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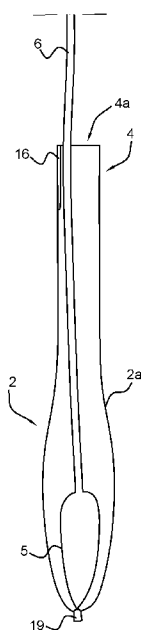
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(54) Title: CARDIAC ASSIST DEVICE

Fig. 12



(57) Abstract: A cardiac assist device (1) with a cup element (2), an inner balloon element (5) and a tube element (6). The cup element (2) has a cup wall (2a), one or more in-flow openings (3), and an outflow element (4) having an aperture (4a). The inner balloon element (5) is positioned inside the cup element (2) free from the outflow element (4). The tube element (6) is arranged for inflating and deflating the inner balloon element (5) during operation. During operation in a pumping operational mode, the combination of first material, dimensions of the cup wall (2a), and dimensions of the outflow element (4) provides a containment force by the cup element (2) counteracting an outward directed force of the inner balloon element (5).

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Cardiac assist device

Field of the invention

The present invention relates to a cardiac assist device comprising a cup element, an inner
5 balloon element and a tube element.

Background art

US Patent Publication US-B-5,169,378 describes an intraventricular assist pump. The pump comprises a body pump, or external chamber, having a double lumen wall, that is expansible
10 and of variable rigidity, i.e. an inflatable but static outer cup. In operation the (inflatable) external chamber is rigid and static during operation. A transvalvular segment, or flexible neck of the pump, is provided that conforms itself to the situation or position of "open" or "closed" of the aortic or pulmonary valves and avoids the need of using a valve in the discharge of blood from the pump. An internal balloon having a progressive wall thickness is provided and causes a sequential rhythm
15 of inflation and deflation.

International patent publication WO2015/131879 discloses a catheter device for conducting a fluid, in particular a bodily fluid, in a directed manner. The catheter device is described as being positioned in the aorta, and comprises a shell having an interior and comprising a frame, wherein the shell comprises at least three openings and is designed as a line for the fluid in a region between
20 a first opening and a second opening, and wherein a non-return valve is arranged at the second opening. During operation, the shell is in an expanded state and fully rigid (e.g. implemented as a stent). The non-return valve comprises a valve film, which is at least partially fastened to the shell such that the second opening can be completely covered by the valve film.

International patent application WO2020/022905 discloses a heart support device for
25 circulatory assistance having a chamber body with a first opening. A dynamic volume body is provided for increasing and decreasing the interior volume of the chamber body. The outflow of blood during operation is directed using a directional flow structure.

Summary of the invention

30 The present invention seeks to provide an improved cardiac assist device allowing proper and efficient operation.

According to the present invention, a cardiac assist device as defined above is provided, in which the cardiac assist device comprises a cup element having a cup wall comprising a first material and defining an inner cup volume, one or more in-flow openings arranged in the cup wall
35 to allow a first fluid (such as blood) to flow into the cup element during operation, and an outflow element connected in fluid communication with the cup wall and having an aperture for expelling the first fluid during operation. An inner balloon element is present having a balloon wall comprising

a second material and defining an inner balloon volume, the inner balloon element being positioned inside the cup element free from the outflow element. A tube element is provided in fluid communication with the inner balloon element for inflating and deflating the inner balloon element during operation, creating a pumping operational mode and a filling operational mode, respectively.

5 During operation in the pumping operational mode, the combination of first material, dimensions of the cup wall, and dimensions of the outflow element provides a containment force by the cup element counteracting an outward directed force of the inner balloon element.

The present invention embodiments allow a very good and efficient operation of the cardiac assist device with a very limited number of components.

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Short description of drawings

The present invention will be discussed in more detail below, with reference to the attached drawings, in which

Fig. 1A and 1B show cross sectional views of a first embodiment of the present invention;
15 Fig. 2A-2D show cross sectional views of the second embodiment of the present invention;
Fig. 3A shows a perspective view of a third embodiment of the present invention, and Fig. 3B shows a cross sectional view of an alternative embodiment of the skeleton structure for the embodiment shown in Fig. 3A;

Fig. 4 shows a side view of a further embodiment of the cardiac assist device according to
20 the present invention,

Fig. 5 shows a cross sectional view along the line V-V in Fig. 4,
Fig. 6 shows a cross sectional view along the line VI-VI in Fig. 4,
Fig. 7A and 7B show a cross sectional view along the line VII-VII in Fig. 4 in two operational
states,

25 Fig. 8A-C show perspective views of (parts of) yet a further embodiment of the present invention,

Fig. 9 shows an exploded perspective view of one-way valves used in a further embodiment of the present invention,

Fig. 10 shows a side view of an even further embodiment of the cardiac assist device
30 according to the present invention,

Fig. 11 shows a perspective view of an embodiment of the cardiac assist device with details on retrieve elements, and

Fig. 12 shows a cross sectional view of an embodiment of the present invention cardiac assist device.

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Description of embodiments

The present invention seeks to provide an intra-lumen cardiac assist device that more closely approximates the natural function of the heart. The resulting cardiac assist device according to the present invention embodiments can function to provide circulatory assistance in a patient by

pumping blood from a cardiovascular lumen (e.g. the left ventricular chamber) with a sufficiently high stroke volume and efficient placement.

In the present invention embodiments, two pumping mechanisms are implemented that co-operate and make the functioning of the cardiac assist device more efficient.

5 Fig. 1A and 1B show two cross sectional views of a first embodiment of the present invention cardiac assist device 1, Fig. 1A showing the cardiac assist device 1 at the start of a pumping operational mode, and Fig. 1B showing the cardiac assist device 1 at the start of a filling operational mode, wherein the two operational modes are alternating. The cardiac assist device 1 e.g. has a generally ellipsoid or ovoid outer shape, with a longitudinal axis of symmetry.

10 The cardiac assist device 1 comprises a cup element 2 and an inner balloon element 5, the inner balloon element 5 inflating during the pumping operational mode and deflating during the filling operational mode. The inner balloon element 5 has a balloon wall 5a, and the cup element 2 has a cup wall 2a, which is provided with inflow openings 3, allowing a first fluid (blood) to enter the space between cup wall 2a and balloon wall 5a. The cup element 2 further comprises an outflow element
15 4 connected in fluid communication with the cup wall 2a and having an aperture 4a for expelling the first fluid during operation. A tube element 6 is present in fluid communication with the inner balloon element 5, and serves for inflating and deflating the inner balloon element 5 during operation, creating a pumping operational mode and a filling operational mode, respectively. As shown in Fig. 1A, the cup element 2 has an inner cup volume V_{c1} , which is substantially the same during the
20 pumping operational mode and the filling operational mode. The inner balloon element has an initial inner volume V_{b1} at start of pumping operational mode as shown in Fig. 1A and an expanded inner volume V_{b2} at the start of the filling operational mode as shown in Fig. 1B. The obtainable stroke volume SV of the cardiac assist device 1 of this embodiment is thus $V_{b2}-V_{b1}$.

To obtain this pumping and filling operational modes, the one or more inflow openings 3
25 need to be closed off during the pumping operational mode, and open during the filling operational mode. This may be achieved as described below, or by a further group of embodiments, wherein the one or more inflow openings 3 comprise one-way valves.

Furthermore, in a group of embodiments, the outflow element 4 has a tube like structure. The tube like structure may be dimensioned long enough to extend through the aortic valve when
30 the cardiac assist device 1 is positioned in the left ventricle (e.g. having a length of at least 20mm), ensuring the aperture 4a is in the aorta during operation. Additionally or alternatively, the outflow element 4 is a directional flow element. This allows to obtain a directed flow of first fluid during the pumping operational mode, e.g. directed towards the aortic valve during operation.

The cardiac assist device 1 of the present invention, in fact combines two pumping
35 mechanisms in order to obtain a small as possible outer volume of the cardiac assist device 1 with a high as possible stroke volume, with an unobstructed as possible outflow of first fluid through the outflow element 4, This is made possible by the (dynamic) balance of forces during the alternating pumping operational mode and filling operational mode.

