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International application number:	PCT/GB2018/051436
International filing date:	25 May 2018 (25.05.2018)
Document type:	Certified copy of priority document
Document details:	Country/Office: GB
	Number: 1709072.1
	Filing date: 07 June 2017 (07.06.2017)
Date of receipt at the International Bureau:	15 June 2018 (15.06.2018)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a),(b) or (b-bis)

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

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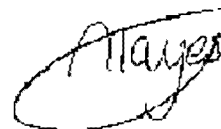
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Request for grant of a patent

Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

Application number GB1709072.1

1. Your reference	P50067GB		
2. Full name, address and postcode of the applicant or of each applicant	NDM Technologies Ltd Advanced Technology & Innovation Centre Loughborough University Science and Enterprise Parks Loughborough LE11 3QF Leicestershire United Kingdom Patents ADP number (<i>if you know it</i>) 41502846004 11636818002		
3. Title of the invention	INJECTOR DEVICES		
4. Name of your agent (<i>if you have one</i>) "Address for service" to which all correspondence should be sent. This may be in the European Economic area or Channel Islands (see warning note below) (<i>including the postcode</i>) Patents ADP number (<i>if you know it</i>)	Smith, Mr Peter James Serjeants LLP Dock 75 Exploration Drive Leicester LE4 5NU United Kingdom 11456142001 ✓		
5. Priority declaration: Are you claiming priority from one or more earlier-filed patent applications? If so, please give details of the application(s)	Country	Application number	Date of filing
6. Divisionals etc: Is this application a divisional application, or being made following resolution of an entitlement dispute about an earlier application. If so, please give the application number and filing date of the earlier application			PDAS Access Code
			Number of earlier UK application
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Patents Form 1

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Description: **9**

Claim(s): **3**

Abstract: **1**

Drawing(s): **6**

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10. If you are also filing any of the following, state how many against each item.

Priority documents: **0**

Statement of inventorship and right to grant of a patent

(Patents Form 7): **1**

Request for search (Patents Form 9A): **1**

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Any other documents (please specify): **PDAS Registration Form**

11. I/We request the grant of a patent on the basis of this application.

Date: **07 Jun 2017**

12. Name, e-mail address, telephone, fax and/or mobile number, if any, of a contact point for the applicant

Smith, Mr Peter James
Email: mail@serjeants.co.uk
Telephone: 0116 233 2626
Fax: 0116 319 2848

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TITLE

Injector devices

DESCRIPTION

5 Technical field

The invention relates to disposable needle hubs for injector devices. Such hubs comprise at one end a needle used to administer drugs to a subject and at the other end a needle used to pierce the septum of a drug cartridge.

10 Background

Injector devices used to administer drugs to humans or animals can be described as having two broad components in addition to the body of the injector device itself: a drug-filled disposable cartridge or reservoir and a disposable needle hub. The drug-filled cartridge usually has a rubber septum at the proximal end and a rubber plunger at
15 the distal end. The needle hub generally has a thin needle at the proximal end, which pierces the skin of the patient, and a thicker, stronger needle at the distal end, which pierces the septum at the proximal end of the drug reservoir.

The same arrangement may be used for devices for withdrawing samples (e.g. blood
20 samples) from a subject into a reservoir and the use of “injector”, “drug cartridge” and similar terms in this specification is not intended to exclude such applications of the invention.

From a cost perspective it is beneficial to use a single needle for both the distal and
25 proximal ends, consisting of the same diameter throughout. However, if the needle is of a high gauge, i.e., thin and often somewhat flexible, then it may buckle and bend when it is pressed into the septum of the drug reservoir due to the hardness of the septum, or due to rapid and high forces being applied when the cartridge and the needle hub are pushed together. The risk of buckling is particularly acute if the needle is
30 intended to curve around an arc, such that the needle portion piercing the skin is not in line with an axis of the needle portion entering the drug cartridge. In this way the two ends of the needle may be mutually inclined at an angle, which is usually a right angle.

This arrangement is very useful where the device is intended to be applied flat on the skin rather than in the form of an elongated device applied vertically to the skin, with the associated psychological impact of injections and needle phobia. There exists a need for a device that allows controlled movement of the needle into the septum, or the
5 septum over the needle, without high or rapid forces being applied, while maintaining the desired alignment of the needle to prevent buckling.

Summary of the invention

The invention provides an injector device as defined in claim 1.
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The invention further provides a method of coupling a drug cartridge to an injector device as defined in claim 13.

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

Although the invention is described in terms of moving the neck of the drug cartridge into the collar of the injector device, it will be understood that only their relative movement is important so the injector device may equally be pushed onto the neck of
20 the drug cartridge.

In this specification, “disposable” is used in relation to the needle and/or needle hub to indicate that the component will normally be replaced after each use; and in relation to the drug cartridge to indicate that the component will normally be replaced after each
25 use or when it is empty. “Non-disposable” is used in relation to the housing of the injector device to indicate that the component will normally be retained for use on multiple occasions with different needle hubs and/or drug cartridges.

The device is suitable for use with straight or angled single-needle hubs where, without
30 support, the needle would not have the integrity to remain firm when being inserted into a septum due to the hardness of the septum material relative to the hardness of the needle. The needle consists of a bore and an outer wall, whereby the outer wall and

bore are continuous and constant throughout the length of the needle or may be slightly tapered to make one end thinner than the other. Preferably, though not an essential feature, the needle hub comprises a single length of needle of constant internal and external diameter as this is significantly cheaper to manufacture.

