



US 20130037509A1

(19) **United States**(12) **Patent Application Publication**
Rahimy et al.(10) **Pub. No.: US 2013/0037509 A1**(43) **Pub. Date: Feb. 14, 2013**(54) **CLOSURE CAP FOR A RECEPTACLE FOR
RECEIVING MEDICAL LIQUIDS, AND
RECEPTACLE**(30) **Foreign Application Priority Data**

Feb. 16, 2010 (EP) 10153721.5

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(DE)(51) **Int. Cl.**
B65D 47/36 (2006.01)
B65D 41/32 (2006.01)
B65D 47/00 (2006.01)(73) Assignee: **Fresenius Kabi Deutschland GmbH**,
Bad Homburg (DE)(52) **U.S. Cl.** **215/247**; 215/316; 215/250(21) Appl. No.: **13/577,016**(22) PCT Filed: **Feb. 15, 2011**(86) PCT No.: **PCT/EP11/52190**

§ 371 (c)(1),

(2), (4) Date: **Sep. 17, 2012****ABSTRACT**

The invention relates to a closure cap for a receptacle for receiving medical liquids and to a receptacle for medical liquids which has such a closure cap.

The closure cap (1) according to the invention comprises a first connector (2) for the needle-free injection of a medical liquid and a second connector (3) for the needle-free withdrawal of a medical liquid, wherein the first connector (2) has an outwardly directed first connector part (4) with a conical recess (8) for sealingly receiving a cone stem (26) of a first device (28, 29) to be connected, and the second connector (3) has an outwardly directed second connector part (5) with a conical recess (9) for sealingly receiving a cone stem of a second device to be connected.

Related U.S. Application Data

(60) Provisional application No. 61/304,831, filed on Feb. 16, 2010.

