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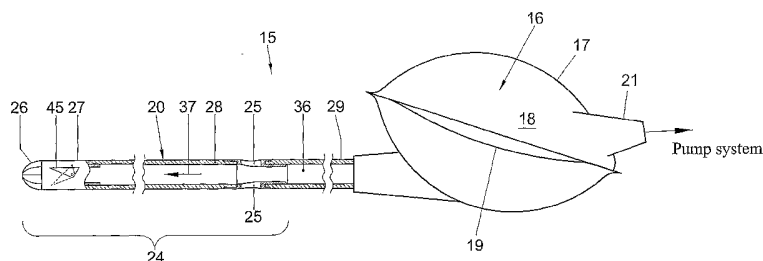
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ning of each regular issue of the PCT Gazette.*

(54) Title: CATHETER PUMP, CATHETER AND FITTINGS THEREFORE AND METHODS OF USING A CATHETER PUMP.



(57) **Abstract:** A catheter pump includes a catheter channel (36) communicating with a distal end portion of the catheter for alter-
nately leading fluid in proximal and distal directions. At least one outlet passage (26) is distally spaced from the inlet passage or
passages (25). The catheter pump further includes a displacement structure (16) communicating with the proximal end portion of
the catheter for alternately applying suction and pressure for driving the fluid displacement. At least in operating condition, the
inlet passage or passages (25) is resp. are continuously open. A catheter and fittings (27, 28) for such a catheter pump and method
of using a catheter pump are also described.

TITLE: Catheter pump, catheter and fittings therefore and methods of using a catheter pump

TECHNICAL FIELD

The invention relates to a catheter pump, to a catheter, to fittings therefore and to a method of using a catheter pump.

5

BACKGROUND ART

From U.K. patent specification 1,370,546 a heart assist catheter pump is known which includes a catheter having a distal end for insertion
10 from the aorta past the aortic valve into the left ventricle. The distal end has inlet openings. Spaced from the distal end, the catheter has outlet openings and a set of check valves for allowing outward flow. Valves are provided for controlling the direction of the flow. A fluid displacement device communicating with the proximal end of the catheter alternately generates
15 a suction causing blood to be withdrawn from the left ventricle into the catheter and to the displacement device and an excess pressure causing blood to be expelled from the catheter downstream side of the aortic valve.

Later catheter pumps for assisting the left ventricle heart by pumping blood from a distal catheter tip portion to an outlet spaced from the
20 distal tip are disclosed in U.S. patents 3,995,617, 4,014,317, 6,007,479 and 6,398,714. U.S. patent application 2002/0123661 discloses the use of a catheter pump with an inlet distally from the outlet for causing blood pressure pulsations in the aorta, for instance in addition to a non-pulsatile flow maintained by a heart lung machine.

25 However, for some clinical applications, blood is pumped through the catheter in opposite direction, i.e. from an inlet in a position spaced from the distal tip towards the distal tip.

One example of such a clinical application is assisting the function of the right ventricle of the heart. Devices for assisting this function are known
30 as Right Ventricular Assist Devices (RVAD). An example of a RVAD in the form of catheter pump is disclosed in U.S. patent 4,985,014 in which the catheter is a double lumen or coaxial channel catheter and the pump a roller

pump. Examples of single lumen catheter pumps for use as a RVAD are disclosed in International patent applications WO99/26677 and WO00/13736.

Another example of a clinical application in which blood is pumped from an inlet in a position spaced from the distal tip to the distal tip is
5 proposed in International patent application WO99/26676. According to this document, the catheter is inserted through an incision in the left ventricle and advanced until the distal end is in the aorta while a more proximal portion including an inlet is in the left ventricle. The catheter then functions as a left ventricular assist device.

10 An important problem associated with pumping blood is that blood cells are easily damaged in the valves, where the blood experiences abrupt changes in either the rate or direction of its flow under influence of mechanical forces and that, at the valves, the risk of thrombosis is increased. In International patent application WO 98/57698, the problem of blood cell
15 damage is addressed and special valves are proposed. U.S. patent 6,398,714 discloses to reduce the risk of thrombosis by providing a single valve that alternately closes off a passage in the wall of the catheter and the lumen of the catheter. However, these solutions are still relatively complex and specifically suitable for catheters in which blood is displaced away from the
20 tip towards an outlet more spaced from the tip than the inlet.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a simple and
25 reliable catheter pump of the type in which blood is alternately displaced towards and away from a proximal displacement structure and, generally, moves from an inlet spaced from the tip to a more distal outlet, in which the risk of blood damage and thrombosis is at least reduced.

According to the invention, this object is achieved by providing a
30 catheter pump according to claim 1.

The invention can also be embodied in a catheter according to claim 16 adapted to form a catheter pump in combination with a displacement device communicating with the proximal end of the catheter.

The invention can further be embodied in a fitting according to claim
35 17 or 18, specifically adapted for a catheter pump according to the invention.

According to one aspect of the invention such a fitting is adapted for forming the inlet passages of the catheter pump and, to that end, includes a tubular section having a wall bounding a channel, at least one inlet passage in the wall, wherein, at least in operating condition, the at least one inlet
5 passage is continuously open.

According to another aspect of the invention such a fitting is adapted for providing a check valve of a catheter pump according to a particular embodiment of the invention and, to that end, includes a tubular section bounding a channel, a valve located in the channel, the valve including a
10 valve body pivotably suspended for rotation about an axis extending across the channel, between a closed position, substantially closing off the channel and an open position allowing fluid to pass past the valve, wherein the valve body in open position extends along a plane parallel to the channel, in axial view, has a central portion spaced from the pivoting axis and, in side view,
15 projecting from the pivoting axis further in distal direction than in proximal direction.

In spite of the inlet passage or passages being continuously open, when the displacement device alternately urges blood through the channel in distal and proximal direction, over a complete cycle, a net displacement of
20 blood from the inlet through the channel to the outlet is obtained. If any, the volume of blood that is pushed back through the inlet opening or openings when the displacement device displaces blood in distal direction is smaller than the volume of blood that enters the channel via the inlet opening or openings when blood is pulled through the catheter channel in proximal
25 direction. This effect is achieved because during flow in distal direction, blood reaches the inlet passages as a flow having a direction determined by the direction in which the channel extends immediately proximally of the inlet passage or passages, i.e. the flow in distal direction has a substantial directional effect on the flow in the area of the inlet passage or passages. In
30 contrast, the direction of the flow in proximal direction away from the inlet passage or passages has relatively little directional effect on the flow in the area of the inlet passage or passages. Therefore, in response to the withdrawal of blood from behind the inlet passage or passages, blood can flow into the channel via the inlet passage or passages in directions having a
35 component transverse to the direction of the channel via the inlet relatively easily.

Since, in operation, the inlet passage or passages are continuously open, there is no need to provide valves at the inlet passage or passages. In turn, this allows a very simple construction and blood cell damage and risk of thrombosis as typically caused by valves are avoided.

5 The catheter pump and the catheter according to the invention are very suitable for carrying out a method according to claim 19 or claim 23.

 The catheter is thus arranged in the aorta with its distal end portion oriented in downstream direction with the fluid inlet located proximally of the fluid outlet. Withdrawing the fluid from an area upstream of the section
10 of the aorta where the fluid is expelled from the catheter is relatively easy and the pulsatile outflow in the narrower section of the aorta is very effective for causing pulsatile pressure peaks of the blood pressure in a section of the aorta where the arteries towards the organs branch off from the aorta.

 Particular embodiments of the invention are set forth in the
15 dependent claims.

