(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 4 534 064 A1**

(12) **EUROPEAN PATENT APPLICATION**

(43) Date of publication:
09.04.2025 Bulletin 2025/15

(21) Application number: **24203621.8**

(22) Date of filing: **30.09.2024**

(51) International Patent Classification (IPC):
A61J 1/10 *(2006.01)*

(52) Cooperative Patent Classification (CPC):
A61J 1/10; A61J 1/1481; A61J 1/2089

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC ME MK MT NL NO PL PT RO RS SE SI SK SM TR
Designated Extension States:
BA
Designated Validation States:
GE KH MA MD TN

(30) Priority: **02.10.2023 IT 202300020301**

(71) Applicant: **Guardant S.r.l.**
00044 Frascati (RM) (IT)

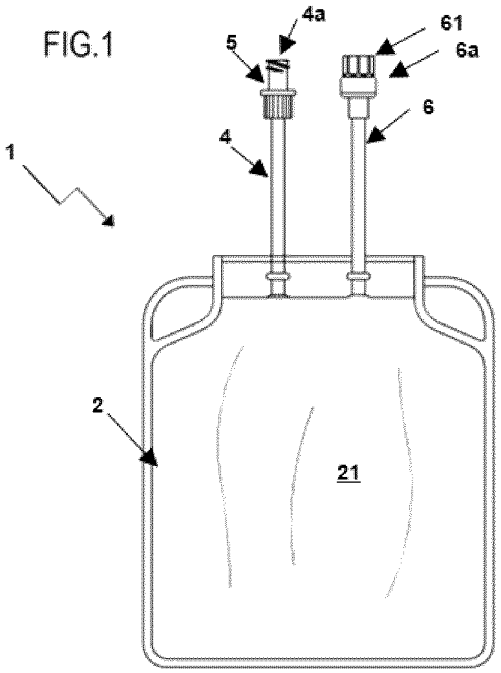
(72) Inventor: **Pelloni, Vittorio**
00046 Grottaferrata RM (IT)

(74) Representative: **Papa, Elisabetta et al**
Società Italiana Brevetti S.p.A
Piazza di Pietra, 39
00186 Roma (IT)

(54) **BAG INCLUDING A PHARMACOLOGICAL FLUID AND RELATED KIT**

(57) The present invention relates to a pharmacological package comprising a container of fluids which receives a solution containing a drug, a medical package comprising a container of fluids which receives a physiological solution, as well as a kit of parts comprising the two packages

FIG.1



EP 4 534 064 A1

Description

Technical field of the invention

[0001] The present invention relates to a pharmacological package comprising a container of fluids which receives a solution containing a drug, a medical package comprising a container of fluids which receives a physiological solution, as well as a kit of parts comprising the two packages.

Background

[0002] In the hospital sector, the preparation and dosage of pharmacological solutions at a wished concentration can be implemented exclusively by operating under a laminar flow flood, by manipulating manually the original solution and by mixing it with physiological solutions. In particular, the preparation and the dosage of alkalinized local anaesthetic solutions requires to mix the original solution with sodium bicarbonate (NaHCOs).

[0003] Such procedures, apart from being impractical due to the weighs of sodium bicarbonate and the calculations required to determine the suitable dilutions, have the disadvantage of exposing the personnel in charge to errors in the preparations, as well as accidental cuts or punctures.

[0004] Moreover, the human intervention in manipulating the solutions increases significantly the risk of microbiological contamination of the used drugs.

[0005] The document US2015/306288A1 describes a system of bags provided with a bag for containing placental blood. The bag comprises a first collection hose at the ends thereof there are sampling needles to take the placental blood, a second hose provided with collection element, and a third tube which, in case, can be provided at one end with a connector of Luer type for the connection with the other bag.

[0006] The document WO2017/140824A1 describes a container apt to preserve inside thereof a pharmaceutical substance, a cell culture and/or microorganisms. The container preferably provides two or three attachments to connection tubes for filling-in or emptying the same.

[0007] The document EP0092528A1 describes a device for the endoperitoneal dialysis comprising a bag with two compartments for containing different substances, or solutions. Two tubular mouths are connected to one chamber, whereas only one tubular mouth is connected to the other chamber.

[0008] The document US2019/038887A1 describes a drainage unit which comprises a bag containing a physiological solution and provided on the lower side with two connectors, wherein one thereof is a connection connector of Luer Lock type which allows the connection with a drip chamber.

