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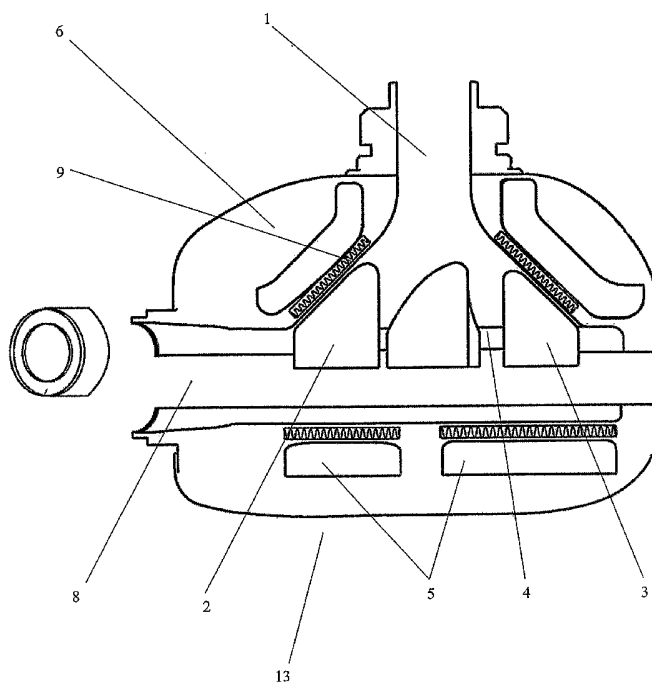
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(54) Title: IMPROVED BLOOD PUMP



(57) Abstract: An implantable rotary blood pump including an impeller adapted to rotate within a pump housing, and a motor having at least one stator mounted on or within the pump housing that interacts with magnetised regions in the impeller. At least a portion of the pump is made of glassy carbon.

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IMPROVED BLOOD PUMP

Field of Invention

The present invention relates to an improved implantable blood pump.

Background of Invention

Previously, congestive heart failure may have been treated with the use of a blood pump to assist the pumping of blood around the circulatory system of a patient.

A prior art implantable blood pump is described in US Patent 6,609,883 - Woodard et al. in which the blood pump is primarily fabricated from a titanium or its alloys that may include by weight 6% aluminium and 4% vanadium (Ti-6Al-4V). In particular, the pump housing of this blood pump is metallic and includes a magnetic drive motor acting on a hydrodynamic impeller within the pump housing. Whilst the material from which the pump is made is biocompatible, one of the disadvantages with this is that titanium is a relatively costly material to machine.

Blood pumps created from polymers and ceramics have previously been described extensively in this field. Polymers generally have fluid permeable quantities which reduces the biocompatibility, wear resistance and dimensional stability of parts. Ceramics components are generally overly brittle and relatively difficult to machine and manufacture.

It is known to coat components of implantable medical devices with biocompatible materials, which are less likely to promote adverse biological reactions. One such known material is Diamond-Like Carbon (DLC). Whilst DLC is a biocompatible material its use is generally limited to forming thin layers or coatings, typically by ion beam deposition or sputter deposition. However, DLC cannot be used to manufacture components by moulding or machining.

It is also an object of the present invention to address or ameliorate one or more of the abovementioned disadvantages.

Brief Description of the Invention

In accordance with a first aspect the present invention consists of an implantable rotary blood pump including an impeller adapted to rotate within a pump housing, and a motor having at least one stator mounted on or within the pump housing that interacts with magnetised regions in said impeller, characterised in that at least a portion of said pump is made of glassy carbon.

Preferably said housing includes said portion of glassy carbon.

Preferably said impeller includes said portion of glassy carbon.

Preferably said portion of glassy carbon forms a hydrodynamic bearing.

Preferably said portion of glassy carbon is not positioned between stators.

Preferably said portion of glassy carbon is implanted with any one or more of hydrogen, oxygen, helium, carbon, nitrogen or metal ions.

Preferably said portion of glassy carbon is heat-treated.

Preferably said housing includes an upper portion screwably connected to a lower portion.

Preferably said glassy carbon has a density between 1.40 and 1.60.

Preferably said glassy carbon has a thickness less than 8mm.

Preferably said portion of glassy carbon is covered by an impermeable layer adapted to minimise the egress of bio-toxic compounds.

