

AXIAL CARDIAC ASSISTING DEVICE

FIELD OF INVENTION

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

5 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) and the complexity of the installation will increase the mortality risk during surgery.

20 [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 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 hybrid 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.

15 [0009] However, delivering an assist device percutaneously inside the right ventricle presents some issues like the sizing of its constitutive elements, and the positioning and securing of said elements inside the patient's heart. Particularly, the size and shape of the assist device can hinder or prevent its percutaneous implantation by means of a catheter.

20 [0010] The technical problem to be solved by the present invention is thus to propose an assist device which can provide an efficient cardiac assist device, preferably a right ventricular support, within dimensions that allows a safe and easy percutaneous implantation through catheters.

SUMMARY

25 [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 of the patient's heart towards a reception conduct of the patient's heart by bypassing at least one second chamber of the

patient's heart, the second chamber putting the reception conduct and the first chamber in fluidic communication, said assisting device comprising:

- a device inlet configured to open in the first chamber,
 - a device outlet comprising at least one outlet opening (142) configured to open in
5 the reception conduct,
 - a rotary pump connecting the device inlet to the device outlet, the rotary pump comprising a pump body with a pump inflow in fluidic communication with the device inlet and a pump outflow in fluidic communication with the device outlet, the rotary pump further comprising an impeller located inside the pump body between the pump inflow
10 and the pump outflow,
 - a support device configured to pass through at least one membrane of the patient's heart, said support device comprising an outlet support element configured to secure the device outlet to a conduct membrane of the reception conduct, the outlet support element being configured to pass through the conduct membrane.
- 15 In the present invention:
- the rotary pump extends axially along an elongation axis X, the pump inflow, the impeller and the pump outflow being all aligned along the elongation axis X,
 - the device inlet being aligned along the elongation axis X, in order to guide the blood flow inside the device from the device inlet to the pump outflow along the
20 elongation axis X,
 - the device outlet being configured to change an orientation of the outlet opening with regards to the elongation axis X.

[0012] Thus, this solution achieves the above objective. In particular, it allows the obtention of a functional cardiac assist device presenting a shape enabling a safe
25 percutaneous implantation. It further enables a high adaptation to a wide range of patient's hearts shapes and size due to the flexibility of the outlet while ensuring a steady straight blood flow in the pump due to its elongated shape.

[0013] 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:

- 30 - the device outlet comprises a deformable cannula,

- the deformable cannula comprises a coated coil,
- the cardiac assisting device is specially designed to be a right cardiac assisting device, the device inlet and the rotary pump being configured to be located inside the right atrium or the vena cava as the first chamber, and the at least one outlet support element being configured to be secured to the conduct membrane separating the right atrium or the vena cava from the pulmonary artery as the **reception conduct of the patient's heart**,
- the outlet support element is configured to be secured to a wall of the superior or inferior vena cava as the conduct membrane,
- the support device further comprises a pump support element configured to secure the pump body to a chamber membrane of the first chamber, the pump support element being configured to pass through the chamber membrane,
- the impeller is surrounded by a compression chamber located inside the pump body,
- the rotary pump comprises a diffusor between the pump outflow and the impeller,
- **the rotary pump is configured to be anchored to the patient's heart at one of proximal and distal extremities of the pump body.**

[0014] The present invention is also about a heart assisting kit comprising:

- an assisting device according to any one of the preceding claims,
- a control unit for controlling the rotary pump,
- a power supply for supplying power to the rotary pump.

[0015] Finally, the present invention has also for object an implantation method for a cardiac assisting device according to the description here-above, wherein the method includes following steps:

- preparation and creation of an anastomosis hole:
 - o create needed accesses through an access vein of the patient,
 - o insert a guidewire and place it at first chamber,
 - o insert a needle,
 - o puncture the membrane at the cross section between the first chamber and the reception conduct,

- place a guidewire through the anastomosis inside the reception conduct CR,
- assist device 10 placement:
 - dilate the access vein with a dilator set,
 - insert an introducer and a dilator over the guidewire and place its distal end inside the reception conduct C_R,
 - withdraw the dilator from the introducer,
 - insert a pump catheter into the introducer,
 - place the rotary pump at the distal end of the introducer,
 - deliver the rotary pump by pulling back the introducer,
 - disconnect the rotary pump from the pump catheter,
 - withdraw the pump catheter and the introducer,
 - run the device.

