

Adaptor with injection device for coupling to 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 comprising an injection device and allowing for aseptic needle piercing of the septum of the medical container so as to fill said injection device 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 medical container 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 temperatures 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 may 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 ambient air. In such cases, the septum of the vial may be contaminated either by the ambient 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 safe piercings of a multidose vial septum and that would guaranty 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, said adaptor comprising an injection device provided at its distal end with a needle intended to pierce said septum via said outer surface in order to fill in said injection device with product from the medical container, the adaptor further comprising :

- a tubular lodging for receiving at least partly said injection device, said tubular lodging being substantially closed at its distal end by a transversal wall provided with a central hole in which is lodged a pierceable elastomeric piece having at least a distal face intended to be in contact with the outer surface of the septum when said adaptor is secured on said medical container, the needle of said injection device being aligned with said pierceable elastomeric piece and being movable within said tubular lodging with respect to said pierceable elastomeric piece between an inactive position, in which said needle is entirely located proximally to said pierceable elastomeric piece, and an active position, distally spaced with respect to said inactive position, in which only a part of the needle is located proximally to said pierceable elastomeric piece, the other part of said needle piercing said pierceable elastomeric piece and protruding out of said distal face of said pierceable elastomeric piece,

- said tubular lodging further comprising a chamber filled with decontaminated air and receiving the needle or part of the needle located proximally to said pierceable elastomeric piece, the volume of said chamber being capable of varying from a first volume, when said needle is in its inactive position, to a second volume less than said first volume, when said needle is in its active position,

- an air passage for allowing air coming in and out from said chamber, said air passage comprising a first filtering system for

decontaminating the air coming from the outside before it reaches said chamber,

- an air inlet for allowing air from the outside entering the adaptor and reaching the distal face of said pierceable elastomeric piece when said adaptor is secured on said medical container, said air inlet comprising a second filtering system (64) for decontaminating said entering air before it reaches said distal face of said pierceable elastomeric piece,

- a gripping member connected to said transversal wall, for releasably securing the adaptor to the medical container.

The adaptor of the invention is intended to be mounted on a medical container, such as 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 by a dose of 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 vial, and in particular around the collar of the vial, in a temporary way.

The pierceable elastomeric piece of the adaptor of the invention has at least a distal face intended to be in contact, in particular in close contact, with the outer surface of the septum when said adaptor is secured on said vial. In other words, the elastomeric piece has a design, shape, and location on the adaptor, allowing a distal face of it to be in contact with the outer surface of the

septum when said adaptor is secured on said vial. For example, the distance between the distal face of the pierceable elastomeric piece and the outer surface of the septum may range from about 1 mm to about 5 mm : preferably this distance allows air flow to reach interface between the distal face of the pierceable elastomeric piece and the outer surface of the septum.

The adaptor of the invention allows piercing the septum of the medical container in good hygienic conditions multiple successive times while maintaining the sterility inside the medical container over its lifetime. Indeed, when the user decides to fill in the empty injection device provided on the adaptor with a dose of drug contained in the medical container, he simply secures the adaptor of the invention with its injection device 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, in particular in close contact, with the outer surface of the septum of the medical container. In addition, the needle of the injection device is stored in a chamber filled with decontaminated air. As a consequence, introducing the needle of the injection device in the medical container implies that a sterile needle pierces first the pierceable elastomeric piece of the adaptor and then the septum of the medical container. The piercing step therefore takes place in good hygienic conditions as no contaminant is introduced into the medical container, neither by the needle nor by any air that would enter the medical container during or after the product removal.

In the adaptor of the invention, the needle is received in a decontaminated atmosphere at any time, namely in the storage and before use position of the adaptor, when the needle is in an inactive position, during the filling step of the injection device, when the needle is in its active state, and also in an end of use position of the adaptor, when the needle is back to its inactive position, once the injection device is filled with the adequate dose of product retrieved from the medical container. As such, not only the needle may not contaminate the septum or the product of the medical container, but it is also prevented from being contaminated between the end of use position of the adaptor and the moment the dose of product, for example a vaccine, now filling the injection device, is injected into a patient. Moreover, the injection device and its needle are enclosed into the adaptor from a storage state of said adaptor to the successive steps of dose of product removals. Therefore, the risk of misuse of the injection device is reduced. Furthermore, the adaptor of

the invention not only allows a safe withdrawal step, but also a safe subsequent injection step.

The adaptor of the invention, because it incorporates an injection device is intended for single use. The user may repeat the piercing step of the multidose medical container described above with the needle of the injection device of a new adaptor until all the doses contained in the medical container are removed. The septum of the medical container is therefore protected. In addition, the air inlet of the adaptor of the invention with its second filtering system allows only decontaminated air to reach the distal face of the pierceable elastomeric piece which is in contact with the outer surface of the septum of the medical container. As a consequence, at the time the needle is removed from the medical container, the air sucked from the outside by the vacuum created inside the medical container by the removal of the needle arrives on the outer surface of the septum in a decontaminated state. Then, the air may then be sucked inside the medical container through the hole left in the septum by the previous piercing of the needle with no risk of polluting the medical container or the product stored therein.

In embodiments, the pierceable 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 about 1 to about 6 mm, preferably from about 2 to about 4 mm. The elastomeric piece may show a hardness ranging from about 10 to about 100 Shore A, preferably from about 40 to about 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" it is meant that the elastomeric piece closes again 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 pierceable

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 present in the multidose medical container. 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 adaptor further comprises elastic return means for urging said needle from its active position to its inactive position. Such an embodiment facilitates the step of withdrawal of the dose of product from the medical container.

