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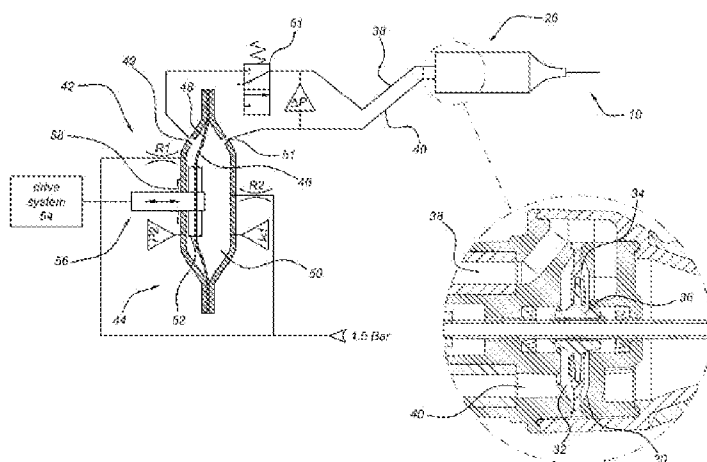
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54 VITRECTOME ACTUATOR

57 An actuation system for an ophthalmic cutting tool is disclosed. The system comprises a chamber (44) separated by a diaphragm (46) into a first compartment (48) a second compartment (50). A first port (49) is provided in fluid communication with the first compartment (48) and a first conduit (38) connected to the ophthalmic cutting tool and a second port (51) is provided in fluid communication with the second compartment (50) and a second conduit (40) connected to the ophthalmic cutting tool. The diaphragm (46) is movably mounted within the chamber (44) and is configured for alternate movement between a first position and a second position to alternately increase and decrease the volume of the first and second compartments. A drive system (54) is provided to drive oscillation of a diaphragm actuator (52) for moving the diaphragm between the first and second positions.



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## VITRECTOME ACTUATOR

### Field of the Invention

5           The invention relates to an actuation system for an ophthalmic cutting tool, such as a vitrectomy tool.

### Background of the Invention

10           Ophthalmic surgical procedures for the removal of tissue from the eye require small, precise surgical cutting instruments. Vitrectomy is a surgical procedure in which vitreous humour is removed from within the eye ball. Such a procedure may be indicated or required in cases of retinal detachment, vitreous entanglement with an intraocular lens, clouded or bloodied humour, or other ocular complaints in which removal of some or all of the vitreous humour is indicated.

15           Known vitrectomy devices can comprise a hollow, reciprocating cutting blade and a sheath, one disposed within the other.

          United States Patent Publication No. 5,106,364 describes a known ophthalmic surgical cutting instrument comprising an outer tubular member with a closed distal end, an aperture adjacent to the closed distal end and an inner tube slidably disposed within the outer tube. The inner tube reciprocates  
20           between first and second positions, and as tissue is drawn into the inner tube via suction, the reciprocation of the cutting member severs the tissue so that it can be aspirated through the inner tubular member.

          United States Patent Application Publication No. US2012310146 describes a system for conducting vitrectomy, which includes a gas source, a vitrector including a cutting mechanism that opens  
25           and closes according to a pressure at the vitrector and a pulse generating system receiving gas from the gas source and generating pulses at the vitrector. The pulses cause the pressure at the vitrector to vary according to a cycle, and the varying pressure at the vitrector causes the cutting mechanism of the vitrector to open and close.

          Known vitrectomy tools and associated pneumatic control systems suffer from high gas  
30           consumption, high noise levels during operation, and sub-optimal response times for the cutting tool. The present invention seeks to provide an improved actuation system for an ophthalmic surgical cutting tool that overcomes problems associated with known systems and devices.

### Summary of the Invention

35           In a first aspect of the present invention, there is provided an actuation system for an ophthalmic cutting tool comprising a chamber fluidically separated by a diaphragm into a first compartment defining a first internal volume and a second compartment defining a second internal volume. A first port is provided in fluid communication with the first compartment and is configured for connection to a first conduit connected to a handheld ophthalmic cutting tool. A second port is provided in fluid  
40           communication with the second compartment, and is configured for connection to a second conduit connected to the ophthalmic cutting tool.

The diaphragm is movably mounted within the chamber and is configured for alternate movement between a first position and a second position, such that movement from the first position to the second position decreases the first volume and increases the second volume. It will be understood that as the volume of the first compartment increases, the volume of the second chamber decreases and vice versa.

To move the diaphragm back and forth within the chamber to alternately vary the volume of the first and second compartments, a diaphragm actuator is coupled to the diaphragm and is configured to oscillate back and forth to move the diaphragm between the first position and the second position. A drive system is configured to drive the oscillation of the diaphragm actuator.

In a second aspect of the invention, first and second variable volume compartments can be fluidically separated from each other by two diaphragms. These aspects operate according to the same principle as the first aspect of the invention because the oscillation of the first and second diaphragms can be driven by a common drive system. In the second aspect of the invention, there is provided an actuation system for an ophthalmic cutting tool comprising a chamber comprising a first compartment at least partially defined by a first diaphragm and having a first internal volume, a second compartment at least partially defined by a second diaphragm and having a second internal volume. The first compartment is fluidically separated from the second compartment.

A first port is provided in fluid communication with the first compartment and is configured for connection to a first conduit connected to a handheld ophthalmic cutting tool. A second port is provided in fluid communication with the second compartment, and is configured for connection to a second conduit connected to the ophthalmic cutting tool.

The first diaphragm is movably mounted with respect to the chamber, and is configured for alternate movement between a first position and a second position, such that movement of the first diaphragm from its first position to its second position decreases the first volume. The second diaphragm is movably mounted with respect to the chamber, and is configured for alternate movement between a first position and a second position, such that movement of the second diaphragm from its first position to its second position increases the second volume. Since movement of the first and second diaphragms in the first direction causes an increase in the volume of the first compartment and a decrease in the volume of the second compartment, operation of two-diaphragm aspects of the invention function in a similar manner to single-diaphragm embodiments.

To move the first and second diaphragms back and forth within the chamber to alternately vary the volume of the first and second compartments, a diaphragm actuator is coupled to the diaphragm and is configured to oscillate back and forth to simultaneously move the first and second diaphragms between the first position and the second positions. A drive system is configured to drive the oscillation of the diaphragm actuator.

In a third aspect of the invention, there is provided a surgical cutting assembly comprising an actuation system as described above and a surgical cutting tool comprising a pneumatically actuated hand-held ophthalmic cutting tool including a conduit comprising a cutting opening and a cutting blade arranged for reciprocating movement within the cutting opening. The hand-held tool comprises a reciprocable separator fluidically separating a first sealed chamber in fluid communication with the first

compartment of the actuator system from a second sealed chamber in fluid communication with the second compartment of the actuator system. The reciprocable separator is coupled to the cutting blade and is configured for reciprocating movement in response to relative change in pressure in the first and second sealed chambers.

5 In any of the above described aspects of the invention, additional features may be incorporated to provide additional benefits. For example, the drive system for driving the membrane actuator can comprise a linear electric motor, such as a Lorentz motor or a reluctance motor. The electric motor can comprise an energisable coil and an array of magnets (e.g. a Hallbach array) providing a stator-mover arrangement. The energisable coil can be movable mounted with respect to a fixed Hallbach array or  
10 the Hallbach array can be movably mounted with respect to a fixed coil.

To guide the mover in linear reciprocating motion, the drive system can further comprise one or more flexible elements. The flexible element can be configured to guide the motion of the mover directly, or it can be configured to guide motion of the membrane actuator.

Optionally, the diaphragm actuator can be positioned within the chamber whilst the linear motor  
15 is position outside the chamber. In such cases, the system further comprises a coupling between the linear motor and the diaphragm actuator that extends through the wall of the chamber. Such an arrangement can allow for improved sound proofing of the oscillating membrane parts, and enhanced cooling structures (e.g. cooling fins) to dissipate heat from the electric motor.

In embodiments comprising first and second membranes, the motor can be disposed in the  
20 space in the chamber between the first and second membranes, and the coupling can extend from the motor towards the first and second membranes.

Optionally, position sensors may be employed to monitor the position of the diaphragm(s) within the chamber. For example, position sensors may be employed to directly measure the position of the diaphragm(s) and/or a position sensor may be employed to measure the position of the stator with  
25 respect to the position of the mover of the linear motor. In both cases, an optical position sensor can be used.

Pressure sensors can also be employed to determine the pressure (i) within the first and second compartments; (ii) within the first and second conduits leading to the handheld device; and/or (iii) within  
30 the first and second chambers of the reciprocator in the handle of the tool. In each case, absolute pressure sensors can be employed to measure the absolute pressure in one or more locations, or a differential pressure sensor can be employed to measure the differential pressure between two components.

Additional pneumatic components can be employed to provide enhanced functionality and safety. For example, systems according to the present invention can comprise a 'retract' valve  
35 configured to vent one of the first and second conduits upon deactivation of the motor (i.e. when the cutting mode is not in use). Venting one of the first and second fluid conduits causes the above-atmospheric pressure within the system to bias the diaphragm within the chamber 44 towards either the first position or the second position (depending on which conduit is vented). Biasing the diaphragm in towards either the first or second position means that the cutting member is either fully advanced or fully

retracted with respect to the conduit. Such an arrangement can be used to ensure that the cutting opening is (substantially) not occluded during an aspiration mode (cutting mode disabled).

