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(54) **Fecskendő nagynyomású injektorhoz**

Syringe for a high pressure injector

Description:

The invention relates to a syringe for a high-pressure injector, comprising a syringe cylinder having for the hose line a hose connection that is formed at a patient-side end and a piston that is guided inside the syringe cylinder in an advance direction and that is constructed with sealing faces for sealing abutment against an inner wall of the syringe cylinder.

Syringes of this type are used to hold a fluid to be administered to the patient, for example a contrast agent, and are inserted into an injector that then injects this fluid in a controlled manner into the patient, for example during an imaging examination procedure. Such an imaging examination procedure is for example angiography, which requires high-pressure injectors that inject the prepared fluid, such as a contrast agent, from the syringe provided for this and into the patient at a pressure of up to 1200 psi or 83 bar (8.3 MPa).

The syringes for high-pressure injectors used until now have a piston guided in the syringe cylinder that is made of a hard and correspondingly dimensionally stable plastic on which a soft, flexible plastic cap with at least two moulded raised sealing rings is mounted or in which at least two sealing rings are inserted in order to resist the high working pressures of up to 83 bar during a high-pressure injection without leaking.

DE 100 06 560 A1 discloses a piston stopper consisting of 2 components, of which an inner component is made of a harder material and is provided with a covering layer composed of a softer material that is integrally joined to the inner component and produces the seal in the syringe cylinder.

In addition to the good seal, considerable attention should also be given to preventing improper use of such syringes, particularly to prevent an air volume being injected into a patient as a result of such an improper use, which can lead to life-threatening complications.

The object of the present invention is to propose a syringe for a high-pressure injector of the aforementioned type that can be efficiently produced, ensures a reliable seal even

at the high injection pressures that can be reached, modulates the friction between the piston and the syringe cylinder as a function of the pressure and therefore determines the power consumption of the injector as a function of the pressure, and offers a high level of safety in preventing injections of air due to improper use.

To achieve this object, the embodiment of a syringe according to the features of claim 1 is proposed according to the invention.

Advantageous embodiments and further developments of the invention are the subject-matter of the dependent claims.

The invention proposes to construct the piston of the syringe according to the invention as a two-component injection-moulded component on the basis of thermoplastic plastics materials with a core component of a harder plastics material and a covering layer that comprises a softer plastics material, is applied to the core component and is thermally connected to the core component in a rigid manner, so that the piston can be simply and efficiently produced using the known two-component injection moulding method and can suitably cooperate with conventional syringe cylinders. The covering layer forms at least the sealing faces of the piston and the piston surface of the piston facing the patient-side end of the syringe cylinder. In order to absorb air volumes possibly contained in the syringe, the piston has recesses situated in the region of its piston surface.

Such a syringe for a high-pressure injector with a piston constructed as a two-component injection-moulded component with a harder core component and a softer covering layer can be simply and inexpensively manufactured, offers a high level of functional safety, and, for example during sterilisation with ethylene oxide, is easier to wet with the sterilising agent and can therefore be sterilised in a shorter amount of contact time.

With proper use of a syringe according to the invention, a hose line of defined length and with a defined cross-section is first connected to the hose connection, via which the syringe is subsequently filled, by drawing, with the fluid to be injected, for example a contrast agent. In this respect, when the syringe is drawn, first the air volume from the

hose line travels into the interior of the syringe cylinder, followed by the drawn fluid. For this reason, a syringe drawn in this way is then vented by advancing the piston in the advance direction until the air volume contained has been expelled before the hose line is connected to the patient and the injection is carried out. If, however, this venting of the syringe is omitted due to improper use, there is the danger of injecting the air volume into the patient.

In the embodiment according to the invention, this danger is averted by the recesses provided in the piston surface because even when the piston has been advanced all the way in the advance direction, said recesses define a residual volume inside the syringe cylinder in which the existing air volume remains and insofar cannot be injected into the patient. In this regard, the invention takes advantage of the fact that the syringes in a high-pressure injector are usually situated in a downward-inclined position of the hose connection, such as at 120°, so that air contained in the syringe cylinder rises to the piston.

Since usually only especially associated hose lines are used with such syringes, their maximum inner volume is known and it is proposed to design the recesses in the piston so that their total volume corresponds to or exceeds the inner volume of the hose line.

