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EP 1 393 763 B9

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Description

[0001] The present invention relates to an automatic injection device and a method of preparing a charge of medicament.

5 **[0002]** An automatic injector is a device that enables intramuscular (IM) or subcutaneous administration of a dosage of medicament. Generally, the medicament is stored as a liquid formulation which is then injected intramuscularly. An advantage of automatic injectors is that they contain a measured dosage of a liquid medicament in a sealed sterile cartridge. As such, automatic injectors allow for quick and simple IM injection of a liquid medicament in emergency situations without the need for measuring dosages. Another advantage of automatic injectors is that the administration of the medicament is accomplished without the user initially seeing the hypodermic needle through which the medicament is delivered, and without requiring the user to manually force the needle into the patient. This is particularly advantageous when the medicament is being self-administered.

10 **[0003]** There are drawbacks associated with the long-term storage of medicament in a liquid formulation. For instance, some medicaments are not stable in solution and thus have a shorter shelf life than their solid counterparts. To address this concern, automatic injectors have been developed which store the medicament in solid form and mix the solid medicament with a liquid solution immediately prior to injection. These injectors, disclosed for example in US reissue patent no. 35,986, entitled "Multiple Chamber Automatic Injector", however, require the user of the injector to manually rupture a sealing member between the solid and liquid components and then manually shake the injector body to expedite dissolution of the solid component prior to injection. This increases the time needed to administer a dose of the medicament. However, rapid delivery of the medicament is needed in many emergency medical situations (e.g., nerve gas and chemical agent poisoning). Other wet/dry injection devices have been expensive to manufacture or provided unsatisfactory mixing of components prior to injection. Therefore, there is a need for a cost-effective automatic injector that stores medicament in solid form that does not require manual premixing by the user.

15 **[0004]** US-A-2002/049407 discloses an automatic injection device having separate wet and dry compartments with a filter assembly therebetween.

20 **[0005]** WO-A-94/09839 discloses another automatic two-chamber injector, which has a flexible sealing structure to separate the wet and dry components.

25 **[0006]** US-A-6080131 discloses a vial comprises a tubular syringe barrel closed at one end and open at the other, a stopper in the open barrel end formed by a piston head of a syringe, and valve means in the barrel between the stopper and the closed barrel end. The valve means is normally closed and actuatable to an open condition by movement of the stopper into the barrel, and is slidable with the piston head to the closed barrel end.

30 **[0007]** According to a first aspect of the present invention, there is provided an automatic injection device for containing a pre-loaded charge of medicament for automatically administering the medicament upon actuation thereof, the device comprising:

- 35
- a housing having an interior chamber, the interior chamber including a dry compartment for containing a dry medicament component, and a wet compartment for containing a liquid component to be mixed with a said dry component;
 - a seal structure between the dry compartment and the wet compartment, the seal structure being initially in a sealing condition that maintains the dry compartment sealed from the liquid compartment;
 - 40 a needle assembly for dispensing a charge of medicament from the housing;
 - a plunger disposed within the chamber and movable through the chamber to force the charge of medicament through the needle assembly; and
 - an activation assembly received within the housing and including a stored energy source, wherein activation of the activation assembly releases the stored energy from the stored energy source;

45 characterized in that:

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- the seal structure comprises an outer seal member, a flow path, an inner seal plug movable with respect to the outer seal member, and a filter or membrane that creates a laminar fluid flow as the liquid component passes through the seal structure from the wet compartment to the dry compartment;
 - the inner seal plug sealing the wet compartment from the dry compartment in the sealing condition and allowing the contents of the wet and dry compartments to mix when moved into a mixing position; and in that:
 - the release of the stored energy by the activation assembly causes:

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- the inner seal plug to move to the mixing position, which converts the seal structure from the sealing condition to a mixing condition that permits a said liquid component to pass through the flow path from the wet compartment to the dry compartment;

a said liquid component to be forced through the filter or membrane to the dry compartment for mixing with a said dry medicament component; and,
 said mixed liquid and dry components to be forced through the needle assembly.

5 **[0008]** According to a second aspect of the present invention, there is provided a method of preparing a charge of medicament, the method comprising:

loading a dry medicament component into a dry compartment of an interior chamber of a housing of an automatic injection device;

10 sealing the dry compartment from a wet compartment of the interior chamber with a seal structure, the seal structure having an outer seal member that forms a peripheral seal with an interior wall of the interior chamber, the seal structure also having a movable inner seal plug that is movable with respect to the outer seal member and that initially seals a flow path between the wet and dry compartments, the chamber having a plunger disposed within and movable through the chamber to force the charge of medicament through a needle assembly of the injection device;

15 loading a liquid component into the wet compartment; and
 activating an activation assembly received within the housing to release stored energy for:

pressurizing the liquid component in the wet compartment;
 20 moving the movable inner seal plug to open the flow path between the wet and dry compartments;
 forcing the liquid component through a filter or membrane disposed between the wet and dry compartments to create a laminar fluid flow from the wet compartment to the dry compartment; and,
 mixing the liquid and dry components in the dry compartment to form the charge of medicament.

25 **[0009]** Other aspects and advantages of the present invention will become apparent from the following detailed description, drawings and claims.

[0010] The invention will be described in conjunction with the following drawing in which like reference numerals designate like elements and wherein:

30 FIG. 1 is a longitudinal cross-sectional view of a wet/dry automatic injector assembly in accordance with an embodiment of the present invention;

FIGs. 2A-2B illustrate longitudinal cross-sectional views of needle support assemblies;

FIGs. 3A-3D illustrate cross-sectional side views of various cartridge or chamber configurations and corresponding needle assembly options according to certain embodiments of the present invention;

35 FIG. 4 is an enlarged partial cross-sectional side view of a needle assembly/cartridge engagement according to the embodiment illustrated in FIG. 3A;

FIGs. 5A-5D illustrate cross-sectional side views of various embodiments of a seal structure according to the present invention;

40 FIG. 6A is a longitudinal cross-sectional side view of a seal structure in accordance with another embodiment of the present invention, wherein the movable sealing plug is in a closed sealing position blocking the flow of the liquid injection solution;

FIG. 6B is a longitudinal cross sectional side view of seal structure similar to 6A, but showing the movable sealing plug in an open by-pass position permitting the flow of the liquid injection solution;

45 FIG. 6C is a lateral cross sectional view of the seal structure of the present invention taken through the line 6C-6C in FIG. 6A;

FIG. 6D is a lateral cross sectional view of the seal structure of the present invention taken through the line 6D-6D in FIG. 6B;

FIG. 7 is a longitudinal cross-sectional view of a wet/dry automatic injector cartridge or chamber configuration in accordance with another embodiment of the present invention; and,

50 FIGs. 8A and 8B are longitudinal cross sectional views of two seal structures outside the scope of the present invention.

[0011] Referring now more particularly to the figures, there is shown in FIG. 1 an automatic injector assembly 10 in accordance with an embodiment of the present invention. The present invention is described in connection with a push button type auto injector, whereby the user removes an end cap assembly and presses a button to trigger the injection process. The present invention, however, is not limited to push button type automatic injectors; rather, it is contemplated that the present invention may be incorporated into a nose activated auto injector, as described for example in U.S. Patent No. 5,354,286.

[0012] The automatic injector assembly 10 includes a generally hollow tubular plastic housing 110. Generally, the housing 110 includes an injection end 111 and an activation end 112, as shown in FIG. 1. In the embodiment shown, an actuator assembly 120 is inserted into the rearward end of the housing 110. The actuator assembly 120 is received within the housing 110 until flange 115 of a sleeve member 144 snaps into angular groove 117 on the interior surface of housing 110. A removable safety cap 130 is releasably secured to the actuator assembly 120.