Further advantages of various aspect of the present invention will be apparent to the skilled person from the following description and the appended claims.

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### **Brief Description of the Drawings**

The present invention will be described with reference to the following drawings, which illustrate non-limiting exemplary embodiments of the invention. In the drawings:

Fig. 1 shows an exemplary cutting arrangement for a vitrectomy device;

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Fig. 2 shows a handheld vitrectomy tool, comprising a pneumatic actuator;

Fig. 3 shows a schematic view of a vitrectomy system comprising a handheld vitrectomy tool, a pneumatic actuation system and a control loop;

Fig. 4 shows a schematic view of an actuation system in accordance with a first embodiment of the invention;

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Fig. 5 shows a schematic view an actuation system in accordance with a second embodiment of the invention.

Fig. 6 shows a detailed cross-sectional view of an actuation system according to the present invention.

Fig. 7 shows a pneumatic diagram for an exemplary control loop.

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### **Detailed Description of Illustrative Embodiments**

The following description provides a number of exemplary embodiments that illustrate the invention and should not be construed as limiting to the scope of the invention. Modifications or additions can be made to the illustrated embodiments without departing from the scope of the invention. It will be appreciated that the advantages associated with the present invention may be achieved by modification or replacement of the described features with equivalent features or means. Such equivalents are intended to be included within the scope of the invention. Although the present invention is described herein with reference to a vitrectomy tool comprising concentrically arranged reciprocating cutting parts, which integrally provide an aspiration conduit, it will be appreciated that the present invention can be applied to other reciprocating cutting instruments, with or without integrated aspiration.

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Fig. 1 shows a cutting tip of an exemplary vitrectomy device. As shown in Fig. 1, the cutting tip 10 comprises a hollow outer sheath 12, having a closed distal end 14. An inner tube 16 having an open distal end is disposed within the outer sheath 12. The inner tube 16 defines a lumen through which material can be aspirated from the eye and can thus be operatively coupled to a vacuum source (not shown) which is configured to draw material into the cutting tip 10 and through the lumen provided by the inner tube 16.

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The outer sheath 12 and the inner tube 16 are configured for relative movement with respect to each other between an first 'advanced' position in which the inner tube 16 is fully advanced within the outer sheath 12 (as shown in view A of Fig. 1) and a second 'retracted' position (shown in view B of Fig. 1) in which the inner tube 16 is fully retracted with respect to the outer sheath 12.

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As shown in Figure 1, the outer sheath 12 comprises a first aperture 18 and the inner tube 16 comprises a second aperture 20. When the inner tube 16 is in the advanced position with respect to the outer sheath 12, the first and second apertures 18, 20 are aligned and in register with each other (as shown in view A). As the inner tube 16 is retracted with respect to the outer sheath 12, the second aperture 20 is retracted with respect to the first aperture 18, such a distal edge of the second aperture 20 is moves at least to a position at which it meets a proximal edge of the first aperture 18 (as shown in view B). Preferably, when the inner tube 16 is in the fully retracted position, a distal end of the inner tube is positioned proximally (towards the user) of the first aperture 18, such that the first aperture 18 is not occluded by the inner tube 16.

An edge of at least one of the first aperture 18 and the second aperture 20 forms a first cutting edge 22 such that tissue can be severed at the point where the cutting edge 22 meets an opposing surface formed by the edge of the other aperture (shown in view B). In the embodiment shown in Fig. 1, a first cutting edge 22 is formed at the distal edge of the second aperture 20 in the inner tube 16. However, the skilled person will appreciate that a cutting edge may similarly be formed at a proximal edge of the first aperture 18, or that both apertures may comprises cutting edges.

Referring now to view C of Fig. 1, a second cutting edge 24 can also be formed at the open distal end of the inner tube 16, such that tissue drawn though the first aperture 18 with the inner tube 16 in the retracted position can be severed as the inner tube 16 returns to its advanced position. The skilled person will appreciate that a cutting edge can alternatively or additionally be formed at the distal edge of the first aperture 18.

Oscillation of the cutting tip 10 can be controlled pneumatically. Referring now to Fig. 2, the handheld portion of a vitrectomy tool is shown. As shown in Fig. 2, the handheld portion of the tool comprises the cutting tip 10 described with reference to Fig. 1 and a housing 26. The housing 26 is shaped and sized for one-handed use by a healthcare professional, and comprises a generally elongate shape. The outer sheath 12 and the inner tube 16 extend into the housing 26. As shown in Fig. 2, the outer sheath 12 is fixed with respect to the housing 26, whilst the inner tube 16 is slidably mounted therein. The inner tube 16 is operatively coupled to a reciprocator assembly 28, which is configured to oscillate back and forth to drive reciprocal movement of the inner tube 16 with respect to the sheath 12 in a cutting action, as described with reference to Fig. 1.

The reciprocator assembly 28 comprises a first chamber 30 and a second chamber 32 fluidically separated from each other by a flexible membrane or separator 34. The separator 34 comprises a linkage or coupling 36, which couples the separator 34 to the inner tube 16. The first chamber 30 is in fluid communication with a first conduit or pneumatic line 38 and the second chamber 32 is in fluid communication with a second conduit or pneumatic line 40. To drive oscillation of the separator 34 (and thus the inner tube 16) back and forth, the pressure within the first and second chambers 30, 32 is alternately increased and decreased. When the pressure differential between the first chamber 30 and the second chamber 32 biases the flexible membrane in a distal direction, the inner tube 16 moves distally with respect to the fixed outer sheath 12. When the pressure differential between the first chamber 30 and the second chamber 32 biases the membrane 34 in a proximal direction, the inner tube

16 moves proximally with respect to the outer sheath 12. The pressure differential between the first chamber 30 and the second chamber 12 is controlled via the first and second pneumatic lines 38, 40.

Referring now to Fig. 3, the pneumatic lines 38, 40 are coupled to an actuation system 42 that alternately varies the pressure within the first and second chambers 30 and 32. As shown in Fig. 3, the system 42 comprises a housing forming a chamber 44, which is fluidically separated by a diaphragm 46 into a first compartment 48 defining a first internal volume and a second compartment 50 defining a second internal volume. A first port 49 is provided in fluid communication with the first compartment 48 and is configured for connection to a first conduit 38. A second port 51 is provided in fluid communication with the second compartment 50, and is configured for connection to a second conduit 40.

The diaphragm 46 is movably mounted within the chamber 44. The diaphragm can be formed of a flexible material (such as a thermoplastic elastomer or a rubber) and/or it may be fixed within the chamber with some slack to allow reciprocating movement. In any event, the diaphragm 46 shown in Fig. 3 is configured for alternate movement between a first position and a second position, such that movement from the first position to the second position decreases the first volume (in the first compartment 48) and increases the second volume (in the second compartment 50). Conversely, movement of the diaphragm 46 in the opposite direction, from the second position to the first position, increases the volume of the first compartment 48, and decreases the volume of the second compartment 50. The system further comprises a diaphragm actuator 52 configured to oscillate back and forth to move the diaphragm 46 between the first position and the second position and a drive system 54 configured to drive the oscillation of the diaphragm actuator 52.

To drive the diaphragm actuator 52 back and forth, the drive system 54 can comprise a linear motor. In some embodiments, the linear motor is linear oscillator motor configured to drive the diaphragm 46 back and forth at a desired frequency in response to an alternating control current or voltage supplied to the motor. In exemplary embodiments, the driver 54 can comprise a Lorentz-type actuator, also known as a Lorentz driver, e.g. implemented using a Tecnotion UL series linear motor. In other embodiments, the driver 54 can comprise a reluctance motor. Further details of the driver 54 will be described below with reference to Figure 6.

Each of the first and second compartments 48, 50 can be coupled to an above-ambient air supply. For example, as shown in Fig. 3, each of the first and second compartments can be in fluid communication with a 1.5 bar air supply, e.g. via flow-restrictions  $R_1$  and  $R_2$ . By providing the first and second compartments with above-atmosphere air supply, the stiffness of the 'gas spring' that drives the reciprocator in the handle housing 26 is increased, improving the responsiveness of the pneumatic system. Moreover, above atmospheric pressure within the first and second compartments 48, 50 can allow the diaphragm to be biased into the first or second position if one of the compartments 48, 50 or one of the pneumatic lines 38, 40 is vented. It is worth noting that the complete pneumatic system is a closed volume, and part of it is only vented when the retract valve 61 (see below) is opened. Therefore the air consumption of the total system is low, and a very small built-in compressor can suffice for the air supply, removing the need for an external air-supply line.

As shown in Figure 3, a control loop can be implemented to provide the desired pressure levels within the first and second compartments 48, 50 (and thus within the chambers 30 and 32 of the

handheld tool). The control loop can comprise an alternating current or voltage supply configured to drive the linear motor back and forth. The control loop can drive the actuator at an oscillating frequency of between 5-200 Hz, e.g. 166 Hz. This allows for a handheld vitrectomy tool that is operable at 10.000 movement per minute or more. The skilled person will appreciate that the oscillating frequency of the drive system 54 can continuously be varied depending on the requirements of the procedure, the architecture of the handheld device and the preference of the health care provider.

To provide improved control of the actuator, the control loop can further comprise one or more sensors to determine the oscillation of the diaphragm 46 within the chamber 44.

For example, a position sensor can be integrated to measure the position of the diaphragm 46 within the chamber 44. The position of the diaphragm 46 provides information regarding the relative volumes of the first and second compartments 48, 50, and thus the pressures supplied via pneumatic lines 38, 40.

