

DISTAL ANCHORING FOR CARDIAC ASSISTING DEVICE

FIELD OF INVENTION

5 [0001] The present invention relates to a percutaneous implantable heart assisting device.

BACKGROUND OF INVENTION

[0002] Heart failure remains a major health problem, with an estimated prevalence of 1-2% in the adult population of developed countries increasing to 10% from the age of 70 years.

10 [0003] Today, the reference treatment for irreversible bi-ventricular dysfunctions remains heart transplantation. However, the criteria for eligibility for the transplant (selection of candidates) and the shortage of grafts make this therapy available for only a few selected patients. In addition, the waiting lists are very long, leading thus to long waiting times, which incompatible with the precarious health of some candidates.

15 [0004] One way of overcoming this lack of grafts, some systems have been developed based on the combination of Left Ventricular Assis Device (LVAD) and Right Ventricular Assis Device (RVAD) leaving in place the native heart and assisting the two ventricles by two external chambers. Although it is the most usable device in clinical practice, it remains subject to a major risk of complication (infectious, thromboembolic)
20 and the complexity of the installation will increase the mortality risk during surgery.

[0005] As an alternative treatment, the development of total artificial hearts has gradually emerged, with the issue of allowing a return home under the cover of a good quality of life. However, there are many drawbacks that limit their development, including ergonomic limitations, heavy surgery, and the instantaneous death of the patient
25 in the event of a pump stops.

[0006] In addition, most of those patients having bi-ventricular dysfunctions are aged patients and have severe comorbidities and/or diseases, and in this case, no reasonable therapeutic solution is available, as heavy open-heart surgery is excluded.

5 [0007] In the absence of a satisfying solution to treat terminal bi-ventricular dysfunctions, the future directions include the miniaturization of LVADs allowing their implantation by percutaneous or mini-invasive access and the development of a right cardiac assistance fully implantable percutaneously to limit the surgical and infectious risk could be the solution to many patients without therapeutic project.

10 [0008] The development of a miniaturized RVAD used as a destination therapy combine or not with LVAD, implanted without heavy surgery is the solution aimed at to increase the number of patients to be treated, especially patients who are not eligible for heart transplant. A further benefit is to avoid a re-intervention in case of complication or pump malfunction and the possibility to replace it percutaneously, especially in frail elderly patients. However, delivering an assisting device percutaneously inside the right
15 ventricle presents some issues like the sizing of its constitutive elements, and the positioning and securing of said elements inside the patient's heart.

[0009] Regarding human anatomy, the best location for the assisting device is inside the ventricle or atrium of the heart. It is necessary to ensure that the implanted assisting device remains in place in order to avoid its unwanted displacement with the heart of the patient
20 leading to injury risks and to a decrease in its assisting function. The blood flow has to be precisely and safely guided from a first chamber towards a reception conduct and to do so, the assisting device has to be precisely located and maintained in that precise position. This is especially important, as the assisting devices are smaller and smaller and thus more and more likely to embed in some unwanted and dangerous corner or the patient's
25 heart, if not correctly secured. Such a unfortunate displacement may obstruct a functional opening of the patient's heart, for example.

[0010] The technical problem to be solved by the present invention is thus to propose an assisting device which can be safely implanted and maintained inside the human heart,

without significantly changing its position inside the patient's heart, without damaging neither the device nor the patient's heart and without any decrease in its assisting function.

SUMMARY

5 [0011] The present invention aims at solving this problem and thus relates to a cardiac assisting device configured to be percutaneously implanted inside a patient's heart, and configured to drive a blood flow from a first chamber towards a reception conduct by bypassing at least one second chamber, the second chamber putting the reception conduct and the first chamber in fluidic communication, said assisting device comprising:

- an inlet,
- 10 - an outlet conduct,
- a rotary pump configured to drive the blood flow through the assisting device, comprising a pump body surrounding a rotor, said rotary pump connecting the inlet to the outlet conduct, and being designed to be located inside the right atrium or vena cava of the patient's heart.

15 [0012] The assisting device further comprises at least one outlet anchoring element, the at least one outlet anchoring element being configured to anchor the device to the patient's heart and thus to be secured to a membrane of the reception conduct by passing through said membrane, the membrane having an internal side facing the inside of the reception conduct and an external side facing the outside of the reception conduct, the at least one
20 outlet anchoring element is integral with the outlet conduct thus forming an outflow canula, and enables the patient's blood flow to be driven from the inlet to the outlet conduct through the membrane of the reception conduct, the outflow canula is configured to extend, once the device is installed inside the patient's heart, on the internal side and the external side of the membrane.

