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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
12 November 2015 (12.11.2015)

WIPO | PCT

(10) International Publication Number
WO 2015/171964 A1

(51) International Patent Classification:
A61M 5/30 (2006.01)

(21) International Application Number:
PCT/US2015/029794

(22) International Filing Date:
7 May 2015 (07.05.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/990,003 7 May 2014 (07.05.2014) US

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(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,

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(54) Title: NEEDLE FREE INJECTION DEVICE

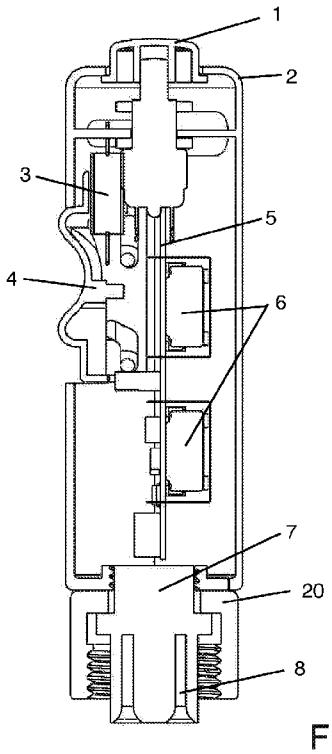


Fig 1

(57) Abstract: Devices, systems and methods for needle free injection include a multi-use needle-free injection device comprising reversibly connected proximate and distal sections, wherein the proximate section comprises a power supply, actuator, circuitry and a housing, and the distal section comprises a disposable nozzle tip prefilled with an injectate, a chemical energetic device, and a dual seal piston barrier between the energetic device and the injectate, wherein the proximate and distal sections and their components are operably linked and configured for single-hand injecting of the injectate.

WO 2015/171964 A1

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))*

Needle Free Injection Device

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This application claims priority to Ser No. 61/990,003; filed May 07, 2014.

Introduction

[01] Many prior needle free injectors are heavy and difficult to use because of large springs or compressed gas chambers necessary to generate pressure, not configured to use prefilled vials, require complicated steps to use, insufficiently robust for repetitive field use, and/or incapable of diverse injection modalities (e.g. intramuscular, subcutaneous and intradermal).

[02] Addressing these limitations we developed Variable, Injector, Safe, Tailorable, Affordable (VISTA) jet needle free injection technology. The VISTA-jet is simple, easy to use, tailorable, and safe. Anyone using a syringe or needle free injection device can benefit from the easy to use and safe VISTA-jet, including field medics, doctor, nurse, diabetic, veterinarian, emergency personnel (EMT, firefighter, police, ER personnel, nursing home staff, etc.

Summary of the Invention

[03] The VISTA-jet is a safe, easy-to-use needle free injector configured with prefilled disposable tips. The device does not use needles, but rather pressurizes the injectate (e.g. drug/medicine) that exits through a nozzle in a high velocity microjet that penetrates the skin. The bottom end of the device comprises a prefilled disposable tip, typically plastic, that contains the injectate and a hole for a nozzle. A small energetic device is sealed into the disposable tip with electric leads protruding. Also in the tip is a dual seal piston, as a barrier between the energetic device and the injectate. The amount of energetic material, initial expansion volume, and nozzle configuration can be drug specific and designed to penetrate to different depths in tissue. The disposable nozzle tip may be contained in a safety sleeve, typically a metal like stainless steel or aluminum or durable plastic, that may lock into the top of the device, such as with a connector. Such connector may be a bayonet style connector and/or comprise pins protruding from the sleeve that align and reversibly lock into the top end of the device, such as by rotating a lock ring with angled channels. The electrical leads for the energetic device connect to the top end via pin connectors. The top end includes a power supply, such as batteries, circuitry including capacitors, and switches. When the switches are activated, charged

capacitors discharge current that activates the energetic device. Once activated, the resultant pressure gradient moves the piston to pressurize the injectate, which exits out the nozzle and can then penetrate the skin. Everything on the VISTA-jet is designed to be reusable for multi-use injections with the exception of the disposable tips which are designed for a one time use.