According to a proposal of the invention, the sealing faces have at least one sealing lip that can be placed on the inner wall of the syringe cylinder.

A further proposal of the invention provides that two sealing lips are provided, of which one sealing lip protrudes in the advance direction and the other sealing lip protrudes in the opposite direction. This achieves an even higher degree of tightness in the desired pressure range of the syringe of up to 83 bar, while simultaneously improving the travelling properties of the piston. The sealing lip protruding in the advance direction is therefore oriented towards the hydraulic side of the piston and the sealing lip protruding in the opposite direction is oriented towards its pneumatic side

It is further proposed that a sealing lip is constructed so as to protrude in the advance direction and is spaced apart from the remaining body of the piston by means of a free

space that is open in the advance direction, whereas a further sealing lip is constructed so as to protrude counter to the advance direction and is spaced apart from the remaining body of the piston by means of a free space that is open counter to the advance direction.

This configuration of the sealing lips ensures that with increasing injection pressure of the injector, these sealing lips exert a correspondingly increasing surface pressure on the inner wall of the syringe cylinder and therefore offer reliable protection from leakage even at high pressures expected during use in a high-pressure injector.

According to a proposal of the invention, the piston surface oriented in the advance direction and a conical tip of the piston are formed by the covering layer, so that a particularly simple manufacture is ensured. In this embodiment, the covering layer thus covers all of the surfaces of the piston or core component thereof that come into contact with the fluid with which the syringe cylinder is to be filled.

If two sealing lips are used, according to a proposal of the invention, they are spaced apart from each other by means of a groove counter to the advance direction, whereby a particularly smooth sliding of the piston inside the syringe cylinder is ensured without the risk of a tilting and the attendant weakening of the sealing function of the sealing lip. If fluid unexpectedly slips over a sealing lip, it is captured in the groove that serves as a catch basin in this case and is prevented from escaping between the piston and syringe cylinder.

According to a proposal of the invention, the core component of the piston can be produced from a suitably hard polycarbonate or a possibly reinforced acrylonitrile butadiene styrene.

According to an embodiment of the invention, the covering layer is formed from a thermoplastic elastomer material that can be connected to the core component in an adhesive manner and that has a Shore hardness of from 60 - 90 A. Examples of a thermoplastic elastomer for the covering layer of polycarbonate or acrylonitrile butadiene styrene that can connected to the core component in an adhesive manner

include, for example, include PP/EPDM-based thermoplastic elastomers. For example, the partially cross-linked EPDM/PP blends sold under the trade names Sarlink® by Teknor Apex Company or Badaprene® by Bada AG can be used for the covering layer. Possible alternatives also include polyurethanes of an appropriate hardness.

Furthermore, the core component can be constructed with a formed-on coupling journal for connection to the piston rod of an injector.

Finally, the core component can be provided with a base plate at the end thereof located counter to the advance direction that can be, for example, produced from polycarbonate or acrylonitrile butadiene styrene. The base plate serves to axially stabilise the core component and also as a pressure absorber for the piston rod of the injector.

Further embodiments and details of the invention are explained in greater detail below with reference to the drawings that show exemplary embodiments, wherein:

Fig. 1 shows a longitudinal section through a syringe according to the invention;

Fig. 2 shows the section D-D through the syringe according to Fig. 1;

Fig. 3a schematically shows the section through a first embodiment of a piston of the syringe according to the invention, taken along the line A-A in Fig. 3b;

Fig. 3b shows the top view of the piston according to Fig. 3a

Fig. 4a schematically shows the half-section through a second embodiment of a piston of the syringe according to the invention, taken along the line B-B in Fig. 4b; and

Fig. 4b shows the top view of the piston according to Fig. 4a

Figs. 1 and 2 show a syringe 1 for a high-pressure injector that is used as an accessory for a high-pressure injector and serves to prepare a fluid that is to be administered to a patient, for example a contrast agent for an imaging examination procedure.

In a known way, the syringe 1 comprises a syringe cylinder 2 that can be manufactured for example from PETG or polycarbonate or can also be produced from POM with lubricant incorporated into the matrix. This syringe cylinder 2 is usually transparent.

