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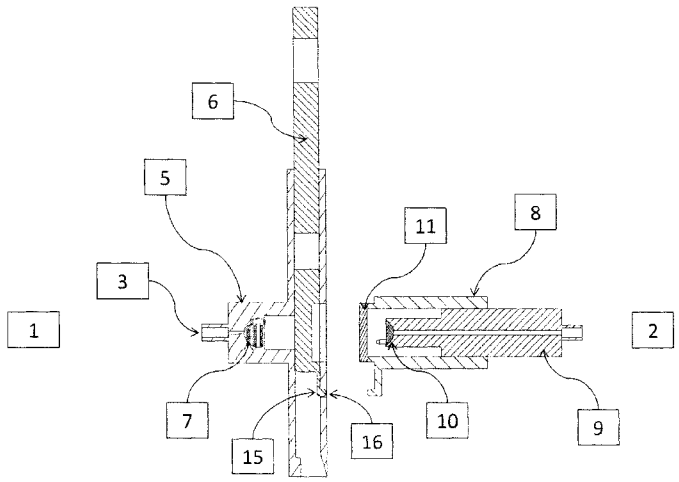
(54) **Title**: ASEPTIC SAMPLING SYSTEM

Figure 3a



(57) **Abstract**: An aseptic sampling system comprises a sampler assembly and an interface assembly. Each assembly comprises a housing, each housing defining a separate sterile enclosure for each of the assemblies. An air lock is arranged to provide, in use, the aseptic joining of the sterile enclosures within the sampler and interface assemblies, and a re-sealable liquid connection mechanism is positioned to operate within the air lock. The sampler assembly and interface assembly are arranged such that, when connected together, they form an outer protective surface comprising the housings of each of the sampler and interface assemblies, theouter protective surface providing a sterile internal enclosure and air lock and an air-tight barrier between the outer non-sterile atmosphere and the inner sterile atmosphere. The re-sealable liquid connection mechanism is contained within the sterile enclosure and contains at least one liquid connector from each of the sampler and interface assemblies and is configured such that, in use, at least one of the liquid connectors can move across the sterile enclosure and air lock to connect with the other connector in the liquid connection mechanism, without contacting any internal surfaces within the air lock, and is configured such that the liquid connectors, in use, can subsequently be re-sealed, disconnected and separated.

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Aseptic sampling system

The present invention relates to an aseptic sampling system. In industries such as bioprocessing and medical devices, there is an identified need for the aseptic and ultra clean removal and injection of multiple samples from a reservoir. The sample and reservoir must not be contaminated by infectious agents that may be present in the atmosphere or on the surfaces outside the vessel. The present invention seeks to address the need for a sterile, ultra clean, fluidic connection to be made and broken, time after time, without contaminating any of the sample, any mechanism in the sampler that is in contact with the sample or reservoir, or the liquid in the reservoir itself. The name for this process is 'aseptic sampling'.

In the medical industry, for example in intravenous therapy, clean sampling is currently achieved to satisfaction using a single or dual rubber septum to ensure a minimum of dirt is transferred to any samples. One common method is to use a system where a needle is encased in one septum, and when pushed against a second septum, the needle pierces both, creating a fluid pathway with very low risk of contamination. However, when the two surfaces of the two septa touch, infectious particles can be trapped between them and be transferred to the needle as it pierces and slides through the join between the two septa. In many processes where a nutrient medium is incubated, a single infectious particle may destroy the product.

According to the present invention there is provided an aseptic sampling system comprising: a sampler assembly and an interface assembly, each assembly comprising a housing, each housing defining a separate sterile enclosure for each of the assemblies; an air lock arranged to provide, in use, the aseptic joining of the sterile enclosures within the sampler and interface assemblies; and a re-sealable liquid connection mechanism positioned to operate within the air lock, wherein: the sampler assembly and interface assembly are arranged such that, when connected together, they form an outer protective surface comprising the housings of each of the sampler and interface assemblies, the outer protective surface providing a sterile internal enclosure and air lock and an air-tight barrier between the outer non-sterile atmosphere and the inner sterile atmosphere, and wherein the re-sealable liquid connection mechanism is contained within the sterile enclosure and contains at least one liquid connector from each of the sampler and interface assemblies and is configured such that, in use, at least one of the liquid connectors can move across the sterile enclosure and air lock to connect with the other connector in the liquid connection mechanism, without contacting any internal surfaces within the air lock.

The system may be arranged such that the liquid connectors, in use, can subsequently be re-sealed, disconnected and separated.

This invention provides a means of sampling where both the reservoir and sample remain free of contaminants that may be present in the atmosphere or on the surfaces of the

sampling device and reservoir, and where many samples can be taken using the same equipment. Furthermore, the invention does not require external means of sterilization, for example, to inject high pressure steam or ethylene oxide. Rather the invention can be made from entirely disposable parts.

Examples of the present invention will now be described with reference to the accompanying drawings, in which:

Figures 1a and 1b are schematic diagrams showing the principle of the invention;

Figure 2 shows the outward form of the first preferred embodiment of the invention;

Figures 3a to 3e show the mechanism and operation of the first preferred embodiment of the invention;

Figures 4a to 4e show the mechanism and operation of the second preferred embodiment of the invention;

Figure 5 shows a cut-away detail of the first preferred embodiment of the invention; and

Figure 6 shows further descriptions of the first preferred embodiment of the invention.

The invention is an aseptic sampling system which comprises two mating assemblies shown schematically in Figure 1a. A sampler assembly 2 whose function is to withdraw or infuse a single sample, and an interface assembly 1 whose function is to provide the interface between the sampler assembly and the reservoir 38 to be sampled. The interface assembly 1 is usually retained with the reservoir 38 for the duration of an aseptic culture, and allows the repeated taking of samples through the use of one or more units of the sampler assembly 2.

The sampler and interface assemblies 2,1 together comprise the following parts. Firstly, an outer protective surface is provided, made up of a housing 8,5 of each of the sampler and interface assemblies 11,6. This outer protective surface makes a sterile enclosure by forming a barrier between the outer non-sterile atmosphere and the inner sterile atmosphere. Secondly, an air lock is provided that allows the joining of the sterile enclosure in the sampler and interface assemblies. Thirdly, a re-sealable liquid connection mechanism is provided that contains a connector in each of the sampler and interface assemblies 2,1. At least one of the connectors is moved through the sterile enclosure and air lock to mate with the opposite connector in the liquid connection mechanism, without sliding on any surfaces that could be non-sterile.

The liquid connection mechanism, sterile enclosure 18 , outer protective surface 5,8 and air lock 11,6 each are shown schematically and operated as shown in Figure 1 and described as follows. First the sampler assembly 2 is mated with the interface assembly 1 via the air lock 11,6 (Figure 1bi). The air lock is opened, keeping the sterile enclosure 18 free of contamination of outside air. Second, the parts of the liquid connection mechanism 7,9,10 are joined within the sterile enclosure, and without sliding past surfaces 11,6 of the air lock

that may be non-sterile (Figure 1bii). The liquid connection mechanism 7,9,10 thus creates a sealed aseptic liquid flow path. A sample is then infused or withdrawn from the reservoir 38. The sampler and interface assemblies 2,1 are then separated by reversing the above procedure: first the liquid connection mechanism 7,9,10 is resealed and separated, and then the air lock is disengaged.

The invention does not depend on particular forms of the component mechanisms. The novelty of this aseptic sampling system is the combination of a re-sealable liquid connection mechanism within a sterile enclosure 18, protected by an air lock 11,6 and an outer protective surface 5,8, so that the liquid connection can be made without the parts of the connection mechanism being exposed to outside air or being made to contact any surfaces that could be non-sterile, and that the liquid connection can be disconnected without contamination of the sampler or interface assemblies. These properties of the invention are necessary for the utility of the system: to take repeated samples without contamination of sample or reservoir 38, or the use of external sterilizing equipment.

The description below starts with to a first embodiment, but the invention is not limited to the geometry, mechanisms and motions described below.

The first embodiment, as shown in Figure 2, comprises two mechanical assemblies, an interface assembly 1 and a sampler assembly 2. The interface assembly provides a connector 3 to a reservoir and the sampler assembly provides a connector 4 to a sample vessel. Figure 2 shows female luer connectors for features 3 and 4. However, alternative embodiments would include barbed tube fittings, flanged sanitary fittings and flanged welded seals to connect to disposable bag bioreactors or disposable sampling bags.

