(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
8 December 2016 (08.12.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/191819 A1

(51) International Patent Classification:
A61M 5/24 (2006.01) *A61M 5/48* (2006.01)
A61M 5/315 (2006.01)

(21) International Application Number:
PCT/AU2016/050444

(22) International Filing Date:
2 June 2016 (02.06.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

2015902089	2 June 2015 (02.06.2015)	AU
2015902669	7 July 2015 (07.07.2015)	AU
2015903087	3 August 2015 (03.08.2015)	AU

(71) Applicant: **INTRAVITAL PTY LTD** [AU/AU]; 1/54 Coogee Bay Rd, Randwick, New South Wales 2031 (AU).

(72) Inventor: **EVISTON, Timothy J.**; 1/54 Coogee Bay Road, Randwick, New South Wales 2031 (AU).

(74) Agent: **GRIFFITH HACK**; Level 29 Northpoint, 100 Miller Street, North Sydney, New South Wales 2060 (AU).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

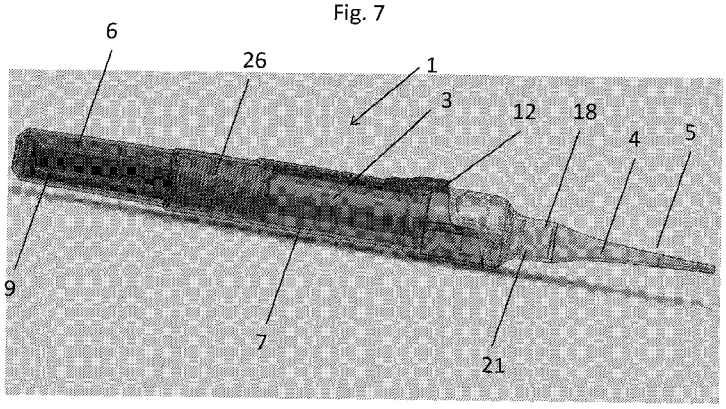
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: DRUG DELIVERY DEVICE WITH PRE-ASSEMBLED CARTRIDGE

Fig. 7



(57) Abstract: Disclosed in some forms is a delivery device for delivering a gel or liquid pharmaceutical to a treatment site, the delivery device comprising a body extending from a delivery tip, the body defining a cavity for retaining a the pharmaceutical or a pre-assembled cartridge holding the pharmaceutical; and a driver for mechanically discharging the pharmaceutical from the cartridge to the delivery tip. In some forms the driver is adapted to release a consistent flow of the pharmaceutical. In some forms the delivery device is biased into a release configuration.

WO 2016/191819 A1

DRUG DELIVERY DEVICE WITH PRE-ASSEMBLED CARTRIDGE

BACKGROUND

The present invention relates to a delivery device for delivering a therapeutic substance in a liquid or gel form.

SUMMARY

Disclosed in some forms is a delivery device for delivering a gel or liquid pharmaceutical to a treatment site, the delivery device comprising a body extending from a delivery tip, the body defining a cavity for retaining a the pharmaceutical or a pre-assembled cartridge holding the pharmaceutical; and a driver for mechanically discharging the pharmaceutical from the cartridge to the delivery tip. In some forms the driver is adapted to release a consistent flow of the pharmaceutical. In some forms the delivery device is biased into a release configuration.

Delivery of a therapeutic substance in a liquid or gel form is complicated by the need for sterile supply of therapeutic substances. It is therefore desirable to maintain the therapeutic substance in a sealed capsule for use, in a way that does not break the sterile supply.

Further, the viscosity of the liquid or gel means delivery can be inconsistent or difficult, particularly when manually controlled by the user. It is desirable to have continuous, predictable and controlled release of the

liquid or gel with low levels of variation for different users. When a viscous substance is delivered, the initial inertia on the plunger can require significant force from a user or can mean that the initial dispensing is rushed or unpredictable.

The device provides for improved delivery of the therapeutic substance, improved consistency, greater ease for the doctor or other user. In some forms delivery of the drug beyond a selected site is minimised.

Further, surgical nerve injury peripheral to the surgery is a danger of surgery. Nerve dysfunction can result from trauma to the nerves despite the nerves appearing to be intact. This makes nerve dysfunction difficult to predict during surgery. Traumatic mechanisms such as stretch, thermal injury, electrical injury, compression and ischaemia can accumulate to cause activation of pathways of cellular degradation within a nerve's axon. This can cause nerve break down and loss of function.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 shows a front top perspective view of one embodiment of the delivery device;
Fig. 2 shows a rear top perspective view of the body of the delivery device of Fig. 1;
Fig. 3 shows a top view of the delivery device of Fig. 1;
Fig. 4 shows a top partially translucent view of the delivery device of Fig. 1;
Fig. 5 shows a side partially translucent view of the

delivery device of Fig. 1;

Fig. 6 shows a top perspective partially phantom view of the delivery device of Fig. 1;

Fig. 7 shows a side perspective partially phantom view of the delivery device of Fig. 1;

Fig. 8 shows a front perspective view of the delivery device of Fig. 1;

Fig. 9 shows a perspective view of a device of a second embodiment of the disclosure;

Fig. 10 shows a side view of the device of Fig. 9;

Fig. 11 shows a front perspective view of the device of Fig. 9;

Fig. 12 shows a side cutaway view of a third embodiment of a delivery device of the disclosure;

Fig. 13 shows a cutaway detail of the embodiment of Fig. 12;

Fig 14 shows a perspective cutaway detail of the embodiment of Fig. 12.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE DISCLOSURE

Disclosed in some forms is a delivery device for delivering a gel or liquid pharmaceutical to a treatment site, the delivery device comprising a body extending from a delivery tip, the body defining a cavity for retaining a pre-assembled cartridge holding the pharmaceutical; and a driver for mechanically discharging the pharmaceutical from the cartridge to the delivery tip.

In some forms the device further comprises a perforator for creating an opening in the cartridge to allow for discharge of the pharmaceutical from the cartridge to the

delivery tip. In some forms the perforator is a manual perforator. In some forms the perforator acts by relative movement of the cartridge and the perforator. In some forms the perforator comprises a needle positioned proximal the delivery tip.

In some forms the cartridge and perforator are relatively moveable between a sealed configuration and an active configuration in which the cartridge is perforated.

In some forms movement of the cartridge and the perforator into the active configuration is activated by a manual activator.

In some forms the driver is adapted to release a consistent flow of the pharmaceutical. In some forms the driver has a ratchet action.

In some forms the device further includes an actuator for actuating the driver. In some forms actuation of the actuator releases causes the driver to drive motion of a displaceable plunger, the plunger being configured to move such that the pharmaceutical is discharged from the cartridge to the tip.

In some forms the driver is in the form of a pretensioned spring.

In some forms the device further includes a brake adapted to retain the plunger with respect to the cartridge.

In some forms the delivery tip comprises a replaceable portion to allow for variation of tip size and shape configurations.

In some forms the device is adapted for single use. In some forms the device is sized and configured for single hand use.

Further disclosed is a method of treatment during surgery comprising applying a gel or liquid pharmaceutical to a treatment site exposed during surgery using the delivery device described above.

In further aspects, disclosed is a device for applying a therapeutic substance to a nerve, the device comprising a reservoir adapted to contain the therapeutic substance, an outlet and a plunger, the plunger being biased to adopt a release motion in which the therapeutic substance is expelled from the reservoir through the outlet, the plunger being retained relative to the reservoir by a retainer.

In some forms the outlet comprises a tip, the tip being removable from the device to allow interchange with one or more alternative tips having different dimensions.

In some forms the rate of release of the therapeutic substance is controlled.

The device allows for supply of the therapeutic substance without interrupting sterile supply or perforating the cartridge until the time of use. It also allows for continuous predictable delivery which is not reliant upon manual actuation so has a decreased variability between users and greater consistency of application. In some forms the tip allows for a variety of tip designs for different uses.

The device and process may provide for improved levels of pain, improved recovery, improved muscle function, improved autonomy, or improved sensation. In some forms chronic pain or inflammation can be reduced or avoided.

In some forms the therapeutic substance comprises a formulation comprising a biodegradable carrier and a therapeutic ingredient.

In some forms the therapeutic ingredient comprises a local anaesthetic.

In some forms the therapeutic ingredient comprises an anti-inflammatory agent.

In some forms the therapeutic ingredient comprises an antibiotic.

In some forms the therapeutic substance is selected from substances that can intervene in the activation of pathways of cellular degradation within the nerve.

Positioning of a therapeutic substance during surgery allows for work around vital structures.

The device allows controlled, predictable and continuous application of a therapeutic substance in the form of a liquid or a gel directly to a location for treatment such as a nerve, a burn site, a surgical site or a cancer. The device can limit or prevent peripheral damage, trauma or injury occurring during treatment and peripheral delivery of the therapeutic substance beyond the intended site.

In some forms the therapeutic substance comprises a carrier, which is in some forms, adapted to slow release, to prolong the pharmacokinetics of the active pharmaceutical, and to reduce dissemination of the active pharmaceutical ingredient beyond the site at which its effect is intended. This provides greater concentration of the active pharmaceutical to the relevant cells and limits waste.

The device has been described for treatment of burns, cancer or surgery. However it will be clear that the device can be utilised beyond the described circumstances.

Referring now to the Figures, Fig. 1 shows a perspective view of one embodiment of a delivery device 1.

The delivery device 1 comprises a body 3 extending from a tip 4 at a leading end 5 to a trailing end 6. The body 3 is configured to define an interior retaining cavity 6 within the body, along with a spring cavity 9, also within the body.

