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ROTOR FOR A FLUID PUMP, AND METHOD AND MOLD FOR MANUFACTURING SAME

[0001] The present patent application lies in the field of mechanics and relates specifically to rotors for fluid pumps. It can be used particularly advantageously in the field of medical engineering with respect to catheter pumps.

[0002] In the field of fluid pumps, rotor pumps are already known in various embodiments in the form of axial pumps or radial pumps. In both cases, the fluid to be conveyed is accelerated, either in the axial direction or in the radial direction, by a rotation of a rotor and impeller elements secured to said rotor.

[0003] Pumps of this type can also be compressed already in accordance with the prior art so as to arrange or transport them in a space-saving manner. This applies in particular to catheter pumps for medical application, which often can be radially compressed and expanded so as to be able to be transported to the site of application through a catheter or through cavities in the body of a patient and then expanded at the site of application, before being set in operation. Such pumps are used for example to assist a patient's heart in the pumping of blood, and for this purpose are advanced through a blood vessel as far as, or into a chamber of the heart.

[0004] In this case, particular challenges are posed by the small size of the rotor and additionally the compressibility thereof. In the expanded state, in spite of its compressibility, the rotor must reproducibly assume an operating form that changes as little as possible, even in the event of operation at maximum rotational conveying speeds, in order to prevent a reduction in efficiency and also damage to the blood constituents to be conveyed.

[0005] EP 2 407 185 A1 shows a radially compressible and expandable rotor for a pump with at least one blade, the blade having a blade body whose material is elastically deformable, and at least one stiffening strut at least partially embedded in the material of the blade body. In order to stabilize the blade, the struts are suitably designed in terms of size, shape and arrangement and integrated into suitable cavities in the blade body. In addition, high-tensile elements may be provided.

[0006] EP 2 194 278 A1 relates to a fluid pump, in particular a fluid pump having a rotor with at least one rotor blade for conveying the fluid, wherein the rotor is variable with respect to its diameter between a first, compressed state and a second, expanded state. To realize ease of compressibility and expandability of the rotor of the pump, it is provided that the at least one rotor blade is deformable between a first state, which it assumes when the rotor is in the compressed state, and a second state, which it assumes when the rotor is in the expanded state, by a fluid counterpressure upon rotation of the rotor during pumping operation.

[0007] EP 2 407 186 A1 relates to a rotor for a pump, with at least one blade, wherein the rotor can be driven in rotation in the axial or radial direction about an axis of rotation in order to convey a fluid, and wherein the rotor is reversibly elastically deformable in the radial direction between a first, radially compressed state and a second, radially expanded state.

[0008] For this reason, the use of a wide range of materials and material combinations has already been considered and examined for the aforementioned purpose. By way of example, the use of a wide range of elastomers, also in conjunction with a fiber reinforcement, is already known from WO 2010/063494 A1.

[0009] WO 2012/007141 A1 discloses a reinforcement of a pump rotor by fibers, which can be arranged in the rotor in oriented form, for example in the radial direction.

[0010] Lastly, WO 2012/007140 A1 discloses a pump rotor with reinforcement elements which can be provided substantially outside the impeller elements, for example on surfaces thereof.

[0011] Against the background of the prior art, the object of the present invention thus lies in creating a plastic rotor of the above-mentioned type which has a minimal relaxation after deformations between the compressed and the expanded state as well as the most accurate possible reproducibility of its geometry, at least in the expanded state.

[0012] The object is achieved by a rotor according to the invention.

[0013] The invention is defined by independent claim 1.

[0014] This results, *inter alia*, in a rotor for a compressible fluid pump, in particular a blood pump which can be introduced through a blood vessel into a patient's body, which rotor has one or more impeller elements and can be radially compressed and expanded between a compressed state and an expanded state, and consists at least in part of a plastic reinforced by strand-like reinforcement elements, in particular fibers, and is intended to rotate about an axis of rotation, wherein the plastic has a Shore hardness < 100 D. Due to the low Shore hardness, which is selected to be < 80 D, it is made possible, with heavy bending or buckling of the material, for the embedded strand-like reinforcement elements, in particular fibers, to push into the resilient base material and thus limit the radius of curvature downwardly. This results in a reduction of the risk of breakage of the reinforcement elements/fibers.

[0015] In addition, in the case of a rotor of this type, it can also be provided that a first proportion of the reinforcement elements/fibers in the expanded state of the rotor runs in a substantially stretched manner from their first end disposed closest to the axis of rotation to a second end disposed further away from the axis of rotation. As a result of this positioning, orientation and forming of the reinforcement elements/fibers, an overstretching of the rotor beyond the expanded state is effectively avoided. The term "in a substantially stretched manner" can be understood here for example to mean the state in which the two ends of a reinforcement element have a distance from one another of at least 95%, in particular at least 99% of the distance from one another which is possible without any longitudinal elongation. The stretched state can also be present only over a partial length of the reinforcement elements, for example over 90% of the length or over 50% of the length. However, the term "in a substantially stretched manner" also characterizes the state of maximum stretching which can be assumed maximally by a fiber in a cross-woven fabric.

[0016] In addition, a rotor is provided for a compressible fluid pump, in particular a blood pump which can be introduced through a blood vessel into a patient's body, which rotor has one or more impeller elements and can be radially compressed and expanded between a compressed state and an expanded

state and consists at least in part of a plastic reinforced by reinforcement elements, in particular fibers, and is intended to rotate about an axis of rotation, wherein a first proportion of more than 30%, in particular more than 50% of the reinforcement elements/fibers in the expanded state of the rotor runs in a substantially stretched manner from their first end disposed closest to the axis of rotation to a second end disposed further away from the axis of rotation.

[0017] By means of such an arrangement and orientation of a sufficient proportion of the reinforcement elements/fibers in the rotor, in particular within the impeller elements of the rotor, an optimized stabilization of the rotor in the expanded state is achieved. A further deformation is practically prevented by the reinforcement elements, or it is at least ensured that there is a return to the previous rotor geometry after an overstretching. Certain changes, such as material creep of the plastic from which the rotor is made, thus also cannot cause a permanent change in the geometry of the rotor in the expanded state. This can be achieved by way of example with use of a polymer rotor made of a thermoplastic or made of a thermoplastic or chemically weakly cross-linked elastomer for production of the rotor.

[0018] Suitable materials in particular for the fibers, but also for strip-like reinforcement elements are in this case in particular glass, but also carbon or polycarbonate. The reinforcement elements/fibers are for this purpose introduced into the polymer during the production process, for example an injection molding method or a vacuum casting method. The individual reinforcement elements/fibers usually have a high modulus of elasticity and are advantageously integrated into the matrix in a stretched, un-curved state. In order to stabilize the rotor, a sufficient proportion of the reinforcement elements/fibers must satisfy the condition according to the invention, for example more than 30% of the total reinforcement elements/fibers disposed in the rotor material, measured on the basis of the fiber mass or on the basis of the fiber volume or on the basis of the mass/volume of the reinforcement elements.

[0019] At least 50% of the provided fibers advantageously can be introduced, positioned and oriented accordingly. It can also be provided that more than 50%, for example 60% or 70% or even 80% or 90% of the reinforcement ele-

ments/fibers are positioned and oriented accordingly. Here, the largest proportion possible of the reinforcement elements/fibers can be arranged advantageously in a bending neutral plane within the volume of the impeller elements of the rotor so as not to cause any longitudinal compression or elongation of the reinforcement elements/fibers during the compression or expansion. However, a positioning in parallel at a distance from the bending neutral plane might also be desired purposefully in order to achieve, a particular stabilization in a direction by stretching of the reinforcement elements/fibers when the impeller elements bend out. In any case, the reinforcement elements/fibers should run advantageously completely or for the most part within the impeller elements and in particular should maintain a specific minimum distance from the outer delimiting faces of the impeller elements.

[0020] A plurality of groups of reinforcement elements/fibers of different length can also be provided in the rotor, wherein at least one group has a specific minimum length, whereas the reinforcement elements/fibers of one or more groups are shorter or have a length distribution that has only a negligible number of reinforcement elements/fibers above a length which is below a typical length of the first proportion of the reinforcement elements/fibers. The average length of the shorter reinforcement elements/fibers is typically less than a third of the length of the first proportion of the reinforcement elements/fibers.

[0021] The rotor can advantageously be designed such that each reinforcement element/each fiber of the first proportion of the reinforcement elements/fibers deviates in its course by at most 45° in the axial direction and/or azimuthal direction from a position aligned radially with the rotor axis (14). The reinforcement elements/fibers then run in a plane in which the entire axis of rotation of the rotor also runs, such that the reinforcement elements/fibers can extend radially outwardly perpendicularly directly from the axis of rotation, for example. However, an orientation of the reinforcement elements/fibers from the axis of rotation radially at an angle between 45° and 90° to the axis of rotation is also possible. In one embodiment, the extent of the reinforcement elements/fibers at any rate does not have an azimuthal orientation (running in the peripheral direction) or only has a small orientation of this type.

[0022] A further embodiment provides that each reinforcement element/each fiber of the first proportion of the reinforcement elements/fibers runs substantially perpendicularly to the axis of rotation. This results in a particularly efficient stabilization of the impeller elements, if these are bent in the peripheral direction with respect to the axis of the rotor and for example are placed against a rotor hub for compression.

