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(54) Closure for a vial

(57) A closure (170) for a vial (100) comprising a vial container (110) and a sealing (280). The closure (170) comprises a body (180), at least one holding element (190) adapted to hold the closure (170) permanently secure on the vial container (110) and such that the sealing (280) is adapted to provide a tight connection between the vial container (110) and the body (180), a penetrable portion (290) adapted to allow a liquid transfer is dis-

closed and a cap (200) adapted to provide a germ free protection of the penetrable portion (290), wherein the body (180) and the penetrable portion (290) are integrally formed.

Further, a vial (100) with such a closure (170), a method for closing a vial container (110) with such a closure (170) and a method for manufacturing such a closure (170) are disclosed.

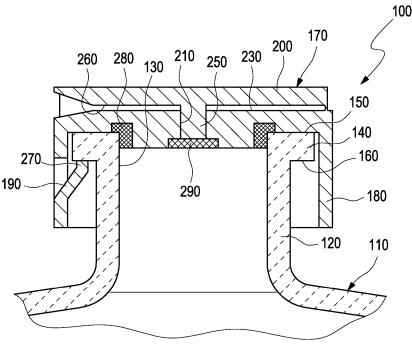


Fig. 1

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Field of the invention

[0001] The present invention relates to closures for vials such as medical vials containing medicaments and serums.

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Related art

[0002] Conventional vials such as medical vials containing medicaments and serums include a penetrable member extending across the open top of a vial container and being held thereon by an aluminum collar crimped to the neck portion of the vial container. A hypodermic needle may be inserted through the penetrable member for removal of the contents therefrom.

[0003] The process of crimping the aluminum collar to the neck of the vial container is susceptible to accidents and damages. Such accidents and damages may cause complaints and production blackouts. The reasons are, on the one hand side, that particles are generated during crimping, which contravenes the requirements of sterility, and, on the other hand side, the aluminum collar or the vial container may be damaged during crimping.

[0004] Further, due to its construction, the penetrable member is not sterile and requires the user of the vial to disinfect the penetrable member before inserting the needle therethrough. Further, the collar may not be closed again after opening the vial.

[0005] For this purpose, WO 99/53886 A1, EP 1 094 012 A2 and US 5,088,612 A describe plastic closures for vials

[0006] US 2011/0000872 A1 describes a stopper device comprising a supporting cap and a container provided with such a cap.

[0007] US 2010/0224632 A1 describes a closure comprising a stopper made of elastomer and a cover for covering a neck of a container and the stopper.

[0008] Even though the above strategies for closing the vial container provide advantages, there is still a potential for improvements. While these conventional vials have been satisfactory for their intended purpose, the possibility of toxicity caused by the aluminum and the exposure of the penetrable member to atmospheric particulates such as dust during the storage of the vial require an improvement to the conventional vial to enhance its sterility.

Problem to be solved

[0009] It is therefore an object of the present invention to provide a closure for a vial, a vial, a method for closing a vial container and a method for manufacturing a closure, which reduces or avoids the above disadvantages. Particularly, the present invention provides a closure which may be used in a simple manner, provides advantages in view of sterility, decreases the manufacturing

costs and reduces the number of used materials for closing the vial container as well as the number of elements to be handled.

Summary of the invention

[0010] This problem is solved by a closure for a vial, a vial and a method for closing a vial container with the features of the independent claims. Specific embodiments, which might be realized in an isolated fashion or in any arbitrary combination are listed in the dependent claims.

[0011] As used in the following, the terms "have", "comprise" or "include" or any arbitrary grammatical variations thereof are used in a non-exclusive way. Thus, these terms may both refer to a situation in which, besides the feature introduced by these terms, no further features are present in the entity described in this context and to a situation in which one or more further features are present. As an example, the expressions "A has B", "A comprises B" and "A includes B" may both refer to a situation in which, besides B, no other element is present in A (i.e. a situation in which a solely and exclusively consists of B) and to a situation in which, besides B, one or more further elements are present in entity A, such as element C, elements C and D or even further elements. [0012] Further, as used in the following, the terms "preferably", "more preferably", "more preferably", "particularly", "more particularly", "specifically", "more specifically" or similar terms are used in conjunction with optional features, without restricting alternative possibilities. Thus, features introduced by these terms are optional features and are not intended to restrict the scope of the claims in any way. The invention may, as the skilled person will recognize, be performed by using alternative features. Similarly, features introduced by "in an embodiment of the invention" or similar expressions are intended to be optional features, without any restriction regarding alternative embodiments of the invention, without any restrictions regarding the scope of the invention and without any restriction regarding the possibility of combining the features introduced in such way with other optional or non-optional features of the invention.

[0013] A closure for a vial comprising a vial container and a sealing, according to the present invention comprises:

- a body,
- at least one holding element adapted to hold the closure permanently secure on the vial container and such that the sealing is adapted to provide a tight connection between the vial container and the body,
- a penetrable portion adapted to allow a liquid transfer, and
- a cap adapted to provide a germ free protection of the penetrable portion, wherein the body and the penetrable portion are integrally formed.

