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Gagliardoni et al.(10) **Pub. No.: US 2016/0199635 A1**(43) **Pub. Date: Jul. 14, 2016**(54) **NEEDLEFREE VALVE DEVICE**(71) Applicant: **CEDIC S. R. L.**, Peschiera Borromeo
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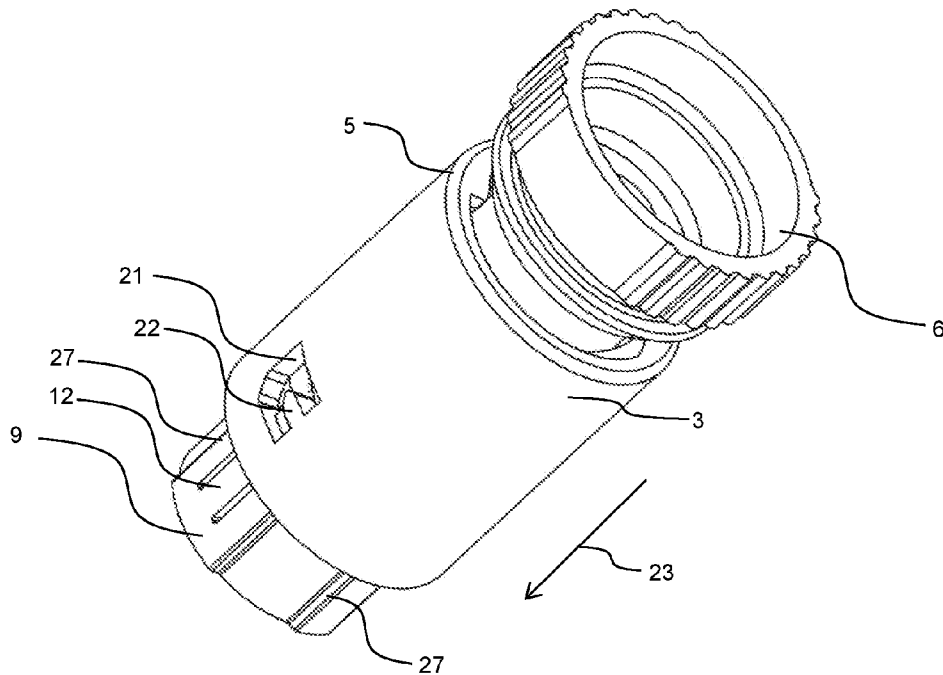
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(2013.01); **A61M 2039/1088** (2013.01); **A61M**
2039/1083 (2013.01)(57) **ABSTRACT**

Needlefree valve device (1) for controlling the flow of fluid in a pathway, the device (1) being operable in a closed and in an open configuration and comprising a first component (3), a second component (9), a locking means configured to selectively engage the first component (3) with the second component (9) in the open configuration when the first component (3) is displaced in an opening direction (23) along a valve axis toward the second component (9) or in the closed configuration when the first component (3) is displaced against the opening direction (23) away from the second component (9), and a sealing component (15) having a first resilient portion (19) and a second resilient portion (16), the first resilient portion (19) comprising at least one slit (26) and contacting the first component (9) to provide a seal in the closed configuration, wherein the first resilient portion (19) is adapted to move, buckle or flex to enable fluid flow through the at least one slit (26) upon application of a mechanical force of the first component (3) on the first resilient portion (19) in the opening direction (23) to assume the open configuration, and wherein the second resilient portion (16) is adapted to apply a counterforce to return the valve device (1) to the closed configuration when the mechanical force is no longer applied.