[0009] Other solutions of bags or devices for containing pharmacological solutions are known from the documents US6179822B1, EP0495330A1 and US2023/302456A1.

[0010] In such context, then, the need is strongly felt for detecting more effective solutions for the preparation of pharmacological solutions at a predetermined concentration, allowing in particular to obviate the above-mentioned drawbacks.

Summary of the invention

[0011] The technical problem underlying the present invention is then to provide a drug or active principle in adequate pharmaceutical form allowing to obviate the drawbacks just mentioned with reference to the known art.

[0012] Such problem is solved by a pharmacological package according to claim 1, a medical package according to claim 10 and by a kit of parts according to claim 14. Preferred features of the present invention are set forth in the dependent claims.

[0013] The pharmacological package of the invention comprises a container implemented in form of bag containing a solution of a drug of interest, in particular an alkalinized local anaesthetic, advantageously with a connection element carrying at least an opening, distal from said container, to allow the introduction of a diluent fluid in the container or the extraction of the solution containing the drug from the container, and a collection element for the repeated withdrawal of the solution containing the drug by inserting temporarily and/or partially a needle, and by inserting in said solution, containing said drug and present in said containment compartment, an anaesthetic and/or additional drug.

[0014] In other words, the connection element and the collection element are defined by preferably flexible tubular elements. The connection element has an opening at one end, distal from said container. At such end there is preferably a connection connector.

[0015] The collection element at one end, distal from said container, has a self-sealing element apt to allow the repeated withdrawal of said solution by inserting a needle and, through the same, by inserting in said solution an anaesthetic and/or additional drug.

[0016] The presence of a self-sealing element at one end of the preferably flexible collection element is fundamental to

allow an operator to perform in an easy and quick way, and in total safety, the procedures for preparing the pharmacological solution.

[0017] Preferably, the connection element of the pharmacological package carries a connector of male or female *Luer Lock* type at the opening, configured to allow the connection of the container with a system for inserting the diluent fluid or extracting the solution from the container, in particular with a medical package according to the present invention.

[0018] Preferably, the self-sealing element can be associated removably to the end of the collection element.

[0019] According to embodiments, the self-sealing element can comprise, or can consist of, a removable plug provided with one or more elastomeric membranes, in case arranged in sequence.

[0020] The medical package of the invention comprises a container implemented shaped as a bag, which contains a predefined volume of physiological solution suitable for diluting the drug at a specific concentration, wherein said physiological solution is an alkalinized physiological solution, in particular comprising sodium bicarbonate. To this purpose, the container of the medical package carries a connection element having at least an opening, distal from the container, for the extraction of the alkalinized physiological solution from the container or for the insertion, into the above-mentioned container, of the drug solution present in the pharmacological package according to the invention.

[0021] Moreover, the medical package comprises a collection element in tubular shape which extends from the container and puts said internal containment compartment in communication with the outside of the container, which collection element is provided with a self-sealing element, at one end distal from said container, apt to allow the repeated withdrawal of the solution received into said container by temporarily and/or partially inserting a needle and by inserting, in the diluted solution, an anaesthetic and/or additional drug.

[0022] In other words, the connection element and the collection element of the medical package are defined by, preferably flexible, tubular elements.

[0023] Even in this case, the presence of a self-sealing element at one end of the, preferably flexible, collection element is fundamental to allow an operator to perform in an easy and quick way, and in total safety, the procedures for preparing the pharmacological solution.

[0024] Preferably, the connection element of the medical package carries a connector of *Luer Lock* type complementary to the connector of the pharmacological package of the invention and connectable thereto.

[0025] Preferably, the self-sealing element of the medical package can be associated removably to the end of the corresponding collection element.

[0026] According to embodiments, even the self-sealing element of the medical package can comprise, or consist of, a removable plug provided with one or more elastomeric membranes, in case arranged in sequence.

[0027] The present invention provides some relevant advantages. The main advantage consists in that the connection between the connector of the bag containing the drug with the complementary connector of the bag containing the physiological solution allows to pour easily the content of a bag inside the other one. This advantageously allows to modify, in whole microbiological safety, the dosage of the drug of interest directly inside the container of the pharmacological package of the invention as well as by pouring inside the container of the medical package of the invention, without requiring extemporary preparation of the drug solution at the wished concentration by an operator under controlled conditions. By connecting the connectors of the two bags, it is then possible to perform the dilution of the solution of a drug of interest with the physiological solution directly in the hospital department, with simple procedures and capable of reducing to negligible levels the risks of human error and microbiological contamination of the pharmacological solution resulting from the dilution. This is particularly convenient in case of preparation of alkalinized local anaesthetic solutions at predefined concentrations, for which the conventional procedures at hospital level provide to perform weighs of sodium bicarbonate and calculations for determining the suitable dilutions, by exposing the personnel in charge to errors in the preparations.