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[0014] The body and the penetrable portion may be made of different materials. The body and the penetrable portion may be made of different compounds. The body may comprise an opening, wherein the penetrable portion may be disposed within the opening, wherein the cap may be moveable between a closed position in which the opening is closed and the penetrable portion protected by the cap and an open position in which the opening and the penetrable portion are exposed. The cap may comprise a pin, wherein the pin may be disposed at the cap such that the pin contacts the penetrable portion, such as an outer surface thereof, in the closed position. The cap may be adapted to reclose the opening and reprotect the penetrable portion after a displacement. The closure may further comprise at least one guiding element disposed at the body to allow a fixation of the closure on the vial container without sealing the vial container. This means, the closure may be disposed on the vial container by means of the at least one guiding element without the sealing providing a tight connection between the vial container and the body. With other words, the at least one guiding element allows to loosely dispose the closure on the vial container. The cap may be hinged to the body. The cap and the body may be integrally formed. The body, the sealing and the penetrable portion may be integrally formed. The body, the sealing, the penetrable portion, the holding element and the cap may be integrally formed. The pin may comprise at least one germicide. The germicide may be adhered to a surface of the pin. The germicide may be integrated into the pin. The germicide may be doped into the pin. The germicide may be silver iodide. The holding element may be adapted to be deformed inwardly from the body. The holding element may comprise at least one hook portion which is elastically deformable.

[0015] A vial according to the present invention may comprise:

- a vial container for holding a liquid,
- a sealing, and
- a closure according to any preceding embodiment, wherein the closure is held permanently secure on the vial container and such that the sealing is adapted to provide a tight connection between the vial container and the body of the closure.

[0016] The cap may be disposed such that the cap covers the penetrable portion. The cap may comprise a pin, wherein the pin may be disposed at the cap such that the pin contacts the penetrable portion in a closed position of the cap. The sealing may be disposed between the vial container and the body. The sealing may be disc shaped. The sealing may be an elastomeric stopper. The closure may comprise the sealing and/or the penetrable portion. The pin may comprise a germicide. [0017] A method for closing a vial container with a closure according to the present invention comprises:

- providing a vial container for holding a liquid,
- disposing a sealing so as to close vial container, and
- attaching the closure to vial container such that the holding element is partially deformed such that the closure is permanently secured to the vial container.

[0018] The method steps may be performed in the given order or in a different order. Further, two or more or even all of the method steps may be performed simultaneously and/or overlapping in time. Further, one, two or more or even all of the method steps may be performed repeatedly. The method may further comprise additional method steps.

[0019] The closure may be attached to the vial container after freeze drying the liquid. The sealing may be disposed between the vial container and the body of the closure. The holding element of the closure may comprise at least one hook portion which is elastically deformed so as to engage a surface of the vial container.

[0020] A method for manufacturing a closure according to the present invention comprises:

- forming the body of a first material,
- forming the at least one holding element,
- forming the penetrable portion of a second material different from the first material,
- forming the cap, wherein the body and the penetrable portion are integrally formed.

[0021] The method steps may be performed in the given order or in a different order. Further, two or more or even all of the method steps may be performed simultaneously and/or overlapping in time. Further, one, two or more or even all of the method steps may be performed repeatedly. The method may further comprise additional method steps.

[0022] The body and the penetrable portion may be made of different materials such as different compounds. For example, the body and the penetrable may be manufactured by means of sandwich injection molding. In this case, different materials may be injection molded for forming the body and the penetrable portion. The penetrable portion may be made of an elastomeric material. The body may be made of plastics. Needless to say, the complete closure may be formed by means of injection molding.

[0023] The term "vial" as used herein relates to any kind of vessel or bottle which is adapted to store medication as liquids, powders or capsules. Such vials may also be called as a phial or flacon. The vial basically comprises a vial container and a closure. The vial container may be made of glass or plastics such as polypropylene. The vials of the present invention may be used as sample vessels, for instance, in autosampler devices in analytical chromatography.

[0024] The vial may further comprise additional components such as a sealing which may be part of the clo-

sure. Preferably, the sealing may be integrally formed with the closure. Alternatively, the sealing may be a separate constructional member. In this case, the sealing may be connectable or connected to the closure. In any case, the sealing is adapted to provide a gas and/or liquid tight connection between the vial container and the closure. For this purpose, the sealing may be an elastomeric sealing or the like.

[0025] The penetrable portion may be adapted to allow a solid and/or liquid transfer from the vial container to an exterior thereof. For this purpose, the penetrable portion may be an elastomeric penetrable member. For example, the penetrable portion may be penetrated by a needle or the like in order to remove the contents such as the liquid or solid from the vial container. The needle may be a separate constructional member or may be part of an autosampler device such as an autosampler device in analytical chromatography.

[0026] The term "closure" as used herein relates to any element which is adapted to cover or seal the vial container. Preferably, the closure is one that completely closes the vial container. The closure may be at least partially made of plastics.

[0027] The closure of the present invention basically comprises a body, a holding element, a penetrable portion and a cap.

[0028] The term "holding element" as used herein relates to any kind of element which is adapted to hold the closure permanently secure on the vial container. For this purpose, the holding element may be adapted to be deformed inwardly from the closure. For example, the holding element may comprise at least one hook portion which is elastically deformable. This hook portion may interact with a portion of the vial container such as a neck portion similar to a snap-fit.