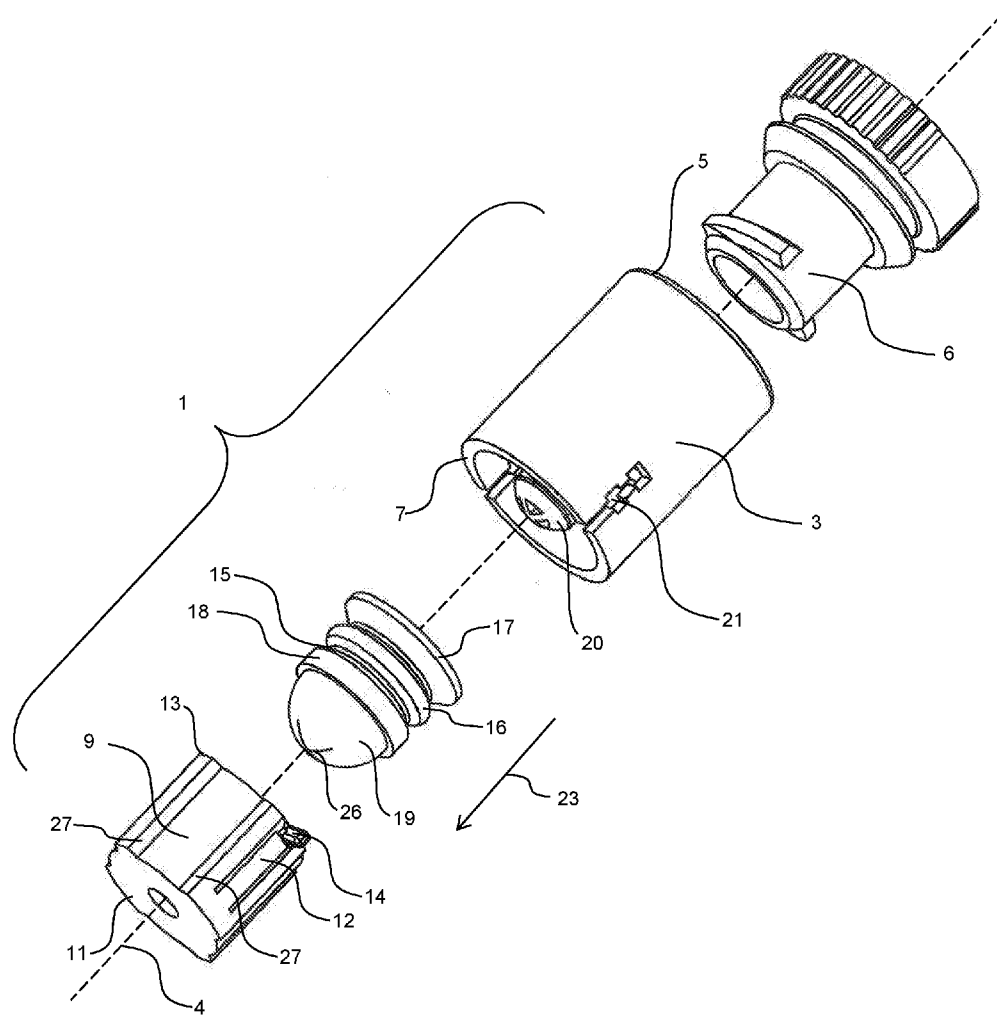


Fig. 1

Fig. 2

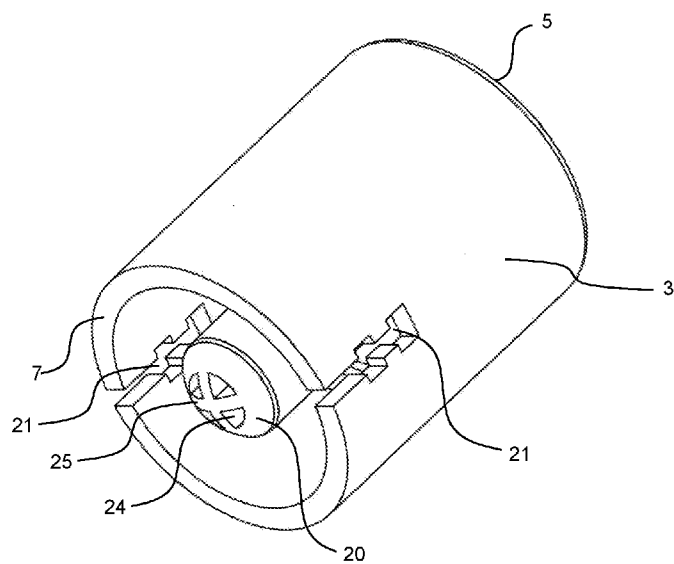


Fig. 3

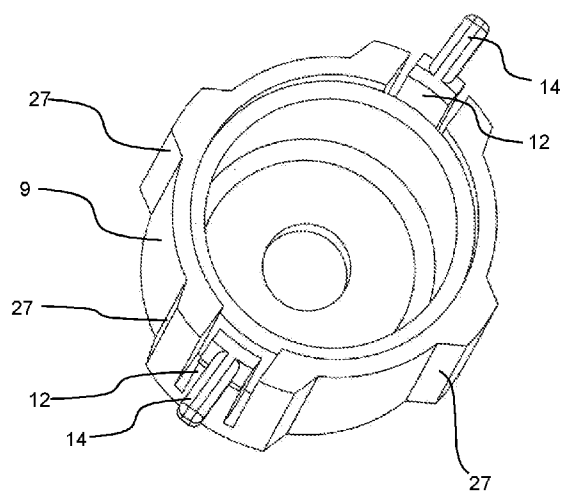
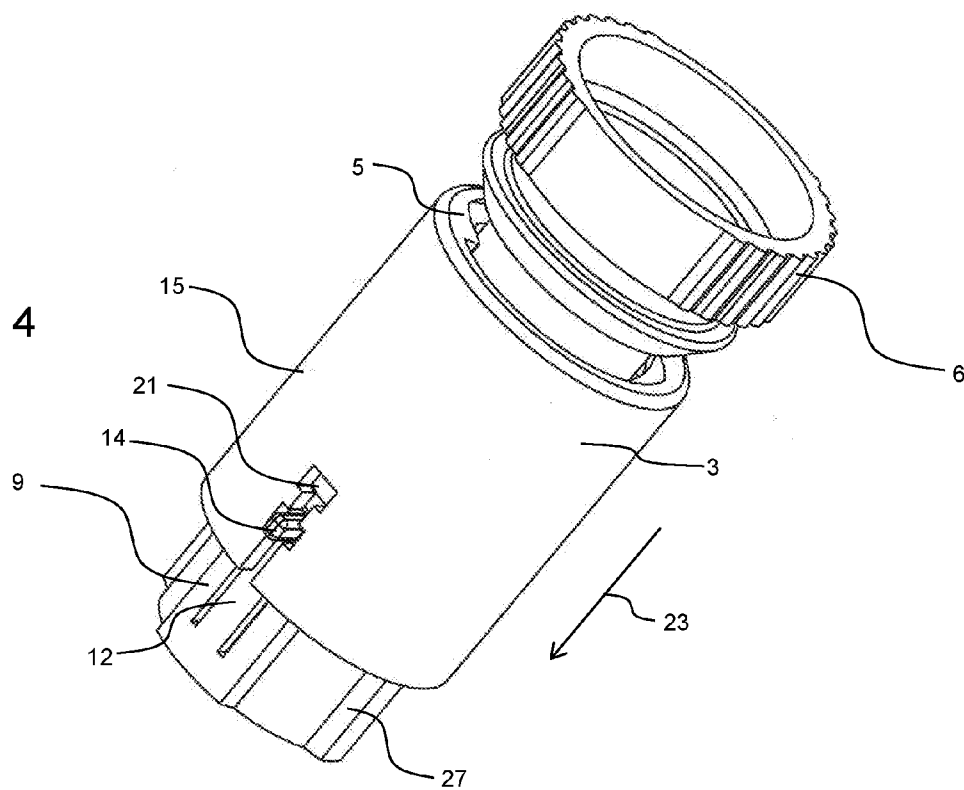


