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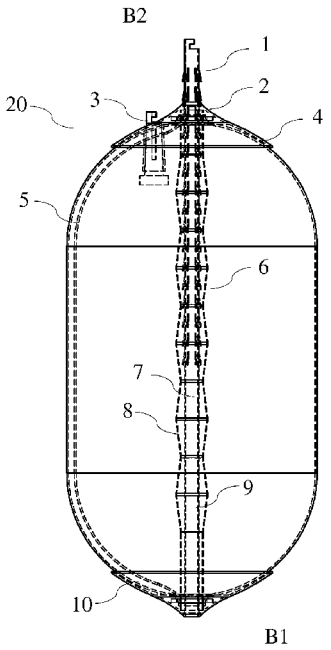

FIG. 1a

(57) Abstract: An occluder device (20) for occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue comprises: - a compliant balloon (5) defining a fluid-tight balloon chamber and provided with a balloon channel (7) forming a longitudinal passage from a proximal side (B2) to a distal side (Bl) of the balloon; - a tip element (10) disposed at the distal side of the balloon, a base element (4) disposed at the proximal side of the balloon, and connecting means comprising at least one connecting strut (9) attached to the tip element and to the base element, the tip element and the base element each having a guide opening (105a, 105b) substantially coaxial to the balloon channel (7) for slidingly receiving therein a guidewire (106) for the device; - elongated actuating means disposed longitudinally slidable in the balloon channel (7), releasably connectable to the tip element (10), and longitudinally slidable with respect to the base element (4); - locking means (2, 13) for maintaining a predetermined distance between the tip element (10) and the base element (4); - proximal connector means (1) for releasably connecting the occluder device (20) to correspondingly configured distal connector means of a catheter device (107); - the balloon (5) comprising a fluid port (19) for filling and unfilling a fluid into and from the balloon chamber. An occluder system comprises an occluder device (20) and a catheter device (107) cooperating therewith.

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Medical occluder device

Field of the Invention

The present invention generally relates to an occluder device for occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue. In particular, it relates to a paravalvular leak occluder device. The devices of the present invention are intended to be implantable by means of a percutaneous or minimally invasive intervention.

Background of the Invention

There are several types of unnecessary or even pathologic passageways within the body. If located in blood vessels or in the heart, such passageways can cause a highly undesirable reduction of blood flow or the bypass of blood flow around an organ.

WO 95/32018 discloses a method and a device for blocking a body passageway by inserting an expandable frame into the passageway and expanding the frame with an expandable balloon to partially embed the frame in the walls of the passageway. The frame can be provided with a separate sealing membrane, or the balloon can function as the sealing membrane. The balloon can be removed along with the inflation tube after the expansion step if it is not serving as the sealing membrane, or the balloon can be detached from the inflation tube and left in place, either as a sealing membrane or simply to lock the frame in place. The frame can be maintained in its expanded state by being plastically deformed during the expansion step. The expandable frame has substantially cylindrical shape and is described as being suitable e.g. for closing a patent ductus arteriosus, in which an unwanted passageway or duct connects the aorta to the main pulmonary artery, close to the heart.

US 4,836,204 describes a device for effecting closure of a perforation in the septum of the heart. The device comprises a double-balloon septal defect occlusion catheter which is to be inserted such that the two initially deflated balloons are positioned on opposing sides of the septum. Upon inflating, the balloons snugly engage the respective septum wall sections and thereby prevent leakage through the perforation.

Paravalvular leak is a common complication that occurs in up to 30% of patients undergoing implantation of either surgical or transcatheter prostheses. The option to treat these defects percutaneously may offers safer solution for high-risk patients, without exposing them to risk related to open heart reoperation. However, the currently used devices are suboptimal since they have not been specifically developed with this intended use. Today, paravalvular leak closure is generally accomplished with devices originally designed for occlusion of congenital heart defects. They are usually implanted in low flow environment such as patent foramen ovale or atrial septum defect, and in simple geometries. In contrast, paravalvular leaks develop in high pressure and flow environment, and they are characterized by complex geometry. The defect is often crescent or oval shaped, which may include a tubular section with several deformities, and the structure is marginally compliant at best. In this environment, most of the currently available occlusion devices are limited by the poor adaptability of the device to the defect (lack of conformability) and by a lack of intra-device sealing (due to the high flow environment).

Nevertheless, there are some concepts and implementations of occlusion devices that were specifically designed for paravalvular leak occlusion.

US 2014/0277426 A1 describes various devices for occluding a gap between a medical device and adjacent body tissue. The devices generally comprise a conformable body with a hollow interior and provided with a fluid port intended to supply a pressurizing fluid to inflate the conformable body. Various shapes and constitutions of the conformable body, delivery means and fixing means are described.

US 7,628,805 B2 generally discloses a multitude of concepts for locating and for repairing paravalvular leaks. The concepts include sealing stents and also multicomponent and radiation-cured adhesive compounds.

US 2012/078295 A1 discloses an occluder device for closing a passage in a circulatory system. The device comprises an expandable fixation unit for fixing the occluder on the passage, which is achieved by switching between a compact form and an expanded form.

In spite of the above, there is still a need for an improved occluder device which avoids the shortcomings or presently known devices.

Summary of the Invention

The above and other objects are achieved by the present invention.

According to one aspect, there is provided an occluder device for occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue, the occluder device comprising:

- a compliant balloon defining a fluid-tight balloon chamber and provided with a balloon channel forming a longitudinal passage from a proximal side to a distal side of the balloon;
- a tip element disposed at the distal side of the balloon, a base element disposed at the proximal side of the balloon, and connecting means comprising at least one connecting strut attached to the tip element and to the base element, the tip element and the base element each having a guide opening substantially coaxial to the balloon channel for slidingly receiving therein a guidewire for the device;
- elongated actuating means disposed longitudinally slidable in the balloon channel, releasably connectable to the tip element, and longitudinally slidable with respect to the base element;
- locking means for maintaining a predetermined distance between the tip element and the base element;
- proximal connector means for releasably connecting the occluder device to correspondingly configured distal connector means of a catheter device;
- the balloon comprising a fluid port for filling and unfilling a fluid into and from the balloon chamber.

According to another aspect, there is provided an occluder system comprising an occluder device as defined above and a catheter device cooperating therewith, the catheter device comprising an implant catheter tube connected to an operating handle, the implant catheter tube comprising a longitudinal passageway for a guidewire, distal connector means for releasably connecting the catheter device to correspondingly configured proximal connector means of the occluder device, and a fluid transfer system releasably connectable to a corresponding fluid port of the occluder device. The distal connector means and the proximal connector means are generally configured as coop-

erating members disposed, respectively, at the distal end of the catheter device and at the proximal end of the occluder device. Examples for such cooperating members comprise cooperating threads, bajonets or snap connections.

Clinical indications include but are not limited to paravalvular leak (PVL), patent foramen ovale (PFO), atrial septum defect (ASD), ventricular septum defect (VSD), intravalvular leak (IVL), intraleaflet leak, leaflet perforation, type I endovascular leaks after vascular graft implant, and left atrial appendage occlusion.

The device is designed to be delivered into the region to be treated in its compressed, i.e. longitudinally extended form, then the device will be adapted to the landing zone anatomy with two mechanisms: inflation of the balloon and shortening of the longitudinal dimension of the frame formed between the base element and the tip element. Under the influence of internal pressure the balloon will assume a certain volume which, for a given longitudinal frame dimension, implies a certain transversal or radial dimension. Changing the longitudinal frame dimension by selecting a different distance between the tip element and the base element will lead to a corresponding change in radial extension. In other words, shortening the distance between the tip element and the base element will lead to a corresponding increase in radial extension under otherwise constant conditions.

In the context of the present disclosure, the terms “distal” and “proximal” are used accordingly to their standard meaning in the field of percutaneous cardiovascular devices. The term "proximal" refers to those components of the device assembly which, when following a delivery catheter during percutaneous delivery, are closer to the end of the catheter that is configured for manipulation by the user (e.g., catheter handle manipulated by a physician). The term "distal" is used to refer to those components of the device assembly that are more distant from the end of the catheter that is configured for manipulation by the user and/or that are inserted further into the body of a patient. Accordingly, in a device for use in a gap between a medical device and the adjacent body tissue, like a paravalvular mitral leak, the proximal end may face towards the left atrium and the distal end may face towards the left ventricle, when the device is deployed in the defect using a transseptal approach.