25 [0013] Thus, this solution achieves the above objective. In particular, it allows the obtaining of a cardiac assisting device of any possible size, which can be safely implanted in any chamber of a patient's heart without the risk of an unwanted displacement, ensuring the blood flow to be correctly driven from the first chamber towards the reception conduct. It also avoids any obstruction of the device inlet (by an unfortunate

displacement) or of any patient's heart opening or conduct and thus prevents any malfunctioning of said device or damaging of the patient's heart.

[0014] The device according to the invention may include one or more of the following characteristics, taken in isolation from one another or in combination with one another:

- 5 - the outflow cannula is one single functional element that cannot be dissociated,
- the outflow cannula is one single piece made of flexible material,
- the outflow canula can extend at least partially along an elongation axis, the outlet anchoring element presenting at least one contact surface extending radially from said elongation axis and being configured to cooperate by abutment with the membrane,
- 10 - the outlet anchoring element can present a circular radial groove configured to radially cooperate with the membrane,
- the at least one outlet anchoring element can be configured to cooperate with a first cooperation zone of the membrane and is further configured to cooperate, by abutment, with a second cooperation zone of the membrane, the first and second
- 15 cooperation zones being separated from each other by an anatomical space inside the reception conduct,
- the outlet anchoring element can comprise at least one expandable inner flange, said inner flange being configured, once the device is installed inside the patient's heart, to extend inside the reception conduct of the patient's heart,
- 20 - the outlet anchoring element can comprise an expandable inner flange and further comprises an expandable outer flange the expandable inner flange being configured, once the device is installed inside the patient's heart, to extend inside the reception conduct of the patient's heart, the expandable outer flange being configured, once the device is installed inside the patient's heart, to extend outside the reception conduct
- 25 of the patient's heart, the cooperation of the inner and outer flanges enabling the pinching of the membrane between the inner and the outer flanges,
- the outlet anchoring elements may be deployable from a retracted configuration to an expanded configuration, the retracted configuration enabling the outlet anchoring element to be introduced through the membrane of the reception conduct, and the
- 30 expanded configuration enabling the outlet anchoring element to stay in place inside the membrane,

- the pump body may present two extremities, and wherein the pump is configured to be anchored to the patient's heart at least at one of the extremities of the pump body,
 - the two extremities of the pump body may be respectively a distal and a proximal extremity, and wherein the pump is configured to be anchored at its distal extremity
- 5 to the patient's heart or the reception conduct.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] The invention will be better understood, and other aims, details, characteristics and advantages thereof will emerge more clearly on reading the detailed description which follows, of one or several embodiments of the invention given by way of illustration. Those are purely illustrative and non-limiting examples, with reference to the

10 accompanying schematic drawings. On these drawings:

- **figure 1** is a schematical open view of a classic human heart,
- **figures 2a** schematical perspective view of a classic human heart showing the transverse section planes of figures 2b and 2c,
- 15 - **figure 2b** is a schematical transverse sectional view of a classic human heart on a first section plane,
- **figure 2c** is a schematical transverse sectional view of a classic human heart on a second section plane,
- **figure 3a** is the schematical sectional view of figure 2a presenting the second
- 20 anastomosis according to the present invention,
- **figure 3b** is the schematical sectional view of figure 2b presenting the first anastomosis according to the present invention,
- **figure 4a** is a perspective view of an assisting device with exception to the pump anchoring element , according to the present invention and its localization inside
- 25 a patient's heart,
- **figure 4b** is a second perspective view of the assisting device according to figure 4a inside a longitudinal heart section,
- **figures 5a to 5c** are a series of different views of a first embodiment of an outlet anchoring element of the device according to the present invention,

- **figures 6a to 6c** are a series of different views of a second embodiment of an outlet anchoring element of the device according to the present invention,
- **figure 7a to 7c** are a series of different views of a third embodiment of an outlet anchoring element of the device according to the present invention,
- 5 - **figure 8a to 8c** are a series of different views of a fourth embodiment of an outlet anchoring element of the device according to the present invention,
- **figure 9** is a perspective view of an embodiment of an assisting device,
- **figure 10** is a perspective view of another embodiment of an assisting device,
- 10 - **figure 11** is a perspective view of an outflow cannula according to the preceding invention.