[0023] A radial course of the reinforcement elements/fibers with respect to the axis of rotation can also be provided in a simple manner.

[0024] A further embodiment provides that each fiber of the first proportion of the reinforcement elements/fibers runs along the longitudinal axis of an impeller element. Due to an arrangement of this type of the reinforcement elements/fibers, the individual impeller elements are stabilized particularly efficiently in their expanded form. Here, it can be expedient that the reinforcement elements/fibers extend radially over the region in which the greatest deformation occurs during the compression and expansion of the rotor. However, it can also be provided to arrange the reinforcement elements/fibers in such a way that the region in which the strongest deformation occurs during the compression and expansion of the rotor is left free from reinforcement elements or is provided only with a reduced proportion of reinforcement elements.

[0025] The longitudinal axis of an impeller element is understood essentially to mean the direction of extension of the impeller element radially with respect to the rotor axis of the rotor. This also applies if the height of the impeller element in question in the axial direction of the rotor is greater than its radial extent.

[0026] In order to achieve a sufficient stabilization of the rotor or of the impeller elements in the expanded state, it can be provided advantageously that the length of the reinforcement elements/fibers of the first proportion of the reinforcement elements/fibers is at least 10%, in particular at least 30%, even more advantageously at least 50% of the radius of the rotor. Here, it is particularly advantageous if the first proportion of the reinforcement elements/fibers having such a length is at least 70% of the total reinforcement ele-

ments/fibers provided, measured on the basis of the number of the reinforcement elements/fibers or on the basis of the mass of the reinforcement elements/fibers.

[0027] In order to prevent a breakage of the reinforcement elements/fibers with maximum compression of the rotor, a specific maximum diameter or a maximum thickness of the individual reinforcement elements/fibers should not be exceeded, in particular when these are produced from glass. It can therefore be provided advantageously in one embodiment of the invention that the diameter or the thickness of the reinforcement elements/fibers of the first proportion of the reinforcement elements/fibers is less than 40 µm. This diameter condition should be met where possible for all reinforcement elements/fibers of the first proportion of the reinforcement elements/fibers, but at least for 90% or 80% of the first proportion of the reinforcement elements/fibers, provided a certain scattering of the diameter values is unavoidable during the production.

[0028] In order to prevent a breakage of the reinforcement elements/fibers with maximum deformation of the rotor, for example with buckling of specific points of the impeller elements, it can be provided in a further advantageous embodiment by way of example that the plastic in which the reinforcement elements/fibers are embedded has a Shore hardness < 100 D, in particular < 80 D. With such a Shore hardness or resilience of the material, it is ensured that the reinforcement elements/fibers in the material of the matrix can deflect sufficiently in the event of a strong deformation so as not to drop below a specific bending radius. The reinforcement elements/fibers of the first proportion of reinforcement elements/fibers are thus protected against breakage.

[0029] The rotor can also be designed such that the impeller elements consist of a foam material. Here, a closed-pore foam material is envisaged in particular, which can be effectively stabilized by the reinforcement elements and which can still be compressed easily and to a sufficient degree. Particularly in the case of a foam material, a deflection of the reinforcement elements/fibers in order to avoid dropping below a critical bending radius is possible particularly easily during the compression movement. Foam materials of this type

usually have corresponding pores within the volume of the impeller elements, but are practically completely closed at the outer delimiting surfaces.

[0030] The innovation also relates to a rotor of the above described type and also to a method for producing a rotor by means of a molding method, in particular an injection molding method, in which the material of the impeller elements is introduced into the volumes of the impeller elements in the radial direction with respect to the rotor axis, in such a way that the injection molding material flows into the volumes of the impeller elements in the radial direction.

[0031] Due to the largely predominantly radial flow of the injection molding material into the mold or into the volumes of the impeller elements, the reinforcement elements are also entrained and embedded in the inflow direction, i.e. in the radial direction. The claimed positioning and orientation of the reinforcement elements/fibers in the material of the rotor can thus be ensured in a particularly simple and effective manner.

[0032] It can also be provided that the injection molding material is injected into the volumes of each of the impeller elements in the radial direction from the region closest to the rotor axis or from the region furthest away from the rotor axis.

[0033] The innovation additionally relates to a mold for a rotor of the above-described type, with which it is advantageously provided that overflow channels are provided at the volumes of the impeller elements at the radial edges thereof in order to enable an uninterrupted flow of the molding material in the radial direction. Due to the provision of overflow channels at the edges of the impeller elements, it is ensured that the reinforcement elements/fibers are not entrained at the walls of the mold by swirls of the inflowing injection molding material in this region and thus deformed so that they follow the swirls and are no longer present in the rotor in a stretched radial orientation. It is also provided to be able to discharge the polymer in part, but not the reinforcement elements/fibers (the height of the overflow channels is consequently advantageously smaller in at least one direction of extent than the fiber diameter or the thickness of the reinforcement elements). This can result

in a desired concentration of the reinforcement elements/fibers in the impeller elements. As a result of the targeted overflow, the radial orientation of the reinforcement elements/fibers is also improved. The injection molding material overflowing accordingly can be removed later from the impeller elements once it has solidified. The longitudinal edges of the impeller elements are understood to mean the edges of the impeller elements running substantially in the radial direction in expanded form and substantially forming the leading and trailing edges of the impeller elements, for example impeller blades, in respect of the interaction between the impeller elements and the fluid to be conveyed.

[0034] The rotor can also be formed in such a way that a proportion of reinforcement elements/fibers in the expanded state of the rotor runs transversely to the reinforcement elements/fibers of the first part and in particular encloses an angle therewith of at least 30° on average. The particular group of fibers can thus almost completely prevent a bending of the rotor or an impeller element of the rotor in the longitudinal direction of the fibers, provided the bending occurs in a direction in which the fibers are loaded by a tensile stress. If two directions are distinguished in the described manner by the different arrangement of two fiber groups, a three-dimensional form of the rotor or of part of the rotor can be stabilized very efficiently and strengthened against bending in various directions.

[0035] It can additionally be provided that the reinforcement elements/fibers are present at least in part in the form of fabric portions having fibers that run longitudinally and transversely. The fabric portions by way of example can extend in their longitudinal direction at least twice, three times, five times or ten times as far as in the transverse direction perpendicularly thereto, such that they form an elongate strip in each case. First fibers are then readily provided within this fabric in a longitudinal direction, and second fibers running transversely thereto are then readily provided perpendicularly or at an obtuse angle thereto.

[0036] By way of example, it can also be provided that the reinforcement elements are present in the form of film strips, of which the length is at least three times, in particular at least five times, more particularly at least ten times as great as their width. These film strips can consist of an anisotropic

polymer, which for example has a much greater tensile strength in the longitudinal direction than in the transverse direction. However, they can also consist of an isotropic film, for example made of high-tensile plastic material or also made of a metal, such as aluminum, silver, nitinol, titanium, or gold.

[0037] In addition, it can be provided advantageously that the reinforcement elements are surrounded by the plastic from which the rotor is predominantly made, at least to a proportion of 90%, in particular 99% of their surface, and more particularly completely. In an individual case it can be that reinforcement elements in the injection mold contact the wall of the mold so that they appear at the outer surface of the rotor in the finished product. However, in the normal case, only the ends of the reinforcement elements are arranged in an exposed manner on the outside of the rotor, wherein even this is relatively unlikely due to the introduction of reinforcement elements and a suitable flow guidance of injection molding material during the injection molding process.

[0038] In the case of the rotor, it can additionally also be provided that the plastic material in which the reinforcement elements are embedded has different properties, at least in regions, on the side of the impeller elements not loaded by the fluid counterpressure during operation compared to the side of the impeller elements that is loaded by the fluid counterpressure, in particular is more heavily cross-linked or shrunk on the side not loaded by the fluid counterpressure or carries there, on the surface, a support shrunk on the impeller element, said support being provided in the form of one or more films, coatings or fibers. In this regard, the two sides of the impeller elements are intended to mean, in the volume of a particular impeller element, the volume regions on the two sides of the plane or surface constituting the bending neutral plane or surface under bending load.

[0039] One of the sought objectives of the invention is that the second state of the rotor, assumed by the rotor in the state free from external forces, differs to a minimal extent from the third state assumed by the rotor during operation as it rotates in a fluid under the action of the fluid counterpressure. It is therefore desirable that the reinforcement fibers already in the second state of the rotor are stretched to the greatest possible extent and run in a direction in which they delimit at least any bending of the rotor.

[0040] This can be assisted in that the form of the rotor in the second state, in which the rotor is free from forces, differs from the form assumed by the rotor in the injection mold. By means of suitable design of the plastic matrix formed by the injection molding material, it is possible that already in the state free from external forces a deformation occurs in the direction of the third state by means of resilient forces of the injection molding material, said deformation preloading the fibers. This effect can be achieved by way of example in that a material different from the reinforcement elements is provided in or on the rotor and brings the rotor, in particular the impeller elements, into a form in which the reinforcement elements are preloaded. Since, during the actual molding of the reinforcement elements in the matrix, these elements are more or less free from forces, this is achieved by a modification of the plastic matrix or of the body of the rotor on the whole after the completion of the injection molding process. By way of example, the plastic matrix can be treated in a particular manner following removal from the injection mold, in such a way that the material of the impeller elements is lengthened on the side subjected to the fluid counterpressure during operation or is shrunken or anisotropically shortened on the opposite side. This can be implemented by way of example by an irregular cross-linking of the plastic matrix, which is different on the two sides of the neutral fibers of the impeller elements. However, this can also be achieved by coating the impeller elements, on the side opposite the side of the impeller elements exposed to the fluid counterpressure during operation, with a film which shrinks or can be shrunk after the coating, for example by electron beam cross-linking or UV cross-linking or by thermal treatment.

