#### (19) DANMARK

#### (10) **DK/EP 2814446 T3**



(12)

# Oversættelse af europæisk patentskrift

#### Patent- og Varemærkestyrelsen

(56)

Fremdragne publikationer: EP-A1- 2 351 548 WO-A1-2009/112489 US-B1- 6 364 866

(51)Int.Cl.: A 61 J 1/20 (2006.01) (45)Oversættelsen bekendtgjort den: 2016-12-19 (80)Dato for Den Europæiske Patentmyndigheds bekendtgørelse om meddelelse af patentet: 2016-09-14 (86)Europæisk ansøgning nr.: 13721118.1 Europæisk indleveringsdag: 2013-04-07 (86)(87)Den europæiske ansøgnings publiceringsdag: 2014-12-24 (86)International ansøgning nr.: IL2013050313 (87)Internationalt publikationsnr.: WO2013150538 (30)Prioritet: 2012-04-05 IL 21906512 Designerede stater: AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV (84)MC MK MT NL NO PL PT RO RS SE SI SK SM TR Patenthaver: Medimop Medical Projects Ltd., 17 Hatidhar St., P.O. Box 2499, 43665 Ra'anana, Israel (73)(72)Opfinder: LEV, Nimrod, 1 Havradim Street, 56905 Savion, Israel BEN SHALOM, Niv, 4/24 Asher Street, 42524 Netanya, Israel Fuldmægtig i Danmark: Budde Schou A/S, Hausergade 3, 1128 København K, Danmark (74)Benævnelse: Fluidoverføringsindretninger med patronåbning med patronudkastningsarrangement (54)

#### DESCRIPTION

#### Field of the Invention

[0001] The invention relates to fluid transfer devices for filling a cartridge with a liquid drug dosage.

#### Background of the Invention

[0002] Auto-injectors for self-administration of liquid drugs such as insulin typically employ so-called carpules or cartridges including an open ended tube hermetically sealed by a rubber septum at a leading cartridge end and a slidable seal at an opposite trailing cartridge end. Cartridges can contain a single liquid drug dosage or a multiple liquid drug dosage. Home users are typically supplied with cartridges pre-filled with a liquid drug dosage but may be supplied with empty cartridges requiring a manual cartridge filling procedure for filling with a liquid drug dosage. The manual cartridge filling procedure includes the following steps: A user prepares a syringe with a liquid drug dosage, mounts a needle on the syringe, punctures the cartridge's rubber septum and injects the liquid drug dosage into the cartridge. The user may have an additional step of reconstituting a liquid drug dosage from a powdered medicament.

**[0003]** Commonly owned PCT International Application No. PCT/IL2007/000343 entitled Fluid Transfer Devices for Use with Cartridges and published under PCT International Publication No. WO 2007/105221 discloses fluid transfer devices discussed hereinbelow for use with needleless syringes and cartridges for assisting a manual cartridge filling procedure.

[0004] Commonly owned PCT International Application No. PCT/IL2010/000530 entitled Fluid Transfer Devices for Filling a Cartridge with Liquid Drug Dosage and published under PCT International Publication No. WO 2011/004360 discloses fluid transfer devices discussed hereinbelow for use with cartridges and vials for assisting a manual cartridge filling procedure. WO 2011/004360 discloses provisioning otherwise conventional cartridges including a slidable seal with a releasable attachment arrangement and a manual push rod for releasable attachment to the slidable seal for enabling manual displacement of same for injection and aspiration purposes. Suitable releasable attachment arrangements include *inter alia* a screw thread arrangement, and the like

[0005] Another fluid transfer device is known from WO2009/112489.

[0006] There is a need for fluid transfer devices for facilitating a manual cartridge filling procedure for filling a cartridge with a liquid drug dosage and manual sliding ejection of the filled cartridge for subsequent deployment in an auto-injector.

#### Summary of the Invention

[0007] The present invention provides a fluid transfer device as claimed in claim 1.