More specifically, during operation in the pumping operational mode, the combination of a
40 first material of the cup wall 2a, dimensions of the cup wall 2a, and dimensions of the outflow

element 4 provides a containment force by the cup element 2 counteracting an outward directed force of the inner balloon element 5 being inflated. These structural features of the cup wall 2a (first material properties, dimensions of cup wall 2a (thickness, radius, surface area), and dimensions of the outflow element 4 (area of opening 4a, diameter and/or length of outflow element 4) determine the containment force. It is noted that further parameters may be relevant during operation, such as the speed in volume change of the stroke volume, the resistance over the outflow element 4, the viscosity of the first fluid, and/or back pressure from the outside environment of the cardiac assist device, (such as the aortic pressure in case of ventricular assist type of use of the cardiac assist device 1). However, these can be taken into account when setting the structural features of the cup element 2.

Furthermore, during the filling operational mode, the structure and material of the cup element 2 ensures that the shape of the cup wall 2a remains substantially the same (i.e. with inner cup volume V_{c1}), counteracting a force generated by the deflating inner balloon element 5. It is noted that further parameters in this case may be relevant during operation, such as the resistance over the total inflow surface area of the inflow openings 3 in the cup wall 2a, the speed of deflation of the inner balloon element 5, and the viscosity of the first fluid. Again, these further parameters can be taken into account when selecting the structural features of the cup element 2 for the overall design of the cardiac assist device 1.

Thus, in general wording, the present invention provides a cardiac assist device 1 comprising a cup element 2 having a cup wall 2a comprising a first material and defining an inner cup volume V_{c1} , one or more in-flow openings 3 arranged in the cup wall 2a to allow a first fluid to flow into the cup element 2 during operation, an outflow element 4 connected in fluid communication with the cup wall 2a and having an aperture 4a for expelling the first fluid during operation. An inner balloon element 5 is present having a balloon wall 5a comprising a second material and defining an inner balloon volume V_{b1} ; V_{b2} , the inner balloon element 5 being positioned inside the cup element 2 free from the outflow element 4, and a tube element 6 in fluid communication with the inner balloon element 5 for inflating and deflating the inner balloon element 5 during operation, creating a pumping operational mode and a filling operational mode, respectively. During operation in the pumping operational mode, the combination of first material, dimensions of the cup wall 2a, and dimensions of the outflow element 4 provides a containment force by the cup element 2 counteracting an outward directed force of the inner balloon element 5.

In a group of embodiments, during the pumping and filling operational modes, the cup element 2 has a substantially constant inner cup volume V_{c1} .

In the exemplary embodiment shown in Fig. 1A and 1B, furthermore, the cup element 2 is provided with a skeleton (or reinforcement) structure 7b, e.g. as an integral part of the cup wall 2a, providing rigidity to the cup wall 2a. In other words, in further embodiments, the cup element 2 comprises a skeleton structure 7a, 7b integrated with the cup wall 2a.

In a further group of embodiments, the cup element 2 has a dynamic inner cup volume V_{c1} - V_{c2} as shown in the exemplary embodiment shown in cross section in Fig. 2A-2D. The cup wall 2a will co-operate synchronously with the inflating/deflating balloon element 5 during operation, to

obtain an even more effective stroke volume SV. In sequence, Fig. 2a-2D show there are two major actions in the cardiac assist device 1, i.e. in Fig. 2A the cup element 2 is kept fully open (i.e. maximum inner cup volume Vc1) until the inner balloon element 5 is fully deflated and the inner volume is filled with the first fluid via the one or more in-flow openings 3. Fig. 2B then shows the next step in the sequence, wherein the cup wall 2a is contracted (or tightened) to a minimum inner cup volume Vc2, and the inner balloon element 5 is inflated from inner balloon volume Vb1 to Vb2, thereby combining the two forces Fc and Fb for the pumping operational mode. Subsequently, the inner balloon element 5 is allowed to deflate again, filling the inner volume of the cardiac assist device 1 again with the first fluid (filling operational mode), which is continued with an increase of the inner cup volume to its maximum level Vc1 again (Fig. 2D). Then a new cycle can start again.

In one group of embodiments, the varying dynamic volume of the cup element 2 is achieved by proper selection of structural features of the cup element 2, such as choice of first material, dimensions of the cup wall 2a, and dimensions of the outflow element 4.

In a further group of embodiments, this dynamic volume of the cup element 2 is obtained by having a skeleton structure 7a, 7b which is a flexible skeleton structure arranged to control the cup volume during operation. Note that the skeleton structure 7b shown in the exemplary embodiment of Fig. 1A and 1B can also be applied to the exemplary embodiment shown in Fig. 2a-2D.

In a further embodiment, the flexible skeleton structure 7a, 7b comprises hollow channels, which can e.g. be inflated and deflated to obtain the varying inner cup volume Vc1-Vc2. To that end, the hollow channels are in fluid communication with the tube element 6 in a further embodiment. Alternatively, the cardiac assist device 1 further comprises a secondary tube element in communication with the hollow channels. All these components allow operation of the cardiac assist device 1 according to these embodiments with a relatively high pressure, e.g. between 0.5 and 20 bar. As this is higher than prior art systems which operate with an inflation pressure of 0.5-1 bar (see e.g. US patent publication US-B-5,169,378), a quicker and more robust operation of the cardiac assist device 1 is possible.

In order to obtain the containment force counteracting the inflating force of the inner balloon, the skeleton structure 7a, 7b comprises shape-memory material in a further group of embodiments. The shape memory material is e.g. wire shaped, and may comprise nitinol as memory material. E.g. the skeleton structure 7b may then be implemented as a helical wire included in the cup wall 2a, as shown in the embodiment of Fig. 1A and 1B.

Fig. 3A shows a perspective view of yet a further embodiment of the present invention cardiac assist device 1. In this embodiment, the skeleton structure 7b comprises a helical shaped wire element integrated with the cup wall 2a. Fig. 3B shows a cross sectional view of a further embodiment, wherein the skeleton structure 7a, 7b, comprises a spine element 7a arranged along a longitudinal direction of the cardiac assist device 1 and a plurality of rib elements 7b, each of the plurality of rib elements 7b being attached to the spine element 7a on one side thereof. The rib elements 7b are e.g. extending from the spine element 7a in a substantially perpendicular manner, forming a rib-cage type of skeleton structure. An added benefit of this embodiment is that the rib

element 7b can easily fold, allowing more easy entry and exit of the cardiac assist device before being put into operation (e.g. via a vascular catheter into the left ventricle). In an even further alternative embodiment, the spine element 7a and/or rib element 7b may be partially of solid material (e.g. nitinol) and partially open (e.g. hollow polyurethane material).

5 In an even further group of embodiments, the cardiac assist device further comprises a control unit 10 arranged to control fluid flow of a second fluid through the tube element 6 during operation. This allows to inflate/deflate the inner balloon element 5 periodically to obtain the pumping and filling operational modes as described above. The second fluid can be (compressed) air, a gas, a liquid, water, etc. The tube element 6 is e.g. implemented as a catheter (able to
10 transport the second fluid), allowing the use of a remote control of the inflation/deflation of the inner balloon element 5 by a remote pressure source. If present, the hollow channels of the skeleton structure 7a, 7b described above can also be controlled in this manner. E.g. when using a high pressure fluid, the hollow channels will eventually become rigid providing shape consistency of the cup element 2. By adding resistor elements and selecting the inner volumes of hollow channels
15 versus inner balloon 5 dimensions, the same second fluid source and control unit 10 may be used to first inflate the skeleton structure 7a, 7b and subsequently the inner balloon element 5.