[04] Our hand-held drug delivery system provides numerous innovations, including all combinations of:

[05] -energetic source to deliver doses with required speed and penetration;

[06] -nozzle designs configured to control dosage depth, spread and distribution;

[07] -dual-seal piston design configured to prevent contamination between injections;

[08] -housing design that can be integrated with other hand-held devices and/or include functionalities, such as a light, GPS, camera, phone, etc;

[09] -inter-changeable, pre-loaded tips that can be coded by color, shape or other feature to enable safe and reliable selection of injectate and dosage, even in low light conditions;

[10] -single shot delivery of multiple injectates that are prefilled in separate compartments of the disposable nozzle… the delivery could be through a single orifice where the drugs or injectants are mixed just before delivery or through multiple orifices in close proximity at the tip of the disposable nozzle;

[11] -safety enhanced by two-button operation to limit accidental injections, such as self-injections;

[12] - configured/configurable to wirelessly identify unit dose of injectant loaded in the device as well as the patient/provider (armbands/badge); and comprise a lock-out feature to improve safety, wherein if not the correct med/patient/time/etc., the device locks and will not administer the injectant;

[13] - configured/configurable to wireless interface to enable communication of administered medicines to electronic health records;

[14] -disposable nozzle tips prefilled with a drug or other injectant, such as medicament, vaccine, nanoparticle sensors, etc.;

[15] -a wide variety of nozzles and drugs can be used in the same VISTA-jet device;

[16] -different drugs can be in different nozzles with different volumes and a respective design for different depths of injections, including angled nozzles for shallow large area injections of nanoparticle sensors;

[17] -a chemical energetic device contained and used in each nozzle to create pressure (instead of a large spring or compressed gas), such as a pyrotechnical initiator including a pyrogen, such as a metal oxidizer, e.g. zirconium potassium perchlorate (ZZP), boron-potassium nitrate (BPN or BKNO3), aluminium-potassium perchlorate and titanium-aluminium-potassium

perchlorate, or a metal hydride oxidizer, e.g. zirconium hydride – potassium perchlorate (ZHPP) and titanium hydride potassium perchlorate (THPP), intermetallics such as titanium-boron, nickel-aluminum, palladium-aluminum, or others, like cis-bis-(5-nitrotetrazolato)tetraminecobalt(III) perchlorate (BNCP), lead azide, Hexamethylene triperoxide diamine (HMTD), tetrazene explosive, lead mononitro-resorcinates, lead dinitro-resorcinates, and lead trinitro-resorcinates;

[18] - injection activation by pressing a button or sensor that contains an electric switch, such as on the top or side of the VISTA-jet device;

[19] -accommodate varying skin thicknesses;

[20] -dispense injectant to pre-set delivery depths;

[21] –dispense injectant to a variety of body locations;

[22] -accommodate a plurality of medical "payloads";

[23] -operable safely in low light and tactile-limiting conditions; and/or

[24] -operable for extended periods of time without recharging or replacing power supply.

[25] In embodiments, a dye or contrast agent may be employed in the injectate to provide a marker for what was injected to hospital/EMT/medic in the field and/or remote location. The marker may be detected with visible, ultraviolet or infrared light depending on specific user needs.

[26] In embodiments, a pressure sensitive adhesive (PSA) can be placed at the end of the nozzle, which may also be color coded and/or bar coded, to assist in later clarifications of what was injected, and/or the PSA bar code affixed onto the patient's chart/skin/jacket etc., e.g. to improve continuity of care, safety, and improve ease of appropriate billing.

[27] In an embodiment the device is further configured to penetrate a thin membrane over the skin, such as chemical and biological protection suit, so that an injection can be administered without removing the user from the protective suit, preferably without affecting the usability of the suit.

[28] This embodiment incorporates a small pinpoint to the tip of the needle free injector to nick the suit and provide a pathway through the suit for the delivery of the jet of medicine. By physically initiating the pathway, the needle free jet of medicine is able to penetrate the suit and the underlying skin of the patient without causing significant openings in the suit.

[29] The pinprick is typically colocated with the injection nozzle aperture so that the injection can pass through the hole provided by the pinprick. The pinprick will not break the skin to any significant depth, but penetrate membrane materials of protective clothing. Thus, the pinprick can serve two purposes - one is to penetrate protective clothing such as chem/bip suits which typically contain a membrane that is difficult to penetrate with standard NFIDs, and the second

is to simply retain the NFID nozzle in position (mechanically) to prevent the nozzle from moving out of position during an injection.

[30] The pin prick orifice size generally matches the needle free injector orifice, typically 0.005" to 0.020", depending on application. Outside dimensions are selected to be rigid, sturdy and durable enough for field use, to provide the membrane penetration function and to avoid the disadvantages and dangers of hypodermic needles (broken needles, sharps handling procedures, etc.), and depend on the fabrication material; exemplary stainless steel, integrated pin pricks of the device are typically of about 0.5 or 1mm to about 3 or 5mm long and wide.