[0008] The present invention is directed toward fluid transfer devices for use in manual cartridge filling procedures for filling cartridges with liquid drug dosages from medicament containing vials. The fluid transfer devices include a double ended main body having a longitudinal axis, a vial port for telescopic receiving a drug vial and a cartridge port for slidingly receiving a leading cartridge end. The cartridge ports include a cartridge securing arrangement for releasably securing a leading cartridge end in a cartridge port and a cartridge ejection arrangement for at least partially ejecting a filled cartridge therefrom for assisting its complete sliding ejection. The fluid transfer devices preferably include a pair of outward transverse directed finger supports for enabling a user to use them in a similar manner as a syringe.

[0009] Cartridge ports can include a combined cartridge securing and ejection arrangement including one or more lever members for securing a cartridge in a cartridge port and imparting a levering action for at least partially ejecting a filled cartridge therefrom. Alternatively, the cartridge ports can include a discrete cartridge securing arrangement and a discrete cartridge ejection arrangement. Such a discrete cartridge ejection arrangement can include one or more cartridge ejection members which are biased into a primed state on manual sliding insertion of a cartridge into a secured position in a cartridge port. On manual release of the cartridge securing arrangement, the one or more cartridge ejection members revert to their unbiased state for at least partially ejecting a filled cartridge from a cartridge port.

#### **Brief Description of Drawings**

**[0010]** In order to understand the invention and to see how it can be carried out in practice, preferred embodiments will now be described, by way of nonlimiting examples only, with reference to the accompanying drawings in which similar parts are likewise numbered, and in which:

- Fig. 1 corresponds with hitherto mentioned PCT International Publication No. WO 2007/105221 Figure 2;
- Fig. 2 corresponds with hitherto mentioned PCT International Publication No. WO 2007/105221 Figure 5;
- Fig. 3 corresponds with hitherto mentioned PCT International Publication No. WO 2011/004360 Figure 2;
- Fig. 4 corresponds with hitherto mentioned PCT International Publication No. WO 2011/004360 Figure 6;

Fig. 5 is a pictorial representation of a kit including a pre-filled cartridge, a push rod, a drug vial and a fluid transfer device having a combined cartridge securing and ejection arrangement in accordance with a first preferred embodiment of the present invention:

- Fig. 6 is an exploded view of Figure 5's fluid transfer device;
- Fig. 7 is a front elevation view of Figure 5's fluid transfer device with its combined cartridge securing and ejection arrangement in an initial cartridge insertion position;
- Fig. 8A is a longitudinal cross section of Figure 5's fluid transfer device along line A-A in Figure 7;
- Fig. 8B is an enlarged view of the encircled area in Figure 8A showing a leading lever member end of the combined cartridge securing and ejection arrangement;
- Fig. 9 is a front elevation view of Figure 5's fluid transfer device with its combined cartridge securing and ejection arrangement in a final cartridge ejection position;
- Fig. 10 is a longitudinal cross section of Figure 5's fluid transfer device along line B-B in Figure 9;
- Fig. 11A is longitudinal cross section of Figure 5's fluid transfer device showing a cartridge secured in its combined securing and ejection arrangement;
- Fig. 11B is an enlarged view of the encircled area in Figure 11A showing the securing of the leading cartridge end;
- Fig. 12 is a longitudinal cross section of Figure 5's fluid transfer device showing partial ejection of the cartridge from the cartridge port;
- Figs. 13A to 13H show the use of Figure 5's fluid transfer device for filling a cartridge with a reconstituted liquid drug dosage;
- Fig. 14 is a front perspective view of a fluid transfer device including a combined cartridge securing and ejection arrangement in accordance with a second preferred embodiment of the present invention;
- Fig. 15A is a longitudinal cross section of Figure 14's fluid transfer device along line C-C in Figure 14 on sliding insertion of a cartridge into its cartridge port;
- Fig. 15B is a longitudinal cross section of Figure 14's fluid transfer device along line C-C in Figure 14 on manual operation of its combined cartridge securing and ejection arrangement for at least partially ejecting the cartridge from the cartridge port;
- Fig. 16 is a front perspective view of a fluid transfer device including a discrete cartridge securing arrangement and a discrete cartridge ejection arrangement in accordance with a third preferred embodiment of the present invention;
- Fig. 17 is a longitudinal cross section of Figure 16's fluid transfer device along line D-D in Figure 16; and
- Fig. 18 is a longitudinal cross section of Figure 16's fluid transfer device along line D-D in Figure 16 on sliding insertion of a cartridge into its cartridge port to prime its cartridge ejection arrangement.

