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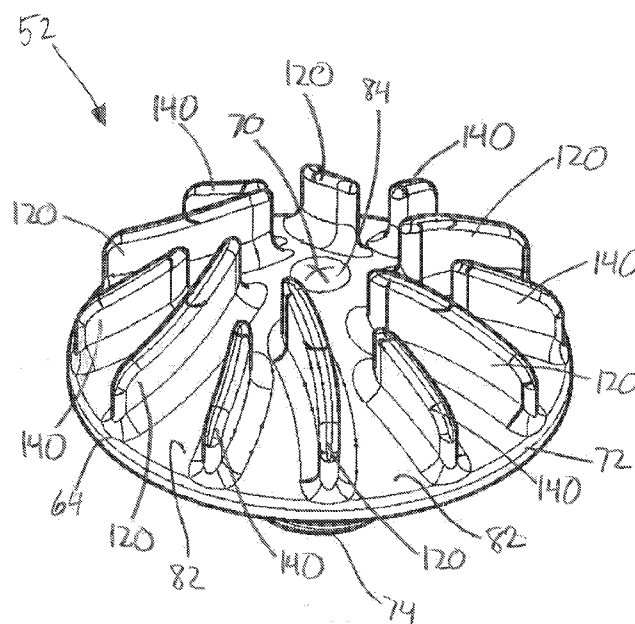


Fig. 3

(57) Abstract: A right impeller for a continuous flow total artificial heart (CFTAH) includes a back plate including a front surface having a conical configuration centered on an axis of impeller rotation and including a rounded apex. A plurality of primary vanes protrudes from the front surface and is arranged equidistantly from the apex and spaced radially about the apex. A splitter vane is positioned between each adjacent pair of primary vanes. Each primary vane has a leading edge proximate the apex and an opposite trailing edge. The leading edge of each primary vane has an elliptical configuration. The back plate includes an annular rim portion that extends radially beyond the trailing edges of the primary vanes.



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IMPELLER FOR ARTIFICIAL HEART BLOOD PUMPS

RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 62/572,757, entitled "IMPELLER FOR TOTAL ARTIFICIAL HEART," filed October 16, 2017. The entirety of this provisional application is hereby incorporated by reference for all purposes.

GOVERNMENT FUNDING

[0002] This invention was made with government support under HL096619 awarded by the National Institutes of Health. The government has certain rights in the invention.

TECHNICAL FIELD

[0003] This invention relates generally to blood pumps. More particularly, the invention relates to impellers for artificial heart blood pumps, particularly for the right (pulmonary) impeller of an artificial heart.

BACKGROUND

[0004] Heart transplant is a course of action for patients with end stage heart failure, a leading cause of premature death. Due to the unavailability of donor hearts, electromechanical blood pumping systems are being developed and are increasingly coming into use. These devices can provide a bridge to transplant, a bridge to recovery, or a permanent treatment for patients who may not receive a donor heart. Most of these patients will be treated with a ventricular assist device ("VAD"), which assists the beating heart by drawing blood from the left or right ventricle and discharging the blood to the aorta or pulmonary artery, respectively. Some patents require a total artificial heart (TAH), which replaces the patient's left and right ventricles, as a bridge to transplant or as a permanent therapy.

[0005] One known type of TAH is a continuous flow total artificial heart (CFTAH). The CFTAH includes two centrifugal pumps on one rotor supported on a hydrodynamic bearing and driven by a single motor. The CFTAH

replaces the function of both ventricles of the heart, and delivers blood flow to both the systemic (left) and pulmonary (right) circulation of the patient. Examples of CFTAH pumps are described in U.S. Patent Numbers US 8,210,829 B2, US 7,704,054 B2, US 8,657,874 B2, and US 9,162,019 B2.

[0006] One of the issues that can be encountered in the implantation and operation of CFTAH is that of thrombosis. Blood pumps introduce shear forces on the blood being pumped when their impeller vanes interact with the blood. Shear activated platelets can stick to pump components, such as impellers and other internal structures. The danger here is that these clots will break loose and enter the bloodstream. Thrombosis can also affect pump performance.

[0007] The introduction of some shear to pumped blood is unavoidable. It has been found that shear activated platelets tend to stick to pump components, forming thrombosis in regions of recirculation where the blood flow is moving more slowly. Regions of sustained higher flow tend to see little or no thrombosis formation.

SUMMARY

[0008] A continuous flow total artificial heart (CFTAH) includes two centrifugal pumps on one rotor supported on a hydrodynamic bearing and driven by a single motor. The CFTAH replaces the function of both ventricles of the heart, and delivers blood flow to both the systemic (left) and pulmonary (right) circulation of the patient.

[0009] According to one aspect, a right impeller for the CFTAH includes a back plate including a front surface having a conical configuration centered on an axis of impeller rotation and including a rounded apex. A plurality of primary vanes protrudes from the front surface and is arranged equidistantly from the apex and spaced radially about the apex. A splitter vane is positioned between each adjacent pair of primary vanes. Each primary vane has a leading edge proximate the apex and an opposite trailing edge. The leading edge of each primary vane has an elliptical configuration. The back

plate includes an annular rim portion that extends radially beyond the trailing edges of the primary vanes.

[0010] According to another aspect, alone or in combination with any other aspect, the right impeller can include 5-7 primary vanes and 5-7 splitter vanes.

[0011] According to another aspect, alone or in combination with any other aspect, the right impeller can include six primary vanes and six splitter vanes.

[0012] According to another aspect, alone or in combination with any other aspect, the back plate can have a cone angle of 23-27 degrees.

[0013] According to another aspect, alone or in combination with any other aspect, the back plate can have a cone angle of 25 degrees.

[0014] According to another aspect, alone or in combination with any other aspect, the primary vanes can have a curved configuration selected such the leading edges of the primary vanes have a blade angle of 32-38 degrees.

[0015] According to another aspect, alone or in combination with any other aspect, the primary vanes can have a curved configuration selected such the leading edges of the primary vanes have a blade angle of 35 degrees.

[0016] According to another aspect, alone or in combination with any other aspect, the leading edges of the primary vanes can be arranged along a diameter of about 0.30-0.40 inches.

[0017] According to another aspect, alone or in combination with any other aspect, the leading edges of the primary vanes can be arranged along a diameter of about 0.35 inches.

[0018] According to another aspect, alone or in combination with any other aspect, the elliptical configuration of the leading edges can be that of an ellipse having a major axis to minor axis ratio of 2:1.

[0019] According to another aspect, alone or in combination with any other aspect, the primary vanes include a pressure side and a suction side, wherein the primary vanes can have a curved configuration in which the pressure side of the vane is curved concavely.

[0020] According to another aspect, the CFTAH can include a housing that helps define a left pump and a right pump. The left pump can include a left inlet for receiving left atrial blood flow, a left volute in fluid communication with the left inlet, a left impeller at least partially disposed in the left volute, and a left outlet in communication with the left volute for discharging systemic blood flow via the aorta. The right pump includes a right impeller according to any of the preceding aspects, a right inlet for receiving right atrial blood flow, a right pumping chamber in fluid communication with the right inlet, a right volute in fluid communication with the right pumping chamber, and a right outlet in communication with the right volute for discharging pulmonary blood flow via the pulmonary artery, wherein the primary and splitter vanes of the right impeller are at least partially positioned in the right pumping chamber and the annular rim of the right impeller is at least partially positioned in the right volute. A pumping aperture is defined between the annular rim and the housing at the interface between the right pumping chamber and the right volute. The CFTAH also includes a motor supported by the housing and comprising a stator and a rotor to which the left and right impellers are connected. The motor is operable to rotate the left and right impellers. The motor is configured to permit the rotor to move axially relative to the stator during operation of the pump such that differentials in left and right atrial pressures adjust the axial position of the rotor. The right pump is configured to adjust its hydraulic performance characteristics by adjusting the size of the pumping aperture in response to the axial position of the right impeller in the right pumping chamber and right volute.

