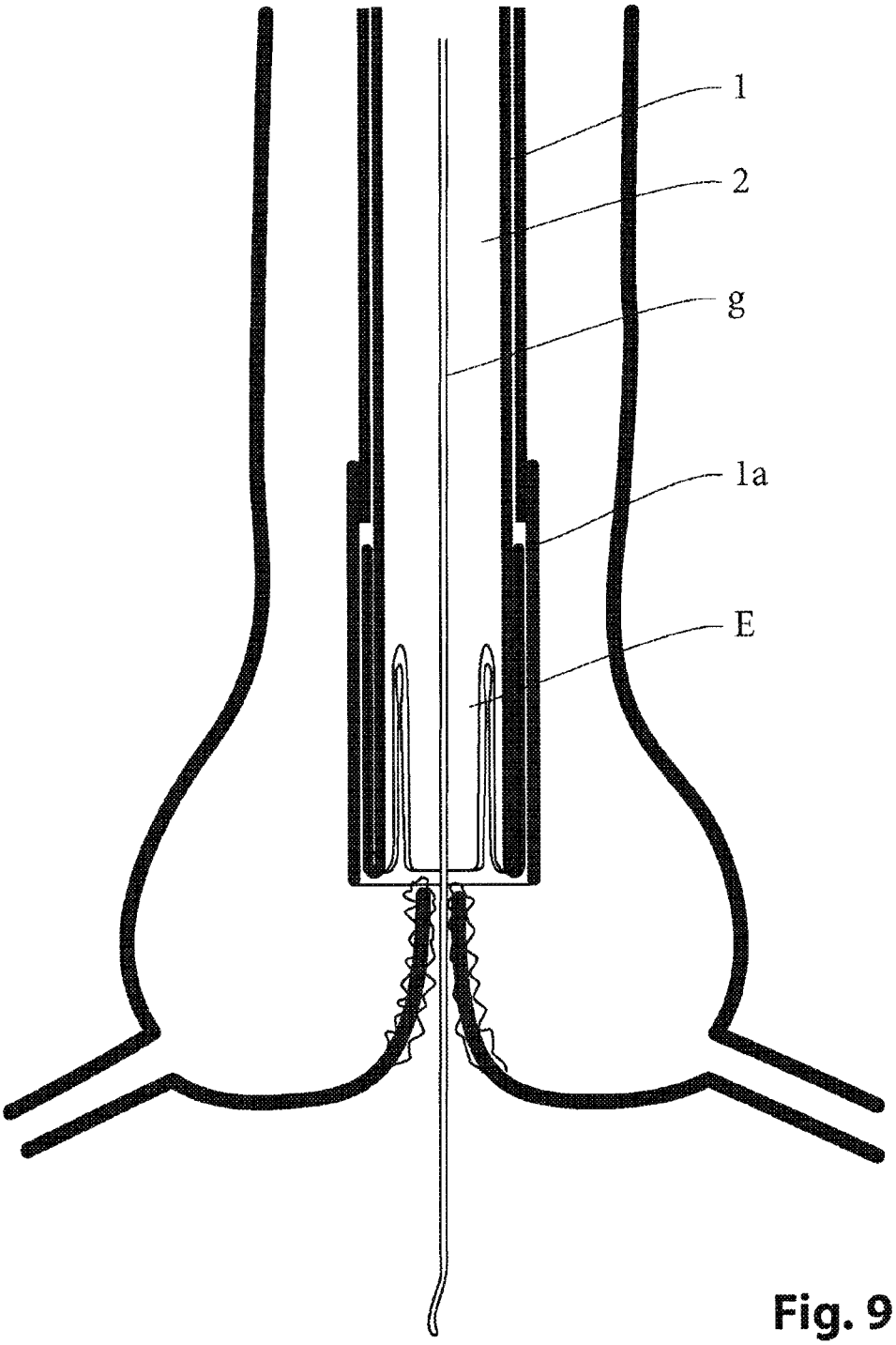


Fig. 9

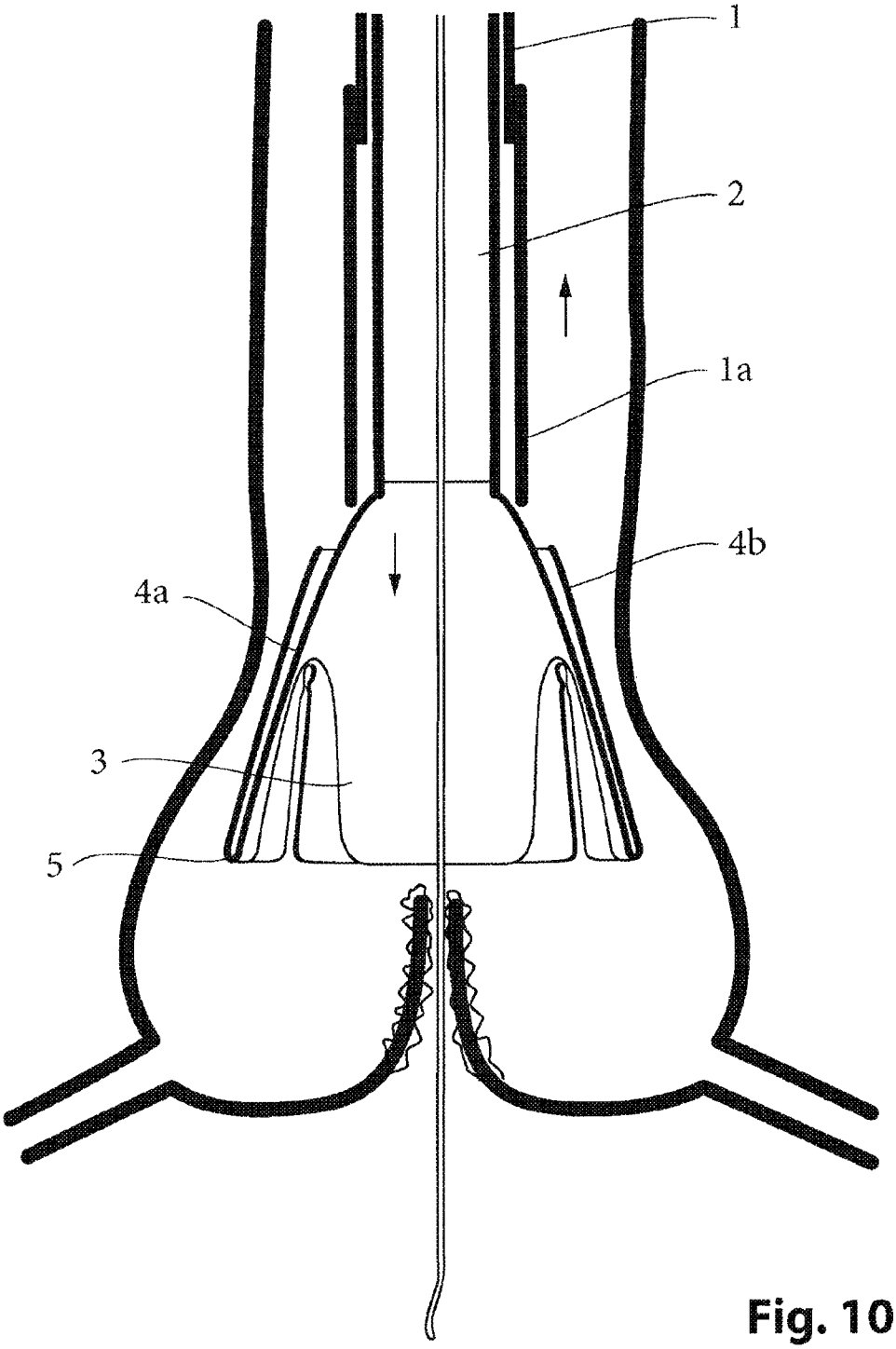