#### **Detailed Description of Preferred Embodiments of the Invention**

**[0011]** Figure 1 corresponds with hitherto mentioned WO 2007/105221 Figure 2 showing a fluid transfer device 30 including a double ended main body 31, a longitudinal axis 32, a syringe port 33 for receiving a needleless syringe and a cartridge port 34 for telescopically receiving a cartridge.

**[0012]** Figure 2 corresponds with WO 2007/105221 Figure 5 showing a fluid transfer device 50 similar in construction and operation to the fluid control device 30 with rotationally detachable vial adapters as disclosed in commonly owned US Patent No. 6,238,372 to Zinger et al.'s Figures 11 to 15.

[0013] Figure 3 corresponds with WO 2011/004360 Figure 2 showing a fluid transfer device 40 including a double ended main body 42 having a cartridge port 43 for sliding receiving a cartridge's leading end and a vial port 44 for snap fitting onto a vial.

**[0014]** Figure 4 corresponds with WO 2011/004360 Figure 6 showing a fluid transfer device 60 including a male connector 61, an open ended cartridge holder 62 for slidingly receiving a cartridge and a finger operated cartridge snap fit arrangement 63 for initially snap fitting onto a cartridge on its sliding insertion into the cartridge holder 62 and enabling a user to manually release the cartridge for enabling the cartridge to be freely slidingly withdrawn from the cartridge holder 62.

**[0015]** Figure 5 shows a kit 100 including a pre-filled cartridge 110, a push rod 124 having a screw threaded leading end 126, a drug vial 130 and a fluid transfer device 140 for use in a manual cartridge filling procedure for filling the cartridge 110 with a liquid drug dosage.

[0016] Figures 6 to 12 show the cartridge 110 includes an open ended tube 111 having a longitudinal axis 112, a small diameter leading cartridge end 113, an intermediate neck 114 and a wide diameter trailing cartridge end 116. The leading cartridge end 113 is hermetically sealed by a rubber cartridge septum 117 capped by a metal band 118. The leading cartridge end 113 has a forwardmost cartridge surface 119 including an exposed 2mm to 3mm diameter circular rubber surface 119A. The trailing end 116 is hermetically sealed by a slidable seal 121. The slidable seal 121 has an exposed trailing surface 122 formed with a screw thread blind bore 123 for screw thread attachment with the push rod's screw threaded leading end 126. The cartridge 110 is prefilled with liquid contents 127. The liquid contents 127 are typically diluent for reconstituting a powder drug. Alternatively, the liquid contents 127 can include an active component.

**[0017]** The drug vial 130 includes an open topped vial bottle 131 having a longitudinal axis 132 and hermetically sealed by a vial stopper 133 capped by a metal band 134. The drug vial 130 can contain a powder or liquid drug contents 136. Powdered drug contents 136 are typically stored under negative pressure and require reconstitution prior to administration. Alternatively, the drug vial 130 can contain a liquid drug suitable for direct transfer to an empty cartridge.

[0018] The fluid transfer device 140 has a longitudinal axis 141 and includes a double ended main body 142 having a vial port 143 for telescopically receiving a drug vial 130 and a cartridge port 144 for slidingly receiving a leading cartridge end 113.

**[0019]** The vial port 143 includes a slotted skirt 146 with a plurality of flex members 147 having inwardly directed ridges 148 for snap fitting onto the drug vial 130 and a puncturing cannula 149 co-axial with the fluid transfer device's longitudinal axis 141 for puncturing the vial stopper 133 on snap fit insertion of the drug vial 130 thereinto.