In embodiments, the adaptor further comprises a safety system for temporarily securing said needle in its active position. Such embodiments allow the user to safely proceed to the filling step of the injection device, by pulling in the proximal direction on a piston rod of the injection device, with no risk that the needle be also withdrawn in the proximal direction and escape from the medical container.

In embodiments, the elastic return means comprises an elastic foldable sleeve surrounding the needle or part of the needle located proximally to said pierceable elastomeric piece, a proximal end of said elastic foldable sleeve being fixed with respect to a proximal end of the needle, and a distal end of said elastic foldable sleeve being sealingly attached to the proximal face of the pierceable elastomeric piece, said elastic foldable sleeve thereby further delimiting the chamber. Such embodiments allow to combine elastic return means and walls defining the chamber in a single part. For example, the elastic foldable sleeve is made of a material selected from 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, thermoplastic elastomers, or the like or a combination thereof.

The elastic foldable sleeve protects the needle from the outside environment and maintains its sterility.

In embodiments, the needle being located at a distal end of a barrel of said injection device, said distal end of barrel is fixedly received within a

tubular holder with a space being present between an outer wall of said distal end of said barrel and the inner wall of said tubular holder, the proximal end of said elastic foldable sleeve being sealingly attached to an outer wall of said tubular holder, said space thereby forming said air passage. The air passage allows air coming in and out the chamber, in particular when the needle goes from its inactive position to its active position and vice-versa.

In embodiments, the first filtering system comprises a plurality of interrupted circumferential ridges provided on the inner wall of said tubular holder, said plurality of interrupted circumferential ridges defining a labyrinthic path within said space, said labyrinthic path decontaminating air circulating within said space. As a result, when the needle moves from its active position to its inactive position, once the removal of product is completed, air sucked from the outside environment inside the chamber delimited by the elastic foldable sleeve is decontaminated and the sterility of the needle is maintained.

In embodiments, the safety system comprises a safety sleeve fixedly received within said tubular lodging, the wall of said safety sleeve being provided with at least a cam, said tubular holder being slidably received within said safety sleeve with at least an outer peg of said tubular holder being engaged in said cam, so that movement of said tubular holder with respect to said safety sleeve is dictated by movement of said peg in said cam. For example, said cam comprises at least a stop for releasably engaging said peg when said needle is in its active position. Such embodiments allow the user to pull on a piston rod of the injection device in the proximal direction in order to fill in the injection device with a dose of product without fearing that the needle be also withdrawn in the proximal direction and escape the medical container.

In embodiments, said cam comprises a final stop, for preventing said needle from returning to an active position after it has already been once to said active position. Such embodiments provide for a particularly secured adaptor, where the needle is prevented from going back to its active position and therefore from protruding distally out of the pierceable elastomeric piece, where it could be contaminated by the outside air, once the injection device is filled with the product to be injected in a patient. This allows to maintain the needle in a closed and decontaminated environment until the injection step in a patient is completed.

In embodiments, the pierceable elastomeric piece being provided with a circular transversal wall bearing on a proximal face of said transversal

wall of said tubular lodging, and with a distal plug lodged within said central hole, a ring extending from the periphery of said circular transversal wall in the proximal direction, said ring is fixedly received within a circular tubular wall extending from the transversal wall of said tubular lodging, with a space being present between the outer wall of said ring and the inner wall of said circular tubular wall, and between said proximal face of said transversal wall of said tubular lodging and the distal face of said circular transversal wall of said pierceable elastomeric piece, and between the outer wall of said distal plug and the inner wall of said central hole, said space thereby forming said air inlet.

In embodiments, the second filtering system comprises a plurality of interrupted circumferential ridges provided on the outer wall of said ring, said plurality of interrupted circumferential ridges defining a labyrinthic path within said space, said labyrinthic path decontaminating air coming from the outside and circulating within said space towards the distal face of said distal plug. As a negative pressure is created inside the medical container at the time the dose of product is withdrawn therefrom, it is this thus decontaminated air which is sucked into the medical container. The remaining doses of product left inside the medical container are therefore not contaminated by this entry of air.

In embodiments, the gripping member is a lateral clipping member capable of being laterally mounted on the collar of said medical container. For example, said lateral clipping member comprises a U-shaped body intended to be engaged on said collar via the open part of the U, the curved part of the U partially surrounding the collar.

In embodiments, the adaptor further comprises a cleaning pad, said cleaning pad being configured so as to at least partially slide on said outer surface of said septum during the step in which the adaptor is being mounted on the medical container to be secured thereon.

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 imbibed 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 medical container. 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 medical container.

For example, in embodiments where the lateral clipping member comprises a U-shaped body 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 arms of the U, 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 arms of the U of the lateral clipping member towards the collar of the medical container, 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.