[0028] The presence of the removable self-sealing element, whether it refers to the pharmacological or to the medical package, has the advantage that it can be replaced in a quick and simple way in case of malfunctions, or losses, by preventing or limiting possible contaminations of the pharmaceutical solution.

[0029] Advantageously, the packages, the invention relates to, can be packed under the shape of a kit, comprising, for example, bags containing different volumes of physiological solution, each one suitable to implement a predefined drug dilution. This allows to reduce the need for stocking or purchasing solutions of the drug of interest at different concentrations, by reducing the costs of disposal of the solutions as well as the consumption of specialized resources required for the extemporary preparation of solutions in the department.

[0030] Thanks to the above-illustrated advantages, the present invention then allows to wide significantly the concentrations for using drugs, especially alkalinized local anaesthetics, in the hospital compartment, by reducing for example the costs for purchasing and storing local anaesthetic solutions at different concentrations which in practice become necessary for the interventions.

[0031] Other advantages, features and use modes of the present invention will result evident from the following detailed description of some embodiments, shown by way of example and not for limitative purpose.

Brief description of figures

[0032] The figures of the enclosed drawings will be referred to, wherein:

- Figure 1 shows a front perspective view of a pharmacological package according to a preferred embodiment of the invention;
- Figure 2 shows a front perspective view of a medical package for the dilution of a drug according to a preferred embodiment of the invention;
- Figure 3 shows a front perspective view of a kit of parts comprising the package of Figure 1 and the package of Figure 2 connected to each other through corresponding complementary *Luer lock* connectors.

[0033] The thicknesses and the curvatures represented in the above-mentioned figures are to be meant as purely exemplifying and they are not necessarily shown in proportion.

Detailed description of preferred embodiments

[0034] Various embodiments and variants of the invention will be described hereinafter and this with reference to the above-mentioned figures.

[0035] Analogous components are designated in the different figures with the same numeral reference.

[0036] In the following detailed description, additional embodiments and variants with respect to embodiments and variants already treated in the same description will be illustrated limitedly to the differences with what already exposed.

[0037] Moreover, the different embodiments and variants described hereinafter are subject to be used in combinations, where compatible.

[0038] By firstly referring to Figure 1, a pharmacological package according to a preferred embodiment of the invention is designated as a whole with 1.

[0039] The pharmacological package 1 comprises a substantially bag-shaped container body 2 made of biocompatible material, which defines an internal containment compartment 21 which receives inside thereof a pharmacological fluid consisting in a solution of a drug.

[0040] According to the invention, the solution includes a local anaesthetic with an alkalinizing agent, in particular sodium bicarbonate (NaHCOs).

[0041] According to the invention, the local anaesthetic can be any amide local anaesthetic known to a person skilled in the art, preferably it can be selected in a group of amide local anaesthetics comprising, but not limited to, mepivacaine, bupivacaine and lidocaine.

[0042] In the present embodiment, the local anaesthetic is mepivacaine hydrochloride and the package 1 includes alkalinized mepivacaine at concentration 2% by weight with respect to the total volume of the solution (w/v). Still in the present example, 1 ml of solution of injectable anaesthetic includes:

- active principle: mepivacaine hydrochloride mg 20, equal to mepivacaine mg 17.4;
- excipients: sodium chloride mg 6, sodium bicarbonate quantum sufficit for correcting pH, water for injection quantum sufficit to 1 ml.

[0043] Other embodiments can have even concentration equal for example to 0.08%, 0.12%, 0.25%, 1%, 1.5% by weight with respect to the total volume of the solution or other and different volumes (10, 20, 60, 100 ml).

[0044] The solution of local anaesthetic with alkalinizing agent is preferably saturated. Generally, the pH value of the saturated solution depends upon viscosity, the surrounding environmental conditions and the material of the container 2. In an embodiment, the pH of the drug solution, in particular the pH of the solution of local anaesthetic with alkalinizing agent, is comprised between 6.5 and 7.5.