Fig. 10

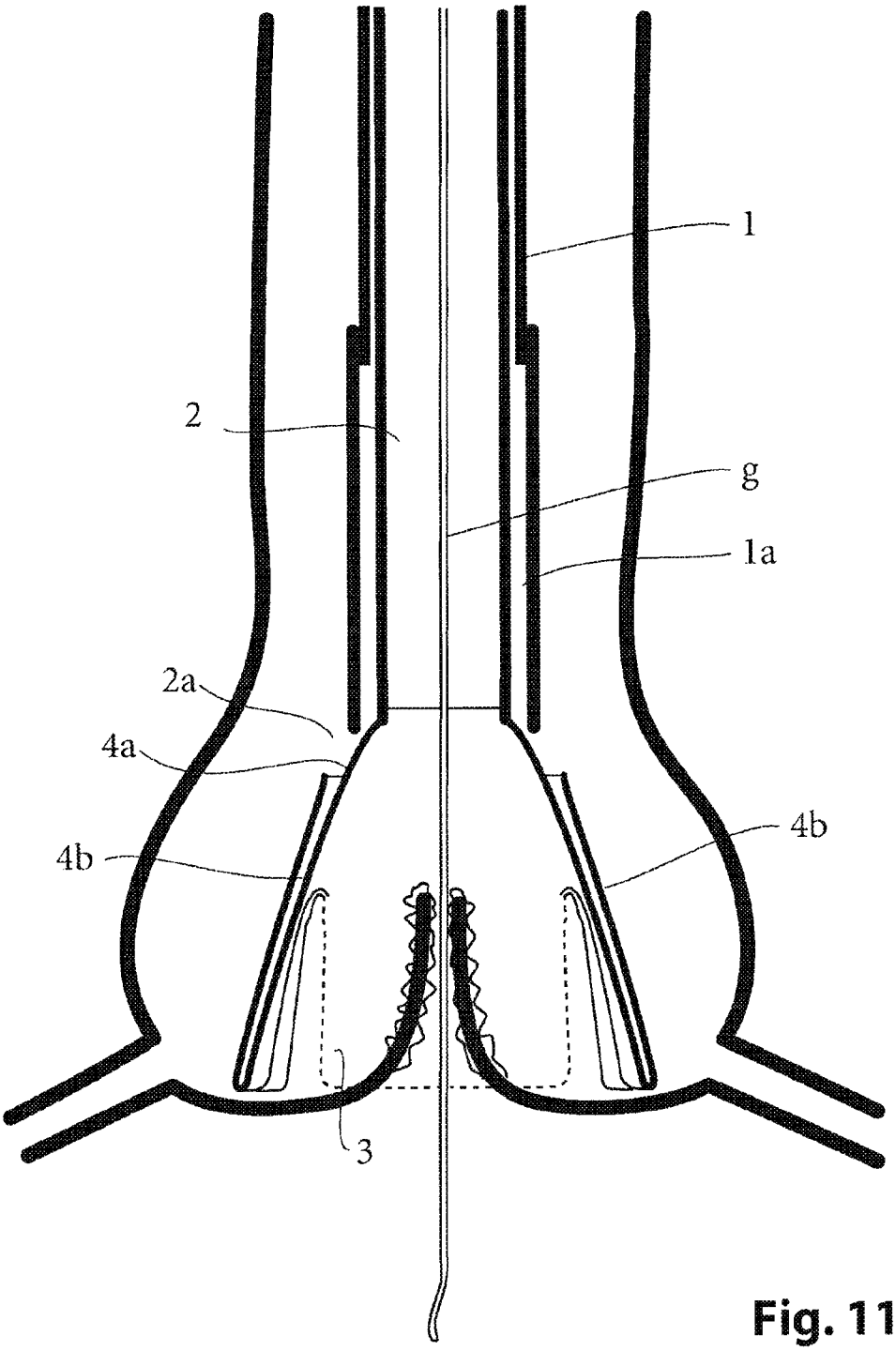


Fig. 11

