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(54) Title: LATERAL FLOW TEST KITS

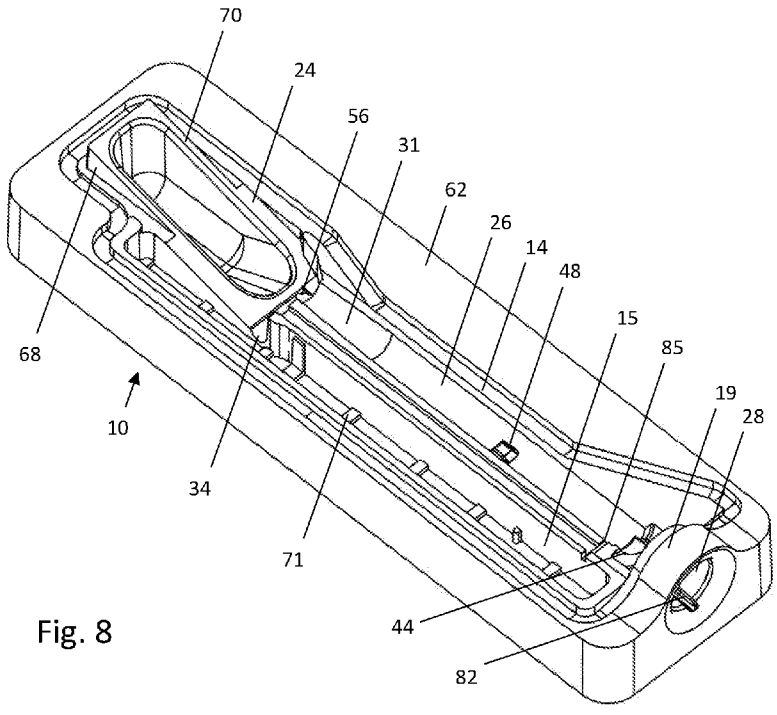

Fig. 8

(57) Abstract: A cassette (2) for a lateral flow test kit comprises first and second housing parts (8,10) that enclose an interior of the cassette (2). A liquid-tight seal (12,14) between the first and second housing parts (8,10) is continuous around the interior of the cassette (2) and an opening (28) through which a sample collector (3) may be inserted into the interior of the cassette (2) is formed entirely in the second housing part 10 to avoid interrupting the seal (12,14). Preferably, the majority of the seal (12,14) lies in a plane that intersects the opening (28); the seal (12,14) deviating from the plane in the region of the opening (28) to avoid being interrupted by the opening (28). A further seal (102,104) between the cassette (2) and a sample collector (3) may be provided in the opening (28) or may be axially offset from the opening (28) for ease of manufacture.

[Continued on next page]

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TITLE

Lateral flow test kits

DESCRIPTION

Technical field

The invention relates to lateral flow test kits, in which a sample in a liquid medium is applied to a test strip to carry out a chromatographic assay. It specifically relates to test kits in which the sample is obtained from a source on a collection device and needs to be introduced to the liquid medium before being applied to the test strip.

The nature of the test strip itself does not form part of the present invention. It may be conventional or novel and may be used to detect the presence of any desired target such as a virus or other disease-causing agent, a hormone, a toxin, an illegal drug or an environmental contaminant. The source may be a human or animal subject or the collector may be used to collect samples from the environment. Accordingly, the sample may be organic, biological or non-biological and may be in liquid form (e.g. blood) or solid form (e.g.faecal matter).

Background of the invention

Lateral flow tests have been used for a long time, for example in pregnancy tests, but the scale of their use has increased enormously since the Covid-19 pandemic. A typical lateral flow test kit comprises a cassette containing the test strip; a collector for taking a sample from a subject; a vial of liquid medium such as a buffer solution; and an extraction tube, in which the sample from the collector is mixed, and from which a prescribed number of drops of the liquid are then squeezed into a well in the cassette to begin the test. In some known test kits, the vial doubles as the extraction tube.

The large number of components in typical lateral flow test kits requires a fairly complex sequence of steps to be followed to carry out a successful test. The complex sequence of manual steps may also result in a significant proportion of tests being carried out incorrectly, leading to invalid results. Further, the handling of the

components and the transfer of the liquid between them introduce possibilities for contamination of the sample if good practice is not followed while performing the test.

The typical test kits, with multiple steps and components, require a flat, clean surface on which the components can be arranged and successive steps of the test can be carried out, for example to squeeze drops of liquid from the extraction tube into a well. Such a surface might not always be available, especially if a test needs to be conducted outside a domestic setting.

To maintain sterility of the kit before use, each of the components is normally supplied in separate, single-use packaging, which leads to additional waste. Each of the components also needs to be disposed of hygienically after use.

Such test kits are typically used to detect disease-causing agents or toxins so, once the sample has been mixed with liquid medium from the vial, the liquid becomes potentially infectious or toxic and there exists a health risk if it is permitted to leak out of the cassette.

It would be desirable to provide a lateral flow test kit that is improved in one or more of the following ways:

- The kit comprises a smaller number of distinct components at the point of use.
- The kit is simpler to use.
- The kit does not require a clear, flat surface on which to conduct a test.
- Tests performed using the kit have a higher proportion of valid results.
- Components of the kit are efficient to manufacture.
- The risk of leakage of the sample from the test kit is reduced.

Summary of the invention

The invention provides a cassette for a lateral flow test kit, the cassette comprising:

a first housing part attached to a second housing part so that the first and second housing parts face one another to enclose an interior of the cassette;

a liquid-tight seal between the first and second housing parts, the seal being continuous around the interior of the cassette; and

an opening through which a sample collector may be inserted into the interior of the cassette to lie between the first and second housing parts, the opening being formed entirely in the second housing part.

Features of the invention that are preferred but not essential are defined in the dependent claims.

In accordance with the invention, the sample collector may be inserted through the opening to lie between the first and second housing parts. The opening is formed entirely in the second housing part to avoid interrupting the continuous seal around the interior of the cassette, which thereby ensures a good seal against the leakage of liquid out of the cassette between the two housing parts. For ease of manufacture, the axis of the opening should lie on the interface between the two housing parts. The interface may be a plane that intersects the opening, with the majority of the seal preferably lying in that plane. However, the seal deviates from the plane to avoid being interrupted by the opening, preferably following a "bridge" over the opening.

In preferred embodiments of the invention, the vial of liquid is supplied as part of the cassette and remains within the cassette throughout the use of the test kit. The user does not need to remove a seal from the vial or transfer liquid from the vial to an extraction tube. The user also does not need to transfer the liquid from the extraction tube to the cassette. For these reasons, the sequence of steps to be followed by the user is simpler, the risk of error is lower and opportunities for contamination of the sample are avoided. There are not multiple components to be arranged on a surface and it may be possible to carry out the test while holding the cassette in one hand.

The smaller number of distinct components also results in less packaging, less waste and a simpler process for the supplier to assemble and distribute such test kits. The first and second co-operating elements may retain the collector in the cassette after use, thereby further reducing the number of distinct components that need to be disposed of

and decreasing the risk that the sample may come into contact with the environment. In preferred embodiments, additional sealing means are provided to prevent leakage of the liquid medium – now containing a fraction of the sample – from the opening through which the collector is received in the cassette.

In the present specification, terms such as "upper" and "lower" refer to the orientation of the cassette as shown in the drawings. In some embodiments of the invention the orientation may be important once the seal of the vial has been broken, to ensure that the liquid flows in the correct way to reach the test strip. However, test kits according to the present invention are generally less dependent than earlier test kits on being used in a specific orientation. It is understood that the cassette may be manufactured, stored and distributed in any orientation, at least after the vial has been sealed.

The term "proximal" refers to an end of the cassette through which the collector is inserted and the term "distal" refers to an opposite end of the cassette. The "longitudinal" direction extends between the proximal end and the distal end (in either direction). A "transverse" direction is one that is oblique or perpendicular to the longitudinal direction.

An "oblique" angle to a plane is one that is neither parallel to the plane nor perpendicular to the plane.

Drawings

Figure 1 is an exploded, perspective view of a test kit that comprises a cassette according to the invention.

Figure 2 is a perspective view of the test kit of Figure 1, following assembly and insertion of the collector into the cassette.

Figures 3 and 4 are longitudinal cross-sections through the test kit of Figure 1, showing successive stages in the insertion of the collector into the cassette.

Figure 5 is a partial, perspective, longitudinal cross-section through the distal end of the test kit of Figure 1.

Figure 6 is a perspective, transverse cross-section through the distal end of the test kit of Figure 1.

Figure 7 is a perspective view, from below, of the upper half of the cassette of Figure 1.

Figure 8 is a perspective view, from above, of the lower half of the cassette of Figure 1.

Figure 9 is a longitudinal cross-section showing a detail of the engagement between the collector and the cassette in the test kit of Figure 1.

Figure 10 is an exploded, perspective view of a cassette according to a second embodiment of the invention.