Another aspect of the present 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-2C are respectively a front view, a cross section view, and another cross section after 90° rotation, in accordance with an embodiment of the adaptor of the invention,

Figures 3A-3E are respectively a perspective view from the top, a perspective view from the bottom, a front view , a side view and a top view of the tubular lodging of the adaptor of figures 2A-2C,

Figures 4A-4B are respectively a perspective view from the top and a side view of the second filtering system of the adaptor of figures 2A-2C,

Figures 5A-5B are respectively a perspective view from the top and a side view of the second filtering system and chamber of the adaptor of figures 2A-2C,

Figures 6A-6C are respectively a side view, a cross section view and a perspective view from the top of the first filtering system of the adaptor of Figures 2A-2C,

Figures 7A-7C are respectively a perspective view from the bottom, a side view and a front view of the safety system of the adaptor in accordance with an embodiment of the invention,

Figures 8A and 8B are a cross section view and another cross section view after rotation of 90° of the adaptor in accordance with an embodiment of the invention once coupled to a vial,

Figures 9A and 9B are respectively a partial front view and a partial cross section view of the adaptor of Figures 8A and 8B on which the injection device is not shown for sake of clarity,

Figures 10A and 10B are respectively a front view and a cross section view of the adaptor of Figures 8A-8B showing the piercing step,

Figures 11A and 11B are respectively a front view and a cross section view of the adaptor of Figures 8A-8B showing the filling step, with the injection device secured in a use position,

Figures 12A and 12B are respectively a front view and a cross section view of the adaptor of Figures 8A-8B showing the disengagement of the injection device from its use position,

Figures 13A and 13B are respectively a front view and a cross section view of the adaptor of Figures 8A-8B in an end-of-use position,

Figure 14 is a partial front view showing the safety system in the end-of-use position of the adaptor, after the user has pushed distally on the injection device.

With reference to Figures 2A-2C is shown an adaptor 10 in accordance with an embodiment of the invention, with an injection device 100 incorporated therein, the adaptor 10 being in a storage position, before being mounted on a multidose vial as the vial 1 shown on Figures 1A-1C. The adaptor 10 has a longitudinal axis A aligned on the longitudinal axis of the injection device 100, and comprises a tubular lodging 20 substantially closed at its distal end by a transversal wall 22 and a pierceable elastomeric piece 30. The adaptor 10 further comprises a gripping member under the form of U-shaped body 25 extending distally from the transversal wall 22 and intended to secure the adaptor on the collar 3 of the vial 1. Within the tubular lodging 20 is received at least partly the injection device 100.

The injection device 100 comprises in a conventional manner a needle 5 located at the distal end of a barrel 6. Within the barrel 6 is lodged a plunger 7 attached to a piston rod 8 for moving the plunger 7 inside the barrel 6, in order to fill in or on the contrary to empty said barrel 6. The distal end of the barrel 6 is fixedly received within a holder 40 located within the tubular lodging 20, and from which a part of the needle 5 protrudes in the distal direction. The part of the needle 5 protruding out of the holder 40 is received within a chamber 50 filled with decontaminated air and defined by an elastic foldable sleeve 51 closed at a distal end by the pierceable elastomeric piece 30 and tightly sealed at its proximal end on the outer wall of the holder 40. The injection device 100 may be plugged in the holder 40 for example by an annular rib provided on a distal part of the barrel and cooperating with a circumferential ridge present on the inner wall of the holder 40. In embodiments where the injection device is pre-plugged inside the holder, the user may simply couple the adaptor to the vial without having to perform any additional step.

As will be seen from the description below, the adaptor 10 is intended to be mounted on a vial 1 such as the one shown on Figures 1A-1C, in order to withdraw a dose of product, such as a vaccine, contained in said vial 1 in good hygienic conditions, and while avoiding any contamination and

preserving the sterility and efficiency of the pharmaceutical product contained in the vial 1.

In particular, in this view, the needle 5 is intended to move from an inactive position, in which the adaptor 10 may be handled from the storage position to a before use position, in which it is secured on the vial 1, and ready to be used, to an active position, in which the needle 5 pierces the pierceable elastomeric piece 30 and then the septum 4 of the vial 1, so as to reach the product to be withdrawn from the vial 1. In such an active position of the needle 5, the user may pull on the piston rod 8 in order to fill in the barrel 6 with the product from the vial 1. Once the adequate dose of product is withdrawn, it is desirable that the needle 5 returns to its inactive position, so that the adaptor 10 may further be removed from the collar 3 of the vial 1 and the dose of product be injected to a patient with no risk of accidental needle pricking.

As shown from the description below, the movement of the needle 5 from its inactive position to its active position and back to its inactive position implies that the elastic foldable sleeve 51 transition from an unfolded state to a folded state and back to an unfolded state, thereby reducing the volume of the chamber 50 and further increasing it again. Anyway, during these steps, the chamber 50 must remain filled with decontaminated air in order to maintain the sterility of the needle and of the product during the withdrawal of the dose of product from the vial 1.

As shown below, part of the holder 40 forms an air passage and first filtering system for allowing air from the outside entering the chamber 50 while decontaminating said air before it reaches the chamber 50, at the time the needle 5 is moved from its active position to its inactive position. This air passage also forms an air outlet for air leaving the chamber 50 when the needle 5 moves from its inactive position to its active position. Motion of the injection device when the needle 5 goes from its inactive position to its active position is easy as no air is trapped inside the elastic foldable sleeve 51.

In addition, the vial 1 is tightly closed by a septum 4. When one withdraws a dose of product from a tightly closed vial 1, especially if the vial 1 is in glass material or not collapsible plastic material, a vacuum is created inside the vial 1. As a consequence, when the needle 5 of the injection device used for the withdrawal step is removed from the vial 1, air from the outside is sucked inside the vial 1 via the hole left in the septum 4 by the needle 5.