[0013] The actuator assembly 120 is of any conventional type as known in the art, such as that disclosed in commonly assigned U.S. Patent No. 5,391,151. The present example employs a rear-end activating device, similar to that in the aforementioned U.S. Patent No. 5,391,151, and is therefore only briefly discussed herein. The actuator assembly 120 includes an activation button sleeve 132 having internal activation surfaces 134. The activation assembly further includes a plastic collet 122 with a split rearward portion forming spring fingers 136 as known in the art. The safety cap 130 has a pin portion 138 that extends between the spring fingers 136 so as to keep them spread apart when the injector is in a storage condition. The spring fingers 136 terminate in semi-conical configurations including rearwardly facing sloping surfaces 139 and forwardly facing flat surfaces 142. The collet 122 is surrounded by a cylindrical sleeve 144 having inwardly extending flange 146 at the rearward end thereof. The collet 122 has a forward annular flange 148. A coil spring 250 surrounds the collet 122 and is compressed between the flange 148 and flange 146. The collet flat surfaces 142 are retained in engagement with the rearwardly facing surfaces of the flange 146, and thus prevented from moving off of the flange surfaces by the pin 138 when the injector is stored.

[0014] To activate the injector, the safety pin 130 is manually pulled off of the rear end of the injector, thus removing pin 138 from between the fingers 136. The activation button 132 can then be pushed inwardly, and as a result of the activation surfaces 134 thereof engages the sloping surfaces 139 of the spring fingers 136. This forces the spring fingers 136 inwards toward one another and off of the retaining surfaces of the flange 146. The compressed spring 250 is then free to release the stored energy therein to move the collet 122 forwardly under the force of the spring to effect an injection operation as will be described later in more detail.

[0015] It is contemplated that the actuator assembly 120 can be of any type known in the automatic injector art that employs releasable stored energy. For example, rather than employing a spring, it may employ a charge of compressed gas.

[0016] Located within the interior of the housing 110 is a vial or chamber 150, preferably made of glass, for containing both the liquid injection solution and the dry medicament. The chamber 150 is preferably a hollow cylinder, with a smooth cylindrical inner surface. The liquid injection solution is located within a wet portion 151 of the chamber 150. The dry medicament is located within a dry portion 152 of the chamber 150. It is contemplated that the dry medicament may be in powder, lyophilized, freeze-dried, or any other solid formulation known in the art. A seal structure 160 engages the interior side walls of the chamber 150 to seal the dry portion 152 from the wet portion 151 and to prevent seepage of the liquid injection solution into the dry portion 152 prior to activation of the injector assembly. Further, a needle assembly 140 mounts to the forward end of vial or chamber 150 to inject the medicament upon activation of the injector assembly. In this embodiment, the forward end portion of the chamber 150 has an annular groove 153 formed therein for attachment of the needle assembly 140. The needle assembly 140 includes a funnel-shaped needle support 143. The wide end of the needle support 143 has an annular rib 145 that is snap-fit into groove 153 to form a seal with the chamber 150. The needle support 143 can be made of a resilient plastic material, or metal with a rubber seal that seats into groove 153. The forward narrow end 147 (see FIG. 2A) of the needle support 143 sealingly receives the rearward end of hollow needle 141. The needle support 143 forms a sealed fluid channel from the chamber 150 to the needle 141. A rubber needle sheath 202 surrounds the needle 141 and receives the narrow end 147 of the needle support 143. A filter 190 is sealingly retained across the entire wide-end mouth of the needle support 143 by an annular sealing washer 156.

[0017] FIGs. 2B, 3A, and 4 illustrate another embodiment of a needle assembly 140 and chamber 150. The chamber 150 in this embodiment is known in the art as a dental cartridge. The dental cartridge has a cylindrical rear portion and a narrowed forward neck portion defining an outer annular groove 153. The forward end of the dental cartridge defines an annular flange portion 154. In this embodiment, the needle support 143 has a rearward annular flange 155 that receives an annular sealing member 156 that surrounds both sides of flange 155. The sealing member 156 serves to seal a filter 190 over the wide end of the funnel shaped needle support 143. The rearward surface of the sealing member 156 is sealingly clamped against the forward surface of chamber flange 154 by a metal retaining clamp 157 as best seen in FIG. 4.

[0018] Returning to FIG. 1, forward end 1221 of the collet 122 extends into the rearward end of chamber 150 and is adapted to connect with a plunger 170 rearwardly sealing the wet container 151. The plunger 170 is adapted to sealingly engage the side wall of the wet container 150 to prevent leakage of the contents (e.g., liquid injection solution) of the wet container 151. The plunger 170 is preferably formed from a material having low frictional properties such that the collet 122 and plunger 170 may easily slide within the wet container 150 when operated. Alternatively, the plunger 170 may be lubricated with silicone or other suitable non-reactive lubricant. The movement of the collet 122 and the plunger 170 pressurizes the liquid located within the wet container 151. A suitable medicament is located within a dry container 152.

[0019] The embodiment of FIGs. 1 and 2A is advantageous in that it has an open mouth configuration wherein the

needle-end of the vial or chamber is not significantly narrowed or tapered. Such an open mouth configuration permits direct access to the dry portion 152 of chamber 150 for easy loading. Further, the open mouth configuration aids in preventing cross contamination between wet portion 151 and dry portion 152 in that the dry portion 152 does not have to be filled through liquid portion 151 of chamber 150. Needle assembly 140 can be mounted to vial or chamber 150 in a snap-on configuration (FIG. 3B), an internal mount configuration (FIG. 3C), or an external needle assembly configuration (FIG. 3D).

[0020] As mentioned above, the seal structure 160 is adapted to engage the interior side walls of chamber 150 to prevent passage of the contents (e.g., liquid injection solution) of wet portion 151 into the dry portion 152 prior to activation of the automatic injection assembly. Generally, seal structure 160 includes an outer sealing member 180, a movable sealing plug 166, a by-pass zone 165, at least one flow path 167, and a filter or membrane 164. With reference to FIG. 5A-D, seal structure 160 can preferably be formed as a six piece (FIG. 5A), five piece (FIG. 5B), four piece (FIG. 5C), or three piece (FIG. 5D) configuration.

[0021] More particularly, with reference to FIG. 5A, the outer sealing structure 180 of the six piece configuration can comprise a two piece annular rigid body 181 wherein members 181a, 181b thereof are formed into the two piece rigid body using, e.g., annular weld connections or other bonding techniques known in the art. Outer sealing structure 180 can further include multiple external sealing members 182, e.g., two O-rings, to provide an annular sealing engagement with the inner wall of vial or compartment 150. The sealing structure 180 further includes an internal plug member 166 and a filter or dispersion membrane 164 as will be discussed in greater detail later.

[0022] In another embodiment, as shown in FIG. 5B, rather than plural O-rings, outer sealing structure 180 can include a single external sealing member 182, e.g., a unitary gasket, to provide an annular sealing engagement with the inner wall of vial or compartment 150. External sealing member 182 may optionally be secured to two piece rigid body 181 using any bonding techniques known in the art. Further, rigid body members 181a, 181b may be shaped such that they securely engage external sealing members 182 within notched recesses 183. Alternately, sealing members 182 may be secured to rigid body members 181a, 181b by an interference fit. As with the first embodiment, a filter or membrane 164 is clamped in place at the proximal end of flow path 167 between member 181a and member 181b of the two piece rigid body.

[0023] In another embodiment, as shown in FIG. 5C, outer sealing structure 180 comprises a unitary internal rigid member 181 and an external sealing member 182. Again, internal rigid member 181 and external sealing member 182 may optionally be secured together using any bonding techniques known in the art. Further, internal rigid member 181 and external sealing member 182 may be formed such that they securely engage each other using a combination of notched recesses 183 and extending shoulders 184. The filter or membrane 164 can be held in place between internal rigid member 181 and shoulder 184 of external sealing member 182. In yet another embodiment, as shown in FIG. 5D, outer sealing object 180 can comprise a unitary external sealing member 182 which can optionally be molded so as to accommodate filter or member 164 within retaining recess 185. FIGs. 6A and 6B illustrate another embodiment that is very similar to that of FIG. 5A, but provides a slightly different shape for outer annular rigid body 181 and particularly the members 181a, 181b thereof.