DETAILED DESCRIPTION

[0016] As can be seen on figures 1 and 2a, a classic human heart 100 presents a long heart axis X and a short heart axis Y. Considering a classic human heart 100, oxygen-poor blood enters the heart 100 through the inferior vena cava IVC or the superior vena cava SVC towards the right atrium RA, crosses the tricuspid valve 101, enters the right ventricle RV, crosses the pulmonary valve 102 into the pulmonary arteries PA and moves on to the lungs. Oxygen-rich blood comes back from the lungs into the heart 100 through the left atrium LA, crosses the mitral valve 103, enters the left ventricle LV, eventually crosses the aortic valve 104 and leaves the heart through the aorta AO.

20 [0017] The present invention is about a cardiac assisting device 10 configured to be percutaneously implanted inside a patient's heart 100 as described above, and configured to drive a blood flow from a first chamber 110 (for example the left atrium LA, the superior vena cava SVC or the right atrium RA) towards a reception conduct 120 (for example the aorta AO or the pulmonary artery PA) by bypassing at least one second chamber (for example the right atrium RA, the left atrium LA or the superior vena cava SVC), the second chamber putting the reception conduct 120 and the first chamber 110 in fluidic communication. The term "bypassing" means than, with regards to the natural circuit of the blood flow inside a patient's heart 100, at least one of the chambers of this natural circuit (right atrium RA, right ventricle RV, left atrium LA, left ventricle LV), is

bypassed by the blood flow once the cardiac assisting device 10 is implanted and functioning.

[0018] According to the present invention, said assisting device 10 comprises:

- an inlet 12 (on a proximal extremity of the device 10),
- 5 - an outlet conduct 14 (on a distal extremity of the device 10),
- a rotary pump 16 connecting the inlet 12 to the outlet conduct 14.

[0019] In this context, "connects" means "putting in communication", more precisely putting in communication, more precisely putting in fluidic communication, in order to constitute a continuous channel forming one single functional piece. This single
10 functional piece thus enables a fluid to circulate from the inlet conduct 12 towards the outlet conduct 14 through the pump housing 16. The outflow conduct 14 may present a tubular shape or present a conical shape, the outflow conduct 14 then presenting a lower diameter at its extremity connected to the pump 16 and a higher diameter towards the outlet of the device 10. The diameter(s) of the outlet conduct 14 ranges from 5 to 15mm.

15 **[0020]** The device inlet 12, device outlet 14 and rotary pump 16 can be located, once implanted, either in the same chamber of the patient's heart 100 or in different chambers of the patient's hearts 100. Depending on the size of the patient's heart 100, the device inlet 12 might be located very close to an anatomical wall of the patient's heart 100. In order to enable the patient's blood flow to be safely driven from the inlet 12 to the outlet
20 conduct 14, and thus from the first chamber 110 (LA, SVC or RA) to the reception conduct 120 (AO or PA) of the patient's heart 100, the device 10 is further configured to cross a membrane M of the reception conduct 120. The membrane M presents an internal side S_1 facing the inside of the reception conduct 120 and an external side S_2 facing the outside of the reception conduct 120. The membrane M can be a single membrane or a
25 double membrane (see figures 6a and 6b). The diameter of the reception conduct 120 is comprised, depending on the patient, between 20 to 40mm.

[0021] The rotary pump 16 is configured to drive the blood flow through the assisting device 10. The rotary pump 16 comprises a pump body 160 surrounding a rotor. In order to enable the patient's blood flow to be driven from the inlet 12 to the outlet conduct 14

from the first chamber 110 to the reception conduct 120 of the patient's heart 100, the pump 16 presents a global tubular shape and is tightly connected to both the inlet 12 and the outlet conduct 14. The rotary pump 16 is further designed to be located inside the right atrium RA, the Superior vena cava SVC or the inferior vena cava IVC of the patient's heart 100.

[0022] The rotary pump 16 provides a fluidic pressure ranging from 70 to 130mmHg for a left-side implantation and ranging from 10 to 40mmHg for a right-side implantation. The rotary pump 16 further provides a fluidic debit ranging from 2 to 4L/min for a left-side implantation and a fluidic debit ranging from 2 to 4 L/min for a right-side implantation.

[0023] The pump body 160 presents two extremities, a distal and a proximal extremity. The proximal extremity of the pump body 160 is connected to the inlet 12 and the distal extremity of the pump body 160 is connected to the outlet conduct 14.