Each mechanical assembly comprises separate parts, detailed in the cross section diagram of Figure 3. The interface 1 comprises a housing 5, shutter 6, and liquid valve 7. The connector to the reservoir is here a moulded pipe fitting 3 on the outside of the housing 5. The sampler 2 comprises a housing sheath 8, slider 9, inner cap 10 and outer cap 11. The shutter 6 is locked in position in the housing 5 by an interlock hook 15, which fits in an interlock aperture 16.

The operating mechanism and sequence for the first embodiment is described with reference to Figures 3a-3e. Figure 3a shows the first embodiment before sampling.

The first step of sampling is shown in Figure 3b, where the sampler assembly 2 is pushed into a mating aperture 12 of the interface assembly 1. The outer cap 11 is then fully contained in a slot 13 of the shutter 6. Simultaneously an interlock protrusion 14 pushes the interlock hook 15 out of the interlock aperture 16. This allows the shutter 6 to slide vertically. The mating faces of the housing sheath 8 and housing 5 form an air-tight surface 17.

The second step of sampling is shown in Figure 3c, where the shutter 6 is slid down. This moves the outer cap 11 away from the housing sheath 8 which has the effect of joining the sterile atmospheres in the sampler and interface assemblies 2,1 into a single sterile

enclosure 18. At this point, the sterile enclosure 18 contains a direct path between the inner cap 10 and the liquid valve 7, while the outer cap 11 is fully stored away from the sterile enclosure 18.

The third step of sampling is shown in Figure 3d. The slider 9 is now pushed towards the interface assembly so that the inner cap 10 mates with the liquid valve 7. The inner cap 10 contains a registration feature 19 that mates with an indentation on the liquid valve 7. The liquid valve 7 and the inner cap 10 form a continuous, sealing, cylindrical sliding surface 20 within the housing 5.

The fourth step of sampling is shown in Figure 3e. The liquid valve 7 is rotated to the open position, such that the channel 22 now forms an open path between connector 3 from the reservoir and connector 4 to the sample vessel. The sample then flows through using the positive pressure of the reservoir or by applying suction to the sample vessel.

Having taken the sample, the sampler assembly 2 is then removed. The movements are exactly opposite to the four steps above, leading to the disconnection of the sampler assembly 2 as shown in Figure 3a.

Additional details of the first embodiment are as follows.

As shown in the cross-section illustration in Figure 5, tab features 23 may be provided on the housing sheath 8 to interlock with slots 24 in the shutter 6 so that the housing sheath 8 is held against the housing 5 in order to create an air seal between the two parts. Figure 6 shows the location of this air seal 17, which also includes a compliant material on at least one of the two mating surfaces. . Similar tab features can be provided between components shown in Figure 3a: between the outer cap 11 and the housing sheath 8 and between the inner cap 10 and the slider 9.

The sealing surfaces that are required for the preferred embodiment are shown in Figure 6, and are: the surface 17 between the housing sheath 8 and the housing 5; the surface 25 between the housing sheath 8 and the slider 9; the surface 26 between the housing 5 and the shutter 6; the surface 27 between the housing 5 and the liquid valve 7; the surface 28 between the housing 5 and the inner cap 10; the surface 29 between the slider 9 and the inner cap 10; the surface 30 between the slider 9 and the liquid valve 7; the surface 31 between the inner cap 10 and the liquid valve 7; and the surface 32 between the housing sheath 8 and the outer cap 11.

All sealing surfaces can be made by incorporation of a compliant material on at least one surface in each pair of the parts listed above or by incorporation of an additional, compliant sealing component such as an O-ring between the mating surfaces of pairs of parts.

A further optional feature which limits the range of movement between the slider 9 and the housing sheath 8 is shown in Figure 6. Here a post 33 is attached to the slider 9 and runs within a groove 34 in the housing sheath 8. The post 33 ensures that the slider 9 cannot be pulled completely out of the housing sheath 8.

A gas permeable vent 35 which is assembled into the housing 5 is also shown in Figure 6. This vent 35 ensures that displacement of air caused by motion of internal parts does not generate an air pressure change within the sterile enclosure 18 described in Figure 3c. The vent 35 also ensures that changes in external air pressure do not generate a leakage of air between any of the sealing surfaces described previously. The vent is likely to be made of a filter material that excludes particles of greater that 0.22 μm in diameter.

A variation on this embodiment is to use a different liquid connection mechanism such that the liquid valve 7 and inner cap 10 are replaced with alternative linear or rotary valve mechanisms. Such valves are well known in the art.

A further variation of this embodiment is a modification of the shutter 6 and housing 5, so that the shutter describes a circular sliding motion rather than a linear sliding motion.

A second embodiment of the invention is shown in Figures 4a-4e. This embodiment is consistent with the principle of the invention and the sequence of steps is similar to the first embodiment. The differences from the first embodiment are described below.

As shown in Figure 4a, the liquid connection mechanism in this case comprises a needle 35 and a pair of septa: a sample septum 36 and an interface septum 37. The interface septum 37 seals the interface assembly 1 from the reservoir 38. Figures 4b to e show the sequence of operations to connect the sampler assembly 2 to the contents of the reservoir 38. Referring to Figures 4b-4e, the difference from the operational sequence of the first embodiment (Figures 3b-3e) is that the liquid connection is now made by pushing the slider 9 directly through the position shown in Figure 4d to the position shown in Figure 4e as shown by the arrow 41. Thus the needle 35 pierces both septa 36 and 37 and enters the reservoir 38 so that an aseptic liquid connection 39 is made. Removal of the sampler is performed by reversing the sequence of steps in Figures 4b to 4e. The septa 36 and 37 are both made of an elastomeric material that has the ability to reseal the pierced hole after removal of the needle. The interface septum 37 is designed to ensure that when the needle 35 is removed, the interface septum 37 can still maintain both a liquid and air tight seal, even after multiple piercings. One possible embodiment of the sampling vessel is a syringe 40 as shown in Figure 4a.

CLAIMS

1. An aseptic sampling system comprising: a sampler assembly and an interface assembly, each assembly comprising a housing, each housing defining a separate sterile enclosure for each of the assemblies; an air lock arranged to provide, in use, the aseptic joining of the sterile enclosures within the sampler and interface assemblies; and a re-sealable liquid connection mechanism positioned to operate within the air lock, wherein: the sampler assembly and interface assembly are arranged such that, when connected together, they form an outer protective surface comprising the housings of each of the sampler and interface assemblies, the outer protective surface providing a sterile internal enclosure and air lock and an air-tight barrier between the outer non-sterile atmosphere and the inner sterile atmosphere, and wherein the re-sealable liquid connection mechanism is contained within the sterile enclosure and contains at least one liquid connector from each of the sampler and interface assemblies and is configured such that, in use, at least one of the liquid connectors can move across the sterile enclosure and air lock to connect with the other connector in the liquid connection mechanism, without contacting any internal surfaces within the air lock.

2. An aseptic sampling system according to claim 1, where the air lock is provided by an outer cap in the sampling assembly which mates with a shutter that slides within a housing in the interface assembly.

3. An aseptic sampling system according to claim 2, where the shutter slides in a linear path.

4. An aseptic sampling system according to claim 2, where the shutter slides in the path of a circle or arc.

5. An aseptic sampling system according to any preceding claim, where the liquid connection mechanism is provided by a rotating valve comprising two parts that, when joined, provide a sealing cylindrical surface with at least one internal channel.

6. An aseptic sampling system according to any of claim 1 to 4, where the liquid connection mechanism is provided by a re-sealing linear or rotary valve.

7. An aseptic sampling system according to any of claims 1 to 4, where the liquid connection mechanism is provided by a deformable septum, a piercing needle and an interface septum.

8. An aseptic sampling system according to any of claims 1 to 4, where the liquid connection mechanism is provided by a piercing needle, a septum and a linear valve.

9. An aseptic sampling system according to any preceding claim, arranged such that the separate sterile enclosure within the sampler assembly is no longer provided after the sampler assembly has been removed from the interface assembly.

10. An aseptic sampling system according to any preceding claim, configured such that the liquid connectors, in use, can subsequently be re-sealed, disconnected and separated.

