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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: WO1997037696 (Rau – DE).


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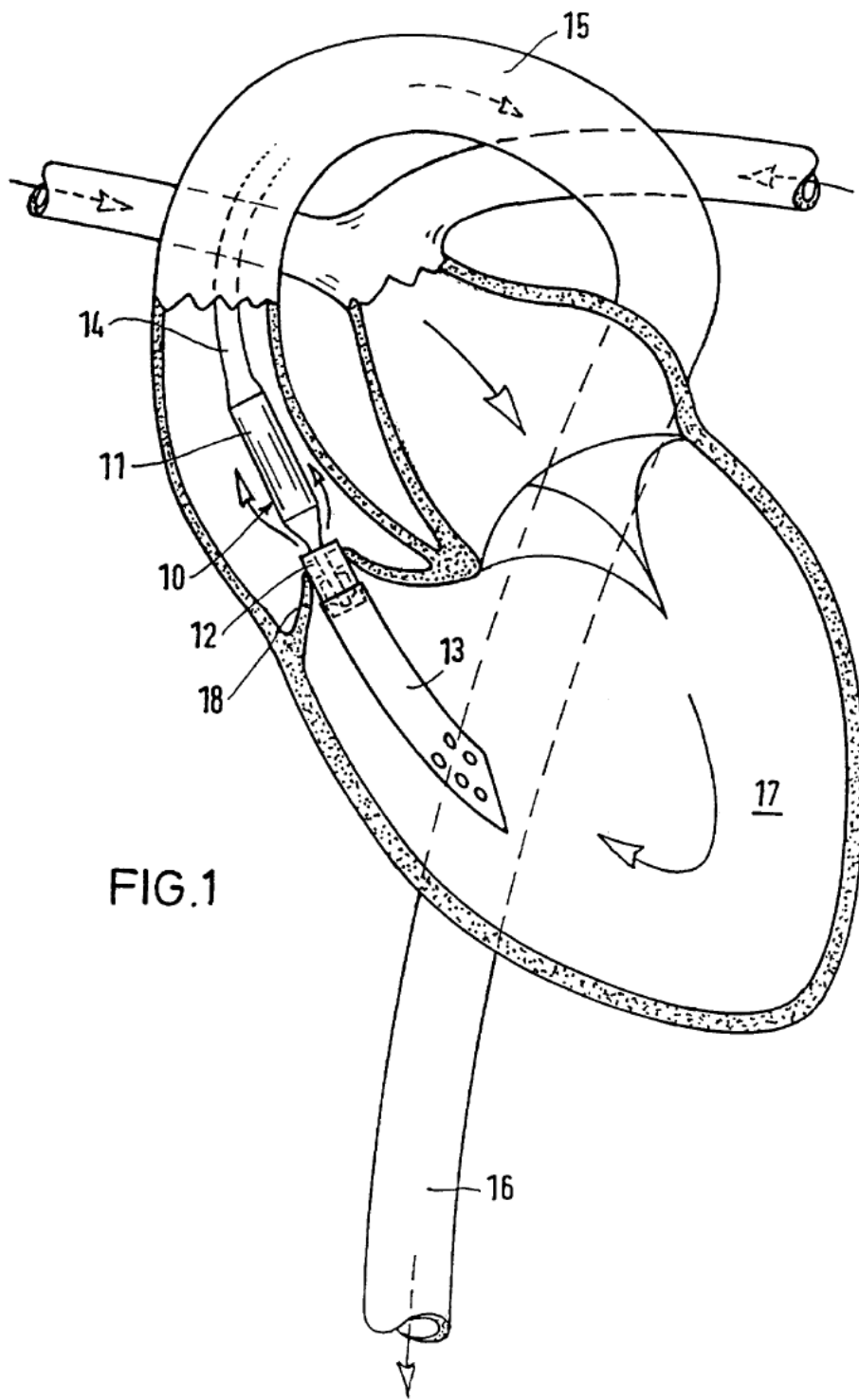
