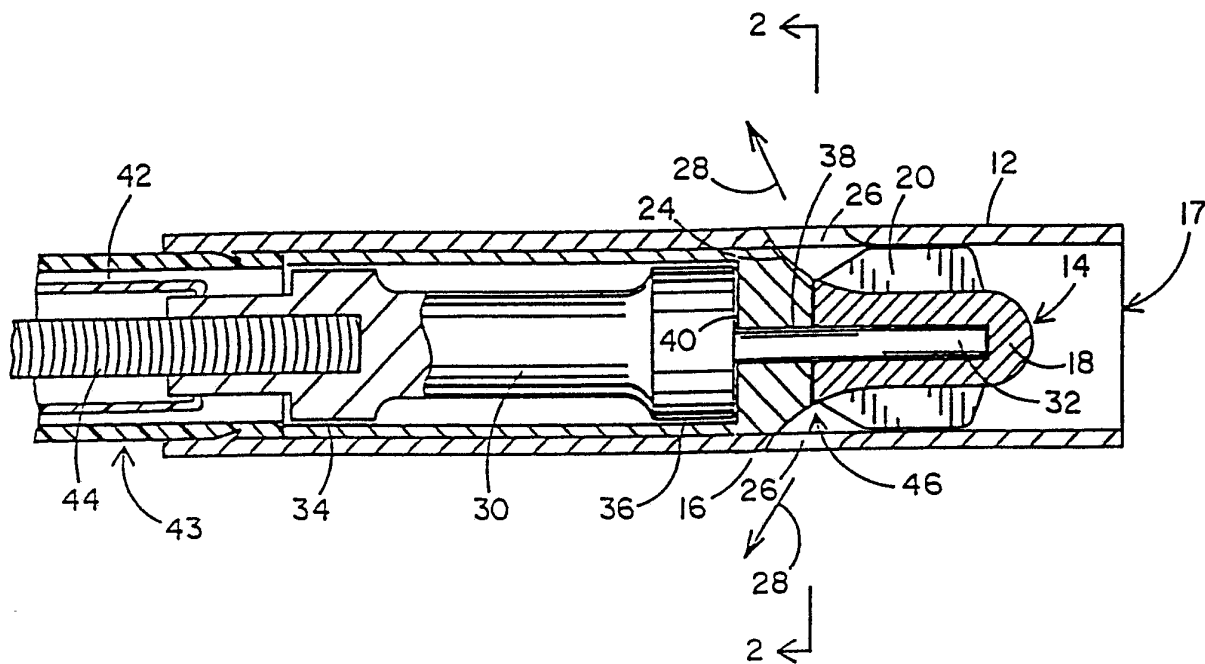




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁴ : A61F 2/22	A1	(11) International Publication Number: WO 89/ 04645 (43) International Publication Date: 1 June 1989 (01.06.89)
<p>(21) International Application Number: PCT/US88/04194</p> <p>(22) International Filing Date: 22 November 1988 (22.11.88)</p> <p>(31) Priority Application Number: 124,560</p> <p>(32) Priority Date: 24 November 1987 (24.11.87)</p> <p>(33) Priority Country: US</p> <p>(71) Applicant: NIMBUS MEDICAL, INC. [US/US]; 2890 Kilgore Road, Rancho Cordova, CA 95670 (US).</p> <p>(72) Inventor: WAMPLER, Richard, K. ; 11571 Sutters Mill, Gold River, CA 95670 (US).</p> <p>(74) Agent: WEISSENBERGER, Harry, G.; Weissenberger & Peterson, 24012 Calle de la Plata, # 470, Laguna Hills, CA 92653-3621 (US).</p>		<p>(81) Designated States: AT (European patent), AU, BE (European patent), BR, CH (European patent), DE (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: PERCUTANEOUS BLOOD PUMP WITH MIXED-FLOW OUTPUT



(57) Abstract

The outside diameter of an intravascular axial flow blood pump is reduced without reducing the size of its journal bearings (34, 36, 38) by causing the pumped blood stream to exit through apertures (26) in the cylindrical outside wall of the pump housing between the rotor blades (20) and the rotor journal. This allows the journal to have a diameter of the housing, without the need for a space-consuming blood flow path around the journal.

