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(54) **AN ARRANGEMENT FOR USE WITH A MEDICAL DEVICE**

ANORDNUNG ZUR VERWENDUNG MIT EINEM MEDIZINPRODUKT

MONTAGE DESTINÉ À ÊTRE UTILISÉ AVEC UN DISPOSITIF MÉDICAL

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Description

TECHNICAL FIELD

[0001] The invention relates to a medical device and an arrangement for use with the medical device.

[0002] The invention can be implemented in various medical equipments and be used for a number of purposes, but hereinafter the particular, but not in no way limiting for the invention, fields of application constituting an arrangement used together with a device for aseptic preparation of drugs will be described.

BACKGROUND OF THE INVENTION

[0003] In the field of drug preparation for injection or infusion generally two basic problems have to be considered. Firstly, certain demands are made on aseptic conditions so as to avoid contamination of the drug, and, secondly, the drug has to be handled in such a way that drug leakage to the environment is prevented or minimized. By a sterile or aseptic handling of the drug, the risk for transferring bacteria or any other undesired substance to the patient is reduced. By preventing drug leakage to the environment, the exposure of medical and pharmacological staff to hazardous drugs is decreased.

[0004] In order to achieve aseptic conditions special safety boxes, cabinets or isolators are being used where the air is filtered through HEPA filters to prevent contamination during preparation of drugs. Ventilated cabinets are also used to reduce uncontrolled leakage to the environment and prevent occupational exposure to possibly hazardous drugs. Such facilities, however, require a lot of space and are associated with relatively high costs. Furthermore, the offered protection can be insufficient and working environment problems due to accidental exposure to drugs, for example cytotoxins, have been reported.

[0005] Another solution of the problems mentioned above is to create a so called "closed" or "non-vented" system for handling the drugs during preparation. Such systems exist and enable the preparation to be accomplished without the use of special clean rooms or fume cupboards. In such a closed system the drugs are handled isolated from the environment during every single step so as to avoid contamination of the drug and undesired drug leakage to the environment.

[0006] A known problem associated with the preparation of drug solutions is the fact that medical bottles or vials normally are made of a non-compressible material, such as glass or plastic. To enable the vial to be drained off, air has to flow into the vial so as to avoid negative pressure in the drug vial which negative pressure otherwise counteracts or prevents further transportation of liquid from the vial to another receptacle such as syringe.

[0007] Different systems for providing sterilised or cleaned gas are described for example in WO 00/35517 and WO 02/11794. However, these systems have drawbacks due to the number of manipulations to be accomplished and/or the requisite special equipment for providing the gas.

[0008] Within the field of medical devices very often any kind of needle for penetration is used. For example, hollow needles are used for penetration of a closing (which can be made of rubber for instance) covering an opening of a drug vial. Such injection needles or cannulae can be used for enabling gas or liquid transportation between a drug vial and another receptacle. The expression "piercing member" or "needle" used hereinafter is meant to comprise also spikes and similar components for penetration of such a closing in order to create a channel for the transportation of gas or liquid.

[0009] A medical device comprising such a needle has drawbacks because the person handling the device can due to incautiousness be injured by the needle. Furthermore, the package enclosing the device can be damaged by the needle during transport and storage of the device. To solve this problem such medical devices can be provided with a needle shield covering the tip of the needle, which shield functions as a protection during storage and the initial handling of the device.

[0010] US 5,102,406 is directed to a clean air tube which provides a constantly renewable source of purified air for loading into a medicament syringe prior to use of the syringe for withdrawing liquid medicament from a multi-dose vial. The tube is fitted with a clean-filtering membrane, through which ambient air is filtered upon being drawn into the tube.

[0011] The disclosure also describes the sequence of steps involved in loading the syringe with clean-filtered air.

[0012] WO 02/11794 relates to a method for aseptic preparation with an injection syringe. The syringe comprises a container for injection agent and an immovable connection nozzle connected to the container. The method entails charging the container with air. Air is forced to pass through an air filter arranged on the connection nozzle. This enables the syringe container to be charged with aseptic air in a simple and reliable fashion. The disclosure also concerns devices for performing the method, viz. an injection syringe equipped with an air filter in the connection nozzle, a filter unit connectable to an injection syringe's connection nozzle and a system comprising an injection syringe and a separate filter unit.

[0013] FR 2 850 564 relates to a device and a procedure for the extemporaneous preparation of an individual quantity of sterile treatment fluid that may be compressible, in particular a treatment gas, said device comprising a rigid cartridge with an outlet valve, an administration syringe and a filtration-type connection/sterilisation device. The cartridge simply contains an individual quantity of treatment fluid under pressure, and the cylinder of the syringe is adapted to contain this individual quantity of sterile treatment fluid.

[0014] US 6,073,759 discloses a unit dose, gas-filled syringe that is filled with gas and packaged in a gas barrier

material prior to use to increase shelf-life, that is, to minimize gas leakage and dilution of the contents of the springe. The syringe is filled with a selected gas and sealed inside a container made from a high gas barrier material. The container is also filled with the selected gas. The container material is selected to have a gas transmission rate sufficient to prevent the selected gas from diffusing out of the container into the atmosphere. The volume of gas in the container is greater that atmospheric pressure to prevent atmospheric contaminants from entering the container and springe.