In an even further embodiment, the cup element 2 is provided with an inflatable skeleton structure 7a, 7b, wherein the internal volume of the inflatable skeleton 7a, 7b is smaller than the (possible) internal volume of the inner balloon element 5, e.g. 1cc versus 20cc. This allows the
20 inflatable skeleton 7a, 7b and the inner balloon element 5 to be connected to a single (remote) pressure source via the tube element 6, as the lower volume will ensure an inflation of the skeleton structure first, and subsequently inflation of the inner balloon element 5. In order to implement the operational use of the present invention embodiment with a dynamic inner cup volume, in a further embodiment the control unit 10 is arranged to control the inner cup volume V_{c1} ; V_{c2} and the inner
25 balloon volume V_{b1} ; V_{b2} independently.

The control unit 10 may be arranged to apply a specific synchronization timing between inflating/deflating the cup element 2 and inflating/deflating the inner balloon element 5. The cup element 2 may change from inner cup volume V_{c1} to V_{c2} just before, simultaneously with or just after the change of inner balloon volume from V_{b1} to V_{b2} . In a specific embodiment, the maximum
30 inner cup volume V_{c1} may be timed (just) prior to the inflation of the inner balloon element 5, thus ensuring an optimal stroke volume.

Furthermore, in an even further exemplary embodiment, the frequency of pumping may be set by the control unit 10 to obtain an optimal performance. This frequency of pumping may be controlled synchronous to an actual (sensed) heartbeat. Even further, the frequency of pumping
35 may be higher, e.g. a factor of 2-10 higher than the actual heartbeat, to obtain a higher flow of the first fluid.

As shown in the exemplary embodiment of Fig. 3, the tube element 6 is provided in contact with the outflow element 4 along a predetermined length thereof in a further embodiment. This off-centre positioning of the tube element 6 allows a generally unobstructed flow of the first fluid in the
40 outflow element 4, and out of the aperture 4a.

The combination of the cup element 2 and the inner balloon element 5 are adjustable in a further embodiment to a transport mode, in which the maximum diameter of the combination is less than 7mm, e.g. less than 5mm. This e.g. allows to bring the cardiac assist device to the left ventricle via the aorta and a regular catheter system in a reliable and safe manner. The combination is e.g. elongated in the transport mode, and ellipsoid shaped in an operational mode.

In the exemplary embodiment shown in Fig. 3A, the tube element 6 is a multi-lumen (e.g. dual lumen) catheter. One of the lumens 6a is e.g. used for inflation/deflation of the inner balloon element 5, and a further lumen 6b is providing space for a guide wire 8, all along the cardiac assist device 1, or even extending therefrom, e.g. for proper positioning of the cardiac assist device 1 in the left ventricle.

As a further alternative embodiment, the inner balloon element 5 comprises a multi-stage balloon assembly having at least two balloon parts with different rigidity material. The multi-stage balloon assembly is e.g. a shaped balloon, or with a controlled volume expansion (or directional thrust). Even further, the shaped balloon 5 may be positioned with respect to the outflow element 4 such that a directional inflation occurs, from the apex of the cup element 2 towards the outflow element 4. Alternatively, or additionally, the shaped balloon 5 may be dimensioned and positioned to close off the in-flow openings 3 at an early stage of inflation, thereby creating a one-way valve assembly. In other words, one of the two balloon parts is positioned to close off the one or more inflow openings 3 in the pumping operational mode.

Fig. 4 shows a side view of yet a further embodiment of the cardiac assist device 1 according to the present invention having the cup element 2 and outflow element 4, similar to the embodiments described above. In this exemplary embodiment, the skeleton structure 7b is provided as a wire mesh structure, e.g. using nitinol or another shape-memory material. As an example, the skeleton structure 7b is manufactured similar to a laser cut stent. The skeleton structure 7b in this embodiment allows to decrease the diameter of the cardiac assist device 1 when it is stretched along its longitudinal axis (see also description with reference to Fig. 10 and 11). Once positioned in the heart, the shape of the cup element 2 returns to its intended shape, with the wire mesh structure ensuring a shape of the cup element 2 having the inner volume V_{c1} . During operation (both inflation and deflation) the skeleton structure 7b of this embodiment provides a radial stiffness maintaining the inner volume V_{c1} . At the end of the cup element 2, the skeleton structure 7b and further local components of the cardiac assist device 1 are held together and protected by an end cap 19, which is e.g. shaped or rounded off to provide as little as possible damage to (heart) tissue during use of the cardiac assist device 1.

In order to prevent overstretching of the cup element 2 outer surface during operation, the skeleton structure 7b has a wire mesh structure, provided with one or more circumferential restraining elements 11. The restraining elements 11 are e.g. made of a non-compliant material, ensuring a local maximum diameter of the cup element 2.

Fig. 5 shows a cross sectional view along the line V-V in Fig. 4, and Fig. 6 shows a cross sectional view along the line VI-VI in Fig. 4. In a group of embodiments, the cup wall 2a comprises an inner layer 12 and/or an outer layer 13. The inner and/or outer layer 12, 13 are made of

compliant, high stretch force material, or may even be made of non-compliant material (or a combination of compliant and non-compliant material). Furthermore the outer layer 13, spanning across the wire mesh shaped skeleton structure 7b (and the restraining elements 11), also provides a (more) smooth outer surface, such that the cardiac assist device 1 interferes as little as possible with heart tissue (during insertion and during operation).

In the exemplary embodiment shown in Fig. 4-6 the cup element 2 further comprises a trans-valve section 14 in communication with the outflow element 4. In use, this part (in which the skeleton structure 7b extends) can be positioned at the height of e.g. the aortic valve, providing an always open passageway from the inner volume Vc1 of the cup element 2 to the outflow element 4.

Fig. 7A and 7B show a cross sectional view along the line VII-VII in Fig. 4 in two operational states, which shows the working of the outflow element 4 comprising a collapsible tubular element 15. The collapsible tubular element 15 is made of a material providing radial stiffness (the collapsible tubular element 15 has a maximum diameter, even when fluid is pumped through it at high pressure and/or velocity), yet sufficient flexibility to allow the collapsible tubular element 15 to collapse in order to act as a one-way valve. The open position of the collapsible tubular element 15 is shown in Fig. 7A, and the closed position in Fig. 7B. The collapsible tubular element 15 e.g. has a length of between 0.5 and 4cm, e.g. 2cm, and a diameter of between 5 and 15mm, e.g. 12mm. The collapsible tubular element 15 is e.g. made from flexible material such as Tecotane 85.

In the exemplary embodiment shown, the outflow element 4 comprises an outflow skeleton structure 7c which is formed by an extension of the skeleton structure 7b. This provides for a partial support of the outflow element 4, compatible with the intended function of the collapsible tubular element 15, and with the intended retrieve mechanism function. In addition or alternatively, the collapsible tubular element 15 is at least partially fixed to the outflow skeleton structure 7c. In addition, or alternatively, the collapsible tubular element 15 may be provided with a shaped outer end to even further improve the one-way valve function, e.g. by providing angulation of the upper end of the collapsible tubular element 15 (e.g. at 40 degrees to the longitudinal direction of the cardiac assist device 1).

This exemplary embodiment of the cardiac assist device 1 has a stiff part (cup element 2) which during operation is positioned in the ventricle, including a trans-valve section 14 which during operation passes through the aortic valve, and a one-way valve mechanism formed by the collapsible tubular element 15 of the outflow element 4. During systole, the stiff part translates energy provided by the action of the internal balloon element 5, pushing fluid towards the outflow element 4. Already at the end of this stage, the collapsible tubular element 15 starts closing when the ejection is over as the fluid flow decreases, causing the pressure inside the collapsible tubular element 15 to be lower than the surrounding pressure. During diastole, the outflow skeleton structure 7c prevents collapse of the outflow element 4, yet the collapsible tubular element 15 remains closed, thus preventing possible back flow of fluid.

Furthermore, as shown in Fig. 4, 7A and 7B an attachment element 16 is provided at the upper end of the skeleton structure 7b (or even only at the upper end of outflow skeleton structure

7c), which is effective in use when retrieving the cardiac assist device 1. Fig. 10 shows a side view of parts of an even further embodiment of the cardiac assist device 1 according to the present invention, playing a role in positioning and retrieving the cardiac assist device 1. A wire 16a can be attached to the attachment element 16 of the skeleton structure 7b/outflow skeleton structure 7c.