 Further objects, features, effects, advantages and details of the invention are described with reference to examples shown in the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

20

 Figs. 1 and 2 are partially cut-away views of a human thorax illustrating methods according to the invention in which examples of catheter pumps according to the invention are used;

 Figs. 3 and 4 view according to Figs. 1 and 2 are illustrating two
25 other methods in which examples of catheter pumps according to the invention are used;

 Fig. 5 is a side view, partially in longitudinal cross-section of an example of a catheter pump according to the invention;

 Fig. 6 is a side view in cross-section of an inlet section of the catheter
30 according to Fig. 5;

 Figs. 7-12 are enlarged views in cross-section of inlet sections of other examples of catheter pumps according to the invention;

 Fig. 13 is a side view in cross-section of a section of the catheter according to Fig. 5 where a one-way valve is located; and

35 Fig. 14 is a view in cross-section along the line XIV-XIV in Fig. 13.

DETAILED DESCRIPTION

In Fig. 1 a human thorax is illustrated in a view showing the heart 1, the aorta 2, the superior vena cava 3, the inferior vena cava 4, the right pulmonary veins 5, the left pulmonary veins 6, right pulmonary arteries 7, the left pulmonary arteries 8, the aortic arch 9, the left ventricle 10 and the right ventricle 11. Arrows indicate blood flow directions when the heart 1 is in operation. During open-heart surgery on an inactive heart 1, in practice, blood circulation is usually maintained using a heart lung machine 12 (shown schematically only) including a pump 13 and an oxygenator 14. The heart lung machine is connected to the human body for pumping blood from the vena cava 3 to the aorta 2 and maintains the blood circulation in the patient. The blood flow from the heart lung machine 13 to the patient is essentially non-pulsatile. This essentially non-pulsatile blood flow enters the aorta 2 closely adjacent the heart 1, which has been deactivated. The pump 13 is a non-pulsatile pump, which provides advantages in terms of design and compatibility with the function of the oxygenator (Allen et al.; "The importance of Pulsatile and Nonpulsatile Flow in the Design of Blood Pumps"; Artificial Organs 21(8): 922-928).

Organ failure after open-heart surgery is a frequent cause of complications. Different theories regarding the causes of such organ failure exist. One of these theories is, that the use of a heart-lung machine has several side effects that may influence blood pressure and organ perfusion. For example, the heart-lung machine causes a non-physiological (non-pulsatile flow pattern and a decreased blood viscosity when the priming liquid from the tubing and the oxygenator is introduced into the patient's blood circulation. Other instances when reduced blood pressure may disturb organ functions are during toxic shock, which may for instance be caused by an allergic reaction and, prolonged cardiac malfunction, which frequently entails multi-organ failure.

Several research results indicate that a pulsatile flow is advantageous for obtaining sufficient blood flow to the organs. For instance, pulsatile flow in a cardio pulmonary bypass has been found to have a positive effect on the blood flow rate to the kidneys of neonate pigs (Lodge et al.; "Regional Blood Flow During Pulsatile Cardiopulmonary Bypass and After Circulatory Arrest in an Infant Model"; Ann Thorac Surg 1997; 63:1243-50).

During an acute heart attack of a pig, blood flow to the liver and to the kidneys and microcirculation at cellular level were found to be improved if during three hour biventricular cardiac assist, the flow was pulsatile (Sezai et al.; "Major Organ Function Under Mechanical Support: Comparative
5 Studies of Pulsatile and Nonpulsatile Circulation"; Artificial Organs 1999; 23(3): 280-285). During left ventricle cardiac assist in a similar situation, pulsatile cardiac assist provided superior circulation in the liver and superior microcirculation on a cellular level, at least in the initial phase of the treatment after the heart attack.

10 During open-heart surgery on neonate pigs, a positive effect of pulsatile flow on the blood flow to the organs, the brain and the heart muscles was found (Ündar et al.; "Effects of Perfusion Mode on Regional and Global Organ Blood Flow in a Neonatal Piglet Model"; Ann Thorac Surg; 68: 1336-43).

15 In clinical cardiopulmonary bypass cases, the results of measurement of cytokine, endothelium and other metabolic parameters indicated that the damage to the endothelium was less and the cytokine activation was reduced in a patient group treated with a pulsatile flow compared with another group treated with a non pulsatile flow (Orime Y. et al., "Cytokine and Endothelial
20 Damage in Pulsatile and Nonpulsatile Cardiopulmonary Bypass"; Artificial Organs 1999; 23(6):508-512).

In Fig. 1, clinical use of a catheter pump 15 for causing the blood pressure pulsations in the aorta 2 is illustrated. The pulsatile catheter pump 15 (which is shown in more detail in Figs. 5, 6, 13 and 14) has a displacement
25 structure 16 in the form of a rigid housing 17 enclosing a chamber 18 divided by a flexible membrane 19. The catheter pump 15 further has a catheter 20 projecting from that displacement structure 16 and bounding a channel 36 that extends longitudinally inside the catheter for leading fluid on longitudinal direction of the catheter. The channel 36 communicates with a
30 portion of the chamber 18 on a distal side of the membrane 19 and a sleeve 21 for connection of a pneumatic conduit communicating with a pump drive system (not shown) to a portion of the chamber 18 on a proximal side of the membrane 19. The displacement structure 16 can be driven via the pneumatic conduit for alternately applying suction for displacing fluid from
35 the distal portion 24 of the catheter 20 to the displacement structure 16 via the channel 36 and for applying pressure for displacing fluid from the

displacement structure 16 to the catheter 20, thus driving a flow through the catheter 20 which reverses in a pulsating manner.

The catheter 20 projects from the displacement structure 16 into the aorta 2 via the left subclavian artery 22 leading to the left arm 23 and is
5 inserted into the aorta 2 of a patient in a position having its distal end portion 24 in the aorta 2 of the patient.

The distal end portion 24 of the catheter 20 is provided with inlet passages 25 arranged in a fitting 28 of the catheter 20. Spaced in distal direction from the inlet passages 25, the catheter 20 has an outlet passage
10 26. According to the present example, the outlet passage is arranged in a catheter tip fitting 27.

The displacement structure 16 is connected to a proximal end 29 of the catheter 20 and alternately withdraws blood from the aorta 2 and feeds blood to the aorta 2 via the catheter 20, such that pressure pulsations are
15 generated in the area of the distal end portion 24 of the catheter 20. The displacement structure 16 preferably has a stroke of 10-40 ml and is preferably constructed from a transparent polymer such as PC, PMMA or MEBS. For driving the displacement structure 16 a commercially available drive system can be employed, for instance a conventional balloon pump.

20 In the use of the catheter pump shown in Fig. 1, pulsations are generated in the blood flow in the aorta 2. Blood is pumped into the catheter 20 via the inlet passages 25 located in the aortic arch 9 and pumped out of the catheter 20 via the outlet passage 26 in a descending section of the aorta 2 in close proximity of arteries 30-33 towards the bowels, the liver and the
25 kidneys.

The pulsations in the blood pressure pass into the arteries 30-33 towards the bowels, the liver and the kidneys. Such local blood pressure pulsations have a positive effect on the organ perfusion (for instance expressed as a flow rate per unit of mass of organ tissue), which is believed to
30 be caused by increased effective organ perfusion pressure differentials. Because the pulsations are introduced in a section of the aorta 2 where its cross-section is relatively small and in close proximity of the arteries 30-33 towards the bowels, the liver and the kidneys the aorta, the magnitude of the pulsatile blood pressure peaks is relatively large in the area of the arteries
35 30-33 towards the abdominal organs where the pulsating effect is desired. The outflow opening 25 is preferably located between the junctions where

arteries 30-33 towards the organs connect to the aorta, when the catheter is in its operating position inserted in a patient.

Moreover, since the pulsations are generated in the aorta 2, i.e. in an area downstream of and remote from the oxygenator 14, the pulsations do not
5 interfere significantly with the operation of the oxygenator 14.

The inlet passages 25 are located upstream of the outlet passages 26, in a section of the aorta 2 that is wider than the section of the aorta 2 where the outlet passage 26 is located, so that blood can flow to the inlet passages 25 relatively easily. Moreover, this provides the advantage that the pressure
10 reduction during intake of blood occurs at a distance upstream of the arteries 30-33 leading to the organs, so that it has relatively little influence on reducing blood flow towards the organs, while the peak pressures of the pulsations are applied closely adjacent the arteries 30-33 leading to the organs. Furthermore, the pulsations involve displacement of blood along the
15 aorta 2, so that the reduction of its cross-section available for blood flow due to the presence of the catheter 20 is at least partially compensated by blood transport through the catheter 20. It is observed that the intake of blood may also take place outside the aorta, for instance form a buffer reservoir communicating with an outflow canula of the heart lung machine.

20 The spacing between the inlet passages 25 and the outlet passage 26 is preferably at least 8 cm and more preferably at least 13 cm and preferably at most 25 cm and more preferably at most 20 cm.

More in particular, the inlet passages 25 are located downstream of a section of the aorta 2 where the subclavian arteries 22, 34 connect to the
25 aorta 2. This provides a particularly positive control over the pulsations in the arteries 30-33 towards the organs.

Because the catheter 20 is inserted into the aorta 2 via a subclavian artery 22, it can be manipulated relatively easily and from a position near the thorax of a patient that can be reached relatively easy during thorax
30 surgery.