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PERCUTANEOUS BLOOD PUMP WITH MIXED-FLOW OUTPUTField of the invention

5 This invention relates to intravascular blood pumps, and particularly to a miniature axial flow pump with a mixed radial and axial outflow pattern.

Background of the invention

10 U.S. Patent No.4,625,712 and copending application Serial No.124,874, filed Nov. 24,1987 and entitled SINGLE-STAGE AXIAL FLOW BLOOD PUMP disclose intravascular axial flow blood pumps. Inasmuch as such pumps must be percutaneously inserted and threaded through an artery into the
15 vicinity of the heart, it is physiologically desirable to make them as small as possible; yet in order to maintain a given blood flow, the smaller the pump, the higher its rotational speed must be. This objective, however, is restricted by practical
20 limitations on the miniaturization of the bearings, which must have a certain minimum diameter in order to function reliably. Consequently, it has not previously been possible to construct blood pumps of this type with an outside diameter substantially
25 smaller than 7 mm, which is physiologically acceptable but not ideal because it would be highly desirable to make the pump fit through conventional 14-french (4.7 mm) ID percutaneous introducers.

30 Summary of the invention

The present invention makes it possible to construct an intravascular axial flow blood pump which has an outside diameter substantially smaller

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than prior art pumps, yet has bearings of the same size.

5 The invention accomplishes this by discharging the pumped blood not axially through the downstream end of the pump's cylindrical housing, but at an angle through elongated slots located near the center of the housing. This construction makes it possible to use the full inner diameter of the housing for the rotor journals without having to
10 leave room for a blood path and stator blades around the journals.

It is therefore the object of the invention to provide a miniaturized axial-flow intravascular blood pump in which the space available for bearings
15 is maximized by discharging the pumped blood partially radially and partially axially through openings formed in the pump's cylindrical housing upstream of the bearings.

20 Brief description of the drawings

Fig. 1 is an axial section of the blood pump of this invention; and

Fig. 2 is a section along line 2-2 of Fig. 1.

25 Description of the preferred embodiment

In Fig. 1, the blood pump of this invention is generally shown at 10. The pump 10 is contained within a cylindrical housing 12 and includes a rotor 14 and a stator 16. The housing 12 has a blood
30 intake opening 17. The rotor 14 has a narrow, elongated hub 18. The hub 18 preferably carries a set of rotor blades 20. The hub 18 increases in diameter in the downstream direction substantially

continuously throughout its entire length, so that the blood flow in the area of the rotor blades 20 is in a mixed axial and radial direction.

5 The radial component of the blood flow produced by rotor 14 is enhanced by the curvature of the deflection surface 24 of stator 16, so that the blood is propelled outwardly of the housing 12 through openings 26 in the housing wall in the general direction of arrows 28.

10 This construction makes it possible to use the entire inner diameter of housing 12 to house the journals 30 of the rotor shaft 32. The journal bearings 34, 36, 38 and the thrust bearing 40 are preferably of the purged-seal hydrodynamic type.
15 Fluid for these bearings is supplied from an outside source (not shown) through the outer lumen 42 of cable sheath 43 which contains the rotor drive cable 44. The details of the construction of cable sheath 43 are described in copending application Serial No. 124,874 and are not material to this invention. The
20 cross section, number and shape of the openings 26 should be such as to avoid as much as possible any impediment to the blood flow, and to avoid any hemolysis-producing or thrombogenic turbulence,
25 while maintaining the structural integrity of the housing 12. Their specific optimum geometry depends in large measure on the design of the rotor blades 20 and on the curvature of the stator surface 24 in any particular application.

30 The rotor hub 18 is preferably firmly but removably attached to the rotor shaft 32 by any conventional means such as screwthreads to

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facilitate assembly and disassembly of the pump 10 while holding it firmly together during operation.

5 It will be seen that the present invention provides a miniature mixed flow blood pump which can be manufactured with a substantially smaller diameter than prior art pumps of the same type, yet can accommodate a sufficiently large rotor shaft journal to provide reliability in operation, by causing the blood stream to exit the pump housing
10 upstream of the journal bearings.