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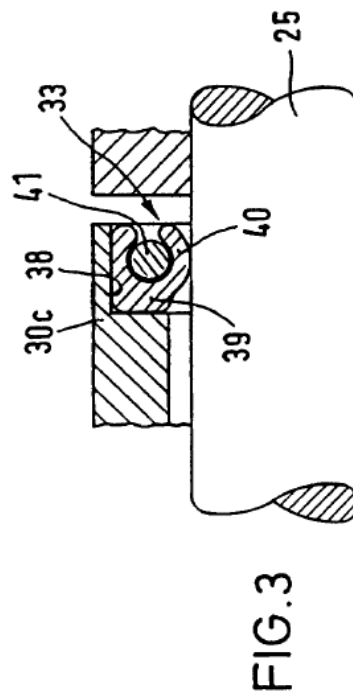
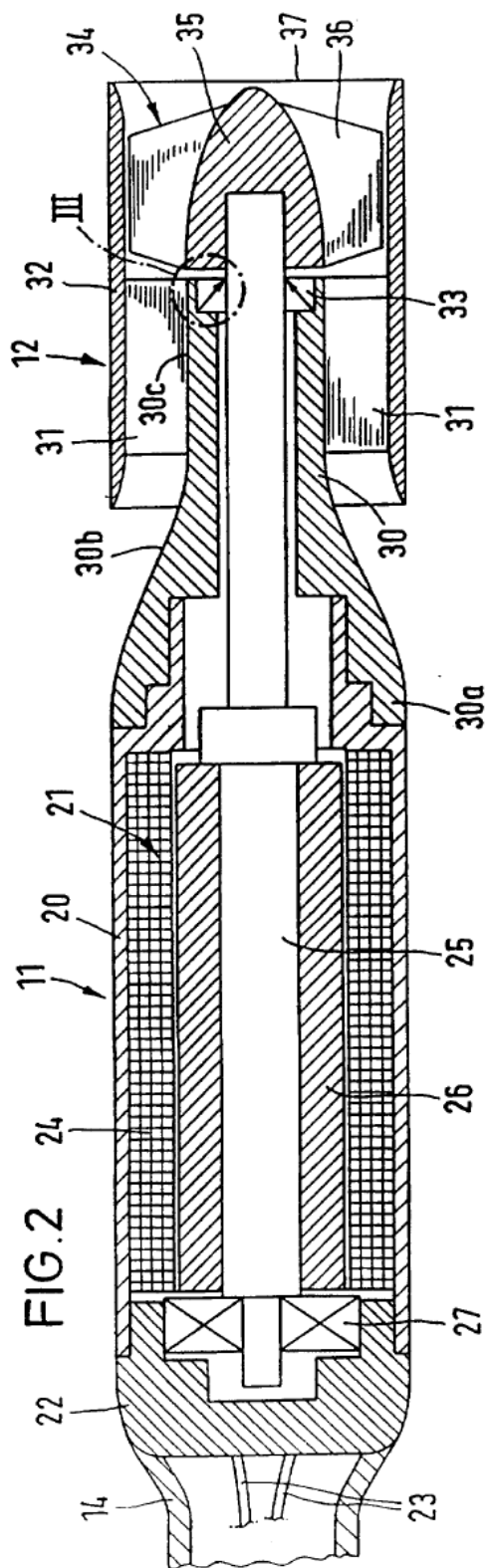
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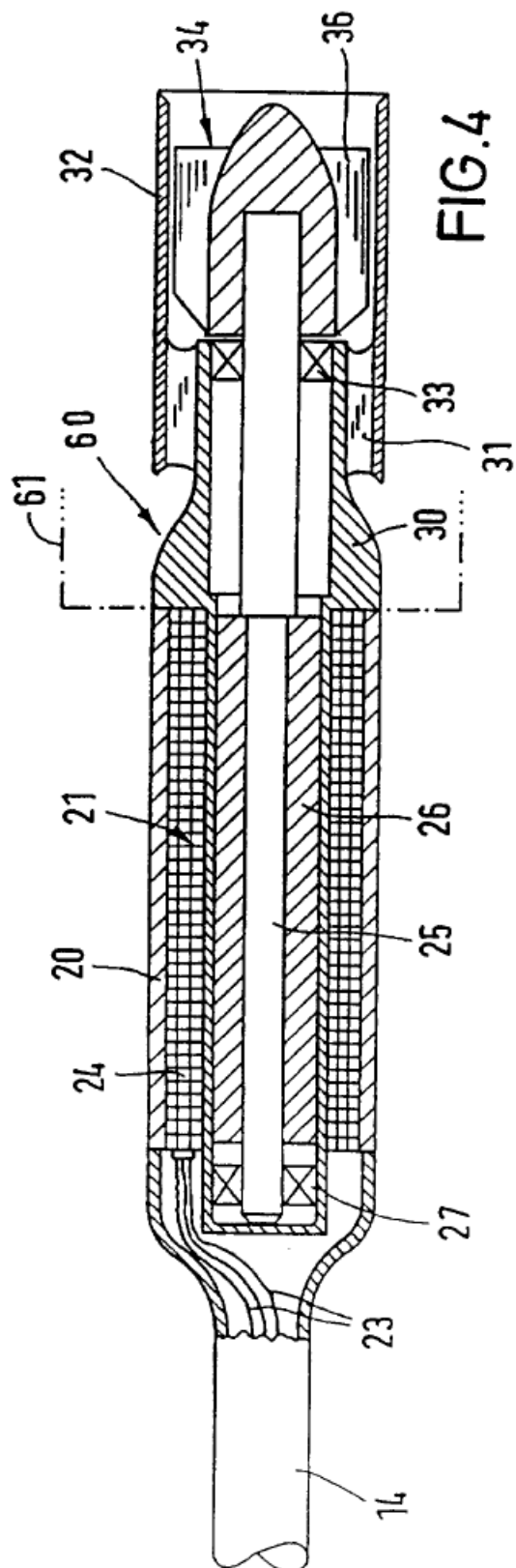