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The needle may curve through a slight angle or an entire right angle; in such case the outer case of the needle hub may be used to secure the needle without the use of glue, using only sonic welding, laser welding or another form of fixing not based on chemical adhesives. Where the needle is completely straight, the needle is liable to be forced out
10 of its casing longitudinally if an additional chemical adhesive is not used, however an angled needle will have significantly more friction to overcome due to the angled contacts between the needle and the inner case walls. The absence of glue reduces a process step and an additional material and hence the overall unit cost.

15 The invention further provides a needle aligning device which provides resistance and therefore controlled movement of the septum portion of a drug reservoir, prior to and after the insertion of the needle into and through the septum of the drug reservoir, intended to provide fluid communication between the contents of the reservoir and the
20 needle. The needle aligning device consists of a support member that may be either directly attached to the needle hub or a separate component that is positioned adjacent to the septum-piercing portion of the needle in the needle hub, such that in both cases the rest position of the needle support member is close to the tip or extends beyond the tip of the needle, and gradually retracts as soon as the septum on the drug reservoir comes into contact with the tip of the needle and the needle inserts into the septum.
25 Thereafter the needle support member will collapse to allow the required length of the needle to pierce through the septum to provide the fluid communication path with the drug reservoir. Collapsing of the needle support member will provide frictional force, through contact between the housing of the drug reservoir and the walls of the needle hub, or a resistant force as the support member collapses. It is preferable that the needle
30 support member collapses in a manner, such as by folding against the inner wall, such that the length of the needle does not have to be elongated to accommodate the collapse, as longer needles lead to higher forces being required to inject the liquid through them.

The drawings

5 Figures 1A and 1B are cross section schematics of a needle hub according to a first embodiment of the invention, showing a needle support member positioned in a rest position and an activated position respectively.

Figure 2 is an expanded view of the needle and needle support member of the first embodiment.

10 Figure 3A is a cross section schematic of a needle hub according to the first embodiment of the invention, with its needle touching the septum of a drug reservoir.

Figure 3B is the same view as Figure 3A, showing the drug reservoir having been pushed further into the needle hub.

15 Figure 4A is a cross section schematic of a needle hub and a drug reservoir aligned in an external housing of an injector device according to the invention.

20 Figure 4B is the same view as Figure 4A, showing the drug reservoir having been guided by the housing into engagement with the needle hub.

25 Figures 5A and 5B are cross section schematics of a needle hub according to a second embodiment of the invention, showing a needle support member positioned in a rest position and an activated position respectively.

Figures 6A and 6B are cross section schematics of a needle hub according to a third embodiment of the invention, showing a needle support member in a rest configuration and an activated configuration respectively.

30 Description of preferred embodiments

Figure 1A is a cross section schematic of a needle hub, which shows a needle 4 curved through an arc 11, within a housing 1. The housing 1 of the needle hub consists of two

parts, or two halves, which enclose the needle 4. The proximal end of the needle 4A intended to pierce the skin is at a right angle to the distal end of the needle 4B. The distal end 4B is housed within a shroud or needle hub collar 3, a region within which the neck of a drug reservoir would fit and where the needle 4B pierces the septum of the drug reservoir to provide fluid communication between the contents of the drug reservoir and the needle 4 in the needle hub. The needle 4 does not have to be in the centre of the collar 3.

It will be understood that this collar 3 does not necessarily have to be part of the disposable needle hub and instead may be a feature of a permanent housing of the injector device (shown in Figure 4), within the region where the needle hub and drug reservoir interface. The collar also does not have to be a physical structure that surrounds the needle: any structure may be used to align the drug cartridge with the needle and to guide them towards one another and such a region where the needle and drug cartridge meet satisfies the definition of a collar/collar region for the present invention. The drug reservoir (which does not form part of the invention) may be a standard glass or polymeric vial, or a syringe or a compressible or collapsible reservoir, consisting of at least one septum which is to be pierced to enable fluid communication between the contents of the reservoir and a needle. The septum may be composed of natural or synthetic rubber, silicone or polymeric material.

A needle support member 6 is shown attached to the needle hub collar 3, allowing the distal end of the needle 4B to rest upon it. If the needle is curved through an angle, the support mechanism will be positioned to oppose the resilient force that tends to restore the needle to a straight configuration. This allows the needle 4B to rest within the support member 6 with some degree of downward force (in the illustrated orientation). In the case of a straight needle (or otherwise), two or more needle support members 6 could be distributed around the circumference of the needle hub to provide support for the needle 4 from different sides.

There is a recess 7 within the collar 3 of the needle hub intended to allow the support member 6 to be collapsed against the wall of the collar 3, to accommodate the entry of

the neck of the drug reservoir into the needle hub collar 3. Arrow 12 in Figure 1B shows the movement of the support member 6 from its rest position (in dashed lines) to its activated position within the recess 7 (in solid lines). The support member 6 may be connected to the collar 3 by an articulated hinge or a living hinge to allow the member 6 to fold out of the way of the drug reservoir. The hinge may be designed to offer some resistance to the insertion of the reservoir, as described below. Additionally or alternatively, the displaced support member 6 may protrude slightly from the recess to offer frictional resistance as the reservoir pushes past it.