[0045] The container 2 can receive 10, 20, 40, 60, 80, 100 ml of solution or other volumes. The container 2 is preferably externally and internally sterile and transparent. The container 2 is preferably made of a bi-coupled material bearing an internal layer, that is in contact with the solution, made of polypropylene and an external layer made of polyvinyl chloride (PVC). In this way, the container 2 has the plastic quality of PVC upon contact and keeps the optimum properties of compatibility with the solution of polypropylene.

[0046] The container 2 has a connection element 4 which extends from the container 2 and puts said internal containment compartment 21 in communication with the outside of the container 2. The connection element 4 of the package 1 is in tubular or channel shape which puts the internal compartment 21 of the container 2 itself in communication

with the outside.

[0047] The connection element 4 in particular carries an opening 4a, distal from the container 2, for inserting a diluent fluid into the container 2 or for the extraction of the solution containing the drug from the container 2.

[0048] To this purpose, the connection element 4 is provided with joining means 5 of *Luer* type at the opening 4a, configured for coupling to means for introducing the diluent fluid in the container 2 and/or for extracting the drug solution from the container 2, in particular with connecting means of a medical package according to any one of the embodiments described in the present description.

[0049] The joining means 5 can comprise or consist of a connector of *Luer* cone-like type or of *Luer-Lock* type.

[0050] Preferably, as shown in Figure 1, the joining means 5 of the connection element 4 is in shape of connector of, male or female, *Luer lock* type configured for coupling with a complementary *Luer Lock* connector. In particular, in the present example a female *Luer lock* connector is provided.

[0051] Still as shown schematically in Figure 1, the container 2 has a collection element 6 in tubular shape which extends from the container 2 and puts said internal containment compartment 21 in communication with the outside of the container 2. The collection element 6 is provided with a pierceable and self-sealing element or septum 61, also denominated as point-needle, at one end 6a of the same element 6 distal from the container 2, apt to allow the repeated withdrawal of the solution of local anaesthetic by temporarily and/or partially inserting a needle or the like. Said point-needle can also be used for inserting, in the solution containing the drug received in the containment compartment, an anaesthetic and/or additional drug.

[0052] Preferably, the self-sealing element 61 can be associated removably to the end 6a of the collection element 6.

[0053] According to embodiments, the self-sealing element 61 can comprises, or consist of, a removable plug provided with one or more elastomeric membranes, in case arranged in sequence.

[0054] With reference to Figure 2, a medical package according to a preferred embodiment of the invention is designated as a whole with 10. The medical package 10 is configured to allow the dilution or dosage of a solution containing a drug contained in the pharmacological package 1 according to any one of the embodiments described in the present description.

[0055] The medical package 10 comprises a substantially bag-shaped container body 20 made of biocompatible material, which defines an internal containment compartment 210 which receives inside thereof a pharmacological fluid consisting in a physiological solution.

[0056] In an aspect of the invention, the physiological solution comprises 0.9% by weight of NaCl with respect to the total volume of the solution (w/v).

[0057] In an additional aspect of the invention, the physiological solution is an alkalinized physiological solution.

[0058] In the present embodiment, the physiological solution is an alkalinized physiological solution comprising 0.9% by weight of NaCl with respect to the total volume of the solution (w/v) and sodium bicarbonate.

[0059] The alkalinized physiological solution is saturated, having a pH comprised in a range of about 6.5-7.5. The container 20 can receive 20, 60, 140, 230, 480, 780 800, 1000 ml of physiological solution or other volumes.

[0060] The container 20 is preferably externally and internally sterile and transparent. The container 20 is preferably made of bi-coupled material carrying an internal layer, that is in contact with the physiological solution, made of polypropylene and an external layer made of polyvinyl chloride (PVC). In this way, the container 20 has the plastic quality of PVC upon contact and it keeps the optimum properties of compatibility with the physiological solution of polypropylene.

[0061] The container 20 of the medical package 10 has a connection element 40 which extends from the container 20 and puts the internal containment compartment 210 in communication with the outside of the container. The connection element 40 of the package 10 is in tubular or channel shape which puts the internal compartment 210 of the container 20 itself in communication with the outside.

[0062] The connection element 40 in particular carries an opening 40a, distal from the container 20, for the extraction of the physiological solution from the container 20 or the insertion or pouring, within the above-mentioned container 20, of the drug solution of a pharmacological package 1 according to any one of the embodiments described in the present description.

[0063] In order to allow the dilution of the drug contained in the pharmacological package 1, preferably by pouring the drug solution from the container 2 of the pharmacological package 1 into the container 20 of the medical package 10 according to the invention, the connection element 40 of the medical package 10 is provided with connection means 50 of *Luer* type at the opening 40a, which is configured for coupling to the joining means 5 of the pharmacological package 1.