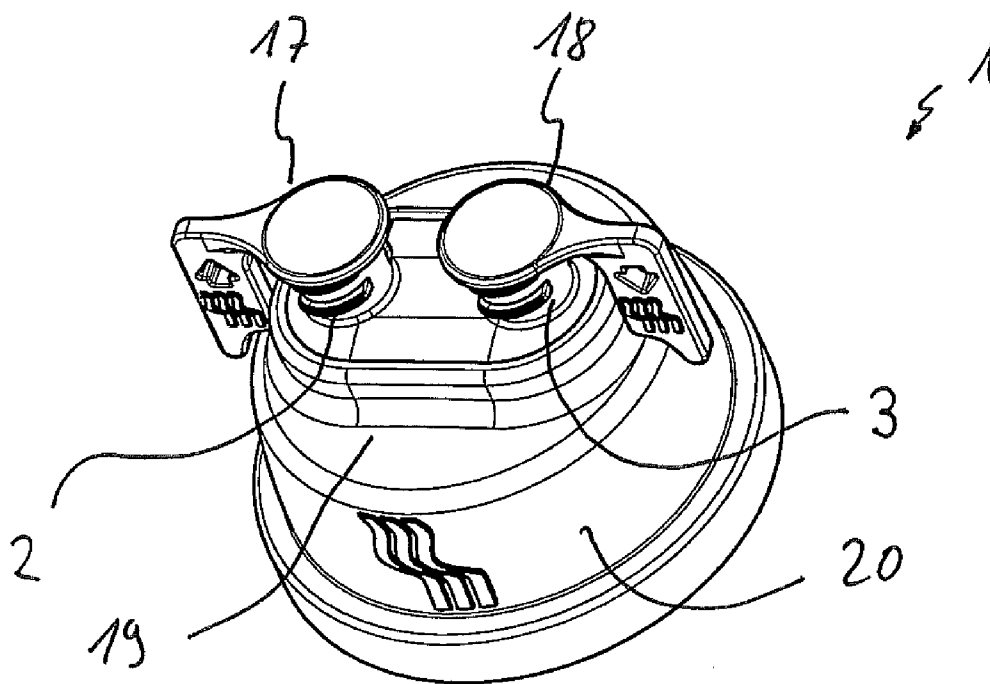


Fig. 1

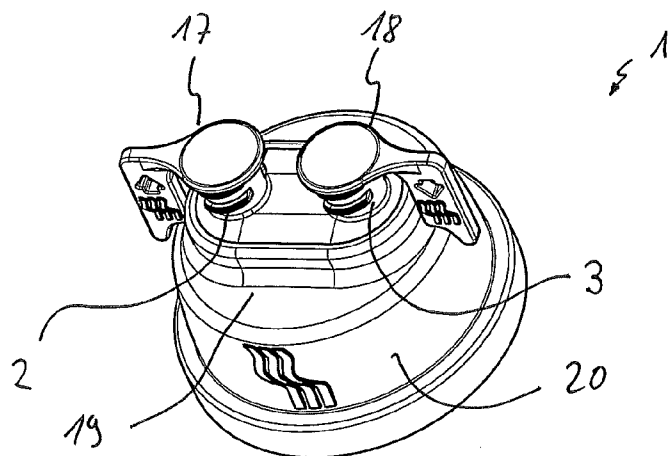


Fig. 2

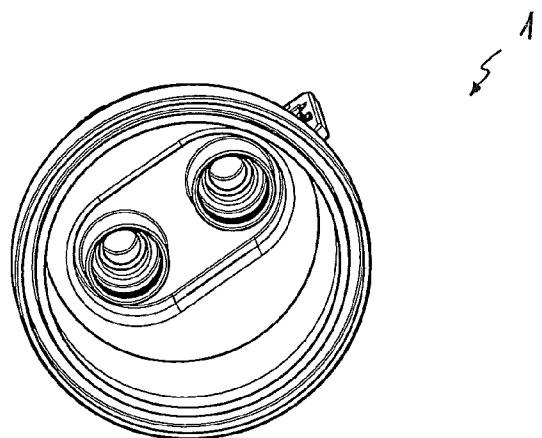


Fig. 3

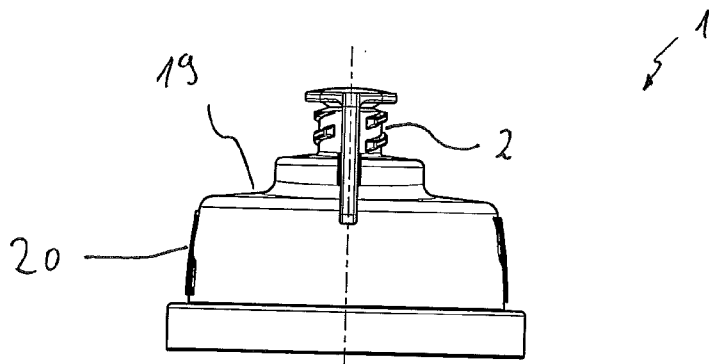


Fig. 4

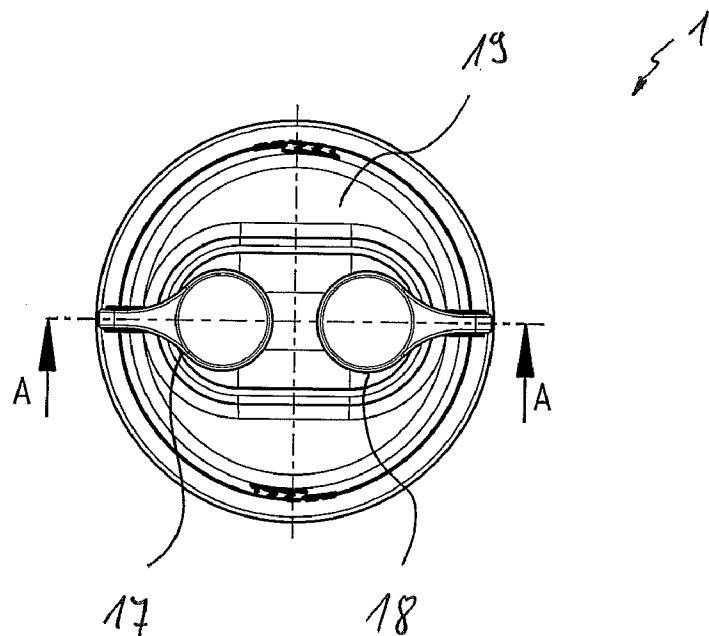


Fig. 5

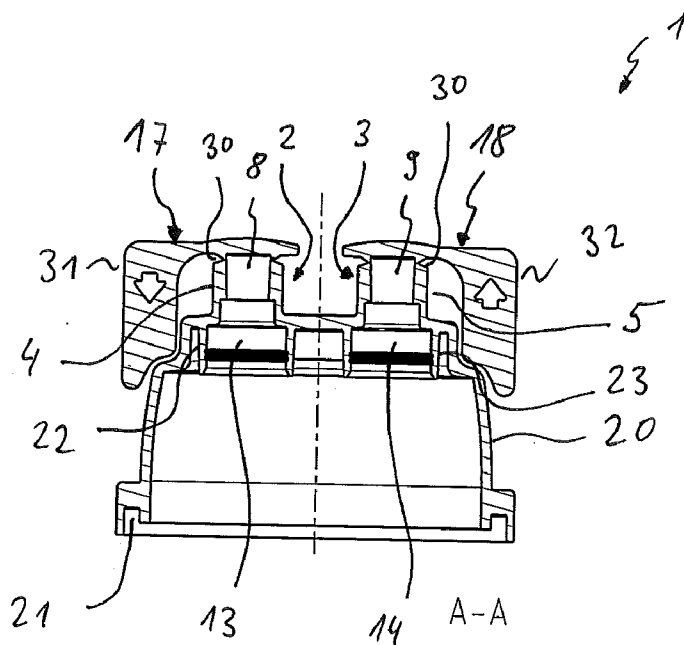


Fig. 6

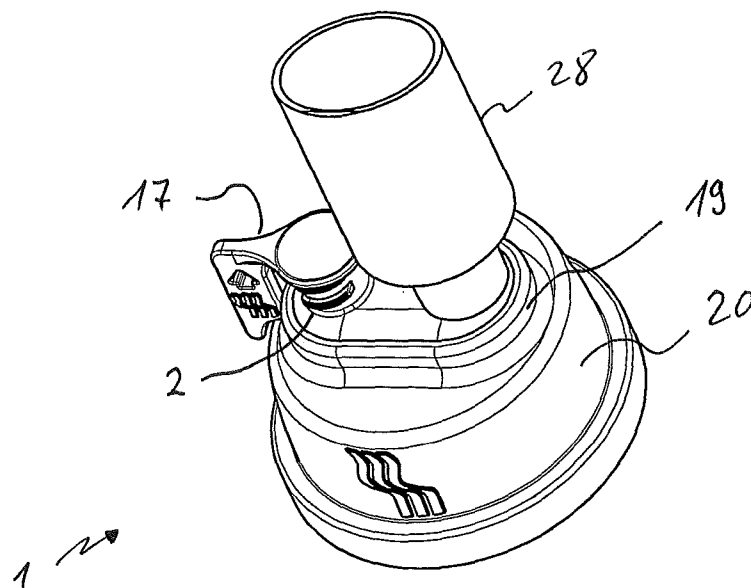


Fig. 7

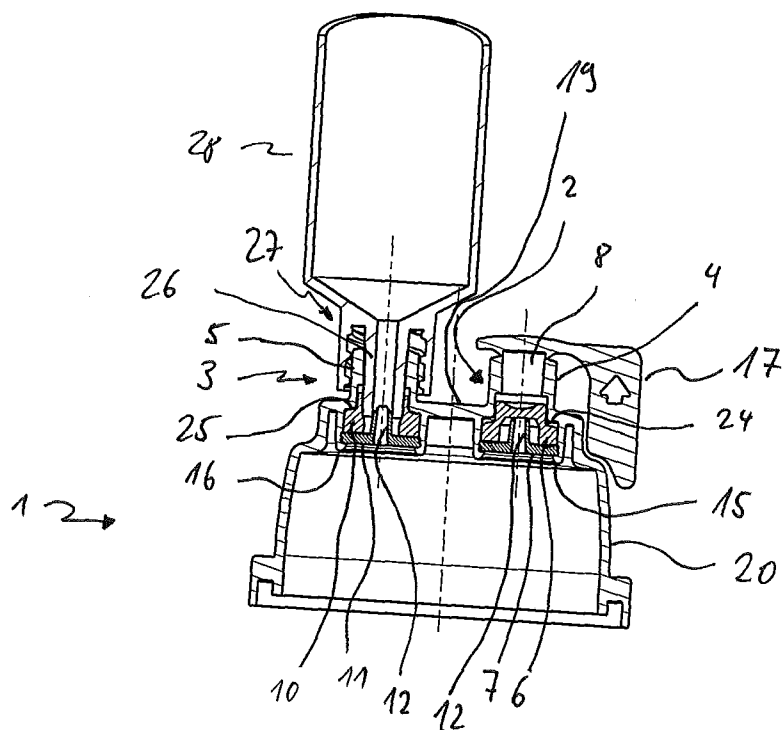


Fig. 8

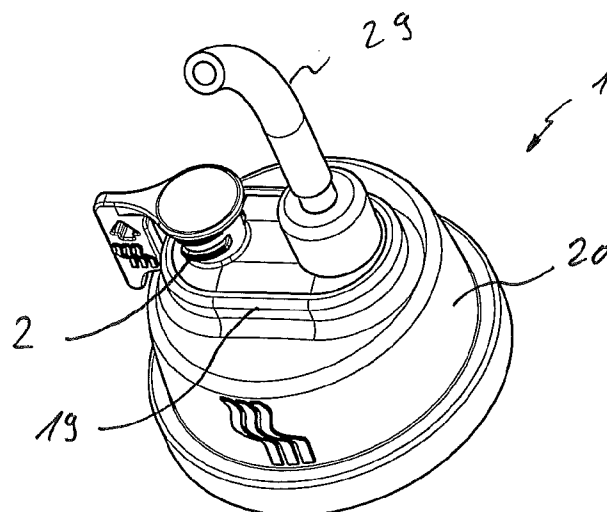
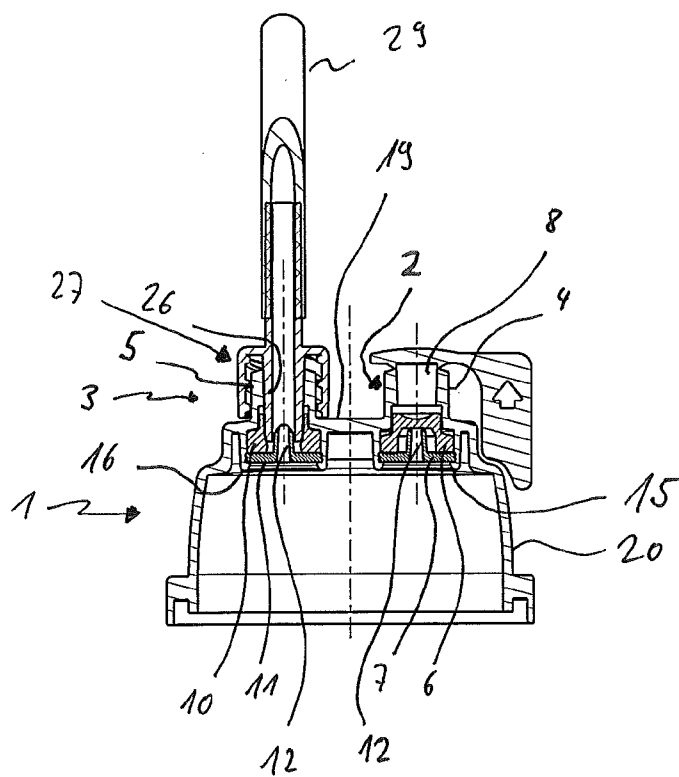


Fig. 9



CLOSURE CAP FOR A RECEPTACLE FOR RECEIVING MEDICAL LIQUIDS, AND RECEPTACLE

TECHNICAL FIELD

[0001] The invention relates to a closure cap for a receptacle for receiving medical liquids, in particular for receiving liquids which are used in the field of infusion, transfusion, clinical nutrition or dialysis. Furthermore, the invention relates to a receptacle for medical liquids which has such a closure cap.

PRIOR ART

[0002] DE 10 2007 005 407 A1 discloses a closure cap for a receptacle for receiving medical liquids. The closure cap has a cover part and an edge part and a first connector and second connector arranged in the cover part. The first connector is designed as an injection part. It comprises an outwardly directed connector part with a conical recess for sealingly receiving the cone stem of a needleless injection syringe and an inwardly directed closure part which has a self-sealing membrane for closing the recess of the connector part. The second connector is designed as a withdrawal part and comprises an outwardly directed connector part with a cylindrical recess and an inwardly directed closure part which has a self-sealing membrane for closing the recess of the connector part. The closure cap makes it possible via the first connector to inject a liquid without having to use an injection needle, while the second connector can be used to withdraw liquid via an infusion spike from the receptacle connected to the closure cap.

