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(54) **Title:** ROTARY BLOOD PUMP

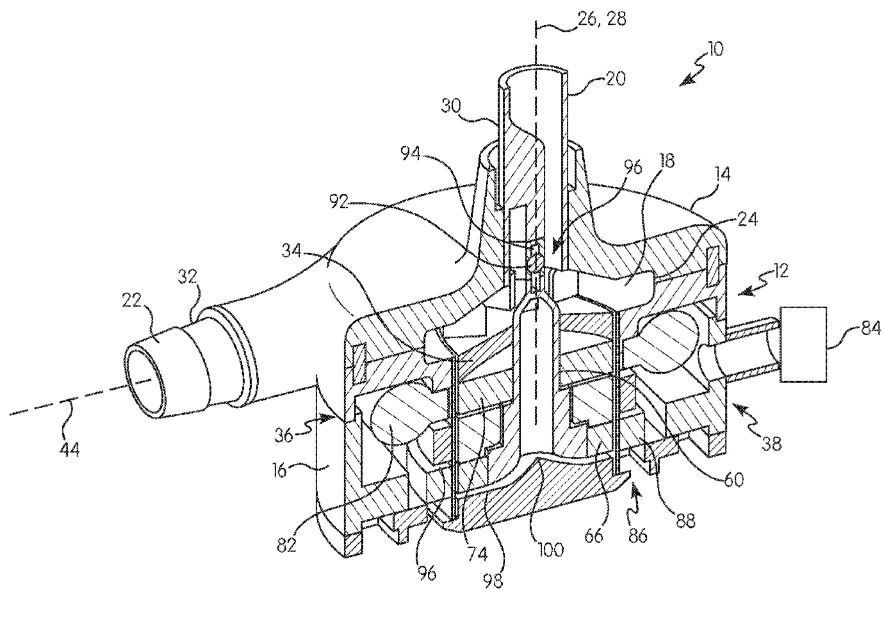

FIG. 1

(57) **Abstract:** A centrifugal blood pump includes a housing having a pumping chamber, an inlet having an inlet axis, and an outlet having an outlet axis. The inlet and the outlet are in fluid communication with the pumping chamber. The pump further includes an impeller rotatably disposed within the pumping chamber, and a strut connected to the housing at the inlet. The strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis. The circumferential position of the strut relative the outlet axis reduces or eliminates damage to blood flowing around the strut.

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ROTARY BLOOD PUMP

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to United States Provisional Application No. 62/702,562, filed on July 24, 2018, the disclosure of which is hereby incorporated by reference in its entirety.

BACKGROUND OF THE DISCLOSURE

Field of the Disclosure

[0002] The present disclosure is generally related to a rotary blood pump, and, in particular, to a rotary blood pump having a bearing mechanism for supporting an impeller within a pumping chamber and a drive mechanism for rotatably driving the impeller within the pumping chamber.

Description of Related Art

[0003] Rotary blood pumps have long been used with assisting or supplementing the function of a human heart. For example, rotary blood pumps assist heart function due to a damaged left ventricle, or for temporary heart bypass during cardiac surgery. In general, a rotary blood pump has an impeller disposed within a pumping chamber of a pump housing. Blood is delivered via an axial inlet of the housing and is pumped by the impeller to a radial outlet. The impeller is rotatably driven within the pumping chamber by a drive mechanism, such as a drive magnet in the impeller that is rotatably driven by an electromagnet in the housing.

[0004] Due to high rotating speeds of the impeller during pump operation (2,000 to 7,500 rpm), the impeller must be adequately supported within the pump housing to prevent damage to the blood cells due to shearing or flow stagnation. In some existing pump designs, the impeller is fully magnetically suspended within the pumping chamber. Such impeller support systems often require complex control of the magnets used for suspending the impeller. In other designs, the impeller may be hydrodynamically suspended within the pumping chamber, where hydrodynamic force of blood within the pumping chamber is used to support the impeller and prevent the impeller from contacting the sidewalls of the pumping chamber. With hydrodynamic impeller support, the impeller is often free to contact the sidewalls of the pumping chamber during pump startup until a sufficient fluid pressure is built. As a result, blood cells may be damaged during pump startup. Some rotary blood pumps have a fully mechanical bearing supporting the impeller within the pump housing. A disadvantage of mechanical bearings is that they may transfer heat to the blood and may result in blood clotting.

[0005] In view of these and other disadvantages of conventional rotary blood pumps, there is a need in the art for improved rotary blood pumps having a bearing mechanism for supporting the impeller in a manner that overcomes the shortcomings of existing rotary blood pumps.

SUMMARY OF THE DISCLOSURE

[0006] The present disclosure is generally related to a rotary blood pump, and, in particular, to a rotary blood pump having a bearing mechanism for supporting an impeller within a pumping chamber, and a drive mechanism for rotatably driving the impeller within the pumping chamber.

[0007] In some examples of the present disclosure, a centrifugal blood pump may have a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber. The pump may further have an impeller rotatably disposed within the pumping chamber, and a strut connected to the housing at the inlet. The strut may be connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis. The circumferential position of the strut relative the outlet axis may reduce thrombosis of blood flowing around the strut.

[0008] In other examples of the present disclosure, the strut may have a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis. The predetermined angle may be about 15° to about 75°, such as about 45°. At least a portion of the strut may have a teardrop cross-sectional shape. The impeller may have at least one passage defining a secondary flow path. The at least one passage may be substantially perpendicular to the outlet axis. During operation of the blood pump, the impeller may deliver a first portion of blood flow from the inlet directly to the outlet, and may deliver a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0009] In other examples of the present disclosure, a bearing mechanism for supporting the impeller within the pumping chamber may include a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the pumping chamber. The bearing mechanism further may have an axial bearing comprising a first bearing element associated with the impeller and a second bearing element connected to the strut.

[0010] In other examples of the present disclosure, the impeller may have at least one passage defining a secondary flow path such that, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the secondary flow path to cool the axial bearing. The first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material. The first permanent magnet may be axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force. A motor mechanism for rotating the impeller within the pumping chamber may have a permanent magnet rotor associated with the impeller and an electromagnetic coil stator associated with the housing.

[0011] In other examples of the present disclosure, a centrifugal blood pump may have a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber. The pump may further have an impeller rotatably disposed within the pumping chamber and having at least one passage defining a secondary flow path, a bearing mechanism supporting the impeller within the pumping chamber, and a strut connected to the housing at the inlet to support at least a portion of the bearing mechanism. The strut may be connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis. The circumferential position of the strut relative to the outlet axis may reduce thrombosis of blood flowing around the strut.

[0012] In other examples of the present disclosure, the strut may have a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis. The predetermined angle may be about 15° to about 75°, such as about 45°. At least a portion of the strut may have a teardrop cross-sectional shape. The at least one passage defining the secondary flow path may be substantially perpendicular to the outlet axis. During operation of the blood pump, the impeller may deliver a first portion of blood flow from the inlet directly to the outlet, and may deliver a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0013] In other examples of the present disclosure, the bearing mechanism may have a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the pumping chamber. The bearing mechanism may further have an axial bearing having a first bearing element associated with the impeller and a second bearing element connected to the strut. During operation of the blood pump, the impeller may deliver a first portion of blood flow from the inlet directly to the outlet, and may deliver a second portion of the blood flow from the inlet to the outlet via the secondary flow path to cool the axial bearing. The first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material. The first permanent magnet may be axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0014] In other examples of the present disclosure, a centrifugal blood pump may have a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber. The pump may further have an impeller rotatably disposed within the pumping chamber, and a bearing mechanism for supporting the impeller within the pumping chamber. The bearing mechanism may have a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the pumping chamber. The bearing mechanism may further have an axial bearing having a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet. The first permanent magnet may be axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0015] In other examples of the present disclosure, the first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material.

[0016] In other examples of the present disclosure, a centrifugal blood pump may have a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet in fluid communication with the pumping chamber. The pump may have an impeller rotatably disposed within the pumping chamber, and a bearing mechanism for supporting the impeller within the pumping chamber. The bearing mechanism may have a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the pumping chamber. The bearing mechanism may further have an axial bearing having a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet. The strut may be connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis. The circumferential position of the strut relative to the outlet axis may reduce or eliminate damage to blood flowing around the strut.

[0017] In other examples of the present disclosure, the strut may have a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis. The predetermined angle may be about 15° to about 75°, such as about 45°. At least a portion of the strut may have a teardrop cross-sectional shape. The impeller may have at least one passage defining a secondary flow path. The at least one passage may be substantially perpendicular to the outlet axis. During operation of the blood pump, the impeller may deliver a first portion of blood flow from the inlet directly to the outlet, and may deliver a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0018] In other examples of the present disclosure, the pump has a motor mechanism for rotating the impeller within the pumping chamber. The motor mechanism may have a permanent magnet rotor associated with the impeller and an electromagnetic coil stator associated with the housing.

The first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material.

[0019] In other examples of the present disclosure, a centrifugal blood pump may have a housing having a pumping chamber, an inlet having an inlet axis, and an outlet having an outlet axis, the inlet and the outlet in fluid communication with the pumping chamber. The pump may also have an impeller rotatably disposed within the pumping chamber, and a bearing mechanism for supporting the impeller within the pumping chamber. The bearing mechanism may have a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the pumping chamber. The bearing mechanism may further have an axial bearing with a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet. The strut may have a single connection point with the housing in a cross-sectional plane perpendicular to the inlet axis.

[0020] In other examples of the present disclosure, the strut may be connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in the cross-sectional plane perpendicular to the inlet axis. The predetermined angle may be about 15° to about 75°, such as about 45°. At least a portion of the strut may have a teardrop cross-sectional shape. The impeller may have at least one passage defining a secondary flow path. The at least one passage may be substantially perpendicular to the outlet axis. During operation of the blood pump, the impeller may deliver a first portion of blood flow from the inlet directly to the outlet, and may deliver a second portion of the blood flow from the inlet to the outlet via the at least one passage. The first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material. The first permanent magnet may be axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0021] In other examples of the present disclosure, a bearing mechanism for supporting an impeller within a housing of a centrifugal blood pump may have a radial bearing having a first permanent magnet configured for mounting on the impeller and a second permanent magnet configured for mounting on the housing. The first permanent magnet may magnetically interact with the second permanent magnet to radially position the impeller within the housing. The first permanent magnet may be axially offset relative to the second permanent magnet to urge the impeller axially with a predetermined axial force. The bearing mechanism may further have an axial bearing having a first bearing element configured for mounting on the impeller and a second bearing element mounted on a strut configured for connecting to at least a portion of the housing. The axial bearing may be configured to counteract the predetermined axial force. The strut may have a single attachment point on the housing in a cross-sectional plane of the housing.

