Adaptor for coupling with a medical container

The present invention relates to an adaptor for coupling to a medical container such as a vial containing a pharmaceutical product, such as a vaccine, said adaptor allowing for multiple aseptic needle piercing with an injection device to be filled with part of the product contained in the medical container.

In this application, the distal end of a component or apparatus must be understood as meaning the end furthest from the hand of the user and the proximal end must be understood as meaning the end closest to the hand of the user, with reference to the injection device intended to be used with said component or apparatus. As such, in this application, the distal direction must be understood as the direction of injection with reference to the injection device, and the proximal direction is the opposite direction, i.e. the direction of the transfer of the product from the vial to the injection device.

One of the ways to improve health is to immunize entire populations against a number of diseases. To date, injection administration is the most common method of administering vaccines.

Each year, numerous drugs, for example vaccines, need to be prepared throughout the world by healthcare institutions. Many vaccine compositions are usually not stable at room temperature and they must be stored at rather specific cold temperatures. Indeed, due to their biological nature, vaccines are complex to handle and to store. Vaccines are usually temperature sensitive and typically need to be maintained and stored at all time between 2 and 8 degrees Celsius (°C). Some vaccines will be more sensitive to heat exposure and others will be sensitive to freezing. Therefore, maintaining and monitoring the appropriate temperatures during the storage and the handling of vaccines is a critical issue in order to sustain their efficacy. Overexposure to heat as well as overcooling may result in the destruction of the biological elements of the vaccines. Use of vaccines not stored in appropriate conditions may lead to not effective vaccination of the populations against diseases and would lead to expensive campaigns with limited results.

Furthermore, it is critical that the cold chain be not interrupted from production of the drug at a pharmaceutical company to its administration to the patient.

From a supply chain perspective, the most efficient vaccine packaging is the multidose container such as multidose vial, that is to say, vial that may contain up to 10, 100 or 1000 doses of vaccine, one dose being intended for one patient. These vials are usually closed by a septum. In preparation of an injection of a vaccine, the user pierces the septum of the vial with the needle of an empty syringe, he then fills the syringe with one dose of vaccine and proceeds to the injection of the vaccine to the patient.

As such, multidose vials imply that the septum of the vial be pierced successively a high number of times, namely as many as the number of doses present in the vial. In order to ensure safe injections, the sterility of the septum of the vial should be maintained during the whole time the vial is used.

Anyway, in locations where it is difficult to maintain good hygienic conditions such as remote locations which are far from towns and from hospital facilities, the multidose vials may be handled and manipulated at ambiant air. In such cases, the septum of the vial may be contaminated either by the ambiant air, or, each time a dose of vaccine is removed, by the needle of the empty syringe used.

In addition, in regions where there is limited or potentially no supply of energy to power cooling equipment such as a refrigerator, the multidose vials may be maintained in cold conditions by simple contact with ice packs. As time goes by, part of the ice may melt and turn into water, and the septum of the multidose vials may be in contact with such water that may contaminate the septum of the vial.

It may then happen that a multidose vial, such as for example a 10-dose vial, is opened and that only three doses are used, for vaccinating three patients only, the remaining content of the vial being wasted because not intended to be administered in a sufficiently short time after opening of the vial in order to guaranty the vaccine or drug sterility.

Vaccination campaigns can therefore be made difficult in some regions and a significant proportion of vaccines may be wasted by the time they reach their target. This has an unacceptable cost to the health organizations in charge of immunization campaigns. In addition, it may happen that in case of vaccination campaigns, or pandemic, hundreds of patients need to be vaccinated in a very short time, in locations where it is difficult to maintain good hygienic conditions such as remote locations which are far from towns and from hospital facilities.

Therefore, it would be desirable to provide a device that would allow several successive piercings of a multidose vial septum and that would guarranty that said piercings be carried out in aseptic conditions, in particular that the septum be made sterile at the time of injection act, or be maintained sterile during the lifetime of the multidose vial, and that would prevent wastage of the drug, even if the multidose vial is not stored in aseptic conditions.

A first aspect of the present invention is an adaptor for coupling with a medical container having a collar closed by a septum, said septum having an outer surface directed towards the outside of the medical container, the adaptor comprising:

- a gripping member for securing the adaptor to the medical container,

- a pierceable elastomeric piece having at least a part intended to be in contact with the outer surface of the septum when said adaptor is secured on said medical container.

The adaptor of the invention is intended to be mounted on a medical container, such as for example a conventional vial for storing pharmaceutical products, such as multidose vials for vaccines. Such a vial 1 is shown on Figures 1A-1C and generally comprises a tubular barrel 2 having a longitudinal axis A, closed at an end and having a collar 3 at the opposite end, said collar 3 being closed by a septum 4. Usually, the septum 4 is fixedly attached to the collar 3 of the vial 1 by a peripheral band 5, said peripheral band 5 leaving a part of the septum 4, herein called outer surface 4a of the septum, directly facing the outside of the vial 1, namely the outside environment. The septum 4 is usually made of a material impermeable to gas and liquid and it seals hermetically the content of the vial 1. The septum 4 is also pierceable by the needle of an injection device intended to be filled with the product contained in the vial, said septum 4 being accessible to said needle via its outer surface 4a.

In the present application, "pierceable" means that the septum or the elastomeric piece of the adaptor may be pierced and traversed by the needle of an injection device such as a syringe, an auto-injector, or a reconstitution device, for example for administering a pharmaceutical product such as a drug or vaccine.

The gripping member of the adaptor of the invention may be any member capable of securing the adaptor around on the medical container, and

in particular around the collar of the medical container, either in a temporary or permanent way.

The pierceable elastomeric piece of the adaptor of the invention has at least a part intended to be in contact with the outer surface of the septum when said adaptor is secured on said medical container: in other words, the elastomeric piece has a design, shape, and location on the adaptor, allowing a part of it to be in contact with the outer surface of the septum when said adaptor is secured on said medical container.