In Fig. 2, an example of a similar method according to the invention in which another example of a catheter pump 115 according to the invention used is shown. The catheter 120 is inserted into the aorta 2 via an incision 135 in the aorta 2. This provides the advantage that no further wounds have
35 to be made in the patient's skin, that the need of guiding a catheter through an artery over a substantial distance is avoided, that a relatively short

catheter can be used and that the position where the catheter 20 enters the aorta 2, is easily reached during open-heart surgery.

The catheter 120 is equipped with a fitting that seals off the catheter 120 against the incision 135. To avoid the need of making a separate incision
5 for inserting the catheter, an outflow canula of the heart-lung machine 12 may enter into the aorta via the same incision, for instance by providing a fitting that seals off the catheter of the catheter pump and the outflow canula of the heart-lung machine against the same incision.

In both the clinical applications illustrated by Figs. 1 and 2, the distal
10 end of the catheter 20, 120 is oriented in downstream direction of the aorta and the pulsatile blood intake takes place upstream of the pulsatile blood outflow.

To provide on the one hand a sufficiently large cross-section for fluid displacement through the catheter, while on the other hand allowing easy
15 insertion of the catheter and sufficient remaining room for blood flow through the aorta 2 or through the artery 22 through which the catheter 20 is inserted, the catheter 20 preferably has an external diameter of at least 4-5 mm and at most 6-7 mm. The optimal diameter will vary from patient to patient.

20 The catheter 20 has a filament (e.g. fiber or wire) reinforced wall having a thickness of 0.2 to 0.5 mm. This small wall thickness is advantageous for obtaining a large internal cross-sectional area of the catheter channel 36 combined with a small outer cross-sectional area for easy entry of the catheter 20 while the fiber reinforcement provides sufficient
25 stiffness for easy insertion and effective pressure pulse transfer from the displacement structure 16 to the outlet passage 26.

The drive structure including the displacement structure 16 and the drive system for driving the displacement structure 16 and the catheter are preferably adapted for generating a maximum drive pressure of at least 300
30 mmHg and preferably at least 400 mmHg and at most about 600 mmHg. At such pressures, sufficient flow is generated to create effective pulsations while blood cell damage due to excessive shear stresses are avoided.

It is observed that in the examples according to Figs. 1 and 2, the catheter is shown in a treatment involving the deactivation of the heart and
35 use of a heart lung machine. However, the proposed treatment using the proposed catheter and catheter pump can also be applied advantageously for

the treatment of other medical indications such as during and after heart-lung machine assist (for instance in an intensive care unit), during open heart surgery in which the heart is not deactivated and/or during periods of unwanted hypotension (shock).

5 Fig. 3 illustrates another example of a further use of yet another example of a catheter pump 215 according to the invention. According to this example, the catheter pump 215 is used as a right ventricular assist device (RVAD). In such clinical use, the catheter 220 is passed through the superior vena cava 3 and through the right ventricle 11 until the outlet passage 226 is
10 located just downstream of the right ventricle 11. The inlet passages 225 are preferably located in the right ventricle 11, so that the discharge of blood from the right ventricle is supported, but may also be located upstream of the right ventricle 11.

 Fig. 4 illustrates yet another clinical use of yet another example of a
15 catheter pump 315. According to this example, the catheter pump 315 is used as a left ventricular assist device. In this clinical use, the catheter 320 is passed through an incision in a wall portion of the left ventricle 10 and through the left ventricle 10 until the outlet passage 326 is located just
20 downstream of the right ventricle 11. The inlet passages 325 are preferably located in the left ventricle 10, so that the discharge of blood from the left ventricle 10 is supported, but may also be located upstream of the left ventricle 10.

 In the present examples, the fluid that is displaced to and fro in the catheter is blood from the patient. In principle, it is also possible to transfer
25 the pulsations applied by the displacement structure 16 using another fluid such as air or a liquid. The displacement structure may also be provided in another suitable form, such as for example in the form of a piston in a cylinder or of a bellows.

 The fitting 28 in which the inlet passages 25 are located and adjacent
30 sections of the catheter 20 are shown in more detail in Fig. 6. The fitting 27 in which the outlet passage is located is shown in more detail in Figs. 13 and 14. The catheter pump, the catheter and the fittings as shown in Figs. 1, 5, 6, 12 and 14 represent the presently most preferred embodiment of the invention.

The fitting 28 forms an inlet tube in which inlet passages 25 are arranged. According to this example, the inlet tube fitting 28 has a circular cross-section, but other cross-sectional shapes are conceivable as well.

In operation, blood that is urged by the displacement structure in
5 distal direction (arrow 37) is jetted out of a section of the channel 36 immediately proximally of the inlet passages 25, mainly or completely past the inlet passages 25 and into a section of the channel 36 immediately distally of the inlet passages 25. Because the sections of the channel 36 immediately distally and proximally of the inlet passages 25 are in-line with
10 each other, very little or no blood is urged out of the inlet passages 25, in spite of the inlet passages 25 being continuously open.

When the displacement structure 16 is reversed and pulls blood in proximal direction, blood flow is not specifically directed from the channel section immediately distally of the inlet passages 25, but is, at least to a large
15 extent, attracted via the inlet passages as is indicated by arrows 38.

Thus, the net result of the alternating displacement of blood through the channel 36 by the displacement structure is, that during each cycle at least more blood is displaced from the inlet passages 25 towards and out of the outlet passage 26 than from the outlet passage 26 to the inlet passages,
20 even if no valve is arranged between the inlet passages 25 and the outlet passage 26.

Because blood flow through the inlet passages 25 may be controlled without moving valve bodies, a simple and therefore reliable operation is achieved and the risk of thrombosis and causing damage to the blood cells
25 normally associated to moving valve bodies in blood pumps are avoided.

Several features may be provided for improving the net blood displacement per cycle in distal direction. However, depending on the clinical application, for instance a channel 836 as shown in Fig. 11 having a constant cross-section from a proximal side of the inlet passages 825 to a distal side of
30 the inlet passages 825 may be sufficiently effective. The inlet passages may also be provided directly in a wall of catheter tubing, although providing the inlet passage or passages in an inlet tube fitting generally allows more freedom of design and a more accurate finish. Supply tubes may connect to the inlet passages. In each embodiment, a single inlet passage or a larger
35 number of inlet passages may in principle be provided. In each of Figs. 6-12 an arrow 37 indicates the distal direction.

In the embodiments shown in Figs. 6-8 and 10, a section of the channel 36; 436; 536; 736 immediately distally adjacent the inlet passages 25; 425; 525; 725 is wider than a section of the channel 36; 436; 536; 736 immediately proximally adjacent the inlet passages 25; 425; 525; 725. With
5 this feature, a partial vacuum is generated at the inlet passages 25; 425; 525; 725, when a blood flow in distal direction is passed through the channel, so that outflow of blood via the inlet passages 25; 425; 525; 725 is at least counteracted and blood may even be caused to be drawn into the channel via the inlet passages 25; 425; 525; 725 during the stroke of the displacement
10 structure 16 in distal direction.

Throughput of the catheter pump in distal direction may also be improved by providing that, as in Figs. 6-9, at least a portion of an inlet section of the channel 36; 436; 536; 636 between most upstream and most downstream boundaries 39, 40; 439, 440; 539, 540; 639, 640 of the inlet
15 passages 25; 425; 525; 625 is narrower than sections of the channel 36; 436; 536; 636 distally and proximally adjacent the inlet section. Thus a construction of the channel causing a venturi effect is achieved.

In the embodiments shown in Figs. 6-8 and 10, an inlet section of the channel 36; 436; 536; 736 between most upstream and most downstream
20 boundaries 39, 40; 439, 440; 539, 540; 739, 740 of the inlet passages 25; 425; 525; 725 widens in distal direction from a narrowest section of the channel 36; 436; 536; 736 immediately upstream of the inlet section, so that the blood flow in distal direction is guided in a direction from which the inlet passages diverge, until immediately upstream of the inlet passages, so that the flow is
25 effectively kept away from the inlet passages.

In the embodiment shown in Fig. 8, moreover, a section of the channel 536 proximally adjacent the inlet passages 525 gradually tapers in distal direction to a narrowest cross-section and an apex 541 closely proximal of the inlet passages 525 forms a transition between the gradually narrowing
30 and widening channel sections. This causes blood flowing in distal direction 37 to converge away from the inlet passages 525, at least over some distance along the inlet passages 525.