BRIEF DESCRIPTION OF THE DRAWINGS

- **Figure 1** is a schematic longitudinal section view of a patient's heart,
- **Figure 2** is the same schematic view as figure 1, in which a cardiac assisting device has been inserted inside the patient's heart,
- **Figure 3** is a perspective view of an embodiment of an assisting device according to the present invention,
- **Figures 4a** and **4b** are a perspective view of a device outlet according to the present invention, comprising a cannula in a straight (before implantation) position and a bent (after implantation) position,
- **Figure 5** is a perspective view of another embodiment of an assisting device according to the present invention.

DETAILED DESCRIPTION

- [0016]** Classically, as can be seen on figure 1, the oxygen-poor blood flow coming from a patient's body is led to the patient's heart 100 by the inferior/superior vena cava 101 and enters the patient's heart 100 through the right atrium 102. The oxygen-poor blood flow then crosses the tricuspid valve and enters the right ventricle 104. The oxygen-poor blood flow then leaves the right ventricle 104 by crossing the pulmonary valve and flows towards the lungs through the pulmonary artery 106. The blood flow is oxygenated in the

lungs and is fled once again towards the heart 100 by the pulmonary veins and reinters the heart 100 through the mitral valve inside the left atrium 108 and then into the left ventricle 110. The oxygen-rich blood flow then crosses the aortic valve and leaves the heart 100 through the aorta towards the patient's body. For a purpose of simplification, in the present invention, it is considered that the vena cava 101 is part of the human heart 100, in a broad interpretation of the human heart 100.

[0017] The present invention is about a cardiac assisting device 10 configured to be implanted inside a patient's heart 100. The cardiac assisting device 10 can be implanted in any chamber of the patient's heart 100. The cardiac assisting device 10 is classically configured to circulate a blood flow from a first chamber C_1 of the patient's heart 100 towards a reception conduct C_R by bypassing a second chamber of the patient's heart 100 through which the blood would naturally flow. Generally speaking, the second chamber puts the reception conduct C_R and the first chamber C_1 in natural fluidic communication. When the cardiac assisting device 10 is implanted, it is the cardiac assisting device 10 which puts the reception conduct C_R and the first chamber C_1 in fluidic communication. In the particular case of the present invention, the first chamber C_1 might be the right atrium 102, the vena cava 101 or the left atrium 108, the reception conduct C_R might be the aorta or the pulmonary artery 106 and the second chamber might be the right ventricle 104 or the left ventricle 110.

[0018] 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 102, right ventricle 104, left atrium 108, left ventricle 110), is bypassed by the blood flow once the cardiac assisting device 10 is implanted and functioning.

[0019] Each chamber of the patient's heart 100 is delimited by at least one anatomical wall or membrane presenting some natural elasticity.

Assisting device

[0020] The cardiac assisting device 10 according to the present application, is configured to be percutaneously implanted inside a patient's heart 100.

[0021] Regardless of the embodiment and implantation place, said assisting device 10 extends partially along a straight extension axis X and comprises:

- a device inlet 12 configured to open in the first chamber C₁,
- a device outlet 14 configured to open in the reception conduct C_R,
- 5 - a rotary pump 16 connecting the device inlet 12 to the device outlet 14.

[0022] 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.

[0023] In one particular embodiment, the cardiac assisting device 10 according to the present invention is specially designed to be a right cardiac assisting device. In this embodiment, the device inlet 12 and the rotary pump 16 are configured to be located inside the right atrium 102 or the vena cava 101 as the first chamber C₁.

[0024] Thus, depending on the embodiment, the rotary pump 16 is designed to be located inside the right atrium 102 or the vena cava 101 of the patient's heart 100.

15 [0025] The device inlet 12 is coaxially arranged at an upstream portion of the device 10 and comprises at least one inlet opening 121 enabling blood to flow from the first chamber C₁ through the rotary pump 16. The at least one inlet opening 121 may open axially or radially with respect to the elongation axis X.

