



September 8, 2017

Certification

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This is to certify that the attached translation is, to the best of my knowledge and belief, a true and accurate translation from German into English of:
WO 2014195296 A1

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Park Case # WIL_1511_010

(19) FEDERAL REPUBLIC OF
GERMANY
[LOGO]
GERMAN PATENT AND
TRADEMARK OFFICE

(12) Unexamined Patent
Application
(10) DE 40 12 224 A1



(51) Int. Cl.⁶:
A 61 M 1/12
A 61 M 25/01

(21) File No. 198 21 307.7-35
(22) Application Date: 13 May 1998
(43) Publication Date –
(45) Publication Date of Patent
Application: 21 Oct. 1999

DE 198 21 307 C 1

An objection may be submitted within 3 months after publication of the patent granting notice

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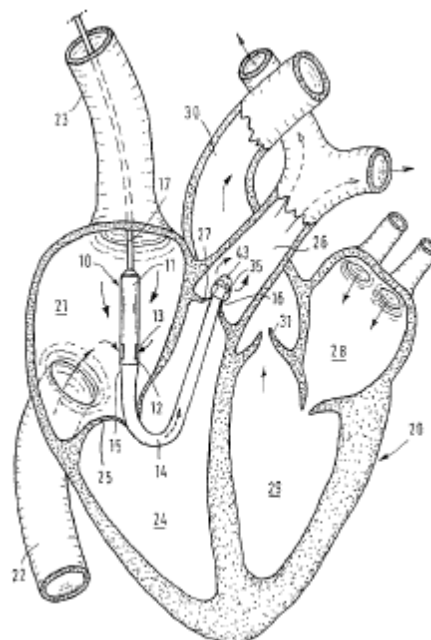
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(56) Documents considered in evaluating the
patentability:
US 47 53 221
WO 97 37 697
WO 97 37 696
WO 94 09 835

(54) Intracardiac blood pump

(57) The intracardiac blood pump (10) comprises a drive
section (11) and a pump section (12). A flexible
pump hose (14) is connected to the pump section
(12). To lay the pump hose (14) from the right atrium
(21) to the pulmonary artery (26), the distal end of
the pump hose (14) comprises a balloon (35) which
acts as a guide element in the blood flow and is
entrained by the natural blood flow. This facilitates
placing the blood pump in the heart.



DE 198 21 307 C 1

FEDERAL GERMAN PRINT SHOP 08.99 902 142/286/7A

5 Description

The invention relates to an intracardiac blood pump according to the preamble of Claim 1 and is especially suitable for a blood pump that can be inserted completely into the heart through adjacent blood vessels to support the natural pumping function of the heart or replace it by continuous pumping operation.

10 A pump device supporting the heart function is described in WO 94/09835 (Jarvik). Said pump device comprises pumps operating independently of one another, each pump being provided with a pump section and a drive section rigidly connected with the pump device. The pump section of one pump is introduced through an apical surgical opening into the left ventricle such that it delivers from the left ventricle into the aorta. The other pump section is introduced through another, preferably apical, surgical
15 opening into the right ventricle in such a way that it delivers from the right atrium into the pulmonary artery. Each of the pumps is extended at its pump outlet with by a hose-type outlet cannula which may be guided through the respective heart valve.

An intracardiac blood pump which is inserted from the aorta through the aortic valve into the left ventricle is known from WO 97/37696 (Rau et al.). Here the pump inlet is extended by a hose passing
20 through the aortic valve.

From WO 97/37697 (Rau et al.) an intravascular blood pump is known which can be moved through a blood vessel. This blood pump is also extended at its inlet end by an intake hose. Said intake hose comprises an inflatable balloon serving as isolating device and preventing blood from flowing laterally alongside the intake hose.

25 Finally, a pump catheter is known from US Patent 4,753,221 (Kinsey), which has a pump to be placed in the heart. Said pump comprises an impeller and a pump casing surrounding said impeller. The pump casing in the collapsed condition can be placed in the heart and then unfolded by inflating a balloon connected with the pump housing.

Furthermore, small-lumen catheters for pressure and volumetric flow measurement for diagnostic
30 purposes are known, which comprise an inflatable balloon at the distal end of the catheter. Said balloon is used for positioning the catheter tip in the pulmonary artery.

In the case of intracardiac blood pumps which are inserted into the heart through a blood vessel, correct placement of the blood pump in the heart is difficult. In particular when the blood pump is inserted through the upper vena cava to pump blood from the right atrium into the pulmonary artery,
35 correct placement of the blood pump is difficult, since the pump must perform a direction change of nearly 180° in order for the intake opening to lie in the right atrium and the outlet opening in the pulmonary artery. In addition, numerous fibers and tendons are present in the right ventricle to hold the tricuspid valve in place and protect the leaflets of the valve from turning inside out and guarantee the form stability of the heart. A blood pump inserted through a vena cava must be guided between such
40 fibers and tendons.