DRAWINGS

[0021] The invention may be best understood by reference to the following description taken in conjunction with the accompanying drawing figures in which:

[0022] Fig. 1 is a schematic illustration of a CFTAH system, according to an example configuration of the invention.

[0023] Fig. 2 is schematic illustration of the CFTAH of the system of Figure 1.

- [0024] Fig. 3 is a top perspective view of a right impeller of the CFTAH of Fig. 2.
- [0025] Fig. 4 is a bottom perspective view of the right impeller.
- [0026] Fig. 5 is a side view of the right impeller.
- [0027] Fig. 6 is a sectional view of the right impeller.
- [0028] Fig. 7 is a top view of the right impeller.
- [0029] Fig. 8 is a magnified view of a portion of the right impeller.

DESCRIPTION

- [0030] Referring to the drawings in which identical reference numerals denote the same elements throughout the various views, Figure 1 depicts an example configuration of a total artificial heart system 100. The artificial heart system 100 includes a continuous flow total artificial heart in the form of a two-stage centrifugal blood pump that serves as a continuous flow total artificial heart (“CFTAH”) 10 for temporarily or permanently supporting a human patient. The CFTAH 10 replaces the native left and right ventricles and valves, which are surgically excised or removed, and is adapted to connect the left and right pump inlets to the remaining atria, and the left and right outlets to the aorta and pulmonary artery, respectively.
- [0031] The CFTAH 10 includes a housing 12 that supports a rotating assembly or rotor 20 for rotation about a pump axis 18. The CFTAH 10 operates as a brushless DC motor, which is well-known in the art of blood pumps. To facilitate this operation, the CFTAH 10 includes an electrical stator 14 mounted in the housing 12 and the rotor 20 includes one or more permanent magnets 16. Rotation is imparted to the rotor 20 through the application of varying electrical currents to the stator. To achieve this, the CFTAH 10 is coupled by a cable to a controller, which is in turn powered by a power supply. The controller is operative to control the operation of the blood pump and also to perform system monitoring and condition detection functions, according to conventional methods and approaches.

[0032] The CFTAH 10 includes a left pump 30 and a right pump 50. During operation of the CFTAH 10, the left pump 30 pushes blood through the body's systemic vasculature via the aorta, which defines a fluid circuit "S" and is represented from a hydraulic standpoint by a systemic vascular resistance labeled "SVR". Blood then flows back to the right pump 50 via the right atrium. The right pump 50 pushes the blood through the body's pulmonary vasculature via the pulmonary artery, which defines another fluid circuit "P" and is represented from a hydraulic standpoint by a pulmonary vascular resistance labeled "PVR". Blood flows from the PVR back to the left pump 30 via left atrium.

[0033] Referring to Fig. 2, the left pump 30 includes a left impeller 32, which includes a plurality of impeller vanes 40 and is carried by, and rotatable with, the rotor 20. Portions of the housing 12 help define the left pump 30 and include a left inlet 34, a left outlet 36, and a left volute 38. The right pump 50 includes a right impeller 52, which includes a plurality of impeller vanes 120, 140, and is carried by and rotatable with the rotor 20. Portions of the housing 12 help define the right pump 50 and include a right inlet 54, a right outlet 56, and a right volute 58. Because the left impeller 32 and right impeller 52 are components of the same rotating assembly 20, the left pump 30 and right pump 50 always operate at the same speed.

[0034] Considering the system's connectivity shown in Fig. 1, if the systemic (i.e., left) flow is lower than the pulmonary (i.e., right) flow, then the left atrial pressure increases, and the right atrial pressure decreases. If the left output is greater than the right, then the atrial pressures reverse. Thus, an unbalance in flows is automatically accompanied by an unbalance in atrial (pump inlet) pressures.

[0035] The CFTAH 10 is configured to allow a degree of free axial movement of the rotor 20, in response to any unbalance of pump inlet (*i.e.*, atrial) pressures. This axial movement changes the distances "D1" and "D2" (see Fig. 2) which represent the axial operating clearances of the left impeller 32 and the right impeller 52. The operating clearance D1 of the left impeller 32 is measured between the impeller vanes 40 and/or a back plate of the left

impeller and a back wall of the left volute 38. It can be seen that, within the range of axial movement of the rotor 20 within the housing 12, the left impeller 32 and impeller vanes 40 remain positioned in the left volute 38. This allows the left pump 30 to maintain the comparatively high pumping performance and operating pressures required to perform the left ventricle pumping function to the systemic vasculature (SVR).

[0036] The operating clearance $D2$ of the right impeller 52 is measured at a pumping aperture 60. As shown in Fig. 1, the right pump 50 includes a pumping chamber 62 into which the right impeller 52 can move when the rotor 20 moves axially to the right. The right impeller 52 can move completely into the pumping chamber 62. The right impeller 52 is configured to have an annular rim 64 that extends radially outward beyond the extent of the vanes 120, 140 so that it is the rim along with a corresponding portion 66 of the housing at the interface between the right volute 58 and the pumping chamber 62 that defines the pumping aperture 60. The right pump 50 can be configured to prevent complete closure of the pumping aperture 60 (*i.e.*, $D2=0$) and maintain some minimum opening size of the pumping aperture 60 (*i.e.*, $D2>0$). Alternatively, the right pump 50 can be configured to allow complete closure of the pumping aperture 60 (*i.e.*, $D2=0$) in response to an emergency situation, such as a suction event at the right inlet 54.

[0037] The CFTAH 10 is configured so that the respective geometries of the left and right pumps 30, 50 change in response to axial movement of the rotor 20 in response to inlet pressure imbalances. This change in pump geometry affects the relative left/right performance in a direction that tends to correct the pressure imbalance. As a result, the CFTAH 10 is passively self-balancing, acting as a pressure balancing regulator while at the same time balancing both systemic and pulmonary circulation flow rates. To achieve this, the CFTAH 10 can be constructed and can operate in accordance with the construction and principles of operation detailed in the aforementioned and incorporated U.S. Patent Numbers US 8,210,829 B2, US 7,704,054 B2, US 8,657,874 B2, and US 9,162,019 B2, which describe this function in detail.

[0038] In operation, the CFTAH 10 is controlled in a known manner to deliver a volumetric flow rate of blood to the systemic vasculature (SVR). An example of a system and method for controlling the operation of the CFTAH 10 is described in US 8,657,874 B2. Under the control method, the controller delivers power to the CFTAH 10 to rotate the rotor 20 and the attached left and right impellers 32 and 52. The speed of the rotor 20 can be modulated in order to create pulsatory flow in the patient. Independent of the control process, the self-balancing characteristics of the CFTAH 10 take place throughout its operation.

[0039] Fundamental to the passive, self-balancing, artificial heart operation of the CFTAH 10, there are distinct differences in the blood flow paths through the left pump 30 and right pump 50. For the left pump 30, the impeller 32 is positioned within the volute 38 in a manner that is typical of conventional centrifugal pump designs. Blood flows through the left pump 30 in the conventional manner, *i.e.*, axially into the pump through the inlet 34 where the impeller 32 pumps the blood centrifugally, and the impeller flow empties directly into the volute 38 and out the outlet 36. As a result, recirculation resulting flow imbalances in the left pump 30 occurs primarily within the left volute 38, away from the surfaces of the impeller vanes 40. Also, any recirculation within the left volute 38 would typically be very transient and not experience sustained low shear regions where thrombus could form.