5 This attachment to the tip of the outflow element 4 allows to put tension on the cup element 2 while retracting, elongating the cup element 2 and decreasing its width.

Fig. 11 shows a perspective view of an embodiment of the cardiac assist device 1 with details on retrieve elements. In this perspective view, also the inner balloon element 5 and tube element 6 are shown, as well as guide wire 8, and an outer shaft 18 (forming part of the catheter used for positioning and retracting the cardiac assist device 1).

The tapered shape of the outflow element 4 (more specifically the outflow skeleton structure 7c) allows the cardiac assist device 1 to be retracted into the outer shaft 18. The tube element 6 can act as fixation of the end cap 19 (also attached to the inner balloon element 5), allowing to put sufficient force to stretch the cardiac assist device 1 in order to reduce the diameter thereof in order to (again) fit into the outer shaft 18.

Fig. 8A-C show perspective views of (parts of) yet a further embodiment of the present invention, relating to the in-flow openings 3 of the cardiac assist device 1, and Fig. 9 shows an exploded perspective view of implementations of one-way valves 12, 17 used in a further embodiment of the present invention. In these embodiments, the one or more inflow openings 3 comprise one-way valves 17.

Fig. 8A shows the cup wall 2a of cup element 2, which is provided with a row of inflow openings 3 (rendered as a thick line), and Fig. 8B shows the leaf-like element 17 which in cooperation with the outer surface 2a as acting as one-way inlet valve. In Fig. 8C the mutual positioning is shown, wherein the leaf-like element 17 is attached to the inside surface of cup wall 2a along the dotted line, thereby creating a coaptation area with in the region below the row of inflow openings 3.

Fig. 9 shows an exploded view of a simplified embodiment of the one-way inlet valve implementation. The cup wall 2a is formed by the skeleton structure 7b (partially shown), inner layer 12 (provided with the inflow openings 3) and the leaf-like element 17. The leaf-like element 17 is positioned to allow closure of the inflow openings 3. The coaptation area thus formed e.g. has a dimension of between 0.5 and 4mm, e.g. 2.5mm, to allow for a sufficiently rapid opening and closing of the formed one-way inlet valves. The inflow openings 3 are at least 2mm in diameter, e.g. 3.5mm. The coaptation area also provides for a directional inflow of fluid inside the cup element 2, with the spiral flow aiding in closing off the one-way inflow valve in a sufficiently quick manner. Multiple such one-way inflow valve lines may be provided in parallel along the longitudinal direction of the cup wall 2a, with the added benefit of an increased directional and spiral flow inside the cup element 2. The inflow openings 3 may furthermore have an orientation in the same direction, to get an even more directed inflow of the fluid. Fluid flow over the leaf-like elements 17 in this manner helps to close them faster.

Fig. 12 shows a cross sectional view of an embodiment of the present invention cardiac assist device, showing a further embodiment of the inner balloon element 5. In this embodiment, the inner balloon volume V_{b2} is smaller than the inner cup volume V_{c1} during operation. During inflation, this will ensure that the inner balloon element 5 will not trap or even encapsulate any fluid
5 between the inner balloon element 5 and inner surface of cup element 2. During deflation, there will be fluid present between the inner balloon element 5 and inner surface of cup element 2, preventing a 'vacuum' of the area between and possible sticking of the two surfaces.

In the exemplary embodiment shown, the inner balloon element 5 is positioned distally within the cup element 2, i.e. nearer to the end cap 19 than to the outflow element 4. This will
10 prevent an increased outflow resistance created by the inner balloon element 5 itself.

In addition, or alternatively, the inner balloon element 5 may be provided with a conical shape. This causes a predefined flow of fluid towards the outflow element 4.

Using one or more of the features described above with reference to Fig. 12, or above, it is possible to inflate the inner balloon element 5 in two phases, e.g. using variable compliance of the
15 inner balloon element 5 material, using a specific shape (e.g. conical), or a combination thereof.

In the above described embodiments, a tube element 6 is used in communication with the inner balloon element 5. Fluid (air or helium) may be used to inflate and deflate the inner balloon element 5. In order to obtain a high enough frequency and timing of the inflation/deflation actions, the tube element 6 may be provided with specific technical features. E.g. to keep the flow resistance
20 sufficiently low an inner diameter of between 4 and 8mm², e.g. 5.3mm² and a length of between 100 and 150cm (e.g. 110 cm) of the tube element 6 is advantageous. This may be combined with an optimized inflation area of the inner balloon element 5 of 80mm². Furthermore the material of the tube element 6 may be chosen to obtain a sufficient high radial stiffness (allowing rapid flow of e.g. helium in both directions), and at the same time a sufficiently high longitudinal push/pull
25 strength in order to allow placing, positioning and retrieving the cardiac assist device 1.

The present invention has been described above with reference to a number of exemplary embodiments as shown in the drawings. Modifications and alternative implementations of some parts or elements are possible, and are included in the scope of protection as defined in the appended claims.

CLAIMS

1. A cardiac assist device (1), comprising
a cup element (2) having
5 a cup wall (2a) comprising a first material and defining an inner cup volume (V_{c1}),
one or more in-flow openings (3) arranged in the cup wall (2a) to allow a first fluid to flow into the
cup element (2) during operation,
an outflow element (4) connected in fluid communication with the cup wall (2a) and having an
aperture (4a) for expelling the first fluid during operation, and
10 an inner balloon element (5) having a balloon wall (5a) comprising a second material and defining
an inner balloon volume (V_{b1} ; V_{b2}), the inner balloon element (5) being positioned inside the cup
element (2) free from the outflow element (4),
a tube element (6) in fluid communication with the inner balloon element (5) for inflating and
deflating the inner balloon element (5) during operation, creating a pumping operational mode and
15 a filling operational mode, respectively,
wherein during operation in the pumping operational mode, the combination of first material,
dimensions of the cup wall (2a), and dimensions of the outflow element (4) provides a containment
force by the cup element (2) counteracting an outward directed force of the inner balloon element
(5).
20
2. The cardiac assist device according to claim 1, wherein during the pumping and filling
operational modes, the cup element (2) has a substantially constant inner cup volume (V_{c1}).
3. The cardiac assist device according to claim 1 or 2, wherein the cup element (2) comprises
25 a skeleton structure (7a, 7b) integrated with the cup wall (2a).
4. The cardiac assist device according to any one of claims 1-3, wherein the skeleton structure
(7a, 7b) has a wire mesh structure, provided with one or more circumferential restraining elements
(11).
30
5. The cardiac assist device according to any one of claims 1-4, wherein the cup wall (2a)
comprises an inner layer (12) and/or an outer layer (13).
6. The cardiac assist device according to any one of claims 1-5, wherein the cup element (2)
35 further comprises a trans-valve section (14) in communication with the outflow element (4).
7. The cardiac assist device according to any one of claims 1-6, wherein the outflow element
(4) comprises a collapsible tubular element (15),

8. The cardiac assist device according to any one of claims 3-7, wherein the skeleton structure (7a, 7b) comprises shape-memory material.
- 5 9. The cardiac assist device according to any one of claims 3-8, wherein the outflow element (4) comprises an outflow skeleton structure (7c) which is formed by an extension of the skeleton structure (7a, 7b).
- 10 10. The cardiac assist device according to any one of claims 7-9, wherein the collapsible tubular element (15) is at least partially fixed to the outflow skeleton structure (7c).
11. The cardiac assist device according to any one of claims 1-10, further comprising a control unit (10) arranged to control fluid flow through the tube element (6) during operation.
- 15 12. The cardiac assist device according to any one of claims 1-11, wherein the tube element (6) is provided in contact with the outflow element (4) along a predetermined length thereof.
- 20 13. The cardiac assist device according to any one of claims 1-12, wherein the combination of the cup element (2) and the inner balloon element (5) are adjustable to a transport mode, in which the maximum diameter of the combination is less than 7mm, e.g. less than 5mm.
14. The cardiac assist device according to claim 13, wherein the combination is elongated in the transport mode, and ellipsoid shaped in an operational mode.
- 25 15. The cardiac assist device according to any one of claims 1-14, wherein the tube element (6) is a multi-lumen catheter.
- 30 16. The cardiac assist device according to any one of claims 1-15, wherein the inner balloon volume (Vb2) is smaller than the inner cup volume (Vc1) during operation.
17. The cardiac assist device according to any one of claims 1-16, wherein the inner balloon element (5) is positioned distally within the cup element (2).
18. The cardiac assist device according to any one of claims 1-17, wherein the inner balloon element (5) has a conical shape.
- 35 19. The cardiac assist device according to any one of claims 1-18, wherein the inner balloon element (5) comprises a multi-stage balloon assembly having at least two balloon parts with different rigidity material.

