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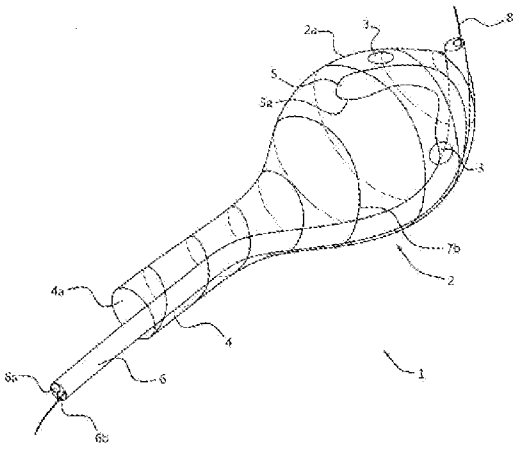
(54) **Cardiac assist device**

(57) 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) defining an inner cup volume (Vc1; Vc2), one or more in-flow openings (3), and an outflow element (4 having an aperture (4a). The inner balloon element (5) has a balloon wall (5a) defining an inner balloon volume (Vb1; Vb2), and 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 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 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 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 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.

Summary of the invention

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 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.

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.

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;

Fig. 2A-2D show cross sectional views of the second embodiment of the present invention; and

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.

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.

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.

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 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 Vc1, which is substantially the same during the

pumping operational mode and the filling operational mode. The inner balloon element has an initial inner volume Vb1 at start of pumping operational mode as shown in Fig. 1A and an expanded inner volume Vb2 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 Vb2-Vb1.

To obtain this pumping and filling operational modes, the one or more inflow openings 3 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 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 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 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 Vc1), 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 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. An inner balloon element 5 is present 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, 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 Vc1.

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 Vc1-Vc2 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).

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 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 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 inflatable skeleton 7a, 7b ànd 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 Vc1; Vc2 and the inner balloon volume Vb1; Vb2 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 Vc1 to Vc2just before, simultaneously with or just after the change of inner balloon volume form Vb1 to Vb2.In a specific embodiment, the maximum inner cup volume Vc1 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 may be higher, e.g. a factor of 2 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 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.

The above described exemplary embodiments, referring to the drawings as attached, can also be described by the following numbered and interrelated embodiment clauses:

Embodiment 1. 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 (Vc1; Vc2),

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

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 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).

Embodiment 2.The cardiac assist device according to embodiment 1, wherein during the pumping and filling operational modes, the cup element (2) has a substantially constant inner cup volume (Vc1).

Embodiment 3. The cardiac assist device according to embodiment 1 or 2, wherein the cup element (2) comprises a skeleton structure (7a, 7b) integrated with the cup wall (2a).

Embodiment 4. The cardiac assist device according to embodiment 3, wherein the skeleton structure (7a, 7b) is a flexible skeleton structure arranged to control the cup volume during operation.

Embodiment 5. The cardiac assist device according to embodiment 4, wherein the flexible skeleton structure (7a, 7b) comprises hollow channels.

Embodiment 6. The cardiac assist device according to embodiment 5, wherein the hollow channels are in fluid communication with the tube element (6).

Embodiment 7. The cardiac assist device according to embodiment 5 or 6, wherein the cardiac assist device (1) further comprises a secondary tube element in communication with the hollow channels.

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

Embodiment 9. The cardiac assist device according to any one of embodiments 3-8, 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.

Embodiment 10. The cardiac assist device according to any one of embodiments 1-9, further comprising a control unit (10) arranged to control fluid flow through the tube element (6) during operation.

Embodiment 11. The cardiac assist device according to embodiment 10, when referring to embodiment 7, wherein the control unit (10) is arranged to control the inner cup volume and the inner balloon volume independently.

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

Embodiment 13. The cardiac assist device according to any one of embodiments 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.

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

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

Embodiment 16. The cardiac assist device according to any one of embodiments 1-15, wherein the inner balloon element (5) comprises a multi-stage balloon assembly having at least two balloon parts with different rigidity material.

Embodiment 17. The cardiac assist device according to embodiment 16, wherein one of the two balloon parts is positioned to close off the one or more inflow openings (3) in the pumping operational mode.