The delivery device 1 further includes an actuator 12 located outwardly of the body 3.

The tip 4 is a delivery tip and includes an outlet 14 positioned at the leading end of the tip 4. The outlet 14 is adapted to allow discharge of a liquid or gel.

The retaining cavity 7 is configured to retain a cartridge 15 within the cavity. The cartridge contains a therapeutic substance (not illustrated) in the form of a liquid or gel.

The cartridge 15 comprises a prefilled cartridge composed, for example, of glass or plastic and sterilised for use. Once the cartridge 15 is sterilised, it is critical to maintain sterility.

The tip includes a perforator 17 in the form of a perforating needle composed of stainless steel. The perforator 17 is maintained within a tip cavity 18 within the tip 4.

A tip spring 19 is also retained within the tip cavity 18. The tip spring 19 acts to separate the cartridge 15 from the perforator 17 to maintain the sterility of the cartridge until opening is required. In another form the cartridge may be separated from the perforating needle by a “crown” of polycarbonate fingers which can be overcome by the activation of the device.

The tip cavity 18 is in communication with the retaining

cavity by means of a neck portion 21. The neck portion 21 is hollow and includes ribs such that in a disassembled state the cartridge can be correctly aligned with the needle.

In the illustrated form the tip 4 is removable from the body 3 and the device 1 includes a release clip 23 which allows removal of the tip 4 for reloading of cartridges.

A plunger 25 is located within the retaining cavity 7. The plunger 25, in use, acts upon the cartridge 15 to discharge the therapeutic substance from the cartridge into the outlet 14. The plunger, in the illustrated form, surrounds the cartridge 15 to hold it in place while the plunger 25 pushes the contents of the cartridge 15 out of the cartridge and through the outlet 14.

The plunger 25 is powered by a plunger spring 26 which is located in the plunger cavity 9 of the body 3. In the illustrated form, the plunger spring 26 is locked in place by, for example, a pin, until the device is armed for use.

The plunger 25 acts directly on the cartridge 15 to discharge the contents.

In use, an operator actuates the device 1 by depressing the actuator 12. The actuator 12 is a button connected to a gate or ratchet which allows the release of the pretensioned plunger spring 26.

In some forms that actuator is in the form of a brake and release can be controlled by releasing the actuator 12

again and allowing the brake actuator to act to restrain the discharge. In some forms the brake configuration is a twist grip or a ratchet controlled twisting grip, a tilting slit, a toothed ratchet or a lever and spring. The braking force may be increased by using a spring under the button actuator to actively engage the braking mechanism upon release of the button by the user.

The cartridge contacts the perforator 17 to perforate the cartridge, creating an opening for release of the therapeutic substance within the cartridge.

The tip 4 in some forms comprises an interchangeable end portion 28. This allows either changing of the tip dimensions and configuration to best suit the use. Further the tip 4 can include an attachment such as a luer lock to allow connection to standard needle, intravenous or canula configurations.

Turning now to Figure 2, the device body 3 and tip 4 are composed of plastic and are configured such that the retaining cavity 7, the spring cavity 9, the tip cavity 18 and the neck portion 21 for a single joined cavity extending through the device 1. The cavity includes a plunger shoulder 29 positioned to limit the movement of the plunger toward the trailing end.

As shown in Figs. 3 through 8, the delivery device body 3 extends from the tip 4 to the trailing end. In this form, the spring 26 is positioned at a wider portion of the body to allow a larger calibre spring in an embodiment of the design which has a shorter overall profile. In this

configuration the spring aids in maintaining the plunger in position with regards to the contained cartridge.

The actuator is adapted to ratchet so that the spring 26 acts on the plunger 25 when the actuator button is actuated.

In the illustrated form the tip 4 is removable from the body 3 and the device 1 includes a release clip 23 which allows removal of the tip 4 for reloading of cartridges. Alternative tips may include integrated LEDs, a long, thin, curved nozzle for specific fine applications, a spray nozzle for wider surface area applications, a luer lock or similar tip for connection to a standard IV drip, cannula or needle, a pliable tip for endoscopy or laparoscopy.

A plunger 25 is located within the retaining cavity 7. The plunger 25, in use, acts upon the cartridge 15 to discharge the therapeutic substance from the cartridge into the outlet 14. The plunger, in the illustrated form, surrounds the cartridge 15 to hold it in place while the plunger 25 pushes the contents of the cartridge 15 out of the cartridge and through the outlet 14.

The plunger 25 is powered by a plunger spring 26 which is located in the plunger cavity 9 of the body 3. In the illustrated form, the plunger spring 26 is locked in place by, for example, a pin, until the device is armed for use.

The plunger 25 acts directly on the cartridge 15 to discharge the contents.

In use, an operator actuates the device 1 by depressing the actuator 12. The actuator 12 is a button connected to a gate or ratchet or similar braking mechanism which allows the release of the pretensioned spring. In some forms that actuator is in the form of a brake and release can be controlled by releasing the actuator 12 again and allowing the brake actuator to act to restrain the discharge. In some forms the rate of release can be adjusted by a user by utilising the brake.

The cartridge contacts the perforator 17 to perforate the cartridge, creating an opening for release of the therapeutic substance within the cartridge.

The device is configured for use with a single hand. This comprises having a slender device with a fine motor or a pen grip. The actuator or braking mechanism allows a user to control the discharge without requiring the user to apply significant pressure to effect manual discharge. The user can therefore control a continuous or consistent rate of delivery using this grip without significant strain. The device also allows the continuous and consistent release of therapeutic without the user applying pressure or force beyond the activation of the actuator.

In some not illustrated forms, the device is activated for use by a twisting mechanism which moves the cartridge forward onto the perforating cannula. Alternatively the device is activated by removal of a restraining clip which allows the force of a spring to move the cartridge forward onto the cannula or by cocking forward of an external

lever which moves the cartridge onto the cannula.

The accuracy of volume dispensing may be increased by using an adjustable actuator or electromechanical actuator (e.g. piezo-electric actuator) , manually setting the limit of plunger movement inside or outside the device. optimising the plunger spring force and length or decreasing the caliber of the tip or canula or using a reservoir in series with the canula to limit flow rate for consistent or small volume dispensing, among other means.

The controlled rate of delivery may be may be further optimized by limiting the caliber of the internal canula/tip to restrict maximum flow, using opposed springs to even the force/time and force/distance characteristics of the spring, using a "constant force" spring, using an extension spring, a shape memory alloy, or using an electro-mechanical actuator eg. a piezoelectric actuator.

Further disclosed is a device for applying a therapeutic substance to a nerve, the device comprising a reservoir adapted to contain the therapeutic substance, an outlet and a plunger. In some forms the plunger is biased to adopt a release motion in which the therapeutic substance is expelled from the reservoir through the outlet, the plunger being retained relative to the reservoir by a retainer. In some forms the device further comprises an actuator, actuation of the actuator releasing the plunger to adopt a release motion and expel the therapeutic substance.

In some forms the outlet comprises a tip, the tip being removable from the device to allow interchange with one or

more alternative tips having different dimensions.

In some forms the rate of release of the therapeutic substance is controlled.

Referring to Figs. 9 - 11, disclosed is a delivery device for delivering a formulation.

The device is specifically described in relation to delivery of a formulation that can intervene in pathways of cellular degradation of a nerve. The device is specifically described for applying the formulation to a nerve directly. This limits trauma to the nerve or reduces the effects of that trauma on the nerve, thus providing for a lower likelihood of nerve dysfunction.

However it will be clear that the driver of the device can be utilised in alternative delivery devices.

The illustrated device 101 comprises a body 102 which is shaped to be held in an ergonomic manner in one hand. The body 102 contains a reservoir (not illustrated) in which a formulation is stored for use.

In some forms the formulation is held in a capsule in order to effect sterile delivery. The capsule is positioned within the body 102 for use.

The device 101 extends between a delivery end 103 and a rear end 104. The delivery end comprises a delivery conduit 105 extending from the body 102. The shape of the delivery end 103 and conduit 105 are elongate to allow for delivery of the formulation to a nerve during surgery when spaces can be compact and restrictive to movement.

The delivery end 103 further comprises a tip 106 which is

shaped to allow accurate and precise delivery of the formulation to cells. The tip 106 is removable from the delivery end 103 to allow the tip 106 to be interchanged for a tip having a different dimension. This allows a surgeon to control the shape of the delivery, through changing aperture size and shape. The tip 106 is blunt to limit damage to the tissue and nerve.

In some forms, the tip dimensions are suited to different fields. For example, endoscopic surgery could utilise a long tip, microsurgery a fine tip and a curved tip could be utilised in applications that require the tip in a confined space. The tips 106 are selectable or interchangeable such that a single body can be provided with multiple tips for use.

In some forms the delivery end 103 and conduit 105 can also be shaped specifically for various surgical uses.

The device further includes an actuator 108 in the form of a button. Actuation of the actuator 108 by pressing the button causes the formulation to be released through the tip 106.

The reservoir of the interior of the body 102, includes a plunger (not illustrated) which is adapted to expel the formulation from the reservoir through the tip 106. The plunger is moveable with respect to the reservoir to perform this expulsion.

In one form, the plunger is biased toward the tip, that is, biased into a release motion that releases the formulation. The plunger is biased by means of a pretensioned spring, pushing the plunger with respect to the reservoir.

