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(54) **IMPROVED SYRINGE ASSEMBLY**

VERBESSERTE SPRITZENANORDNUNG

ENSEMBLE SERINGUE AMÉLIORÉ

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Description

[0001] This invention relates to an improved syringe assembly, and, more particularly, relates to an improved syringe assembly having a stopper defining and separating a first volume and a second volume within the syringe assembly.

BACKGROUND

[0002] It is known in the prior art to provide a syringe assembly with a stopper that defines and separates a first volume and a second volume within the syringe assembly. Such arrangements are used in mixing devices where two or more medicaments or other substances are mixed prior to delivery to an injection site, or in devices where two or more medicaments or other substances are delivered to an injection site separately and sequentially.

[0003] US-A-2005/0245880 (Howlett et al.) describes a multi-chamber, sequential dose dispensing syringe that has a moveable valve assembly that has a mechanical impact sensor that causes the valve to open when the valve assembly impacts ("bottoms out") with the bottom internal end of the syringe barrel.

[0004] A two-compartment sequential dose device for sequentially delivering doses of multivitamin preparation is described in US-A-3914419 (American Cyanamid Company). The two compartments are separated by a stopper that has a central valved passage for allowing multivitamin preparation in the upper chamber to pass out through the needle after delivery of the multivitamin preparation in the lower chamber adjacent the needle.

[0005] FR-A-2750051 (Debiotech SA) and US-A-4929230 (Pfleger) each describe a medical syringe having a free piston slidable in the barrel of the syringe for fluidly separating two internal volumes in the syringe. The free piston maintains a sealing configuration until it bottoms out at the bottom internal end of the syringe barrel, at which point fluid from the lower volume has been delivered through the needle of the syringe under the force of an upper plunger in the barrel of the syringe. Fluid pressure in the upper volume then causes the whole free piston to deform to allow fluid from the upper volume to bypass the free piston and exit through the needle.

[0006] A similar device is described in US-A-2008/0255521 (Hisamitsu Pharmaceutical Co. Inc.) except formations at the bottom internal end of the syringe cause the free piston to deform allowing fluid in the upper volume to bypass the free piston and exit the syringe through the needle.

[0007] Another syringe for sequentially administering different fluids is described in US-A-2004/0171984 (Greenfield) which also has a floating piston which acts to selectively separate two fluid volumes in the syringe. In one described embodiment, the floating piston is made of a compressible body that has a central valve that opens upon axial compression of the body.

[0008] US-A-5713857 (Becton Dickinson France, S.A.) describes a stopper for use in a sequential delivery device. The stopper has a collapsible portion down one side that collapses when a predetermined fluid pressure is exceeded such that an axial channel is opened up along the side of the stopper. Thus, in a collapsed configuration, the stopper no longer forms a complete circumferential seal with the inner surface of the syringe barrel to allow the passage of fluid.

[0009] An automatic injection device for mixing a dry medicament component and a fluid (such as a diluent) and subsequently delivering the mixture/solution is described in US-A-2002/042592 (Wilmot, John G. et al.). A floating stopper initially separates the dry component from the wet component and is moveable to a position where a fluid passageway is opened which fluidly connects the volumes containing the wet and dry components. The fluid passageway is described as recesses (acting as bypass channels) in the inner surface of the syringe barrel. In an alternative described embodiment, the inner surface of the syringe barrel comprises ribs that distort the stopper when it reaches a particular axial position within the barrel to allow fluid to bypass the stopper and mix with the dry component.

[0010] A further two-compartment syringe is described in EP-A-0112574 (Meditec S.A.) which has a floating stopper having a central valve assembly for selectively allowing fluid communication between the two volumes separated by the stopper. The central valve assembly consists of a blocking component moveable relative to the remainder of the stopper between a blocking position where the central valve assembly is closed and an open position where the central valve assembly is open and fluidly connects the two compartments. The blocking component is biased by a spring to the blocking position so that a force (such as fluid pressure) is required to move the blocking component to the open position.

[0011] An automatic injector device is described in WO-A-9409839 which has a plunger rod disposed in a syringe barrel with a flexible stopper at the end of the plunger rod. Initially, the flexible stopper separates a dry medicament component from a fluid in a compartment rear of the dry compartment. The plunger rod and flexible stopper are moved rearwardly into the fluid compartment to initiate mixing as the flexible element flexes during movement through the fluid allowing fluid to bypass the flexible element and mix with the dry component. To actuate delivery of the mixed medicament, a rigid stopper is moved forward through the barrel of the syringe to expel mixed medicament from the syringe through the needle.

[0012] A further prior art syringe assembly is given in WO97/41909 (Kestrel S.A.).

[0013] It is an object of the present invention to provide an improved or alternative syringe assembly that permits the selective separation of volume spaces therein.

BRIEF SUMMARY OF THE DISCLOSURE

[0014] The present invention is defined in the appended claims.

[0015] In accordance with a first aspect of the present invention there is provided a syringe assembly comprising:

a barrel for containing one or more medicaments, a narrowed outlet for allowing the expulsion of said one or more medicaments from said barrel through said outlet; and

a stopper disposed in the barrel defining and separating a first volume and a second volume within the syringe assembly, the stopper comprising:

a permanent seal fluidly sealing the stopper to the barrel about the entire perimeter of the stopper intermediate the first volume and second volume; and

a channel bypassing the permanent seal, the channel having a first opening in fluid communication with the second volume and a second opening selectively sealed from the first volume by a resilient seal;

where the resilient seal is moveable between a sealing configuration and an open configuration to selectively seal the channel from the first volume, where in the sealing configuration the resilient seal fluidly seals the stopper to the barrel so as to fluidly isolate said second opening of the channel from the first volume, and in the open configuration the second opening of the channel is in fluid communication with the first volume; and

wherein the resilient seal is moveable from the sealing configuration to the open configuration upon fluid pressure in the first volume or second volume exceeding a first pressure threshold.

[0016] Preferably, the stopper is axially moveable within the barrel upon application of an axial force on the stopper.

[0017] In one embodiment, the axial force required to move the stopper within the barrel is less than the force provided by a fluid at the first pressure threshold.

[0018] In an alternative embodiment, the axial force required to move the stopper within the barrel is greater than the force provided by a fluid at the first pressure threshold.

[0019] In any embodiment, the resilient seal may comprise one or more flexible elements, wherein said one or more flexible elements preferably partly extends circumferentially around said stopper and the remainder of the stopper forms a seal with the barrel circumferentially around said one or more flexible elements. Preferably, said one or more flexible elements extends entirely circumferentially around said stopper. The resilient seal preferably comprises at least two flexible elements, wherein the at least two flexible elements are preferably axially aligned with one another.

[0020] Preferably, the channel comprises at least one axial channel part and at least one additional channel part arranged substantially perpendicularly to said at least one axial channel and in fluid communication therewith.

[0021] In one preferable embodiment, the permanent seal comprises at least one flange projecting outwardly from said stopper about the entire perimeter of the stopper. The permanent seal may comprise at least two flanges projecting outwardly from said stopper about the entire perimeter of the stopper, wherein the at least two flanges are arranged in axial alignment with one another.

[0022] The syringe assembly optionally comprises a pressure source for pressurising a fluid in the barrel. Said pressure source may comprise an axially moveable plunger element disposed in the barrel, where the stopper is disposed in the barrel intermediate the plunger element and the narrowed outlet of the barrel. Preferably, said plunger element comprises a plunger stopper and a plunger rod connected to the plunger stopper for axially moving the plunger stopper in the barrel. Preferably, said pressure source includes a power source.

[0023] Preferably, one or both of said first volume and second volume is a medicament volume for containing one or more medicaments.

[0024] In one embodiment, said first volume is a first medicament volume for containing a first medicament and said second volume is a second medicament volume for containing a second medicament. Said first medicament volume may contain a first fluidic medicament and said second medicament volume contains a second fluidic medicament.

[0025] Said first volume may be a medicament volume for containing a medicament and said stopper is arranged in said barrel to selectively isolate the medicament volume from the outlet of the barrel, wherein preferably, said medicament volume contains a fluidic medicament.

[0026] In one embodiment, the stopper further comprises a friction clamp that is moveable between a clamping position and a non-clamping position, where a higher force is required to axially move the stopper in the barrel when the friction clamp is in the clamping position than when the friction clamp is in the non-clamping position. The syringe assembly preferably further comprises a moveable plunger element disposed in the barrel for pressurising a fluid in the first volume, where the stopper is disposed in the barrel intermediate the plunger element and the narrowed outlet of the barrel, wherein the plunger element comprises a key and the stopper comprises a socket complementary to said key, and wherein engagement of the key in the socket moves said friction clamp to said non-clamping position. Preferably, the stopper further comprises a nozzle or spray head at the first opening of the stopper.

[0027] Said first volume may contain a fluidic sub-

stance and said second volume contains a dry or lyophilized substance.

[0028] The syringe assembly may further comprise a needle in fluid communication with the narrowed outlet of said barrel.

[0029] Said barrel and said narrowed outlet may be integrally formed. That is, the narrowed outlet may be a hole in the delivery (forward) end of the syringe barrel, where the hole has a diameter less than the diameter of the barrel (as in a "standard" syringe).

[0030] Preferably said barrel tapers towards said narrowed outlet.

[0031] In one preferable embodiment, said stopper is a first stopper, and the syringe assembly further comprises one or more additional stoppers each comprising the features of the first stopper as defined in accordance with the first aspect of the present invention, wherein the one or more additional stoppers separate and define further volumes within the syringe assembly axially rearward of the first stopper.

[0032] In accordance with a second aspect of the present invention, there is provided an autoinjector comprising a syringe assembly according to the first aspect of the present invention.

[0033] In accordance with a third aspect of the present invention, there is provided a method of using a syringe assembly comprising the steps of:

i) providing a syringe assembly according to the first aspect of the present invention where the axial force required to move the stopper within the barrel is less than the force provided by a fluid at the first pressure threshold, the syringe assembly containing a fluid in the first volume; and
ii) applying a force to pressurise the fluid so that the resilient seal moves to the open configuration and permits the expulsion of the fluid through the narrowed outlet via the channel of the stopper.

[0034] In accordance with a fourth aspect of the present invention, there is provided a method of using a syringe assembly comprising the steps of:

i) providing a syringe assembly according to the first aspect of the present invention where the axial force required to move the stopper within the barrel is less than the force provided by a fluid at the first pressure threshold, the syringe assembly containing a first fluid in the first volume and a second fluid in the second volume;
ii) applying a force to pressurise the first fluid to move the stopper axially forwardly within the barrel to expel the second fluid through the narrowed outlet;
iii) allowing the stopper to travel axially forwardly in the barrel to its forwardmost position; and
iv) continuing to apply a force to pressurize the first fluid so that the resilient seal moves to the open configuration and permits the expulsion of the first fluid through the narrowed outlet via the channel of the stopper.

[0035] In one embodiment, the syringe assembly provided in step i) further comprises a first applicator in fluid communication with the narrowed outlet, wherein subsequent to performing step ii) and prior to performing step iv) the first applicator is replaced with a second applicator. Further preferably, one or both of the first applicator and second applicator is a needle.

[0036] In accordance with a fifth aspect of the present invention, there is provided a method of using a syringe assembly comprising the steps of:

i) providing a syringe assembly according to the first aspect of the present invention where the axial force required to move the stopper within the barrel is greater than the force provided by a fluid at the first pressure threshold, the syringe assembly containing a fluidic substance in the first volume and a dry or lyophilized substance in the second volume;
ii) applying a force to pressurise the fluidic substance so that the resilient seal moves to the open configuration and permits the flow of the fluidic substance from the first volume to the second volume via the channel to form a solution or mixture in the second volume; and
iii) applying a force to the stopper to move the stopper axially forwardly so as to expel the solution or mixture from the second volume through the narrowed outlet.

[0037] Preferably, the applied forces are provided by moving a plunger element axially forwardly in the barrel, wherein the stopper is disposed intermediate the plunger element and the narrowed outlet, and wherein the force applied to the stopper in step iii) occurs when the plunger element contacts the stopper following the expulsion of substantially all of the fluidic substance from the first volume.