The adaptor of the invention allows piercing the septum of the medical container in good hygienic conditions multiple successive times. Indeed, when the user decides to fill in an empty syringe with a dose of drug contained in the medical container, he simply secures the adaptor of the invention on the medical container by means of the gripping member. Once the adaptor is secured on the medical container, the pierceable elastomeric piece of the adaptor is in contact with the outer surface of the septum of the medical container. As a consequence, introducing the needle in the medical container implies that the needle pierces and traverses the elastomeric piece of the adaptor in the first place. During this step, the needle mechanically rubs against the material forming the elastomeric piece and it is naturally cleaned, as the potential bacteria are wiped out from the needle when said needle penetrates the elastomeric piece. In addition, once the needle protrudes out of the elastomeric piece of the adaptor, it directly enters the septum of the medical container and may therefore not be contaminated by foreign elements.

The user may repeat the piercing step with the needle of a new empty injection device until all the doses contained in the medical container are removed. The adaptor of the invention acts as a protection of the septum.

In embodiments, the elastomeric piece is made of a gas and liquid impermeable material capable of flexing under pressure. For example, the elastomeric piece has a thickness ranging from 1 to 8 mm, preferably from 2 to 4 mm. The elastomeric piece may show a hardness ranging from 10 to 100 Shore A, preferably from 40 to 70 Shore A, measured according to standard DIN 53505.

Suitable materials for the pierceable elastomeric piece of the adaptor of the invention include natural rubber, acrylate-butadiene rubber, cis-polybutadiene, chloro or bromobutyl rubber, chlorinated polyethylene elastomers, polyalkylene oxide polymers, ethylene vinyl acetate, fluorosilicone

rubbers, hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers, butyl rubbers, polyisobutene, synthetic polyisoprene rubber, silicone rubbers, styrene-butadiene rubbers, tetrafluoroethylene propylene copolymers, thermoplastic-copolyesters, thermo-plastic elastomers, or the like or a combination thereof.

In embodiments, the pierceable elastomeric piece is self-resealing. By "self-resealing" is meant that the elastomeric piece closes automatically and rapidly the hole produced by the piercing of the needle, for example in less than 0.5 seconds, once the needle is removed from the elastomeric piece. This automatic closure step may occur a high number of times, for example as many times as necessary for removing the numerous doses of products contained in the multidose medical container. This automatic obstruction restricts or prevents air and/or contaminants from entering inside the medical container, and thus allows asepsis maintenance. Moreover, the presence of the pierceable elastomeric piece of the adaptor of the invention gives time to the septum of the medical container to reseal, as the needle is still present in the pierceable elastomeric piece after it is removed from the septum. As such, neither air nor contaminants may be introduced in the medical container, even if the medical container is maintained under negative pressure after the removal of one or more doses of product. In addition, the septum of the medical container may itself be self-resealing.

Suitable materials for self-resealing pierceable elastomeric piece of the adaptor of the invention include synthetic polyisoprene, natural rubber, silicone rubber, thermo-plastic elastomers, or the like or a combination thereof.

In embodiments, the surface of said part of the pierceable elastomeric piece is complementary to the whole outer surface of the septum. As such, whatever the piercing location of the pierceable elastomeric piece of the adaptor by the needle, the user is ensured that the distal tip of the needle will directly pierce the septum after being passed through the pierceable elastomeric piece. Therefore, said distal tip is not in contact with ambient air or with other elements that would be trapped between the outer surface of the septum and the surface of the pierceable elastomeric piece. In particular, in such embodiments, the outer surface of the septum and the complementary surface of the pierceable elastomeric piece match each other in such a way that they are in intimate contact together on their entire surface and lead to a closed interface.

In embodiments, the adaptor further comprises a compressive member for pressing said pierceable elastomeric piece onto said outer surface of the septum, when said adaptor is secured on said medical container, said compressive member being capable to transition from an inactive state, in which it does not exert pressure on said pierceable elastomeric piece, to an active state, in which it exerts pressure. For example, the distal pressure on the compressive member may be exerted by the user at the time he mounts the adaptor on the medical container. Such embodiments ensure that the outer surface of the septum and the complementary surface of the pierceable elastomeric piece are in tight contact together and that no ambient air is trapped between the outer surface of the septum and the complementary surface of the pierceable elastomeric piece. The distal tip of the needle may not enter in contact with other elements than the pierceable elastomeric piece and the septum.

In embodiments, the adaptor further comprises a fixing system for preventing releasing of said gripping member and definitively securing the adaptor on said medical container. Such embodiments ensure that the adaptor is not separated from the medical container. The good hygienic conditions of the medical container are therefore maintained.

In embodiments, the adaptor further comprises a transversal wall connected to said gripping member, said transversal wall having a hole in which is lodged said pierceable elastomeric piece. For example, the gripping member and the transversal wall may be formed of one single piece. In embodiments, the transversal wall is proximally deflectable. For example, the transversal wall may be proximally deflected by the collar of the medical container when the adaptor is mounted on the medical container, the transversal wall coming back to a non deflected position once the adaptor is correctly fitted on the collar of the medical container.

For example, the gripping member may be a lateral clipping member capable of being laterally mounted on the collar of said medical container. The lateral clipping member may comprise a U-shaped element intended to be engaged on said collar via the open part of the U-shaped element, the curved part of the U-shaped element partially surrounding the collar. For example, the transversal wall may join together the two branches of the U of the U-shaped element.

In other embodiments, the gripping member is an axial clipping member capable of being axially mounted on the collar of said medical container. For example, the axial clipping member may comprise a tubular element capable of being axially engaged on said collar. For example, the transversal wall may then be a disk wall contained within the tubular element.

In embodiments, the adaptor further comprises a cleaning pad, said cleaning pad being configured to at least partially slide on said outer surface of said septum when the adaptor is being mounted on the medical container. Such embodiments allow the outer surface of the septum, where the distal tip of the needle is intended to penetrate, to be automatically cleaned before the adaptor is secured to the medical container.