CLAIMS

1. An intravascular axial flow blood pump, comprising;

a) a generally cylindrical housing having a blood intake at one end thereof;

5 b) a rotor disposed in said housing adjacent said one end, said rotor including

i) a hub carrying rotor blades and having a diameter substantially smaller than the inside diameter of said housing;

10 ii) a journal positioned adjacent the other end of said housing and having a diameter substantially equal to the inside diameter of said housing; and

15 iii) drive means associated with said journal for driving said rotor; and

c) said housing having blood exit apertures therein between said blades and said journal.

2. The blood pump of Claim 1, in which the diameter of said hub increases from the intake end of said hub toward said exit apertures, whereby a partially radial flow is imparted to said blood to
5 direct it toward said apertures.

3. The blood pump of Claim 2, in which said diameter increase is continuous.

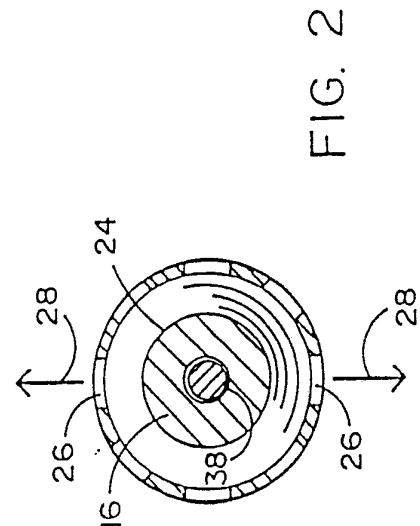
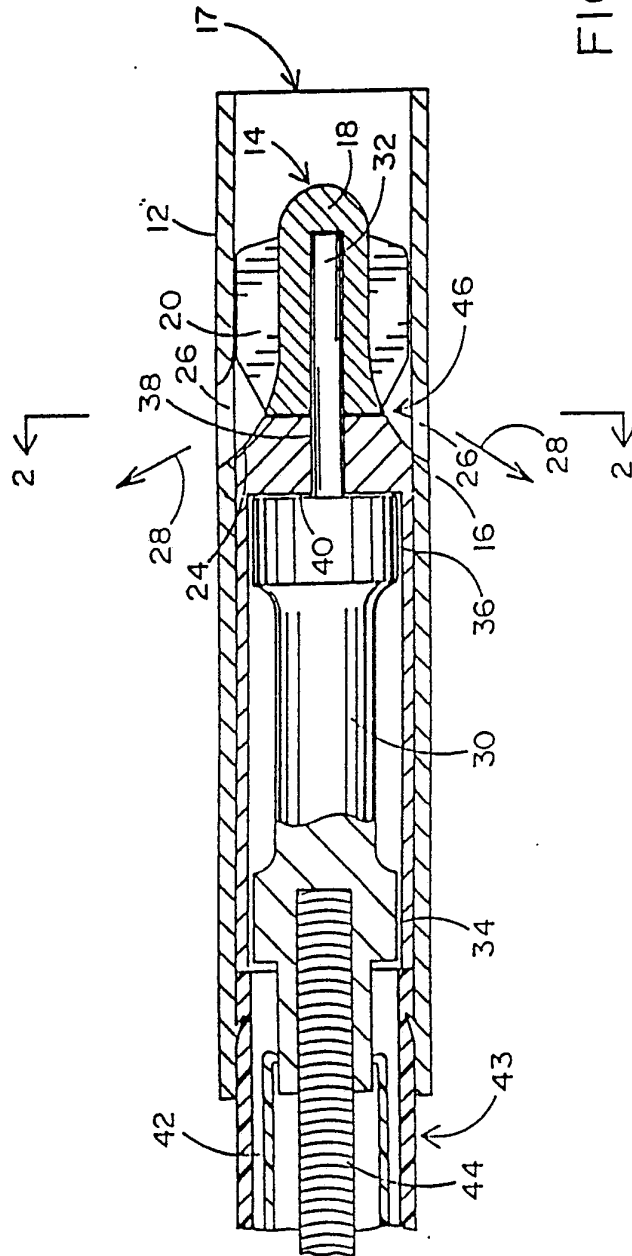
4. The blood pump of Claim 1, in which said drive means include a drive cable contained within a cable sheath.