BRIEF DESCRIPTION OF THE INVENTION

[0003] The closure cap according to the invention comprises a first connector for injecting a medical liquid into a receptacle connected to the closure cap, in particular into an infusion receptacle, and a second connector for withdrawing a medical liquid from a receptacle connected to the closure cap, in particular from an infusion receptacle, wherein the first connector has an outwardly directed first connector part with a conical recess for sealingly receiving a cone stem of a first device to be connected, and the second connector has an outwardly directed second connector part with a conical recess for sealingly receiving a cone stem of a second device to be connected. This makes it possible to form a closure cap with at least two connectors which can each be sealingly connected to a needleless or infusion spike-less device. Since devices without a needle or infusion spike can be connected to both connectors, there is a considerable reduction in the risk of injury of the user or of damage to the receptacle which is connected to the closure cap. Moreover, the tightness of such a connection is ensured. If the first and/or second connector part is designed with a lock, which is preferred according to the invention, it is furthermore possible to prevent a situation in which, for example, jerky movements of the patient or tensile loading cause the connection to be inadvertently released, with the result that the patient and/or the care personnel could be contaminated with highly toxic medicaments, and expensive medicaments such as antibiotics or cytostatics would possibly have to be discarded.

[0004] In principle, the closure cap can be used for any desired receptacles. The closure cap is preferably a closure cap for a receptacle for receiving medical liquids which are

used in infusion, transfusion, clinical nutrition or dialysis. The receptacle is preferably designed as a bottle, in particular as a plastic bottle. The plastic bottle is preferably designed as an SBM (stretch-blow--molding) receptacle.

[0005] In an advantageous development, the first and/or the second connector part is designed as a Luer connector. Lower connectors are component parts of standardized cone connections which are used in particular in medical technology and which have a cone stem and a cone sleeve which are used for the connection of medical devices. The first and/or the second connector part can be designed both as a non-lockable Luer connector or as a lockable Luer connector (also referred to as a "Luer lock connector"). Owing to the standardization, the design of the first and/or second connector part as a Luer connector ensures a defined connection mechanism. Moreover, universality of the connectors is provided, the situation does not arise of having available different variants of connectors for different countries, and the risk of misuse as a result of a connection of unsuitable devices is reduced. The first and/or the second connector part is preferably designed as a Luer lock connector, thereby allowing a defined locking of the connection with a device to be connected and thus contributing to the safety of the connection, in particular against unintended release of the connection.

[0006] According to a further advantageous development, the first connector comprises a first membrane and a first piercing element, wherein the first membrane is arranged between the conical recess of the first connector part and the piercing element such that, by connecting the first device, the first membrane is pressed against the first piercing element and pierced. The membrane makes it possible, in its closed state, to prevent transport of liquid through the connector and to allow liquid transport only on opening. The piercing element allows easy and defined piercing of the membrane and ensures that the membrane is actually opened. The membrane is preferably designed in such a way and arranged in such a way that a device to be connected to the connector opens the membrane during the connection. For example, the device may comprise a Luer male connector with an inner cone which pierces the membrane during connection and opens it in this way. The first connector part is correspondingly designed as a Luer female connector or Luer lock female connector, which is preferred according to the invention. Furthermore, the membrane is preferably designed as an elastic body such that, when releasing the device, the membrane returns to its starting position in which the connector is closed off in a liquid-tight manner by the membrane.

[0007] The piercing element is preferably designed as a hollow body with a tip. The membrane can be pierced by the tip. Since the piercing element is designed as a hollow body, liquid transport can take place through the piercing element. The tip can be suitably sharpened to facilitate piercing of the membrane.

[0008] In a further advantageous configuration, the second connector comprises a membrane and a piercing element in a corresponding manner to the first connector. The second connector part is preferably designed as a Luer female connector or Luer lock female connector. It is possible in particular for the same membrane and/or the same piercing element to be used for the first connector and the second connector, with the result that the number of different parts is reduced and thus production costs can be lowered. Furthermore, the first connector and second connector can be designed to be identical. This has the advantage that in time-critical situations as may

occur, for example, in the rescue service or in the operating room, the error rate can be substantially minimized since it is no longer necessary to pay attention to which connector is intended for withdrawal and to which connector is intended for injection.

[0009] The receptacle according to the invention for medical liquids comprises a closure cap according to the invention. The receptacle is preferably designed as a bottle.

[0010] The dependent claims describe further advantageous developments of the invention.

[0011] The invention will be explained in more detail below with reference to exemplary embodiments which are illustrated by means of multiple figures.