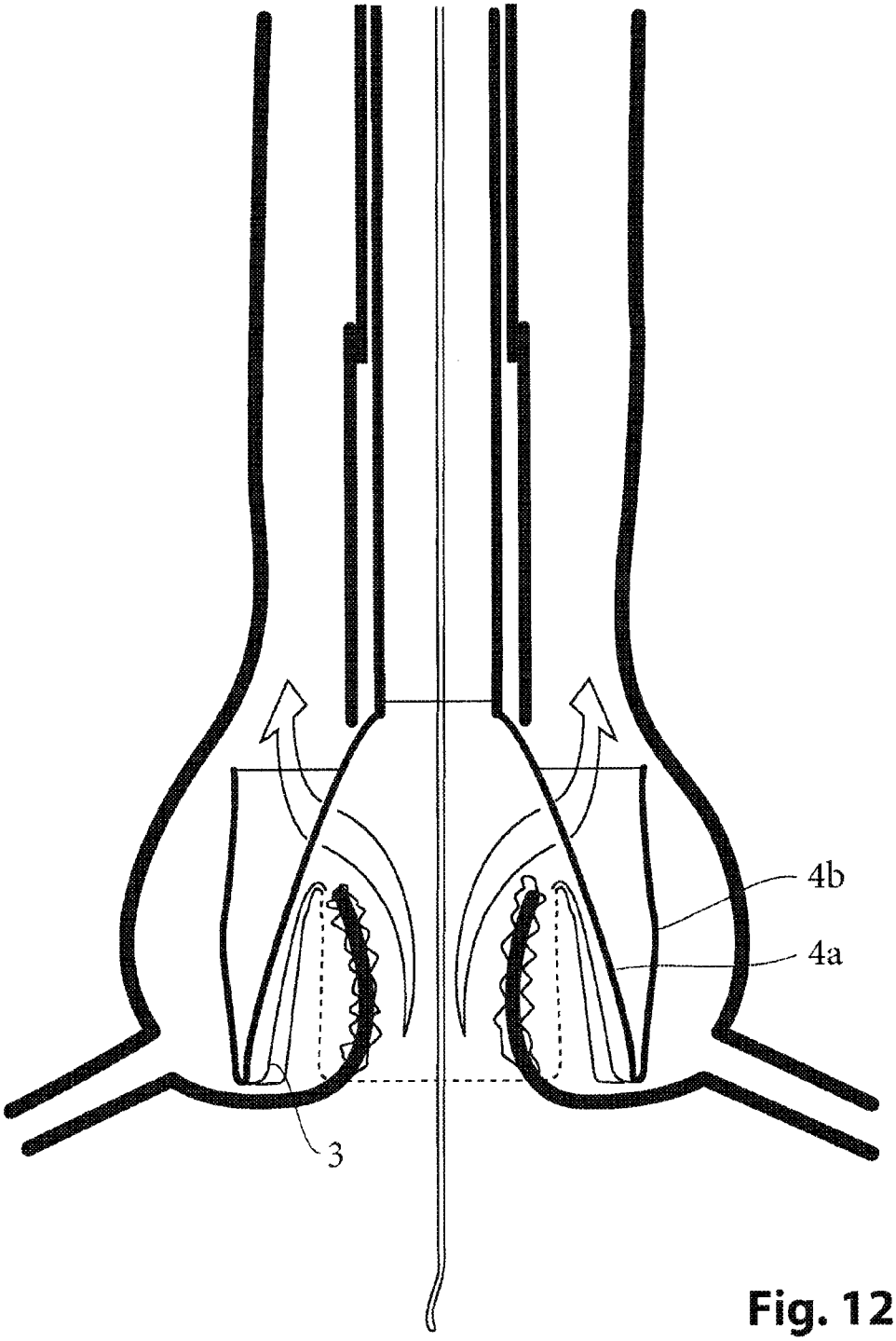


Fig. 12

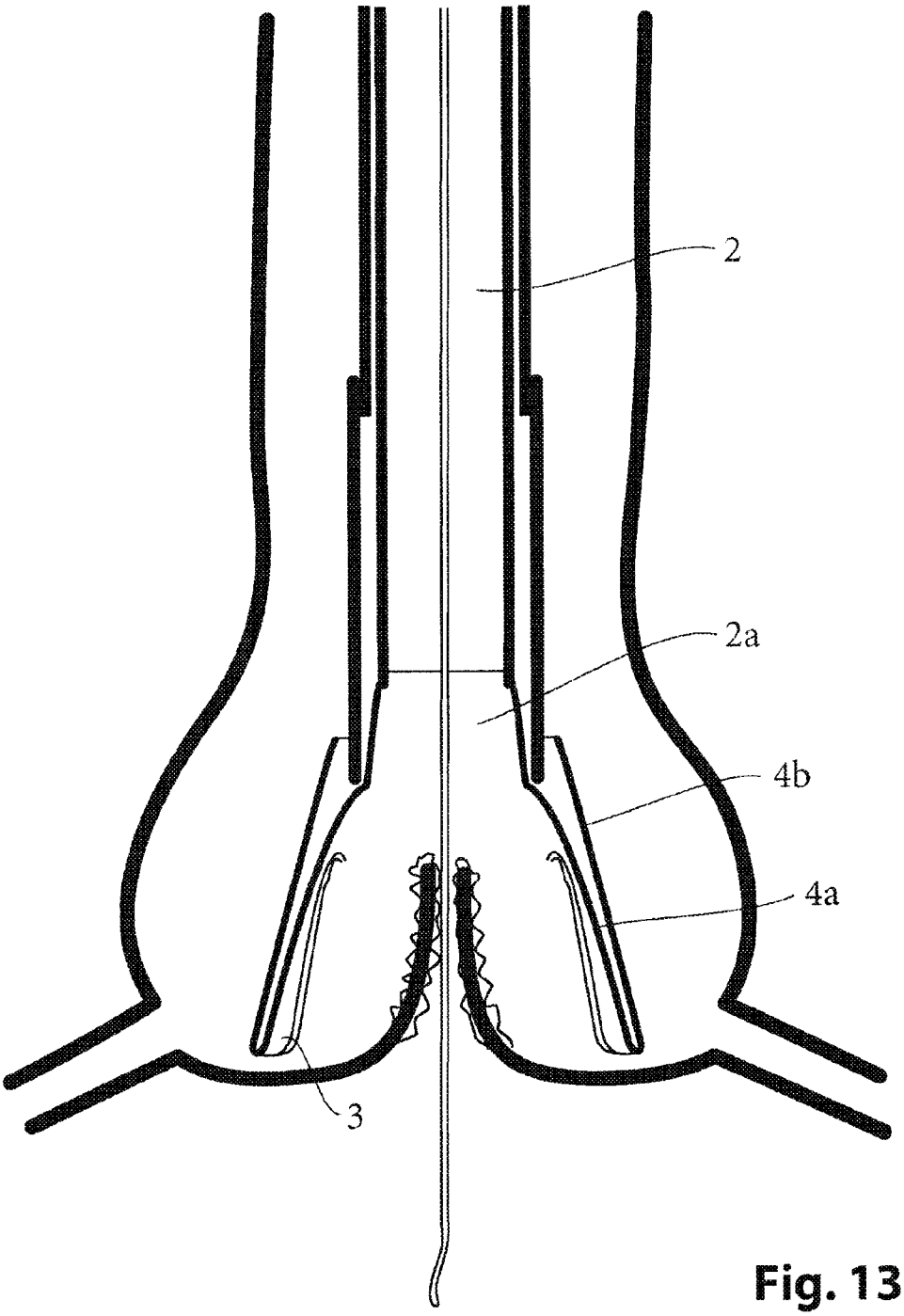


Fig. 13