Inside the syringe cylinder 2, a piston 3 is guided so that it is able to slide in a sliding direction V for the purpose of injecting the fluid from the syringe cylinder 2, the piston 3 naturally also being movable in the opposite direction in order to draw the syringe. In this respect, the maximum diameter of the piston 3 corresponds to the inner diameter Di of the syringe cylinder 2.

The syringe cylinder 2 has for the hose line, not shown here, a hose connection 11 at its patient-side end 10, whereas the piston 3 has a coupling journal 311 for connecting to the piston rod, not shown here, of the injector. In addition, the flange projections 12 at the back end of the syringe cylinder 2 are used for attachment to the injector; see Fig. 2.

The piston 3 is constructed as a two-component injection-moulded component on the basis of thermoplastic plastics materials and comprises a core component 31 of a harder plastics material, for example polycarbonate or acrylonitrile butadiene styrene (ABS), which can possibly be reinforced. Using the two-component injection moulding method, this core material 31 is covered in an adhesive manner with a suitable softer plastics material as a covering layer 30, for example a thermoplastic elastomer or a polyurethane with lubricant incorporated into the matrix and with a shore hardness of from 60-90 A that simultaneously covers all of the surfaces of the piston 3 that come into contact with the fluid that can be held inside the syringe cylinder 2, which surfaces are explained in greater detail below.

The piston thus has a tip 300 with a surrounding piston surface 301 that terminates at a sealing face 302 that rests in a sealed fashion against the inner wall 13 of the syringe

cylinder 2. The tip 300, the piston surface 301, and the adjoining sealing face 302 are integrally formed from the softer covering layer 30.

More details of the design of the sealing face 302 are also shown in the schematised representation according to Fig. 3a.

Starting from the piston surface 301, the sealing face 302 comprises a sealing lip 303a that protrudes in the advance direction V and that is separated from the remaining piston surface 301 by means of a groove-like free space 304 that is open in the advance direction V. Counter to the advance direction V, the sealing lip 303a is first adjoined by an annular groove 305 and then an additional sealing lip 303b as well as a shoulder 307. In the selected exemplary embodiment, the sealing lips 303a and 303b have the same diameter relative to the central axis M, which corresponds to the inner diameter Di of the syringe cylinder 2, whereas the annular groove 305 and the shoulder 307 likewise have the same diameter, which is smaller than that of the sealing lips 303a, b, relative to the central axis M.

If the piston 3 is properly advanced inside the syringe cylinder 2, at the high working pressures of up to 83 bar of a high-pressure injector used for this purpose, corresponding opposing forces of the fluid expelled over the patient-side end 10 act on the piston 3 and its sealing lip 303a, which action is indicated by arrows P1 in the schematic depiction according to Fig. 3a. Because of the shape of the piston surface 301 that rises in a tapering manner to a tip 300, fluid therefore enters the free space 304 that is open in the advance direction V (see arrow P2) and brings about an increase of the surface pressure of the sealing lip 303a on the inner wall 13 of the syringe cylinder 2 in the region F, which increase is proportional to the injection pressure, so that a reliable seal is ensured in this region even at extremely high pressures. Should fluid nevertheless slip over the sealing lip 303a, it is collected in the annular groove 305 situated behind this sealing lip and prevented from escaping from the annular groove 305 by the sealing lip 303b. The sealing lip 303b also provides a precise axial guidance of the piston along the inner wall 13 of the syringe cylinder 2.

The drawing, that is filling, of a syringe of this type with the fluid to be injected is generally effected by a hose line that is connected to the hose connection 11 and that later establishes the connection to the patient. In this regard, during the drawing of the syringe, the air contained in the hose line is first drawn into the interior of the syringe cylinder 2 before being followed by the fluid, and this air must then be removed by advancing the piston 3 a limited distance in the advance direction in order to prevent an injection of air into the patient. If this venting is forgotten, a situation can arise that is extremely dangerous for the patient.

In order to counteract this danger, the piston surface 301 of the piston is constructed with a plurality of, here four, recesses 308 in the piston surface 301 that are offset from one another by 90 degrees and whose volume with respect to the notional surface of revolution of the piston corresponds at least to the volume of the lumen of the hose line. When the piston (3) is advanced to its farthest position in the advance direction (V), an air volume that is present in the syringe cylinder (2), for example due to the failure to perform a venting, can be completely accommodated inside these recesses 308 and is reliably prevented from being discharged from the syringe into the patient. As a result, the syringe shown achieves an extremely high level of protection from improper use.

