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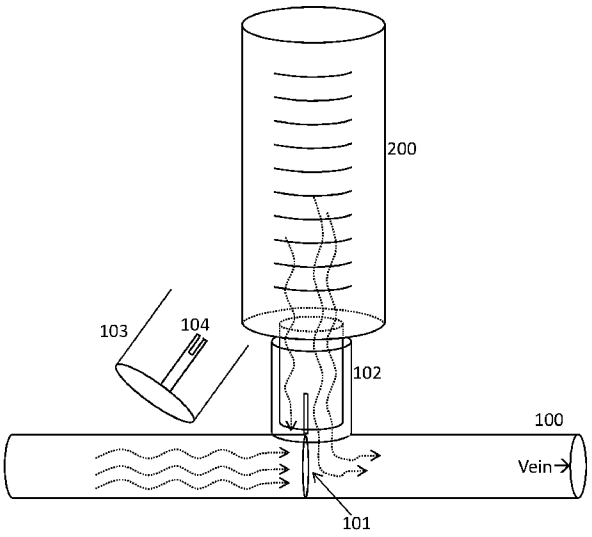

Figure 2

(57) Abstract: The present invention provides a novel catheter device having a lateral injection port and a safety faucet-valve which enables easy and simple insertion thereof into a vain of an individual without the risk of blood splashing out during insertion, said safety faucet- valve further enables preventing any loss of fluids injected through said lateral injection port due to back-flow.

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CATHETER WITH A SAFETY FAUCET-VALVE

FIELD OF THE INVENTION

[0001] The present invention relates to a catheter device, more particularly a catheter device having a lateral injection port and a safety faucet-valve which enables easy and simple insertion of the catheter device into a vain of an individual without the risk of blood splashing out during insertion, said safety faucet-valve further enables to prevent any loss of fluids injected through said lateral injection port due to back-flow.

BACKGROUND OF THE INVENTION

[0001] In medical procedures that require the introduction of fluids into a patient, a catheter is usually inserted into blood vessels of said patient. The catheter includes a hollow needle which is used to pierce the skin and the blood vessel, and is then withdrawn out of the catheter, leaving the flexible catheter tube in place in the blood vessel.

[0002] Most catheters are configured to indicate that the hollow needle has pierced the blood vessel and that the catheter was properly placed, namely by reverse blood flashback or double flashback indications (i.e. a needle flash followed by a catheter flash). However, this configuration includes the possibility of an unintentional blood-splash or blood-backflow, i.e. blood splashing or oozing through the rear opening of the catheter (a.k.a. the infusion port) when the hollow needle is extracted therefrom due to low pressure venous blood flow, until the infusion set is connected to the catheter or until a cup is screwed thereon. This blood-splash poses a health risk to the health practitioner.

[0003] Several attempts were made to solve the problem of blood-splash. For instance, US 5,613,663 and DE 2817102 describe catheter devices with a valve unit designed to prevent blood backflow during the removal of the hollow needle. Both valves are opened when a connection cone of an infusion tube or a tip of a syringe are inserted into the infusion port, and are closed upon their removal. However, both configurations are suitable only for catheters with a short connecting unit/infusion port since said valve units need to be in physical contact with the tip of the infusion tube or syringe, and as such cannot be implemented in catheters with a lateral injection port, which by nature have a longer connecting unit/infusion port.

[0004] A lateral injection port has been added to catheter devices as a mean to provide an easy and simple way to administer medications and other supplements directly into the veins of a patient without disconnecting the infusion tube from the infusion port of the catheter and connecting a syringe comprising said medication or supplement thereto. Direct administration of medications is essential in cases where said medication or supplement quickly lose their activity and thus cannot be added into the infusion liquid. In addition, in order to prevent liquids from exiting said lateral injection port, a silicon valve is placed inside the catheter underneath the opening of said lateral injection port, thereby preventing liquids from exiting while enabling liquids injected through the injection port to pass directly into the vein. However, these injection port and silicon valve add to the complexity of the catheter unit and further prevent incorporation of the known valve units aimed at preventing blood-splash.

[0005] Another drawback of catheters having a lateral injection port is that upon injection of fluids through said lateral injection port, some of the injected fluids might flow backwards, namely towards the infusion tube instead of only towards the vein. As explained above, this might cause a problem when using medications which have a short life span and must be administered in a precise dosage. Accordingly, health practitioners have to bend or squeeze the infusion tube to prevent such backflow (a.k.a. "kinking").

[0006] Another issue of catheters is an unintentional needle stick from the needle unit after placing the catheter in place. Several developments were made to protect the health practitioner from such an accidental needle stick, known as needle guard elements. Examples of such developments for shielding the needle after its extraction can be found in many documents, such as US 5,215,528, US 5,201,713, US 4,952,207, and US 4,978,344.

[0007] Several catheters have been developed which include a combination of both a blood-splash seal and a needle guard. However, none of them include a lateral injection port. This is, as explained above, since the presence of such a lateral injection port prevents the addition of a blood-splash seal, and only a needle guard element might be incorporated in such catheters. Other catheters, which do include a blood-splash seal and a needle guard as well as a lateral injection port, are constructed as two separate units that are attached together with a connecting tube, which both increases the overall cost of the catheter and complicates its use by the health practitioner. An example of

such a catheter is the BD NEXIVA™ Closed IV catheter system, by Becton, Dickinson and Company.

[0008] Therefore, there is an unmet need for developing new and simple to use catheter devices that are based on existing catheters having a lateral injection port, which include a blood-splash seal, prevent unintentional backflow of fluids injected through the lateral injection port, and have the possibility of including a needle guard element if desired. Such catheters, based on conversion of existing catheters are also cost efficient and simple to use.

SUMMARY OF INVENTION

[0009] It has now been found, in accordance with the present invention, that the drawbacks of blood splashing and backflow of fluids associated with catheter devices having a lateral injection port, can be overcome by incorporating therein a gate that both prevents blood-splash during needle removal and prevents backflow of fluids injected through the injection port.

[0010] Accordingly, the present invention relates to a catheter device **100** comprising: (a) a connecting means having a front end, a rear end with an infusion port, and a lateral injection port **102**; (b) an injection port cup **103**; (c) a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end; (d) a removable needle unit comprising a hollow needle **201** and a flashback chamber; (e) optionally, a needle guard element **207**; (f) a valve **203** optionally placed within said connecting means underneath the inner side of said lateral injection port **102**; and (g) a gate unit comprising a gate **101** and a handle **105**, placed within, adjacent to or in association with said valve **203**; wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle **201** keeps said gate **101** in an open state and extends through said catheter tube; and (ii) an in-use state, in which said needle guard element **207**, if present, and said removable needle unit are absent, wherein upon removal of said removable needle unit, said catheter device **100** transforms from the pre-use state to the in-use state, wherein said gate **101** becomes a barrier preventing blood from splashing out of said connecting means, and wherein in the in-use state said gate **101** may be rotated or moved from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port **102**, into (ii) an open position that allows fluids to pass

through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port **102**, and *vise-versa*.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] **Figs. 1A-1D** illustrate 2 possible configurations of a catheter according to the invention with a rotational gate in an in-use state: when the rotational gate is in an open position allowing fluids to pass through the infusion port (**Figs. 1A** and **1B**), and when the rotational gate is in a closed position preventing fluids from passing through the infusion port of the catheter (**Figs. 1C** and **1D**). **Figs. 1A** and **1C** are a side-view, and **Figs. 1B** and **1D** are an upper-view.

[0012] **Fig. 2** illustrates a catheter according to the invention in an in-use state when the gate is in a closed position with a syringe attached to the lateral injection port of the catheter, wherein fluids injected by the syringe are blocked from flowing backwards through the infusion port.

[0013] **Figs. 3A-3D** illustrate two configurations of a catheter according to the invention with a gate made of a single rigid material and with a handle. **Figs. 3A** and **3C** show a pre-use state in which the hollow needle holds the gate in an open state, and **Figs. 3B** and **3D** show an intermediate state in which the hollow needle is being extracted while the gate springs into a closed state.

[0014] **Figs. 4A-4C** illustrate another configuration of a catheter according to the invention with a rotational gate made of a single rigid material and a rotational handle. **Fig. 4A** shows a pre-use state in which the hollow needle holds the rotational gate in an open state, **Fig. 4B** shows an intermediate state in which the hollow needle is being extracted while the rotational gate springs into a closed state, and **Fig. 4C** shows an in-use state in which the hollow needle is absent and the rotational gate can be rotated by rotation of the injection port cup.

[0015] **Figs. 5A-5F** illustrate one configuration of a catheter according to the invention with a gate unit adjacent to the valve and underneath the lateral injection port, wherein said gate unit comprises a rotational gate made of a rigid outer ring and an inner-ring area. **Fig. 5A** shows an upper-view of the catheter showing the parts of the valve and the gate unit visible through the injection port. **Fig. 5B** shows a side-view of the same catheter, and **Fig. 5C** is an enlargement of the valve and the gate unit. **Figs.**

5D-5F show a front view of the gate unit in closed (**5D**), partially open (**5E**), and fully open (**5F**) rotation positions.

[0016] **Figs. 6A-6C** illustrate another configuration of a catheter according to the invention in which the gate unit is adjacent to the valve underneath the lateral injection port, and configured to enable the placement of a needle guard element. **Fig. 6A** shows an upper-view, **Fig. 6B** shows a side-view, and **Fig. 6C** is an enlargement of the valve and the gate unit.

[0017] **Figs. 7A-7E** illustrate yet another configuration of a catheter according to the invention with a gate unit which is placed in between two valves underneath the lateral injection port. **Fig. 7A** shows an upper-view of the catheter showing the parts of the valve and the gate unit visible through the injection port. **Fig. 7B** shows a side-view of the catheter, and **Fig. 7C** is an enlargement of the valve(s) and of the gate unit. **Figs. 7D** and **7E** illustrate how the gate unit may be moved forward and backwards during use.

[0018] **Figs. 8A-8B** illustrate one configuration of a gate unit according to the invention comprised of a gate made of a rigid outer ring and an inner-ring area made of two sections of a flexible material: **Fig. 8A** shows the hollow needle passing through said two flexible sections thereby creating a passage hole for the needle, and **Fig. 8B** shows the gate after needle extraction, wherein the two flexible sections merge into a barrier that prevents blood splashing.

[0019] **Figs. 9A-9C** illustrate another configuration of a gate according to the invention comprised of a rigid outer ring and an inner-ring area made of two sections: **Fig. 9A** shows a front-view of the gate in a closed position; **Fig. 9B** shows a side-view of the gate in which the hollow needle keeps the upper section of the inner-ring in an open state; and **Fig. 9C** shows the gate after needle extraction, in which the upper section of the inner-ring sprung into place thereby creating a barrier.

[0020] **Figs. 10A-10B** illustrate front view of one configuration of a gate according to the invention comprised of a rigid ring and an inner-ring area with a dedicated hole for the hollow needle to pass through and a dedicated shutter: **Fig. 10A** shows the shutter in a shifted position that allows the hollow needle to pass through the inner-ring area, and **Fig. 10B** shows the shutter in a closed position that blocks the dedicated hole after needle extraction, thereby creating a barrier.

[0021] **Figs. 11A-11E** illustrate one configuration of a catheter according to the invention with a gate unit having a horizontal gate. **Fig. 11A** shows a side-view of the

catheter, and **Fig. 11B** is an enlargement of a valve, a gate unit, and a solid wall. **Figs. 11C** and **11D** illustrate how the horizontal gate may be moved forward and backwards for enabling or preventing (respectively) fluids from passing through. **Fig. 11E** is a front view of the gate unit showing how the horizontal gate overlaps the solid wall.

[0022] **Figs. 12A-12D** illustrate another configuration of a catheter according to the invention with a gate unit having a vertical gate. **Fig. 12A** shows a side-view of the catheter, and **Fig. 12B** is an enlargement of a valve, the gate unit, and a rail in which the vertical gate moves. **Figs. 12C** and **12D** illustrate how the vertical gate may be lifted or lowered (respectively). **Figs. 12E** and **12F** are a front view of two possible configurations a vertical gate according to the invention, either as a whole circle (**Fig. 12E**) or as a section/part of a circle (**Fig. 12F**), wherein in both cases the rail is adjusted to create a barrier together with the gate.

[0023] **Figs. 13A-13C** illustrate another configuration of a catheter according to the invention in a pre-use state. **Fig. 13A** is an upper view; **Fig. 13B** is a side view; and **Fig. 13C** is an enlargement of the gate unit with the hollow needle passing therethrough and holding the gate open.

[0024] **Figs. 14A-14H** illustrate an in-use state of the catheter of Fig. 13 in a closed position after extraction of the hollow needle. **Fig. 14A** is a 3-dimentional view; **Fig. 14B** is an upper view and **Fig. 14D** is a cut view thereof; **Fig. 14C** is a side-view and **Fig. 14E** is a cut view thereof; **Figs. 14F** and **14G** are enlargements of the gate unit in the in-use state after the removal of the hollow needle; and **Fig. 14H** illustrates how liquid entered from the lateral injection port pushes a valve in the gate unit to thereby enter into the veins of a patient, without flowing backwards through the infusion port.

[0025] **Figs. 15A-15G** illustrate an in-use state of the catheter of Fig. 13 in an open position. **Fig. 15A** is a 3-dimentional view; **Fig. 15B** is an upper view and **Fig. 15D** is a cut view thereof; **Fig. 15C** is a side-view and **Fig. 15E** is a cut view thereof; and **Figs. 15F** and **15G** are enlargements of the gate unit in the open position, also showing possible liquid flow directions.

[0026] **Figs. 16A-16F** illustrate one embodiment of the gate unit of the invention: **Figs. 16A** and **16D** show how a gate is mounted onto the lateral injection port unit prior to its assembly into the connecting means; **Figs. 16B** and **16E** show an assembled gate unit or a gate unit constructed as a single unit; and **Figs. 16C** and **16F** illustrate a cut view of the assembled gate unit.

[0027] **Figs. 17A-17C** illustrate another embodiment of the gate unit of the invention: **Fig. 17A** shows how the gate is mounted onto the lateral injection port unit prior to its assembly into the connecting means; **Fig. 17B** shows the assembled gate unit; and **Fig. 17C** illustrates a cut view of the assembled gate unit.

[0028] **Fig. 18** illustrates an exploded-view of a lateral injection port catheter according to the invention, showing the connecting means, the gate unit and the lateral injection port cup.