[0064] Preferably, as shown in Figure 2, the connection means 50 of the connection element 40 of the medical package is in shape of connector of *Luer lock* type, complementary with respect to the *Luer Lock* connector of the pharmacological package 1 and connectable thereto. In particular, in the present example a male *Luer lock* connector is provided.

[0065] Still as shown schematically in Figure 2, the container 20 of the medical package has a collection element 60 in tubular shape which extends from the container 20 and puts the internal containment compartment 210 in communication with the outside of the container 20. The collection element 60, at one end 60a distal from the container 20, carries a

pierceable and self-sealing element or septum 610, also denominated as point-needle, apt to allow the repeated withdrawal of the solution received into said container 20, by temporarily and/or partially inserting a needle or the like.

[0066] After pouring the drug solution received in the container 2 of a pharmacological package 1 according to the invention within the container 20 of the medical package 10, said self-sealing element 610 can be then used to withdraw the so-diluted drug solution received into the container 20, as well as for inserting, in the diluted solution, an anaesthetic and/or additional drug.

[0067] Preferably, the self-sealing element 610 can be associated removably to the end 60a of the collection element 60.

[0068] According to embodiments, the self-sealing element 610 can comprise, or consist of, a removable plug provided with one or more elastomeric membranes, in case arranged in sequence.

[0069] With reference to Figure 3, a kit of parts according to a preferred embodiment of the invention is designated as a whole with 100.

[0070] The kit of parts 100 comprises at least a pharmacological package 1 and a medical package 10 according to any one of the embodiments described in the present description. Such kit is configured to allow the dosage or dilution of the drug solution received in the pharmacological package 1 at a wished concentration.

[0071] In fact, as previously described, the joining means 5 of the pharmacological package 1 according to the invention is complementary to the connection means 50 of the medical package 10 and connectable thereto, by allowing to pour the drug solution from the container 2 of the pharmacological package 1 into the container 20 of the medical package 10 or vice versa.

[0072] According to an aspect, the kit of parts 100 comprises at least a pharmacological package 1 according to any one of the variants defined in the present description and claims, and a plurality of medical packages 10 according to any one of the variants defined in the present description and claims, wherein each one of the above-mentioned medical packages 10 includes a different volume of physiological solution within the corresponding container 20. The container 2 of the pharmacological package 1 containing the drug can be connected - through the connection element - to one to be selected from the containers carrying a predefined volume of physiological solution, so as to allow - by pouring the drug solution into the container 20 or vice versa - the preparation of a final solution of the drug having the wished concentration.

[0073] Preferably, the kit of parts 100 comprises at least a pharmacological package 1 carrying within the container 2 a solution of alkalinized local anaesthetic according to any one of the variants defined in the present description and claims. In such embodiment, the kit 100 further comprises at least a medical package 10 containing an alkalinized physiological solution, preferably it comprises a plurality of medical packages 10, wherein each one of the above-mentioned medical packages 10 includes a different volume of alkalinized physiological solution within the corresponding container 20.

[0074] In a particularly preferred embodiment according to the invention, the kit of parts 100 comprises a pharmacological package 1 carrying within the container 2 a volume equal to 20 mL of solution of 2% (w/v) alkalinized local anaesthetic. In such embodiment, the kit 100 further comprises a plurality of medical packages 10, wherein each one of the above-mentioned medical packages 10 includes a different volume of alkalinized physiological solution within the corresponding container 20.

[0075] The container 2 of the pharmacological package 1 containing the 2% w/v alkalinized local anaesthetic can be connected - through the connection element - to one to be selected from the containers carrying a predefined volume of alkalinized physiological solution, so as to allow - by pouring the anaesthetic solution into the container 20 or vice versa - the preparation of a final solution of local anaesthetic having the wished concentration.

[0076] By pure way of example, the container 2 of the pharmacological package 1 containing 20 ml of 2% (w/v) alkalinized local anaesthetic can be connected with the above-described modes to a corresponding container of the medical package 10 carrying a predefined volume of alkalinized physiological solution, by guaranteeing the concentrations of local anaesthetic as shown in the table below:

Volume of the bag of alkalinized physiological solution	Concentration of alkalinized local anaesthetic at the end of pouring (w/v)	Final volume of alkalinized local anaesthetic at the end of pouring
20ml	1%	40ml
60ml	0.5%	80ml
140ml	0.25%	160ml
230ml	0.16%	250ml
480ml	0.08%	500ml
780ml	0.05%	800ml

[0077] As it can be understood from what illustrated above, starting from a solution of 2% (w/v) local anaesthetic through

the above-described pouring procedure it is possible to produce solutions having 1%, 0.50%, 0.25%, 0.16%, 0.08%, 0.05% (w/v) anaesthetic directly in the hospital department without requiring to involve hospital pharmacy equipment. In other terms, said different anaesthetic concentrations can be prepared starting from one single bag containing a solution of 2% w/v local anaesthetic.