Additionally or alternatively, one or more pressure sensors can be incorporated into the actuation system. For example, as shown in Fig. 3, a pressure sensor P1 can be provided in fluid communication with the first compartment 48 to measure the pressure within the first compartment 48 and the first pneumatic line 38. Additionally or alternatively, a pressure sensor P2 can be provided in fluid communication with the second compartment 50 to measure the pressure within the second compartment and the second pneumatic line 40. As an alternative to or in combination with P1 and/or P2, a differential pressure sensor  $\Delta P$  can be provided to measure the differential pressure between the first pneumatic line 38 and the second pneumatic line 40. The differential pressure sensor can be implemented to measure the differential pressure between the first and second compartments 48, 50, or it can be implemented to measure the differential pressure between the first and second conduits 38, 40, close to the handheld device.

The pressure sensors connected to each compartment allow monitoring of the achieved pressure difference between the first and second compartments 48, 50. Each pressure sensor, alone or in combination, can allow verification for proper functioning and can be used for controller feedback.

In at least some embodiments, the actuation system further comprises a retract valve 61 configured to move the diaphragm 34 to the first position upon deactivation of the drive system. Such a retract valve arrangement can advantageously allow the neutral position of the diaphragm to correspond to an intermediate position of the inner tube 16 with respect to the outer sheath 12, without compromising the aspiration flow through the cutting opening whilst the cutting blade is at rest (with the motor deactivated). This is because the retract valve vents one compartment/pneumatic line whilst the other is maintained at 1.5bar. The pressure differential thus biases the diaphragm towards the first position whilst the cutting mode is switched off, even though the neutral position of the membrane equates to an intermediate position of the inner tube 16 with respect to the outer sheath 12. Such a neutral rest position allows for a short stroke for the inner tube 16, and consequently a short stroke for the motor. Such a retract valve 61 could be a regular 3/2 solenoid valve shown in Fig. 3, or alternatively a set of 2/2 solenoid valves, arranged such that conduit 38 can be vented to ambient pressure, and the supply from volume 48 can be blocked.

To ensure that the pressure within the first and second compartments 48, 50 does not exceed a predetermined level, vent valves can also be provided to vent gas from the first and second compartments 48, 50 at a predetermined pressure level or within a predetermined pressure range. An exemplary pneumatic system comprising a series of vent valves and a retract valve will be described in more detail with reference to Figure 7.

The arrangement of the driver 54 and the chamber 44 will now be described in more detail with reference to Figure 4.

As shown in Figure 4, the driver 54 can comprise a coil 60 configured to be energised by an applied current or voltage, and an array of magnets 62 (e.g. a Hallbach array). The array of magnets can be configured as the stator, or it can be configured as mover in the drive system 54 of the present invention.

A guide element, for example a flexible element such as a radial spring 66, is provided to guide the mover in reciprocating linear motion. The moving part of the motor (the array or the coil) is coupled to the diaphragm actuator 52 directly or via a linkage 56.

As shown in Figure 4, the diaphragm actuator 52 is positioned within the chamber 44. The diaphragm actuator 52 can engage the membrane 46 in different ways. For example, the diaphragm actuator 52 can be securely fastened to the diaphragm with adhesive, or it may comprise opposing parts between which the diaphragm is clamped. Alternatively, the diaphragm actuator 52 can be partially embedded within the material of the diaphragm 46.

The stator is positioned outside of the chamber 44, and a coupling 56 extends through a wall of the chamber 44 into the first compartment 48. A seal 58 seals the opening in the chamber wall through which the coupling 56 extends. In some embodiments, an additional opening (not shown) can be provided in second compartment 50, comprising a seal similar to seal 58. The additional opening can be provided to approximate or mirror the leakage experienced through the seal 58, to offset any imbalance in the pressure due to leakage from the first compartment 48.

The skilled person will appreciate that the coupling between the membrane actuator 52, the coupling 56, and the mover can be adapted to suit the requirements of the system, and that these components may also be formed as a single part.

Figure 5 shows a further aspect of the invention in which the configuration of the driver 54 and the first and second compartments 48, 50 differs from the arrangement shown in Figure 4.

As shown in Figure 5, an ophthalmic cutting tool actuation system in accordance with a second aspect of the invention comprises a housing 44' having a first compartment 48' at least partially defined by a first diaphragm 46a and having a first internal volume. A second compartment 50' is at least partially defined by a second diaphragm 46b and has a second internal volume.

A first port is provided in fluid communication with the first compartment 48' and is configured for connection to a first conduit connected to a handheld ophthalmic cutting tool, in the manner described in connection with Figures 2 and 3. Similarly, a second port is provided in fluid communication with the second compartment 50', and is configured for connection to a second conduit connected to the ophthalmic cutting tool.

The first diaphragm 46a is movably mounted with respect to the housing 44', and is configured for alternate movement between a first position and a second position, such that movement of the first diaphragm 46a from its first position to its second position decreases the first volume of the first compartment 48'. The second diaphragm 46b is similarly movably mounted with respect to the housing 44', and is configured for alternate movement between a first position and a second position, such that movement of the second diaphragm 46b from its first position to its second position increases the second volume of the second compartment 50'.

The system further comprises a diaphragm actuator 52' configured to oscillate back and forth to move the first diaphragm 46a and the second diaphragm 46b simultaneously between the first position and the second position. A drive system 54', disposed within the housing 44' in the embodiment shown in Figure 5, is configured to drive the oscillation of the diaphragm actuator 52'.

Simultaneous movement of the diaphragm actuator 52' back and forth within the housing 44' moves the first and second diaphragms 46a, 46b back and forth in unison, alternately increasing and decreasing the interior volumes of the first and second compartments 48', 50', in a similar manner to the single diaphragm embodiment described with reference to Figure 4. The two diaphragms acting in unison operate in an equivalent manner to the single diaphragm of Figure 4.

As shown in Figure 5, the first and second diaphragms 46a, 46b can be separated by a space within the housing 44', and the drive system 54' can be at least partially disposed within the space between the first and second diaphragms 46a, 46b. This provides a simple construction for the actuator 52' and allows reciprocating movement of the motor to be transmitted directly to the parts 52a, 52b of the diaphragm actuator 52'.

The drive system 54' can be configured in a similar manner to the drive system 54 described with reference to Figure 4 and can comprise a linear motor comprising a coil and a Hallbach array. The motor can comprise a Lorentz driver or a reluctance motor.

The diaphragm actuator 52' can comprise multiple parts or can be formed as a single piece, driven by the mover. In the embodiment shown in Figure 5, the diaphragm actuator 52' comprises a first diaphragm actuator 52a that clamps the first diaphragm 46a, and a second diaphragm actuator 52b that clamps the second diaphragm 46b. A common coupling 56' can fixedly connect the two parts 52a, 52b. The common coupling can be integrally formed with or connected to the mover actuator of the motor.

In the embodiment shown in Figure 5, the drive system 54 comprises first and second flexible guiding elements 66a, 66b to guide the linear motion of the actuator.

The actuator and chamber assembly shown in Figure 5 can be combined with the control loop described with reference to Figure 5. For example, a control loop can be provided that comprising a position sensor configured to monitor the position of at least one of the first and second diaphragms within the housing.

Additionally or alternatively, pressure sensors can be provided to measure the pressure within one or both of the first and second compartments 48', 50'. The system can comprise a first pressure sensor configured to measure the pressure within the first compartment and a second pressure sensor configured to monitor the pressure within the second compartment.

First and second vent valves can also be provided in the arrangement shown in Figure 5, to vent the first and second compartments 48', 50' should a predetermined maximum pressure be reached.

As shown in Figure 3, a differential pressure sensor can be provided to measure the differential pressure between the first and second compartments. A retract valve 61 can also be incorporated into the system shown in Figure 5 (similar as in the embodiment described with reference to Fig. 3 above), configured to move the diaphragm 34 (and the inner tube 16) to its respective first position upon deactivation of the drive system.

Figure 6 shows in more detail a drive system 54 and a chamber 44 in accordance with an embodiment of the present invention. As shown in Figure 6, the drive system 54 comprises a linear motor having a mover-coil 60 and a Hallbach array 62 forming the stator. The magnets of the Hallbach array are mounted on back-irons 64. The mover-coil 62 is coupled via linkage 56 to the diaphragm actuator 52, which in the embodiment shown in Figure 6 is partially embedded within the material of the diaphragm 46.

An optical sensor 68 is configured to measure the position of the stator 62 relative to the coil 60, and thus the position of the diaphragm actuator 52 within the chamber 44. Straight-guidance flexures 66 are fixedly coupled to the mover-coil 60 to ensure that the mover-coil moves back and forth in a straight line. The mover-coil 60 can further comprise cooling fins to dissipate heat generated during use.

As shown in Figure 6, the chamber 44, diaphragm 46 and diaphragm actuator 52 can be configured to minimise the air-volume within the first and second compartments 48, 50. The minimised chamber volume results in the largest compression ratio (ratio of neutral volume to compressed volume).

The stroke of the motor in the exemplary embodiment shown in Figure 6 is approximately 4mm (2mm in a first direction from a neutral rest position, and 2mm in an opposite direction away from the neutral rest position). The total air volume of the chamber (consisting of the air volume of the first and second compartments) is approximately 20ml. Such a configuration allows a maximum differential pressure within the first and second compartments of the chamber of approximately 1000mbar, while the preferred working range is between 300 and 700mbar.