In this form the plunger is held in position by a ratchet. Actuation of the actuator 108 causes the ratchet to release, allowing the plunger to move with respect to the reservoir, expelling formulation. The thickness of the formulation and the size of the tip and aperture maintain a consistent flow until the actuator is released at which stage the ratchet retains the plunger with respect to the reservoir again.

In some forms, the device is adapted for a single use application.

While the device has been described with a particular driver, it will be clear to a user that alternative drivers are available.

Referring to Figs 12 – 14, the illustrated device 200 comprises a body 201 which is shaped to be held in an ergonomic manner in one hand. The body 201 contains a reservoir 202 in which a formulation is stored for use.

In the illustrated form the formulation is held in a capsule 203 in order to effect sterile delivery. The capsule is positioned within the body 201 for use.

The device 200 extends between a delivery end 204 and a rear end 205. The delivery end comprises a delivery conduit 206 extending from the body 201. The shape of the delivery end 204 and conduit 206 are elongate to allow for delivery of the formulation to a nerve during surgery when spaces can be compact and restrictive to movement.

The delivery end 204 further comprises a tip 207 which is shaped to allow accurate and precise delivery of the formulation to cells. In some forms the tip is removable from the delivery end to allow the tip to be interchanged

for a tip having a different dimension. This allows a surgeon to control the shape of the delivery, through changing aperture size and shape. The tip 207 is blunt to limit damage to the tissue and nerve.

In some forms, the tip dimensions are suited to different fields. For example, endoscopic surgery could utilise a long tip, microsurgery a fine tip and a curved tip could be utilised in applications that require the tip in a confined space. The tips 207 are selectable or interchangeable such that a single body can be provided with multiple tips for use.

In some forms the delivery end 204 and conduit 206 can also be shaped specifically for various surgical uses.

The device further includes an actuator 208 in the form of a button. Actuation of the actuator 208 by pressing the button causes the formulation to be released through the tip 207.

The reservoir of the interior of the body 201, includes a plunger 209 which is adapted to expel the formulation from the reservoir through the tip 207. The plunger is moveable with respect to the reservoir to perform this expulsion.

In one form, the plunger is biased toward the tip, that is, biased into a release motion that releases the formulation. The plunger is biased by means of a pretensioned spring 210, pushing the plunger with respect to the reservoir.

In this form the plunger is held in position by a retaining member 211. Actuation of the actuator 208 causes the retaining member 211 to release, allowing the plunger 209 to move with respect to the reservoir 202, expelling

formulation. The force of the spring, the thickness of the formulation and the size of the tip and aperture maintain a consistent flow until the actuator is released at which stage the retaining member 211 retains the plunger 209 with respect to the reservoir again.

In some forms the retaining member and actuator are integral to one another. In some forms the retaining member interacts frictionally with the plunger or a plunger extension to resist the forward movement of the plunger acted on by the spring.

In some forms, the device is adapted for a single use application.

The device is useable for a variety of purposes not limited to the delivery of a topical gel to an exposed structure such as a nerve, wound, muscle, bone, tumour or tumour bed, organ surface breach (eg. bowel anastomosis, dural tear, lung tear, lymph leak, vascular anastomosis), damaged surface or skin, the injection of a viscous or liquid substance subdermally, subcutaneously, intravenously etc, the controlled intraocular injection of a substance (into the eye), the controlled injection of a substance under radiological/imaging guidance such as facet joint, perineural or intra-articular injection or large surface topical application though using a spray tip.

It is to be understood that, if any prior art publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

In the claims which follow and in the preceding description of the disclosure, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

Claims:

1. A delivery device for delivering a gel or liquid pharmaceutical to a treatment site, the delivery device comprising:

    a body extending from a delivery tip, the body defining a cavity for retaining a pre-assembled cartridge holding the pharmaceutical;

    a driver for mechanically discharging the pharmaceutical from the cartridge to the delivery tip.

2. A delivery device as defined in claim 1, further comprising a perforator for creating an opening in the cartridge to allow for discharge of the pharmaceutical from the cartridge to the delivery tip.

3. A device as defined in claim 2, wherein the perforator is a manual perforator.

4. A device as defined in claim 2 or 3, wherein the perforator acts by relative movement of the cartridge and the perforator.

5. A device as defined in any one of claims 2 – 4, wherein the perforator comprises a needle positioned proximal the delivery tip.

6. A device as defined in any one of claims 2 – 5, wherein the cartridge and perforator are relatively moveable between a sealed configuration and an active configuration in which the cartridge is perforated.

7. A device as defined in claim 6, wherein movement of the cartridge and the perforator into the active configuration is activated by a manual activator.

8. A delivery device as defined in any of the preceding claims, wherein the driver is adapted to release a consistent flow of the pharmaceutical.

9. A delivery device as defined in any of the preceding claims further including an actuator for actuating the driver.

10. A delivery device as defined in claim 7, wherein actuation of the actuator releases causes the driver to drive motion of a displaceable plunger, the plunger being configured to move such that the pharmaceutical is discharged from the cartridge to the tip.

11. A delivery device as defined in any of the preceding claims, further including a brake adapted to retain the plunger with respect to the cartridge.

12. A delivery device as defined in any of the preceding claims wherein the delivery tip comprises a replaceable portion to allow for variation of tip size and shape configurations.

13. A delivery device as defined in any of the preceding claims and adapted for single use.

14. A delivery device as defined in any of the preceding claims and sized and configured for single hand use.

15. A method of treatment during surgery comprising applying a gel or liquid pharmaceutical to a treatment site exposed during surgery using the delivery device of any one of claims 1 – 12.

16. A device for applying a therapeutic substance to a nerve, the device comprising a reservoir adapted to contain the therapeutic substance, an outlet and a plunger, the plunger being biased to adopt a release motion in which the therapeutic substance is expelled from the reservoir through the outlet, the plunger being retained relative to the reservoir by a retainer.

17. A device as defined in claim 16, further comprising an actuator, actuation of the actuator releasing the plunger to adopt a release motion and expel the therapeutic substance.

18. A device as defined in claim 16 or 17, wherein the outlet comprises a tip, the tip being removable from the device to allow interchange with one or more alternative tips having different dimensions.

19. A device as defined in any one of claims 16 to 18, wherein the rate of release of the therapeutic substance is controlled.