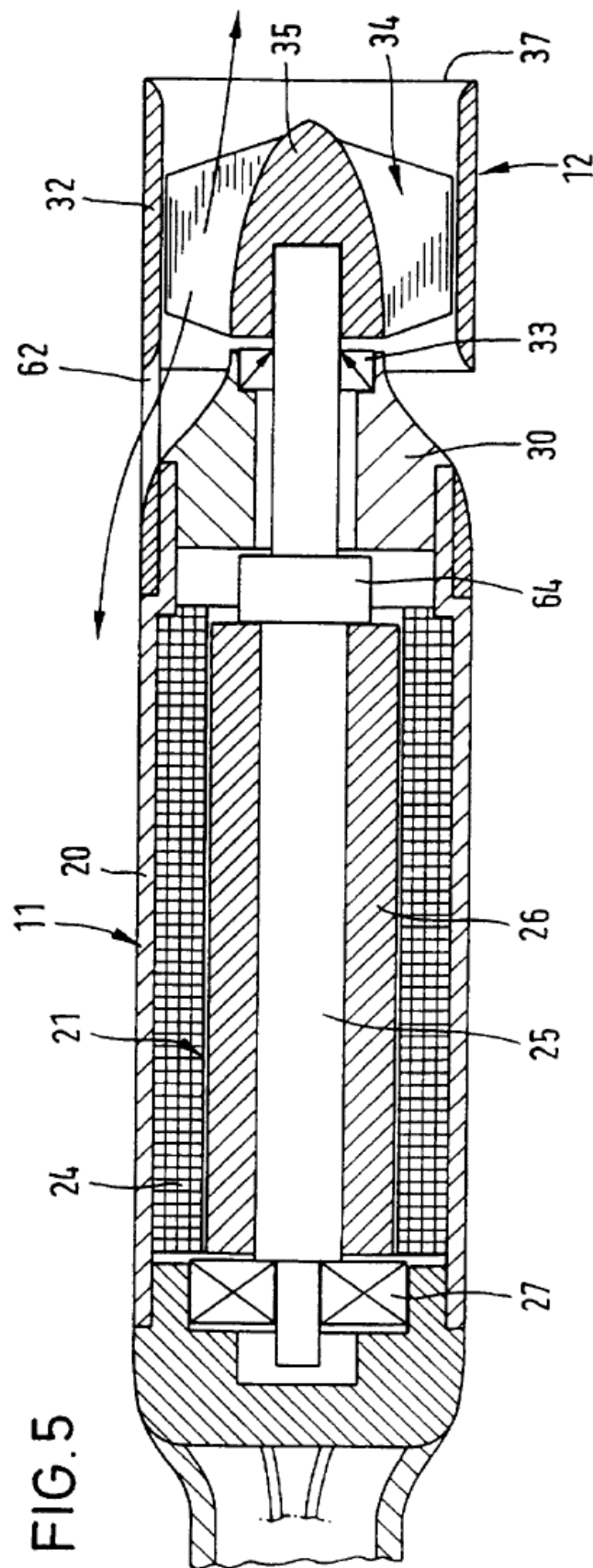
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Title: INTRAVASCULAR BLOOD PUMP