[0041] A rotor for a compressible fluid pump which can be radially expanded and compressed between a first, compressed state and a second, expanded state can also be provided, wherein it can additionally be provided that one or more impeller elements of the rotor is/are produced by injection molding with simultaneous addition of reinforcement elements in the expanded state, wherein the reinforcement elements are surrounded on all sides by an injection molding material and are stretched at least sectionally in the expanded state, in particular are stretched to an extent of at least 90%, more particularly 95%, and more particularly 99% or, with use of a fabric, are stretched to the greatest possible extent.

[0042] By way of example, the rotor can also be designed in such a way that the reinforcement elements in the second, expanded state of the rotor without a fluid counterpressure are stretched to such an extent that they are lengthened upon transition to a third state, which constitutes the operating state with a fluid counterpressure, by less than 5%, in particular less than 1%, wherein the lengthening is measured in particular on the basis of the distance between the two ends of a reinforcement element before and during the tensile load.

[0043] By way of example, it can also be provided in the case of the rotor that in a second, expanded state of the rotor and/or a third operating state with fluid counterpressure, at least a proportion of the reinforcement elements, in particular at least 10%, more particularly at least 30%, run in a stretched and straight manner, at least in a region of an impeller element in which said impeller element is curved.

[0044] It can additionally be provided that, in a region of an impeller element in which this is curved, at least two proportions of reinforcement elements run in a straight and stretched manner, wherein the directions in which the reinforcement elements run are parallel within the same proportion, but are different between the two different proportions. The fibers within the various groups can be introduced into the injection mold already connected to one another in the form of a fabric or can be introduced into the injection mold separately from one another, in particular in succession.

[0045] A further embodiment of the rotor can provide that the length of the reinforcement elements, in the case of at least 30%, in particular at least 50% of the elements, is greater than the average thickness of the impeller elements, in particular at least twice as long, more particularly at least five times or ten times as long. The reinforcement elements of such length can be supplemented when filling the molding material by other filling elements, for example very short fibers and/or particles, wherein the short fibers can also be present in stretched form. However, this has little effect in respect of a delimitation of the curvature of the rotor, since these fibers are usually very short. In this regard, the thickness of the impeller elements at any point of the impeller elements means the extent in the direction in which the extent of the impeller element is smallest.

[0046] A further embodiment of the rotor can provide that reinforcement elements, in particular fibers, are introduced in an injection molding method into the plastic in which said reinforcement elements are embedded and have a sectionally curved course along the flow of the plastic into the injection mold during the time for which the rotor is disposed in the injection mold.

[0047] The invention additionally also relates to an injection mold for a rotor of the above-described type, with overflow channels provided in the volumes of the impeller elements at the radially running edges thereof in order to enable an uninterrupted flow of the molding material in the radial direction.

[0048] A method for producing the above-described rotor can provide that the material of the impeller elements is introduced into the volumes of the impeller elements in the radial direction with respect to the rotor axis in such a way that the molding material flows into the volume of each individual impeller element in the radial direction.

[0049] Due to the arrangement and size of the overflow channels of the casting mold, the flow direction of the inflowing molding material and therefore the orientation of the fibers along the flow can additionally be controlled.

[0050] A further method for producing a rotor can provide that the rotor is produced by molding, in particular injection molding, wherein the injection molding process is performed in two successive phases with different injection directions and/or from two different injection points. Reinforcement elements/fibers that run in groups in different directions can thus be introduced in a targeted manner into the injection molding material.

[0051] In a method for producing a rotor, it can also be provided that the rotor is subjected after the injection molding to a treatment that causes a different shrinking and/or cross-linking of the molding material on the side of the impeller elements loaded by the fluid counterpressure during operation compared to the opposite side. The rotor can thus be preloaded by production of internal stresses in such a way that it already assumes the third state, i.e. an operating state, which is stable, when the rotor is exposed to a fluid counterpressure, without influence of external forces. This is implemented in that the internal stresses are directed and dimensioned in such a way that as a result the reinforcement elements are already loaded by a tensile force which lies in

the order of the forces to which the reinforcement fibers are exposed during operation of the rotor.

[0052] By way of example, it can also be provided that a shrinkable or shrinking layer is applied to at least one of the impeller elements on the side opposite the side of the impeller elements exposed during operation to a fluid counterpressure.

[0053] Alternatively or additionally, it can be provided by way of example that at least two different injection openings are provided in the injection mold for the injection molding material. The flow of the injection molding material in the mold can thus be altered in a targeted manner during the molding process, such that, with addition of reinforcement elements in various phases, the reinforcement elements can be arranged in each case in the primary flow direction of the injection molding material and therefore in different directions in accordance with the various phases of the injection molding process. For this purpose, by way of example, a first quantity of the injection molding material can be injected through a first injection opening and a second quantity can be injected through a second injection opening in succession or simultaneously or in a variable proportion to one another.

[0054] The innovation will be presented and explained hereinafter on the basis of exemplary embodiments in drawings, in which

Fig. 1 schematically shows a sectional view of a catheter pump which is introduced into the chamber of a patient's heart,

Fig. 2a shows a detail of a rotor of a catheter pump for conveying blood,

Fig. 2b shows a cross-sectional illustration of a relaxed rotor with a fiber illustrated by way of example,

Fig. 3 shows a schematic illustration of a plane containing the axis of rotation of the rotor,

Fig. 4 shows a detail of a planar impeller element with a fiber for reinforcement,

Fig. 5a shows the orientation of a fiber during the molding process,

Fig. 5b shows a side view of the portion from Figure 4,

Fig. 6 shows the portion of an impeller element as shown in Figures 4 and 5 after a buckling process,

Fig. 7 shows a schematic view of a molding tool for a rotor, wherein the molding process is indicated by flow arrows,

Fig. 8 shows a mold for a rotor with an injection direction opposite that in Figure 7,

Fig. 9 shows a mold in which measures have been taken to prevent a swirling of the injection molding material in the volume of the impeller elements,

Fig. 10 shows a further mold,

Fig. 11 shows a film-like, strip-shaped reinforcement element,

Fig. 12 shows a fabric-like strip-like reinforcement element, and

Fig. 13 shows a cross-section through an impeller element,

Fig. 14a shows a fabric formed of fibers in a state free from forces,

Fig. 14 b shows the fabric from Fig. 14a in a maximally stretched state under load,

Fig. 15a shows an impeller element in a perspective view in the expanded state without action of external force,

Fig. 15 b shows a sectional view of the impeller element from Fig, 15a in the plane of section denoted there by A-A,

Fig. 16a shows an impeller element in a perspective view in the expanded state without action of external force,

Fig. 16 b shows a sectional view of the impeller element from Fig. 16a in the plane of section denoted there by B-B,

Fig. 17a shows an impeller element in a side view in the expanded state without action of external force, and

Fig. 17b shows a sectional view of the impeller element from Fig. 17a in the plane of section denoted there by C-C.

[0055] Figure 1 shows, in cross-section, the heart 1 of a patient with a plurality of heart chambers, wherein the heart chamber 2 is connected to the aorta 12. A catheter 4 is advanced into the heart chamber 2 through the aorta 12, wherein a pump head 3 with a rotary pump is arranged at the end of the catheter 4. The rotary pump can be driven by means of a rotatable shaft 6 running through the catheter 4, which shaft is connected within the pump head 3 to a pump rotor 42. The pump rotor rotates in a housing (not illustrated in greater detail) of the pump head 3.

[0056] The flexible shaft 6 is connected to a motor 7, which for example is arranged outside the patient's body. The torque can be transferred for example by means of a magnetic coupling from the motor 7 in both directions of rotation 8, 9 to the shaft 6.

[0057] The catheter 4 is usually advanced via a port from outside the body, through the skin and tissue and also the vessel wall, into the aorta 12 and therein.

[0058] The pump sucks in blood in the heart chamber 2 and conveys it into the aorta 12. The heart pump can thus either assist the function of the heart 1 or replace it at least temporarily.

[0059] Besides the catheter pump with mechanical drive illustrated in the drawing, other pumps, in particular for intracorporeal use, also form the subject of this patent, for example pumps with hydraulic or electric drive, including pumps in which the drive is within the human body.

[0060] The pump, together with the pump head, the pump housing and the rotor, is radially compressed for displacement in the aorta and is displaced for example within the catheter 4. The pump can then be slid out axially from the catheter 4 and can radially unfold, i.e. can be expanded. During this process,

high demands are placed on the materials of the pump housing and in particular the pump rotor: The impeller elements of the pump rotor have a very thin wall thickness, but must still remain dimensionally stable and convey blood reproducibly, even at high rotational speeds.

[0061] For this purpose, reinforcement fibers (fibers) are embedded in the matrix of the plastic from which the rotor is made and for example can be provided as glass fibers or polycarbonate fibers. Such reinforcement elements/fibers are illustrated in Figure 2a in three individual examples. The three reinforcement elements/fibers 10, 11, 13 are shown, each of which has a first end or a first portion 10a, 11a, 13a, which is closer to the axis of rotation 14 than the second end/the second portion 10b, 11b, 13b of said reinforcement elements/fibers 10, 11, 13.