20. A single use device as defined in any one of claims 16 to 19.

21. A kit comprising a device as defined in claim 16, and a plurality of tips.

22. A kit as defined in claim 21, wherein the dimensions of the tips are adapted for different surgical contexts.

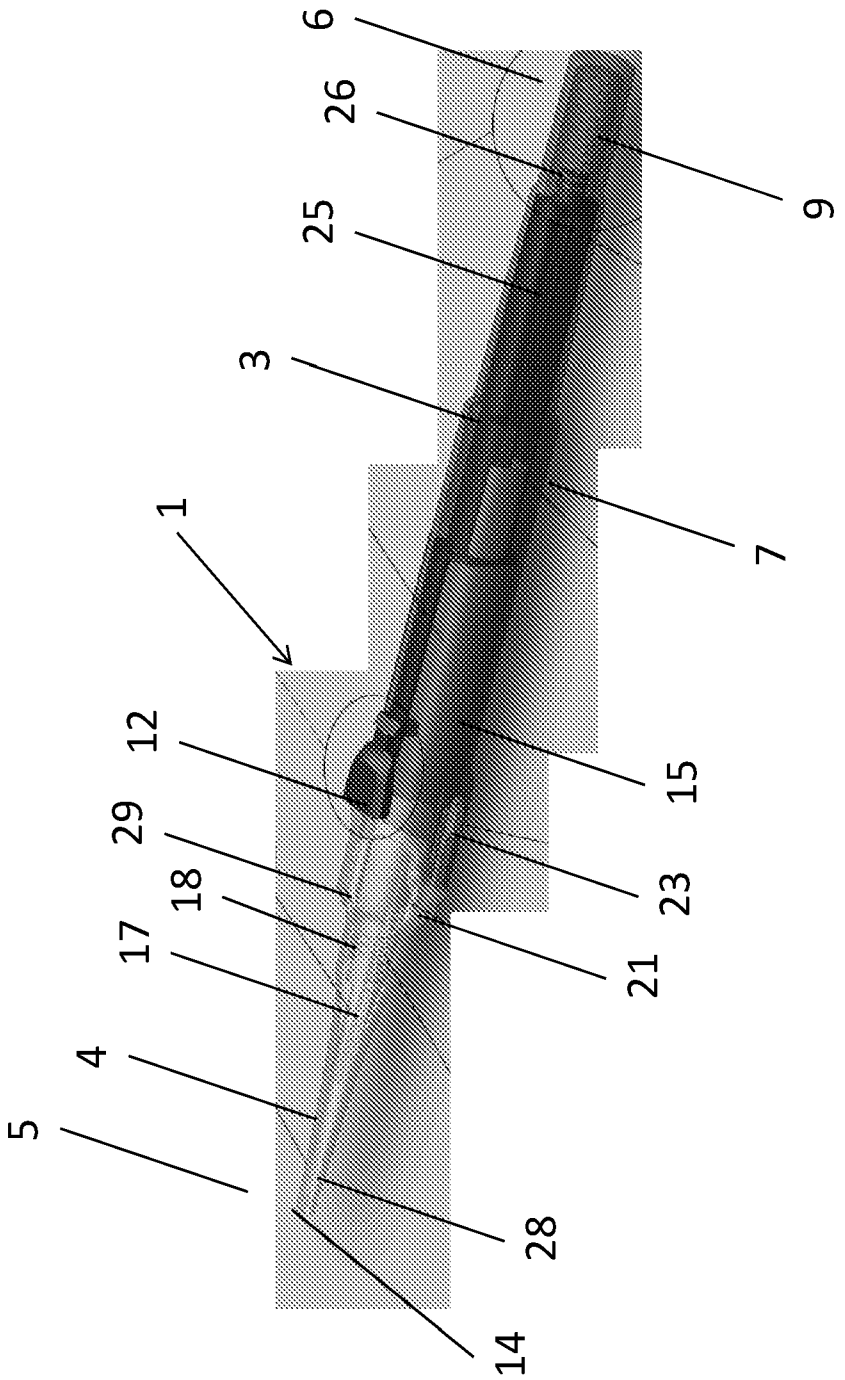


Fig. 1

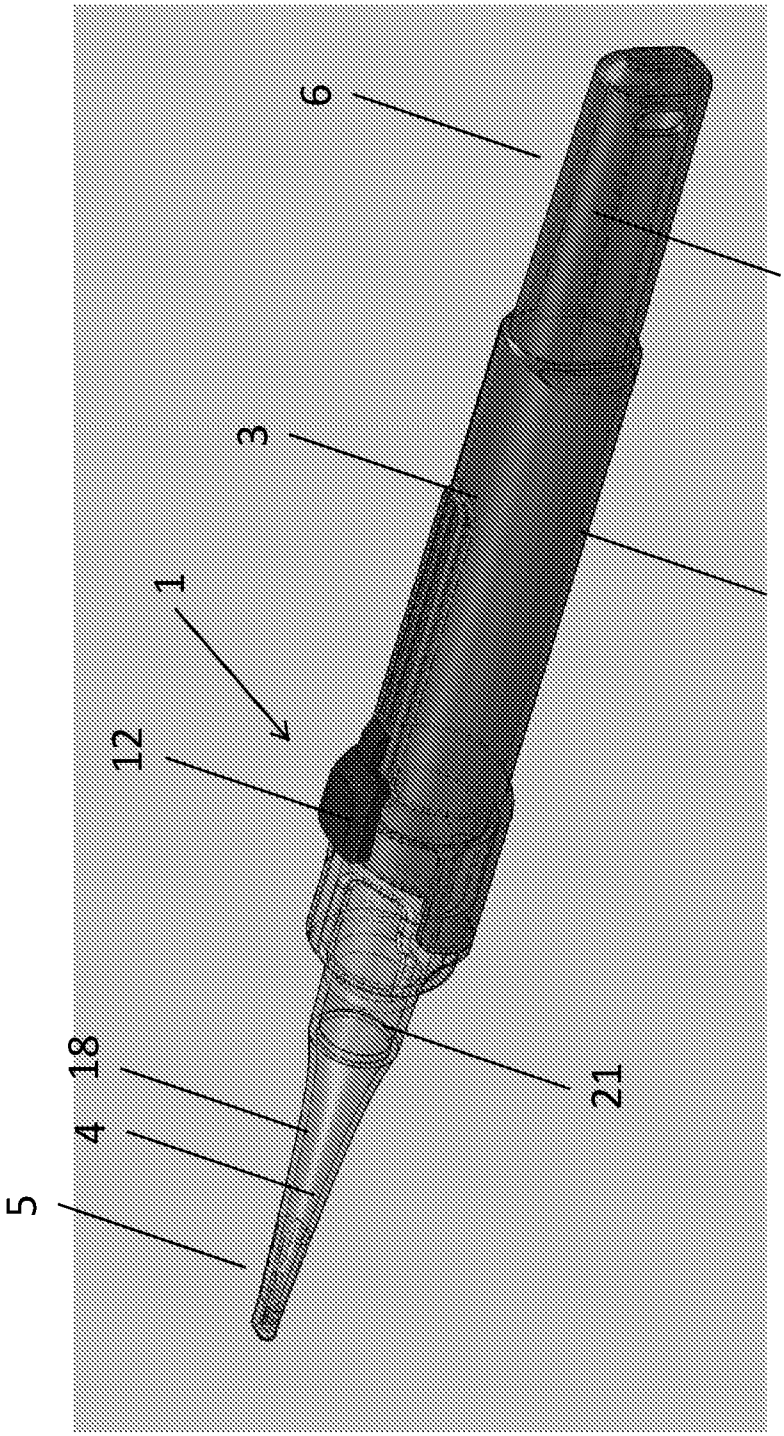


Fig. 2

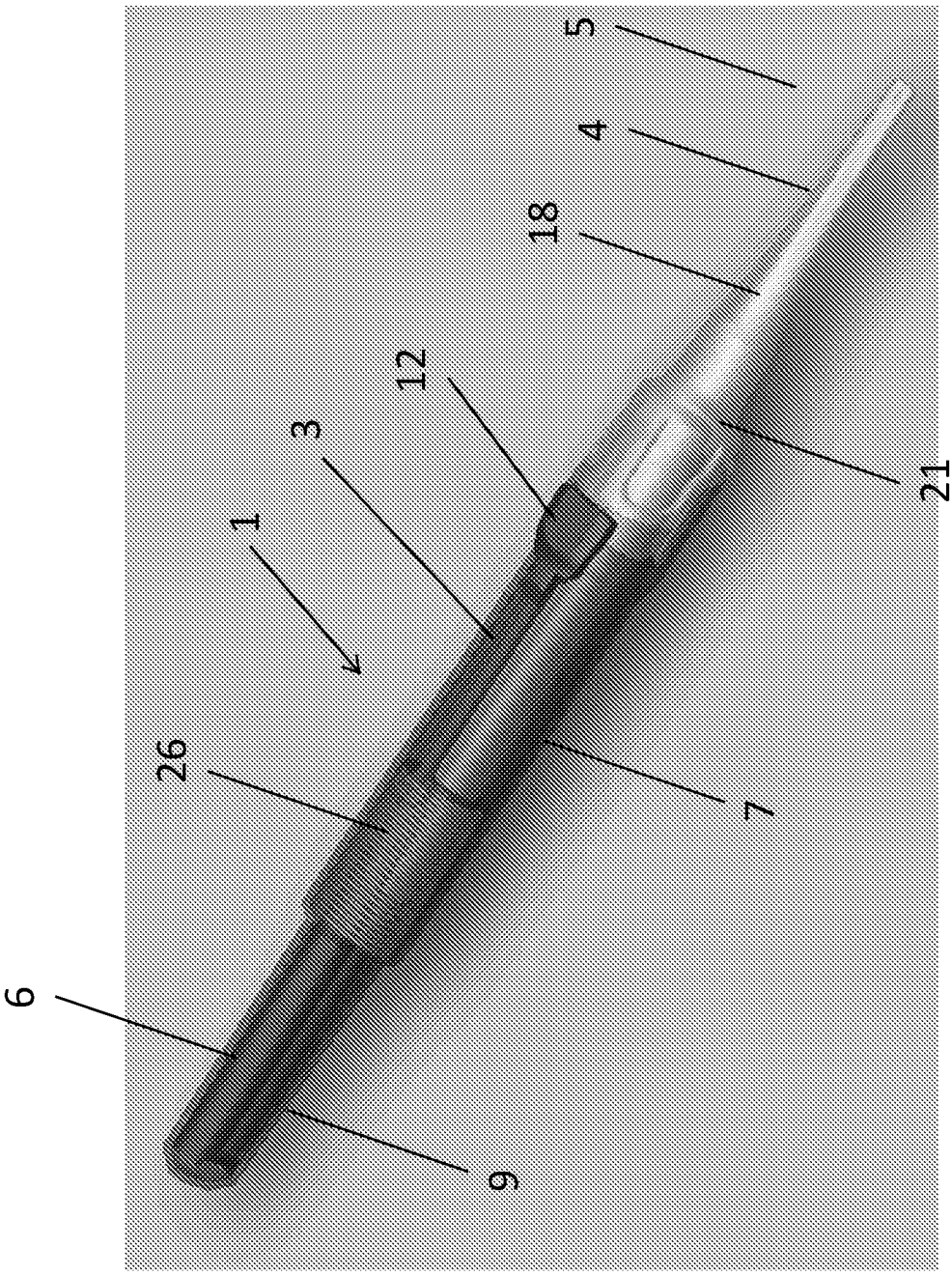


Fig. 3

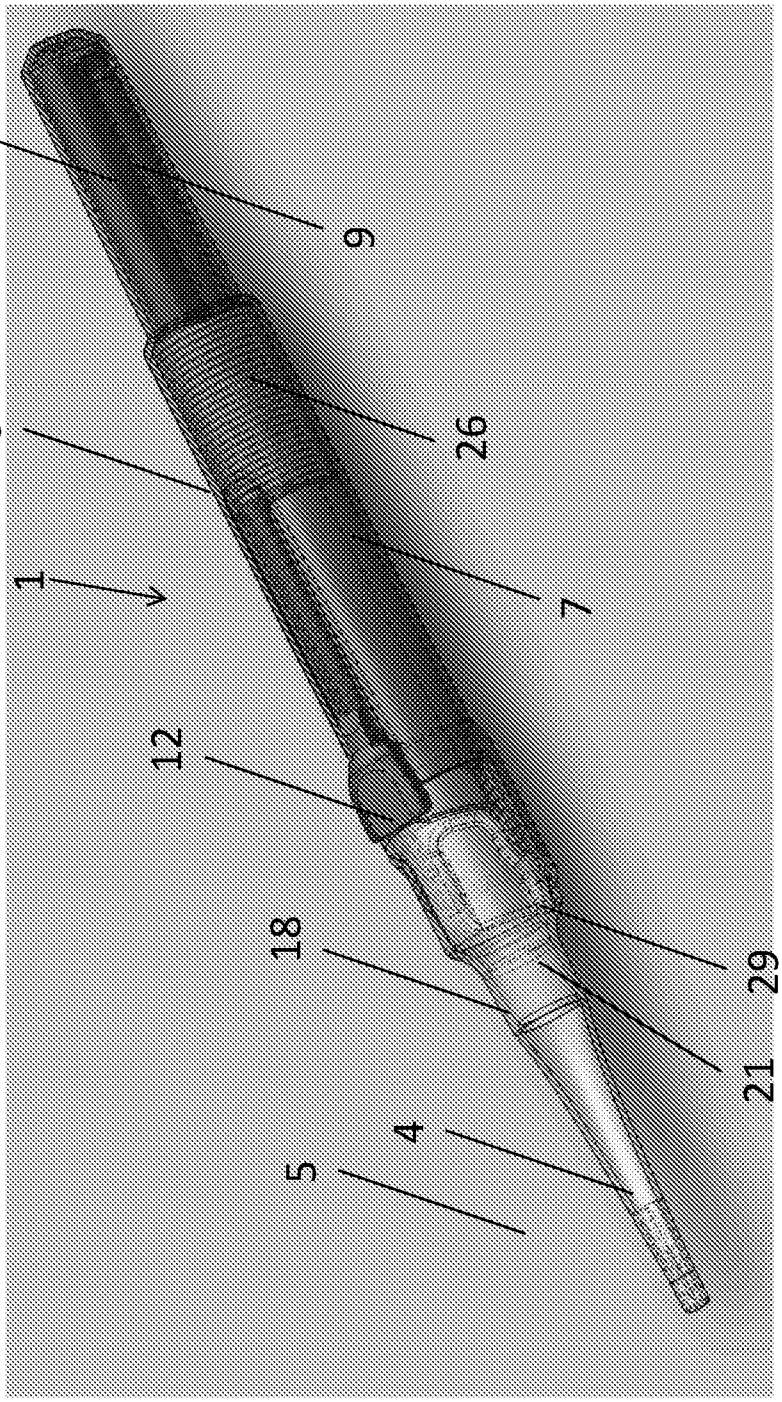


Fig. 4

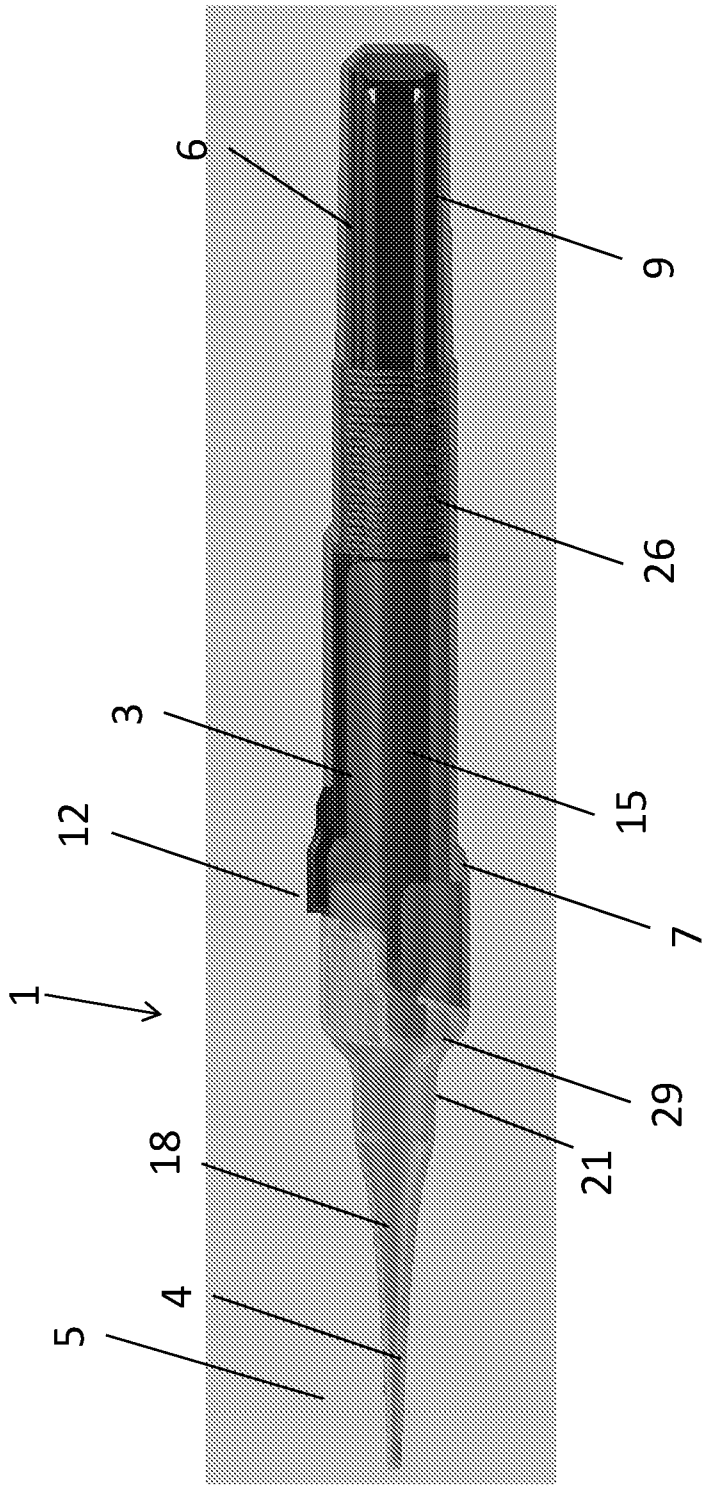


Fig. 5

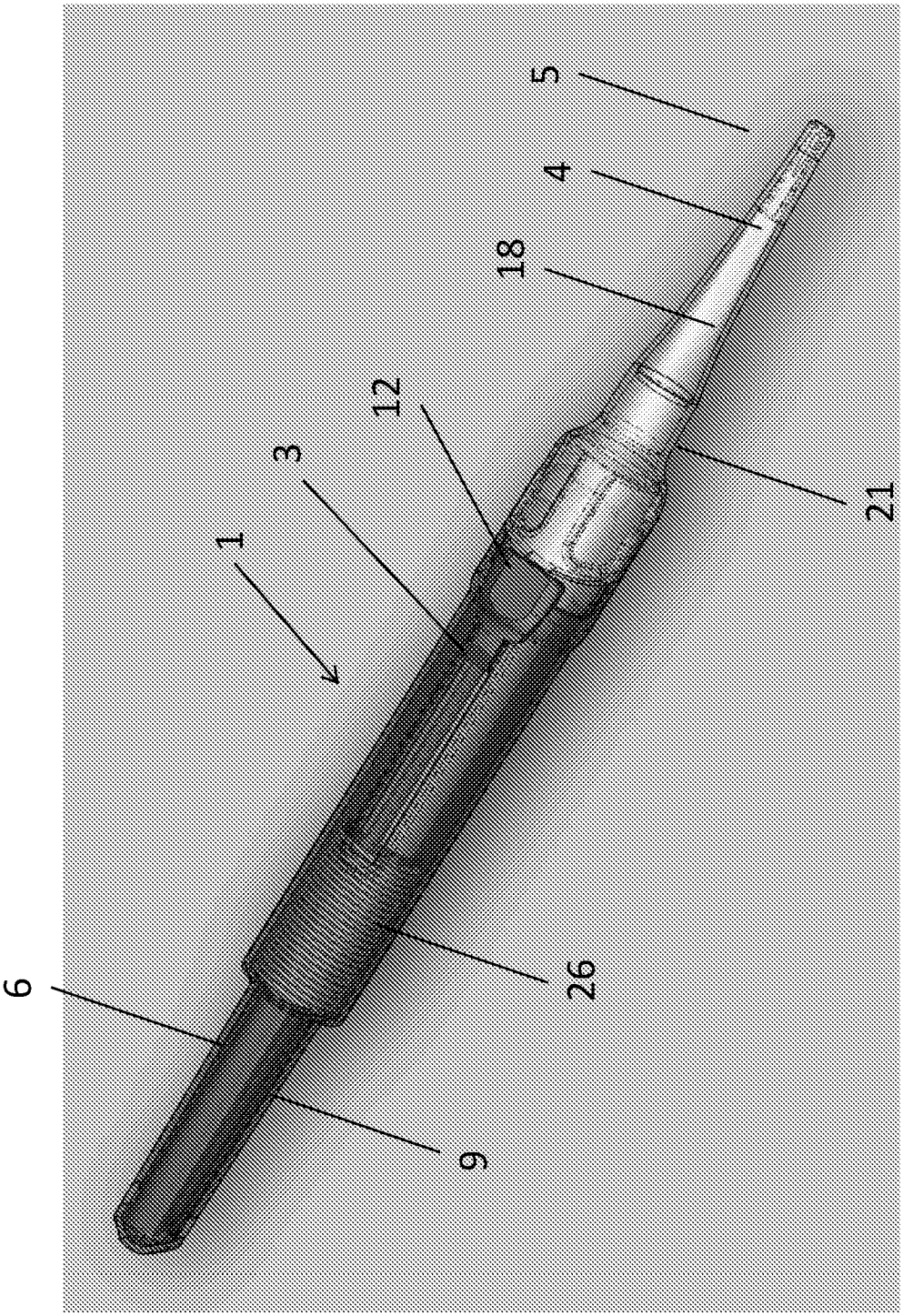


Fig. 6

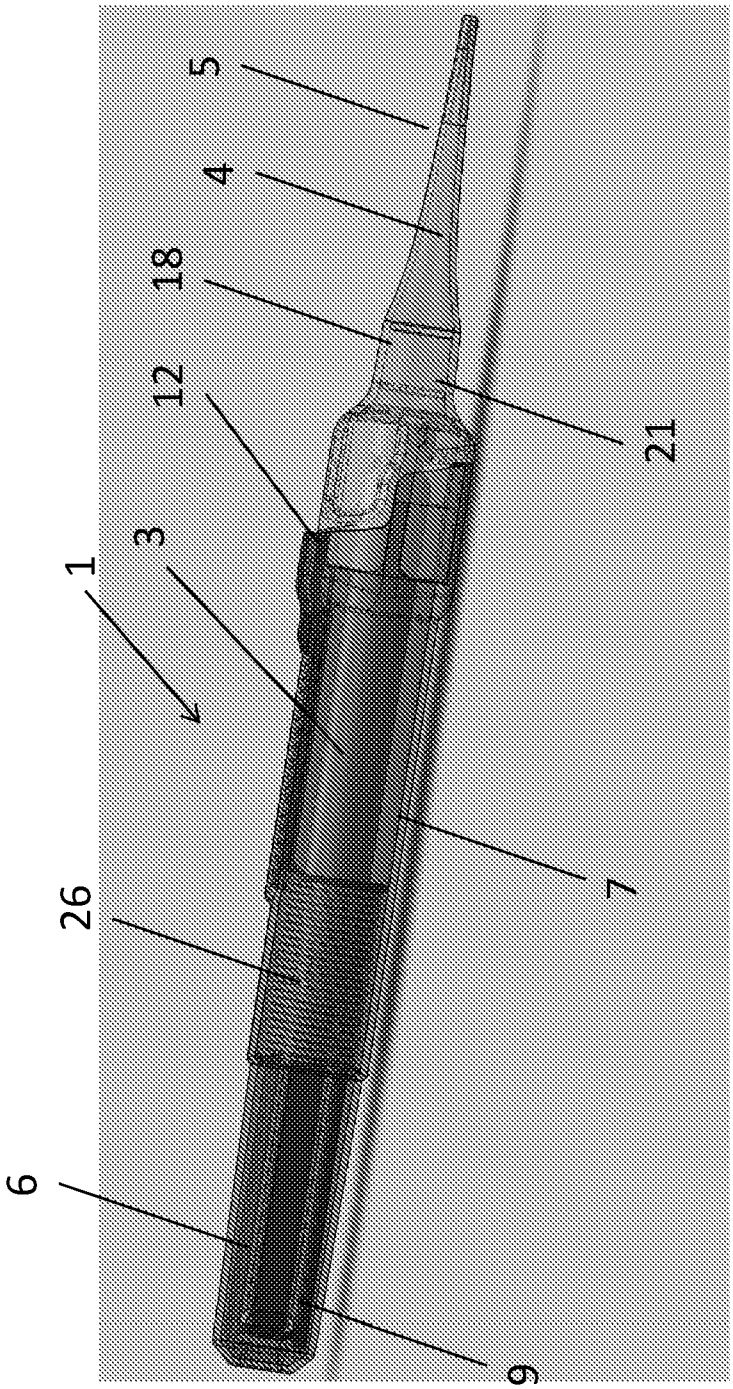


Fig. 7

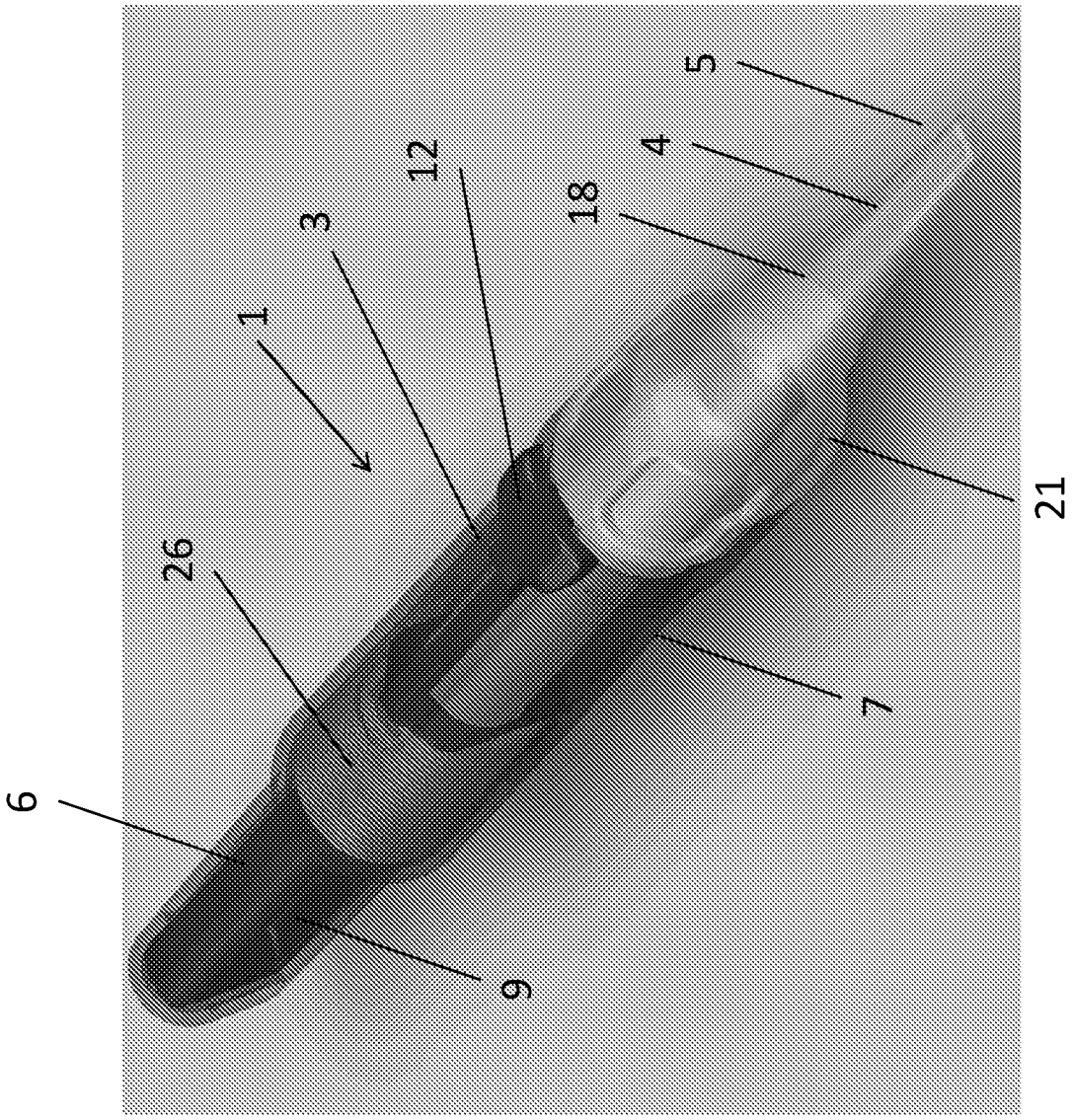


Fig. 8

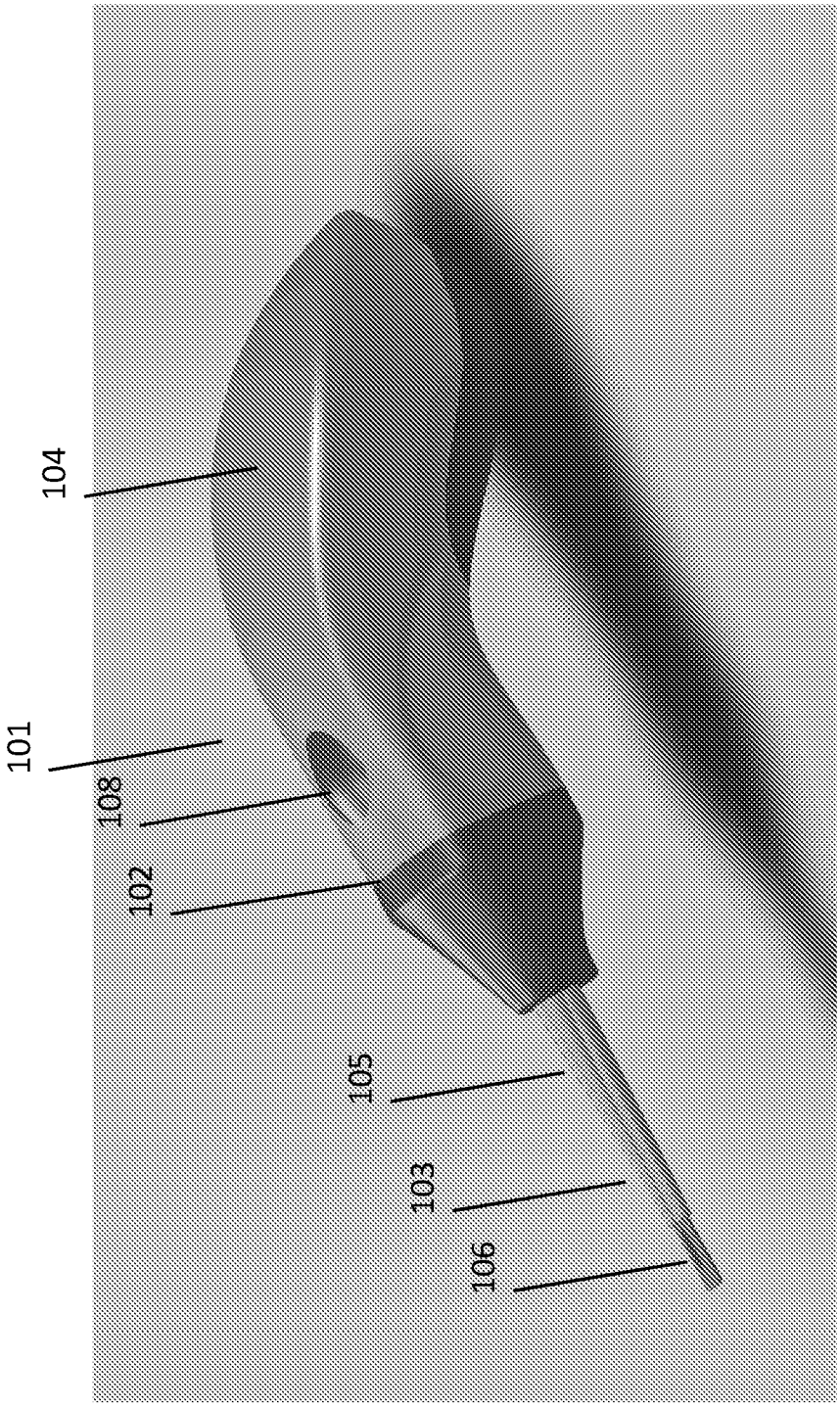


Fig. 9

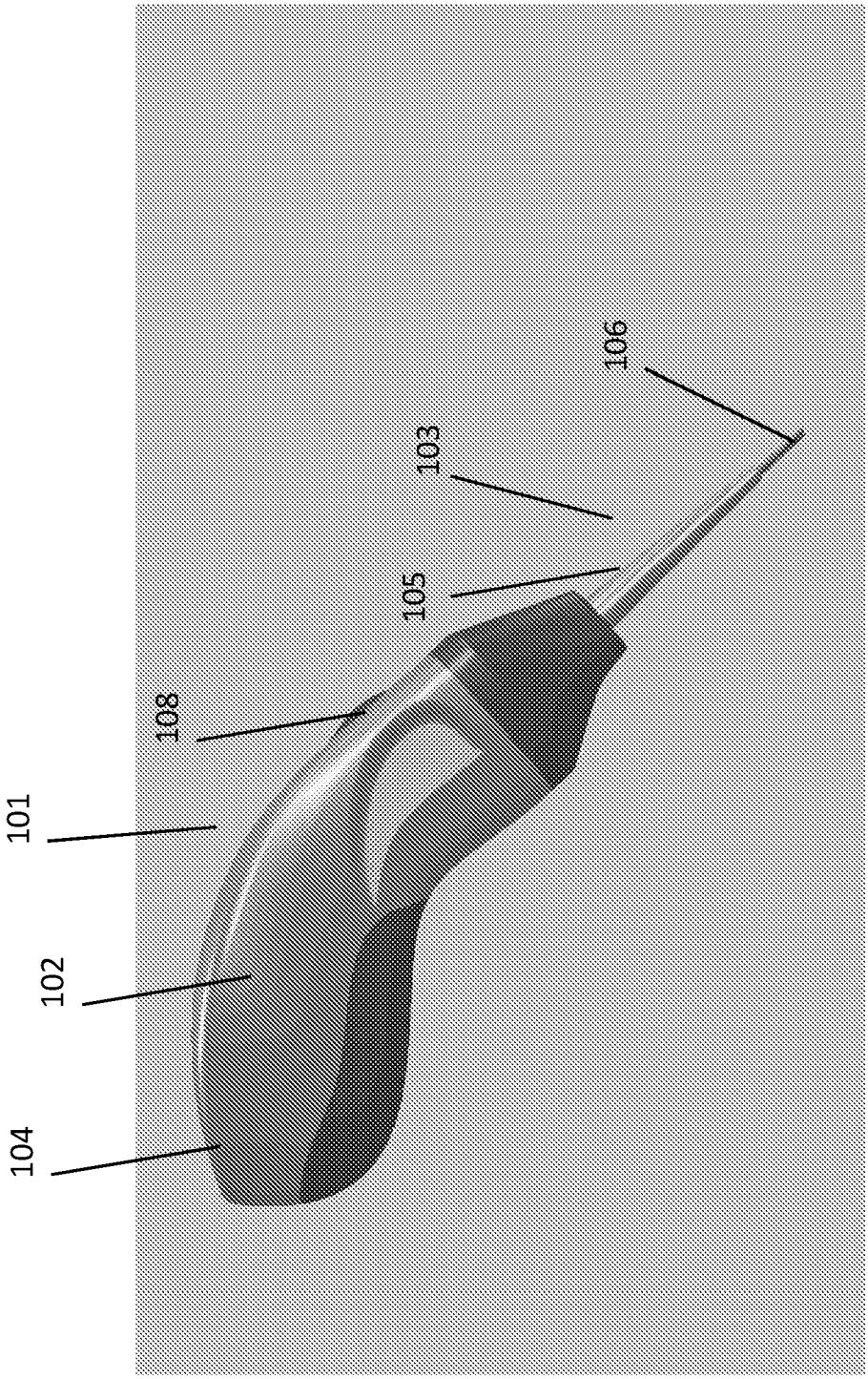


Fig. 10

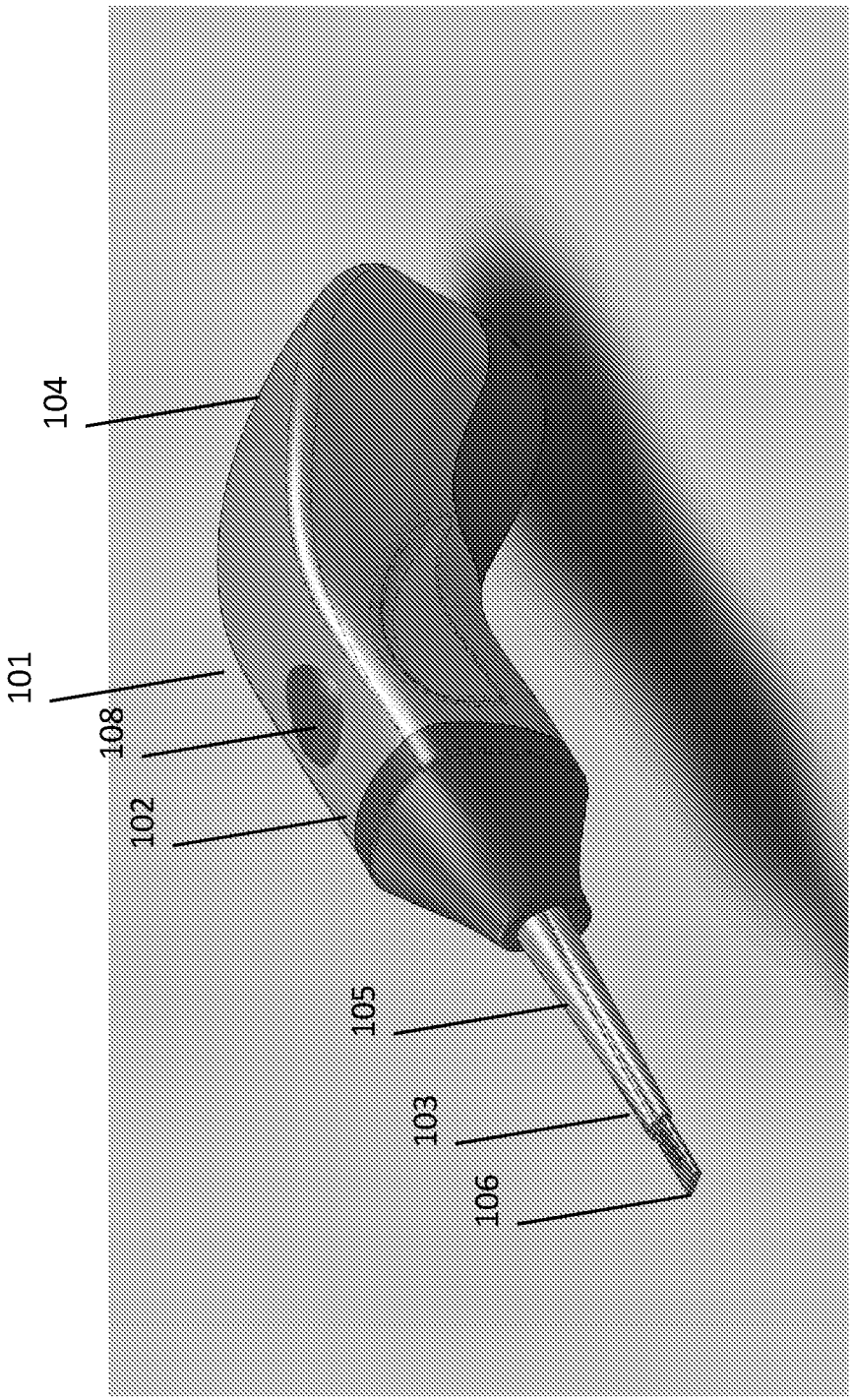


Fig. 11

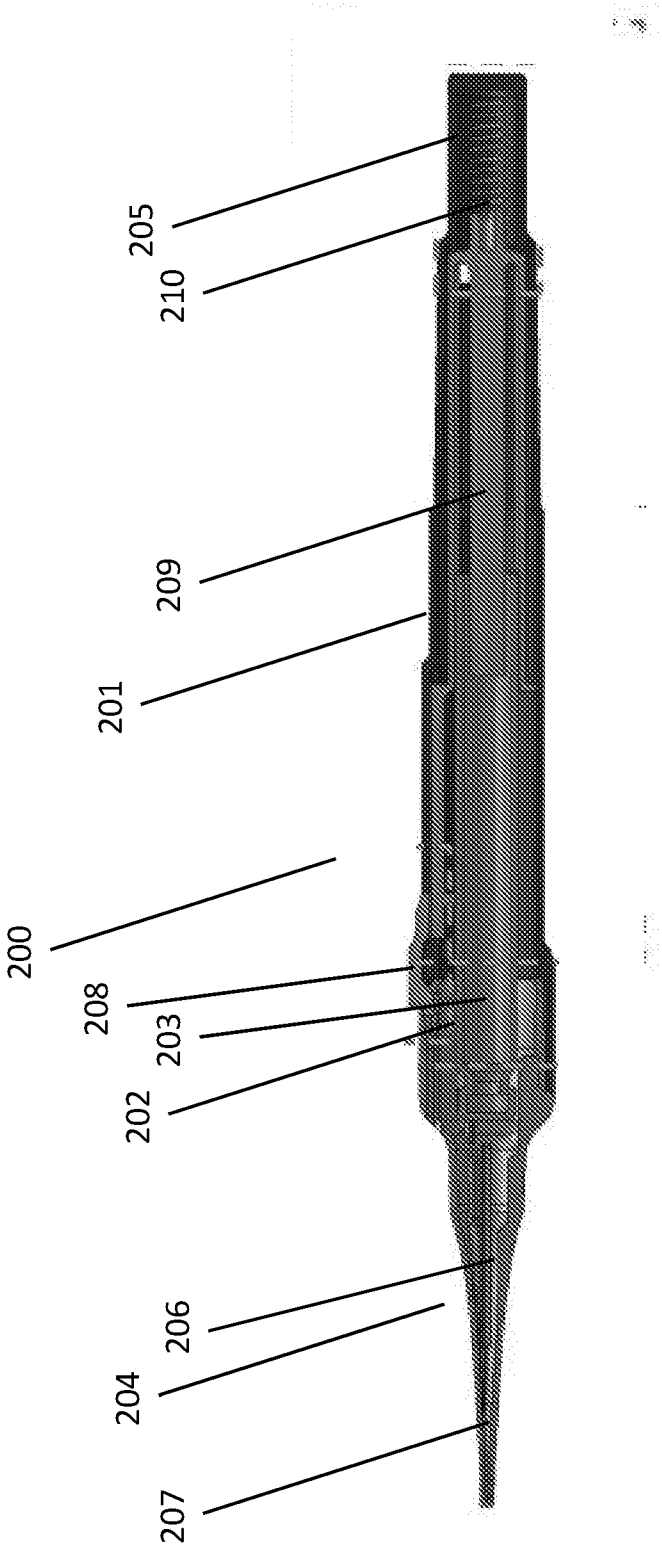


Fig. 12

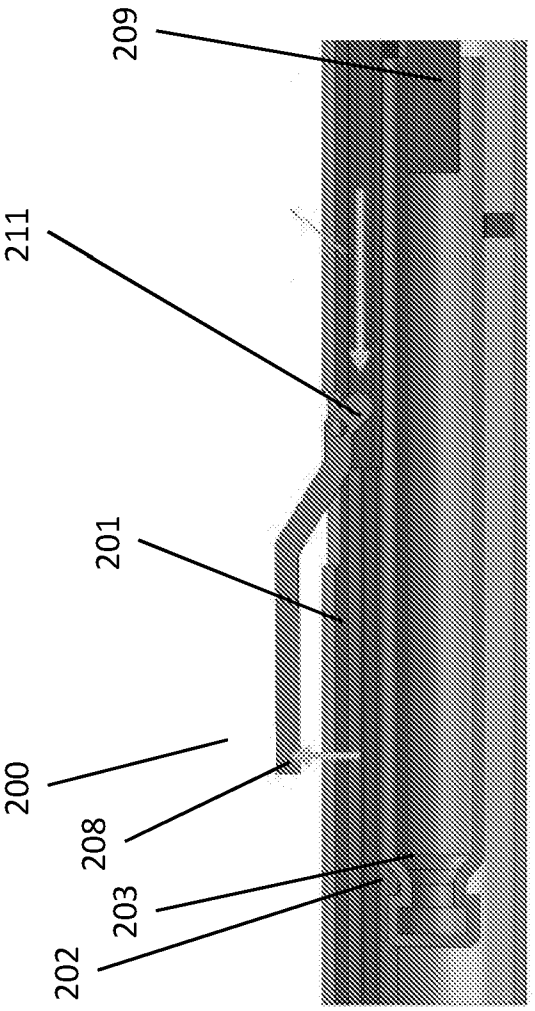