Figure 2 is a schematic illustration of the needle 4B resting on the needle support member 6, which has a concave tip to prevent the needle from slipping off. The support member 6 is positioned adjacent to the tip of the needle 4B such that it continues to support the needle until the tip of the needle 4B has pierced the septum of the drug reservoir and penetrated sufficiently that the support is now provided by the septum itself. At this point the support member function becomes one of purely providing a resistive force against which the drug reservoir neck (containing the septum) moves so as to prevent any rapid and sudden movement, thus reducing the chance of the needle buckling.

Figure 3A is a cross section schematic similar to Figure 1A, additionally showing the neck 10 of a drug reservoir fitted into the needle hub collar 3. A solid arrow indicates the direction of travel of the drug reservoir and in Figure 3A the septum 9 contained in the neck 10 of the drug reservoir is just in contact with the needle tip 4B.

Figure 3B depicts the same arrangement as Figure 3A at a later stage, with the neck 10 of the drug reservoir in its fully engaged position such that the needle 4B has pierced the septum 9 to the extent required. A pre-determined stop position may be defined, for example by a shoulder (not shown) in the collar 3 of the needle hub. At this point the needle support member 6 is now fully collapsed in the recess 7 of the collar 3.

Figures 4A and 4B show how the disposable needle hub 1 and drug cartridge 10 may be supported and guided by a non-disposable external housing 20 of the injector device.

The drug cartridge 10 is schematically shown as mounted on a carriage or bearings 22, on which the cartridge 10 can slide along the axis of the injector device until the needle 4 of the needle hub 1 pierces the septum 9 of the drug cartridge 10 within the collar region 3 of the device. The external housing 20 of the device can take many forms. Typically, the housing 20 encloses the needle hub 1 and the drug cartridge 10 except at their ends but it can be left at least partly open to allow manual access for sliding the drug cartridge along. Alternatively, the housing 20 may provide no more than a surface to rest against the skin of a patient and a track or other means for aligning and engaging the needle hub 1 and the cartridge 10. As seen in Figures 1 to 3, if guidance is provided by a collar 3 of the needle hub 1, the housing 20 can be omitted entirely.

Figures 5A and 5B show a second embodiment of the invention, in which the needle support member is not attached to the needle hub collar 3 but is a standalone component such as a washer 13 with a central bore through which the distal end of the needle 4B protrudes. Arrow 14 in Figure 4B shows how, as the drug reservoir (not shown here) is inserted, it presses the washer 13 to slide into the collar 3 from a rest position (in dashed lines) to an activated position (in solid lines). The needle 4B must provide sufficient length to accommodate the washer 13 sliding along it and also to puncture the septum of the drug reservoir and provide fluid communication with the contents. It is a potential disadvantage of this embodiment that it may require an elongation of the needle 4B, as the longer a needle is, the greater the force required to inject a liquid through it for a given rate of injection/flow. This is not desired as it can lead to large forces that an injector device cannot cope with or lead to injury to humans when large forces are used to push a plunger or compress the contents of a drug reservoir to force the contents out, by way of potentially dislodging the needle 4A from the skin and leading to scraping of the skin.

Figures 6A and 6B show a third embodiment of the invention, which is similar to the second embodiment except that the needle support member is a collapsible washer 15. An inner face of the washer 15 may rest against a shoulder of the needle hub collar 3 or may be attached to the collar in some other manner. Arrow 16 in Figure 6B shows how,

as the drug reservoir (not shown here) is inserted, the washer 15 becomes compressed from its rest position (in dashed lines) to its activated position (in solid lines). During the compression, the material of the support member may be deformed elastically or inelastically.

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The needle support member of any of the embodiments provides controlled resistance against the movement of the neck of the drug reservoir, to prevent the septum from being too rapidly pushed over the needle 4B or needle 4B pushed into the septum as this could lead to buckling and damage of the needle. This resistance can be attained in the case of the first embodiment by the needle support member 6 having a wall thickness and stiffness that requires a certain minimum force to cause it to collapse into the recess 7. The washer-like support member 13 of the second embodiment may be provided with surface features, or protrusions, that may be irregular or around the entire perimeter, to increase the sliding friction between the support member 13 and the inner walls of collar 3. The material of the collapsible support member 15 of the third embodiment may be chosen to have a stiffness or rigidity that provides a desired degree of resistance to being compressed. A rigid disc (not shown) may be provided to reinforce the front and/or rear face of the support member 15.

20 In a variant of the illustrated embodiments, the needle support member 6,13,15 in its rest position may cover the tip of the needle 4B, before the support member starts to be displaced by insertion of the drug cartridge 10. This helps to protect the needle tip and to avoid the risk of scratch injuries from the needle.

25 The illustrated embodiments show a needle that curves through a 90° arc between the proximal end 4A and the distal end 4B, whereby the drug cartridge 10 can lie flat against the skin of the subject as the proximal end of the needle 4A is inserted perpendicularly into the skin. It is important that the radius of the arc 11 should be sufficiently large to prevent the needle from becoming dented or leading to narrowing of the inner bore as it is formed into the arc. For example a fine, 33-gauge needle, having an inner diameter of 0.11mm and an outer diameter of 0.21mm, was observed to be physically deformed when bent around any arc radius of less than 3mm. A 30-gauge needle, having an inner

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diameter of 0.16mm and an outer diameter of 0.31mm produced no flow when bent around an arc radius of 5mm, which suggests that the inner bore was narrowed or occluded. From this point of view, a greater arc radius is to be preferred.