The object of the invention is to provide an intracardiac blood pump which can be placed in the heart relatively easily.

This object is achieved with the subject matter of the claim 1 or claim 13.

5 In the blood pump of claim 1, a flexible hose is attached to the pump outlet, with the distal end of the hose comprising a balloon acting as a guide element in the blood flow. Here, advantage is taken of the fact that the natural blood flow in the heart leads from the vena cava into the right ventricle and through is into the pulmonary artery. The blood pump, which comprises a balloon at the distal end of the hose, is inserted along this pathway as well, with the balloon drifting in the blood flow, automatically finds its way from the right atrium into the pulmonary artery. The hose outlet is subsequently stabilized in the
10 pulmonary artery, whereas the pump section is positioned in the right atrium. The pump hose performs a bend of approximately 180°. In this way it is possible to place the blood pump including the blood hose correctly within the heart, without the need for the hose outlet to touch the ventricular septa or the use of diagnostic aids (x-rays or ultrasound).

15 The term “intracardiac” within the meaning of the present invention includes the heart chambers (ventricles), the atria and the adjacent vascular stumps.

It is advantageous if the pump hose is pre-curved corresponding to the final position that it will assume in the heart. This requires bending by at least about 150°. To be sure, the pump hose must be able to be uncurled to be inserted through the vena cava, but in the slackened state it should assume a U shape or a V shape. It is particularly advantageous if the pump hose has a flexural rigidity which decreases from
20 the proximal end to the distal end. In this way the distal end can be easily moved as a pathfinder, so that the balloon can better follow the natural blood flow.

The balloon need not necessarily be attached directly to the pump hose. It can also be fastened to a catheter which is a component of the pump hose and travels through it on the inside or the outside. In any case, a lumen, through which the balloon can be inflated, must travel to the balloon. A second lumen may
25 be additionally provided, into which a guide wire is inserted, which facilitates fastening the advancing of the pump hose through the vascular system. After removal of the guide wire, said second lumen may be used as a pressure measuring lumen.

According to a preferred embodiment it is provided for the balloon to surround the pump hose as an annular balloon. This has the advantage that the distal end of the hose has an enlarged outside diameter
30 due to the balloon, and thus is retained by the pulmonary valve. In this way the balloon contributes to anchoring the end of the hose to the pulmonary valve, while the hose outlet is located in the pulmonary artery. This prevents the hose outlet from slipping out of the pulmonary artery. An additional advantage is that the annular balloon forms a rounded, blunt end on the pump hose, so that the pump hose cannot damage the vascular or heart walls or other parts of the heart. Finally, the hose end is also prevented from
35 hooking on the valve margin or on tendons in the heart.

Since the pump section pumps blood into the pump hose, the pump hose is automatically kept open. Thus a collapsible hose can be used as a pump hose, for example a hose made of sheet material, the wall of which is not inherently stable. A catheter may extend through this hose to the balloon arranged at the distal end.

40 In an intracardiac blood pump with a flexible pump hose, there is a risk that the blood flowing out of the hose outlet will cause recoil of the hose, which can result in retrograde displacement of the hose. Consequently the hose may slip out of the pulmonary valve. Therefore the invention solves the additional problem of providing an intracardiac blood pump in which displacements of the hose due to hydraulic reaction forces are prevented.

To solve the problem of the invention with the subject matter of claim 13, a traction element, toward which the pumped flow is directed, is fixed on the distal end of the hose. Said traction element may be a leaflet or a balloon. The blood flow emerging from the hose end pushes against the traction element, which produces a forward directed force that opposes the retraction force of the hose. In this way the traction element helps to stabilize the positioning of the pump hose.

In the following, embodiments of the invention will be explained in detail with reference to the drawings, in which:

Fig. 1 shows a cross section of the heart with a blood pump arranged therein,

Fig. 2 shows a representation of the blood pump of **Fig. 1**,

Fig. 3 shows a section through the detail III of **Fig. 2**,

Fig. 4 shows a second embodiment of the blood pump,

Fig. 5 shows a third embodiment and

Fig. 6 shows, on an enlarged scale, a representation of the catheter of the embodiment shown in **Fig. 5**.