[0038] The stopper preferably further comprises a friction clamp that is moveable between a clamping position and a non-clamping position, where a higher force is required to axially move the stopper in the barrel when the friction clamp is in the clamping position than when the friction clamp is in the non-clamping position, wherein the plunger element comprises a key and the stopper comprises a socket complementary to said key, and wherein engagement of the key in the socket moves said friction clamp to said non-clamping position.

BRIEF DESCRIPTION OF THE DRAWINGS

[0039] Embodiments of the invention are further described hereinafter with reference to the accompanying drawings, in which:

Figure 1A is a partial cross sectional view of a syringe assembly in accordance with an embodiment of the

present invention, comprising a stopper in a sealing configuration;

Figure 1B is a partial cross sectional view of the syringe assembly of Figure 1A where the stopper is in an open configuration;

Figure 2A is a partial cross sectional view of a syringe assembly in accordance with an alternative embodiment of the present invention, comprising a stopper in a sealing configuration;

Figure 2B is a partial cross sectional view of the syringe assembly of Figure 2A where the stopper is in an open configuration;

Figure 3A is a partial cross sectional view of a syringe assembly in accordance with an embodiment of the present invention containing two fluids prior to actuation;

Figure 3B is a partial cross sectional view of the syringe assembly of Figure 3A during delivery;

Figure 3C is a partial cross sectional view of the syringe assembly of Figures 3A and 3B after delivery;

Figure 4A is a partial cross sectional view of a syringe assembly in accordance with another embodiment of the present invention containing a single fluid prior to actuation;

Figure 4B is a partial cross sectional view of the syringe assembly of Figure 4A after delivery;

Figure 5A is a partial cross sectional view of a mixing syringe assembly in accordance with an embodiment of the present invention prior to actuation;

Figure 5B is a partial cross sectional view of the mixing syringe assembly of Figure 5A during mixing;

Figure 5C is a partial cross sectional view of the mixing syringe assembly of Figures 5A and 5B at the start of delivery;

Figure 5D is a partial cross sectional view of the mixing syringe assembly of Figures 5A to 5C after delivery;

Figure 6A is a partial cross sectional view of a mixing syringe assembly in accordance with an alternative embodiment of the present invention prior to actuation;

Figure 6B is a partial cross sectional view of the mixing syringe assembly of Figure 6A during mixing;

Figure 6C is a partial cross sectional view of the mixing syringe assembly of Figures 6A and 6B at the start of delivery; and

Figure 6D is a partial cross sectional view of the mixing syringe assembly of Figures 6A to 6C after delivery.

DETAILED DESCRIPTION

[0040] Figures 1A and 1B each show a partial cross section of a syringe assembly 10 in accordance with an embodiment of the present invention in which a stopper 14 is disposed in a barrel 12 of the syringe assembly 10. The barrel 12 and stopper 14 are generally cylindrical in shape.

[0041] The skilled reader will appreciate that references to "axial" or "longitudinal" directions and axes (or similar) are considered to be parallel to the sides defining the barrel 12, with "radial" directions considered to be perpendicular to the longitudinal axis and extending outwards from a longitudinal axis running through the circular center of the syringe assembly 10. Similarly, "circumferential" directions are considered to be defined about a longitudinal axis running through the circular center of the syringe assembly 10.

[0042] References to "forward", "front", "lower", "below" or the like are considered to denote a direction or point at or towards a delivery end of the syringe assembly (i.e. the end that medicament is expelled from). Similarly, references to "rearward", "rear", "upper", "above" or the like are considered to denote a direction at or towards the end of the syringe assembly that is opposite the delivery end.

[0043] The stopper 14 has a permanent seal 16 formed by a pair of axially aligned flanges 16a,16b extending radially from the stopper 14 and forming a fluid tight seal with the barrel 12 around the entire perimeter (circumference) of the stopper 14 at a forward end thereof. In alternative embodiments, any formation or configuration that is capable of forming a fluid-tight seal with the barrel 12 may form the permanent seal 16. Indeed, the present invention is not limited to having two such formations, and any number of flanges 16a,16b or alternative formations or configurations may be used.

[0044] The stopper 14 has a resilient seal 22 axially rearward of the permanent seal 16 where the resilient seal 22 is formed of a pair of axially aligned flexible elements 22a,22b that extend radially from the stopper 14 and extend around the entire circumference of the stopper 14. As is described in more detail below, the resilient seal 22 is moveable between a sealing configuration (as shown in figure 1A) and an open configuration (as shown in Figure 1B), where in the sealing configuration, the resilient seal 22 fluidly seals the stopper 14 to the barrel 12, and in the open configuration, the resilient seal 22 does not fluidly seal the stopper 14 to the barrel 12.

[0045] The stopper 14 defines and separates a first

volume 24 of the syringe assembly 10 and a second volume 26 of the syringe assembly 10 which are each capable of containing a medicament or other substance.

[0046] A channel 18 passes through the stopper 14 and has a first opening 20a in fluid communication with the second volume 26 and two second openings 20b that are each selectively sealed from the first volume 24 by the resilient seal 22. In the embodiment shown in Figures 1A and 1B, the channel 18 has a first axial channel part 18a and a second channel part 18b arranged substantially perpendicularly to the first axial channel part 18a. The first opening 20a is associated with the first axial channel part 18a and the two second openings 20b are associated with the second channel part 18b. In the specific embodiment depicted in Figures 1A and 1B, the channel 18 is T-shaped in cross-section.

[0047] When the resilient seal 22 is in the sealing configuration, the first volume 24 is fluidly isolated from the second volume 26 by the stopper 14. Conversely, when the resilient seal 22 is in the open configuration the first volume 24 is in fluid communication with the second volume 26 via the channel 18. Thus, since the resilient seal 22 is moveable between the sealing configuration and the open configuration, so too is the stopper 14 as a whole, since it selectively fluidly isolates and fluidly connects the first volume 24 and second volume 26 via the channel 18 depending on the configuration of the resilient seal 22.

[0048] The resilient seal 22 is moved from the sealing configuration to the open configuration when a force incident on the resilient seal 22 exceeds at predetermined threshold. Typically, such a force will arise when the fluid pressure of a fluid acting on the resilient seal 22 exceeds a predetermined threshold. For example, if the first volume was filled with a fluid (such as a fluidic medicament), then the resilient seal would move from the sealing configuration to the open configuration when the pressure of the fluid exceeded the predetermined threshold. When the pressure exceeds the predetermined threshold, the flexible elements 22a,22b of the resilient seal 22 flex or deflect so as to move away from the barrel 12 and open a fluid pathway allowing fluid to bypass the resilient seal 22. Alternative components may form the resilient seal 22 in place of the flexible elements 22a,22b that deform, deflect, flex or otherwise move to open a fluid pathway between the stopper 14 and the barrel 12 upon application of a predetermined force. In the embodiment shown in Figure 1B, the flexible elements 22a,22b are shown to be flexed or deflected in a forward direction, such as one might expect to result from the pressure of a fluid in the first volume exceeding the predetermined threshold. However, the resilient seal 22 may be configured to be bi-directional such that a fluid in the second volume 26 is capable of causing the resilient seal 22 to move from the sealing configuration to the open configuration when the pressure of the fluid in the second volume 26 exceeds the predetermined pressure threshold.

[0049] In both sealing and open configurations, the permanent seal 16 remains in place and maintains a seal between the stopper 14 and the barrel 12 at the forward end of the stopper 14. Thus, a fluid connection is only formed between the first volume 24 and the second volume 26 when the resilient seal 22 is in the open configuration. Even when the resilient seal 22 is in the open configuration, fluid must flow along several axes in order to bypass the permanent seal 16 through the channel 18. This arrangement therefore provides a labyrinth pathway between the first volume 24 and the second volume 26, as opposed to a straight channel. A benefit of the labyrinth arrangement is that the likelihood of fluid flow from the first volume to the second volume is substantially reduced in the event that the resilient seal 22 is inadvertently moved to the open configuration for a short period of time. One advantage of having the resilient seal 22 acting between the stopper 14 and the barrel 12 is that this provides a low friction arrangement (particularly when the internal surface of the syringe barrel 12 is siliconised, which it often is) making the resilient seal 22 more reliable at opening when desired, since friction will have less influence of the predetermined pressure threshold.

[0050] An alternative embodiment of the invention is shown in Figures 2A and 2B in which the syringe assembly 10 comprises an alternative stopper 14'. Apart from the alternative stopper 14', the syringe assembly 10 is otherwise identical to that described above in relation to Figures 1A and 1B. The alternative stopper 14' has a permanent seal 16 identical to that described above in relation to Figures 1A and 1B, and comprises a resilient seal 22. The resilient seal 22 depicted in Figures 2A and 2B is formed of a pair of flexible elements 22a',22b' each extending radially from the stopper 14' and arranged in axial alignment with one another. However, different to the resilient seal 22 of Figures 1A and 1B, the resilient seal 22' of Figures 2A and 2B does not extend entirely circumferentially around the stopper 14' but is otherwise identical to resilient seal 22. Instead, the resilient seal 22' extends partly around the circumference of the stopper 14' and a second permanent seal 28 formed of a pair of flanges 28a,28b extending radially from the stopper 14' extend around the remainder of the circumference of the stopper 14' The second permanent seal 28 maintains a permanent seal between the stopper 14' and the barrel 12 across the extent of the circumference that it extends.

[0051] The stopper 14' has a channel 18 that bypasses the permanent seal 16 and is formed of a first axial channel part 18a and a second channel part 18b arranged substantially perpendicularly to the first axial channel part 18a. A first opening 20a is associated with the first axial channel part 18a and a single second opening 20b is associated with the second channel part 18b. The channel 18 of Figures 2A and 2B is L-shaped in cross section, in contrast to the channel 18 of Figures 1A and 1B which is T-shaped in cross section. However, either channel arrangement may be used in either embodiment. Alternatively, other channel arrangements may be employed

that bypass the permanent seal 16 from an outer radial position via an inner radial position that is radially inwards of the permanent seal 16.

[0052] In preferable embodiments, the stopper 14,14' is made from a deformable elastomeric material that is able to achieve a fluid tight seal with the barrel 12.

[0053] The resilient seal 22' and the second permanent seal 28 are arranged relative to one another such that when the resilient seal 22' is in the sealing configuration (as shown in Figure 2A) the combination of the resilient seal 22' and the second permanent seal 28 fluidly isolate the second opening 20b of the channel 18 from the first volume 24, and hence fluidly isolate the first volume 24 from the second volume 26. In the open configuration (as shown in Figure 2B), the resilient seal 22' permits a fluid pathway that fluidly connects the first volume 24 to an annulus circumferentially surrounding the stopper 14' between the axial positions of the permanent seal 16 and the second permanent seal 28.

[0054] In an alternative embodiment, axial ribs or similar formations (not shown) may be arranged on the stopper 14' on either side of the second opening in each circumferential direction so as to form an axial channel that forms a circumferential boundary around the second opening and seals with the barrel 12. In this embodiment, the axial channel would be bound at a forward end by the permanent seal 16 and the axial channel would be bound at a rear end by resilient seal 22'. Since the second opening 20b is disposed within the bound axial channel, the second permanent seal 28 would not be necessary, however it is preferable that it still be present to minimise the risk of inadvertent fluid flow from the first volume 24 to the second volume 26.

[0055] A preferred mode of operation and arrangement of the syringe assembly 10 is shown in Figures 3A to 3C. Figure 3A shows the syringe assembly 10 prior to actuation containing a first fluid in the first volume 24 and a second fluid in the second volume 26. The first and second fluids may be medicaments and/or may be the same or different to one another. In the embodiment shown in Figure 3A, the first volume 24 is greater than the second volume 26, however this need not necessarily be the case.

[0056] The barrel 12 has a tapered forward portion 12b that tapers to a narrowed opening or outlet 12a at the forwardmost end of the barrel 12, where the narrowed opening 12a has a diameter less than the diameter of the barrel 12. A hollow needle 30 is connected to the opening 12a of the barrel 12 to permit the expulsion of fluid from the barrel 12 through the opening 12a.