[0062] The reinforcement elements/fibers 10, 11, 13 extend substantially radially outwardly away from the axis of rotation or a point in the vicinity of the axis of rotation 14 of the rotor. Here, it is not necessary for the rotor 42, as in the illustrated example, to have a hub 43. The spiraled impeller element 15 can also have an inherent stability such that a rotor hub is not necessary.

[0063] In principle, the plastic matrix of the impeller element or the impeller elements 15 can be reinforced with reinforcement elements/fibers, which are distributed and arranged irregularly in respect of length and/or thickness and/or orientation. One aspect is that a certain minimum proportion of the reinforcement elements/fibers in the expanded state of the rotor, which is illustrated in Figure 2, runs in a substantially stretched manner away from the axis of rotation. The proportion of the reinforcement elements/fibers that meets the aforesaid condition in the total amount of reinforcement elements/fibers embedded in the plastic of the rotor should be at least 30% or advantageously 50% or even more advantageously for example 70%, measured in percent by volume or mass of the reinforcement elements/fibers or also on the basis of the number of reinforcement elements/fibers. Here, a certain minimum length of the reinforcement elements/fibers is advantageously given, for example approximately at least 20% or at least 40% or 50% of the radius of the rotor. The reinforcement elements/fibers can change easily during the filling of the mold from the axial orientation, corresponding to that of the hub 43, into the radial position of the impeller elements 15 without being

bent for this purpose, since the angle between the impeller element 15 and the hub 43 runs relatively flat at < 30° or preferably < 20°. The reinforcement elements/fibers, during the radial filling of the impeller elements 15, are thus easily entrained by the surrounding matrix and are oriented radially with the material flow in the impeller element, according to Figure 2.

[0064] Further advantageous properties of the reinforcement elements/fibers are a specific maximum thickness, wherein a diameter of at most 40 µm can be advantageous in order to produce no breakage of the reinforcement elements/fibers in the event of a strong bending of said reinforcement elements/fibers. By contrast, with a measurement of approximately 40 µm, the reinforcement elements/fibers are flexurally rigid enough to return the matrix surrounding them back into the starting state following deformation and to prevent a long-term creep of the matrix under permanent bending load. Reinforcement elements/fibers with a diameter of 40 µm are also resistant to compressive and tensile stresses, such that, with an arrangement outside the bending neutral region, they also produce a restoring moment and act against a remaining deformation.

[0065] The reinforcement elements/fibers can be coated with an adhesion promoter in order to improve the connection to the matrix.

[0066] Figure 2b shows, in cross-section, a rotor 42' with impeller elements 15', 15'' in the relaxed, expanded state. The reinforcement elements/fibers 55, 56 in this state have a maximally stretched form, such that they resist any further deformation of the rotor on account of their longitudinal rigidity.

[0067] The possible orientation of the reinforcement elements/fibers will be explained in greater detail on the basis of Figure 3. The rotor hub is denoted in Figure 3 by 16, and the axis of rotation is denoted by 14. A plane 17 on the basis of a cut rectangle is illustrated, wherein the plane 17 contains the axis of rotation 14, that is to say the axis of rotation 14 runs completely in the plane 17.

[0068] Two reinforcement elements/fibers 18, 19 have been shown by way of example and both run in the plane 17 substantially radially with respect to the axis of rotation 14. The fiber 18 runs at an angle α to the axis of rotation 14, partially in the axial direction, wherein the angle α is advantageously between

45° and 90°. The fiber 19 is oriented in such a way that it is arranged at right angles to the axis of rotation 14. An actual blade is curved in a spiraled manner in three dimensions, such that in many cases a limited extent of the reinforcement elements/fibers is added in the azimuthal direction.

[0069] The individual reinforcement elements/fibers do not have to be positioned in such a way that their first start point/end point is in the region of the axis of rotation 14 or the rotor hub 16. They can also be arranged such that they run between two end points which are both radially distanced from the rotor axis 14 and/or from the rotor hub 16. However, they can also extend from a first radially outer blade edge to a second, radially opposite blade edge, in any case beyond the axis.

[0070] A detail 20 of an impeller element is illustrated schematically in Figure 4, wherein the detail 20 is cuboidal. A fiber 19 is illustrated in the portion 20.

[0071] Figure 5a clarifies how the central orientation of the fiber 19 is achieved. The preferably laminar flow profile when filling the mold between the delimiting walls 53 and 54 has the fastest flow speed in the middle and the slowest speed in the vicinity of the walls. The fiber 19, which is initially skewed, is illustrated in three angular positions reached successively from left to right and is drawn by the material flow, indicated by the arrows 50, 51, into the middle of the flow profile as a result of the speed distribution in the mold. The speed distribution of the flow is illustrated in the graph 52 of the diagram with the axes x (=speed) and y (≙ location coordinate in the mold).

[0072] Figure 5b shows a side view, wherein the material of the portion 20 has been illustrated transparently, such that the course of the fiber 19 approximately in the middle between the delimiting faces of the impeller element is visible.

[0073] The behavior of the fiber under heavy bending or buckling of the impeller element will now be described on the basis of Figure 6.

[0074] Figure 6 shows the portion 20 of the impeller element after buckling. The fiber 19 is also deformed. Due to a certain inherent rigidity of the fiber, however, this can push outwardly in the direction of the arrow 21 in the event of the buckling due to the resilience of the material of the impeller element so

as to achieve a greatest possible radius of curvature of the fiber and thus counteract a breakage of the fiber. In the region of the buckling point, the fiber 19 is therefore deflected from the middle between the delimiting walls of the impeller element for the duration of the buckling. In Figure 6 the central plane of the impeller element has been illustrated at least in part by a dashed line 22 for the sake of clarity. In order to achieve this effect, a softness of the plastic matrix of the rotor is advantageous, corresponding to a Shore hardness < 100 D.

[0075] The design according to the invention of a molding tool/a mold for a rotor according to the invention will now be discussed on the basis of Figure 7.

[0076] Figure 7 shows a longitudinal section of the injection mold, wherein the region comprising the volume of the rotor hub is denoted by 23 and the volumes of the individual impeller elements are denoted by 24, 25, 26 and 27. In addition, an injection direction is indicated in Figure 7 by the arrow 28. The further arrows 29, 30, 31, 32, 33 indicate that the injection molding material flows in axially along the axis of rotation 14 of the resultant rotor and from there flows radially outwardly into the volumes of the impeller elements. By way of example, the longitudinal axis of one of the impeller elements has been indicated by a dot-and-dash line and denoted by 44. If reinforcement elements/fibers of appropriate length are introduced in sufficient number into the injection molding material, these reinforcement elements/fibers will be oriented in accordance with the primary flow direction of the material and will remain in place as the material solidifies.

[0077] Displaced air and excess molding material can flow out at the radially outer ends of the impeller elements through openings 45.

[0078] In Figure 8 an opposite injection direction is indicated, wherein the injection molding material is injected radially inwardly from the radially outer ends 34, 35 of the impeller elements to the volume of the rotor 23. In this case as well, long reinforcement elements/fibers can also be introduced, which are oriented and arranged in the manner and way intended in accordance with the invention.

[0079] On the basis of Figure 9, it is shown that in the case of narrow impeller elements 36, 37 the molding compound flowing radially from the inside out is swirled at the edges 38, 39 of the volume of a specific impeller element by friction, such that there is no laminar flow of the molding material created as said material flows in.

[0080] On the left-hand side in the illustration of Figure 9, a mold variant is illustrated, which in the region of the edges 40, 41 has overflow openings or overflow slots, through which some of the injection molding material can flow out in the axial direction of the rotor, such that the swirling illustrated on the right-hand side of Figure 9 is eliminated. In the central region of the impeller element 37, a quasi-laminar flow is thus created, such that the introduced reinforcement elements/fibers can arrange themselves there in stretched form without being deformed by influencing of the flow with the injection molding material. Once solidified, the parts of the injection molding material that can exit through the openings at the edges 40, 41 of the volumes of the impeller elements in the injection mold are removed, for example by being cut off. The situation can be the same at the outer edges of the impeller elements, as in Figure 7. Here, two overflow channels 45 are provided, through which the plastic without reinforcement elements/fibers can escape.

[0081] Figure 10 schematically shows an injection mold 70 with a first injection opening 71 and a second injection opening 72, wherein the two injection openings 71, 72 are arranged at mutually opposed ends of the central cavity 73, in which the hub of the rotor is formed by the molding process. The cavities in which the impeller elements are created have been indicated only very schematically and have been denoted by 74 and 75. The arrows 76, 77 denote the flow directions of the plastic flowing into the mold. If the plastic is injected successively or in alternating proportions through the first injection opening 71 and the second injection opening 72 into the mold, different flow directions of the liquid molding material are thus created. If the reinforcement elements are added hereto, different orientations of the reinforcement elements in the produced rotor also result accordingly. In this way, different orientation patterns can be provided by controlling the injection speed through the injection openings and by changing the injection speeds or the ratio of the injection speeds through the various injection openings during the molding method.

[0082] A perspective view of a reinforcement element in the form of a metal foil or a plastic film 78 is illustrated in Figure 11, which foil/film by way of example can be just a few micrometers thick, a few tenths of a millimeter wide, and a few millimeters long.