20. The cardiac assist device according to any one of claims 1-19, wherein the one or more inflow openings (3) comprise one-way valves (17).
- 5 21. The cardiac assist device according to claim 3, wherein the skeleton structure (7a, 7b) is a flexible skeleton structure arranged to control the cup volume during operation.
22. The cardiac assist device according to claim 21, wherein the flexible skeleton structure (7a, 7b) comprises hollow channels.
- 10 23. The cardiac assist device according to claim 22, wherein the hollow channels are in fluid communication with the tube element (6).
24. The cardiac assist device according to claim 22 or 23, wherein the cardiac assist device (1) further comprises a secondary tube element in communication with the hollow channels.
- 15 25. The cardiac assist device according to claim 11, wherein the control unit (10) is arranged to control the inner cup volume and the inner balloon volume independently.
- 20 26. The cardiac assist device according to claim 19, wherein one of the two balloon parts is positioned to close off the one or more inflow openings (3) in the pumping operational mode.

AMENDED CLAIMS
received by the International Bureau on 22 March 2022 (22.03.2022)

1. A cardiac assist device (1), comprising
a cup element (2) having
5 a cup wall (2a) comprising a first material and defining an inner cup volume (Vc1),
one or more in-flow openings (3) arranged in the cup wall (2a) to allow a first fluid to flow into the
cup element (2) during operation,
an outflow element (4) connected in fluid communication with the cup wall (2a) and having an
aperture (4a) for expelling the first fluid during operation, and
10 an inner balloon element (5) having a balloon wall (5a) comprising a second material and defining
an inner balloon volume (Vb1; Vb2), the inner balloon element (5) being positioned inside the cup
element (2) free from the outflow element (4),
a tube element (6) in fluid communication with the inner balloon element (5) for inflating and
deflating the inner balloon element (5) during operation, creating a pumping operational mode and
15 a filling operational mode, respectively,
wherein during operation in the pumping operational mode, the combination of first material,
dimensions of the cup wall (2a), and dimensions of the outflow element (4) provides a containment
force by the cup element (2) counteracting an outward directed force of the inner balloon element
(5).
20
2. The cardiac assist device according to claim 1, wherein during the pumping and filling
operational modes, the cup element (2) has a substantially constant inner cup volume (Vc1).
3. The cardiac assist device according to claim 1 or 2, wherein the cup element (2) comprises
25 a skeleton structure (7a, 7b) integrated with the cup wall (2a).
4. The cardiac assist device according to any one of claims 1-3, wherein the skeleton structure
(7a, 7b) has a wire mesh structure, provided with one or more circumferential restraining elements
(11).
30
5. The cardiac assist device according to any one of claims 1-4, wherein the cup wall (2a)
comprises an inner layer (12) and/or an outer layer (13).
6. The cardiac assist device according to any one of claims 1-5, wherein the cup element (2)
35 further comprises a trans-valve section (14) in communication with the outflow element (4).
7. The cardiac assist device according to any one of claims 1-6, wherein the outflow element
(4) comprises a collapsible tubular element (15).
40

8. The cardiac assist device according to any one of claims 3-7, wherein the skeleton structure (7a, 7b) comprises shape-memory material.

9. The cardiac assist device according to any one of claims 3-8, wherein the outflow element
5 (4) comprises an outflow skeleton structure (7c) which is formed by an extension of the skeleton structure (7a, 7b).

10. The cardiac assist device according to any one of claims 7-9, wherein the collapsible tubular
10 element (15) is at least partially fixed to the outflow skeleton structure (7c).

11. The cardiac assist device according to any one of claims 1-10, further comprising a control
unit (10) arranged to control fluid flow through the tube element (6) during operation.

12. The cardiac assist device according to any one of claims 1-11, wherein the tube element
15 (6) is provided in contact with the outflow element (4) along a predetermined length thereof.

13. The cardiac assist device according to any one of claims 1-12, wherein the combination of
the cup element (2) and the inner balloon element (5) are adjustable to a transport mode, in which
the maximum diameter of the combination is less than 7mm, e.g. less than 5mm.

20 14. The cardiac assist device according to claim 13, wherein the combination is elongated in
the transport mode, and ellipsoid shaped in an operational mode.

15. The cardiac assist device according to any one of claims 1-14, wherein the tube element
25 (6) is a multi-lumen catheter.

16. The cardiac assist device according to any one of claims 1-15, wherein the inner balloon
volume (Vb2) is smaller than the inner cup volume (Vc1) during operation.

30 17. The cardiac assist device according to any one of claims 1-16, wherein the inner balloon
element (5) is positioned distally within the cup element (2).

18. The cardiac assist device according to any one of claims 1-17, wherein the inner balloon
element (5) has a conical shape.

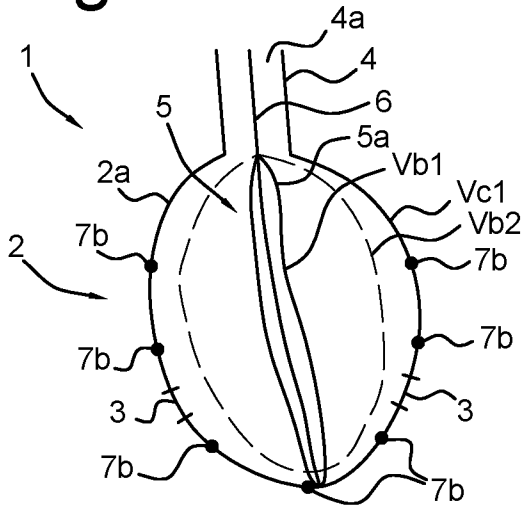
35 19. The cardiac assist device according to any one of claims 1-18, wherein the inner balloon
element (5) comprises a multi-stage balloon assembly having at least two balloon parts with
different rigidity material.

40

20. The cardiac assist device according to any one of claims 1-19, wherein the one or more inflow openings (3) comprise one-way valves (17).
21. The cardiac assist device according to claim 3, wherein the skeleton structure (7a, 7b) is a flexible skeleton structure arranged to control the cup volume during operation.
22. The cardiac assist device according to claim 21, wherein the flexible skeleton structure (7a, 7b) comprises hollow channels.
23. The cardiac assist device according to claim 22, wherein the hollow channels are in fluid communication with the tube element (6).
24. The cardiac assist device according to claim 22 or 23, wherein the cardiac assist device (1) further comprises a secondary tube element in communication with the hollow channels.
25. The cardiac assist device according to claim 11, wherein the control unit (10) is arranged to control the inner cup volume and the inner balloon volume independently.
26. The cardiac assist device according to claim 19, wherein one of the two balloon parts is positioned to close off the one or more inflow openings (3) in the pumping operational mode.
27. The cardiac assist device according to any one of claims 11-26, wherein the control unit (10) is arranged to inflate and deflate the inner balloon element (5) at a frequency of pumping.
28. The cardiac assist device according to claim 27, wherein the control unit (10) is arranged to set the frequency of pumping synchronously to a sensed heartbeat.
29. The cardiac assist device according to claim 27 or 28, wherein the control unit (10) is arranged to set the frequency of pumping substantially higher than an actual heartbeat.
30. The cardiac assist device according to claim 27 or 28, wherein the control unit (10) is arranged to set the frequency of pumping to at least 2 times higher than an actual heartbeat.
31. The cardiac assist device according to claim 27 or 28, wherein the control unit (10) is arranged to set the frequency of pumping to at least a factor 2-10 higher than an actual heartbeat.
32. The cardiac assist device according to claim 27 or 28, wherein the control unit (10) is arranged to set the frequency of pumping to a factor 2-10 higher than an actual heartbeat.