[0029] **Figs. 19A-19B** illustrate yet another embodiment of the catheter of the invention having a double gate feature: in a pre-use state (**Fig. 19A**) and in an in-use state at a closed position (**Fig. 19B**).

DETAILED DESCRIPTION OF THE INVENTION

[0030] The present invention provides a safe catheter device with superior properties. More particularly, the present invention provides a catheter device with a lateral injection port which further comprises a gate that both prevents blood-splash during needle extraction as well as prevents backflow of fluids injected through said lateral injection port.

[0031] Specifically, the invention provides a catheter device **100** comprising: (a) a connecting means having a front end, a rear end with an infusion port, and a lateral injection port **102**; (b) an injection port cup **103**; (c) a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end; (d) a removable needle unit comprising a hollow needle **201** and a flashback chamber; (e) optionally, a needle guard element **207**; (f) a valve **203** separating between said lateral injection port **102** and said connecting means, which is optionally placed within said connecting means underneath the inner side of said lateral injection port **102**; and (g) a gate unit comprising a gate **101** and a handle **105**, placed within, adjacent to, or associated-with said valve **203** and optionally associated with said injection port cup **103**; wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, such that said hollow needle **201** keeps said gate **101** in an open state and extends through said catheter tube; and (ii) an in-use state, i.e., when the catheter device **100** is placed in the vein of a patient, in which said needle guard element **207** if present, and said removable needle unit are absent, wherein upon removal of said removable needle unit, said catheter device **100** transforms from the pre-use state to the in-use state, wherein said

gate **101** becomes a barrier preventing blood from splashing out of said connecting means, and wherein in the in-use state said gate **101** may be rotated or moved, e.g., by turning the handle **105**, optionally by turning said injection port's cup **103**, from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port **102**, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port **102**, and *vise-versa*.

[0032] It should be noted that the valve **203** mentioned herein refers to a valve which is made of any suitable material that enables preventing fluids from passing outwardly through the lateral injection port, while enabling fluids to pass inwardly through the lateral injection port. Non-limiting examples of such materials are silicon, rubber, polyethylene, plastic, etc.

[0033] The catheter device **100** according to the present invention may have various lengths and sizes (gouge), depending on the designated use of such a catheter. For instance, when intended to be used in an adult, a smaller gouge catheter is to be used, and when intended to be used in a child or an infant, a higher gouge catheter is to be used. Exemplary gouge possibilities of the catheter device **100** of the invention are 14G, 16G, 18G, 20G, 22G, and 24G. The size of the gate unit and the gate **101** therein are adapted to the size of the catheter device **100**.

[0034] The connecting means of the catheter device **100** according to the invention may comprise external wings for ease of insertion and subsequent fixation to the patient's body, or may not comprise any such wings. In a specific embodiment, the catheter device **100** according to the invention might not comprise a lateral injection port **102**, in which case said catheter device **100** may not comprise a valve **203**.

[0035] The gate unit of the invention and the gate **101** therein may be made of any suitable material, preferably medical graded material. The term "medical graded material" as used herein refers to any biocompatible material, rigid or flexible, which can be sterilized by any suitable procedure/technique. In certain embodiments, the gate unit of the invention, the gate **101**, and any other component therein, are made of stainless steel, e.g., stainless steel 304, 304L, 316 or 316L; titanium or a titanium alloy, e.g., Ti-6Al-7Nb or nickel-titanium (nitinol); plastic; polyethylene; silicon; or rubber, or any combination thereon.

[0036] After production and assembly of the catheter device **100** of the invention it is preferably packed in a sealed and sterilized package until use.

[0037] In a specific embodiment, the catheter device **100** of the invention comprises a needle guard element **207**. In certain embodiments, said needle guard element **207** is placed within said connecting means or attached to said removable needle unit. Non limiting examples of such needle guard elements can be found in, e.g., US 5,215,528 and US 4,978,344, respectively. In a specific embodiment, when said needle guard element **207**, is present in the catheter device **100** of the invention, it is placed within, and at the rear end of, said connecting means, and is removed from the catheter device **100** upon removal of said removable needle unit.

[0038] In certain embodiments, the gate **101** according to the invention may have a flat or curved shape. In specific embodiments, the gate **101** has a curved shape, such as an S-, bell-, arc-, or wavy-shape. The term curved refers to any shape that is not completely flat, including protrusions and bumps therein. The overall shape of the gate **101** according to the invention may be round, orbital, sphere, partially round, arced, or any other suitable shape. In certain embodiments, said gate **101** may be in any shape and size, such as round, square or half-circle, and may be complete or with a niche or hole suited for enabling passage of the hollow needle **201**. In a specific embodiment, said gate **101** is a flat circle, as exemplified in, e.g., Fig. 1 and Fig. 5, or has another flat shape, as exemplified in, e.g. Fig. 11E and Fig. 12F.

[0039] In certain embodiments, the handle **105** of the catheter device **100** of the invention is not associated with said injection port cup **103** in the pre-use state said, and in the in-use state said handle **105** interlocks with said injection port cup **103**. In this configuration, the handle is attached or is part of the gate **101** and moves together with the gate **101**, e.g., when transforming from the pre-use state to the in-use state.

[0040] In other embodiments, said handle **105** is not attached or is not part of said gate **101**, and upon removal of said removable needle unit and the transformation from the pre-use state to the in-use state, said handle **105** interlocks with said gate **101**, thereby enabling moving or rotating said gate **101** when rotating said handle **105**, by rotating said injection port cup **103**.

[0041] In a specific embodiment, said handle **105** interlocks with said injection port cup **103** in both the pre-use and the in-use states. In this configuration, the handle **105** is interlocked with said injection port cup **103** already in the pre-use state, and the removal of said removable needle unit enables to move said gate **101** when rotating said injection port cup **103** which is interlocked with said handle **105**.

[0042] In another specific embodiment, said handle **105** and said injection port cup **103** are not interlocked, and are independent from one another. In this configuration, said handle **105** is associated, optionally directly, with said gate **101** in both the pre-use and the in-use states, such that in the in-use state said gate **101** can be moved/rotated by simply rotating said handle **105**.

[0043] In certain embodiments, the gate **101** in the gate unit of the catheter device **100** of the invention is rotational, capable of axial rotation; horizontal, capable of moving forwards and backwards; or vertical, capable of moving up and down. As explained above, in the in-use state said gate **101** is associated with said handle **105** which is associated with said injection port cup **103** optionally *via* a designated structure **104**, and rotation of said injection port cup **103** would inherently lead to the turning of the gate **101** (e.g. Fig. 5), moving it forward and/or backwards (e.g. Fig 11), or lifting it up and down (e.g. Fig. 12), depending on the type of gate being used. Alternatively, in the in-use state said gate **101** is directly associated with said handle **105**, and rotation of said handle **105** directly leads to the turning of the gate **101** (e.g. Figs. 13-18).

[0044] In certain embodiments, the gate **101**, vertical, horizontal or rotational, may be made of any suitable material, such as rigid material like plastic, polyethylene, silicon, rubber, metal, or metal alloy, or any combination thereof. In a specific embodiment, said gate **101** is made of two, three, four or more components each made from the same or different material. Such components may include said handle **105**, and a shutter **306**.

[0045] In an alternative embodiment, the gate **101** is made of a rigid outer-ring **300** and an inner-ring area **301**, each made of any suitable material. In certain embodiments, said outer ring **300** and said inner ring area **301** are made from the same material, such as silicon, rubber, metal, metal alloy, plastic, polyethylene; or any combination thereof. Alternatively, said outer ring **300** and said inner ring area **301** are made from two, three, four or more different materials. For instance, said rigid outer ring **300** may be made from rigid plastic and said inner-ring area **301** may be made from silicon, rubber or any combination thereof. Alternatively, both the outer-ring **300** and the inner-ring area **301** may be made from polycarbonate, polyethylene, metal, silicon, rubber, or any combination thereof.

[0046] In a specific embodiment, said gate **101** is vertical and is made of a single rigid material. In another embodiment, said gate **101** is vertical and is made of a rigid outer-ring and an inner-ring area. In one embodiment, when the said gate **101** is vertical,

said gate unit further comprises at least one rail **108** designed to fit and hold said gate **101** while enabling it to slide up and down therein.

[0047] Said at least one rail **108** is adapted to receive and retain said vertical gate **101** and may be located either at the bottom of the gate unit, at the two side walls of the gate unit, or both, e.g. in a U-shaped arrangement. Examples of a suitable rail **108** comprise any combination of cavities, channels, recesses, grooves, tracks, ledge & depression, etc. The rail **108** may be created during the preparation of the gate unit. In a specific embodiment, if the gate unit is absent, said rail **108** may be constructed as part of said connecting means.

[0048] In a specific embodiment, when the gate **101** is vertical, in the pre-use state said hollow needle **201** prevents said gate **101** from closing, i.e. keeping it lifted and leaning on said hollow needle **201** which prevents said gate **101** from moving down, and upon removal of said removable needle unit, the gate **101** springs down, optionally by a spring mechanism located in the gate unit, within said at least one rail thereby creating a barrier that prevents blood splashing. Said spring mechanism is designed to push said gate **101** down upon the removal of the hollow needle **201** holding said gate **101** up to thereby create a barrier that prevent blood splash. In certain embodiments, once said gate **101** has sprung down, it interlocks with said injection port cup **103**, optionally via said handle **105** and said designated structure **104**, thereby enabling lifting and lowering said gate **101** when rotating either said injection port cup **103** or said handle **105** directly. Alternatively, said handle **105** is interlocked with said injection port cup **103**, even before the removal of said removable needle unit, and upon the removal of said removable needle unit the gate **101** can be lifted and lowered by rotating said injection port cup **103**. This lifting and lowering of said vertical gate **101** by twisting said injection port cup **103** is achieved, e.g., by using an elliptical-shaped cup **103**, an elliptical-shaped inner part of said cup **103**, or by using a screw-like mechanism/engraving on said handle **105** and in said designated structure **104**, within said cup **103**, or by any other configuration that allows transferring the rotational movement of said injection port cup **103** or said handle **105** into a horizontal movement of said gate **101**.

[0049] In specific embodiments, said gate **101** is vertical and is made of flexible material. In other specific embodiments, said gate **101** is vertical and is made of outer ring **300** and an inner ring area **301**, said inner ring area **301** is made of flexible material. In specific embodiments, in the pre-use state, said hollow needle **201** keeps

said gate **101** open by passing through said flexible material, and upon removal of said removable needle unit said flexible material becomes sealed and transforms said gate **101** into a barrier that prevents blood splashing. In this context, said flexible material is any material that strives to return to its original form, and upon the removal of obstacles, such as the hollow needle **201**, returns to its original shape to create a barrier that prevents blood and fluids from passing therethrough. Examples for such materials are silicon and rubber.

[0050] In another specific embodiment, said hollow needle **201** keeps said gate **101** in an open state by preventing said gate from sliding all the way down. Only upon the removal of said removable needle unit said gate **101** is released and slides down to create the barrier, while said handle **105** optionally interlocks with said injection port cup **103**. Alternatively, said gate **101** is comprised of at least two sections, and said hollow needle **201** keeps at least one of said at least two sections uplifted, optionally overlapping with the other sections or bend (Fig. 9), and upon removal of said removable needle unit, said uplifted or bent section aligns with said other sections to form a barrier. After said alignment and formation of said barrier, said gate **101** can be lifted and lowered by rotating said injection port cup **103** or by directly rotating said handle **105**.

[0051] In a specific embodiment, the present invention provides a catheter device **100**, comprising: (a) a connecting means having a front end, a rear end with an infusion port, and a lateral injection port **102**; (b) an injection port cup **103**; (c) a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end; (d) a removable needle unit comprising a hollow needle **201** and a flashback chamber; (e) a needle guard element **207**; (f) a valve **203** having a front end and a rear end, placed within said connecting means underneath the inner side of said lateral injection port **102**; and (g) a gate unit placed adjacent to said valve **203**, said gate unit comprising a flat-circle shaped vertical gate **101** made of a single rigid material, a handle **105** attached to said gate **101**, and a rail **108** designed to fit and hold said gate **101** while enabling it to slide up and down therein, wherein said catheter device **100** has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle **201** keeps said vertical gate **101** in an open state by keeping said vertical gate **101** lifted and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element **207**, are absent, wherein upon removal of said removable needle

unit, said catheter device **100** transforms from the pre-use state to the in-use state, wherein said vertical gate **101** slides or springs down within said rail **108**, and becomes a barrier preventing blood from splashing out of said connecting means, and wherein in the in-use state said vertical gate **101** can be lifted from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port **102**, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port **102**, and *vice versa*.

[0052] In a specific embodiment, said gate **101** is horizontal or rotational, and is made of a single rigid material. In another embodiment, said gate **101** is horizontal or rotational and is made of a rigid outer-ring and an inner-ring area. In a specific embodiment of the invention, in the in-use state of the catheter device **100** of the invention said rigid outer-ring is movable together with said inner-ring area.

[0053] In another specific embodiment, said gate **101** is made of a flexible material. In another specific embodiment, said inner-ring area **301** of said gate is made of a flexible material. Accordingly, in the pre-use state, said hollow needle **201** keeps said gate **101** open by passing through said flexible material, and upon removal of said removable needle unit said flexible material becomes sealed and transforms said gate **101** into a barrier that prevents blood splashing. In this context, and as detailed above, said flexible material is any material that strives to return to its original form, and upon the removal the hollow needle **201**, returns to its original shape to create a barrier that prevents blood and other fluids from passing. Non-limiting examples of such flexible materials are silicon and rubber.

[0054] In certain embodiments, at least part of said gate **101** in the catheter device **100** of the invention is movable. In other embodiments, at least part of said inner-ring area **301** of said gate is movable. In these configurations, in the pre-use state said hollow needle **201** passes through said movable part of said gate, and upon removal of said removable needle unit said movable part moves thereby transforming said gate **101** into a barrier that prevents blood splashing.

[0055] In a specific embodiment, in the pre-use state said movable part allows said hollow needle **201** to pass through said gate **101**, either by revealing an opening or a dedicated passage in said gate for said hollow needle to pass through, or by enabling said hollow needle **201** to squeeze through. In either case, upon the removal of said

removable needle unit, said movable part moves, shifts, slides, or springs to block said opening or dedicated passage, to thereby create a barrier that prevents blood splashing.