[0024] The rotary pump 16 is preferably an axial pump (see figure 10). The rotary pump 16 thus extends axially along the elongation axis X. The pump inflow 16i, any rotor comprised in the pump 16 and the pump outflow 16o are thus all aligned along the elongation axis X. The device inlet 12 is thus aligned along the elongation axis X, in order to guide the blood flow inside the device 10 from the device inlet 12 to the pump outflow 16o along the elongation axis X. The assisting device 10 thus extends in a straight line along the extension axis X from the pump inflow 16i to the pump outflow 16o, and preferably from the inlet inflow 12 to the pump outflow 16o. This particular straight-line shape enables the assisting device 10 to maintain a small diameter all over the length of the assisting device 10 and make it thus easily implantable via catheter, without any need of deforming the pump body 160 during (or after) implantation.

[0025] The device inlet 12 is coaxially arranged at an upstream portion of the device 10 and comprises at least one inlet opening 12o enabling blood to flow through the pump body 18. The at least one inlet opening 12o may open axially or radially with respect to the elongation axis X. The device inlet 12 presents at least one inlet opening 12o

configured to enable a blood flow to pass through the pump body 18. Preferably, the at least one inlet opening 12o opens transversally with regards to the elongation axis X.

[0026] On the other side of the pump body 160, the device outlet 14 is coaxially arranged at a downstream portion of the device 10 and comprises at least one outlet opening O enabling blood to flow out the device 10 inside the reception conduct 120.

[0027] As can be seen on figures 4b and 10, the device outlet 14 is configured to change an orientation of the outlet opening O with regards to the elongation axis X. In other words, the device outlet 14 extends at least partially along an outflow axis Y, different from the extension axis X. More precisely, the outflow axis Y and the elongation axis X intersect each other at an angle ranging from 1 to 189°. Preferably the outflow axis Y and the elongation axis X intersect each other at an angle ranging from 1 to 90°. This way the outlet opening O is not aligned with the pump outflow 16o. This variable unalignment of the outlet opening O with the pump outflow 16o, enables the device 10 to adapt to a higher variety of heart sizes and shapes without causing any damages.

[0028] The device outlet 14 is, contrary to the rotary pump 16, deformable. The device outlet 14 is preferably a bendable cylinder. The device outlet 14 is configured to adapt to the patient's heart 100 morphology. Preferably, the device outlet 14 is preferably made of flexible tube materials, and can for example be a coated meshed or braided or spiraled stent made for example of *Nitonol*, and/or *stainless steel*. Depending on the used materials, the device outlet 14 folds and unfolds, thus enabling an easy introduction and it can further, once implanted, adapt the patient's heart shape depending on the position of the rotary pump 16 inside the patient's heart 100. This flexibility precisely offers the possibility to vary the angle between the pump outflow 16o and the device outlet 14 thus improving the adaptation of the device 10 to the natural shape of the patient's heart 100 without affecting the shape of the pump 16.

[0029] In order to stabilize the implantation of the device 10, the device 10 and more particularly the pump 16 is configured to be anchored to the patient's heart 100 at least at one of the extremities of the pump body 160. Preferably, the pump 16 is configured to be anchored to the patient's heart 100 at its distal extremity, by means of a pump anchoring

element 17, as can be seen on figure 9. The pump anchoring element 17 is configured to secure the pump 16, and more particularly the pump body 160 of the pump 16 to a chamber membrane of the first chamber 110. More particularly, this chamber membrane is the wall of the right atrium 102 and/or vena cava inferior 101. Depending on the shape of the pump anchoring element 17, it might also expand inside the vena cava inferior 101, be stuck like a spherical or cylindrical shaped element inside a cylindrical conduct and secure the device 10 this way.

[0030] As can be seen on figures 5a to 8c the assisting device 10 further comprises at least one outlet anchoring element 18. This outlet anchoring element 18 is configured to anchor the device 10, and more particularly the device outlet 14, to the patient's heart 100. More particularly, as mentioned above, the anchoring element 18 is configured to secure the distal extremity of the device 10 to the patient's heart 100 to a membrane of the patient's heart. The anchoring element 18 is thus configured to be secured to the membrane M of the reception conduct 120 by passing through said membrane M. The outlet anchoring element 18 crosses the membrane M by means of an artificial anastomosis created percutaneously by a surgeon or an interventional cardiologist. Said anastomosis presents an aperture 200 with a diameter ranging from 5 to 15mm opening inside the reception conduct 120. The aperture 200 is also circumscribed by an edge presenting the regular elasticity and width of the membrane M of the patient's heart 100.