SUMMARY OF THE INVENTION

[0015] An object of the invention is to provide a medical device and an arrangement for use with the medical device, which arrangement can reduce the total number of requisite components and/or provide an additional function to a medical device. In particular, the invention aims to provide such an arrangement suitable for use together with a medical device for providing cleaned gas in a rational and safe way during preparation of drugs.

[0016] According to the invention the object is achieved by a medical device and an arrangement according to claim 1.

[0017] By the provision of an arrangement which comprises a shield for a tip of a needle member of a medical device, wherein the arrangement comprises a filter, preferably a particulate air filter for filtering gas to be transferred out from or into the medical device via the needle member when the arrangement is interconnected with the medical device, and the filter is integrated with or constitutes at least a portion of the needle member tip shield, two important functions are provided in one single component. The needle member tip is protected or shielded and gas can be cleaned by means of the filter. Thus, the invention is based on the insight that by providing a needle member tip shield with a filter two functions can be achieved in one and the same component.

[0018] According to a preferred embodiment of the invention the needle member tip shield is mainly or entirely constituted by the filter. By manufacturing the needle shield from a filter material a single component having two functions can be obtained in a very rational way. Further advantages and advantageous features of the medical device and arrangement according to the invention are disclosed in the following description and remaining dependent claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0019] With reference to the appended drawings, below follows a more detailed description of preferred embodiments of the invention cited as examples.

[0020] In the drawings:

Fig. 1 is a perspective view of a medical device and an arrangement according to the invention,

Fig. 1b is a cross section view illustrating a portion of a filter having a channel for receiving a needle member,

Fig. 2 is a view corresponding to figure 1 illustrating the medical device in another condition,

Fig. 3 is a perspective view of the device according to figure 1 where the arrangement according to the invention has been removed from the medical device,

Fig. 4 is an exploded view corresponding to figure 3,

Fig. 5 is a partly cut view illustrating a variant of the arrangement according to the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

[0021] In figures 1 and 2 a medical device 1' for providing cleaned gas, for example air, to a receptacle and thereby facilitating conveyance of a substance out of the receptacle is illustrated. Such a substance can be various solutions and liquids constituting drugs, for example cytotoxic drugs or antibiotics, for use in the field of medicine. The device comprises a connector 2' and a container 3' which may form an integrated unit 4'. The connector 2' is provided with a first means 5' for connection to a receptacle 6' or in other words a first connector portion 5'. See also figure 3 illustrating the device connected to a medicine bottle or vial 6', and the exploded view in figure 4.

[0022] The first connection means 5' can be designed for connection to a bottle, such as the neck of a vial. In the embodiment illustrated in figures 1-4, the first connection means 5' is constituted by a ring-shaped portion 7' for enclosing the neck 8' of a vial 6'. The ring-shaped portion 7' has slits 9' so as to form flanges 10' which protrude downwardly. The flanges 10' can be provided with hooks 11' or barbs for gripping around the neck 8' of the vial 6'. The connector 2' is suitably provided with a second means 12' for connection to a transfer member 13' (illustrated in figures 3 and 4), such as an injector device to be interconnected with the connector, for conveyance of a substance out of the receptacle 6', or in other words; the connector 2 is suitably provided with a second connector portion 12'.

[0023] In another embodiment the second connection means 12' can comprise a luer lock coupling or bayonet coupling (not shown) to enable an injection device to be connected. Both the injector device and the connector are suitably provided with a membrane so as to create a double membrane coupling between the injector and the current device.

[0024] The connector 2' is preferably provided with a piercing member, such as a hollow needle 14' (as illustrated) for penetration of a closing (not illustrated) made

of rubber for instance, which closing covers the opening of a receptacle 6, such as vial. In addition to injection needles or cannulae, the expression "needle" is meant to comprise spikes and similar components for penetration of such a closing in order to create a channel for transportation of gas. Herein, a channel between the container 3' and the receptacle 6' to which the connector 2' is connected is created. By a channel or passage 15' of the needle 14', gas contained in the container 3' can be transferred from the container to the receptacle 6', i.e. gas can flow from the container 3' to the receptacle 6'.

[0025] The connector 2' and the container 3' may form an integrated unit 4'. This implies that the connector and the container are made in one piece or the connector 2' and the container 3' can be coupled to each other so as to form an integral unit. For such a reason, different types of coupling means 16' known from prior art can be used as long as an airtight, or at least a substantially airtight connection can be obtained between the current components 2', 3'.

[0026] The container 3' has to be filled with gas before connection of the connector 2' to a receptacle 6'. The volume of the container 3' is variable. To obtain a container 3' having a variable volume the container comprises a first portion 17' made by a relatively rigid material which first portion is coupled to the connector 2', and a second portion 18' made by a relatively flexible material attached to the first portion 17'. The second portion 18' can be extensible by manipulation of for example a handle 20' arranged at the end of the container 3'. Hereby the volume of the container 3' can be increased and decreased, respectively. For example, the container 3' can be designed as a bellow which is compressible and extendable by affecting the container manually. The container 3' is preferably provided with said handle 20' for regulating the volume of the container 3'. Although the volume of the container is variable as illustrated, there may be other ways to fill the container and at the same time ensure that the gas passes a filter 21'. For example, the gas container could be constituted by a sealed vacuum-packed flexible bag whose seal can be broken to allow gas to flow into the bag.