[0056] In certain embodiments, in the pre-use state of the catheter device **100** of the invention, said hollow needle **201** keeps said gate **101** in a parallel position, i.e. pressed against the inner wall of said gate unit or said connecting means or said valve, and upon removal of said removable needle unit said gate **101** springs to an upright position, e.g., by a dedicated spring **106** or using a shape-memory material (desiring to return to its original shape), thereby creating a barrier that prevents blood splashing immediately when said hollow needle **201** passes said gate **101**, i.e. stop pressing it against said inner wall. When said gate **101** springs to an upright position it may interlock with a dedicated nudge, bump or groove in the opposite wall, to affix said gate **101** in place or to assist in bringing said gate into the proper upright position that enables movement of said gate **101**, or it may remain in place mainly by the liquid pressure and/or the properties of said shape-memory material. In such a case, said gate **101** may further comprise a nudge, bump or groove that interlocks with said dedicated nudge, bump or groove located in the opposite wall.

[0057] In certain embodiments, when the gate **101** is in an upright position, i.e. after placement of the catheter device **100** inside a patient's vein and after removal of the removable needle unit, said gate **101** may interlock with said injection port cup **103**, e.g., via said handle **105**, thereby enabling rotating said rotational gate (see Fig. 5) or moving said horizontal gate (see Fig. 11) forwards/backwards when rotating said injection port cup **103**. Said rotating or moving of the gate is enabled due to special configuration of said injection port cup **103** and/or of said handle **105**. Non-limiting examples of said configurations are an oval injection port cup **103**, an oval-shaped handle **105**, a unique channel in said injection port cup **103** in which said handle moves along when turning said cup, a leaver-shaped handle (⌙), etc. Alternatively, said gate **101** is associated with said handle **105**, which is an external handle, thereby enabling rotating said rotational gate **101** (see Figs. 14 and 15) by simply twisting / rotating said handle **105**.

[0058] In certain embodiments, when the catheter device **100** of the invention comprises a gate unit with a horizontal gate, said gate unit or optionally said connecting means may further comprise a solid wall **107** within, which together with said horizontal gate **101**, when in an upright position after the removal of said removable

needle unit at the in-use state and at the closed position, creates a barrier that prevents blood splashing. Such a solid wall **107** may be made of any suitable material and may be constructed to be of any desired height, width, shape and size. For instance, said solid wall **107** may be located solely at the bottom of said gate unit or may have additional side walls. In any configuration involving such a solid wall **107**, said horizontal gate **101** and said solid wall **107** are configured to fit one another in the closed position to create a barrier that prevents blood splashing during the removal of the hollow needle **201**, while in the open position said gate **101** is located away from said solid wall **107** thereby enabling passage of fluids (see Fig. 11).

[0059] In a specific embodiment, said gate unit of the catheter device **100** of the invention comprises a rotational gate **101** made of a rigid outer ring **300** and an inner ring area **301**, wherein in the in-use state said rigid outer-ring **300** is affixed, and said inner-ring area **301** interlocks with said injection port cup **103** via said handle **105**, wherein said rigid outer-ring **300** does not rotate together with said inner-ring area **301**. In a more specific embodiment, in the pre-use state said hollow needle **201** keeps said rotational gate **101** in an open state by keeping said gate **101** in a parallel position, i.e. pressed against the inner wall of said gate unit, and upon removal of said removable needle unit said gate **101** springs to an upright position, e.g., by a dedicated spring **106**, thereby affixing said rigid outer ring **300** in place creating a barrier that prevents blood splashing.

[0060] In another specific embodiment, said gate unit comprises a rotational gate **101** made of a rigid outer ring **300** and an inner ring area **301**, wherein in the pre-use said gate is already in an upright position and said handle **105** is optionally interlocked with said injection port cup **103**. In this configuration, said hollow needle **201** passes through said inner-ring area **301** of the gate, thereby keeping said gate **101** open, and upon removal of said removable needle unit, said gate **101** transforms into a barrier that prevents blood splashing.

[0061] In a specific embodiment, when the gate **101** is a rotational gate made of a rigid outer ring **300** and an inner ring area **301**, in the in-use state, i.e. after placing the catheter **100** of the invention in a patient's vein and removing said removable needle unit, said inner-ring area **301** of said gate can be rotated by rotation of said injection port cup **103**, from an open position to a closed position, and *vice versa*.

[0062] In a specific embodiment the present invention provides a catheter device **100** comprising: (a) a connecting means having a front end, a rear end with an infusion

port, and a lateral injection port **102**; (b) an injection port cup **103**; (c) a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end; (d) a removable needle unit comprising a hollow needle **201** and a flashback chamber; (e) a needle guard element **207**; (f) a valve **203** having a front end and a rear end, placed within said connecting means underneath the inner side of said lateral injection port **102**; and (g) a gate unit placed adjacent to said valve **203**, said gate unit comprising a flat-shaped rotational gate made of a single rigid material, and a handle **105**; wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle **201** keeps said rotational gate **101** in an open state by keeping said rotational gate **101** in a parallel position, and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element **207** are absent, wherein upon removal of said removable needle unit, said catheter device **100** transforms from the pre-use state to the in-use state, wherein said rotational gate **101** springs to an upright position and becomes a barrier preventing blood from splashing out of said connecting means, and wherein in the in-use state said rotational gate **101** interlocks with said injection port cup **103** thereby enabling rotation of said gate **101**, e.g., by turning the injection port's cup **103**, from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port **102**, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port **102**, and *vice versa*.

[0063] In another specific embodiment, the present invention provides a catheter device **100** comprising: (a) a connecting means having a front end, a rear end with an infusion port, and a lateral injection port **102**; (b) an injection port cup **103**; (c) a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end; (d) a removable needle unit comprising a hollow needle **201** and a flashback chamber; (e) a needle guard element **207**; (f) a valve **203** having a front end and a rear end, placed within said connecting means underneath the inner side of said lateral injection port **102**; and (g) a gate unit placed adjacent to said valve **203**, said gate unit comprising a flat-shaped rotational gate made of an outer rigid ring **300** and an inner-ring area **301** and a handle **105**; wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle **201** keeps said rotational gate **101** in an open

state by passing through said inner-ring area **301** of said rotational gate, and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element **207** are absent, wherein upon removal of said removable needle unit, said catheter device **100** transforms from the pre-use state to the in-use state, wherein said rotational gate **101** becomes sealed and transforms into a barrier that prevents blood from splashing out of said connecting means, and wherein in the in-use state said inner-ring area **301** of said rotational gate interlocks with said injection port cup **103** thereby enabling rotation of said inner-ring area **301** from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port **102**, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port **102**, and *vice versa*.

[0064] In certain embodiments, when the catheter device **100** of the invention is in the in-use state and in the closed position, said gate **101** presses the rear end of said valve **203**, thereby directing fluids injected through said lateral injection port **102** towards said catheter tube while preventing said fluids from flowing backwards through said infusion port.

[0065] In certain embodiments, when the catheter device **100** of the invention is in the pre-use state, said hollow needle **201** passes through either said gate **101** when it is made of a single rigid material, or through said inner-ring area **301** when said gate is made of an outer rigid ring **300** and an inner-ring area **301**, thereby keeping said gate **101** in an open position. This open position can be obtained, e.g., by keeping a part of said gate or inner ring area tilted, shifted or partially open, and after removal of said removable needle unit, said tilted or shifted part **304**,**306** returns, moves, slides or springs into place thereby transforming said gate **101** into a barrier that prevents blood splashing upon removal of said removable needle unit. Said tilted or shifted part **301**,**304**,**306** may comprise a spring mechanism designed to push said shifted part of the gate **101** into place upon the removal of said hollow needle **201** to thereby create a barrier that prevent blood splash.

[0066] In certain embodiments, the gate **101** is made of a rigid outer-ring **300** and an inner-ring area **301**, and at least part of said inner-ring area **301** is movable and/or rotatable. For instance, an example in which the entire inner part **301** is rotatable is exemplified in Figs. 5D-5F; an example in which about half of said inner-ring area **304** is tilted is exemplified in Fig. 9; and an example in which a small part **306** of said inner

ring area is movable/shiftable is exemplified in Fig. 10. In such cases, i.e. when a part of said inner-ring area **301** is movable, said movable part is designed to enable passageway for the hollow needle **201** when the catheter device **100** is in the pre-use state, whereas immediately upon removal of said removable needle unit said movable part moves/shifts to block said passageway to create a barrier that prevent blood splash. In certain embodiments, said inner-ring area **301** and said movable part thereof **304,306** are made of the same material or from two different materials. Examples for such materials are plastic, silicon, rubber, metal, alloys, polyethylene, etc.

[0067] In certain embodiments, when the gate **101** comprises a rigid outer-ring **300** and an inner-ring area **301**, said rigid outer-ring **300** may be either fixed or movable and said inner-ring area **301** may be made of flexible material, such as silicon. Alternatively, both said outer ring **300** and said inner ring area **301** can be moved together in the in-use state by rotating said injection port cup **103**.

[0068] In certain embodiments, when the catheter device **100** of the invention transforms into the in-use state, i.e. immediately after placement of the catheter device **100** in the vein of a patient and the removal of said removable needle unit, said gate **101** becomes a barrier that prevents blood from splashing out of the connecting means. As explained above, in the in-use state, said gate **101** has two main positions, each with its own functions: (i) an open position which allows fluids to pass through said infusion port and into the vein of the patient, and (ii) a closed position that prevents fluids from passing through the infusion port into the vein of the patient. In this closed position, the gate **101** has an additional function, i.e., preventing the backflow of fluids which are injected via the lateral injection port **102**, thereby enabling directing all the fluids injected through said lateral injection port **102** directly towards said catheter tube and into the vein of the patient without unintentional loss of fluids due to backflow into the infusion tube or infusion set. In addition, as mentioned above, said gate **101** may be rotated, moved or lifted from said (i) closed position into said (ii) open position, and *vise-versa*. Such rotating, moving or lifting of said gate **101** is carried out by turning or moving said handle **105**, either directly or by twisting said cup **103**.

[0069] In a specific embodiment, the present invention provides a catheter device **100** comprising an optional needle guard element **207**, and a gate unit which comprises also said lateral injection port **102** and said valve **203**, wherein said gate unit is designed such that it can be assembled onto said connecting means, wherein said valve **203** is positioned in between said lateral injection port **102** and said gate **101** (Figs. 14-18),

such that it prevents liquid from exiting outwardly through said lateral injection port **102** while enabling inwardly flow of liquids that are injected into said lateral injection port **102**. As noted above, in certain embodiments, said valve **203** can be made of any suitable flexible-rigid material such as, but not limited to silicon, polyethylene and rubber.

[0070] In a more specific embodiment, said gate unit comprising said gate **101**, said handle **105**, said lateral injection port **102** and said valve **203**, is designed to be assembled, permanently or reversibly, onto said connecting means (see illustration in Fig. 18). In another specific embodiment, the gate unit further comprises at least one sealing means, such as a rubber or silicon ring to thereby enable sealing the connection between said gate unit and said connecting means. When assembled, the external borderlines **500** of the gate unit, located within said connecting means, are designed such that they enable complete sealing between the gate unit and the inner walls of said connecting means, such that when the catheter is in an in-use state in a closed position, no fluid can pass therethrough from or to the infusion port.

[0071] It should be noted that the gate unit may be fabricated in any known technique, such as 3-dimentional printing, injection molding, press molding, etc.; from any suitable material(s), such as plastic, polycarbonate, polyethylene, rubber, silicon, or any combination thereof, and can be constructed as a single unit comprising all components as a whole (e.g. Fig. 18), or from several components that are assembled together (as illustrated in Figs. 16A, 16D and 17A), wherein the different components may be made from the same or different material. For instance, the entire gate unit may be made of polyethylene while only the gate **101** is made of silicon.

[0072] Specific, non-limiting, embodiments of the invention will now be illustrated with reference to the accompanying figures.

[0073] Fig. 1 describes one possible example of a catheter device **100** according to the invention in an in-use state, from two viewing angles: a side cross section and an upper view. As illustrated in this figure, the catheter device **100** comprises a spring mechanism **106** located at the lower part of the connecting means, which also indicates how such a spring mechanism **106** may be located at the lower part of the gate unit. Figs. 1A and 1B show the catheter device **100** with a rotational gate **101** in an open position that allows fluids to pass through the infusion port and into the vein of a patient. Figs. 1C and 1D show the catheter device **100** with a rotational gate **101** in a closed position that prevents fluids from passing through the infusion port of the

catheter into the vein of the patient. In order to shift from the open position to the closed position, the lateral injection port cup **103** needs to be turned or rotated. This cup **103** is associated with the gate **101** through a dedicated structure **104** that interlocks with the handle **105** of the gate. Examples of such an interaction may be a cross-shaped protrusion at the tip of the handle **105** which fits into a cross-shaped frame in the lateral injection port cup **103** or in said dedicated structure **104** therein. This configuration enables the opening and closing of the lateral injection port cup **103** while maintaining the ability to turn the gate **101** when turning the cup **103**, even after opening and closing it several times.

[0074] Fig. 2 illustrates one possible example of a catheter device **100** according to the invention in an in-use state with a gate **101** in a closed position, wherein said gate **101**, in addition to its function of preventing fluids from passing through the infusion port, also prevents fluids injected by a syringe **200** through the lateral injection port **102** to backflow and forces said fluids to flow only towards the vein of the patient. It should be noted that although in Fig. 2 the gate **101** is positioned at about the middle of the opening of the lateral injection port **102**, it may be positioned at any point therein. In addition, as seen in Fig. 2, the inner opening of said lateral injection port **102** may comprise a rigid extension of the connecting means, which together with the gate **101** in a closed position, creates a blockade that prevents the fluids injected through said lateral injection port **102** to backflow and directs their flow forward- towards the catheter tube and into the vein of the patient.

[0075] Fig. 3 illustrates two configurations of a catheter device **100** according to the invention with a gate **101** having a handle **105** and attached to the inner side of the lateral injection port **102** via a spring mechanism **106**. This figure illustrates two possible forms of the handle **105**: A fixed upright handle (Figs. 3A and 3B) and a handle that moves together with the gate (Figs. 3C and 3D). The dedicated structure **104** within the lateral injection port cup **103** is designed according to each handle in terms of length and shape. Fig. 3A and Fig. 3C show two possibilities of said handle **105**: either a long one (Fig. 3A) or a short one (Fog. 3C). The injection port cup **103** is constructed in accordance with the length of the handle **105**. Fig. 3A and Fig. 3C show a pre-use state in which the hollow needle **201** holds the gate **101** in an open state, whereas Figs. 3B and 3D show an intermediate state in which the hollow needle **201** is being extracted from the catheter device **100** and upon passing the edge of the gate **101**, it is released and springs into a closed state. As seen in this figure, the spring mechanism **106** is

located at the upper part of the connecting means, specifically at the opening of the lateral injection port **102**, which further indicates how such a spring mechanism **106** may be located at the upper part of the gate unit.