[0031] The outlet anchoring element 18 thus presents a central hole presenting a diameter ranging from 5 to 15mm, corresponding to the diameter of the aperture 200 of the anastomosis of the membrane M.

[0032] As can be seen on the figures, the at least one outlet anchoring element 18 is integral with the outlet conduct 14 thus forming an outflow cannula 20. The outflow cannula 20 is one single functional element that cannot be dissociated. The outlet anchoring element 18 and the outlet conduct 14 form a single functional element and cannot be dissociated from each other. This enables a higher stability and a higher safety as this leads to lesser elements to be inserted and/or combined once inserted. The outflow cannula 20 is one single piece, preferably made of flexible material. Thus, in some specific embodiment illustrated on figures 4b and 11, the device outlet 14 comprises a

bendable outflow cannula 20. The outflow cannula 20 presents the general shape of a tube with a tapered end at a distal extremity. The outflow cannula 20 thus comprises a central part formed by a coil (made of, for example Nitinol, and/or stainless steel), a proximal extremity configured to secure the outflow cannula 20 to the pump outflow 16a and a distal extremity formed by a mesh and presenting a tapered shape with a small diameter at an upstream extremity and a large diameter at a downstream extremity. The tapered end can be crimped during implantation and expands after implantation. The outflow cannula 20 is further coated with, for example, PU, PTFE, and/or ePTFE. The diameter of the coil ranges from 6 to 10mm, preferably 8mm and the larger diameter of the tapered extremity ranges from 18 to 21mm, preferably 20mm. The wall thickness of the coil and the tapered end ranges from 0,2 to 0,4mm. The coil is formed one single wound wire (spiral), thus forming a structure of parallel filaments. This specific structure enables the outflow cannula 20 to be folded with a small bending radius while presenting high radial forces (with regards to the state of the art) and avoiding the cannula to be kinked as a kink would block the blood flow circulation.

[0033] The device 10 thus enables the patient's blood flow to be driven from the inlet 12 to the outlet conduct 14 through the membrane M of the reception conduct 120. The outflow cannula 20 presents a tubular or a conical shape in the continuity of the rotary pump 16. (see figure 5c) with a diameter ranging from 5 to 12mm at the connection with the pump 16 and ranging from 7 to 15mm at the outlet of the device 10. In those embodiments, the diameter of the outflow cannula 20 is thus higher in the reception conduct 120 than at the pump 16. The outflow cannula 20 thus extends at least partially along an elongation axis X. Preferably, the outflow cannula 20 extends partially along an elongation axis X and partially along the outflow axis Y.

[0034] In a more convenient embodiment, the device 10 is deployable from a retracted configuration to an expanded configuration in order to ease its implantation. Thus, more particularly, the outlet anchoring elements 18 is deployable from a retracted configuration to an expanded configuration:

- the retracted configuration enables the outlet anchoring element 18 to be introduced through the membrane M of the reception conduct 120, and

- the expanded configuration enables the outlet anchoring element 18 to stay in place inside the membrane M.

When expanded, the outlet anchoring element 18 presents an outer diameter ranging from 10mm to 30mm.

- 5 **[0035]** In order to securely drive the blood flow inside the reception conduct 120, the outflow canula 20 is configured to extend, once the device 10 is installed inside the patient's heart 100, from the internal side S_1 and from the external side S_2 of the membrane M.

- 10 **[0036]** The outflow canula 20 is thus configured to cooperate radially with the edge of the aperture 200 of the second inside the membrane M. This radial cooperation ensures a tight and strong cooperation between the membrane M and the outflow canula 20. This radial cooperation thus ensures that the blood flow driven by the assisting device 10 (around 30 to 70% of the complete patient's blood flow) flows through the membrane M, from the inside of the assisting device 10 inside the reception conduct 120 of the patient's
- 15 heart 100.