[31] In one aspect the invention provides a multi-use needle-free injection device comprising reversibly connected proximate and distal sections, wherein the proximate section comprises a power supply, actuator, circuitry and a housing, and the distal section comprises a disposable nozzle tip prefilled with an injectate, a chemical energetic device, and a dual seal piston barrier between the energetic device and the injectate, wherein the proximate and distal sections and their components operably linked and configured for single-hand injecting of the injectate.

[32] Embodiments include:

[33] - wherein the disposable nozzle tip is circumscribed with a metal sleeve or shroud, and a bayonet connector comprising pins protruding from the sleeve or shroud aligns and locks onto the proximate section, such as by rotating a lock ring with angled channels or by snap-locking an elastic retaining clip.

[34] - wherein the actuator is a button activated electric switch.

[35] - wherein the proximate section further comprises a second safety switch configured to reduce or eliminate unintended injections/misfires

[36] - wherein the proximate section further comprises connector components configured to make electric and mechanical connection to the distal section.

[37] - wherein the distal section comprises a disposable cartridge containing the nozzle, energetic device and piston barrier.

[38] - wherein the nozzle tip comprises a non-hypodermic pin prick configured to penetrate a protective clothing barrier membrane but not underlying skin, such as wherein the pin prick is integrated, 0.25-2 or 0.5-1.5, 0.75-1.25, 0.9-1.1 or about 1mm long, stainless steel, and/or has an orifice diameter 0.005" to 0.020".

[39] The invention also provides a kit comprising a subject device and a set of disposable nozzle tips prefilled with injectate.

[40] The invention also provides a method of using a subject device comprising pressing the distal end against skin and activating the actuator, wherein the actuator signals the power supply through the circuitry to trigger the energetic device to create a pressure gradient which

translocates the piston barrier and ejects the injectate out an orifice of the nozzle into a microjet that penetrates the skin.

[41] The invention specifically provides all combinations of the recited embodiments, as if each had been laboriously individually set forth.

Brief Description of the Figures

[42] Fig. 1 CAD details of VISTA-jet top end.

[43] Fig. 2. CAD details of VISTA-jet bottom end.

[44] Fig. 3. Different disposable tip and sleeve designs.

Detailed Description of Particular Embodiments and Examples Thereof

[45] The device generally comprises a top or proximate end (Fig. 1) which comprises a power supply (e.g. batteries), circuitry, buttons and switches and a housing, and a bottom or distal end (Fig. 2) comprising a disposable nozzle, sleeve with pins, a bayonet connector and plug.

[46] Description of CAD details of VISTA-jet bottom end (Fig 2).

[47] The energetic device, initiator, or igniter (13), for example part # CSK14276_NC (Special Devices Inc) contains 35mg of Zirconium/Potassium Perchlorate (ZPP) may be used as the energetic material to power a needle free injection device (NFID). The ZPP ignition reaction is fully contained in a sealed nozzle assembly that prevents any gasses or other products produced from the chemical reaction to escape. The nozzle assembly may be encased with a stainless steel sleeve.

[48] The ZPP is bound with Viton on a nichrome wire/heater in the igniter with two leads sticking out the back. The ZPP needs at least a temperature of 350C to ignite. The nichrome wire/heater can provide this temperature reliably with 1.2 amps for 2ms or 1.75 amps for 0.5ms.

[49] The ZPP igniters are designed to be inert from static electricity, and are safe if 0.4amps or less flows through the terminals for any amount of time. SDI does not use any anti-electrostatic equipment when handling and assured us that static electricity would never be able to set off the igniters.

[50] The plastic nozzle body (15) is machined from ultem plastic (polyetherimide), a high temperature, high strength thermoplastic that can be injection molded. The ID of the nozzle in the larger end accepts the initiator. There is an empty volume below where the initiator goes off, of slightly smaller diameter than the initiator which is the initial expansion chamber for the initiator's reaction to expand into (14). The smaller the volume, the higher the pressure the initiator will create. The volume can be modified to tailor the pressure, and the two initial engineered volumes were designed to create about 3000 psi for the low pressure design and

6000 psi for the high pressure design. Below the larger volume expansion chamber is a smaller bore (0.180") that holds the plunger (16) and the drug or injectant (17) on the other side of the plunger. At the end of the 0.180" bore is one or more orifices that are nozzles through which the drug can exit when pressurized (18).

[51] Different engineered orifices and nozzle architecture can modulate to different injection depths and spread. A single, large diameter orifice in straight out of the nozzle will inject the deepest and smaller orifices that are radial around the tip at an angle will inject shallower. The baseline designs that we have tested will be to have several nozzle configurations. Single holes that exit straight out of the nozzle tip at diameters of 6, 7, 8, 10, 12, and 16 mil. Four radial holes that exit at a 45 degree angle from the nozzle tip have successfully worked a 6 mil diameters and can be configured at larger diameters as well to increase the area of the injectant.