Embodiment 18. The cardiac assist device according to any one of embodiments 1-17, wherein the one or more inflow openings (3) comprise one-way valves.

Embodiment 19. The cardiac assist device according to any one of embodiments 1-18, wherein the outflow element (4) has a tube like structure.

Embodiment 20. The cardiac assist device according to any one of embodiments 1-19, wherein the outflow element (4) is a directional flow element.

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.

Conclusies

1. Een hartondersteuningsinrichting (1), omvattend

een cup-element (2) met

een cup-wand (2a) die een eerste materiaal omvat en die een binnenste cup-volume (Vc1; Vc2) definieert,

één of meer instroomopeningen (3) die in de cup-wand (2a) gepositioneerd zijn om het mogelijk te maken dat een eerste fluïdum in het cup-element (2) stroomt tijdens bedrijf,

een uitstroomelement (4) dat in fluïdumverbinding staat met de cup-wand (2a) en een opening (4a) heeft voor het uitdrijven van het eerste fluïdum tijdens bedrijf,

een binnenste ballonelement (5) met een ballonwand (5a) die een tweede materiaal omvat en die een binnenste ballonvolume (Vb1; Vb2) definieert, waarbij het binnenste ballonelement (5) gepositioneerd is binnen het cup-element (2) en vrij van het uitstroomelement (4),

een buiselement (6) in fluïdumverbinding met het binnenste ballonelement (5) voor het opblazen en leeg laten lopen van het binnenste ballonelement (5) tijdens bedrijf, waardoor respectievelijk een pompbedrijfsmodus en een vulbedrijfsmodus worden gecreëerd,

waarbij tijdens bedrijf in de pompbedrijfsmodus, de combinatie van eerste materiaal, afmetingen van de cup-wand (2a), en afmetingen van het uitstroom (4) een opsluitkracht verschaft die tegen een naar buiten gerichte kracht van het binnenste ballonelement (5) in werkt.

2. De hartondersteuningsinrichting volgens conclusie 1, waarbij tijdens de pomp- en vulbedrijfsmodus het cup-element (2) een in hoofdzaak constant binnenste cup-volume (Vc1) heeft.

3. De hartondersteuningsinrichting volgens conclusie 1 of 2, waarbij het cup-element (2) een skeletstructuur (7a, 7b) omvat die geïntegreerd is met de cup-wand (2a).

4. De hartondersteuningsinrichting volgens conclusie 3, waarbij de skeletstructuur (7a, 7b) een flexibele skeletstructuur is die is ingericht om het cup-volume tijdens bedrijf te regelen.

5. De hartondersteuningsinrichting volgens conclusie 4, waarbij de flexibele skeletstructuur (7a, 7b) holle kanalen omvat.

6. De hartondersteuningsinrichting volgens conclusie 5, waarbij de holle kanalen in fluïdumverbinding staan met het buiselement (6).

7. De hartondersteuningsinrichting volgens conclusie 5 of 6, waarbij de hartondersteuningsinrichting (1) verder een secundair buiselement omvat in verbinding met de holle kanalen.

8. De hartondersteuningsinrichting volgens één van de conclusies 3-7, waarbij de skeletstructuur (7a, 7b) een vormgeheugenmateriaal omvat.

9. De hartondersteuningsinrichting volgens één van de conclusies 3-8, waarbij de skeletstructuur (7a, 7b) een ruggegraatelement (7a) omvat dat is ingericht langs een longitudinale richting van de hartondersteuningsinrichting (1) en een veelvoud ribelementen (7b), waarbij elk van het veelvoud van ribelementen (7b) aan één zijde daarvan bevestigd is aan het ruggegraatelement (7a).

10. De hartondersteuningsinrichting volgens één van de conclusies 1-9, verder omvattend a regeleenheid (10) die is ingericht om tijdens bedrijf fluïdumstroom door het buiselement (6) te regelen.

11. De hartondersteuningsinrichting volgens conclusie 10, wanneer deze verwijst naar conclusie 7, waarbij de besturingseenheid (10) is ingericht om onafhankelijk het binnenste cup-volume en het binnenste ballonvolume te regelen.