- 20 **[0037]** In order to optimize the cooperation with membrane M, the outlet anchoring element 18 presents at least one contact surface 22 extending radially (or perpendicularly) from said elongation axis X. Said contact surface 22 is configured to cooperate by abutment with the membrane M. More precisely, the contact surface 22 abuts again the internal side S_1 of the membrane M of the reception conduct 120. Said contact surface 22 can, for example, be a discontinues surface (see figures 5a, 5b, 5c) and can for example present a disc shape (figure 5c) or a serrated shape (figures 5a, 5b). It can be expandable and, depending on the embodiment, can thus be foldable along the elongation axis X. Thus, the outlet anchoring element 18 comprises at least one inner flange 24 configured,
- 25 once the device 10 is installed inside the patient's heart 100, to extend inside the reception conduct 120 of the patient's heart 100. In some embodiments, the inner flange 24 presents a leaf shape.

- [0038]** In some further embodiment, the contact surface 22 can be a double contact surface which, cooperates with both the internal side S_1 and the external side S_2 of the

membrane M. In those embodiments, the outlet anchoring element 18 comprises an inner flange 24 and an outer flange 26. In those embodiments, the inner flange 24 is configured, once the device 10 is installed inside the patient's heart 100, to extend inside the reception conduct 120 of the patient's heart 100, while the outer flange 26 is configured, once the device 10 is installed inside the patient's heart 100, to extend outside the reception conduct 120 of the patient's heart 100. The cooperation of the inner and outer flanges 24, 26 enable the pinching of the membrane M between the inner and the outer flanges 24, 26. The inner and the outer flanges 24, 26 can be expandable. They also can be foldable along the elongation axis X. They can present the same shape. They also can present different shape. They can present the same size. They also can present different sizes (see figure 6c). They can present a leaf shape, or a disc shape (figure 6c) or a serrated shape (figure 6a, 6b), for example. The inner and the outer flanges 24, 26 may present a continuous or a discontinuous surface. The outer diameter of each flange 24, 26 at the inner side S₁ and/or outer side S₂ of the membrane M, is from 3 to 12mm larger than the diameter of the central hole of the outlet anchoring element 18.

[0039] The outlet anchoring element 18 thus cooperates both radially and longitudinally (with regards of the elongation axis X) with the membrane M: radially with the edges of the of the aperture 200 of anastomosis and longitudinally with the contact surface 22 of the membrane M.

[0040] In order to optimize the radial cooperation with the edge of the aperture 200 of anastomosis, in some embodiments, the outlet anchoring element 18 can present, on its circumference, a reinforced zone 27 with a distal and a proximal extremity (see figure 5c). Alternatively, in some embodiment, the outlet anchoring element 18 can present a circular radial groove 28 configured to radially cooperate with the aperture 200 of the anastomosis of the membrane M. This radial groove 28 can be defined and/or circumscribed by one or several radial flanges which can include the contact surface 22 (see figures 5c and 6c).

[0041] In some embodiments, as depicted on figures 5a to 7c, the at least one outlet anchoring element 18 is configured to cooperate with a first cooperation zone Z₁ of the membrane M and is further configured to cooperate, by abutment, with a second

cooperation zone Z_2 of the membrane M. Both cooperation zones Z_1 , Z_2 are preferably located on the internal side S_1 of the membrane M. The first and second cooperation zones Z_1 , Z_2 are separated from each other by an anatomical space A inside the reception conduct 120.

- 5 **[0042]** In those embodiments, the inner flange 26 thus expands inside the reception conduct 120 from the first cooperation zone Z_1 towards the second cooperation zone Z_2 , along the diameter D of the reception conduct 120. In those embodiments, the inner flange 26 presents an open shape which enables the blood flow to circulate inside the reception
10 **conduct 120 of the patient's heart 100. Those shapes can include, for example, tubular or circular shapes (see figures 7a to 8c). Those kinds of inner flanges 26 can be made of mesh (see figures 7a, 8a), or made of arches (see figures 7b, 7c).**

- [0043]** In a well-known way, the rotor generates depression in order to drive the blood flow inside the assisting device 10. This negative pressure is thus exerted in the chamber
15 **of the patient's heart 100 in which the assisting device 10 is implanted (more particularly in which the device inlet 12 and more particularly the inlet opening 12o, is located). Said negative pressure is therefore also exerted on the anatomical wall of the chamber of the patient's heart 100. If the device inlet 12 is located closely to the anatomical wall of the chamber, said anatomical wall could be deformed and drawn towards the device inlet 12. This deformation could lead to injuries and/or an obstruction of the device inlet 12.**

- 20 **[0044]** In order to avoid such deformation and/or obstruction issues, the pump body 160 comprises a spacing organ 30, as can be seen on figures 9 and 10. The spacing organ 30 extends at least partially radially from an external surface S of the pump body 160. More precisely, the spacing organ 30 extends at least partially away from the elongation axis X. This way, the spacing organ 30 is configured to maintain a predefined space between
25 **any anatomical walls of the patient's heart 100 and the device inlet 12. Preferably, the space ranges from 15 mm to 30 mm.**

[0045] The spacing organ 30 extends at least partially along the elongation axis X. It thus presents a longitudinally length ranging from 10 mm to 40 mm along the elongation axis X.