[0040] For the right pump 50, however, blood flow into the right volute 58 is controlled/limited by the size of the aperture 60, which is the key to the passive, self-balancing operation of the CFTAH 10. As a result, recirculation resulting from flow imbalances in right pump 50 cause larger recirculating flows within the right pumping chamber 62 extending in between the impeller vanes 120, 140. This recirculating flow (with potentially activated platelets) has experienced higher shear through the impeller vanes 120, 140 and is now moving slowly near the impeller surfaces again, which can lead to thrombus formation. Therefore, the inclusion of the aperture 60 in the right pump 50 necessitates a need to improve the overall hemodynamics within the right pump 50, especially within the right pumping chamber 62.

[0041] Advantageously, the right impeller 52 of the CFTAH 10 has a configuration that exhibits desired pump performance characteristics with an improved, high resistance to thrombosis formation, by minimizing areas of sustained low shear stress along its surfaces. Referring to Figs. 3-8, the right impeller 52 includes six primary vanes 120 and six splitter vanes 140. The primary vanes 120 are configured and arranged along a diameter D equidistantly from and radially about a center 70 of the right impeller 52, which coincides with the rotor axis 18. The splitter vanes 140 are positioned between the primary vanes 120 and are configured and arranged along diameter E equidistantly from and radially about the center 70 of the right impeller 52.

[0042] The right impeller 52 includes a back plate 72. The right impeller 52 can also include a threaded shaft portion 74 that facilitates connecting the impeller to the rotor 20. The back plate 72 has a generally flat back surface 76 that extends generally perpendicular to the rotor axis 18. The back surface 76 can include an annular recessed portion 78 that defines a ring-shaped annular bottom surface portion 80. The purpose of the recessed portion 78 can be to help ensure a tight seal between the annular bottom surface portion 80 and the engaging surface of the rotor 20 when the right impeller 52 is screwed-on.

[0043] The back plate 72 also includes a front surface 82 from which the vanes 120, 140 extend/project. The front surface 82 is conical in form and has a rounded apex 84. The vanes 120, 140 extend axially from the front surface 82 and have a slightly curved profile. Fig. 8 illustrates a single primary vane 120 and splitter vane 140 in a magnified view. As shown in Fig. 8, each primary vane 120 has a leading edge 122, a trailing edge 124, a pressure side 126, and a suction side 128. The spaces between the impeller vanes 120, 140 define impeller passages 130 (see Fig. 8) through which the blood is pumped. The annular rim 64 of the back plate 72 extends radially beyond the outer diameter of the impeller vanes 120, 140, *i.e.*, beyond their trailing edges. The axial position of the right impeller 52 in the pumping chamber 62, specifically the position of the annular rim 64 relative to the housing portion 66, that

defines the size of the pumping aperture 60, the amount of blood flow into the right volute 58.

[0044] During operation of the CFTAH 10, the right impeller rotates in a direction indicated generally by “R” in Figs. 7 and 8, which is clockwise in those figures. Blood enters the right pumping chamber 62 through the right inlet 54 (see Fig. 2) and is engaged by the vanes 120, 140 of the rotating right impeller 52. The leading edges 122 of the primary vanes 120 engage the incoming blood and, through centrifugal force, move the blood radially outward, toward the pumping aperture 60.

[0045] Advantageously, the configuration of the right impeller 52 is optimized for implementation in the CFTAH 10. More specifically, the right impeller 52 is optimized for use in a pump where the pumping aperture 60 is at the outside diameter (OD) of the impeller, *i.e.*, outside the impeller vanes 120, 140, and where an axial clearance between the impeller and the housing is provided to allow for axial movement of the right impeller 52 between the volute 58 and the pumping chamber 62.

[0046] Due to this design, the blood flow from the right impeller 52 needs to push through the narrow pump aperture 60 to enter the right pump volute 58 and then exit the pump through the right outlet 56. In this design, if the blood flow cannot exit through the aperture 60, it recirculates within the pumping chamber 62. This recirculation results in backflow, *i.e.*, flow radially inward through the impeller passages 130, opposite the centrifugal flow.

[0047] Recirculating blood can potentially lead to thrombus formation because the blood is exposed to high shear from interaction with the impeller vanes 120, 140 and then low shear in the recirculation regions within the impeller passages 130, where shear-activated platelets can stick, causing thrombus to form on the impeller surfaces. The recirculating blood is slow moving and, in effect, has more time/opportunity to stick to the pump components. Because of the unique configuration of the right pump 50 in the passive self-balancing design of the CFTAH 10, impeller surfaces in the right-pump can be exposed to back-flowing blood.

[0048] The right impeller 52 is configured to help minimize the amount of this recirculating, inward moving blood flow near the impeller surface and also reduce the overall recirculation flow within the right pumping chamber 62. Of course, pump performance must be maintained. The right impeller 52 of the illustrated example configuration maintains the desired pressure rise, which is a key aspect of the CFTAH 10 performance.

[0049] The right impeller 52 implements several features that help to achieve this performance. Increasing the cone angle A (see Fig. 6) and reducing the vane heights reduces the cross-sectional flow area between the vanes 120, 140, *i.e.*, of the impeller passages 130. In helping to reduce the flow area of the impeller passages 130, the likelihood of blood recirculation inward through the impeller passages and along the impeller vanes from outer edges of impeller (near the pumping aperture 60) is reduced. It should be noted, however, that the reduced cross-sectional flow area reduces the flow volume between the vanes 120, 140, which reduces the flow rate pumped by the right pump 50 at a given impeller rotational speed. Therefore, while the increased cone angle A reduces the amount of blood recirculation in the impeller passages 130, it also tends to reduce the pressure rise of the right pump 50. A cone angle A of 23-27 degrees showed improved anti-thrombus performance over lesser angles, such as 15 or 20 degrees. In one example configuration of the CFTAH 10, an especially effective cone angle A was found to be 25 degrees.

[0050] To counteract the reduction in pressure rise produced by the increased cone angle, the right impeller 52 includes splitter vanes 140 in combination with the primary vanes 120. The addition of splitter vanes 140 increases the number of blood contacting impeller surfaces, which increases the overall impeller surface area contacting and pumping the blood. Adding splitter vanes 140 instead of simply increasing the number of primary vanes 120 allows for reducing or minimizing the number of primary vanes, which serves to increase the open area between their leading edges 122 and can thereby increase the flow rate between the vanes. The splitter vanes 140 allow the number of primary vanes 120 to be kept low, such as 5 to 7 vanes, while providing

improved pressure rise and also increased area between the primary vane leading edges 122. The six primary and splitter vane configuration of the illustrated example CFTAH 10 was found to be ideal.

[0051] Increasing the area between the leading edges 122 and the increased flow rate between the primary vanes 120 provides several advantages. The increased spacing between the leading edges 122 provides increased open area to pass any blood clots that form upstream and are carried into the right pump 50. The larger spacing also may be beneficial if clotting starts to occur on the suction side 128 of the primary vanes 120. The increased spacing between the leading edges 122 also helps to maintain the blood flow between the primary vanes 120 and reduce the potential for entire blade passage 130 clotting off.

[0052] Additionally, the increased open area between the leading edges 122 reduces the shear stress acting on the platelets as they flow through the initial opening between the primary vanes 120. The increased open area also reduces the flow velocity near the leading edges 122, which can reduce the potential for flow separation off the leading edges. Higher flow speeds at the leading edges 122 would tend to produce larger separation along the suction side 128 of the vanes 120 (*i.e.*, the flow moving at increased speeds could not as easily negotiate turning around the curvature of the leading edges). Larger separation along the suction side 128 would lead to increased flow recirculation downstream of the leading edge 122.

[0053] The inclusion of the splitter vanes 140 helps reduce separation along the suction side 128 of the primary vanes 120. This is due to the splitter vanes 140 occupying some of the flow volume between the primary vanes 120 where recirculation could occur. As a result, the splitter vanes 140 help direct or maintain the flow along the suction side 128 of the primary vanes 120. The six primary vane 120, six splitter vane 140 configuration of the right impeller 52 produces the increased pressure rise of the right pump 50, while simultaneously helping to prevent flow separation along the suction sides 128 of the primary vanes 120 and recirculation downstream of the leading edges

122. This decreases the likelihood of thrombus formation between and near the leading edges 122 of the primary vanes 120.