[0022] In other examples of the present disclosure, the first bearing element may be ball-shaped and the second bearing element may be cup-shaped to receive at least a portion of the ball-shaped first bearing element. Alternatively, the second bearing element may be ball-shaped and the first bearing element may be cup-shaped to receive at least a portion of the ball-shaped second bearing element. The first bearing element may be a jewel bearing. The second bearing element may be made from a ceramic material.

[0023] Various other aspects of the present invention are recited in one or more of the following clauses:

[0024] Clause 1: A centrifugal blood pump comprising: a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber; an impeller rotatably disposed within the pumping chamber; and a strut connected to the housing at the inlet, wherein the strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis, and wherein the circumferential position of the strut relative the outlet axis reduces or eliminates damage to blood flowing around the strut.

[0025] Clause 2. The centrifugal blood pump of clause 1, wherein the strut has a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis.

[0026] Clause 3. The centrifugal blood pump of clauses 1 or 2, wherein the predetermined angle is about 15° to about 75°, such as about 45°.

[0027] Clause 4. The centrifugal blood pump of any of clauses 1-3, wherein at least a portion of the strut has a teardrop cross-sectional shape.

[0028] Clause 5. The centrifugal blood pump of any of clauses 1-4, wherein the impeller has at least one passage defining a secondary flow path.

[0029] Clause 6. The centrifugal blood pump of clause 5, wherein the at least one passage is substantially perpendicular to the outlet axis.

[0030] Clause 7. The centrifugal blood pump of clauses 5 or 6, wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0031] Clause 8. The centrifugal blood pump of any of clauses 1-7, further comprising a bearing mechanism supporting the impeller within the pumping chamber, the bearing mechanism comprising: a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and an axial bearing comprising a first bearing element associated with the impeller and a second bearing element connected to the strut.

[0032] Clause 9. The centrifugal blood pump of clause 8, wherein the impeller has at least one passage defining a secondary flow path such that, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the secondary flow path to cool the axial bearing.

[0033] Clause 10. The centrifugal blood pump of clauses 8 or 9, wherein the first bearing element is ball-shaped and the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element or wherein the second bearing element is ball-shaped and the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0034] Clause 11. The centrifugal blood pump of any of clauses 8-10, wherein the first bearing element is a jewel bearing.

[0035] Clause 12. The centrifugal blood pump of any of clauses 8-11, wherein the second bearing element is made from a ceramic material.

[0036] Clause 13. The centrifugal blood pump of any of clauses 8-12, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0037] Clause 14. The centrifugal blood pump of any of clauses 1-13, further comprising a motor mechanism for rotating the impeller within the pumping chamber, the motor mechanism having a permanent magnet rotor associated with the impeller and an electromagnetic coil stator associated with the housing.

[0038] Clause 15. A centrifugal blood pump comprising: a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber; an impeller rotatably disposed within the pumping chamber and having at least one passage defining a secondary flow path; a bearing mechanism supporting the impeller within the pumping chamber; and a strut connected to the housing at the inlet to support at least a portion of the bearing mechanism, wherein the strut is connected to the housing at a circumferential position about the inlet axis such that the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis, and wherein the circumferential position of the strut relative the outlet axis reduces or eliminates damage to blood flowing around the strut.

[0039] Clause 16. The centrifugal blood pump of clause 15, wherein the strut has a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis.

[0040] Clause 17. The centrifugal blood pump of clauses 15 or 16, wherein the predetermined angle is about 15° to about 75°, such as about 45°.

[0041] Clause 18. The centrifugal blood pump of any of clauses 15-17, wherein at least a portion of the strut has a teardrop cross-sectional shape.

[0042] Clause 19. The centrifugal blood pump of any of clauses 15-18, wherein the at least one passage defining the secondary flow path is substantially perpendicular to the outlet axis.

[0043] Clause 20. The centrifugal blood pump of any of clauses 15-19, wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0044] Clause 21. The centrifugal blood pump of any of clauses 15-20, the bearing mechanism comprising: a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and an axial bearing comprising a first bearing element associated with the impeller and a second bearing element connected to the strut.

[0045] Clause 22. The centrifugal blood pump of clause 21, wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the secondary flow path to cool the axial bearing.

[0046] Clause 23. The centrifugal blood pump of clauses 21 or 22, wherein the first bearing element is ball-shaped and the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element or wherein the second bearing element is ball-shaped and the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0047] Clause 24. The centrifugal blood pump of any of clauses 21-23, wherein the first bearing element is a jewel bearing.

[0048] Clause 25. The centrifugal blood pump of any of clauses 21-24, wherein the second bearing element is made from a ceramic material.

[0049] Clause 26. The centrifugal blood pump of any of clauses 21-25, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0050] Clause 27. A centrifugal blood pump comprising: a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber; an impeller rotatably disposed within the pumping chamber; and a bearing mechanism for supporting the impeller within the pumping chamber, the bearing mechanism comprising: a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and an axial bearing comprising a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0051] Clause 28. The centrifugal blood pump of clause 27, wherein the first bearing element is ball-shaped and the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element or wherein the second bearing element is ball-shaped and the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0052] Clause 29. The centrifugal blood pump of clauses 27-28, wherein the first bearing element is a jewel bearing.

[0053] Clause 30. The centrifugal blood pump of any of clauses 27-29, wherein the second bearing element is made from a ceramic material.

[0054] Clause 31. A centrifugal blood pump comprising: a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet in fluid communication with the pumping chamber; an impeller rotatably disposed within the pumping chamber; and a bearing mechanism for supporting the impeller within the pumping chamber, the bearing mechanism comprising: a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and an axial bearing comprising a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet, wherein the strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis, and wherein the circumferential position of the strut relative to the outlet axis reduces or eliminates damage to blood flowing around the strut.

[0055] Clause 32. The centrifugal blood pump of clause 31, wherein the strut has a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis.

[0056] Clause 33. The centrifugal blood pump of clauses 31 or 32, wherein the predetermined angle is about 15° to about 75°, such as about 45°.

[0057] Clause 34. The centrifugal blood pump of any of clauses 31-33, wherein at least a portion of the strut has a teardrop cross-sectional shape.

[0058] Clause 35. The centrifugal blood pump of any of clauses 31-34, wherein the impeller has at least one passage defining a secondary flow path.

[0059] Clause 36. The centrifugal blood pump of any of clauses 31-35, wherein the at least one passage is substantially perpendicular to the outlet axis.

[0060] Clause 37. The centrifugal blood pump of any of clauses 31-36, wherein during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0061] Clause 38. The centrifugal blood pump of any of clauses 31-37, further comprising a motor mechanism for rotating the impeller within the pumping chamber, the motor mechanism having a permanent magnet rotor associated with the impeller and an electromagnetic coil stator associated with the housing.

[0062] Clause 39. The centrifugal blood pump of any of clauses 31-38, wherein the first bearing element is ball-shaped and wherein the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element.

[0063] Clause 40. The centrifugal blood pump of any of clauses 31-39, wherein the second bearing element is ball-shaped and wherein the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0064] Clause 41. The centrifugal blood pump of any of clauses 31-40, wherein the first bearing element is a jewel bearing.

[0065] Clause 42. The centrifugal blood pump of any of clauses 31-41, wherein the second bearing element is made from a ceramic material.

[0066] Clause 43. A centrifugal blood pump comprising: a housing having a pumping chamber, an inlet having an inlet axis, and an outlet having an outlet axis, the inlet and the outlet in fluid communication with the pumping chamber; an impeller rotatably disposed within the pumping chamber; and a bearing mechanism for supporting the impeller within the pumping chamber, the bearing mechanism comprising: a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and an axial bearing comprising a first bearing element associated with the impeller and a second bearing element associated with a strut connected to the housing at the inlet, wherein the strut has a single connection point with the housing in a cross-sectional plane perpendicular to the inlet axis.

[0067] Clause 44. The centrifugal blood pump of clause 43, wherein the strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in the cross-sectional plane perpendicular to the inlet axis.

[0068] Clause 45. The centrifugal blood pump of clauses 43 or 44, wherein the predetermined angle is about 15° to about 75°, such as about 45°.

[0069] Clause 46. The centrifugal blood pump of any of clauses 43-45, wherein at least a portion of the strut has a teardrop cross-sectional shape.

[0070] Clause 47. The centrifugal blood pump of any of clauses 43-46, wherein the impeller has at least one passage defining a secondary flow path.

[0071] Clause 48. The centrifugal blood pump of clause 47, wherein the at least one passage is substantially perpendicular to the outlet axis.

[0072] Clause 49. The centrifugal blood pump of clauses 47 or 48, wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

[0073] Clause 50. The centrifugal blood pump of any of clauses 43-49, wherein the first bearing element is ball-shaped and wherein the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element.

[0074] Clause 51. The centrifugal blood pump of any of clauses 43-50, wherein the second bearing element is ball-shaped and wherein the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0075] Clause 52. The centrifugal blood pump of any of clauses 43-51, wherein the first bearing element is a jewel bearing.

[0076] Clause 53. The centrifugal blood pump of any of clauses 43-52, wherein the second bearing element is made from a ceramic material.

[0077] Clause 54. The centrifugal blood pump of any of clauses 43-53, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

[0078] Clause 55. A bearing mechanism for supporting an impeller within a housing of a centrifugal blood pump, the bearing mechanism comprising: a radial bearing having a first permanent magnet configured for mounting on the impeller and a second permanent magnet configured for mounting on the housing, wherein the first permanent magnet magnetically interacts with the second permanent magnet to radially position the impeller within the housing, and wherein the first permanent magnet is axially offset relative to the second permanent magnet to urge the impeller axially with a predetermined axial force; and an axial bearing having a first bearing element configured for mounting on the impeller and a second bearing element mounted on a strut configured for connecting to at least a portion of the housing, wherein the axial bearing is configured to counteract the predetermined axial force, and wherein the strut has a single attachment point on the housing in a cross-sectional plane of the housing.