[0046] In the embodiment depicted on figures 9 and 10, the spacing organ 30 presents a distal extremity and a proximal extremity with regards to the elongation axis X, each extremity being secured to the surface S of the pump body 160. In those embodiments, the spacing organ 30 surrounds at least partially the device inlet 12. More particularly,
5 the spacing organ 30 surrounds the at least one inlet opening 12o.

[0047] In the embodiment depicted on figure 10, the spacing organ 30 comprises several distinct spacing elements 300 distributed around the external surface S of the pump body 160 and more particularly over the device inlet 12. Those spacing elements 300 could for example be arched or bent stent's struts.

10 [0048] In some alternative embodiments, the spacing organ 30 comprises several spacing elements 300 connected to each other in order to form a spacing structure at least partially surrounding the pump body 160. In those cases, the spacing structure is at least partially made of mesh. More particularly, in the embodiments of figures 8 and 10, the complete spacing structure is an expandable mesh. This mesh can be radially elastically
15 deformable. In some embodiments, the spacing structure could be expandable struts.

[0049] In some embodiments, the spacing organ 30 presents a distal extremity and a proximal extremity with regards to the elongation axis X, the distal extremity being a free extremity. The spacing organ 30 could comprise at least one spike at least partially extending along the elongation axis X. In those embodiments also, the spacing organ 30
20 could comprise several distinct spacing elements 300 distributed around the external surface S of the pump body 160 and more particularly over the device inlet 12, like a sort of crown.

[0050] Regardless of the detailed structure of the spacing elements 300 of the spacing organ 30, the spacing organ 30 comprises at least one radial portion extending along a
25 secondary elongation axis. This secondary elongation axis extends radially with regards to the elongation axis X. This ensures that at least a part of the spacing organ is remote from the pump body 160 and particularly from the inlet opening 121.

[0051] Regardless of the embodiment, the spacing organ 30 comprises a part at least partially surrounding the pump body 160. In a preferred embodiment, the spacing organ

30 comprises a part at least partially surrounding the device inlet 12. More particularly, the spacing organ 30 surrounds the at least one inlet opening 12o. Preferably, the spacing organ 22 comprises at least one remote portion facing the inlet opening 12o at a distance.

5 [0052] In some embodiments, the spacing organ 30 is secured to the pump body 160 by means of a securing ring strapping the pump body 160. In some embodiments, the spacing organ 28 is welded to the pump body 160. In some other embodiments, the spacing organ 28 forms one single piece with the pump body 160 and is part of the surface S.

10 [0053] In order to ease the adaptation of the assisting device 10 to the specific shape of the chamber of the patient's heart 10, the spacing organ 30 is radially elastically deformable. For example, the spacing organ 30 could be at least partially made of Nitinol material.

15 [0054] In order to avoid any tension on the anatomic walls of the patient's heart 100, the spacing organ 30 is configured to be free to move with regards of any of the anatomical walls of the patient's heart 100. This way, regardless of the movements of the implanted assisting device 10, the spacing organ 30 does not pull or tear the anatomic walls and is not pulled or torn by an anatomical wall to which it would be attached, and remains thus entirely functional and able to generate the necessitated space between any anatomical walls of the patient's heart 100 and the device inlet 12.

20 [0055] In order to ease the implantation of the assisting device 10, the spacing structure 30 is a radially expandable structure, with regards to the elongation axis X. The spacing organ 30 is thus inserted inside the patient's heart 100 in a folded configuration and, once the assisting device 10 is rightfully in place inside the patient's heart 100, the spacing organ 30 expands inside the chamber of the patient's heart, thus protecting the device inlet 12 once everything is in place. In its expanded configuration, the spacing organ 30 displays an extended diameter ranging from 15 to 30mm. In its expanded configuration, the spacing organ 30 is configured to maintain the predefined space between the anatomical wall of the patient's heart 100 and the device inlet 12.