In the embodiment shown in Figure 6, the seal 58 comprises a sealing bellow. The sealing bellow allows the motion of the coupling 56 to be transferred through the chamber wall to the diaphragm 46, without sliding components and without leakage.

Referring now to Figure 7, an exemplary embodiment of a pneumatic control system will be described in more detail. As shown in Figure 7, the control system comprises pressure sensors P1 and P2, in fluid communication with the first and second compartments of chamber 44 respectively. Pressure sensors P1 and P2 are absolute pressure sensors. Differential pressure sensor  $\Delta P$  is arranged between the first and second pneumatic lines 38, 40 and is configured to monitor the differential pressure within the system. By configuring the differential pressure sensor  $\Delta P$  to measure the differential pressure between the first and second pneumatic lines 38, 40, the achieved pressure differential close to the reciprocator 28 is observed.

A bias pressure inlet 74 comprising a pressure regulator is also provided to supply above-atmospheric pressure supplied to the chamber 44 (e.g. 1.5bar). The above atmospheric pressure leads to increased stiffness of the effective gas spring that drives the reciprocator 28 within the hand-held

device. A bias pressure inlet valve 72 and a bias pressure vent valve 70 are provided to apply the bias pressure before use, and vent it to a safe state after use respectively. In exemplary embodiments, the supply to the chamber 44 is maintained at 1.5 bar. An allowable error range in this respect would be 0... +0.2 mbar, i.e. 1.5 to 1.7 bar.

5           A retract valve 61 can be provided in fluid communication with one of the first and second pneumatic lines 38, 40. In the system shown in Figure 6, the retract valve 61 is provided in communication with the first pneumatic line. The retract valve 61 is configured to vent one of the pneumatic lines 38, 40. The bias pressure supplied by the system through the other (un-vented) pneumatic line pushes the actuator in the hand-held device to one end (see Figures 1A-C) to ensure  
10           that the first aperture in the outer sheath is not occluded by the inner sheath, thereby allowing maximum flow through the inner tube when a cutting action is not used. As an exemplary implementation, an SMC VDW 250 3/2 valve is applied, which is a commercially available valve. In some embodiments, the retract valve 61 is configured to bias the diaphragm 46 in a direction that results in retraction of the inner tube 16 to its maximum extent within the outer sheath 12 when the cutting operation is ceased. However, the  
15           skilled person will appreciate that the retract valve 61 can be configured to bias the inner tube 16 distally towards its maximum distal extent. In either embodiment, the extreme distal or extreme proximal location of the inner tube 16 relative to the outer sheath 12 means that the first opening 18 in communication with the aspiration lumen is (substantially) not occluded to allow free flow of material (including severed material and fluid) through the lumen of the inner tube 16.

20           It will be appreciated that the drive system described with reference to Figure 6 and the control loop described with reference to Figure 7 can be employed in combination with either of the chamber assemblies described with reference to Figures 4 and 5. Other structural arrangements comprising two variable volume chambers that can be combined with the exemplary drive system 54 will be apparent to the person skilled in the art in light of the present disclosure, and such arrangements are intended to  
25           fall within the scope of the present invention.

          The foregoing description provides a number of exemplary embodiments that illustrate the invention and should not be construed as limiting to the scope of the invention. Modifications or additions can be made to the illustrated embodiments without departing from the scope of the invention. Although the present invention is described herein with reference to a vitrectomy tool comprising concentrically  
30           arranged reciprocating cutting parts, with integrated aspiration, it will be appreciated that the present invention can be applied to other reciprocating instruments.

## Conclusies

1. Een bekrachtigingssysteem voor een oftalmisch snijwerktuig, omvattende:  
5 een behuizing omvattende een kamer (44) die fluïdummatig gescheiden is door een diafragma (46) in een eerste compartiment (48) dat een eerste intern volume definieert en een tweede compartiment (50) dat een tweede intern volume definieert;  
een eerste poort (49) die in fluïdumverbinding met het eerste compartiment (48) is voorzien, en is ingericht voor verbinding met een eerste kanaal (38) dat verbonden is met een met  
10 de hand vast te houden oftalmisch snijwerktuig;  
een tweede poort (51) die in fluïdumverbinding met het tweede compartiment (50) is voorzien, en is ingericht voor verbinding met een tweede kanaal (40) dat verbonden is met het oftalmisch snijwerktuig;  
waarbij het diafragma (46) beweegbaar is gemonteerd binnen de kamer (44) en is  
15 ingericht voor afwisselende beweging tussen een eerste positie en een tweede positie, zodat de beweging van de eerste positie naar de tweede positie het eerste volume verkleint en het tweede volume vergroot;  
waarbij het systeem verder omvat:  
een diafragma-actuator (52) die is ingericht om heen en weer te oscilleren om het  
20 diafragma (46) te bewegen tussen de eerste positie en de tweede positie, en  
een aandrijfsysteem (54) dat is ingericht om de oscillatie van de diafragma-actuator (52) aan te drijven.
2. Het systeem volgens conclusie 1, waarbij het aandrijfsysteem (54) een lineaire motor  
25 (bijvoorbeeld een Lorentz aandrijfeenheid of een reluctantiemotor) omvat die is ingericht om de diafragma-actuator (52) in ten minste een eerste richting aan te drijven.
3. Het systeem volgens conclusie 2, waarbij het aandrijfsysteem verder omvat een flexibel  
element (66) dat is ingericht om de lineaire beweging van de actuator (52) te geleiden.  
30
4. Het systeem volgens één van de conclusies 1-3, waarbij de diafragma-actuator (52) binnen de kamer (44) is gepositioneerd.
5. Het systeem volgens conclusie 4, waarbij de lineaire motor is gepositioneerd buiten de  
35 kamer (44), en waarbij het aandrijfsysteem (54) verder omvat een koppeling (56) tussen de lineaire motor en de actuator (52), waarbij de koppeling (56) zich uitstrekt door een wand van de kamer (44).
6. Het systeem volgens één van de conclusies 1-5, verder omvattende een positiesensor  
40 (68) die is ingericht om de positie van het diafragma (52) binnen de kamer (44) te bewaken.

7. Het systeem volgens één van de conclusies 1-6, verder omvattende een eerste druksensor (P1) die is ingericht om de druk binnen het eerste compartiment (48) te meten en/of een tweede druksensor (P2) die is ingericht om de druk binnen het tweede compartiment (50) te meten.
- 5
8. Het systeem volgens één van de conclusies 1-7, verder omvattende een differentiële druksensor ( $\Delta P$ ) die is ingericht om de verschillendruk tussen het eerste compartiment (48) en het tweede compartiment (50) te meten.
- 10
9. Het systeem volgens één van de conclusies 1-8, verder omvattende een terugtrekklep (61), ingericht om de eerste pneumatische leiding (38) te ventileren om het diafragma (52) naar de eerste positie te bewegen bij de-activatie van het aandrijfsysteem (54).
- 15
10. Het systeem volgens één van de conclusies 1-9, waarbij:  
het eerste compartiment (48) een ventilatieklep omvat; en/of  
het tweede compartiment (50) een ventilatieklep omvat.
- 20
11. Een bekrachtigingssysteem voor een oftalmisch snijwerktuig omvattende:  
een behuizing (44') omvattende:  
een eerste compartiment (48') dat ten minste gedeeltelijk gedefinieerd wordt door een eerste diafragma (46a) en met een eerste intern volume, een tweede compartiment (50') dat ten minste gedeeltelijk gedefinieerd wordt door een tweede diafragma (46b) en met een tweede intern volume, waarbij het eerste compartiment (48') fluïdummatig gescheiden is van het tweede compartiment (50');
- 25
- een eerste poort (49') in fluïdumverbinding met het eerste compartiment (48'), en ingericht voor verbinding met een eerste kanaal (38) dat verbonden is met een met de hand vast te houden oftalmisch snijwerktuig;
- 30
- een tweede poort (51') in fluïdumverbinding met het tweede compartiment (50'), en ingericht voor verbinding met een tweede kanaal (40) dat verbonden is met het oftalmisch snijwerktuig;
- waarbij het eerste diafragma (46a) beweegbaar is bevestigd ten opzichte van de behuizing (44'), en is ingericht voor afwisselende beweging tussen een eerste positie en een tweede positie, zodat beweging van het eerste diafragma (46a) van zijn eerste positie naar zijn tweede positie het eerste volume verkleint;
- 35
- waarbij het tweede diafragma (46b) beweegbaar is bevestigd ten opzichte van de behuizing (44'), en is ingericht voor afwisselende beweging tussen een eerste positie en een tweede positie, zodat beweging van het tweede diafragma (46b) van zijn eerste positie naar zijn tweede positie het tweede volume vergroot;
- waarbij het systeem verder omvat:

een diafragma-actuator (52') die is ingericht om heen en weer te oscilleren om het eerste diafragma (46a) en het tweede diafragma (46b) simultaan te bewegen tussen de eerste posities en de tweede posities, en

5 een aandrijfsysteem (54') dat is ingericht om de oscillatie van de diafragma actuator (52') aan te drijven.

12. Het systeem volgens conclusie 11, waarbij het aandrijfsysteem (54') omvat een lineaire motor (bijvoorbeeld een Lorentz aandrijfeenheid of een reluctantiemotor) die is ingericht om de diafragma-actuator (52') in ten minste een eerste richting aan te drijven.