12. De hartondersteuningsinrichting volgens één van de conclusies 1-11, waarbij het buiselement (6) verschaft is in contact met het uitstroomelement (4) over een vooraf bepaalde lengte daarvan..

13. De hartondersteuningsinrichting volgens één van de conclusies 1-12, waarbij de combinatie van het cup-element (2) en het binnenste ballonelement (5) instelbaar zijn naar een transportmodus, waarin de maximale doorsnede van de combinatie minder is dan 7mm, bijvoorbeeld minder dan 5mm.

14. De hartondersteuningsinrichting volgens conclusie 13, waarbij de combinatie is langgerekt is in de transportmodus, en ellipsvormig is in een bedrijfsmodus.

15. De hartondersteuningsinrichting volgens één van de conclusies 1-14, waarbij het buiselement (6) multi-lumen katheter is.

16. De hartondersteuningsinrichting volgens één van de conclusies 1-15, waarbij het binnenste ballonelement (5) meertraps ballonsamenstel omvat met ten minste twee ballondelen met materiaal van verschillende stijfheid.

17. De hartondersteuningsinrichting volgens conclusie 16, waarbij één van de twee ballondelen gepositioneerd om de één of meer instroomopeningen (3) in de pompbedrijfsmodus af te sluiten.

18. De hartondersteuningsinrichting volgens één van de conclusies 1-17, waarbij de één of meer instroomopeningen (3) één-wegkleppen omvatten.

19. De hartondersteuningsinrichting volgens één van de conclusies 1-18, waarbij het uitstroomelement (4) een buisvormige structuur heeft.

20. De hartondersteuningsinrichting volgens één van de conclusies 1-19, waarbij het uitstroomelement (4) een gerichte-stroomelement is.