Fig. 13

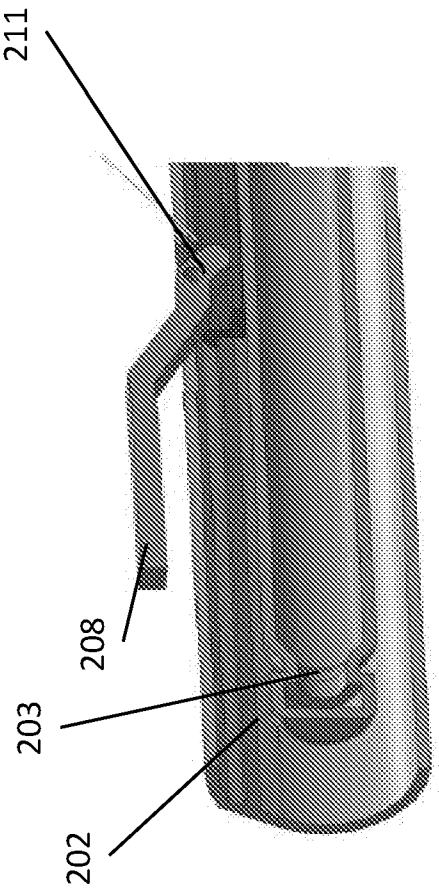


Fig. 14

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/050444

A. CLASSIFICATION OF SUBJECT MATTER

A61M 5/24 (2006.01) A61M 5/315 (2006.01) A61M 5/48 (2006.01)

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)

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)

Google Scholar/PubMed- keywords: therapeutic/treatment, applicator, gel, nerve/intraneural, surgery/repair/damage, drug, deliver/delivery/inject, syringe/driver, treatment, nerve/intraneural (and like terms in various combinations)

Google Patents- keywords: intraneural/'neural block'/nerve, deliver, therapeutic, ampoule/ampule/vial/cartridge, syringe, single, drug, pen, pierce, gel, inject/or, pharmaceutical (and like terms in various combinations)