[0076] Fig. 4 illustrates another configuration of a catheter device **100** according to the invention with a rotational gate **101** made of a single rigid material and a rotation handle **105** which is designed to associate with the dedicated structure **104** within the injection port cup **103** to enable rotation of said gate **101** upon rotation of said cup **103**. The spring mechanism **103** is attached to the lower part of the connecting means, which also indicates how such a spring mechanism **106** may be located at the lower part of the gate unit. Fig. 4A shows a pre-use state in which the needle guard element **207** is present in the device **100** and the hollow needle **201** holds the gate **101** in an open state; Fig. 4B shows an intermediate state in which the hollow needle **201** is being extracted after penetrating the patient's vein wherein said guard element **207** is locked onto the tip of said hollow needle **201**, while the rotational gate **101** springs into a closed state and interlocks with the rotation handle **105**; and Fig. 4C shows an in-use state in which the hollow needle **201** together with the needle guard element **207** are absent and the rotational gate **101** can be rotated by rotation of the injection port cup **103**. As illustrated in the figures, the rotation of said gate **101** may be at any angle in the range of 25° to 300°, such as 30°, 45°, 60°, 75°, 90°, 105°, 120°, 145°, 180°, 210°, 270°, or 360°, or any angle in between.

[0077] It should be noted that although the figures illustrate that the rotation and/or movement of the gate **101** is carried out by rotation of the injection port cup **103**, said gate **101** may be rotated and/or moved by any other suitable alternative means, such as an external handle or knob.

[0078] Fig. 5 illustrates one configuration of a catheter device **100** according to the invention comprising a gate unit **204** placed within said device adjacent to the valve **203** and underneath the opening of the lateral injection port **102**, wherein the rotational gate **101** of said gate unit **204** comprises a rigid outer ring **300** and an inner-ring area **301**. Fig. 5A shows an upper-view of the catheter device **100** showing the sections of said valve **203** and said gate unit **204** which are visible through the injection port's opening. Fig. 5B shows a side-view of the same catheter device **100**, and Fig. 5C is an enlargement of the valve **203** and the gate unit **204**.

[0079] Figs. 5D-5F illustrate a front view of a gate **101** according to the invention having an outer rigid ring **300** and an inner-ring area **301**, in closed (Fig. 5D), partially open (Fig. 5E), and fully open (Fig. 5F) rotation positions.

[0080] Fig. 6 illustrated yet another configuration of a catheter device **100** according to the invention in which the gate unit **204** adjacent to the valve **203** underneath the opening of said lateral injection port **102**, is configured to enable the placement of a needle guard element **207** in a designated cavity or engraving **205**.

[0081] Fig. 7 illustrates another configuration of a catheter device **100** according to the invention with a gate unit **204** which is placed in between two valves **203** underneath the lateral injection port. Figs. 7D and 7E demonstrate how the gate unit **204** can be moved forward or backwards according to the desired immediate use. For instance, when dripping liquids through the infusion port, the gate unit **204** is moved forward and the rotational gate **101** is rotated into an open position to allow flow of fluids. On the other hand, when liquids are to be inserted through the lateral injection port **102**, the rotational gate **101** is rotated into a closed position to prevent flow of fluids through the infusion port, and the gate unit **204** is moved backwards to block any possible backflow of liquids injected through said lateral injection port **102**.

[0082] Fig. 8 is a front view illustration of one configuration of a gate unit **204** according to the invention which comprises a gate **101** made of a rigid outer ring **300** and an inner-ring area **301**, when said inner-ring area **301** is made of two halves of a flexible material. Fig. 8A shows the hollow needle **201** passing through said two flexible sections by creating a passage hole, and Fig. 8B shows the gate unit **204** after needle extraction, wherein the two flexible halves of the inner ring area **301** merge together to form a barrier that prevents blood splashing. It should be noted that although Fig. 8 illustrates an inner ring area **301** composed of two halves, the invention includes any possible configuration of said inner ring area **301**, e.g. composed of one complete part, or three-, four-, five-, etc. parts. Non-limiting examples of material from which said inner ring area **301** is made of are silicon and rubber.

[0083] Fig. 9 illustrates yet another configuration of a gate **101** according to the invention comprised of a rigid outer ring **300** and an inner-ring area made of two sections **303**,**304**, which might be identical halves or uneven sections. Fig. 9A shows a front-view of the gate **101** in a closed position, Fig. 9B shows a side-view of the gate **101** in which the hollow needle **201** keeps the upper section **304** of said inner-ring in an open state; and Fig. 9C shows the gate **101** after needle extraction, which releases the

upper section **304** of said inner-ring area and allows it to sprung into place to thereby create a barrier that prevents blood splash. Notably, although Fig. 9 describes a gate **101** in which the upper section **304** of the inner ring area is being kept open by the hollow needle **201**, the lower section **303** of the inner ring area may be kept open by the hollow needle **201**, or the two sections may be in a right/left orientation instead of an up/down orientation as illustrated in Fig. 9.

[0084] Fig. 10 illustrates a front view of one additional configuration of a gate **101** according to the invention comprised of a rigid ring **300** and an inner-ring area **301** having a dedicated hole **302** for the hollow needle to pass through and a dedicated shutter **306** that can close said hole **302** once the hollow needle is extracted. Fig. 10A shows the shutter **306** when shifted to allow the hollow needle to pass through said **302** in said inner-ring area **301**, and Fig. 10B shows said shutter **306**, after needle removal, in a closed position that blocks said hole **302** and thus creates a barrier that blocks blood splash.

[0085] Fig. 11 illustrates another configuration of a catheter device **100** according to the invention comprising a gate unit **204** having a horizontal gate **101**. Figs. 11C and 11D illustrate how the horizontal gate **101** may be moved (i) forward (Fig. 11C) for enabling fluids to pass from the infusion port, or (ii) backwards (Fig. 11D) for preventing such fluids flow from the infusion port, while further assisting in preventing back flow of fluids injected through the lateral injection port **102**. Fig. 11E is a front view of said horizontal gate **101** showing one possibility of how it overlaps the solid wall **107** to prevent fluids flow. The solid wall **107** may be in any shape, size and height as long as it enables passage of fluids when the horizontal gate **101** is moved forward, wherein the gate **101** is configured to fit said solid wall **107** so that when moved backwards it creates, together with said solid wall **107** a barrier that prevents floe of fluids.

[0086] Fig. 12 illustrates yet another configuration of a catheter device **100** according to the invention comprising a gate unit **204** having a vertical gate **101**. Fig. 12C illustrates how the vertical gate **101** may be lifted to enable passage of fluids from the infusion port, and Fig. 12D illustrates the vertical gate **101** in a lowered position that prevents such fluids flow from the infusion port, while assisting in preventing back flow of fluids injected through the lateral injection port **102**. Figs. 12E and 12F are a front view of two possible configurations of such a vertical gate **101** of the invention, either as a whole circle (Fig. 12E) or as a part of a circle (Fig. 12F). The gate unit **204** may

further comprise a rail **108** in which the gate **101** slides or moves, said rail **108** is configured to create, together with said gate **101**, a barrier that prevents flow of fluids.

[0087] In the pre-use state, such a vertical gate **101** may be positioned in a lifted position to enable passage of said hollow needle **201** while optionally being pressed down against said needle **201** by, e.g., a spring. Accordingly, upon removal of the removable needle unit said vertical gate **101** springs or slides down to create a barrier to prevent blood splash. Alternatively, and as illustrated in Fig. 12F, said vertical gate **101** has a shape that on its own is not capable of creating full barrier, and thus the gate unit **204** further comprises a dedicated wall **108** that together with the vertical gate **101** creates a barrier after the removal of the hollow needle **201**.

[0088] In another configuration, said vertical gate **101** may be comprised of two overlapping parts wherein in the pre-use state, such one of said parts is lifted and overlaps the other part to enable passage of said hollow needle **201** while optionally being pressed down against said needle **201** by, e.g., a spring. Accordingly, upon removal of the removable needle unit said overlapping part of the vertical gate **101** springs or slides down to create a complete and barrier that prevents blood splash. In either case, in the in-use state, the vertical gate **101** may be lifted and lowered by simply turning the injection port cup **103** as needed.

[0089] Fig. 13 illustrates one configuration of a catheter device **100** according to the invention with a gate **101** having a handle **105** positioned outside the lateral injection port. Fig. 13 shows a pre-use state in which the hollow needle **201** holds the gate **101** in an open state, whereas Fig. 14 shows an in-use state in which the hollow needle **201** has been extracted and the gate **101** springs down into a closed position thereby preventing blood splash as the hollow needle **201** is extracted. In certain embodiments, said gate **101** springs down and optionally irreversibly interlocks in place, i.e. cannot be lifted back up. In this in-use state, fluids cannot pass from the infusion bag into the patient's body (Figs. 14F and 14G). However, fluids that are injected via the lateral injection port **102** can pass directly into the patient's body without the risk of back-flowing towards the infusion bag (Fig. 14G). The passage of fluids via said lateral injection port **102** into the patient's body is possible thanks to a valve **203** positioned between said lateral injection port **102** and the connecting means, which bends/moves under the pressure of the injected fluids (Fig. 14H), i.e. when the liquid is injected it is pushed/pressed against said valve **203** at a force that can push it aside and let the fluid pass.

[0090] Fig. 15 illustrates the same catheter as in Figs. 13 and 14, but in an in-use state and in an open position, which allows fluids to from the infusion bag into the patient's body (Fig. 15F). It should be noted that even in this open position, fluids can still be injected via the lateral injection post **102** if so desired.

[0091] Figs. 16-18 illustrate a specific embodiment of the gate unit according to the invention. The gate unit as illustrated constitutes a part of the lateral injection port **102** with an external handle **105**. In this configuration, the gate unit is assembled into the connecting means, e.g. via a screw mechanism or clip-on, such that the dedicated hole **302** and the gate **101** are positioned in the center of the fluids passage way within the connecting means. After assembly, the hollow needle **201** is inserted into the catheter **100**, pushes the gate **101** upwards to thereby bring the catheter **100** into its pre-use state.

[0092] Fig. 19 illustrates yet another embodiment of the catheter **100** of the invention, which comprises in addition to the standard gate **100** an additional supplementary gate **101'** covering the designated hole **302** from its other side to thereby provide additional percussion measures of preventing fluids from passing through the gate unit when it is in an in-use state at the closed position. As seen in Fig. 19A, when in the pre-use state, the hollow needle **201** keeps both the gate **101** and the supplementary gate **101'** lifted. Once the hollow needle **201** is extracted, the gate **101** and the supplementary gate **101'** drop / spring down, and are optionally irreversibly secured into place, to thereby prevent, when in a closed position, passage of fluids from the body outside, as well as from the infusion bag into the patient's body. The double gate configurations provides superior fluid block and completely eliminates the risk of opening the gate **101** due to high liquid pressure, e.g. when the infusion bag is squeezed.

CLAIMS

1. A catheter device comprising

a. a connecting means having a front end, a rear end with an infusion port, and a lateral injection port;

b. an injection port cup;

c. a catheter unit comprising a retentive catheter tube attached to a catheter hub placed within said connecting means at its front end;

d. a removable needle unit comprising a hollow needle and a flashback chamber;

e. optionally, a needle guard element;

f. a valve; and

g. a gate unit comprising a gate and a handle,

wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle keeps said gate in an open state and extends through said catheter tube; and (ii) an in-use state, in which said needle guard element, if present, and said removable needle unit are absent,

wherein upon removal of said removable needle unit, said catheter device transforms from the pre-use state to the in-use state, wherein said gate becomes a barrier that prevents back splash, and

wherein in the in-use state said gate may be rotated or moved from (i) a closed position that prevents fluids from passing through said infusion port and prevents the back-flow of fluids injected *via* said lateral injection port, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port, and *vise-versa*.

2. The catheter device of claim 1, wherein said valve has a front end and a rear end, and is placed within said connecting means underneath the inner side of said lateral injection port.

3. The catheter device of claim 1, comprising said needle guard element.

4. The catheter device of claim 3, wherein said needle guard element is placed within said connecting means or attached to said removable needle unit.

5. The catheter device of claim 4, wherein said needle guard element is placed within, and at the rear end of, said connecting means.

6. The catheter device of claim 1, wherein said gate has a flat or curved shape.

7. The catheter device of claim 6, wherein said curved shaped gate is S-, bell-, arc-, or wavy-shaped.

8. The catheter device of claim 6, wherein said gate has a flat circle shape.

9. The catheter device of claim 1, wherein in the pre-use state said handle is not associated with said injection port cup, and in the in-use state said handle interlocks with said injection port cup.

10. The catheter device of claim 1, wherein in both the pre-use and the in-use states, said handle interlocks with said injection port cup.

11. The catheter device of claim 1, wherein said gate is rotational, horizontal or vertical.

12. The catheter device of claim 11, wherein said gate is vertical and made of a single rigid material.

13. The catheter device of claim 11, wherein said gate is vertical and made of a rigid outer-ring and an inner-ring area.

14. The catheter device of claim 12 or 13, wherein said gate unit further comprises at least one rail designed to fit and hold said gate while enabling it to slide up and down therein.

15. The catheter device of claim 14, wherein in the pre-use state said hollow needle prevents said vertical gate from closing by keeping said vertical gate lifted, and upon removal of said removable needle unit said gate springs down within said at least one rail thereby creating a barrier that prevents blood splashing.

16. The catheter device of claim 15, wherein upon removal of said removable needle unit said gate interlocks with said injection port cup via said handle, thereby enabling lifting and lowering said vertical gate by rotating said injection port cup.

17. The catheter device of claim 12, wherein said gate is made of a flexible material.

18. The catheter device of claim 13, wherein said inner-ring area of said gate is made of a flexible material.

19. The catheter device of claim 17 or 18, wherein in the pre-use state said hollow needle passes through said flexible material, and upon removal of said removable needle unit said flexible material becomes sealed and transforms said gate into a barrier that prevents blood splashing.