[0078] Moreover, through the point-needle of the package it is possible to insert in the the so-obtained final solution of local anaesthetic an additional amide local anaesthetic or other drug of interest.

[0079] It will be better appreciated at this point that the invention allows to widen significantly the use concentrations of the local anaesthetic alkalinized by simple procedures, which can be performed in the department, and capable of reducing to negligible levels the risks for safety, quality and sterility.

[0080] The present invention has been sofar described with reference to preferred embodiments. It is to be meant that other embodiments belonging to the same inventive core may exist, as defined by the protective scope of the herebelow reported claims.

Claims

1. A pharmacological package (1) comprising:

- a substantially bag-shaped container (2) which defines an internal containment compartment (21) apt to receive a pharmacological fluid;
- a solution containing a drug received in said containment compartment (21), wherein said drug is an alkalinized local anaesthetic;
- a connection element (4) in tubular shape which extends from the container (2) and puts said internal containment compartment (21) in communication with the outside of the container (2), which connection element (4) carries an opening (4a), distal from said container (2), to allow the introduction of a diluent fluid into said container (2) or the extraction of said solution from the container (2), and wherein said connection element (4) is provided with joining means (5) of *Luer* type at said opening (4a) configured for coupling to means for introducing the diluent fluid into the container (2) or for extracting the solution from the container (2); and
- a collection element (6) in tubular shape which extends from the container (2) and puts said internal containment compartment (21) in communication with the outside of the container (2), which collection element (6) is provided with a self-sealing element (61), at one end (6a) distal from said container (2), apt to allow the repeated withdrawal of said solution by inserting a needle and by inserting in said solution, containing said drug and present in said containment compartment (21), an anaesthetic and/or additional drug.

2. The pharmacological package (1) according to claim 1, wherein said *Luer*-type joining means (5) comprises or consists of a *Luer Lock* connector.

3. The pharmacological package (1) according to claim 1 or 2, wherein said local anaesthetic is an amide local anaesthetic, in particular is an amide local anaesthetic selected from mepivacaine, bupivacaine and lidocaine.

4. The pharmacological package (1) according to any one of the preceding claims, wherein said solution has a pH within a range of 6.5-7.5.

5. The pharmacological package (1) according to any one of the preceding claims, wherein said container (2) is transparent.

6. The pharmacological package (1) according to any one of the preceding claims, wherein said container (2) is made of a bi-coupled material.

7. The pharmacological package (1) according to any one of the preceding claims, wherein said container (2) has an internal layer, in contact with said solution, made of polypropylene.

8. The pharmacological package (1) according to claim 6 or 7, wherein said container has an external layer made of PVC.

9. The pharmacological package (1) according to any one of the preceding claims, wherein said container (2) is sterile.

10. A medical package (10) for the dilution of a drug comprising:

- a substantially bag-shaped container (20) which defines an internal containment compartment (210) and is apt to receive a pharmacological fluid;
- a physiological solution received in said containment compartment (210), wherein said physiological solution is an alkalinized physiological solution, in particular comprising sodium bicarbonate;
- a connection element (40) in tubular shape which extends from the container (20) and puts said internal containment compartment (210) in communication with the outside of the container (20), which connection element (40) carries an opening (40a), distal from said container (20), to allow the introduction into said container (20) of a solution containing a drug as defined in any one of claims 1 to 4 or the extraction of the physiological solution from the container (20), and wherein said connection element (40) is provided with connection means (50) of *Luer* type at said opening (40a) configured for coupling to joining means of a pharmacological package as defined in any one of claims 1 to 9; and
- a collection element (60) in tubular shape which extends from the container (20) and puts said internal containment compartment (210) in communication with the outside of the container (20), which collection element (60) is provided with a self-sealing element (610), at one end (60a) distal from said container (20), apt to allow the repeated withdrawal of the solution received into said container (20) by inserting a needle and the insertion, in the diluted solution, of an anaesthetic and/or additional drug.