It is also clear that the piston 3, in the region of its core component 31, is constructed with cavities 313 for an improved load-bearing capacity and for a reduced cycle time in the manufacture of the piston 3. In addition, the coupling journal 311 is formed from the rear end onto the core component 31 and has a hole 312.

To improve the load-bearing capacity of the piston rod, not shown here, that engages the coupling adapter 311, a base plate made of polycarbonate or ABS is inserted into the core component 31 and secured in position by screws, for example.

Figs. 4a and 4b show a shape of the piston 3 that has been modified in relation to the exemplary embodiment shown above, in which the same parts have the same reference numerals and, in order to avoid repetition, are not explained again separately wherever this is not required for comprehension of the invention.

In contrast to the exemplary embodiment according to Figs. 3a and 3b, the piston 3 comprises a second sealing lip 303b that is constructed so as to protrude counter to the advance direction V and likewise separated from the remaining body of the piston 3 by a free space 304b, as is also the case with the sealing lip 303a protruding in the advance direction V and its free space 304a. This yields better properties of the piston 3 when it is acted on by pressure and improves its travelling properties. The first sealing lip 303a is accordingly oriented towards the hydraulic side of the piston and the second sealing lip 303b is oriented toward its pneumatic side. The first sealing lip 303a mainly functions when the piston is moving in the advance direction V, whereas the second seal 303b primarily functions when the piston is moving in the opposite direction.

Naturally, the dimensions and geometric designs of the syringe cylinder 2 and the piston 3 that can be inferred from the drawings are merely intended to serve as examples and depend on the injector used and the area of application.

In any case, it is possible according to the invention to produce syringes that are safe to use and leakproof even for applications in high-pressure injectors at injection pressures of up to 1200 psi, which corresponds to 83 bar.

SZABADALMI IGÉNYPONTOK

FECSKENDŐ NAGYNYOMÁSÚ INJEKTORHOZ

1. Fecskendő egy 83 bár (8,3 MPa) befecskendezési nyomásig injektáló nagynyomású injektor zárt tömlőszerelvényével, amely fecskendő magába foglal egy fecskendőhengert (2) egy, a páciens oldali végén (10) a tömlővezeték számára kialakított tömlőcsatlakozóval (11), és egy, a fecskendőhenger (2) belsejében egy előtolási irányba (V) vezetett dugattyút (3), amely a fecskendőhenger (2) belső falazatán (13) az eszköz tömítésére tömítő felületekkel (302) van kialakítva, és amely egy termoplasztikus műanyag alapra egy keményebb műanyag magrésszel (31) és egy, a magrészre (31), a magrészhez képest lágyabb, felhordott műanyag bevonati réteggel (30) kétkomponensű fröccsöntött alkatrészként van kialakítva, ahol bevonati réteg (30) legalább a tömítő felületek (302) és a dugattyú (3) fecskendőhenger páciens oldali végével (10) határos dugattyúfelületét (301) alkotja, azzal jellemezve, hogy a dugattyú (3) a környező dugattyúfelülettel (301) egy csúccsal (300) rendelkezik, és a dugattyú (3) dugattyúfelület (301) területén kivágásokkal (308) van ellátva, amelyeknek térfogata a dugattyú (3) képzeletbeli forgásfelületével ellentétben legalább a tömlőcsatlakozóhoz (11) csatlakoztatott tömlővezeték térfogatának felel meg, és a tömítő felületek (302) legalább egy előtolási irányba (V) mutató, és egy előtolási irányban (V) nyitott, horonyszerű szabad téren keresztül, a dugattyúfelülettől (301) elválasztott tömítőajkat (303a) foglal magába, amely a fecskendőhenger (2) belső falazatára (13) belehelyezhető, ahol a dugattyú egy nagynyomású injektor előtolási irányba (V) történő előtolása által a folyadék a szabad térbe (304) jut be, és a tömítőajak (303a) felületi nyomása növekedve a befecskendező nyomással arányosan hat a fecskendőhenger (2) belső falazatára (13).

2. Az 1. igénypont szerinti fecskendő, azzal jellemezve, hogy a két tömítőajak egy horonnyal (305) egymástól térközzel van elválasztva.