[0027] The amount of gas, preferably air, provided by the pre-filled container, should be adapted to the volume of the receptacle which is to be drained off. The volume of the gas when being in the receptacle should preferably correspond to the volume of the receptacle so as to enable the receptacle to be completely drained off. This implies that the volume of the cleaned or sterilized gas in the pre-filled container is preferably approximately equal to or larger than the volume of the receptacle provided that the pressure of the gas is substantially the same in the receptacle as in the container. For most medicine bottles or vials, the volume of the gas should be in the interval 1-100 cm^3 at atmospheric pressure.

[0028] By the expression "cleaned" gas is meant that the gas has been filtered by a filter, such as a particulate air filter to remove particles and/or viable micro-organisms to such an extent that the gas is classified to be aseptic and accepted by the relevant authority and/or any standards. The degree of purity can be expressed in the largest particles allowed to pass the filter for a given flow rate of gas. In some cases no or very few particles having a size exceeding 5μm are allowed to occur in the cleaned gas. However, the allowed particle size is determined by the requirements in the current application. Some drug treatments require that substantially all particles having a size exceeding 0.15μm are removed from the gas by the particulate air filter. As an example, a filter with the mesh size 0.2μm can be used to remove substantially all particles and micro organisms of that size.

[0029] The arrangement 30' and the medical device 1' are interconnected with each other. In the embodiment illustrated in figure 1, the arrangement comprises a shield 22' for covering the tip 23' of a needle member 14' of the medical device 1'. In accordance with the invention a filter 21' is integrated with or constitutes at least a portion of the needle member tip shield 22'. In the illustrated embodiment the filter is arranged to filter the gas to be transferred into the medical device via the needle member 14'. The filter 21' is preferably a particulate air filter, for cleaning gas, such as air to be transferred into the medical device via the needle member 14'. In this example the needle member shield 22' comprises a holder or a frame 24' for accommodating the filter 21', hereinafter called particulate air filter, which frame 24' is connectable to the medical device 1', i.e. to the connector 2'. The main portion of the needle member shield 22' is suitably constituted by the particulate air filter 21' which is arranged for cleaning gas to be transported from the environment into the container 3'. In other words; the particulate air filter 21' is arranged to clean gas which passes the particulate air filter 21' during filling the container 3' with gas (by increasing the volume of the container 3') before connection of the connector 2' to a receptacle 6'. According to the invention the filter is integrated with or constitutes at least a portion of the needle member tip shield. The expressions "integrated with" and "constitutes at least a portion of" are intended to comprise an arrangement where the filter is releasably or permanently connected to the needle member tip shield or is made in one piece with the shield, as well as embodiments where the filter itself constitutes a portion of or the entirely needle member tip shield. Furthermore, in another embodiment of the invention the arrangement could comprise two or more filters.

[0030] The needle member tip shield is adapted to be arranged to at least partially cover or surround the tip of a needle member of a medical device when the arrangement is interconnected with the medical device. This implies that the needle member tip shield covers the tip at least in one direction so as to avoid a user of the arrangement to be injured by the needle due to incautiousness. For example, the shield can be arranged immediately in front of the tip so as to cover the tip in the longitudinal direction of the needle member. The shield can also be

designed as a tube, or as a part or parts of a tube, which surrounds the needle tip. Such a shield rather covers the tip in a direction substantially perpendicular to the longitudinal direction of the needle member but extends beyond the tip in the longitudinal direction of the needle and away from the needle member so as to prevent contact with the needle member tip also in the longitudinal direction.

[0031] The particulate air filter 21' is preferably adapted to be arranged in front of the tip 23' of the needle member 14' and to at least partially cover or surround the tip of the needle member 14' of the medical device when the arrangement is interconnected with the medical device. As already described, the particulate air filter 21' may be arranged in a frame or holder 24' or similar which in turn fits to the connector 2'. Furthermore, alternatively or in combination, the air particulate filter 21' itself can be designed to be engaged with the connector 2' and/or with the needle member 14', or the particulate air filter 21' can be partly penetrated by the needle member 14' so as to keep the particulate air filter 21' in position. Thus, in one embodiment of the invention the particulate air filter 21' is adapted to be arranged to enclose the tip 23' of the needle member 14' of the medical device 1' when the arrangement 30' is interconnected with the medical device 1'.

[0032] Instead of being partly penetrated by the needle 14', the particulate air filter 21' can be provided with a channel 31' (illustrated in Fig. 1b) for receiving the tip 23' of the needle member 14' therein. In both cases, the particulate air filter 21' preferably encloses the tip 23' of the needle member tightly so as to prevent gas transportation into or out from the needle member 14' without passing the particulate air filter 21'.

[0033] In accordance with a preferred embodiment of the invention the particulate air filter 21' is designed and arranged as a protection portion of the needle member shield 22'. This implies that the particulate air filter 21' cleans the gas and at the same time the particulate air filter 21' functions as a protection during handling of the device 1', since the particulate air filter 21' at least partially covers or surround the tip 23' of the needle 14'. Furthermore, the needle member tip shield 22' protects the sterile package enclosing the device during transport and storage of the device.