On figures 2A-2C, the distal end of the foldable sleeve 51 is received within a ring 60, said ring 60 being received in a circular wall 27 extending proximally from the transversal wall 22.

The circular wall 27 and the ring 60 form part of an air inlet and second filtering system for allowing the passage and the decontamination of air coming from the outside and going towards a distal face of the pierceable elastomeric piece 30 and then inside the vial 1, when the needle is removed once the injection device is filled with the adequate dose of product. The vial 1 is therefore not kept under negative pressure and the sterility of the remaining contents of the vial 1 is maintained during the lifetime of the vial 1.

As shown below, the injection device 100 together with the needle 5 is movable with respect to said lodging 20 and to said pierceable elastomeric piece 30 between an inactive position of the needle 5, in which the needle 5 does not pierce the pierceable elastomeric piece 30, and an active position of the needle 5, distally spaced with respect to said inactive position, in which the needle 5 pierces the pierceable elastomeric piece 30 and protrudes out of the pierceable elastomeric piece 30 : in its active position, as will be clear from Figures 10A-11B, the needle 5 protrudes out of the pierceable elastomeric piece 30 on a length sufficient for the distal tip of the needle 5 to pierce the septum 4 of the vial 1 on which the adaptor 10 is intended to be mounted.

The adaptor 10 further comprises a sleeve 70 received within the tubular lodging 20 and receiving the holder 40 : the sleeve 70 provides for a safety system for temporary securing said needle 5 in its active position, so that the user may safely proceed to the filling step of the injection device 100.

With reference to Figures 3A-3E, the tubular lodging 20 closed by the transversal wall 22 and bearing the gripping member under the form of a U-shaped body 25 will now be described in details. The tubular lodging 20 comprises a tubular wall 21 closed at its distal end by a transversal wall 22, the transversal wall 22 being provided with a central hole 23. The tubular wall 21 comprises a longitudinal opening 24 defining the front side of the adaptor 10 according to the present description. The transversal wall 22 is provided with an extension 22a in the direction of this front side, said extension 22a extending radially beyond said longitudinal opening 24. The distal face of this extension 22a is provided with a cleaning pad 80, the function of which will be explained later below.

The transversal wall 22 is further provided with a U-shaped body 25 as a gripping member extending in the distal direction, and forming an integrate part with the transversal wall 22 and tubular lodging 20. The U-shaped body 25 has a semi-tubular wall 25a showing a height suitable for surrounding the collar 3 of the vial 1 (see figure 8B), with two arms 26 extending in the front direction and corresponding to the ends of the branches of the U. The semi-tubular wall 25a is provided on its inner wall with a forward projection 25b. Such a U-shaped body 25 provides for a lateral clipping member allowing the adaptor 10 to be laterally mounted on the collar 3 of the vial 1.

In an embodiment not shown, the gripping member could be an axially clipping member, for example comprising a flexible distal skirt capable of being axially snap-fitted on the collar 3.

The U-shaped body 25 shown on Figures 3A-3E further provides for a releasable gripping member, for releasably securing the adaptor 10 to the vial 1. Indeed, as the adaptor 10 of the invention already incorporates the injection device 100 intended to be used for injecting to a patient the dose of product that will be withdrawn from the vial 1, it is for single use.

The transversal wall 22 is provided with a circular wall 27 surrounding the central hole 23 and extending from the transversal wall 22 in the proximal direction, said circular wall 27 being received within said tubular lodging 20. A plurality of radial channels 27a, six of them on the example shown (see figure 3E), located in the transversal wall 22, connects the central hole 23 to the inner face of the circular wall 27.

The circular wall 27 is provided on its outer face with two diametrically opposed hooks 27b extending in the proximal direction, the function of which will be explained later.

The tubular element 21 is provided in its distal region with an outer flange 28, and at its proximal end with an inner annular rim 29.

With reference to Figures 4A and 4B will now be described in details the ring 60 and elastic foldable sleeve 51 : the ring 60 defines a recess 61 and is provided at its proximal end with two diametrically opposed outer ears 62 extending in the radial direction. On its outer wall, the ring 60 is further provided with a plurality of interrupted circumferential ridges 63. As shown from the description below in connection with Figure 13B, this plurality of interrupted circumferential ridges 63 defines a labyrinthic path 64 for air to circulate from a proximal end 60a to a distal end 60b of the ring 60 when the needle 5 is

removed from the vial 1 once the injection device 100 has been filled with the adequate dose of product.

On figures 5A and 5B is shown the ring 60 with the pierceable elastomeric piece 30 attached at the distal end 60b of the ring 60 and the elastic foldable sleeve 51 received and attached in the recess 61 of the ring 60.

The pierceable elastomeric piece 30 is made of a transversal wall 31 provided on its distal face with a distal plug 32 having a distal face 32a.

The elastomeric piece 30 is made of a gas and liquid impermeable material capable of flexing under pressure. For example, the elastomeric piece has a thickness ranging from about 1 to about 6 mm, preferably from about 2 to about 4 mm. The elastomeric piece may show a hardness ranging from about 10 to about 100 Shore A, preferably from about 40 to about 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, chlorobutyl 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 pierceable 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 s, once the needle is removed from the pierceable 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 products 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.