The term "compliant" used in relation with balloons or with structural components shall be understood as implying a deformability that substantially follows an applied force. Accordingly, a "compliant balloon" shall be understood as a balloon which progressively expands under the effect of increasing radial pressure as long as a certain burst pressure is not exceeded.

The connecting means comprise at least one connecting strut attached to the tip element and to the base element. The term "strut" shall be understood as an elongated structural element which can be formed e.g. as a thin wire, rod, thick-walled tube, all of which do not necessarily have a circular cross section.

According to a further aspect, a method of occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue by means of an occluder system as defined above comprises the following steps:

- providing the occluder system with the occluder device connected to the catheter device;
- positioning the occluder device in a compressed, longitudinally extended form thereof in a region to be occluded;
- inflating the balloon by filling a fluid into the balloon chamber;
- expanding the balloon in radial or lateral direction by shortening the distance between the tip element and the base element to said predetermined distance and locking said distance;
- releasing the occluder device from the catheter device.

Advantageous embodiments of the invention are defined in the dependent claims and/or are described hereinbelow.

The compliant balloons of the present invention do not need to be pre-shaped. However, pre-shaped balloons can be used to establish a predetermined, non-uniform local resilience against an applied radial pressure. Preferably (claim 2), the balloon is made of a compliant material selected from polycaprolactone (PCL), polyglycolic acid (PGA), polylactic acid (PLA) and polydioxanone (PDO or PDS). Most preferably, the compliant material is PCL.

Depending on the specific application, various configurations of the connecting means may be contemplated. According to one embodiment, the connecting means comprise a single connecting strut disposed within the balloon channel (claim 3) or outside the balloon (claim 4).

Advantageously (claim 5), the connecting means comprise multiple connecting struts disposed in cage-like manner outside the balloon. Applying internal pressure to the balloon will lead to inflation thereof against a resilient force of the compliant balloon material and also against the structural limitation provided by the plurality of external connecting struts. In particular, such a configuration offers the advantage of an improved stability of the compliant balloon against unwanted local deformation. This will generally result in an improved adaptation of the occluder device to the geometry of the leak to be occluded.

The locking means for maintaining a predetermined distance between the tip element and the base element may also be configured in various manners. For example, they may comprise a rotatable actuating wire with a threaded portion formed to cooperate with a corresponding section formed in the distal disk. According to an advantageous embodiment (claim 6), the locking means are configured as a ratchet mechanism whereby said predetermined distance between the tip element and the base element is selectable from a range of distances. This allows for precise and reliable definition of the radial extension of the occluder device and accordingly to an improved reliability of the device.

The elongated actuating means are disposed longitudinally slidable in the balloon channel, releasably connectable to the tip element and longitudinally slidable with respect to the base element. For this purpose, the acutating means are formed as an elongated, flexible member with a smooth surface. According to an advantageous embodiment (claim 7), the elongated actuating means are configured as actuating wire. The use of actuating wires is well established in the field of cardiovascular interventions. In the present context, the use of a wire together with appropriate proximal counterpieces allows for simple, precise and reproducible selection of the distance between the tip element and the base element.

Means for filling and unfilling balloons and other inflatable devices are also well known in the field of cardiovascular interventions. According to an advantageous embodiment (claim 8), the balloon has a fluid port configured as a self-closing valve when it is not connected to a corresponding fluid transfer system. In particular, this allows filling the balloon through a longitudinal fluid line which can subsequently be disconnected and retracted and which only needs to be reinserted and reconnected if an additional filling or an unfilling of the balloon is needed.

The aforementioned elements as well as those claimed and described in the following and to be used according to the invention, shall generally be understood with their meaning as established in the field of medicine.

Brief description of the drawings

The above mentioned and other features and objects of this invention and the manner of achieving them will become more apparent and this invention itself will be better understood by reference to the following description of various embodiments of this invention taken in conjunction with the accompanying drawings, wherein:

FIG. 1 (a) shows a cross-sectional view of an expanded occlusion device according to an embodiment of the invention comprising one connecting component within the balloon embodiment;
(b) and (c) show side elevational views of the device illustrated in FIG. 1a;

FIG. 2 (a) shows a cross-sectional view of an expanded occlusion device according to an embodiment of the invention comprising multiple connecting components outside the balloon embodiment;
(b) and (c) show side elevational views of the device illustrated in FIG. 2a;

FIG. 3 (a) shows a cross-sectional view of an expanded occlusion device according to an embodiment of the invention comprising one connecting component outside the balloon embodiment;
(b) and (c) show side elevational views of the device illustrated in FIG. 3a;

FIG 4 (a) shows a cross-sectional view of an expanded occlusion device according to an embodiment of the invention when deployed within a cardiovascular defect comprising a ratchet longitudinal adjustment component within the balloon embodiment;
(b) and (c) show side elevational views of the device illustrated in FIG. 4a;

FIG. 5 (a) shows a cross-sectional view of the device illustrated in FIG 4a after the ratchet component actuation and longitudinal shortening;
(b) and (c) show side elevational views of the device illustrated in FIG. 5a;

FIG. 6 shows a side view of the device illustrated in FIG 2a when connected with the implant delivery system comprising a steerable catheter and a multiple knobs delivery handle;

FIG. 7 shows a side view of the device illustrated in FIG 2a when expanded within a congenital defect;

FIG. 8 shows a side view of the device illustrated in FIG 2a when expanded within a cardiovascular defect intended as cavity or discontinuity of the body tissue; and

FIG. 9 shows a side view of the device illustrated in FIG 2a when expanded within a gap between a medical device and the adjacent body tissue.

It will be understood that the figures are not necessarily drawn to scale. In some instances, relative dimensions may be substantially distorted for ease of visualization.

Detailed description of the invention

FIG. 1a shows a cross-sectional view of an expanded occlusion device 20 according to an embodiment of the invention comprising one connecting component within the balloon embodiment. As shown, the device 20 comprises a compliant balloon 5 as well as a central lumen 6 and a frame formed of two plastic or metallic deformable disks, placed at the distal end 10 and proximal end 4 of the implant and connected by one strut 9 passing within the balloon 5 central lumen 6. The frame allows structural support to the

balloon. The frame may be formed from a cut structure so that each component of the frame is integrally connected with each other. The strut may have a linear or nonlinear section and may have plastic or metallic deformable characteristics. The occluder forms a closed three-dimensional device. The embodiment comprises a connection element 1 of the device 20 to attach and release it from the implant catheter 14. An inflation port 3 entering into the balloon along the central axis or in the close vicinity of it is connected to the implant catheter 14 and allows inflation and deflation of the balloon 5 while connected before the device 20 release. Within the central lumen 6 of the balloon may be the guidewire lumen 7 allowing a guidewire to freely move axially through the device 20.

According to an embodiment of the present invention, the compliant balloon 5 can be inflated by means of any fluid component, including but not limited to saline solution, blood, foam, liquid polymer that can change its proprieties becoming rigid. This fluid will act as the long-term shape setting, sealing and occluding component of the chronic device 20. The balloon 5 act as acute shape setting, sealing, and as occluding component of the chronic device 20. The implant catheter 14 and the inflation port 3 may contain specific channels, valves and membranes designed to be compatible with the fluid considered, including filter membranes that can be permeable to blood in the case blood is used as filling fluid of the balloon 5.

Moreover, the frame allows longitudinal adjustment of the balloon 5 to enhance device 20 stability and defect occlusion. A locking wire is passing into a locking mechanism 1, within the central lumen 6 and is connected to the distal disk 20. When an actuating wire is placed within the central lumen 6, passing into a locking mechanism 1 in the proximal end of the device 20 and is connected to the distal disk 10, after longitudinal variation of the device 20 dimension by means of change in the distance of the two disks 10 and 4, and after its release from the distal disk 10, the locking mechanism is activated securing the locking wire within its structure, to maintain fixed the distance between the two disks 10 and 4. The actuating wire may be pulled directly by the user, in which case the axial movement of the actuating wire pulls the distal disk 10 in the proximal disk 4 direction. Alternatively, the actuating wire may be rotated by the user, in which case it engages a screw mechanism placed within the locking mechanism 1, so that rotating the wire it pulls the distal disk 10 in the direction of the proximal disk 4 and causes shortening of device 20.