The cleaning pad may be any pad, such as fabric or sponge, for example out of cotton or any other porous material, and may be treated by a cleaning solution. For example, the cleaning pad may comprise a disinfecting agent. The outer surface of the septum is therefore disinfected before the elastomeric piece of the adaptor comes in contact with it. The disinfecting agents may be selected from alcohols, such as ethanol or isopropanol, organic solvents, such as nitrofurane, toluene, phenol and derivatives thereof, derivatives of quinoline and acridine, salts such as sodium hypochlorite, sodium chlorite or sodium chlorate, chlorine dioxide, salts of iodine, mercury, silver, ammonium, or the like, or a combination thereof. For example, the disinfecting agent may be selected according to the most common bacteria and viruses that may be found in the area of use of the medical container.

In particular, the cleaning pad may be provided as a part of the adaptor, for example as a part of the transversal wall. The user has no additional operation or action to do than simply mounting the adaptor on the vial. Because of the location and configuration of the cleaning pad on the adaptor, the cleaning pad automatically slides on the outer surface of the septum, thereby wiping out potential bacteria or contamination agents present on said outer surface, when the user completes the step of mounting the adaptor on the collar of the vial.

For example, in embodiments where the lateral clipping member comprises a U-shaped element intended to be engaged on said collar via the open part of the U, the curved part of the U partially surrounding the collar, said transversal wall may be provided in the direction of the free ends of the U-shaped element, with a projection provided with said cleaning pad. For

example, the cleaning pad is located on the distal face of the projection. As such, when the user approaches the free ends of the U of the lateral clipping member towards the collar of the vial, the cleaning pad enters in contact with an edge of the outer surface of the septum. While the user continues to move the lateral clipping member towards the collar so as to mount it thereon, the cleaning pad slides on the outer surface of the septum, until it loses contact with said septum when the lateral clipping member reaches its position where it is secured on the collar. In this position, because of its location at the free ends of the U, the cleaning pad does not face the septum anymore and it does not prevent the piercing of the septum by the needle to take place. During the mounting step of the adaptor on the collar as described above, the sliding of the cleaning pad onto the outer surface of the septum has wiped out the bacteria and/or contamination elements potentially present on said outer surface. The outer surface of the septum is therefore decontaminated when the elastomeric piece of the adaptor comes in contact with it.

In embodiments where the axial clipping member comprises a tubular element capable of being axially engaged on said collar, said transversal wall being located within said tubular element, the cleaning pad may be a breakable membrane attached to the inner wall of said tubular element, and located distally with respect to said transversal wall. As such, when the user approaches the distal free end of the tubular element of the axial clipping member towards the collar of the vial, the breakable membrane enters in contact with the outer surface of the septum. While the user continues to move the axial clipping member distally so as to mount it on the collar of the vial, the breakable membrane, which is attached to the inner wall of the tubular element, becomes stretched out on the outer surface of the septum and finally breaks on said outer surface and is torn in several parts that slide on said outer surface while the axial clipping member reaches its position where it is secured on the collar. In this position, because it is now torn in several parts hanging along the inner walls of the tubular element, the membrane does not face the septum anymore and it does not prevent the piercing of the septum by the needle to take place. During the mounting step of the adaptor on the collar as described above, the sliding of the several torn parts of the breakable membrane on the outer surface of the septum has wiped out the bacteria and/or contamination elements potentially present on said outer surface. The

outer surface of the septum is therefore decontaminated when the elastomeric piece of the adaptor comes in contact with it.

In embodiments, the cleaning pad is located on a removable part of said adaptor. For example, said removable part may be removed from said adaptor once said adaptor is secured on said medical container. Such embodiments allow extensive cleaning by healthcare workers of the medical container septum and/or of other surfaces such as injector needle or patient's skin, as well as prompt disposal of the cleaning pad after use, or may allow avoiding contamination with a harmful disinfecting agent.

In embodiments, a tubular lodging extends from said transversal wall in the proximal direction, said tubular lodging being shaped and dimensioned for receiving an injection device. For example, the tubular lodging may be capable of receiving an empty injection device to be filled with a dose of the drug contained in the medical container. In embodiments, a cavity filled with decontaminated atmosphere is provided in the tubular lodging, the needle of the injection device or syringe received in said tubular lodging being lodged in said cavity. Such embodiments allow better hygienic conditions for proceeding to the piercing of the outer surface of the septum of the medical container.

In embodiments, the removable part on which the cleaning pad is located is a portion of a blister surrounding said adaptor in a storage state. For example, said portion of said blister may remain on the adaptor while the adaptor is mounted on the collar and may be removed thereafter, once the cleaning pad has completed its function of decontaminating the outer surface of the septum.

In embodiments, the adaptor further comprises an air inlet for allowing air entrance into the medical container, once the adaptor is secured on said medical container. Such embodiments are advantageous in the case the medical container is made of glass or polymeric materials the walls of which are not collapsible. The presence of an air inlet prevents the formation of vacuum in the medical container when medical fluid is withdrawn therefrom. For example, the air inlet comprises a cannula extending from the adaptor in the distal direction and provided with a sharp distal tip, capable of piercing the septum of the medical container, the proximal end of the cannula protruding outside the adaptor in ambient atmosphere. In embodiments, the air inlet is provided with a filter to restrict, in embodiments to prevent, entry of particulates

or bacteria from the ambient atmosphere into the medical container, in particular during the vaccine withdrawal process. For example, this filter has a pore size of approximately 0.22 microns.

In embodiments, the adaptor further comprises a pierceable decontamination insert located proximally with respect to said elastomeric piece. In such embodiments, the distal tip of the needle therefore first pierces the decontamination insert, in which it is decontaminated, then the pierceable elastomeric piece, in which it is submitted to a mechanical cleaning as explained above, before entering in contact with the outer surface of the septum of the vial. For example, the pierceable decontamination insert may be a sterilizing gel.

In embodiments, the adaptor further comprises a counting system. Such embodiments allow the user to be provided with information about how many doses of product have already been withdrawn from the medical container or how many doses of product remain in the medical container. For example, the counting system may be manually actionable.