[0057] Rearward of the stopper 14 there is a plunger element 32 in the form of a plunger stopper disposed in the barrel 12. In the embodiment of Figures 3A to 3C, the first volume 24 is defined as the volume between the plunger element 32 and the stopper 14 and the second volume is defined as the volume in the syringe assembly 10 forward of the stopper 14 and may include the volume inside the hollow needle 30.

[0058] The stopper 14 is axially displaceable within the barrel 12 upon the application of an axial force on the stopper 14. Similarly, the plunger element 32 is axially displaceable within the barrel 12 upon the application of an axial force on the plunger element 32.

[0059] To actuate the syringe assembly 10, the needle 30 is inserted into an injection site and the plunger element is moved axially forwards within the barrel 12. The axially forward movement of the plunger element 32 may be achieved using a power source or by manually moving the plunger element 32. The plunger element 32 may additionally comprise a plunger rod connected to the plunger stopper to facilitate axial movement of the plunger stopper within the barrel 12. As the plunger element 32 moves axially forwards within the barrel 12, it increases the fluid pressure of the first fluid in the first volume 24. Due to the incompressible nature of the first fluid, the force from the plunger element 32 is transferred axially to the stopper 14. The skilled reader will appreciate that any suitable mechanism that can apply a force to the first fluid may be used in alternative embodiments in place of the plunger element 32.

[0060] The stopper 14 is configured such that the axial force required to axially move the stopper 14 within the barrel 12 is less than the force provided by a fluid at the pressure threshold that determines when the resilient seal 22 moves from the sealing configuration to the open configuration.

[0061] Therefore, initial forward force from the plunger element 32 on the first fluid causes the stopper 14 to move axially forwardly within the barrel 12. This action increases the pressure of the second fluid contained in the second volume 26 and causes the second fluid to be expelled from the syringe assembly 10 through the opening 12a and needle 30. Assuming that a continual axially forward force is applied on the plunger element 32, the stopper 14 will continue to move axially forwards and expel the second fluid until the stopper 14 reaches the tapered forward portion 12b of the barrel 12. At this point, the axially forward force acting on the stopper 14 is met with an equal and opposite (i.e. axially rearward) reaction force from the tapered forward portion 12b of the barrel 12 and the stopper 14 ceases to move forwards. Subsequent force on the plunger element 32 causes the pressure of the first fluid in the first volume 24 to increase in pressure until the predetermined pressure threshold required to move the resilient seal 22 from the sealing configuration to the open configuration is exceeded. Once exceeded, the resilient seal 22 moves from the sealing configuration to the open configuration and the first fluid in the first volume 24 bypasses the permanent seal 18 into the second volume 26 and is expelled out of the syringe assembly through the opening 12a and the needle 30, as shown in Figure 3B.

[0062] Further force on the plunger element 32 causes the plunger element 32 to move further axially forwards towards the now stationary stopper 14, decreasing the first volume 24 as it does so. Eventually, the plunger el-

ement 32 reaches the stopper 14 and reduces the first volume 24 to substantially zero, as shown in Figure 3C. At this point, two volumes of fluid have been expelled from the syringe assembly 10 and delivery is complete. The needle 30 may then be removed from the injection site.

[0063] The device described in relation to Figures 3A to 3C may thus be used to deliver two sequential doses of medicament to an injection site, where the stopper 14 ensures the two volumes of fluid remain separate from one another prior to actuation. A syringe assembly 10 of this type may be useful for delivery of two medicaments that are unstable or less effective when mixed with one another. Further stoppers 14,14' may be included to permit the separation and subsequent sequential delivery of three or more substances. In one embodiment, a first substance may be delivered using the syringe assembly 10 and the delivery process may then be interrupted so that the needle 30 (or alternative applicator) may be changed prior to the delivery of the second substance using the same syringe assembly 10. Indeed, in the case where three or more substances are to be delivered, the needle 30 or other applicator may be changed prior to the delivery of each or any of the substances during the (interrupted) delivery procedure.

[0064] In another arrangement, the stopper 14 may be used to isolate a single volume of fluid from contact with certain components of the syringe assembly 10. In the example shown in Figure 4A, the first volume 24 is defined between the stopper 14 and the plunger element 32 and contains a first fluid. The stopper 14 is disposed in the barrel 12 against the tapered forward portion 12b of the barrel 12 such that no further forward axial movement of the stopper 14 in the barrel 12 is possible. The second volume 26, axially forward of the stopper 14, does not contain any fluid or medicament. Thus, the first fluid is maintained in the first volume 24 and is isolated from the opening 12a of the barrel 12 and the needle 30. In some embodiments, it may be desirable to have some "take-up" such that the stopper 14 is initially disposed axially rearward of the tapered forward portion 12b of the barrel 12.

[0065] This arrangement may be advantageous in keeping sensitive medicaments isolated from the materials of the needle 30 and any adhesives used to affix the needle 30 to the opening 12a prior to actuation of the syringe assembly 10. Such contact between sensitive medicaments and the materials of the needle, any adhesives used to affix the needle in place, or any residual tungsten left from the manufacture of the syringe assembly (i.e. when forming the narrowed outlet 12a) may reduce or null the efficacy of the medicament over time. The arrangement shown in Figure 4A therefore allows sensitive medicaments to be stably stored in a syringe assembly 10 without the risk of its efficacy being reduced through material contamination. In an isolated configuration (which may be achievable in any embodiment of the present invention), the medicament is only in contact with a limited number of materials, for example the stopper 14, the syringe barrel 12 and any silicon, if present (if, for example, the internal surface of the barrel 12 is siliconised). With limited contact between the materials of the syringe assembly 10 and the medicament, it is easier to determine extractables and leachables.

[0066] When the user is ready to deliver the first fluid in the first volume 24, the needle is inserted into the injection site and a force is applied to the plunger element 32 which in turn applies a force to the stopper 14 via the incompressible fluid in the first volume 24. If the stopper 14 is initially in the position shown in Figure 4A against the tapered forward portion 12b, then the stopper is unable to move axially forwards and the pressure of the first fluid increases. If, however, there is some "take-up", and the stopper 14 is initially axially rearward of the tapered forward portion 12b, then the stopper 14 moves axially forwardly under the influence of the force applied to the plunger element 32 until it reaches the tapered forward portion 12b, at which point the pressure of the first fluid begins to increase. When the pressure of the first fluid exceeds the pressure threshold required to move the resilient seal 22 from the sealing configuration to the open configuration, the resilient seal 22 moves to the open configuration and the stopper permits the first fluid to leave the first volume 24 and enter the second volume 26 and be expelled from the syringe assemble 10 through the opening 12a and needle 30.

[0067] Continued force on the plunger element 32 causes the plunger element 32 to continue to move axially forwardly towards the stationary stopper 14, decreasing the size of the first volume as it does so until the first volume 24 is reduced to substantially zero. At this point, delivery is complete and the user may remove the needle 30 from the injection site.

[0068] Since the stopper 14 is not required to move axially within the barrel 12, the stopper 14 may be fixed axially within the barrel 12. Examples of how the stopper 14 may be axially fixed within the barrel include but are not limited to radio frequency (RF) welding or heat welding. In other preferred embodiments, the stopper 14 may be retained axially within the barrel 12 simply by friction between the stopper 14 and the barrel 12. Alternatively or additionally, the stopper 14 may be prevented from moving axially forwardly in the barrel 12 by abutment with the tapered forward portion 12b of the barrel 12.

[0069] A further embodiment of the invention is shown in Figures 5A to 5D which depict the various stages of operation of a syringe assembly 10. In particular, the syringe assembly 10 of Figures 5A to 5D is for mixing two substances prior to delivery. For example, the two substances may include a dry or lyophilized medicament and a fluid diluent, or a dry or lyophilized medicament and a fluid medicament. It may be desirable for stability and/or efficacy reasons to keep the wet and dry substances separated prior to delivery (e.g. during storage of the syringe assembly 10).

[0070] The syringe assembly 10 of Figure 5A is largely

similar to that described above in relation to Figure 3A. The first volume 24 contains a fluid while the second volume 26 contains a dry or lyophilized substance. The stopper 14 initially separates the first and second volumes 24,26 just as described above with reference to Figure 3A. However, the stopper 14 of the syringe assembly 10 of Figure 5A is configured in the barrel 12 such that the force at the fluid pressure threshold that determines when the resilient seal 22 moves from the sealing configuration to the open configuration is less than the force required to move the stopper 14 axially in the barrel 12 (i.e. that required to overcome friction and other axial resistive forces).

[0071] Therefore, when the syringe assembly is actuated by applying a forwardly axial force on the plunger element 32, the increase in fluid pressure in the first volume 24 causes the resilient seal 22 to move from the sealing configuration to the open configuration whilst the stopper 14 remains axially stationary in the barrel 12. Figure 5B shows the syringe assembly of Figure 5A during the "mixing" stage, where the resilient seal 22 is in its open configuration and the axially forwardly advancing plunger element 32 is pressurizing the fluid in the first volume and causing it to flow into the second volume via the channel 18, while the stopper 14 remains axially stationary within the barrel 12. The fluid from the first volume 24 therefore mixes with the dry or lyophilized substance in the second volume 26 to form a solution or mixture. In some embodiments, the stopper 14 may additionally comprise a nozzle or spray head (not shown) at or near the first opening 20a to facilitate mixing of the fluid and dry or lyophilized substance in the second volume 26.

[0072] Continued axially forward movement of the plunger element 32 results in the plunger element 32 reaching the stopper 14 and reducing the first volume 24 to zero. At this point, substantially all of the fluid from the first volume 24 has flowed through the channel 18 and into the second volume 26 to form a solution or mixture. Once the plunger element 32 has met the stopper 14, as shown in Figure 5C, further axially forwardly movement of the plunger element 32 causes the stopper 14 to move axially forwardly in the barrel as the forward force applied to the stopper 14 exceeds the axially rearwardly acting frictional and resistive forces that resist forward axial movement of the stopper 14 in the barrel 12.

[0073] Axially forwardly movement of the stopper 14 in the barrel 12 causes the solution or mixture contained in the second volume 26 to be expelled through the opening 12a of the barrel through the needle 30 and into the injection site that the needle is staked into. Figure 5D shows the syringe assembly 10 at the end of delivery where the plunger element 32 and stopper 14 have moved to their forwardmost axial position in the barrel 12, with the stopper 14 abutting the tapered forward portion 12b of the barrel 12. At this point, the syringe assembly 10 may be removed from the injection site.

[0074] An alternative embodiment of a mixing-type syringe assembly 10 in accordance with the present invention is shown in Figures 6A to 6D. In this embodiment, the stopper 14" includes a friction clamp 34 that increases the frictional forces required to move the stopper 14" axially forwardly within the barrel 12. In one embodiment, the stopper 14" may be a two-shot moulding where the first shot forms the friction clamp 34 from a plastics material or the like and the second shot forms the remainder of the stopper 14" from an elastomer material or the like. The stopper 14" additionally has a socket 36 formed therein that is capable of receiving a complementary key 32a that is formed on the front side of the plunger element 32. When the key 32a is received in the socket 36, the clamping load (i.e. the frictional and resistive forces) provided by the friction clamp 34 is reduced, thereby lowering the threshold force required to move the stopper 14" axially forwardly in the barrel 12.

[0075] The arrangement shown in Figure 6A is equivalent to that shown in Figure 5A where a fluid substance is contained in the first volume 24 and a dry or lyophilized substance is contained in the second volume 26, prior to actuation. Similarly, Figure 6B shows an equivalent arrangement to that shown in Figure 5B, where the axially forwardly force on the plunger element 32 has caused the plunger element 32 to move axially forwardly in the barrel 12 towards the stationary stopper 14" causing the resilient seal to move into the open configuration and forcing the fluid from the first volume 24 to flow into the second volume 26 through the channel 18.