[0034] The particulate air filter 21' is preferably arranged to abut against the needle member tip 23', or rather in immediate contact with the needle portion having an opening 32' for fluid transportation into or out from the needle member 14'. By covering the opening 32' of the needle 14' by means of the particulate air filter 21', it is ensured that the gas which is brought into the container 3' has to pass the particulate air filter 21'. The arrangement and thus the needle member tip shield 22' is preferably adapted to be removably arranged on a medical device 1'. In the illustrated examples the needle member shield 22' is removed before connection of the medical device 1' to a vial 6' as further described hereinafter. The arrangement 30' according to the invention, and, thus the particulate air filter 21' is arranged to be removed from the integrated unit 4' after the container 3' has been filled with cleaned gas. Subsequently to filling the container 3' the particulate air filter 21' is removed and the connector 2' is to be connected to the receptacle 6'. By removing the particulate air filter 21', after the container 3' has been filled with the gas and prior to interconnection of the connector 2' and the receptacle 6' to each other, any contamination particles removed from the gas and collected in the particulate air filter 21' are removed from the integrated unit 4'. Thus, one and the same channel 15' can be used for both filling the container 3' with cleaned gas and transferring the cleaned gas from the container 3' to a receptacle 6'.

[0035] In Fig. 5 a variant of the arrangement 30' according to the invention is illustrated. The particulate air filter 21' is arranged in a frame 24' to be connected to a medical device and the particulate air filter 21' covers the needle member tip 23'. According to such an embodiment of the invention illustrated in Fig. 5, where the particulate air filter 21' does not enclose the needle member tip 23', but is arranged somewhat spaced apart from the needle member tip 23', the arrangement 30' can preferably be connected to the medical device, for example to the connector 2', so as to obtain a substantially airtight connection between the medical device and the needle member shield 22'. This implies a limited space 35', which space 35' is sealed off relative the environment, being created around the tip 23' of a needle member 14' of the medical device, thereby allowing gas transportation between the space 35' and the environment only via the particulate air filter 21'.

[0036] A cover means, for example a lid (not illustrated) can be arranged for covering the particulate air filter, preferably in an airtight manner. The lid may have the function of preventing transportation of liquid, gas or any vapour in the direction from the medical device to the environment or in the opposite direction, i.e. into the medical device from the environment, so as to counteract that any undesired substance in the receptacle escapes to the environment or is introduced into the medical device, respectively.

[0037] Such a lid can be used to prevent further communication between the interior of the medical device and the environment via the particulate air filter after the container has been filled. The container can be filled with the cleaned gas and thereafter the lid is mounted to cover the particulate air filter and prevent further gas transportation through the air particle filter. Thereafter, the arrangement can be removed from the medical device and the connector and the receptacle can be interconnected, and the subsequent manipulations can be safely executed.

[0038] It is to be understood that the present invention is not limited to the embodiments described above and illustrated in the drawings; rather, the skilled person will recognize that many changes and modifications may be

made within the scope of the appended claims.

Claims

1. "A medical device (1') provided with a needle member (14') and an arrangement (30') for use with a the medical device (1') for providing cleaned gas to a receptacle (6'), the arrangement (30') comprising a shield (22') for a tip (23') of a the needle member (14') of a the medical device (1'), whereby the arrangement (30') comprises a filter (21') for filtering gas to be transferred out from or into the medical device (1') via the needle member (14') when the arrangement (30') is interconnected with the medical device, and in that the filter (21') is integrated with or constitutes at least a portion of the needle member tip shield (22'), whereby the filter (21') is adapted to be arranged to at least partially cover or surround the tip (23') of a needle member of a medical device (1') when the arrangement is interconnected with the medical device (1'), wherein the medical device (1') comprises a connector (2') and a container (3') configured to be filled with gas that is passed through the filter (21') before the medical device (1') is connected to the receptacle (6') wherein the container (3') has a variable volume, **characterized in that** the container (3') comprises a first portion (17') made of a relatively rigid material, which first portion is coupled to the connector (2'), and a second portion (18') made of a relatively flexible material attached to the first portion (17'), thereby rendering the volume of said container variable.

2. A medical device (1') and an arrangement (30') according to claim 1,
characterized in that the filter (21') is adapted to be arranged to cover an opening (32') of a needle member (14') of the medical device (1') when the arrangement is interconnected with the medical device.

3. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the filter (21') is adapted to be arranged to enclose the tip (23') of a needle member (14') of the medical device (1') when the arrangement is interconnected with the medical device.

4. A medical device (1') and an arrangement (30') according to claim 3,
characterized in that the filter (21') is adapted to be partly penetrated by the tip (23') of the needle member (14').

5. A medical device (1') and an arrangement (30') according to claim 3,
characterized in that the filter (21') is provided with a channel (31') for receiving the tip (23') of the needle member (14').

6. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the filter (21') is adapted to be arranged in front of the tip (23') of a needle member (14') of the medical device (1') when the arrangement is interconnected with the medical device.

7. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the needle member tip shield (22') is mainly or entirely constituted by the filter (21').

8. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the arrangement (30') is adapted to be removably arranged on medical device (1').

9. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the arrangement (30') is adapted to be connected to the medical device (1') so as to obtain a substantially airtight connection between the medical device and the arrangement.

10. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the filter (21') is a particulate air filter.

11. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the arrangement (30') comprises a frame (24') for accommodating the filter (21'), which frame is connectable to the medical device (1').

12. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the arrangement (30') is removably arranged on the medical device (1').

13. A medical device (1') and an arrangement (30') according to any preceding claim,
characterized in that the arrangement (30') is arranged on the medical device (1') so as to obtain a substantially airtight connection between the medical device and the arrangement.

14. A medical device and an arrangement (30') according to any preceding claim,
characterized in that the medical device (1') is a device to be used in preparation of drugs.