BRIEF DESCRIPTION OF THE FIGURES IN THE DRAWING

[0012] In the drawing:

[0013] FIG. 1 shows a perspective view of an embodiment of a closure cap according to the invention,

[0014] FIG. 2 shows a bottom view of the closure cap shown in FIG. 1,

[0015] FIG. 3 shows a side view of the closure cap shown in FIG. 1,

[0016] FIG. 4 shows a plan view of the closure cap shown in FIG. 1,

[0017] FIG. 5 shows a cross section through the closure cap shown, along the section line A-A indicated in FIG. 4,

[0018] FIG. 6 shows a perspective view of the closure cap shown in FIG. 1, with a syringe connected to the first connector,

[0019] FIG. 7 shows a cross section through the closure cap shown in FIG. 6, with a connected syringe, along a section line corresponding to the section line A-A indicated in FIG. 4,

[0020] FIG. 8 shows a perspective view of the closure cap shown in FIG. 1, with a tube connected to the first connector,

[0021] FIG. 9 shows a cross section through the closure cap shown in FIG. 6, with a connected transfer tube, along a section line corresponding to the section line A-A indicated in FIG. 4.

DESCRIPTION OF THE TYPES OF EMBODIMENT

[0022] FIGS. 1 to 8 show an embodiment of a closure cap 1 according to the invention in various views and having various connected devices.

[0023] The closure cap 1 is designed as a closure cap for a receptacle of medical liquids and comprises a first connector 2 for injecting a medical liquid and a second connector 3 for withdrawing a medical liquid. The first connector 2 and the second connector 3 are arranged in a cover region 19 of the closure cap 1. Furthermore, the closure cap 1 comprises an edge region 20 which surrounds the cover region 19 and which is designed to place the closure cap 1 on a receptacle. In this exemplary embodiment, the edge region 20 is designed in such a way that it allows the closure cap 1 to be placed on an SBM plastic bottle, which is not represented in more detail, and to be connected therewith in a liquid-tight and germ-tight/bacteria-tight manner. For this purpose, the edge region comprises a peripheral groove 21, see FIG. 5, with which a corresponding web or edge of a connector of the bottle can be engaged. The liquid-tight and germ-tight connection between the receptacle and the closure cap 1 can be produced in

various ways, for example by welding, plugging, snap-fastening, screwing, overmolding and/or adhesive bonding.

[0024] The first connector 2 comprises, see FIG. 5 and FIG. 7, a first outwardly directed (i.e. directed away from the receptacle to be connected) connector part 4 with a conical recess 8 for sealingly receiving a cone stem of a first device to be connected and a second outwardly directed connector part 5 with a conical recess 9 for sealingly receiving a cone stem of a second device to be connected. In this exemplary embodiment, both the first connector part 4 and the second connector part 5 are designed as a Luer connector, here as a Luer lock female connector according to ISO standard 594-2:1998 or EN1707:1996.

[0025] Furthermore, the first connector 2 comprises a first closure part 22 with a first socket 13 which adjoins flush with the first connector part 4 and is directed inwardly, i.e. faces the receptacle to be connected, and the second connector 3 comprises a second closure part 23 with a second socket 14 which likewise adjoins flush with the first connector part 4 and is directed inwardly. In this exemplary embodiment, the first socket 13 and the second socket 14 are designed to be substantially cylindrical. The first closure part 22 and the second closure part 23 are situated on the side of the cover region 19 facing the receptacle to be connected, and the first connector part 4 and the second connector part 5 are situated on the side of the cover region 19 facing away from the receptacle to be connected.

[0026] A first membrane 6 and a first piercing element 7 are arranged in the first socket 13, and a second membrane 10 and a second piercing element 11 are arranged in the second socket 14; in this respect see FIG. 7 or FIG. 9 (in FIG. 5 the membranes 6, 10 and the piercing elements 7, 11 have been omitted for the sake of clarity). The first membrane 6 is arranged between the conical recess 8 of the first connector part 4 and the first piercing element 7, and the second membrane is arranged between the conical recess 9 of the second connector part 5 and the second piercing element 11. In the closed state, the membranes 6, 7 prevent liquid transport through the two connectors 2, 3 and in the opened state of the membranes 6, 10 liquid transport through the connectors 2, 3 is enabled. The membranes 6, 7 are made of an elastic material such that the membranes pass automatically from an opened position into the closed position and can thus close off the connectors in a liquid-tight and germ-tight manner. FIGS. 7 and 9 show the first membrane 6 in a closed state, that is to say in a state in which liquid transport through the first connector 2 is prevented, and the second membrane 10 in an opened state in which liquid transport through the second connector 3 is ensured.