Brief Description of Drawings

Embodiments of the invention will now be described with reference to the drawings in which:

Fig. 1 shows a cross-sectional view of a first embodiment of an implantable rotary blood pump in accordance with the present invention;

Fig. 2 shows an enlarged cross-sectional view of a second embodiment of a blade of an impeller for an implantable rotary blood pump in accordance with the present invention; and

Fig. 3 shows a cross-sectional view of a third embodiment of an implantable rotary blood pump in accordance with the present invention.

Detailed Description of Embodiments

A first embodiment of the present invention is shown in Fig. 1. In this embodiment, an implantable rotary blood pump 13 is shown. This blood pump 13 includes an inlet 1 and an outlet 8; an impeller 2 which rotates and propels blood from the inlet 1 using centrifugal propulsion through the pump housing 6 to the outlet 8. A motor generates the torque force for rotating the impeller 2. The motor is formed by the interaction of stators 5 axially mounted within the pump housing 6 interacting with magnetic regions in the impeller 2.

In use, the impeller 2 is hydrodynamically suspended on a fluid bearing formed by a restriction gap 9 between each of the four blades 3 of impeller 2 and the inner wall of the pump housing 6. The four blades 3 are joined together by struts 4 in a substantially square configuration.

In this embodiment, the housing 6 is entirely comprised of glassy carbon. Glassy carbon is generally a class of non-graphitizing carbon and has relatively increased strength and hardness characteristics when compared to ordinary graphite. Glassy carbon generally includes linkages of small graphite like regions and has a lustrous surface and homogenous structure resembling glass. Glassy carbon may be produced using precursor materials such as cellulose, kerosene, palm oil or a thermosetting resin such as phenolic resin and sucrose with polyvinylidene chloride. The preparation of

glassy carbon involves subjecting the organic precursors to a series of heat treatments at temperatures up to 3000°C. Unlike many non-graphitizing carbons, they are impermeable to gases and are chemically extremely inert, including those which have been prepared at very high temperatures. Typically, the rates of oxidation of certain glassy carbons in oxygen, carbon dioxide or water vapour are lower than those of any other carbon making them ideally suited to applications in implantable medical devices.

The structure of glassy carbon typically contains more than 90% sp² hybridised carbon atoms, with less than 10 at.% hydrogen. Glassy carbon may typically have a hardness of <20GPa and a preferred hardness range of between 5 – 15 GPa. Structurally, glassy carbon is generally understood to be composed of a high proportion of fullerene-related structures which contain varying ratios of pentagonal and hexagonal components, depending on the heat treatment to which the structures were exposed during manufacture. Sheet and ribbon-like components may also be contained within the glassy carbon structure.

Through moulding of the precursor material, such as a resin, glassy carbon can be moulded into solid shapes. It can also be applied as a coating and impregnated into graphite, and a range of other materials.

Glassy carbon may also contain a plurality of pores of about 20-50 Å diameter. The diameter of the pores may be varied depending on the treatment when the glassy carbon is formed. Glassy carbon has many properties that make it suitable for use with blood pumps and these include: relatively low density and high corrosion resistance, when compared to metals; and relatively high strength, and low fluid permeability, when compared to plastics.

Please note that the definition of glassy carbon within this specification includes vitreous carbon. Glassy carbon is relatively amorphous and generally shows little or no signs of crystallinity. Glassy carbon may exhibit no or few diffraction peaks and only an amorphous halo when viewed by x-ray diffraction. Please note that the glassy carbon may include a low level of relatively small crystals. Most graphites (excluding HOPG and pyrolytic graphite) exhibit considerable porosity whereas glassy carbon is

relatively denser. As a consequence, glassy carbon lacks the porosity of other types of graphite.

Glassy carbon may be ultrasonically cleaned without significant damage and machined to tight tolerances using laser ablation.

The preferred thickness of any pump component made from glassy carbon is less than 8mm. This is due to the method of manufacturing the glassy carbon. To manufacture glassy carbon, a precursor resin is formed by moulding. The moulded resin is then heat-treated to a temperature generally greater than 1000°C. The temperature of the treatment process may be modulated or reduced to create a material with a lower electrical conductivity. For components and parts of a thickness greater than about 8mm, the treatment of heat may preferably be carried out under high pressure. The resulting glassy carbon is relatively easy to machine and polish, if post-process dimensional adjustments are required.