[52] The outside of the nozzle is tapered at an angle for ease of loading and unloading in the stainless steel sleeve. The nozzle assembly can fully contain the products and pressure from the initiator.

[53] An ultem cap (19) has holes for the initiator leads to stick through and helps hold the initiator into the nozzle. The holes are aligned to a tab that sticks out the side of the cap for aligning the leads when loading the VISTA-jet.

[54] A double plunger (16) comprises two soft silicone cups that slip over the ends of a double sided ultem plastic holder. One silicone cup seals on the initiator side and the other silicone cup seals on the drug or injectant side. When the initiator is activated, the double plunger is pushed by the gas pressure which in turn pushes and pressurizes the liquid. The double plunger keeps the gas and liquids separate and does not allow leaks.

[55] The nozzle is prefilled with a single, predetermined dose of a drug or the injectant (17). The nozzle may be sterilized and filled in a sterile environment. A sterile cap can cover the end of the nozzle keeping it sterile for storage, to be removed immediately before using the one time use nozzle in the VISTA-jet.

[56] The one time use nozzle assembly slips into a reusable stainless steel sleeve (12). The sleeve may be used for safety, as a shield to cover the plastic nozzle in case. The sleeve has the same angled taper as the outside plastic nozzle assembly which makes for easy loading and unloading. The wide end of the sleeve has a notch in the top that accepts the tab in the cap. This aligns the electrical leads with respect to the pins that stick out the side of the sleeve. The sleeve has cylindrical section at the top with a chamfer that allows for easy loading in the plug with a small amount of clearance to the inner diameter of the plug. The nozzle tip sticks out the end of the sleeve so the sterile nozzle tip can make contact with the skin.

[57] The plug (11) is stainless steel and accepts the sleeve. The plug has two slots in the side that guide the sleeve pins and keep them from rotating so the electrical leads in the nozzle assembly are in the correct orientation. The plug has two chamfered holes that allow the electrical leads to stick through. The plug also as alignment pins to guide the integration part so the connectors sticking out of the integration part are correctly oriented to stick in the plug counter bores. The plug also has a shelf for the lock ring to rest on and threads for the top end slip ring to screw onto, to connect the top end to the bottom end. On the bottom of the plug is some elastic material to preload the nozzle and sleeve slightly when it is locked into place to keep it there. An O-ring is currently used but could be other material, such as a spring or foam.

[58] The lock ring (10) is stainless steel with channels that guide the sleeve pins when twisted, a bayonet style connector. Twisting the lock ring one way will pull up the sleeve and lock it and the nozzle assembly into place. To release the sleeve and nozzle assembly, rotate the lock ring the opposite way. The channels start straight at the lower end of the lock ring to accept the sleeve and nozzle assembly, and are angled near the top to pull the sleeve up when rotated. The finished position has a small bump that the pins have to slide over and the resting position is stable (so it will not rotate by itself). Exterior surfaces, particularly of the lock ring, may be decorated with traction patterns and/or ribs to increase grip.

[59] The disposable tip and/or sleeve may be configured in a variety of operable designs, depending on application, such as shown in embodiments (1)-(9) in Fig 3.

[60] Description of CAD details of VISTA-jet top end (Fig 1).

[61] The integration part (7) houses the female connectors for the initiator leads (9 in Fig 2) and mating alignment holes for the plug pins to guide the connectors into the plug counter bores. The integration part screws into the top of the top end body and has a shoulder to hold the slip ring on. The first prototype was 3D printed out of UV curable material, however aluminum provides a more robust fabrication.

[62] The slip ring (20) screws onto the top of the plug, holds the integration part against the plug, and holds the top end to the bottom end as well. The first prototype was 3D printed out of UV curable material, however aluminum provides a more robust fabrication. This is designed to screw on to the plug and not ever be removed, so thread sealer should be used.

[63] The housing (2) for the top end is 3D printed for the initial prototypes as well, however aluminum provides a more robust fabrication. The housing accepts the threads from the integration part on the bottom. It also houses the circuit board, the injection switch and push button on the top, and the charging switch on the side.

[64] The circuit board (5) is a custom designed and made board that mounts the capacitors, charging circuit, battery holders, batteries (LR44) (6), and shorting/charging switch.

[65] The side button (4) is an arming switch for safety. It is designed with slots that ride on pins in the housing and it can activate a single pole double throw switch on the circuit board. The default state is spring loaded in the up and out position, and the switch shorts the connectors that accept the initiator for safety. When the side button is pushed down and in, it activates switch on the circuit board to charge the capacitors in the circuit, which arms the device to make it ready to fire.