According to **Fig. 1** the blood pump **10** is an intravascular blood pump, i.e., a blood pump that can be inserted through a patient's blood vessel system to enter the heart. The outside diameter of such a blood pump is no larger than 8 mm at any point. The pump **10** comprises a drive section **11** and a pump section **12** rigidly connected with the drive section. The pump corresponds, e.g., to that of WO 97/37696, and therefore its internal structure will not be explained in greater detail here. In the transition region between the drive section **11** and the pump section **12**, intake openings **13** are arranged, through which blood is radially drawn in from the outside. The pump section **12** comprises an impeller (not shown), which drives the blood in an axial direction. To the outlet of the pump section **12** a pump hose **14** is connected. This has a proximal end **15** connected with the pump outlet and a distal end **16** forming the hose outlet.

The proximal end of the pump **10** is connected with a catheter **17**, which also contains the electrical supply lines for the drive section **11**. In addition the catheter **17** has a lumen which can be connected to a compressed air source.

The pump hose **14** and the catheter **17** are flexible. The rigid length of the pump **10** does not exceed 35 mm, so that the pump can pass through the curvatures of the blood vessel system. The length of the pump hose **14** is at least twice as great as the rigid length of the pump. The pump hose has a length of about 12 cm and an outside diameter of about 8 mm. Its wall thickness is 0.05 mm to 0.2 mm. The radius of curvature of the hose bend is 40 mm to 60 mm.

In **Fig. 1** a cross section through the heart **20** is shown. The lower vena cava **22** and the upper vena cava **23** end in the right atrium **21**. The tricuspid valve **25** is located between the right atrium **21** and the right ventricle **24**. The pulmonary valve **27** is located between the right ventricle **24** and the pulmonary artery **26**. From the pulmonary artery **26**, the blood flows to the lung, and from there back into the left atrium **28** and the left ventricle **29**. The aortic valve **31** is located between the left ventricle **29** and the aorta **30**.

The pump **10** is positioned as a right heart pump such that it delivers from the right atrium **21** into the pulmonary artery **26**. For this purpose in the embodiment shown it is passed through the upper vena cava **23**. It would also be possible to perform the laying through the lower vena cava **22**. During the insertion of the pump **10** the pump hose **14** of the pump lies ahead, i.e., it is positioned downstream of the pump **10** viewed in the flow direction of the blood surrounding the pump.

At the distal end **16** of the pump hose **14** a balloon **35** is arranged, which is configured here as an annular balloon as shown in **Fig. 2** and **Fig. 3**. The balloon **35**, inflated with gas (e.g., air, helium, CO₂) or

with a liquid, has a larger outside diameter than the pump hose **14**. Consequently the balloon **35** acts as a guide element entrained by the natural blood flow. Thus the balloon **35** is washed along the natural blood path, first into the right ventricle **24** and then into the pulmonary artery **26**.

The balloon **35** is inflated by generating a pressure in a pressure lumen **36** of the pump hose **14**. The pressure lumen **36** is connected via openings **37** with the inside of the annular balloon **35**. In the pump hose **14**, the blood flows through the blood lumen **38**, the cross section of which is substantially larger than that of the pressure lumen **36**. The pressure lumen **36** is connected to a corresponding pressure lumen of the proximal catheter **17** so that its pressure can be controlled extracorporeally.

The pump hose **14** is shown in the slackened state in **Fig. 2**. The pump hose is pre-curved in a U shape or a V shape, i.e., it has shape memory, so that it is not subjected to any substantial constraint in the heart according to **Fig. 1** and in turn does not exert any substantial constraint on the heart. In **Fig. 2** the darker shading of the dotted area indicates the rigidity of the pump hose **14**. At the proximal end **15**, this rigidity is very large, and it then decreases continuously toward the distal end **16**. This means that the distal end **16**, where the balloon **35** is located, can be freely moved and guided by the balloon.

As is apparent from **Fig. 3**, at its distal end, the balloon **35** projects beyond the end **39** of the pump hose **14**, so that the balloon **35** forms a rounded hose end **40**, which does not present the risk of hooking onto obstacles. At the proximal end of the balloon **35** an annular undercut **41** is formed, into which the tips of the pulmonary valve **27** can penetrate, as shown in **Fig. 1**, so that the pulmonary valve prevents the hose end from drawing back.

As is shown in **Fig. 2** and **3**, a traction element **43** extends over the hose outlet **42** in the form of a dome-shaped leaflet. This traction element **43** consists of a thin, flexible membrane which is fixed to the balloon **35** by means of webs **44**. The blood emerging from the hose outlet **42** flows against the traction element **43**, thus exerting a tractive force on the pump hose **14**, which counteracts the recoil effect. This prevents the distal end **16** of the pump hose from being moved as a result of the hydraulic recoil and possibly slipping out of the pulmonary valve **27**.