Glassy carbon generally has a high electrical conductivity or a low resistivity, which may be generally undesirable in certain applications. Glassy carbon may be modified with ion implantation to reduce the electrical conductivity by creating insulating regions within the surface of the material. Preferably, hydrogen, oxygen, carbon, nitrogen or metal ions may be used for this ion implantation. As pump 13 is to be implanted within a patient's body, it may be further preferred to implant titanium ions with the glassy carbon components. The electrical conductivity may also be reduced by minimising the pyrolysis temperature as used in the preparation of the material from its precursors.

In the first embodiment, the housing 6 may include an upper portion screwably connected to a lower portion. These portions may both be constructed of glassy carbon.

Fig. 2 shows a second embodiment of the present invention wherein a section of the blade 3 of an impeller 2 for an implantable rotary blood pump is shown. Blade 3 includes a layer of glassy carbon 7, which encapsulates a permanent magnet 11. Permanent magnets 11 are constructed of generally bio-toxic material. In use, it is

necessary to prevent the bio-toxic material from contacting the blood in the pump. Additionally, it is important to note that glassy carbons are slightly fluid permeable and as such bio-toxic compounds may degrade and release toxic chemicals or compounds in a patient's circulatory system.

Hence the glassy carbon layer 7 of the blade 3 is coated in an impermeable barrier 12a to block, stop or greatly impede the eluting or release of bio-toxic compounds or chemicals into the patient's blood stream. A similar barrier 12b also encapsulates, coat and seal the permanent magnet 11.

Preferably, these barriers 12a and 12b may be constructed from gold, zinc, Paralene™ or similar impermeable coating material.

A third embodiment is shown in Fig. 3, a blood pump 13 is shown in an axial flow configuration. Similar numbering has been used in this embodiment as previous embodiments. The impeller 2 includes a shaft 103 running along the axis of rotation; an annular ring 102 with hydrodynamic bearings on the upper and lower angular surfaces of the annular ring 102; and a set of blades 3 which join the shaft 103 to the annular ring 102. In this embodiment, the permanent magnets 11 are encased within the annular ring 102 rather than in the blades 3. The stators 5 are also mounted radially in relation to the axis of rotation of the impeller 2 rather than axially as shown in Fig 1.

Whilst the body of housing 6 is primarily Ti-6Al-4V, this embodiment includes a member 102 constructed of glassy carbon. This member 102 is mounted on a portion of the housing 6, and in particular over the hydrodynamic bearing regions of the housing 6. This has the effect of creating the hydrodynamic bearings or bearing surfaces out of glassy carbon material and gives the bearing surfaces the benefit of the glassy carbon properties, which may include low friction under contact conditions.

The member 102, may be disposed so as not to be directly positioned between the stators 5. This positioning of the member 102 allows the glassy carbon to be substantially removed from the electromagnetic path of the motor formed by the pump

13. The positioning of the member 102 outside the electromagnetic path of the motor reduces electromagnetic eddy currents occurring in the glassy carbon and increases the motor efficiency of the pump 13.

In a further embodiment, not shown, and in a similar fashion to the glassy carbon member 102 of the third embodiment, a glassy carbon member may be mounted or disposed on the impeller 2, thereby also providing the benefits of glassy carbon properties to the hydrodynamic bearing regions of the impeller 2. One such benefit is that of low friction.

It should be understood that whilst the third embodiment depicts a pump 13 having a composite structure including a glassy carbon member 102, it should be understood that in other embodiments other components or portions of the pump may be of glassy carbon.

Also, whilst the blade 3 of the impeller of the abovementioned second embodiment is described as having a magnet 11 substantially encapsulated by glassy carbon 7, in other not shown embodiments other parts of the impeller may wholly be of glassy carbon or a composite of materials including glassy carbon.

The above descriptions only describe some of the embodiments of the present invention and modifications. It may be obvious to those skilled in the art that further modifications can be made thereto without departing from the scope and spirit of the present invention.

Significant focus elsewhere has been directed towards the use of Diamond-Like Carbon (DLC), whereas the present invention described within this specification is directed towards an implantable blood pump at least partially made of glassy carbon. In order to further distinguish between glassy carbon and DLC in this specification, we define DLC as a term covering a class of amorphous carbon materials containing a significant amount of sp^3 hybridised carbon atoms. DLC can be synthesized as thin films using ion beam deposition or sputter deposition. Depending on the sp^3 to sp^2 hybridization ratio

(in some cases exceeding 60%) DLC films can appear transparent, possess high hardness, and be electrically insulating. Some forms of DLC may contain more than 10% hydrogen.

DLC is also generally unlike glassy carbon in terms of electrical conductivity. Typically, DLC is generally limited to forming thin layers or coatings.