[0083] Figure 12 shows, as reinforcement element, an elongate fabric strip, which schematically has only two fibers 79, 80 running in the longitudinal direction and a multiplicity of shorter fibers 81 running transversely thereto. A fabric of this type can take up tensile forces particularly well in both longitudinal directions of the fibers present.

[0084] Figure 13 shows a region of an impeller element 82 schematically in cross-section. Here, 83 denotes the cover face that lies on the pressure side during operation and that is exposed to the fluid counterpressure, indicated by the arrow 84.

[0085] The cover face opposite this side or cover face 83 is denoted by 85. In the illustrated example a coating 86 is provided on this side of the impeller element 82 and can be provided by a glued-on film or a liquid coating, for example a varnishing.

[0086] What is known as the neutral "fiber" or plane in the sense of mechanics in the event of a bending of the impeller element 82 during pump operation is shown in a dashed manner and has been denoted by 87.

[0087] If it is assumed that the impeller element, as illustrated in Figure 13, is in the state free from forces, that is to say no external forces are acting on the impeller element, it can be provided that in this state the reinforcement elements, of which one has been shown by way of example and denoted by 88, are present in a stretched form and free from forces.

[0088] If, by the action of the fluid counterpressure 84, a bending force is applied to the impeller element in the direction of the arrow 84 upon rotation of the rotor in a fluid, the reinforcement elements 88 are subjected to tensile loading, since an elongation occurs on the side of the neutral fibers 87 arranged on the left in the drawing as a result of the bending of the impeller element. This bending is limited by the reinforcement elements 88 since these are practically stretch-resistant.

[0089] In order to further reduce the difference in form of the rotor between the second state free from forces and a third state, i.e. the loaded state, it can be provided that in the state free from forces, that is to say without any action of external forces on the rotor, the reinforcement elements 88 are already preloaded by internal material stress. This is achieved in that, after production of the rotor, more specifically once the injection molding process is completely finished, the impeller element is either stretched on the side of the cover face 83 or is shrunk on the side of the cover face 85.

[0090] This is achieved by way of example in that a coating 86 is applied to the cover face 85 after the injection molding process or during the injection molding process, for example by impregnation of the injection mold, which coating can be shrunk during the drying or cross-linking or by a subsequent treatment, in particular radiation cross-linking, UV cross-linking, or thermal treatment. The radiation cross-linking by way of example can also be introduced by means of one or more laser beams and thus can be locally applied in a very focused manner.

[0091] However, it is also conceivable that, additionally or alternatively to a cover layer 86, the material of the impeller element 82 on the side of the neutral plane of the fibers 87 facing towards the cover layer 85 is shrunk, for example by means of a heat treatment or by means of a cross-linking/polymerization, which does not take place on the other side of the impeller element or takes place there only to a lesser extent.

[0092] Figures 14a and 14b show, by way of example, a fabric formed of fibers. Here, the fiber 90 runs as part of a fiber bundle at an angle to further fiber bundles 91, wherein the fiber bundles 91 are arranged perpendicularly to the plane of the drawing and the fiber 90 passes the fiber bundles 91 on the left-hand and right-hand side in alternation. In Fig. 14a, which represents the relaxed state of the rotor, the fiber bundles 91 are arranged at a distance a from one another and the fiber 90 has a course that is curved back and forth. In Fig. 14b, which represents the state of the rotor during operation, the fiber bundles 91 are arranged at a greater distance a from one another and the fiber 90 has a course that is curved to a lesser extent. It is clear from Figures 14a and 14b that a system of this type is already substantially stabilized before a complete stretching of the fiber 90 is achieved, since, beyond the state

of Fig. 14b, the fiber bundles 91 would have to move at right angles to the fiber 90 in the basic material, which is fundamentally prevented thereby and by the fiber 90.

[0093] Fig. 15a shows a rotor in an expanded state free from forces in a perspective view and also denotes a plane of section A-A. Fig. 15b shows the same rotor in said sectional view. The dashed lines 101 and 102 represent the neutral fibers or surface of the respective blades. The fibers 103 and 104 show, by way of example, the course of two fibers in the illustrated planar section. The fibers are curved in this state. In the operating state under load, a pressure acts on the blades in the direction of the illustrated arrows on account of the fluid, whereby said blades open out further. Under full operating load, the fibers 103 and 104 are stretched at least in the regions denoted by 105 and 106 respectively, whereby a further opening out of the blades is prevented, since the very high-tensile fibers would then have to be stretched in their axial extent. The advantage of such a design is that the form of the blade is practically constant above a minimum rotational speed.

[0094] Fig. 16a shows a rotor in an expanded state free from forces in a perspective view and denotes a plane of section B-B. Fig. 16b shows the same rotor in a sectional view along said plane of section. The dashed lines 111 and 112 represent the neutral fibers or surface of the respective blades. The fibers 113 and 114 show, by way of example, the course of two fibers in the illustrated plane of section. As can be seen, the fibers in this example are already stretched in a wide area. Since the fibers are very high-tensile, a further elongation of the fibers is hardly possible. Even under the forces that occur in the operating state, which act on the blades due to the flow pressure and which are illustrated in Fig. 16b by arrows, such a blade will not significantly deform further, with the advantage that the blade form remains practically unchanged over practically the entire range of rotational speed.

[0095] Fig. 17a shows a rotor in an expanded state free from forces in a view from the side with illustration of a plane of section C-C. Fig. 17b shows the same rotor in a sectional view along said planar section. The dashed lines 121 and 122 represent the neutral fibers or surface of the respective blades. The fibers 123 and 124 show, by way of example, the course of two fibers in the

illustrated planar section. As can be seen, the fibers in this example are already stretched in a wide area. Since the fibers are very high-tensile, a further elongation of the fibers is hardly possible. Even under the forces that occur in the operating state, which act on the blades due to the flow pressure and which are illustrated in Fig. 17b by arrows, such a blade will not significantly deform further.

[0096] As a result of the above-mentioned features, in particular as a result of the design of the rotor and introduction of suitable reinforcement elements/fibers, a stable design of a rotor with sufficient form accuracy is achieved, even after partial overstretching or frequent alternating load or constantly applied bending load. As a result of the production method according to the invention and the presented injection mold, an expedient and advantageous possibility for production of the rotor according to the invention has been demonstrated.

[0097] The invention is defined by the claims. The following aspects are also part of the disclosure and may serve to clarify the invention:
One aspect relates to a rotor for a compressible fluid pump, in particular a blood pump which can be introduced through a blood vessel into a patient's body, which rotor has one or more impeller elements 15 and can be radially compressed and expanded between a first, compressed state and a second, radially expanded state, and consists at least in part of a plastic reinforced by strand-like reinforcement elements, in particular fibers, and is intended to rotate about an axis of rotation, wherein the rotor is tensioned in the first, compressed state and is free from external stresses in the second, expanded state, and wherein a third state exists, which the rotor 42 assumes in the operating state under load, wherein various materials of the rotor and their distribution are adapted to one another in such a way that, in the second state of the rotor, material stresses are produced selectively, which tension and/or stretch the reinforcement elements.

[0098] According to one example, it can beis additionally provided that the reinforcement elements are surrounded by the plastic from which the rotor is predominantly made, at least to a proportion of 90%, in particular 99% of their surface, and more particularly completely.

[0099] According to a further example, it is additionally provided that the plastic material in which the reinforcement elements are embedded has different properties, at least in regions, on the side of the impeller elements not loaded by the fluid counterpressure during operation, in particular on the corresponding side of the impeller element with respect to the fiber or surface constituting the bending neutral fiber or plane during pump operation under bending load, compared to the side of the impeller elements that is loaded by the fluid counterpressure, in particular is more heavily cross-linked or shrunk on the side not loaded by the fluid counterpressure or carries there, on the surface, a support shrunk on the impeller element, said support being provided in the form of one or more films, coatings or fibers.

[0100] According to a further example, it is additionally provided that one or more impeller elements of the rotor is/are produced by injection molding with simultaneous addition of reinforcement elements in the expanded state, wherein the reinforcement elements are surrounded on all sides by an injection molding material and are present in a stretched form at least in part in the expanded state, in particular are present in a form stretched to an extent of at least 90 %, more particularly 95 %, more particularly 99 %.

[0101] According to a further example, it is additionally provided that the reinforcement elements in the second, expanded state of the rotor, without a fluid counterpressure, are present in a form stretched to such an extent that when transitioning to a third state, which constitutes the operating state with a fluid counterpressure, they are lengthened by less than 5 %, in particular less than 1 %, wherein the lengthening is measured in particular on the basis of the distance between the two ends of a reinforcement element.

[0102] According to a further example, it is additionally provided that in a second, expanded state of the rotor and/or a third operating state with fluid counterpressure at least a portion of the reinforcing elements, in particular at least 10%, and further in particular at least 30%, run stretched and straight in at least one region of an impeller element in which it is curved.

[0103] A further aspect relates to a method for producing a rotor for a fluid pump, in particular according to the above-described aspect, wherein it is provided that the rotor, after the injection molding, is subjected to a treatment

which causes a different shrinkage and/or cross-linking of the molding material on the side of the impeller elements loaded by the fluid counterpressure during operation than on the opposite side.