[66] The push button switch (1) is on the top of the device and when pushed, can fire the device. If it is pushed when the side button switch is not activated, nothing will happen.

[67] Disposable nozzle assembly.

[68] The initiators are one-time use and are sealed in the disposable plastic nozzle with the leads sticking through a cap. The initiators may be sealed in the nozzles, such as with epoxy (e.g. 3M DP460NS), but may also be sealed in the plastic when the nozzles are created by injection molding.

[69] To prep for assembly, the end of the nozzle, bottom side of the cap, and outside diameter of the initiator are sanded with a rough sandpaper (such as 100 or 200 grit). All parts are cleaned with isopropyl alcohol and the nozzle orifice(s) are ensured not to be clogged. Silicone mold release (Jet Lube) is applied to the smaller inner bore (.180") of the nozzles with a Comfort-In plunger going all the way down to the nozzle end. Silicone mold release is also applied on the outside of the double plunger.

[70] To fill nozzles with the injectant, the .180" bore is slightly overfilled filled with the injectant in the vertical orientation and a double plunger is pushed into the bore using a rod with a slightly smaller bore. The plunger is pushed to a specific depth into the bore leaving a predetermined volume of injectant in the bore. While pushing the plunger down, the rest of the injectant exits the nozzle and no air is allowed in. Once the plunger is in the correct location, a cover is placed over the nozzle end. The current process uses electrical tape and is not sterile. The future manufacturing plan would be to sterilize everything before this step and fill in a sterile environment. The larger bore chamber and sanded nozzle ends are rewashed with isopropyl alcohol.

[71] To seal in the initiator, the leads are placed through the holes in the cap with the sanded side toward the initiator and at least a .2" gap between the back of the initiator and cap. 3M DP460NS epoxy is applied (at least 1/16" thick) around the outside diameter of the initiator and at least a 0.2" diameter amount is applied between the initiator and cap. The initiator with epoxy is loaded into the nozzle body by holding the sides of the cap while twisted the cap and initiator 360 degrees. The epoxy uniformly fills the gap between the initiator outer diameter and nozzle inner diameter and the extra epoxy flows back towards the cap (not into the bore). The end of

the initiator seats on the larger bore of the nozzle body and the cap is pushed to the nozzle end with slight pressure (~1 pound of force) which leaves about a 10-15 mil bond line of the epoxy. The extra epoxy flows out sides between the nozzle and cap and is wiped away. A 1ml syringe with 25 gauge needle tip is filled with the epoxy the side vent hole of the nozzle is filled. The nozzles are left upright in a glass scintillation vial to cure for a minimum of 48 hours and ideally 72 hours or longer.

[72] The nozzle assemblies are currently made and assembled by hand. The future manufacturing vision is to injection mold the nozzle body and caps in two pieces. The initiator can be injection molded and sealed in the cap end, such as in nylon injection mold. The plunger is added in the other end, sterilized, filled with the drug, and capped in a sterile environment. The two halves are joined with an adhesive or solvent, depending on what material is chosen.

[73] In embodiments the nozzle assembly is color coded, bar coded, and or labeled with large easy to understand letters (for example, M for morphine).

[74] Usage.

[75] This device is easy to use and can be operated with no gloves, latex gloves, or even thick combat gloves.

[76] To load the device, rotate the lock ring to release the sleeve. Remove the tape from the nozzle end load the nozzle into the sleeve aligning the tap sticking out on the cap with the notch in the top of the sleeve. Load the sleeve and nozzle into the plug, aligning the sleeve pins with the plug and lock ring notches. Rotate the lock ring so the sleeve pins click into place, which ensures the nozzle and sleeve are properly loaded.

[77] To make an injection, push the side button down and in to arm the device. While holding the side button in that position, press the top button to cause the injection. When making an injection, make sure to hold the nozzle tip in contact the skin (or other substrate) with light pressure. Do not move slide the nozzle on the skin when making an injection, hold it stationary and normal to the skin.

[78] To unload, rotate the lock ring to release the sleeve and nozzle assembly. Tap or push the nozzle tip to release the used plastic nozzle assembly and discard in the appropriate manner. The device is now ready to be loaded with another nozzle assembly.

[79] Testing, characterization, and performance of the device.

[80] A working prototype of the VISTA-jet has been tested and validated, including: injecting on a load cell to measure the force of the micro jet over time, injecting in gel, and injecting in deceased and harvested animal tissue.