Fig. 4



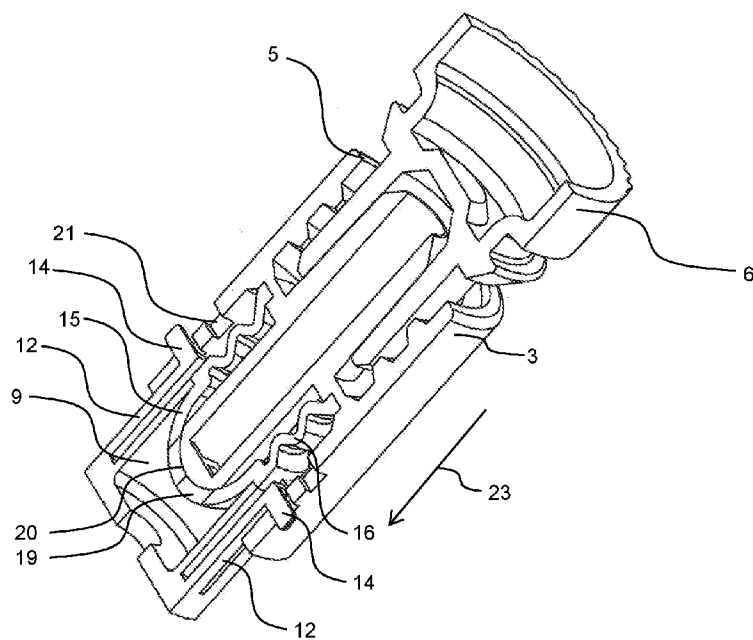


Fig. 5

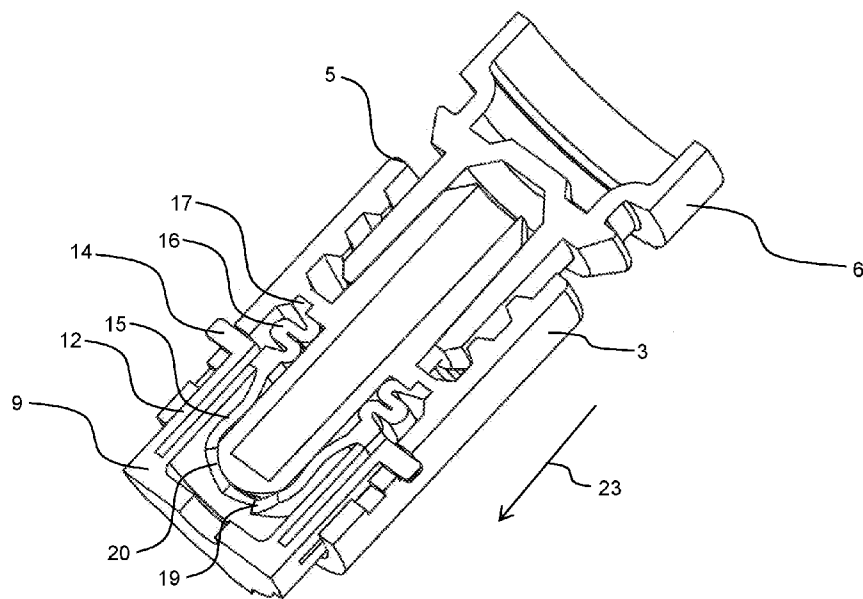


Fig. 6

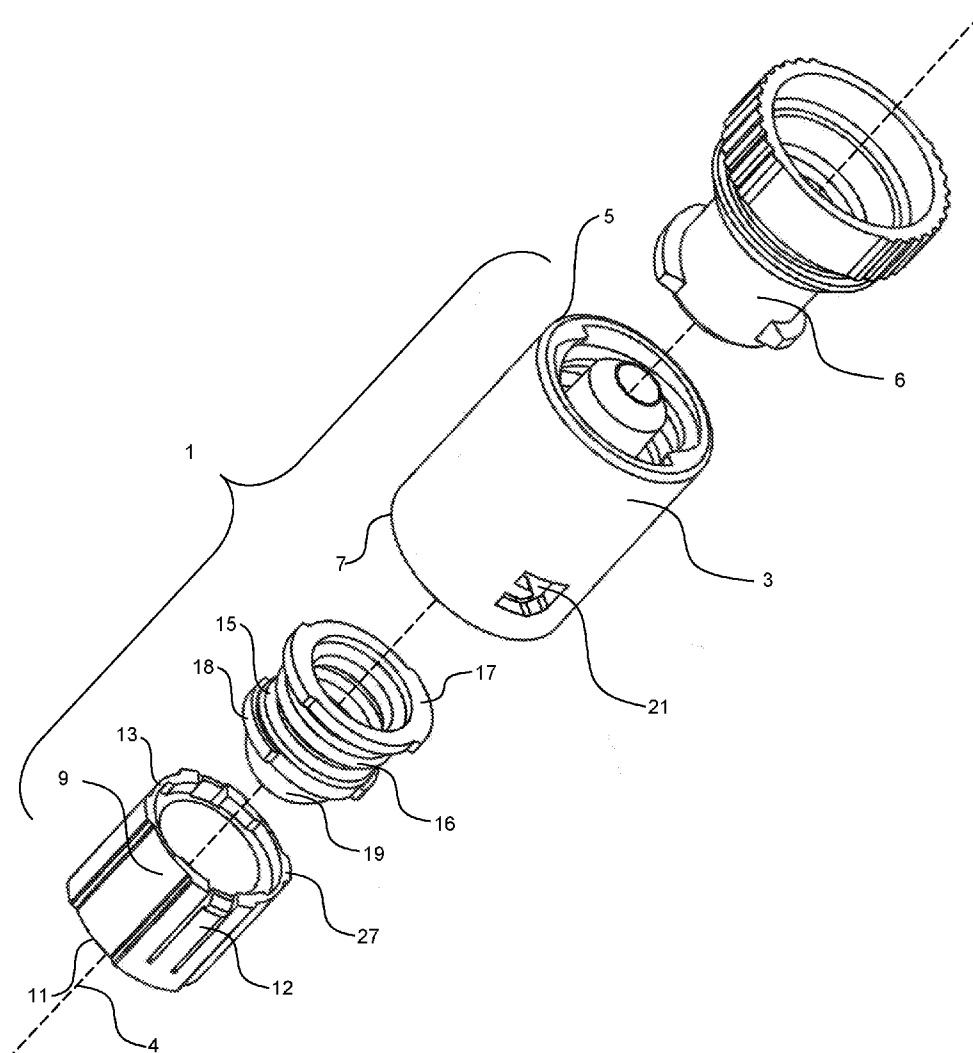


Fig. 7

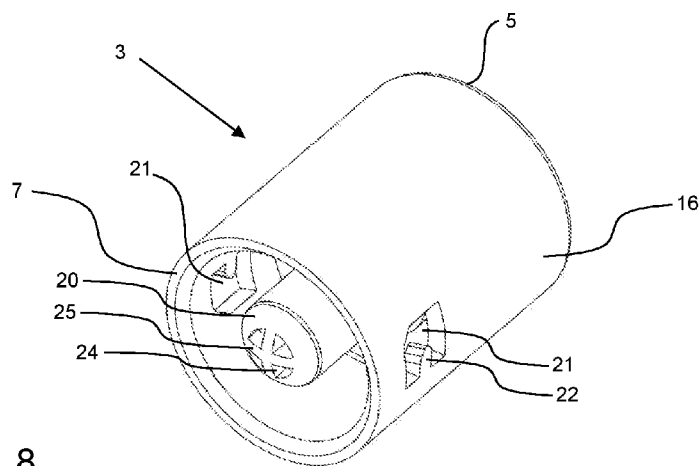


Fig. 8

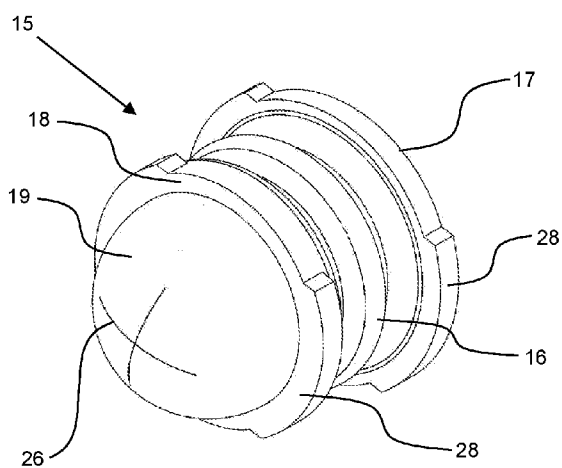


Fig. 9

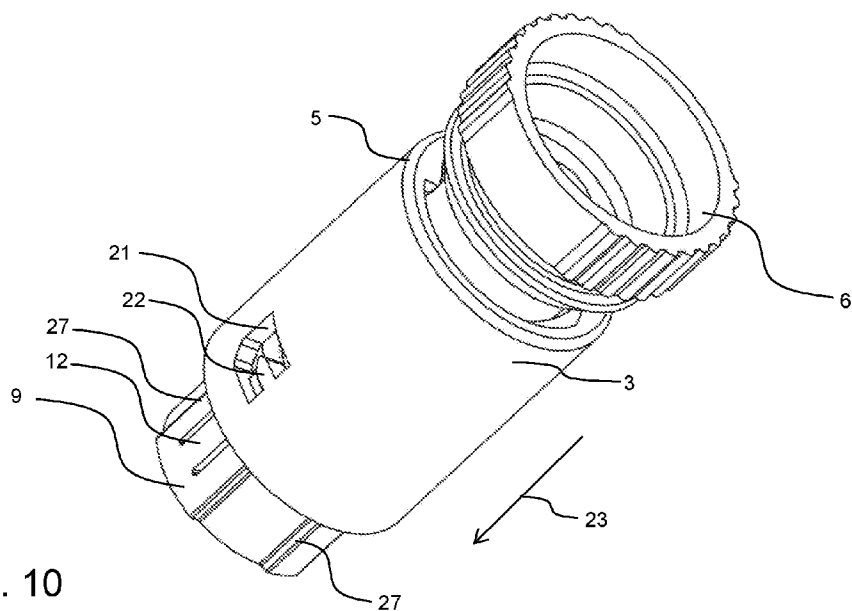


Fig. 10

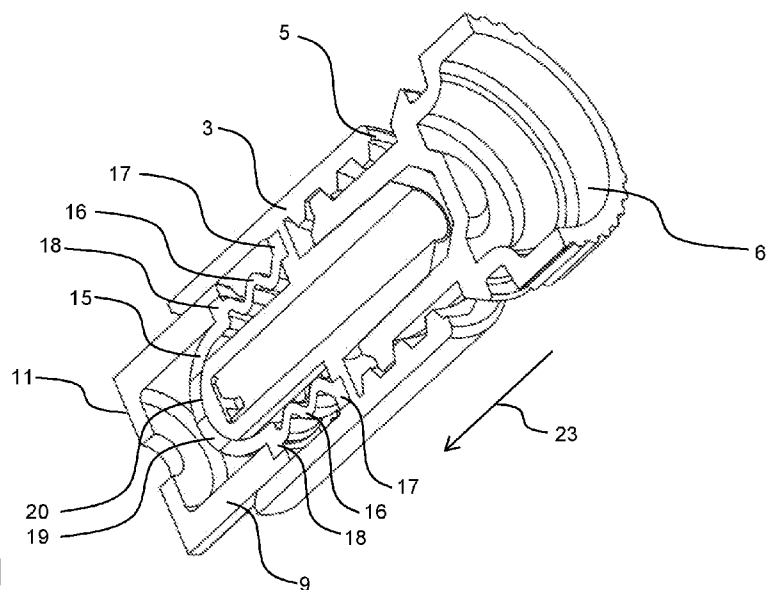
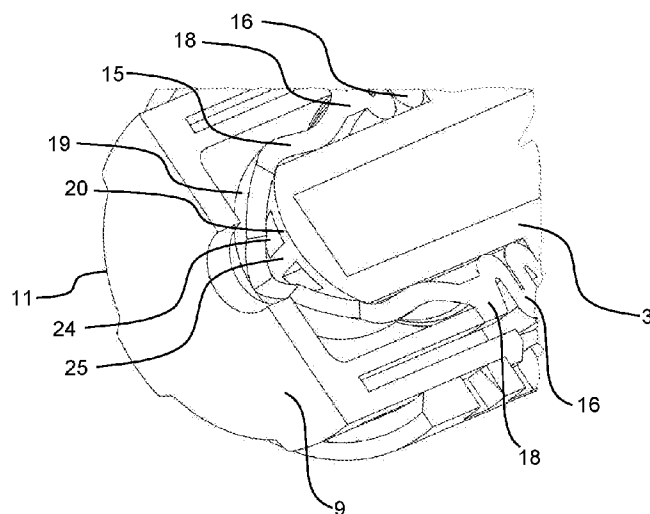
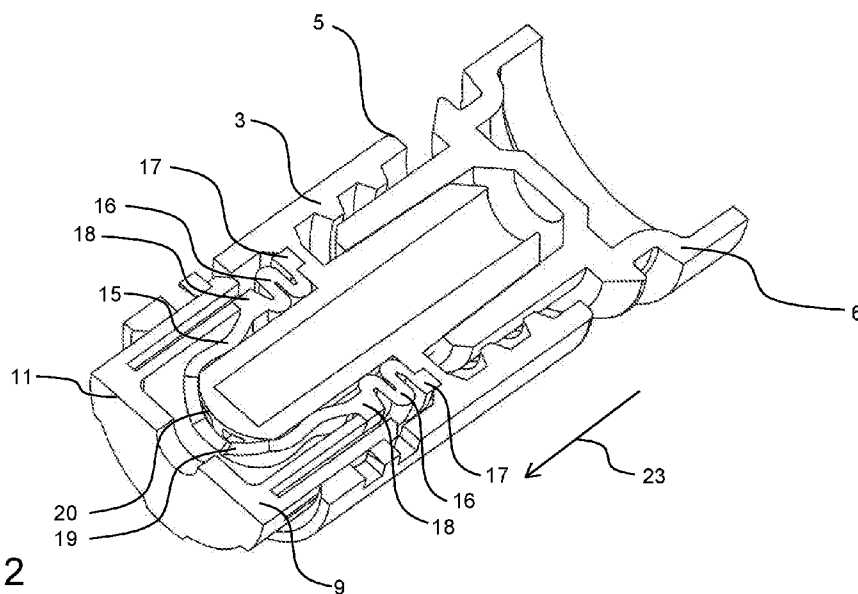