**[0020]** The cartridge port 144 includes a base surface 151 formed with a pair of opposite cartridge supports 152 for providing axial support to the leading cartridge end 113 on being slidingly inserted thereinto. The cartridge port 144 also includes a puncturing member 153 for puncturing the cartridge septum 117 on sliding insertion of a leading cartridge end 113 thereinto. The puncturing member 153 is preferably constituted by a metal needle having an outer diameter of, say, about 0.5 mm. The puncturing member 153 is also co-axial with the fluid transfer device's longitudinal axis 141 and in flow communication with the puncturing cannula 149 to enable direct fluid communication between a cartridge 110 and a drug vial 130 in an assemblage of the fluid transfer device 140, the cartridge 110 and the drug vial 130. The cartridge support pair 152 has indents 154 (see Figure 10).

**[0021]** The cartridge port 144 is additionally provisioned with a combined cartridge securing and ejection arrangement 160 for releasably securing a leading cartridge end 113 therein and at least partially ejecting a cartridge 110 filled with a liquid drug dosage therefrom. The combined cartridge securing and ejection arrangement 160 includes a pair of opposite elongated lever members 161A and 161B. The lever member pair 161 extend beyond the cartridge supports 152 and are co-directional with the longitudinal axis 141 in an initial cartridge insertion position to assist guiding manual sliding insertion of the cartridge 110 into the cartridge port 144 (see Figures 5, 7 and 8A).

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[0022] The lever member pair 161A and 161B correspondingly have leading lever member ends 162A and 162B adjacent the vial port 143 and trailing lever member ends 163A and 163B remote from the vial port 143. The lever member pair 161 is pivotal on the main body 142 at their leading lever member ends 162 for being manually levered from their initial cartridge insertion position to being outwardly inclined with respect to the longitudinal axis 141 in a final cartridge ejection position (see Figures 9, 10 and 12).

[0023] The leading lever member end pair 162A and 162B have correspondingly forwardmost rims 164A and 164B, rearmost rims 166A and 166B and intermediate sections 167A and 167B. The forwardmost rims 164 have uppermost surfaces 168 and lowermost surfaces 169 respectively facing away and towards the vial port 143. The forwardmost rims 164 are formed with indents 171 for snap fit receiving pins 172 formed on the opposite cartridge supports 152 for enabling the pivotal action of the lever member pair 161. In the initial cartridge insertion position, the forwardmost rims 164 overlie the base surface 151 and define a separation therebetween which is less than the leading cartridge end 113's diameter.

[0024] The lever member pair 161 are dimensioned such that they extend midway along the cartridge 110 on its full insertion into the cartridge port 144 and its trailing lever member ends 163A and 163B are formed with outward transverse directed finger supports 173A and 173B with respect to the longitudinal axis 141 for enabling use of the fluid transfer device 140 in a similar manner as a syringe.

**[0025]** The lever member pair 161 is formed with projections 174 for engaging the indents 154 on the cartridge support pair 152 for securing the lever member pair 161 in their initial co-directional position during the sliding insertion of the cartridge 110 into the cartridge port 144.

**[0026]** Figures 11A and 11B show a forwardmost cartridge surface 119 abuts against the uppermost surfaces 168 of the forwardmost rims 164 on full insertion of its leading cartridge end 113 into the cartridge port 144 to be spaced apart from the base surface 151. Figures 11A and 11B also show the intermediate sections 167 are dimensioned such that the rearmost rims 166 snap fit onto the leading cartridge end 113 for securing purposes.

[0027] Figure 12 shows manual levering of the lever member pair 161 causes them to pivot at their leading lever member ends 162 such that their forwardmost rims 164 act against the cartridge's forwardmost cartridge surface 119 to at least partially eject the cartridge 110 from the cartridge port 144 for assisting its complete manual sliding ejection therefrom.

[0028] Figures 13A to 13H show the use of the kit 100 to reconstitute a liquid drug dosage and aspirate same into the cartridge as follows:

[0029] Figure 13A shows a user inserting a cartridge pre-filled with diluent into the cartridge port as depicted by arrow A.

[0030] Figure 13B shows a user screw threading a push rod into the pre-filled cartridge as depicted by arrow B.

[0031] Figure 13C shows a user snap fitting the vial port onto a drug vial as depicted by arrow C.

**[0032]** Figure 13D shows a user injecting the cartridge's contents into the vial for reconstitution purposes as depicted by arrow D for reconstituting the powder drug in the drug vial to form a reconstituted liquid drug LD.

[0033] Figure 13E shows the drug vial filled with the liquid drug LD.