Another aspect of the invention is an assembly comprising a medical container having a collar closed by a septum, said septum having an outer surface directed towards the outside of the medical container, and an adaptor as described above.

The present invention will now be described in greater detail based on the following description and the appended drawings in which :

Figures 1A-1C are respectively a perspective view, a partial side view and a partial cross section view of a conventional vial on which the adaptor of the invention is to be mounted,

Figures 2A-2B are perspective views of an adaptor in accordance with an embodiment of the invention, respectively from the top front and from the bottom front, in a position for being mounted on the collar of a vial : Figure 2C is a cross section view of the adaptor of Figures 2A-2B,

Figures 3A-3C are perspective views of the gripping member of the adaptor of Figures 2A-2C, respectively from the top front, from the bottom front and from the rear; Figure 3D is a cross section view of the gripping member of Figure 3C along line I-I',

Figures 4A and 4B are perspective views of the compressive member of the adaptor of Figures 2A-2C, respectively from the bottom front and from the top front,

Figure 5 is a perspective view of the elastomeric piece of the adaptor of Figures 2A-2C,

Figures 6A-6B are perspective views of the adaptor of Figures 2A-2C, respectively from the top front and from the bottom front, in a position where it is definitely secured on the collar of a vial (not shown); Figure 6C is a cross section view of the adaptor of Figures 6A-6B,

Figure 7 is a cross section view of the adaptor of Figure 2C packed in a closed blister in a storage position,

Figure 8 is a cross section view of the adaptor of figure 7 with the blister open, and of the proximal region of the vial onto which the adaptor is to be secured,

Figure 9A and 9B are cross section views of the adaptor of Figure 8 once it is mounted on the collar of the vial, and once it is definitively secured on the collar of the vial, with the blister partially surrounding the adaptor,

Figure 10A is a partial cross section view of a needle of an injection device ready to pierce the elastomeric piece of the adaptor and assembly of Figure 9B, once the blister has been fully removed, in order to remove a dose of product from the vial,

Figure 10B is a side view of the injection device and assembly of Figure 10A at a larger scale,

Figures 11A and 11b are schematic cross section views of another embodiment of the adaptor and assembly of the invention, in which the clipping member is axial and the cleaning pad is a breakable membrane,

Figures 12A and 12b are respectively a perspective view and a partial perspective section view of another embodiment of an assembly of the invention,

Figure 13 is a cross section view of another embodiment of the adaptor and assembly of the invention, comprising a pierceable decontamination insert,

Figure 14 is a cross view of another embodiment of the adaptor and assembly of the invention, comprising an air inlet,

Figure 15 is a side view of another embodiment of the adaptor and assembly of the invention, comprising a tubular lodging shaped and dimensioned for receiving an injection device,

Figure 16 is an exploded view of another embodiment of the adaptor of the invention, comprising a dose counter,

Figure 17 is a top perspective view of the dose counter of the adaptor of Figure 16,

Figures 18A and 18B are respectively a top perspective view and a bottom perspective view of the adaptor of Figure 16.

With reference to Figures 2A-2C is shown an adaptor 10 in accordance with an embodiment of the invention, in a position for being mounted on a multidose vial 1 as shown on Figures 1A-1C. The adaptor 10 comprises a gripping member 20 intended to secure it onto the vial 1, and an elastomeric piece 30 which is pierceable by the needle of an injection device. The adaptor 10 also comprises a compressive member 40, for pressing the elastomeric piece 30 onto the outer surface 4a of the septum 4, when the adaptor 10 is secured on the vial 1. As will be shown from the description below, the compressive member 40 is capable to transition from an inactive state, in which it does not exert any pressure on the elastomeric piece 30, to an active state, in which it exerts such a pressure. In the embodiment shown, parts of the gripping member 20 and of the compressive member 40 are also useful in combination for forming a fixing system for preventing the release of the gripping member 20 and definitively securing the adaptor 10 on the vial 10, as will be explained below.

With reference to Figures 3A-3D, the gripping member 20 will now be described in detail. The gripping member 20 comprises a U-shaped body 21, having a partially tubular wall 22 showing a height suitable for surrounding the collar 3 of the vial 1 (see figures 9A-B), with two free ends 22a corresponding to the ends of the branches of the U, the U-shaped body 21 therefore forming a clipping member. Close to each free end 22a, the tubular wall 22 is provided on its outer surface with a first recess 23, and with a second recess 24, distally spaced with respect to the first recess 23. First recesses 23 are provided with sloped distal faces 23a. In its circular portion, the partially tubular wall 22 is further provided on its outer surface with a pair of first rear recesses 25, and with a pair of second rear recesses 26, distally spaced with respect to the pair of first rear recesses 25. First rear recesses 25 are provided with sloped distal faces 25a. Still in its circular portion, the partially tubular wall 22 is further provided on its outer surface with a rear projection 29 located between the two second rear recesses 26, and on its inner surface with a forward projection 29a.

Each free end 22a is further provided with a distal front projection forming a radial rim 27.

The U-shaped body 21 is further provided at its proximal end with an inner annular rim 21a, forming a central hole 28.

With reference to Figures 4A and 4B, the compressive member 40 will now be described in detail. The compressive member 40 comprises a cap 41, formed of a tubular wall 42 closed at its proximal end by a transversal wall 41a. The cap 41 is sized and shape for receiving therein the gripping member 20. The transversal wall 41a is provided with a central hole 43 for receiving the elastomeric piece 30 (see Figure 2B). The tubular wall 42 is provided with an opening 44 on a part of its circumference, herein called "front part" of the compressive member 40, said opening 44 being intended to face and receive the free ends 22a of the gripping member 20 when the gripping member 20 and the compressive member 40 are assembled together to form the adaptor of Figures 2A-2D.