[0024] In each embodiment illustrated in FIGs. 5A-5D and 6A-6B, external sealing member 182 is preferably formed from a non-reactive elastomer material which can provide for the necessary sealing engagement with the inner wall of vial or compartment 150. Further, external sealing member 182 can optionally be lubricated with silicone or other suitable non-reaction lubricant to facilitate movement of the outer sealing object 180 forwardly within vial or compartment 150 upon receiving sufficient force as will be described. The movable sealing plug 166 is preferably formed from a material having low frictional properties such that the sealing plug 166 may easily slide within outer sealing object 180 when the injector is activated. The movable sealing plug 166 may also optionally be lubricated with silicone or other suitable non-reactive lubricant. In each of the embodiments illustrated, the outer annular structure 180 defines an inner surface having a smooth cylindrical configuration towards the rearward portion 169 thereof, and longitudinally extending grooves 168 towards the forward portion thereof. The grooves 168 create a flowpath or flowpaths 167 through which liquid in the wet compartment 151 can bypass seal plug 166 when the plug 166 is moved forwardly from sealing engagement with cylindrical surface portion 169 into the grooved portion 168. The movement of the sealing plug 166 into the by-pass area 165 opens the fluid flow path 167 between wet portion 151 and dry portion 152. The movable sealing plug 166 preferably includes a plurality of circumferential grooves 186 to provide for enhanced sealing engagement and to facilitate sliding action of the plug 166.

[0025] As mentioned above, the seal structure 160 preferably includes filter or membrane 164 at the end of flow path 167 through which the liquid injection solution may pass after the injector has been activated. The liquid injection solution then enters the dry portion 152 of the chamber 150 where it mixes with and dissolves the dry medicament. More particularly, the filter 164 disperses the liquid injection solution exiting the seal structure 160 to present laminar fluid flow to the full surface of the dry medicament, thereby wetting the entire surface of the dry medicament for rapid and complete dissolution. The filter membrane 164 can be any structure that generally uniformly distributes the liquid across the entire diameter of the chamber 150 for enhanced dissolution of the dry medicament.

5 [0026] During operation, manual activation of the actuator assembly 120 releases the collet 122 (as described above), which applies pressure on the plunger assembly 170. The application of pressure on the plunger assembly 170 by the collet and spring assembly 124 moves the plunger 170 in the direction of the needle assembly 140. As a result, the entire chamber 150 and needle assembly 140 are moved forwardly in the housing 110 such that needle 141 pierces through the front end of sheath 202 and exits through the forward end of the housing 110, and particularly through a hole 204 in the front nose-cone portion 206 of the housing. The sheath 202, which serves to maintain the needle 141 sterile when the injector is in storage, also serves as a shock absorber during activation as it is compressed in generally accordion like fashion between the nose cone 206 and needle support 143.

10 [0027] When the needle 141 is extended from the housing 110 and the chamber 150 and needle support 143 approach the nose cone 206 portion of the housing so that further forward movement of chamber 150 is substantially resisted, the plunger 170 then begins to travel forwardly through the chamber 150. This pressurizes the liquid injection solution located within the wet compartment 151. With reference to FIG. 6A - 6B, the increased pressure within the wet compartment 151 moves the sealing plug 166 from a first sealed position wherein sealing plug 166 is sealingly engaged with surface 169 of outer sealing structure 180 (FIG. 6A) to a second by-pass position (FIG. 6B) that allows the injection solution to flow through flow path 167 created by grooves 168 and thereby through seal structure 160.

15 [0028] As described above, the high pressure developed within the wet portion 151 in response to movement of the collet 122 and the plunger assembly 170 forces the liquid injection solution through the seal structure 160 dissolving the drug into a medicament injection solution which will then be forced out through the needle 141 and into the patient. As the collet 122 and plunger assembly 170 continue forward, the plunger 170 will eventually contact the seal structure 160, which, in a preferred embodiment, causes the seal structure 160 to move in the direction of the needle assembly 140. Movement of the seal structure 160 would cause any remaining solution within the portion 152 to be dispersed through the needle assembly 140, so as to reduce the amount of residual medicament remaining within the chamber 150.

20 [0029] Referring to FIGs. 2A, 2B and 4, a membrane or filter 190 is preferably provided adjacent the needle assembly 140 to prevent any dry medicament particles from clogging the rearward end of needle 141 prior to an injection operation. The membrane 190 may also serve to slightly restrict or slow injection of medicament into the patient, to facilitate more thorough dissolution during injection.

25 [0030] More particularly, to prevent the passage of undissolved dry medicament to the needle assembly 140, a medicament support 190 is preferably provided between the end of the dry compartment 152 and the needle assembly 140. The support 190 can serve to prevent blockage of the needle assembly 141 by preventing the dry medicament from entering the area surrounding the needle assembly 140 while permitting passage of the mixture of dissolved medicament and liquid injection solution. The support 190 may be configured as described in US provisional application no. 60/238,448 (from which for example EP-A-1324791 claims priority). It is contemplated that multiple supports 190 may be located within the dry compartment 152. The provision of the supports 190 may also improve the laminar flow of the liquid injection solution through the dry medicament thereby improving dissolution.

30 [0031] Further, a diaphragm assembly (not shown) may also be provided adjacent the medicament support 190, as known in the art. The diaphragm assembly acts to prevent the passage of the liquid injection solution to the needle assembly 140 prior to activation of the actuator assembly 120. More particularly, the diaphragm assembly will not rupture until either the butt end of the needle assembly 140 ruptures the expanded diaphragm or sufficient pressure builds in the dry compartment 160 to rupture the diaphragm, again as known in the art.

35 [0032] As discussed above, the movement of the collet 122 causes the injection needle 141 of the injection assembly 140 to advance and protrude through the housing 110. As such, the injection of the medicament can be performed with a simple operation. In sum, the user simply removes the end cap assembly 130, locates the injection end of the housing 110 adjacent the injection site, and presses the push button 132. This operation automatically triggers the operation of the drive assembly or spring 250 to advance the collet 122 causing the liquid injection solution located within the wet portion 151 to enter the dry portion 152 through the seal structure 160. The dissolved medicament is then transmitted through the injection needle 141 to provide the user with the necessary dose of medicament. The automatic injector 10 in accordance with the present invention reduces the amount of time required to administer medicament compared to other wet/dry injectors and eliminates the need for mixing by the user.

40 [0033] The seal structure 160 advantageously enables the manufacture of a superior wet/dry auto injector with a complementary combination of components that are either known in the art of conventional auto-injectors or are otherwise relatively simple to manufacture. The seal structure 160 enables sufficient mixing of wet and dry medicament components without requiring manual shaking. This mixing action is enhanced by the filter or membrane 164. In a preferred embodiment, the filter 164 is a supported, hydrophobic acrylic copolymer cast on a non-woven nylon support. Preferably, it is a FlouRepel treated membrane for superior oleophobicity/hydrophobicity.

45 [0034] In some embodiments outside the scope of the present invention (see FIGs. 8A and 8B), no inner plug 166 is provided. Rather, the outer structure 180 is simply complemented by a seal membrane 226 that extends across the inner area defined by the inner surface of the outer structure. When the chamber 150 reaches the forward end of the housing during an injection operation, pressurization of the wet compartment 151 causes the seal membrane 226 to

rupture, thereby allowing the seal structure 160 to permit liquid to pass therethrough. In this embodiment, it may be desirable to provide the seal structure 160 with a pointed member 228 disposed adjacent to the seal membrane 226 to facilitate rupturing of the seal membrane upon pressurized expansion thereof during an injection operation. The member 232 on which the pointed member 228 is mounted has a plurality of passages 234 that permits fluid to pass therethrough. Filter or membrane 164 is preferably mounted distal to the passages 234 to present laminar or distributed flow to the dry medicament.

EXAMPLES

[0035] An injector according to the present invention was loaded with liquid injection solution and dry medicament and activated with the following results.

Loaded		Dispensed			Operational Time
Dry Powder	Fluid	Dry	Powder	Fluid	
mg	ml	%	mg	ml	Secs.
531	2.7	94	497	2.3	4.0
557	2.7	93	515	2.3	4.5
582	2.6	92	537	2.2	4.4

[0036] It will be apparent to those skilled in the art that various modifications and variations may be made without departing from the scope of the present invention. For example, it is contemplated that a cover assembly, described for example in U.S. Patent No. 5,295,965 may be secured to the injection end of the housing 110 after deployment of the medicament.

[0037] In yet a further embodiment, the forward dry chamber 152 contains the needle 141, as shown in FIG. 7. The needle 141 is forced through a forward plug stopper upon initial compression of the two chamber system. As known in the art, providing the needle in the forward chamber provides improved longitudinal compactness of the design.