[0079] Clause 56. The bearing mechanism of clause 55, wherein the first bearing element is ball-shaped and wherein the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element.

[0080] Clause 57. The bearing mechanism of clauses 55 or 56, wherein the second bearing element is ball-shaped and wherein the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

[0081] Clause 58. The bearing mechanism of any of clauses 55-57, wherein the first bearing element is a jewel bearing.

[0082] Clause 59. The bearing mechanism of any of clauses 55-58, wherein the second bearing element is made from a ceramic material.

[0083] Further details and advantages of the various examples described in detail herein will become clear upon reviewing the following detailed description of the various examples in conjunction with the accompanying drawing figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0084] **FIG. 1** is a front, perspective cross-sectional view of a rotary blood pump in accordance with one example of the present disclosure;

[0085] **FIG. 2** is an exploded side view of the rotary blood pump shown in **FIG. 1** shown without a lower housing portion;

[0086] **FIG. 3** is a perspective view of an inlet housing of the rotary blood pump shown in **FIG. 1**;

[0087] **FIG. 4A** is a top view of the inlet housing shown in **FIG. 3**;

[0088] **FIG. 4B** is a bottom view of the inlet housing shown in **FIG. 3**;

[0089] **FIG. 4C** is a detailed top view of the inlet housing of **FIG. 3** showing a strut;

[0090] **FIG. 5A** is a side cross-sectional view of the inlet housing shown in **FIG. 3**;

[0091] **FIG. 5B** is a longitudinal cross-sectional view of the strut taken along line **A-A** in **FIG. 4C**;

[0092] **FIG. 5C** is a lateral cross-sectional view of the strut taken along line **B-B** in **FIG. 4C**;

[0093] **FIG. 6** is a perspective view of an impeller of the rotary blood pump shown in **FIG. 1**;

[0094] **FIG. 7** is a side view of the impeller shown in **FIG. 6**;

[0095] **FIG. 8** is a top view of the impeller shown in **FIG. 6**;

[0096] **FIG. 9** is a side cross-sectional view of the impeller shown in **FIG. 6**;

[0097] **FIG. 10** is an exploded side view of the impeller shown in **FIG. 6**;

[0098] **FIG. 11** is a pressure distribution graph showing static pressure at various portions of the inlet housing; and

[0099] **FIG. 12** is a top view of the inlet housing showing a net force diagram based on static pressure values from **FIG. 11**.

DETAILED DESCRIPTION OF THE INVENTION

[00100] The illustrations generally show preferred and non-limiting examples of the apparatus and methods of the present disclosure. While the description presents various aspects of the apparatus, it should not be interpreted in any way as limiting the disclosure. Furthermore, modifications, concepts, and applications of the disclosure's aspects are to be interpreted by those skilled in the art as being encompassed by, but not limited to, the illustrations and descriptions herein.

[00101] The following description is provided to enable those skilled in the art to make and use the described examples contemplated for carrying out the disclosure. Various modifications, equivalents, variations, and alternatives, however, will remain readily apparent to those skilled in the art. Any and all such modifications, variations, equivalents, and alternatives are intended to fall within the spirit and scope of the present disclosure.

[00102] For purposes of the description hereinafter, the terms “upper”, “lower”, “right”, “left”, “vertical”, “horizontal”, “top”, “bottom”, “lateral”, “longitudinal”, and derivatives thereof shall relate to the disclosure as it is oriented in the drawing figures.

[00103] As used herein, the term “substantially parallel” means a relative angle as between two objects (if extended to theoretical intersection), such as elongated objects and including reference lines, that is from 0° to 5°, or from 0° to 3°, or from 0° to 2°, or from 0° to 1°, or from 0° to 0.5°, or from 0° to 0.25°, or from 0° to 0.1°, inclusive of the recited values.

[00104] As used herein, the term “substantially perpendicular” means a relative angle as between two objects (if extended to theoretical intersection), such as elongated objects and including reference lines, that is from 85° to 90°, or from 87° to 90°, or from 88° to 90°, or from 89° to 90°, or from 89.5° to 90°, or from 89.75° to 90°, or from 89.9° to 90°, inclusive of the recited values.

[00105] It is to be understood, however, that the disclosure may assume alternative variations and step sequences, except where expressly specified to the contrary. It is also to be understood that the specific devices and processes illustrated in the attached drawings, and described in the following specification, are simply exemplary aspects of the disclosure. Hence, specific dimensions and other physical characteristics related to the examples disclosed herein are not to be considered as limiting.

[00106] It should be understood that any numerical range recited herein is intended to include all sub-ranges subsumed therein. For example, a range of “1 to 10” is intended to include all sub-ranges between (and including) the recited minimum value of 1 and the recited maximum value of 10, that is, having a minimum value equal to or greater than 1 and a maximum value of equal to or less than 10.

[00107] In this application, the use of the singular includes the plural and plural encompasses singular, unless specifically stated otherwise. In addition, in this application, the use of “or” means “and/or” unless specifically stated otherwise, even though “and/or” may be explicitly used in certain instances. Further, in this application, the use of “a” or “an” means “at least one” unless specifically stated otherwise. The term “at least” is synonymous with “greater than or equal to”.

As used herein, "at least one of" is synonymous with "one or more of". For example, the phrase "at least one of A, B, and C" means any one of A, B, or C, or any combination of any two or more of A, B, or C. For example, "at least one of A, B, and C" includes one or more of A alone; or one or more B alone; or one or more of C alone; or one or more of A and one or more of B; or one or more of A and one or more of C; or one or more of B and one or more of C; or one or more of all of A, B, and C.

[00108] Referring to the drawings, in which like reference characters refer to the like parts throughout the several views thereof, **FIG. 1** illustrates a rotary blood pump **10** in accordance with one example of the present invention. The rotary blood pump **10** may be used, for example, in an extracorporeal circuit for supporting the function of a patient's heart and/or lungs. Generally, the rotary blood pump **10** has a pump housing **12** with an upper or inlet housing portion **14** and a lower or outlet housing portion **16**. The inlet housing portion **14** and the outlet housing portion **16** may be removably or non-removably coupled together and define a pumping chamber **18** therebetween. In some examples, the inlet housing portion **14** is formed as a separate component that is removably or non-removably secured to the outlet housing portion **16** (see **FIG. 2**). The pumping chamber **18** may have a substantially cylindrical structure defined by a sidewall **24** extending circumferentially around a central longitudinal axis **26**.

[00109] With continued reference to **FIG. 1**, the inlet housing portion **14** has an inlet **20** that is in fluid communication with the pumping chamber **18** for delivering blood into the pumping chamber **18**. The inlet **20** has a tubular shape with an inlet axis **42** that is substantially parallel with the central longitudinal axis **26** of the pumping chamber **18**. The inlet **20** may have a circular cross-sectional shape, an oval cross-sectional shape, or any other geometric shape, such as polygonal. In some examples, the inlet axis **42** may be angled relative to the central longitudinal axis **26**. The inlet axis **42** may be substantially coaxial with the central longitudinal axis **26**. In some examples, the inlet axis **42** may be offset radially relative to the central longitudinal axis **26**. The inlet **20** has one or more barbs **30** or other connection elements to facilitate connecting with an inlet tube (not shown).

[00110] With continued reference to **FIG. 1**, the outlet housing portion **16** has an outlet **22** in fluid communication with the pumping chamber **18** for delivering blood from the pumping chamber **18**. The outlet **22** has a tubular shape with an outlet axis **44** that is substantially perpendicular relative to the central longitudinal axis **26** of the pumping chamber **18**. The outlet

22 may have a circular cross-sectional shape, an oval cross-sectional shape, or any other geometric shape, such as polygonal. In some examples, the outlet axis **44** may be angled relative to the central longitudinal axis **26** and/or the inlet axis **42**. The outlet **22** has one or more barbs **30** or other connection elements to facilitate connecting with an outlet tube (not shown).

[00111] With continued reference to **FIG. 1**, an impeller **34** is rotatably supported within the pumping chamber **18** and is configured for pumping blood from the inlet **20** to the outlet **22**. The impeller **34** is rotatably driven by a drive mechanism **36**. As described herein, the drive mechanism **36** is configured to rotate the impeller **34** about the central longitudinal axis **26** such that the impeller **34** pumps blood from the inlet **20** to the outlet **22**. The impeller **34** is rotatably supported within the pumping chamber **18** by a bearing mechanism **38**. As described herein, the bearing mechanism **38** assists in positioning the impeller **34** within the pumping chamber **18** such that the impeller **34** rotates about the central longitudinal axis **26** without touching the sidewall **24** of the pumping chamber **18**.

[00112] With reference to **FIG. 3**, the inlet housing portion **14** has a cover **40** that encloses the pumping chamber **18**. The inlet **20** is monolithically formed with the cover **40** and protrudes therefrom in a direction of inlet axis **42**. As described herein, the inlet axis **42** may be substantially parallel with the central longitudinal axis **26** (shown in **FIG. 2**). The cover **40** may have a substantially circular shape with at least a portion of the outlet **22** extending tangentially from an outer circumference of the cover **40** in a direction of an outlet axis **44**. As described herein, the inlet axis **42** and the outlet axis **44** may be substantially perpendicular to one another. In some examples, the cover **40** may have a first portion of the outlet **22** while the outlet housing portion **16** (shown in **FIG. 1**) may have a second portion of the outlet **22** such that, when combined, the cover **40** and the outlet housing portion **16** together define the outlet **22**. In some examples, the cover **40** may have a circumferential groove **32** (shown in **FIG. 5**) that interacts with a corresponding projection on the outlet housing portion **16** to position the cover **40** over the outlet housing portion **16**.