33. The cardiac assist device according to any one of claims 1-26, wherein the inner balloon element is configured to be inflated and deflated at a pumping frequency substantially higher than an actual heartbeat.
- 5 34. The cardiac assist device according to claim 33, wherein the pumping frequency is at least 2 times higher than an actual heartbeat.
35. The cardiac assist device according to claim 33, wherein the pumping frequency is at least 2-10 higher than an actual heartbeat.

Fig. 1A



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Fig. 1B

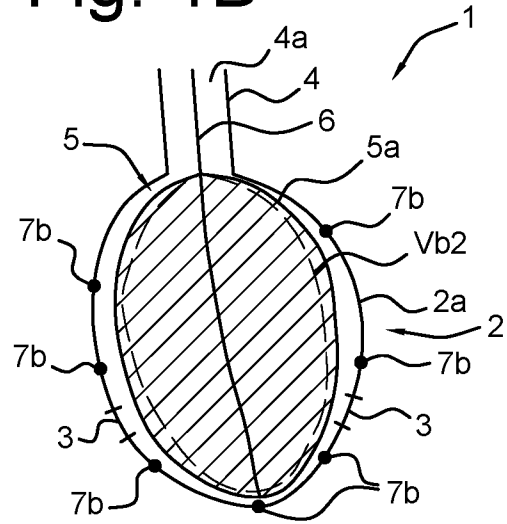


Fig. 2A

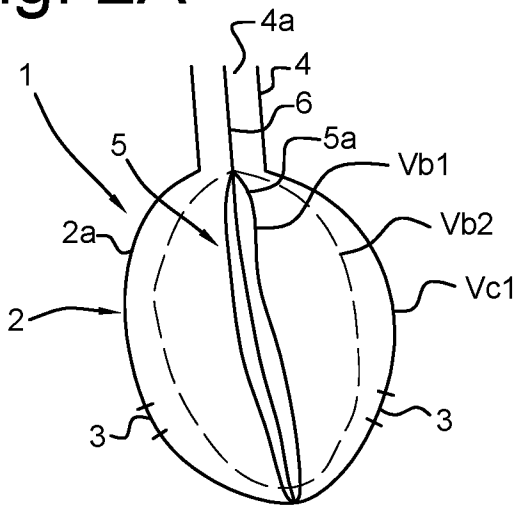


Fig. 2B

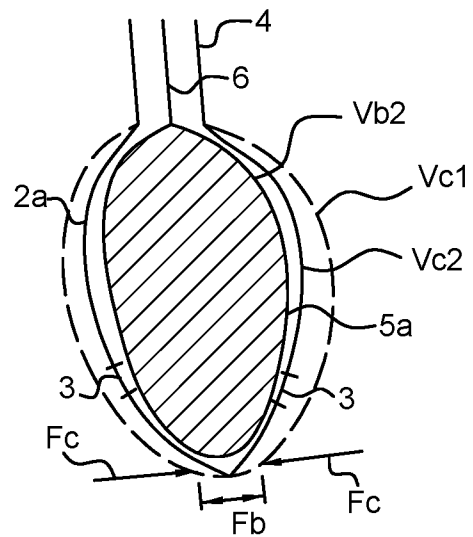


Fig. 2C

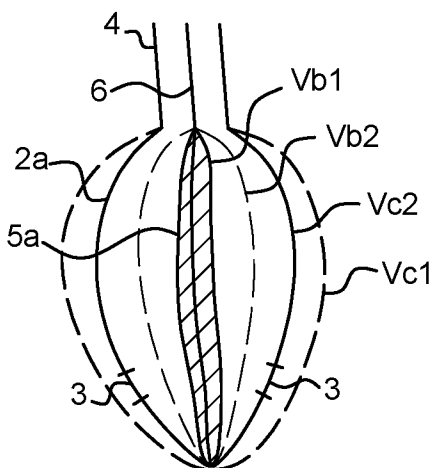


Fig. 2D

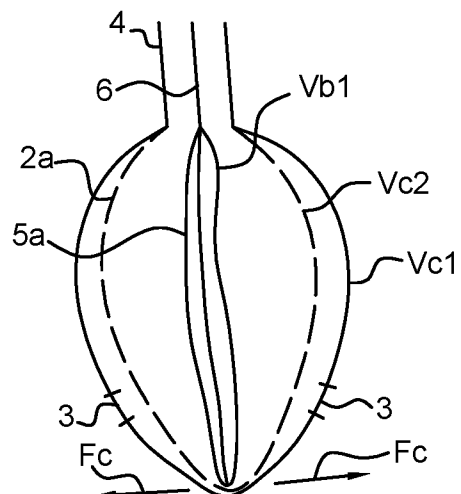


Fig. 3A

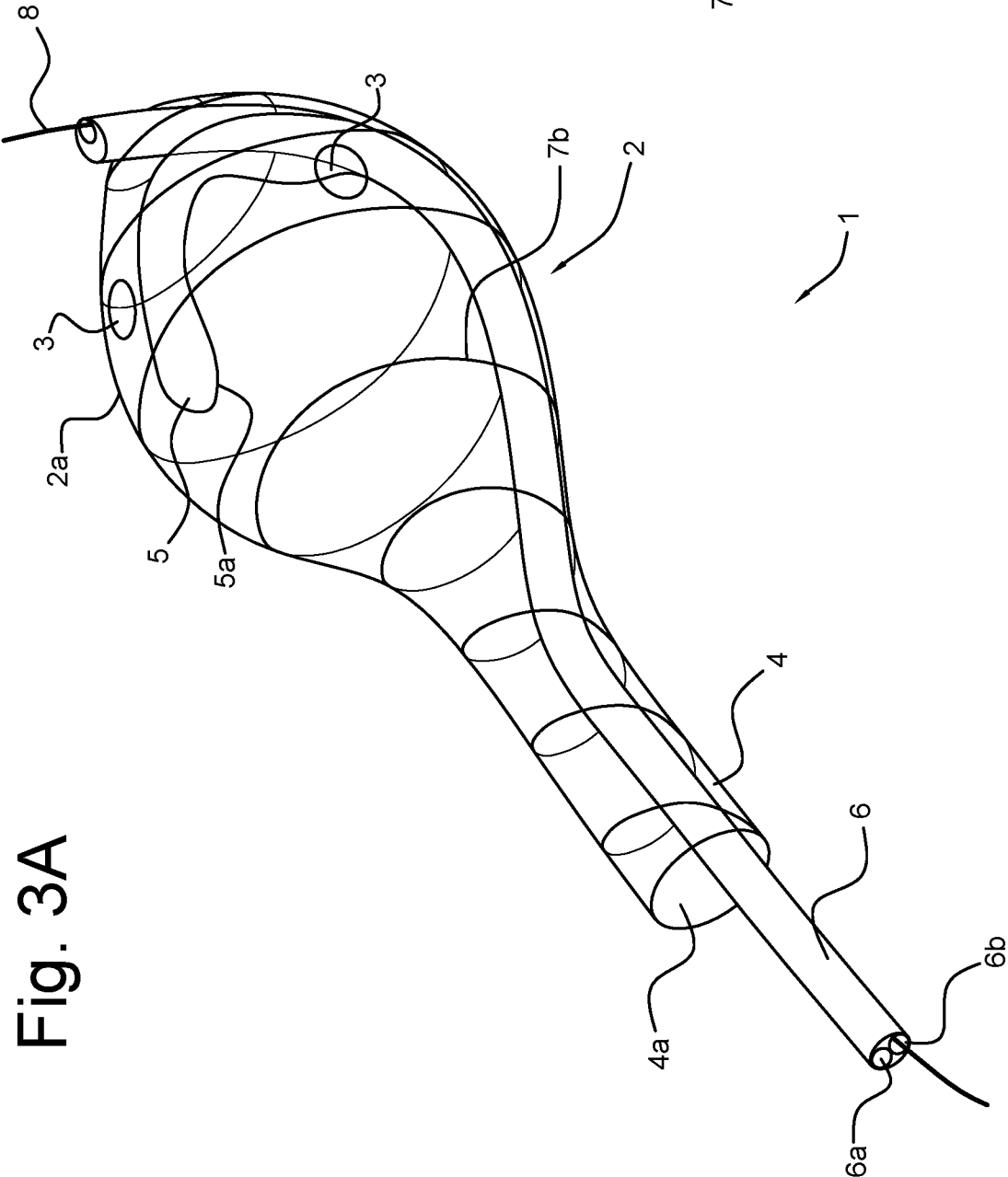
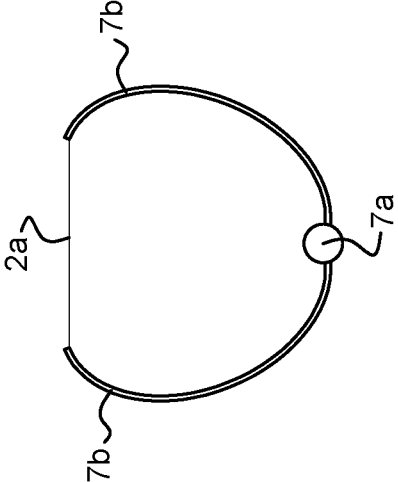