[0034] Figure 13F shows a user inverting the assemblage of the fluid transfer device, the drug vial and the cartridge and a user aspirating the liquid drug LD into the cartridge as depicted by arrow E.

[0035] Figure 13G shows a user inverting the assemblage.

[0036] Figure 13H shows a user manually levering the lever member pair outwards relative to the longitudinal axis as depicted by arrows F to partially eject the filled cartridge from the cartridge port. The filled cartridge can be readily completely slidingly ejected from the cartridge port.

[0037] Figures 14 and 15 show a fluid transfer device 180 similar in construction and operation to the fluid transfer device 140. The former 180 differs from the latter 140 insofar as the former 180 includes an elongated cartridge port 181 extending about

midway along a cartridge 110 on its full insertion thereinto and integrally formed with a pair of outward transverse directed finger supports 182 for enabling use of the fluid transfer device 180 in a similar manner as a syringe. The fluid transfer device 180 includes a combined cartridge securing and ejection arrangement 183 with a single lever member 184 for securing and ejection purposes. The level member 184 at least partially ejects a filled cartridge 110 by urging against a leading end of its open ended tube 111 as opposed to the forwardmost cartridge surface 119 in the case of former 140.

[0038] Figures 16 to 18 show a fluid transfer device 190 similar in construction and operation to the fluid transfer device 140. The former 190 differs from the latter 140 insofar as the former 190 includes an elongated cartridge port 191 with opposite cartridge supports 192 terminating at an annular cartridge port base 193 formed with a pair of outward transverse directed finger supports 194 for enabling use of the fluid transfer device 190 in a similar manner as a syringe. The elongated cartridge port 191 is formed with a discrete cartridge securing arrangement 196 for securing a cartridge 110 in the cartridge port 191. The cartridge securing arrangement 196 is similar to WO 2011/004360 Figure 6's finger operated cartridge snap fit arrangement 63 (see Figure 4) and includes a pair of opposite flex members 197 resiliently flexibly mounted at the cartridge port base 193. The flex members 197 each have an outwardly directed finger operated member 198 and terminate in an inwardly directed ridge 199 for snap fit insertion against a cartridge's intermediate neck 114 on sliding insertion of a cartridge 110 into the cartridge port 191. Depression of the pair of finger operated members 198 towards one another as denoted by arrows G outwardly urges the inwardly directed ridges 199 thereby releasing a cartridge 110.

[0039] The fluid transfer device 190 also includes a discrete cartridge ejection arrangement 201 for selectively at least partially ejecting a cartridge 110 from the cartridge port 191 for assisting complete manual sliding ejection of a filled cartridge therefrom. The discrete cartridge ejection arrangement 201 includes at least one cartridge ejection member 202 biased into a primed state on manual sliding insertion of a leading cartridge end 113 into the cartridge port 191 into a secured position secured by the discrete cartridge securing arrangement 196. The cartridge ejection members 202 can be constituted by spring leaf members, springs, and the like. The cartridge ejection arrangement 201 includes a pair of spring leaf members 202. On manual releasing the cartridge securing arrangement 196 by depressing the pair of finger operated members 198, the cartridge ejection members 202 outwardly urge the leading cartridge end 113 from the cartridge port 191 for assisting complete manual sliding ejection of the filled cartridge.

[0040] While the invention has been described with respect to a limited number of embodiments, it will be appreciated that many variations, modifications, and other applications of the invention can be made within the scope of the appended claims.

#### REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

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- WO2011004360PCT [0010] [0010]
- WO2007105221A [0011] [0012]
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#### **PATENTKRAV**