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5. The blood pump of Claim 1, in which said journal is supported for rotation in hydrostatic purge-sealed bearings, the purge fluid for said bearings being discharged into said blood.

6. The blood pump of Claim 5, in which said drive means include a drive cable contained within a cable sheath, and said purge fluid is supplied to said pump through said cable sheath.

7. The blood pump of Claim 5, in which said purge fluid is discharged in the vicinity of said apertures.



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INTERNATIONAL SEARCH REPORT

International Application No. **PCT/US 88/04194**

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC IPC(4): A61F 2/22 U.S. CL. 128/1D 604/151,264																	
II. FIELDS SEARCHED <div style="text-align: center;">Minimum Documentation Searched ⁷</div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Classification System</th> <th style="width: 80%;">Classification Symbols</th> </tr> <tr> <td style="padding: 5px; vertical-align: top;">U.S. CL.</td> <td style="padding: 5px; vertical-align: top;">128/1D, DIG 3 604/151,264 623/3 415/170A, 175, 198.1, 198.4, 198.6, 210</td> </tr> </table> <div style="text-align: center; padding: 5px;">Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	U.S. CL.	128/1D, DIG 3 604/151,264 623/3 415/170A, 175, 198.1, 198.4, 198.6, 210											
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III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 10%;">Category *</th> <th style="width: 60%;">Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²</th> <th style="width: 30%;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="text-align: center; vertical-align: top;">X</td> <td style="vertical-align: top;">US, A 4,704,121 MOISE 3 November 1987 (Note Figure 1)</td> <td style="text-align: center; vertical-align: top;">1-3,5,7</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">X</td> <td style="vertical-align: top;">US, A 4,589,822 CLAUSEN 20 May 1986 (Note Figures 3-4)</td> <td style="text-align: center; vertical-align: top;">1-3</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td style="vertical-align: top;">US, A 4,688,998 OLSEN 25 August 1987</td> <td style="text-align: center; vertical-align: top;">1-7</td> </tr> <tr> <td style="text-align: center; vertical-align: top;">A</td> <td style="vertical-align: top;">US, A 4,625,712 WAMPLER 2 December 1986</td> <td style="text-align: center; vertical-align: top;">1-7</td> </tr> </table>			Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	US, A 4,704,121 MOISE 3 November 1987 (Note Figure 1)	1-3,5,7	X	US, A 4,589,822 CLAUSEN 20 May 1986 (Note Figures 3-4)	1-3	A	US, A 4,688,998 OLSEN 25 August 1987	1-7	A	US, A 4,625,712 WAMPLER 2 December 1986	1-7
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<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Special categories of cited documents: ¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 50%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&" document member of the same patent family</p> </div> </div>																	
IV. CERTIFICATION <table style="width: 100%;"> <tr> <td style="width: 50%;">Date of the Actual Completion of the International Search</td> <td style="width: 50%;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="text-align: center; padding: 10px;">19 January 1989</td> <td style="text-align: center; padding: 10px;">03 APR 1989</td> </tr> <tr> <td>International Searching Authority</td> <td>Signature of Authorized Officer</td> </tr> <tr> <td style="text-align: center; padding: 10px;">ISA/US</td> <td style="text-align: center; padding: 10px;">ALAN COHAN </td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	19 January 1989	03 APR 1989	International Searching Authority	Signature of Authorized Officer	ISA/US	ALAN COHAN							
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FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE ¹

This international search report has not been established in respect of certain claims under Article 17(2) (a) for the following reasons:

1. ☐ Claim numbers , because they relate to subject matter ¹² not required to be searched by this Authority, namely:

2. ☐ Claim numbers _____, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out ¹⁻³, specifically:

3. ☐ Claim numbers _____, because they are dependent claims not drafted in accordance with the second and third sentences of PCT Rule 6.4(a).

VI. ☐ **OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING ²**

This International Searching Authority found multiple inventions in this international application as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
4. ☐ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
☐ No protest accompanied the payment of additional search fees.