3. Az 1. vagy a 2. igénypont szerinti fecskendő, azzal jellemezve, hogy egy tömítőajak (303a) az előtolási irányba (V) van elrendezve, és egy előtolási irányban (V) nyitott szabad téren (304a) keresztül a dugattyú (3) fennmaradó korpuszától térközzel van elválasztva, miközben egy további tömítőajak (303b) az előtolási iránnyal (V) szemben van kialakítva, és egy az előtolási iránnyal (V) ellentétesen nyitott szabad tér (304b) a dugattyú további korpuszától (3) térközzel van elválasztva.

4. Az 1-3. igénypontok egyike szerinti fecskendő, azzal jellemezve, hogy a dugattyú (3) magrésze (31) polikarbonátból, vagy akril-butadién-sztirolból van kialakítva.

5. Az 1-4. igénypontok egyike szerinti fecskendő, azzal jellemezve, hogy a bevonati réteg (30) egy a magrésszel (31) szilárdan összekötött termoplasztikus elasztomerből egy 60-90 A felületi keménységgel van kialakítva.

6. Az 1-5. igénypontok egyike szerinti fecskendő, azzal jellemezve, hogy a magrész (31) egy injektor egy dugattyúrúdja számára egy csatlakozócsappal (311) van kialakítva.

7. Az 1-6. igénypontok egyike szerinti fecskendő, azzal jellemezve, hogy a magrész (31) a betolási iránnyal (V) ellentétesen fekvő végén egy alaplappal (32) van ellátva.