Abstract

The blood pump comprises a motor housing (20) and a pump housing (32) which are
5 arranged spaced apart from one another and firmly connected to one another. The two housings
(20, 32) have substantially the same diameter, which is only approximately 6 mm, so that the
blood pump can be positioned by means of a catheter (14) through the blood vessel system of the
body at its site of use. The motor shaft (25) extends from the electric motor (21) to the impeller
(34). Said motor shaft is mounted on the rear end by means of a bearing (27) and on the extreme
10 front end by means of a bearing (33) which at the same time forms a seal.

Intravascular Blood Pump

The invention relates to an intravascular blood pump having a drive part and a pump part which can be guided through the vascular system of the human body, for example, to perform pump work in the heart.

By puncturing a blood vessel, an intravascular blood pump is introduced into the vascular system of the body and pushed forward to the heart or another site where blood is to be pumped. The parts that are introduced into the body have to be of sufficiently small diameter so that they fit through the externally accessible large vessels. The largest permissible diameter is approximately 7 mm.

From EP 0 157 871 B1 and EP 0 397 668 B1, intravascular blood pumps are known, wherein the pump part comprises a tubular housing, in which an impeller is rotatably arranged. The impeller is connected via a flexible shaft, which extends through a catheter, to an extracorporeal drive part. The drive part drives the flexible shaft, which in turn drives the pump part. Here, the drive part can be designed to be of any desired size, since it is operated extracorporeally. In order to reduce the friction between shaft and catheter, continuous lubrication with fluid is necessary. Some of this fluid, together with abraded material, reaches the blood stream through the sliding bearing and the seal of the pump unit. The rest is collected extracorporeally after the passage through the catheter along the shaft. Furthermore, the flexible shaft limits the possibilities of use of the blood pump, since the pump can only be brought to sites in the body where no excessive bending of the catheter and the shaft contained therein is necessary.

From WO94/09835, a blood pump for temporary cardiac assistance is known. This blood pump, which is used on surgically opened hearts, comprises a rod-shaped housing which contains the motor and the pump and which can be introduced with the pump part thereof into the aorta, while the motor part remains outside of the aorta.

Furthermore, from EP 0 157 859 B1 a blood pump is known, in which the motor part and the pump part are structurally joined. This pump is implantable, but it is not an intravascular blood pump that can be introduced in a minimally invasive manner into the body.