[0027] The first piercing element 7 and the second piercing element 11 are each designed as rigid, disk-shaped bodies with a hollow tip 12 arranged in the centre. The hollow tip ensures transport of a liquid through the piercing element 7, 11. The tips 12 are arranged below the assigned membranes 6, 10 and oriented with respect to the respective membrane 6 or 10 such that, with a pressure on the connector side, the respective membrane 6 or 10 is pressed against the piercing element 7, 11 and is opened in this manner. To facilitate opening, the tips 12 of the piercing elements 7, 11 are sharpened. As a further measure to facilitate opening, the first membrane 6 and the second membrane 11 are slit in the centre.

[0028] In the region of the first closure part 22, the first connector has an inwardly directed peripheral flange 15 behind which the first piercing element 7 positively engages

and is pressed against the first membrane 6, with the result that the first membrane 6 is positively clamped in between the first piercing element 7 and a step 24 formed by the first closure part 22. Here, the membrane 6, supported by the pressing force exerted by the first piercing element 7, seals against the inner wall of the closure part 22, with the result that no liquid or germs can pass unwantedly through the first connector 2 between the membrane 6 and inner wall of the closure part 22. It is thus ensured that liquid transport occurs only when the membrane 6 is opened. Correspondingly, in the region of the second closure part 23, the second connector has an inwardly directed peripheral flange 16 behind which the second piercing element 11 positively engages and is pressed against the second membrane 10, with the result that the second membrane 10 is clamped in positively between the second piercing element 11 and a step 25 formed by the second closure part 23. The second membrane 10, supported by the pressing force exerted by the second piercing element 11, seals against the inner wall of the second closure part 23, with the result that no liquid can pass unwantedly through the second connector 3 between the membrane 10 and inner wall of the closure part 23.

[0029] FIG. 5 shows the closure cap 1 without the flanges 15, 16. Connectors 2, 3, cover region 19 and edge region 20 do not have any undercuts, allowing a simple and cost-effective production of the closure cap 1, since complicated mechanisms for demolding are dispensed with. The edges of the closure parts 22, 23 are flanged after inserting the membranes 6, 10 and the piercing elements 7, 11, resulting in the closure cap 1 shown in FIGS. 7, 9.

[0030] The first connector 2 and the second connector 3 are designed in such a way that, by connecting a device having a Luer lock male connector, the hollow inner core of the Luer lock male connector presses the respective membrane 6, 10 of the connector 2, 3 against the piercing element 7, 11 in the course of locking the device with the respective connector 2, 3, with the result that the membrane 6, 10 is opened. The force to be applied for piercing the piercing point is very low by comparison with a conventional connection using an infusion spike. Consequently, this connection is user friendly, safe, reliable and protected from contact.

[0031] The outer diameter of the hollow tip 12 is tailored to the inner diameter of the inner cone of the Luer lock male connector, with the result that the inner cone can be pushed over a portion of the tip 12. This is depicted by way of example in FIGS. 7, 9, where a needleless syringe 28 and a transfer tube 29 having a Luer lock male connector 27 which comprises a hollow inner cone 26 are connected to the second connector 3. After connecting the respective device 28, 29, liquid transport takes place through the inner cone 26 and the tip 12 of the piercing element 11. If the connected device is removed, the membranes 6, 10 move back into their starting state owing to their elasticity and restoring force and close the connectors 2, 3 in a liquid-tight manner again.

[0032] Apart from the external thread of the Luer lock, the first connector 2 and the second connector 3 are designed to be substantially rotationally symmetrical. Furthermore, in this exemplary embodiment, the connector 2 and connector 3 including the membranes 6, 10 and piercing elements 7, 11 are identical.

[0033] The first connector 2 is closed off in a liquid-tight and bacteria-tight manner with a break-off part 17, and the second connector 3 is closed off in a liquid-tight and bacteria-tight manner with a second break-off part 18. The break-off

parts 17, 18 prevent any contamination of the connectors 2, 3 prior to their use and ensure sterility and integrity of the interior. The break-off parts 17, 18 are connected via a pre-determined breaking point 30, see FIG. 5, to the respective connector 2, 3 and each have a tab 31, 32 via which the break-off parts 17, 18 can be broken off manually from the respective connector. The break-off parts 17, 18 can be provided with symbols which indicate a liquid transport direction, for example with arrows in the form of a recess or an embossing. Irrespective of such symbols, the connectors 2, 3 are designed for liquid transport in both directions in this exemplary embodiment.