[81] By injecting on a load cell with nozzle tips that are normal to the surface, the load cell can measure the force from the fluid stream over time at a high data rate. Pressure can be

calculated from the force of the stream as well as velocity and jet power. Jet power directly relates to the depth of injections and the jet power can be compared to other COTS NFID's. Validated data include measures of force, pressure, velocity, and jet power over time of a lower pressure nozzle of the VISTA-jet designed to inject to a shallower depth to a higher jet power COTS NFID device.

[82] 20% polyacrylamide gel (in water) is a consistent and uniform substrate that can be used to characterize different nozzles and injections. It's clear, cheap, and easy to mix and the injection depths and spread can be measured. Typically, an injection from a NFID device injects in a narrow channel then at a certain depth blooms or spreads out in one or more planes. This is likely because the gel is not porous, and once the gel rips, there is a stress concentration at that rip and the fracture can propagate along that plane.

[83] We also performed test injecting in deceased and harvested animal tissue, such as Wistar rat skin. The skin was previously frozen for storage and is thawed, placed on top of a compliant substrate to simulate muscle tissue, and injected. The VISTA-jet was compared to a COTS device by injecting on the rat skin. The purpose of the VISTA-jet nozzle that were tested was to spread out the injectant (blue food coloring in water) in a larger area than the COTS device, which is exactly what it did.

[84] The invention encompasses all combinations of recited particular and preferred embodiments. It is understood that the examples and embodiments described herein are for illustrative purposes only and that various modifications or changes in light thereof will be suggested to persons skilled in the art and are to be included within the spirit and purview of this application and scope of the appended claims. All publications, patents, and patent applications cited herein, including citations therein, are hereby incorporated by reference in their entirety for all purposes.

WHAT IS CLAIMED IS:

1. A multi-use needle-free injection device comprising reversibly connected reusable proximate and disposable distal sections,

the proximate section comprising components: a power supply, actuator, circuitry and a housing;

the distal section comprising components: a disposable nozzle tip prefilled with an injectate, a chemical energetic device, and a dual seal piston barrier between the energetic device and the injectate; and

the proximate and distal sections and their components operably linked and configured for single-hand injecting of the injectate.

2. The device of claim 1 wherein the disposable nozzle tip is circumscribed with a metal sleeve or shroud, and a bayonet connector comprising pins protruding from the sleeve or shroud aligns and locks onto the proximate section, such as by rotating a lock ring with angled channels or by snap-locking an elastic retaining clip.

3. The device of claim 1 wherein the actuator is a button activated electric switch.

4. The device of claim 1 wherein the proximate section further comprises a second safety switch configured to reduce or eliminate unintended injections/misfires

5. The device of claim 1 wherein the proximate section further comprises connector components configured to make electric and mechanical connection to the distal section.

6. The device of claim 1 wherein the distal section comprises a disposable cartridge containing the nozzle, energetic device and piston barrier.

7. The device of claim 1 wherein the nozzle tip comprises a non-hypodermic pin prick configured to penetrate a protective clothing barrier membrane but not underlying skin.

8. The device of claim 1 wherein the nozzle tip comprises a non-hypodermic pin prick configured to penetrate a protective clothing barrier membrane but not underlying skin, wherein the pin prick is integrated, 0.25-2 or 0.5-1.5, 0.75-1.25, 0.9-1.1 or about 1mm long, stainless steel, and/or has an orifice diameter 0.005” to 0.020”.

9. A kit comprising the device of claim 1 and a set of disposable nozzle tips prefilled with injectate.

10. A method of using the device of claim 1 comprising pressing the distal end against skin and activating the actuator, wherein the actuator signals the power supply through the circuitry to trigger the energetic device to create a pressure gradient which translocates the piston barrier and ejects the injectate out an orifice of the nozzle into a microjet that penetrates the skin.