In the embodiment shown in Fig. 12, an inlet section of the channel 936 between most upstream and most downstream boundaries 939, 940 of the inlet passages 925 is recessed relative to an interior surface 942 of a
35 catheter wall section 942 closely proximal of the inlet passages 925. This also

contributes to keeping the blood flow in distal direction away from the inlet passages 925. In the embodiment according to Fig. 12, the recessed channel section containing the inlet passages 925 is achieved in a simple manner by providing the inlet passages 925 in a portion of the inlet tube fitting 928 and
5 arranging the catheter tubing connected to the inlet fitting 928 inside the inlet tube 928.

In the embodiments shown in Figs. 6-9, at least a proximal end portion of the inlet tube fitting 28; 428; 528; 628 includes a sleeve 43; 443; 543; 643. A section of catheter tubing proximal of the inlet passages 25; 425; 525; 625 is mounted over the sleeve 43; 443; 543; 643 and a section of the
10 channel 36; 436; 536; 636 inside the sleeve 43; 443; 543; 643 is narrower than at least one adjacent section of the channel 36; 436; 536; 636. Thus, an efficient construction is obtained, because the construction of the channel upstream of the inlet passages also forms the sleeve for receiving catheter
15 tubing connected to the inlet tube fitting.

In the embodiment according to Fig. 6, the catheter tubing at the distal side of the inlet tube fitting 28 is arranged inside a sleeve 44 at a distal side of the inlet tube fitting 28. This allows to inject into the inlet tube fitting 28 more easily, since the internal cross-section of the channel only
20 stays equal or widens in distal direction 37. Moreover, a relatively wide channel section is obtained distally of the inlet passages 25, because no sleeve constricts the internal cross section of the channel inside the catheter tubing distally of the inlet passages 25.

To further reduce the risk of blood damage and thrombosis and to
25 further simplify the design of the catheter pump, it is advantageous if, at least in operating condition, the channel 36 is free from valves between the inlet passages 25 and the outlet passage 26. This is particularly advantageous in applications in which the main purpose of the catheter is to generate pulsatile blood pressure for improving organ perfusion.

30 However, in particular in applications as shown in Figs. 3 and 4, in which the catheter extends through a ventricular valve of an active heart, it has been found to be advantageous to provide a check valve 27 with a movable valve body 45 between the inlet passages and the outlet passage, for instance as is shown in Fig. 5, to avoid creating a substantial open passage
35 across a ventricular valve.

According to the example shown in more detail in Figs. 13 and 14, the valve body 45 pivotably suspended for rotation about an axis 46 extending across the channel 36, between a closed position (shown in dash-and-dot lines), substantially closing off the channel 36 and an open position (shown in full lines and in Fig. 14) allowing fluid to pass past the valve 27. In open position, the valve body 45 extends along a plane parallel to the channel 36 and, in axial view, has a central portion 47 spaced from the pivoting axis 46 and, in side view, the valve body projects from the pivoting axis further in distal direction than in proximal direction.

Starting from a closed position of the valve body 45, since (at least in open condition) the valve body 45 projects from the pivoting axis 46 further in distal direction than in proximal direction, blood pressure in distal direction 37 results in the exertion of a couple on the valve body 45 which causes it to pivot to its open position and it is held in that position by the blood flow in distal direction 37. After the stroke of the displacement structure 16 urging blood in distal direction has ended, the displacement structure 16 starts to draw blood in proximal direction. Already a small backflow at the valve body resulting from the reversal of the action of the displacement structure 45 causes the valve body 45 to pivot back to its closed position. Initial movement of the valve body 45 is believed to be caused by a difference in flow velocities between the centre and the periphery of the channel 36. As soon as the valve body is tilted a little in closing sense, the flow pushes against the surface of the valve body 45 facing away from the axis 46, which causes the valve body to be pivoted into its closed position, blocking any substantial backflow.

Because, in open position, the valve body 45 extends along a plane parallel to the channel 36 and, in axial view, has a central portion 47 spaced from the pivoting axis 46, the valve 45 leaves open a large portion of the lumen of the catheter for the passage of tools and causes very little resistance to the blood flow. Furthermore, opening and closing of the valve 45 does not require any material to bend, which is advantageous for obtaining reliable operation over prolonged periods of time.

For closing off the channel 36, which has a round cross-section, it is advantageous that the pivoting axis 46 extends across a widest portion of the channel 36 (measured in the direction of the axis), because this allows the valve body 45 to be wide enough to close off the channel along the entire

circumference of the channel 36, while still allowing pivotal movement about the axis 46 between the closed and open positions.

Moreover, it is made possible that, as in the present example, a section of the channel 36 containing the valve body 45 has a constant cross-
5 section so that flow resistance is minimized, while nevertheless, the valve body 45 in closed condition substantially abuts the continuing interior wall surface of the channel 36 along the entire circumference of the channel 36.

According to the present example, the valve body 45 is a curved plate. In open position, the valve body 45 leaves open passages between the plate
10 and the catheter wall on both sides of the plate, so that blood can flow past the plate on both sides, which is favourable for avoiding areas of little flow where the risk of thrombosis is increased. The space between the plate and the interior wall of the channel 36 when the plate is in open position also allows the plate to pivot to its closed position.

15 According to the present example, the valve fitting 27 also forms a distal tip of the catheter 20. It is, however, also possible to position the valve fitting more proximally or to integrate the valve in the inlet tube fitting.

The fittings 22, 28 may be coupled to catheter tubing in a manner as is described in International patent application WO 97/18936.

WHAT IS CLAIMED IS:

1. A catheter pump comprising:
a catheter (20) comprising:
 - a catheter wall bounding a channel (36) inside said catheter (20);
 - a distal end portion (24);
 - 5 - a proximal end portion, said channel (36) communicating with said distal end portion (24) for alternately leading fluid in said channel (36) in a direction away from said distal end portion towards said proximal end portion and in a direction away from said proximal end portion towards said distal end portion;
 - 10 - at least one inlet passage (25) in said wall; and
 - at least one outlet passage (26) distally spaced from said inlet passage (25); anda displacement structure (16) communicating with said proximal end portion for alternately applying suction and pressure for driving said fluid
15 displacement;
wherein, at least in operating condition, said at least one inlet passage (25) is continuously open.
2. A catheter pump according to claim 1, wherein a section of said channel (36) distally adjacent said at least one inlet passage (25) is wider
20 than a section of said channel (36) proximally adjacent said at least one inlet passage (25).
3. A catheter pump according to claim 1 or 2, wherein at least a portion of an inlet section of said channel (36) between most upstream and most downstream boundaries (39, 40) of said at least one inlet passage (25) is
25 narrower than sections of said channel (36) distally and proximally adjacent said inlet section.
4. A catheter pump according to any one of the preceding claims, wherein an inlet section of said channel (36) between most upstream and most downstream boundaries (39, 40) of said at least one inlet passage (25) widens
30 in distal direction from a narrowest section of said channel (36) immediately upstream of said inlet section.
5. A catheter pump according to claim 4, wherein a section of said channel proximally adjacent said at least one inlet passage (25) gradually

tapers in distal direction to a narrowest cross-section and wherein an apex closely proximal of said at least one inlet passage (525) forms a transition between said gradually narrowing and widening channel sections.

6. A catheter pump according to any one of the preceding claims, wherein
5 an inlet section of said channel (936) between most upstream and most downstream boundaries (939, 940) of said at least one inlet passage (925) is recessed relative to an interior surface of said catheter wall closely proximal of said at least one inlet passage (925).
7. A catheter pump according to any one of the preceding claims, wherein
10 said catheter includes at least one inlet tube fitting (28), said at least one inlet passage being arranged in a catheter wall portion of said inlet tube fitting.
8. A catheter pump according to claim 7, wherein at least a proximal end portion of said inlet tube fitting (28) includes a sleeve (43), a section of said
15 catheter proximal of said at least one inlet passage (25) being mounted over said sleeve (43) and a section of said channel (36) inside said sleeve (43) being narrower than at least one adjacent section of said channel (36).
9. A catheter pump according to any one of the preceding claims, wherein, at least in operating condition, said channel is free from valves between said
20 at least one inlet passage and said outlet passage.
10. A catheter pump according to any one of the preceding claims, further comprising a valve in a section of said channel (36) between said at least one inlet passage (25) and said outlet passage (26), said valve comprising a valve body (45) pivotably suspended for rotation about an axis (46) extending
25 across said channel (36), between a closed position, substantially closing off said channel (36) and an open position allowing fluid to pass past said valve (45), wherein said valve body (45) in open position extends along a plane parallel to said channel (36), in axial view, has a central portion (47) spaced from said pivoting axis (46) and, in side view, projects from said pivoting axis
30 (46) further in distal direction than in proximal direction.
11. A catheter pump according to claim 10, wherein said pivoting axis extends across a widest portion of said channel (36) and said channel (36) has a round cross-section.
12. A catheter pump according to claim 11, wherein a section of said
35 channel (36) containing said valve body (45) has a constant cross-section, and

wherein said valve body (45) in closed condition abuts a continuing interior wall surface of said channel (36).