[0034] The connectors 2, 3, break-off parts 17, 18, cover region 19 and edge region 20 are designed here as a one-part, in particular integral, injection molding made of a plastic. Connectors 2, 3, cover region 19, edge region 20 and break-off parts 17, 18 are made of polypropylene in this case. Alternatively, for example, polyethylene (PE) or HDPE (high-density PE) would also be suitable. The respective piercing element 7, 11 is likewise an injection molding made of plastic, for example of polypropylene (PP) or polycarbonate (PC) or acrylonitrile-butadiene-styrene (ABS). Alternatively, the piercing element 7, 11 can also be made of metal. This is particularly advantageous in the case that there is to be no slitting of the membranes 6, 10. The respective membrane 6, 10 is a membrane made of an elastic material, for example of a thermoplastic elastomer (TPE) or of polyisoprenes. Alternatively, the membrane can also consist of a silicone, chlorobutyl or bromobutyl.

[0035] A closure cap 1 having two identical connectors 2, 3 has been described in the exemplary embodiment. Although this is a preferred embodiment, it is of course possible to design the connectors 2, 3 to be different from one another. As a further alternative, one of the connector parts 4, 5 or both connector parts 4, 5 can be designed as a Luer connector without lock function, in particular as a Luer female connector. Alternatively, the first and/or the second connector part 4, 5 can furthermore also be designed as a Luer-like connector, for example as a large-bore connector or as a super large-bore connector. A large-bore connector or super large-bore connector allows a higher flow rate than a Luer connector, thus being advantageous, for example, for dialysis or for the transfer of a flushing solution in urology or arthroscopy.

1-13. (canceled)

14. A closure cap for a receptacle for receiving medical liquids, comprising a first connector for injecting a medical liquid and a second connector for withdrawing a medical liquid, wherein the first connector has an outwardly directed first connector part with a conical recess for sealingly receiving a cone stem of a first device to be connected, and the second connector part with a conical recess for sealingly receiving a cone stem of a second device to be connected.

15. The closure cap as claimed in claim 14, wherein the first connector part and/or the second connector part are designed as a Luer lock female connector.

16. The closure cap as claimed in claim 14, wherein the first connector has a first membrane and a first piercing element, wherein the first membrane is arranged between the conical recess of the first connector part and the piercing element such that, by connecting the first device, the first membrane is pressed against the first piercing element and pierced by the first piercing element.

17. The closure cap as claimed in claim 14, wherein the second connector has a second membrane and a second pierc-

ing element, wherein the second membrane is arranged between the conical recess of the second connector part and the second piercing element such that, by connecting the second device, the second membrane is pressed against the second piercing element and pierced by the second piercing element.

18. The closure cap as claimed in claim **16**, wherein the first piercing element is designed as a hollow body with a tip and/or the second piercing element is designed as a hollow body with a tip.

19. The closure cap as claimed in claim **14**, wherein the first membrane and/or the second membrane are slit.

20. The closure cap as claimed in claim **14**, wherein the first connector has a first socket in which the first membrane and the first piercing element are inserted and/or the second connector has a second socket in which the second membrane and the second piercing element are inserted.

21. The closure cap as claimed in claim **20**, wherein the first connector has a first flange by means of which the first membrane and first piercing element are fastened positively in the first socket and/or the second connector has a second flange

by means of which the second membrane and second piercing element are fastened positively in the second socket.

22. The closure cap as claimed in claim **14**, additionally comprising a first break-off part which is connected to the first connector and closes it off in a liquid-tight manner, and/or a second break-off part which is connected to the second connector and closes it off in a liquid-tight manner.

23. The closure cap as claimed in claim **14**, additionally comprising a cover region and an edge region, wherein the first connector and the second connector are arranged in the cover region.

24. The closure cap as claimed in claim **14**, wherein the first connector, second connector and, if appropriate, edge region and cover region and, if appropriate, first break-off part and second break-off part are designed in one part, preferably integrally.

25. A receptacle for medical liquids comprising a closure cap as claimed in claim **14**.

26. The receptacle as claimed in claim **25**, wherein the receptacle is designed as a bottle, preferably as an SBM (stretch-blow-molding) bottle.

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