Figure 11 is an exploded, perspective view of a cassette according to a third embodiment of the invention.

Figure 12 shows, in a perspective view, an alternative collector which is a swab.

Figure 13 shows, in a perspective view and in section, an alternative collector comprising a cup.

Figure 14 shows, in a perspective view, an alternative collector comprising a loop.

Detailed description of the drawings

Figures 1 to 9 illustrate a preferred embodiment of a test kit that comprises a cassette 2 in accordance with the present invention. Figure 1 shows in an exploded view the complete test kit (excluding packaging), which comprises a cassette 2 and a collector 3. Figure 2 shows the test kit of Figure 1 after assembly, with the collector 3 received in the cassette 2.

The cassette 2 is formed by assembling a first housing part, namely, an upper half 8 with a second housing part, namely, a lower half 10 to sandwich a test strip 4 and a vial 6 of a liquid buffer solution between the two halves. The upper and lower halves 8,10 are not intended to be separable by the user and may be clipped, press-fitted, adhered or welded together. The mutually facing surfaces of the upper and lower halves 8,10 include complementary sealing features 12,14 to reduce leakage of the liquid from the cassette 2 during and after use.

The test strip 4 is securely mounted in a strip chamber 15, which is formed in the lower half 10 of the cassette 2 and closed by the upper half 8 during assembly. It may be a

conventional strip used for carrying out a chromatographic assay, typically comprising a strip of absorbent paper on which are deposited one or more transverse lines of a substance that responds to the presence of a target, for example an antigen or reagent that changes colour in the presence of a particular target. A small quantity of liquid containing a sample to be tested is applied near one end of the strip and is transported along the strip by capillary action. Different components of the sample may be transported at different rates and, if a component triggers one of the deposited substances to respond, the colour change of the respective line will be visible through a window 16 in the upper half 8 of the cassette 2. The window 16 may be a simple opening in the upper half 8 or, in order to reduce the risk of leakage from the cassette 2, it may comprise a transparent element attached to the upper half 8 or formed integrally with it. A second, similar window 17 may be provided above a distal end of the test strip 4, through which a user can observe whether the liquid medium has successfully been delivered to the test strip 4, without waiting for it to be transported along the strip as far as the indicator lines. Alternatively, the entire upper half 8 may be formed from a transparent material so that no distinct window is needed to allow the test strip 4 to be viewed.

In the illustrated embodiment, a label portion 18 on the upper half 8 includes a moulded letter "T" to mark the position of a test line that indicates the presence of a target in the sample; and a moulded letter "C" to mark the position of a control line, which indicates the successful completion of the test by showing that either the liquid itself or a component of it that is expected to be present in any valid sample has reached the position of the control line.

The vial 6 comprises a vial reservoir 20 that is closed by a seal 22, which in this embodiment takes the form of a substantially planar film. The upper and lower halves 8,10 of the cassette 2 respectively define the upper and lower walls of a longitudinal passage 26. A proximal end of the passage 26 has a mouth 28 that opens to the exterior of the cassette 2. The passage 26 is substantially circular in cross-section and extends along a substantially straight portion 29 in the distal direction from the mouth or opening 28. The centreline of the straight portion 29 defines an axis 30,

which is generally parallel to the length of the test strip 4. The axis 30 is also parallel to a base of the cassette 2 so that when the cassette rests on a horizontal surface, the straight portion 29 of the passage 26 is orientated horizontally. A distal end of the passage 26 is adjacent to the vial chamber 24. The distal end of the passage 26 is oriented towards the seal 22 of a vial 6 located in the chamber 24, such that the tip 38 of a collector 3 pushed along the passage 26 with sufficient force will be directed to penetrate the seal 22 and enter the vial 6. In the embodiment of the invention illustrated in Figures 1 to 9, the distal end of the passage 26 widens and deepens to form a volume 32 adjacent to the vial chamber 24. Within the volume 32, a curved portion 50 of the upper wall of the passage 26 directs the tip 38 of the collector 3 towards the seal 22. A narrow conduit 34 extends transversely from the volume 32 to provide fluid communication between the distal end of the passage 26 and the distal end of the test strip 4.

A collector 3 forms part of the test kit and comprises a shaft 35 with a grip 36 at the proximal end and a tip 38 at the distal end 40. The shaft 35 is able to flex resiliently, at least in a portion towards its distal end 40. The tip 38 of the collector 3 is capable of at least partially entering the vial 6. The illustrated collector 3 is a pipette for delivering a liquid sample into the cassette 2. The shaft 35 of the collector 3 is hollow, forming a receptacle for containing the sample prior to its delivery. The grip 36 comprises a hollow, compressible bulb that is coupled in an airtight manner to the shaft 35, whereby the user can apply pressure to the grip 36 to squeeze the liquid sample out of the shaft 35 via an opening at the tip 38 and can release the pressure on the grip 36 to draw liquid into the shaft 35 through the opening at the tip 38.

The diameters of the shaft 35 and the distal end 40 of the collector 3 are such that they can pass through the passage 26 but the grip 36 has a greater transverse dimension that prevents it from entering the passage mouth 28. The grip 36 may be provided with features such as a concave profile and a knurled texture to make it easier for a user to hold and manipulate the collector 3, both when obtaining a sample and when using the test kit to test the sample. At an intermediate position along the shaft 35, the collector 3 comprises an outward projection 46 in the general shape of a cone tapering towards the

tip 38. The outward projection 46 of the collector 3 co-operates with wedge-shaped inward projections 48 at an intermediate position along the passage 26, as will be described below.

Figures 7 and 8 show more detail of the respective opposing faces 60,62 of the upper and lower halves 8,10 of the cassette 2. Except as explained below, each half 8,10 can be formed by injection moulding in a two-part mould from a plastics material such as polypropylene. In accordance with the present invention, the opening 28 of the passage 26 is formed entirely in one of the two housing parts, for example the lower cassette half 10. In the illustrated embodiment the interface, which may defined by the upper surface 62 of the lower cassette half 10, is substantially planar. The plane coincides, at least approximately, with the axis 30 of the passage 26, which enables the upper and lower cassette halves 8,10 respectively to form the upper and lower walls of the passage 26, while being capable of being manufactured using simple moulds. The plane therefore also intersects the opening 28. To enable the opening 28 to be formed entirely in the lower cassette half 10, that half 10 is provided with a bridge portion 19, in which the upper surface of the deviates from the plane to pass over the opening 28. It should be noted that the opening 28 thereby constitutes a re-entrant feature when viewed from above so the mould used to form the lower cassette half 10 will require a third part, removable along the axis 30, to create the opening 28. It will be understood that in alternative embodiments of the invention, an inverted bridge portion could equally well be provided on the upper cassette half 8 so that the opening 28 of the passage 26 would then be formed entirely in the upper cassette half 8.

It may be seen than the lower sealing feature 14 takes the form of a groove that extends in a continuous circuit around the periphery of the cassette 2, enclosing the passage 26 and the vial chamber 24, while the upper sealing feature 12 takes the form of a complementary rib following the same path. The two sealing features 12,14 may be joined to one another in a liquid-tight manner, e.g. by ultrasonic welding or press-fitting, to prevent leakage of liquid from the passage 26 along the interface between the upper and lower halves 8,10, except where permitted by the capillary conduit 34.

The path of the sealing features 12,14 lies in the plane of the interface between the upper and lower cassette halves 8,10 over most of its length except that, in the region of the passage opening 28, it deviates from the plane to pass over the bridge portion 19. This allows the seal to follow a continuous circuit around the periphery of the cassette 2 without being interrupted by the opening 28.

The lower cassette half 10 further comprises an upstanding boss 68, in which the vial chamber 24 is formed. The boss 68 further provides an inclined, planar seat 70 for the rim 55 of the vial 6, while the upper cassette half 8 provides the inclined, planar upper wall 52 of the vial chamber 24 that clamps the vial 6 in place after assembly.

The strip chamber 15 in the lower cassette half 10 supports the test strip 4 at a low level in the cassette 2, approximately level with the bottom of the well 56. The strip 4 rests on a series of transverse bars 71, which minimize contact with the underlying surface to prevent the longitudinal transfer of liquid by capillary action between the strip 4 and the surface, rather than through the strip itself. The upper cassette half 8 comprises securing bosses 72, which project into the proximal end of the strip chamber 15, downstream of the window 16, to clamp the test strip 4 in place. The upper cassette half 8 may further comprise at least one metering boss 74, which projects into the strip chamber 15 upstream of the window 16 to exert pressure on the test strip 4 and regulate the rate of transport of liquid from the conduit 34 along it.

Figures 3 and 4 illustrate successive stages in the insertion of a collector 3 into the cassette 2.