Fig. 11



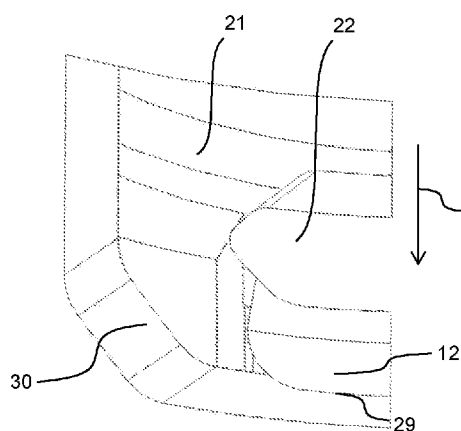


Fig. 14

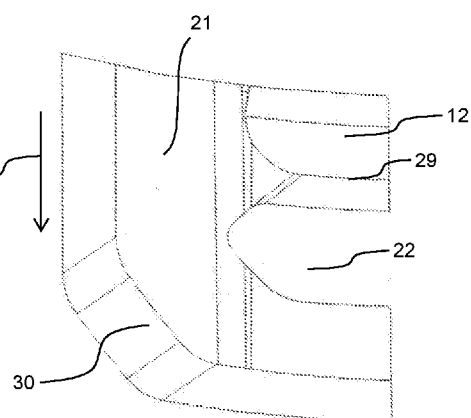


Fig. 15

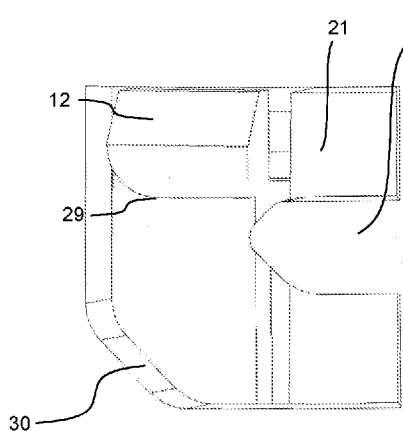


Fig. 16

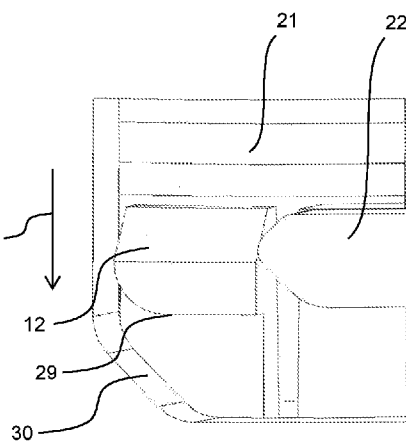


Fig. 17

NEEDLEFREE VALVE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application is a U.S. national phase entry of pending International Patent Application No. PCT/EP2013/070279, international filing date Sep. 27, 2013, which claims priority to International Patent Application No. PCT/EP2013/067361, international filing date Aug. 21, 2013, the contents of which are incorporated by reference in their entireties.

FIELD OF THE INVENTION

[0002] The present invention generally relates to valve devices of the type used in the handling and administration of fluids, and more particularly to a needlefree medical valve device adapted to be used in any type of tube connection such as between the different kinds of ports and syringes, catheters, pumps, or the like which are used in the administration of all kinds of fluids. Examples of such administration are intravenous, enteral or parenteral delivery of fluids to or from a body.

BACKGROUND OF THE INVENTION

[0003] Needlefree valve connectors are known in the art reducing the accidental needle stick exposure to medical personnel, reducing the risk of contamination and patient infection due to repeat needle sticks to the ports, and providing easy connection and disconnection without compromising sterility.

[0004] EP 2 269 687 A2 discloses a connector for controlling the flow of fluid the construction of which is complex and comprises certain limitations.

[0005] Some of the known needlefree medical connectors are repeatedly connectable with a range of other medical implements and are self-sealing when disconnected from other medical implements. Examples of such needlefree medical connectors are disclosed in WO 2010/111546 A2, WO 2006/062912 A1, and WO 2012/151222 A1 which is "configured to operate similar to the valve stem shown and described in U.S. Pat. No. 6,651,956" incorporated therein. The structures of these connectors are complex, thus leading to high manufacturing costs.

[0006] Different types of connectors are used throughout various kinds of medical fields such as intravenous administration, enteral or parenteral administration, for the taking of blood samples, for artificial ventilation or respiration and the like. These different types of connections must not be mixed up because lethal misconnections must be avoided. Therefore, there are standardized configurations which are intended to regulate the usage of different connectors with different sizes such that misconnections cannot occur.

[0007] It is therefore an object of the present invention to remedy or reduce at least one of the shortcomings of the prior art and to provide a needlefree valve device or connector having a relatively simple structure, which offers a wide variety of connection possibilities and is also self-sealing when disconnected from other ports.

SUMMARY OF THE INVENTION

[0008] According to an aspect of the invention, a needlefree valve device for controlling the flow of fluid in a pathway is provided, the device being operable in a closed and in an open configuration and comprising a first component, a second

component, a locking mechanism configured to selectively engage the first component with the second component in the open configuration when the first component is displaced in an opening direction along a valve axis toward the second component or in the closed configuration when the first component is displaced against the opening direction away from the second component, and a sealing component having a first resilient portion and a second resilient portion, the first resilient portion comprising at least one slit and contacting the first component to provide a seal in the closed configuration, wherein the first resilient portion is adapted to move, buckle or flex to enable fluid flow through the at least one slit upon application of a mechanical force of the first component on the first resilient portion in the opening direction to assume the open configuration, and wherein the second resilient portion is adapted to apply a counterforce to return the valve device to the closed configuration when the mechanical force is no longer applied.

[0009] The structure of the valve device (it can also be said to be a valve connector as in the previously mentioned prior art documents) is rather simple since it is comprised of only three main components which are produced using known technologies such as injection molding. Also, the setup, managing and handling of the valve device is free of complex procedural steps. In the closed position of the valve device, the first component and the first resilient portion provide a sufficient sealing of the valve due to the slight pretension when the first component and the first resilient portion are engaged with each other. This keeps the flexible and elastic material of the first resilient portion compressed so that any fluid is prevented from flowing through the passageway. Further, the configuration of the valve device is such that counterpressure coming from the side of the second component will increase the sealing capability because the first resilient portion is pressed against the first component. Finally, the simple structure of the valve device offers various possibilities for the design of the connecting ports of the first and the second component. Thus, a large number of standardized or customized connector types including tube mating ports may be applied to either end of the valve device. The counterforce exerted by the second resilient portion against the opening forces ensures that a self-opening of the valve device is prevented. It is preferred that the counterforce is created due to the forces inherent to the resilient material of the second resilient portion but it is also envisioned that an external spring may be used alternatively or in addition.

[0010] Preferably, the first component, the second component and the sealing component are substantially axially symmetric with respect to the valve axis and the locking mechanism is configured such that the first component is rotatable with respect to the second component around the valve axis by a predetermined angle. As a large number of connector types, particularly in the medical field, have a circular cross-section and, for example, use threaded connecting portions or bayonet-type connections, the valve device of the present invention supports these kinds of connections where two components are connected by pressing the ports onto one another and subsequently turning the ports in a clockwise direction with respect to one another. Similar considerations apply for disconnecting two components in the counterclockwise direction. Thus, the valve device is highly compatible with practically any type of connector, particularly in the medical field.