Patentansprüche

1. Medizinische Vorrichtung (1), die mit einem Nadelteil (14') und einer Anordnung (30') zur Verwendung mit der medizinischen Vorrichtung (1') zur Zuführung von gereinigtem Gas zu einem Aufnahmeteil (6') ausgerüstet ist, wobei die Anordnung (30') eine Abschirmung (22') für eine Spitze (23') des Nadelteils (14') der medizinischen Vorrichtung aufweist, wobei die Anordnung (30') einen Filter (21') zum Filtern des Gases aufweist, das über das Nadelteil (14') aus der medizinischen Vorrichtung (1') oder in die medizinische Vorrichtung zu leiten ist, wenn die Anordnung (30') mit der medizinischen Vorrichtung verbunden ist, und wobei der Filter (21') in mindestens einen Abschnitt der Abschirmung (22') der Spitze des Nadelteils integriert ist oder diesen bildet, wobei der Filter (21') so ausgelegt ist, dass er in der Weise angeordnet ist, dass er zumindest teilweise die Spitze (23') eines Nadelteils einer medizinischen Vorrichtung (1') überdeckt oder diese umgibt, wenn die Anordnung mit der medizinischen Vorrichtung verbunden ist, bei welchem die medizinische Vorrichtung (1') ein Anschlussteil (2') und einen Behälter (3') aufweist, der so ausgebildet ist, dass er mit Gas befüllt wird, das durch den Filter (21') geleitet wird, ehe die medizinische Vorrichtung (1') man dem Aufnahmeteil (6') angeschlossen wird, wobei der Behälter (3') ein veränderliches Volumen besitzt, **dadurch gekennzeichnet, dass** der Behälter (3') einen ersten Abschnitt (17') aufweist, der aus einem vergleichsweise steifen Werkstoff hergestellt ist, wobei der erste Abschnitt an das Anschlussteil 2') angekoppelt wird, sowie einen zweiten Abschnitt (18'), der aus einem vergleichsweise biegsamen Werkstoff hergestellt und an dem ersten Abschnitt (17') angebracht ist, wodurch das Volumen des Behälters veränderlich wird.

2. Medizinische Vorrichtung (1') und eine Anordnung (30') nach Anspruch 1, **dadurch gekennzeichnet, dass** der der Filter (21') so ausgelegt ist, dass er in der Weise angeordnet wird, dass er eine Öffnung (32') eines Nadelteils (14') der medizinischen Vorrichtung (1') überdeckt, wenn die Anordnung mit der medizinischen Vorrichtung verbunden wird.

3. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Filter (21') so ausgelegt ist, dass er in der Weise angeordnet wird, dass er die Spitze (23') eines Nadelteils (14') der medizinischen Vorrichtung (1') umschließt, wenn die Anordnung mit der medizinischen Vorrichtung verbunden wird.

4. Medizinische Vorrichtung (1') und eine Anordnung (30') nach Anspruch 3, **dadurch gekennzeichnet, dass** der Filter (21') so ausgelegt ist, dass er von der Spitze (23') des Nadelteils (14') teilweise durchdrungen wird.

5. Medizinische Vorrichtung (1') und eine Anordnung (30') nach Anspruch 3, **dadurch gekennzeichnet, dass** der Filter (21') mit einem Kanal (31') zur Aufnahme der Spitze (23') des Nadelteils (14') versehen ist.

6. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Filter (21') so ausgelegt ist, dass er vor der Spitze (23') eines Nadelteils (14') der medizinischen Vorrichtung angeordnet ist, wenn die Anordnung mit der medizinischen Vorrichtung verbunden wird.

7. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Abschirmung (22') der Spitze am Nadelteil vorwiegend oder zur Gänze vom Filter (21') gebildet wird.

8. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Anordnung (30') so ausgelegt ist, dass sie entfernbar auf der medizinischen Vorrichtung (1') angeordnet wird.

9. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Anordnung (30') so ausgelegt ist, dass sie mit der medizinischen Vorrichtung in der Weise verbindbar ist, dass eine im Wesentlichen luftdichte Verbindung zwischen der medizinischen Vorrichtung und der Anordnung erreicht wird.

10. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Filter (21') ein Schwebstoff-Luftfilter ist.

11. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Anordnung (30') einen Rahmen (24') zur Unterbringung des Filters (21') aufweist, wobei der Rahmen an die medizinische Vorrichtung anschließbar ist.

12. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Anordnung (30') abnehmbar auf der medizinischen Vorrichtung (1') angeordnet ist.

13. Medizinische Vorrichtung (1') und eine Anordnung

(30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die Anordnung (30') so auf der medizinischen Vorrichtung (1') angeordnet ist, dass eine im Wesentlichen luftdichte Verbindung zwischen der medizinischen Vorrichtung und der Anordnung erreicht wird.

14. Medizinische Vorrichtung (1') und eine Anordnung (30') nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** die medizinische Vorrichtung (1') ein Gerät zur Verbindung bei der Zubereitung oder Vorbereitung von Medikamenten ist.