CLAIMS

1. An implantable rotary blood pump including an impeller adapted to rotate within a pump housing, and a motor having at least one stator mounted on or within the pump housing that interacts with magnetised regions in said impeller, characterised in that at least a portion of said pump is made of glassy carbon.
2. The implantable rotary blood pump as claimed in claim 1, wherein said housing includes said portion of glassy carbon.
3. The implantable rotary blood pump as claimed in claim 1, wherein said impeller includes said portion of glassy carbon.
4. The implantable rotary blood pump as claimed in claim 1, wherein said portion of glassy carbon forms a hydrodynamic bearing.
5. The implantable rotary blood pump as claimed in claim 2, wherein said portion of glassy carbon is not positioned between stators.
6. The implantable rotary blood pump as claimed in claim 1, wherein said portion of glassy carbon is implanted with any one or more of hydrogen, oxygen, helium, carbon, nitrogen or metal ions.
7. The implantable rotary blood pump as claimed in claim 1, wherein said portion of glassy carbon is heat-treated.
8. The implantable rotary blood pump as claimed in claim 1, wherein said housing includes an upper portion screwably connected to a lower portion.
9. The implantable rotary blood pump as claimed in claim 1, wherein said glassy carbon has a density between 1.40 and 1.60.
10. The implantable rotary blood pump as claimed in claim 1, wherein said glassy carbon has a thickness less than 8mm.
11. The implantable rotary blood pump as claimed in claim 1, wherein said portion of glassy carbon is covered by an impermeable layer adapted to minimise the egress of bio-toxic compounds.

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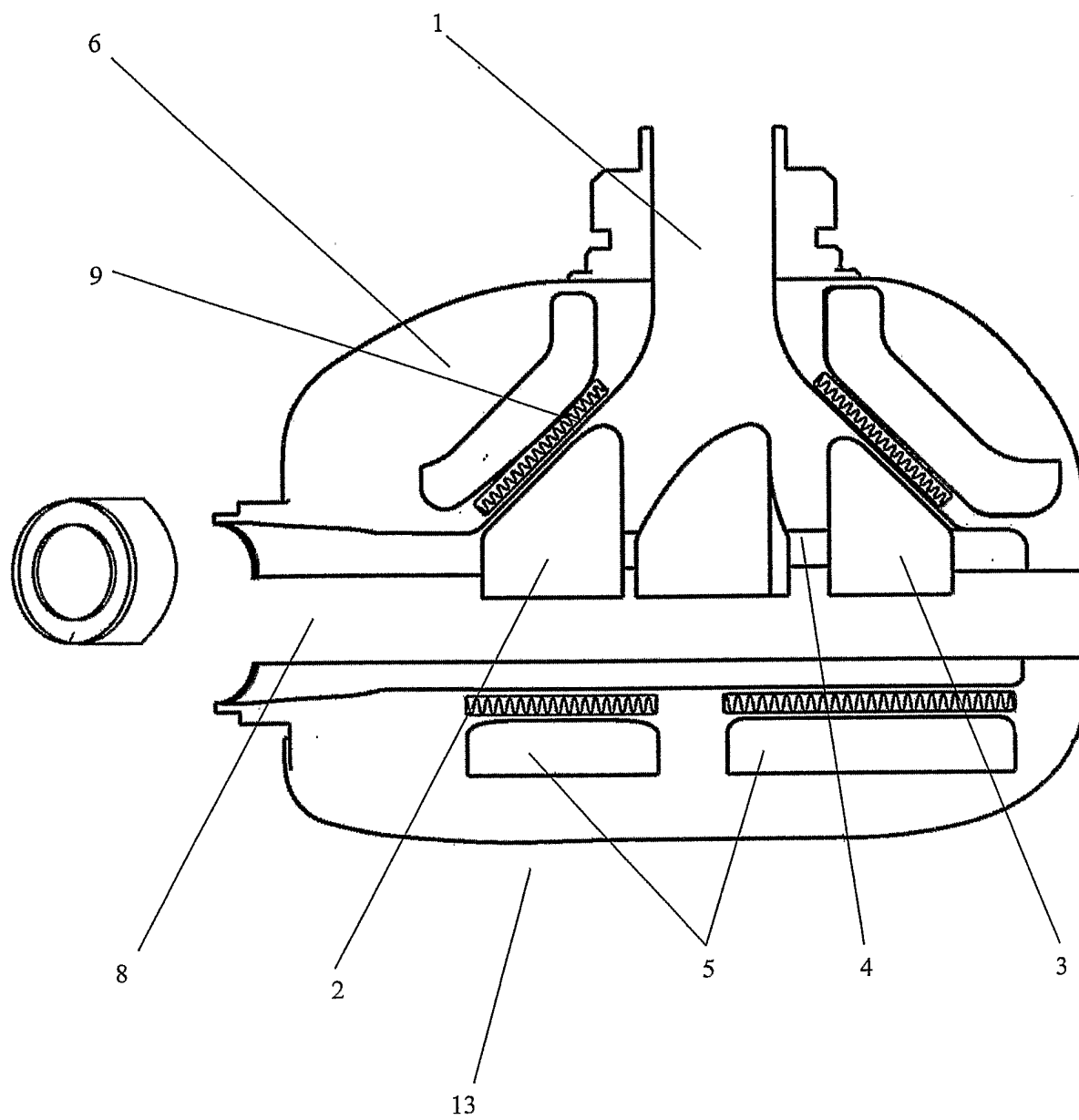