[0011] It is advantageous, that the sealing component comprises a first flange portion connected to the first component in a press fit. Further, it is preferred that sealing component comprises a second flange portion connected to the second component in a press fit. The second flange portion is preferably near the first resilient portion, and the first flange portion is preferred to be at the end towards the first component of the valve device, such that the second resilient portion is arranged between the first and the second flange portions. This firm attachment of the first flange portion to the first component and of the second flange portion to the second component enables an exact determination of the sealing pretension between the first resilient portion and the first component. It also ensures that the movement of the first and the second component relative to each other reduces the compressing and extending of the sealing component to the area between the two flange portions, i.e. the second resilient portion. In other words: the first resilient portion moves directly together with the movement of the second component while the first flange portion is kept in place fitted to the first component. It should be noted that a press fit of the flanges may also be achieved by additional supporting members such as a clamp or bracket or by any other suitable means. Optionally, glue may be used to support the press fit. The flange portions may be configured to press fit into a corresponding groove on the first or second component, respectively.

[0012] It is preferred that the locking member (also referred to herein interchangeably as a “locking mechanism”) comprises a latch arranged on the second component adapted to engage with at least one corresponding recess in the first component (also referred to herein as “locking-member engagers”). By this possibility to lock the valve device in the open or in the closed position, the safety of the valve device is highly increased. Particularly in the closed, locked position, the valve device can be disconnected from or connected to another component. The combination of a latch in engagement with a recess is only one possibility for the locking mechanism interlocking the first component with the second component. Other locking mechanisms such as a bayonet-type coupling may also be used. It should be noted that the valve device provides a security feature because the second resilient portion provides a self-restoring function for the valve device as soon as the engagement of the locking mechanism between the first and the second component in the open position of the valve is released. This means that an unintentional release of the locking mechanism in the open position will automatically close the valve. This safety mechanism also works in the reverse direction: a significant amount of force is needed to bring the valve into the open position by pressing the first and the second component together once the locking mechanism in the closed position is released. It should be noted that without manual interaction, such opening movement should under normal circumstances not be possible.

[0013] It is especially preferred that the recess comprises a rectangular shape and a locking arm extending in a circumferential direction such that the latch of the second component is adapted to engage with the locking arm in the open and in the closed configuration. This structure of the locking mechanism which can be referred to as a bayonet type mechanism takes into account that many connector types use threaded portions on at least one port. In a case where the first component includes a male Luer lock port, the corresponding female Luer component is screwed onto said male Luer lock

port in a clockwise direction. When the user continues to connect the first component, now connected to the female Luer component, to the second component, the clockwise movement is generally continued such that the latch of the second component engages with the portion of the recess which is in the opening direction of the valve device, i.e. below the locking arm when the second component is generally located below the first component, until the stop is reached. In this position, the valve device is in the closed configuration, and it is a relatively stable configuration due to the fact that any force of opening the valve device must first counter the forces inherent to the first and second resilient portion. It should be noted that the counterforces of the second resilient portion are higher than those of the first resilient portion. From this closed configuration the user can exert an (axial) force onto the first component with respect to the second component to open the valve. Thus, a “self-opening” movement of the valve device without the use of a dedicated axial force against the self-restoring force of the second resilient portion is not possible. Such a dedicated axial opening force will disengage the latch from the lower recess portion and bring it in engagement with the upper recess portion, i.e. with the portion of the recess above the locking arm when the second component is generally located below the first component. It must be noted that the full functionality of the locking mechanism will be explained in detail with respect to the drawings below.

[0014] Preferably, the sealing component including the first and second resilient portions is made of silicone rubber material. Silicone rubber is a well-known material for medical applications. It is relatively cheap and easy to manufacture, comprises resilient characteristics among other characteristics which are beneficial in the medical field such as impermeability, low toxicity, thermal stability, does not support microbiological growth etc. It should be noted that other suitable materials may be used such as silicon-based deformable materials, thermoplastic elastomer material (TPE) or the like. Also, it is possible that the material of the first resilient portion and/or the second resilient portion is not identical to the material of the rest of the sealing component. In other words, separate materials could be used considering the needed functions of the respective portions or elements so as to form the sealing component having the first and second resilient portions and, potentially, the two flange portions.

[0015] It is preferred that the second resilient portion of the sealing component comprises a bellows shape. Such a shape is particularly suited to provide the required compression function and spring function of the second resilient portion. Further, the bellows shape also provides sufficient flexibility to allow a torsional movement of the second resilient portion when using the bayonet type locking mechanism described above. The bellows shape consumes little space when compressed and when the second resilient portion restores its shape by the forces inherent to the material out of the compressed or folded state. Such a bellows shape is also well suited when an axial force as well as a radial force is applied to the second resilient portion at the same time because it enables compression, torsion and expansion in a defined way such that little space is consumed. The bellows shape also provides the necessary fluid impermeability which is necessary for the valve function. The second resilient portion may have a rounded bellows curvature or a zigzag form or any other suitable shape having the above listed capabilities.

[0016] It is further preferred that the first resilient portion comprises a surface having one slit or at least two slits each extending from a central point on the surface. Preferably, the surface of the first resilient portion comprises a hemispherical shape. The hemispherical or generally arcuate, dome-shaped surface is best suited for any type of cylinder-type valve device having a circular cross-section. Other shapes such as an ellipsoidal shape or any other surfaces of revolution are also envisioned. One slit through the central point of the hemisphere already provides sufficient area for fluid flow when a mechanical force is applied on the surface, be it from within the hemisphere or from outside. A plurality of slits extending from this central point provide an even larger opening and thus a larger passageway for the fluid. At the same time, the restoring forces are high. It is also possible that the first resilient portion and its counterpart surface on the first component are substantially even, i.e. planar in the plane perpendicular to the valve axis.

[0017] It must further be noted that a "slit" in the first resilient portion in the context of the present invention relates to a thin, narrow cut which enables the cutting surfaces to contact each other in a sealing fashion. The properties of the resilient material such as silicone rubber are such that the restoring forces of the bent-away portions also provide a fluid-tight sealing function. Further, the thickness of the material of the first resilient portion needs not be equal over its entire surface: it is possible that the side walls are substantially thicker than the hemispherical portion of the sealing component. In general, the first resilient portion shall be configured to retain substantially the same initial shape upon removing any mechanical force from its surface so as to provide the necessary fluid tightness.

[0018] Preferably, the first component comprises a protrusion having a contact surface substantially matching the surface of the first resilient portion and comprising at least two flow channels and at least one divider element. It is preferred that the shape of the contact surface is hemispherical. In this context it is further preferred that the at least one divider element of the contact surface is adapted to contact the one slit or the at least two slits of the first resilient portion in the closed position. When the valve device is opened, i.e. the first and the second component are moved towards each other with the sealing component arranged in between, the male protrusion of the first component is no longer in sealing engagement with the inner surface of the first resilient portion but penetrates the first resilient portion of the sealing component by pushing away the portions near the slits so that the flow of fluid through the flow channels of the protrusion and through the slits is enabled. Therefore, the first resilient portion must be axially moveable with respect to the protrusion of the first component. In other words, the first resilient portion is pushed against the contact surface of the protrusion of the first component to finally reach the open position. In the closed position, the divider elements of the protrusion are in engagement with the slits such that the sealing of the slits is further supported when a counterpressure presses the first resilient portion towards the first component against the opening direction of the valve device. For a good sealing function in the closed position, the configuration of the protrusion and the first resilient portion is such that the number of slits corresponds to the number of divider elements wherein each slit area engages a surface area of each divider element.

[0019] It is preferred that the first and/or second component comprises a medical connecting portion such as a male Luer

lock entry, male Luer lock exit, female Luer lock entry, female Luer lock exit, a catheter exit, and the like. A large variety of connections can be applied to the distal ends of the first and second components providing an extensive flexibility. It is noted that the valve mechanism of the present invention may also be applied in other fields than medical connectors such as hydraulic or other connectors where the advantageous characteristics of the subject matter of the present invention can be beneficial.

[0020] Preferably, the latch comprises a grip portion extending through the recess beyond the outer surface of the first component wherein pressing the grip portion will release the engagement of the latch with the recess. This may apply for the closed position as well as for the open position.

[0021] With further advantage, the second component comprises a guiding element enabling a guidance along the valve axis of the second component inside the first component. The guiding element allows for a smooth axial movement of the first and second component with respect to each other to ensure the closing and opening of the valve device. It should be noted that either component can comprise guiding elements, and that the guiding elements should enable a sufficient radial movement of the first and second component with respect to each other if the bayonet type locking mechanism is used.