- 5 On the other hand, a greater arc radius may require a greater overall length of the needle, which increases the force needed to force liquid through, as shown in the following table based on experiments conducted with a 33-gauge needle.

Needle length (mm)	Average force required (N)
16	3.5
20	6.5
50	16.0

- 10 For a 33-gauge needle, an arc radius of 3mm or 4mm was not seen to obstruct the bore of the needle. This can be accommodated within an overall needle length of approximately 20mm, which permits flow through the needle with an acceptable level of force.

CLAIMS

1. An injector device comprising:
 - a needle having a proximal end for insertion into the skin of a patient and a distal end for insertion through a septum in the neck of a drug cartridge, the alignment of the distal end defining an axis;
 - a collar region for receiving the neck of the drug cartridge; and
 - a needle support member, which supports the distal end of the needle before the neck of the drug cartridge is received in the collar region, and which is displaceable by the neck of the drug cartridge as the neck moves into the collar region.

2. An injector device according to claim 1, wherein the needle support member is attached to the collar via a hinge.

3. An injector device according to claim 2, wherein the collar comprises a recess for receiving the needle support member when it has been displaced by the drug cartridge.

4. An injector device according to claim 2 or claim 3, wherein the needle curves such that the proximal end is aligned at an angle relative to the axis, and wherein the needle support member is attached to the collar on the opposite side of the axis from the proximal end.

5. An injector device according to claim 1, wherein the needle support member surrounds the distal end of the needle.

6. An injector device according to claim 5, wherein the needle support member is capable of sliding in the collar, parallel to the axis, as the needle support member is displaced by the drug cartridge.

7. An injector device according to claim 6, further comprising protrusions for increasing friction between the needle support member and the collar.

8. An injector device according to claim 5, wherein the needle support member is capable of being compressed in a direction parallel to the axis as a distal face of the needle support member is displaced by the drug cartridge.
9. An injector device according to any preceding claim, wherein the proximal end and the distal end are opposite ends of a single needle of constant diameter.
10. An injector device according to claim 9, wherein the needle curves through an arc such that the proximal end is aligned substantially at a right angle to the axis.
11. An injector device according to any of claims 1 to 10, wherein the collar and the needle form part of a disposable needle hub.
12. An injector device according to any of claims 1 to 10, wherein the needle forms part of a disposable needle hub and the collar forms part of a non-disposable housing of the device.
13. A method of coupling a drug cartridge to an injector device comprising the steps of:
 - using a needle support member to support a distal end of a needle within a collar of the injector device;
 - inserting a neck of the drug cartridge into the collar;
 - piercing a septum of the drug cartridge with the distal end of the needle; and
 - pushing the drug cartridge further into the collar to displace the needle support member.
14. A method according to claim 13, wherein the step of displacing the needle support member comprises bending the needle support member about a hinge.
15. A method according to claim 13, wherein the step of displacing the needle support member comprises sliding the needle support member parallel to an axis of the collar.

16. A method according to claim 13, wherein the step of displacing the needle support member comprises compressing the needle support member parallel to an axis of the collar.

TITLE

Injector devices

ABSTRACT

An injector device comprises a needle support member 6,13,15 for supporting a distal end of a needle 4 within a collar region 3 of the device. On insertion of the neck of a drug cartridge 10 into the collar region 3, the tip of the needle 4B pierces a septum 9 in the drug cartridge and is thereafter supported by the septum 9. The needle support member 6,13,15 is then displaced by the drug cartridge 10 as it moves further into the collar region 3. The displacement may comprise hinging, sliding or compression of the support member 6,13,15. By supporting the needle 4B as it pierces the septum 9 and by providing controlled resistance to rapid or violent insertion of the drug cartridge 10, the needle support member 6,13,15 enables a single, fine needle 4 to be used for both the distal end and the proximal end without buckling, even if the needle 4 is curved so that the two ends are mutually inclined.

(Figure 1B)