[0054] Additionally, the leading edges 122 of the primary vanes 120 are configured to have an elliptical configuration (*e.g.*, 2:1 major axis to minor axis ratio). This streamlines the leading edges 122, which reduces the stream wise pressure gradient in their vicinities. This decreases blood flow separation off the leading edges 122 of the primary vanes 120.

[0055] Furthermore, referring to Fig. 8, the leading edges 122 of the primary vanes 120 are curved (concavely toward the pressure side 126). The curvature of the primary vanes 120 is configured (*i.e.*, increased) to better align the leading edge 122 with the incoming flow direction. This also decreases blood flow separation off the leading edges 122 of the primary vanes 120.

[0056] As used herein, the blade angle B is the effective blade angle at the leading edge 122 of the primary vane 120. As shown in Fig. 8, the blade angle B is measured between a tangent line where the primary vane 120 meets the diameter D, and the major axis of the elliptical leading edge 122. The increased curvature of the primary vanes 120 can produce a blade angle B of 32-38 degrees. This blade angle B is reduced from that of more conventional CFTAH right impeller designs, which fall in the range of 50 degrees. The diameter D can be about 0.30–0.40 inches. In the example configuration, a diameter D of about 0.35 inches or, more precisely, 0.357 inches, was found to be effective. In this example configuration, the vane curvature was adjusted to produce a blade angle B of 35 degrees. This better aligned the leading edge 122 with approaching blood flow near center 70 of the right impeller 52. This also decreased blood flow separation off the leading edges 122 of the primary vanes 120.

[0057] From the above, it can be seen that these features are not independently tunable parameters that can be adjusted as desired in order to achieve the desired results. It must be recalled that the pump performance parameters, *i.e.*, pressure rise, flow rates, *etc.* need to be maintained within a

specific, narrow range of values that is coordinated with the performance of the left impeller in order for the self-balancing operation of the CFTAH 10 to be maintained. Thus, for example, as stated above, while increasing the cone angle reduces the flow area through the impeller passages 130, it also results in a reduced pressure rise, which must be accounted for. Intuitively, one may be inclined to simply increase the number of impeller vanes, but this would also close the spacing between their leading edges, which increases the likelihood of thrombus formation. Thus, the addition of splitter vanes is advantageous in maintaining primary impeller leading edge spacing.

[0058] To verify the efficacy of this configuration, computational fluid dynamics (CFD) modeling was used to identify areas of potential thrombus formation: areas of sustained low shear stress near impeller surfaces, flow separation downstream of the impeller vanes leading edges, inward moving flow between the impeller vanes, and separated flow regions/recirculation zones in impeller vane passages (the space between the impeller vanes). Modelling was performed under both normal *in vivo* operating conditions (*e.g.*, 8 lpm flow rate, 3100 rpm pump speed) and at low flow/low speed conditions (*e.g.*, 3 lpm flow rate, 2200 rpm pump speed).

[0059] The CFD modelling shows that the improved configuration of the right impeller 52 provides:

- Smaller areas of flow separation, generally, and especially in the areas of the primary vane leading edges.
- Maintains pressure rise necessary to perform as a right pump for the CFTAH configuration.
- Improved consistency of high fluid shear stress/residence time within the impeller vane passages.
- Majority of recirculation/inward flow is in the space between the impeller vanes and not near the impeller surfaces.

[0060] The foregoing has described an artificial heart system implementing a right impeller configuration with improved resistance to thrombosis formation. While specific example embodiments have been described, it will be apparent

to those skilled in the art that various modifications thereto can be made without departing from the spirit and scope of the invention. Accordingly, the foregoing description of the example embodiment are provided for the purpose of illustration only and not for the purpose of limitation.

WHAT IS CLAIMED IS:

1. A right impeller for a continuous flow total artificial heart (CFTAH), comprising:

a back plate comprising a front surface having a conical configuration centered on an axis of impeller rotation and including a rounded apex;

a plurality of primary vanes protruding from the front surface and being arranged equidistantly from the apex and spaced radially about the apex;

a splitter vane positioned between each adjacent pair of primary vanes;

wherein each primary vane has a leading edge proximate the apex and an opposite trailing edge;

wherein the leading edge of each primary vane has an elliptical configuration;

wherein the back plate comprises an annular rim portion that extends radially beyond the trailing edges of the primary vanes.

2. The right impeller recited in claim 1, wherein the right impeller includes 5-7 primary vanes and 5-7 splitter vanes.

3. The right impeller recited in claim 1 or 2, wherein the right impeller includes six primary vanes and six splitter vanes.

4. The right impeller recited in any of the preceding claims, wherein the back plate has a cone angle of 23-27 degrees.

5. The right impeller recited in any of the preceding claims, wherein the back plate has a cone angle of 25 degrees.

6. The right impeller recited in any of the preceding claims, wherein the primary vanes have a curved configuration selected such the leading edges of the primary vanes have a blade angle of 32-38 degrees.

7. The right impeller recited in any of the preceding claims, wherein the primary vanes have a curved configuration selected such the leading edges of the primary vanes have a blade angle of 35 degrees.

8. The right impeller recited in any of the preceding claims, wherein the leading edges of the primary vanes are arranged along a diameter of about 0.30-0.40 inches.

9. The right impeller recited in any of the preceding claims, wherein the leading edges of the primary vanes are arranged along a diameter of about 0.35 inches.

10. The right impeller recited in any of the preceding claims, wherein the elliptical configuration of the leading edges is that of an ellipse having a major axis to minor axis ratio of 2:1.

11. The right impeller recited in any of the preceding claims, wherein the primary vanes comprise a pressure side and a suction side, and wherein the primary vanes have a curved configuration in which the pressure side of the vane is curved concavely.

12. A CFTAH comprising:

a housing that helps define a left pump and a right pump;