Revendications

1. Dispositif médical (1') comportant un élément formant aiguille (14') et un agencement (30') destinés à être utilisés avec le dispositif médical (1') de manière à délivrer un gaz purifié à un réceptacle (6'), l'agencement (30') comprenant une protection (22') pour une pointe (23') d'un élément formant aiguille (14') d'un dispositif médical (1'), de telle sorte que l'agencement (30') comprend un filtre (21') destiné à filtrer un gaz à transférer à partir du dispositif médical (1') et dans celui-ci par l'intermédiaire de l'élément formant aiguille (14') lorsque l'agencement (30') est raccordé au dispositif médical, et en ce que le filtre (21') est intégré à la protection de la pointe de l'élément formant aiguille (22') ou constitue au moins une partie de celle-ci, de telle sorte que le filtre (21') est adapté afin d'être agencé de manière à recouvrir ou à entourer au moins partiellement la pointe (23') d'un élément formant aiguille d'un dispositif médical (1') lorsque l'agencement est raccordé au dispositif médical (1'), dans lequel le dispositif médical (1') comprend un raccord (2') et un conteneur (3') configuré de manière à être rempli avec un gaz qui passe à travers le filtre (21') avant que le dispositif médical (1') soit raccordé au réceptacle (6'), dans lequel le conteneur (3') présente un volume variable, **caractérisé en ce que** le conteneur (3') comprend une première partie (17') réalisée en un matériau relativement rigide, laquelle première partie est couplée au raccord (2'), et une seconde partie (18') réalisée en un matériau relativement flexible fixée sur la première partie (17'), de telle sorte que la restitution du volume dudit conteneur est variable.

2. Dispositif médical (1') avec un agencement (30') selon la revendication 1, **caractérisé en ce que** le filtre (21') est adapté afin d'être agencé de manière à recouvrir une ouverture (32') d'un élément formant aiguille (14') du dispositif médical (1') lorsque l'agencement est raccordé au dispositif médical.

3. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le filtre (21') est adapté afin d'être agencé de manière à envelopper la pointe (23') de l'élément formant aiguille (14') du dispositif médical (1') lorsque l'agencement est raccordé au dispositif médical.

4. Dispositif médical (1') avec un agencement (30') selon la revendication 3, **caractérisé en ce que** le filtre (21') est adapté de manière à être pénétré partiellement par la pointe (23') de l'élément formant aiguille (14').

5. Dispositif médical (1') avec un agencement (30') selon la revendication 3, **caractérisé en ce que** le filtre (21') comporte un canal (31') destiné à recevoir la pointe (23') de l'élément formant aiguille (14').

6. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le filtre (21') est adapté afin d'être agencé face à la pointe (23') de l'élément formant aiguille (14') du dispositif médical (1') lorsque l'agencement est raccordé au dispositif médical.

7. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** la protection de la pointe de l'élément formant aiguille (22') est constituée principalement ou totalement par le filtre (21').

8. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'agencement (30') est adapté afin d'être agencé de manière amovible sur le dispositif médical (1').

9. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'agencement (30) est adapté de manière à être raccordé au dispositif médical (1') afin d'obtenir une liaison sensiblement étanche à l'air entre le dispositif médical et l'agencement.

10. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le filtre (21') est un filtre à air particulaire.

11. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'agencement (30') comprend un châssis (24') destiné à recevoir le filtre (21'), lequel châssis peut être raccordé au dispositif médical (1').

12. Dispositif médical (1') avec un agencement (30') se-

lon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'agencement (30') est agencé de manière amovible sur le dispositif médical (1').

13. Dispositif médical (1') avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** l'agencement (30') est agencé sur le dispositif médical (1') de manière à obtenir un raccordement sensiblement étanche entre le dispositif médical et l'agencement.

14. Dispositif médical avec un agencement (30') selon l'une quelconque des revendications précédentes, **caractérisé en ce que** le dispositif médical (1') est un dispositif destiné à être utilisé pour la préparation de médicaments.