[00113] With reference to **FIGS. 4A-4B**, the inlet housing portion **14** has at least one strut **46** connected to an inner sidewall **48** and extending radially inward toward the inlet axis **42**. For example, the strut **46** may be monolithically formed with the inlet housing portion **14**, or it may be formed as a separate component that is removably or non-removably connected to the inner sidewall **48** of the inlet **20**. The strut **46** has a single connection point with the inner sidewall **48**

of the inlet **20** in a circumferential direction around the inlet axis **42** when viewed in a cross-sectional plane perpendicular to the inlet axis **42**. With reference to **FIG. 4C**, the strut **46** has a first radial end **46a** connected to the inner sidewall **48** of the inlet **20** and a second radial end **46b** protruding a radially inward from the first radial end **46a** and toward the inlet axis **42**. In some examples, the first radial end **46a** of the strut **46** is connected to the inner sidewall **48** of the inlet housing portion **14** at a circumferential position about the inlet axis **42** such that a major axis of the strut **46** between the first radial end **46a** and the second radial end **46b** and the outlet axis **44** define a predetermined angle **α** in the cross-sectional plane perpendicular to the inlet axis **42**, such as shown in **FIGS. 4A-4B**. The major axis of the strut **46** between the first radial end **46a** and the second radial end **46b** may be coincident with the inlet axis **42**. In some examples, the predetermined angle **α** has an absolute value of about 0° to about 135°, preferably about 15° to about 90°, more preferably about 30° to about 60°, more preferably about 40° to about 50°, more preferably about 43° to about 47°, such as about 45°. The predetermined angle **α** is based on an orientation of the strut **46** wherein the second radial end **46b** of the strut **46** extends in a direction toward the outlet axis **44** rather than away from the outlet axis **44**, or wherein the second radial end **46b** of the strut **46** extends in a direction away from the outlet axis **44** rather than toward the outlet axis **44**.

[00114] With reference to **FIGS. 5A-5C**, the first radial end **46a** of the strut **46** may be connected to the inner sidewall **48** of the inlet **20** along a connection surface **47** that is substantially parallel with the inlet axis **42**. As shown in **FIG. 5B**, a first axial end **49a** of the strut **46** is positioned proximate to the inlet **20** (shown in **FIG. 3**) at an angle **β** relative to the inlet axis **42** when viewed in a cross-sectional plane parallel to the inlet axis **42**. The angle **β** is about 15° to about 75°, preferably about 30° to about 60°, more preferably about 40° to about 50°, such as about 45°. The angle **β** is configured to smooth the blood flow around the strut **46** at a leading end of the strut **46** defined by the first axial end **49a**. A second axial end **49b** of the strut **46** is positioned opposite the first axial end **49a**. The second axial end **49b** of the strut **46** is positioned proximate to the outlet **22** (shown in **FIG. 3**) at an angle γ relative to the inlet axis **42** when viewed in a cross-sectional plane parallel to the inlet axis **42**. The angle γ is about 15° to about 75°, preferably about 30° to about 60°, more preferably about 40° to about 50°, such as about 45°. The angle γ is configured to smooth the blood flow around the strut **46** at a trailing end of the strut **46** defined by the second axial end **49b**. A terminal portion **50** of the second axial end **49b** is positioned substantially coaxially with the inlet axis **42**. The terminal portion **50** has a bearing support member **51** configured for supporting at least a portion of an axial bearing. As described herein, the axial bearing is configured for supporting the axial load on the impeller **34** directed along the inlet axis **42**.

[00115] With reference to **FIG. 5C**, the strut **46** is desirably shaped to reduce flow stagnation around the strut **46**. In some examples, at least a portion of the strut **46** has a teardrop or an airfoil cross-sectional shape. In such examples, the first axial end **49a** defines a leading edge or end, while the second axial end **49b** defines a trailing edge or end. The strut **46** may gradually widen from the first axial end **49a** to a maximum thickness point **T**, and then gradually narrow from the maximum thickness point **T** to the second axial end **49b** along a chord line **C**. The chord line **C** is substantially parallel with the inlet axis **42**. By varying the position of the maximum thickness point **T** between the first and second axial ends **49a, 49b**, a pressure profile of the strut **46** can be changed to reduce or eliminate damage to the blood cells within the blood flowing around the strut **46**.

[00116] Without intending to be bound by theory, it has been found that positioning the strut **46** at the predetermined angle **α**, particularly in the range a range of about 45°, reduces or eliminates fluttering or vibration of the strut **46** due to blood flowing through the inlet **20** during pump operation. Such fluttering or vibration of the strut **46** may lead to premature damage or failure of the strut **46**, in addition to disrupting the blood flow around the strut **46**. While it is possible to reduce such vibration of the strut **46** by making the strut **46** and the inlet housing **14** from a high strength material, such as stainless steel or titanium, positioning the strut **46** at the predetermined angle **α** allows the strut **46** and the inlet housing **14** to be made from a lower strength material, such as medical grade plastic.

[00117] The circumferential position of the strut **46** relative to the inlet axis **42** is chosen to minimize or eliminate static pressure on the strut **46** which may cause a deflection, vibration, or wobble of the strut **46** in a radial direction relative to the inlet axis **42**. With reference to **FIG. 11**, a pressure distribution graph shows a static pressure (in mmHg) at various points of the inlet housing portion **14** (shown in **FIG. 3**) during pump operation at 5 l/min for various pump rotations per minute (rpm) ranging from 3,500 rpm to 7,500 rpm. Pressure spots **A-O** in the graph represent various positions on the inlet housing portion **14** at which measurements were taken, with points **A-H** measuring the static pressure at positions surrounding the inlet axis **42** of the inlet **20** and leading to the outlet **22**. By plotting the resultant pressure measurements as force vectors around the inlet axis **42** of the inlet housing **14**, it can be seen in **FIG. 12** that various circumferential positions on the inner sidewall **48** of the inlet **14** are subject to various pressures. Positioning the strut **46** at a circumferential position about the inlet axis **42** such that a major axis of the strut **46** and the outlet axis **44** define a predetermined angle **α** in the cross-sectional plane perpendicular to the inlet axis **42** minimizes or eliminates the net side or radial loads on the strut **46** which lead to strut vibration or fluttering. In this manner, damage to blood (such as thrombosis of blood) due to strut vibration or fluttering is reduced or eliminated.

[00118] With reference to **FIGS. 6-8**, the impeller **34** has a generally cylindrical shape that corresponds to the shape of the pumping chamber **18** (shown in **FIG. 1**). The impeller **34** has a plurality of blades **52** at an upper end thereof that are configured for pumping blood from the inlet **20** toward the outlet **22**. In some examples, the impeller **34** has six blades **52** radially spaced apart at equal or unequal angular intervals. The blades **52** may be identical to each other. In some examples, a first subset **52a** of blades **52** may be different from a second subset **52b** of blades **52**. The first and second subsets **52a, 52b** of blades **52** may be arranged in an alternating manner (see **FIG. 8**). The blades **52** may be substantially planar. In some examples, the blades **52** may be curved.

[00119] With reference to **FIGS. 9-10**, the impeller **34** has a hollow central portion **54** surrounded by an outer shell **56**. The hollow central portion **54** is disposed within a hollow interior of the outer shell **56**. In some examples, the hollow central portion **54** and the outer shell **56** may be formed as separate components which are removably or non-removably connected together. A cap **58** having the blades **52** is positioned on an upper end of the outer shell **56**. The cap **58** encloses at least a portion of the hollow interior of the outer shell **56**.

[00120] With particular reference to **FIG. 9**, the hollow central portion **54** has at least one passage **60** that is substantially coaxial with the central longitudinal axis **26** (shown in **FIG. 1**). The at least one passage **60** is in fluid communication with the pumping chamber **18** via one or more openings **62** on an end piece **64** at an upper end of the hollow central portion **54**. The at least one passage **60** defines a portion of a secondary flow path, as discussed herein. During operation of the blood pump **10**, the impeller **34** delivers a first portion of blood flow from the inlet **20** directly to the outlet **22**, and delivers a second portion of the blood flow from the inlet **20** to the outlet **22** via the at least one passage **60** and the one or more openings **62** on the end piece **64**. In some examples, the at least one passage **60** is shaped such that its diameter increases in a direction from an upper end to a lower end. In other examples, the at least one passage **60** may have a uniform diameter throughout its length.

[00121] With reference to **FIGS. 9-10**, the impeller **34** has a first bearing magnet **66** at a lower end thereof. The first bearing magnet **66** may be disposed in a first cavity **68** between the hollow central portion **54** and the outer shell **56**. In some examples, the first bearing magnet **66** engages a lower skirt **70** that surrounds a central post **72** of the hollow central portion **54**. The first bearing magnet **66** is desirably a permanent magnet. In some examples, the first bearing magnet **66** has an annular shape comprised from a single, monolithically formed element. In other examples, the first bearing magnet **66** may be formed from a plurality of discrete magnet segments. For example, the first bearing magnet **66** may have a plurality of arcuate segments having an equal or unequal angular span. The first bearing magnet **66** is configured to magnetically interact with a second bearing magnet associated with the pump housing **12**, as described herein.

[00122] With continued reference to **FIGS. 9-10**, the impeller **34** has a rotor magnet **74** axially spaced apart from the first bearing magnet **66**. A spacer **80** (shown in **FIG. 9**) may be provided to axially separate the first bearing magnet **66** from the rotor magnet **74**. In some examples, the spacer **80** is monolithically formed with the outer shell **56**. In other examples, the spacer **80** is removably or non-removably insertable into a hollow interior of the outer shell **56**.

[00123] With continued reference to **FIGS. 9-10**, the rotor magnet **74** may be disposed in a second cavity **76** between the hollow central portion **54** and the outer shell **56**. In some examples, the rotor magnet **74** is at least partially supported on a lip **78** extending radially outward from the central post **70** of the hollow central portion **54**. The rotor magnet **74** is desirably a permanent magnet. In some examples, the rotor magnet **74** has an annular shape comprised from a plurality of discrete magnet segments. For example, the rotor magnet **74** may have a plurality of arcuate segments having an equal or unequal angular span. In some examples, the rotor magnet **74** has four magnet segments each spanning 90°. The magnet segments may form a continuous shape. In some examples, the magnet segments are separate from each other by predetermined spacing.