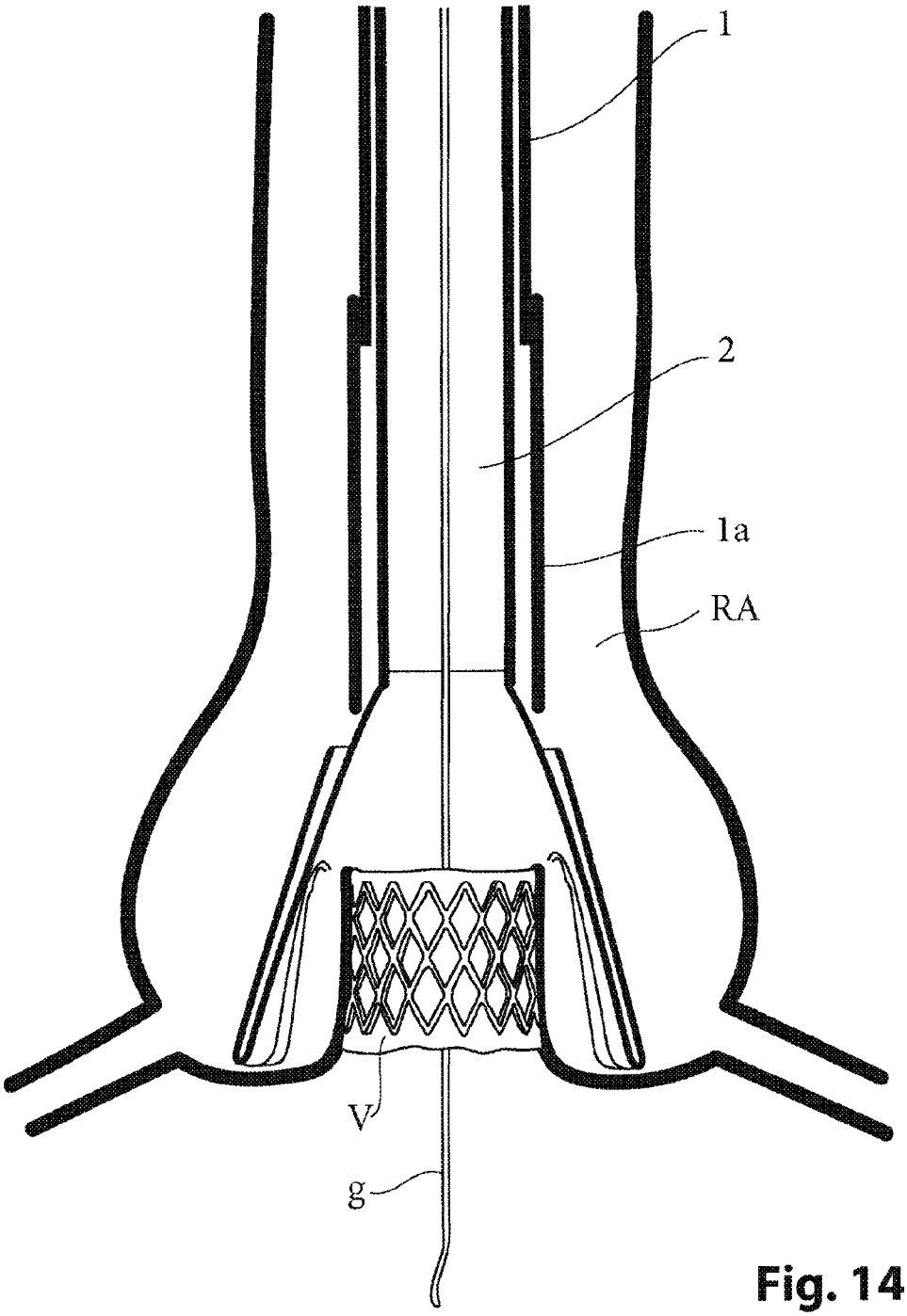


Fig. 14

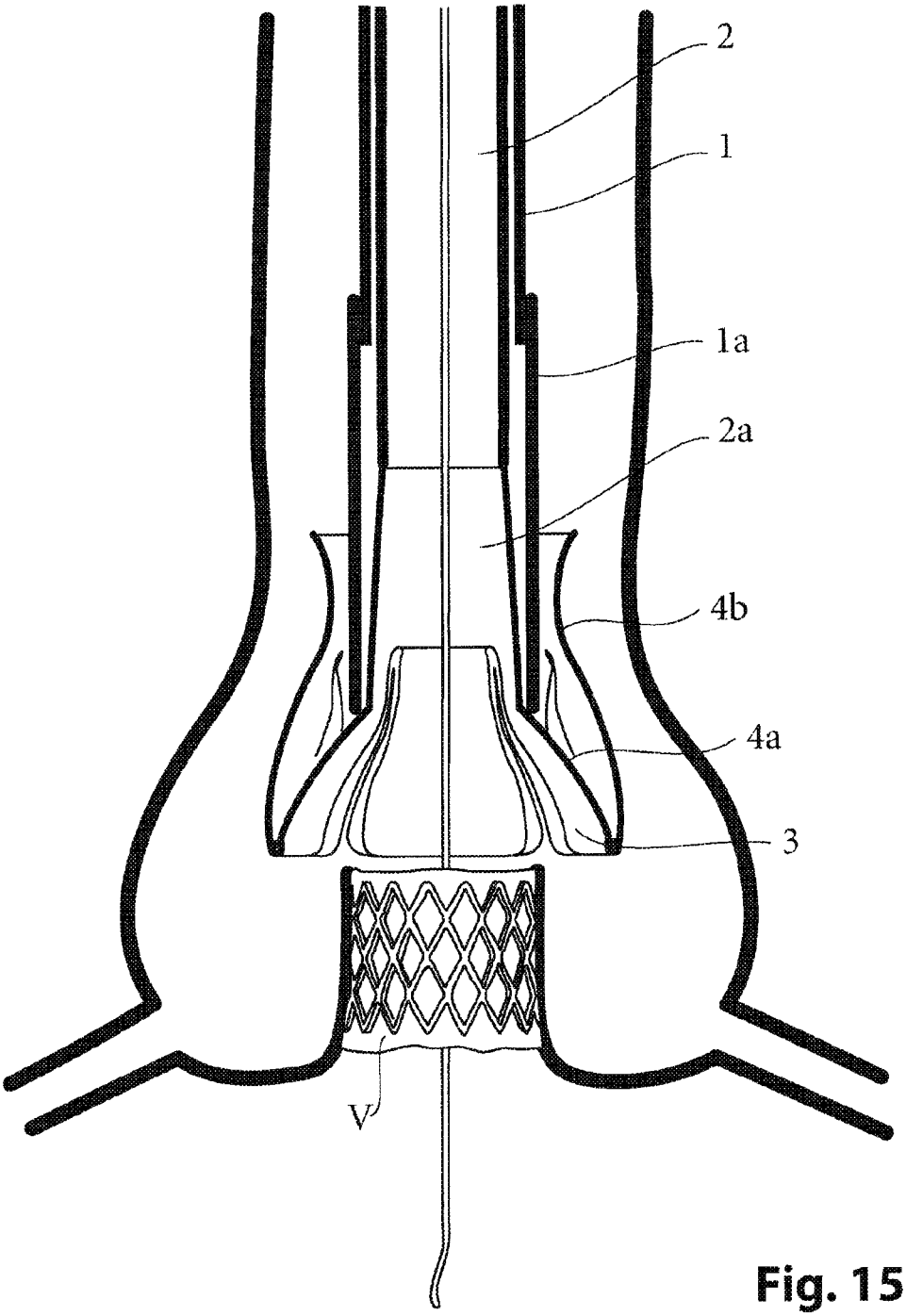