With reference to Figures 5A and 5B, the ring 60 is further provided with the elastic foldable sleeve 51, the inside of which defining the chamber 50 of the adaptor 10. The foldable sleeve 51 is sealingly attached to the inner wall of the central recess 61 and it extends from the ring 60 in the proximal direction. The elastic foldable sleeve 51 is made of an elastic material allowing

the sleeve 51 to fold along the longitudinal direction when submitted to a pressure, such as a distal pressure for example, and then to unfold to come back automatically to its rest position, when no more pressure is exerted thereon. The proximal end of the elastic foldable sleeve 51 is provided with an inner annular rim 52. On Figures 5A and 5B, the elastic foldable sleeve 51 is shown in its rest position.

Materials suitable for forming the foldable sleeve may be selected from natural rubber, acrylate-butadiene rubber, cis-polybutadiene, chlorobutyl 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, thermoplastic elastomers, or the like or a combination thereof.

On the embodiment shown on Figures 4A to 5B, the ring 60, the pierceable elastomeric piece 30 and the elastic foldable sleeve 51 are made of three different parts attached together and the ring 60 may be made of rigid material for example.

In embodiments not shown, the ring 60 could be made of the same material as the pierceable elastomeric piece 30 and these two parts could form one single part.

With reference to Figures 6A-6C will now be described in details the holder 40.

The holder 40 comprises a proximal tubular part 41, an intermediate tubular part 42 of less inner diameter than said proximal tubular part 41, and a distal tubular part 43 of less inner diameter than said intermediate tubular part 42. The intermediate tubular part 42 and the distal tubular part 43 are linked to each other by a frustoconical portion 44. The inner wall of the proximal tubular part 41 is provided with longitudinal ridges 41b, only two of them being visible on Figure 6C. The proximal region of the inner wall of the intermediate tubular part 42 is provided with a plurality of interrupted circumferential ridges 42b. As shown from the description below in connection with Figures 9B, 10B and 13B, this plurality of interrupted circumferential ridges 42b defines a labyrinthic path 42c for air to circulate from a proximal end 40a to a distal end 40b of the holder 40 and vice-versa, in and out of the chamber 50.

The inner volumes of the distal region of the intermediate tubular part 42, of the frustoconical part 44 and of the distal tubular part 43 define a cavity 47.

The holder 40 is provided on its outer wall with two diametrically opposed pegs 45 having a triangular shape. The holder 40 is further provided on the outer wall of its distal tubular part 43 with an annular groove 46.

With reference to Figures 7A to 7C, the sleeve 70 will now be described in details. The sleeve 70 is made of a tubular wall 71 open at both ends. The tubular wall 71 is provided at its proximal end with an outer radial flange 71a and at its distal end with an outer radial rim 71b. The tubular wall 71 is further provided with two diametrically opposed cams 72, each forming a track for an outer peg 45 of the holder 40 once the adaptor 10 is in use, as shown later below: each cam 72 has the global shape of a W, namely a first and a second longitudinal paths 73 and 74 linked at their respective distal ends by a bending path 75. The bending path 75 is provided with a distal stop 75a and with a proximal stop 75b. The second longitudinal path 74 is further provided with a recess forming a stop 76 in the distal direction.

The use of the adaptor 10 will now be described with reference to Figures 1A-14.

The adaptor 10 is provided to the user in a storage position, with the injection device 100 lodged in the adaptor 10, as shown on Figures 2A-2C.

The adaptor 10 may be packed before use in a blister (not shown) surrounding the adaptor 10 and injection device 100.

The adaptor 10 is then mounted on the collar 3 of the vial 1 (see figures 1A-1C) before being used. Such a before use position, once the adaptor 10 is secured on the collar 3 of the vial 1 is shown on Figures 8A-8B and partially on Figures 9A-9B. For clarity's sake, the injection device 100 is not shown on Figures 9A and 9B, although such an injection device 100 is of course present in the adaptor 10 in its before use position, as shown on Figures 8A and 8B.

The relationships between the various elements forming the adaptor 10 as such being identical for the storage position, shown on Figures 2A-2C, and for the before use position, shown on Figures 8A-8B and 9A-9B, these relationships will therefore be described with reference to Figures 2A-2C, 8A-8B and 9A-9B.

Anyway, beforehand, the mounting of the adaptor 10 onto the collar 3 of the vial 1 will be described with reference to Figures 2C and 8B.

With reference to Figure 2C, the distal face of the extension 22a of the transversal wall 22 in the front region of the adaptor 10 is provided with a cleaning pad 80.

The cleaning pad 80 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, and combinations 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 vial 1.

For securing the adaptor 10 onto the collar 3 of the vial 1, the user approaches the front region of the adaptor 10 towards the collar 3 of vial 1, in order to mount laterally the adaptor 10 onto the collar 3 of the vial 1, via engaging the U-shaped body 25 around the collar 3. During this step, the cleaning pad 80 enters first in contact with an edge of the outer surface 4a of the septum 4. While the user continues to move laterally the adaptor 10, and thus the U-shaped-body 25 towards the collar 3 so as to mount it thereon, the cleaning pad 80 slides on the outer surface 4a of the septum 4, until it loses contact with said septum 4 when the U-shaped-body 25 reaches its position where it is secured on the collar 3, by means of forward projection 25b and arms 26 surrounding the collar 3, as shown on Figure 8B.