11. The medical package (10) according to claim 10, wherein said connection means (50) of Luer type comprises or consists of a *Luer Lock* connector.

12. The medical package (10) according to claim 10 or 11, wherein said alkalinized physiological solution has a pH within a range of about 6.5-7.5.

13. The medical package (10) according to any one of claims 10 to 12, wherein said container (20) is sterile.

14. A kit of parts (100) for dosing a drug, in particular an alkalinized local anaesthetic, comprising at least a pharmacological package (1) as defined in any one of claims 1 to 9, and at least a medical package (10) as defined in any one of claims 10 to 13, wherein the joining means (5) of said at least a pharmacological package (1) is complementary to the connection means (50) of said at least a medical package (10) and connectable thereto.

15. The kit of parts (100) according to claim 16, wherein said joining means (5) of at least a pharmacological package (1) comprises or consists of a female *Luer Lock* connector and said connection means (50) of at least a medical package (10) comprises or consists of a *Luer Lock* male connector or vice versa.

FIG.1

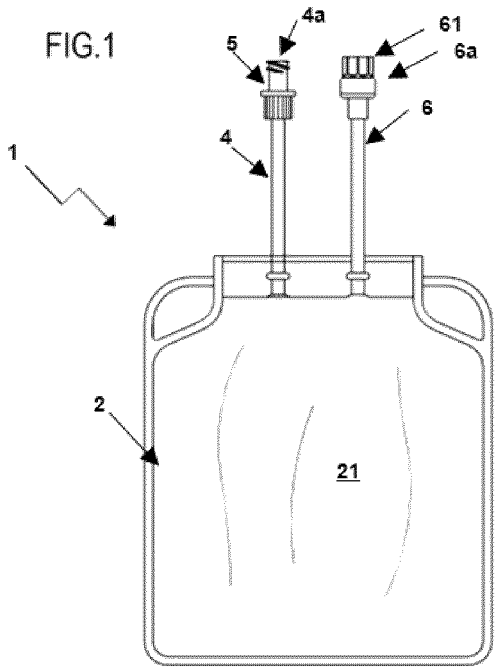


FIG.2

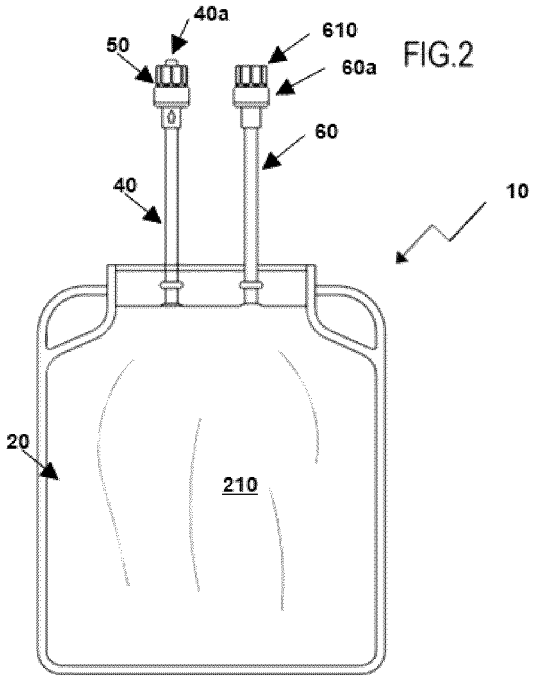
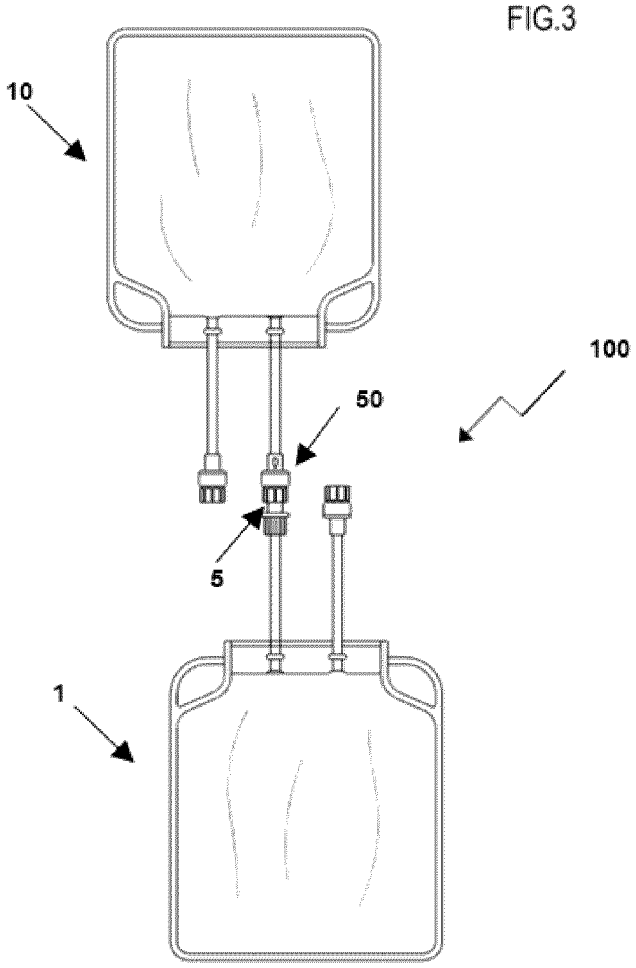