[0056] In some embodiments, the pump anchoring element 17 and the spacing organ 30 form two functional parts of a single structural element (see figure 9). In those

embodiments, the pump anchoring element 17 and the spacing organ 30 can even be merged and thus be the same element (for example in figure 10).

CLAIMS

1. Cardiac assisting device (10) configured to be implanted inside a patient's heart (100), and configured to drive a blood flow from a first chamber (110) towards a reception conduct (120) by bypassing at least one second chamber, the second chamber putting the reception conduct (120) and the first chamber (110) in fluidic communication, said assisting device (10) comprising:
- an inlet (12),
 - an outlet conduct (14)
 - a rotary pump (16) configured to drive the blood flow through the assisting device (10), comprising a pump body (160) surrounding a rotor, said rotary pump (16) connecting the inlet (12) to the outlet conduct (14), and being designed to be located inside the right atrium (RA) or vena cava (VC) of the patient's heart (100),
- wherein**
- the assisting device (10) further comprises at least one outlet anchoring element (18), the at least one outlet anchoring element (18) being configured to anchor the device (10) to the patient's heart (100) and thus to be secured to a membrane (M) of the reception conduct (120) by passing through said membrane (M), the membrane (M) having an internal side (S₁) facing the inside of the reception conduct (120) and an external side (S₂) facing the outside of the reception conduct (120),
 - the at least one outlet anchoring element (18) is integral with the outlet conduct (14) thus forming an outflow cannula (20), and enables the patient's blood flow to be driven from the inlet (12) to the outlet conduct (14) through the membrane (M) of the reception conduct (120),
 - the outflow cannula (20) is configured to extend, once the device (10) is installed inside the patient's heart (100), on the internal side (S₁) and the external side (S₂) of the membrane (M).
2. Cardiac assisting device (10) according to the preceding claim, **wherein** the outflow cannula (20) is one single functional element that cannot be dissociated.
3. Cardiac assisting device (10) according to the preceding claim, **wherein**, the outflow cannula (20) is one single piece made of flexible material.

4. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the outflow canula (20) extends at least partially along an elongation axis (X), the outlet anchoring element (18) presenting at least one contact surface (22) extending radially from said elongation axis (X) and being configured to cooperate by abutment with the membrane (M).
5. Cardiac assisting (10) device according to the preceding claim, **wherein** the outlet anchoring element (18) presents a circular radial groove (28) configured to radially cooperate with the membrane (M).
6. Cardiac assisting device (10) according to the preceding claim, **wherein** the at least one outlet anchoring element (18) is configured to cooperate with a first cooperation zone (Z₁) of the membrane and is further configured to cooperate, by abutment, with a second cooperation zone (Z₂) of the membrane (M), the first and second cooperation zones (Z₁, Z₂) being separated from each other by an anatomical space (A) inside the reception conduct (120).
7. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the outlet anchoring element (18) comprises at least one expandable inner flange (24), said inner flange (24) being configured, once the device (10) is installed inside the patient's heart (100), to extend inside the reception conduct (120) of the patient's heart (100).
8. Cardiac assisting device (10) according to the preceding claim, **wherein** the outlet anchoring element (18) comprises an expandable inner flange (24) and further comprises an expandable outer flange (26) the expandable inner flange (24) being configured, once the device (10) is installed inside the patient's heart (100), to extend inside the reception conduct (120) of the patient's heart (100), the expandable outer flange (26) being configured, once the device (10) is installed inside the patient's heart (100), to extend outside the reception conduct (120) of the patient's heart (100), the cooperation of the inner and outer flanges (24, 26) enabling the pinching of the membrane (M) between the inner and the outer flanges (24, 26).

9. Cardiac assisting device (10) according to the preceding claims, **wherein** the outlet anchoring elements (18) is deployable from a retracted configuration to an expanded configuration, the retracted configuration enabling the outlet anchoring element (18) to be introduced through the membrane (M) of the reception conduct
5 (120), and the expanded configuration enabling the outlet anchoring element (18) to stay in place inside the membrane (M).
10. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the pump body (160) presents two extremities, and **wherein** the pump (16) is
10 **configured to be anchored to the patient's heart (100)** at least at one of the extremities of the pump body.
11. Cardiac assisting device (10) according to the preceding claim, **wherein** the two extremities of the pump body (160) are respectively a distal and a proximal extremity, and **wherein** the pump (16) is configured to be anchored at its distal extremity **to the patient's heart (100) or the reception conduct (120)**.