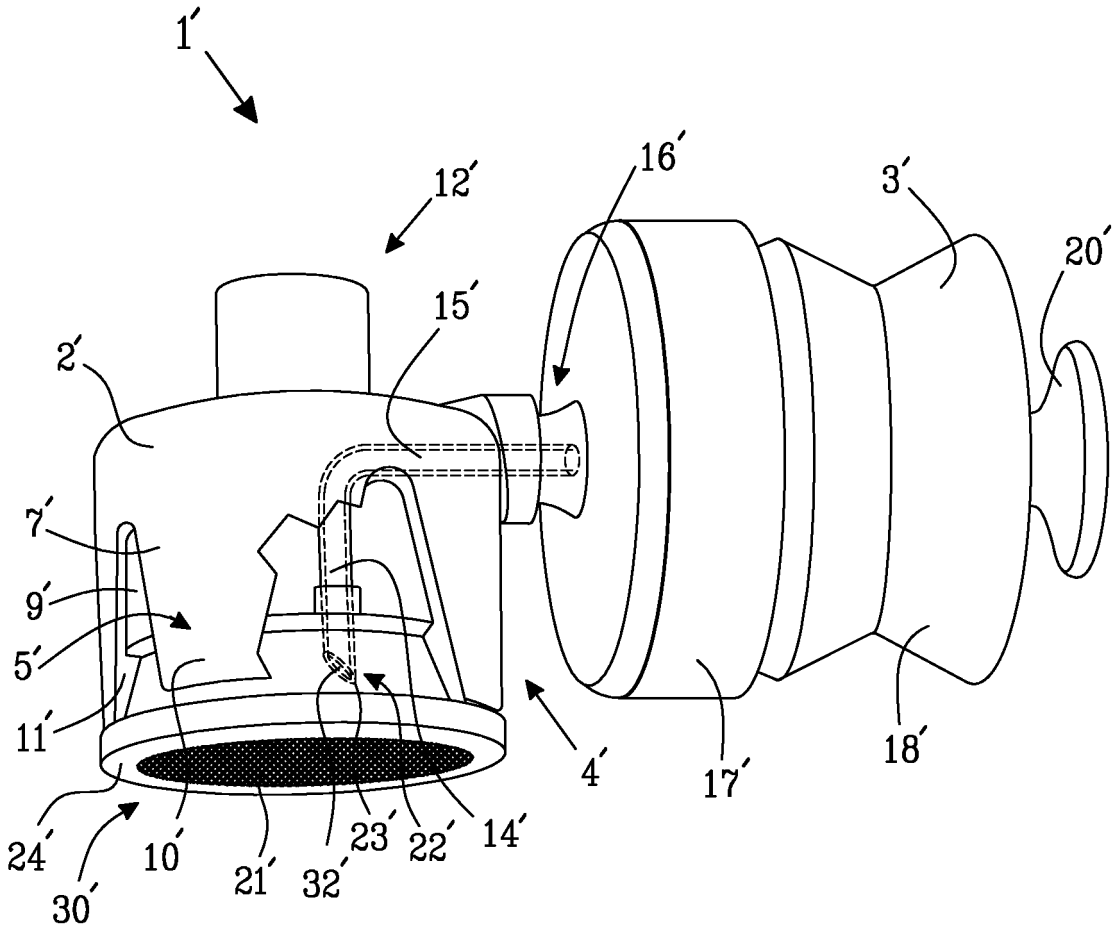

Fig. 1

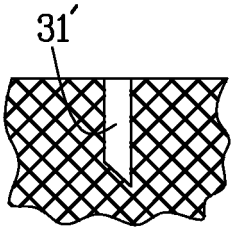

Fig. 1b

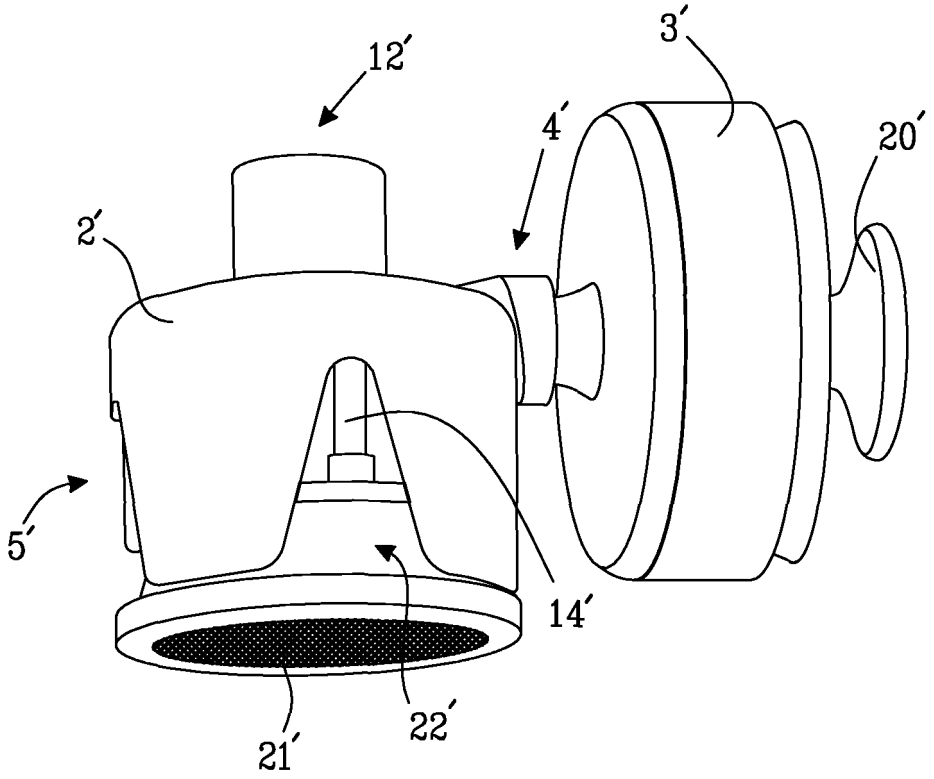

Fig.2

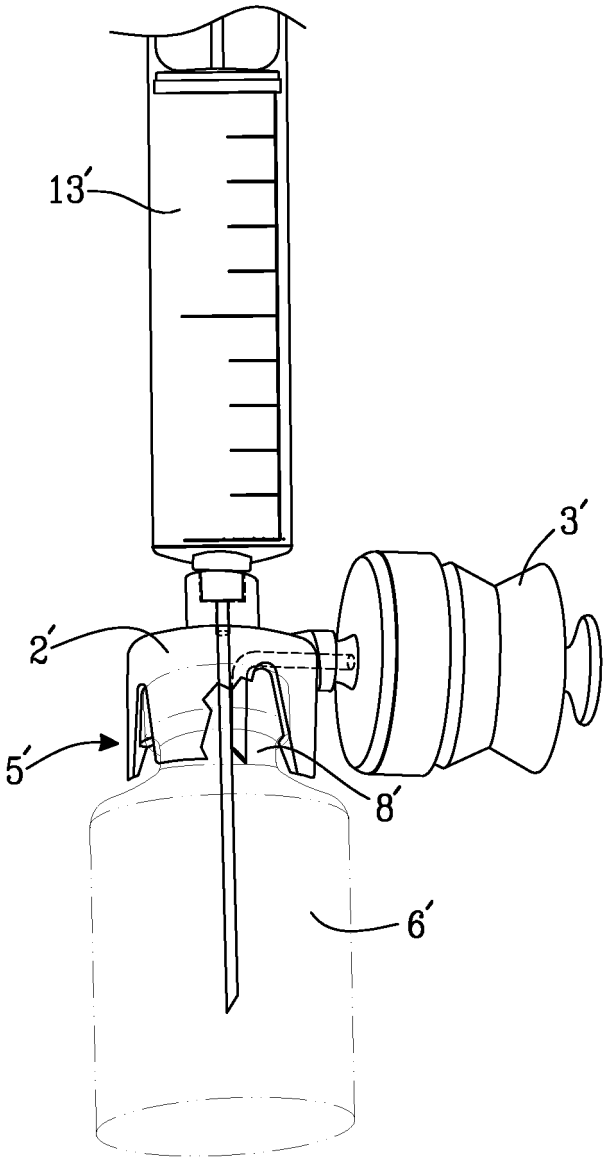