[0029] The term "cap" as used herein relates to any element which is adapted to protect the penetrable portion from external influences ad particularly from the entrance of germs, bacteria, microorganisms, contaminants or the like. The cap may be flat, hemispherical-shaped or the like.

[0030] The term "germ free" as used herein relates to a state of the penetrable portion in which absolutely no or only very few germs are present on the penetrable portion at least in the period from manufacturing the vial until use of the vial. Accordingly, the "term germ" free comprises exact germ free and, if applicable, low-germ as far as the vial with such a low-germ penetrable portion may still be used in the intended chemical, biological, physical or medical field without any risk of adverse effects such as illness or contamination.

[0031] The term "pin" as used herein relates to any long body having a sharp, edged, rounded or flat tip. The pin may be at least partially made of plastics. The pin may be integrally formed with the closure such as a cap of the closure. In order to provide the germ free ef-fect of the penetrable portion, the pin may comprise at least one germicide. In addition the design of the pin allows to

cover the whole surface of the opening in which the penetrable portion is arranged.

[0032] The term "germicide" as used herein relates to any agent that is adapted to kill germs, bacteria, microorganisms and the like, especially pathogenic microorganisms. The germicide may be adhered to a surface of the pin. For example, the germicide may be sprayed onto the pin in a manner so as to remain thereon. Alternatively, the germicide may be integrated into the pin. For example, the germicide may be doped into the pin. The germicide may be silver iodide or the like.

[0033] The term "compound" as used herein relates to a mixture of different mono-material raw materials into which further filling materials, enhancing materials and/or additives are mixed. Thus, at least two substances are compounded to a homogenous mixture.

[0034] The term "injection molding" as used herein relates to a manufacturing process for producing parts by injecting material into a mold. Injection molding can be performed with a host of materials, including metals, glasses, elastomers, confections, and most commonly thermoplastic and thermosetting polymers. In the field of the present invention, plastic materials are used for injection molding. The material for the to be formed part such as the body and the penetrable portion is fed into a heated barrel, mixed, and forced into a mold cavity corresponding to the desired shape of the body and the penetrable portion where it cools and hardens to the configuration of the cavity.

[0035] A basic idea of the present invention is to use a closure that provides germ free protection of the penetrable portion and that is easily as well as securely mountable to the vial container. With other words, the closure of the present invention allows a secure handling for the user and is fraud resistant. For this purpose, the body and the penetrable portion are integrally formed and the closure comprises a cap. The cap covers at least the penetrable portion such that the same is protected in a germ free manner as described above. In a specific embodiment, the cap is adapted to re-cover the penetrable portion after a displacement. For example, the cap may be hinged to the body of the closure so as to be movable between a closed position, in which the penetrable portion is covered by the cap, and an open position, in which the penetrable portion is uncovered or exposed by the cap. In the open position, the penetrable portion is adapted to be penetrated by a needle or the like. If the cap is hinged to the body, the closure may be integrally formed so as to decrease the manufacturing costs.

[0036] Summarizing the findings of the present invention, the following embodiments are preferred:

Embodiment 1: A closure for a vial comprising a vial container and a sealing, wherein the closure comprises:

- a body.
- at least one holding element adapted to hold the

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closure permanently secure on the vial container and such that the sealing is adapted to provide a tight connection between the vial container and the body,

- a penetrable portion adapted to allow a liquid transfer, and
- a cap adapted to provide a germ free protection of the penetrable portion,
- wherein the body and the penetrable portion are integrally formed.

Embodiment 2: The closure according to the preceding embodiment, wherein the body and the penetrable portion are made of different materials.

Embodiment 3: The closure according to any preceding embodiment, wherein the body and the penetrable portion are made of different compounds.

Embodiment 4: The closure according to any preceding embodiment, wherein the body comprises an opening, wherein the penetrable portion is disposed within the opening, wherein the cap is moveable between a closed position, in which the opening is closed and the penetrable portion protected by the cap, and an open position in which the opening and the penetrable portion are exposed.

Embodiment 5: The closure according to the preceding embodiment, wherein the cap comprises a pin, wherein the pin is disposed at the cap such that the pin contacts the penetrable portion in the closed position.

Embodiment 6: The closure according to any of the two preceding embodiments, wherein the cap is adapted to reclose the opening and re-protect the penetrable portion after a displacement.

Embodiment 7: The closure according to any preceding embodiment, further comprising at least one guiding element disposed at the body to allow a fixation of the closure on the vial container without sealing of the vial container.

Embodiment 8: The closure according to any preceding embodiment, wherein the cap is hinged to the body.

Embodiment 9: The closure according to any preceding embodiment, wherein the cap and the body are integrally formed.

Embodiment 10: The closure according to any preceding embodiment, wherein the body, the sealing and the penetrable portion are integrally formed.

Embodiment 11: The closure according to any pre-

ceding embodiment, wherein the body, the sealing, the penetrable portion, the holding element and the cap are integrally formed.

Embodiment 12: The closure according to any one of embodiments 5-11, wherein the pin comprises at least one germicide.