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1. Fluidoverføringsindretning (140; 180; 190) til anvendelse i forbindelse med en patron (110) og en lægemiddelampul (130) til at fylde patronen med en flydende lægemiddeldosis, idet patronen omfatter et rør (111) med en åben ende, med en forreste patronende (130) og en bageste patronende (116), idet den forreste patronende er forseglet med en patronskillevæg (117) og den bageste patronende er forseglet med en forskydelig forsegling (121), idet den forreste patronende har en forreste patronflade (119), lægemiddelampullen omfatter en lægemiddelampulflaske (131), som indeholder en lægemiddelkomponent (136), og som har en lægemiddelampulåbning, der er forseglet med en lægemiddelampulprop (133), hvilken fluidoverføringsindretning (140; 180; 190) omfatter:

et dobbeltsidet hovedlegeme (142) med en langsgående akse (141) og omfattende en ampulåbning (143) til teleskopisk at modtage lægemiddelampullen (130) og med en punkteringskanyle (149) til at punktere lægemiddelampulproppen (133) for strømningsforbindelse med lægemiddelampulflasken (131) og en patronåbning (144; 181; 191), som har

- i) en punkteringsnål (153) til at punktere patronskillevæggen (117) for strømningsforbindelse med røret (111) med åben ende ved manuel forskydende indsætning af patronen deri imod ampulåbningen (143), idet punkteringskanylen (149) er i strømningsforbindelse med punkteringsnålen (153) for at muliggøre en manuel patronfyldningsprocedure til fyldning af patronen med den flydende lægemiddeldosis, og
  - ii) et patronfastholdelsesarrangement (160; 183; 184; 196) til udløseligt at fastholde patronen (110) i patronåbningen (144; 181; 191) ved den manuelle forskydende indsætning deri, **kendetegnet ved**, **at** patronåbningen yderligere omfatter
- iii) et patronudkastningsarrangement (160; 183; 184; 201) til i det mindste delvis at udkaste den fyldte patron fra patronåbningen for at medvirke til fuldstændig forskydende udkastning af den fyldte patron derfra.
- 2. Indretning ifølge krav 1, hvor patronåbningen (144; 181) omfatter et kombineret patronfastholdelses- og udkastningsarrangement (160; 183; 184), som har i det mindste et vippearmeelement (161A; 161B; 184) med en forreste vippearmselementende (162A;

162B) og en bageste vippearmselementende (163A; 163B) tilsvarende i tilstødning til og fjernt fra ampulåbningen (143),

idet hver af det i det mindste ene vippearmeelement (161A; 161B; 184) er hængslet på hovedlegemet (142) ved dens nævnte forreste vippearmselementende (162A; 162B) til at blive manuelt vippet fra en ampulindsætningsposition i samme retning som den langsgående akse (141) for at muliggøre den manuelle forskydende indsætning i den nævnte patronåbning (144; 181), til en patronudkastningsposition for den i det mindste delvise udkastning af den fyldte patron fra patronåbningen.

- 3. Indretning ifølge krav 2, hvor det kombinerede patronfastholdelses- og udkastningsarrangement (160) omfatter et par modstående aflange vippearmeelementer (161A; 161B), i samme retning som den langsgående akse (141) og dimensionerede til føring af den manuelle glidende indsætning af patronen (110) i patronåbningen (144).
- 4. Indretning ifølge krav 3, hvor parret af modstående aflange vippearmselementer (161A; 161B) er anbragt til under brug at strække sig midtvejs langs patronen (110) i den indledende patronindsætningsposition og hver af de bageste vippearmselementender (163A; 163B) af parret af modstående vippearmselementer omfatter en udadrettet tværgående fingerunderstøtning til at muliggøre brug af fluidoverføringsindretningen (140) på tilsvarende måde som en sprøjte.
  - 5. Indretning ifølge krav 2, hvor patronåbningen (181) er aflang og dimensioneret til under brug at strække sig midtvejs langs patronen (110) ved den manuelle glidende indsætning deri og udformet med et par modstående udad på tværs rettede finger-understøtninger (182) til at muliggøre brugen af fluidoverføringsindretningen (180) på en tilsvarende måde som en sprøjte.