In Figure 3, the tip 38 and distal end 40 of the collector 3 of the collector 3 have been inserted through the mouth 28 of the passage 26. The collector 3 initially slides easily along the passage 26, with the outward projection 46 keeping the shaft 35 substantially centred. At an intermediate position of the collector 3 along the passage 26, the outward projection 46 on the shaft 35 wedges against the inward projections 48 formed on the upper and lower halves of the passage 26. The mutual engagement between the inward and outward projections 46,48 resists further movement of the collector 3 in the

distal direction so that the user must apply an increased longitudinal force to push the collector 3 past the projections 48. As soon as the mutual engagement of the projections 46,48 has been released, the increased force now being applied by the user causes the movement of the collector 3 to accelerate so that the tip 38 moves towards the distal end of the passage 26 at higher speed.

As shown in Figure 4, when the collector 3 moves in the distal direction at the higher speed that results from overcoming the mutual engagement of the projections 46,48, this causes the distal end 40 of the collector 3 to be deflected downwards by the upper wall 50 and causes the tip 38 to pierce the seal 22 of the vial 6. The shape and rigidity of the tip 38 may be designed to facilitate this piercing. The collector 3 may also be provided with one or more flanges or other projecting elements 39 adjacent to the tip 38, which enhance its penetration of the seal 22 or increase the size of the hole that the penetrating tip 38 creates in the seal 22.

Preferably, when the collector 3 is fully inserted into the cassette 2, a substantial length of the distal end 40 of the collector 3 is submerged in the liquid 54. The vial 6 may be filled with liquid 54 to a level such that when the cassette 2 is horizontal, the tip 38 of the collector 3 pierces the seal 22 below the surface of the liquid 54. Thereby, the liquid 54 will naturally flow under gravity through the resulting opening into the volume 32. The submerged distal end 40 of the collector 3 will also displace liquid through the opening.

In the illustrated embodiment of the invention, where the collector 3 is a pipette, once the tip 38 of the collector 3 is located in the vial 6, the user squeezes the grip 36 to expel the liquid sample from the collector 3. This causes the sample to mix with the liquid 54 in the vial 6 and also displaces the mixture of liquids from the vial 6 via the opening created in the seal 22. Additionally – and particularly in alternative embodiments of the invention where the Collector 3 is not a pipette but is a swab or contains the sample in a receptacle such as a cup or a loop – the user may manipulate the grip 36 to move the distal end 40 of the collector 3 within the vial 6. This encourages both the transfer

of the sample from the collector 3 into the liquid 54 in the vial 6 and also the mixing of the sample with the liquid 54.

As seen in Figure 5, liquid 54 that escapes from the vial 6 will flow over the rim 55 of the vial 6 into a well 56 in the lower half of the volume 32. The conduit 34 is configured to transport the liquid 54 – now containing a fraction of the sample – from the well 56 to the test strip 4. In some embodiments, the conduit 34 may be of small cross section in order that the liquid does not flow freely and flood the test strip 4, its rate of transport through the conduit 34 being controlled by capillary forces.

Provided the cassette 2 is generally orientated such that liquid can flow from the vial 6, collect in the well 56 and flow from there towards the test strip 4, successful operation of the test kit is not particularly sensitive to the orientation. Therefore it is suitable for hand-held use, i.e. with the cassette 2 being held in one hand and the collector 3 being inserted using the other hand. Embodiments of the invention that use capillary forces, rather than gravitational flow, to transport the liquid 54 through the conduit 34 may be even less sensitive to orientation.

In embodiments of the invention where the tip 38 of the collector 3 comprises an enlarged head, additional liquid may be encouraged to flow from the vial 6 into the well 56 by the user withdrawing the head of the collector 3 from the vial 6. The withdrawing head tends to draw liquid 54 over the rim 55 and into the well 56. The user preferably moves the head into and out of the vial 6 several times, which also functions to achieve good mixing between the sample and the liquid 54 within the vial, ensuring a homogenous mixture.

After a suitable delay to allow time for the chromatographic assay to be completed, the user can read the result of the test by inspecting the lines of the test strip 4 through the window 16. Then the cassette 2, including the test strip 4, vial 6 and collector 3 can be disposed of safely as a single, sealed unit.

When the user has finished transferring the sample, and optionally after they have waited to observe liquid being transported successfully along the test strip 4, they preferably insert the collector 3 to the position shown in Figure 4. Figure 4 shows the collector 3 inserted into the cassette 2 to the maximum extent that is possible by moving it purely axially, without rotation. The axial movement is stopped by an initial contact between a first co-operating element 42 on the collector 3 and a second co-operating element 44 on the cassette 2. Then, the user manipulates the collector 2 to cause the first co-operating element 42 to engage the second co-operating element 44, which constrains the collector 3 against being withdrawn axially from the cassette 2. It is thereby permanently or releasably locked against withdrawal so that after the test kit has been used, it can be handled as medical waste with minimal risk that the collector 3 will become separated from the cassette 2 and expose the potentially hazardous distal end 40 of the collector to the environment.

In the illustrated embodiment, the first co-operating element is a male thread 42 about the shaft 35 of the collector 3 adjacent to the grip 36 and the second co-operating element is a female thread 44 about the proximal end of the passage 26. The thread 44 of the second co-operating element may be a broken thread, to enable respective portions of the thread to be formed on the upper and lower halves 8,10 of the cassette using simple moulds. To enable the female thread 44 to be formed in this way, it is offset distally from the mouth 28 of the passage to be clear of the bridge portion 19. In alternative embodiments of the invention (not illustrated) the second co-operating element could be formed as a continuous female thread inside the mouth 28 of the passage 26 but this would require the use of a rotary mould part, adding to the complexity of manufacture.

Thus, from the position in Figure 4, the user can rotate the grip 36 of the collector clockwise and engagement between the thread 42 of the first co-operating element and the thread 44 of the second co-operating element draws the collector 3 further into the cassette 2. Once the threads are engaged, the collector 3 becomes constrained against being withdrawn axially from the cassette 2 as previously described.

Rotation of the collector 3 through a predetermined angle relative to the cassette 2, e.g. 180°, causes the first and second co-operating elements 42,44 to reach a fully engaged configuration, as shown in the detailed view of Figure 9. At least one small rib or pip 80 may be provided at a specific angular position on the collector 3, which clicks into a corresponding notch 82 in the mouth 28 of the cassette 2 to provide tactile feedback to the user that the elements 42,44 are fully engaged and to prevent accidental rotation of the collector 3 away from the locked position during subsequent handling. In alternative embodiments, the locations of the rib 80 and the notch 82 could clearly be interchanged.

A test kit according to the present invention preferably includes a further seal between the collector 3 and the cassette 2, in order to prevent or reduce the leakage of liquid out of the test kit via the mouth 28 of the passage 26. When the collector 3 is in its most distal position, the aforementioned outward projection 46 from the shaft 35 may engage with a constriction 31 in the passage 26 to create a seal that prevents or reduces the flow of liquid from the volume 32 into the straight portion 29 of the passage 26. In other embodiments of the invention, a plug that seals against the constriction 31 at the most distal position of the collector 3 could be provided as a separate feature from the outward projection 46 that resists initial insertion and prevents withdrawal of the collector 3. In other words, the plug and the outward projection 46 could be formed as discrete elements at different positions along the shaft 35. Alternatively, instead of such a plug feature, the shaft 35 could be provided with one or more thin, radial fins 41 (illustrated in Figs. 13 and 14), which can seal around the shaft 35 at any position of the collector 3 along the passage 26, while being able to flex to permit the forward or backward movement of the collector 3 along the passage 26.

If sealing means such as fins 41 are provided between the collector 3 and the passage 26, distally of the mouth 28, then moving the collector 3 distally along the passage 26 might increase the air pressure on the distal side of the sealing means, i.e. in the volume 32 at the distal end of the passage 26, in the vial chamber 24 and, via the conduit 34, also in the test strip chamber 15. If the interior air pressure of the test kit becomes elevated in this way relative to the ambient air pressure, it could drive the

movement of liquid from the interior to the exterior, resulting in leakage. To mitigate this risk, embodiments of the invention can include a small air vent 85 between the proximal end of the strip chamber 15 and the proximal end of the passage 26, through which air can flow to equalize the interior pressure of the test kit on both sides of the sealing means.

Figure 9 illustrates an O-ring 90 that is located in an annular recess about the mouth 28 of the passage 26, within the bridge portion 19 of the lower cassette half 10. When the collector 3 is received in the cassette 2 – and at least when it is advanced to its most distal position – the O-ring 90 bears on a circumferential surface 92 of the collector 3 to prevent liquid leaking from the test kit via the mouth 28.

Figure 10 illustrates a second embodiment of the invention, which is substantially similar to the embodiment of Figures 1 to 9, except that it further comprises a gasket 100 sandwiched between the upper and lower cassette halves 8,10. The gasket 100 mostly comprises a thin sheet of a compliant material, which forms a liquid-tight seal when it is compressed between the facing surfaces 60,62 of the upper and lower cassette halves 8,10. The gasket 100 lies within the circuit of the sealing means 12,14 and supplements their function of resisting leakage of liquid from the interior to the exterior of the cassette 2. In the embodiment of Figure 10, the gasket further comprises an annular insert 102, which is shaped and located to fit within the mouth 28 of the passage 26, below the bridge portion 19 of the lower cassette half 10. The compliant annular insert, thereby forms a liquid-tight seal between the collector 3 and the cassette 2 and it may avoid the need for the O-ring 90 of Figure 9.