20. A catheter device according to claim 1, comprising

(e) a needle guard element; and

(g) a gate unit comprising a flat-circle shaped vertical gate made of a single rigid material, a handle attached to said gate, and a rail designed to fit and hold said gate while enabling it to slide up and down therein,

wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle keeps said vertical gate in an open state by keeping said vertical gate lifted and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element, are absent,

wherein upon removal of said removable needle unit, said catheter device transforms from the pre-use state to the in-use state, wherein said vertical gate slides or springs down within said rail, and becomes a barrier preventing blood from splashing out of said connecting means, and

wherein in the in-use state said vertical gate can be lifted from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port, and *vice versa*.

21. The catheter device of claim 11, wherein said gate is horizontal or rotational, and is made of a single rigid material.

22. The catheter device of claim 11, wherein said gate is horizontal or rotational, and is made of a rigid outer-ring and an inner-ring area.

23. The catheter device of claim 22, wherein in the in-use state said rigid outer-ring is movable together with said inner-ring area.

24. The catheter device of claim 21, wherein said gate is made of a flexible material.

25. The catheter device of claim 22, wherein said inner-ring area of said gate is made of a flexible material.

26. The catheter device of claim 24 or 25, wherein in the pre-use state said hollow needle passes through said flexible material, and upon removal of said removable needle unit said flexible material becomes sealed and transforms said gate into a barrier that prevents blood splashing.

27. The catheter device of claim 21, wherein at least part of said gate is movable.

28. The catheter device of claim 22, wherein at least part of said inner-ring area of said gate is movable.

29. The catheter device of claim 27 or 28, wherein in the pre-use state said hollow needle passes through said movable part of said gate, and upon removal of said removable needle unit said movable part moves thereby transforming said gate into a barrier that prevents blood splashing.

30. The catheter device of any one of claims 21 to 25, wherein in the pre-use state said hollow needle keeps said gate in a parallel position, and upon removal of said removable needle unit said gate springs to an upright position thereby creating a barrier that prevents blood splashing.

31. The catheter device of claim 30, wherein said gate, when in an upright position, interlocks with said injection port cup via said handle, thereby enabling rotating said rotational gate or moving said horizontal gate forwards/backwards when rotating said injection port cup.

32. The catheter device of claim 31, wherein said gate is horizontal and said gate unit further comprises a solid wall that together with said gate, when in an upright position at the closed position, creates a barrier that prevents blood splashing.

33. The catheter device of claim 22, wherein said gate is rotational, and in the in-use state said rigid outer-ring is affixed, and said inner-ring area interlocks with said injection port cup via said handle, wherein said rigid outer-ring does not rotate together with said inner-ring area.

34. The catheter device of claim 33, wherein in the pre-use state said hollow needle keeps said gate in an open state by keeping said gate in a parallel position, and upon removal of said removable needle unit said gate springs to an upright position thereby affixing said rigid outer ring in place creating a barrier that prevents blood splashing.

35. The catheter device of claim 33, wherein in the pre-use state said handle interlocks with said injection port cup, and said hollow needle passes through said inner-ring area of the gate, thereby keeping said gate open, and upon removal of said removable needle unit, said gate transforms into a barrier that prevents blood splashing.

36. The catheter device of any one of claims 33-35, wherein in the in-use state said inner-ring area of said gate can be rotated by rotation of said injection port cup.

37. A catheter device according to claim 1, comprising

(e) a needle guard element; and

(g) a gate unit comprising a flat-shaped rotational gate made of a single rigid material, and a handle,

wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle keeps said

rotational gate in an open state by keeping said rotational gate in a parallel position, and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element are absent,

wherein upon removal of said removable needle unit, said catheter device transforms from the pre-use state to the in-use state, wherein said rotational gate springs to an upright position and becomes a barrier preventing blood from splashing out of said connecting means, and

wherein in the in-use state said rotational gate interlocks with said injection port cup thereby enabling rotation of said gate from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port, and *vice versa*.

38. A catheter device according to claim 1, comprising

(e) a needle guard element; and

(g) a gate unit comprising a flat-shaped rotational gate made of an outer rigid ring and an inner-ring area and a handle,

wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle keeps said rotational gate in an open state by passing through said inner-ring area of said rotational gate, and extends through said catheter tube; and (ii) an in-use state, in which said removable needle unit and said needle guard element are absent,

wherein upon removal of said removable needle unit, said catheter device transforms from the pre-use state to the in-use state, wherein said rotational gate becomes sealed and transforms into a barrier that prevents blood from splashing out of said connecting means, and

wherein in the in-use state said inner-ring area of said rotational gate interlocks with said injection port cup thereby enabling rotation of said inner-ring area from (i) a closed position that prevents fluids from passing through said infusion port and back-flow of fluids injected *via* said lateral injection port, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port, and *vice versa*.

39. The catheter device of claim 2, wherein in the in-use state and the closed position, said gate presses the rear end of said valve, thereby directing fluids injected through said lateral injection port towards said catheter tube while preventing said fluids from flowing backwards through said infusion port.

40. The catheter device of claim 1, wherein said valve constitutes part of said gate unit and is placed in between said lateral injection port and connecting means above said gate.

41. A catheter device according to claim 1, wherein said gate unit comprises also said lateral injection port and said valve, wherein said gate unit is designed such that it can be assembled onto said connecting means,

wherein said catheter device has (i) a pre-use state, in which said removable needle unit is placed within said connecting means, and said hollow needle passes through a designated hole while keeping said gate in an open state and extends through said catheter tube; and (ii) an in-use state, in which said needle guard element, if present, and said removable needle unit are absent,

wherein upon removal of said removable needle unit, said catheter device transforms from the pre-use state to the in-use state, wherein said gate becomes a barrier that prevents back splash, and

wherein in the in-use state said gate may be rotated from (i) a closed position that prevents fluids from passing through said infusion port and prevents the back-flow of fluids injected *via* said lateral injection port, into (ii) an open position that allows fluids to pass through said infusion port and consequently back-flow of fluids, if injected *via* said lateral injection port, and *vise-versa*.