10

13. Het systeem volgens conclusie 12, waarbij het aandrijfsysteem verder omvat een flexibel element (66a, 66b) dat is ingericht om de lineaire beweging van de actuator (52') te geleiden.

14. Het systeem volgens conclusie 11, waarbij de eerste en tweede diafragma's (46a, 46b) gescheiden zijn door een ruimte binnen de behuizing (44'), en waarbij de lineaire motor ten minste gedeeltelijk geplaatst is binnen de ruimte tussen de eerste en tweede diafragma's (46a, 46b).

15

15. Het systeem volgens één van de conclusies 11-14, waarbij de diafragma-actuator (52') omvat een eerste diafragma-actuatorlichaam (52a) en een tweede diafragma-actuatorlichaam (52b) die vast met elkaar gekoppeld zijn met een koppeling (56').

20

16. Het systeem volgens één van de conclusies 11-15, verder omvattende een positiesensor (68) die is ingericht om de positie te bewaken van ten minste één van de eerste en tweede diafragma's (46a, 46b) binnen de behuizing (44').

25

17. Het systeem volgens één van de conclusies 11-16, verder omvattende een eerste druksensor (P1) die is ingericht om de druk binnen het eerste compartiment (48') te meten en een tweede druksensor (P2) die is ingericht om de druk binnen het tweede compartiment (50') te meten.

30

18. Het systeem volgens één van de conclusies 11-17, waarbij:  
het eerste compartiment (48') een ventilatieklep omvat; en/of  
het tweede compartiment (50') een ventilatieklep omvat.

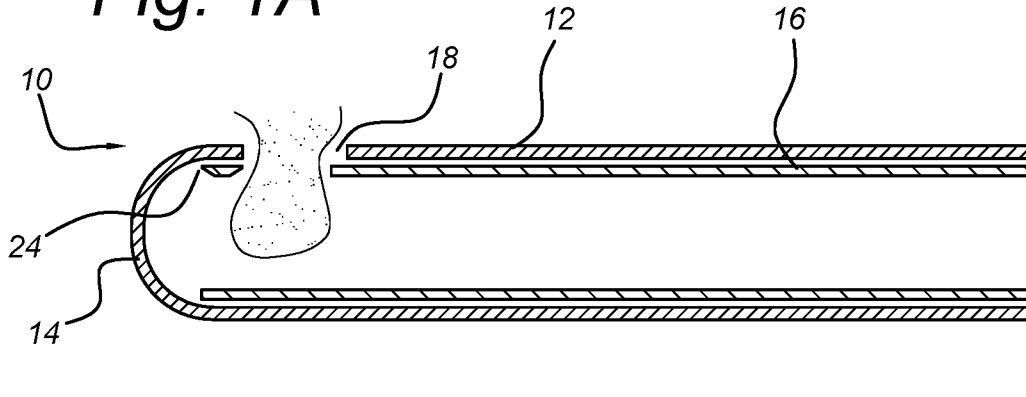
35

19. Het systeem volgens één van de conclusies 11-18, verder omvattende een differentiële druksensor ( $\Delta P$ ) die is ingericht om de verschuldruk te meten tussen:  
het eerste compartiment (48') en het tweede compartiment (50'); en/of  
het eerste kanaal (38) en het tweede kanaal (40).

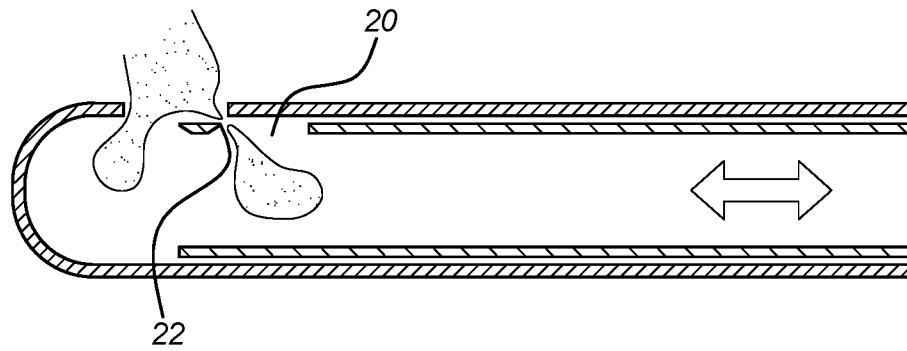
40

20. Het systeem volgens één van de conclusies 11-19, verder omvattende een terugtrekklep (61), die is ingericht om het diafragma naar de eerste positie te bewegen bij de-activatie van het aandrijfsysteem.
- 5 21. Een chirurgisch snijsamenstel omvattende het systeem volgen één van de conclusies 1-20, en verder omvattende:
- een pneumatisch bekrachtigd met de hand vast te houden oftalmisch snijwerktuig, omvattende:
- 10 een kanaal met een snijopening;  
een snijblad dat is ingericht voor reciprocerende beweging binnen de snijopening;  
een reciproceerbare scheider die fluïdummatig een eerste afgedichte kamer die in fluïdumverbinding staat met het eerste compartiment van het bekrachtigingssysteem en een tweede afgedichte kamer die in fluïdumverbinding staat met het tweede compartiment van het actuatorsysteem, scheidt;
- 15 waarbij de reciproceerbare scheider gekoppeld is aan het snijblad, en  
waarbij de reciproceerbare scheider is ingericht voor reciprocerende beweging in reactie op relatieve verandering in druk in de eerste en tweede afgedichte kamers.