Figure 11 illustrates a third embodiment of the invention, which is substantially similar to the embodiment of Figure 10 and also comprises a gasket 100 of a compliant material sandwiched between the upper and lower cassette halves 8,10. In this embodiment, the gasket 100 comprises a different form of annular insert 104, which is shaped and located to fit within the passage 26 at a position distally of its mouth 28. The annular insert 104 has a bore that is wide enough to allow the distal end 40 of the collector 3 to pass through it. However, when the collector 3 is advanced to its most distal position

after use of the test kit, the annular insert 104 engages a feature such as the outward projection 46 on the shaft 35 of the collector 3 to form a liquid-tight seal between the collector 3 and the cassette 2.

Each of the illustrated embodiments of the cassette 2 according to the invention comprises a single test strip 4. However, it can easily be envisaged that a single cassette 2 could comprise two or more test strips 4, each used for detecting the presence of a different substance in the sample (or for detecting the same substance as a way of verifying the validity of the result of the test). It will generally be convenient for the multiple test strips 4 to be arranged in parallel. They may be disposed on one side or on both sides of the passage 26. Liquid containing the sample may be delivered from the vial 6 to more than one test strip 4 via a common conduit 34. Alternatively, each test strip 4 may be supplied by a separate conduit 34.

Figures 12 to 14 illustrate alternative collectors 3 that may be used with a cassette 2 substantially according to any of the illustrated embodiments of the invention, subject to the provision of suitable first co-operating elements on the collector 3 and complementary second co-operating elements on the cassette 2. In these embodiments, no fluid communication is required between the proximal and distal ends of the collector 3 so the shaft 35 may be solid (but a hollow shaft is not excluded).

The collector 3 in Figure 12 is a swab, which comprises a head 37 at or adjacent to the tip 38. The head 37 may comprise a roughened, flocked or absorbent material that is capable of picking up, retaining and then releasing a sample to be tested, e.g. from the oral or nasal cavity of a subject.

The collector 3 in Figure 13 comprises a receptacle for containing the sample, in the form of a cup 96 at the distal end 40. Such a cup 96 may carry a small quantity of blood or another biological or organic liquid. It may alternatively carry a solid or semi-solid sample. A set of flexible, radial fins 41 about the shaft 35 provide a seal between the shaft and the passage 26 as the collector is manipulated to move forwards and

backwards in the passage 26. This helps to contain the liquid from the vial 6 and the potentially hazardous sample within the cassette 2 during and after use of the test kit.

The collector 3 in Figure 14 is similar to that in Figure 13, except that the receptacle for the sample comprises one or more loops 98. Each loop 98 is suitable for holding a drop of blood or another liquid sample, which is kept in place by surface tension. This illustrates that a receptacle suitable for use in a collector 3 according to the invention does not need to enclose the sample fully or even substantially in order to perform its functions of containing the sample and delivering it into the vial 6.

CLAIMS

1. A cassette (2) for a lateral flow test kit, the cassette (2) comprising:

a first housing part (8) attached to a second housing part (10) so that the first and second housing parts (8,10) face one another to enclose an interior of the cassette (2);

a liquid-tight seal (12,14) between the first and second housing parts, the seal (12,14) being continuous around the interior of the cassette (2); and

an opening (28) through which a sample collector (3) may be inserted into the interior of the cassette (2) to lie between the first and second housing parts (8,10), the opening (28) being formed entirely in the second housing part (10).

2. A cassette (2) according to claim 1, wherein the second housing part (10) defines a plane that intersects the opening (28); the seal (12,14) lying substantially in the plane except in the region of the opening (28).

3. A cassette (2) according to claim 1 or claim 2, wherein the seal (12,14) comprises an ultrasonic weld.

4. A cassette (2) according to any preceding claim, further comprising a gasket (100) between the first and second housing parts.

5. A cassette (2) according to any of claims 1 to 4, further comprising means (90,102) for forming a liquid-tight seal between the cassette (2) and the collector, the sealing means (90,102) being provided in the opening (28).

6. A cassette (2) according to any of claims 1 to 4, further comprising sealing means (41; 104) for forming a liquid-tight seal between the cassette (2) and the collector (3), the sealing means (41; 104) being offset in the distal direction from the opening (28).

7. A cassette (2) according to any of claims 1 to 6, further comprising means for securing the collector (3) in the cassette (2), the securing means being provided in the opening (28).

8. A cassette (2) according to any of claims 1 to 6, further comprising means (42,44) for securing the collector in the cassette (2), the securing means (42,44) being offset in the distal direction from the opening (28).

9. A cassette (2) according to any preceding claim, further comprising:

a passage (26) for receiving the collector (3), the passage (26) having a proximal end at the opening (28) of the cassette (2) and a distal end remote from the opening (28);

a test strip chamber (15) disposed generally parallel to the passage (26); and

a conduit (34) extending from the distal end of the passage (26) to a distal portion of the test strip chamber (15).

10. A cassette (2) according to claim 9, further comprising a vial (6) adjacent to the distal end of the passage (26), the vial (6) comprising a vial seal (22) for retaining liquid (54) in the vial (6) until the vial seal (22) is broken by the distal end (38) of a collector (3) inserted along the passage (26).

11. A cassette (2) according to claim 9 or claim 10, further comprising a vent (85) that permits air to flow from a proximal portion of the test strip chamber (15) into the passage (26).

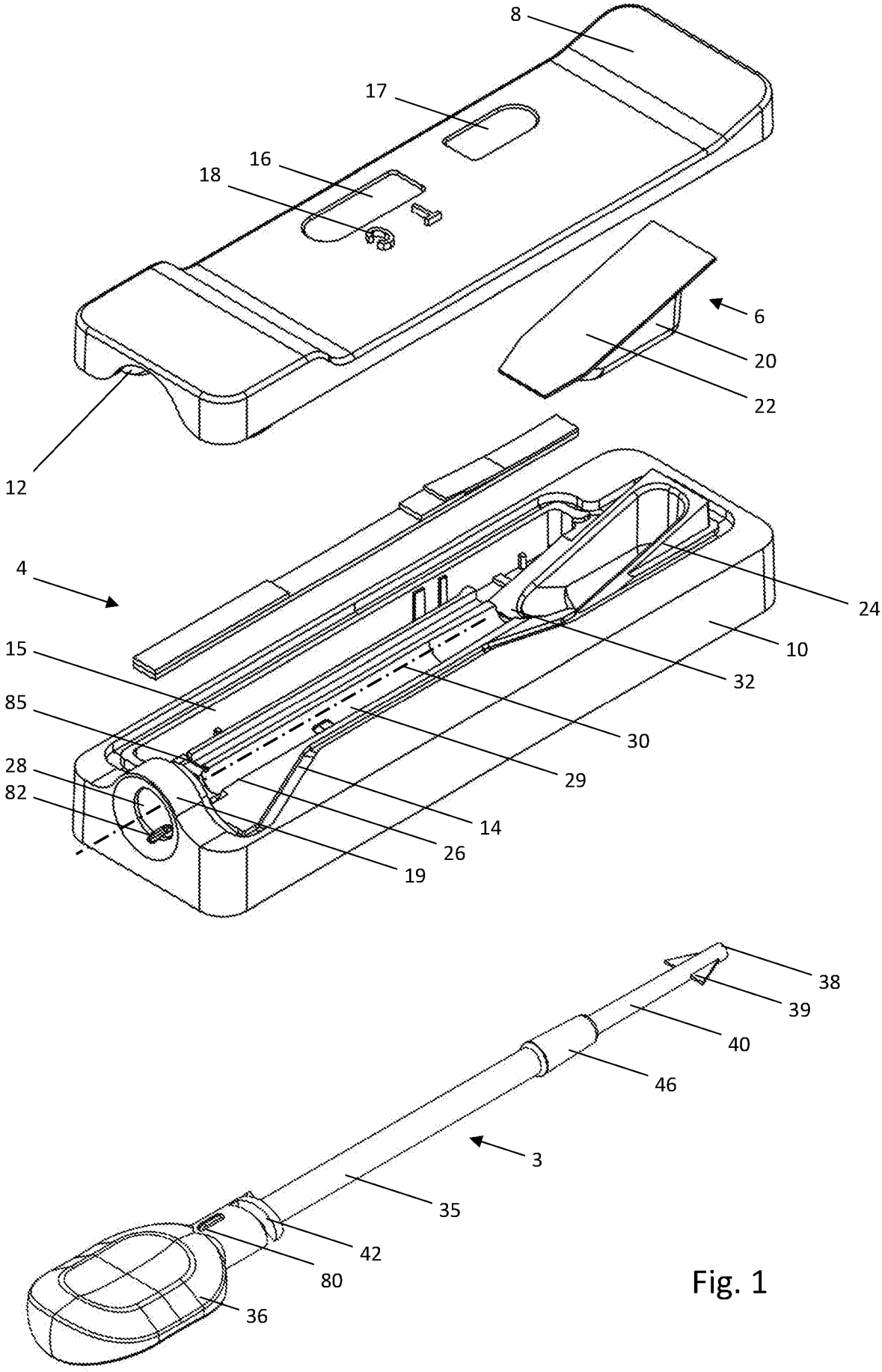
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Fig. 1