Embodiment 13: The closure according to the preceding embodiment, wherein the germicide is adhered to a surface of the pin.

Embodiment 14: The closure according to any of the two preceding embodiments, wherein the germicide is integrated into the pin.

Embodiment 15: The closure according to any of the three preceding embodiments, wherein the germicide is doped into the pin.

Embodiment 16: The closure according to any of the four preceding embodiments, wherein the germicide is silver iodide.

Embodiment 17: The closure according to any preceding embodiment, wherein the holding element is adapted to be deformed inwardly from the body.

Embodiment 18: The closure according to the preceding embodiment, wherein the holding element comprises at least one hook portion which is elastically deformable.

Embodiment 19: A vial comprising

- a vial container for holding a liquid,
- a sealing, and
- a closure according to any preceding embodiment, wherein the closure is held permanently secure on the vial container and such that the sealing is adapted to provide a tight connection between the vial container and the body of the closure.

Embodiment 20: The vial according to the preceding embodiment, wherein the cap is disposed such that the cap covers the penetrable portion.

Embodiment 21: The vial according to any of the two preceding embodiments, wherein the cap comprises a pin, wherein the pin is disposed at the cap such that the pin contacts the penetrable portion in a closed position of the cap.

Embodiment 22: The vial according to any of the three preceding embodiments, wherein the sealing is disposed between the vial container and the body.

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Embodiment 23: The vial according to any of the four preceding embodiments, wherein the sealing is disc shaped.

Embodiment 24: The vial according to any of the five preceding embodiments, wherein the sealing is an elastomeric stopper.

Embodiment 25: The vial according to any of the six preceding embodiments, wherein the closure comprises the sealing.

Embodiment 26: The vial according to any of the six preceding embodiments, wherein the pin comprises a germicide.

Embodiment 27: A method for closing a vial container with a closure according to any one of embodiments 1 to 18, comprising:

- providing a vial container for holding a liquid,
- disposing a sealing so as to close vial container,
- attaching the closure to vial container such that the holding element is partially deformed such that the closure is permanently secured to the vial container.

Embodiment 28: The method according to the preceding embodiment, wherein the closure is attached to the vial container after freeze drying the liquid.

Embodiment 29: The method according to any of the two preceding embodiments, wherein the sealing is disposed between the vial container and the body of the closure. Embodiment 30: The method according to any of the three preceding embodiments, wherein the holding element of the closure comprises at least one hook portion which is elastically deformed so as to engage a surface of the vial container.

Embodiment 31:A method for closing a vial container with a closure according to any one of embodiments 1 to 18, comprising:

a fully integrated vial closure including all elements such that only one process step is necessary to place the closure on the vial container.

Embodiment 32: A method for manufacturing a closure according to any of the embodiments 1-18, comprising:

- forming the body of a first material,
- forming the at least one holding element,
- forming the penetrable portion of a second material different from the first material,
 and

 forming the cap, wherein the body and the penetrable portion are integrally formed.

Embodiment 33: The method according to the preceding embodiment, wherein the body and the penetrable portion are made of different materials.

Embodiment 34: The method according to any of the two preceding embodiments, wherein the body and the penetrable portion are made of different compounds.

Embodiment 35: The method according to any of the three preceding embodiments, wherein at least the body and the penetrable are manufactured by means of sandwich injection molding.

Short description of the Figures

[0037] Further optional features and embodiments of the invention will be disclosed in more detail in the subsequent description of specific embodiments, preferably in conjunction with the dependent claims. Therein, the respective optional features may be realized in an isolated fashion as well as in any arbitrary feasible combination, as the skilled person will realize. The scope of the invention is not restricted by the specific embodiments. The embodiments are schematically depicted in the Figures. Therein, identical reference numbers in these Figures refer to identical or functionally comparable elements.

[0038] In the Figures:

Figure 1 shows a cross-sectional view of a vial according to an embodiment of the present invention;

Figure 2 shows a perspective view of a closure according to the present invention in a closed position;

Figure 3 shows a perspective view of the closure according to the present invention in an open position;

Figure 4 shows a cross-sectional view of a vial according to another embodiment of the present invention with the closure before being mounted to the vial container; and

Figure 5 shows a cross-sectional view of the vial of Figure 4 with the closure after being mounted to the vial container.

Detailed description of the embodiments

[0039] Figure 1 shows a perspective view of a vial 100 according to an embodiment of the present invention. The vial 100 comprises a vial container 110. The vial container 110 may be adapted to hold a liquid such as a

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medical liquid. The vial container 110 comprises a neck portion 120 defining a container opening 130 through which the liquid may be filled into and removed from the vial container 110. The vial container 110 further comprises a rim portion 140 arranged at the free end of the neck portion 120. The rim portion 140 comprises an upper side 150 facing away from the neck portion 120 and a lower side 160 facing the neck portion 120.

[0040] The vial 100 further comprises a closure 170. The closure 170 is at least partially made of plastics. The closure 170 comprises a body 180, at least one holding element 190 adapted to hold the closure 170 permanently secure on the vial container 110, and a cap 200. The body 180 defines an opening 210. Further, the body 180 comprises two flat protrusions 220 (Figures 2 and 3) at an upper side 230 thereof. The protrusions 220 are arranged parallel to one another so as to form a rectangular gap or recess 240 (Figure 3) therebetween. The opening 210 is defined within the recess 240.