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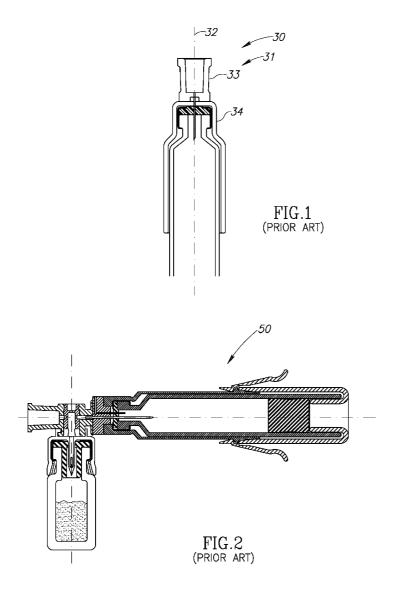
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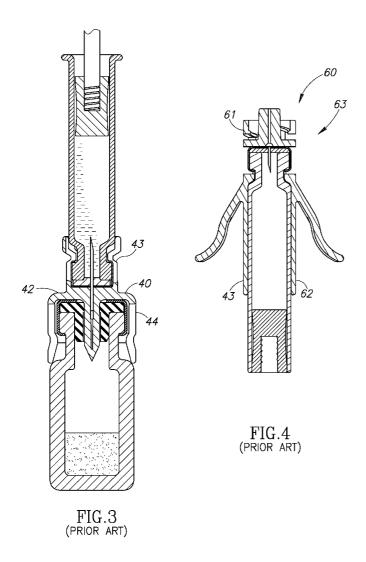
- 6. Indretning ifølge krav 1, hvor patronudkastningsarrangementet (201) omfatter i det mindste ét patronudkastningselement (202), som forspændes til en forberedt tilstand ved fastgørelsen af patronen (110) i patronåbningen (191), hvorpå, ved manuel udløsning af patronfastholdelsesarrangementet (196), det i det mindste ene patronudkastningselement (202) i det mindste delvis udkaster patronen fra patronåbningen.
- 7. Indretning ifølge krav 6, hvor patronåbningen (191) er aflang og dimensioneret til under brug af strække sig midtvejs langs patronen (110) ved den manuelle glidende

indsætning deri og udformet med et par modstående udad på tværs rettede fingerunderstøtninger (194) til at muliggøre brug af fluidoverføringsindretningen (190) på en tilsvarende måde som en sprøjte.

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# **DRAWINGS**





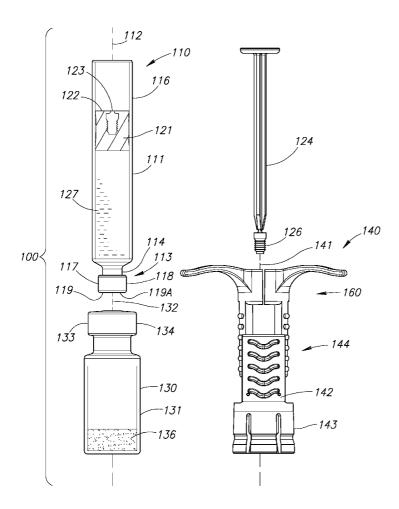
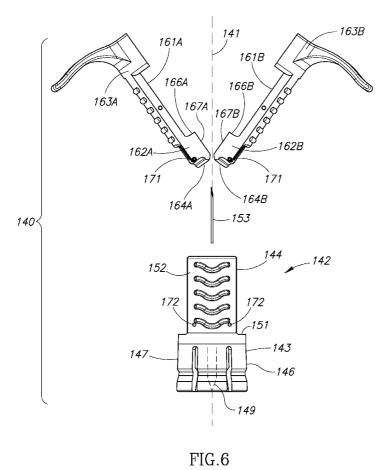
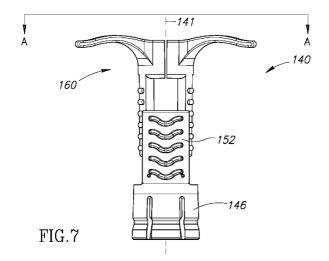
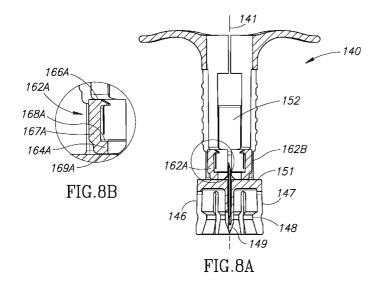
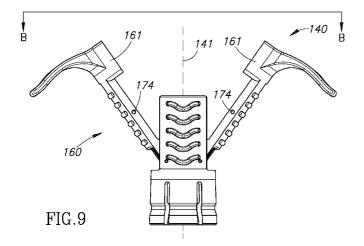