The pump hose **14** is preferably made of polyurethane, which has proven to be particularly suitable.

In the embodiment of **Fig. 4**, a pump hose **14a**, which comprises an elastic supporting structure **45** in the form of a carbon or metal helical coil made of carbon or metal is connected to the pump **10**. Said supporting structure **45** keeps the pump hose open and effects the desired flexural rigidity, which may also differ over the length of the hose. A catheter **46** extends through the pump hose **45**, provided with a balloon **35a** at its distal end. Said balloon forms the guide element for the pump hose **14a**. The catheter **46** contains a pressure lumen. Its outside diameter is substantially smaller than the diameter of the pump hose **14a**, so that an adequate cross section for the blood flow is available in the pump hose. The catheter **46** is connected with the catheter **17**.

As a traction element **43**, a ball is arranged at a distance behind the hose outlet **42** and fastened to the catheter **46**. The blood flow pushing against the traction element **43a** prevents the distal hose end **16** from drawing back toward the pump **10**. The pump hose **14a** is anchored to the traction element **43a** by means of a holding fixture **47**.

In the embodiment of **Fig. 5** and **6**, the pump hose **14b** is a collapsible pump hose made of thin sheet material with no inherent form stability. A catheter **48**, comprising a balloon **35a** at its distal end, extends through the pump hose **14b**. Said catheter **48** is connected with catheter **17**. The distal end **16** of the pump hose **14b** is connected with catheter **48** and the pump hose **14b** comprises outlet openings **49** through which the blood flows out. When the pump is inserted according to **Fig. 5**, the pump is not in operation, so that the pump hose **14b** is collapsed. With the aid of the balloon **35a** the soft and flexible catheter **48** is

moved into the heart, thus positioning the pump hose **14b**. When the pump is subsequently put into operation, the pump hose **14b** is expanded.

To facilitate placement, the catheter **48** according to **Fig. 6**, outside of the pressure lumen **49** leading to the balloon **35a**, may contain an additional lumen **50** to accommodate a guide wire **51** and, after removal of the guide wire, for external pressure measurement. This guide wire **51**, which also passes through the catheter **17** and the pump **10**, makes it possible for the operating surgeon to controllably influence the laying of the pump hose. The guide wire **51** is subsequently removed.

According to **Fig. 6**, an opening **52** can be provided on the catheter **48**, which is connected to the lumen **50** and which is blocked by the guide wire **51**. After the guide wire **51** is withdrawn from the lumen **50**, blood enters the lumen **50** through the opening **52**. The lumen **50** can be connected to a blood pressure measuring instrument, so that the blood pressure in the pulmonary artery can be measured and influenced, if necessary, during the pumping process.

If the placement of the pump hose is conducted without a guide wire, the pressure can be measured at that site **52** with the aid of measurable pressure profiles in the further lumen **50**. Thus the exact position of the distal pump hose tip can be determined from the pressure profiles.

The diameter of the balloon must never be so large that it substantially impedes the flow through the pulmonary artery **26** or actually blocks the pulmonary artery. As a rule, the diameter must not exceed 30 mm. Furthermore the balloon should have high elasticity, in contrast to a dilating balloon. Suitable balloon materials in terms of the elasticity properties are silicone, latex and especially polyurethane.

While floating in the blood flow as a guide element for the catheter hose, the balloon may be strongly inflated at high pressure and then its size reduced by decreasing the pressure to act as a traction element toward which the pump flow is directed.

Claims

1. An intracardiac blood pump with a radially drawing and axially delivering pump section (**11**), connected to a catheter (**17**), and a flexible pump hose (**14**) connected to the pump outlet, comprising a proximal end (**15**) adjacent to the pump outlet and a distal end (**16**) forming the hose outlet, **characterized in that** the pump hose (**14**) close to its distal end comprises a balloon (**35**) entrainable by the blood flow and acting as a guide element.
2. The blood pump according to claim 1, characterized in that the pump hose is pre-curved through more than 100°, preferably by about 150°.
3. The blood pump according to claim 1 or 2, characterized in that the pump hose (**14**) has flexural rigidity which decreases from the proximal end (**15**) to the distal end (**16**).
4. The blood pump according to any one of claims 1-3, characterized in that the pump hose (**14**) has a second catheter (**46; 48**) disposed on its inside or its outside, which projects beyond the distal end (**16**) of the pump hose and carries the balloon (**35a**) beyond the distal end.
5. The blood pump according to any one of claims 1-3, characterized in that the balloon (**35**) surrounds the pump hose (**14**) in the form of an annular balloon.
6. The blood pump according claim 5, characterized in that the annular balloon forms a rounded hose tip (**40**).
7. The blood pump according to any one of claims 1-6, characterized in that the pump hose (**14b**) is a collapsible hose.