The disks 4, 10 can have a round shape, an elliptical shape or a flower-like shape, an asymmetrical shape or any other shape as necessary or appropriate for proper cardiovascular defects occlusion and device stabilization.

In some embodiments, the frame may be designed to have a limited confirmability, to create a tapered shape to provide asymmetrical confinement to the balloon 5, for example, tapered at the distal end. The frame may have a generally conical, or frusto-conical shape, cylindrical shape, or any other shape as necessary or appropriate.

FIG. 1b and 1c show side elevational views of the device 20 illustrated in FIG. 1a.

FIGS. 2a to 5c, illustrate further optional features that may be provided in conjunction with the device 20 as presented in the embodiment of FIGS. 1a to 1c. In order to avoid repetitions, only those features differing from the device described above will be addressed. Like reference numbers denominate the same or corresponding features.

As further shown in FIG 2a the frame may be formed by two proximal 4 and distal 10 plastic or metallic deformable disks, connected by more than one strut 11, which may have any suitable form, passing outside and tapering the balloon 5 component. Such embodiment may allow a cage-like structural confinement of the balloon 5 within its assembly, to avoid unnecessary interference of the device 20 with the body tissue or with implanted prostheses and to provide anchoring support of the device 20 within the cardiovascular defect. In this embodiment of the invention frame may have 2, 4, 6, 8, 10, 12 or any other suitable number of struts.

In some embodiments of the invention, the struts 11 forming the frame may differ in wall thickness and/or width along their entire length or a section thereof. As such, a strut 11 may have a first section that is wider than a second section. In other embodiments, a middle or a distal end section of a strut 11 may be provided with a larger or smaller wall thickness and/or strut width. Varying the wall thickness and/or the strut 11 width can be determined the frame radial stability.

FIG. 2b and 2c show side elevational views of the device 20 illustrated in FIG. 2a.

As illustrated in FIG 3a the frame may be formed the two proximal 4 and distal 10 plastic or metallic deformable disks, connected by one strut 12 passing outside and tapering the balloon 5 component.

FIG. 3b and 3c show side elevational views of the device 20 illustrated in FIG. 3a.

As further shown in FIG. 4a, longitudinal adjustment of the device 20 may be achieved having the locking wire designed as ratchet mechanism 13 that is placed at the proximal disk 4 level and is connected to the actuating wire. This mechanism allows longitudinal adjustment of the device 20 in one way, inhibiting movement in the other direction, so the distal and proximal plates can only come closer, before device 20 release form the implant catheter 14, as shown in FIG. 5a.

FIG. 4b and 4c show side elevational views of the device 20 illustrated in FIG. 4a.

FIG. 5b and 5c show side elevational views of the device 20 illustrated in FIG. 5a, equivalent to the FIG. 4a after the ratchet component actuation and longitudinal shortening.

FIG. 6 depicts a perspective view of the device 20 illustrated in FIG 2a, and of its main components, when connected with the implant catheter 14 comprising a multiple knobs delivery system handle 18.

The implant catheter 14 allow the introduction of the device 20 through the cardiovascular system to a defect in the cardiovascular apparatus, to deploy chronic implant 20 to seal the defect and maintain the occlusion.

The implant catheter 14 is connected to the device 20 through a connection element 1. It comprises within its steerable catheter the device 20, in its deflated not expanded form, and all the components and passage to allow controllable device 20 exposure, inflation, deflation, longitudinal adjustment retrievability and release at the end of the implantation.

Device 20 exposure is controlled by the implant knob 16 in the delivery system handle 18.

It allows the course of the guidewire, used to guide the device 20 to the targeted defect, and of the actuating wire, used to adjust the length of the device 20, within its structure and within the device 20 central lumen 6.

It includes the mechanisms to inflate and deflate of the implant from the balloon 5 inflation port 19 in the handle 18.

It features steerability capability to achieve good positioning of the occlusion device 20 in the cardiac defect, controlled by the steering knob 15 including steering limiter within the delivery system handle 18. The steering capability will allow either anterograde approach from the venous groin to the inferior vena cava, to the right atrium, to the left atrium, or retrograde from the arterial groin to the left ventricle, and be to have the device 20 implanted by any of the techniques known in the art.

In another configuration, the implant catheter 14 is flexible instead that steerable.
The balloon 5 implant is one balloon implant fully compliant, where the percentage a balloon v changes in shape, radially and longitudinal, as the pressure and/or the volume of fluid increases in the balloon 5, above the pressure and/or volume necessary for the balloon to reach the minimum targeted shape.

The balloon 5 may be made from any suitable biocompatible material includ-ing polycaprolactone (PCL), Polyglycolic acid (PGA), polylactic acid (PLA), polydioxanone (PDO, PDS).

The frame, comprising the distal 10 and proximal 4 disks and the plethora of struts 9, 11, 12 within the balloon 5 embodiment, has plastic or metallic deformable characteristics, and may be made from any other suitable biocompatible material including stainless steel, titanium, nitinol, tantalum, gold, platinum iridium, tungsten, alloys of any of the above-mentioned met-als, including platinum-iridium alloys, cobalt-chromium alloys, nickel-titanium alloys and nickel-titanium-platinum alloys. Alternatively, it may be made of polymer, including polyester and polycarbonate copolymers, and any metal or polymer or combination of polymer(s) and metal(s) able to soft plastic deformation. Suitable materials include biodegradable materials that are also biocompatible, intending a material that undergoes breakdown or decomposition into non-significant compounds as part

of a normal biological process. Suitable biodegradable materials include polylactic acid, polyglycolic acid (PGA), collagen or other connective proteins or natural materials, polycaprolactone, hyaluronic acid, adhesive proteins, co-polymers of these materials as well as composites and combinations thereof and combinations of other biodegradable polymers.

The frame and the balloon of the device 20 according to the invention may be fabricated in different sizes, as necessary or appropriate for use in different sizes of cardiovascular defects or other suitable areas of the body.

Within the initial configuration of the device 20 and implant catheter 14, to allow the device to be introduced in the patient's body, the device 20 is premounted not expanded within the implant catheter 14, and the entire assembly is sterilized.

List of Reference Numerals

1	connection
2	locking mechanism
3	inflation port
4	proximal disk
5	balloon
6	foldable balloon lumen
7	guidewire lumen
8	locking wire
9	single internal strut
10	distal disk
11	multiple external struts
12	single external strut
13	ratchet mechanism
14	implant catheter
15	steering knob
16	implant advancement and release knob
17	disk actuating knob
18	delivery system handle
19	balloon inflation port
20	occlusion device
105a	distal guide opening
105b	proximal guide opening
106	guidewire
107	catheter device

Claims

1. An occluder device (20) for occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue, the occluder device comprising:
   - a compliant balloon (5) defining a fluid-tight balloon chamber and provided with a balloon channel (7) forming a longitudinal passage from a proximal side (B2) to a distal side (B1) of the balloon;
   - a tip element (10) disposed at the distal side of the balloon, a base element (4) disposed at the proximal side of the balloon, and connecting means comprising at least one connecting strut (9, 11, 12) attached to the tip element and to the base element, the tip element and the base element each having a guide opening (105a, 105b) substantially coaxial to the balloon channel (7) for slidingly receiving therein a guidewire (106) for the device;
   - elongated actuating means disposed longitudinally slidable in the balloon channel (7), releasably connectable to the tip element (10), and longitudinally slidable with respect to the base element (4);
   - locking means (2, 13) for maintaining a predetermined distance between the tip element (10) and the base element (4);
   - proximal connector means (1) for releasably connecting the occluder device (20) to correspondingly configured distal connector means of a catheter device (107);
   - the balloon (5) comprising a fluid port (19) for filling and unfilling a fluid into and from the balloon chamber.

2. The occluder device according to claim 1, wherein the compliant balloon (5) is made of a compliant material selected from polycaprolactone (PCL), polyglycolic acid (PGA), polylactic acid (PLA) and polydioxanone (PDO or PDS).