During the mounting step of the adaptor 10 on the collar 3 as described above, the sliding of the cleaning pad 80 onto 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 distal face 32a of the distal plug 32 of the pierceable elastomeric piece 30 of the adaptor 10 comes in contact with it, as shown on Figure 8B. For example, the distance between the outer surface 4a and the distal face 32a of the pierceable elastomeric piece 30 ranges from about 1 mm to about 5 mm.

In the embodiment shown, the cleaning of the septum 4 is therefore performed automatically while mounting the adaptor 10 onto the collar 3 of the vial 1.

In embodiments not shown, the cleaning pad 80 may be provided as a side part, separate from the adaptor 10, for example in a blister.

With reference to Figures 2A-2C, 8A-8B and 9A-9B, the relationships of the various parts forming the adaptor 10 will now be described in the storage position of the adaptor 10 of Figures 2A-2C, and in the before use position of the adaptor 10 of Figures 8A-8B and 9A-9B.

The pierceable elastomeric piece 30 lies on the transversal wall 22 by means of its transversal wall 31 bearing on the proximal face of said transversal wall 22 and on the radial channels 27a (see Figure 3E). The distal plug 32 of the pierceable elastomeric piece 30 is lodged in the central hole 23 with no tight contact between the outer wall of the distal plug 32 and the inner wall of the central hole 23. The transversal wall 31 of the pierceable elastomeric piece 30 is attached both to the ring 60 and to the distal end of the foldable sleeve 51. The ring 60 is received in the circular wall 27, with its two outer ears 62 being engaged in the two hooks 27b of the circular wall 27, the plurality of interrupted circumferential ridges 63 of the ring 60 contacting the inner face of the circular wall 27 (see Figure 9B).

The distal end of the barrel 6 of the injection device 100 is received within the proximal and intermediate tubular parts (41, 42) of the holder 40 by friction, proximally with respect to the cavity 47 (see Figure 9B), with the longitudinal ridges 41b and the plurality of interrupted circumferential ridges 42b contacting the outer wall of the distal end of the barrel 6. The needle 5 of the injection device 100 therefore extends distally from the distal end of the barrel 6, and traverses the cavity 47, with the distal region of the needle 5 being received in the chamber 50, as shown on Figures 2B-2C and 8A-8B. The chamber 50 is delimited by the elastic foldable sleeve 51. The elastic foldable sleeve 51 is closed at its distal end by the proximal face of the transversal wall 31 of the pierceable elastomeric piece 30. The inner annular rim 52 of the proximal end of the foldable sleeve 51 is engaged in the annular groove 46 of the holder 40.

In the storage and before use position of the adaptor 10, the injection device 100 is empty and the plunger 7 is located at the distal end of the barrel 6, ready to be moved in the proximal direction in order to fill in the

barrel 6 with the adequate dose of product which will be withdrawn from the vial 1.

In the storage and before use position of the adaptor 10, the foldable sleeve 51 is in its rest position, in which it is not folded, and the chamber 50, as well as the cavity 47 is filled with decontaminated air. The needle 5, and in particular its distal end is therefore stored in a decontaminated atmosphere. As shown below, the volume of the chamber 50 is variable, depending on whether the elastic foldable sleeve 51 is in an unfolded state or in a folded state.

Still in the storage and before use position of the adaptor 10 as shown on Figures 2A-2C, 8A-8B and 9A-9B, the holder 40 is received slidably within the sleeve 70, with its two outer pegs 45 being engaged in the cams 72, each peg 45 being located at the proximal end of the first longitudinal path 73 in this before use position of the adaptor 10 (see Figures 2A and 9A). The sleeve 70 is received within the tubular element 21, with its proximal outer radial flange 71a being in distal abutment onto the inner annular rim 29 of the tubular element 21. In the embodiment shown, the sleeve 70 is welded to the tubular element 21, so that the sleeve 70 is not movable with respect to the tubular element 21. In alternative embodiments, the sleeve 70 may be glued or snap-fitted to the tubular element 21.

Once the adaptor 10 of the invention is secured on the collar 3 of the vial 1, the distal face 32a of the distal plug 32 of the pierceable elastomeric piece 30 is in contact with the outer surface 4a of the septum 4, as shown on Figures 8A and 8B. As already seen, the contact between the distal face 32a and the outer surface 4a of the septum 4 is not tight, so as to allow air to flow therein.

For using the adaptor 10 of the invention and for proceeding to the withdrawal of the dose of the product from the vial 1, the user applies a distal pressure onto the injection device 100 : the holder 40 is moved distally and the needle 5 pierces the pierceable elastomeric piece 30 and then the septum 4, as shown on Figure 10B. During this step, the elastic foldable sleeve 51 has been folded onto itself and the volume of the chamber 50 has been reduced. The air present in the chamber has been allowed to escape via the cavity 47 and then through the labyrinthic path 64. Because the air filling the chamber 50 is decontaminated, the piercing of the pierceable elastomeric piece 30 and of the

septum 4 takes place in desired hygienic conditions without any contamination of the needle 5 and of the product stored in the vial 1.

During the piercing step, the outer pegs 45 have moved distally within the first longitudinal path 73 of the cams 72 and they have reached the first distal stop 75a of bending path 75. The distal movement of the injection device 100 is then automatically stopped, even if the user continues to apply a distal pressure on the injection device 100. The use of the adaptor 10 is therefore safe with no risk of misuse.