FIG.3



Europäisches Patentamt
European Patent Office
Office européen des brevets

EUROPEAN SEARCH REPORT

Application Number
EP 24 20 3621

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	US 2015/306288 A1 (DELORME BRUNO [FR] ET AL) 29 October 2015 (2015-10-29) * paragraphs [0135], [0057]; figures 1-3 *	1-15	INV. A61J1/10
X	WO 2017/140824 A1 (SANDOZ AG [CH]) 24 August 2017 (2017-08-24) * figure 1 *	1-15	
X	EP 0 092 528 A1 (SIS TER SPA [IT]) 26 October 1983 (1983-10-26)	1-5,9-15	
A	* figure 1 *	6-8	
X	US 2019/038887 A1 (LEE HYUN WOO [KR]) 7 February 2019 (2019-02-07)	1-5,9	
A	* figure 2 *	6,7	
X	US 6 179 822 B1 (NIEDOSPIAL JR JOHN J [US]) 30 January 2001 (2001-01-30) * figure 8 *	1,10	
X	EP 0 495 330 A1 (INST DE BIOLOG Y SUEROTERAPIA [ES]) 22 July 1992 (1992-07-22) * figure 6 *	1,10	TECHNICAL FIELDS SEARCHED (IPC) A61J
X	US 2023/302456 A1 (PAGLIARO JR ANTHONY P [US] ET AL) 28 September 2023 (2023-09-28) * figure 4e *	1,10	
T	US 2023/270102 A1 (JOHNSON MATTHEW A [US] ET AL) 31 August 2023 (2023-08-31)	1,3,10	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
The Hague	3 February 2025	Kroeders, Marleen

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 24 20 3621

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

03-02-2025

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2015306288 A1	29-10-2015	AU 2013328472 A1	07-05-2015
		CA 2887583 A1	17-04-2014
		EP 2906035 A1	19-08-2015
		FR 2996413 A1	11-04-2014
		US 2015306288 A1	29-10-2015
		WO 2014057220 A1	17-04-2014
WO 2017140824 A1	24-08-2017	NONE	
EP 0092528 A1	26-10-1983	DK 165783 A	17-10-1983
		EP 0092528 A1	26-10-1983
		ES 281023 U	01-09-1985
		IT 1151884 B	24-12-1986
		JP S58188457 A	02-11-1983
		NO 150744 B	03-09-1984
US 2019038887 A1	07-02-2019	CN 108601933 A	28-09-2018
		KR 20180037875 A	13-04-2018
		US 2019038887 A1	07-02-2019
US 6179822 B1	30-01-2001	NONE	
EP 0495330 A1	22-07-1992	EP 0495330 A1	22-07-1992
		ES 1016714 U	01-12-1991
		FI 912922 A	18-07-1992
US 2023302456 A1	28-09-2023	CN 118946338 A	12-11-2024
		EP 4499019 A2	05-02-2025
		US 2023302456 A1	28-09-2023
		WO 2023183265 A2	28-09-2023
US 2023270102 A1	31-08-2023	US 2023270102 A1	31-08-2023
		WO 2022020512 A1	27-01-2022

EPO FORM P0459

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

REFERENCES CITED IN THE DESCRIPTION

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 2015306288 A1 **[0005]**
- WO 2017140824 A1 **[0006]**
- EP 0092528 A1 **[0007]**
- US 2019038887 A1 **[0008]**
- US 6179822 B1 **[0009]**
- EP 0495330 A1 **[0009]**
- US 2023302456 A1 **[0009]**