BRIEF DESCRIPTION OF THE DRAWINGS

[0022] The above object, features and advantages of the present invention will become apparent from a consideration of the following detailed description presented in connection with the accompanying drawings in which:

[0023] FIG. 1 shows an exploded perspective view of a first embodiment of the valve device according to the invention;

[0024] FIG. 2 shows a perspective view of the first component of the first embodiment of the valve device according to the invention;

[0025] FIG. 3 shows a perspective view of the second component of the first embodiment of the valve device according to the invention;

[0026] FIG. 4 shows a perspective view of the first embodiment of the valve device according to the invention in the closed configuration;

[0027] FIG. 5 shows a perspective cross-sectional view of the first embodiment of the valve device according to the invention in the closed configuration;

[0028] FIG. 6 shows a perspective cross-sectional view of the first embodiment of the valve device according to the invention in the open configuration

[0029] FIG. 7 shows an exploded perspective view of a second embodiment of the valve device according to the invention;

[0030] FIG. 8 shows a perspective view of the first component of the second embodiment of the valve device according to the invention;

[0031] FIG. 9 shows a perspective view of the sealing component of the second embodiment of the valve device according to the invention;

[0032] FIG. 10 shows a perspective view of the second embodiment of the valve device according to the invention in the closed configuration;

[0033] FIG. 11 shows a perspective cross-sectional view of the second embodiment of the valve device according to the invention in the closed configuration;

[0034] FIG. 12 shows a perspective cross-sectional view of the second embodiment of the valve device according to the invention in the open configuration;

[0035] FIG. 13 shows a detailed view of the second embodiment of the valve device as depicted in FIG. 12;

[0036] FIG. 14 shows a perspective view of a detail of the locking mechanism of the second embodiment in the closed configuration;

[0037] FIG. 15 shows a perspective view of a detail of the locking mechanism of the second embodiment in the open configuration;

[0038] FIG. 16 shows a perspective view of a detail of the locking mechanism of the second embodiment in an intermediate position; and

[0039] FIG. 17 also shows a perspective view of a detail of the locking mechanism of the second embodiment in an intermediate position.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0040] FIG. 1 shows an exploded perspective view of a first embodiment of the valve device according to the invention. Valve device 1 includes arranged along a valve axis 4 a first component 3 embodied as a sleeve, a second component 9 and a sealing component 15 which in the operating configuration is arranged between the first component 3 and the second component 9. In the shown embodiment first component 3 comprises a connector end 5 adapted to receive a standardized enteral female connector 6 having a threaded portion and a central male portion. It should be noted that the connector end 5 of first component 3 can assume all kinds of connector portions which may have different configurations depending on the characteristic of the connector type. Thus, it is appreciated that the type of connector end 5 and the enteral female connector 6 in the shown embodiment are only exemplary and may be adapted according to the required setup and configuration. The sleeve-like first component 3 in this first embodiment comprises a substantially cylindrical shape having two openings or recesses 21 arranged on opposite sides near valve end 7. Furthermore, first component 3 comprises a central male protrusion near valve end 7, the protrusion including a contact surface 20.

[0041] Second component 9 is also embodied as a substantially cylindrically shaped sleeve adapted to fit within the inner diameter of first component 3. Second component 9 comprises a valve end 13, a connector end 11 and two latches 12 arranged on opposite sides of the outer surface of second component 9. The latches 12 extend substantially from the connector end 11 of the second component 9 parallel to the longitudinal axis of second component 9 and each comprise a grip protrusion 14 extending radially outward from the valve end 13. The latches 12 having the grip protrusions 14 are adapted to engage with the corresponding recesses 21 on first component 3.

[0042] Sealing component 15 which is in the operating position arranged between first component 3 and second component 9 comprises also a substantially cylindrical shape with a first flange portion 17 at the end towards the first component 3, a first resilient portion 19 located at the end which is near the second component 9, a second flange portion 18 located next to the first resilient portion 19, and a second resilient portion 16 arranged between the first flange portion 17 and the second flange portion 18. The first flange portion 17 is adapted to be connected to first component 3

near valve end 7 inside the sleeve-like first component 3 in a press fit configuration. This means that when the sealing component 15 is connected to first component 3, a movement of the first component 3 will also cause the first flange portion 17 of sealing component 15 to move because of the tightly fixed connection between each other. Further, the second flange portion 18 is adapted to be connected to the inside of second component 9 in a press fit configuration. Thus, when sealing component 15 is connected to second component 9, a movement of second component 9 will also cause a corresponding movement of second flange portion 18.

[0043] The latches 12 with their grip protrusions 14 are adapted to be inserted into the recesses 21 on first component 3 when the valve device 1 according to the invention is operable.

[0044] FIG. 2 is a detailed view of the first component of the first embodiment of the valve device shown in FIG. 1. Beyond what was described with respect to FIG. 1, the male protrusion within the inside of sleeve-like first component 3 is clearly visible having a hemispherical contact surface 20 with four divider elements 25 and four flow channels 24 which enable fluid flow in the open configuration of the valve device. It should be noted that the shape of the male protrusion with convex contact surface 20 can be different from hemispherical. It may assume a planar, flat shape or a different curved shape. The main criterion for the shape of the protrusion and its contact surface is that it matches the inner surface of the first resilient portion 19 of sealing component 15 and its slit configuration as will be explained in greater detail below. In addition, a sufficient fluid flow through the flow channels 24 must be achieved. It should also be noted that the number of flow channels 24 and corresponding divider elements 25 may differ from the one described above.

[0045] FIG. 3 is a detailed view of the second component 9 of the first embodiment of the valve device shown in FIG. 1. The perspective view is from the position of the first component 3 into its inner space which is configured to receive sealing component 15. It can be seen that latches 12 with grip protrusions 14 are arranged at opposite sides of the sleeve-like second component 9. Further, latches 12 are firmly attached towards bottom end 11. Thus, latches 12 show some elasticity at their free end with the grip protrusions 14 in a radial direction with reference to the valve axis 4. The outer surface of second component 9 comprises a plurality of guiding elements 27 which help to guide second component 9 within the inner space of first component 3 in an axial direction.

[0046] FIG. 4 shows a perspective view of the first embodiment of valve device 1 in the closed configuration with standardized enteral female connector 6 connected to the connector end 5 of first component 3. Second component 9 is connected to first component 3 with the sealing component 15 arranged in between (not shown) as described above. In the closed configuration depicted in FIG. 4 the latches 12 with the grip protrusion 14 are engaged with the lower portion of recess 21 in the outer surface of first component 3. It must be noted that the structure of the embodiment depicted in FIG. 4 comprises a short portion of second component 9 extending from the valve end 7 of first component 3. This portion may have other dimensions depending on the type of connection at connector end 11 of second component 9. In the shown embodiment, the guiding elements 27 support the guidance of the axial movement of second component 9 with respect to first component 3. In the open configuration (not shown in FIG. 4), the latches 12 with their grip protrusions 14 are

engaged with the upper portion of the corresponding recesses 21 on first component 3. Thus, the first embodiment of the valve device is movable between two positions, the closed and the open configuration.

[0047] In the following, the function of this first embodiment of the valve device will be explained in more detail with respect to FIGS. 5 and 6.

[0048] FIG. 5 shows a perspective cross-section view of the first embodiment of the valve device in the closed configuration, which is a cross-sectional view in the plane defined by the longitudinal axis and the two recesses 21 depicted in FIG. 4. When looking at the latch 12 and the interaction with the outer surface of first component 3, the switching between the open and the closed configuration can be understood. In the closed configuration shown in FIG. 5 the grip protrusion 14 is in engagement with the lower portion of recess 21. By pressing onto grip protrusion 14 against the spring force of the latch 12 in a radial direction, the latch 12 will be disconnected from the lower portion of recess 21 such that the stop function of this engagement is no longer present and a longitudinal movement along the longitudinal valve axis 4 of the valve device 1 in the opening direction 23 is enabled. Moving first component 3 and thus sealing component 15 in the opening direction 23 will lead to an engagement of latch 12 within the corresponding upper portion of recess 21 functioning as a stop. For this embodiment, recess 21 is configured to comprise two widened portions, an upper and a lower portion, which are adapted to engage with the top end of latch 12 in the closed and open position, respectively. It should be noted that the shown embodiment comprises two latches on opposite sides, but it is also possible that more than two locking mechanisms are provided. It is also possible to include only one locking mechanism.

[0049] In the closed configuration shown in FIG. 5, the contact surface 20 of the male protrusion of the first component 3 is in engagement with the inner surface of the first resilient portion 19 of sealing component 15. In detail, the divider elements 25 of the protrusion substantially cover the closed slits 26 of the first resilient portion 19 such that any counterpressure coming from the end 11 of the second component 9 is not able to open the slits against the direction 23 of fluid flow, and thus any opening of the valve device is prevented. It should be noted that the setup of the closed configuration is such that there is a slight pretension of the first resilient portion 19 against the contact surface 20 of the protrusion of the first component 3 which means that the closing function of the valve is also supported by the setup and the properties of the material used for the first resilient portion.