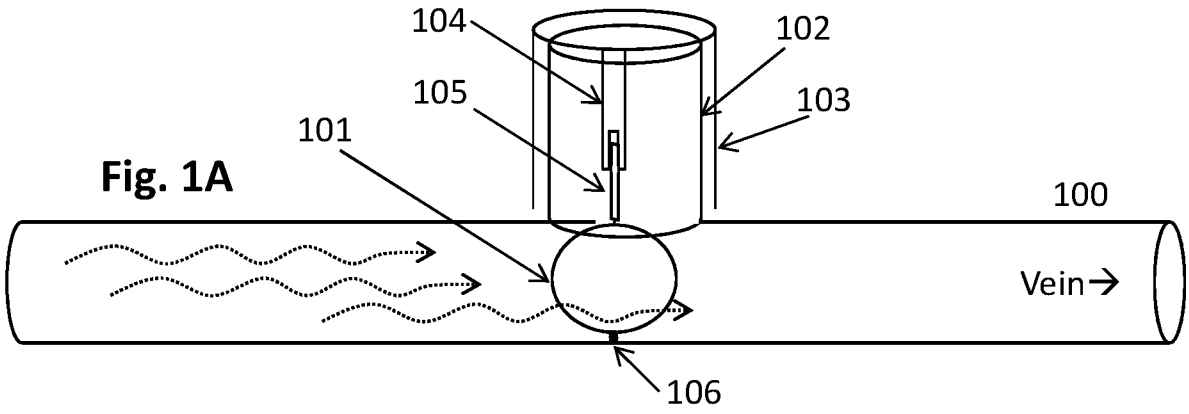


Fig. 1A

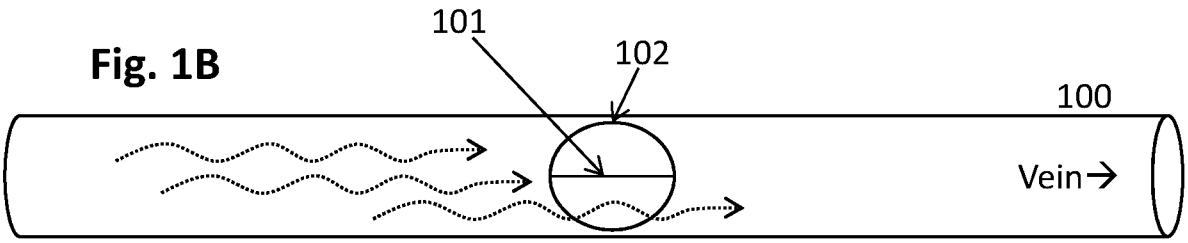


Fig. 1B

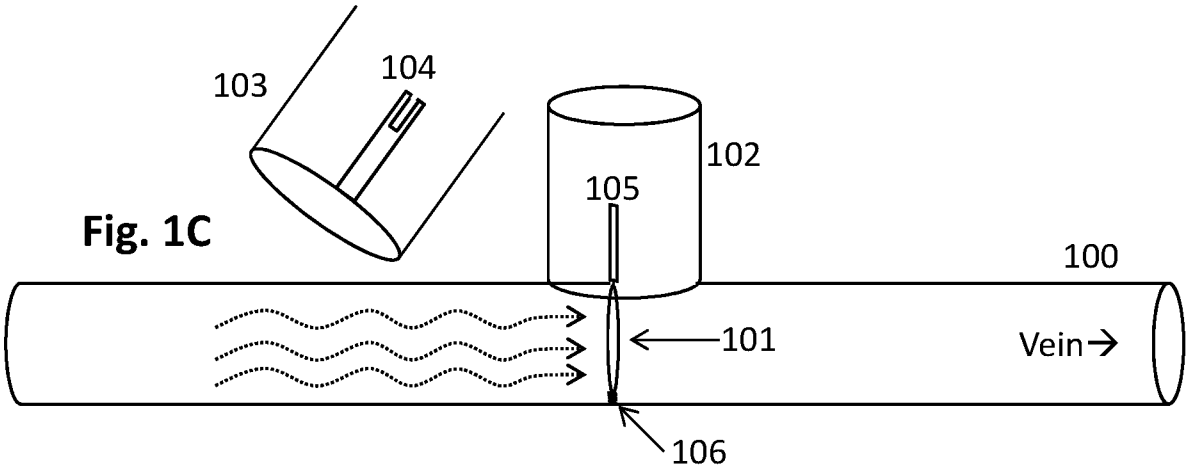


Fig. 1C

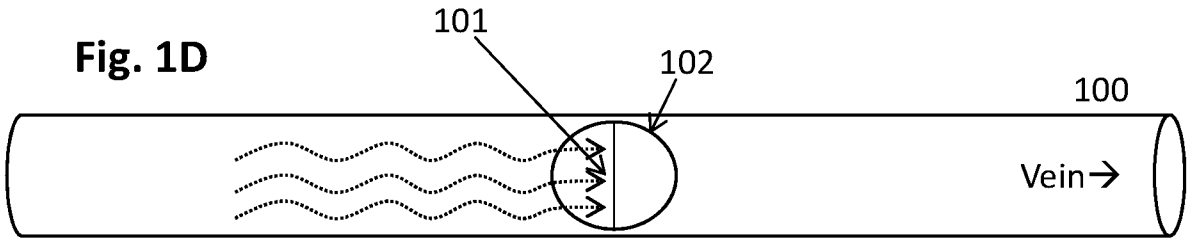


Fig. 1D

Figure 1

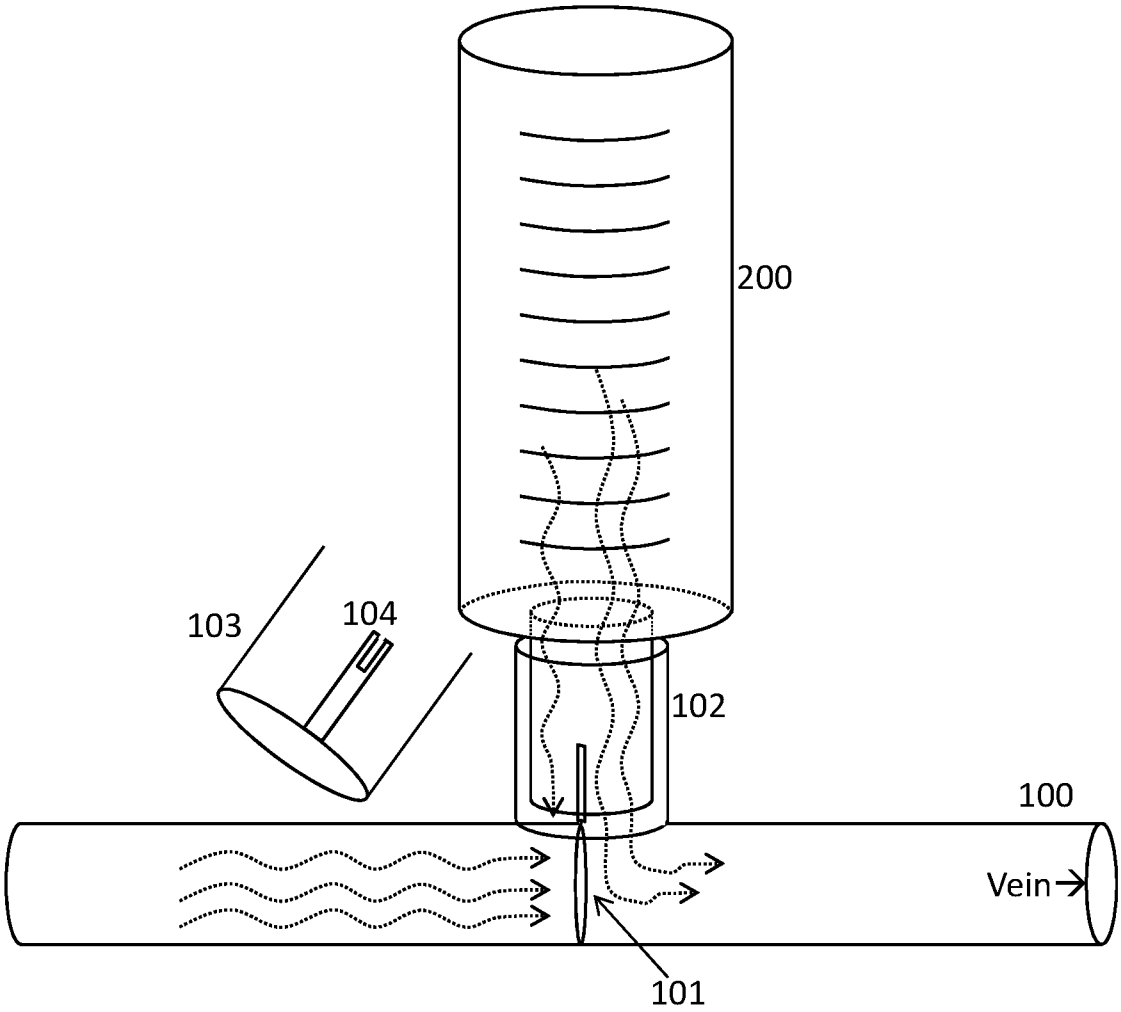


Figure 2

Fig. 3A

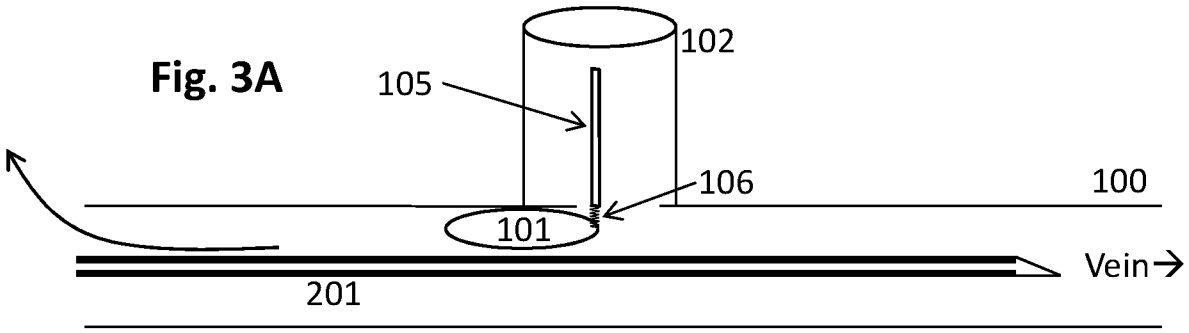


Fig. 3B

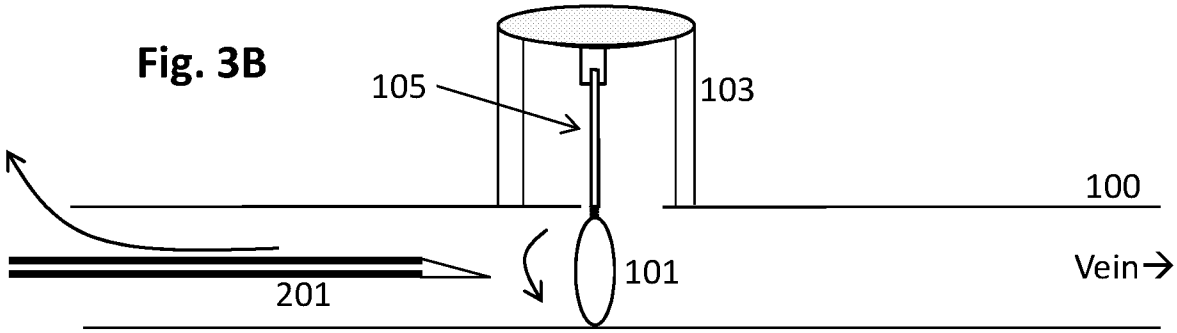


Fig. 3C

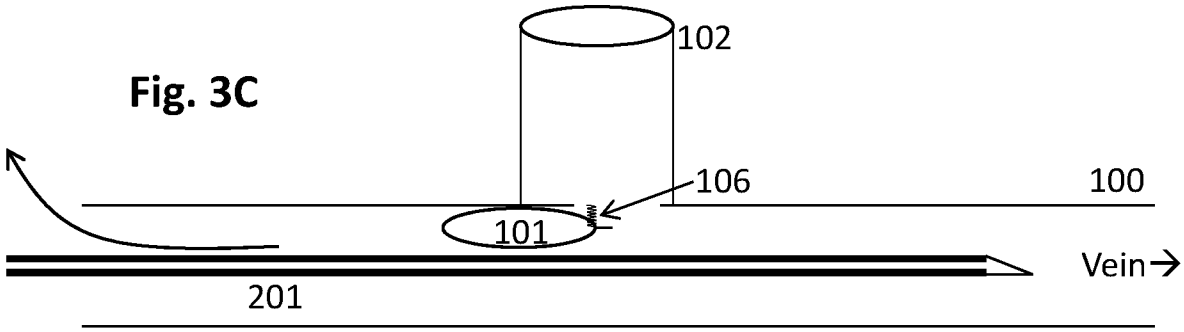


Fig. 3D

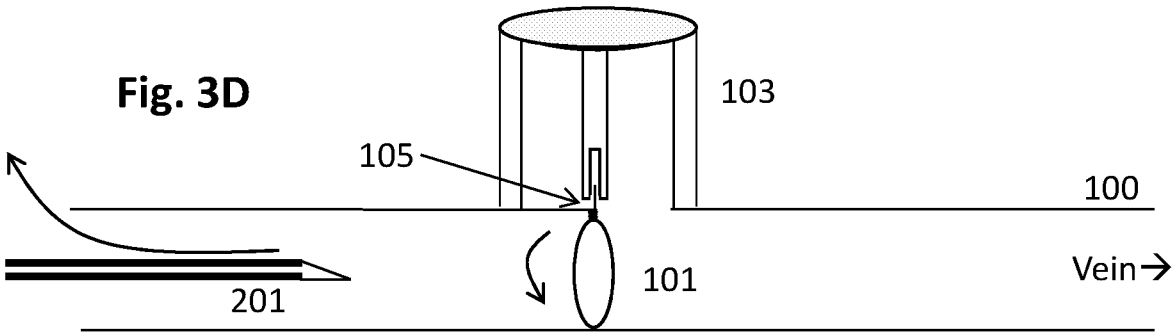


Figure 3

Fig. 4A

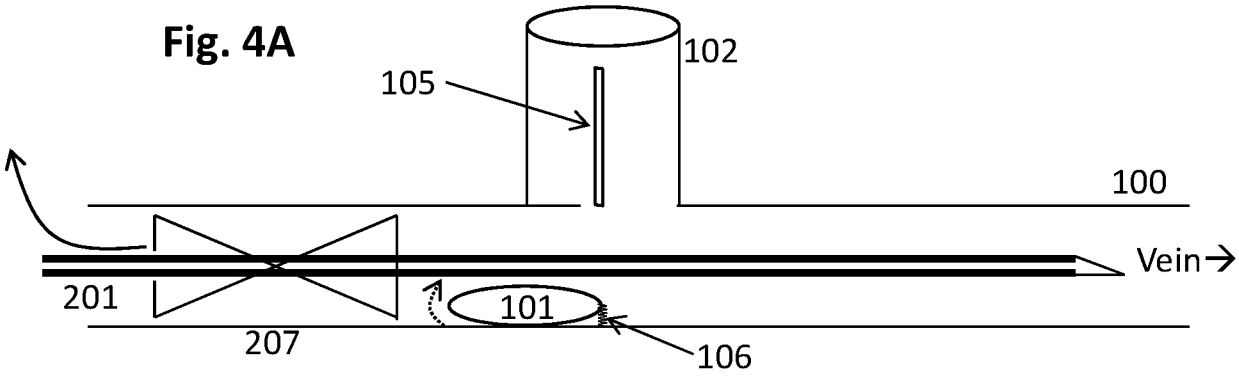


Fig. 4B

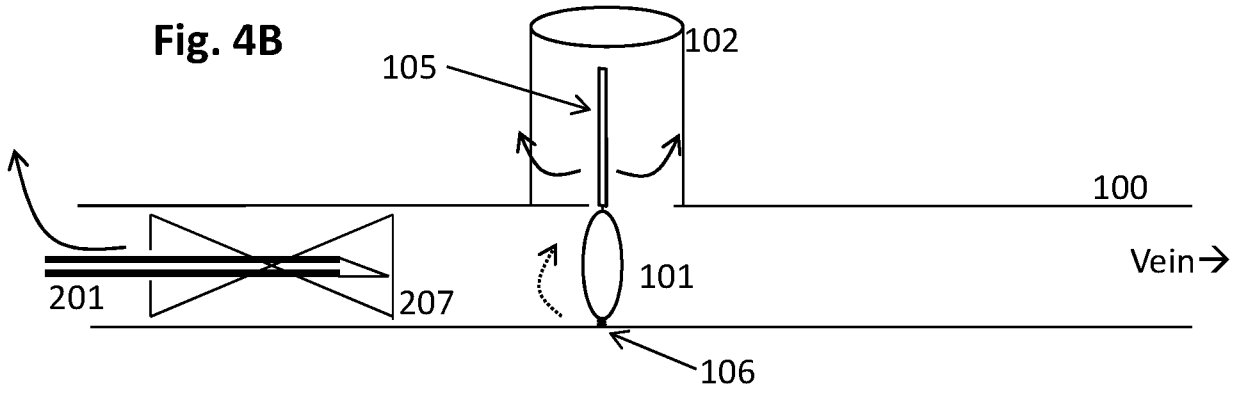


Fig. 4C

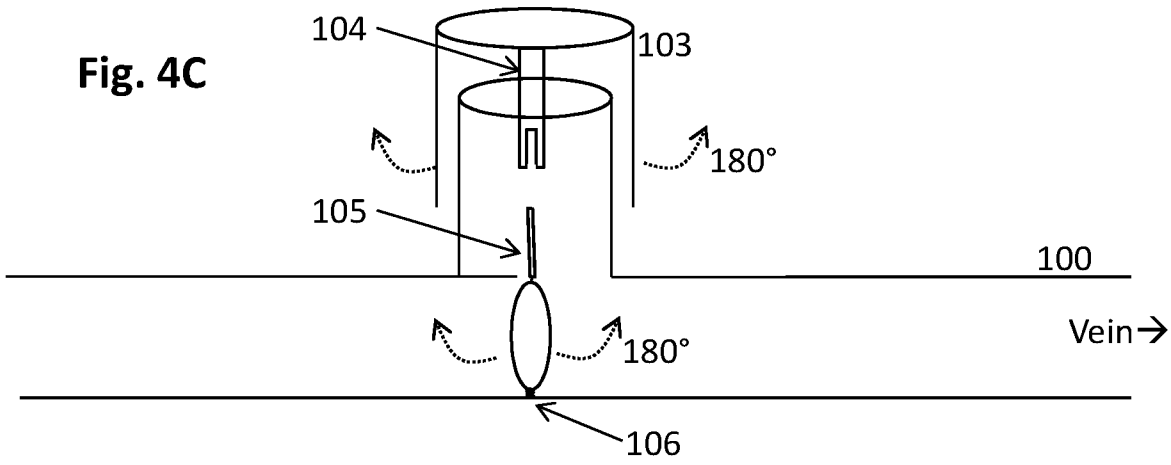


Figure 4

Fig. 5A

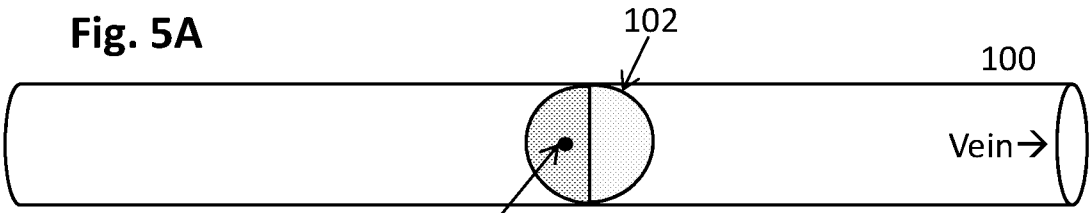


Fig. 5B

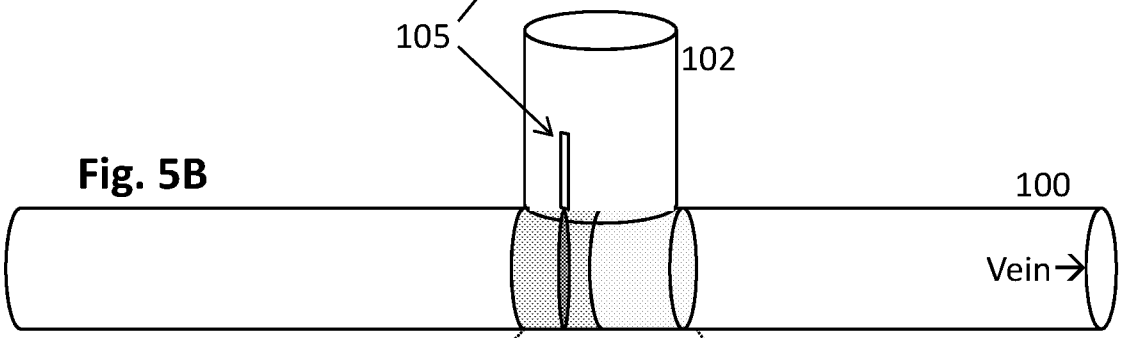
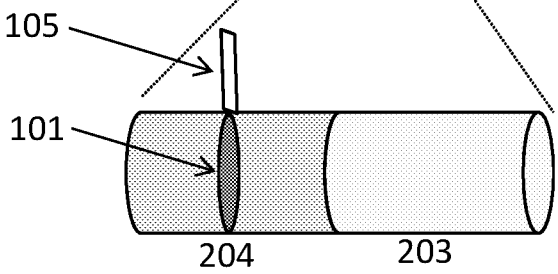