[0076] In the arrangement shown in Figure 6C, the plunger element 32 has moved axially forwardly in the barrel 12 and has met the stopper 14" such that the key 32a of the plunger element 32 is inserted into the socket 36 of the stopper 14". As described above, the mating of the key 32a and socket 36 components causes the clamping load of the stopper 14" to be reduced. Therefore, further axially forward movement of the plunger element 32 causes axially forward movement of the stopper 14", thus expelling the solution or mixture formed in the second volume 26 from the syringe assembly 10 via the opening 12a and needle 30. Figure 6D shows the syringe assembly 10 at the end of delivery where the plunger element 32 and stopper 14" have moved to their forwardmost axial position in the barrel 12, with the stopper 14" abutting the tapered forward portion 12b of the barrel 12. At this point, the syringe assembly 10 may be removed from the injection site.

[0077] The arrangement of Figures 6A to 6D has the additional advantage over the arrangement of Figures 5A to 5D in that the force required to move the stopper 14" is higher due to the presence of the friction clamp 34. However, the key 32a and socket 36 arrangement of the embodiment of Figures 6A to 6D means that the force required to actually move the stopper 14" axially forwardly when desired is achievable within the reasonable operating limits of the syringe assembly 10. Therefore, the friction clamp 34 provides less risk of unwanted axial movement of the stopper 14" prior to the completion of mixing between the first volume 24 and the second vol-

ume 26.

[0078] The syringe assembly 10 of the present invention may be used as a manual device or as part of an autoinjector device. In particular, the syringe assembly 10 may be configured such that the needle 30 is automatically inserted and removed from the injection site, prior to and after delivery, respectively.

[0079] Either of the described stoppers 14,14' and any described alternatives or modifications of the stoppers 14,14' may be utilized in a syringe assembly 10 in accordance with the present invention. Additionally, the stopper 14" described in relation to Figures 6A to 6D may be used in "mixing"-type devices within the scope of the present invention. All stoppers in accordance with the present invention are particularly advantageous as each provides an effective and reliable two-way valve for separating two substances or isolating a single substance. The stopper may be used in existing syringes thereby negating the requirement for bespoke syringes. Additionally, the stopper of the present invention may be easily and cost-effectively moulded in comparison to prior art components that seek to provide a similar effect. Thus the syringe assembly 10 of the present invention is easy to manufacture in comparison to more complicated prior art arrangements. A further advantage of the syringe assembly 10 of the present invention is that it may be filled with relative ease in comparison with prior art devices. Each substance is introduced into the barrel sequentially from the rear (i.e. the end opposite the narrowed opening or outlet) with the stopper (or stoppers) being inserted in the sequence where desired. Therefore, standard syringe filling apparatus that is common in the art may be used to fill the syringe assembly, and no specially adapted filling apparatus need necessarily be used.

[0080] Two or more stoppers 14,14' may be employed in a single syringe assembly 10 to provide selective sealing between several volumes in the syringe assembly 10. For example, three medicaments may be delivered sequentially by utilizing two stoppers 14,14' intermediate the opening 12a and the plunger element 32 or equivalent means for providing a forward force. Indeed, the syringe assembly 10 may consist of a combination of the embodiments shown in Figures 3A to 3C and Figures 4A to 4B in that a front stopper 14,14' may be used to isolate the contents of the syringe assembly 10 from the opening 12a and needle 30 whilst further stoppers 14,14' may be utilized to permit a multi-dose, sequential delivery. Additionally or alternatively, the syringe assembly 10 may be a combination of any of the described embodiments so that the syringe assembly 10 is capable of any one or more of: sequential delivery, mixing of two or more substances, and medicament isolation. Indeed, the syringe assembly 10 may be arranged to be capable of all three of these modes of operation, such that medicaments are initially isolated from one another and the narrowed outlet (and any needle present). Upon actuation of the syringe assembly 10, two or more of the substances may be mixed in accordance with the mechanism described above in relation to Figures 5A to 5D or Figures 6A to 6D and then delivered, before being delivered, following the sequential delivery of one or more substances stored axially rearward of the two or more substances that are mixed.

[0081] Instead of an integral narrowed opening 12a, the syringe assembly 10 may include a separate component that serves as a narrowed opening 12a for allowing the expulsion of fluid from the syringe assembly 10.

[0082] The syringe assembly 10 of the present invention may be used with a needle 30 or other applicator in fluid communication with the opening 12a.

[0083] Throughout the description and claims of this specification, the words "comprise" and "contain" and variations of them mean "including but not limited to", and they are not intended to (and do not) exclude other moieties, additives, components, integers or steps. Throughout the description and claims of this specification, the singular encompasses the plural unless the context otherwise requires. In particular, where the indefinite article is used, the specification is to be understood as contemplating plurality as well as singularity, unless the context requires otherwise.

[0084] Features, integers, characteristics, compounds, chemical moieties or groups described in conjunction with a particular aspect, embodiment or example of the invention are to be understood to be applicable to any other aspect, embodiment or example described herein unless incompatible therewith. All of the features disclosed in this specification (including any accompanying claims, abstract and drawings), and/or all of the steps of any method or process so disclosed, may be combined in any combination, except combinations where at least some of such features and/or steps are mutually exclusive.

[0085] The reader's attention is directed to all papers and documents which are filed concurrently with or previous to this specification in connection with this application and which are open to public inspection with this specification, and the contents of all such papers and documents

Claims

1. A syringe assembly (10) comprising:

a barrel (12) for containing one or more medicaments, a narrowed outlet (12a) for allowing the expulsion of said one or more medicaments from said barrel through said outlet; and
a stopper (14; 14'; 14") disposed in the barrel defining and separating a first volume (24) and a second volume (26) within the syringe assembly, the stopper comprising:

a permanent seal (16) fluidly sealing the stopper to the barrel about the entire perim-

eter of the stopper intermediate the first volume and second volume;
a resilient seal (22, 22'); and
a channel (18) bypassing the permanent seal, the channel having a first opening (20a) in fluid communication with the second volume and a second opening (20b) selectively sealed from the first volume by the resilient seal;

wherein the resilient seal is moveable between a sealing configuration and an open configuration to selectively seal the channel from the first volume, where in the sealing configuration the resilient seal fluidly seals the stopper to the barrel so as to fluidly isolate said second opening of the channel from the first volume, and in the open configuration the second opening of the channel is in fluid communication with the first volume; and
wherein the resilient seal is moveable from the sealing configuration to the open configuration upon fluid pressure in the first volume or second volume exceeding a first pressure threshold.

2. A syringe assembly (10) according to claim 1, wherein the stopper (14; 14'; 14") is axially moveable within the barrel (12) upon application of an axial force on the stopper.

3. A syringe assembly (10) according to claim 2, wherein the axial force required to move the stopper (14; 14'; 14") within the barrel (12) is less than the force provided by a fluid at the first pressure threshold.

4. A syringe assembly (10) according to claim 2, wherein the axial force required to move the stopper (14; 14'; 14") within the barrel (12) is greater than the force provided by a fluid at the first pressure threshold.

5. A syringe assembly (10) according to any preceding claim, wherein the resilient seal (22; 22') comprises one or more flexible elements (22a, 22b; 22a', 22b');
wherein optionally said one or more flexible elements partly extends circumferentially around said stopper and the remainder of the stopper forms a seal with the barrel circumferentially around said one or more flexible elements; or
wherein optionally said one or more flexible elements extends entirely circumferentially around said stopper.

6. A syringe assembly (10) according to claim 5, wherein the resilient seal (22; 22') comprises at least two flexible elements (22a, 22b; 22a', 22b');
wherein optionally the at least two flexible elements are axially aligned with one another.

7. A syringe assembly (10) according to any preceding claim, wherein the channel (18) comprises at least one axial channel part (18a) and at least one additional channel part (18b) arranged substantially perpendicularly to said at least one axial channel and in fluid communication therewith.

8. A syringe assembly (10) according to any preceding claim, wherein the permanent seal (16) comprises at least one flange (16a, 16b) projecting outwardly from said stopper (14; 14'; 14") about the entire perimeter of the stopper;
wherein optionally the permanent seal comprises at least two flanges projecting outwardly from said stopper about the entire perimeter of the stopper, wherein the at least two flanges are arranged in axial alignment with one another.

9. A syringe assembly (10) according to any preceding claim, further comprising a pressure source for pressurising a fluid in the barrel (12);
wherein optionally said pressure source comprises an axially moveable plunger element (32) disposed in the barrel, where the stopper is disposed in the barrel intermediate the plunger element and the narrowed outlet (12a) of the barrel; and
wherein optionally said plunger element comprises a plunger stopper (32) and a plunger rod connected to the plunger stopper for axially moving the plunger stopper in the barrel.

10. A syringe assembly (10) according to claim 3, wherein said first volume (24) contains a fluidic substance and said second (26) volume contains a dry or lyophilized substance.

11. A syringe assembly (10) according to any of claims 1 to 9, wherein one or both of said first volume (24) and second volume (26) is a medicament volume for containing one or more medicaments;
wherein optionally said first volume is a first medicament volume for containing a first medicament and said second volume is a second medicament volume for containing a second medicament; and
wherein optionally said first medicament volume contains a first fluidic medicament and said second medicament volume contains a second fluidic medicament.

12. A syringe assembly (10) according to any of claims 1 to 9, wherein said first volume (24) is a medicament volume for containing a medicament and said stopper (14; 14'; 14") is arranged in said barrel (12) to selectively isolate the medicament volume from the outlet of the barrel;
wherein optionally said medicament volume contains a fluidic medicament.

13. A syringe assembly according (10) to claim 4, or any of claims 5 to 11 when dependent upon claim 4, wherein the stopper (14; 14'; 14") further comprises a friction clamp (34) that is moveable between a clamping position and a non-clamping position, where a higher force is required to axially move the stopper in the barrel (12) when the friction clamp is in the clamping position than when the friction clamp is in the non-clamping position;
wherein optionally the syringe assembly further comprises a moveable plunger element (32) disposed in the barrel for pressurising a fluid in the first volume, where the stopper is disposed in the barrel intermediate the plunger element and the narrowed outlet of the barrel (12a), wherein the plunger element comprises a key (32a) and the stopper comprises a socket (36) complementary to said key, and wherein engagement of the key in the socket moves said friction clamp to said non-clamping position.

14. A syringe assembly (10) according to any preceding claim, wherein said stopper (14; 14'; 14") is a first stopper, and the syringe assembly further comprises one or more additional stoppers each comprising the features of the first stopper as defined in any preceding claim, wherein the one or more additional stoppers separate and define further volumes within the syringe assembly axially rearward of the first stopper.

15. An autoinjector comprising a syringe assembly (10) according to any preceding claim.

Patentansprüche

1. Spritzenanordnung (10), umfassend:

einen Zylinder (12) zum Aufnehmen von einem oder mehreren Medikamenten, einen verengten Auslass (12a) zum Zulassen des Ausstoßens des einen oder der mehreren Medikamente aus dem Zylinder durch den Auslass; und
einen in dem Zylinder angeordneten Stopfen (14; 14'; 14"), der ein erstes Volumen (24) und ein zweites Volumen (26) in der Spritzenanordnung definiert und trennt, wobei der Stopfen Folgendes umfasst:

eine Permanentdichtung (16), die den Stopfen um den gesamten Umfang des Stopfens zwischen dem ersten Volumen und dem zweiten Volumen fluidisch an den Zylinder dichtet;
eine nachgiebige Dichtung (22, 22'); und
einen die Permanentdichtung umgehenden Kanal (18), wobei der Kanal eine erste Öffnung (20a) in Fluidverbindung mit dem zweiten Volumen und eine durch die nachgiebige Dichtung selektiv von dem ersten Volumen gedichtete zweite Öffnung (20b) aufweist;
wobei die nachgiebige Dichtung zwischen einer dichtenden Konfiguration und einer offenen Konfiguration bewegbar ist, um den Kanal selektiv von dem ersten Volumen zu dichten, wobei in der dichtenden Konfiguration die nachgiebige Dichtung den Stopfen fluidisch an den Zylinder dichtet, um die zweite Öffnung des Kanals fluidisch von dem zweiten Volumen abzutrennen, und sich in der offenen Konfiguration die zweite Öffnung des Kanals in Fluidverbindung mit dem ersten Volumen befindet; und
wobei die nachgiebige Dichtung von der dichtenden Konfiguration in die offene Konfiguration bewegbar ist, wenn Fluiddruck in dem ersten Volumen oder dem zweiten Volumen eine erste Druckschwelle überschreitet.