In its front part, on each side of the opening 44, the tubular wall 42 is provided with a flexible leg 45 having a distal free end having an inner radial peg 45a. In its rear part opposite its front part, the tubular wall 42 is provided with two rear flexible legs 46 having a distal free end having an inner radial peg 46a (see Figure 4A).

On Figure 5 is shown the pierceable elastomeric piece 30. In the embodiment shown, the pierceable elastomeric piece 30 has globally the shape of a flat cylinder. As shown on figures 2A-D and 6A-D, the pierceable elastomeric piece 30 is dimensioned and shaped so as to be received within central hole 43 of the transversal wall 41a of the cap 41 with friction. As also shown from these Figures, the distal face of the pierceable elastomeric piece 30 has a plane surface 31 having a rounded shape. In embodiments not shown, the pierceable elastomeric piece may have any suitable shape complementary to that of the central hole of the transversal wall, such as a cubic shape, etc...

The pierceable elastomeric piece 30 is made of a material impermeable to gas and liquid capable of flexing under pressure. For example, the elastomeric piece has a thickness ranging from 1 to 8 mm, preferably from 2 to 4 mm. The elastomeric piece may show a hardness ranging from 10 to 100 Shore A, preferably from 40 to 70 Shore A, measured according to DIN 53505.

Suitable materials for the pierceable elastomeric piece 30 of the adaptor of the invention include natural rubber, acrylate-butadiene rubber, cis-polybutadiene, chlroro or bromobutyl rubber, chlorinated polyethylene elastomers, polyalkylene oxide polymers, ethylene vinyl acetate, fluorosilicone rubbers, hexafluoropropylene-vinylidene fluoride-tetrafluoroethylene terpolymers, butyl rubbers, polyisobutene, synthetic polyisoprene rubber, silicone rubbers, styrene-butadiene rubbers, tetrafluoroethylene propylene copolymers, thermoplastic-copolyesters, thermo-plastic elastomers, or the like or a combination thereof.

Preferably, the elastomeric piece is self-resealing and it automatically seals the hole produced by the piercing of the needle, automatically and rapidly, for example in less than 0.5 seconds, once the needle is removed from the elastomeric piece. This automatic closure step may occur a high number of times, in particular as many times as necessary for removing the numerous doses of product initially present in the multidose vial 1. Suitable materials for self-resealing pierceable elastomeric piece of the adaptor of the invention include synthetic polyisoprene, natural rubber, silicone rubber, thermo-plastic elastomers, or the like or a combination thereof.

The use of the adaptor 10 in connection with a vial of figures 1A-1C will now be explained with reference to figures 2A-10B.

The adaptor 10 is provided to the user with the gripping member 20, the pierceable elastomeric piece 30 and the compressive member 40 assembled together in the inactive state of the compressive member 40 as shown on Figures 2A-2C, and packed in a blister 50 as shown on Figure 7.

With reference to Figures 2A-2C, the pierceable elastomeric piece 30 is lodged in the central hole 43 of the cap 41 in which it remains fixed by friction, with its plane and rounded distal face 31 protruding distally outside said central hole 43, and its proximal face 32 protruding proximally outside the central hole 43. The cap 41 is assembled on the U-shaped body 21 by means of inner radial pegs 46a (Figure 4A) being engaged in first rear recesses 25, and of inner radial pegs 45a being engaged in first recesses 23. In this position, the opening 44 of the tubular wall 42 faces the free ends 22a of the tubular wall 22 of the U-shaped element 21, and the central hole 43 with the elastomeric piece 30 faces the central hole 28 of the gripping member 20.

With reference to Figure 7, the adaptor 10 is packed before use in a blister 50 surrounding the adaptor 10. The blister 50 comprises a shell 51

closed by a pellicle film 52. The shell 51 is provided with a front projection 51a carrying a cleaning pad 60, and with front guiding projections 53 located distally with respect to said front projection 51a.

The cleaning pad 60 may be any pad, such as fabric or sponge, for example out of cotton or any other porous material, and may be imbibed with a cleaning solution or disinfecting composition. For example, the cleaning pad 60 may comprise a disinfecting agent. The disinfecting agents may be selected from alcohols, such as ethanol or isopropanol, organic solvents, such as nitrofurane, toluene, phenol and derivatives thereof, derivatives of quinoline and acridine, salts such as sodium hypochlorite, sodium chlorite or sodium chlorate, chlorine dioxide, salts of iodine, mercury, silver, ammonium, or the like, or a combination thereof.

Once the user is ready to proceed to the withdrawal of a dose of product contained in the vial 1, he removes the pellicle film 52 in order to open the blister 50. In the embodiment shown, the shell 51 remains on the adaptor 10 until the adaptor 10 is secured on the collar 3 of the vial 1. The shell 51 is removed thereafter, before piercing of the elastomeric piece 30 by the needle of the injection device. In other embodiments, the whole blister 50 may be removed before mounting the adaptor 10 on the vial 1.

With reference to Figure 8, the user then approaches the front part of the adaptor 10 with the shell 51 towards the collar 3 of vial 1, in order to mount laterally the adaptor 10 onto the collar 3 of the vial 1. The front guiding projections 53 of the shell 51 slide around the collar 3 so as to guide the adaptor 10 and ensure appropriate positioning and correct fitting of the gripping member 20 on the collar 3 of the vial 1. The cleaning pad 60 enters first in contact with an edge of the outer surface 4a of the septum 4. While the user continues to move laterally the shell 51 containing the adaptor 10, and thus the clipping member 20 towards the collar 3 so as to mount it thereon, the cleaning pad 60 slides on the outer surface 4a of the septum 4, until it loses contact with said septum 4 when the clipping member 20 reaches its position where it is secured on the collar 3, by means of forward projection 29a and radial rims 27 surrounding the collar 3, as shown on Figure 9A.

During the mounting step of the adaptor 10 on the collar 3 as described above, the sliding of the cleaning pad 60 onto the outer surface 4a of the septum 4 has wiped out bacteria and/or contamination elements potentially present on said outer surface 4a. The outer surface 4a of the septum 4 is

therefore decontaminated when the elastomeric piece 30 of the adaptor 10 comes in contact with it.