[0026] The device outlet 14 is coaxially arranged at a downstream portion of the device 20 10 and comprises at least one outlet opening 142 enabling blood to flow out the device 10 inside the reception conduct C_R.

[0027] As can be seen on figures 2 and 4b the device outlet is configured to change an orientation of the outlet opening 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 142 is not aligned with the pump outflow 162. This variable unalignment 25

of the outlet opening 142 with the pump outflow 162, 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 for example Nitinol, 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 162 and the device outlet 142 thus improving the adaptation of the device 10 to the natural shape of the patient's heart 100 without affecting the shape of the rotary pump 16 (see further below).

[0029] In some specific embodiment illustrated on figures 4a and 4b the device outlet 14 comprises a deformable cannula 140. The deformable cannula 140 presents the general shape of a tube with a tapered end at a distal extremity. The deformable cannula 140 thus comprises a central part formed by a coil (made for example of Nitinol, and/or stainless steel), a proximal extremity configured to secure the deformable cannula 140 to the pump outflow 162 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 deformable cannula 140 is further coated with, for example, Polyurethane, PTFE, 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 wounded wired (spiral), thus forming a structure of parallel filaments. This specific structure enables the deformable cannula 140 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.

[0030] The assisting device 10 further comprises a support device 20 configured to secure and/or stabilize the device 10 inside the patient's heart 100. Said support device 20 comprises at least one outlet support element 22 and, in some embodiments, a pump support element 24. In case the device 10 comprises a deformable cannula 140 as described here-above, the tapered end of the deformable cannula 140 forms an outlet support device 22. In those embodiments, the at least one outlet support device 22 is integral with the device outlet 14 thus forming the deformable cannula 140.

[0031] The at least one outlet support element 22 is configured to tightly cooperate with the membrane M in order to immobilize the pump 16 and the device outlet 14 inside the patient's heart 100 (or vena cava 101) and enable the patient's blood flow to be driven from the device inlet 12 to the device outlet 14 through the at least one membrane M of the patient's heart 100, more particularly through the conduct membrane M₁.

[0032] As mentioned, this support device 20 comprises at least one outlet support element 22. The at least one outlet support element 22 is configured to secure the device outlet 14 to a conduct membrane M₁ of the reception conduct C_R. When the assisting device 10 is implanted inside the patient's heart 100, the outlet support element 22 crosses the conduct membrane M₁ and leads the blood of the patient through the conduct membrane M₁. The at least one outlet support element 22 crosses the conduct membrane M₁ by means of an artificial anastomosis created percutaneously by a surgeon or an interventional cardiologist. Said anastomosis presents an aperture with a diameter ranging from 5 to 15mm opening inside the reception conduct C_R. The aperture is also circumscribed by an edge presenting the regular elasticity and width of the membrane M of the patient's heart 100. The at least one outlet support element 22 thus presents a central hole presenting a diameter ranging from 5 to 15mm, corresponding to the diameter of the aperture of the anastomosis of the conduct membrane M₁.

[0033] In a convenient embodiment, the device 10 is at least partly deployable from a retracted configuration to an expanded configuration in order to ease its implantation. Thus, more particularly, the at least one outlet support element 22 is deployable from a retracted configuration to an expanded configuration:

- the retracted configuration enables the at least one outlet support element 22 to be introduced through the conduct membrane M_1 of the reception conduct C_R , and
 - the expanded configuration enables the at least one outlet support element 22 to stay in place inside the conduct membrane M_1 .
- 5 When expanded, the at least one outlet support element 22 presents an outer diameter ranging from 10mm to 30mm.

[0034] In order to securely drive the blood flow inside the reception conduct C_R , the outlet support element 22 is configured to extend, once the device 10 is installed inside the patient's heart 100, from an internal side and from the external side of the conduct membrane M_1 . The outlet support element 22 is thus configured to cooperate radially with the edge of the aperture of the conduct membrane M_1 . This radial cooperation ensures a tight and strong cooperation between the conduct membrane M_1 and the outlet support element 22 (and therefore with the device outlet 14). 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 conduct membrane M_1 , from the inside of the assisting device 10 inside the reception conduct C_R of the patient's heart 100.