Fig. 1

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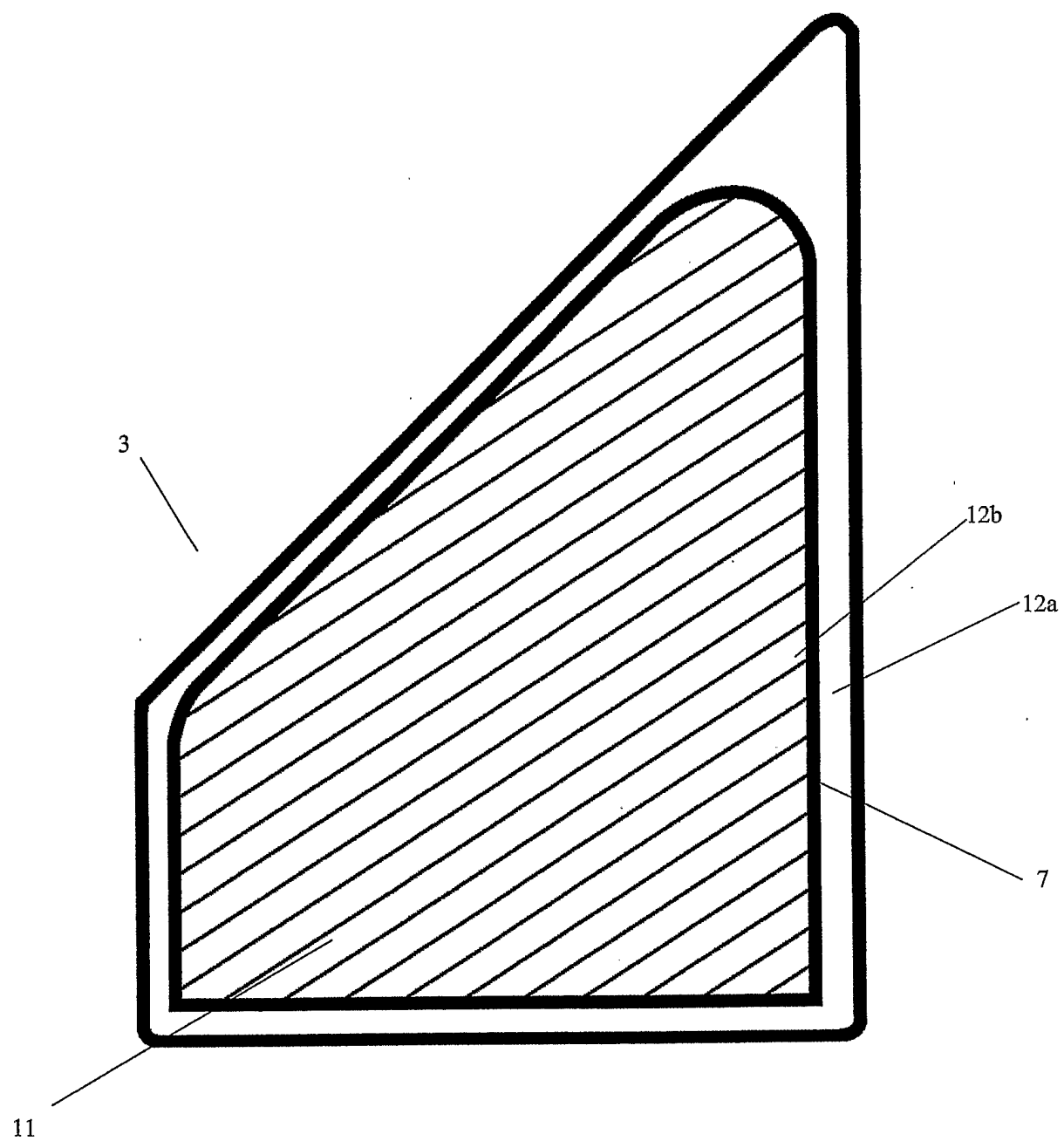