Figure 1

Figure 1a

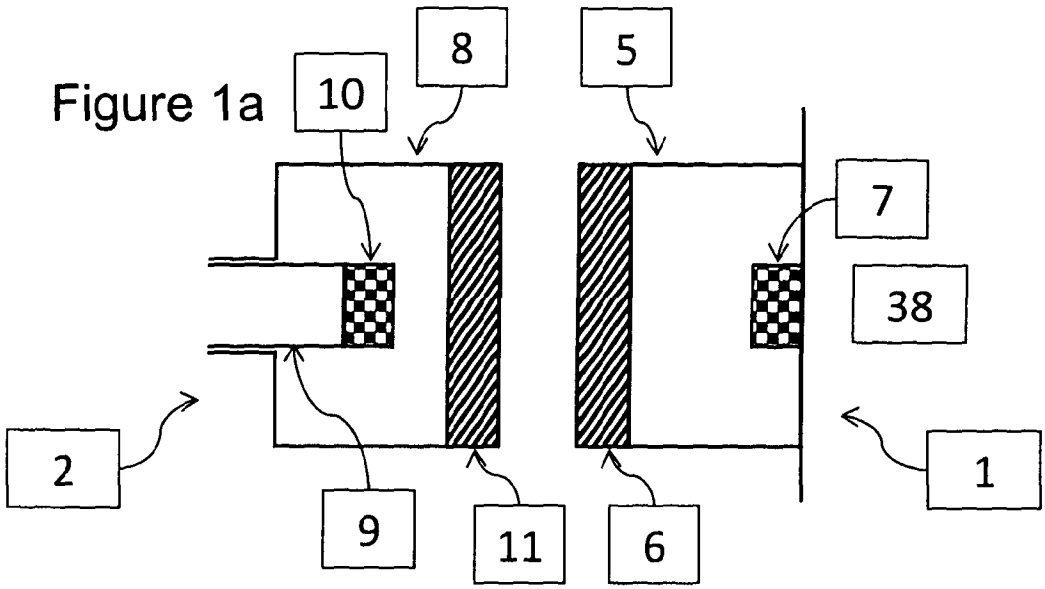


Figure 1bi

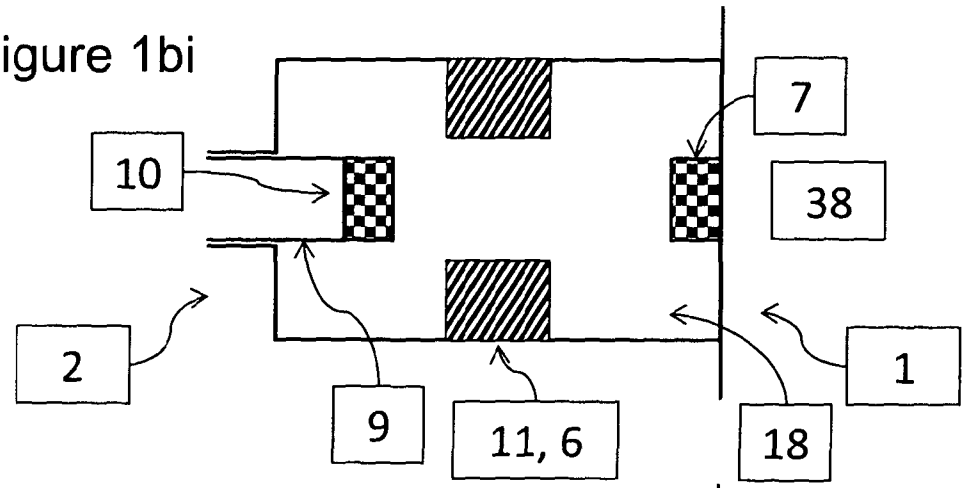


Figure 1bii

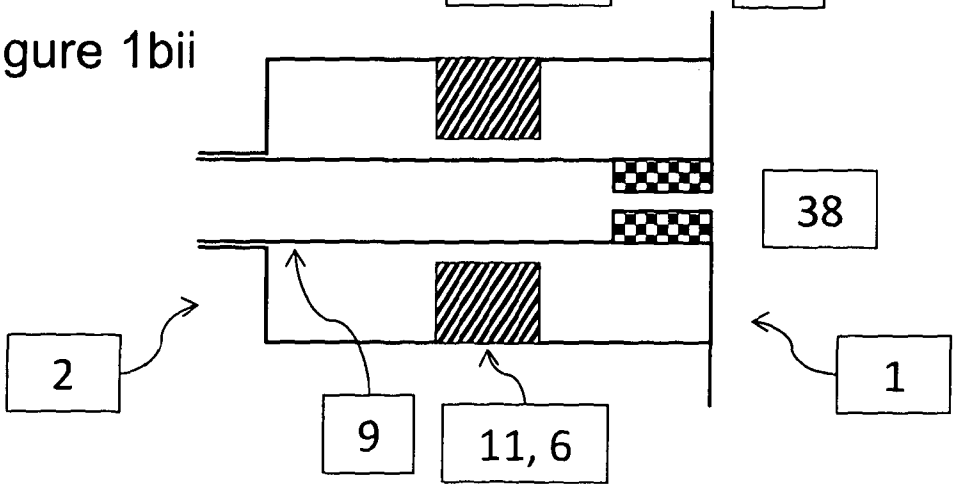


Figure 2

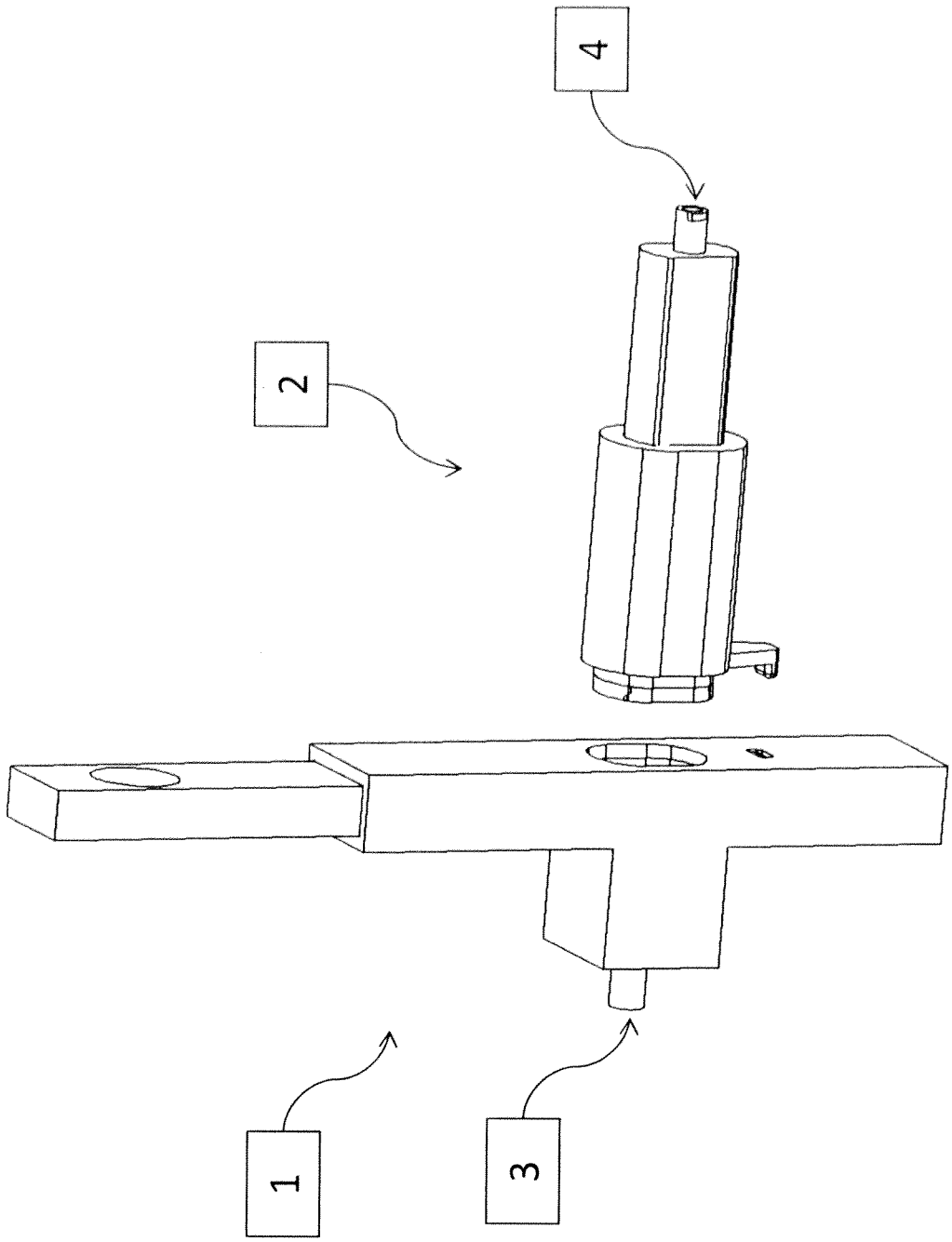


Figure 3a

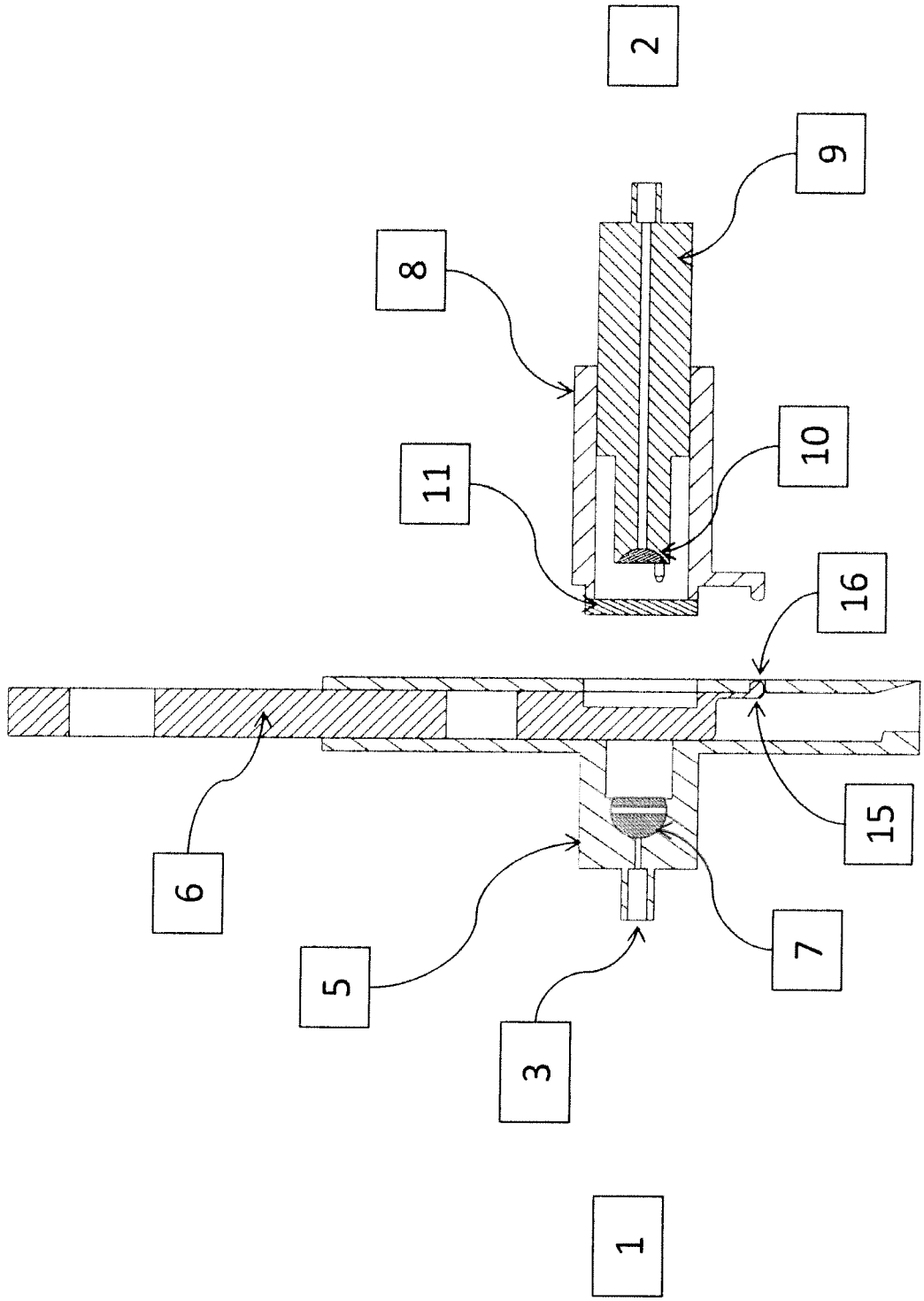


Figure 3b

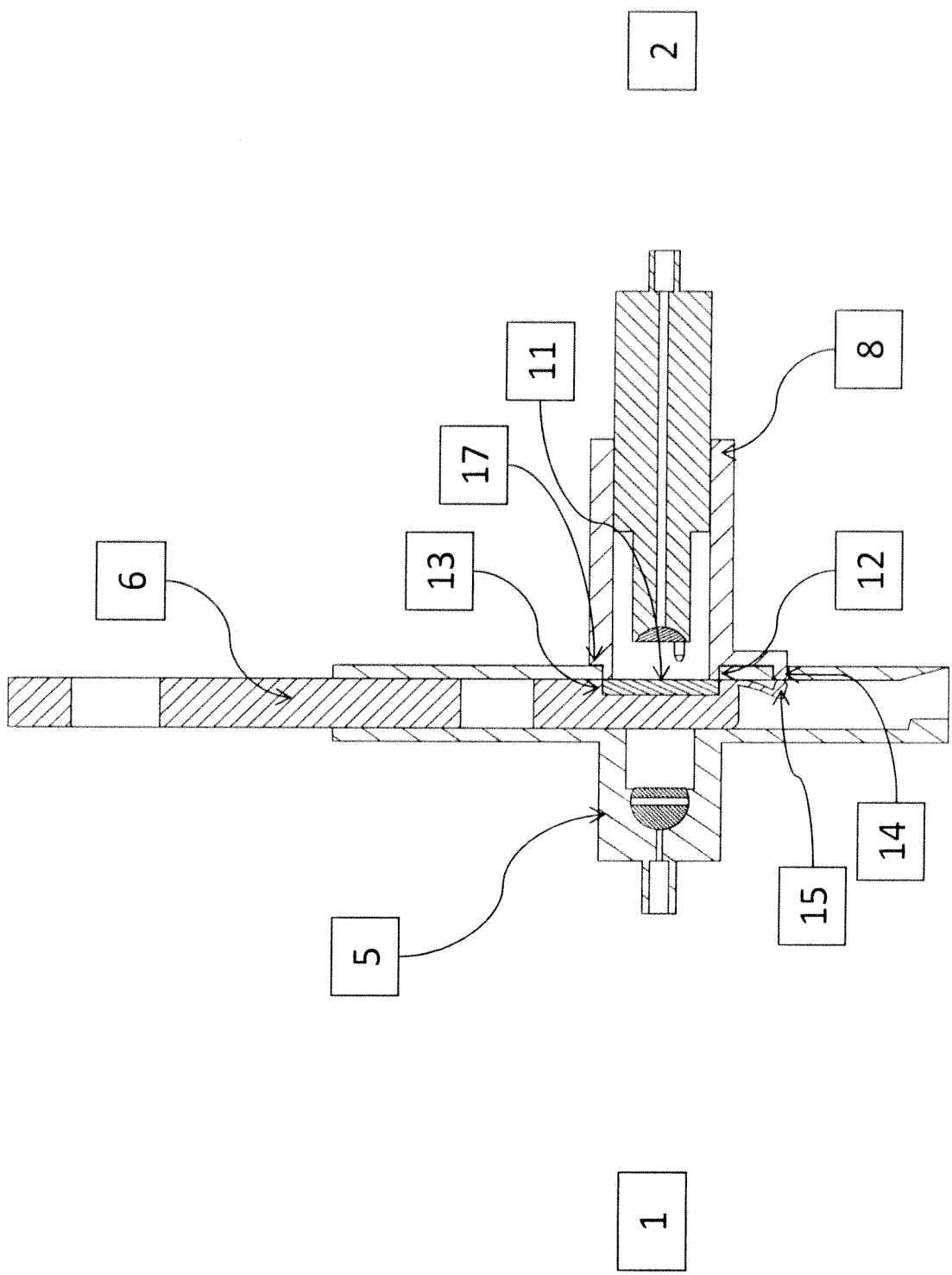


Figure 3c

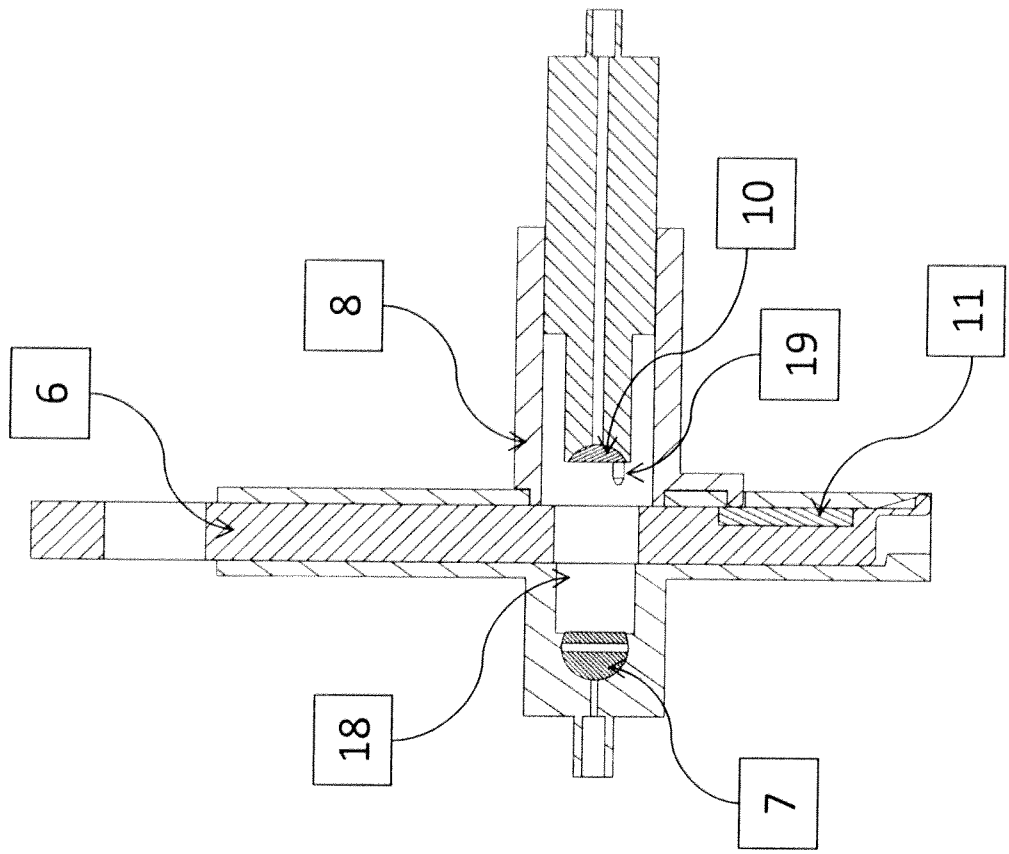