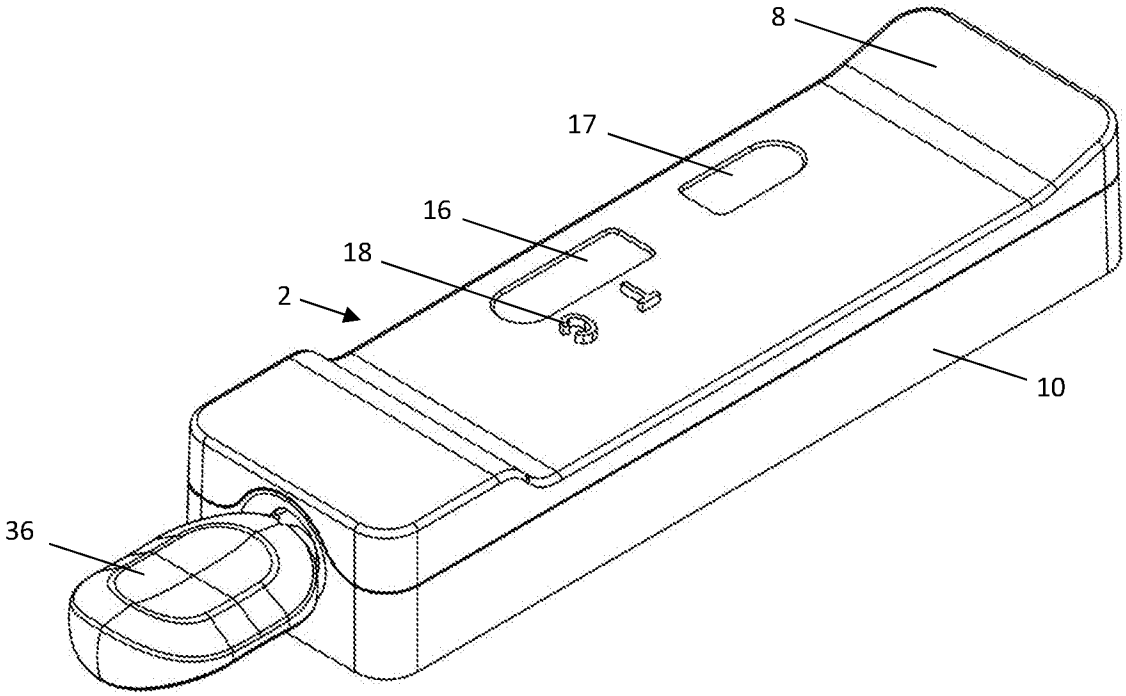

Fig. 2

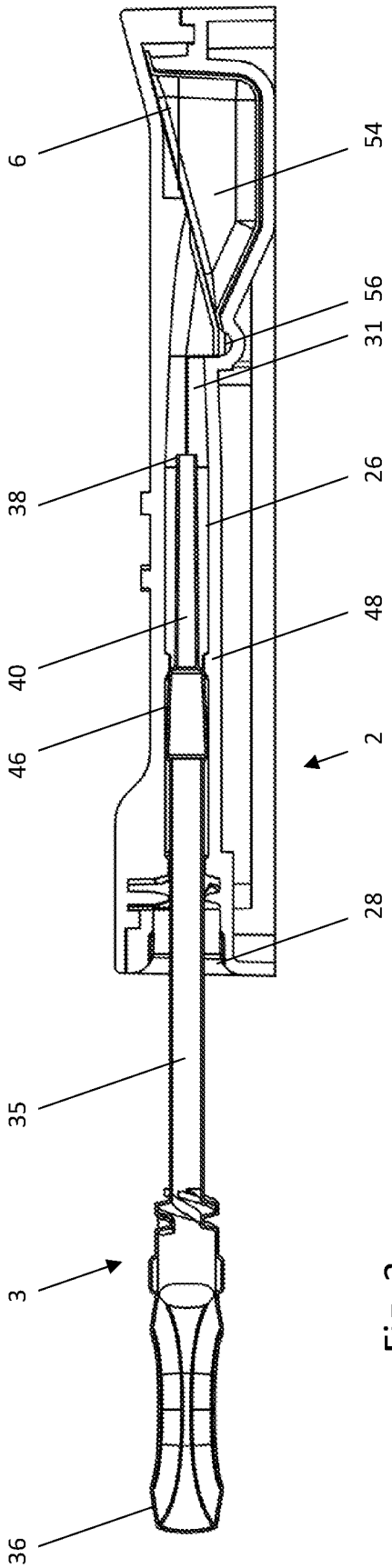
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Fig. 3

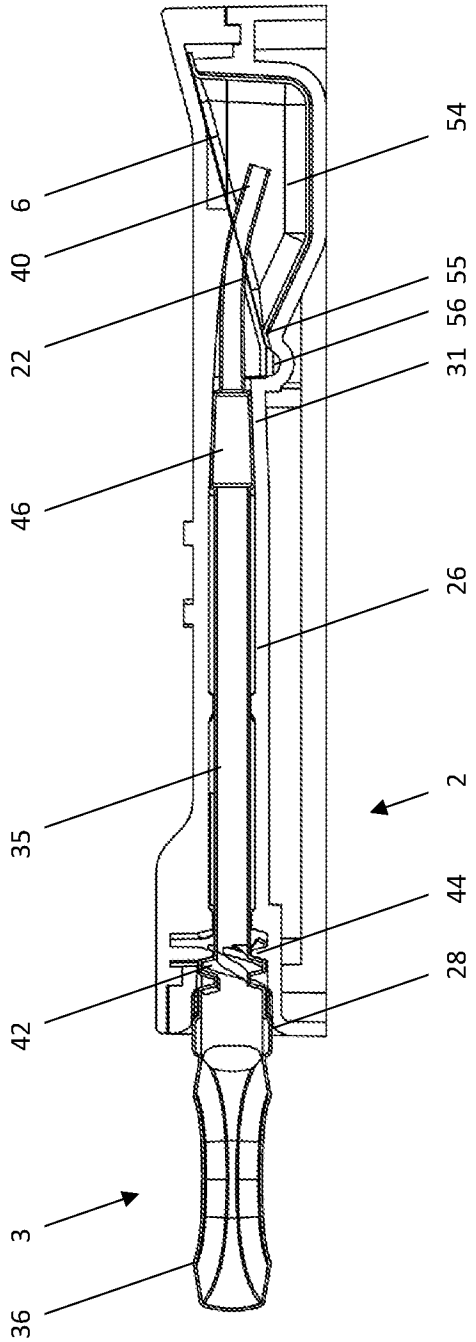
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Fig. 4