[0041] The cap 200 is formed generally rectangular with a size adapted to the size of the recess 240. With other words, the cap 200 may be disposed within the recess 240 and two opposing side surfaces of the cap 200 contact two opposing side surfaces of the protrusions 220 but do not obstruct the cap 200. The cap 200 is hinged to the body 180. The cap 200 and the body 180 are integrally formed. The cap 200 comprises a pin 250. The pin 250 is arranged at a lower side 260 of the cap 200 facing the body 180. The pin 250 comprises at least one germicide. The germicide may be adhered to a surface of the pin 250. Alternatively or additionally, the germicide may be integrated into the pin 250. For example, the germicide is doped into the pin 250. The germicide is silver iodide. Needless to say, the germicide may be any germicide adapted to be adhered to or integrated into the pin 250 such as tosylchloramide, ethanol and isopropanol.

[0042] The holding element 190 is adapted to be deformed inwardly from the body 180. For example, the holding element 190 comprises at least one hook portion 270 which is elastically deformable. For example, three to five holding elements 190 each comprising a hook portion 270 are present. In the embodiment shown in Figure 1, four holding elements 190 each comprising a hook portion 270 are disposed at the body 180 even though only one holding element 190 is shown in Figure 1 for simplification or illustration purposes. More particularly, the holding elements 190 are disposed around the circumference of the body 180 such as evenly spaced apart from one another along the circumference of the body 180. It is to be noted that even reference is made to a single holding element 190 or hook portion 270, the above and below explanations correspondingly apply to all holding elements 190 or hook portions 270. With other words, only for simplification, reference is made to a single holding element 190 or hook portion 270 hereinafter even though the explanations correspondingly to more than one single holding element 190 or hook portion 270 if present. If the closure 170 is attached to the vial container 110, the hook portions 270 engage the lower side 160 of the rim portion 140.

[0043] The vial 100 further comprises a sealing 280 and a penetrable portion 290. The closure 170 comprises the penetrable portion 290. The closure 170 may further comprise the sealing 280. Particularly, the body 180 and the penetrable portion 290 are integrally formed. For example, the body 180, the sealing 280, the penetrable portion 290, the holding element 190 and the cap 200 may be integrally formed. Alternatively, the sealing 280 may be a separate constructional member from the closure 170. The sealing 280 is an elastomeric sealing. For example, the sealing 280 may be an elastomeric stopper. The sealing 280 is ring-shaped. The sealing 280 is disposed between the body 180 of the closure 170 and the vial container 110. More particularly, the sealing 280 is disposed on the rim portion 140 of the neck portion 120 such that sealing 280 is sandwiched between the vial container 110 and the body 180. The holding element 190 is adapted to hold the closure 170 on the vial container 110 such that the sealing 280 is adapted to provide a tight connection between the vial container 110 and the body 180. For this purpose, the body 180 of the closure 170 is pressed to a certain degree onto the rim portion of the vial container 110 by the holding element 190. [0044] The penetrable portion 290 is an elastomeric penetrable portion. Thus, the body 180 and the penetrable portion 290 are made of different materials such as different compounds. The penetrable portion 290 is discshaped. The penetrable portion 290 is disposed within the opening 210 of the body 180. The penetrable portion 290 is adapted to be penetrated by a needle or the like in order to be adapted to allow a liquid transfer as will be explained in more detail below. Further, the cap 200 is adapted to provide a germ free protection of the penetrable portion 290 as will be explained in more detail below.

[0045] The cap 200 is moveable between an open position and a closed position as will be explained in more detail below. Figure 2 shows a perspective view of the closure 170 in a closed position.

[0046] In the closed position, the opening 210 is closed and the penetrable portion 290 protected or covered by the cap 200. The pin 250 is disposed at the cap 200 such that the pin 250 contacts the penetrable portion 290 in the closed position. Thus, the germicide of the pin 250 comes into contact with the penetrable portion 290 so as to disinfect the same. The pin 250 may exert a pressing force onto the penetrable portion 290 in order to ensure that the germicide comes into contact with the penetrable portion 290. As is further shown in Figure 2, the body 180 may comprise a depression 300 or the like allowing a user of the vial 100 to engage or grasp the lower side 260 of the cap 200 with his or her finger in order to move the same from the closed position into the open position. [0047] Figure 3 shows a perspective view of the closure 170 in an open position. In the open position, the

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opening 210 and the penetrable portion 290 are exposed. In this position, the penetrable portion 290 is ready to be penetrated by a needle or the like. As the cap 200 is hinged to the body 180, the cap 200 is adapted to reclose the opening 210 and re-protect or re-cover the penetrable portion 290 after a displacement.