**Fig. 1A**



**Fig. 1B**



**Fig. 1C**

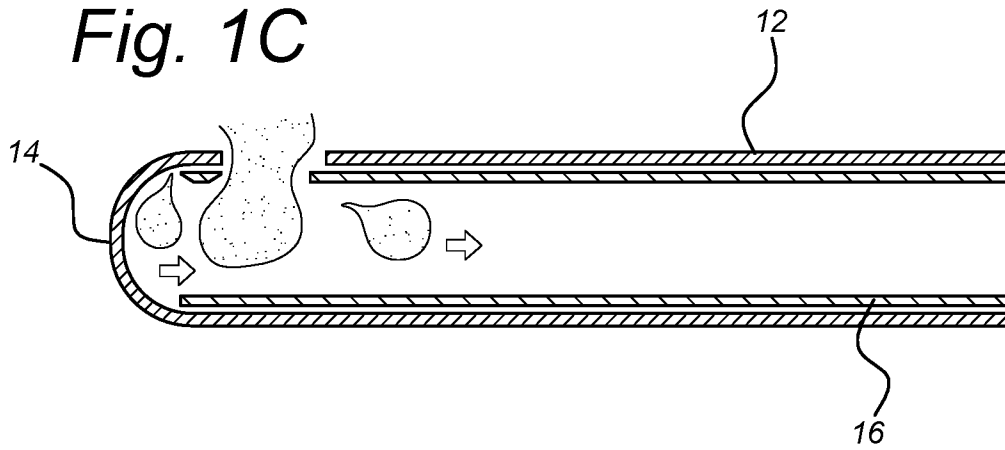


Fig. 2

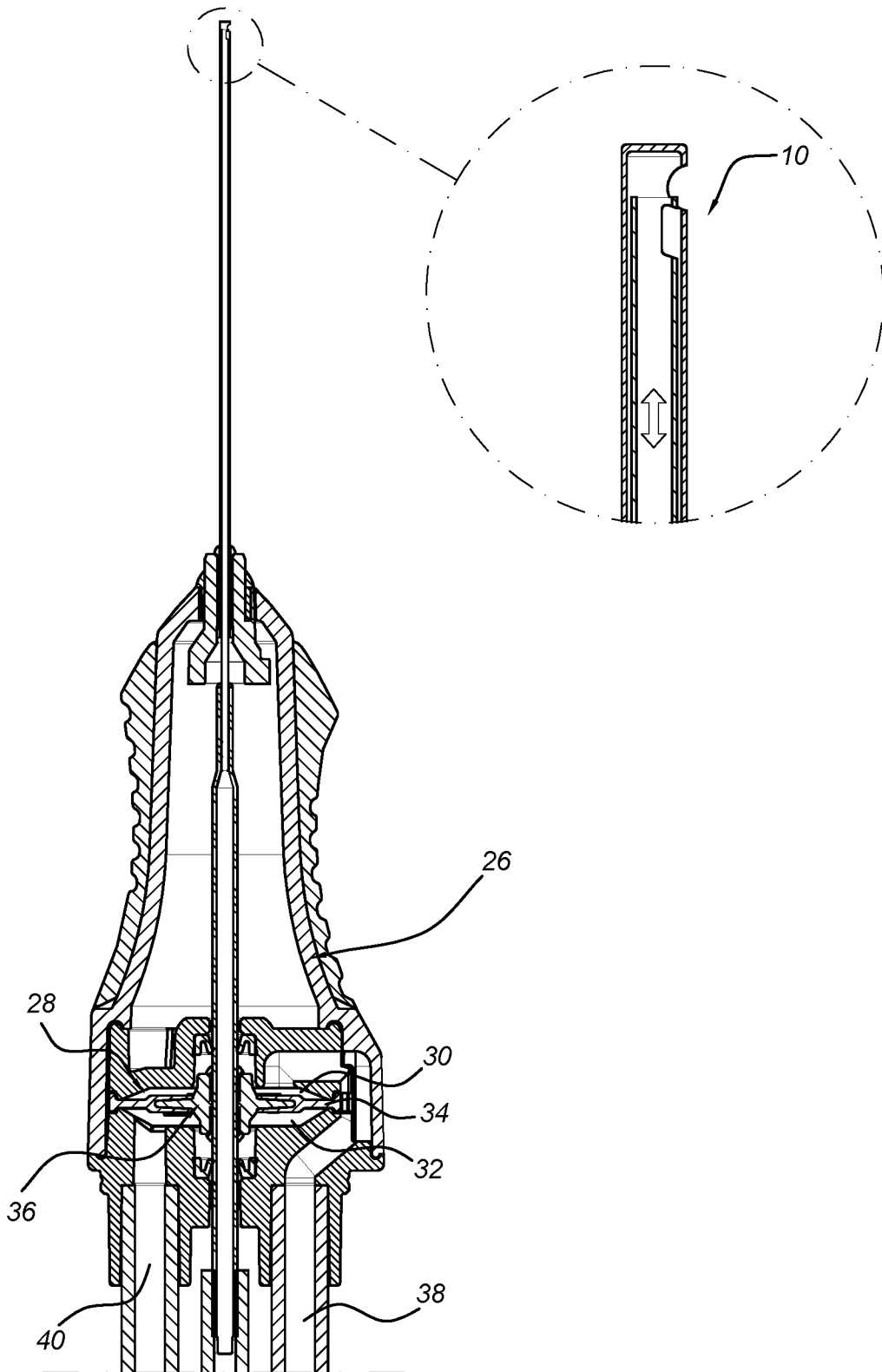


Fig. 3

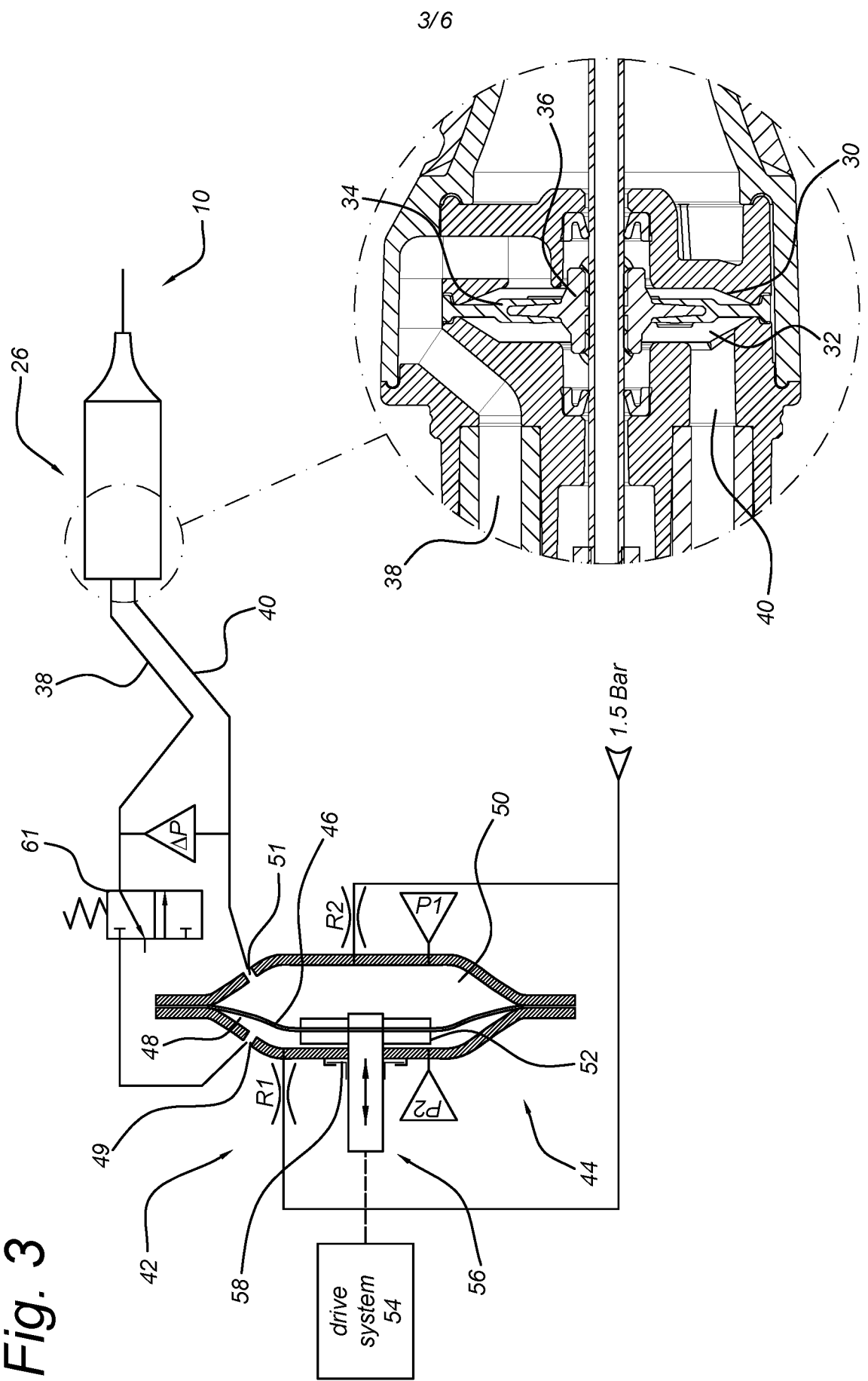


Fig. 4

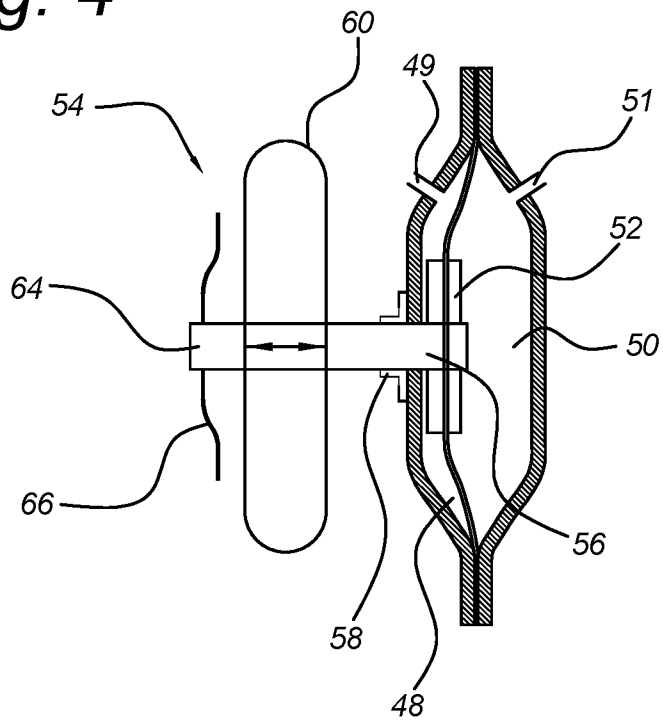
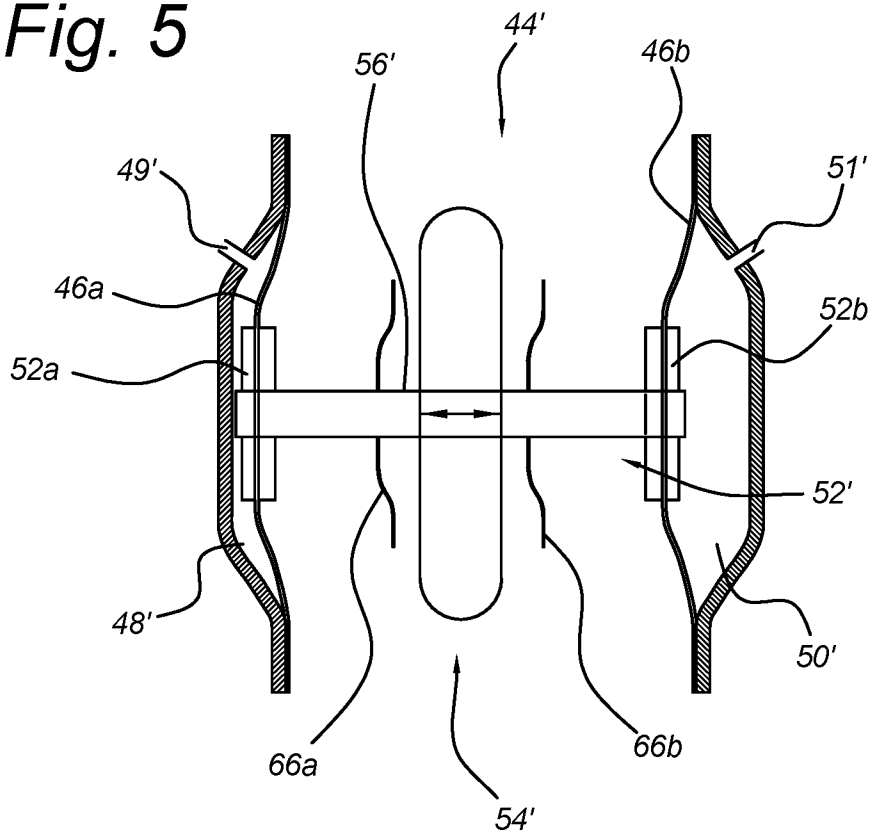