Fig. 5C



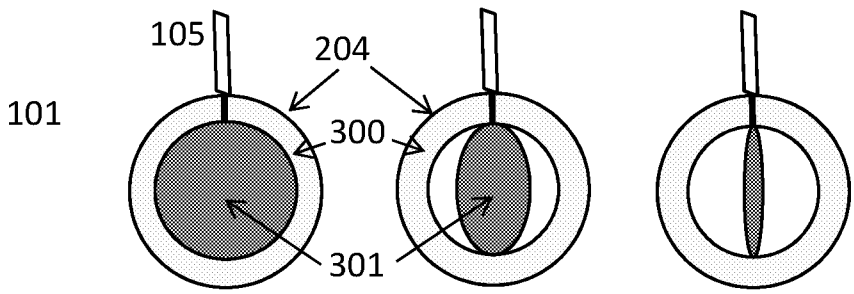


Fig. 5D Fig. 5E Fig. 5F

Figure 5

Fig. 6A

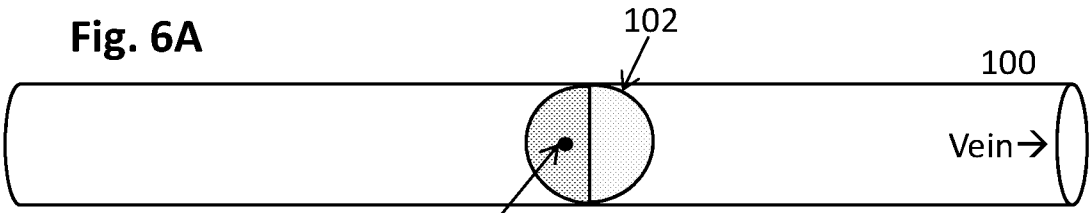


Fig. 6B

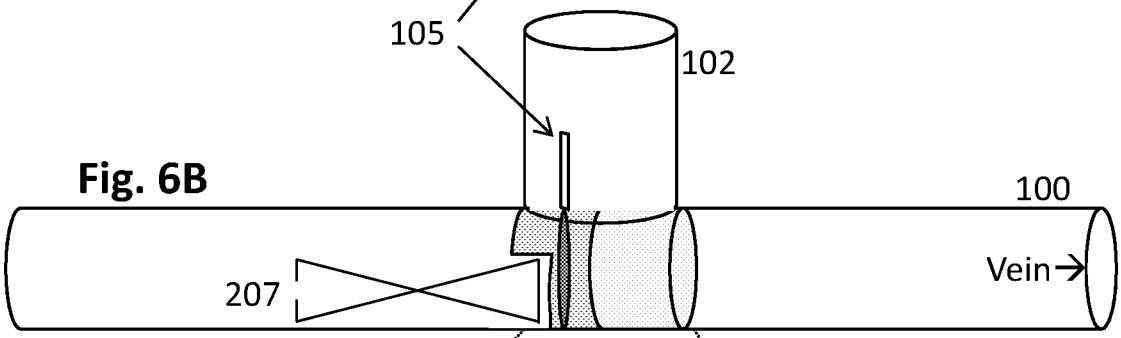


Fig. 6C

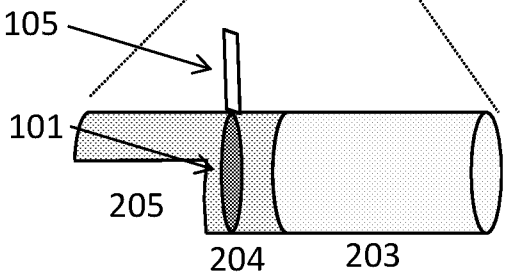
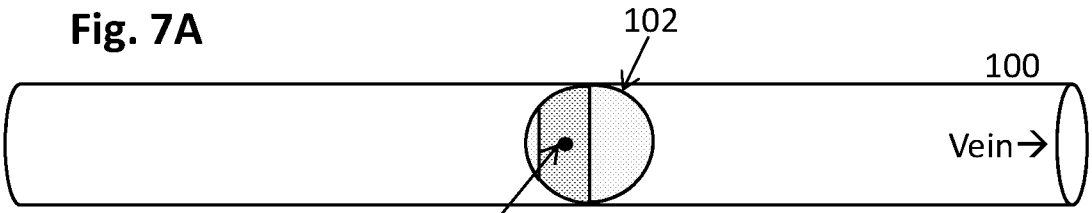


Figure 6

Fig. 7A



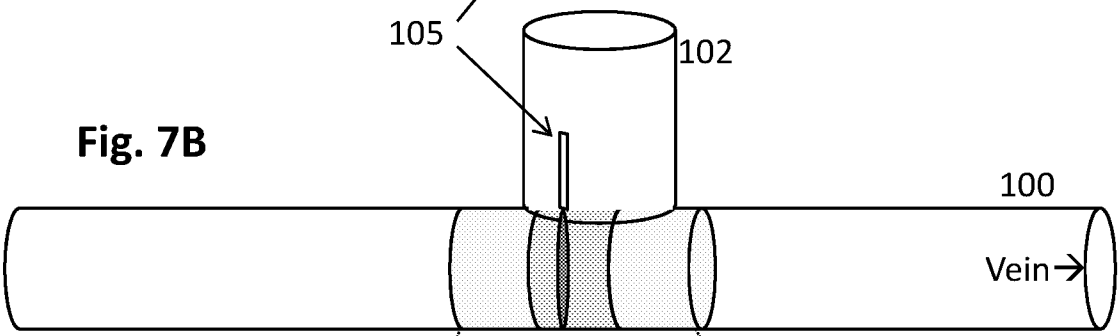
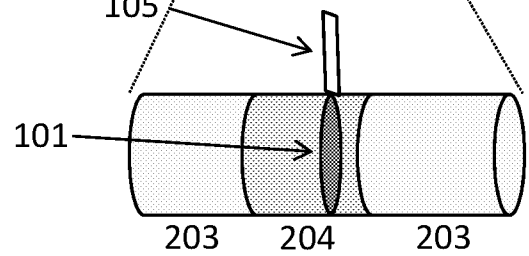