2. Spritzenanordnung (10) nach Anspruch 1, wobei der Stopfen (14; 14'; 14") axial in dem Zylinder (12) bewegbar ist, wenn eine Axialkraft auf den Stopfen ausgeübt wird.

3. Spritzenanordnung (10) nach Anspruch 2, wobei die zum Bewegen des Stopfens (14; 14'; 14") in dem Zylinder (12) benötigte Axialkraft geringer ist als die bei der ersten Druckschwelle von einem Fluid bereitgestellte Kraft.

4. Spritzenanordnung (10) nach Anspruch 2, wobei die zum Bewegen des Stopfens (14; 14'; 14") in dem Zylinder (12) benötigte Axialkraft größer ist als die bei der ersten Druckschwelle von einem Fluid bereitgestellte Kraft.

5. Spritzenanordnung (10) nach einem der vorangehenden Ansprüche, wobei die nachgiebige Dichtung (22; 22') ein oder mehrere biegsame Elemente (22a, 22b; 22a', 22b') umfasst;
wobei optional sich das eine oder die mehreren biegsamen Elemente teilweise in Umfangsrichtung um den Stopfen erstrecken und der Rest des Stopfens eine Dichtung mit dem Zylinder in Umfangsrichtung um das eine oder die mehreren biegsamen Elemente bildet; oder
wobei optional sich das eine oder die mehreren biegsamen Elemente vollständig in Umfangsrichtung um den Stopfen erstrecken.

6. Spritzenanordnung (10) nach Anspruch 5, wobei die nachgiebige Dichtung (22; 22') mindestens zwei biegsame Elemente (22a, 22b; 22a', 22b') umfasst; wobei optional die mindestens zwei biegsamen Ele-

mente axial aufeinander ausgerichtet sind.

7. Spritzenanordnung (10) nach einem der vorangehenden Ansprüche, wobei der Kanal (18) mindestens einen Axialkanalteil (18a) und mindestens einen zusätzlichen Kanalteil (18b), der im Wesentlichen senkrecht zu dem mindestens einen Axialkanal und in Fluidverbindung damit angeordnet ist, umfasst.

8. Spritzenanordnung (10) nach einem der vorangehenden Ansprüche, wobei die Permanentdichtung (16) mindestens einen Flansch (16a, 16b) umfasst, der um den gesamten Umfang des Stopfens von dem Stopfen (14; 14'; 14") nach außen vorsteht;
wobei optional die Permanentdichtung mindestens zwei Flansche umfasst, die um den gesamten Umfang des Stopfens von dem Stopfen nach außen vorstehen, wobei die mindestens zwei Flansche in axialer Ausrichtung aufeinander angeordnet sind.

9. Spritzenanordnung (10) nach einem der vorangehenden Ansprüche, weiter umfassend eine Druckquelle, um ein Fluid in dem Zylinder (12) unter Druck zu setzen;
wobei optional die Druckquelle ein in dem Zylinder angeordnetes axial bewegbares Kolbenelement (32) umfasst, wobei der Stopfen zwischen dem Kolbenelement und dem verengten Auslass (12a) des Zylinders in dem Zylinder angeordnet ist; und
wobei optional das Kolbenelement einen Kolbenstopfen (32) und einen mit dem Kolbenstopfen verbundenen Kolbenschaft zum axialen Bewegen des Kolbenstopfens in dem Zylinder umfasst.

10. Spritzenanordnung (10) nach Anspruch 3, wobei das erste Volumen (24) eine fluidförmige Substanz enthält und das zweite (26) Volumen eine trockene oder lyophylisierte Substanz umfasst.

11. Spritzenanordnung (10) nach einem der Ansprüche 1 bis 9, wobei es sich bei dem ersten Volumen (24) und/oder dem zweiten Volumen (26) um ein Medikamentenvolumen zum Aufnehmen von einem oder mehreren Medikamenten handelt;
wobei optional es sich bei dem ersten Volumen um ein erstes Medikamentenvolumen zum Aufnehmen eines ersten Medikaments handelt und es sich bei dem zweiten Volumen um ein zweites Medikamentenvolumen zum Aufnehmen eines zweiten Medikaments handelt; und
wobei optional das erste Medikamentenvolumen ein erstes fluidförmiges Medikament enthält und das zweite Medikamentenvolumen ein zweites fluidförmiges Medikament enthält.

12. Spritzenanordnung (10) nach einem der Ansprüche 1 bis 9, wobei es sich bei dem ersten Volumen (24) um ein Medikamentenvolumen zum Aufnehmen eines Volumens handelt und der Stopfen (14; 14'; 14") in dem Zylinder (12) angeordnet ist, um das Medikamentenvolumen selektiv von dem Auslass des Zylinders abzutrennen;
wobei optional das Medikamentenvolumen ein fluidförmiges Medikament enthält.

13. Spritzenanordnung (10) nach Anspruch 4 oder einem der Ansprüche 5 bis 11, wenn abhängig von Anspruch 4, wobei der Stopfen (14; 14'; 14") weiter eine Reibklemme (34) umfasst, die zwischen einer klemmenden Position und einer nicht klemmenden Position bewegbar ist, wobei eine höhere Kraft benötigt wird, um den Stopfen axial in dem Zylinder (12) zu bewegen, wenn sich die Reibklemme in der klemmenden Position befindet als wenn sich die Reibklemme in der nicht klemmenden Position befindet;
wobei optional die Spritzenanordnung weiter ein bewegbares Kolbenelement (32) umfasst, das in dem Zylinder angeordnet ist, um ein Fluid in dem ersten Volumen unter Druck zu setzen, wobei der Stopfen zwischen dem Kolbenelement und dem verengten Auslass des Zylinders (12a) in dem Zylinder angeordnet ist, wobei das Kolbenelement eine Nase (32a) umfasst und der Stopfen eine zu der Nase komplementäre Aufnahme (36) umfasst, und wobei der Eingriff der Nase in der Aufnahme die Reibklemme in die nicht klemmende Position bewegt.

14. Spritzenanordnung (10) nach einem der vorangehenden Ansprüche, wobei es sich bei dem Stopfen (14; 14'; 14") um einen ersten Stopfen handelt, und die Spritzenanordnung weiter einen oder mehrere zusätzliche Stopfen umfasst, die jeweils die Merkmale des ersten Stopfens, wie in einem der vorangehenden Ansprüche definiert, umfassen, wobei der eine oder die mehreren zusätzlichen Stopfen weitere Volumen in der Spritzenanordnung axial hinter dem ersten Stopfen trennen und definieren.

15. Autoinjektor, umfassend eine Spritzenanordnung (10) nach einem der vorangehenden Ansprüche.

Revendications

1. Ensemble seringue (10) comprenant :

un barillet (12) pouvant contenir un ou plusieurs médicaments, une sortie rétrécie (12a) pour permettre l'expulsion dudit un ou desdits plusieurs médicaments hors dudit barillet à travers ladite sortie ; et
un bouchon (14; 14'; 14") disposé dans le barillet, définissant et séparant un premier volume (24) et un second volume (26) à l'intérieur de la

seringue, le bouchon comprenant :

un joint d'étanchéité permanent (16) pour sceller le bouchon de manière fluide sur le barillet sur tout le périmètre du bouchon situé entre le premier volume et le second volume ;
un joint d'étanchéité résilient (22, 22') ; et
un canal (18) contournant le joint d'étanchéité permanent, le canal présentant une première ouverture (20a) en communication fluide avec le second volume et une second ouverture (20b) scellée de manière sélective par rapport au premier volume, par le joint d'étanchéité permanent ;
où le joint d'étanchéité résilient est mobile entre une configuration d'étanchéité et une configuration ouverte pour sceller de manière sélective le canal par rapport au premier volume, où dans la configuration d'étanchéité, le joint d'étanchéité résilient scelle de manière fluide le bouchon sur le barillet afin d'isoler de façon fluide ladite second ouverture du canal par rapport au premier volume, et dans la configuration ouverte la second ouverture du canal est en communication fluide avec le premier volume ; et
où le joint d'étanchéité résilient est mobile à partir de la configuration d'étanchéité vers la configuration ouverte lorsque la pression de fluide dans le premier volume ou le second volume dépasse un premier seuil de pression.

2. Ensemble seringue (10) selon la revendication 1, où le bouchon (14; 14'; 14") est mobile axialement dans le barillet (12) lorsque l'on applique une force sur le bouchon.

3. Ensemble seringue (10) selon la revendication 2, où la force axiale nécessaire pour déplacer le bouchon (14; 14'; 14") dans le barillet (12) est inférieure à la force délivrée par un fluide au premier seuil de pression.

4. Ensemble seringue (10) selon la revendication 2, où la force axiale nécessaire pour déplacer le bouchon (14; 14'; 14") dans le barillet (12) est supérieure à la force délivrée par un fluide au premier seuil de pression.

5. Ensemble seringue (10) selon une quelconque revendication précédente, où le joint d'étanchéité résilient (22; 22') se compose d'un ou plusieurs éléments flexibles (22a, 22b, 22a', 22b') ;
où éventuellement ledit un ou plusieurs éléments flexibles s'étendent de manière circonférentielle en partie autour dudit bouchon et le reste du bouchon forme un joint d'étanchéité avec le barillet de manière circonférentielle autour dudit un ou plusieurs éléments flexibles ; ou
où éventuellement ledit un ou plusieurs éléments flexibles s'étendent entièrement autour dudit bouchon de manière circonférentielle.

6. Ensemble seringue (10) selon la revendication 5, où le joint d'étanchéité résilient (22; 22') comprend au moins deux éléments flexibles (22a, 22b, 22a', 22b') ;
où éventuellement lesdits au moins deux éléments flexibles sont alignés axialement l'un avec l'autre.

7. Ensemble seringue (10) selon une quelconque revendication précédente, où le canal (18) comprend au moins une partie de canal axiale (18a) et au moins une partie de canal supplémentaire (18b) agencées sensiblement de manière perpendiculaire audit au moins un canal axial et en communication fluide avec celui-ci.

8. Ensemble seringue (10) selon une quelconque revendication précédente, où le joint d'étanchéité permanent (16) comprend au moins un flasque (16a, 16b) en projection vers l'extérieur dudit bouchon (14; 14'; 14") sur tout le pourtour du bouchon ;
où éventuellement le joint d'étanchéité permanent comprend au moins deux flasques en projection vers l'extérieur dudit bouchon sur tout le pourtour du bouchon, où lesdites au moins deux flasques sont agencées en alignement axial l'une avec l'autre.

9. Ensemble seringue (10) selon une quelconque revendication précédente, comprenant en outre une source de pression pour mettre en pression un fluide dans le barillet (12) ;
où éventuellement ladite source de pression comprend un élément piston mobile axialement (32) agencé dans le barillet, où le bouchon est agencé dans le barillet entre l'élément piston et la sortie rétrécie (12a) du barillet ; et
où éventuellement ledit élément piston comporte un bouchon-piston (32) et une tige de piston connectée au bouchon-piston pour déplacer axialement le bouchon-piston dans le barillet.

10. Ensemble seringue (10) selon la revendication 3, où ledit premier volume (24) contient une substance fluidique et ledit second volume (26) contient une substance sèche ou lyophilisée.

11. Ensemble seringue selon l'une quelconque des revendications 1 à 9, où l'un ou les deux dudit premier volume (24) et dudit second volume (26) est un volume de médicaments pouvant contenir un ou plusieurs médicaments ;

où éventuellement ledit premier volume est un premier volume de médicament pour contenir un premier médicament et ledit second volume est un second volume de médicament pour contenir un second médicament ; et
où éventuellement ledit premier volume de médicament contient un premier médicament fluidique et ledit second volume de médicament fluidique contient un second médicament fluidique.