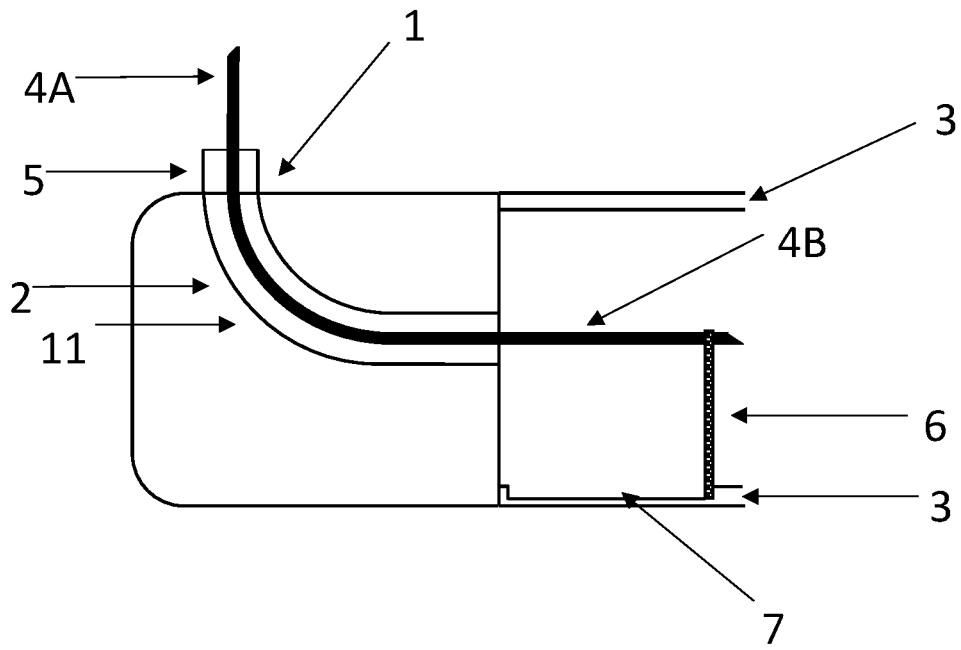


Fig. 1A

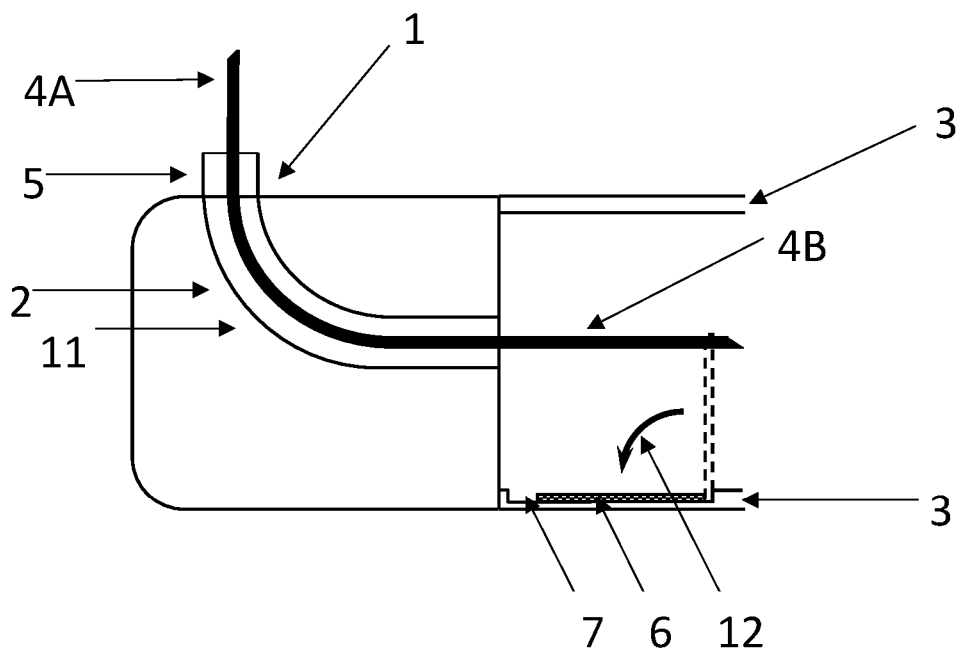


Fig. 1B

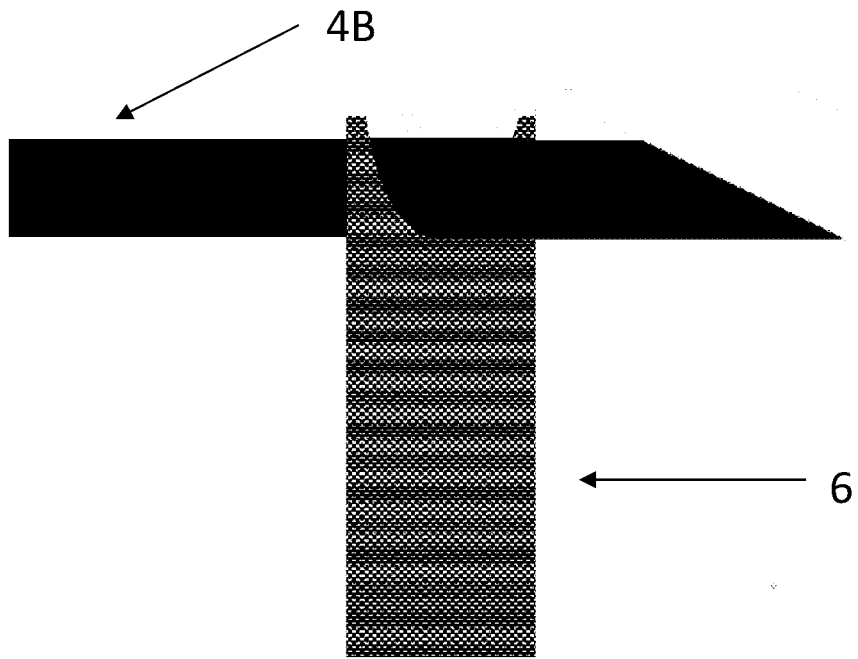