13. A catheter pump according to claim 10, wherein said valve body (45) is a curved plate, said valve body (45) in open position leaving open passages
5 between said plate(45) and the catheter wall on both sides of said plate (45).

14. A catheter pump according to any one of the preceding claims, further comprising a sealing fitting mounted to said catheter, for sealing-off an outer surface of said catheter against an incision in an aortic wall.

15. A catheter pump according to claim 14, further comprising a passage
10 separate from said channel in said catheter for passing through a blood flow from a heart-lung machine (12) through said fitting.

16. A catheter for a catheter pump comprising:

- a catheter wall bounding a channel (36) inside said catheter;
- a distal end portion (24);
- 15 - a proximal end portion for connection to a displacement structure (16) for alternately applying suction and pressure for driving a fluid displacement, said channel (36) communicating with said distal end portion (24) for alternately leading fluid in said channel (36) in a direction away from said distal end portion (24) towards said
20 proximal end portion and in a direction away from said proximal end portion towards said distal end portion (24);
- at least one inlet passage (25) in said wall; and
- at least one outlet passage (26) distally spaced from said inlet passage (25);

25 wherein, at least in operating condition, said at least one inlet passage (25) is continuously open.

17. A fitting for a catheter pump, comprising a tubular section having a wall bounding a channel (36), at least one inlet passage (25) in said wall, wherein, at least in operating condition, said at least one inlet passage (25) is
30 continuously open.

18. A fitting for a catheter pump, comprising a tubular section bounding a channel (36), a valve located in said channel (36), said valve comprising a valve body (45) pivotably suspended for rotation about an axis (46) extending across said channel (36), between a closed position, substantially closing off
35 said channel (36) and an open position allowing fluid to pass past said valve, wherein said valve body (45) in open position extends along a plane parallel

to said channel (36), in axial view, has a central portion (47) spaced from said pivoting axis (46) and, in side view, projects from said pivoting axis (46) further in distal direction than in proximal direction.

19. A method for generating pulsations in the blood flow towards the
5 organs of a patient comprising:

inserting a catheter (120) into the aorta (2) of a patient and bringing the catheter (120) in a position having a distal end portion in the aorta (2) of the patient; and

alternatingly withdrawing fluid in a first area and feeding said fluid
10 towards a second area located in the aorta (2) and downstream of said first area, via said catheter (120), such that pressure pulsations are generated in an area of the aorta (2) where the distal end portion (24) of the catheter (120) is located, wherein said catheter (120) is inserted into the aorta (2) via an incision in the aorta (2).

20. A method according to claim 19, wherein an outflow canula of a heart-lung machine (12) is inserted via said incision in the aorta (2).

21. A method according to claim 19 or 20, wherein said first area is located in the aorta (2).

22. A method according to claim 21, wherein said first area is located in
20 the aortic arch (9).

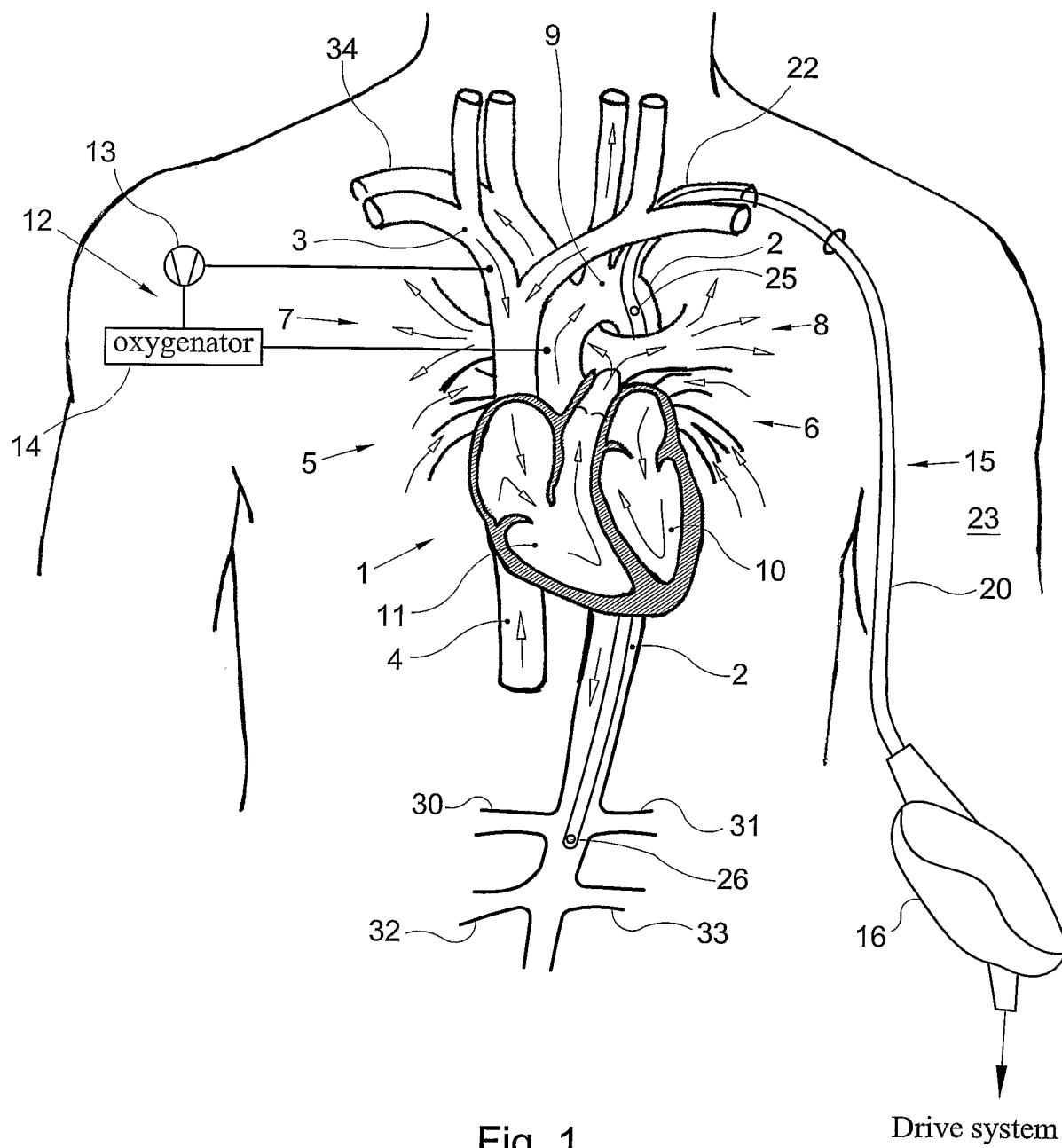
23. A method for generating pulsations in the blood flow towards the organs of a patient comprising:

inserting a catheter (20) into the aorta (2) of a patient and bringing the catheter (20) in a position having a distal end portion in the aorta (2) of the
25 patient; and

alternatingly withdrawing fluid in a first area and feeding said fluid towards a second area located in the aorta (2) and downstream of said first area, via said catheter (20), such that pressure pulsations are generated in an area of the aorta (2) where the distal end portion (24) of the catheter (20) is
30 located, wherein said catheter (20) is inserted into the aorta (2) via an arm or breast area, via a subclavian artery (22).