[0038] In yet another embodiment, a pre-filled syringe is provided with the seal structure disposed between wet and dry components.

[0039] In further contemplated embodiments, the seal structure 160 can be used in the same type of injector described herein, except rather than employing a dry (powder) medicament separated by a liquid component, a first liquid medicament is separated from a second fluid component by the seal structure 160. In yet another embodiment, the seal structure 160 can be used in what is known in the art as a "needleless injector" where an injection can be made into a patient without a needle or cannula. Thus, it is intended that the present invention covers the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

Claims

1. An automatic injection device (10) for containing a pre-loaded charge of medicament for automatically administering the medicament upon actuation thereof, the device comprising:

a housing (110) having an interior chamber (150), the interior chamber (150) including a dry compartment (152) for containing a dry medicament component, and a wet compartment (151) for containing a liquid component to be mixed with a said dry component;

a seal structure (160) between the dry compartment (152) and the wet compartment (151), the seal structure (160) being initially in a sealing condition that maintains the dry compartment (152) sealed from the liquid compartment (151);

a needle assembly (140) for dispensing a charge of medicament from the housing (110);

a plunger (170) disposed within the chamber (150) and movable through the chamber (150) to force the charge of medicament through the needle assembly (140); and

an activation assembly (120) received within the housing (110) and including a stored energy source (250), wherein activation of the activation assembly (120) releases the stored energy from the stored energy source (250);

characterized in that:

the seal structure (160) comprises an outer seal member (180), a flow path (167), an inner seal plug (166) movable with respect to the outer seal member (180), and a filter or membrane (164) that creates a laminar fluid flow as the liquid component passes through the seal structure (160) from the wet compartment (151) to the dry compartment (152);

the inner seal plug (166) sealing the wet compartment (151) from the dry compartment (152) in the sealing condition and allowing the contents of the wet and dry compartments (151, 152) to mix when moved into a mixing position; and **in that**:

the release of the stored energy by the activation assembly (120) causes:

the inner seal plug (166) to move to the mixing position, which converts the seal structure (160) from the sealing condition to a mixing condition that permits a said liquid component to pass through the flow path (167) from the wet compartment (151) to the dry compartment (152);

a said liquid component to be forced through the filter or membrane (164) to the dry compartment (152) for mixing with a said dry medicament component; and,
said mixed liquid and dry components to be forced through the needle assembly (140).

2. An automatic injection device according to claim 1, wherein the outer seal member (180) comprises a pair of O-rings (182) which form a peripheral seal between the seal structure (160) and the interior side walls of the interior chamber (150).

3. An automatic injection device according to claim 1, wherein the outer seal member (180) comprises a unitary gasket (182) which forms a peripheral seal between the seal structure (160) and the interior side walls of the interior chamber (150).

4. An automatic injection device according to claim 1, wherein the outer seal member (180) comprises an external sealing member (182) and an internal rigid body (181) configured to securely engage each other.

5. An automatic injection device according to claim 4, wherein the internal rigid body (181) is formed from two rigid members (181a,b) which are annularly welded or bonded together.

6. An automatic injection device according to claim 5, wherein the filter or membrane (164) is clamped between the two rigid members (181a,b) of the internal rigid body (181).

7. An automatic injection device according to any of claims 1 to 6, wherein the inner side wall of the outer seal member (180) includes grooves (168) which enable flow of the liquid component around the inner seal plug (166) and through the seal structure (160) when the inner seal plug (166) is moved to the mixing position.

8. An automatic injection device according to any of claims 1 to 7, wherein the needle assembly (140) comprises a membrane (190) adjacent the dry compartment (152) to prevent undissolved dry medicament from entering the needle assembly.

9. An automatic injection device according to any of claims 1 to 8, wherein the needle assembly (140) is secured to the interior chamber (150) at the end of the dry compartment (152) in a configuration that is a snap-on configuration (FIG. 3B), or an internal needle assembly configuration (FIG. 3C), or an external needle assembly configuration (FIG. 3D).

10. An automatic injection device according to any of claims 1 to 9, wherein:

the seal structure (160) comprises a bypass zone (165); and
movement of the inner seal plug (166) into the bypass zone (165) opens the flow path (167).

11. An automatic injection device according to any of claims 1 to 10, wherein:

the seal structure (160) moves through the chamber (150) upon contact thereof by the plunger (170).

12. An automatic injection device according to claim 1, wherein the outer seal member (180) has an outer periphery

that forms a peripheral seal with an interior wall of the interior chamber (150), and the inner seal plug (166) is spaced radially inward from the peripheral seal to seal the flow path (167) formed in the seal structure (160).

- 5 13. An automatic injection device according to any of claims 1 to 12, wherein the activation assembly (120) includes a pre-compressed spring (250).
- 10 14. An automatic injection device according to claim 1, wherein the activation assembly (120) includes a pre-compressed spring (250) that urges a collet rod (122) forwardly through the housing (110), the collet rod connected to the plunger (170), the forward movement of the collet rod (122) and plunger creating sufficient pressure on a liquid component in the wet compartment (151) to cause a said liquid component to force the seal structure (160) into the mixing condition.
- 15 15. An automatic injection device according to claim 1, wherein the release of the stored energy by the activation assembly (120) causes the chamber (150) and the needle assembly (140) to move toward the injection end (111) of the housing (110).
- 20 16. An automatic injection device according to claim 1, wherein the release of the stored energy by the activation assembly (120) causes the seal structure (160) to move toward the injection end (111) of the housing (110).
- 25 17. An automatic injection device according to any of claims 1 to 16, wherein the filter or membrane (164) moves from an initial position spaced rearwardly from the needle assembly (140) to a final position disposed closer to the needle assembly (140) relative to the initial position.
- 30 18. A method of preparing a charge of medicament, the method comprising:
loading a dry medicament component into a dry compartment (152) of an interior chamber (150) of a housing (110) of an automatic injection device (10);
sealing the dry compartment (152) from a wet compartment (151) of the interior chamber (150) with a seal structure (160), the seal structure (160) having an outer seal member (180) that forms a peripheral seal with an interior wall of the interior chamber (150), the seal structure (160) also having a movable inner seal plug (166) that is movable with respect to the outer seal member (180) and that initially seals a flow path (167) between the wet and dry compartments (151,152), the chamber (150) having a plunger (170) disposed within and movable through the chamber (150) to force the charge of medicament through a needle assembly (140) of the injection device (10);
35 loading a liquid component into the wet compartment (151); and
activating an activation assembly (120) received within the housing (110) to release stored energy for:
pressurizing the liquid component in the wet compartment (151) ;
40 moving the movable inner seal plug (166) to open the flow path (167) between the wet and dry compartments (151,152);
forcing the liquid component through a filter or membrane (164) disposed between the wet and dry compartments (151,152) to create a laminar fluid flow from the wet compartment (151) to the dry compartment (152); and,
45 mixing the liquid and dry components in the dry compartment (152) to form the charge of medicament.
- 50 19. A method according to claim 18, wherein activating the activation assembly (120) comprises releasing stored energy for moving the seal structure (160) from an initial position spaced rearwardly from the needle assembly (140) to a final position disposed closer to the needle assembly (140) relative to the initial position.
- 55 20. A method according to claim 18, wherein activating the activation assembly (120) comprises releasing stored energy for moving the chamber (150) and the needle assembly (140) toward the injection end (111) of the housing (110).
21. A method according to claim 18, wherein activating the activation assembly (120) comprises releasing stored energy from a pre-compressed spring (250).
22. A method according to claim 18, wherein forcing the liquid component through a filter or membrane (164) further comprises forcing the liquid component around the inner seal plug (166) through grooves (168) that form the flow path (167) and through a filter or membrane (164) disposed between the wet and dry compartments to create a

laminar fluid flow from the wet compartment (151) to the dry compartment (152).