In another embodiment (not shown), where the blister 50 is fully removed before mounting the adaptor 10 on the vial 1, the cleaning pad 60 is provided on a proximal front projection of a free end 22a, for example opposite the radial rims 27.

Back to Figure 9A, once the adaptor 10 is secured on the collar 3 of the vial 1 by means of the gripping member 20, the user applies a distal pressure on top of the shell 51 in order to make the compressive member 40 transition from its inactive state to its active state, as shown on Figure 9B. Under this distal pressure, the compressive member 40 has moved distally with respect to the gripping member 20 : the inner radial pegs 46a have been able to escape the first rear recesses 25 by overcoming distal sloped faces 25a, and have become engaged in second rear recesses 26. In the same manner, inner radial pegs 45a have been able to escape first recesses 23 by overcoming distal sloped faces 23a, and have become engaged in second recesses 24, as shown on Figures 6A-6C and 9B.

As shown from Figure 9B, the pierceable elastomeric piece 30 is now compressed and flexes under the pressure exerted by the compressive member 40 on the gripping member 20. In addition, as is clear from Figure 9B, the distal face 31 of the elastomeric piece 30 has a surface which is complementary to that of the septum 4, and this surface is tightly and intimately in contact with the outer surface 4a of the septum 4 so that no foreign elements may be present between the distal face of the elastomeric piece 30 and the outer surface 4a now cleaned and disinfected.

In addition, by cooperation of the forward projection 29a and radial rims 27 coming in abutment on the collar 3 of the vial 1 and of the pegs (45a, 46a) of the compressive member 40 being engaged in the recesses (24, 26) of the gripping member 20, the adaptor is now secured on the collar in a permanent way and may not be removed. Once the adaptor 10 is secured on the collar 3 of the vial 1, various contaminations of the inside vial 1 are avoided, and this ensures that the contents of the vial 1 will not be polluted.

The forward projection 29a, radial rims 27 and the recesses (24, 26) of the gripping member 20 form, in combination with the pegs (45a, 46a) of the compressive member 40, a fixing system for preventing the releasing of the gripping member 20 and definitively securing the adaptor 10 on the vial 1.

The user then removes the shell 51 of the blister 50 and the adaptor 10 is ready to receive the needle 5 of an injection device 100, as shown on Figures 10A and 10B. It is therefore possible to pierce the elastomeric piece 30 of the adaptor 10 with the needle 5 and then subsequently pierce the septum 4, as many times as necessary, as explained above, with desired hygienic conditions.

Figures 11A-15 show alternative embodiments of the adaptor 10 of Figures 1A-10B. References designating the same elements as in Figures 1A-10B have been maintained for Figures 11A-15.

With reference to figures 11A and 11B is shown schematically another embodiment of the adaptor 10 of the invention, in which the gripping member 120 is an axial clipping member comprising a tubular element 122 capable of being axially mounted on the collar 3 of the vial 1, by means of flexible radial pegs 123 engageable on the collar 3. In the embodiment shown, the adaptor 10 is provided with a transversal wall 121 located within said tubular element 122, and the cleaning pad is a breakable membrane 160 attached to the inner wall of the tubular element 122, and located distally with respect to the transversal wall 121.

As such, when the user approaches the distal free end of the tubular element 122 of the gripping member 120 towards the collar 3 of the vial 1, as shown on figure 11A, the breakable membrane 160 enters in contact with the outer surface 4a of the septum 4. While the user continues to move the gripping member 120 distally so as to mount it on the collar 3 of the vial 1, the breakable membrane 160, which is attached to the inner wall of the tubular element 122, becomes stretched out on the outer surface 4a of the septum 4 and finally breaks on said outer surface 4a and is torn in several parts that slide on said outer surface 4a while the gripping member 120 reaches its position where it is secured on the collar 3. In this position, as shown on Figure 11B, because it is now torn in several parts (160a, 160b) hanging along the inner walls of the tubular element 122, the membrane 160 does not face the septum 4 anymore and it does not prevent the piercing of the septum 4 by the needle of an injection device (not shown). During the mounting step of the adaptor 10 on the collar 3 as described above, the sliding of the several torn parts (160a, 160b) of the breakable membrane 160 on the outer surface 4a of the septum 4 has wiped out the bacteria and/or contamination elements potentially present on said outer surface 4a. The outer surface 4a of the septum 4 is therefore

decontaminated when the elastomeric piece 30 of the adaptor comes in contact with it, as shown on Figure 11B.

In embodiments not shown, the adaptor of Figures 11A and 11B is packed before use in a blister comprising a shell closed at its distal end by a transversal pellicle film. In embodiments, the breakable membrane may be part of the blister and may be attached to the inner surface of the shell parallel to the distal transversal pellicle film.

With reference to Figures 12A and 12B is shown another embodiment of the adaptor 10 of the invention, in which the cleaning pad 260 is part of the gripping member 220. In this embodiment, the gripping member 220 is a lateral clipping member comprising a transversal wall 221 provided with a hole 223 in which is lodged the elastomeric piece 30. The transversal wall 221 is proximally deflectable thanks to a rear hinge member 221a connecting the transversal wall 221 to the gripping member 220. The transversal wall 221 is provided with a front distal projection 224 bearing the cleaning pad 260. In this embodiment, the adaptor 10 does not comprise any compressive member.

When the adaptor 10 of Figures 12A-12B is mounted laterally on the collar 3 of the vial 1, the transversal wall 221 is pushed in a proximal direction when it contacts the collar 3. The cleaning pad 260 is therefore caused to slide onto the outer surface 4a of the septum 4, thereby cleaning and decontaminating said surface. The correct positioning of the adaptor 10 on the vial 1 is obtained when the collar 3 comes in abutment against the front distal projection 224 and the transversal wall 221 comes back to its non deflected position, as shown on figure 12B. In this position, the pierceable elastomeric piece 30 is in close contact with the septum 4 of the vial 1.