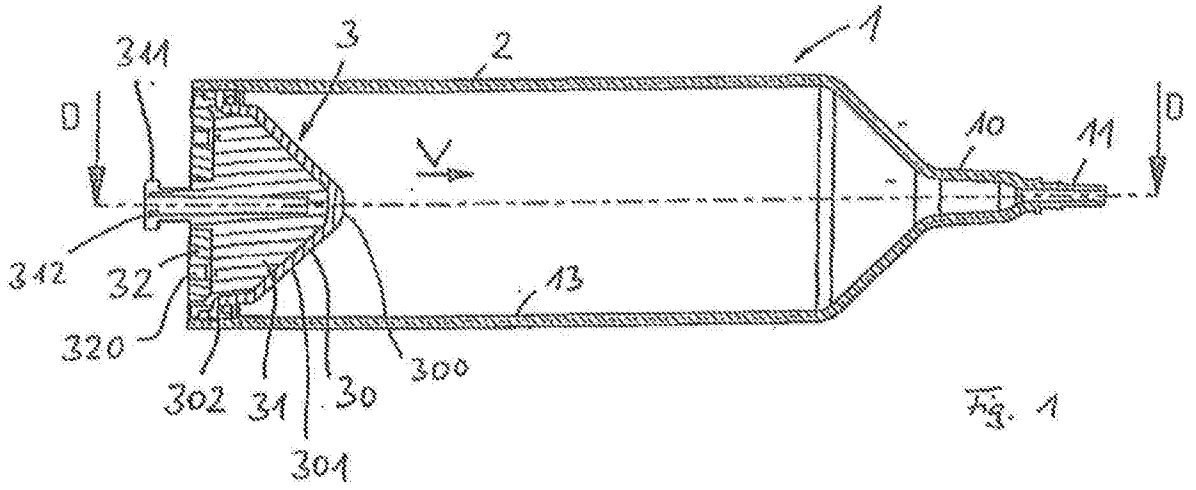


Fig. 1

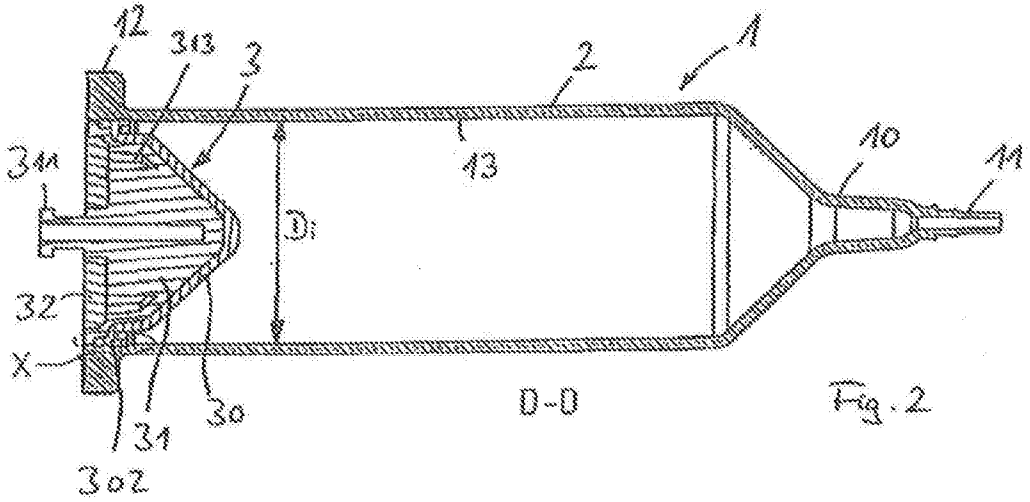


Fig. 2

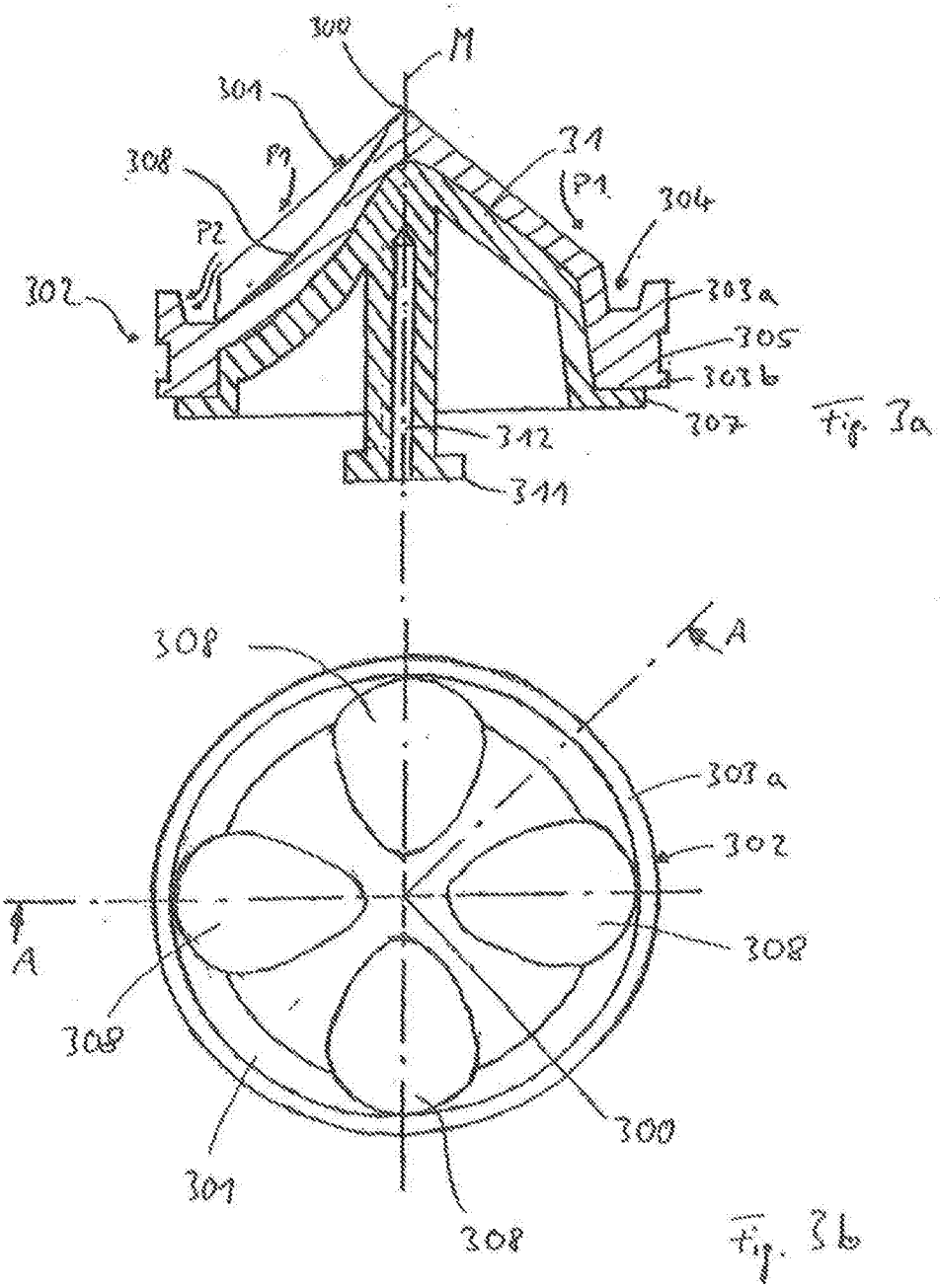
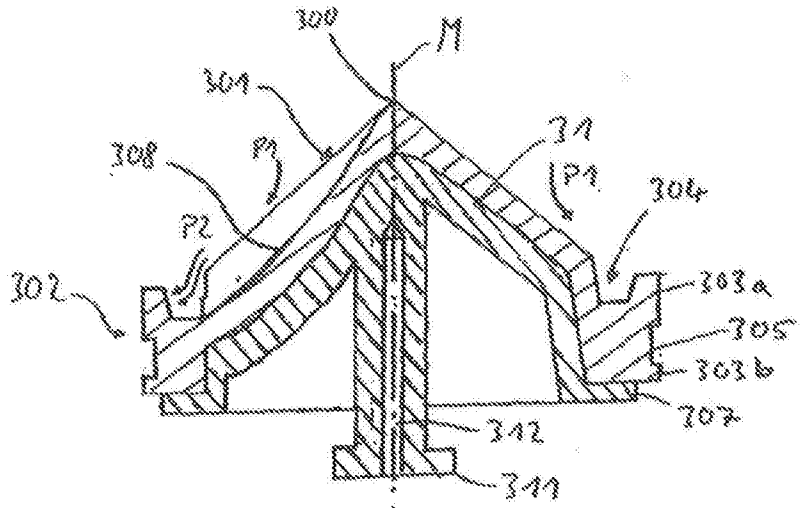