[0048] The closure 170 may be manufactured as will be explained below. The body 180 is formed of a first material. The penetrable portion 290 is formed of a second material different from the first material. For example, the body 180 and the penetrable portion 290 may be formed of the materials as specified above. This means, the body 180 may be formed of plastics and the penetrable portion 290 may be formed of an elastomeric material different from the plastics. Particularly, the body 180 and the penetrable portion 290 are integrally formed. For example, the body 180 and the penetrable portion 290 may be manufactured by means of injection molding such as sandwich injection molding. In this case, the different materials may be injection molded for forming the body 180 and the penetrable portion 290. Further, the at least one holding element 190 and the cap 200 are formed as well. Needless to say, the complete closure 170 may be formed by means of injection molding.

[0049] Now, the operation of closing the vial container 110 with the closure 170 will be explained. First, the vial container 110 for holding a liquid is provided and filled with a liquid. The sealing 280 is disposed so as to close vial container 110. For example, the sealing 280 is disposed onto the rim portion 140 of the vial container 110. This may be carried out in that the closure 170, which is preferably integrally formed with the sealing 280, is loosely disposed on the rim portion 140 of the vial container 110. Thus, the sealing 280 is disposed between the vial container 110 and the body 180 of the closure 170. As the closure 170 also comprises the penetrable portion 290, the penetrable portion 290 is also arranged on the vial container 110 such that penetrable portion 290 is partially disposed within the opening 130 of the neck portion 120. In the open position of the cap 200, the pin 250 of the cap 200 is treated with a germicide in the above explained manner. Then, the cap 200 is moved into the closed position, in which the pin 250 contacts the penetrable portion 290. Thus, the penetrable portion 290 is disinfected as the germicide of the pin 250 comes into contact with the penetrable portion 290. Needless to say, the pin 250 and the penetrable portion 290 may already be disinfected when the closure 170 is loosely disposed on the vial container 110. For example, the pin 290 may be treated with the germicide by a manufacturer of the closure 170 and supplied to a customer in a disinfected state.

[0050] Then, the closure 170 is attached to the vial container 110 such that the holding element 190 is partially deformed such that the closure 170 is permanently secured to the vial container 110. For example, the closure 170 is moved or pushed towards the vial container 110. During this, the holding element 190 is moved over

the rim portion 140 of the vial container 110. Further, the hook portion 270 is elastically deformed outward from the body 180 when being moved over the rim portion 140 of the vial container 110. If the hook portion 270 is completely moved over the rim portion 140 of the vial container 110, the hook portion 270 is deformed inward towards the body 180 and engages a surface of the vial container 110, which is the lower side 160 of the rim portion 140. Thus, the vial container 110 may be closed and sealed in a single step in that the closure is loosely disposed on the vial container 110 and pushed towards the vial container 110. For comparison only, a vial container closed by a conventional closure needs at least two steps to be closed. First, a stopper constituting a sealing and a penetrable portion is put or disposed on the vial container. Then, in a second process step, the crimping cap is placed on top of the stopper and the vial will be crimped such that the engagement portion engages the rim portion and holds the stopper permanently secure on the vial container. These two process steps are necessary for closing the vial container because the stopper and the crimp cap are two separate constructional members. [0051] Figure 4 shows a cross-sectional view of a vial 100 according to another embodiment of the present invention. Hereinafter, only the differences from the first embodiment will be explained and like constructional members are indicated by like reference numerals. Figure 4 shows the closure 170 before being mounted to the vial container 110. The closure 170 comprises at least one guiding element 310 disposed at the body 180. For example, three to five guiding elements 310 are present. In the embodiment shown in Figure 4, three guiding elements 310 are disposed at the body 180. More particularly, the guiding elements 310 are disposed around the circumference of the body 180 such as evenly spaced apart from one another along the circumference of the body 180. It is to be noted that even reference is made to a single guiding element 310, the above and below explanations correspondingly apply to all guiding elements 310 or hook portions 270. With other words, only for simplification, reference is made to a single guiding element 310 hereinafter even though the explanations correspondingly to more than one guiding element 310 if present. As shown in Figure 4, before mounting the closure to the vial container 110, the closure 170 is loosely disposed on the rim portion 140 of the vial container 110 such that the guiding element 310 partly extends through the opening 130 of the vial container 110. Further, the holding element 190 contacts an outer edge of the rim portion 140.

[0052] Figure 5 shows a cross-sectional view of the vial 100 of Figure 4 after freeze-drying with the closure 170 after being mounted to the vial container 110. As shown in Figure 5, the guiding element 310 allows a fixation of the closure 170 on the vial container 110 without sealing of the vial container 110. After the closure 170 is mounted to the vial container 110, the hook portion 270 engages the lower side 160 of the rim portion 140 such

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that the closure 170 is permanently secured to the neck portion 120. Further, the guiding element 310 completely extends through the opening 130 of the vial container 110.

[0053] Now, the operation of closing the vial container 110 with the closure 170 shown in Figures 4 and 5 will be explained. Hereinafter, only the differences from the method for closing the vial container 110 according the embodiment shown in Figures 1 to 3 will be explained. It is to be noted that all other steps for closing the vial container 110 with the closure 170 shown in Figures 4 and 5 are identical to the steps for closing the vial container 110 with the closure 170 shown in Figures 1 to 3.