[00124] With reference to **FIG. 1**, the rotor magnet **74** is configured to magnetically interact with an electromagnetic coil **82** associated with the pump housing **12** to rotatably drive the impeller **34** within the pump housing **12**, as described herein. Together, the rotor magnet **74** and the electromagnetic coil **82** define the drive mechanism **36**. The rotor magnet **74** is desirably positioned radially opposite the electromagnetic coil **82** such that no net axial force is imparted on the impeller **34** during pump operation. In some examples, any axial force on the impeller **34** due to interaction between the rotor magnet **74** and the electromagnetic coil **82** may be compensated by the bearing mechanism **38**, as described herein. The electromagnetic coil **82** is selectively energized to cause the rotor magnet **74** to spin and thereby rotate the impeller **34** about the central longitudinal axis **26**. Operation of the electromagnetic coil **82**, such as the current and/or voltage it receives, is controlled by a controller **84**. The controller **84** is operative for controlling the speed at which the impeller **34** is rotated due to interaction between the rotor magnet **74** and the electromagnetic coil **82**.

[00125] With continued reference to **FIG. 1**, the bearing mechanism **38** has a radial bearing **86** having the first bearing magnet **66** associated with the impeller **34** and a second bearing magnet **88** associated with the pump housing **12**. The first bearing magnet **66** is coaxial with and magnetically interacts with the second bearing magnet **88** to radially position the impeller **34** within the pumping chamber **18**. In particular, the first and second bearing magnets **66**, **88** are configured to provide radial stability to the impeller **34** so that the impeller **34** does not contact the sidewall **24** of the pump housing **12** during rotation. The second bearing magnet **88** is desirably a permanent magnet. In some examples, the second bearing magnet **88** has an annular shape comprised from a single, monolithically formed element. In other examples, the second bearing magnet **88** may be formed from a plurality of discrete magnet segments. For example, the second bearing magnet **88** may have a plurality of arcuate segments having an equal or unequal angular span.

[00126] In some examples, the first bearing magnet **66** and the second bearing magnet **88** are positioned, for example coaxially arranged and axially offset, such that a net axial thrust force urges the impeller **34** in a direction toward the inlet **20**. The net axial thrust force may be generated due to an axial offset between the first bearing magnet **66** and the second bearing magnet **88**, a difference in magnetic properties, such as magnetic strength, between the first bearing magnet **66** and the second bearing magnet **88**, or a combination thereof. In some examples, the axial offset between the first bearing magnet **66** and the second bearing magnet **88** may be such that the impeller **34** is urged in a direction along the central longitudinal axis **26** toward the inlet **20** with an axial thrust force of sufficient magnitude to axially support the weight of the impeller **34** during operation against an axial bearing **90**, and without the engagement between the components of the axial bearing **90** which may generate heat of a degree that may lead to excessive heating of the blood (such as above 42 °C) that flows around the axial bearing **90** that could cause damage to the blood cells.

[00127] With continued reference to **FIG. 1**, the axial bearing **90** is a mechanical bearing that is configured to take up the axial thrust force due to magnetic interaction between the first bearing magnet **66** and the second bearing magnet **88**. The axial bearing **90** has a first bearing element **92** associated with the impeller **34** and a second bearing element **94** associated with the strut **46** connected to the inlet housing portion **14**. In some examples, the first bearing element **92** is ball-shaped and the second bearing element **94** is cup-shaped to receive at least a portion of the ball-shaped first bearing element **92**. Alternatively, the second bearing element **94** is ball-shaped and the first bearing element **92** is cup-shaped to receive at least a portion of the ball-shaped second bearing element **94**. The first bearing element **92** and the second bearing element **94** are shaped to allow a slight pivoting movement about the axial bearing **90** to allow for radial centering of the impeller **34** during pump operation. The axial thrust force generated by the magnetic interaction between the first bearing magnet **66** and the second bearing magnet **88** is transferred to the pump housing **12** by way of the axial bearing **90** and the strut **46**.

[00128] With reference to **FIG. 9**, the first bearing element **92** may be a ball supported on a post **72** connected to the end piece **64** of the hollow central portion **54** of the impeller **34**. In some examples, the first bearing element **92** is a jewel bearing, such as a ruby ball.

[00129] With reference to **FIG. 5**, the second bearing element **94** may be a cup that is formed at the terminal end **50** of the strut **46**. The second bearing element **94** may be removably or non-removably connected to the terminal end **50** of the strut **46**. In some examples, the second bearing element **94** is made from a ceramic material.

[00130] In operation, the rotor magnet **74** magnetically interacts with an electromagnetic coil **82** associated with the pump housing **12** to rotatably drive the impeller **34** within the pump housing **12**. Blood flowing through the inlet **20** flows around the strut **46** and washes over the axial bearing **90**, thereby cooling the axial bearing **90**. As described herein, the strut **46** is desirably shaped to reduce flow stagnation around the strut **46**, as well as eliminate fluttering or vibration as the blood flows around the strut **46**.

[00131] As the blood enters the pumping chamber **18** through the inlet **20**, the impeller blades **52** pump the blood in a radially outward direction relative to the inlet axis **42** to direct a first portion of the blood flow comprising a majority of the blood entering the pumping chamber **18** toward the outlet **22**. A second portion of the blood flow passes through a radial gap **96** between the sidewall **24** of the pumping chamber **12** and the outer surface of the cylindrical portion of the impeller **34** as a secondary fluid path. This secondary flow path allows blood to pass to the bottom **98** of the pumping chamber **12**. In some examples, the bottom **98** of the pumping chamber **12** may have a deflector **100** to direct blood flow in the secondary flow path to the at least one passage **60**. The blood in the secondary flow path then flows axially through the at least one passage **60** in a direction toward the inlet **20** to the bottom of the axial bearing **90** through the one or more openings **62** on the end piece **64** of the hollow central portion **54** of the impeller **34**. This reduces blood stagnation and incidence of thrombus formation. The blood flow from the secondary flow path then enters the pumping chamber **18** before exiting the pumping chamber **18** through the outlet **22**.

[00132] While examples of a rotary blood pump are provided in the foregoing description, those skilled in the art may make modifications and alterations to these examples without departing from the scope and spirit of the disclosure. Accordingly, the foregoing description is intended to be illustrative rather than restrictive. The disclosure described hereinabove is defined by the appended claims, and all changes to the disclosure that fall within the meaning and the range of equivalency of the claims are to be embraced within their scope.

WE CLAIM:

1. A centrifugal blood pump comprising:

a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber;

an impeller rotatably disposed within the pumping chamber;

a bearing mechanism supporting the impeller within the pumping chamber; and

a strut connected to the housing at the inlet to support at least a portion of the bearing mechanism,

wherein the strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis to reduce or eliminate damage to blood flowing around the strut.

2. The centrifugal blood pump of claim 1, wherein the strut has a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis.

3. The centrifugal blood pump of claim 1, wherein the predetermined angle is about 15° to about 75°.

4. The centrifugal blood pump of claim 1, wherein at least a portion of the strut has a teardrop cross-sectional shape.

5. The centrifugal blood pump of claim 1, wherein the impeller has at least one passage defining a secondary flow path.

6. The centrifugal blood pump of claim 5, wherein the at least one passage is substantially perpendicular to the outlet axis.

7. The centrifugal blood pump of claim 5, wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet,

and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

8. The centrifugal blood pump of claim 1, wherein the bearing mechanism comprises:

a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and

an axial bearing comprising a first bearing element associated with the impeller and a second bearing element connected to the strut.

9. The centrifugal blood pump of claim 8, wherein the first bearing element is ball-shaped and the second bearing element is cup-shaped to receive at least a portion of the ball-shaped first bearing element or the second bearing element is ball-shaped and the first bearing element is cup-shaped to receive at least a portion of the ball-shaped second bearing element.

10. The centrifugal blood pump of claim 8, wherein the first bearing element is a jewel bearing.

11. The centrifugal blood pump of claim 8, wherein the second bearing element is made from a ceramic material.

12. The centrifugal blood pump of claim 8, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

13. The centrifugal blood pump of claim 1, further comprising a motor mechanism for rotating the impeller within the pumping chamber, the motor mechanism having a permanent magnet rotor associated with the impeller and an electromagnetic coil stator associated with the housing.

14. A centrifugal blood pump comprising:

a housing having a pumping chamber, an inlet with an inlet axis, and an outlet with an outlet axis, the inlet and the outlet being in fluid communication with the pumping chamber;

an impeller rotatably disposed within the pumping chamber and having at least one passage defining a secondary flow path extending in a direction substantially parallel to the inlet axis; and

a bearing mechanism supporting the impeller within the pumping chamber;

wherein, during operation of the blood pump, the impeller delivers a first portion of blood flow from the inlet directly to the outlet, and delivers a second portion of the blood flow from the inlet to the outlet via the at least one passage.

15. The centrifugal blood pump of claim 14, wherein the at least one passage defining the secondary flow path is substantially perpendicular to the outlet axis.

16. The centrifugal blood pump of claim 14, further comprising a strut connected to the housing at the inlet to support at least a portion of the bearing mechanism, wherein the strut is connected to the housing at a circumferential position about the inlet axis such that a major axis of the strut and the outlet axis define a predetermined angle in a cross-sectional plane perpendicular to the inlet axis.

17. The centrifugal blood pump of claim 16, wherein the strut has a single connection point with the housing in the cross-sectional plane perpendicular to the inlet axis.

18. The centrifugal blood pump of claim 16, wherein the predetermined angle is about 15° to about 75°.

19. The centrifugal blood pump of claim 14, wherein the bearing mechanism comprises:

a radial bearing having a first permanent magnet associated with the impeller and a second permanent magnet associated with the housing, the first permanent magnet magnetically interacting with the second permanent magnet to radially position the impeller within the pumping chamber; and

an axial bearing comprising a first bearing element associated with the impeller and a second bearing element connected to the strut.

20. The centrifugal blood pump of claim 19, wherein the first permanent magnet is axially offset relative to the second permanent magnet by a predetermined distance to urge the impeller in a direction toward the inlet with a predetermined axial force.