The user can then release the distal pressure he applies on the injection device 100. Thanks to the elastic nature of the elastic foldable sleeve 51 which automatically tends to come back to its rest position, the injection device 100 is further slightly moved in the proximal direction, until each peg 45 reaches the proximal stop 75b of the bending path 75, in which it becomes engaged, as shown on Figure 11A. The injection device 100 is therefore secured, at least temporarily, in this position : in particular, the needle 5 is therefore secured in its active position. The user can then safely withdraw the adequate dose of product from the vial 1, by pulling on the piston rod 8 of the injection device 100 in the proximal direction, as shown on Figure 11B, with no risk that the injection device 100 and the needle 5 be also withdrawn in the proximal direction.

When the user has filled the barrel 6 of the injection device 100 with the correct dose of product from the vial 1, he applies again a slight distal pressure onto the injection device 100, so as to disengage each peg 45 from the proximal stop 75b of the bending path 75 of the cam 72, as shown on Figures 12A-12B. the peg 45 thereby reaches the distal end of the second longitudinal path 74.

As a consequence, when the user now releases his distal pressure on the injection device 100, the elastic foldable sleeve 51 is free to come back to its rest position, as shown on Figures 13A and 13B, as the peg 45 is also free to move proximally within the second longitudinal path 74 until it reaches the proximal end of said path, as shown on Figure 13A.

During this step, the volume of the chamber 50 has increased and the chamber 50 has been filled with air coming from the outside : indeed, with reference to Figure 9B for sake of clarity and to Figure 12B, the space created between the outer wall of the distal end of the barrel 6 and the inner wall of the proximal tubular part 41 by the longitudinal ridges 41b forms a first air inlet 90

for allowing passage of air from the outside towards the intermediate tubular part 42 of the holder 40. Once in this intermediate tubular part 42, the air coming from the outside is forced to circulate in the labyrinthic path 42c formed by the plurality of interrupted circumferential ridges 42b contacting the outer wall of the distal end of the barrel 6. This labyrinthic path 42c forms a first filtering system which decontaminates the air coming from the outside. As such, once the air reaches the cavity 47, it is decontaminated and it may then enter the chamber 50 as decontaminated air. The chamber 50 therefore remains filled with decontaminated air, regardless from the fact that air coming from the outside enters said chamber 50.

In addition, during the step of removal of the needle 5 from the vial 1, a vacuum is created in the vial 1 and air is sucked into the vial 1. This air comes from the outside, via the space located between the ring 60 and the circular wall 27. Indeed, with reference to Figure 9B for sake of clarity, to Figure 3E and to Figure 12B, the space created between the outer wall of the ring 60 and the inner wall of the circular wall 27, and between the distal face of the transversal wall 31 of the pierceable elastomeric piece 30 and the proximal face of the transversal wall 22 by the plurality of radial channels 27a forms a second air inlet 91 for allowing passage of air from the outside towards the distal face 32a of the distal plug 32 of the pierceable elastomeric piece 30. Indeed, when the vacuum is created inside the vial 1, the air sucked enters via the proximal end of the ring 60, travels along the labyrinthic path 64 formed by the plurality of interrupted circumferential ridges 63, then circulate into the radial channels 27a towards the central hole 23 of the transversal wall 22, thereby reaching the outer wall of the distal plug 32, along which it travels until it reaches the distal face 32a of the distal plug 32.

This labyrinthic path 64 together with the radial channels 27a form a second filtering system of the adaptor 10, this second filtering system decontaminating the air coming from the outside towards the distal face 32a of the distal plug 32. As such, when this air reaches the space located between the distal face 32a of the distal plug 32 and the outer surface 4a of the septum 4, this air is decontaminated. The air being sucked into the vial 1 through the hole produced by the needle 5, at the time said needle 5 is removed from the septum 4, is therefore decontaminated air. The inside of the vial 1 is therefore prevented from being polluted by the step of withdrawal of the dose of product

and the product is maintained sterile and efficient during the lifetime of the vial 1.

Once the needle 5 has been removed from the vial 1, the user is prevented from reintroducing the needle 5 into the septum 4. Indeed, if the user applies again a distal pressure on the injection device 100, the peg 45 is forced into the distal stop 76 of the second longitudinal path 74, as shown on Figure 14. The adaptor 10 of the invention is therefore safe as it prevents inappropriate handling by the user.

The adaptor 10 of the invention allows proceeding with a step of withdrawal of a dose of product from a multidose vial in good hygienic conditions without polluting the multidose vial.

The adaptor of the invention allows the maintenance of the sterility of the needle before piercing of the septum of the vial, decontamination of air likely to enter the vial, but also the safety of the users as the needle is always enclosed into the adaptor during the use of the adaptor.

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, said adaptor (10) comprising an injection device (100) provided at its distal end with a needle (5) intended to pierce said septum via said outer surface in order to fill in said injection device with product from the medical container, the adaptor (10) further comprising:

- a tubular lodging (20, 21) for receiving at least partly said injection device, said tubular lodging being substantially closed at its distal end by a transversal wall (22) provided with a central hole (23) in which is lodged a pierceable elastomeric piece (30) having at least a distal face (32a) intended to be in contact with the outer surface of the septum when said adaptor is secured on said medical container, the needle of said injection device being aligned with said pierceable elastomeric piece and being movable within said tubular lodging with respect to said pierceable elastomeric piece between an inactive position, in which said needle is entirely located proximally to said pierceable elastomeric piece, and an active position, distally spaced with respect to said inactive position, in which only a part of the needle is located proximally to said pierceable elastomeric piece, the other part of said needle piercing said pierceable elastomeric piece and protruding out of said distal face of said pierceable elastomeric piece,