3. The occluder device according to claim 1 or 2, wherein the connecting means comprise a single connecting strut (9) disposed within the balloon channel (7).

4. The occluder device according to claim 1 or 2, wherein the connecting means comprise a single connecting strut (12) disposed outside the balloon (5).

5. The occluder device according to claim 1 or 2, wherein the connecting means comprise multiple connecting struts (11) disposed in cage-like manner outside the balloon (5).

6. The occluder device according to one of the preceding claims, wherein the locking means are configured as a ratchet mechanism (13) whereby said predetermined distance between the tip element (10) and the base element (4) is selectable from a range of distances.

7. The occluder device according to one of the preceding claims, wherein the elongated actuating means are configured as actuating wire.

8. The occluder device according to one of the preceding claims, wherein the fluid port (19) is configured as a self-closing valve when it is not connected to a corresponding fluid transfer system (19).

9. An occluder system, comprising an occluder device (20) according to one of the preceding claims and a catheter device (107) cooperating therewith, the catheter device comprising an implant catheter tube (14) connected to an operating handle, the implant catheter tube (14) comprising a longitudinal passageway for a guidewire (106), distal connector means for releasably connecting the catheter device (107) to the correspondingly configured proximal connector means (1) of the occluder device (20), and a fluid transfer system (19) releasably connectable to the corresponding fluid port (19) of the occluder device (20).

10. A method of occluding a cardiovascular defect or a gap between a medical device and adjacent body tissue by means of an occluder system as defined above comprises the following steps:

- providing the occluder system with the occluder device connected to the catheter device;
- positioning the occluder device in a compressed, longitudinally extended form thereof in a region to be occluded;
- inflating the balloon by filling a fluid into the balloon chamber;

- expanding the balloon in radial or lateral direction by shortening the distance between the tip element and the base element to said predetermined distance and locking said distance;
- releasing the occluder device from the catheter device.