Fig. 15

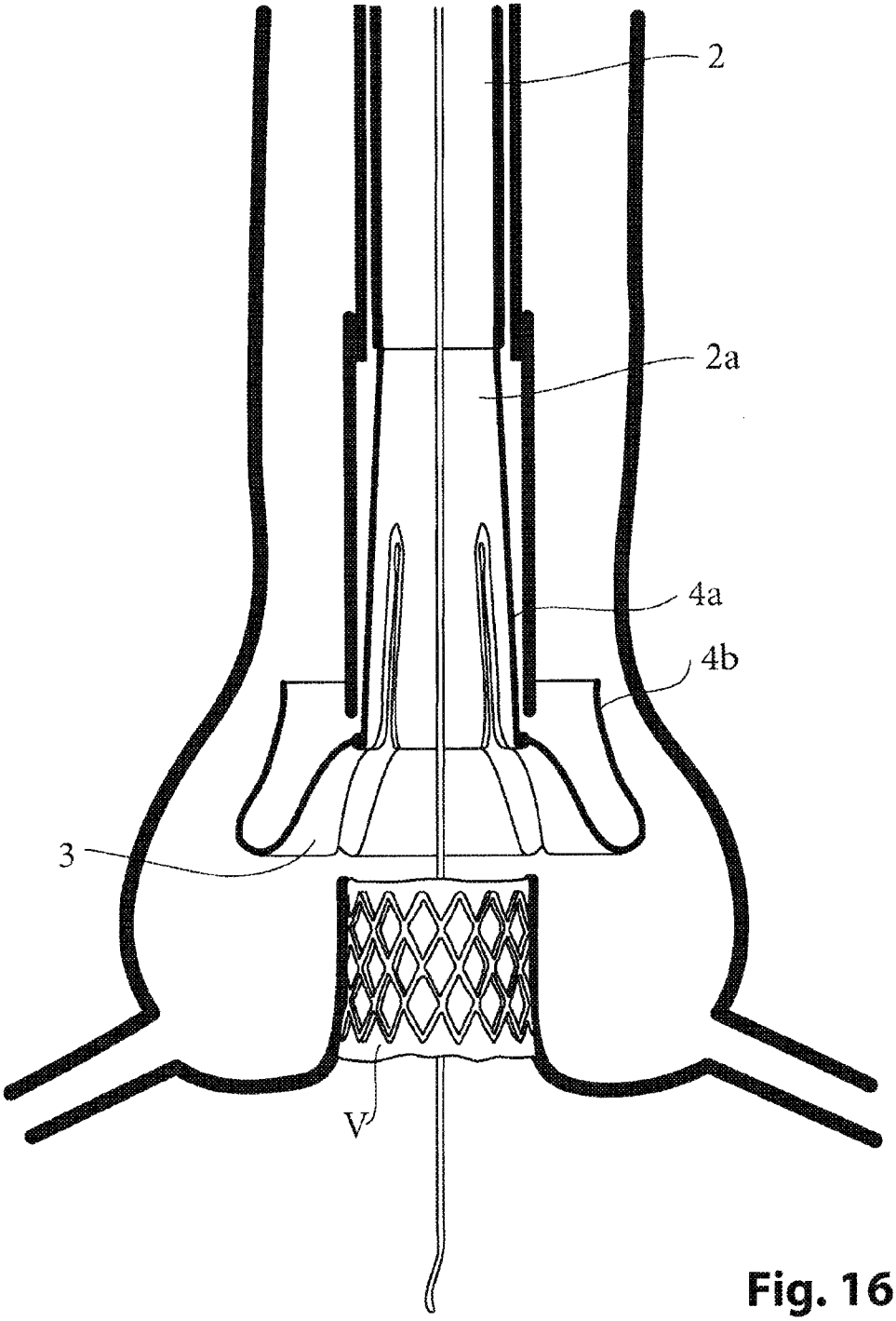


Fig. 16