[0104] According to one example, in a method for producing a rotor for a fluid pump, in particular according to the above-described aspect, by injection molding, it is provided that a shrinkable layer is applied to at least one of the impeller elements on the side opposite the side of the impeller elements exposed to a fluid counterpressure during operation.

[0105] A further aspect relates to a mold for a rotor for a fluid pump comprising impeller elements according to the above-described aspect, in which mold at least two different injection openings are provided.

[0106] A further aspect relates to a rotor as described above, wherein it is provided that the reinforcement elements have a two-dimensional extent, for example are embodied as film pieces or fabric with groups of fibers crossing one another (see Figures 14a and 14b).

[0107] Further aspects of the disclosure are as follows:
One aspect relates to a rotor for a compressible fluid pump, in particular a blood pump which can be introduced through a blood vessel into a patient's body, which rotor has one or more impeller elements and can be radially compressed and expanded between a compressed state and an expanded state, and consists at least in part of a plastic reinforced by strand-like reinforcement elements, in particular fibers, and is intended to rotate about an axis of rotation, wherein the plastic has a Shore hardness < 100 D.

[0108] According to one example, a first portion of more than 30%, in particular more than 50%, of the reinforcing elements, in particular fibers, in the expanded state of the rotor extends essentially stretched from their respective section closest to the axis of rotation to a second section further away from the axis of rotation.

[0109] A further aspect relates to a rotor is provided for a compressible fluid pump, in particular a blood pump which can be introduced through a blood vessel into a patient's body, which rotor has one or more impeller elements and can be radially compressed and expanded between a compressed state

and an expanded state and consists at least in part of a plastic reinforced by strand-like reinforcement elements, in particular fibers, and is intended to rotate about an axis of rotation, wherein a first proportion of more than 30%, in particular more than 50% of the reinforcement elements, in particular fibers in the expanded state of the rotor runs in a substantially stretched manner from their first section disposed closest to the axis of rotation to a second section disposed further away from the axis of rotation. wherein the first portion of reinforcing elements, in particular fibers, has a length which corresponds to at least 30%, in particular 50%, of the maximum height of the conveying elements, measured in radial direction of the rotor in the expanded state.

[0110] According to one example, particularly in the expanded state each reinforcing element/each fiber of the first portion deviates in its course by at most 45° in axial direction and/or azimuthal direction from a position radially aligned with the rotor axis.

[0111] According to a further example, particularly in the expanded state each reinforcing element/each fiber of the first portion extends essentially perpendicular to the axis of rotation.

[0112] According to a further example, particularly in the expanded state each reinforcing element/each fiber of the first portion extends radially with respect to the axis of rotation.

[0113] According to a further example, each reinforcing element/each fiber of the first portion of the first portion extends along the longitudinal axis of a conveying element.

[0114] According to a further example, the length of the reinforcing elements, in particular fibers, in particular the first portion, is at least 10%, in particular at least 30%, of the radius of the rotor.

[0115] According to a further example, the diameter of the reinforcing elements, in particular fibers, in particular of the first portion, is smaller than 40 µm.

[0116] According to a further example, the impeller elements consist of a foam material.

[0117] According to a further example, a portion of reinforcing elements/fibers in the expanded state of the rotor extends transversely to the reinforcing elements/fibers of the first part and, in particular, encloses angles of at least 30° on average with this first part.

[0118] According to a further example, the reinforcing elements/fibers are at least partially in the form of fabric sections having fibers running longitudinally and transversely.

[0119] According to a further example, the reinforcement elements are present in the form of film strips, of which the length is at least three times, in particular at least five times, more particularly at least ten times as great as their width.

[0120] According to one example, it can beis additionally provided that the reinforcement elements are surrounded by the plastic from which the rotor is predominantly made, at least to a proportion of 90%, in particular 99% of their surface, and more particularly completely.

[0121] According to a further example, the plastic material in which the reinforcement elements are embedded has different properties, at least in regions, on the side of the impeller elements not loaded by the fluid counterpressure during operation compared to the side of the impeller elements that is loaded by the fluid counterpressure, in particular is more heavily cross-linked or shrunk on the side not loaded by the fluid counterpressure or carries there, on the surface, a support shrunk on the impeller element, said support being provided in the form of one or more films, coatings or fibers.

[0122] A further aspect relates to a rotor for a compressible fluid pump which can be expanded and compressed radially between a first, compressed state and a second, expanded state, wherein one or more impeller elements of the rotor is/are produced by injection molding with simultaneous addition of reinforcement elements in the expanded state, wherein the reinforcement elements are surrounded on all sides by an injection molding material and are present in a stretched form at least in part in the expanded state, in particular are present in a form stretched to an extent of at least 90%, more particularly 95%, more particularly 99%.

[0123] According to one example, the reinforcement elements in the second, expanded state of the rotor, without a fluid counter pressure, are present in a form stretched to such an extent that when transitioning to a third state, which constitutes the operating state with a fluid counter pressure, they are lengthened by less than 5%, in particular less than 1%, wherein the lengthening is measured in particular on the basis of the distance between the two ends of a reinforcement element.

[0124] According to a further example, in a second, expanded state of the rotor and/or a third operating state with fluid counterpressure at least a portion of the reinforcing elements, in particular at least 10%, and further in particular at least 30%, run stretched and straight in at least one region of an impeller element in which it is curved.

[0125] According to a further example, in a region of an impeller element in which the latter is curved, at least two portions of reinforcing elements run straight and stretched, wherein the directions in which the reinforcing elements of the portions run are parallel for the respective portion but different for the different portions.

[0126] According to a further example, the length of the reinforcing elements in at least 30%, in particular at least 50%, of the elements is greater than the average thickness of the impeller elements, in particular at least twice as long, further in particular at least 5 times or 10 times as long.

[0127] According to a further example, the reinforcing elements, in particular fibers, are introduced into the plastic embedding them in an injection molding process and, during the time in which the rotor is in the injection mold, have a sectionally curved profile along the flow of the plastic into the injection mold.

[0128] A further aspect relates to a method for producing a rotor as described above by means of a molding method, in particular an injection molding method, in which the material of the impeller elements is introduced into the volumes of the impeller elements in the radial direction with respect to the rotor axis, in such a way that the injection molding material flows into the volumes of the impeller elements in the radial direction.

[0129] According to one example, the injection molding material is injected into the volumes of each of the impeller elements in the radial direction from the region closest to the rotor axis or from the region furthest away from the rotor axis.

[0130] According to a further example, the rotor is produced by molding, in particular injection molding, wherein the injection molding process is performed in two successive phases with different injection directions and/or from two different injection points.

[0131] According to the first example, the rotor, after the injection molding, is subjected to a treatment which causes a different shrinkage and/or cross-linking of the molding material on the side of the impeller elements loaded by the fluid counter pressure during operation than on the opposite side.

[0132] According to a further example, a shrinkable layer is applied to at least one of the impeller elements on the side opposite the side of the impeller elements exposed to a fluid counter pressure during operation.

[0133] A further aspect relates to a mold for a rotor according to any one of the above-describedwherein overflow channels are provided in the volumes of the impeller elements at the radial edges thereof in order to enable an uninterrupted flow of the molding material in the radial direction.

[0134] According to one example, the mold has at least two different injection openings.

Patentkrav

1. Rotor til en komprimerbar fluidpumpe, især en blodpumpe, som kan indføres i en patients krop gennem et blodkar, har et eller flere transportelementer (15) og kan komprimeres og udvides radialt mellem en komprimeret tilstand og en ekspanderet tilstand, og som i det mindste delvist består af et plastmateriale, der er forstærket med strenglignende forstærkningselementer, især fibre (10, 11, 13, 18, 19), og er indrettet til rotation omkring en rotationsakse (14), **kendetegnet ved, at** plasten har en Shore hårdhed < 80 D.

2. Rotor ifølge krav 1, **kendetegnet ved, at** en første del på mere end 30 %, især mere end 50 %, af forstærkningselementerne, især fibre (10, 11, 13, 18, 19), i ekspanderet tilstand af rotoren (42) forløber i det væsentlige strakt fra deres respektive sektion (10a, 11a, 13a) tættest på rotationsaksen til en anden sektion (10b, 11b, 13b) længere væk fra rotationsaksen.

3. Rotor ifølge krav 2, **kendetegnet ved, at** den første del af forstærkningselementerne, især fibre, har en længde, der svarer til mindst 30 %, især 50 %, af transportelementernes maksimale højde målt i radial retning af rotoren i ekspanderet tilstand.

4. Rotor ifølge krav 2 eller et af de følgende krav, **kendetegnet ved, at** hvert forstærkningselement/hver fiber (10, 11, 13, 18, 19) af den første del især i den ekspanderede tilstand afviger i sit forløb med højst 45° i aksial retning og/eller azimutretning fra en position, der er radialt på linje med rotoraksen.

5. Rotor ifølge krav 2 eller et af de følgende krav, **kendetegnet ved, at** hvert forstærkningselement/hver fiber (10, 11, 13, 18, 19) af den første del især i den ekspanderede tilstand strækker sig i det væsentlige vinkelret på rotationsaksen.

6. Rotor ifølge krav 2 eller et af de følgende krav, **kendetegnet ved, at** hvert forstærkningselement/hver fiber af den første del især i ekspanderet tilstand strækker sig radialt i forhold til rotationsaksen (14).