Fig. 1A

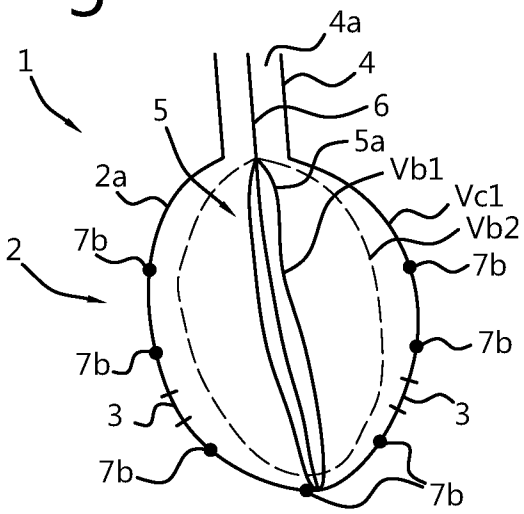


Fig. 1B

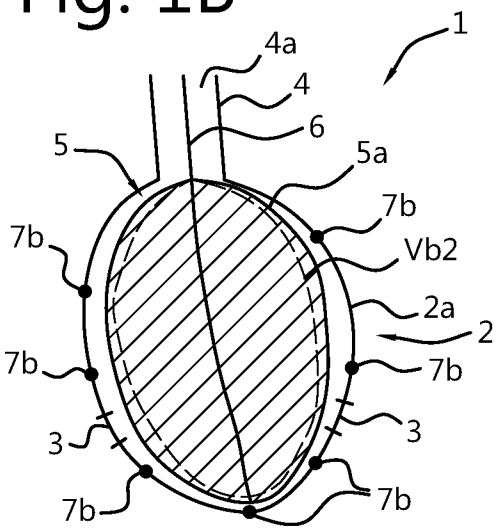


Fig. 2A

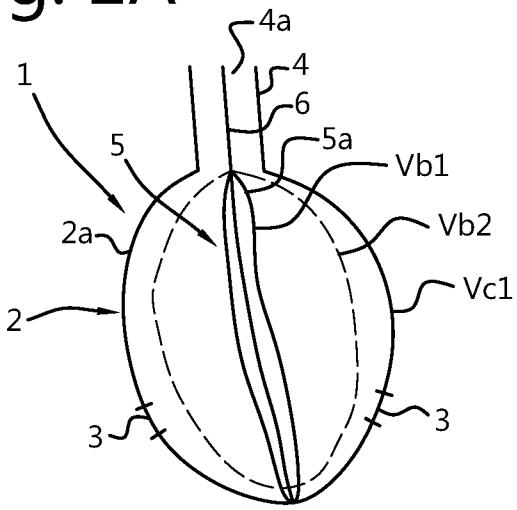


Fig. 2B

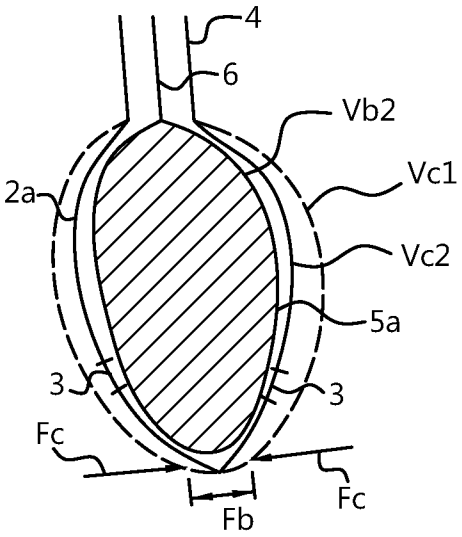


Fig. 2C

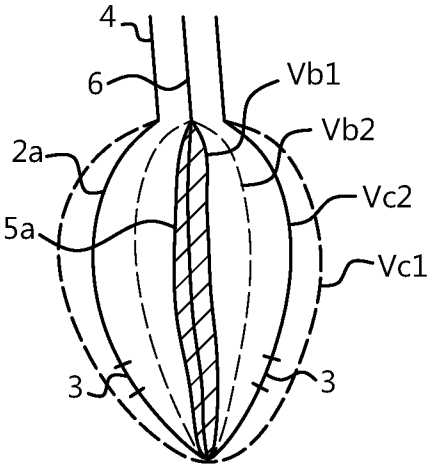


Fig. 2D

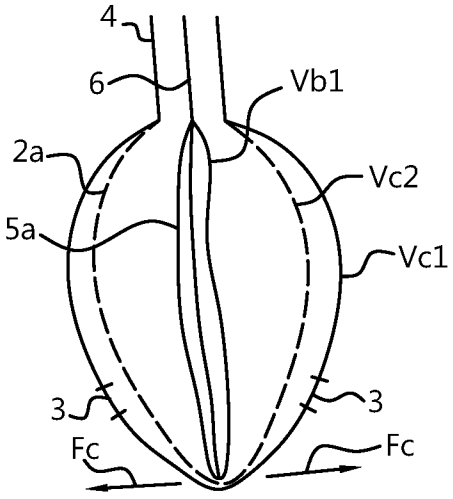


Fig. 3A

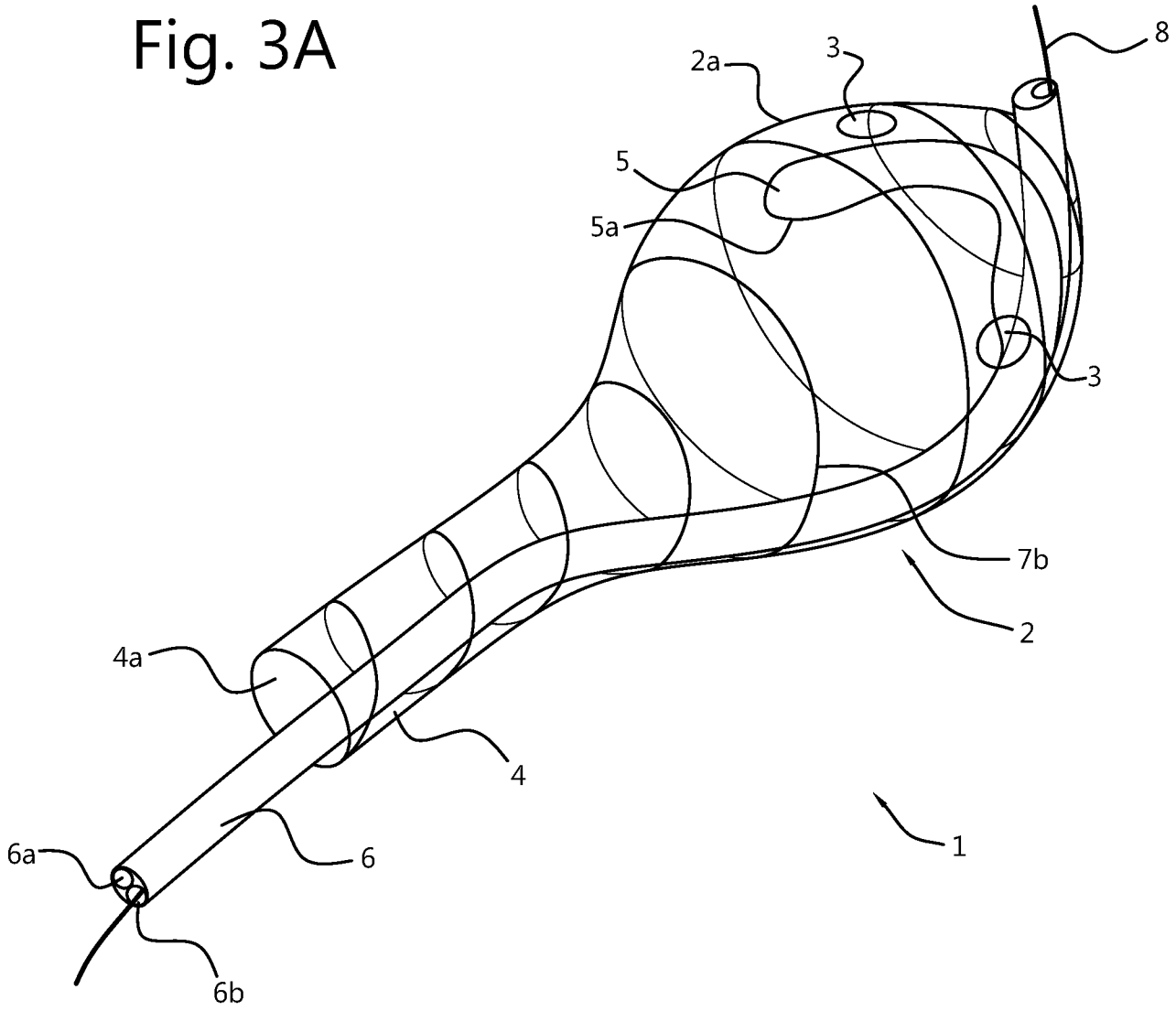
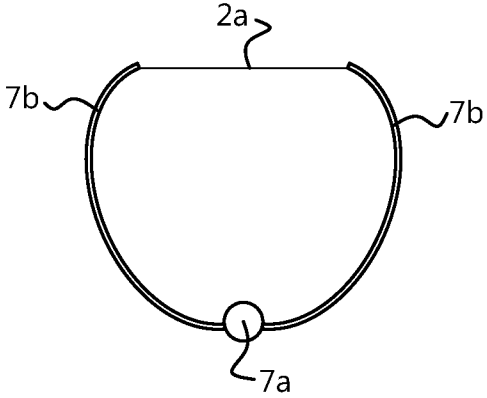


Fig. 3B



SAMENWERKINGSVERDRAG (PCT)

RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE
Nederlands aanvraag nr. **2026671**	Indieningsdatum **14-10-2020**
	Ingeroepen voorrangsdatum
Aanvrager (Naam) **CARDIACBOOSTER B.V.**	
Datum van het verzoek voor een onderzoek van internationaal type **21-11-2020**	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr. **SN77413**

I. CLASSIFICATIE VAN HET ONDERWERP (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)

Volgens de internationale classificatie (IPC)

Zie onderzoeksrapport

II. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte minimumdocumentatie

Classificatiesysteem	Classificatiesymbolen
IPC	**Zie onderzoeksrapport**

Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

III.	☐	**GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES**	(opmerkingen op aanvullingsblad)
IV.	☐	**GEBREK AAN EENHEID VAN UITVINDING**	(opmerkingen op aanvullingsblad)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2026671

A. CLASSIFICATIE VAN HET ONDERWERP
INV. A61M60/174 A61M60/295 A61M60/497 A61M60/515 A61M60/843
A61M60/898
ADD.
Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.