Figure 3d

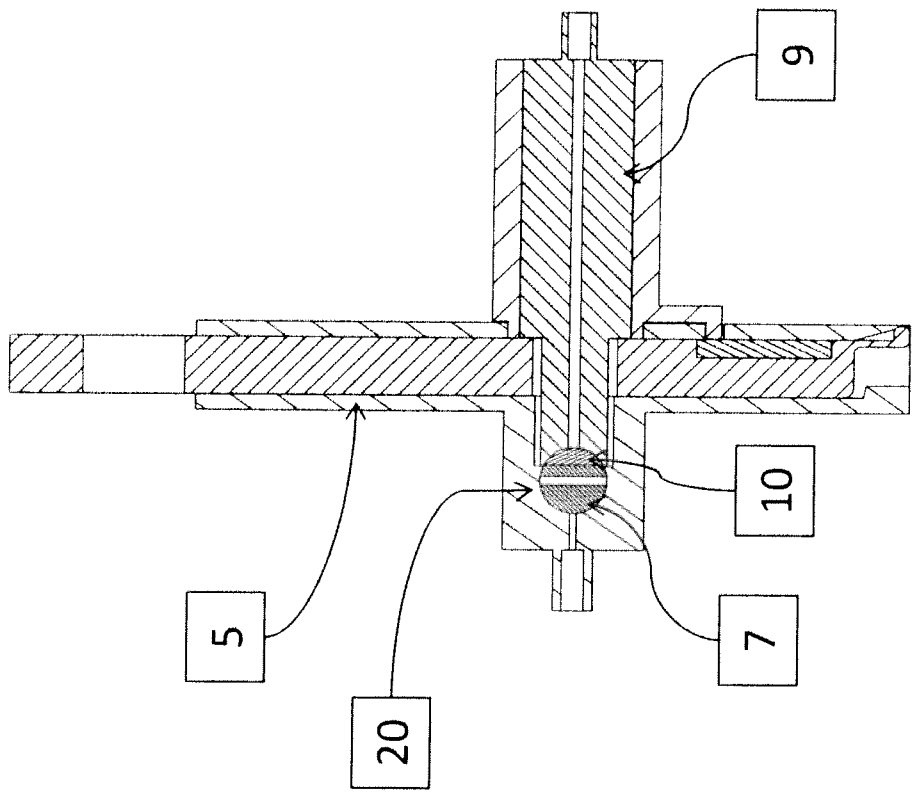


Figure 3e

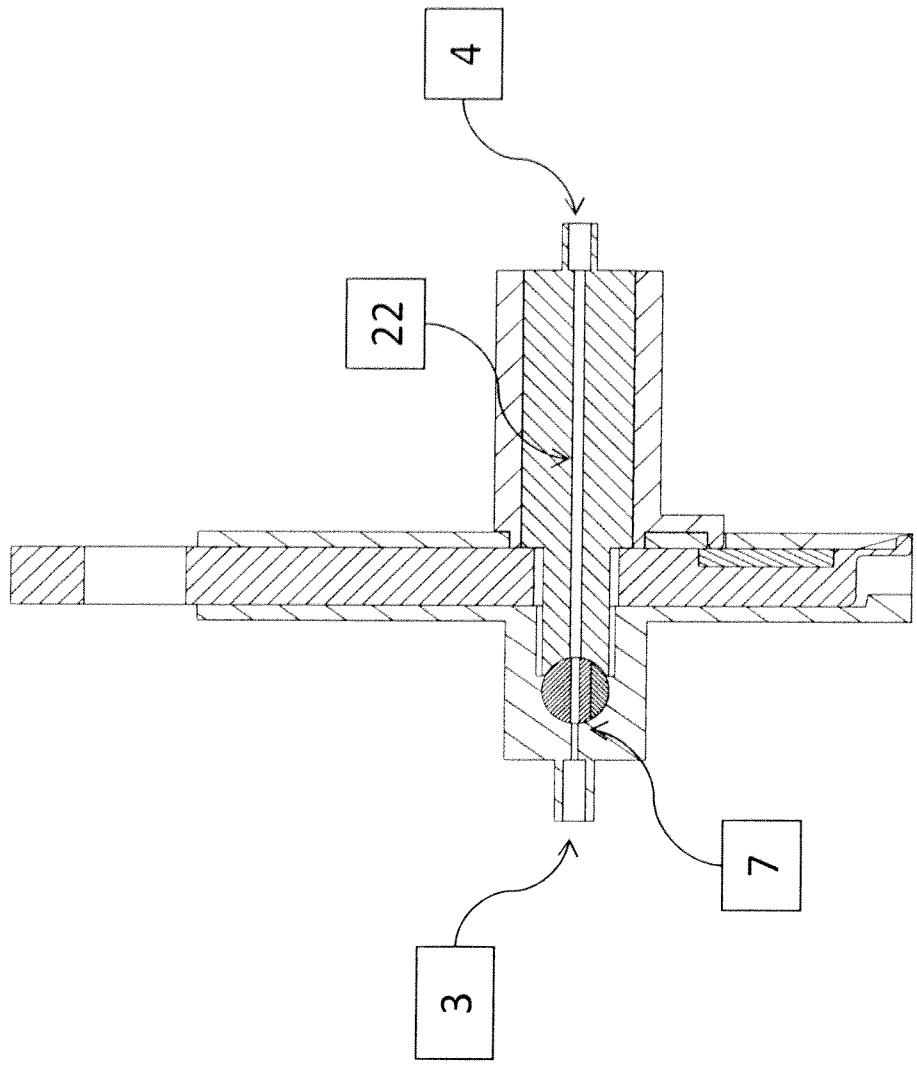


Figure 4a

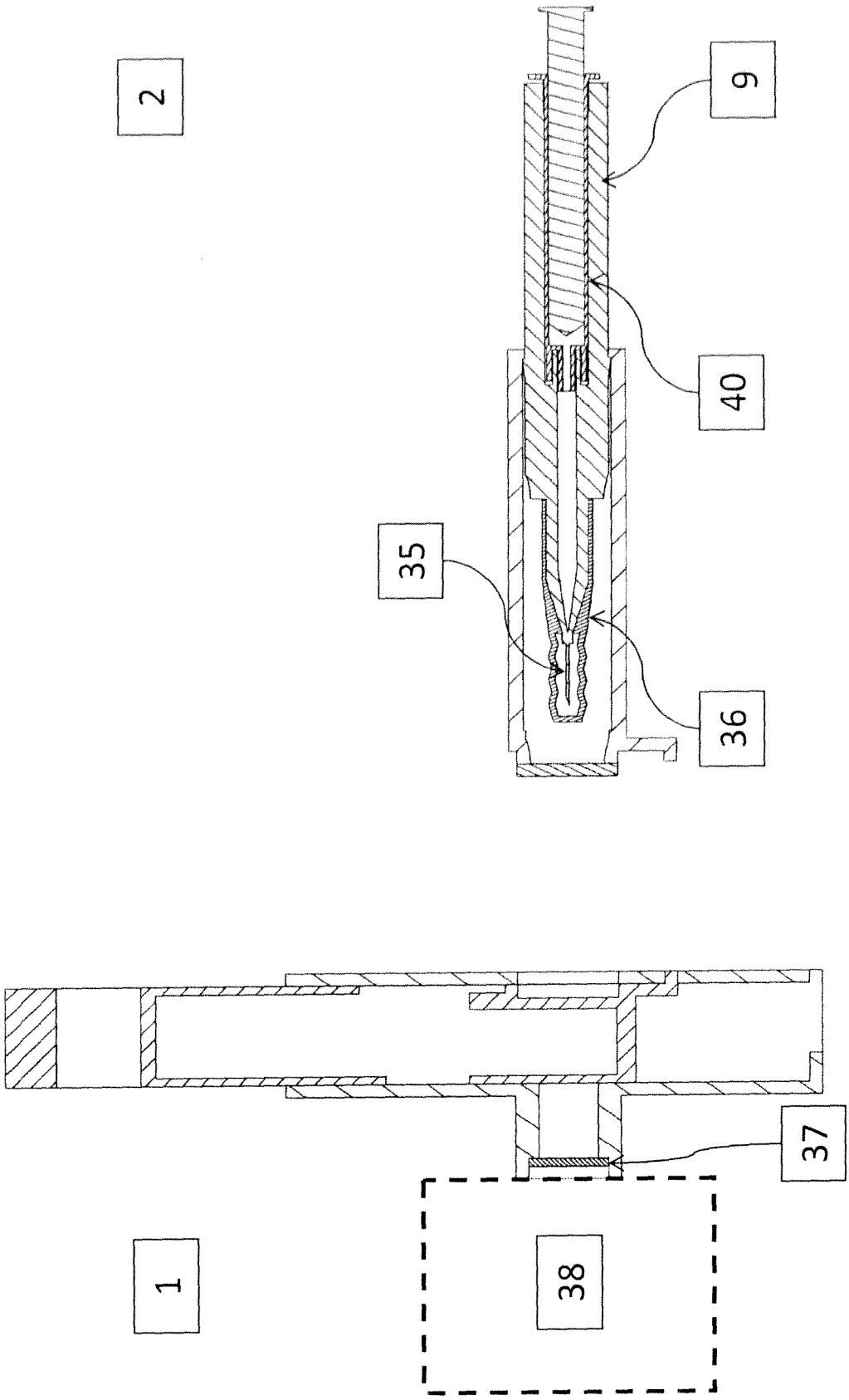


Figure 4b

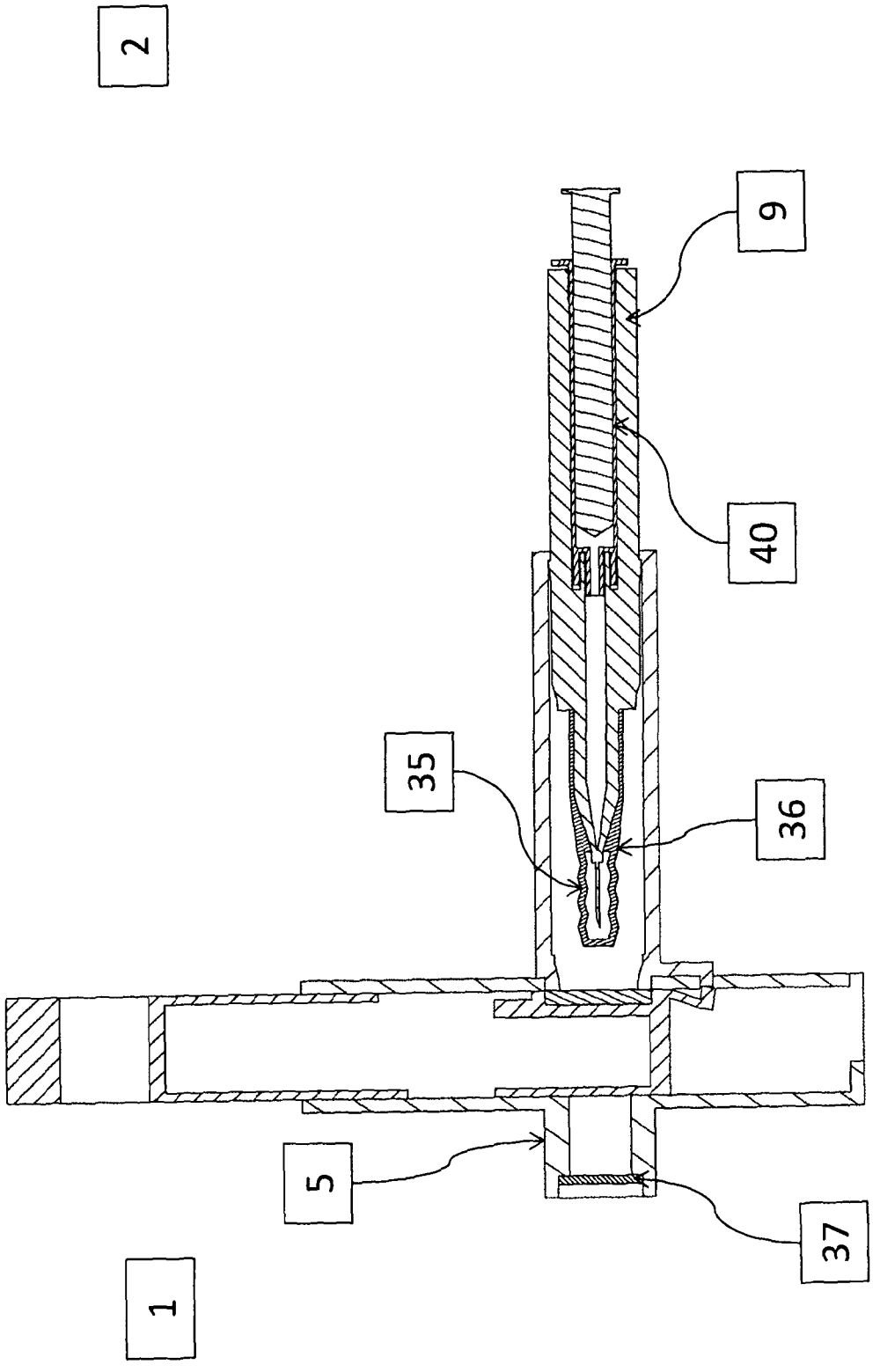


Figure 4c

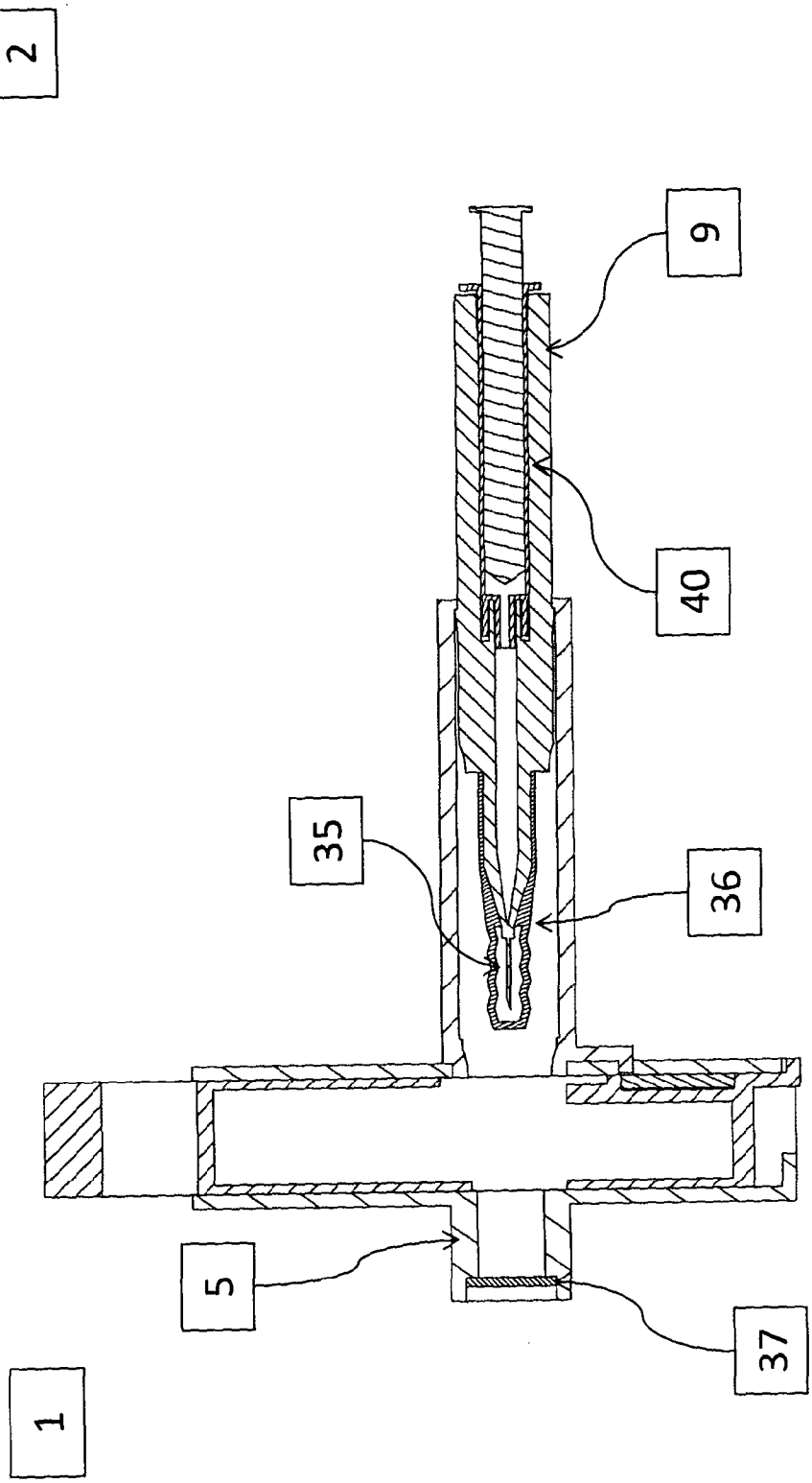


Figure 4d

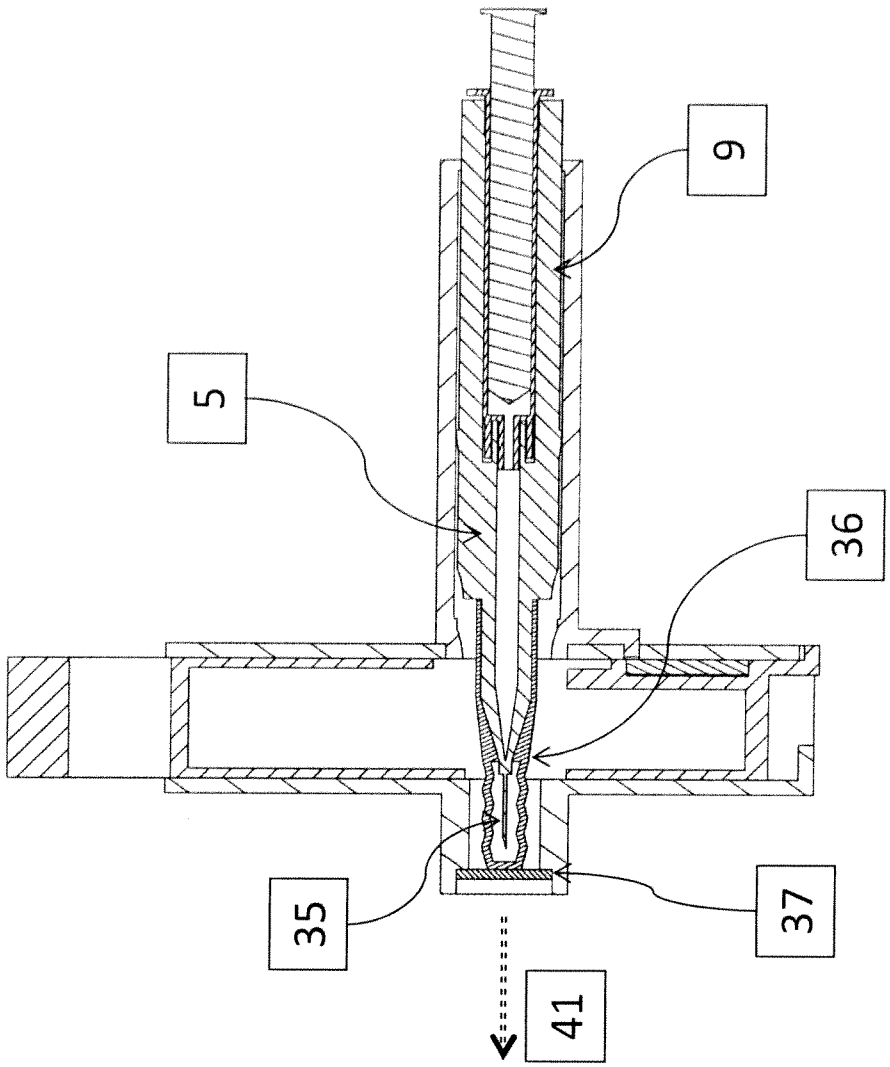


Figure 4e

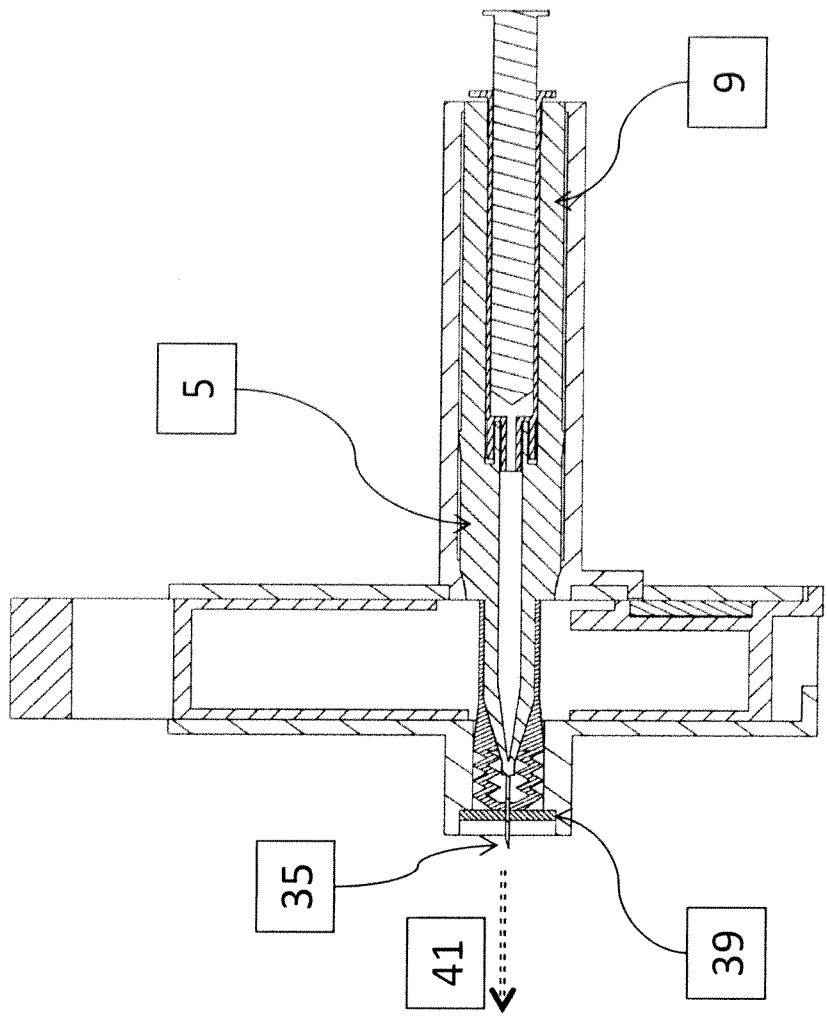


Figure 5