[0035] In the embodiments in which the assisting device 10 is a right assisting device, the at least one outlet support element 22 is configured to be secured to the conduct membrane M_1 separating the right atrium 102 or the vena cava 101 from the pulmonary artery 106 as the reception conduct C_R of the patient's heart 100. In this particular embodiment, the outlet support element 22 is configured to be secured to a wall of the superior vena cava 101 or right atrium 102 as the conduct membrane M_1 .

[0036] Preferably, the support element 22 comprises a first and a second expandable flanges, the expanded configuration of each support element 22 enabling a pinching of the conduct or chamber membrane M_1 between the first and second expandable flanges.

[0037] As already mentioned, in some embodiments, the support device further comprises a pump support element 24 configured to secure the pump 16, and more particularly a pump body 160 of the pump 16 to a chamber membrane M_2 of the first chamber C_1 . The pump support element 24 is configured to be anchored to the chamber

membrane M₂. More particularly, this chamber membrane M₂ is the wall of the right atrium and/or vena cava inferior. Depending on the shape of the pump support element 24, it might also expand inside the vena cava inferior 101, be stuck like a spheric shaped element inside a cylindric conduct and secure the device 10 this way.

- 5 [0038] Each support element 22, 24 is preferably deployable from a retracted configuration to an expanded configuration. The retracted configuration enables each support element 22, 24 to be safely introduced through or in the conduct or chamber membrane M₁, M₂ of the patient's heart 100. On the other hand, the expanded configuration enables each support element 22, 24 to be secured in position inside the
- 10 conduct or chamber membrane M₁, M₂. Preferably, the second support element 24 does not go through any membrane, but is rather deployed inside the vena cava inferior or right atrium.

- [0039] As mentioned above, the rotary pump 16 comprises a pump body 160. The pump body 160 is preferably formed by a casing and presents a pump inflow 161 in fluidic
- 15 communication with the device inlet 12 and a pump outflow 162 in fluidic communication with the device outlet 14. The pump body 160 is not deformable. Before and after the implantation, the shape of the pump body 16 remains the same. This ensures a straight blood flow within the pump body 160 and minimizes the risk of flow turbulences.

- 20 [0040] In order to put the blood flow in motion through the assisting device 10 once it is implanted inside the patient's heart 100, the rotary pump 16 comprises a motor and an impeller 18. The impeller 18 is coupled to the motor. More particularly, the motor of the rotary pump 16 comprises a rotor 25 connected to the impeller 18. More particularly, the impeller 18 is driven in rotation by means of the rotor 25 of the motor. The rotational
- 25 speed of the impeller 18 ranges between 8.000 and 24.000 rpm.

[0041] As mentioned, the rotary pump 16 comprises an impeller 18 placed inside the pump body 160. More particularly, the pump body 160 surrounds the impeller 18 which extends between the pump inflow 161 and the pump outflow 162. The impeller 18 is surrounded by a compression chamber 26 located inside the pump body 160.

[0042] The rotor 25 is preferably surrounded by the pump body 160. In order to be stabilized, the rotary pump 16 is thus preferably configured to be anchored to the patient's heart 100 at the distal extremity of the pump body 160.

5 [0043] In an axial pump, the pump inflow 161 is necessarily located upstream the impeller 18. The rotor 25 is a way to transmit the motor torque to the impeller 18.

[0044] 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
10 implantation.

[0045] In some embodiments, the rotary pump 16 comprises a diffuser 28 between the pump outflow 162 and the impeller 18. Generally speaking, a diffuser changes kinetic energy into pressure energy. In the case of the present invention, the diffuser 28 reduces the blood velocity (downstream the impeller 18) and creates a higher pressure.

15 [0046] As can be seen on figure 3, the rotary pump 16 extends axially along the elongation axis X. The pump inflow 161, the impeller 18 and the pump outflow 162 are thus all aligned along the elongation axis X.

[0047] 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 162
20 along the elongation axis X.

[0048] Regardless of the embodiments and the elements present in the assisting device 10, the assisting device 10 extends in a straight line along the extension axis X from the pump inflow 161 to the pump outflow 162, and preferably from the inlet inflow 12 to the pump outflow 162. This particular straight-line shape enables the assisting device 10 to
25 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.