B. ONDERZOCHTE GEBIEDEN VAN DE TECHNIEK

Onderzochte miminum documentatie (classificatie gevolgd door classificatiesymbolen)
A61M

Onderzochte andere documentatie dan de mimimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen

Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden)
EPO-Internal, WPI Data

C. VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X	WO 2020/022905 A1 (STICHTING KATHOLIEKE UNIV [NL]) 30 januari 2020 (2020-01-30) * bladzijde 8, regel 14 - regel 31; figuren 1,2A-D,5,6A-D * * bladzijde 7, regel 1 - regel 20 * * bladzijde 6, regel 31 - regel 32 * * bladzijde 9, regel 6 - regel 9; figuur 8 * * bladzijde 6, regel 21 - regel 28; conclusie 5 * * bladzijde 6, regel 2 - regel 8 *	1-14, 18-20

X,D	US 5 169 378 A (FIGUERA DIEGO [ES]) 8 december 1992 (1992-12-08) in de aanvraag genoemd	1-15, 18-20
A	* kolom 3, regel 35 - kolom 4, regel 45; figuren 1, 2a-2f *	16,17

	-/--	

[X] Verdere documenten worden vermeld in het vervolg van vak C.

[X] Leden van dezelfde octrooifamilie zijn vermeld in een bijlage

° Speciale categorieën van aangehaalde documenten

"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft

"D" in de octrooiaanvrage vermeld

"E" eerdere octrooi(aanvrage), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven

"L" om andere redenen vermelde literatuur

"O" niet-schriftelijke stand van de techniek

"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur

"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvrage, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding

"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur

"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht

"&" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie

Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid	Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type
18 juni 2021	

Naam en adres van de instantie	De bevoegde ambtenaar
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lakkis, Angeliki

1

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2026671

C.(Vervolg). VAN BELANG GEACHTE DOCUMENTEN

Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
X,D	WO 2015/131879 A1 (NOVAPUMP GMBH [DE]) 11 september 2015 (2015-09-11) in de aanvraag genoemd * bladzijde 11, alinea 3; figuur 2AB * * bladzijde 8, regel 1 - regel 4 * -----	1-3,8, 10,18-20

Formulier PCT/ISA/201 (vervolg tweede blad) (Januari 2004)

ONDERZOEKSRAPPORT BETREFFENDE HET RESULTAAT VAN HET ONDERZOEK NAAR DE STAND VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar de stand van de techniek
NL 2026671

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie
WO 2020022905	A1 30-01-2020	CN 112512623 A	16-03-2021
		EP 3829670 A1	09-06-2021
		WO 2020022905 A1	30-01-2020
US 5169378	A 08-12-1992	DE 4124299 A1	23-01-1992
		ES 2020787 A6	16-09-1991
		ES 2063720 A6	01-01-1995
		US 5169378 A	08-12-1992
WO 2015131879	A1 11-09-2015	DE 102014003153 A1	03-09-2015
		DE 112015001106 A5	22-12-2016
		EP 3113806 A1	11-01-2017
		US 2017056574 A1	02-03-2017
		WO 2015131879 A1	11-09-2015

WRITTEN OPINION

File No.	Filing date *(day/month/year)*	Priority date *(day/month/year)*	Application No.
SN77413	14.10.2020		NL2026671

International Patent Classification (IPC)
INV. A61M60/174 A61M60/295 A61M60/497 A61M60/515 A61M60/843 A61M60/898

Applicant
CARDIACBOOSTER B.V.