- said tubular lodging further comprising a chamber (50) filled with decontaminated air and receiving the needle or part of the needle located proximally to said pierceable elastomeric piece, the volume of said chamber being capable of varying from a first volume, when said needle is in its inactive position, to a second volume less than said first volume, when said needle is in its active position,

- an air passage (90, 42c, 47) for allowing air coming in and out from said chamber, said air passage comprising a first filtering system (42c) for decontaminating the air coming from the outside before it reaches said chamber,

- an air inlet (91, 64, 27a, 23) for allowing air from the outside entering the adaptor and reaching the distal face of said pierceable elastomeric piece when said adaptor is secured on said medical container, said air inlet

comprising a second filtering system (64) for decontaminating said entering air before it reaches said distal face of said pierceable elastomeric piece,

- a gripping member (25) connected to said transversal wall, for releasably securing the adaptor to the medical container.

2. The adaptor (10) of claim 1, further comprising elastic return means (51) for urging said needle from its active position to its inactive position.

3. The adaptor (10) of claim 2, further comprising a safety system (70, 71, 72, 73, 74, 75) for temporarily securing said needle in its active position.

4. The adaptor (10) of claim 2 or 3, wherein the elastic return means comprises an elastic foldable sleeve (51) surrounding the needle or part of the needle located proximally to said pierceable elastomeric piece, a proximal end of said elastic foldable sleeve being fixed with respect to a proximal end of the needle, and a distal end of said elastic foldable sleeve being sealingly attached to the proximal face of the pierceable elastomeric piece, said elastic foldable sleeve thereby further delimiting the chamber (50).

5. The adaptor (10) of claim 4, wherein the needle (5) being located at a distal end of a barrel (6) of said injection device (100), said distal end of barrel is fixedly received within a tubular holder (40) with a space (90, 42c, 97) being present between an outer wall of said distal end of said barrel and the inner wall of said tubular holder, the proximal end of said elastic foldable sleeve being sealingly attached to an outer wall of said tubular holder, said space thereby forming said air passage.

6. The adaptor (10) of claim 5, wherein the first filtering system comprises a plurality of interrupted circumferential ridges (42b) provided on the inner wall of said tubular holder, said plurality of interrupted circumferential ridges (42b) defining a labyrinthic path (42c) within said space (90), said labyrinthic path (42c) decontaminating air circulating within said space (90).

7. The adaptor (10) of claims 2, and 5 or 6, wherein the safety system comprises a safety sleeve (70) fixedly received within said tubular lodging, the wall of said safety sleeve being provided with at least a cam (72), said tubular holder being slidingly received within said safety sleeve with at least an outer peg (45) of said tubular holder being engaged in said cam, so that movement of said tubular holder with respect to said safety sleeve is dictated by movement of said peg in said cam.

8. The adaptor (10) of claim 7, wherein said cam comprises at least a stop (75b) for releasably engaging said peg (45) when said needle is in its active position.

9. The adaptor (10) of claim 8, wherein said cam comprises a final stop (76), for preventing said needle from returning to an active position after it has already been once to said active position.

10. The adaptor (10) of any one of claims 1 to 9, wherein the pierceable elastomeric piece being provided with a circular transversal wall (31) bearing on a proximal face of said transversal wall (22) of said tubular lodging, and with a distal plug (32) lodged within said central hole (23), a ring (60) extending from the periphery of said circular transversal wall in the proximal direction, said ring is fixedly received within a circular tubular wall (27) extending from the transversal wall of said tubular lodging, with a space (91, 64, 27b) being present between the outer wall of said ring and the inner wall of said circular tubular wall, and between said proximal face of said transversal wall (22) of said tubular lodging and the distal face of said circular transversal wall of said pierceable elastomeric piece, and between the outer wall of said distal plug and the inner wall of said central hole, said space thereby forming said air inlet (91).

11. The adaptor (10) of claim 10, wherein the second filtering system comprises a plurality of interrupted circumferential ridges (63) provided on the outer wall of said ring (60), said plurality of interrupted circumferential ridges (63) defining a labyrinthic path (64) within said space (91), said labyrinthic path (64) decontaminating air coming from the outside and circulating within said space (91) towards the distal face (32a) of said distal plug (32).

12. The adaptor (10) of any one of claims 1 to 11, wherein the gripping member is a lateral clipping member (25) capable of being laterally mounted on the collar of said medical container.

13. The adaptor (10) of the preceding claim, wherein said lateral clipping member comprises a U-shaped body (25) intended to be engaged on said collar via the open part of the U, the curved part of the U partially surrounding the collar.

14. The adaptor (10) of any one of claims 1 to 13, further comprising a cleaning pad (80), said cleaning pad being configured so as to at least partially slide on said outer surface of said septum during the step in

which the adaptor is being mounted on the medical container to be secured thereon.

15. The adaptor (10) of any one of claims 1 to 14, wherein the pierceable elastomeric piece is self-resealing.

16. The adaptor (10) of any one of claims 1 to 15, wherein the elastomeric piece is made of a material selected from synthetic polyisoprene, natural rubber, silicone rubber, thermo-plastic elastomers and combinations thereof.

17. The adaptor (10) of any one of claims 14 to 16, wherein the cleaning pad comprises a disinfecting agent.

18. 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 17.