5 The design of an intravascular blood pump, on which the preamble of Claim 1 is based, is described in T. Sieß et al., "Hydraulic refinement of an intraarterial microaxial blood pump" in "The International Journal of Artificial Organs" / Vol. 18 / No. 5, 1995, pp. 273-285. The blood pump described therein comprises a motor housing containing an electric motor and connected on the rear end to a catheter. In the motor housing, the motor shaft is mounted at two ends. From the front end of the motor housing, a tube protrudes, through which the motor shaft extends. On 10 this tube, a tubular pump housing is fastened, in which the impeller connected to the motor shaft rotates. The pump housing and the motor housing have approximately the same diameter, which can be 5.4 to 6.4 mm. In this intravascular blood pump, a precise centering of the impeller in the pump housing can be achieved only with great difficulty. Given the small dimensions, small centering errors already lead to a worsening of the concentricity and can result in serious 15 deleterious effects on the blood.

The aim of the invention is to produce an intravascular blood pump, that is to say a blood pump which can be pushed forward through the blood vessels, which, given the large pump output required, is designed to be of small size, and wherein the deleterious effects on the blood are slight.

20 This aim is achieved according to the invention by the features indicated in Claim 1.

In the blood pump according to the invention, the drive part and pump part are directly connected to one another, and the blood pump is implemented as a thin rod-shaped part, wherein motor housing and pump housing have substantially the same outer diameter. The impeller sits on the motor shaft which extends through a hub part which protrudes from the motor housing and 25 on the end of which the shaft is mounted.

The motor shaft supporting the impeller extends through the motor housing and is mounted on the two ends thereof, so that it has good guidance and constancy of the axial orientation thereof. This is a prerequisite for a smooth, precisely central guiding of the impeller. Such precise guiding is necessary, since, in order to minimize deleterious effects on the blood and avoid hydraulic power losses, the gap between the blades of the impeller and the pump housing should not exceed 1/10 mm. Any out-of-roundness in the rotation of the impeller would also increase the risk of hemolysis. Due to the mounting of the motor shaft at the two ends, which are far apart from one another, and in the immediate vicinity of the impeller, the mounting precision is increased, so that the deleterious effects on the blood due to an eccentric arrangement of the impeller and due to unsatisfactory concentricity are prevented.

The impeller-side bearing is preferably at the same time designed as a shaft seal, whereby blood is prevented from entering the tube or the pump housing.

The diameter of a blood pump that can be positioned in a minimally invasive manner is limited to approximately 5 to 7 mm, since the vessel width in the body's peripheral areas is at most slightly more than 7 mm. With such a blood pump, a pump power of approximately 4 L/min in the case of a counter-pressure of approximately 100 mm Hg can be generated.

The intravascular blood pump according to the invention can have numerous applications due to the good mobility in the vascular system, for example

- a) as left cardiac assistance pump with the option (see b)) of generating a pulsating flow,
- b) as right cardiac assistance pump with the option of pulsed operation by modulation of the pump rotation speed,
- c) as a monoventricular or biventricular assistance system during thoracic/transthoracic operations on the beating or non-beating heart, without the use of a heart-lung machine,
- d) as a blood pump for local organ perfusion with an appropriate sealing device.

Since the pump part is difficult to clean and sterilize after the blood pump has been used, according to a preferred development of the invention, it is provided that the pump housing, the

impeller and the shaft constitute a disposable unit which can be removed as a whole from the motor housing. The rotor of the drive unit can also be part of this disposable unit, if the drive unit is firmly connected to the shaft. In this manner, is possible to combine the parts that can be manufactured without great effort in the disposable unit, while the stator of the motor which
5 requires expensive windings and an easily sterilized housing can be used repeatedly.

Below, in reference to the drawings, embodiment examples of the invention are explained in greater detail.

Fig. 1 shows a diagrammatic representation of the introduction of the blood pump before the left ventricle, with the positioning of the suction cannula in the left ventricle,

10 Fig. 2 shows a diagrammatic longitudinal section of a first embodiment example of the blood pump,

Fig. 3 shows an enlarged representation of detail III from Fig. 2,

Fig. 4 shows a second embodiment example, in which a part of the blood pump is designed as disposable unit, and

15 Fig. 5 shows a third embodiment example, in which the pump housing is connected with a connecting web to the motor housing.