[0050] Furthermore, in the closed configuration the second resilient portion 16 of the sealing component 15 is in its relaxed state. The press fit of the first flange portion 17 and the second flange portion 18 engaging the first and second components 3, 9, respectively leaves the second resilient portion 16 between the two flange portions 17, 18 wherein the second resilient portion 16 comprises a bellows shape. Other shapes having the same functional characteristics are also possible but the bellows shape with rounded edges has shown superior performance with respect to fluid tightness, elasticity, compression, self-restoring force and durability.

[0051] During the movement of first component 3 towards second component 9 in the opening direction indicated with arrow 23 (or vice versa, i.e. moving the second component 9 towards first component 3), the contact surface 20 of the

protrusion of first component 3 will come into contact with the inner surface of first resilient portion 19 of sealing component 15. Since the first resilient portion 19 is on this side tightly connected to the second component 9 via second flange portion 18 and comprises in this embodiment a hemispherical shape having four slits 22 at the very end of the first resilient portion 19, the first resilient portion 19 will give away to the mechanical force exerted by the contact surface 20 of the protrusion thus opening the slits 26. The four slits 26 of the resilient portion 19 will give away as can be seen in FIG. 6, and an opening through the first resilient portion 19 will thus be created allowing fluid to pass between first component 3 and second component 9. In the cross-sectional view of FIG. 6 this opening of the sealing component 15 can be clearly seen. The second resilient portion 16 is further compressed, i.e. the sections of the bellows portion are pressed on top of each other while maintaining a fluid tightness in the region between the first and second flange portions 16, 18.

[0052] In the open position, the engagement of the latch 12 with the upper portion of recess 21 of the first component 3 is created through the spring force of the latch 12 such that the grip protrusions 14 extend radially outward through the corresponding upper part of recess 21. When the user of the valve device intends to close the valve device again, he/she presses the grip protrusions 14 towards each other (towards the central axis 4 of the valve). As soon as the latch 12 disengages from the recess 21, the self-restoring forces of the second resilient portion 16 begin to expand the bellows portion to move the valve device 1 back into the closed position against the direction depicted by arrow 23.

[0053] FIG. 7 shows an exploded perspective view of a second embodiment of the valve device. The configuration of the second embodiment is similar to the configuration of the first embodiment shown in FIG. 1. The difference lies in the locking mechanism which in the second embodiment comprises a different structure of recess 21 located on the outer surface of first component 3 and of latch 12 which extends from the connector end of second component 9. Similar to the first embodiment shown in FIGS. 1 to 6 there are two locking mechanisms located opposite to each other with respect to the longitudinal valve axis 4 of the valve device 1. It must be noted, however, that for all embodiments of the present invention there could be one or three or more locking mechanisms deployed on the outer surfaces of first component 3 and second component 9.

[0054] Recess 21 of first component 3 comprises a substantially rectangular or C-shaped configuration with a larger extension in the circumferential direction than in the axial direction parallel to the opening axis 23. Approximately in the middle of the longitudinal extension of recess 21 there is a locking arm 22 extending in a circumferential direction into recess 21 giving recess 21 a C-shape. In the embodiment shown as the second embodiment in FIGS. 7 to 17 the locking arm 22 extends from the right side wall in the outer surface of first component 3. The reason for this arrangement of locking arm 22 within recess 21 will become clear with respect to the detailed description of FIGS. 14 to 17 below.

[0055] The difference between the first and the second embodiment with respect to the locking mechanism is that in the second embodiment of FIG. 7 the free end of latch 12 near the valve end 13 does not comprise a grip protrusion 14 as in the first embodiment. This means that in the second embodiment a manual pressing of the latch 12 radially in an inward direction from the outer surface of the valve device 1 is not

necessary. This is due to the fact that in the second embodiment first component 3 is configured to be rotated with respect to the second component 9 around the longitudinal valve axis 4, and the dimensions of this rotation are determined by the dimensions of recess 21 along the circumferential direction of which latch 12 may be moved. The details of the rotational and longitudinal movement of first component 3 with respect to the second component 9 will now be described in detail with respect to FIGS. 14 to 17.

[0056] The locking mechanism of the second embodiment of the valve device is a bayonet type mechanism wherein a pin or the like (in this case latch 12) is in engagement with an L- or C-shaped slot (in this case C-shaped recess 21) kept in place by a radial spring force. It must be noted that in this second embodiment there is another spring function which is the one of the second resilient portion as already described with respect to the first embodiment above. In order to function as a spring, the sealing component 15 has to be firmly attached to the first and the second components 3, 9, respectively at the first and second flange portions 17, 18 as described above. Deviating from the first embodiment, the first and second flange portions 17, 18 of the second embodiment comprise protrusions and recesses which match with corresponding recesses and protrusions in the first and second components 3, 9, respectively. Thus, the press fit of the elements is further supported, and a turning movement of the first flange portion 17 with the first component 3 and of the second flange portion 18 with the second component 9 is prevented. This means that the second resilient portion 16 which is the region between the first and the second flange portions 17, 18 is not only configured to be compressed in the axial direction but also to be rotated around the longitudinal valve axis 4 of the valve device, i.e. in a circumferential direction.

[0057] FIG. 8 shows a perspective view of the first component of the second embodiment. Similar to FIG. 2 of the first embodiment, in FIG. 8 the protrusion of the first component 3 is shown having a hemispherically shaped contact surface 20 with dividing walls 25 and flow channels 24.

[0058] FIG. 9 shows a perspective view of the sealing component 15 of the second embodiment. The main difference to the sealing component of the first embodiment is the protrusions 28 on the first and second flange portions 16, 17 which interact with corresponding recesses in the inner surface of the first and second components 3, 9, respectively. It should be noted that the number of protrusions and corresponding recesses may vary, i.e. there may be only one or more than two matching protrusions and recesses.

[0059] FIG. 10 shows a perspective view of the second embodiment of valve device 1 in the closed configuration with standardized enteral female connector 6 connected to the connector end 5 of first component 3. Second component 9 is connected to first component 3 with the sealing component 15 arranged in between (not shown) as described above.

[0060] FIG. 11 shows a perspective cross-section view of the second embodiment of the valve device in the closed configuration. Since the locking mechanism is not visible in FIG. 11, the configuration is, apart from the locking mechanism, identical to the one described with respect to FIG. 5 of the first embodiment.

[0061] FIG. 12 shows a perspective cross-section view of the second embodiment of the valve device in the closed configuration. FIG. 12 is similar to FIG. 6 with the only

difference lying in the configuration of the locking mechanism, and a repeated description is therefore omitted.

[0062] FIG. 13 shows a detailed view of the second embodiment of the valve device as depicted in FIG. 12. In the open position there is sufficient space within in the second component 9 between the inner surface of the bottom of the second component 9 and the contact surface 20 of the protrusion of the first component 3 such that the flexible parts of the first resilient portion 19 may expand according to their material characteristics. Further, it can be seen that the amount of fluid which flows through the valve device is determined by the size of the flow channels 25 and the size of the opening in the second component 9.

[0063] Before going into detail regarding the FIGS. 14 to 17 it must be noted that the locking mechanism according to the second embodiment is used in the optimal way when the connector port of first component 3 includes, for a superior performance of the valve device, a threaded part similar to a Luer lock such that when another component is connected to first component 3 said other component must be turned clockwise in order to effect a proper connection. The clockwise connection movement of the other component 6 with respect to the valve device 1 and also the disconnecting movement in the counterclockwise direction play an important role for the function of the locking mechanism according to the second embodiment. In combination with the turning or rotational movement in and against the opening direction marked with arrow 23 which is partly user initiated and partly an inherent movement due to the self-restoring properties of the second resilient portion 16 of sealing component 15, the movement in the circumferential direction, i.e. around the longitudinal valve axis 4 of the valve device, there are a plurality of positions of the distal end of latch 12 within the area of recess 21.

[0064] FIG. 14 shows a perspective view of the locking mechanism detail of the second embodiment in the closed configuration. As described with respect to FIGS. 10 and 11 the closed configuration is the configuration, where the first component 3 and the second component 9 are connected such that the contact surface 20 of first component 3 is slightly pressed against the inner surface of first resilient portion 19 of the sealing component 15, thus creating a sealing engagement of the protrusion of the first component 3 with the first resilient portion 19 closing the passageway through valve device 1. The slits 26 are substantially closed, and the divider elements 25 are in contact with the corresponding slit portions. Upon pressing first component 3 onto second component 9 in the opening direction following arrow 23 along the longitudinal valve axis 4 of valve device 1, the first resilient portion 19 flexes or gives in to the mechanical force exerted by the contact surface 20 of first component 3 thus leading to an open passageway of valve device 1.