The gripping member 220 is therefore releasingly secured on the collar 3 of the vial 1. The transversal wall 221 is deflectable after the adaptor is mounted, for release of the vial 1 if necessary.

With reference to Figure 13, is shown another embodiment of the adaptor 10 of the invention, in which a pierceable decontamination insert 70 is located proximally with respect to the elastomeric piece 30. On the embodiment shown, the decontamination insert 70 comprises a sterilizing gel 71. For proceeding to the withdrawal of a dose of product from the vial 1, the needle 5 first traverse the sterilizing gel 71, in which it is sterilized, then the elastomeric piece 30, in which it is submitted to a mechanical cleaning, before it contacts

the septum 4. The piercing is therefore completed in improved hygienic conditions.

With reference to Figure 14, is shown another embodiment of the adaptor 10 of the invention, in which the adaptor 10 further comprises an air inlet 80 for allowing air entrance into the vial 1, once the adaptor 10 is secured on the vial 1. On the example shown, the air inlet 80 comprises a cannula 81 extending from the adaptor 10 in the distal direction and provided with a sharp distal tip 82, capable of piercing the septum 4 of the vial 1, the proximal end 83 of the cannula 81 protruding outside the adaptor 10 in outside environment. The air inlet 80 is provided with a filter 84 to restrict or prevent entry of contaminants such as particulates or bacteria from the ambient atmosphere into the vial 1, in particular during the vaccine withdrawal process. For example, this filter 84 has a pore size of 0.22 microns. Such embodiments are advantageous in the case the vial is made of glass or polymeric materials the walls of which are not collapsible. The presence of an air inlet prevents the formation of vacuum in the vial when medical fluid is withdrawn therefrom.

With reference to Figure 15 is shown another embodiment of the adaptor 10 of Figures 12A and 12B, in which a tubular lodging 90 extends from the transversal wall 221 in the proximal direction, the tubular lodging 90 being shaped and dimensioned for receiving an injection device 100. For example, a cavity (not shown) filled with decontaminated atmosphere is provided in the tubular lodging 90, the needle of the injection device received in the tubular lodging 90 being lodged in said cavity. Such embodiments allow better hygienic and aseptic conditions for proceeding to the piercing of the outer surface 4a of the septum 4 of the vial 1, as the needle of the injection device does not enter in contact with outside environment before piercing.

With reference to Figures 16-18B is shown another variant of the adaptor 10 of Figures 2A-6B further comprising a dose counter 91. The references designating the same elements as in Figures 2A-6B have been maintained, augmented of 300.

With reference to Figures 16-18B, the compressive member 340 is formed of a cap 341 formed of a tubular wall 342 closed at its proximal end by a transversal wall 341a provided with a central hole 343. The tubular wall 342 is provided with an opening 344 on a part of its circumference and on its whole height, herein called "front part" of the compressive member 340, the opening 344 comprising a transversal bridge 347 defining a proximal window 347a. The

proximal face of the transversal wall 341a is provided with an opening 341b (see Figure 18A) radially spaced with respect to the center of the transversal wall 341a. The distal face of the transversal wall 341a is provided with a distally extending collar 348 surrounding the central hole 343. In the distal region of the outer wall of the distally extending collar 348 are located two opposite outer ears 348a, only one of them being visible on Figure 16. The distal face of the transversal wall 341a is further provided with a plurality of circumferentially distributed recesses 349 located around the distally extending collar 348.

The dose counter 91 is made of a flat cylinder 92 provided with a plurality of circumferentially distributed peripheral projections 93 extending radially outwardly. The flat cylinder 92 is further provided with a central hole 94 dimensioned and shaped so as to fit around the distally extending collar 348 of the distal face of the transversal wall 341a of the compressive member 340, and so as to be snap-fitted thereon after overcoming the outer ears 348a of said distally extending collar 348. The flat cylinder 92 is snap-fitted on the collar 348 so that it is able to rotate with respect to said collar 348.

With reference to Figure 17, the proximal face of the flat cylinder 92 is further provided with two proximal pegs 95 located around the central hole 94. As will be shown later, these two proximal pegs 95 are intended to cooperate with the recesses 349 of the distal face of the transversal wall 341a of the cap 341 of the compressive member 340. The proximal face of the flat cylinder 92 is further provided with a plurality of circumferentially distributed information data 96, such as digits from "0" to "10" on the example shown.

When the adaptor 10 is assembled, as shown on Figures 18A and 18B, the flat cylinder 92 is snap-fitted onto the distally extending collar 348 of the distal face 341a of the cap 341 and it is therefore received within said cap 341 with a part of it protruding outside via the window 347a. The flat cylinder 92 is capable of rotating with respect to the collar 348, therefore with respect to transversal wall 341a. Anyway, before use, one of the information data, for example digit "0" faces the opening 341b of the transversal wall 341a and it is therefore visible by the user. In addition, in order to temporarily maintain the flat cylinder 92 in this position with respect to the transversal wall 341a, the proximal pegs 95 are each engaged in one of the plurality of circumferentially distributed recesses 349 located around the distally extending collar 348.

The user then uses the adaptor 10 in the same way as described for figures 1A-6B in order to withdraw a dose of product from a medical

container. He then rotates the flat cylinder 92, for example manually by grasping one of the plurality of circumferentially distributed peripheral projections 93 extending radially outwardly, for example in the direction of the arrow 341c shown on Figure 18A. With this rotational movement, the proximal pegs 95 overcome the recesses 349 in which they were engaged, and become engaged in adjacent recesses 349, in which position the digit "1" now appears through opening 341b of the proximal face of the transversal wall 341a.

The flat cylinder 92 therefore forms a dose counter for counting how many doses of product have already been withdrawn or remain from the medical container.