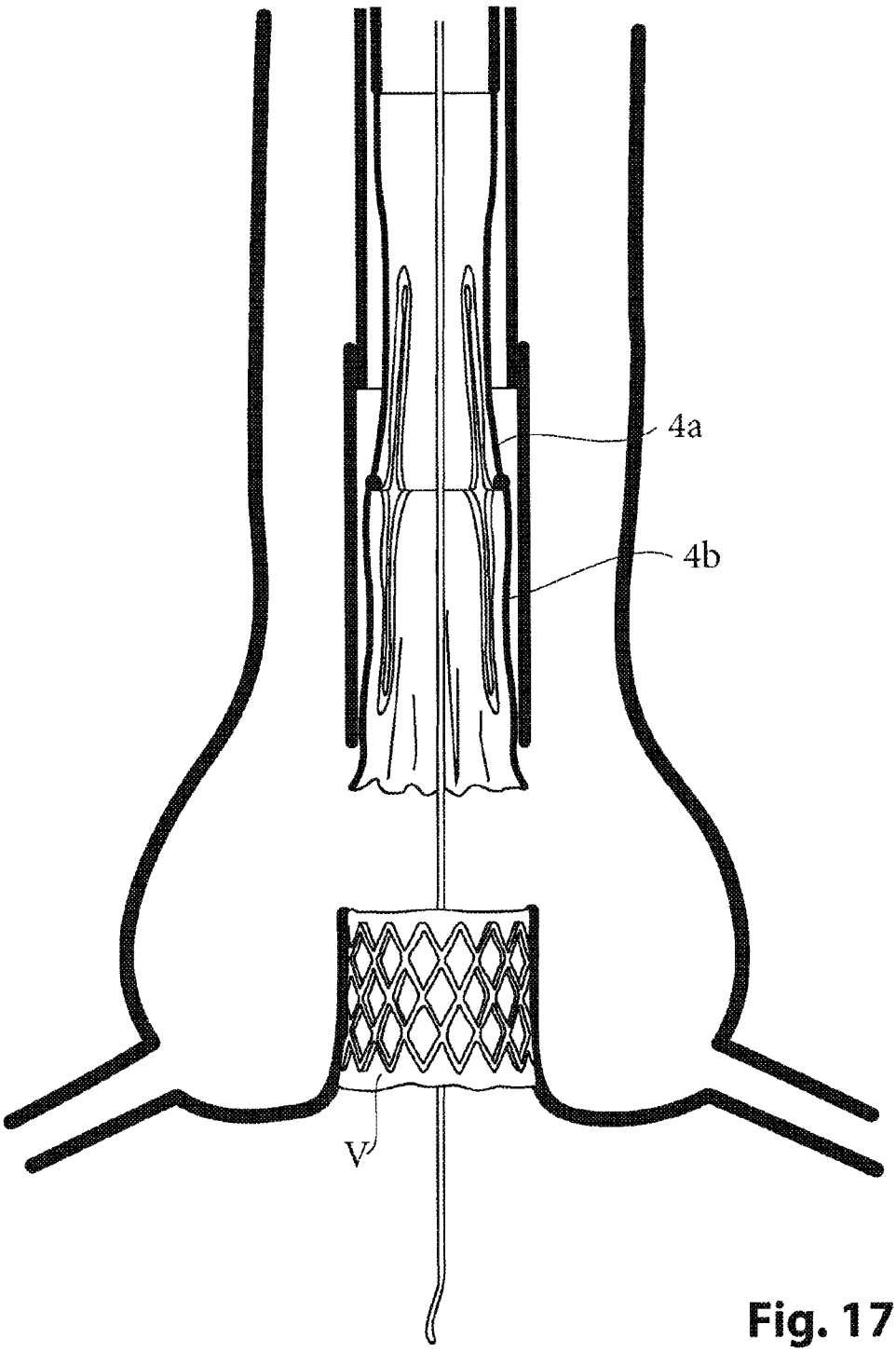


Fig. 17

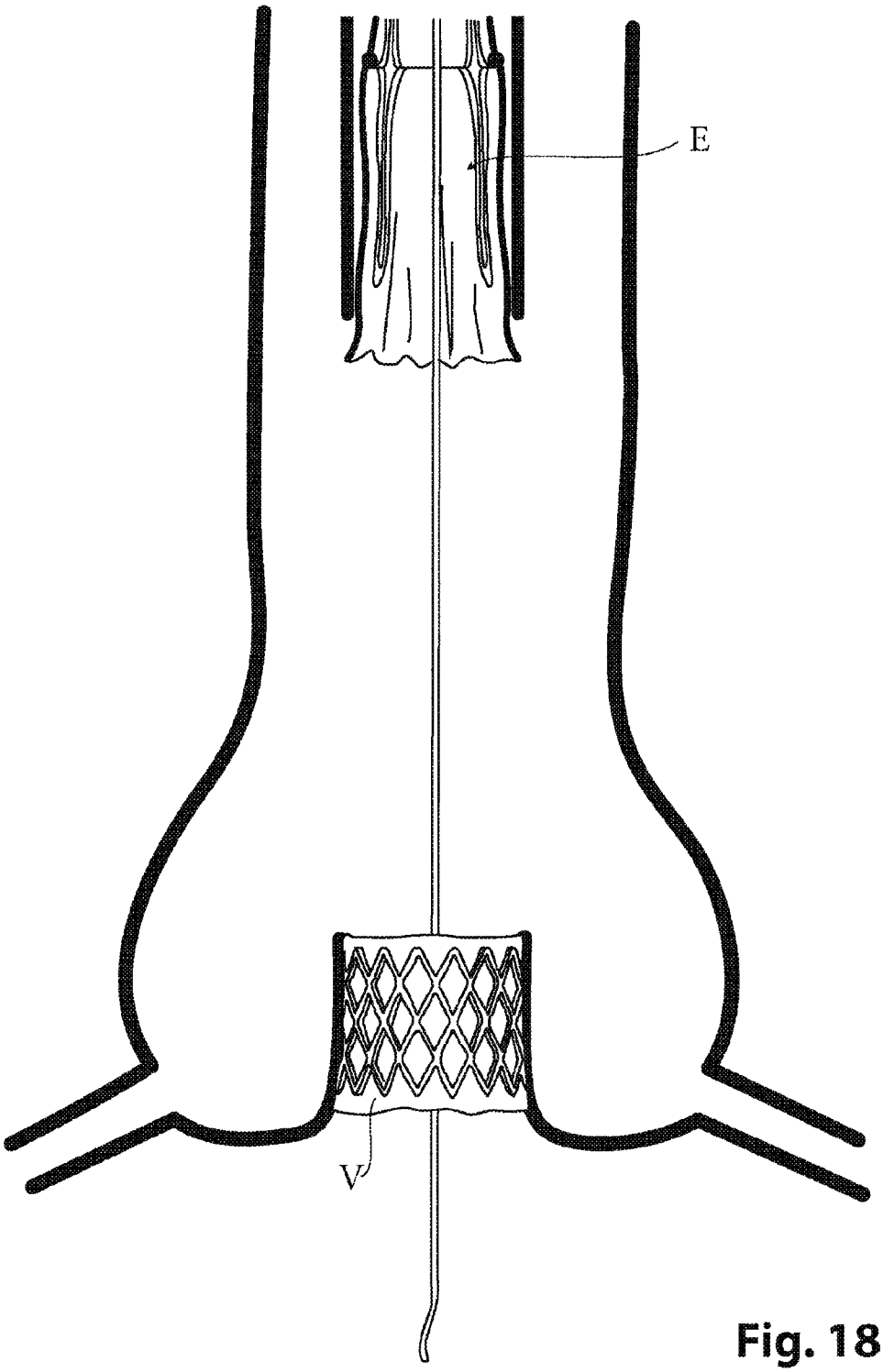