12. Ensemble seringue (10) selon l'une quelconque des revendications 1 à 9, où ledit premier volume (24) est un volume de médicament pouvant contenir un médicament et ledit bouchon (14; 14'; 14") est agencé dans ledit barillet (12) pour isoler sélectivement le volume de médicament de la sortie du barillet ;
où éventuellement ledit volume de médicament contient un médicament fluidique.

13. Ensemble seringue (10) selon la revendication 4, ou l'une quelconque des revendications 5 à 11 en fonction de la revendication 4, où le bouchon (14; 14'; 14") comprend en outre un collier de friction (34) qui est mobile entre une position de serrage et une position de non-serrage, où une plus grande force est nécessaire pour déplacer axialement le bouchon dans le barillet (12) lorsque le collier de friction est en position de serrage de collier que lorsque le collier de friction est dans la position de non-serrage ;
où éventuellement l'ensemble seringue comprend en outre un élément piston mobile (32) agencé dans le barillet pour mettre en pression n fluide dans le premier volume, où le bouchon est agencé dans le barillet entre l'élément piston et la sortie rétrécie du barillet (12a), où l'élément piston comporte une clé (32a) et le bouchon comprend une douille (36) complémentaire de ladite clé, et où l'enclenchement de la clé dans la douille déplace ledit collier à friction vers ladite position de non-serrage.

14. Ensemble seringue (10) selon une quelconque revendication précédente, où ledit bouchon (14; 14'; 14") est un premier bouchon, et l'ensemble seringue comprend un ou plusieurs bouchons supplémentaires présentant chacun les fonctionnalités du premier bouchon tel que défini dans toute revendication précédente, où ledit un ou plusieurs bouchons supplémentaires séparent et définissent de nouveaux volumes dans l'ensemble seringue à l'arrière axialement du premier bouchon.

15. Auto-injecteur comprenant un ensemble seringue (10) selon une quelconque revendication précédente.

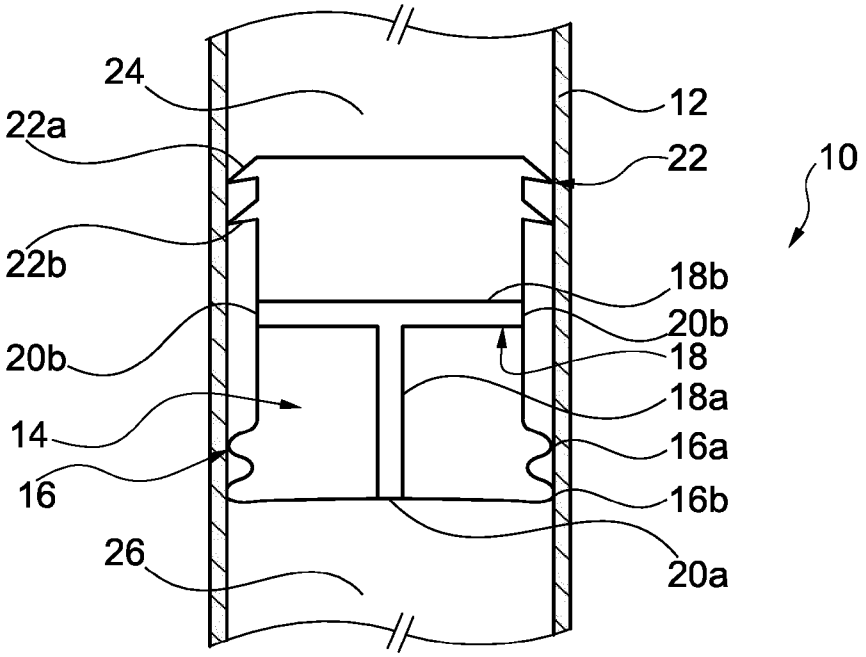
24
22a
22b
20b
14
16
26
12
22
10
18b
20b
18
18a
16a
16b
20a

Fig. 1A

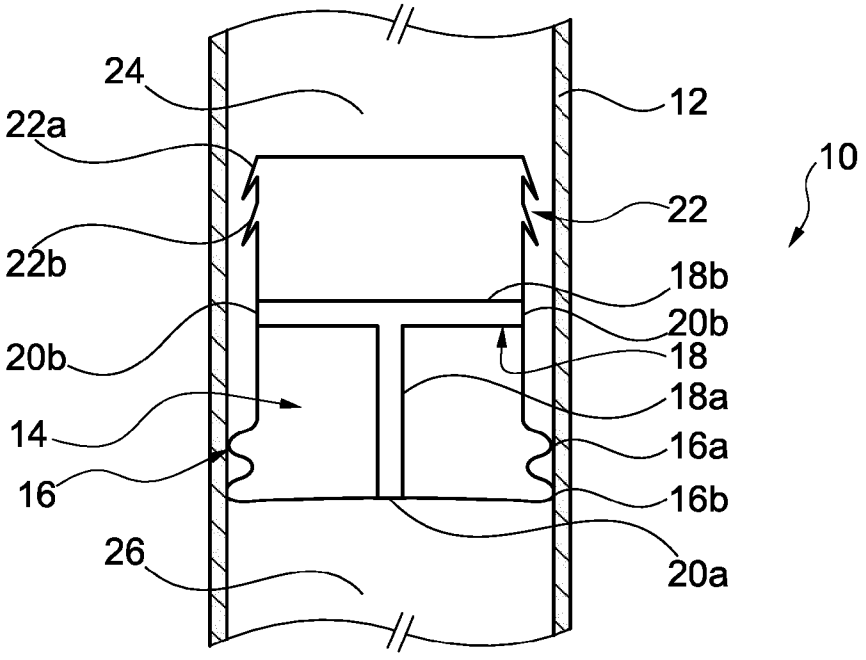
24
22a
22b
20b
14
16
26
12
22
10
18b
20b
18
18a
16a
16b
20a

Fig. 1B

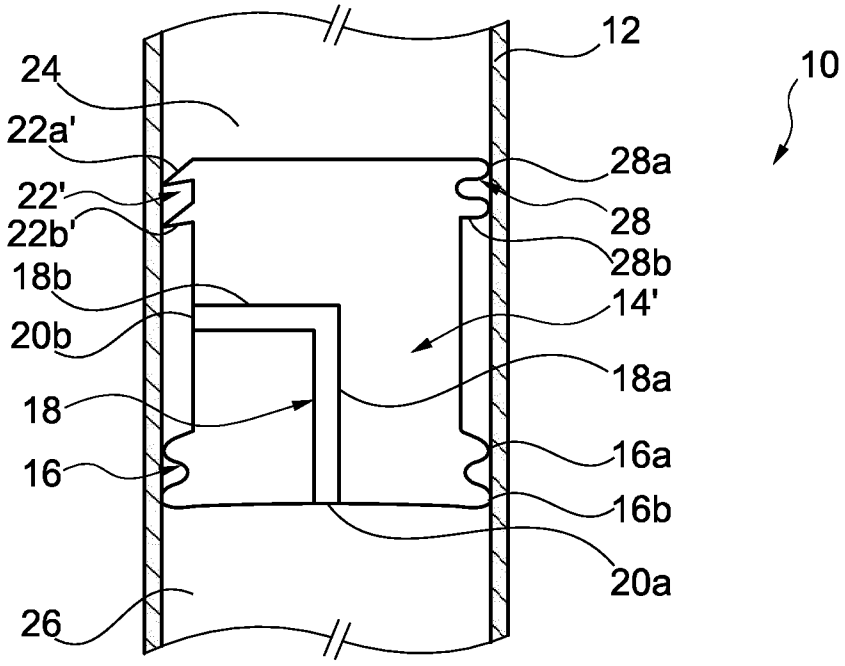
12
10
24
22a'
28a
22'
28
22b'
28b
18b
14'
20b
18a
18
16a
16
16b
20a
26

Fig. 2A

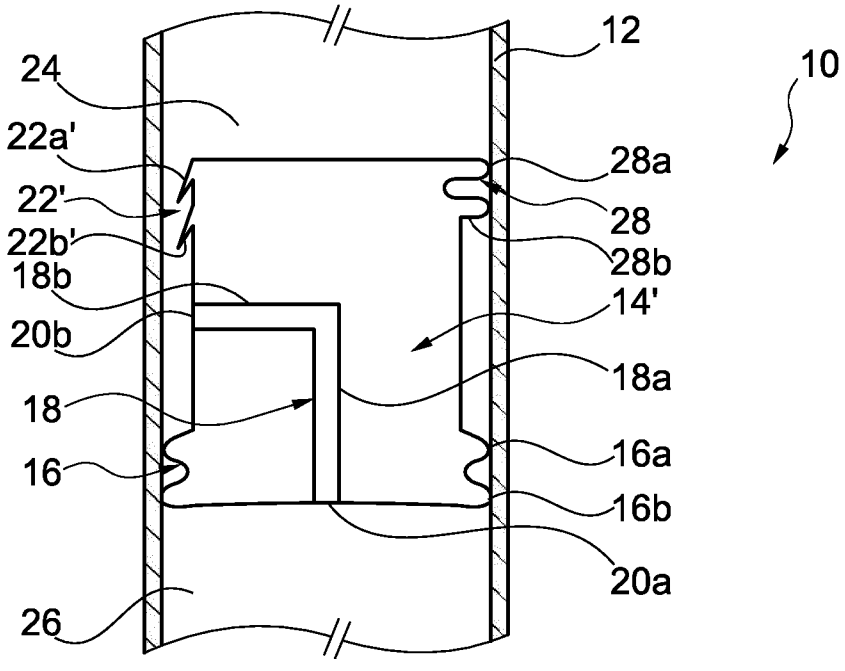
12
10
24
22a'
28a
22'
28
22b'
28b
18b
14'
20b
18a
18
16a
16
16b
20a
26