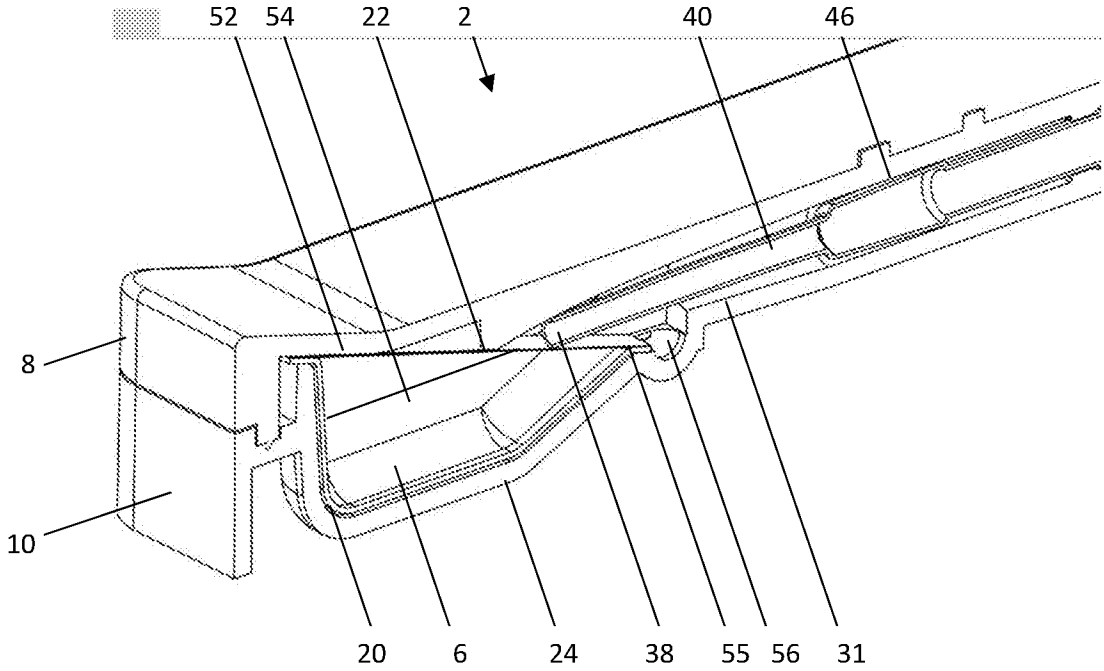

Fig. 5

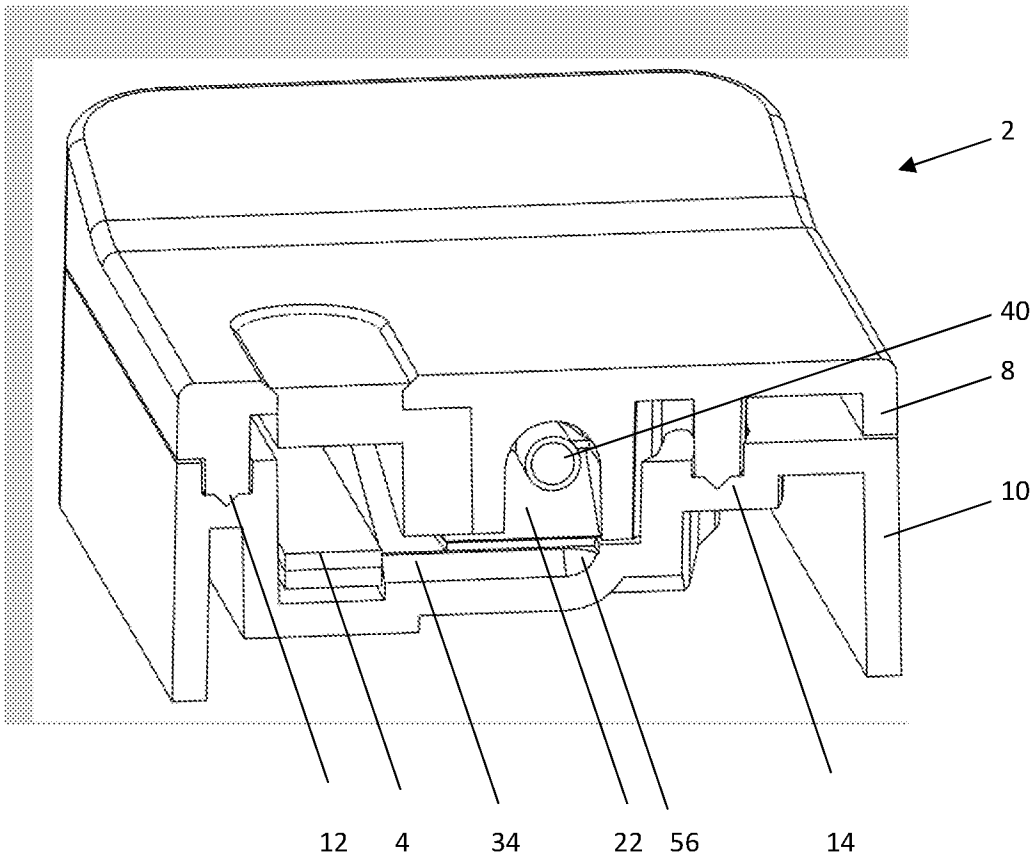

Fig. 6

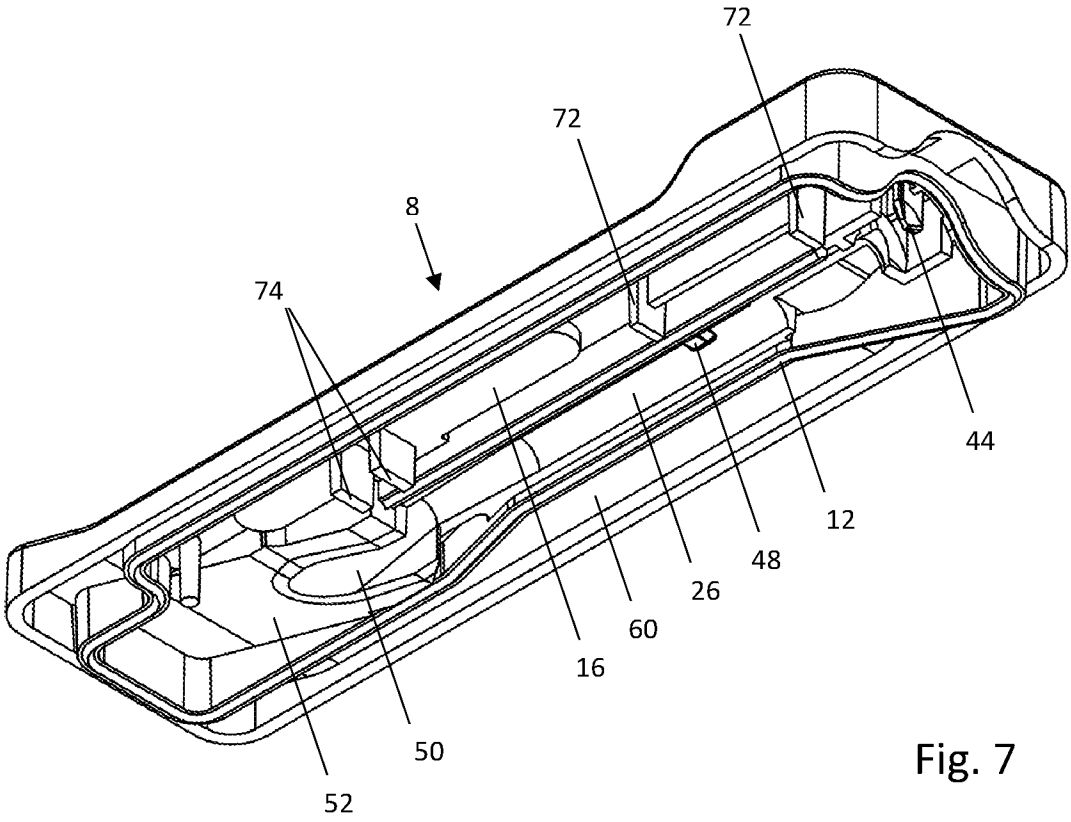
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Fig. 7

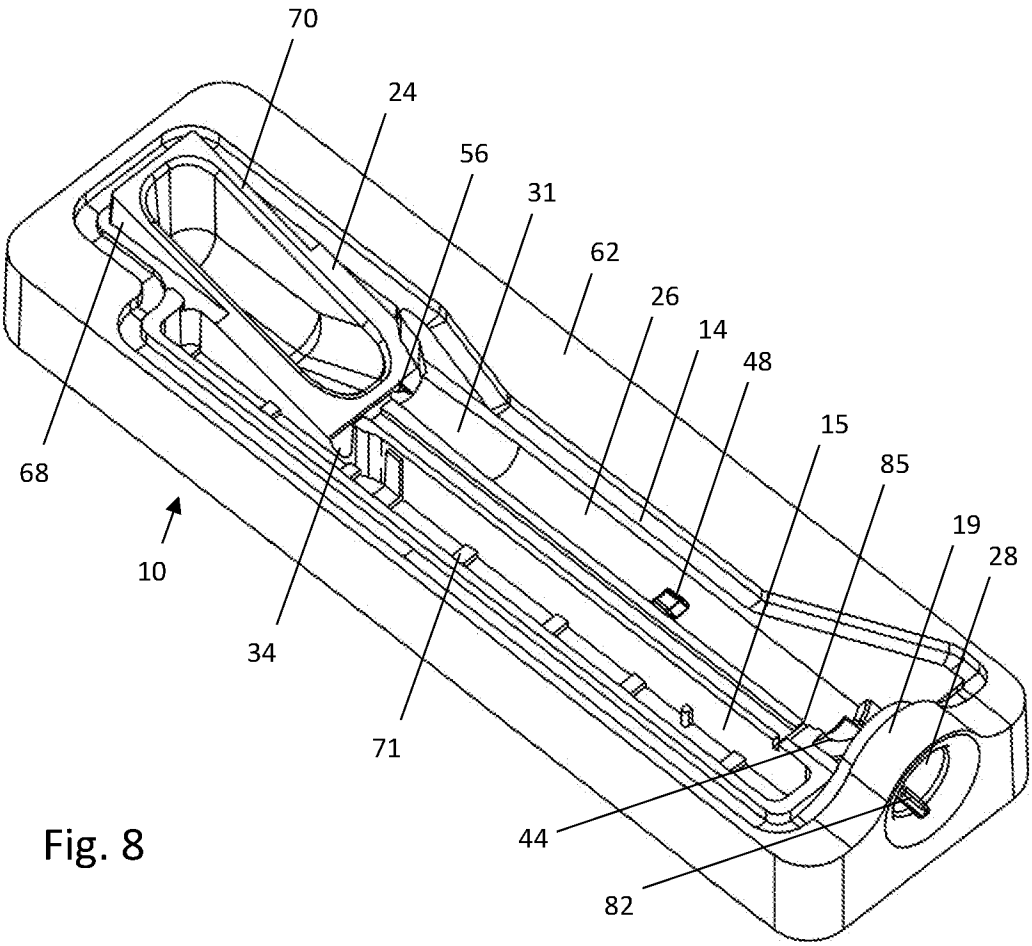
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Fig. 8