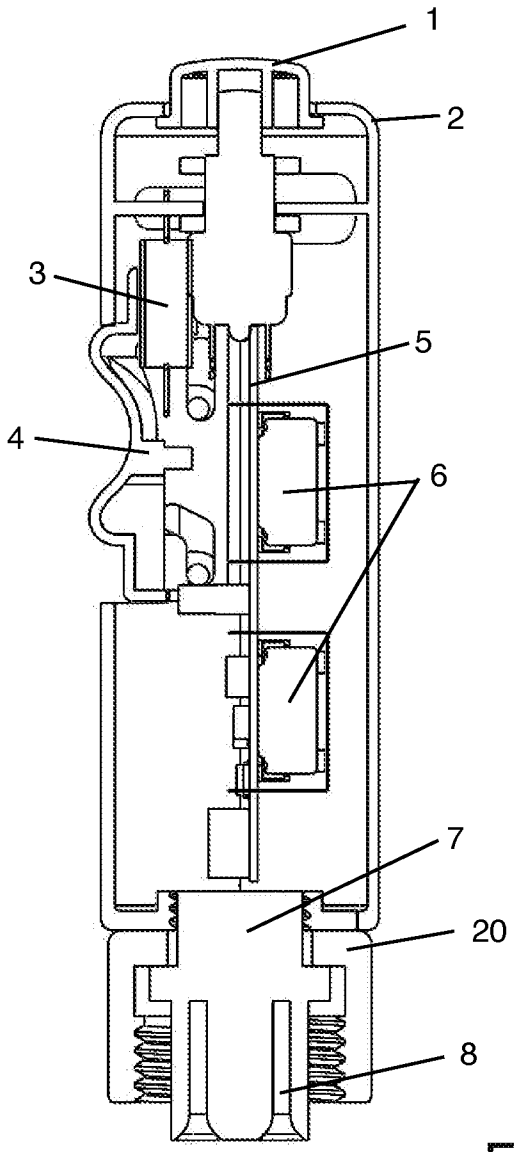


Fig 1

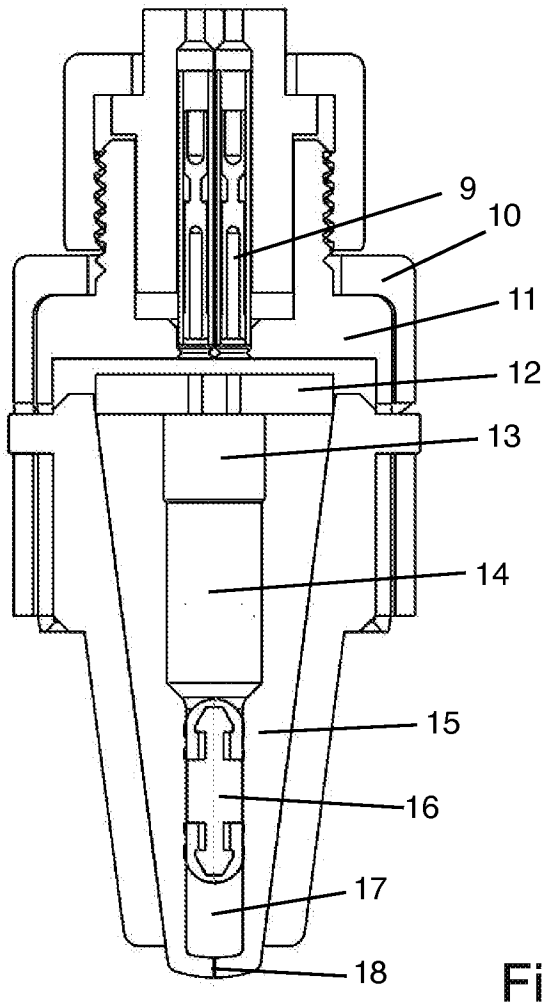
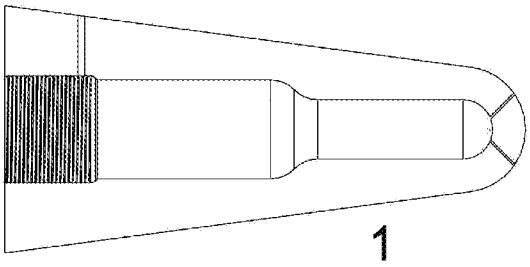
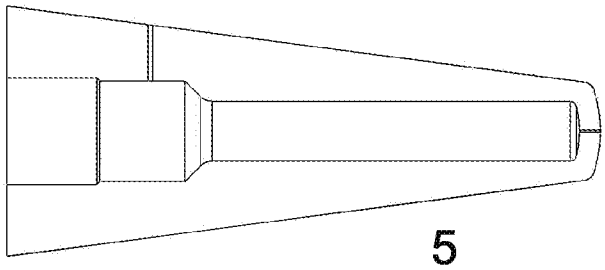
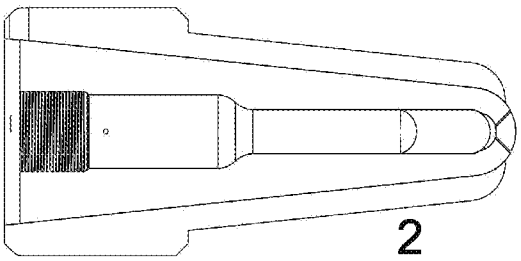
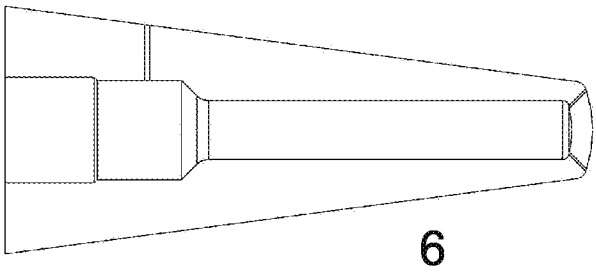