The adaptor and assembly of the invention allow piercing the septum of a multidose vial yielding favorable hygienic and aseptic conditions multiple successive times. Indeed, with the adaptor of the invention, introducing the needle of an injection device into the septum of a vial entails the needle piercing and traversing the elastomeric piece of the adaptor in the first place. During this step, the needle mechanically rubbing against the material forming the elastomeric piece and it is cleaned, as potential bacteria are wiped from the needle when said needle penetrates the elastomeric piece. In addition, once the needle protrudes out of the elastomeric piece of the adaptor, it directly enters the septum of the vial and may therefore not be contaminated by foreign elements.

The user may repeat the piercing step with the needle of a new empty syringe until all the doses contained in the vial are removed. The adaptor of the invention acts as a protection of the septum of the vial.

The pierceable elastomeric piece of the adaptor of the invention and the septum of the medical container are in contact, for example in tight contact, once the adaptor is secured onto the medical container. In embodiments where both the pierceable elastomeric piece of the adaptor of the invention and the septum of the medical container are self-resealing, no possibility of communication exist between the inside of the medical container and the outside environment at the time the needle of the injection device is removed from both the septum and the pierceable elastomeric piece, after withdrawal of a dose of product from the medical container. This therefore restricts or prevents the product contained in the medical container from being contaminated by outside contaminants such as bacteria, unpurified water, particles, viruses, etc...The adaptor of the invention thus allows a hermetic

sealing of the contents of the medical container it is secured on, even during the removal of the needle. The inside of the medical container is kept in aseptic conditions before, during and after a withdrawal of a dose from the medical container.

CLAIMS

1. An adaptor (10) for coupling with a medical container (1) having a collar (3) closed by a septum (4), said septum having an outer surface (4a) directed towards the outside of the medical container, the adaptor comprising:

- a gripping member (20; 120; 220) for securing the adaptor to the medical container,

- a pierceable elastomeric piece (30) having at least a part (31) intended to be in contact with the outer surface of the septum when said adaptor is secured on said medical container.

2. The adaptor (10) of claim 1, wherein the surface of said part of the pierceable elastomeric piece is complementary to the whole outer surface of the septum.

3. The adaptor (10) of claim 1 or 2, further comprising a compressive member (40) for pressing said pierceable elastomeric piece onto said outer surface of the septum, when said adaptor is secured on said medical container, said compressive member being capable to transition from an inactive state, in which it does not exert pressure on said pierceable elastomeric piece, to an active state, in which it exerts pressure.

4. The adaptor (10) of one of claims 1 to 3, further comprising a fixing system (24, 26, 27, 29a, 45a, 46a) for preventing releasing of said gripping member and definitively securing the adaptor on said medical container.

5. The adaptor (10) of any one of claims 1 to 4, further comprising a transversal wall (41a, 121, 221) connected to said gripping member, said transversal wall having a hole in which is lodged said pierceable elastomeric piece.

6. The adaptor (10) of claim 5, wherein said transversal wall (221) is proximally deflectable.

7. The adaptor (10) of any one of claims 1 to 6, wherein the gripping member is a lateral clipping member (20, 220) capable of being laterally mounted on the collar of said medical container.

8. The adaptor (10) of the preceding claim, wherein said lateral clipping member comprises a U-shaped element (21) intended to be engaged on said collar via the open part of the U-shaped element, the curved part of the U-shaped element partially surrounding the collar.

9. The adaptor (10) of any one of claims 1 to 5, wherein the gripping member is an axial clipping member (120) capable of being axially mounted on the collar of said medical container.

10. The adaptor (10) of the preceding claim, wherein the axial clipping member comprises a tubular element (121) capable of being axially engaged on said collar.

11. The adaptor (10) of any one of claims 1 to 10, further comprising a cleaning pad (60, 160, 260), said cleaning pad being configured to at least partially slide on said outer surface of said septum when the adaptor is being mounted on the medical container.

12. The adaptor (10) of claims 5, 8, and 11, wherein said transversal wall (221) is provided in the direction of free ends of the U-shaped element, with a projection provided with said cleaning pad (260).

13. The adaptor (10) of claims 5, 10 and 11, wherein said transversal wall (121) being located within said tubular element (122), the cleaning pad is a breakable membrane (160) attached to the inner wall of said tubular element, and located distally with respect to said transversal wall.

14. The adaptor (10) of any one of claims 11 to 13, wherein said cleaning pad (60) is located on a removable part of said adaptor.

15. The adaptor (10) of any one of claims 5 to 14, wherein a tubular lodging (90) extends from said transversal wall (221) in the proximal direction, said tubular lodging being shaped and dimensioned for receiving an injection device (100).

16. The adaptor (10) of claim 15, wherein a cavity filled with decontaminated atmosphere is provided in the tubular lodging, the needle of the injection device received in said tubular lodging being lodged in said cavity.

17. The adaptor (10) of any one of claims 14 to 16, wherein said removable part is a portion (51) of a blister (50) surrounding said adaptor in a storage state.

18. The adaptor (10) of any one of claims 1 to 17, further comprising an air inlet (80) for allowing air entrance into the medical container, once the adaptor is secured on said medical container.

19. The adaptor (10) of claim 18, wherein said air inlet is provided with a filter (84) to restrict entry of particulates or bacteria from the ambient atmosphere into the medical container.

20. The adaptor (10) of any one of claims 1 to 19, further comprising a pierceable decontamination insert (70) located proximally with respect to said elastomeric piece.

21. The adaptor (10) of any one of claims 1 to 20, wherein the pierceable elastomeric piece is self-resealing.

22. The adaptor (10) of any one of claims 1 to 21, wherein the elastomeric piece is made of a material selected from synthetic polyisoprene, natural rubber, silicone rubber, thermo-plastic elastomers, or the like or a combination thereof.

23. The adaptor (10) of any one of claims 10 to 22, wherein the cleaning pad comprises a disinfecting agent.

24. The adaptor (10) of any one of claims 1 to 23, further comprising a counting system (91, 92, 93).

25. Assembly comprising a medical container (1) having a collar closed by a septum, said septum having an outer surface directed towards the outside of the medical container, and an adaptor (10) according to any one of claims 1 to 24.