24. A method according to claim 23, wherein said first area is located in the aorta (2).

25. A method according to claim 24, wherein said first area is located in
35 the aortic arch (9).



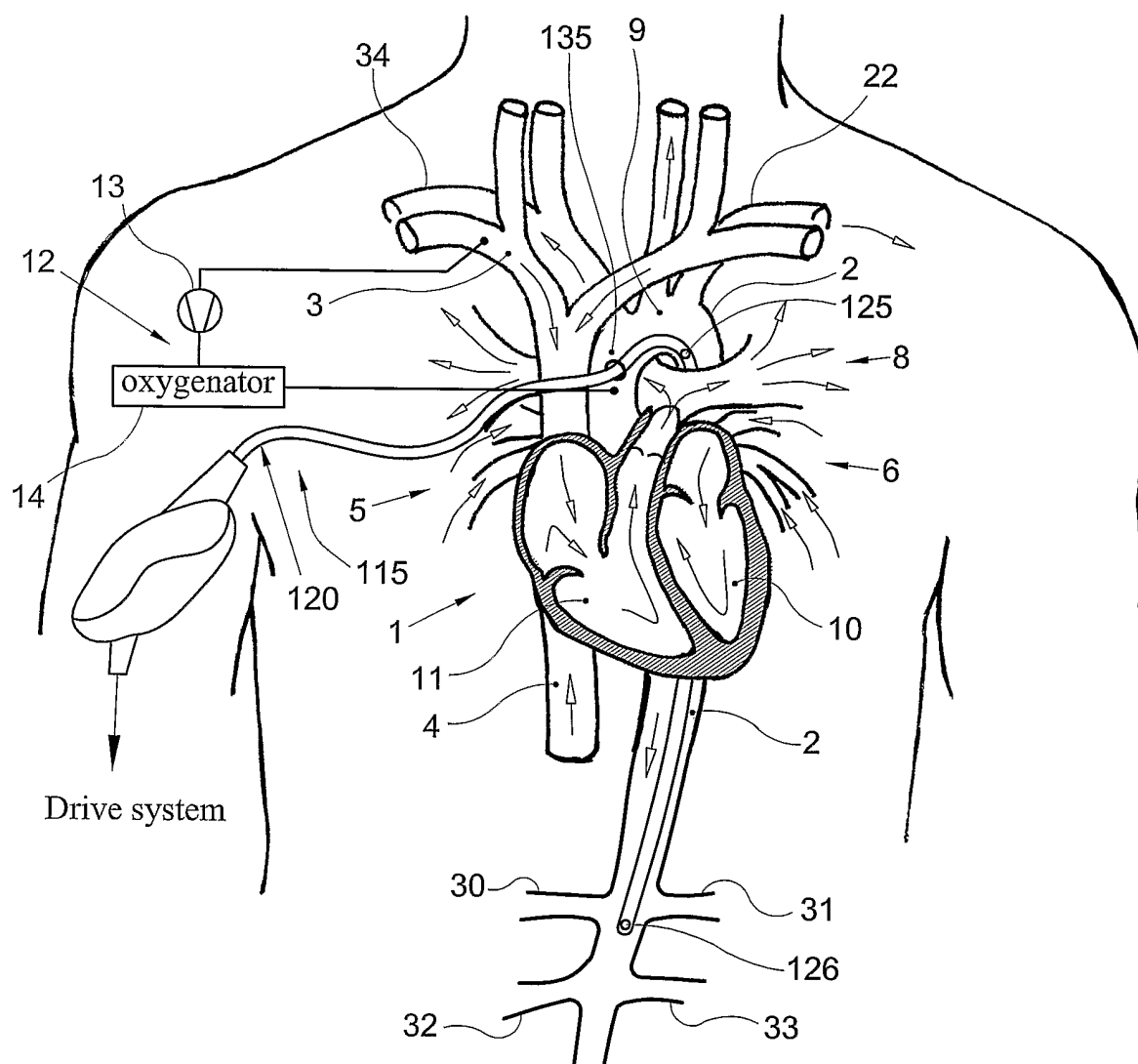
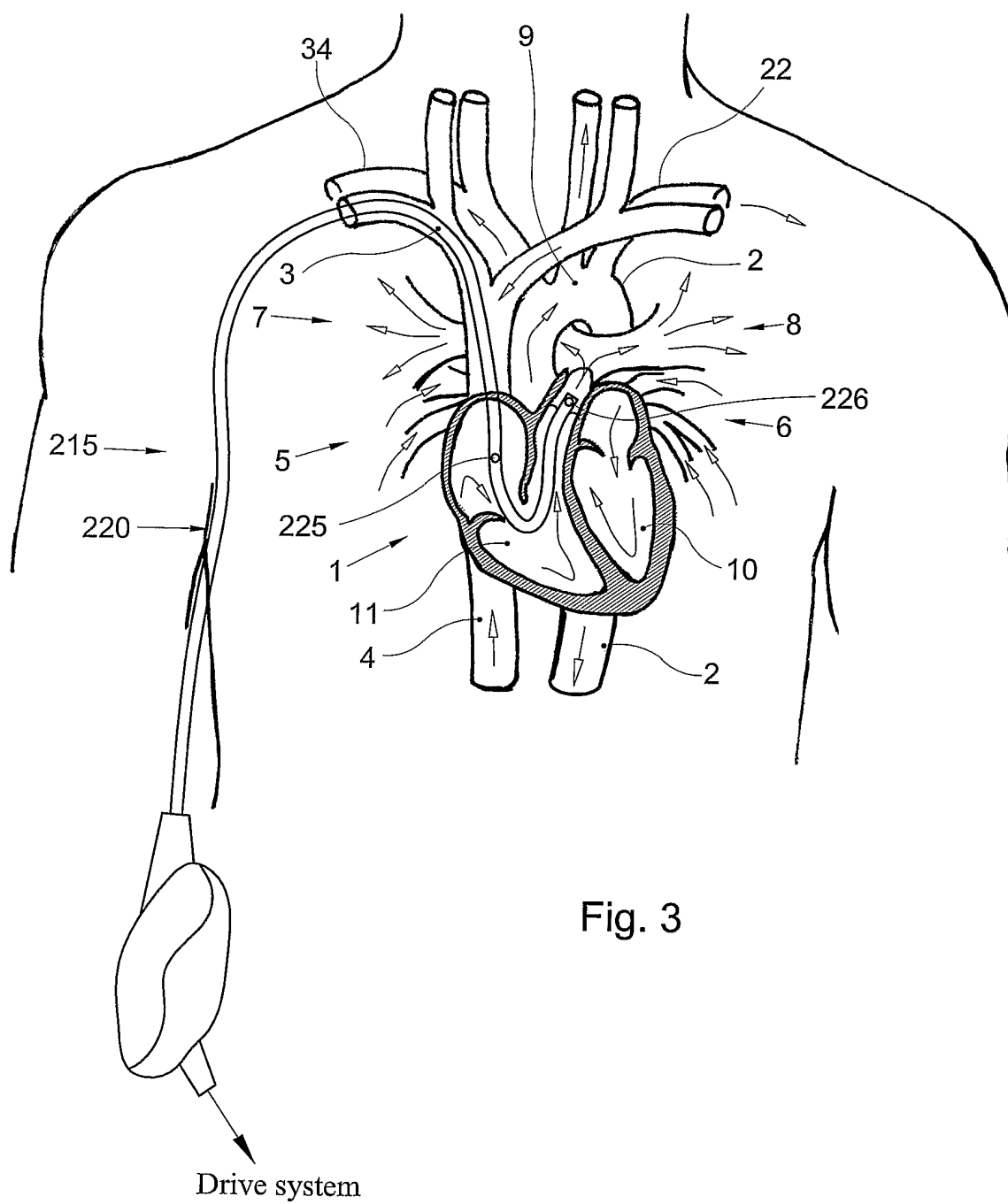
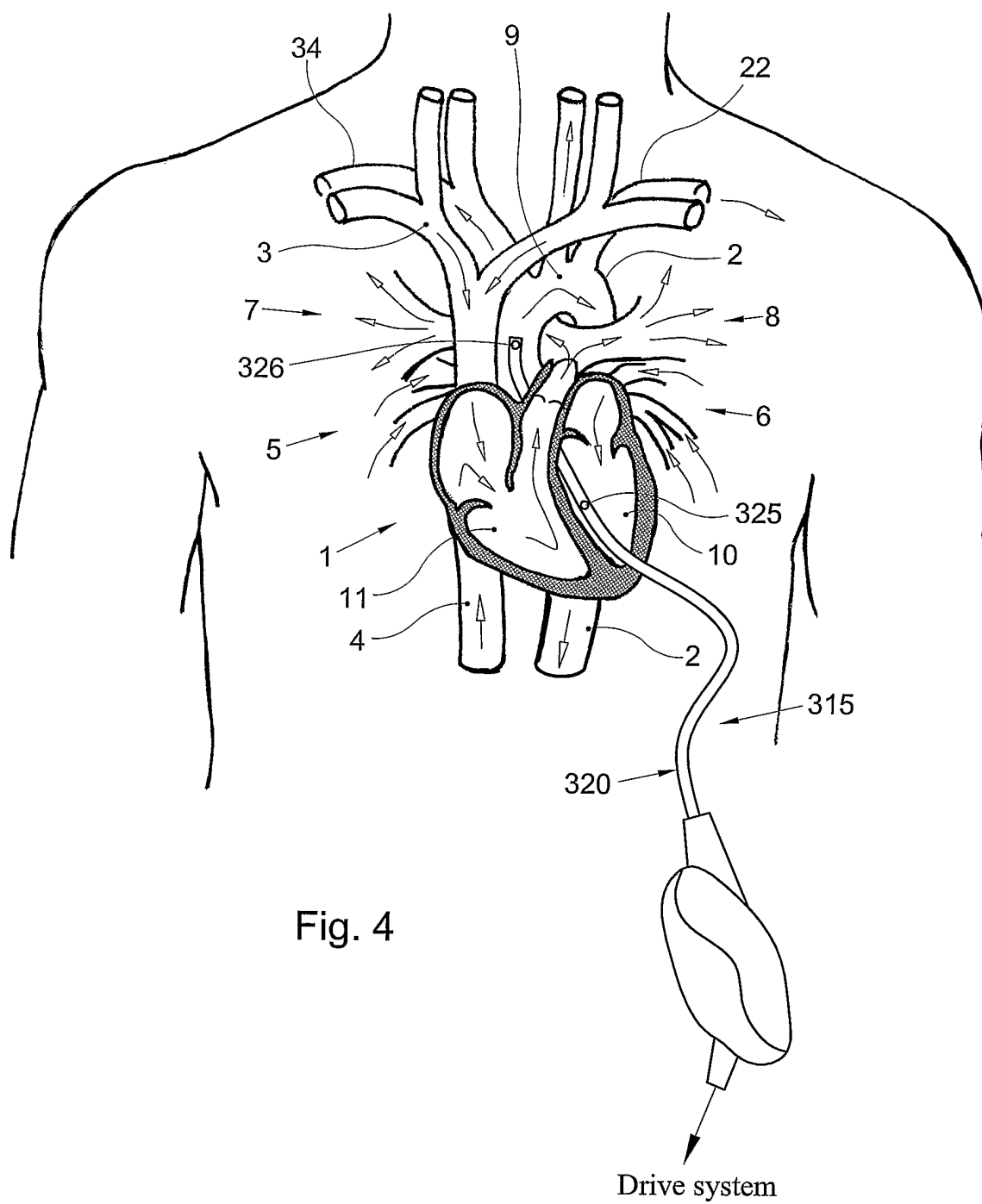