WPIAP/EPODOC- CPC/IPC: A61M5/3158, A61M 5/2459, A61M 5/2455, A61M 2005/247, A61M 5/484, A61M 5/24, A61M 5/28 and keywords: cartridge, pierce, gel (and like terms in various combinations)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [ ] See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"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
24 August 2016	24 August 2016
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au	Emma Francis AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0399359631

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/AU2016/050444**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2013/0211330 A1 (PEDERSEN et al.) 15 August 2013 See Abstract, Figures 2A-2B, [0053], [0073]-[0074], [0082], [0084] & [0088]	1-7, 9-11, 13-15
X	US 2012/0041379 A1 (MACARTHUR et al.) 16 February 2012 See Abstract, Figures, [0015] & [0048], [0062]	1-7, 9-11, 13-15
X	US 2009/0264828 A1 (DETTE et al.) 22 October 2009 See Abstract, Figures 1-5 & 19, [0041]-[0042], [0064], [0067]	1-7, 9-15
X	US 2012/0041384 A1 (FINKE et al.) 16 February 2012 See Abstract, Figure 1A &1C & 6, [0003], [0040]-[0043]	1-7, 9-10, 12-13 & 15
X	US 2011/0166512 A1 (BOTH et al.) 07 July 2011 See Abstract, Figure 18 & [0004], [0041]-[0043]	1-10, 13-15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU2016/050444

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:

because they relate to subject matter not required to be searched by this Authority, namely:

the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☐ Claims Nos.:

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☒ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT	International application No. PCT/AU2016/050444

Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-15 are directed to a delivery device for delivering a gel or liquid pharmaceutical to a treatment site.. The feature of the body of the device including a cavity for retaining a pre-assembled cartridge is specific to this group of claims.

- Claims 16-22 are directed to a device for applying a therapeutic substance to a nerve comprising a reservoir and a plunger.. The feature of the plunger being biased to adopt a release motion in which the therapeutic substance is expelled from the reservoir through the outlet and the plunger being retained relative to the reservoir by a retainer is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a priori*.

It is considered that search and examination for the second invention will require more than negligible additional search and examination effort over that for the first invention and therefore an additional search fee is warranted.

摘要

以某些形式公开用于将凝胶或液体药物输送到治疗部位的输送装置，该输送装置包括从输送尖端延伸的主体，主体限定用于保持药物或保持容纳药物的预组装配药筒的空腔；以及用于将药物从配药筒机械地排放到输送尖端的驱动器。在一些形式中，驱动器应用于释放一致的药物流。在一些形式中，输送装置偏置成释放装置。