[0049] The impeller 18 generates depression in order to drive the blood flow inside the assisting device 10. This negative pressure is thus exerted in the chamber 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 121, 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.

[0050] In order to avoid such deformation and/or obstruction issues, the pump body 160 comprises a spacing organ 30, as can be seen on figure 5. 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 any anatomical walls of the patient's heart 100 and the device inlet 12. Preferably, the space ranges from 15 mm to 30 mm.

[0051] 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.

[0052] In the embodiment depicted on figure 5, 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, the spacing organ 30 surrounds the at least one inlet opening 121.

[0053] In the embodiment depicted on figure 5, 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.

[0054] 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 18. In those cases, the spacing structure is at least partially made of mesh. More particularly, in the embodiments of figure 5, the complete spacing structure is an expandable mesh. This mesh can be radially elastically deformable. In some embodiments, the spacing structure could be expandable struts.

5 [0055] 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 could comprise several distinct spacing elements 300 distributed around the external
10 surface S of the pump body 160 and more particularly over the device inlet 12, like a sort of crown.

[0056] Regardless of the detailed structure of the spacing elements 300 of the spacing organ, the spacing organ 30 comprises at least one radial portion extending along a secondary elongation axis. This secondary elongation axis extends radially with regards
15 to the elongation axis X. This ensures that at least a part of the spacing organ 30 is remote from the pump body 160 and particularly from the inlet opening 121.

[0057] 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,
20 the spacing organ 30 surrounds the at least one inlet opening 121. Preferably, the spacing organ 30 comprises at least one remote portion facing the inlet opening 12o at a distance.

[0058] 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 30 is welded to the pump body 160. In some other embodiments, the spacing organ
25 30 forms one single piece with the pump body 160 and is part of the surface S.

[0059] 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 28 could be at least partially made of Nitinol material.

[0060] 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
5 entirely functional and able to generate the necessitated space between any anatomical walls of the patient's heart 100 and the device inlet 12.

[0061] 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
10 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,
15 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.

[0062] In some embodiments, the pump support element 24 and the spacing organ 30 form two functional parts of a single structural element. In those embodiments, the pump support element 26 and the spacing organ 22 can even be merged and thus be the same
20 element (see for example figure 6). The assisting device 10 according to the present invention is to be used within a heart assisting kit comprising:

- an assisting device 10 as described here-above,
- a control unit for controlling the rotary pump 16,
- a power supply for supplying power to the rotary pump 16.

25 Implantation method

[0063] Implantation method for a cardiac assisting device 10 according to the description here-above, preferably a right cardiac assisting device 10, wherein the method includes following steps:

- preparation and creation of an anastomosis hole:

- create needed accesses through an access vein of the patient, preferably through the femoral and or jugular veins,
- insert a guidewire and place it at first chamber C_1 , preferably at the cross section of the superior vena cava 101 and the right pulmonary artery 106,
- insert a needle,
- puncture the membrane M_1 at the cross section between the first chamber C_1 and the reception conduct C_R , preferably between the superior vena cava 101 and the right pulmonary artery 106,
- lace a guidewire through the anastomosis inside the reception conduct C_R , preferably the right pulmonary artery 106,
- assist device 10 placement:
 - dilate the access vein (preferably the right femoral vein) with a dilator set,
 - insert an introducer and a dilator over the guidewire and place its distal end inside the reception conduct C_R ,
 - withdraw the dilator from the introducer,
 - insert a pump catheter into the introducer,
 - place the rotary pump 16 at the distal end of the introducer,
 - deliver the rotary pump 16 by pulling back the introducer, the rotary pump deploys 16 inside the patient's heart 100,
 - disconnect the rotary pump 16 from the pump catheter,
 - withdraw the pump catheter and the introducer,
 - run the device 10.