Fig. 3B



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Fig. 4

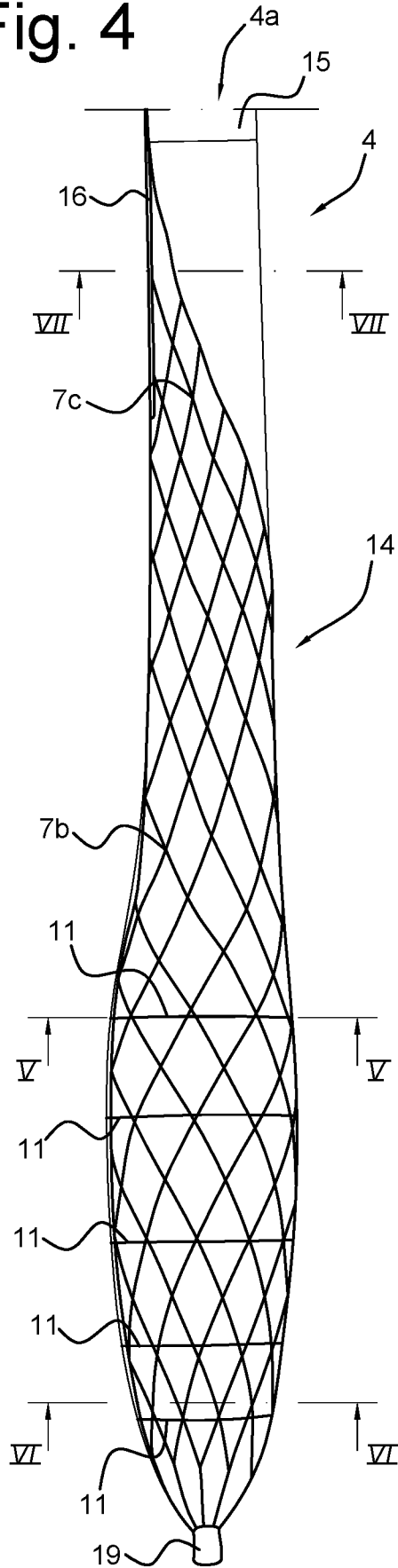


Fig. 5

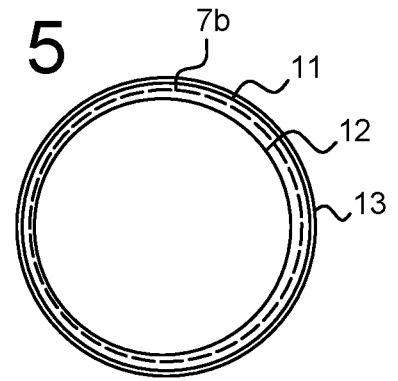


Fig. 6

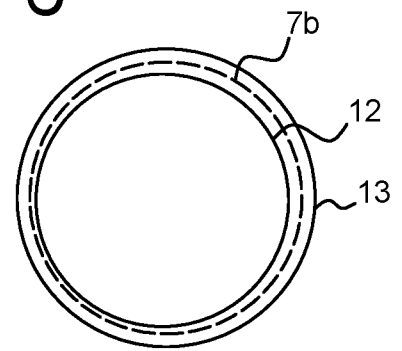


Fig. 7A

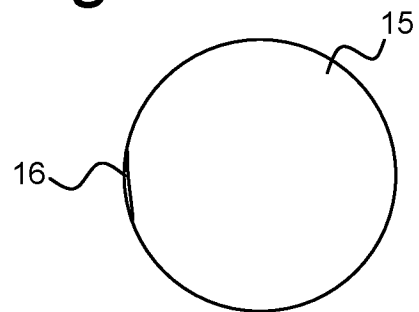
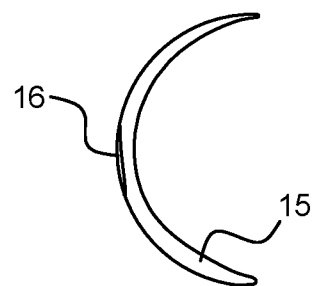