[0065] Considering this for the local interaction of latch 12 within recess 21 and locking arm 22, this means that in the closed position of FIG. 14 the first component 3 is in the position furthestmost rotated in the clockwise direction within recess 21, and thus the right hand side edge of latch 12 abuts with the right side wall of recess 21 in the lower portion below locking arm 22. Latch 12 comprises at its end a protrusion 29 which engages with the lower edge of recess 21 such that first component 3 can not be easily moved in the longitudinal direction (opening/closing direction) with respect to second component 9. The engagement of the protrusion 29 with the lower wall of recess 21 prevents a disconnection of first

component 3 from second component 9 against the opening direction indicated by arrow 23. However, opening the valve device 1 by moving first component 3 towards second component 9 in the opening direction is possible out of the position or configuration depicted in FIG. 14 although a self-opening of the valve is prevented by the compression force required to compress the second resilient portion 16 of sealing component 15.

[0066] FIG. 15 shows a perspective view of the detailed locking mechanism of the second embodiment in the open configuration, i.e. latch 12 is positioned in the upper right corner of “window” embodied by C-shaped recess 21. The protrusion 29 of latch 12 engages with the upper portion of locking arm 22 such that a movement along the longitudinal valve axis 4 against the opening direction indicated by arrow 23 is prevented by this engagement. The configuration depicted in FIG. 15 shows the stable, open configuration in the sense that first component 3 is still correctly connected with another component, and the disconnection of said other component with respect to the first component 3 necessarily implies a rotation of first component 3 with respect to second component 9 in the counterclockwise direction. The open configuration as shown in FIG. 15 is achieved by pressing the first component 3 and the second component 9 towards each other out of the position shown in FIG. 14 such that latch 12 will be disengaged from the position below the locking arm 22. The opening force must counter the compression force of the second resilient portion 16 of the sealing component 15 and the engagement force of latch 12 with locking arm 22. For this purpose, the upper side of latch 12 may be slanted out of the opening direction.

[0067] When the valve device 1 shall be closed again out of the open configuration shown in FIG. 15, a counterclockwise rotation brings latch 12 into the configuration depicted in FIG. 16. In this intermediate, unstable position, latch 12 with protrusion 29 is no longer engaged with locking arm 22 such that the self-restoring forces of the second resilient portion 16 of sealing component 15 will now force the movement of latch 12 towards the lower end or lower side wall of recess 21 to reach the intermediate position depicted in FIG. 17, and then into the closed position shown in FIG. 14 which is the stable closed position.

[0068] As briefly mentioned above, FIG. 17 also shows a perspective view of the detailed locking mechanism of the second embodiment in a second intermediate position where the first component 3 has been rotated counterclockwise with respect to second component 9. In the configuration of FIG. 17 latch 12 has been moved to the left of the “window” of recess 21 and about half way up so that latch 12 is located between the upper and lower edge of recess 21. This position is not a stable configuration because the forces of the second resilient portion 16 will automatically try to move the valve into the closed position (see FIG. 14). Further, the self-restoring forces of the second resilient portion 16 are directed against the opening direction 23 and also comprise a rotational component in the clockwise direction. Since the configuration of FIGS. 16 and 17 has been achieved by turning or rotating first component 3 counterclockwise with respect to second component 9, the latch 12 will try to return to the position shown in FIG. 14. This is supported by the slanted or skewed configuration of the lower left corner of recess 21.

[0069] The rotation angle is a predetermined angle which for example is determined to be 15°. Other angles are possible depending on the connector type such as between 5° and 40°.

As can be understood, the width of the recess 21 determines the angle by which first component 3 may be rotated with respect to second component 9. In the second embodiment depicted in FIGS. 14 to 17 the width of latch 12 is a little larger than the width of locking arm 22, seen in the circumferential direction.

[0070] In essence, when a user tries to disconnect the valve device 1 according to the second embodiment of the invention from the other component which is connected to first component 3 out of the open configuration shown in FIG. 15, the user will turn the first component 3 counterclockwise with respect to second component 9, arriving at the configuration in FIG. 16, and then the self-restoring forces of the first resilient portion 16 of sealing component 15 will move second component 9 away from first component 3 such that the second intermediate position shown in FIG. 17 and subsequently the closed configuration depicted in FIG. 14 is achieved. Upon reconnecting another component to first component 3 by screwing e. g. a Luer lock into the port of first component 3, a movement along the longitudinal valve axis 4 will open the valve because first component 3 and second component 9 are moved towards each other.

[0071] The bayonet type locking mechanism of the second embodiment thus offers a self securing function such that the valve device may not be unintentionally opened or open itself only by connecting it to any type of connector. It is thus ensured that upon connecting or disconnecting a third component to first component 3 on its connection port that in the closed position the valve device 1 will not open, and in the open position, the valve device will 1 automatically move into the closed position because of the self-restoring force of the first resilient portion 16 of the sealing component 15.

[0072] With the subject matter of the present invention a needlefree valve device has been provided which comprises a relatively simple structure, offers a wide variety of connection possibilities and is also self-sealing when disconnected from other ports.

1-15. (canceled)

16. A needlefree valve device for controlling the flow of fluid in a pathway, the device having closed and open configurations and comprising:

- a first flow-through component including a central protrusion comprising at least two flow through channels and at least one divider;
- a second flow-through component, the first and second components being relatively movable along a valve axis from the closed configuration to the open configuration and vice versa;
- a locking member on the second component selectively engageable with closed and open locking-member engagers on the first component to maintain the device in the closed and open configurations, respectively; and
- a sealing component between the first and second flow-through components and having first and second resilient portions, the first resilient portion (a) including at least one slit through a central portion thereof, (b) contacting the first component to provide a seal in the closed configuration, and (c) being adapted to be deformed for fluid flow through the slit upon application of mechanical force thereon by the central protrusion of the first component when assuming the open configuration.

17. The needlefree valve device of claim 16 wherein the second resilient portion of the sealing component is adapted

to apply a counterforce to return the valve device to the closed configuration when the mechanical force is no longer applied.

18. The needlefree valve device according to claim **16** wherein the first component, the second component and the sealing component are substantially axially aligned with respect to the valve axis and the locking member is configured such that the first component is rotatable with respect to the second component around the valve axis by a predetermined angle.

19. The needlefree valve device according to claim **16** wherein the sealing component includes a first flange portion contacting the first component in a press fit.

20. The needlefree valve device according to claim **19** wherein the sealing component includes a second flange portion contacting the second component in a press fit.

21. The needlefree valve device according to claim **16** wherein:

the locking member comprises a latch; and

the closed and open locking-member engagers comprise at least one recess in the first component configured to selectively engage the latch.

22. The needlefree valve device according to claim **21** wherein the recess is a rectangular shape and a locking arm extends into the recess such that the latch of the second component is adapted to engage with the locking arm in the open and closed configurations.

23. The needlefree valve device according claim **21** wherein the latch includes a grip portion extending through the recess beyond the outer surface of the first component such that pressing the grip portion releases the engagement of the latch with the recess.

24. The needlefree valve device according to claim **16** wherein the sealing component is made of silicone.

25. The needlefree valve device according to claim **16** wherein the second resilient portion of the sealing component is a bellows shape.

26. The needlefree valve device according to claim **16** wherein each slit of the at least one slit of the first resilient portion extends from a central point on the central portion.

27. The needlefree valve device according to claim **26** wherein there are at least two slits on the central portion.

28. The needlefree valve device according to claim **16** wherein the protrusion has a contact surface substantially matching the surface of the central portion.

29. The needlefree valve device according claim **28** wherein the contact surface of the protrusion and the surface of the central portion are of a hemispherical shape.

30. The needlefree valve device according claim **29** wherein the at least one divider element is adapted to contact the one or more slits in the closed position.

31. The needlefree valve device according to claim **16** wherein the first and/or second components include a medical connecting portion such as a male Luer lock entry, male Luer lock exit, female Luer lock entry, female Luer lock exit, a catheter exit, a tube mating port and the like.

32. The needlefree valve device according to claim **16** wherein the second component includes a guiding element enabling guidance along the valve axis of the second component inside the first component.

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