Fig. 2





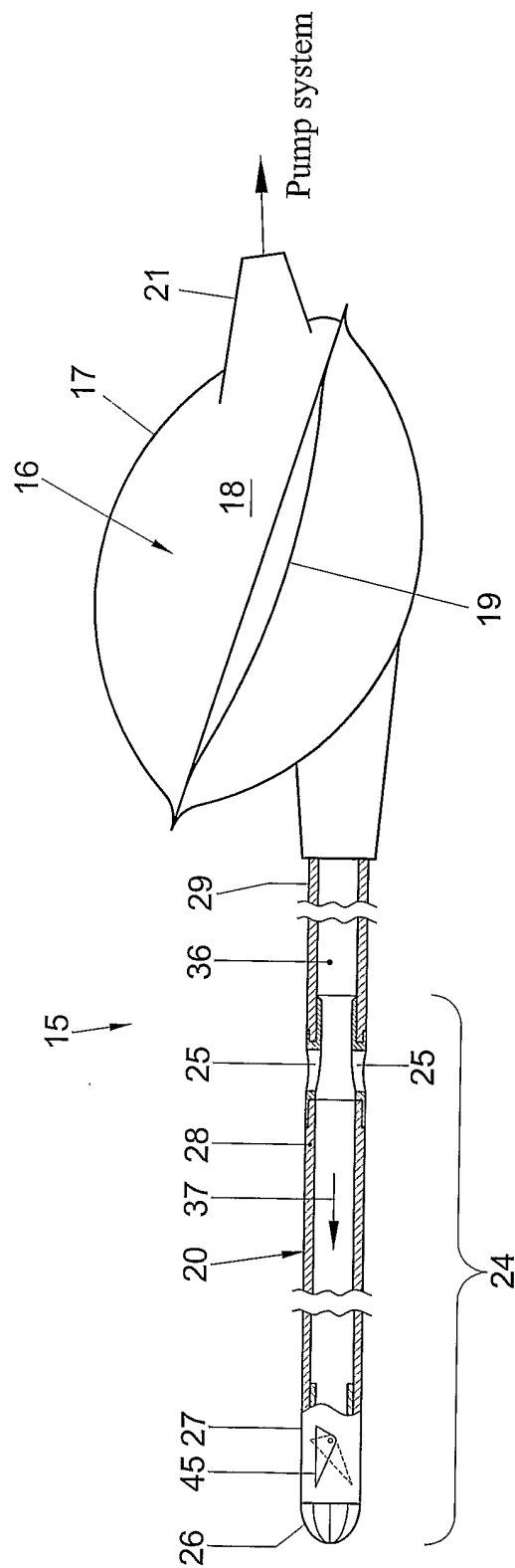


Fig. 5

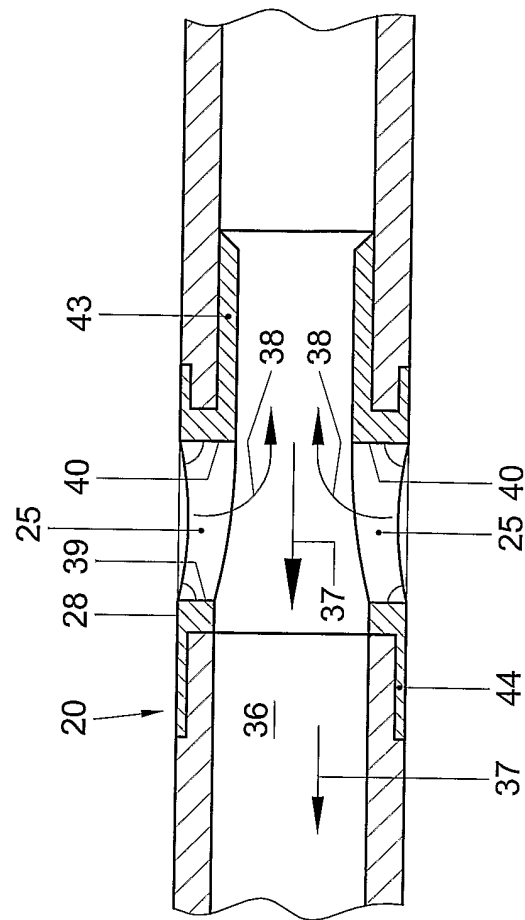


Fig. 6

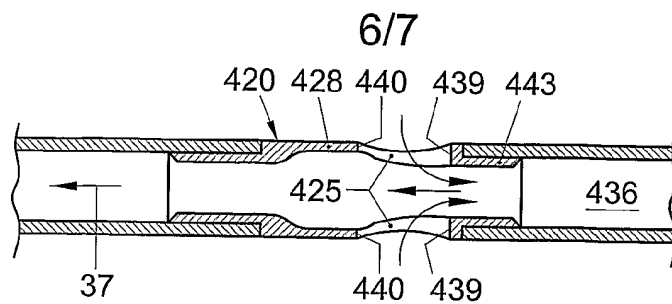


Fig. 7

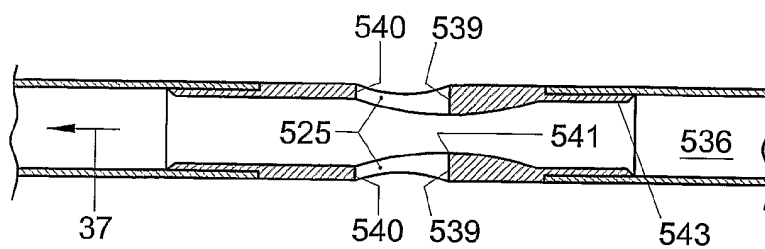


Fig. 8

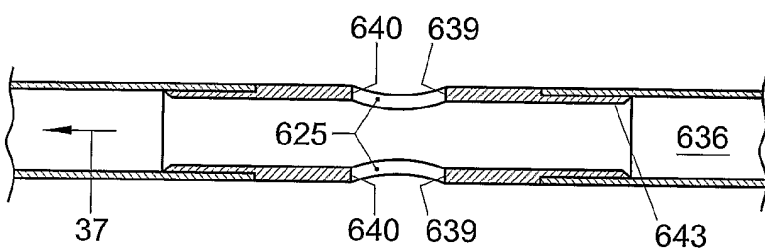


Fig. 9

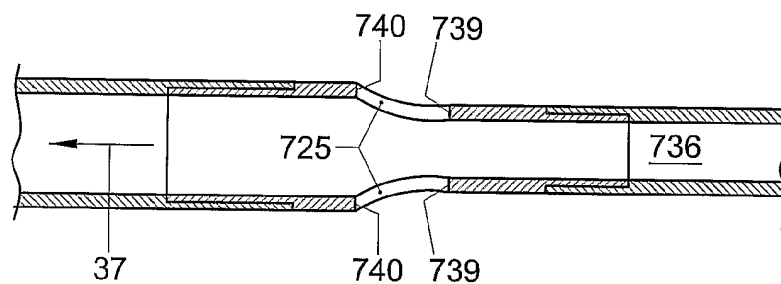


Fig. 10

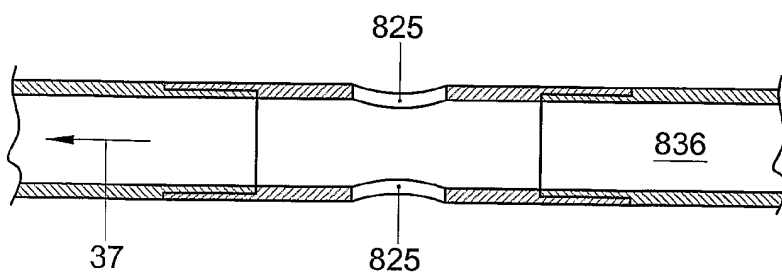


Fig. 11

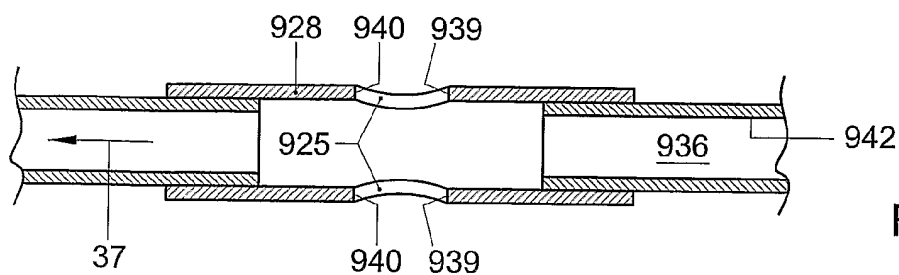


Fig. 12

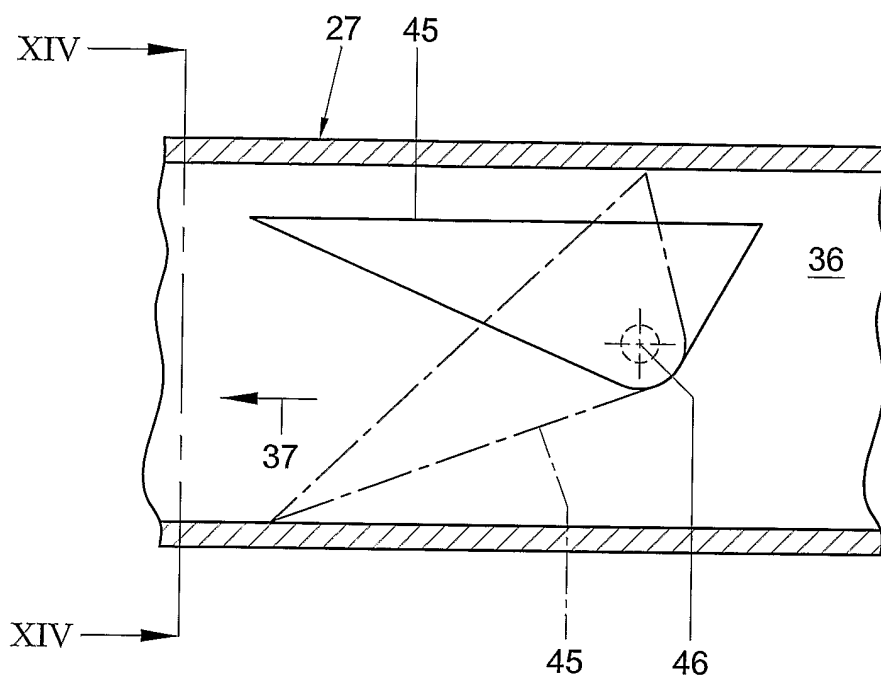


Fig. 13

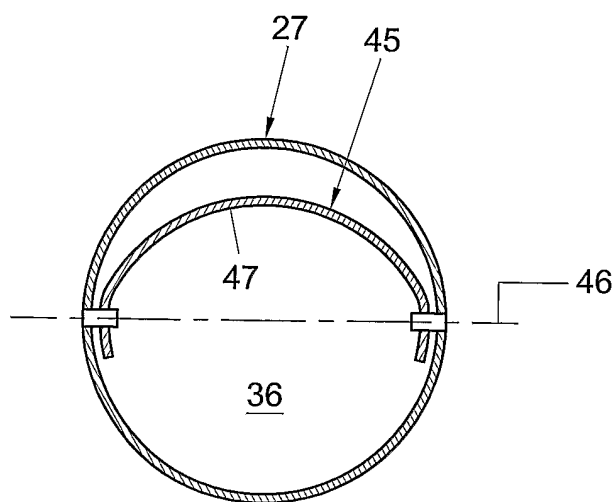


Fig. 14

INTERNATIONAL SEARCH REPORT

ional Application No

PCT/NL 03/00615

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/00 A61M1/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched-

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 754 752 A (GINSBURG ROBERT ET AL) 5 July 1988 (1988-07-05) column 4, line 41 - line 42 column 5, line 6 - line 11 figure 2	1-6, 9, 14-16
X	US 4 173 981 A (MORTENSEN J D) 13 November 1979 (1979-11-13) column 2, line 41 column 4, line 41 - line 43 figure 1	1-6, 9, 14-16
A	US 6 464 662 B1 (POSTON TIMOTHY ET AL) 15 October 2002 (2002-10-15) column 9, line 55 - line 58; figure 3a ----- -/--	7

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *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)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *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
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *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.
- *Z* document member of the same patent family

Date of the actual completion of the international search

30 June 2004

Date of mailing of the international search report

08 JUL 2004

Name and mailing address of the ISA

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Authorized officer

Lakkis, A

INTERNATIONAL SEARCH REPORT

ational Application No
PCT/NL 03/00615

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 398 714 B1 (RAKHORST G ET AL) 4 June 2002 (2002-06-04) cited in the application column 2, line 64 - column 3, line 30; figures 1,3 -----	7,17
X	EP 0 268 733 A (DSS SRL) 1 June 1988 (1988-06-01) column 2, line 32 - line 42; figure 2 -----	17