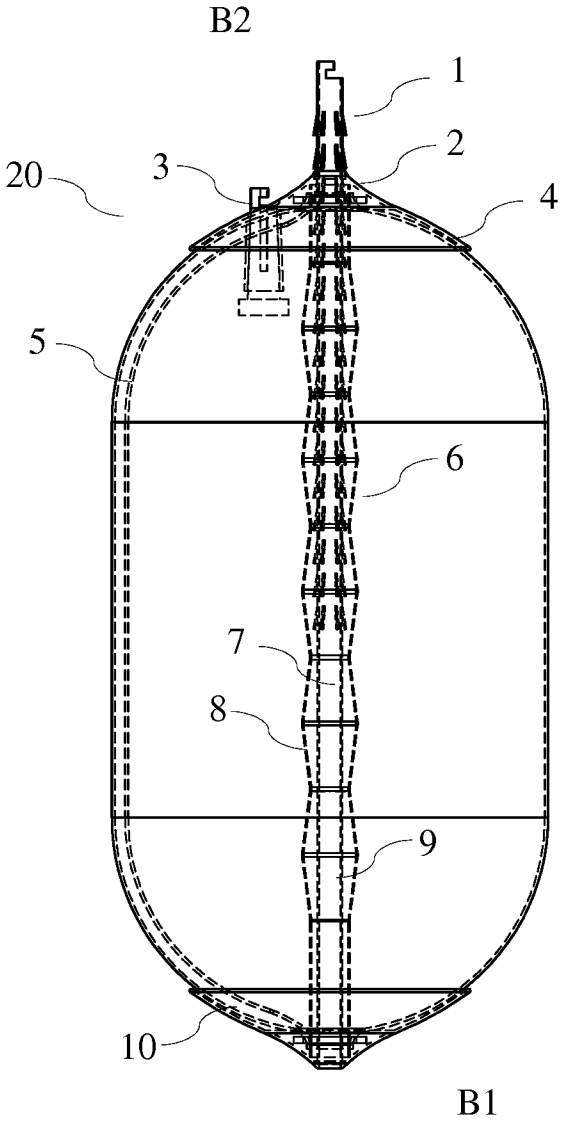

FIG. 1a

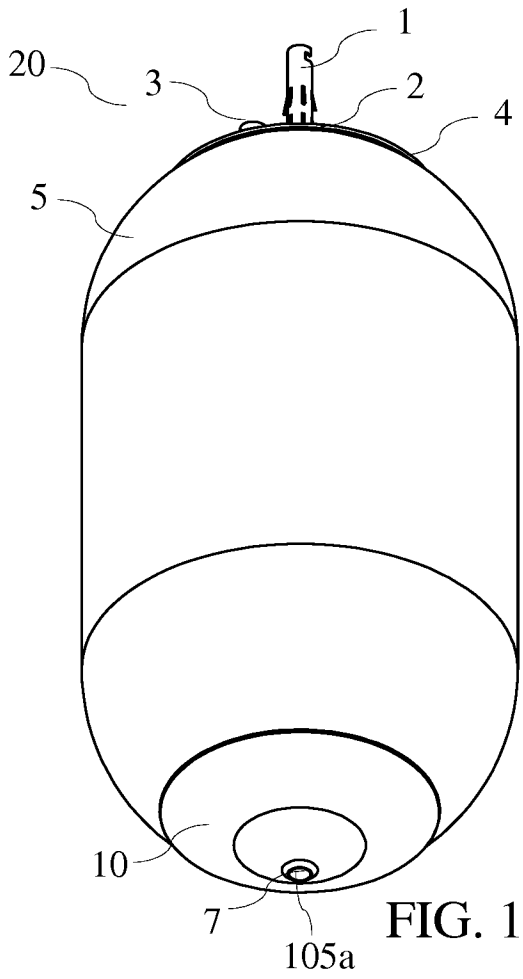

FIG. 1b

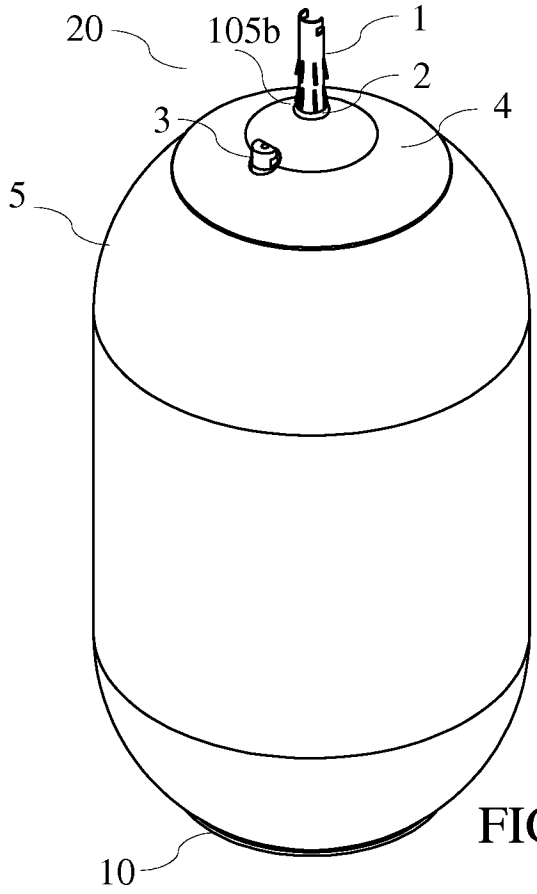

FIG. 1c

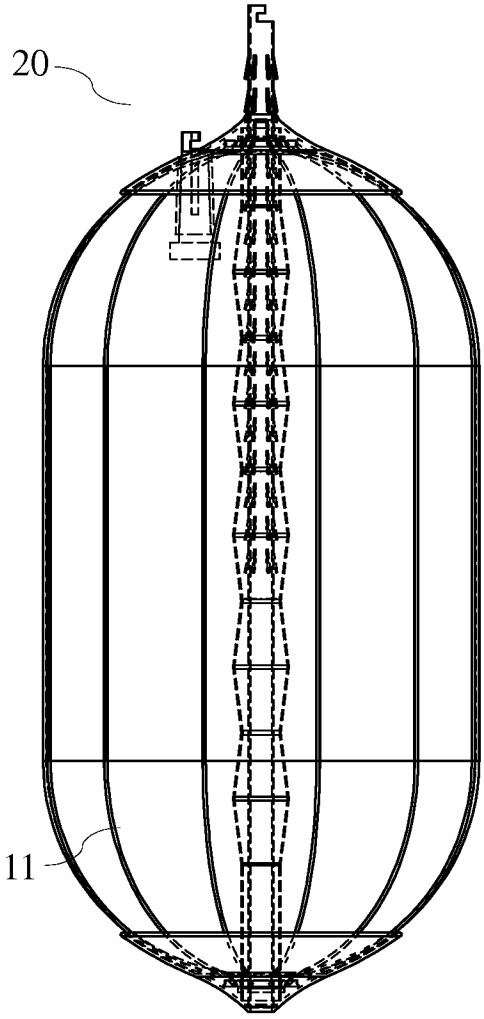

FIG. 2a

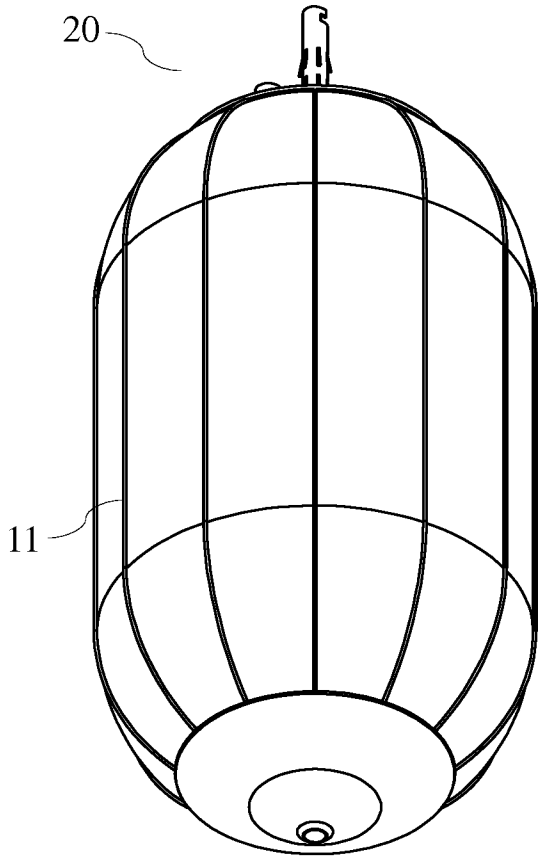

FIG. 2b

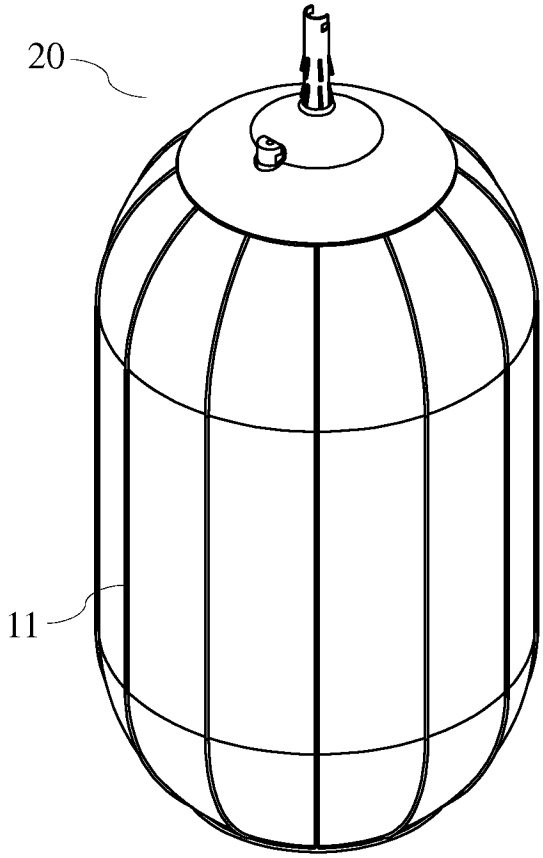

FIG. 2c

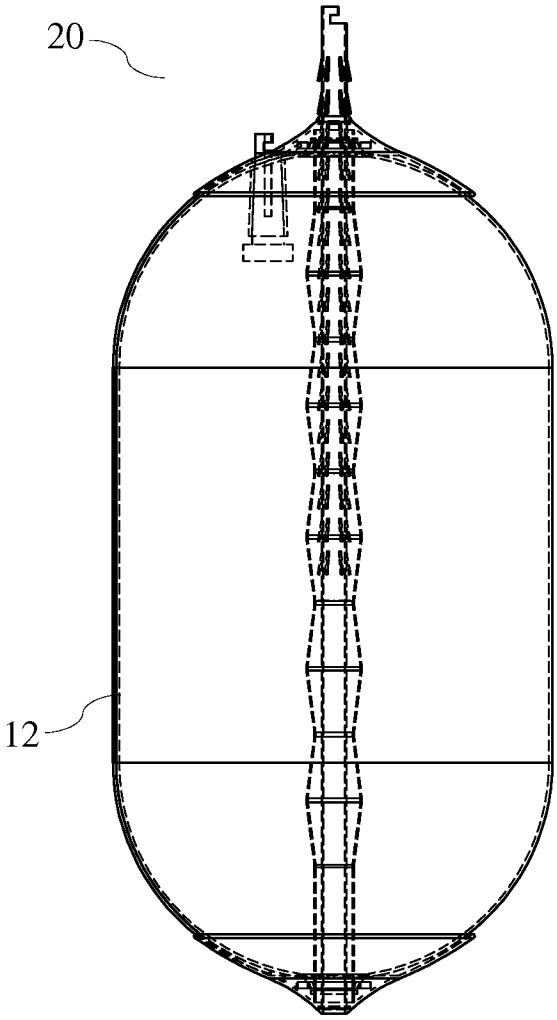

FIG. 3a

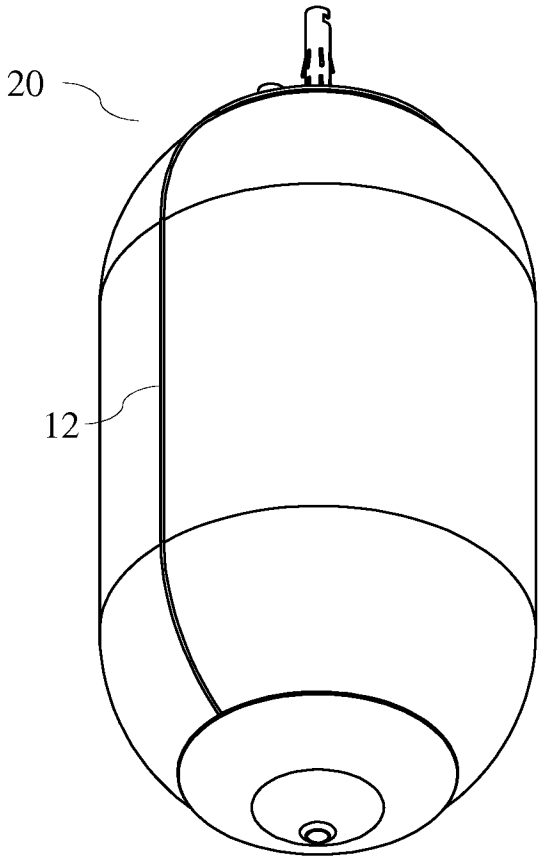

FIG. 3b

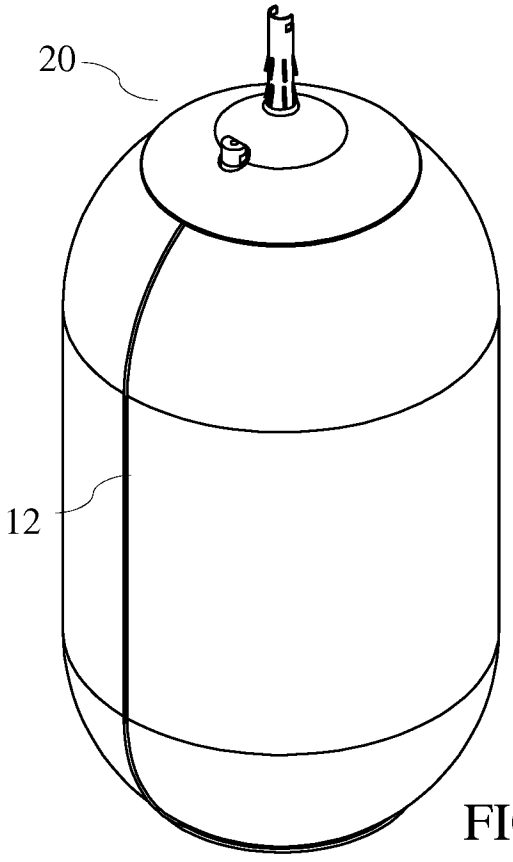

FIG. 3c

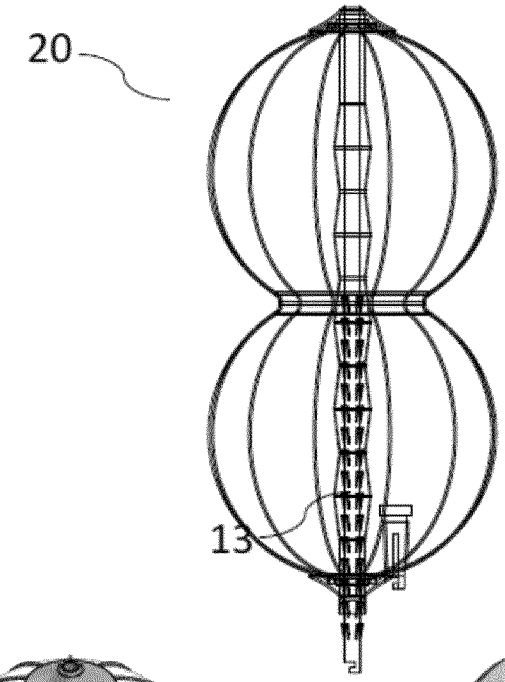

FIG. 4a

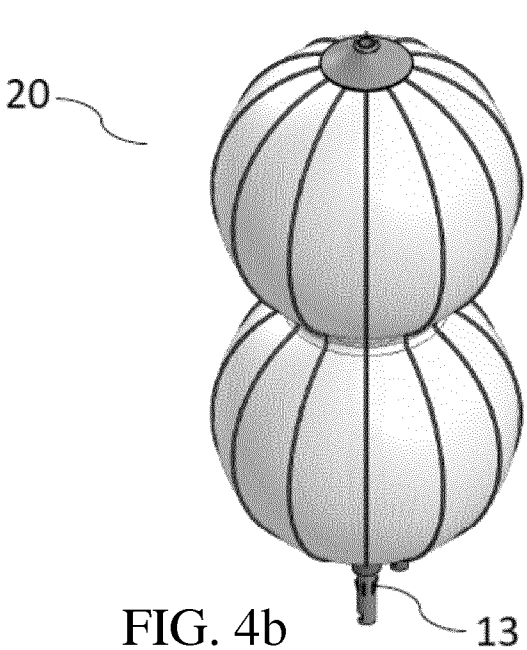

FIG. 4b

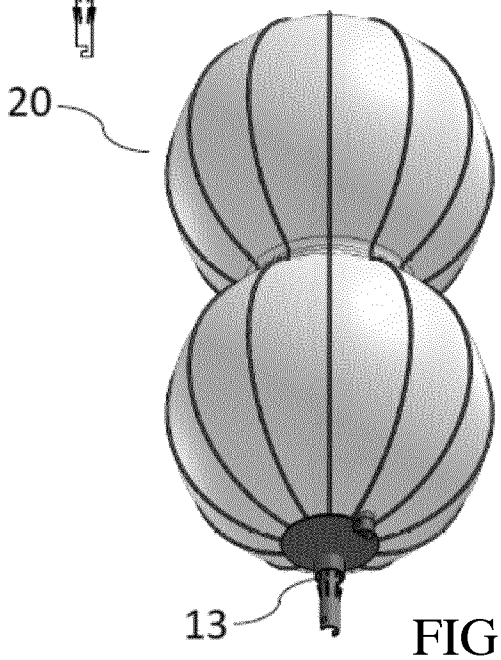

FIG. 4c

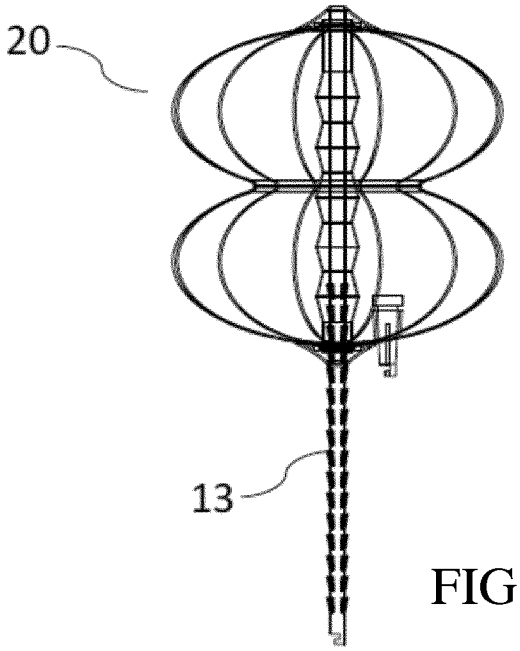

FIG. 5a

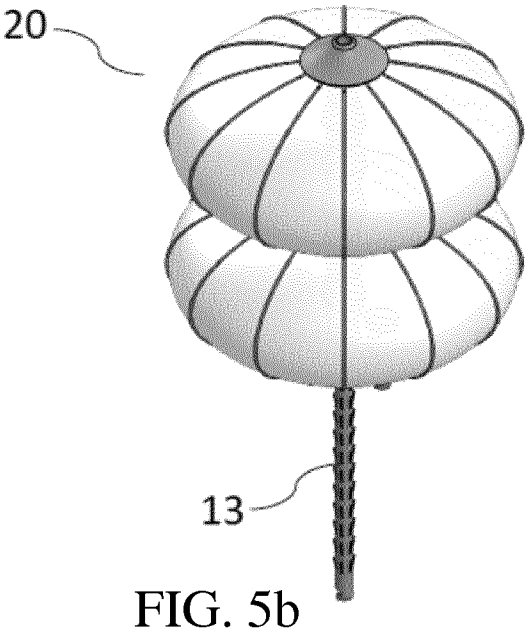

FIG. 5b

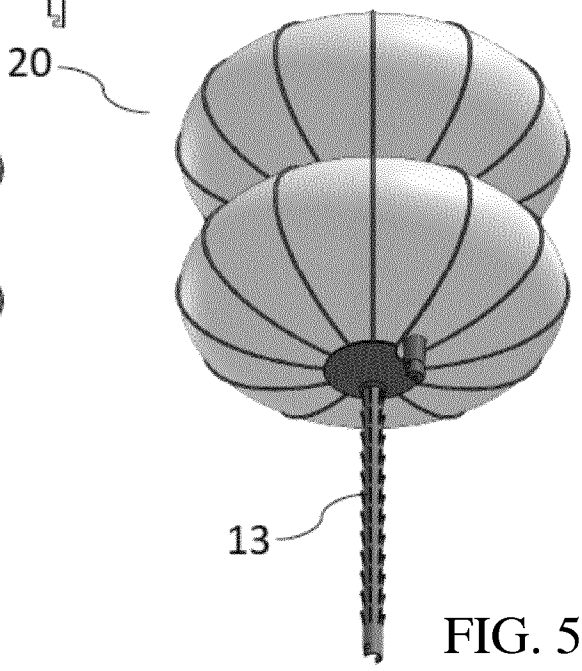