[0054] After the closure 170 is loosely disposed on the rim portion 140 of the vial container 110 and the penetrable portion 290 is disinfected, the liquid within the vial container 110 is freeze dried. After the liquid within the vial container 110 is freeze dried, the closure 170 is attached to the vial container 110 in the manner explained above, i.e. the closure 170 is moved or pushed towards the vial container 110 in order to permanently secure the closure 170 to the vial container 110.

List of reference numbers

[0055]

- 100 vial
- 110 vial container
- 120 neck portion
- 130 opening
- 140 rim portion
- 150 upper sider
- 160 lower side
- 170 closure
- 180 body
- 190 holding element
- 200 cap
- 210 opening
- 220 protrusion
- 230 upper side
- 240 recess
- 250 pin
- 260 lower side
- 270 hook portion
- 280 sealing
- 290 penetrable portion
- 300 depression
- 310 guiding element

Claims

- 1. A closure (170) for a vial (100) comprising a vial container (110) and a sealing (280), wherein the closure (170) comprises:
 - a body (180),

- at least one holding element (190) adapted to hold the closure (170) permanently secure on the vial container (110) and such that the sealing (280) is adapted to provide a tight connection between the vial container (110) and the body (180).
- a penetrable portion (290) adapted to allow a liquid transfer, and
- a cap (200) adapted to provide a germ free protection of the penetrable portion (290), wherein the body (180) and the penetrable portion (290) are integrally formed.
- 2. The closure (170) according to the preceding claim, wherein the body (180) and the penetrable portion (290) are made of different materials.
- 3. The closure (170) according to any preceding claim, wherein the body (180) and the penetrable portion (290) are made of different compounds.
- 4. The closure (170) according to any preceding claim, wherein the body (180) comprises an opening (210), wherein the penetrable portion (290) is disposed within the opening (210), wherein the cap (200) is moveable between a closed position in which the opening (210) is closed and the penetrable portion (290) protected by the cap (200) and an open position in which the opening (210) and the penetrable portion (290) are exposed.
 - 5. The closure (170) according to the preceding claim, wherein the cap (200) comprises a pin (250), wherein the pin (250) is disposed at the cap (200) such that the pin (250) contacts the penetrable portion (290), particularly an outer surface thereof, in the closed position.
- 6. The closure (170) according to any of the two preceding claims, wherein the cap (200) is adapted to re-close the opening (210) and re-protect the penetrable portion (290) after a displacement.
- 7. The closure (170) according to any preceding claim, further comprising at least one guiding element (310) disposed at the body (180) to allow a fixation of the closure (170) on the vial container (110) without sealing the vial container (110).
- The closure (170) according to any preceding claim, wherein the cap (200) is hinged to the body (180).
 - 9. The closure (170) according to any preceding claim, wherein the body (180), the sealing (280), the penetrable portion (290), the holding element (190) and the cap (200) are integrally formed.
 - 10. The closure (170) according to any one of claims

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- 5-9, wherein the pin (250) comprises at least one germicide.
- **11.** The closure (170) according to the preceding claim, wherein the germicide is integrated into the pin (250).
- 12. A vial comprising
 - a vial container (110) for holding a liquid,
 - a sealing (280), and
 - a closure (170) according to any preceding claim, wherein the closure (170) is held permanently secure on the vial container (110) and such that the sealing (280) is adapted to provide a tight connection between the vial container (110) and the body (180) of the closure (170).
- **13.** A method for closing a vial container (110) with a closure (170) according to any one of claims 1 to 11, comprising:
 - providing a vial container (110) for holding a liquid.
 - disposing a sealing (280) so as to close vial container (110), and
 - attaching the closure (170) to vial container (110) such that the holding element (190) is partially deformed such that the closure (170) is permanently secured to the vial container (110).
- **14.** The method according to the preceding claim, wherein the closure (170) is attached to the vial container (110) after freeze drying the liquid.
- **15.** Method for manufacturing a closure (170) according to any one of claims 1 to 11, comprising:
 - forming the body (180) of a first material,
 - forming the at least one holding element (190),
 - forming the penetrable portion (290) of a second material different from the first material, and forming the cap (200), wherein the body (180) and the penetrable portion (290) are integrally formed.

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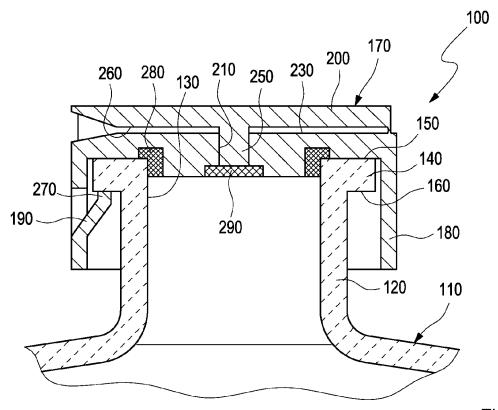