Fig. 18

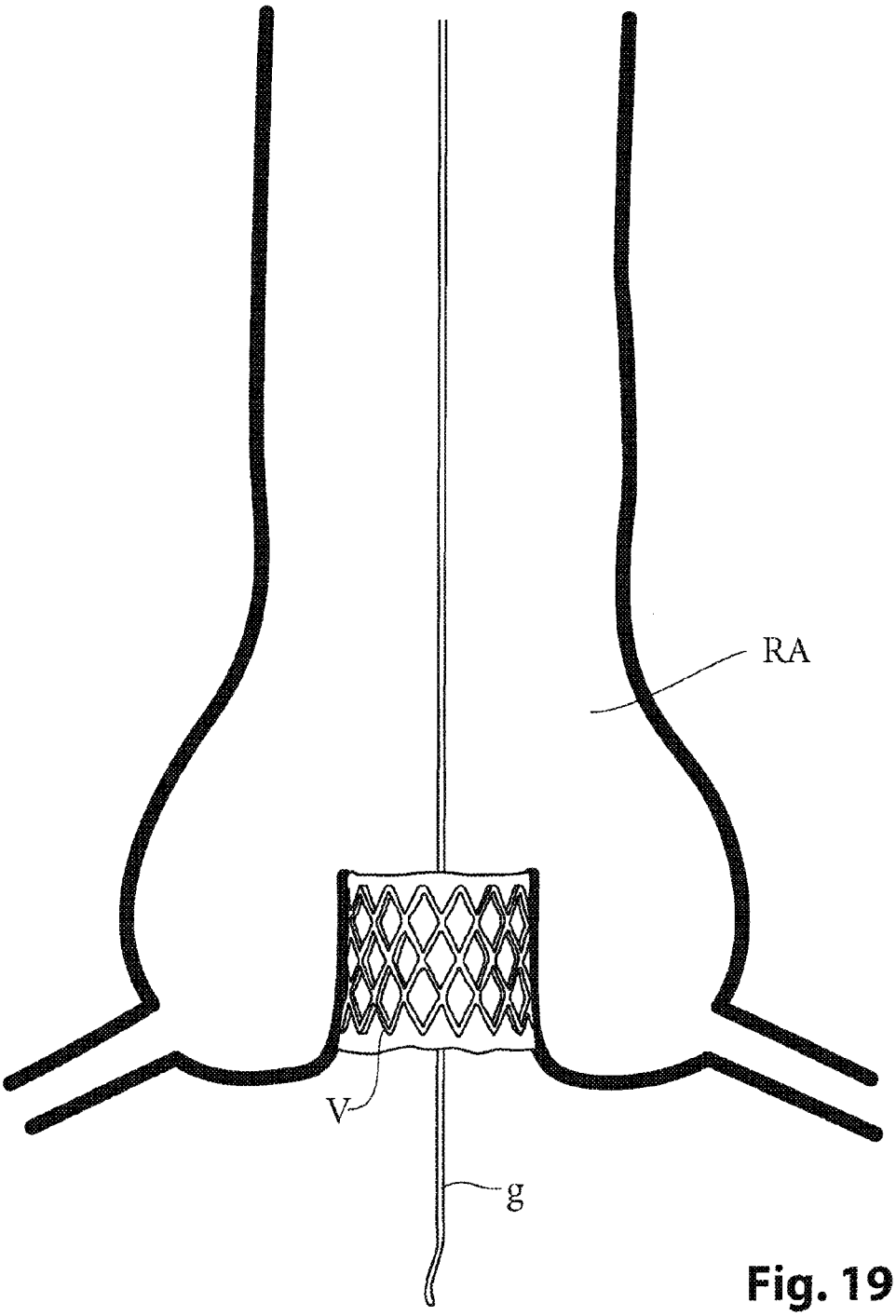


Fig. 19

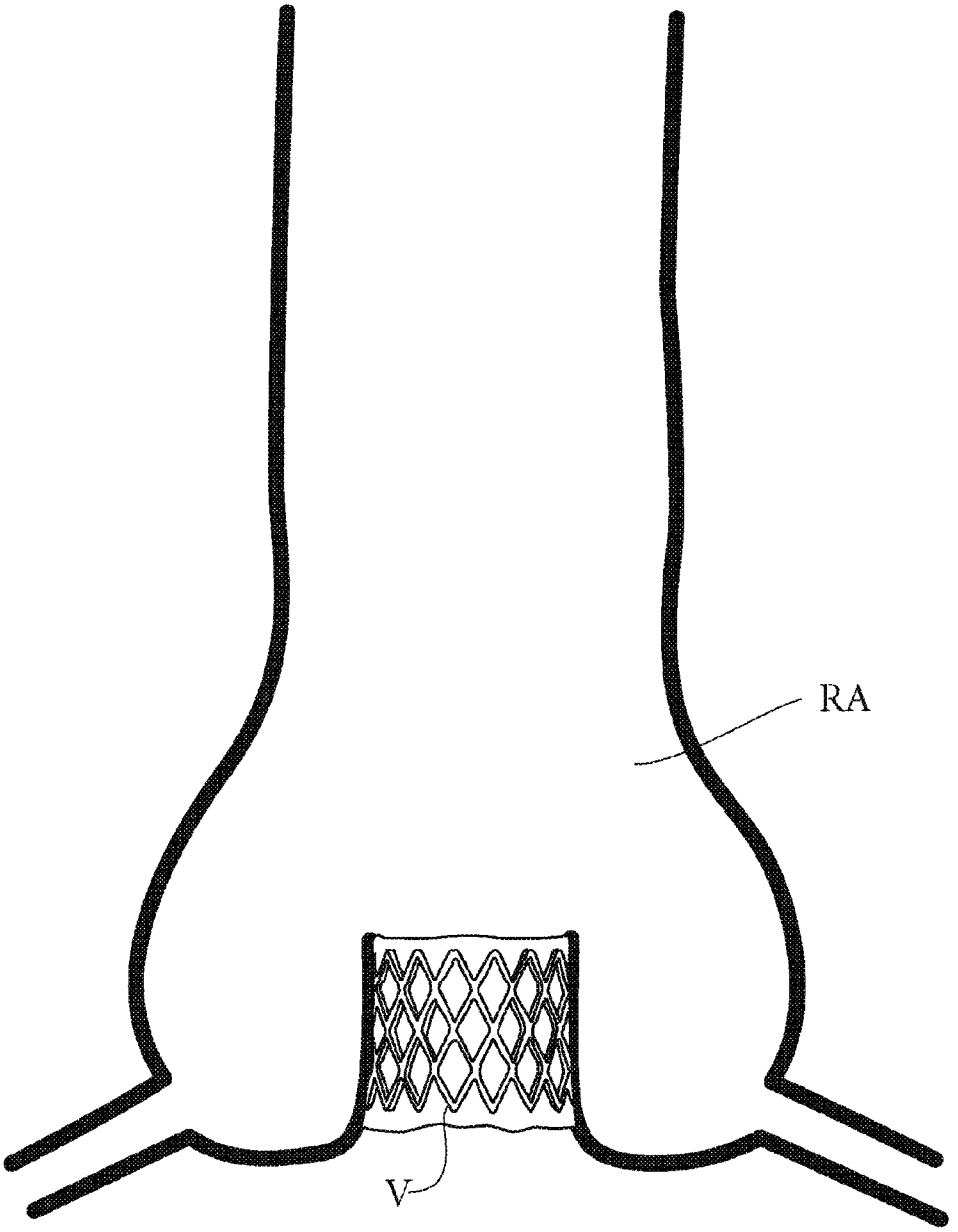