This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the application
- ☒ Box No. VIII Certain observations on the application

	Examiner
	Lakkis, Angeliki

Application number

WRITTEN OPINION

NL2026671

Box No. I Basis of this opinion

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material:

   ☐ a sequence listing

   ☐ table(s) related to the sequence listing

   b. format of material:

   ☐ on paper

   ☐ in electronic form

   c. time of filing/furnishing:

   ☐ contained in the application as filed.

   ☐ filed together with the application in electronic form.

   ☐ furnished subsequently for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty	Yes:	Claims	16, 17
	No:	Claims	1-15, 18-20
Inventive step	Yes:	Claims	16, 17
	No:	Claims	1-15, 18-20
Industrial applicability	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

WRITTEN OPINION

Box No. VIII Certain observations on the application

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1 WO 2020/022905 A1 (STICHTING KATHOLIEKE UNIV [NL]) 30 januari 2020 (2020-01-30)

D2 US 5 169 378 A (FIGUERA DIEGO [ES]) 8 december 1992 (1992-12-08)in de aanvraag genoemd

D3 WO 2015/131879 A1 (NOVAPUMP GMBH [DE]) 11 september 2015 (2015-09-11)in de aanvraag genoemd

2 The present application does not meet the criteria of patentability, because the subject-matter of claim1 is not new.

D1 discloses (page 6, line 2-page 9, line 9; figuress 1, 2A-D, 5, 6A-D):

Een hartondersteuningsinrichting, omvattendeen cup-element (10) met een cup-wand die een eerste materiaal omvat en die een binnenste cup-volume definieert, één of meer instroomopeningen (32) die in de cup-wand gepositioneerd zijn om het mogelijk te maken dat een eerste fluïdum in het cup-element stroomt tijdens bedrijf,een uitstroomelement (12) dat in fluïdumverbinding staat met de cup-wand en een opening heeft voor het uitdrijven van het eerste fluïdum tijdens bedrijf,een binnenste ballonelement (26) met een ballonwand die een tweede materiaal omvat en die een binnenste ballonvolume definieert, waarbij het binnenste ballonelement gepositioneerd is binnen het cup-element en vrij van het uitstroomelement,een buiselement (16) in fluïdumverbinding met het binnenste ballonelement (26) voor het opblazen en leeg laten lopen van het binnenste ballonelement tijdens bedrijf, waardoor respectievelijk een pompbedrijfsmodus en een vulbedrijfsmodus worden gecreëerd, waarbij tijdens bedrijf in de pompbedrijfsmodus, de combinatie van eerste materiaal, afmetingen van de cup-wand, en afmetingen van het uitstroom een opsluitkracht verschaft die tegen een naar buiten gerichte kracht van het binnenste ballonelement in werkt.

3 Note that claim 1 is drafted quite broadly such that even the documents D2 (col. 3, line 35 - col. 4, line 45; figures 1, 2a-2f) and D3 (page 11, line 3; figures 2AB; page 8, lines 1-4) also satisfy the wording of claim 1, so that claim 1 is not new with respect to these documents, either.

4 Dependent claims 2-15, 18-20 do not seem to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of novelty and/or inventive step, see D1-D3 and the passages cited above.

5 The subject-matter of claim 16 (and claim 17 dependent thereon) does not seem to have been disclosed or suggested in the prior art. The provision of a multi-stage balloon assembly allows for a controlled expansion and thus improved control of the cardiac assist device.

Re Item VIII

Certain observations on the application

Claim 1 comprises the feature "een buiselement in fluïdumverbinding met het binnenste ballonelement voor het opblazen en leeg laten lopen van het binnenste ballonelement tijdens bedrijf".

An equivalent passage op page 7 of the description, embodiment 1, lines 15, 16, reads:

"...for inflating and deflating the inner balloon element..."

It could seem that the term "opblazen" in Dutch indicates that the inflation of the inner balloon element should be taking place by a gas, and thus not by a liquid (see e.g. dictionary Van Dale). The description, page 5, lines 30, 31, however lists also a liquid or water as possible second fluids for inflating the inner balloon. It is unclear which type of inflation fluids fall under the definition of claim 1. For the purposes of the present search and opinion, the feature was interpreted as encompassing both gases and liquids.