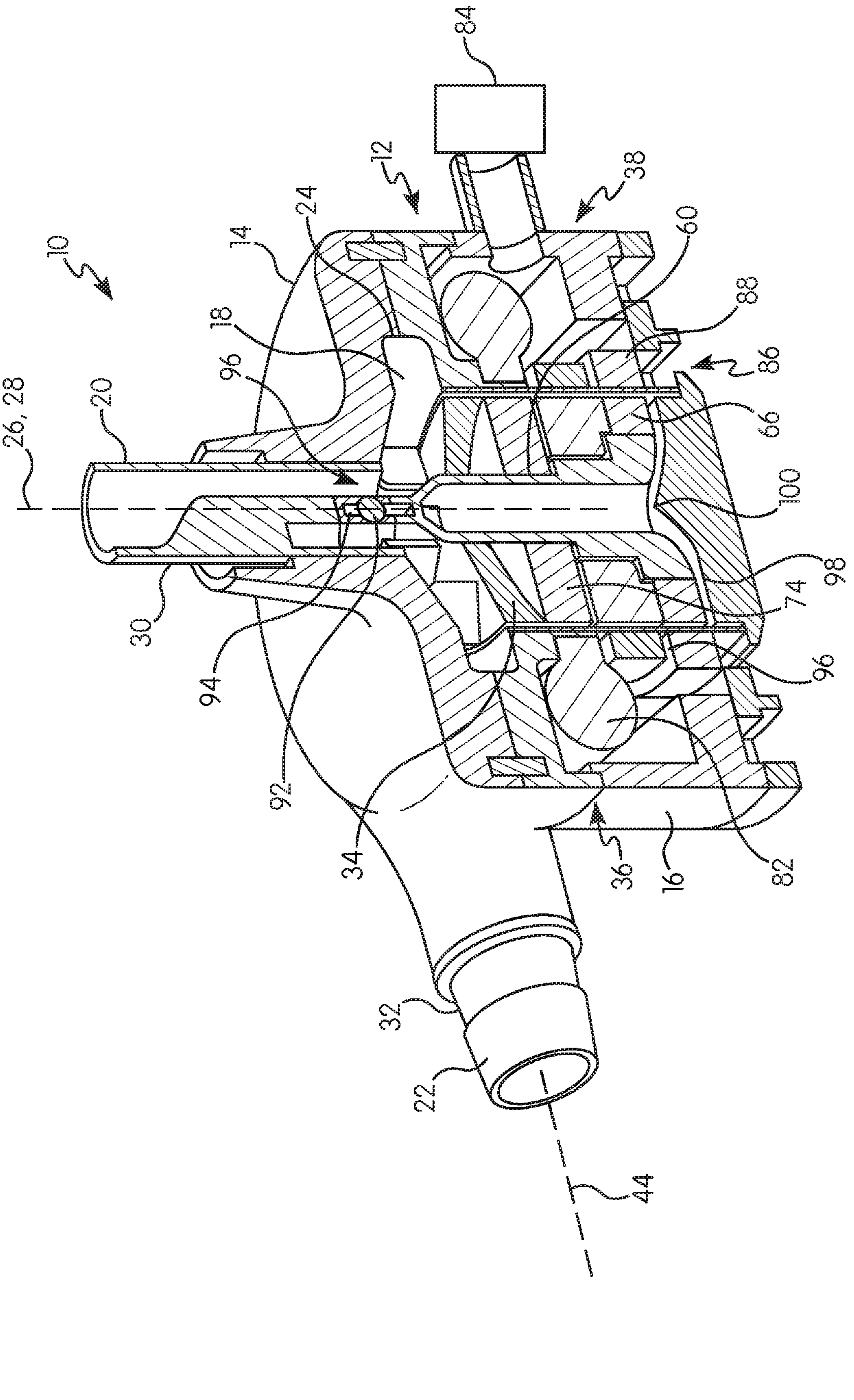
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FIG. 1