Patentansprüche

- 5
1. Eine automatische Injektionsvorrichtung (10) zum Aufnehmen einer vorgeladenen Charge eines Medikaments für das automatische Verabreichen des Medikaments nach Betätigung derselben, die Vorrichtung umfassend:
- 10 ein Gehäuse (110) mit einer inneren Kammer (150), die innere Kammer (150) enthaltend ein trockenes Abteil (152) für das Aufnehmen eines trockenen Medikamentenbestandteils, und ein nasses Abteil (151) für das Aufnehmen eines flüssigen Bestandteils, welcher mit einem genannten trockenen Bestandteil gemischt werden soll;
- 15 einen Dichtungsaufbau (160) zwischen dem trockenen Abteil (152) und dem nassen Abteil (151), wobei sich der Dichtungsaufbau (160) anfänglich in einem Dichtungszustand befindet, in welchem das trockene Abteil (152) zum nassen Abteil (151) abgedichtet erhalten bleibt;
- 20 einen Nadelaufbau (140) für das Abgeben einer Charge eines Medikaments aus dem Gehäuse (110); einen Kolben (170), angeordnet innerhalb der Kammer (150) und bewegbar durch die Kammer (150), um die Medikamentencharge durch den Nadelaufbau (140) zu drücken, sowie einen innerhalb des Gehäuses (110) aufgenommenen und eine gespeicherte Energiequelle (250) umfassenden Aktivierungsaufbau (120), wobei die Aktivierung des Aktivierungsaufbaus (120) die gespeicherte Energie aus der gespeicherten Energiequelle (250) freisetzt, **dadurch gekennzeichnet, dass:**
- 25 der Dichtungsaufbau (160) ein äußeres Dichtungselement (180), einen Strömungsweg (167), einen inneren Dichtungsstopfen (166), bewegbar im Verhältnis zu dem äußeren Dichtungselement (180) und einen Filter oder eine Membran (164) umfasst, welche(r) eine laminare Strömung der Flüssigkeit erzeugt, wenn der flüssige Bestandteil den Dichtungsaufbau (160) von dem nassen Abteil (151) zu dem trockenen Abteil (152) passiert;
- 30 wobei der innere Dichtungsaufbau (166) in dem Dichtungszustand das nasse Abteil (151) von dem trockenen Abteil (152) abdichtet und zulässt, dass sich die Inhalte der nassen und trockenen Abteile (151, 152) vermischen, wenn sie in eine Mischposition bewegt werden, sowie dadurch, dass: das Freisetzen der gespeicherten Energie durch den Aktivierungsaufbau (120) verursacht: dass sich der innere Dichtungsstopfen (166) in die Mischposition bewegt, was den Dichtungsaufbau (160) von dem Dichtungszustand in einen Mischzustand umwandelt, welcher ermöglicht, dass ein genannter flüssiger Bestandteil den Strömungsweg (167) von dem nassen Abteil (151) zu dem trockenen Abteil (152) passieren kann;
- 35 wobei ein genannter flüssiger Bestandteil durch den Filter oder die Membran (164) zu dem trockenen Abteil (152) für das Mischen mit einem genannten Medikamentenbestandteil gedrückt werden soll, und wobei die genannten gemischten flüssigen und trockenen Bestandteile durch den Nadelaufbau (140) gedrückt werden sollen.
- 40
2. Automatische Injektionsvorrichtung nach Anspruch 1, wobei das äußere Dichtungselement (180) ein Paar O-Ringe (182) umfasst, welche eine periphere Dichtung zwischen dem Dichtungsaufbau (160) und den inneren Seitenwänden der inneren Kammer (150) bilden.
- 45
3. Automatische Injektionsvorrichtung nach Anspruch 1, wobei das äußere Dichtungselement (180) einen unitären Dichtungsring (182) umfasst, welcher eine periphere Dichtung zwischen dem Dichtungsaufbau (160) und den inneren Seitenwänden der inneren Kammer (150) bildet.
- 50
4. Automatische Injektionsvorrichtung nach Anspruch 1, wobei das äußere Dichtungselement (180) ein externes Dichtungselement (182) und einen inneren starren Hauptteil (181) umfasst, so ausgebildet, dass sie sicher ineinander einrasten.
5. Automatische Injektionsvorrichtung nach Anspruch 4, wobei der innere starre Hauptteil (181) aus zwei starren Elementen (181a,b) gebildet ist, welche miteinander ringförmig verschweißt oder verklebt sind.
- 55
6. Automatische Injektionsvorrichtung nach Anspruch 5, wobei der Filter oder die Membran (164) zwischen die zwei starren Elemente (181a,b) des inneren starren Hauptteils (181) geklemmt ist.
7. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 6, wobei die innere Seitenwand des

äußeren Dichtungselements (180) Rillen (168) umfasst, welche den Fluss des flüssigen Bestandteils um den inneren Dichtungsstopfen (166) herum und durch den Dichtungs Aufbau (160) ermöglichen, wenn der innere Dichtungsstopfen (166) in die Mischposition bewegt wird.

- 5 8. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 7, wobei der Nadelaufbau (140) eine Membran (190) angrenzend an das trockene Abteil (152) umfasst, um zu verhindern, dass nicht aufgelöstes trockenes Medikament in den Nadelaufbau eintritt.
- 10 9. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 8, wobei der Nadelaufbau (140) an der inneren Kammer (150) am Ende des trockenen Abteils (152) in einer Konfiguration befestigt ist, bei welcher es sich um eine Aufsteck- und Einrastkonfiguration (FIG. 3B) oder um eine innere Nadelaufbau-Konfiguration (FIG. 3C) oder um eine äußere Nadelaufbau-Konfiguration (FIG. 3D) handelt.
- 15 10. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 9, wobei: der Dichtungs Aufbau (160) eine Umgehungszone (165) umfasst, und wobei das Bewegen des inneren Dichtungsstopfens (166) in die Umgehungszone (165) den Strömungsweg (167) öffnet.
- 20 11. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 10, wobei:
sich der Dichtungs Aufbau (160) nach Berührung desselben mit dem Kolben (170) durch die Kammer (150) bewegt.
- 25 12. Automatische Injektionsvorrichtung nach Anspruch 1, wobei das äußere Dichtungselement (180) eine äußere Peripherie umfasst, welche mit einer Innenwand der inneren Kammer (150) eine periphere Dichtung bildet, und wobei der innere Dichtungsstopfen (166) von der peripheren Dichtung in einem radialen Abstand nach innen angeordnet ist, um den im Dichtungs Aufbau (160) gebildeten Strömungsweg (167) abzudichten.
- 30 13. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 12, wobei der Aktivierungsaufbau (120) eine vorgespannte Feder (250) umfasst.
- 35 14. Automatische Injektionsvorrichtung nach Anspruch 1, wobei der Aktivierungsaufbau (120) eine vorgespannte Feder (250) umfasst, welche einen Spannstab (122) nach vorne durch das Gehäuse (110) drängt, und der Spannstab mit dem Kolben (170) verbunden ist, wobei die Vorwärtsbewegung des Spannstabs (122) und des Kolbens ausreichend Druck auf einen flüssigen Bestandteil in dem nassen Abteil (151) ausübt, um einen genannten flüssigen Bestandteil zu veranlassen, den Dichtungs Aufbau (160) in den Mischzustand zu zwingen.
- 40 15. Automatische Injektionsvorrichtung nach Anspruch 1, wobei die Freisetzung der gespeicherten Energie durch den Aktivierungsaufbau (120) die Kammer (150) und den Nadelaufbau (140) veranlasst, sich nach vorne zum Injektionsende (111) des Gehäuses (110) zu bewegen.
- 45 16. Automatische Injektionsvorrichtung nach Anspruch 1, wobei die Freisetzung der gespeicherten Energie durch den Aktivierungsaufbau (120) den Dichtungs Aufbau (160) veranlasst, sich nach vorne zum Injektionsende (111) des Gehäuses (110) zu bewegen.
- 50 17. Automatische Injektionsvorrichtung nach einem beliebigen der Ansprüche 1 bis 16, wobei sich der Filter oder die Membran (164) aus einer anfänglichen Position in einem rückwärtsweisenden Abstand von dem Nadelaufbau (140) in eine endgültige Position bewegt, welche dem Nadelaufbau (140) im Vergleich zu der anfänglichen Position näher liegt.
- 55 18. Verfahren für das Zubereiten einer Charge eines Medikaments, das Verfahren umfassend: Laden eines trockenen Medikamentenbestandteils in ein trockenes Abteil (152) einer inneren Kammer (150) eines Gehäuses (110) einer automatischen Injektionsvorrichtung (10); Abdichten des trockenen Abteils (152) von einem nassen Abteil (151) der inneren Kammer (150) mit einem Dichtungs Aufbau (160), der Dichtungs Aufbau (160) aufweisend ein äußeres Dichtungselement (180), welches mit einer Innenwand der inneren Kammer (150) eine periphere Dichtung bildet, der Dichtungs Aufbau (160) auch verfügend über einen bewegbaren inneren Dichtungsstopfen (166), der im Verhältnis zum äußeren Dichtungselement (180) bewegbar ist, und der anfänglich den Strömungsweg (167) zwischen den nassen und trockenen Abteilen (151, 152)

abdichtet, die Kammer (150) verfügend über einen Kolben (170), angeordnet in der Kammer (150) und durch diese hindurch beweglich, um die Medikamentencharge durch einen Nadelaufbau (140) der Injektionsvorrichtung (10) zu drücken; Laden eines flüssigen Bestandteils in das nasse Abteil (151), und Aktivieren eines in dem Gehäuse (110) aufgenommenen Aktivierungsaufbaus (120), um gespeicherte Energie freizusetzen für:

- 5
- das Druckbeaufschlagen des flüssigen Bestandteils in dem nassen Abteil (151), das Bewegen des bewegbaren inneren Dichtungsstopfens (166), um den Strömungsweg (167) zwischen den nassen und trockenen Abteilen (151, 152) zu öffnen;
- 10 das Drücken des flüssigen Bestandteils durch einen Filter oder eine Membran (164), welche(r) zwischen den nassen und trockenen Abteilen (151, 152) angeordnet ist, um eine laminare Strömung von dem nassen Abteil (151) zu dem trockenen Abteil (152) zu erzeugen, und
- Mischen der flüssigen und der trockenen Bestandteile in dem trockenen Abteil (152), um die Medikamentencharge zu bilden.
- 15 **19.** Verfahren nach Anspruch 18, wobei das Aktivieren des Aktivierungsaufbaus (120) das Freisetzen gespeicherter Energie für das Bewegen des Dichtungsaufbaus (160) aus einer anfänglichen Position in einem rückwärtsweisenden Abstand von dem Nadelaufbau (140) in eine endgültige Position umfasst, welche dem Nadelaufbau (140) im Vergleich zu der anfänglichen Position näher liegt.
- 20 **20.** Verfahren nach Anspruch 18, wobei das Aktivieren des Aktivierungsaufbaus (120) das Freisetzen gespeicherter Energie umfasst, um die Kammer (150) und den Nadelaufbau (140) in Richtung Injektionsende (111) des Gehäuses (110) zu bewegen.
- 25 **21.** Verfahren nach Anspruch 18, wobei das Aktivieren des Aktivierungsaufbaus (120) das Freisetzen gespeicherter Energie aus einer vorgespannten Feder (250) umfasst.
- 22.** Verfahren nach Anspruch 18, wobei das Drücken eines flüssigen Bestandteils durch einen Filter oder eine Membran (164) ferner das Drücken des flüssigen Bestandteils um den inneren Dichtungsstopfen (166) herum durch Rillen (168), welche den Strömungsweg (167) bilden, und durch einen Filter oder eine Membran (164) umfasst, welche(r)
- 30 zwischen den trockenen und den nassen Abteilen angeordnet ist, um eine laminare Strömung von dem nassen Abteil (151) zu dem trockenen Abteil (152) zu erzeugen.

Revendications

- 35
- 1.** Dispositif d'injection automatique (10) destiné à contenir une charge chargée au préalable de médicament permettant d'administrer automatiquement le médicament lors de son actionnement, le dispositif comprenant :
- 40 un boîtier (110) comportant une chambre intérieure (150), la chambre intérieure (150) comprenant un compartiment sec (152) destiné à contenir un constituant sec de médicament, et un compartiment humide (151) destiné à contenir un constituant liquide à mélanger avec ledit constituant sec ;
- une structure d'étanchéité (160) disposée entre le compartiment sec (152) et le compartiment humide (151), la structure d'étanchéité (160) étant initialement dans un état d'assurance d'étanchéité qui maintient le compartiment sec (152) isolé du compartiment liquide (151) ;
- 45 un ensemble aiguille (140) permettant de délivrer une charge de médicament du boîtier (110) ;
- un plongeur (170) disposé à l'intérieur de la chambre (150) et mobile à travers la chambre (150) de façon à forcer la charge de médicament à travers l'ensemble aiguille (140) ; et un ensemble d'activation (120) reçu à l'intérieur du boîtier (110) et comprenant une source d'énergie accumulée (250), dans lequel l'activation de l'ensemble d'activation (120) libère l'énergie accumulée de la source d'énergie accumulée (250) ; **caractérisé**
- 50 **en ce que :**
- la structure d'étanchéité (160) comprend un élément d'étanchéité extérieur (180), un trajet d'écoulement (167), un bouchon d'étanchéité intérieur (166) mobile par rapport à l'élément d'étanchéité extérieur (180), et un filtre ou membrane (164) qui crée un écoulement laminaire de fluide lorsque le constituant liquide traverse la structure d'étanchéité (160) du compartiment humide (151) au compartiment sec (152) ;
- 55 le bouchon d'étanchéité intérieur (166) isolant le compartiment humide (151) du compartiment sec (152) dans l'état d'étanchéité et permettant un mélange des contenus des compartiments humide et sec (151, 152) lorsqu'il est amené dans une position de mélange ; et **en ce que** : la libération de l'énergie accumulée

- par l'ensemble d'activation (120) provoque : un déplacement du bouchon d'étanchéité intérieur (166) dans la position de mélange, qui fait passer la structure d'étanchéité (160) de l'état d'étanchéité à un état de mélange qui permet un passage dudit constituant liquide à travers le trajet d'écoulement (167) du compartiment humide (151) au compartiment sec (152) ;
- 5 le mélange dudit constituant liquide à forcer à travers le filtre ou membrane (164) jusqu'au compartiment sec (152) avec ledit constituant humide de médicament ; et un forçage desdits constituants liquide et sec mélangés à travers l'ensemble aiguille (140).
- 10 **2.** Dispositif d'injection automatique selon la revendication 1, dans lequel l'élément d'étanchéité extérieur (180) comprend deux joints toriques (182) qui forment une étanchéité périphérique entre la structure d'étanchéité (160) et les parois latérales intérieures de la chambre intérieure (150).
- 15 **3.** Dispositif d'injection automatique selon la revendication 1, dans lequel l'élément d'étanchéité extérieur (180) comprend un joint d'étanchéité unitaire (182) qui forme une étanchéité périphérique entre la structure d'étanchéité (160) et les parois latérales intérieures de la chambre intérieure (150).
- 20 **4.** Dispositif d'injection automatique selon la revendication 1, dans lequel l'élément d'étanchéité extérieur (180) comprend un élément d'étanchéité externe (182) et un corps interne rigide (181) conçus pour coopérer de manière sûre l'un avec l'autre.
- 25 **5.** Dispositif d'injection automatique selon la revendication 4, dans lequel le corps interne rigide (181) est formé de deux éléments rigides (181a, b) qui sont soudés ou liés l'un à l'autre de manière annulaire.
- 6.** Dispositif d'injection automatique selon la revendication 5, dans lequel le filtre ou membrane (164) est serré entre les deux éléments rigides (181a, b) du corps interne rigide (181).
- 30 **7.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 6, dans lequel la paroi latérale intérieure de l'élément d'étanchéité extérieur (180) comprend des rainures (168) qui permettent un écoulement du constituant liquide autour du bouchon d'étanchéité intérieur (166) et à travers la structure d'étanchéité (160) lorsque le bouchon d'étanchéité intérieur (166) est amené dans la position de mélange.
- 35 **8.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 7, dans lequel l'ensemble aiguille (140) comprend une membrane (190) adjacente au compartiment sec (152) servant à empêcher que du médicament sec non dissout n'entre dans l'ensemble aiguille.
- 40 **9.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 8, dans lequel l'ensemble aiguille (140) est fixé à la chambre intérieure (150) au niveau de l'extrémité du compartiment sec (152) selon une certaine configuration, c'est-à-dire selon une configuration d'encliquetage (FIG. 3B), ou selon une configuration d'ensemble aiguille interne (FIG. 3C), ou selon une configuration d'ensemble aiguille externe (FIG. 3D).
- 45 **10.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 9, dans lequel : la structure d'étanchéité (160) comprend une zone de dérivation (165) ; et un déplacement du bouchon d'étanchéité intérieur (166) dans la zone de dérivation (165) ouvre le trajet d'écoulement (167).
- 11.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 10, dans lequel :
- la structure d'étanchéité (160) se déplace à travers la chambre (150) lorsque le plongeur (170) vient en contact avec cette dernière.
- 50 **12.** Dispositif d'injection automatique selon la revendication 1, dans lequel l'élément d'étanchéité extérieur (180) possède une périphérie extérieure qui forme une étanchéité périphérique avec une paroi intérieure de la chambre intérieure (150), et le bouchon d'étanchéité intérieur (166) est espacé radialement vers l'intérieur de l'étanchéité périphérique de façon à isoler le trajet d'écoulement (167) formé dans la structure d'étanchéité (160).
- 55 **13.** Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 12, dans lequel l'ensemble d'activation (120) comprend un ressort précontraint (250).