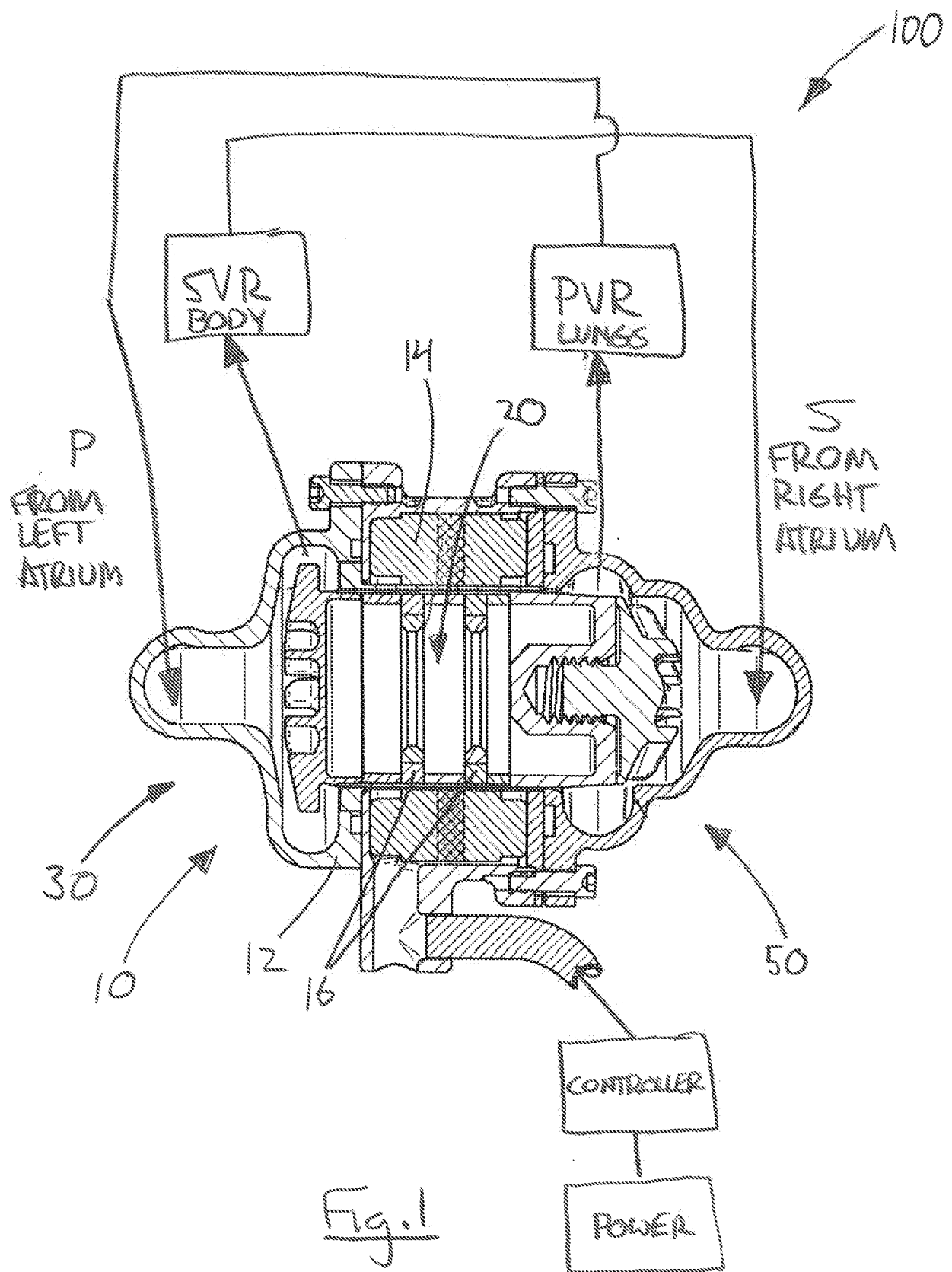
wherein the left pump comprises a left inlet for receiving left atrial blood flow, a left volute in fluid communication with the left inlet, a left impeller at least partially disposed in the left volute, and a left outlet in communication with the left volute for discharging systemic blood flow via the aorta;

wherein the right pump comprises the right impeller of any of the preceding claims, a right inlet for receiving right atrial blood flow, a right pumping chamber in fluid communication with the right inlet, a right volute in

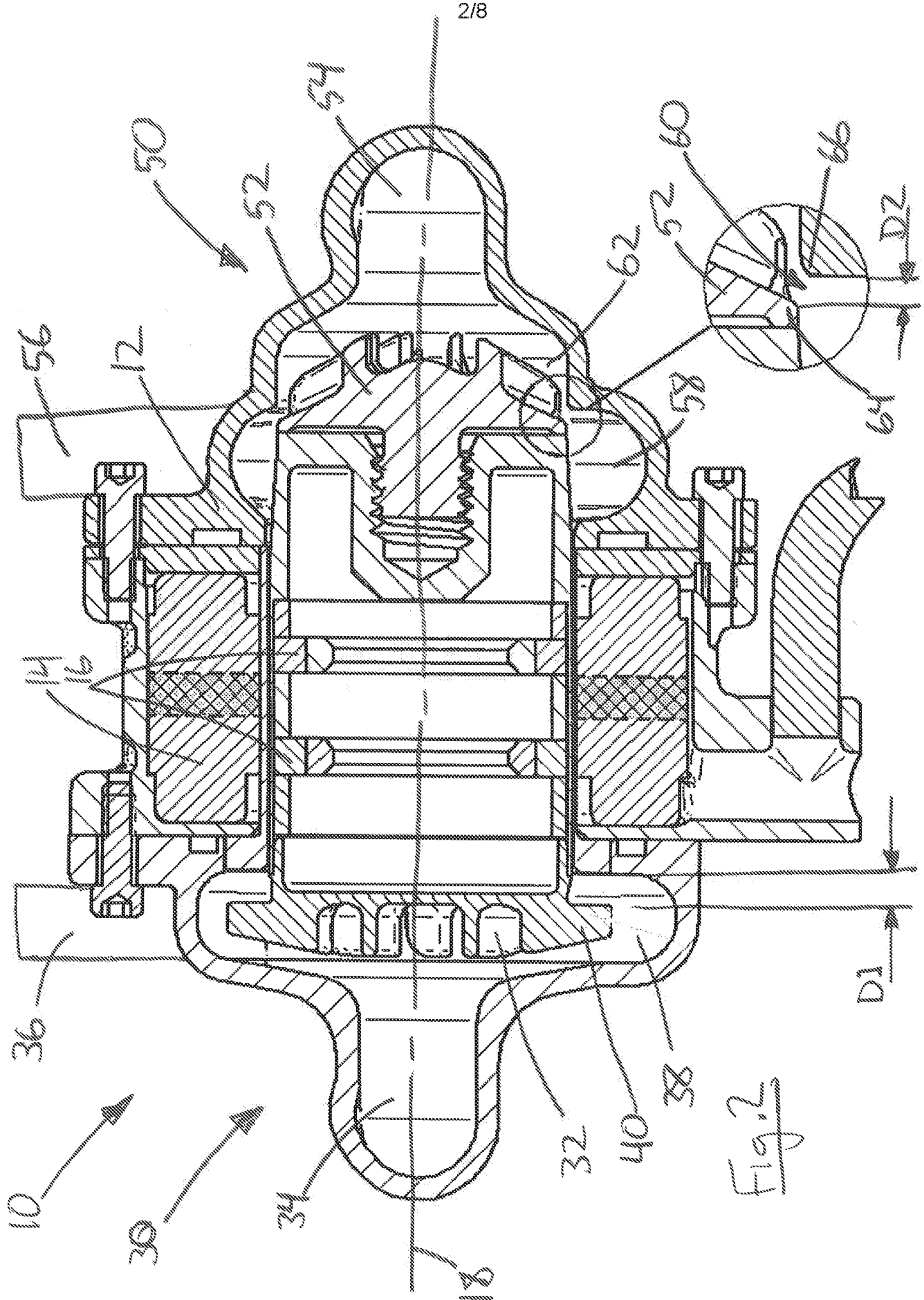
fluid communication with the right pumping chamber, and a right outlet in communication with the right volute for discharging pulmonary blood flow via the pulmonary artery, wherein the primary and splitter vanes of the right impeller are at least partially positioned in the right pumping chamber and the annular rim of the right impeller is at least partially positioned in the right volute, and wherein a pumping aperture is defined between the annular rim and the housing at the interface between the right pumping chamber and the right volute;

a motor supported by the housing and comprising a stator and a rotor to which the left and right impellers are connected, the motor being operable to rotate the left and right impellers;

wherein the motor is configured to permit the rotor to move axially relative to the stator during operation of the pump such that differentials in left and right atrial pressures adjust the axial position of the rotor, wherein the right pump is configured to adjust its hydraulic performance characteristics by adjusting the size of the pumping aperture in response to the axial position of the right impeller in the right pumping chamber and right volute.