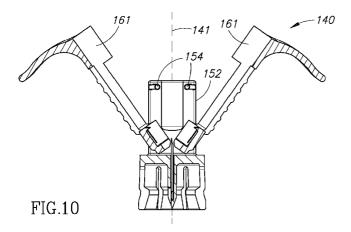
FIG.5

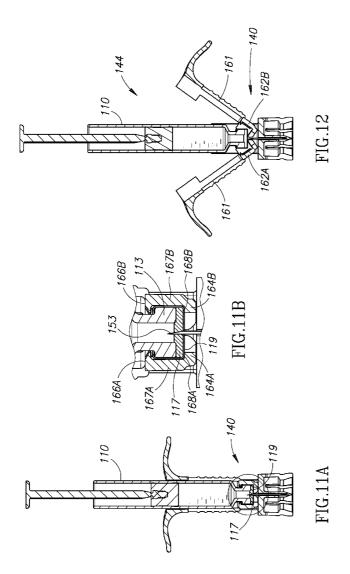


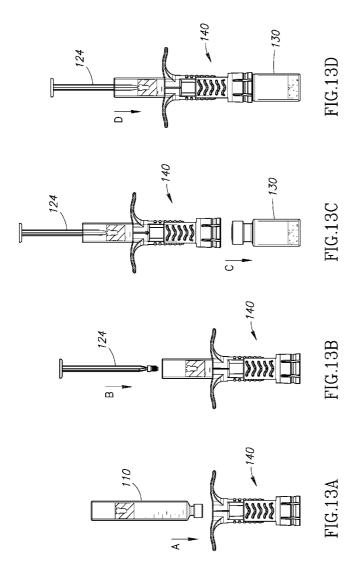


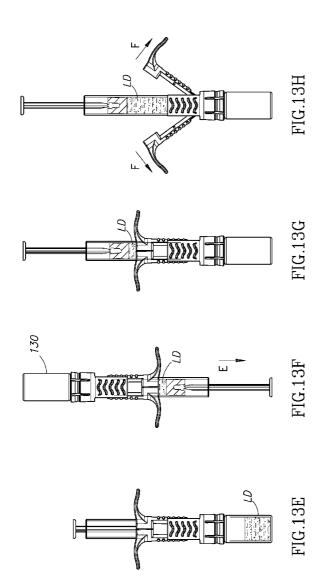












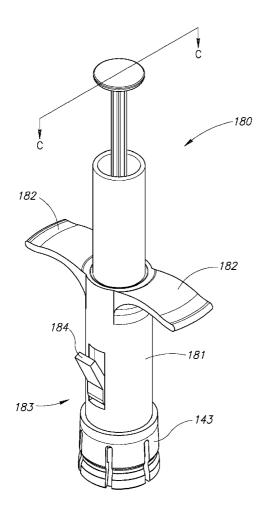


FIG.14

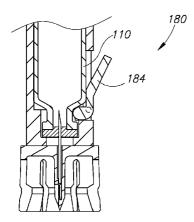


FIG.15A

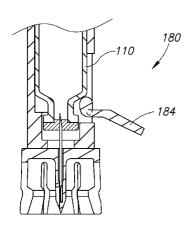


FIG.15B

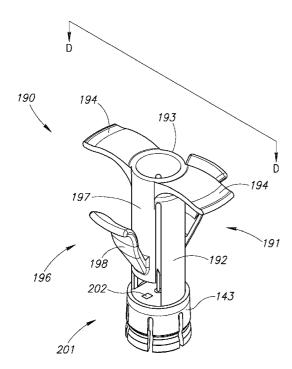


FIG.16

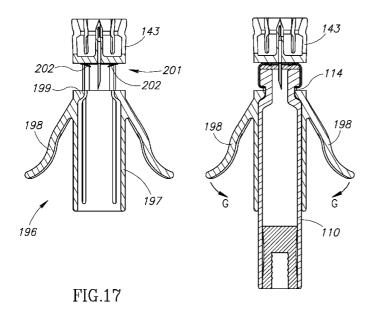


FIG.18