7. Rotoren ifølge krav 2 eller et af de følgende krav, **kendetegnet ved, at** hvert forstærkningselement/hver fiber (10, 11, 13, 18, 19) af den første del af den første del strækker sig langs den langsgående akse (44) af et transportelement.

8. Rotor ifølge krav 2 eller et af følgende, **kendetegnet ved, at** længden af forstærkningselementerne, især fibrene (10, 11, 13, 18, 19), især af den første del, er mindst 10%, især mindst 30% af rotorens radius.

9. Rotor ifølge krav 2 eller et af de følgende krav, **kendetegnet ved, at** diameteren af forstærkningselementerne, især fibrene (10, 11, 13, 18, 19), især af den første del, er mindre end 40 µm.

10. Rotor ifølge krav 1 eller et af de følgende krav, **kendetegnet ved, at** transportelementerne (15) består af et skum.

11. Rotoren ifølge krav 1 eller et af de følgende krav, **kendetegnet ved, at** en del af forstærkningselementerne/fibrene i rotorens ekspanderede tilstand strækker sig på tværs af forstærkningselementerne/fibrene af den første del og især danner en gennemsnitsvinkel på mindst 30° dermed.

12. Rotor ifølge krav 1 eller et af de følgende krav, **kendetegnet ved, at** forstærkningselementerne/-fibrene i det mindste delvist er udformet som stofsektioner med langsgående og tværgående fibre.

13. Rotor ifølge krav 1 eller et af de følgende krav, **kendetegnet ved, at** forstærkningselementerne er i form af filmstrimler, hvis længde er mindst tre

gange, især mindst fem gange, yderligere især mindst ti gange så stor som deres bredde.

14. Rotoren ifølge krav 1 eller et af de følgende krav, **kendetegnet ved, at** forstærkningselementerne er omsluttet af plastmaterialet, hvoraf rotoren for det meste er fremstillet, i det mindste på en del af 90%, især 99%, af deres overflade, nærmere bestemt fuldstændigt.

15. Rotor ifølge krav 1 eller et hvilket som helst af de følgende krav, **kendetegnet ved, at** plastmaterialet, som indlejrer forstærkningselementerne, har forskellige egenskaber, i det mindste i nogle områder, på den side af transportelementerne, der ikke er udsat for fluidmodtrykket under drift end på den side af transportelementerne, der udsættes for fluidmodtryk, især er stærkere tværbundet eller krympet på den side, der ikke er udsat for væskemodtryk, eller bærer på sin overflade en overlejring (86) i form af en eller flere film, belægninger eller fibre, som er krympet på leveringselementet (82).