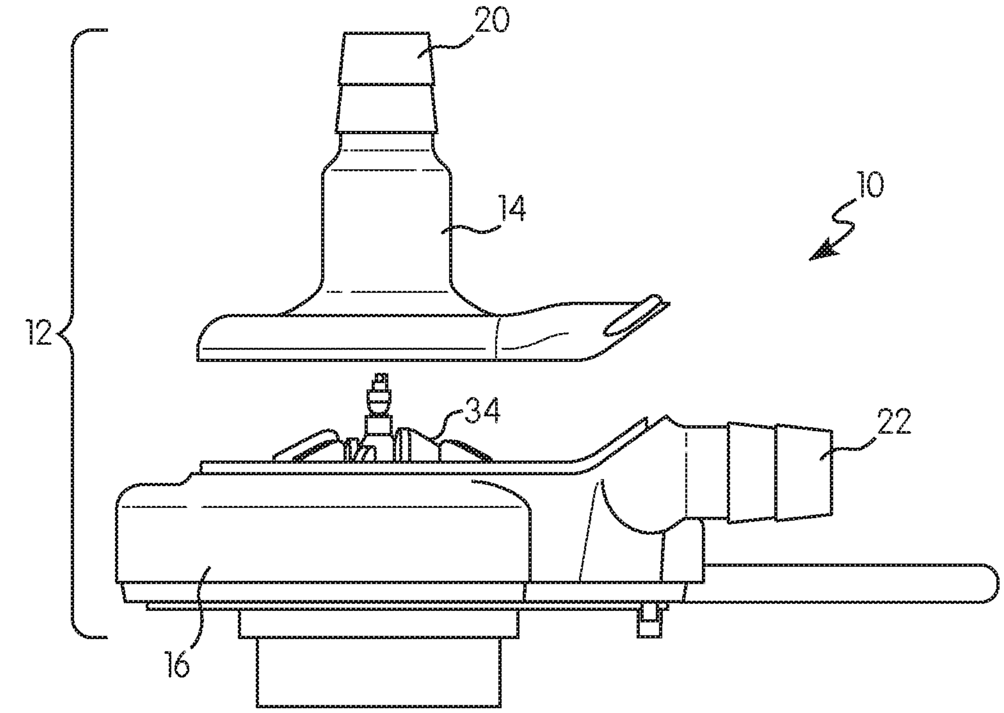

FIG. 2

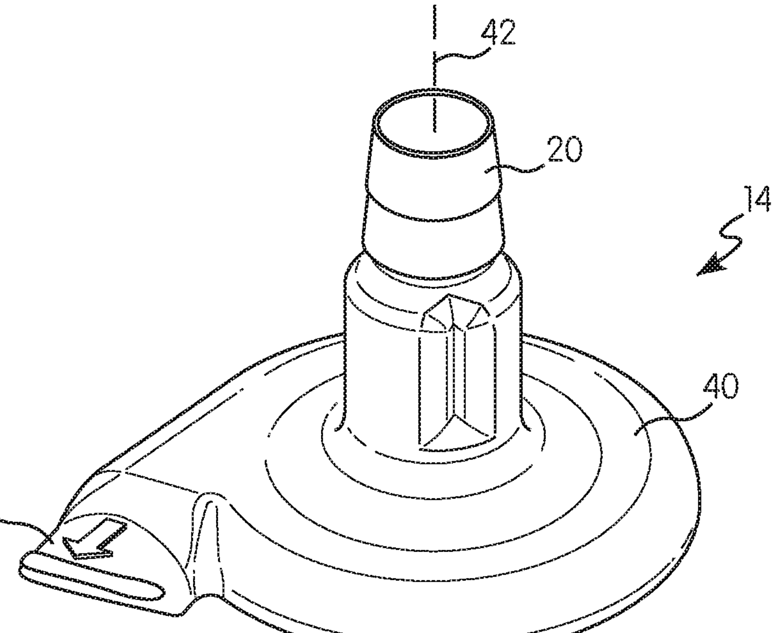

FIG. 3

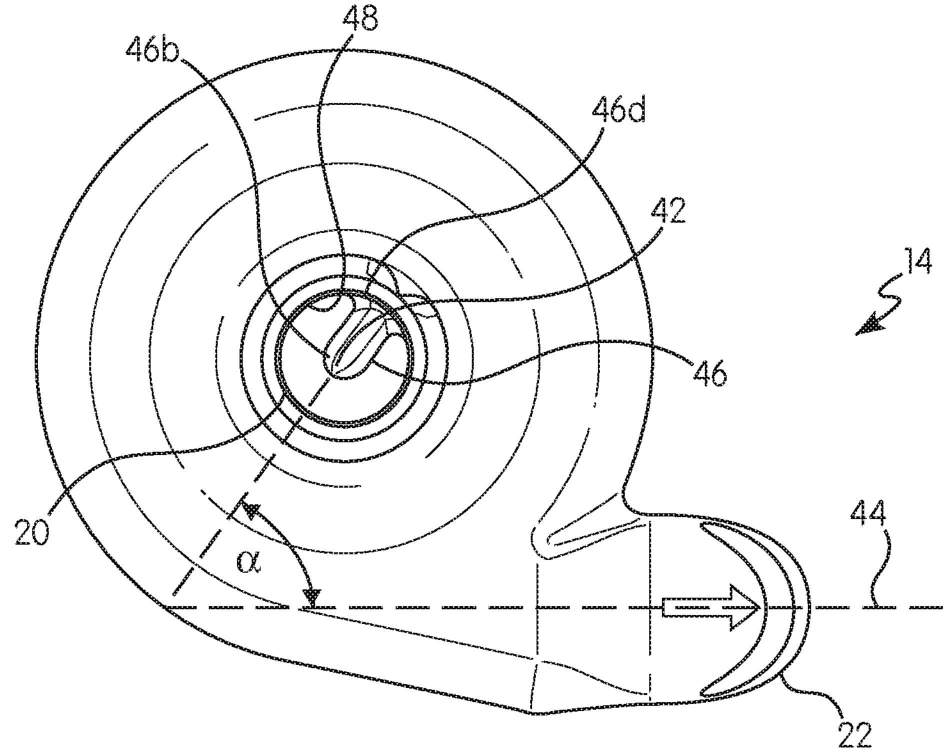

FIG. 4A

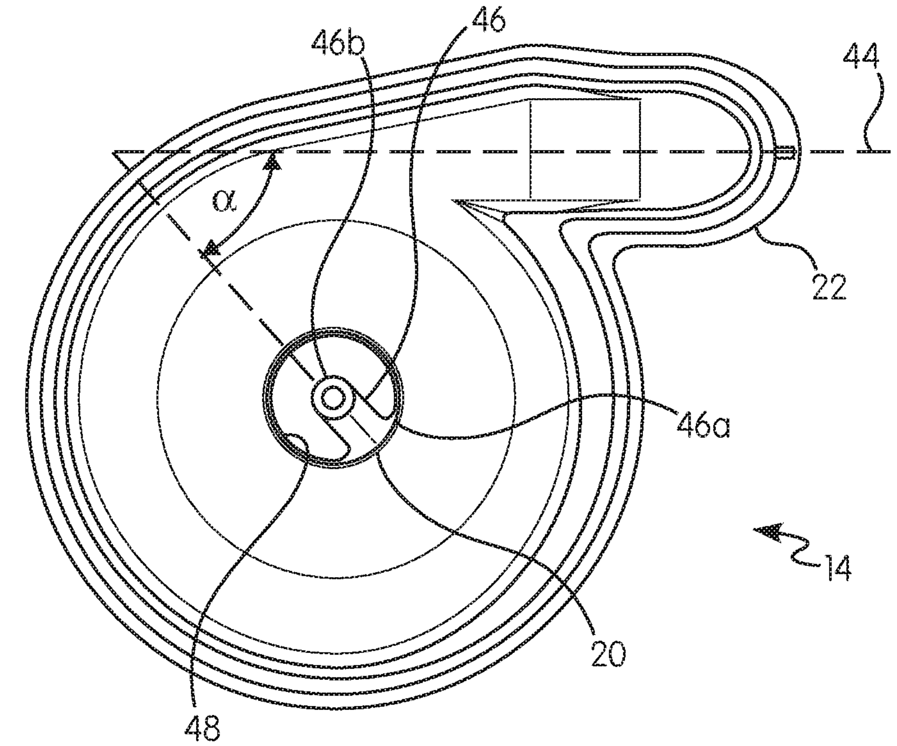

FIG. 4B

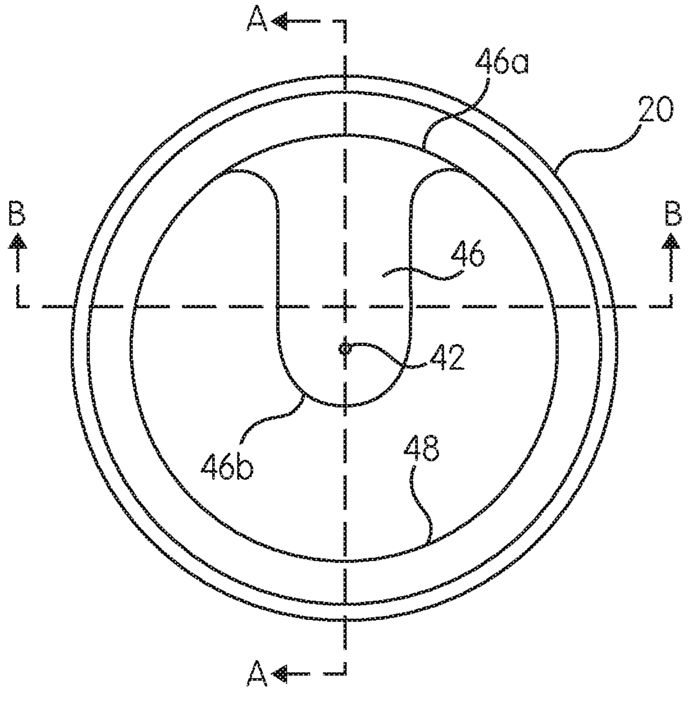

FIG. 4C

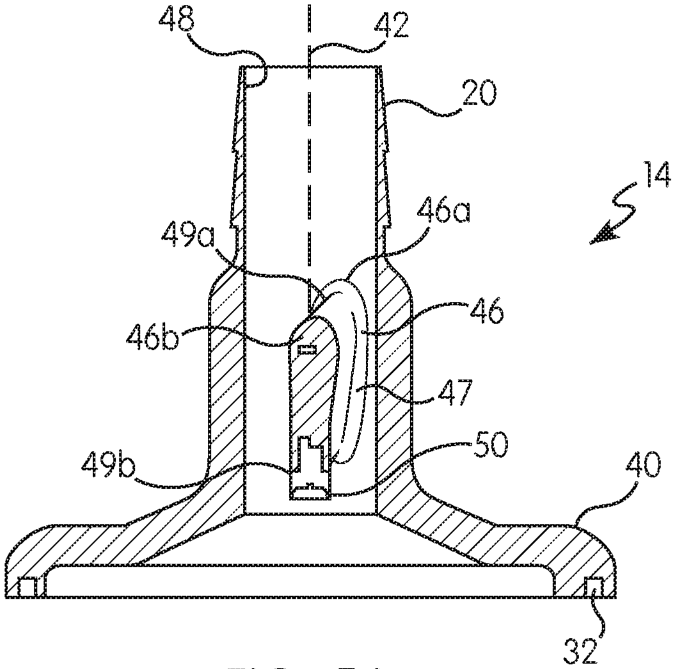

FIG. 5A

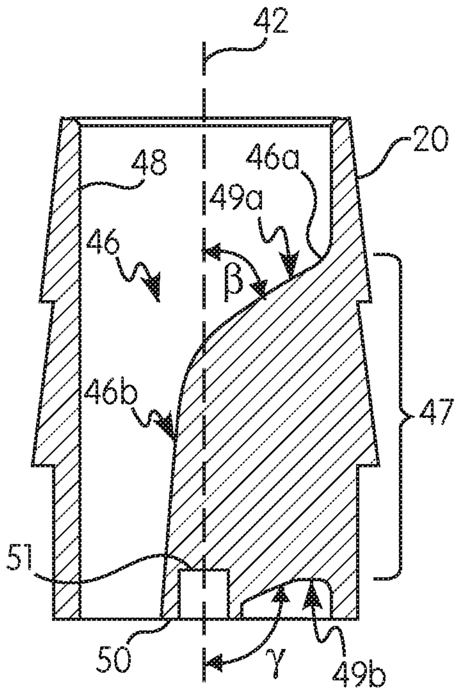

FIG. 5B

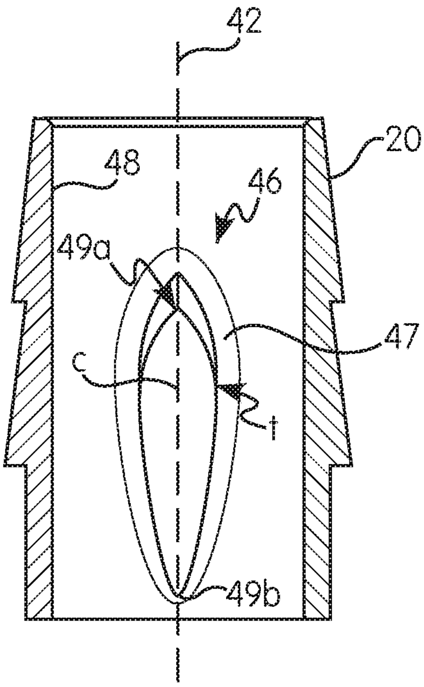

FIG. 5C

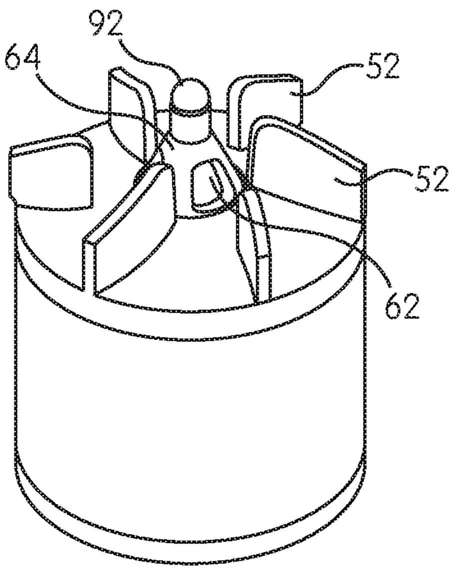

FIG. 6

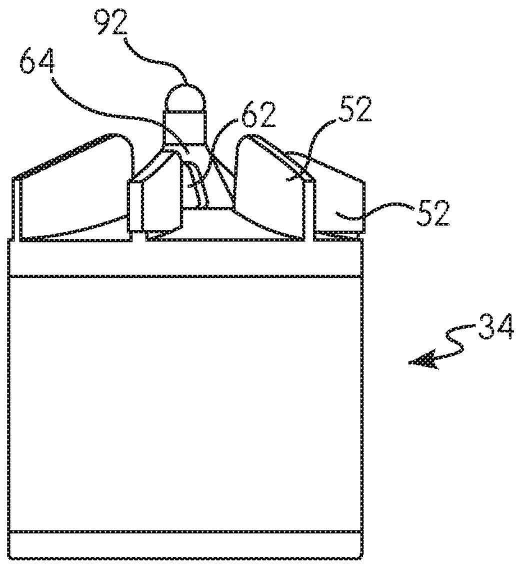

FIG. 7

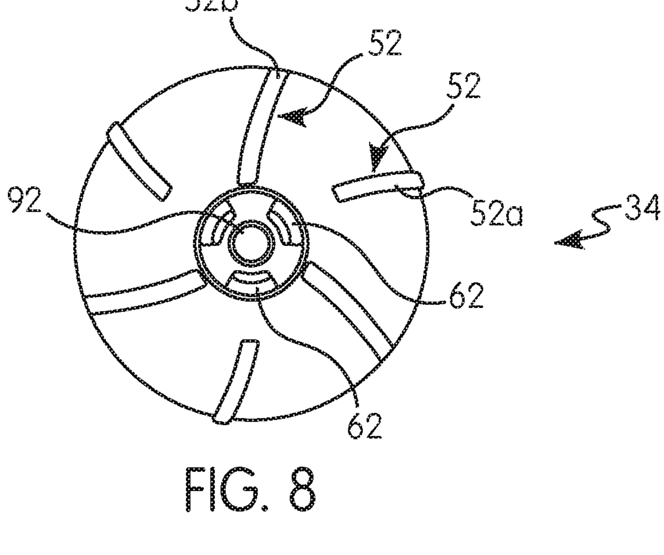

FIG. 8

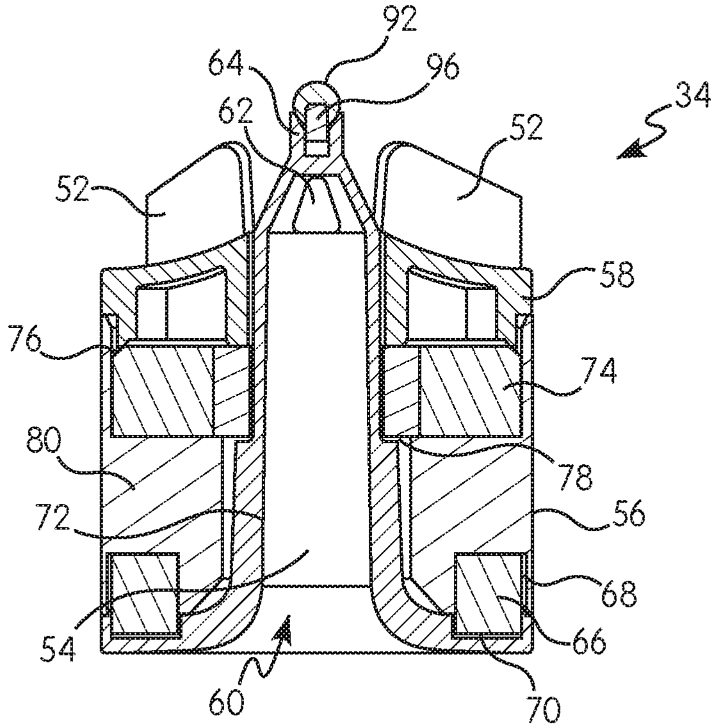
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FIG. 9

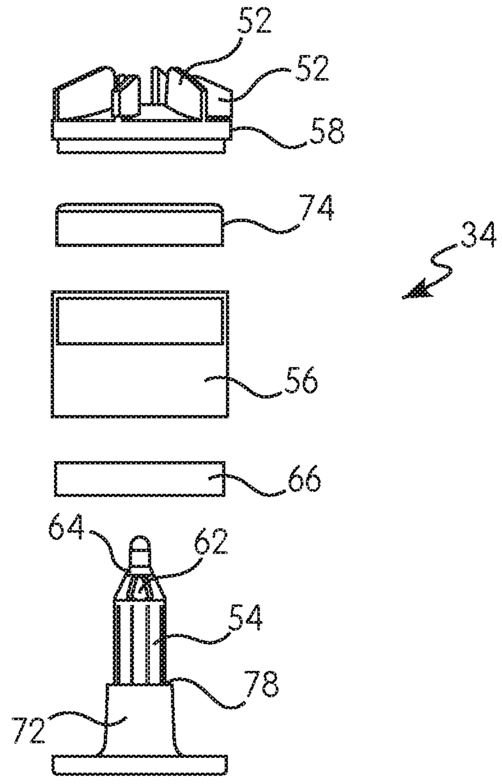
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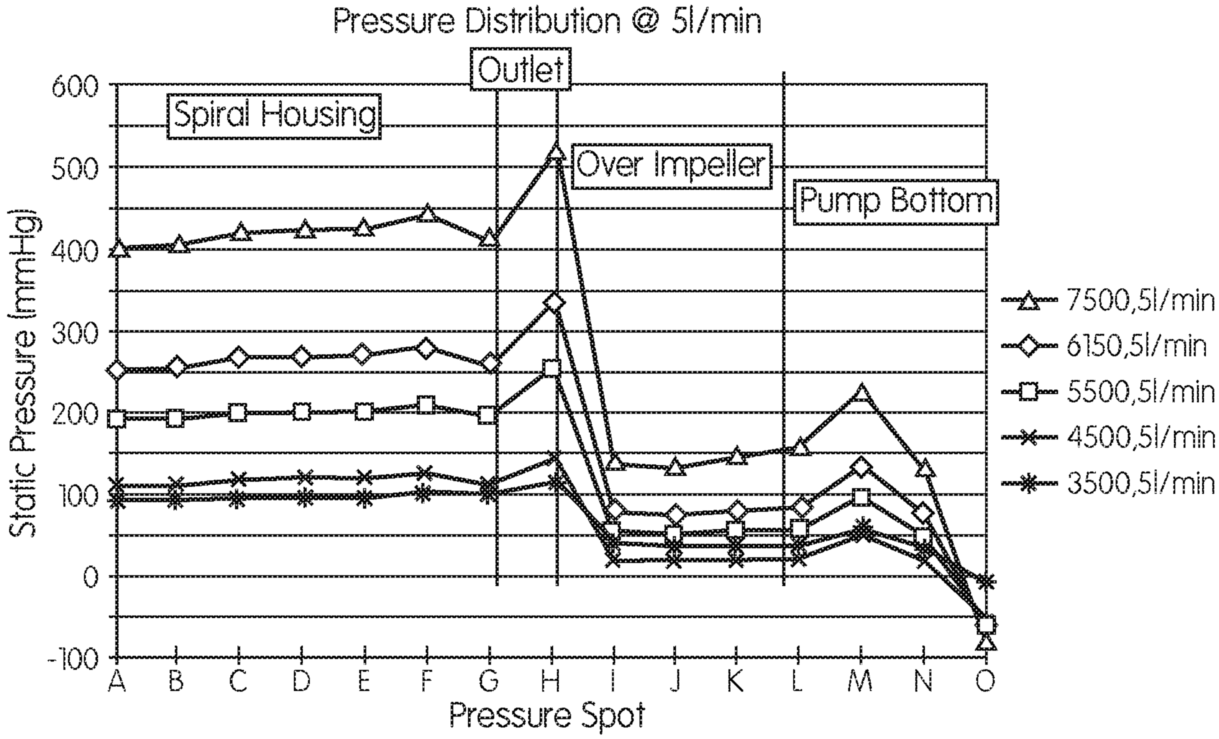
FIG. 10


Pressure Distribution @ 5l/min
Outlet
Spiral Housing
Over Impeller
Pump Bottom
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500
400
300
200
100
0
-100
Static Pressure (mmHg)
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Pressure Spot
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5500,5l/min
4500,5l/min
3500,5l/min

FIG. 11

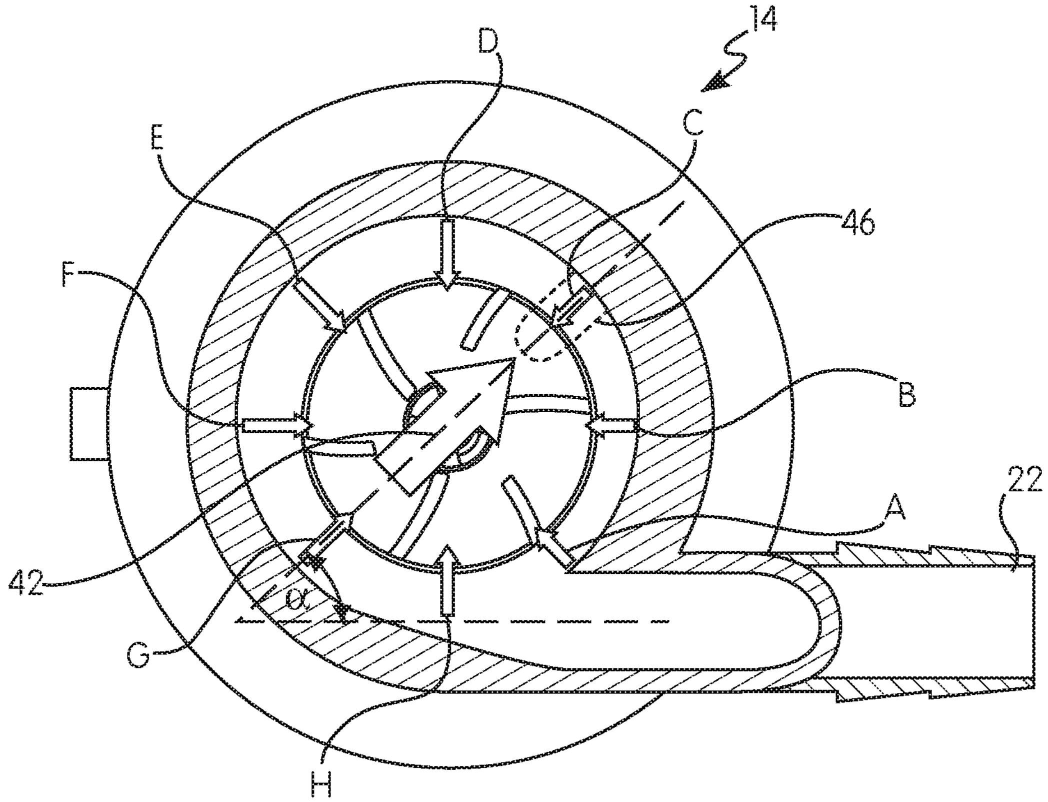
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FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2019/014685

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 1/10; F04D 13/02; F04D 29/048; F04D 29/22 (2019.01)