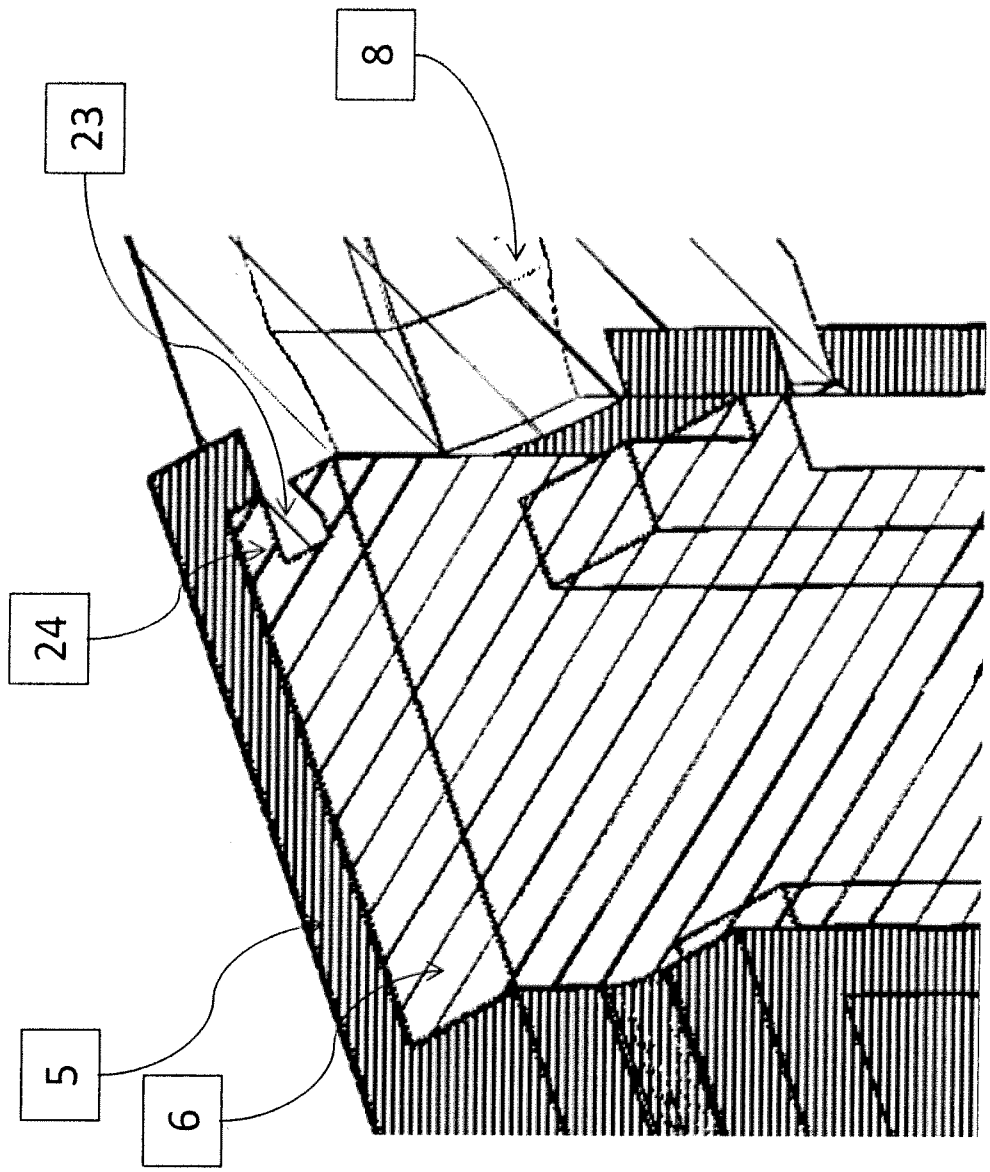
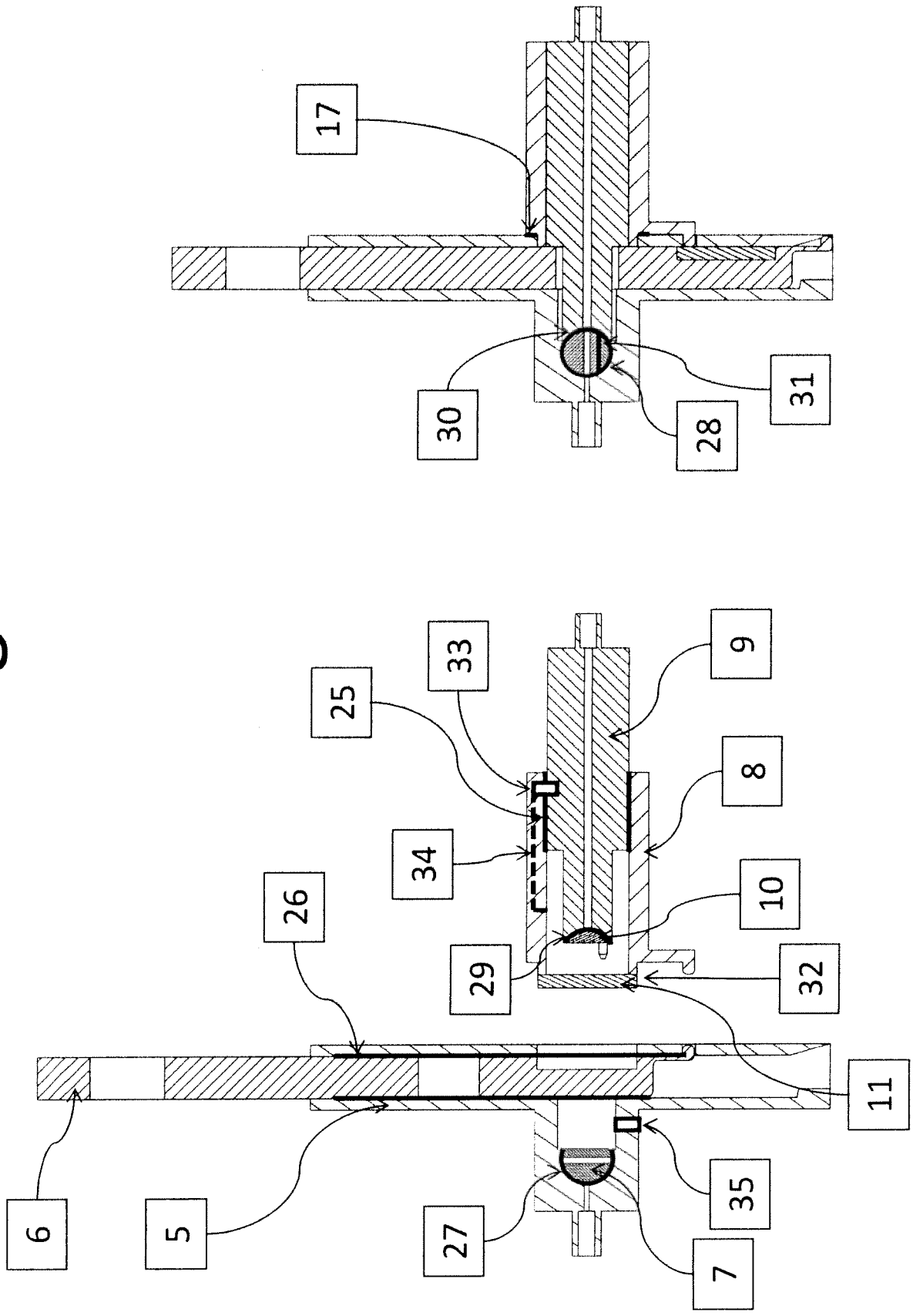


Figure 6



INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/050396

A. CLASSIFICATION OF SUBJECT MATTER
INV. G01N1/10 B01L1/02 B65D81/32 A61M39/14 A61J1/20
ADD. G01N1/20

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)
G01N B01L B65D A61M A61J

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, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/191167 A1 (KOCH MARTIN [DE] ET AL) 16 August 2007 (2007-08-16) paragraph [0159]; figures 5,6,18	1,5-10
X	WO 96/29587 A1 (MOOREPARK PATENTS LTD [IE]; HIGGISSON BRIAN [IE]; MORGAN DAVID [IE]) 26 September 1996 (1996-09-26) page 15, line 10 - page 17, line 30; figures 24-28	1,5-10
Y	US 4 019 512 A (TENCZAR FRANCIS J) 26 April 1977 (1977-04-26) column 2, line 53 - line 68 column 5, line 50 - column 7, line 15	1
Y	US 4 564 054 A (GUSTAVSSON BENGT [SE]) 14 January 1986 (1986-01-14) column 2, line 28 - line 52; figures	1

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[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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25 May 2012	05/06/2012

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INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2012/050396

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 155 027 A (BROOKS RAY G [US]) 5 December 2000 (2000-12-05) column 5, line 3 - line 9; figures 3,5,7,10 column 6, line 50 - line 54; figure 7 column 7, line 20 - line 29 -----	1-10
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