FIG. 5c

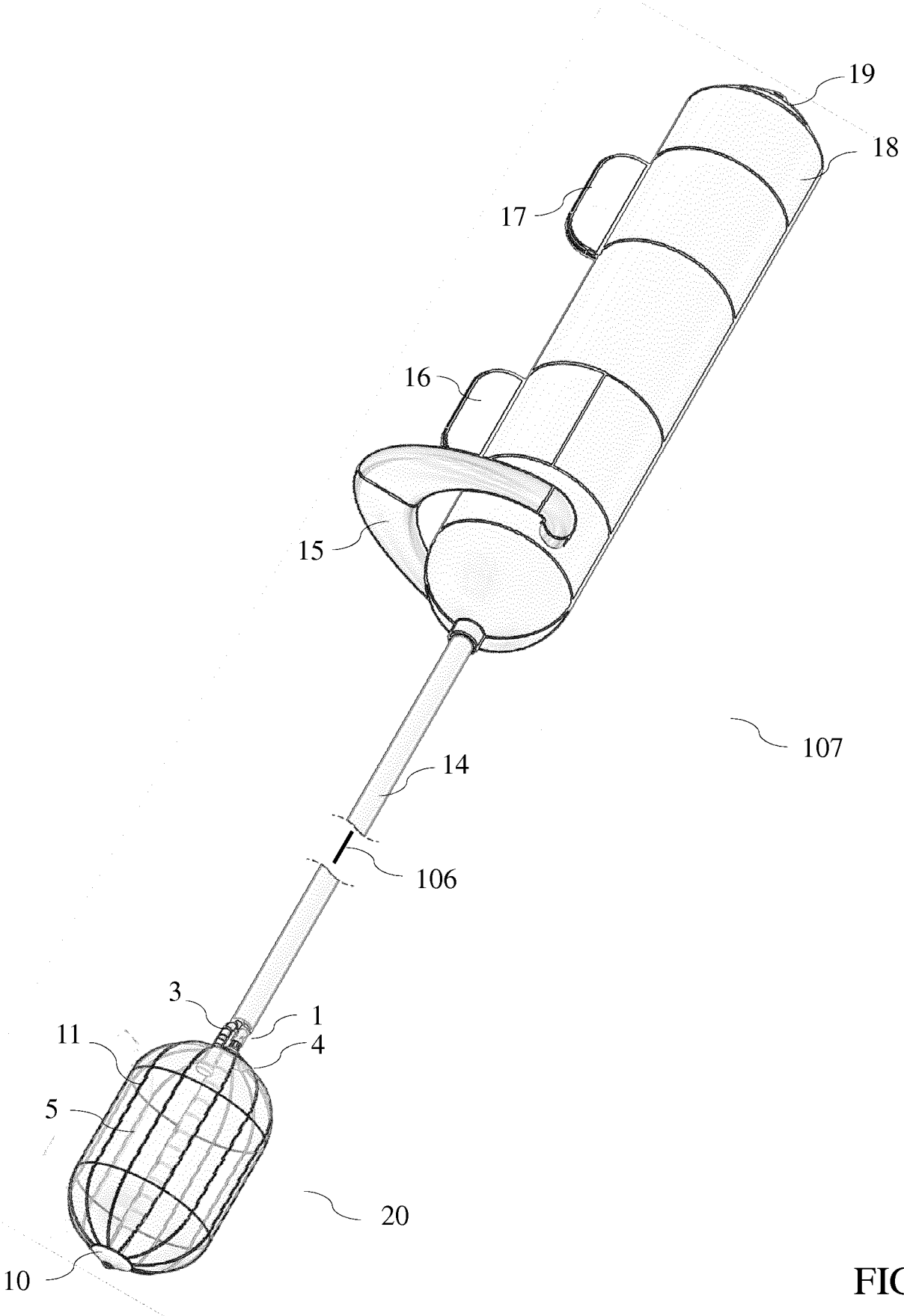

FIG. 6

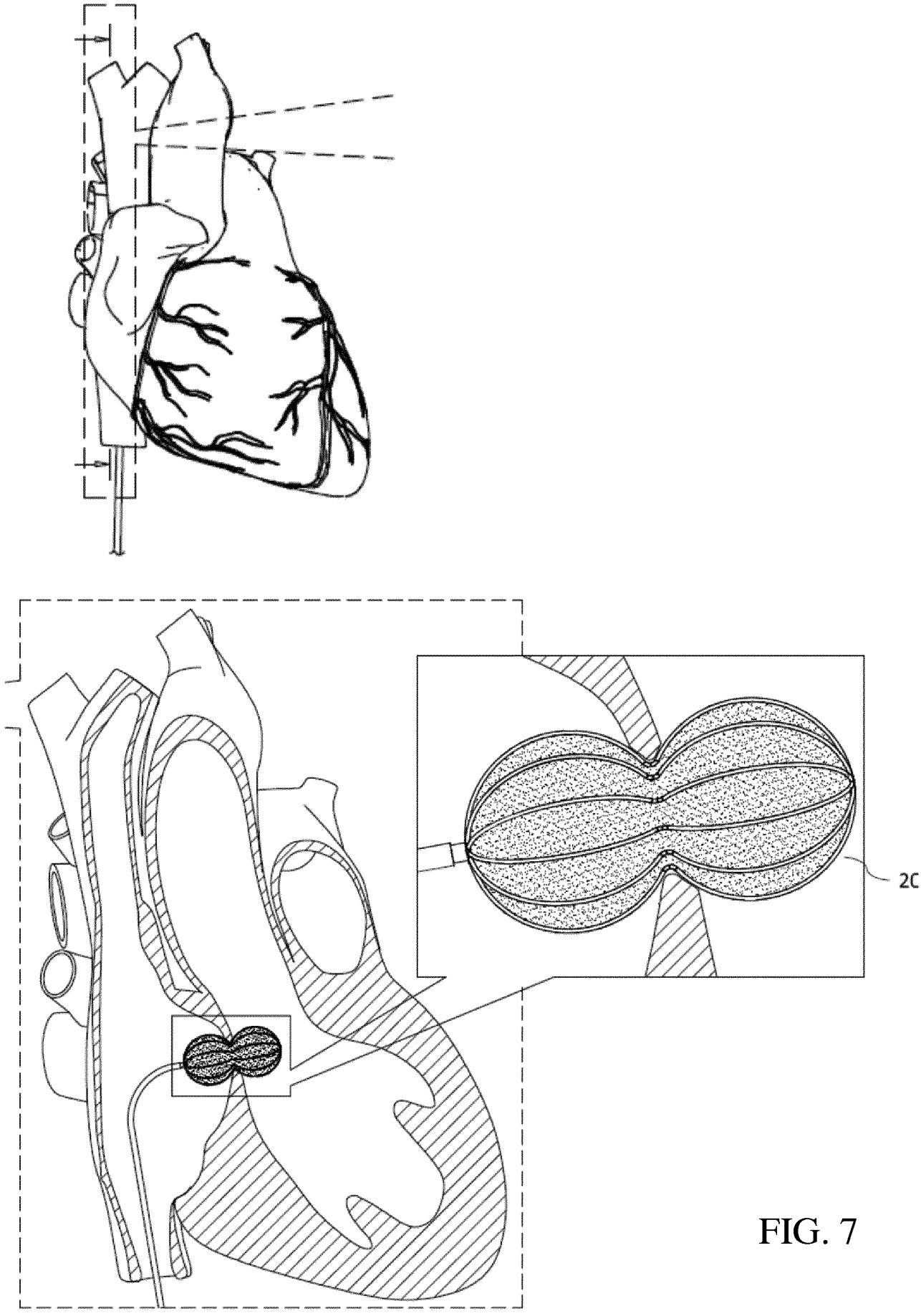

FIG. 7

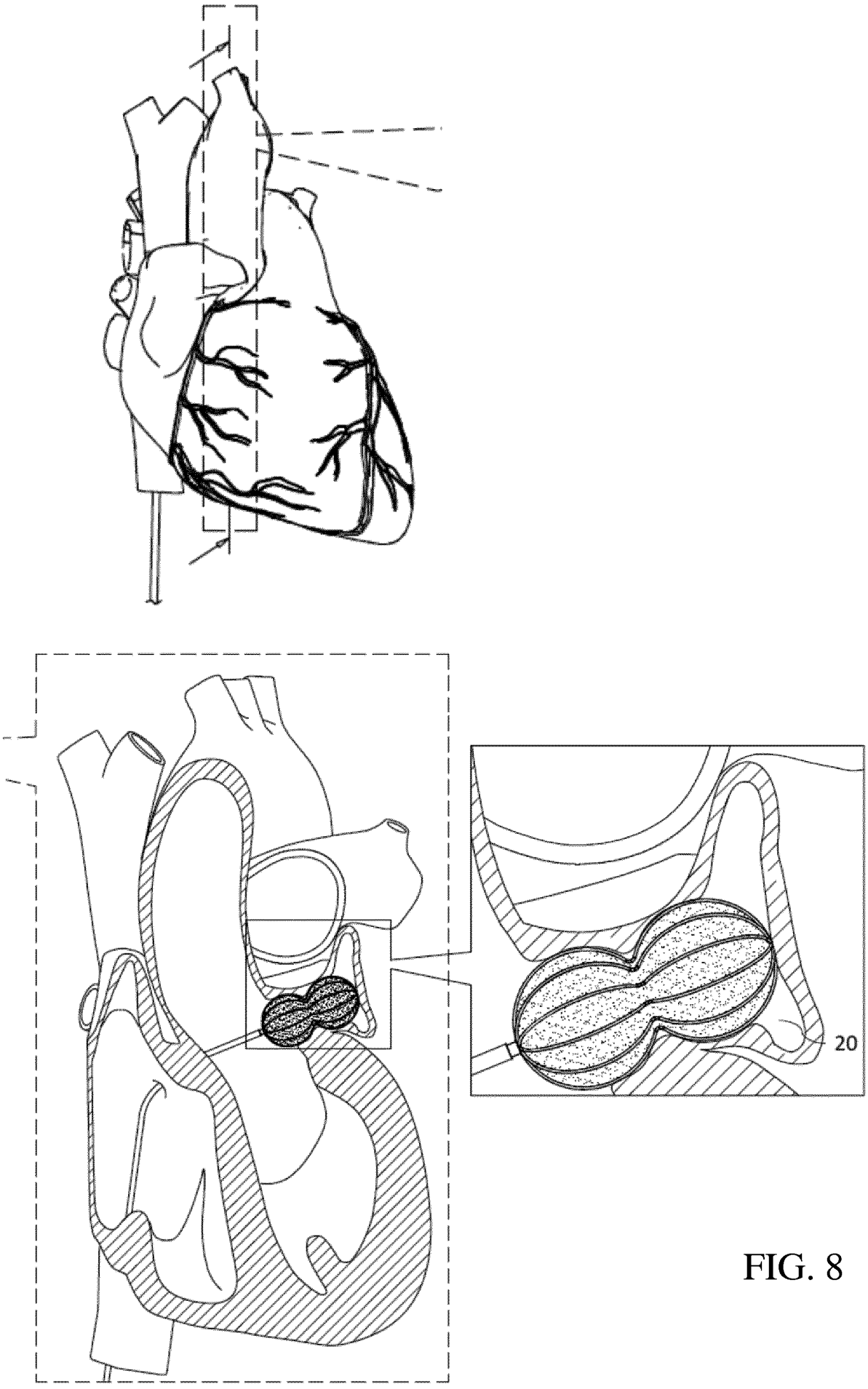

FIG. 8

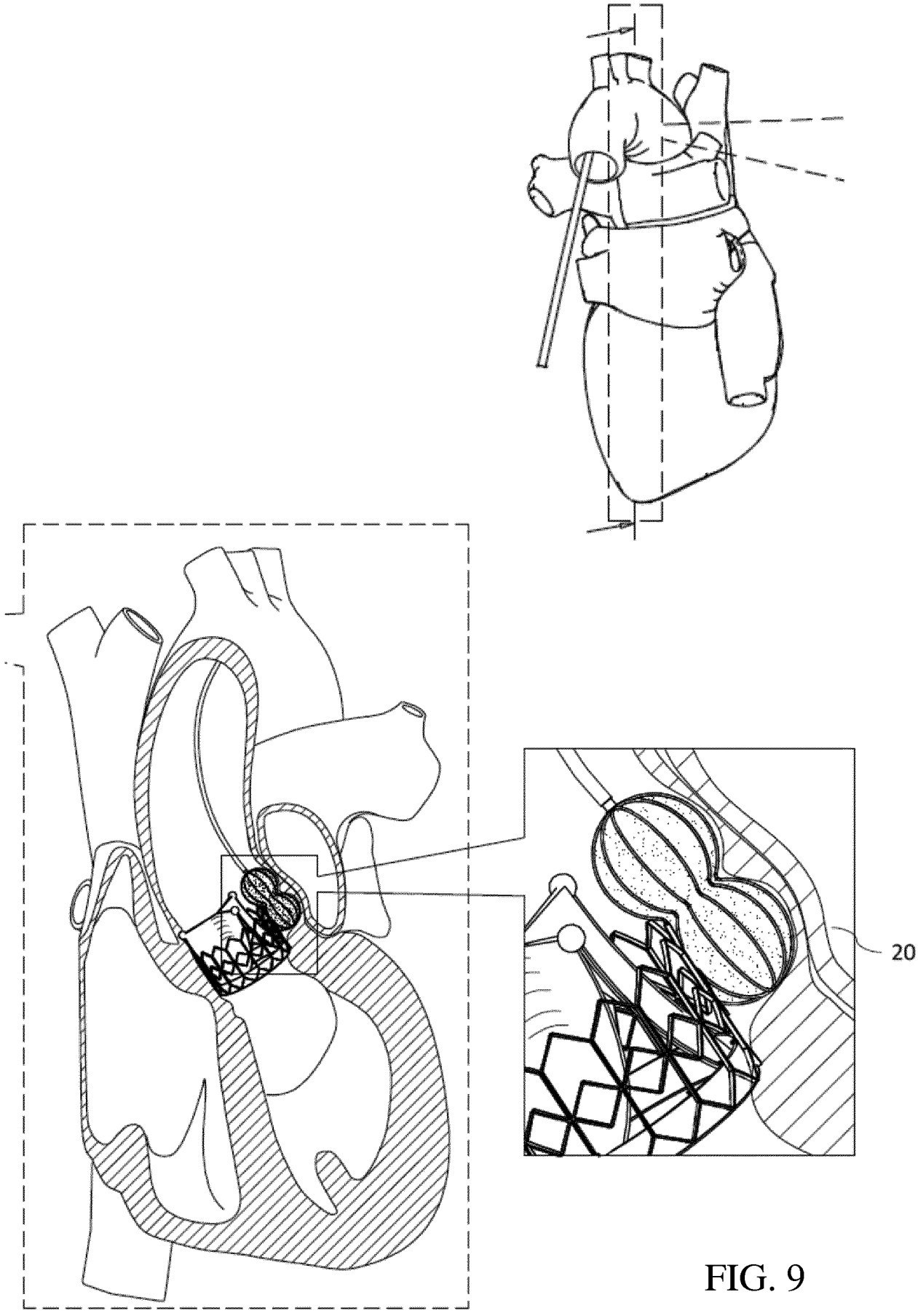

FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/075716

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B17/12 A61B17/00
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

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.
X Y	US 2012/078295 A1 (STEINER CLAUDIO [CH] ET AL) 29 March 2012 (2012-03-29) paragraph [0046] - paragraph [0072] figures 2,5-8	1,5,6,9 2,8
Y A	WO 95/32018 A1 (TEIRSTEIN PAUL S [US]) 30 November 1995 (1995-11-30) cited in the application the whole document	8 1
Y	US 2005/288706 A1 (WIDOMSKI DAVID R [US] ET AL) 29 December 2005 (2005-12-29) paragraph [0011]	2
A	WO 00/12169 A1 (APPLIED MED RESOURCES [US]) 9 March 2000 (2000-03-09) page 5, line 27 - page 8, line 14 figures 1-17	1

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2018	04/12/2018

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

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2018/075716

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 1 891 902 A1 (CARAG AG [CH]) 27 February 2008 (2008-02-27) the whole document -----	1

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2018/075716

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.: 10
because they relate to subject matter not required to be searched by this Authority, namely:

see FURTHER INFORMATION sheet PCT/ISA/210

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.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 10

Claim 10 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 39.1(iv) PCT as it relates to a surgical method performed on the human body. In particular, the steps of inflating the balloon, expanding the balloon and releasing the occluder device are understood to occur in the patient's body at the site of treatment and therefore entail a substantial health risk. Therefore, claim 10 has not been searched.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2018/075716

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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