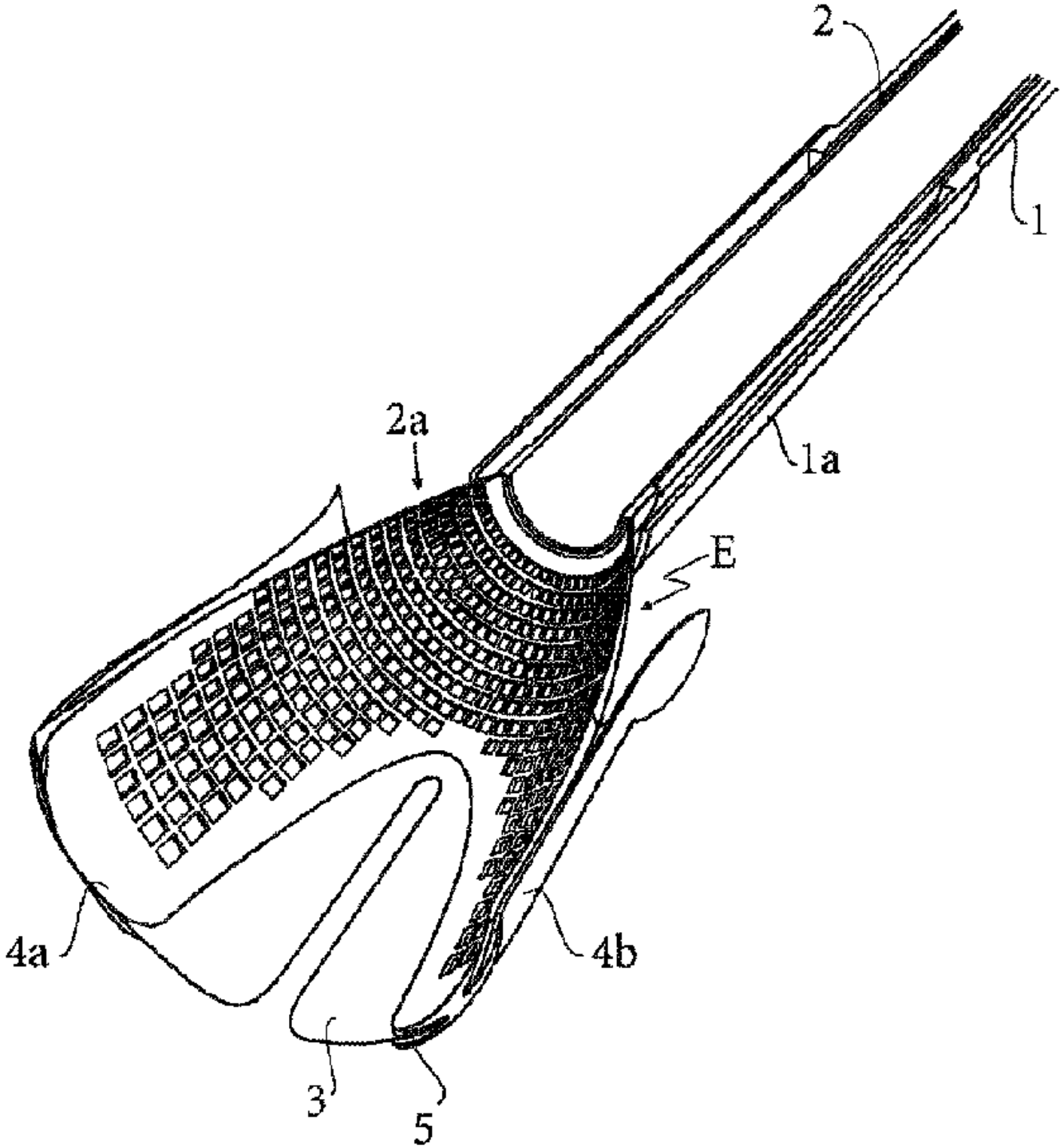


Fig. 20


2
1
2a
1a
E
4a
4b
3
5