Fig.3

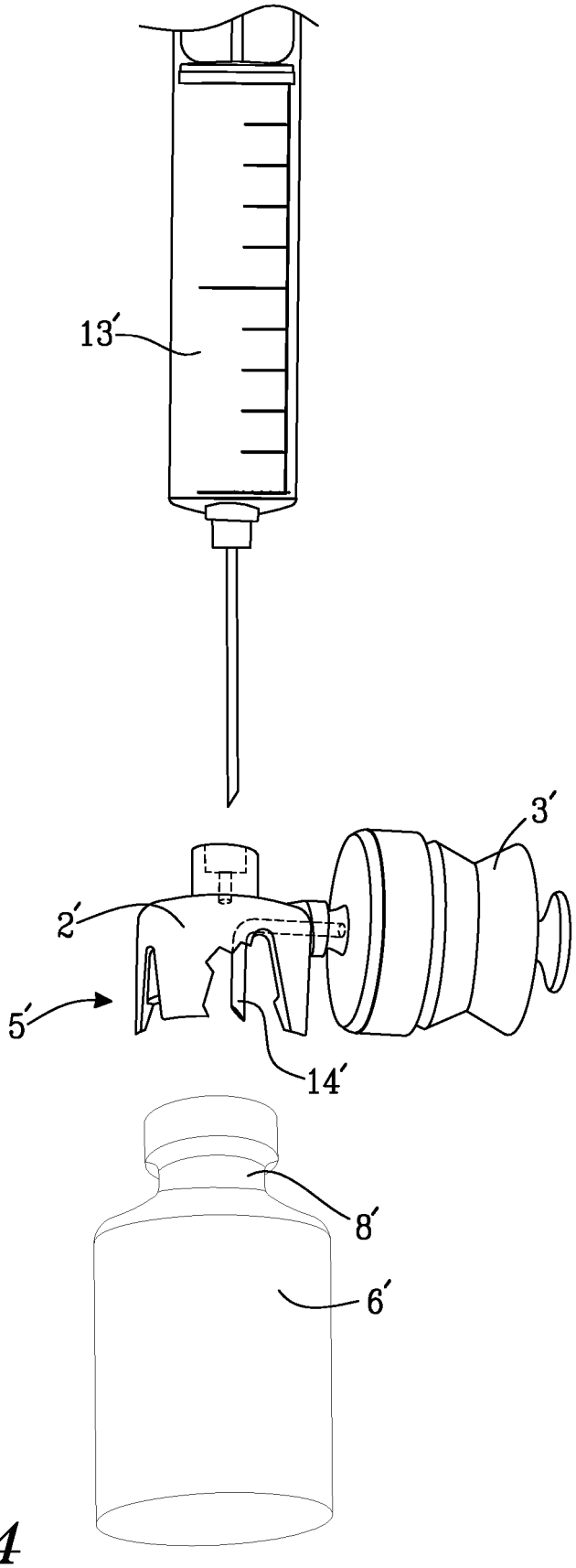

Fig. 4

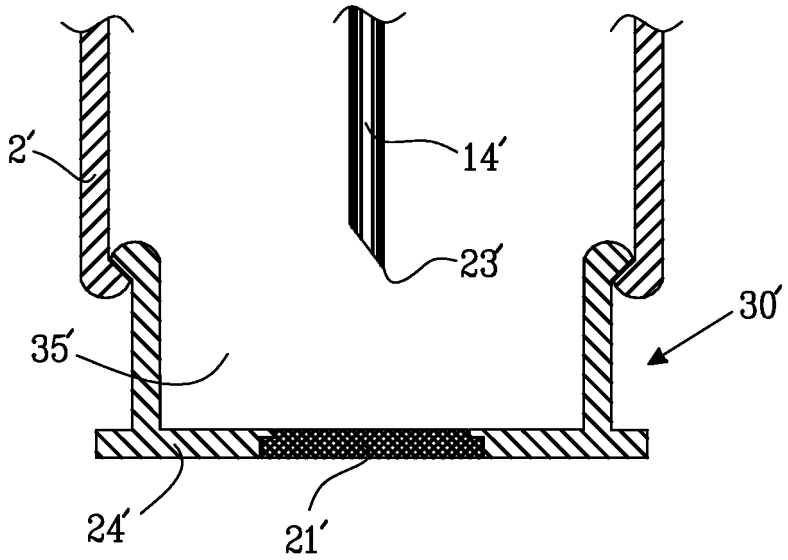

Fig.5

REFERENCES CITED IN THE DESCRIPTION

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