8. The blood pump according to any one of claims 1-6, characterized in that the pump hose (14a) contains an elastic supporting structure (45).

9. The blood pump according to any one of claims 1-8, wherein the pump hose (14b) comprises a second catheter (48) according to claim 4, characterized in that a guide wire (51) insertable into the catheter (48) is provided.

10. The blood pump according to claim 9, characterized in that the second catheter (48) has a lumen (50) for the guide wire (51) and a pressure lumen (49).

11. The blood pump according to claim 9 or 10, characterized in that the catheter (48) has a lumen that can be used as a pressure measurement lumen (50).

12. The blood pump according to any one of claims 1-11, wherein the diameter of the balloon (35) in the inflated state is no larger than 30 mm.

13. An intracardiac balloon pump with a radially drawing and axially delivering pump section (11), connected to a catheter (17), and a flexible pump hose (14) connected to the pump outlet, comprising a proximal end (15) adjacent to the pump outlet and a distal end (16) c forming the hose outlet, characterized in that at the distal end (16) of the pump hose (14) a traction element (43) entrained by the pump flow is affixed.

3 pages of drawings attached

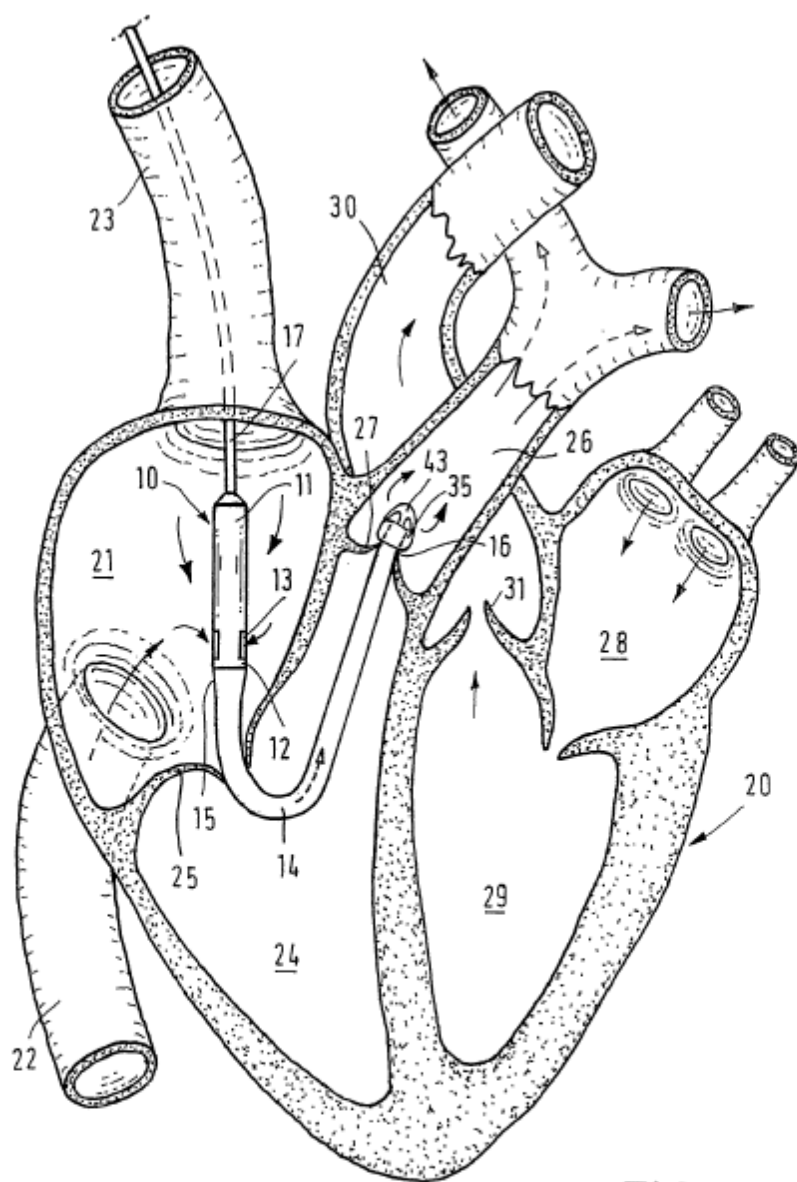


FIG. 1

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