Fig. 2

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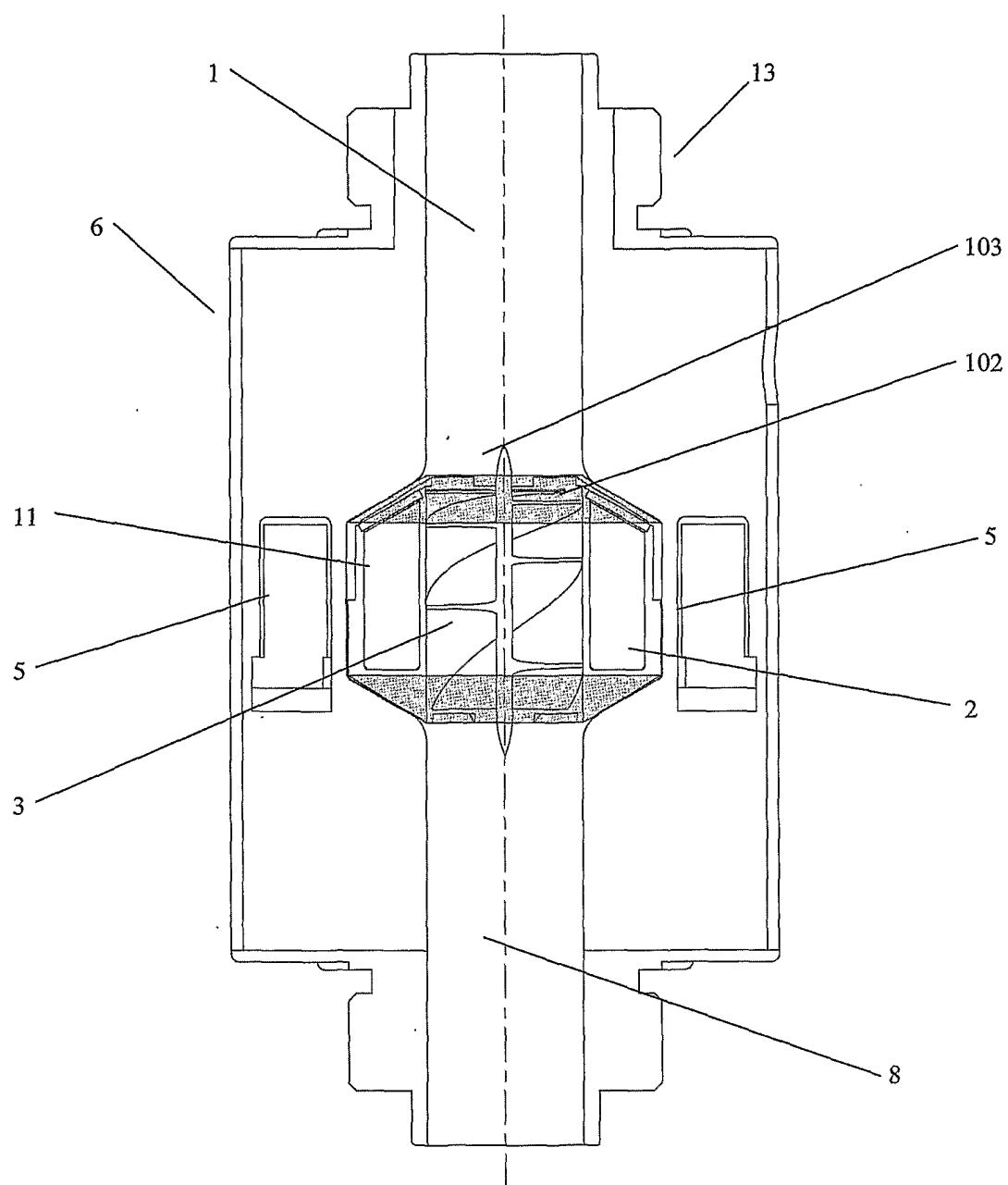


Fig. 3