300
M
301
308
P3
P2
311
P1
304
302
303a
305
303b
307
312
311
308
A
303a
302
A
308
308
300
301
308

Fig. 3a

Fig. 3b


300
M
304
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312
311

Fig. 4a

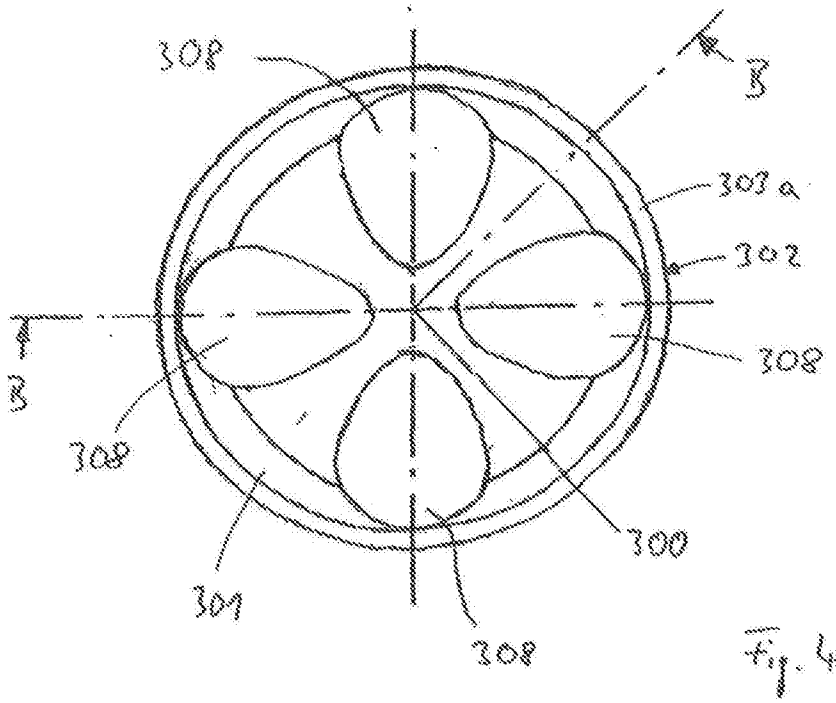
308
B
303a
302
308
B
308
300
301
308

Fig. 4b