Fig. 5



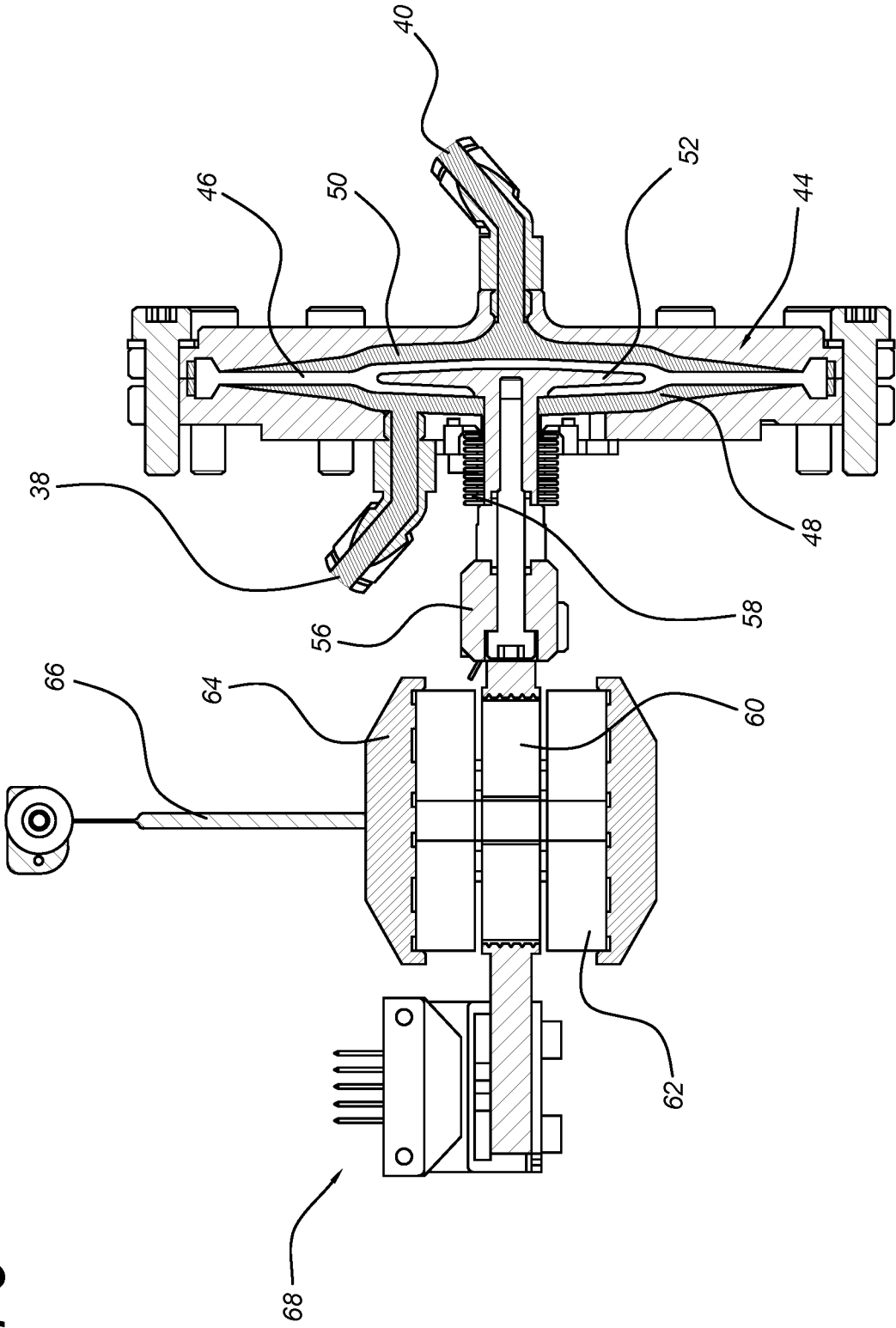
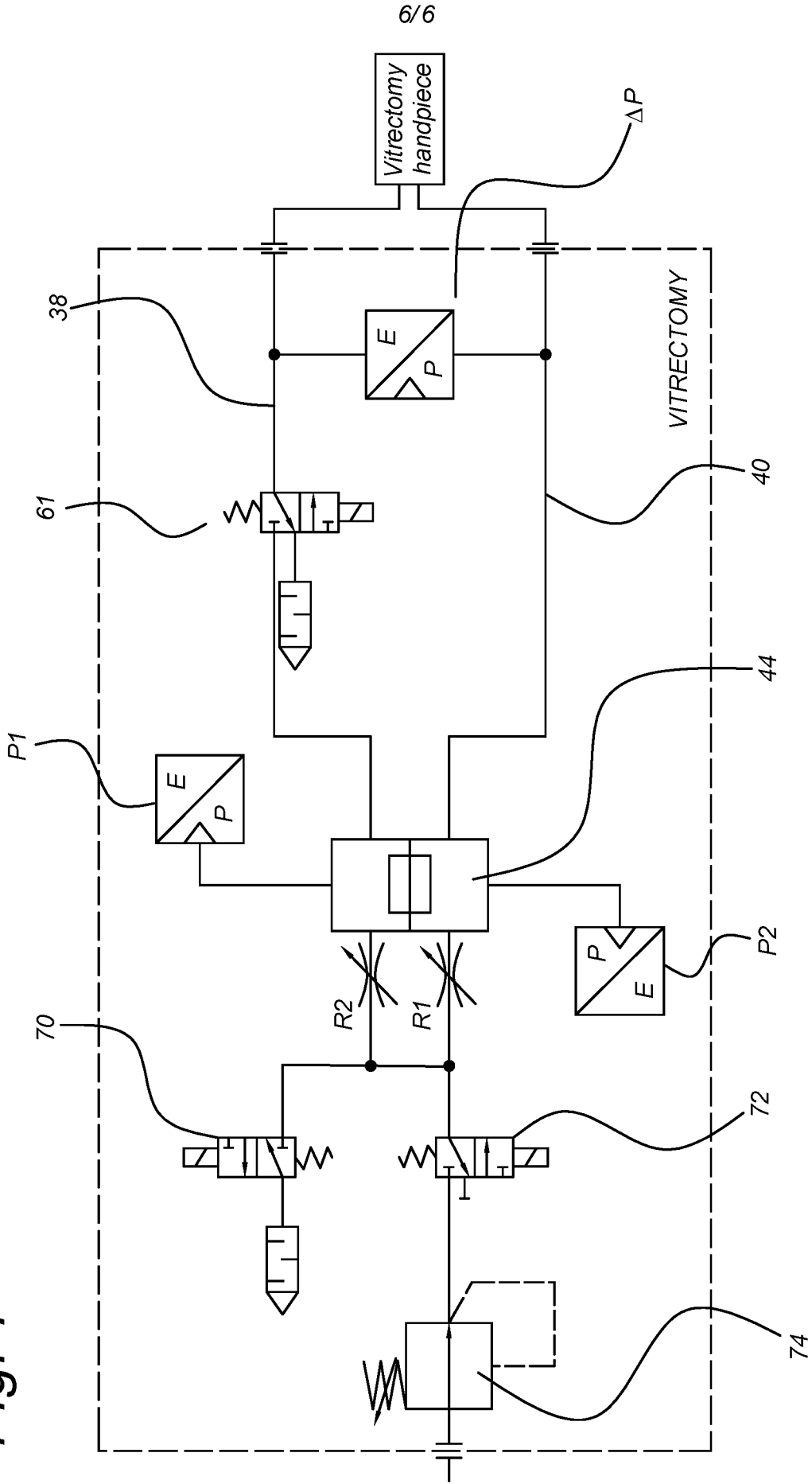


Fig. 6

Fig. 7



# SAMENWERKINGSVERDRAG (PCT)

## RAPPORT BETREFFENDE NIEUWHEIDSONDERZOEK VAN INTERNATIONAAL TYPE

IDENTIFICATIE VAN DE NATIONALE AANVRAGE	KENMERK VAN DE AANVRAGER OF VAN DE GEMACHTIGDE  <b>P6076808NL</b>
Nederlands aanvraag nr.  <b>2022011</b>	Indieningsdatum  <b>16-11-2018</b>
	Ingeroepen voorrangsdatum
Aanvrager (Naam)  <b>Crea IP B.V.</b>	
Datum van het verzoek voor een onderzoek van internationaal type  <b>15-12-2018</b>	Door de Instantie voor Internationaal Onderzoek aan het verzoek voor een onderzoek van internationaal type toegekend nr.  <b>SN72591</b>
<b>I. CLASSIFICATIE VAN HET ONDERWERP</b> (bij toepassing van verschillende classificaties, alle classificatiesymbolen opgeven)	
Volgens de internationale classificatie (IPC)  <b>A61F9/007</b>	
<b>II. ONDERZOCHETE GEBIEDEN VAN DE TECHNIEK</b>	
Onderzochte minimumdocumentatie	
Classificatiesysteem	Classificatiesymbolen
<b>IPC</b>	<b>A61F</b>
Onderzochte andere documentatie dan de minimum documentatie, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen	
III. <input type="checkbox"/>	<b>GEEN ONDERZOEK MOGELIJK VOOR BEPAALDE CONCLUSIES</b> (opmerkingen op aanvullingsblad)
IV. <input type="checkbox"/>	<b>GEBREK AAN EENHEID VAN UITVINDING</b> (opmerkingen op aanvullingsblad)

**ONDERZOEKSRAPPORT BETREFFENDE HET  
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND  
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Nummer van het verzoek om een onderzoek naar  
de stand van de techniek