Fig. 7B



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Fig. 8A

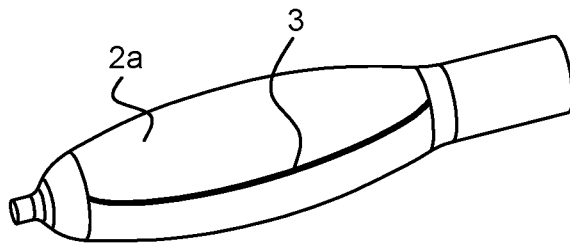


Fig. 8B

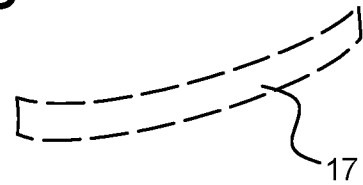


Fig. 8C

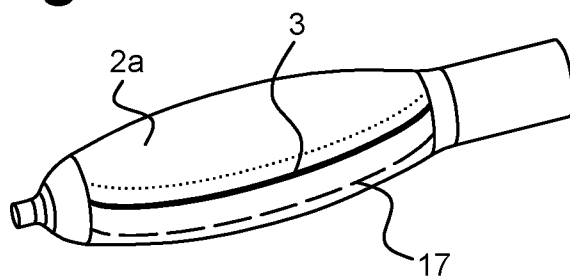


Fig. 9

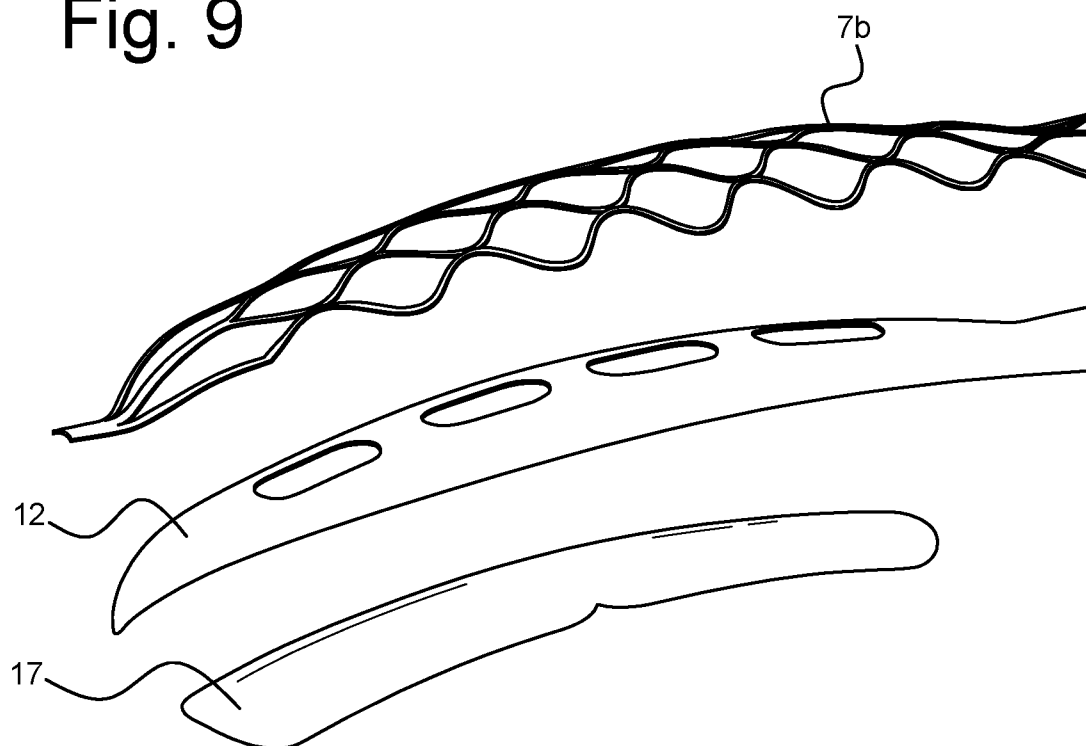


Fig. 10

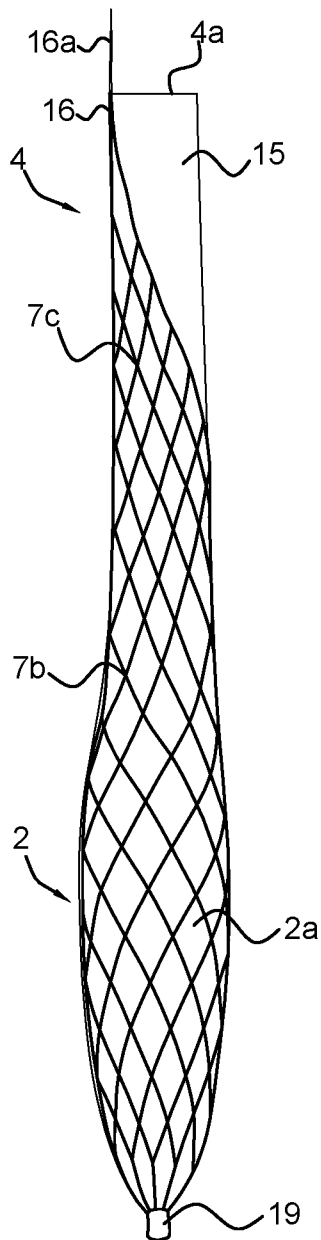


Fig. 11

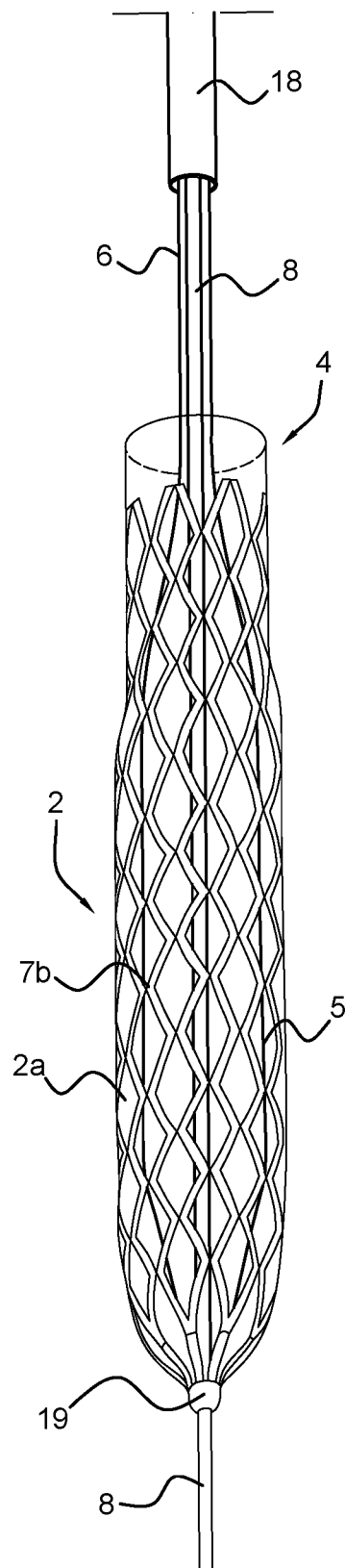
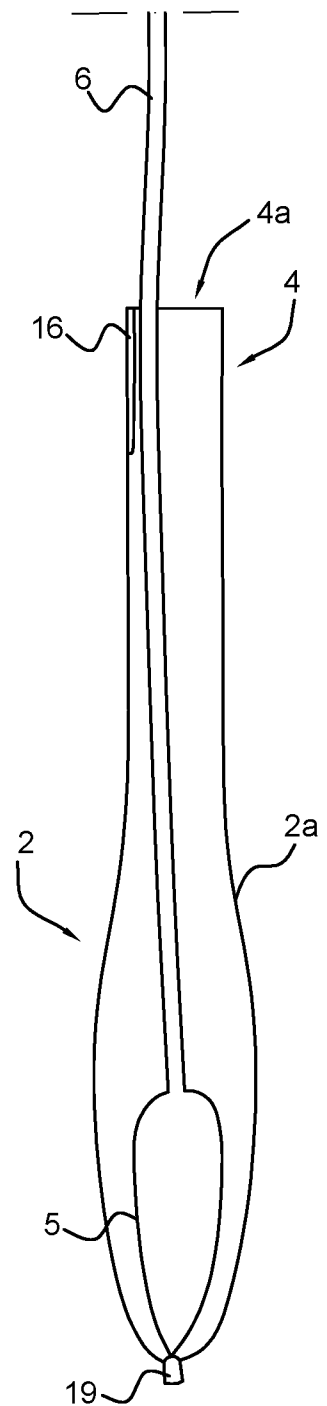


Fig. 12



INTERNATIONAL SEARCH REPORT

International application No
PCT/NL2021/050621

A. CLASSIFICATION OF SUBJECT MATTER INV. A61M60/174 A61M60/295 A61M60/497 A61M60/515 A61M60/843 A61M60/898 A61M60/268 A61M60/427 A61M60/837 A61M60/896 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) A61M Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2020/022905 A1 (STICHTING KATHOLIEKE UNIV [NL]) 30 January 2020 (2020-01-30)	1-3, 5, 6, 8, 9, 11-14, 16-18, 20-24
A	page 8, line 14 - line 31; figures 1, 2A-D, 5, 6A-D page 7, line 1 - line 20 page 6, line 31 - line 32 page 9, line 6 - line 9; figure 8 page 6, line 21 - line 28; claim 5 page 6, line 2 - line 8 -----	7, 10, 19, 26
X	US 5 169 378 A (FIGUERA DIEGO [ES]) 8 December 1992 (1992-12-08) cited in the application	1-6, 8, 9, 11-18, 20-25
A	column 3, line 35 - column 4, line 45; figures 1, 2a-2f ----- -/--	19, 26
☒ Further documents are listed in the continuation of Box C. ☒ 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 21 January 2022		Date of mailing of the international search report 31/01/2022
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Lakkis, Angeliki

INTERNATIONAL SEARCH REPORT

International application No

PCT/NL2021/050621

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2015/131879 A1 (NOVAPUMP GMBH [DE]) 11 September 2015 (2015-09-11) cited in the application page 11, paragraph 3; figure 2AB page 8, line 1 - line 4 -----	1-6, 8, 9, 11, 16-18, 20

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/NL2021/050621

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		ES 2869425 T3	25-10-2021
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