Fig. 2B

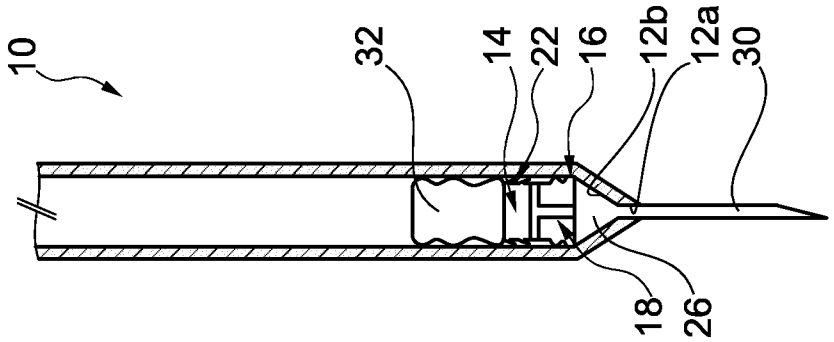

Fig. 3C

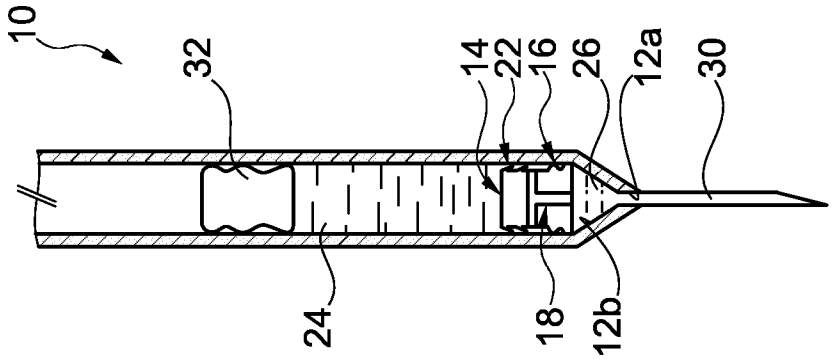

Fig. 3B

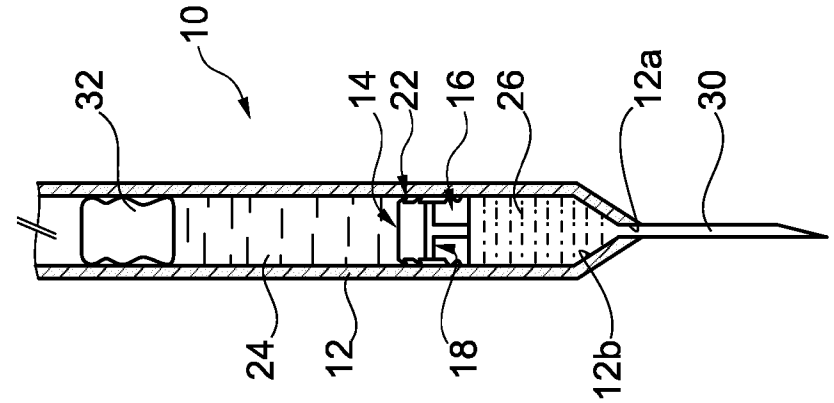

Fig. 3A

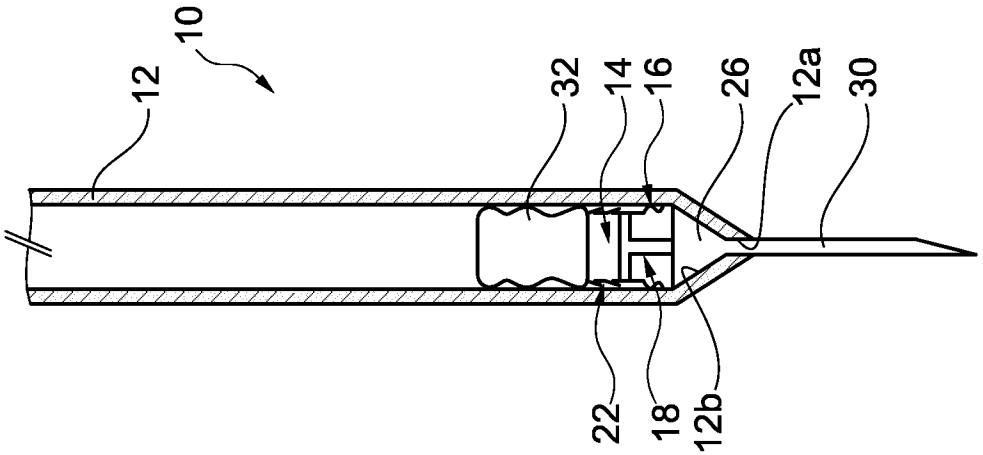
10
12
32
14
16
26
12a
30
22
18
12b

Fig. 4B

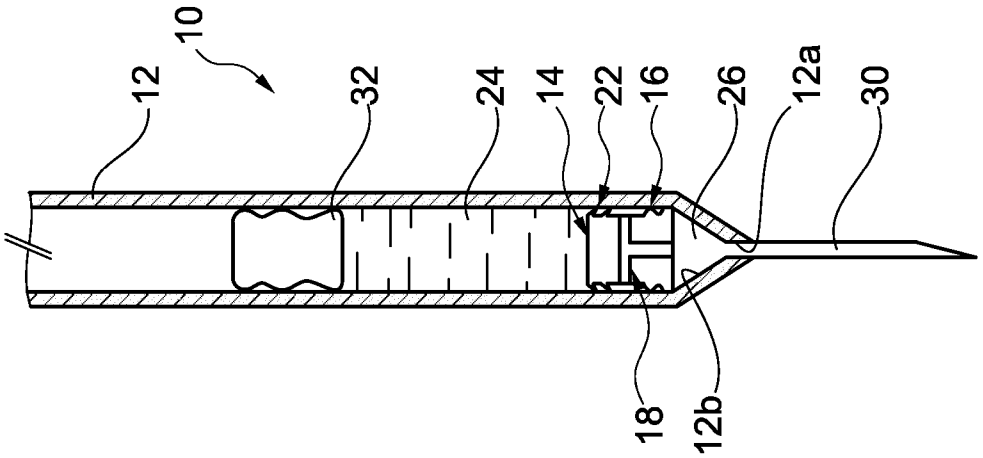
10
12
32
24
14
22
16
26
12a
30
18
12b

Fig. 4A

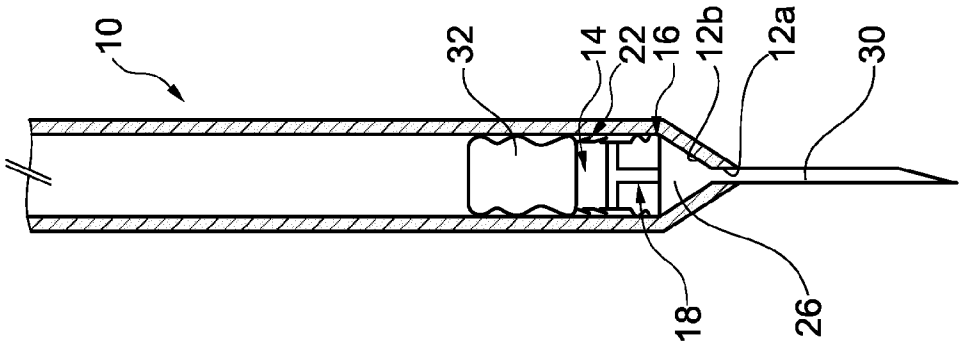

Fig. 5D

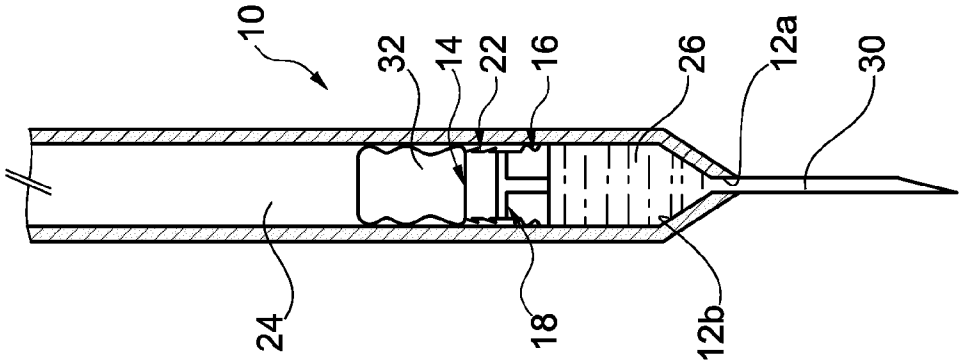

Fig. 5C

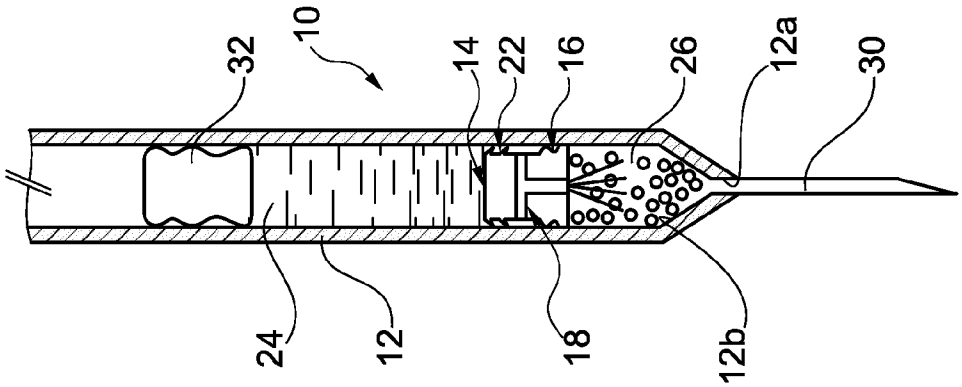

Fig. 5B

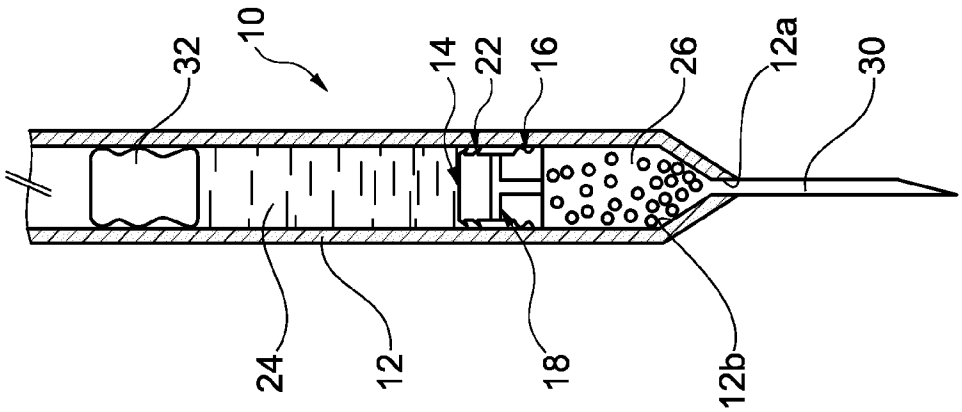

Fig. 5A

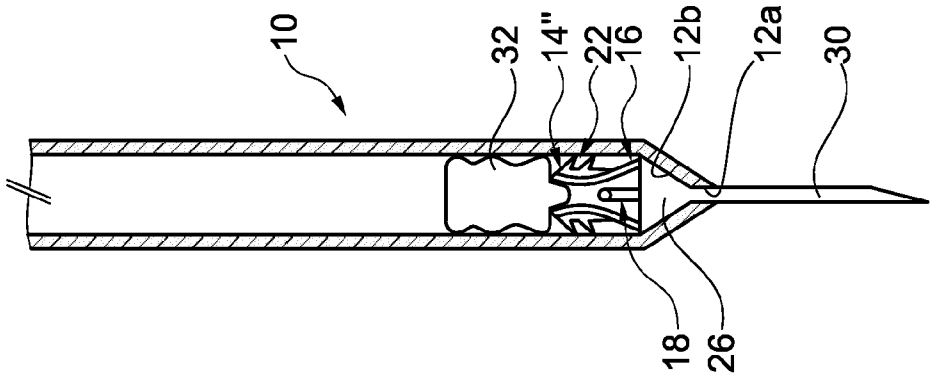

Fig. 6D

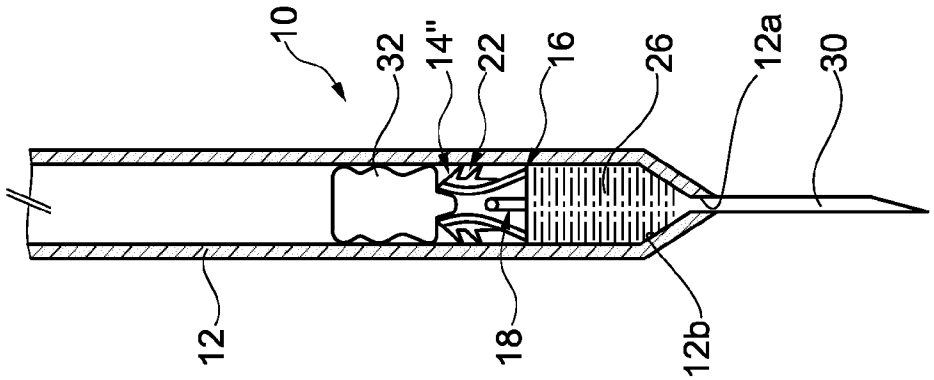

Fig. 6C

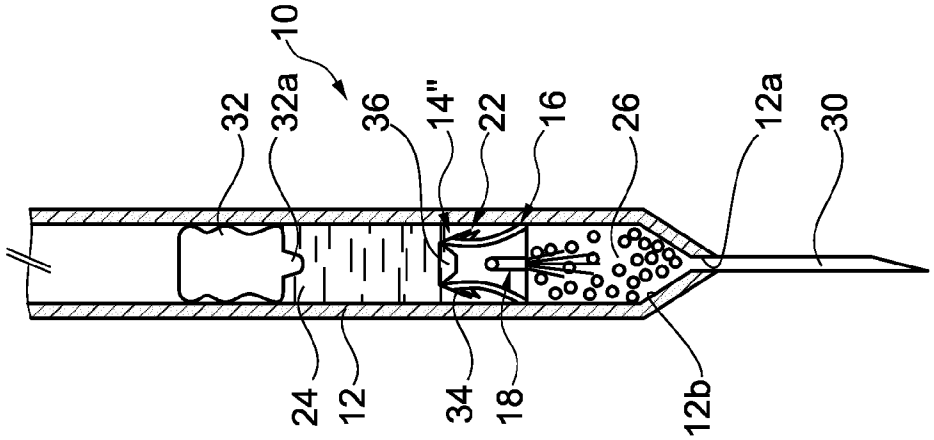

Fig. 6B

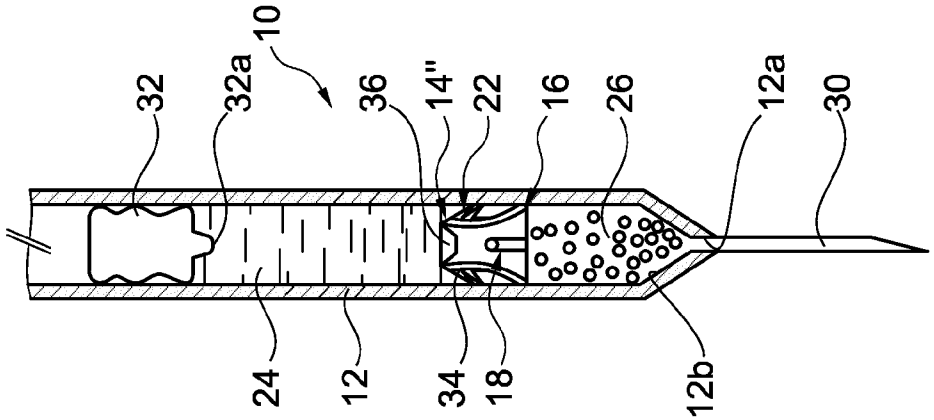

Fig. 6A

REFERENCES CITED IN THE DESCRIPTION

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JAVÍTOTT FECSKENDŐ-EGYSÉG

Szabadalmi igénypontok

1. Fecskendő-egység (10), amely magában foglalja a következőket:

   egy hengeres tartályt (12) egy vagy több gyógyszer befogadására, egy szűkített kivezető nyílást (12a), hogy legyen lehetővé téve a nevezett egy vagy több gyógyszernek a kibocsátása (kifecskendezése) a nevezett hengeres tartályból a nevezett kivezető nyíláson keresztül; és

   egy elzáró elemet (14; 14'; 14"), amely a hengeres tartályban van elrendezve, és amely meghatároz és különválaszt egy első volument (24) és egy második volument (26) a fecskendő-egységen belül, ahol az elzáró elem magában foglalja következőket:

   egy állandó (permanens) tömített lezárást (16), amely fluidumzáró módon (angolul: „fluidly") tömítetten lezárja az elzáró elemet a hengeres tartályhoz képest az elzáró elemnek a teljes kerülete körül az első volumen és a második volumen között;

   egy rugalmas tömített lezárást (22, 22'); és

   egy csatornát (18), amely megkerüli az állandó (permanens) tömítést, ahol a csatorna rendelkezik egy első nyílással (20a), amely fluidumvezető kapcsolatban (angolul: „fluid communication") van a második volumennel, és egy második nyílással (20b), amely szelektív módon van tömítetten lezárva az első volumenhez képest a rugalmas tömített lezárás által;

   ahol a rugalmas tömített lezárás mozgatható egy tömítetten lezáró konfiguráció és egy nyitott konfiguráció között, hogy a csatorna szelektív módon legyen tömítetten lezárva az első volumenhez képest, ahol a tömítetten lezáró konfigurációban a rugalmas tömített lezárás fluidumzáró módon (angolul: „fluidly") tömítetten lezárja az elzáró elemet a hengeres tartályhoz képest azon célból, hogy a csatornának a nevezett második nyílása legyen fluidumzáró módon (angolul: „fluidly") elkülönítve (izolálva) az első volumenhez képest, és ahol a nyitott konfigurációban a csatornának a második nyílása fluidumvezető kapcsolatban (angolul: „fluid communication") van az első volumennel; és

   ahol a rugalmas tömített lezárás mozgatható a tömítetten lezáró konfigurációból a nyitott konfigurációba, amikor a fluidum-nyomás az első volumenben vagy a második volumenben meghalad (túllép) egy első nyomás-küszöbértéket.

2. Fecskendő-egység (10) az 1. igénypont szerint, ahol az elzáró elem (14; 14'; 14") tengelyirányban mozgatható a hengeres tartályon (12) belül, amikor egy tengelyirányú erő van alkalmazva az elzáró elemre.

3. Fecskendő-egység (10) a 2. igénypont szerint, ahol a tengelyirányú erő, amely szükséges az elzáró elem (14; 14'; 14") mozgatásához a hengeres tartályon (12) belül, kisebb, mint egy fluidum által rendelkezésre álló erő az első nyomás-küszöbértéken.

4. Fecskendő-egység (10) a 2. igénypont szerint, ahol a tengelyirányú erő, amely szükséges az elzáró elem (14; 14'; 14") mozgatásához a hengeres tartályon (12) belül, nagyobb, mint egy fluidum által rendelkezésre álló erő az első nyomás-küszöbértéken.

5. Fecskendő-egység (10) az előző igénypontok bármelyike szerint, ahol a rugalmas tömített lezárás (22; 22') magában foglal egy vagy több hajlékony elemet (22a, 22b; 22a', 22b');

   ahol opcionálisan a nevezett egy vagy több hajlékony elem részben kerületi irányban terjed a nevezett elzáró elem körül és az elzáró elemnek a megmaradó része kialakít egy

tömített lezárást a hengeres tartállyal kerületi irányban a nevezett egy vagy több hajlékony elem körül; vagy

ahol opcionálisan a nevezett egy vagy több hajlékony elem teljes mértékben kerületi irányban terjed a nevezett elzáró elem körül.

6. Fecskendő-egység (10) az 5. igénypont szerint, ahol a rugalmas tömített lezárás (22; 22') magában foglal legalább két hajlékony elemet (22a, 22b; 22a', 22b');

ahol opcionálisan a legalább két hajlékony elem tengelyirányban igazítva van egymáshoz (egy vonalban állnak egymással).

7. Fecskendő-egység (10) az előző igénypontok bármelyike szerint, ahol a csatorna (18) magában foglal legalább egy tengelyirányú csatorna-részt (18a) és legalább egy kiegészítő csatorna-részt (18b), amely lényegében merőlegesen van elrendezve a nevezett legalább egy tengelyirányú csatornához képest és fluidumvezető kapcsolatban (angolul: „fluid communication") van azzal.