Fig. 2

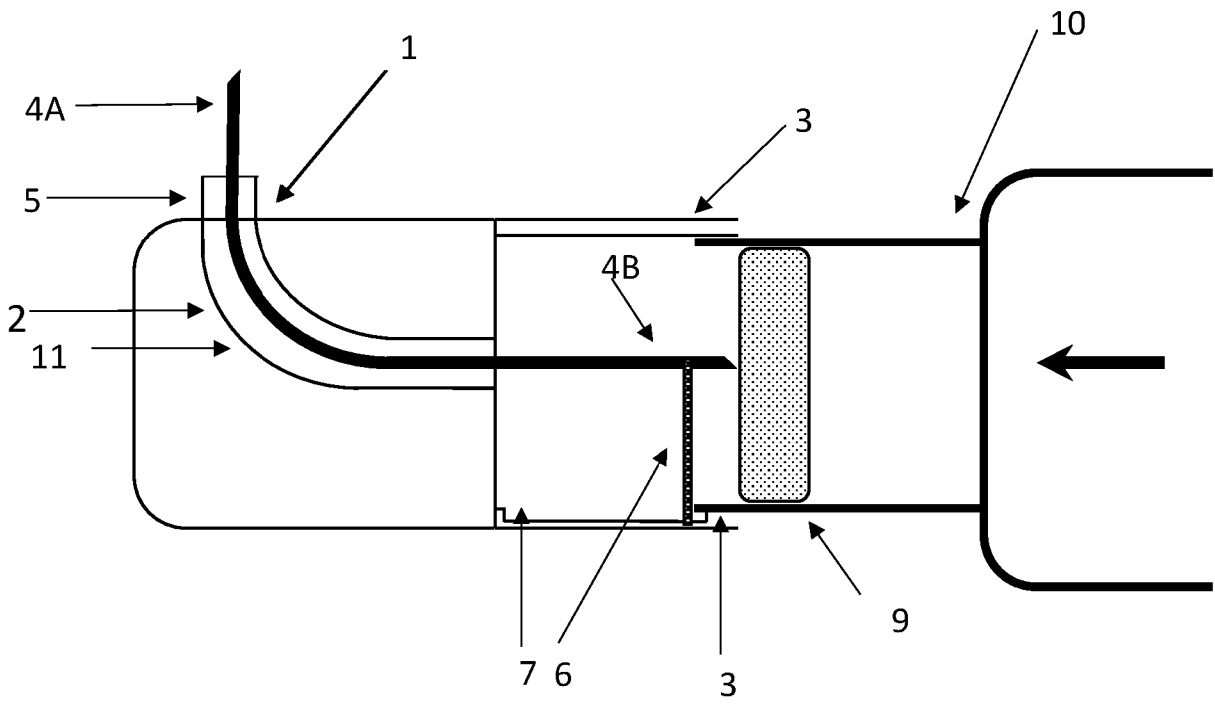


Fig. 3A

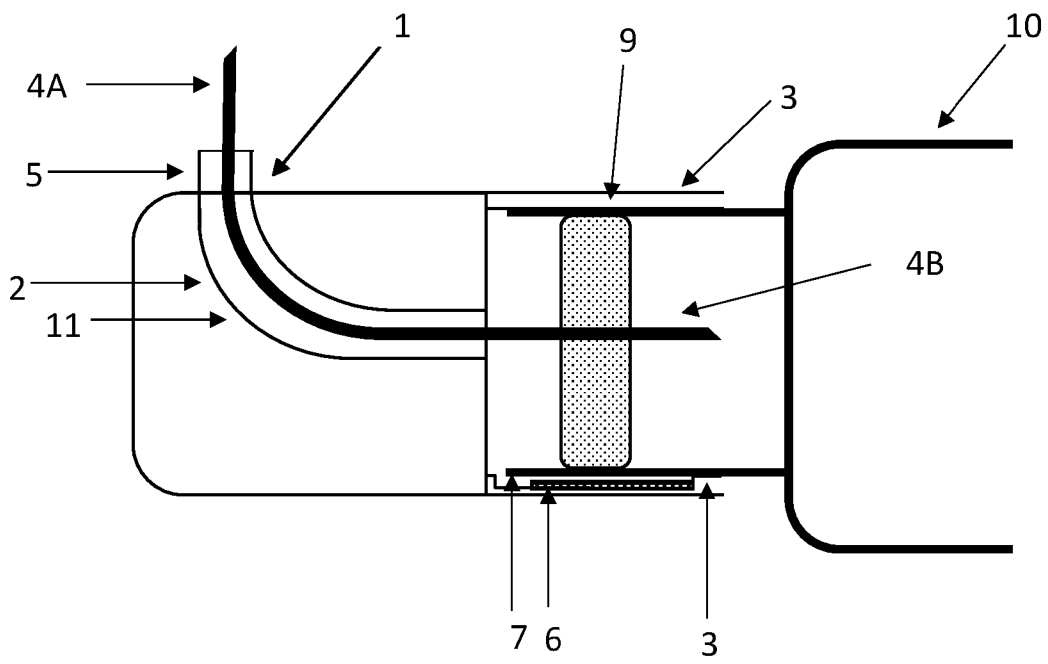


Fig. 3B

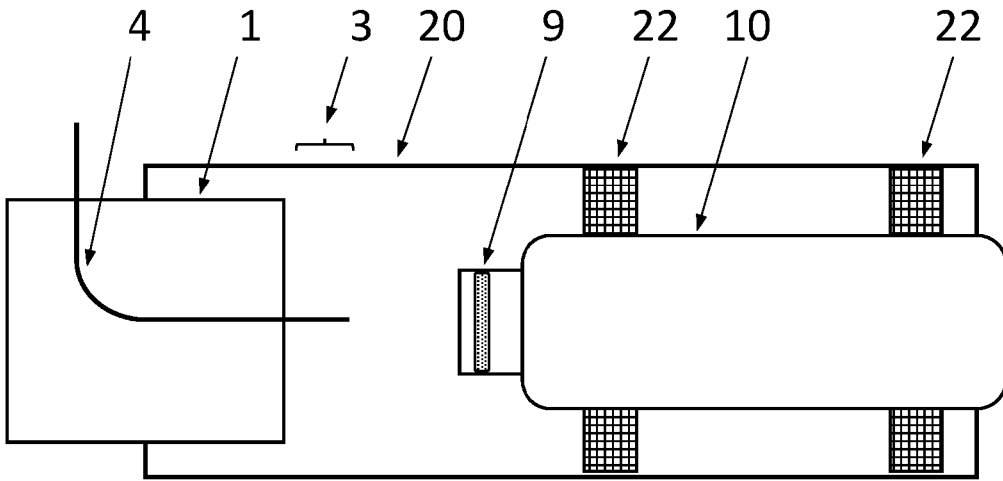