CLAIMS

1. Cardiac assisting device (10) configured to be percutaneously implanted inside a patient's heart (100), and configured to drive a blood flow from a first chamber (C_1) of the patient's heart (100) towards a reception conduct (C_R) of the patient's heart (100) by bypassing at least one second chamber of the patient's heart (100), the second chamber putting the reception conduct (C_R) and the first chamber (C_1) in fluidic communication, said assisting device (10) comprising:
- a device inlet (12) configured to open in the first chamber (C_1),
 - a device outlet (14) comprising at least one outlet opening (142) configured to open in the reception conduct (C_R),
 - a rotary pump (16) connecting the device inlet (12) to the device outlet (14), the rotary pump (16) comprising a pump body (160) with a pump inflow (161) in fluidic communication with the device inlet (12) and a pump outflow (162) in fluidic communication with the device outlet (14), the rotary pump (16) further comprising an impeller (18) located inside the pump body (160) between the pump inflow (161) and the pump outflow (162),
 - a support device (20) configured to pass through at least one membrane (M) of the patient's heart (100), said support device (20) comprising an outlet support element (22) configured to secure the device outlet (14) to a conduct membrane (M_c) of the reception conduct (C_R), the outlet support element (22) being configured to pass through the conduct membrane (M_c),
- wherein**
- the rotary pump (16) extends axially along an elongation axis X, the pump inflow (161), the impeller (18) and the pump outflow (162) being all aligned along the elongation axis X,
 - the device inlet (12) being 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 (162) along the elongation axis X,
 - the device outlet (14) being configured to change an orientation of the outlet opening (142) with regards to the elongation axis X.

2. Cardiac assisting device (10) according to the preceding claim, **wherein** the device outlet (14) comprises a deformable cannula (140).
3. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the deformable cannula (140) comprises a coated coil.
- 5 4. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the cardiac assisting device (10) is specially designed to be a right cardiac assisting device, the device inlet (12) and the rotary pump (18) being configured to be located inside the right atrium (102) or the vena cava (101) as the first chamber (C₁), and the at least one outlet support element (22) being configured to be secured to the
10 conduct membrane (M_c) separating the right atrium (102) or the vena cava superior (101) from the pulmonary artery (106) as the reception conduct (C_R) of the patient's heart (100).
5. Cardiac assisting device (10) according to the preceding claim, **wherein** the outlet support element (22) is configured to be secured to a wall of the superior vena cava
15 (101) as the conduct membrane (M₁).
- ~~6.~~ Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the support device (20) further comprises a pump support element (24) configured to secure the pump body (160) to a chamber membrane (M₂) of the first chamber (C₁) or vena cava inferior, the pump support element (24) being configured to be
20 anchored in the chamber membrane (M₂).
7. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the impeller (18) is surrounded by a compression chamber (26) located inside the pump body (160).
8. Cardiac assisting device (10) according to any one of the preceding claims, **wherein**
25 the rotary pump (16) comprises a diffusor (28) between the pump outflow (162) and the impeller (18).

9. Cardiac assisting device (10) according to any one of the preceding claims, **wherein** the rotary pump (16) is configured to be anchored to the **patient's heart** (100) at one of proximal and distal extremities of the pump body (160).
10. Heart assisting kit comprising:
- 5 - an assisting device (10) according to any one of the preceding claims,
 - a control unit (U) for controlling the rotary pump (16),
 - a power supply (P) for supplying power to the rotary pump (16).
11. Implantation method for a cardiac assisting device (10) according to any one of the preceding claims, **wherein** the method includes following steps:
- 10 - preparation and creation of an anastomosis hole:
 ○ create needed accesses through an access vein of the patient,
 ○ insert a guidewire and place it at first chamber (C₁),
 ○ insert a needle,
 ○ puncture the membrane (M₁) at the cross section between the first chamber
15 (C₁) and the reception conduct (C_R),
 ○ lace a guidewire through the anastomosis inside the reception conduct (C_R),
 - assist device (10) placement:
 ○ dilate right femoral the access vein with a dilator set,
 ○ insert an introducer and a dilator over the guidewire and place its distal end
20 inside the reception conduct C_R,
 ○ withdraw the dilator from the introducer,
 ○ insert a pump catheter into the introducer,
 ○ place the rotary pump (16) at the distal end of the introducer,
 ○ deliver the rotary pump (16) by pulling back the introducer,
25 ○ disconnect the rotary pump (16) from the pump catheter,
 ○ withdraw the pump catheter and the introducer,
 ○ run the device (10).