8. Fecskendő-egység (10) az előző igénypontok bármelyike szerint, ahol az állandó (permanens) tömített lezárás (16) magában foglal legalább egy karimát (16a, 16b), amely kifelé kinyúlik a nevezett elzáró elemből (14; 14'; 14") az elzáró elemnek a teljes kerülete körül;

ahol opcionálisan az állandó (permanens) tömített lezárás magában foglal legalább két karimát, amelyek kifelé kinyúlnak a nevezett elzáró elemből az elzáró elemnek a teljes kerülete körül, ahol a legalább két karima tengelyirányban egymáshoz igazítva (egymással egy vonalba állítva) van elrendezve.

9. Fecskendő-egység (10) az előző igénypontok bármelyike szerint, amely továbbá magában foglal egy nyomásforrást, hogy egy fluidum legyen nyomás alá helyezve a hengeres tartályban (12);

ahol opcionálisan a nevezett nyomásforrás magában foglal egy tengelyirányban mozgatható dugattyú elemet (32), amely a hengeres tartályban van elrendezve, ahol az elzáró elem a hengeres tartályban van elrendezve a dugattyú elem és a hengeres tartálynak a szűkített kivezető nyílása (12a) között; és

ahol opcionálisan a nevezett dugattyú elem magában foglal egy dugattyú-elzáró elemet (32) és egy dugattyú-rudat, amely össze van kapcsolva a dugattyú-elzáró elemmel, hogy a dugattyú-elzáró elem legyen tengelyirányban mozgatva a hengeres tartályban.

10. Fecskendő-egység (10) a 3. igénypont szerint, ahol a nevezett első volumen (24) egy fluid anyagot tartalmaz és a nevezett második volumen (26) egy száraz vagy liofilizált anyagot tartalmaz.

11. Fecskendő-egység (10) az 1.-től 9.-ig igénypontok bármelyike szerint, ahol az egyik vagy mindkettő a nevezett első volumen (24) és második volumen (26) közül egy gyógyszer-volumen, amely egy vagy több gyógyszer befogadására szolgál;

ahol opcionálisan a nevezett első volumen egy első gyógyszer-volumen, amely egy első gyógyszer befogadására szolgál, és a nevezett második volumen egy második gyógyszer-volumen, amely egy második gyógyszer befogadására szolgál; és

ahol opcionálisan a nevezett első gyógyszer-volumen egy első fluid gyógyszert tartalmaz és a nevezett második gyógyszer-volumen egy második fluid gyógyszert tartalmaz.

12. Fecskendő-egység (10) az 1.-től 9.-ig igénypontok bármelyike szerint, ahol a nevezett első volumen (24) egy gyógyszer-volumen, amely egy gyógyszer befogadására szolgál, és a nevezett elzáró elem (14; 14'; 14") a nevezett hengeres tartályban (12) van elrendezve,

hogy a gyógyszer-volumen szelektív módon legyen elkülönítve (izolálva) a hengeres tartálynak a kivezető nyílásától;

ahol opcionálisan a nevezett gyógyszer-volumen egy fluid gyógyszert tartalmaz.

13. Fecskendő-egység (10) a 4. igénypont szerint, vagy az 5.-től 11.-ig igénypontok bármelyike szerint, amikor azok a 4. igényponttól függnek, ahol az elzáró elem (14; 14'; 14") továbbá magában foglal egy súrlódó befogószerkezetet (rögzítőt) (angolul: „friction clamp") (34), amely mozgatható egy befogó (rögzítő) pozíció (angolul: „clamping position") és egy nem-befogó (nem-rögzítő) pozíció (angolul: „non-clamping position") között, ahol egy nagyobb erő szükséges ahhoz, hogy az elzáró elem tengelyirányban legyen mozgatva a hengeres tartályban (12), amikor a súrlódó befogószerkezet (rögzítő) a befogó (rögzítő) pozícióban található, mint amikor a súrlódó befogószerkezet (rögzítő) a nem-befogó (nem-rögzítő) pozícióban található;

ahol opcionálisan a fecskendő-egység továbbá magában foglal egy mozgatható dugattyú elemet (32), amely a hengeres tartályban van elrendezve, hogy egy fluidum legyen nyomás alá helyezve az első volumenben, ahol az elzáró elem a hengeres tartályban van elrendezve a dugattyú elem és a hengeres tartálynak a szűkített kivezető nyílása (12a) között, ahol a dugattyú elem magában foglal egy kulcs-elemet (csap-elemet) (angolul: „key") (32a) és az elzáró elem magában foglal egy foglalatot (36), amely komplementer a nevezett kulcs-elemmel (csap-elemmel), és ahol a kulcs-elemnek (csap-elemnek) a bekapcsolódása a foglalatba a nevezett súrlódó befogószerkezetet (rögzítőt) a nevezett nem-befogó (nem-rögzítő) pozícióba mozgatja.

14. Fecskendő-egység (10) az előző igénypontok bármelyike szerint, ahol a nevezett elzáró elem (14; 14'; 14") egy első elzáró elem, és a fecskendő-egység továbbá magában foglal egy vagy több kiegészítő elzáró elemet, amelyek mind rendelkeznek az első elzáró elemnek a jellemzőivel az előző igénypontok bármelyikében meghatározottak szerint, ahol az egy vagy több kiegészítő elzáró elem különválaszt és meghatároz további volumeneket a fecskendő-egységen belül, tengelyirányban hátrafelé az első elzáró elemhez képest.

15. Autoinjektor (automata befecskendező eszköz), amely magában foglal egy az előző igénypontok bármelyike szerinti fecskendő-egységet (10).