Fig. 4A

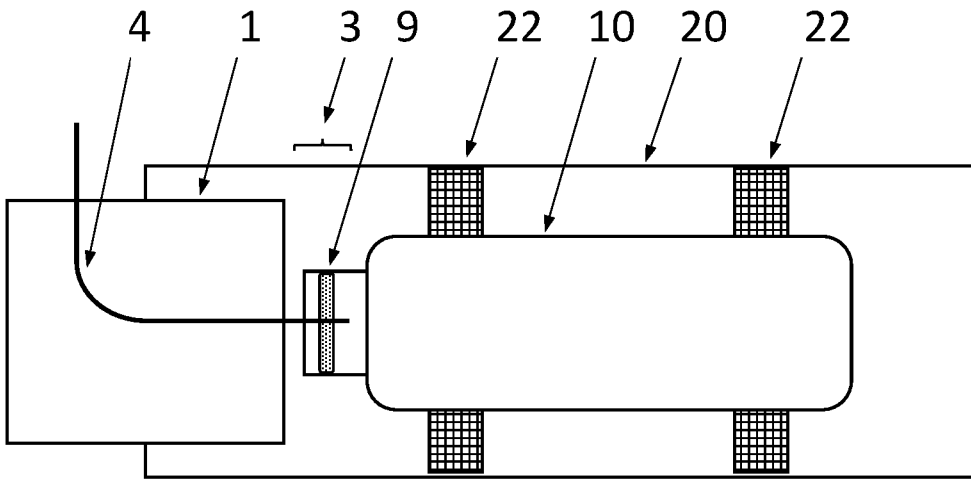


Fig. 4B

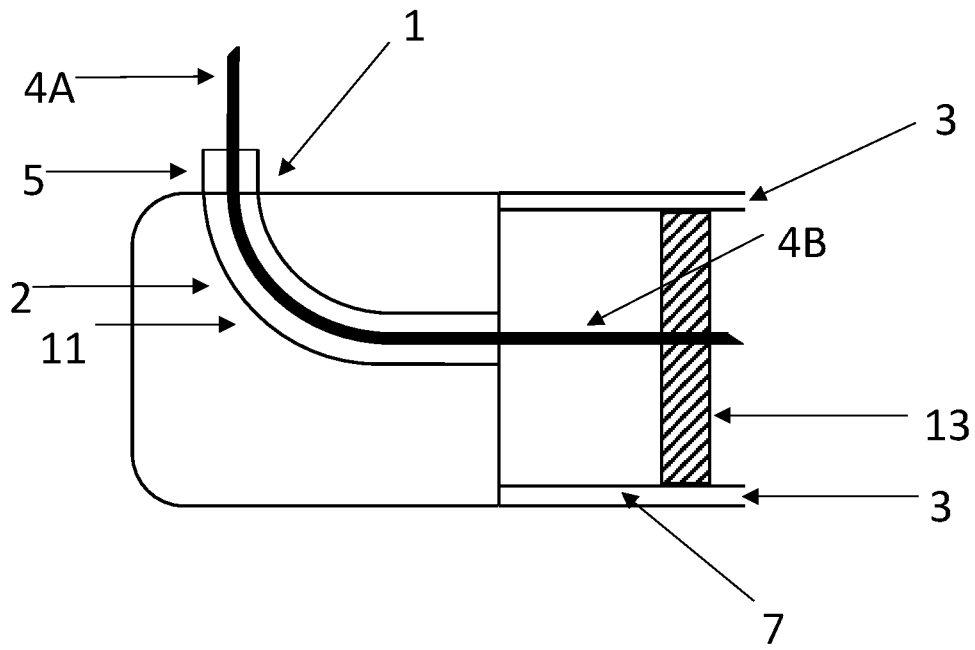


Fig. 5A