In Fig. 1, a use of the blood pump 10 for left cardiac assistance is represented. The blood pump 10 comprises a motor part 11 and a pump part 12 which are arranged coaxially one after the other and which result in a rod-shaped design. The pump part is extended by a suction hose
20 13 which, on the end thereof and/or in the side wall thereof, comprises openings for the entry of blood into the pump. The rear end of the blood pump 10, which faces away from the suction hose 13, is connected to a catheter 14 which is introduced through the aortic arch 15 and the aorta 16. The blood pump 10 is placed in such a manner that it lies primarily in the ascending aorta 15, while the straight, short suction hose 13 protrudes into the ventricle 17. In the closed state, the
25 aortic valve 18 lies against the outer side of the pump housing or of the suction hose. The blood pump 10 with upstream suction hose 13 is pushed forward by pushing the catheter 14 forward,

optionally with a mandrel contained therein or using a guide wire, into the position represented. The suction hose 13 here passes the aortic valve 18 in retrograde motion, so that blood is suctioned through the suction hose 13 and pumped into the aorta 16.

The use of the blood pump according to the invention is not limited to the application represented in Fig. 1, which is just a typical example.

Fig. 2 shows a preferred embodiment example of the blood pump with the motor part 11 and the pump part 12 firmly connected thereto. The motor part 11 comprises an elongate cylindrical housing 20, in which the electric motor 21 is accommodated. On the rear end, the housing 20 is closed with a front wall 22, which the flexible catheter 14 adjoins sealingly. The electric cables 23 for the power supply and control of the electric motor 21 run through the catheter 14.

The stator 24 of the motor, in the usual manner, comprises numerous windings arranged distributed over the circumference, as well as a coil flux guide in longitudinal direction. It is firmly connected to the motor housing 20. The stator 24 surrounds the rotor 26, which is connected to the motor shaft 25 and consists of permanent magnets magnetized in the direction of action. The motor shaft is mounted on the rear end with a bearing 27 in the motor housing or in the front wall 22. It extends through the entire length of the motor housing 20 and protrudes forward from said motor housing.

The front closure of the motor housing 20 forms a tubular stationary hub part 30 which, at the rear end 30a, has the same diameter as the motor housing 20 and is connected sealingly to the motor housing. A tapering section 30b adjoins the rear end 30a and, in it, the outer diameter of the hub part 30 decreases continuously to the cylindrical front end section 30c. Radial ribs 31 protrude from the end section 30c of the tube 30, and the outer ends thereof are connected to the cylindrical tubular pump housing 32. At the front end of the end section 30c, in the tube 30, a bearing 33 for mounting the motor shaft 25 is located. This bearing at the same time is formed as a shaft seal and will be explained further below.

The motor shaft 25 protrudes forward from the tube 30, and there it carries an impeller 34 with a hub 35 sitting on the shaft end and with blades 36 or pump blades protruding therefrom.

When the impeller 34 is rotating, blood is suctioned through the front-side suction opening 37 of the pump housing 32 and is driven backward in axial direction in the pump housing 32. Due to the annular gap between the pump housing 32 and the motor housing 20, the blood flows outward along the section 30b of the pipe 30, flowing further along the motor housing 20. As a result, the removal of the heat generated in the drive is ensured, without deleterious effects on the blood due to excessively high surface temperatures (over 41 °C) on the motor housing 20. Motor housing 20 and pump housing 32 have approximately the same diameter, but the outer diameter of the pump housing 32 can be slightly larger than that of the motor housing, since there is no need for flow to occur outside around the pump housing. In this example and in the following examples, it is also possible to operate the pump part with reversed conveyance direction, wherein blood is suctioned along the motor housing and exits axially from the end 37.