Fig. 1

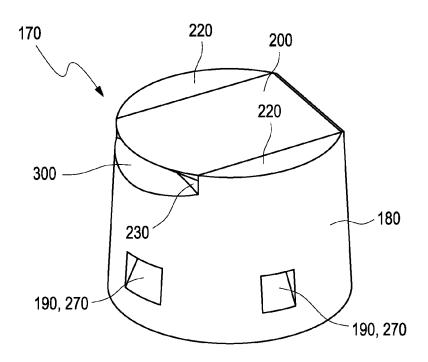


Fig. 2

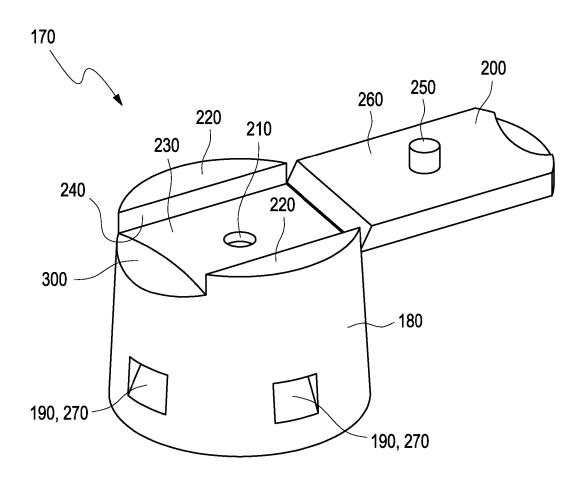
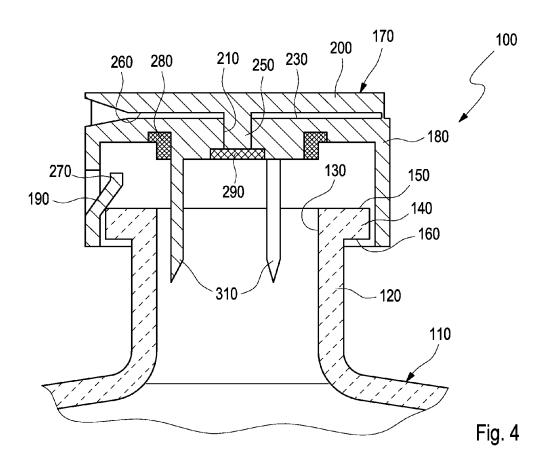
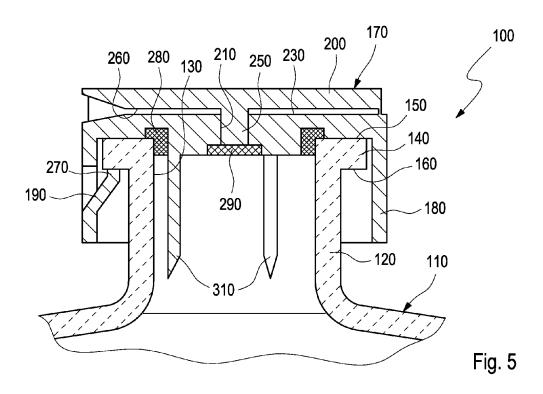


Fig. 3







EUROPEAN SEARCH REPORT

Application Number EP 13 17 6867

DOCUMENTS CONSIDERED TO BE RELEVANT				
ategory	Citation of document with in of relevant pass	ndication, where appropriate, ages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
(EP 1 412 261 A1 (HE 28 April 2004 (2004 * paragraph [0010] figures 4-8 *		1-4,6-9, 12-15	INV. A61J1/14 B65D51/00
	EP 0 769 456 A2 (DA 23 April 1997 (1997 * the whole documer	 NIKYO SEIKO LTD [JP]) 7-04-23) nt * 	1	
				TECHNICAL FIELDS SEARCHED (IPC) A61J B65D
	The propert search report has	boon drawn up for all claims		
	The present search report has Place of search	Date of completion of the search	\perp	Examiner
		11 December 2013	ן נאז	auer, Martin
The Hague CATEGORY OF CITED DOCUMENTS X: particularly relevant if taken alone		T : theory or principle E : earlier patent doc after the filing dat	T: theory or principle underlying the invention E: earlier patent document, but published on, or after the filing date	
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EP 13 17 6867

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

11-12-2013

	Patent document cited in search report	Publication date	Patent family member(s)	Publication date
	EP 1412261	A1 28-04-2004	CN 1538925 A DE 10138191 A1 EP 1412261 A1 JP 2004536686 A US 2004217082 A1 WO 03013972 A1	20-10-2004 27-02-2003 28-04-2004 09-12-2004 04-11-2004 20-02-2003
	EP 0769456	A2 23-04-1997	MO 03013972 A1 AT 195697 T AT 199006 T CA 2188087 A1 DE 69609919 D1 DE 69611722 D1 DE 69611722 T2 DK 0769456 T3 DK 0819617 T3 EP 0769456 A2 EP 0819617 A1 ES 2159374 T3 US 5823373 A US 6042770 A	20-02-2003 15-09-2000 15-02-2001 19-04-1997 28-09-2000 18-01-2001 08-03-2001 10-05-2001 18-12-2000 05-03-2001 23-04-1997 21-01-1998 01-10-2001 20-10-1998 28-03-2000
FORM P0459				

답 이 다 For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

EP 2 826 458 A1

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- WO 9953886 A1 [0005]
- EP 1094012 A2 **[0005]**
- US 5088612 A [0005]

- US 20110000872 A1 [0006]
- US 20100224632 A1 [0007]