- 5 14. Dispositif d'injection automatique selon la revendication 1, dans lequel l'ensemble d'activation (120) comprend un ressort précontraint (250) qui pousse une tige à collet (122) vers l'avant à travers le boîtier (110), la tige à collet étant reliée au plongeur (170), le déplacement vers l'avant de la tige à collet (122) et du plongeur créant une pression suffisante appliquée à un constituant liquide se trouvant dans le compartiment humide (151) pour amener ledit constituant liquide à forcer la structure d'étanchéité (160) dans l'état de mélange.
- 10 15. Dispositif d'injection automatique selon la revendication 1, dans lequel la libération de l'énergie accumulée par l'ensemble d'activation (120) provoque un déplacement de la chambre (150) et de l'ensemble aiguille (140) en direction de l'extrémité d'injection (111) du boîtier (110).
- 15 16. Dispositif d'injection automatique selon la revendication 1, dans lequel la libération de l'énergie accumulée par l'ensemble d'activation (120) provoque un déplacement de la structure d'étanchéité (160) en direction de l'extrémité d'injection (111) du boîtier (110).
- 20 17. Dispositif d'injection automatique selon l'une quelconque des revendications 1 à 16, dans lequel le filtre ou membrane (164) se déplace d'une position initiale espacée vers l'arrière de l'ensemble aiguille (140) à une position finale se trouvant plus près de l'ensemble aiguille (140) par rapport à la position initiale.
- 25 18. Méthode de préparation d'une charge de médicament, la méthode consistant à : charger un constituant de médicament sec dans un compartiment sec (152) d'une chambre intérieure (150) d'un boîtier (110) d'un dispositif d'injection automatique (10) ; isoler le compartiment sec (152) d'un compartiment humide (151) de la chambre intérieure (150) au moyen d'une structure d'étanchéité (160), la structure d'étanchéité (160) comportant un élément d'étanchéité extérieur (180) qui forme une étanchéité périphérique avec une paroi intérieure de la chambre intérieure (150), la structure d'étanchéité (160) comportant également un bouchon d'étanchéité intérieur mobile (166) qui est mobile par rapport à l'élément d'étanchéité extérieur (180) et qui isole initialement un trajet d'écoulement (167) établi entre les compartiments humide et sec (151, 152), la chambre (150) comportant un plongeur (170) disposé à l'intérieur de la chambre (150), et mobile à travers cette dernière, de façon à forcer la charge de médicament à travers un ensemble aiguille (140) du dispositif d'injection (10) ;
- 30 charger le constituant liquide dans le compartiment humide (151) ; et activer un ensemble d'activation (120) reçu à l'intérieur du boîtier (110) de façon à libérer de l'énergie accumulée pour :
- 35 mettre sous pression le constituant liquide dans le compartiment humide (151) ; déplacer le bouchon d'étanchéité intérieur mobile (166) pour ouvrir le trajet d'écoulement (167) établi entre les compartiments humide et sec (151, 152) ; forcer le constituant liquide à travers un filtre ou membrane (164) disposé entre les compartiments humide et sec (151, 152) de façon à créer un écoulement laminaire de fluide du compartiment humide (151) au compartiment sec (152) ; et
- 40 mélanger les constituants liquide et sec dans le compartiment sec (152) de façon à former la charge de médicament.
- 45 19. Méthode selon la revendication 18, dans laquelle l'activation de l'ensemble d'activation (120) consiste à libérer de l'énergie accumulée pour déplacer la structure d'étanchéité (160) d'une position initiale espacée vers l'arrière de l'ensemble aiguille (140) à une position finale se trouvant plus près de l'ensemble aiguille (140) par rapport à la position initiale.
- 50 20. Méthode selon la revendication 18, dans laquelle l'activation de l'ensemble d'activation (120) consiste à libérer de l'énergie accumulée pour déplacer la chambre (150) et l'ensemble aiguille (140) en direction de l'extrémité d'injection (111) du boîtier (110).
- 55 21. Méthode selon la revendication 18, dans laquelle l'activation de l'ensemble d'activation (120) consiste à libérer de l'énergie accumulée d'un ressort précontraint (250).
22. Méthode selon la revendication 18, dans laquelle le forçage du constituant liquide à travers un filtre ou membrane (164) consiste en outre à forcer le constituant liquide autour du bouchon d'étanchéité intérieur (166) à travers des rainures (168) qui forment le trajet d'écoulement (167) et à travers un filtre ou membrane (164) disposé entre les compartiments humide et sec de façon à créer un écoulement laminaire de fluide du compartiment humide (151)

au compartiment sec (152).

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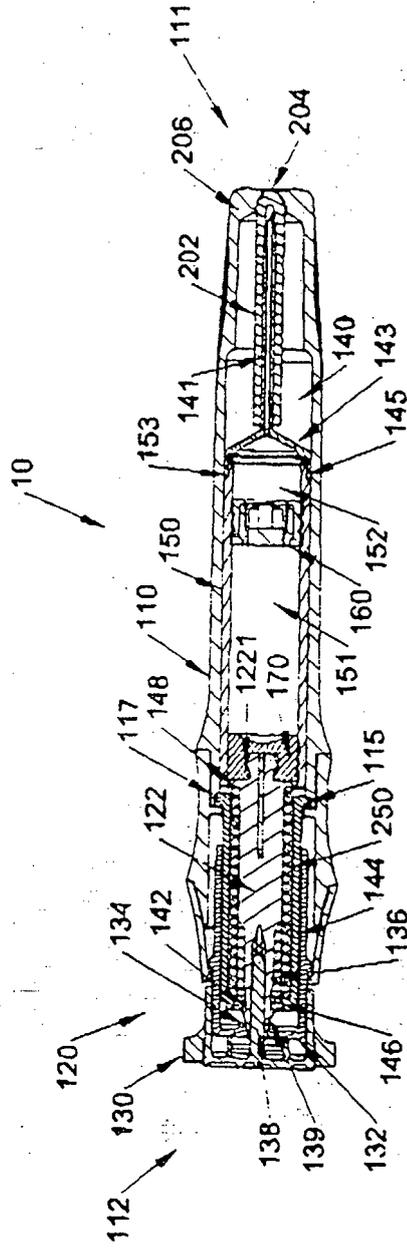