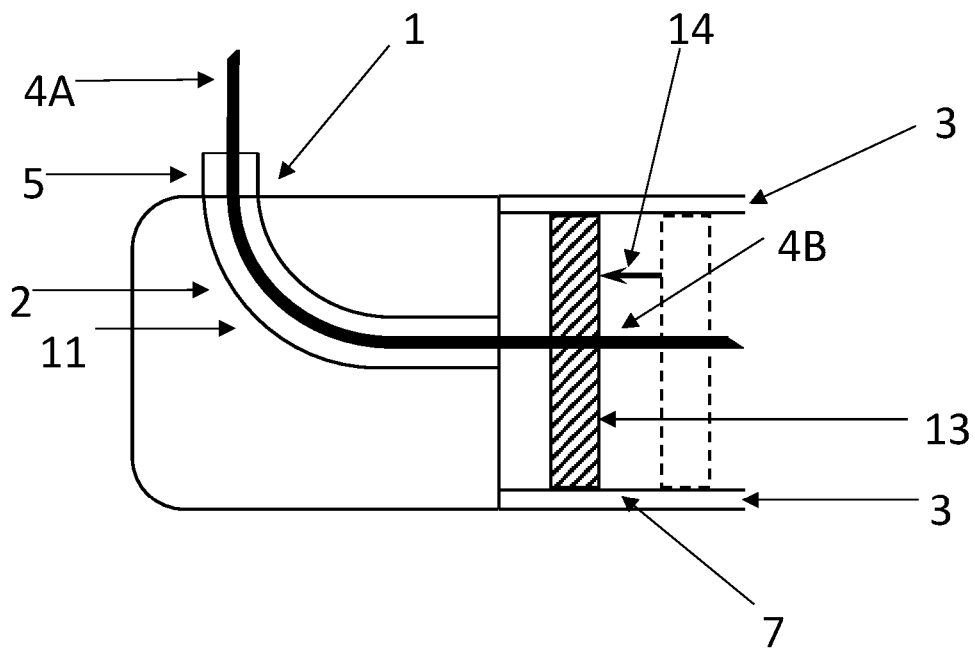


Fig. 5B

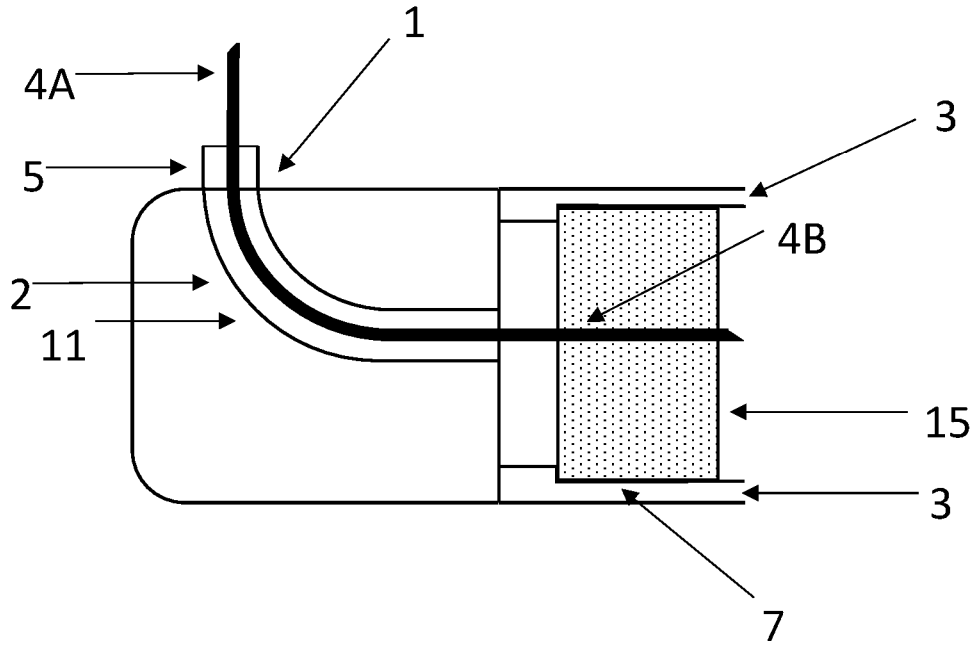


Fig. 6A

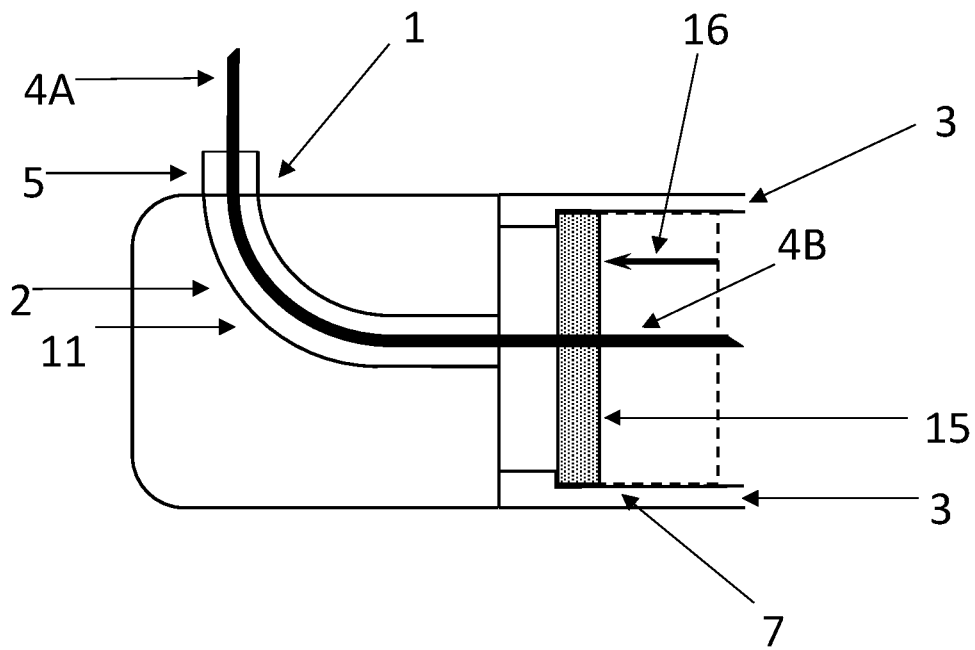


Fig. 6B