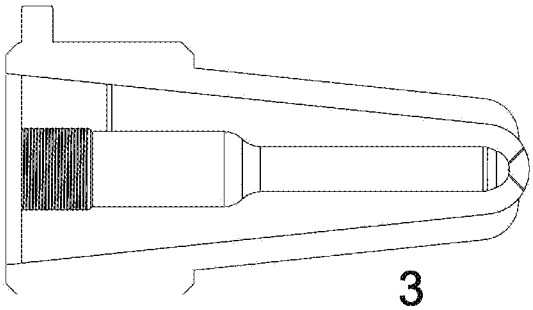
Fig 2

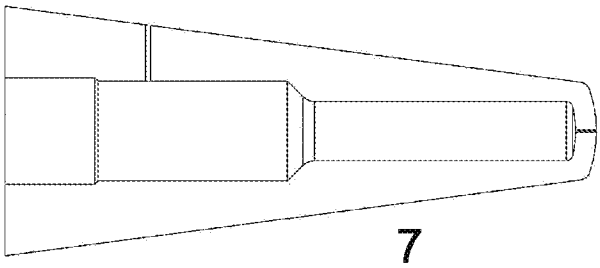


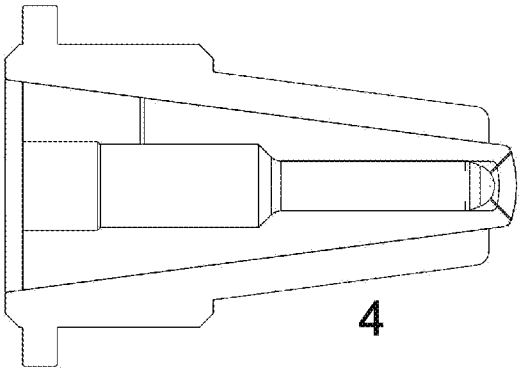


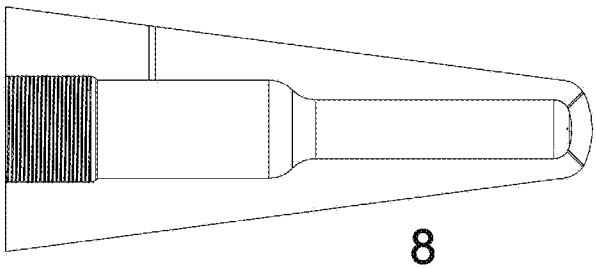












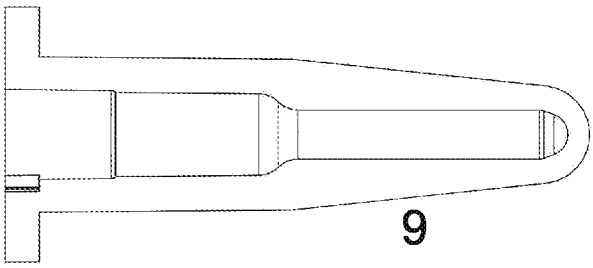


Fig 3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/029794

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/30 (2015.01)
CPC - A61M 5/30 (2015.07)
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)
IPC(8) - A61M 5/20, 5/24, 5/30, 5/31, 5/315 (2015.01)
CPC - A61M 5/2033, 5/2053, 5/24, 5/30, 2005/2073 (2015.07)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/68, 69, 70, 140, 187 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Scholar
Search terms used: multi use needle disposable tip injectate nozzle needleless needle free cap end

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0036868 A1 (PINEDJIAN et al) 05 February 2009 (05.02.2009) entire document	1-10
Y	US 2010/0324531 A1 (HENEVELD et al) 23 December 2010 (23.12.2010) entire document	1-10
Y	US 2007/0275044 A1 (POTTER et al) 29 November 2007 (29.11.2007) entire document	1-10
A	US 2004/0158196 A1 (GARITANO et al) 12 August 2004 (12.08.2004) entire document	1-10
A	US 2002/0188248 A1 (BELLHOUSE et al) 12 December 2002 (12.12.2002) entire document	1-10

☐ 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
22 July 2015	07 AUG 2015
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774