FIG. 1

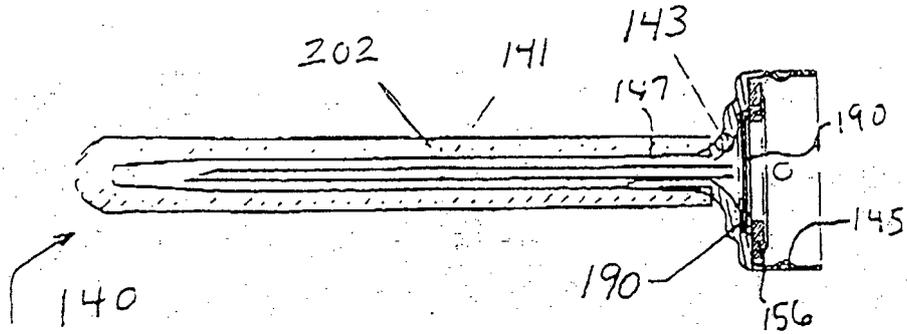


Figure 2A

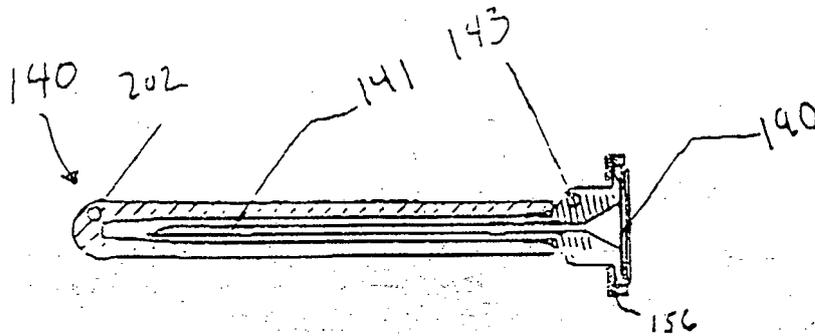


Figure 2B

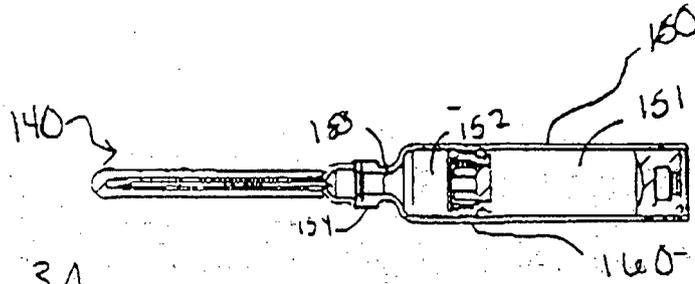


Figure 3A

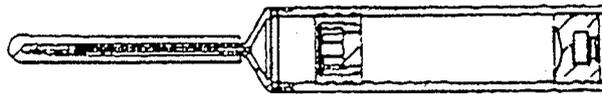


Figure 3B

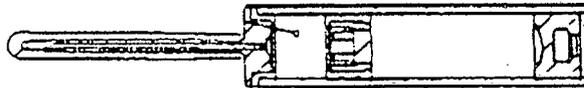


Figure 3C

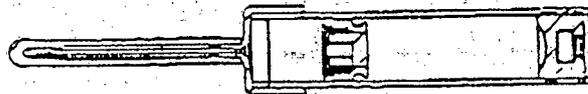


Figure 3D

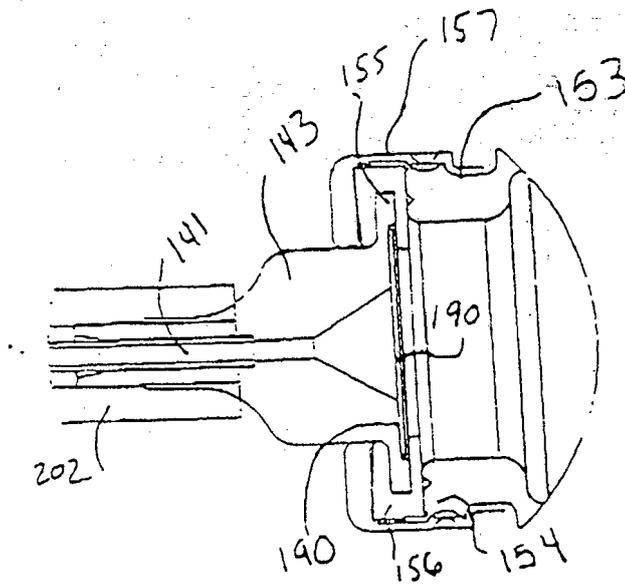


Figure 4

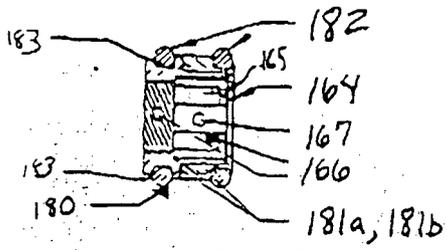


Figure 5A

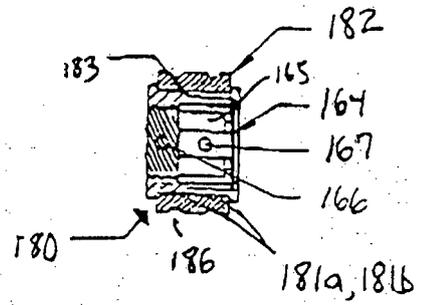


Figure 5B

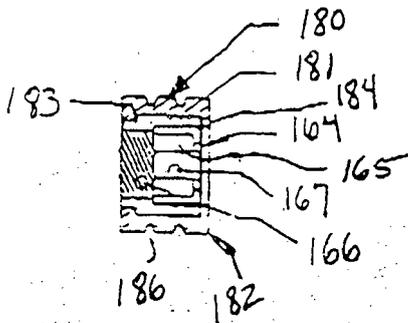


Figure 5C

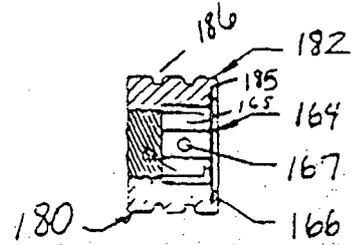
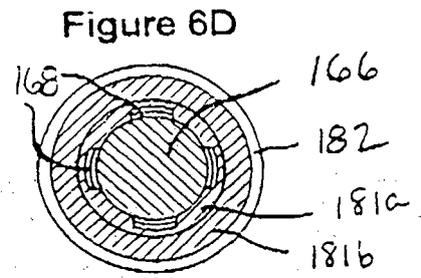
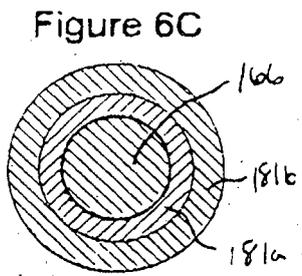
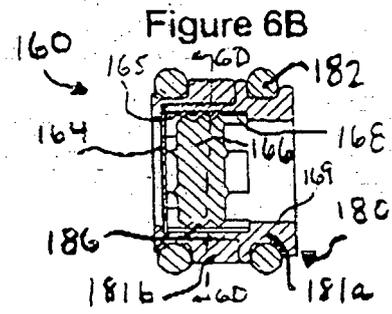
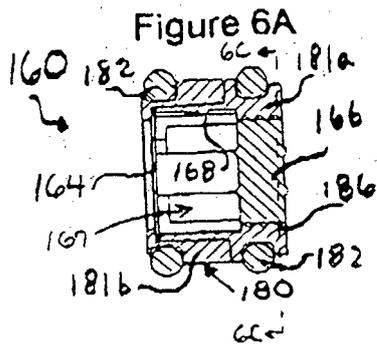


Figure 5D



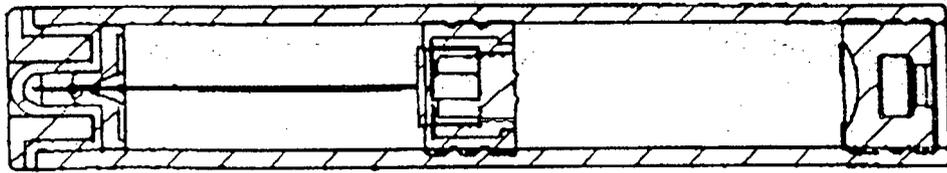


Figure 7

FIG. 8A

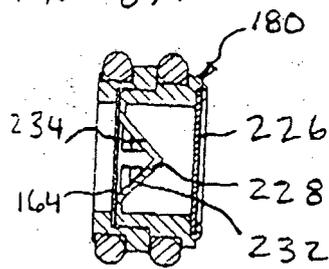
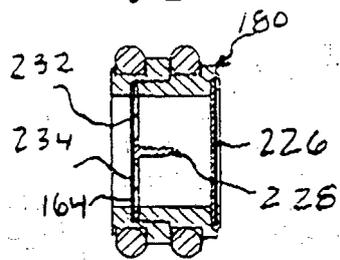


FIG. 8B



REFERENCES CITED IN THE DESCRIPTION

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