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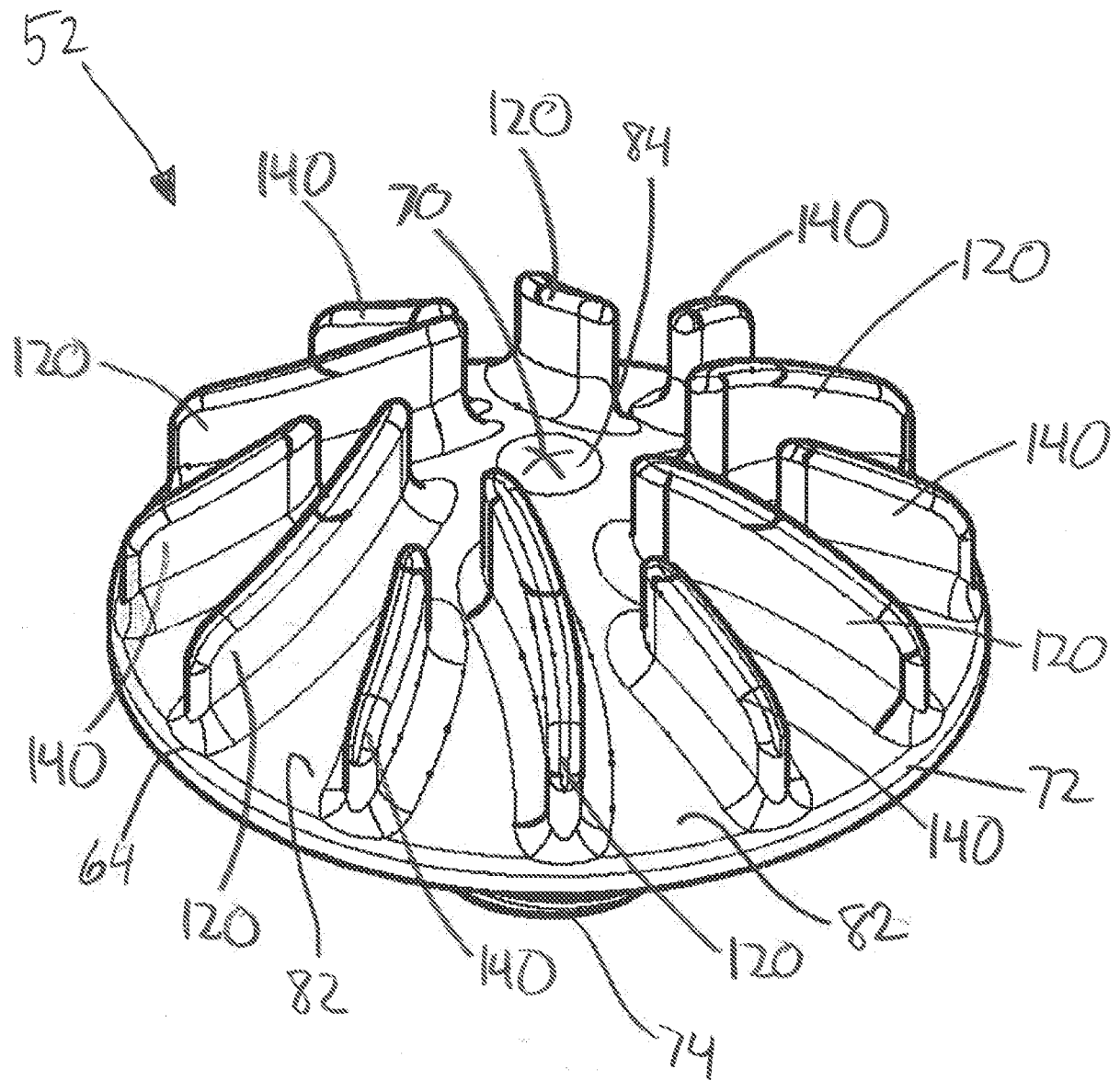