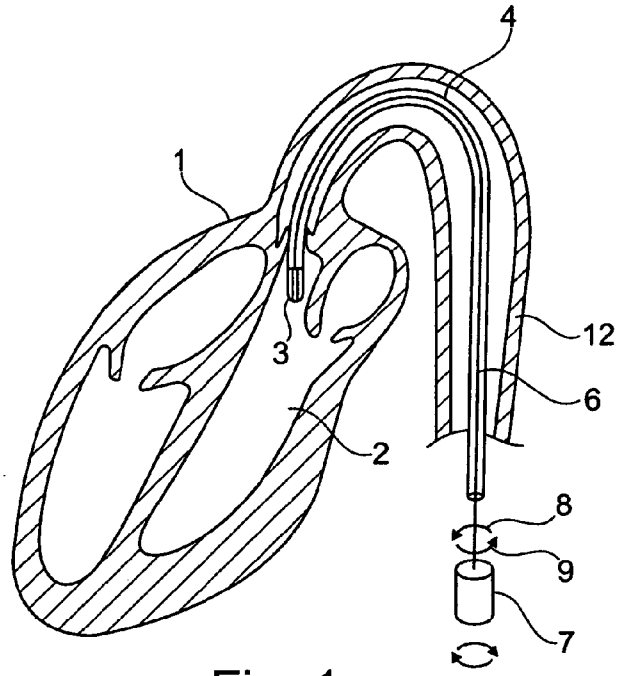


Fig. 1

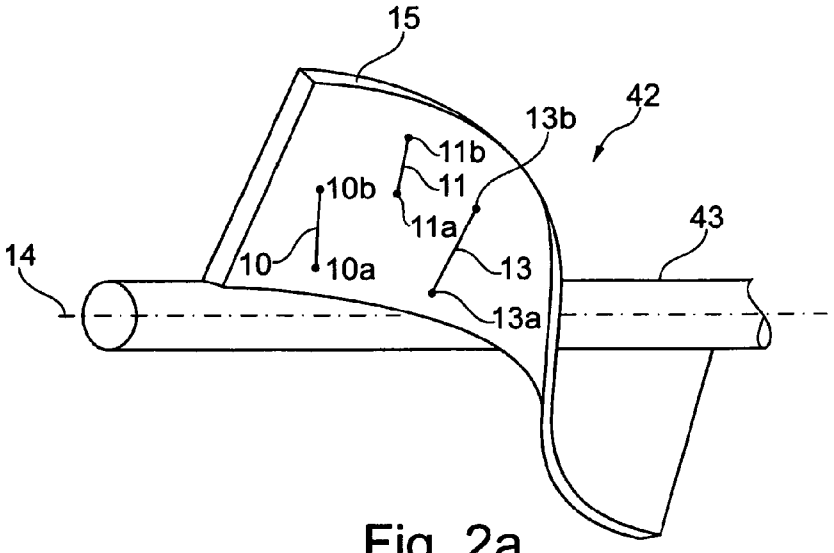


Fig. 2a

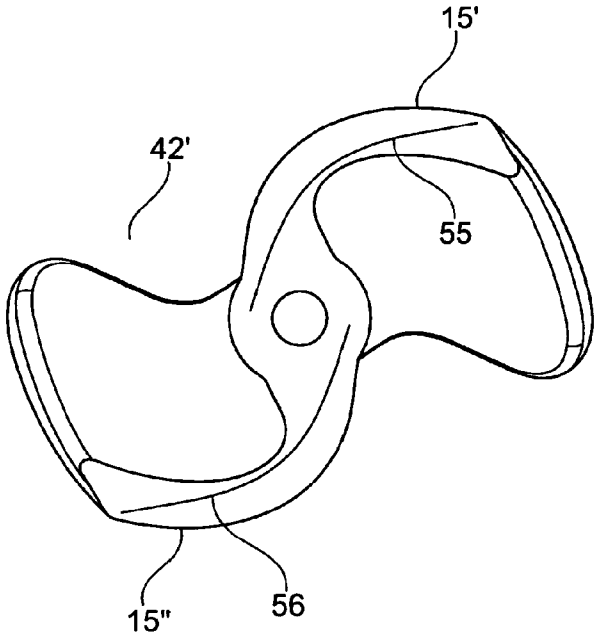


Fig. 2b

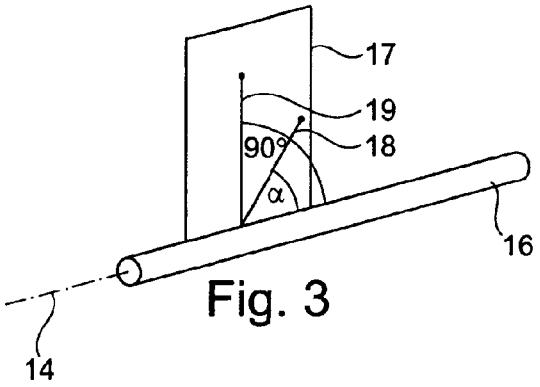


Fig. 3

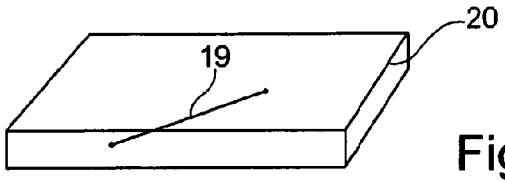


Fig. 4

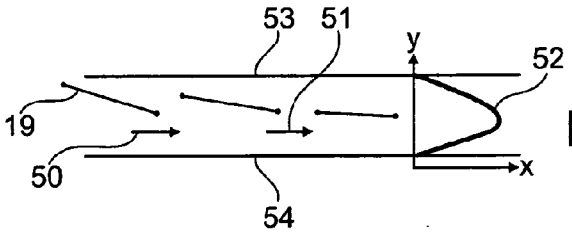


Fig. 5a

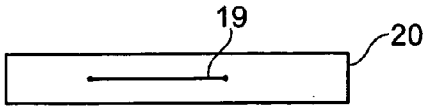


Fig. 5b

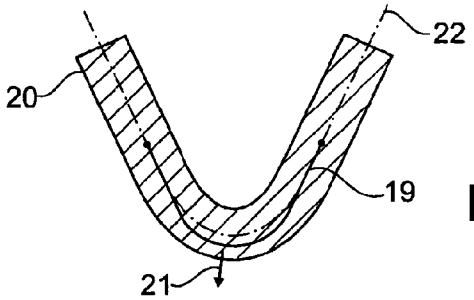


Fig. 6

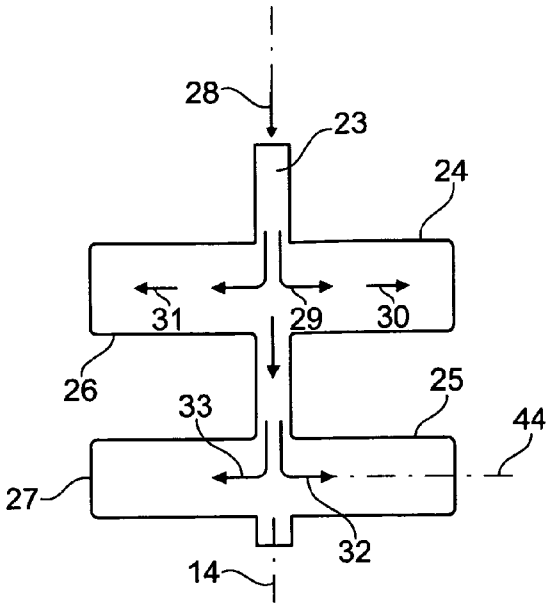


Fig. 7

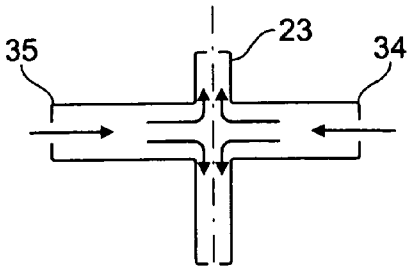


Fig. 8

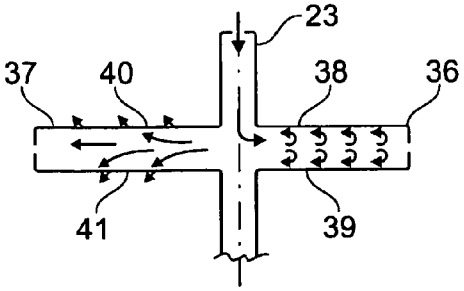


Fig. 9

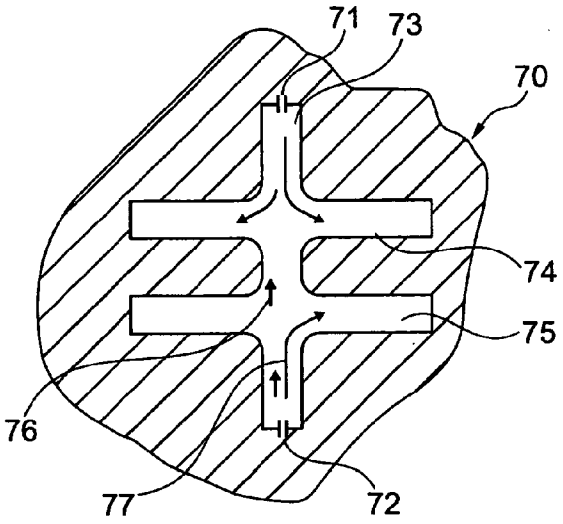


Fig. 10

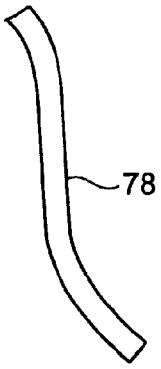


Fig. 11

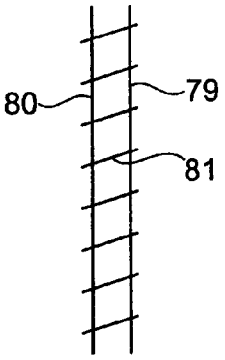


Fig. 12

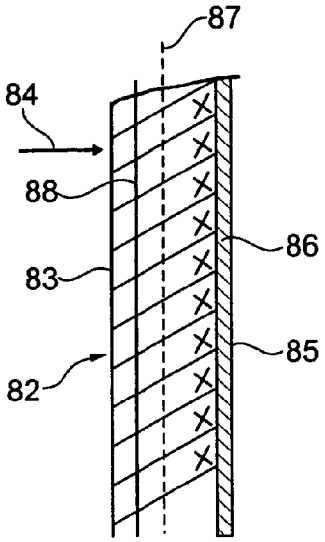


Fig. 13

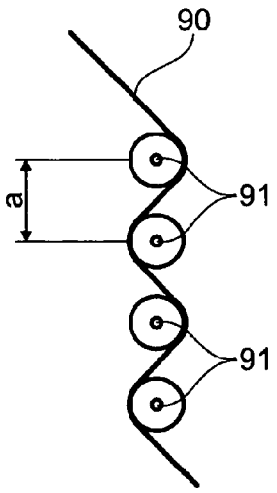


Fig. 14a

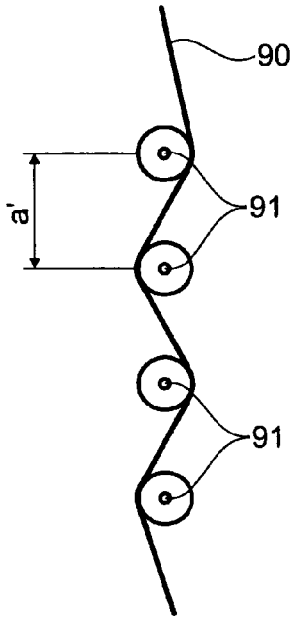


Fig. 14b

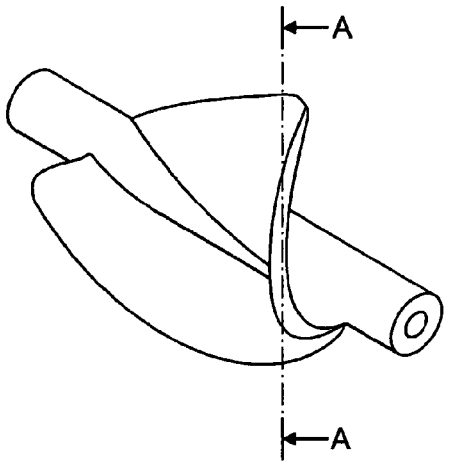


Fig. 15a

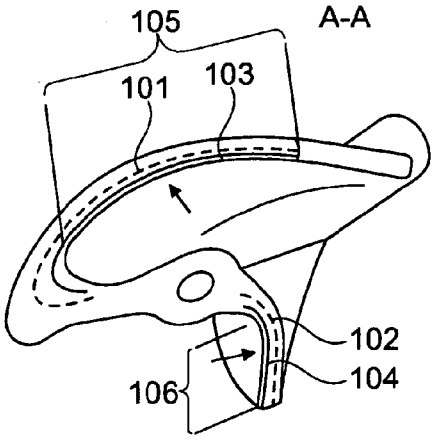


Fig. 15b

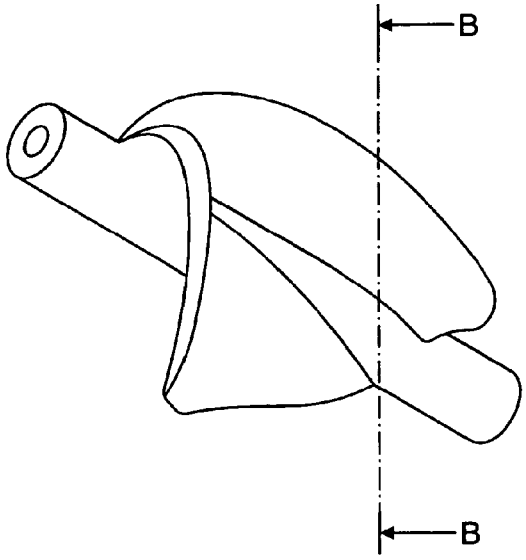


Fig. 16a

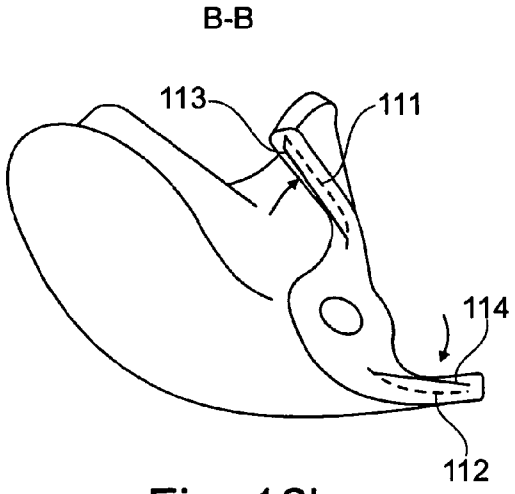


Fig. 16b

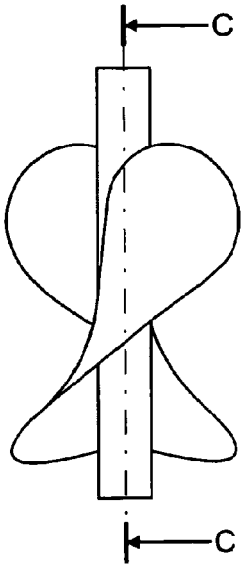


Fig. 17a

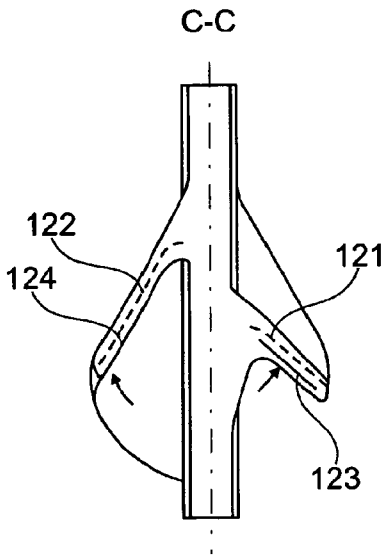


Fig. 17b