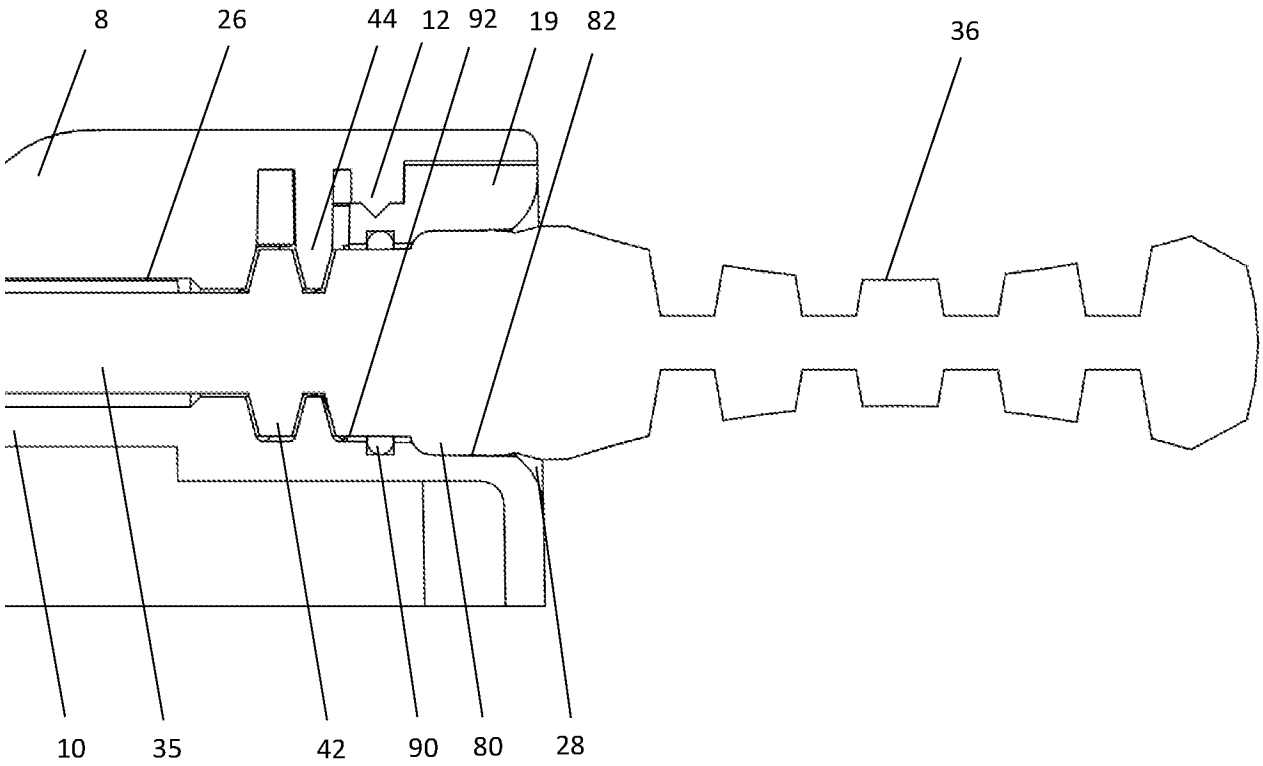

Fig. 9

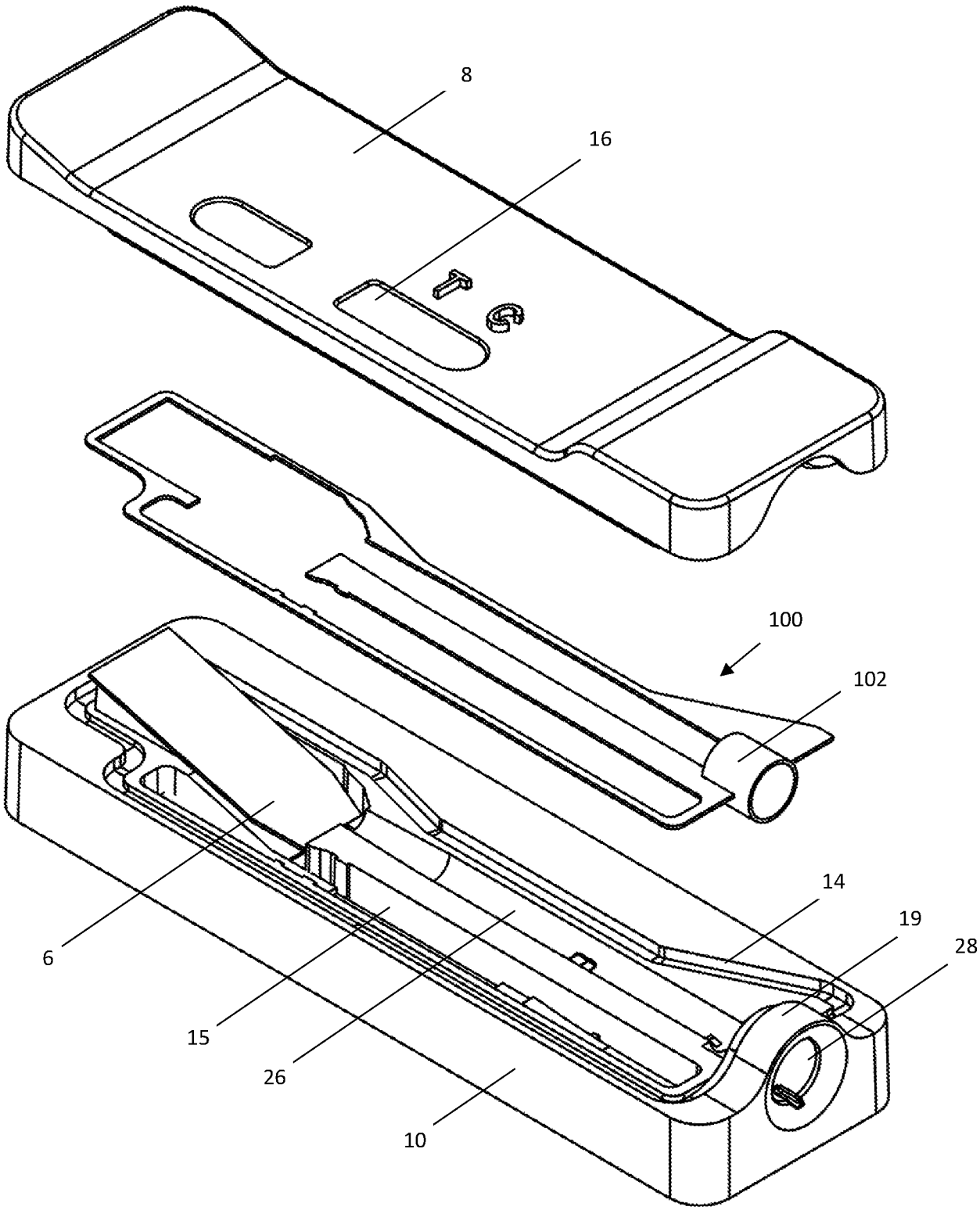

Fig. 10

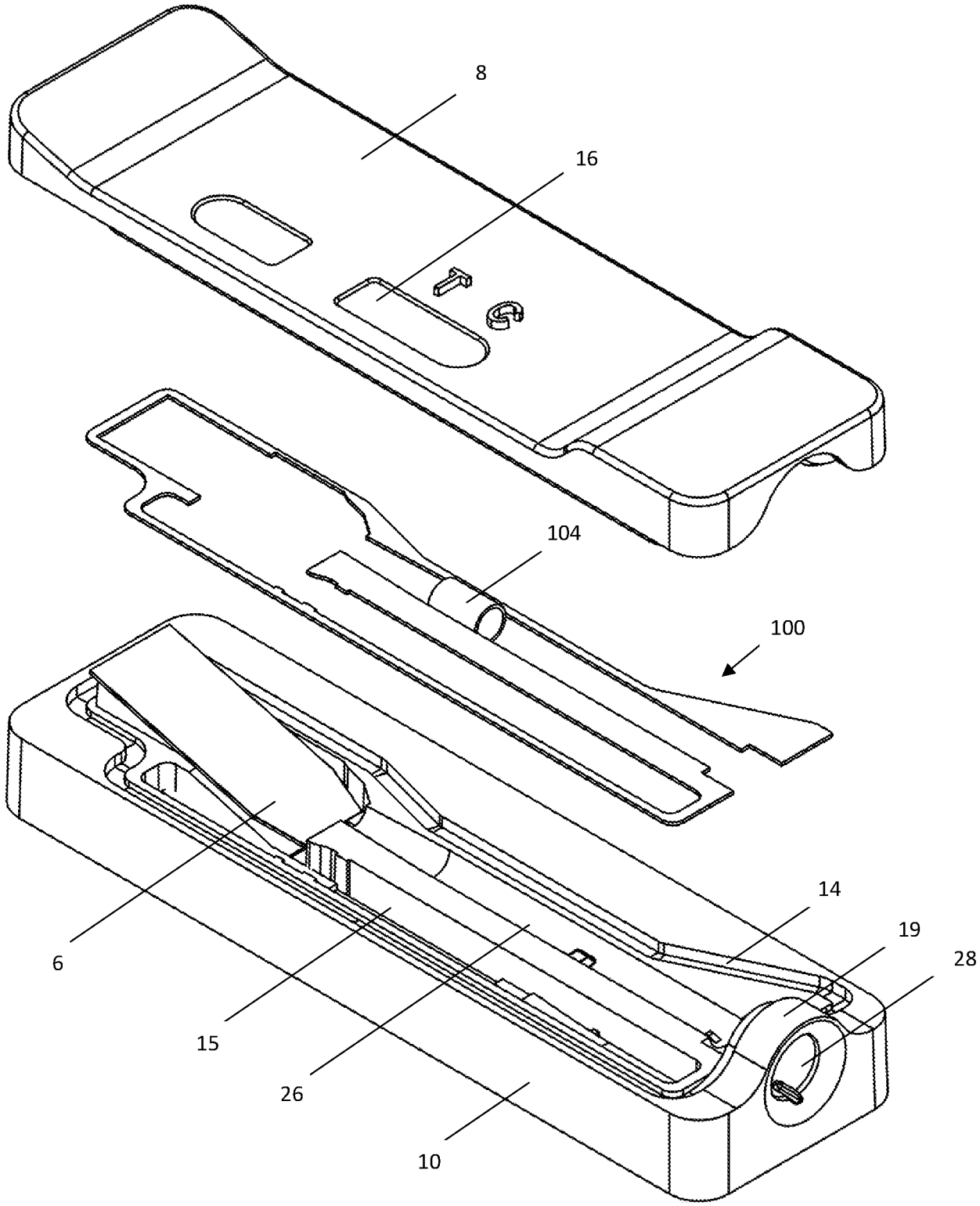

Fig. 11

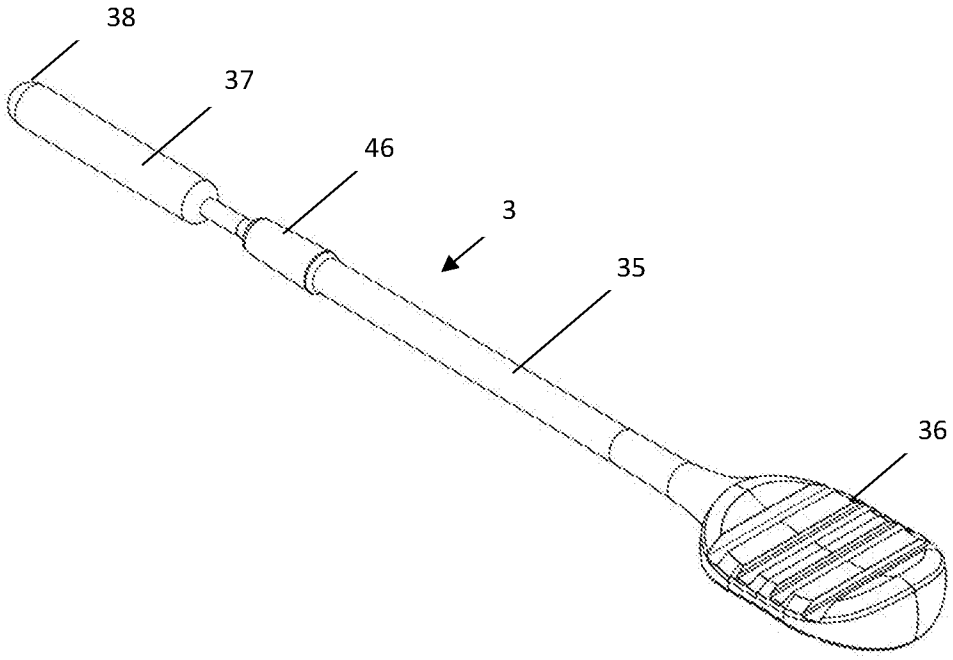

Fig. 12

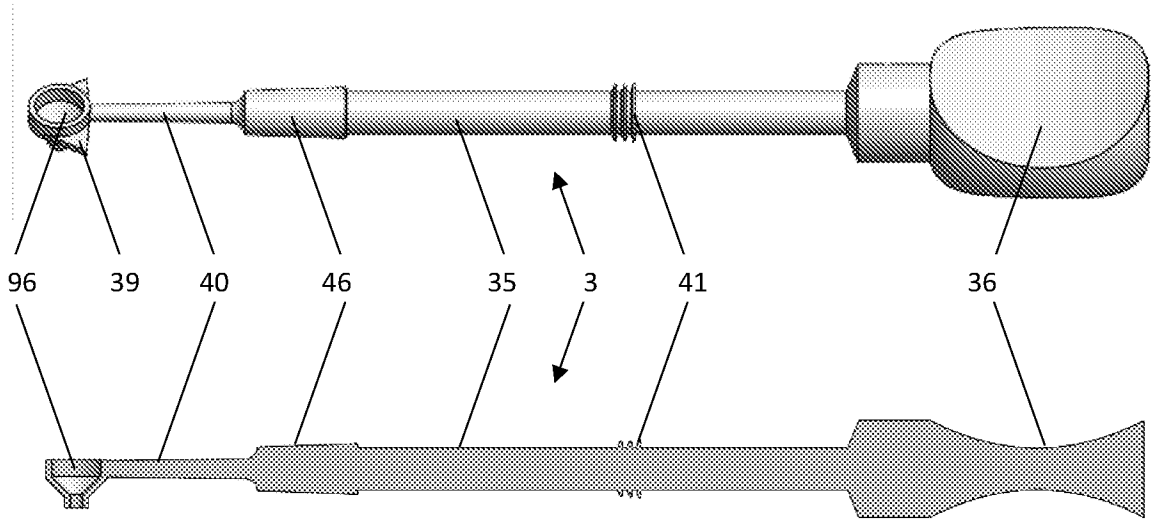

Fig. 13

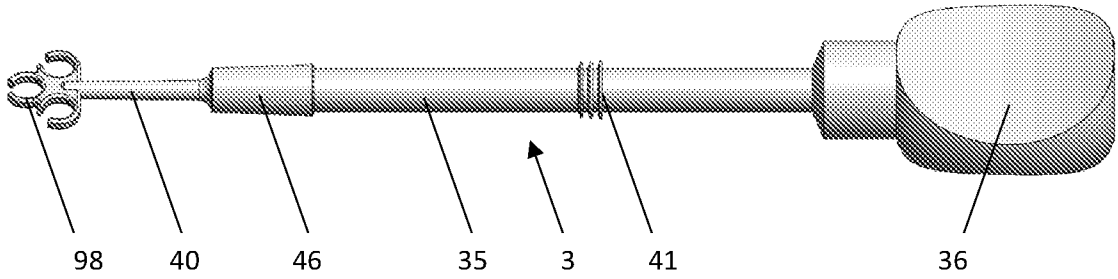

Fig. 14

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2024/051020

A. CLASSIFICATION OF SUBJECT MATTER
INV. B01L3/00 B01L3/02
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
B01L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2020/376483 A1 (LOUDERMILK ALAN R [US] ET AL) 3 December 2020 (2020-12-03) paragraphs [0041], [0042], [0044], [0054], [0056], [0057]; figures 1-4,7,16B	1-11
X	US 2019/339174 A1 (O'NEILL PATRICK [US]) 7 November 2019 (2019-11-07) paragraphs [0030], [0033], [0034]; figures 1-3	1-11
A	US 2013/157381 A1 (PANG ALAN [GB] ET AL) 20 June 2013 (2013-06-20) the whole document	1-11
A	US 9 091 680 B1 (SCHREIBER ROBERT [US]) 28 July 2015 (2015-07-28) the whole document	1-11

☐ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

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"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
4 July 2024	25/07/2024

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Vahidpour, Farnoosh

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2024/051020

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US 9091680 B1	28-07-2015	NONE	