CPC - A61M 1/101; A61M 1/1012; A61M 1/1015; F04D 13/024; F04D 29/0467; F04D 29/22 (2019.02)

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)
See Search History document

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 415/206; 415/900; 417/356; 417/420; 417/423.12; 417/423.14; 604/6.11 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,360,317 A (CLAUSEN et al) 01 November 1994 (01.11.1994) entire document	1-4 --- 5-8, 13-19
Y	US 2014/0205434 A1 (GRAICHEN et al) 24 July 2014 (24.07.2014) entire document	5-8, 14-19
Y	US 6,234,772 B1 (WAMPLER et al) 22 May 2001 (22.05.2001) entire document	8, 19
Y	US 2015/0038769 A1 (HEARTWARE, INC) 05 February 2015 (05.02.2015) entire document	13
A	US 2017/0143884 A1 (TERUMO KABUSHIKI KAISHA) 25 May 2017 (25.05.2017) entire document	1-20
A	US 2017/0234314 A1 (BÜHLER MOTOR GMBH) 17 August 2017 (17.08.2017) entire document	1-20
A	US 4,507,048 A (BELENGER et al) 26 March 1985 (26.03.1985) entire document	1-20

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
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"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
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
03 March 2019	21 MAR 2019

Name and mailing address of the ISA/US	Authorized officer
Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774