The bearing 33 sits in a recess 38 which is open inward and toward the end, on the extreme front end of the hub part 30. It has a bearing body 39 made of polytetrafluoroethylene, which has high hardness and a low friction coefficient with steel. This bearing body comprises, on the inner side thereof, a sealing bead 40 which surrounds the rotating motor shaft 25 nearly linearly. In the interior of the bearing part 39, a spreader spring 41 is located, which presses the bead area 40 with force against the shaft 25.

By means of the bearings 27 and 33 on the extreme ends of the motor shaft 25, exact guiding and satisfactory concentricity of the motor shaft are achieved. It is advantageous in particular that the front bearing 33 is located very close to the impeller 34.

The embodiment example of Fig. 4 is largely similar to that of Fig. 2, so that the subsequent description is limited to the explanation of the differences. The impeller 34 together with the motor shaft 25 and the rotor 26 as well as the tube 30 and the pump housing 32 form a

disposable unit, the limits of which are drawn by means of the dotted line 61. The disposable unit also includes the bearing 33 and optionally the bearing 27. After the blood pump has been used, the mentioned parts may be contaminated, wherein blood particles may also become lodged in the gaps. Therefore, complete disinfection is practically impossible. The disposable unit 60
5 consists of parts that are relatively easy and cost-effective to produce. The disposable unit as a whole is pulled off the motor housing 20 and discarded after use and replaced with another unit.

The embodiment example of Fig. 5 corresponds largely to that of Fig. 2, wherein identical parts are provided with identical reference numerals.

According to Fig. 5, the impeller 34 is firmly attached to the rotating shaft 25 of the
10 electric motor 21. The motor shaft 25 extends through the hub part 30 protruding forward from the motor housing 20 and is mounted on the front end of the hub part by means of a bearing 33.

The pump housing 32 is connected to the motor housing 20 by means of a connecting web 62 which extends in longitudinal direction, and which protrudes forward flush with the wall of the motor housing 20 and transitions also flush into the wall of the pump housing 32. In this
15 way, the radial ribs 31 in Fig. 2 are omitted, and the length of the pump housing 32 can be designed to be shorter than in Fig. 2. Instead of a single connecting web 62, several connecting webs spaced apart from one another on the circumference can be provided.

So that the motor shaft 25 does not shift axially in the motor housing 20, it is provided with a radially protruding collar 64 which is supported with the back side thereof on the rotor 26
20 and which, with the front side thereof, can butt against the hub part 30 so that pulling out of the motor shaft from the motor housing is prevented.

CLAIMS

1. An intravascular blood pump with a drive part (11) which contains an electric motor (21) in a motor housing (20) and is connected to a catheter (14), and with a pump part (12) which
5 contains an impeller (34) which sits on the motor shaft (25) and which can rotate in a tubular pump housing (32),

wherein the motor housing (20) and the pump housing (32) have substantially the same diameter and are arranged coaxially spaced apart from one another, and the motor shaft (25) extends through a stationary hub part (30) which protrudes from the motor housing (20) and
10 supports the pump housing (32),

characterized in that

the motor shaft (25) is mounted on an end of the motor housing (20) as well as on the impeller-side end of the stationary hub part (30), in each case with a bearing (27, 33).

2. The intravascular blood pump according to Claim 1, characterized in that the stationary
15 hub part (30) comprises protruding ribs (31) for holding the pump housing (32).

3. The intravascular blood pump according to Claim 1, characterized in that the pump housing (32) is connected to the motor housing (20) via at least one axially parallel extending connecting web (62).

4. The intravascular blood pump according to Claim 1 or 2, characterized in that the
20 impeller-side bearing (33) at the same time forms a shaft seal.

5. The intravascular blood pump according to any one of Claims 1-4, characterized in that the pump housing (32), the impeller (34) and the shaft (25) form a disposable unit (60) which can be pulled off as a whole from the motor housing (20).

6. The intravascular blood pump according to Claim 5, characterized in that the
25 disposable unit also includes the rotor (26) of the motor (21).