NL 2022011

<p>A. CLASSIFICATIE VAN HET ONDERWERP INV. A61F9/007 ADD.</p>		
<p>Volgens de Internationale Classificatie van octrooien (IPC) of zowel volgens de nationale classificatie als volgens de IPC.</p>		
<p>B. ONDERZOCHETE GEBIEDEN VAN DE TECHNIEK</p>		
<p>Onderzochte minimum documentatie (classificatie gevolgd door classificatiesymbolen) A61F</p>		
<p>Onderzochte andere documentatie dan de minimum documentatie, voor dergelijke documenten, voor zover dergelijke documenten in de onderzochte gebieden zijn opgenomen</p>		
<p>Tijdens het onderzoek geraadpleegde elektronische gegevensbestanden (naam van de gegevensbestanden en, waar uitvoerbaar, gebruikte trefwoorden) EPO-Internal, WPI Data</p>		
<p>C. VAN BELANG GEACHTE DOCUMENTEN</p>		
Categorie °	Geciteerde documenten, eventueel met aanduiding van speciaal van belang zijnde passages	Van belang voor conclusie nr.
A	US 2018/243134 A1 (DEAN JOSHUA [US] ET AL) 30 augustus 2018 (2018-08-30) * alineas [0055] - [0076]; figuren 3A-C, 4 *	1-21
A	----- JP 2010 057642 A (NIDEK KK) 18 maart 2010 (2010-03-18) * samenvatting; figuur 1 * * alineas [0009] - [0010] *	1-21
A	----- US 2010/145374 A1 (PERKINS JAMES T [US] ET AL) 10 juni 2010 (2010-06-10) * alineas [0024] - [0029]; figuur 2 *	1-21
A	----- US 2011/144675 A1 (GAO SHAWN X [US] ET AL) 16 juni 2011 (2011-06-16) * alineas [0022] - [0025]; figuren 2a-b, 3-4 *	1-21
<p><input type="checkbox"/> Verdere documenten worden vermeld in het vervolg van vak C.      <input checked="" type="checkbox"/> Leden van dezelfde octrooifamilie zijn vermeld in een bijlage</p>		
<p>° Speciale categorieën van aangehaalde documenten</p> <p>"A" niet tot de categorie X of Y behorende literatuur die de stand van de techniek beschrijft</p> <p>"D" in de octrooiaanvraag vermeld</p> <p>"E" eerdere octrooi(aanvraag), gepubliceerd op of na de indieningsdatum, waarin dezelfde uitvinding wordt beschreven</p> <p>"L" om andere redenen vermelde literatuur</p> <p>"O" niet-schriftelijke stand van de techniek</p> <p>"P" tussen de voorrangsdatum en de indieningsdatum gepubliceerde literatuur</p>		<p>"T" na de indieningsdatum of de voorrangsdatum gepubliceerde literatuur die niet bezwarend is voor de octrooiaanvraag, maar wordt vermeld ter verheldering van de theorie of het principe dat ten grondslag ligt aan de uitvinding</p> <p>"X" de conclusie wordt als niet nieuw of niet inventief beschouwd ten opzichte van deze literatuur</p> <p>"Y" de conclusie wordt als niet inventief beschouwd ten opzichte van de combinatie van deze literatuur met andere geciteerde literatuur van dezelfde categorie, waarbij de combinatie voor de vakman voor de hand liggend wordt geacht</p> <p>"&amp;" lid van dezelfde octrooifamilie of overeenkomstige octrooipublicatie</p>
<p>Datum waarop het onderzoek naar de stand van de techniek van internationaal type werd voltooid</p> <p>17 juli 2019</p>		<p>Verzenddatum van het rapport van het onderzoek naar de stand van de techniek van internationaal type</p>
<p>Naam en adres van de instantie</p> <p>European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016</p>		<p>De bevoegde ambtenaar</p> <p>Lahorte, Philippe</p>

**ONDERZOEKSRAPPORT BETREFFENDE HET  
RESULTAAT VAN HET ONDERZOEK NAAR DE STAND  
VAN DE TECHNIEK VAN HET INTERNATIONALE TYPE**

Informatie over leden van dezelfde octrooifamilie

Nummer van het verzoek om een onderzoek naar  
de stand van de techniek

NL 2022011

In het rapport genoemd octrooigeschrift	Datum van publicatie	Overeenkomend(e) geschrift(en)	Datum van publicatie	
US 2018243134	A1	30-08-2018	US 2018243134 A1	30-08-2018
			WO 2018154404 A1	30-08-2018
-----				
JP 2010057642	A	18-03-2010	JP 5231902 B2	10-07-2013
			JP 2010057642 A	18-03-2010
-----				
US 2010145374	A1	10-06-2010	CA 2745042 A1	08-07-2010
			CN 102245139 A	16-11-2011
			EP 2384175 A1	09-11-2011
			ES 2426952 T3	28-10-2013
			HK 1162297 A1	07-02-2014
			JP 5628825 B2	19-11-2014
			JP 2012510884 A	17-05-2012
			US 2010145374 A1	10-06-2010
			WO 2010077576 A1	08-07-2010
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US 2011144675	A1	16-06-2011	AU 2010328590 A1	14-06-2012
			BR 112012013974 A2	07-06-2016
			CA 2781157 A1	16-06-2011
			CN 102652006 A	29-08-2012
			EP 2509549 A1	17-10-2012
			ES 2442368 T3	11-02-2014
			JP 5711259 B2	30-04-2015
			JP 2013513426 A	22-04-2013
			RU 2012128873 A	20-01-2014
			US 2011144675 A1	16-06-2011
			WO 2011071655 A1	16-06-2011
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## WRITTEN OPINION

File No. SN72591	Filing date ( <i>day/month/year</i> ) 16.11.2018	Priority date ( <i>day/month/year</i> )	Application No. NL2022011
International Patent Classification (IPC) INV. A61F9/007			
Applicant Crea IP B.V.			

This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the application
- Box No. VIII Certain observations on the application

	Examiner Lahorte, Philippe
--	-------------------------------

**WRITTEN OPINION****Box No. I Basis of this opinion**

1. This opinion has been established on the basis of the latest set of claims filed before the start of the search.
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - a sequence listing
    - table(s) related to the sequence listing
  - b. format of material:
    - on paper
    - in electronic form
  - c. time of filing/furnishing:
    - contained in the application as filed.
    - filed together with the application in electronic form.
    - furnished subsequently for the purposes of search.
3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**Box No. V Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement
 

Novelty	Yes: Claims	1-21
	No: Claims	
Inventive step	Yes: Claims	1-21
	No: Claims	
Industrial applicability	Yes: Claims	1-21
	No: Claims	
2. Citations and explanations  
**see separate sheet**

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1 Reference is made to the following documents:
- D1 US 2018/243134 A1 (DEAN JOSHUA [US] ET AL) 30 augustus 2018 (2018-08-30)
  - D2 JP 2010 057642 A (NIDEK KK) 18 maart 2010 (2010-03-18)
  - D3 US 2010/145374 A1 (PERKINS JAMES T [US] ET AL) 10 juni 2010 (2010-06-10)
- 2 Document D1 discloses (see Fig 3A-C) an actuation system for an ophthalmic cutting tool (100-1) comprising a chamber that is fluidically separated by a diaphragm (304) into a first compartment (325) defining a first internal volume and a second compartment (326) defining a second internal volume, whereby a first port (329) is provided in fluid communication with the first compartment (325) and a second port (328) is provided in fluid communication with the second compartment (326), whereby the diaphragm (304) is movably mounted within the chamber and is configured for alternate movement between a first position and a second position, such that movement from the first position to the second position decreases the first volume and increases the second volume, as defined by claim 1.
- 2.1 From this device the subject-matter of claim 1 is distinguished in that:
- 1) the first and second ports are configured for connection to a first and second conduit, respectively, connected to a handheld ophthalmic cutting tool;
  - 2) a diaphragm actuator is coupled to the diaphragm and is configured to oscillate back and forth to move the diaphragm between the first and second position;
  - 3) a drive system is configured to drive the oscillation of the diaphragm actuator.
- Hence, the subject-matter of claim 1 is new.
- 2.2 The problem to be solved by the present invention may therefore be regarded as providing an alternative actuation system for an ophthalmic cutter.

In essence, the conventional diaphragm disclosed by D1 (as well as in D2, see Fig 1) is pneumatically driven, whereas in the solution of claim 1, the diaphragm is oscillated mechanically, thereby creating a differential pressure configured to pneumatically reciprocate a distal cutter element. In this way, the solution of claim 1 enables a fast-response cutting tool with low gas consumption.

Document D3 (see Fig 2) discloses a vitrectomy probe whereby a diaphragm (220) is moved by a motor. However, only one port and conduit connect the diaphragm pneumatically to the ophthalmic cutting tool.

Hindsight would be required to arrive at the subject matter of claim 1 on the basis of the available prior art. Hence, the subject matter of claim 1 is considered to involve an inventive step.

- 3 Independent claim 11 defines an alternative embodiment of an actuation system for an ophthalmic cutting tool whereby essentially two (instead of one) diaphragms are oscillated back and forth to generate a differential pressure configured to pneumatically reciprocate a distal cutter element, similar as the embodiment of claim 1.

Following a similar argumentation as above - mutatis mutandis - also the subject matter of independent claim 11, is considered new and inventive.

- 4 Claims 2-10 and 12-20 and 21 are dependent on either independent claim 1 or 11 and as such also meets the requirements of novelty and inventive step.