Fig. 3

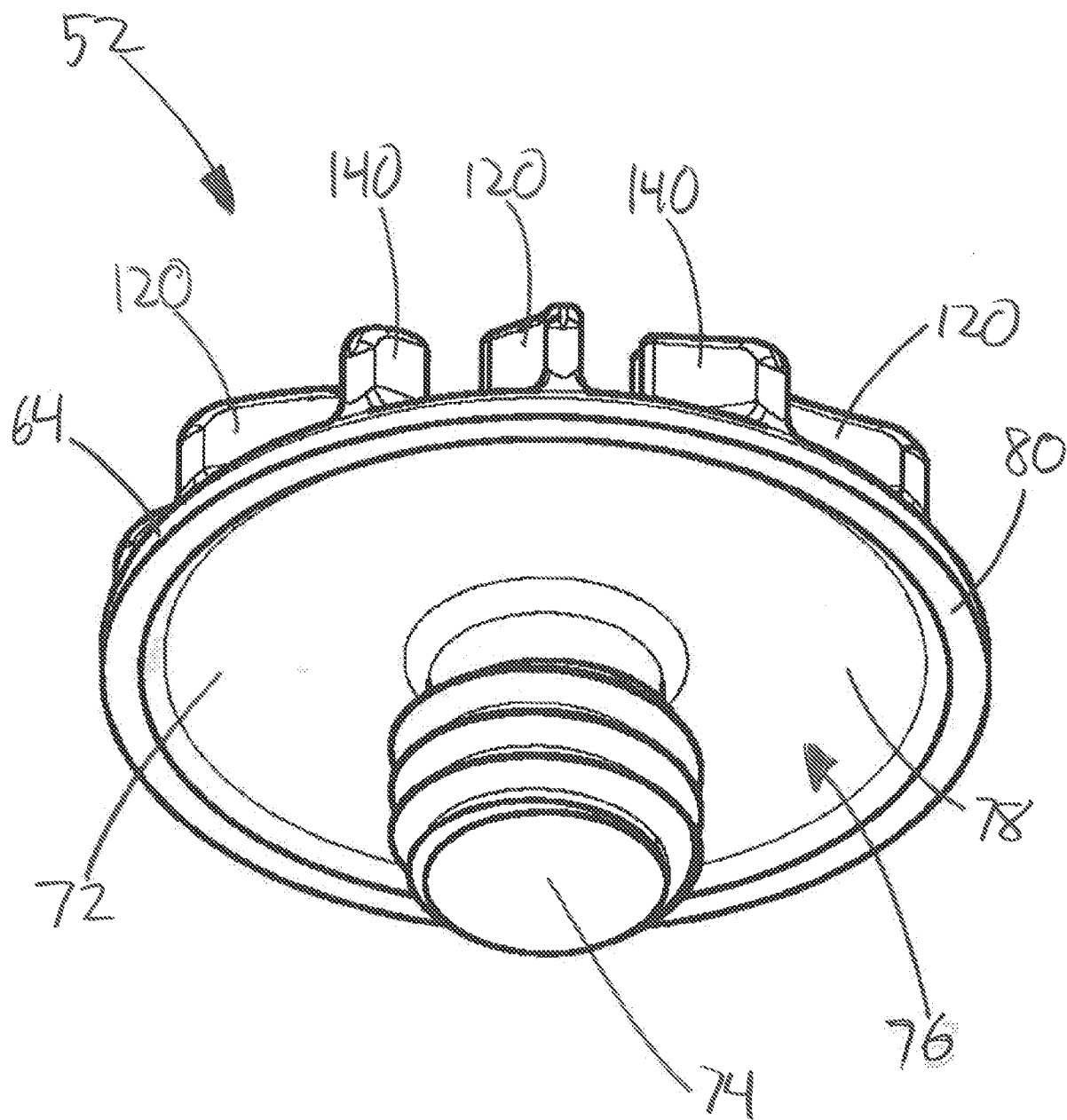


Fig. 4

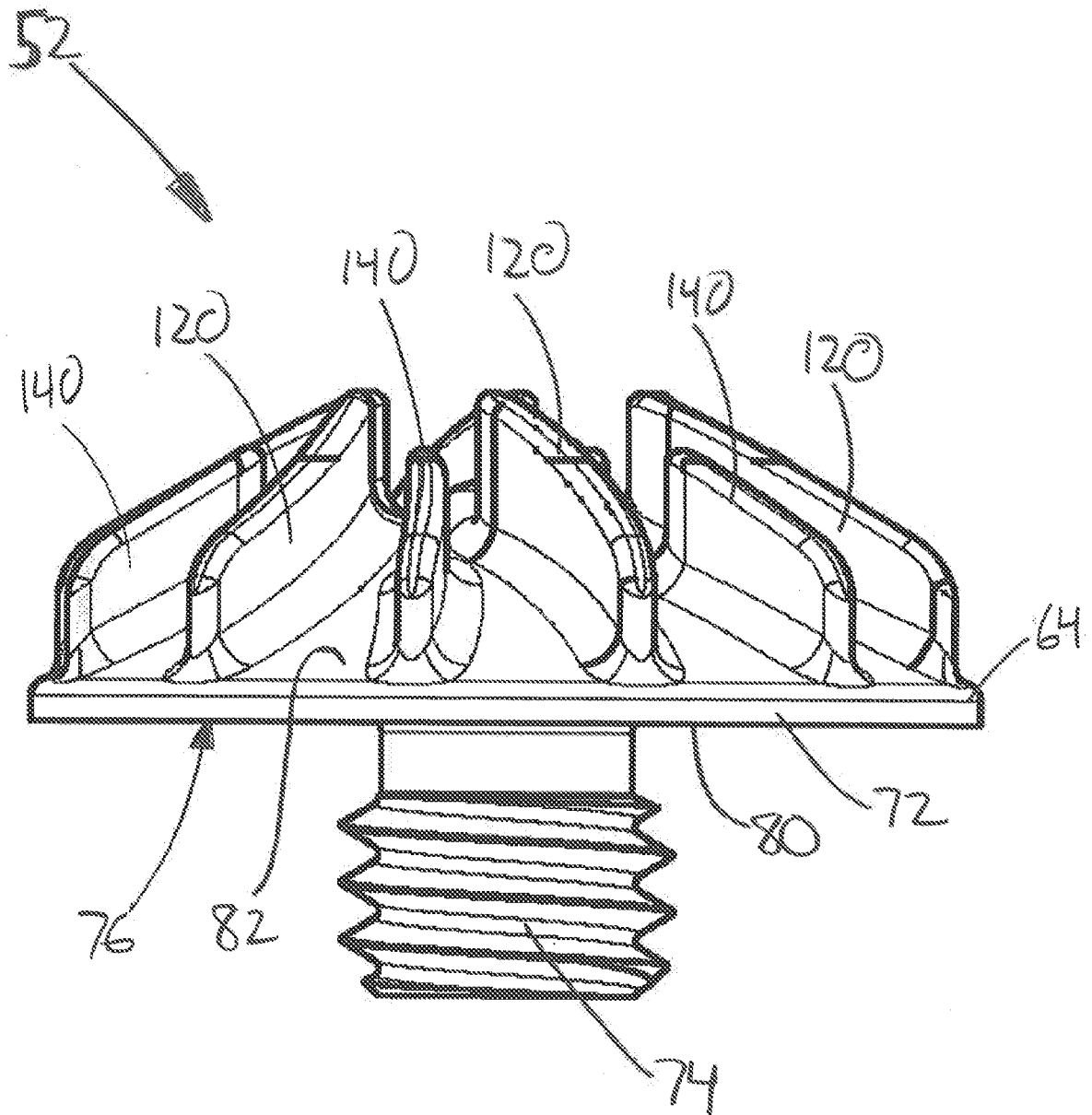


Fig. 5

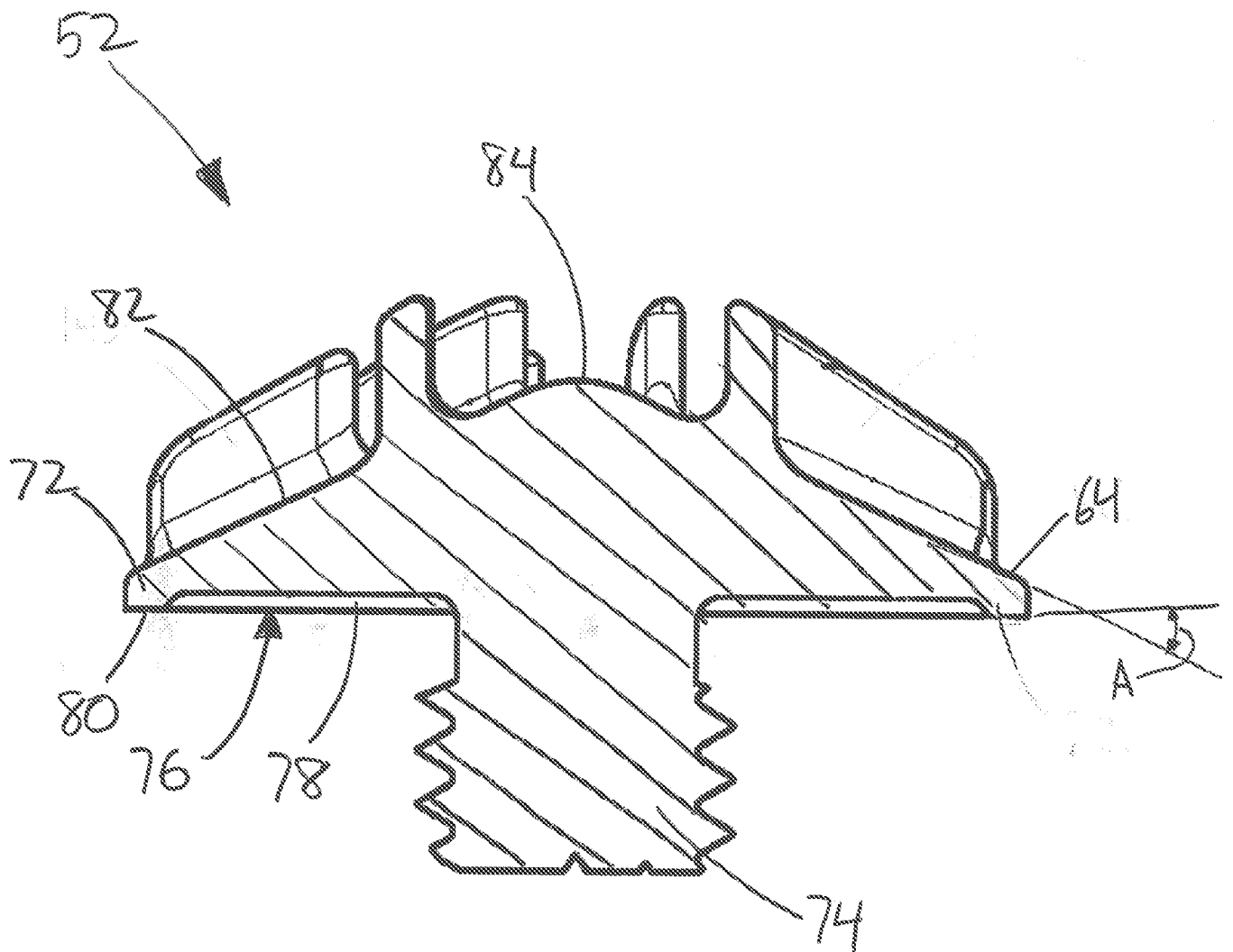


Fig. 6

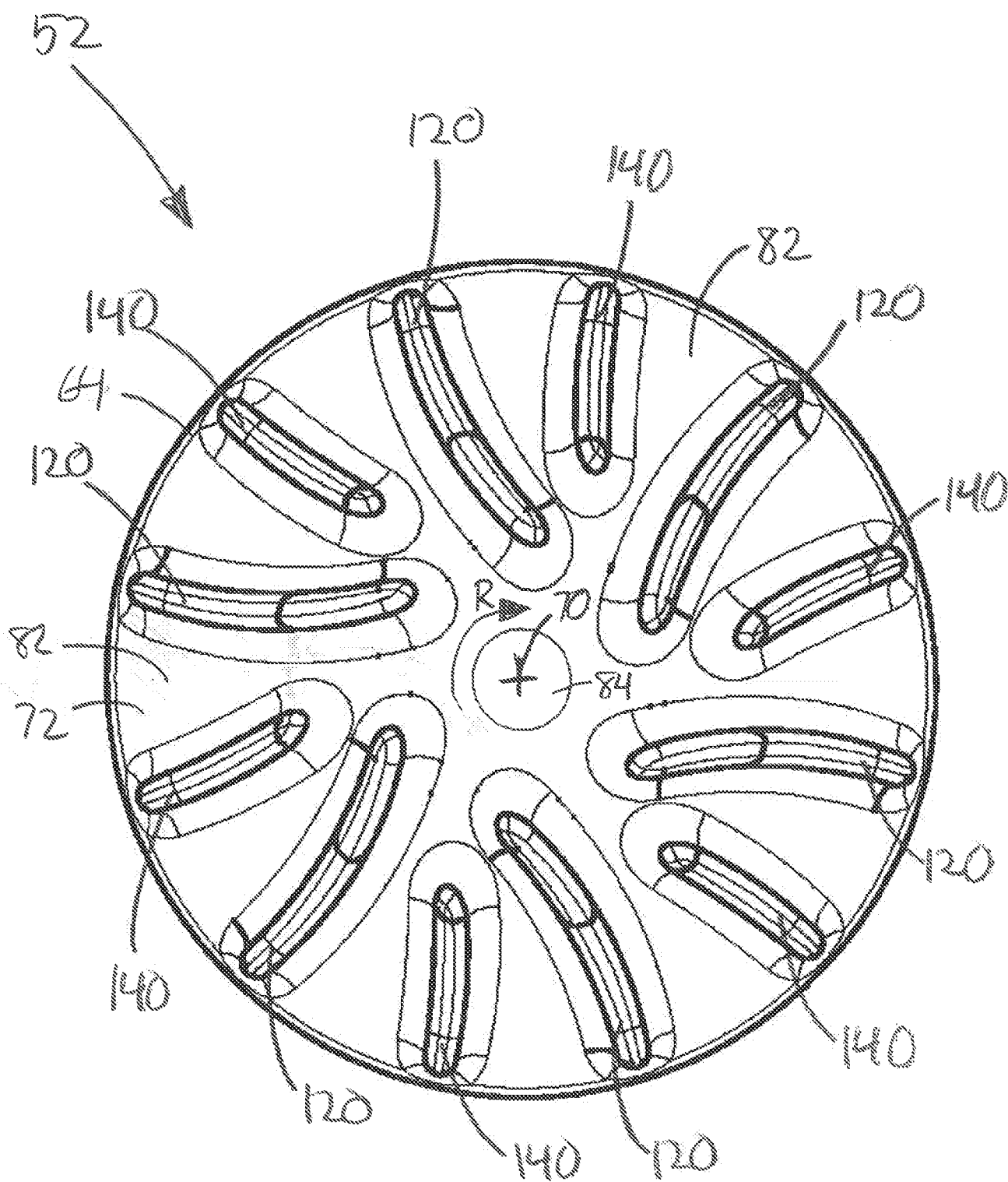


Fig. 7

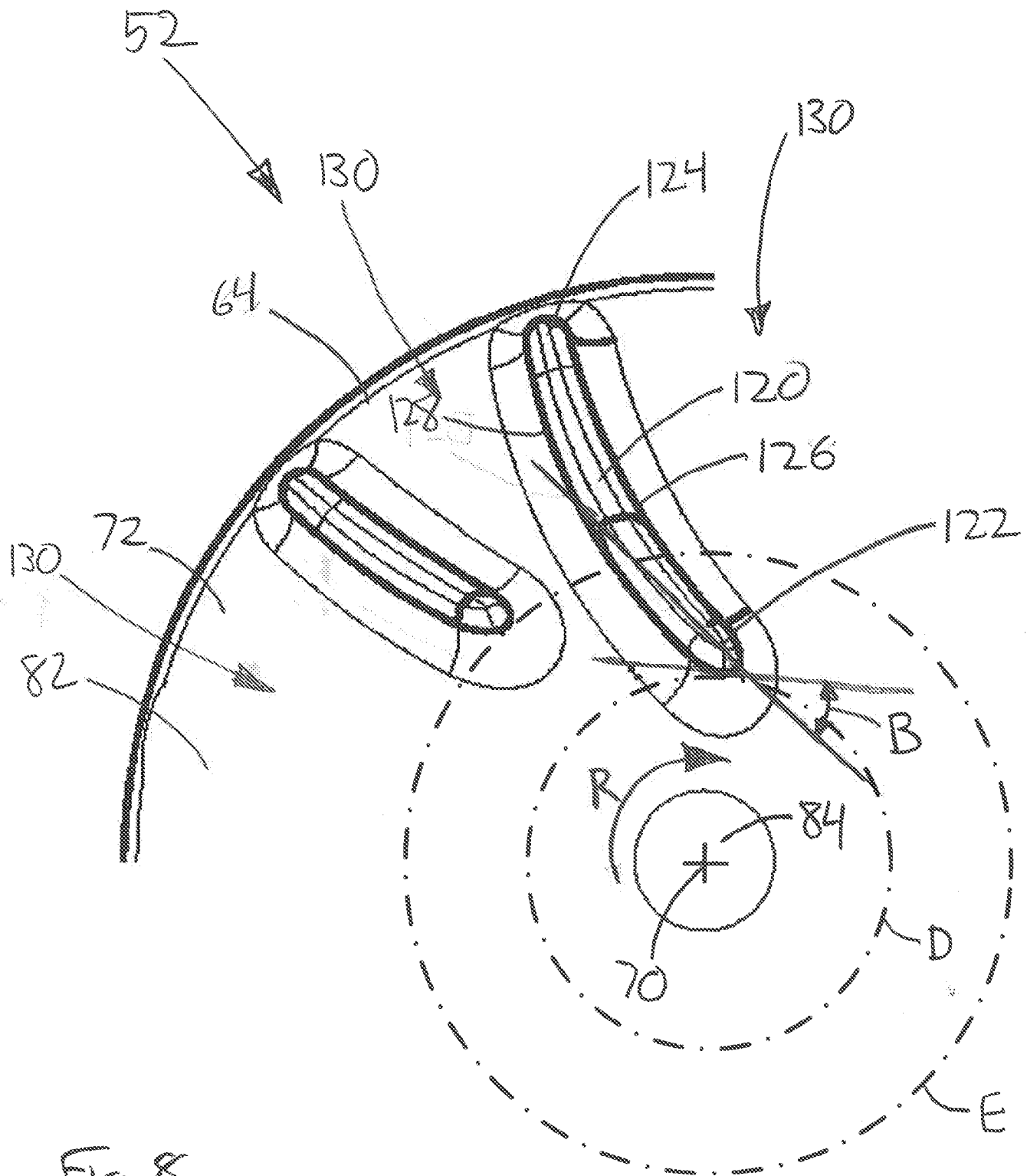


Fig. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2018/056051

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M1/10 A61M1/12
ADD.

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)
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 practicable, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2014/008078 A1 (CLEVELAND CLINIC FOUNDATION [US]) 9 January 2014 (2014-01-09) abstract; figures 4,5,14,15 -----	1-12
Y	US 6 048 363 A (NAGYSZALANCZY LORANT [US] ET AL) 11 April 2000 (2000-04-11) abstract; figures column 10, line 32 - line 45 -----	1-12



Further documents are listed in the continuation of Box C.



See patent family annex.

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"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

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Date of the actual completion of the international search

11 January 2019

Date of mailing of the international search report

18/01/2019

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2018/056051

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