X	WO 01/37923 A (QUINN DAVID G ; RADIUS INTERNAT LTD PARTNERSHI (US)) 31 May 2001 (2001-05-31) page 2, line 7 - line 11 page 12, line 10 - page 13, line 30; figure 14 -----	17

INTERNATIONAL SEARCH REPORT

international application No.
PCT/NL 03/00615

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 19-25
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2. ☐ Claims Nos.:
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, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

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

see additional sheet

As a result of the prior review under R. 40.2(e) PCT,
null additional fees are to be refunded.

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
7 8 17
4. ☐ 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 claims Nos.:

Remark on Protest

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

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims Nos.: 19-25

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1, 2-6, 9, 14-16

A catheter pump comprising a catheter comprising a catheter wall bounding a channel and at least one inlet passage in said wall; A catheter therefor

2. claims: 1, 7, 8; 17

A fitting for a catheter pump comprising a section having a wall bounding a channel and at least one inlet passage in said wall; A catheter pump as in claim 1 where the catheter includes at least one fitting

3. claims: 1, 10-13; 18

A fitting for a catheter pump comprising a valve; A catheter pump as in claim 1 further comprising a valve

INTERNATIONAL SEARCH REPORT

International Application No
PCT/NL 03/00615

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4754752	A	05-07-1988	EP 0335022 A1	04-10-1989
US 4173981	A	13-11-1979	NONE	
US 6464662	B1	15-10-2002	AU 7712001 A WO 0207809 A1	05-02-2002 31-01-2002
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WO 0137923	A	31-05-2001	US 6517529 B1 US 6540714 B1 AU 2045401 A EP 1231979 A1 WO 0137923 A1 US 2001018576 A1 US 2003032918 A1 US 2002026156 A1	11-02-2003 01-04-2003 04-06-2001 21-08-2002 31-05-2001 30-08-2001 13-02-2003 28-02-2002