Fig. 7B

Fig. 7C



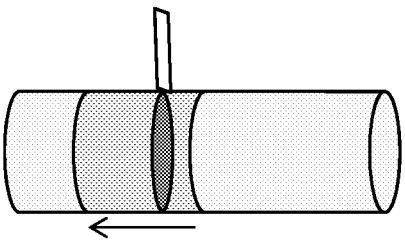


Fig. 7E

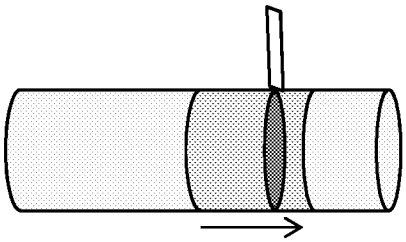


Fig. 7D

Figure 7

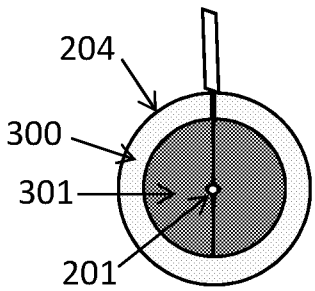


Fig. 8A

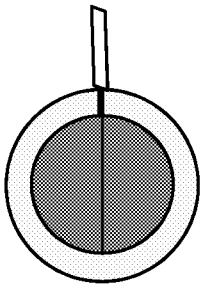


Fig. 8B

Figure 8

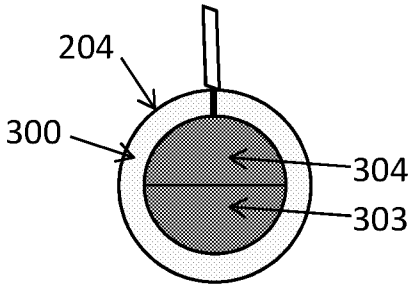


Fig. 9A

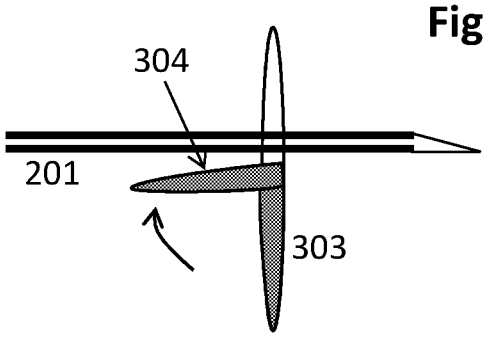


Fig. 9B

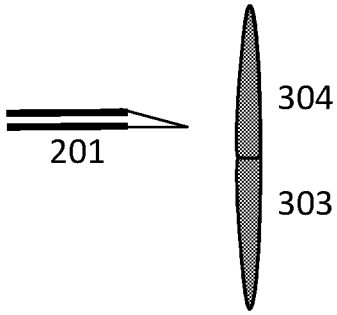


Fig. 9C

Figure 9

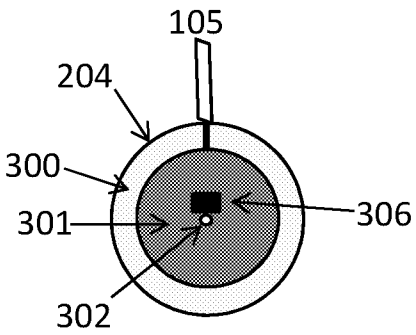


Fig. 10A

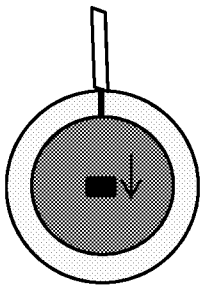


Fig. 10B

Figure 10

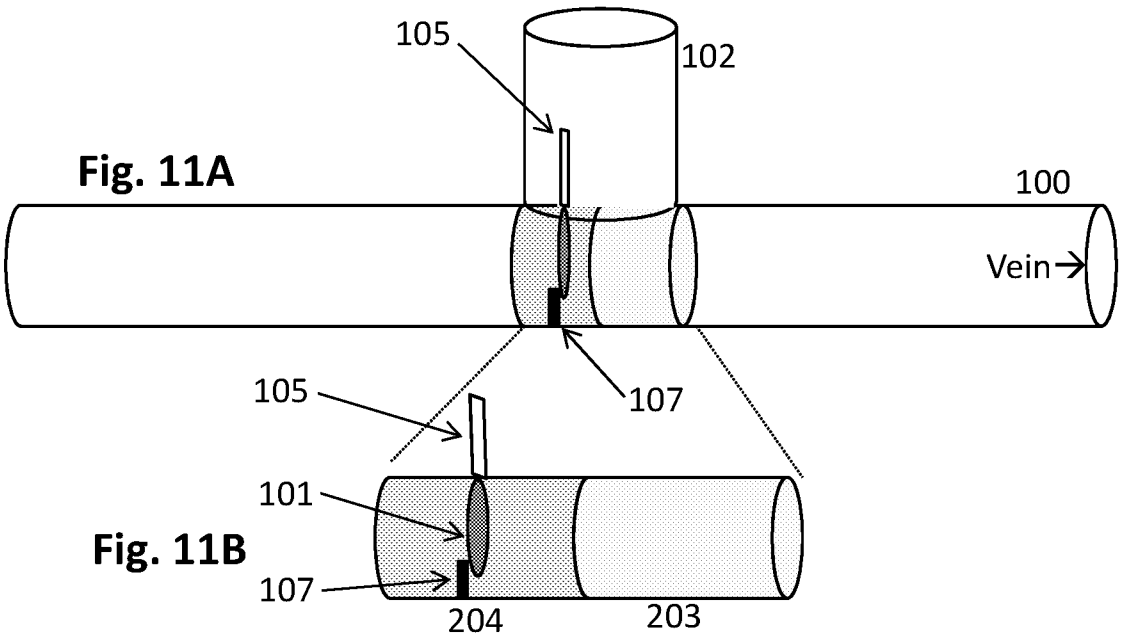


Fig. 11A

Fig. 11B

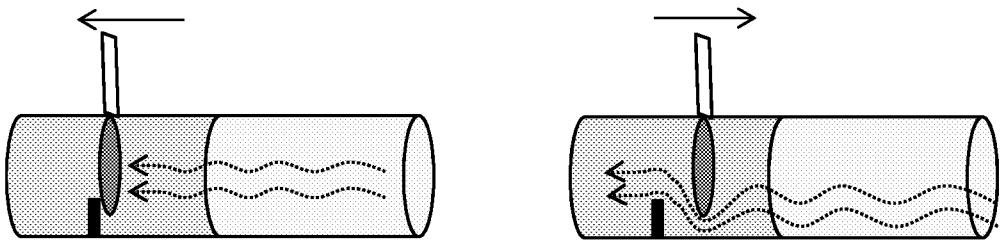


Fig. 11D

Fig. 11C

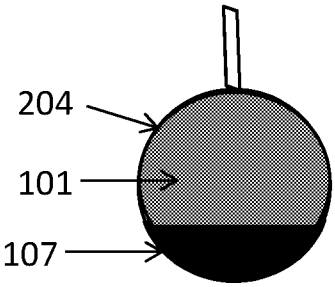


Fig. 11E

Figure 11

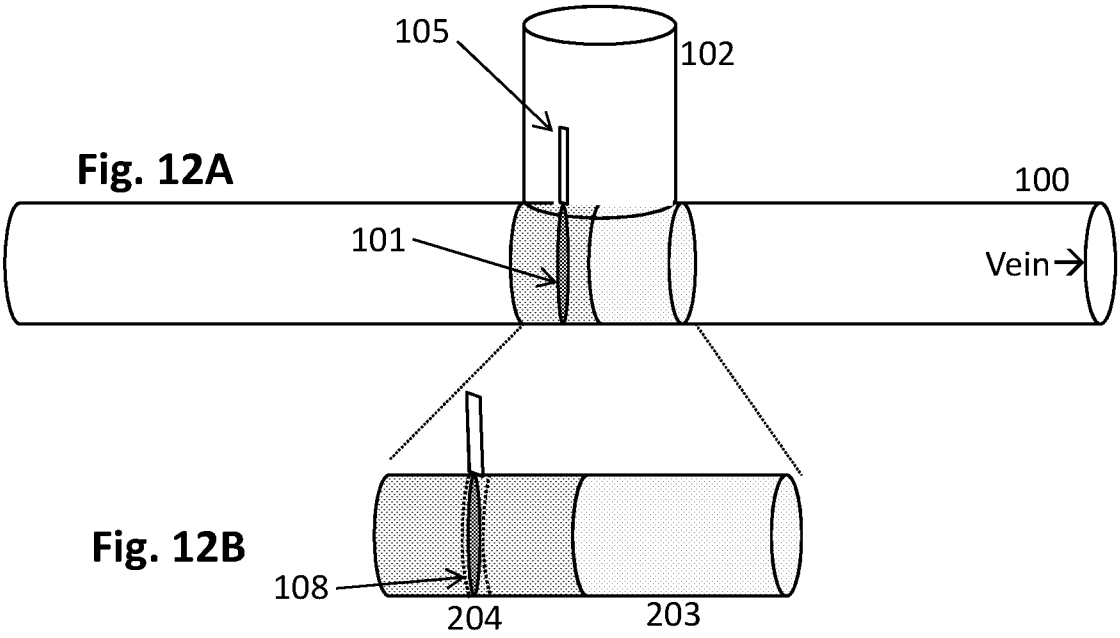


Fig. 12A

Fig. 12B

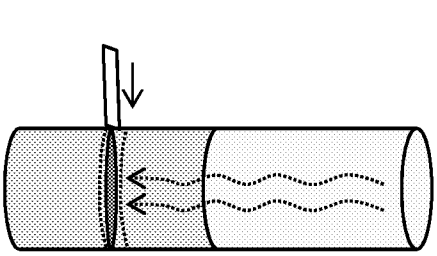


Fig. 12D

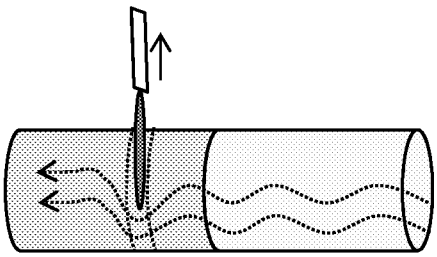


Fig. 12C

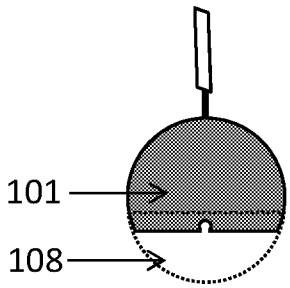


Fig. 12F

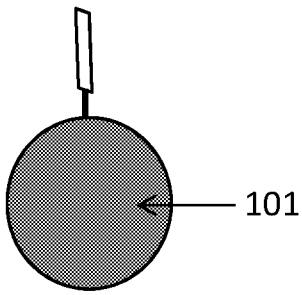


Fig. 12E

Figure 12

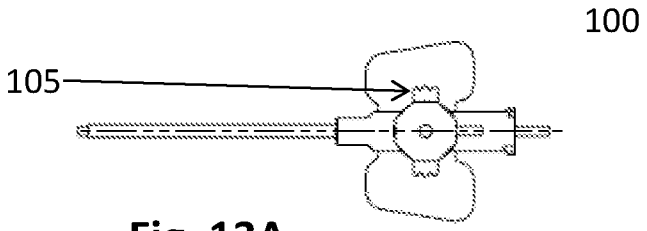


Fig. 13A

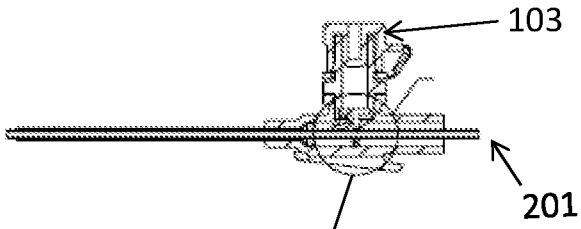


Fig. 13B

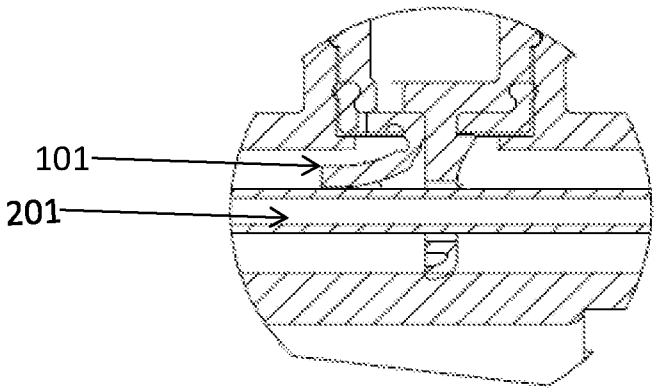


Fig. 13C

Figure 13

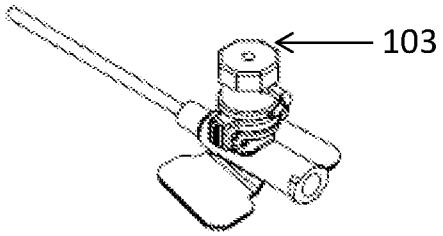


Fig. 14A

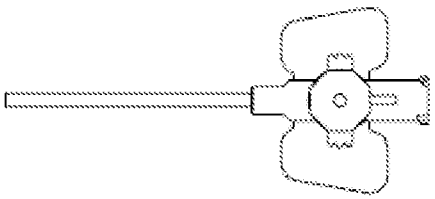


Fig. 14B

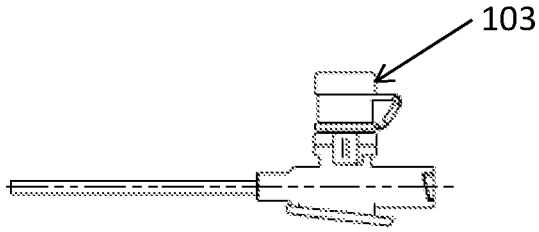


Fig. 14C

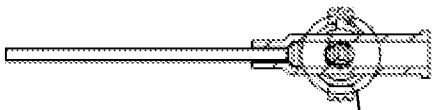


Fig. 14D

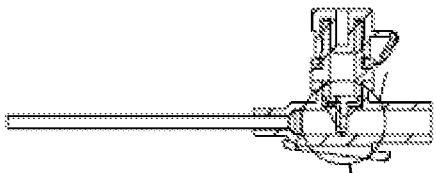


Fig. 14E

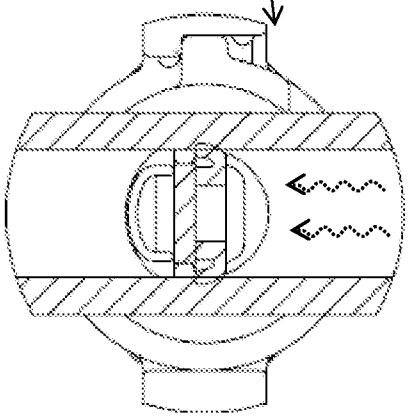


Fig. 14F

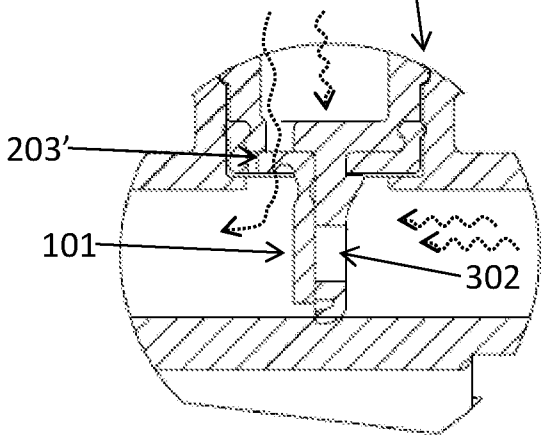


Fig. 14G

Figure 14

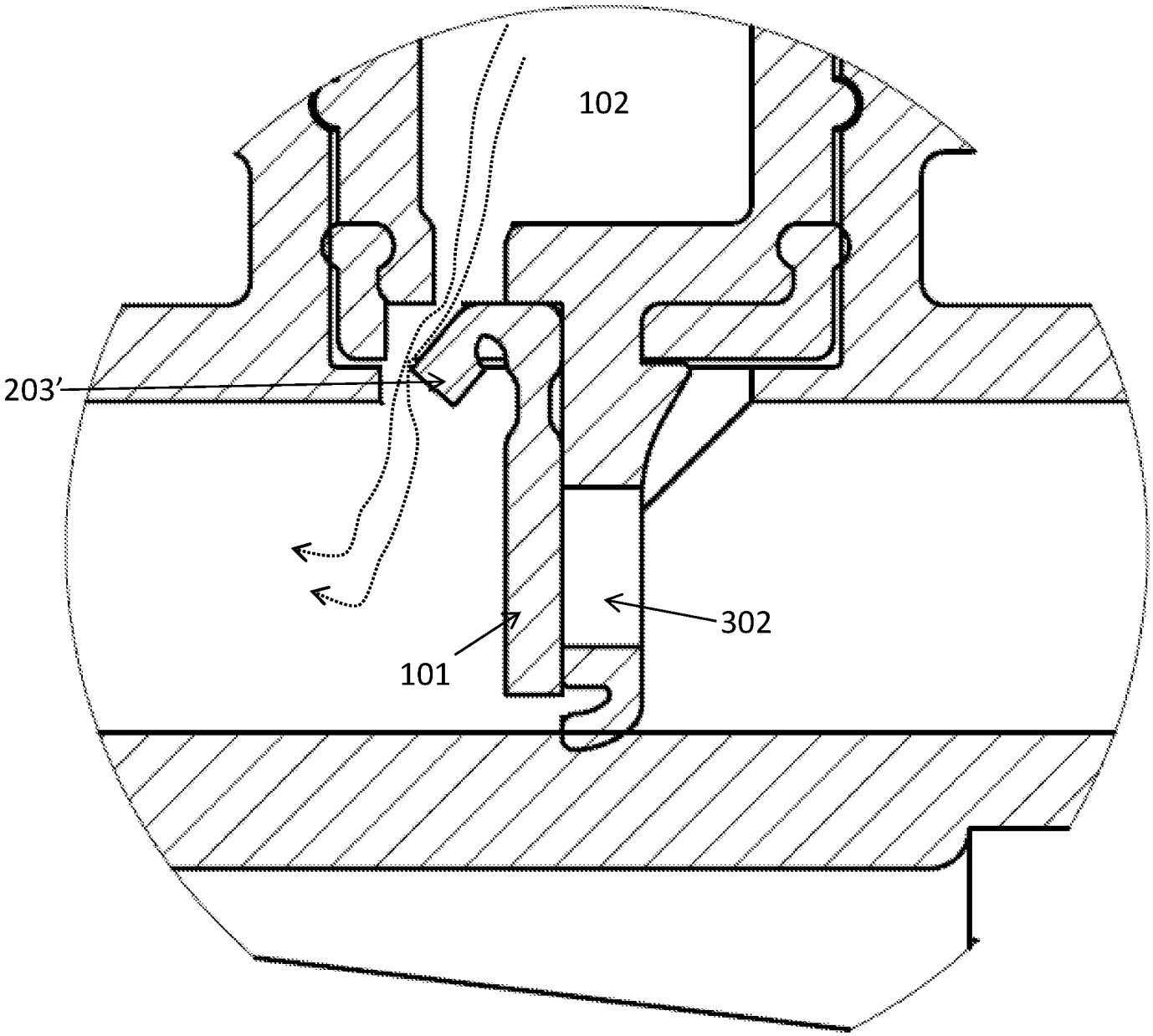


Fig. 14H

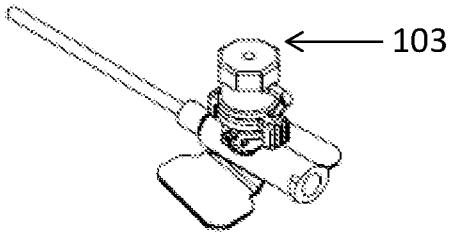


Fig. 15A

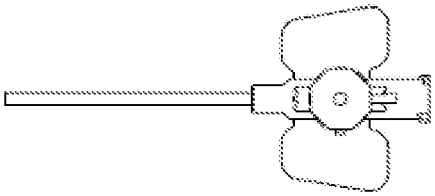


Fig. 15B

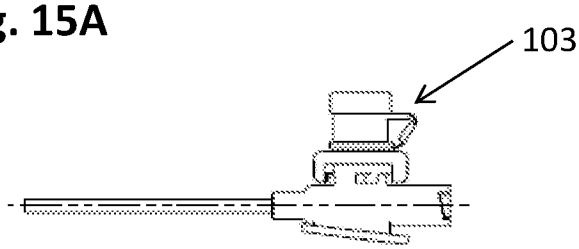


Fig. 15C

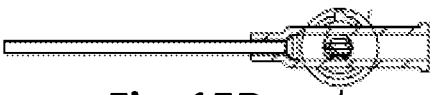


Fig. 15D

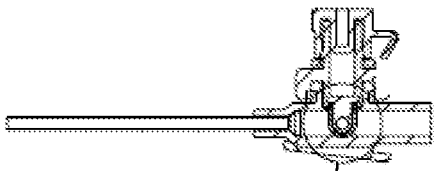


Fig. 15E

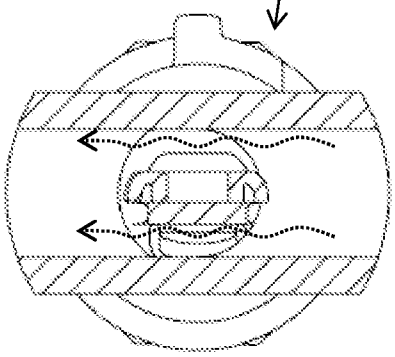


Fig. 15F

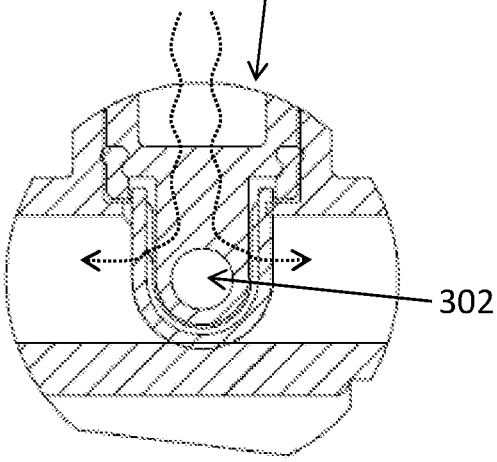


Fig. 15G

Figure 15

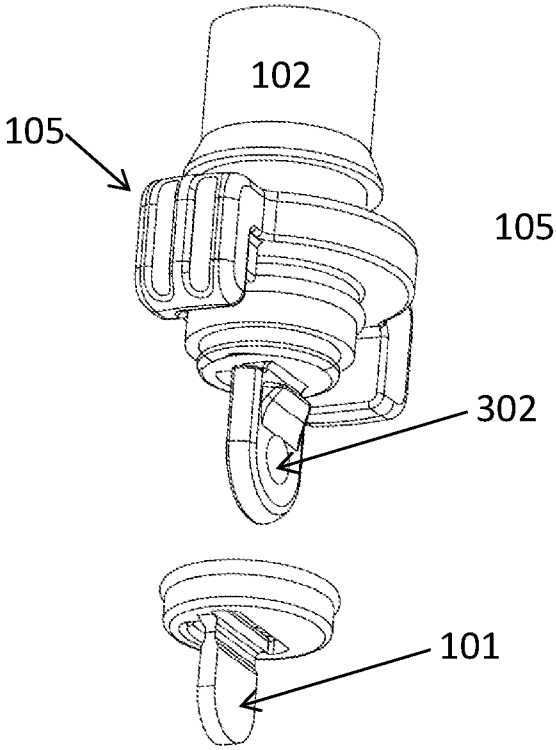


Fig. 16A

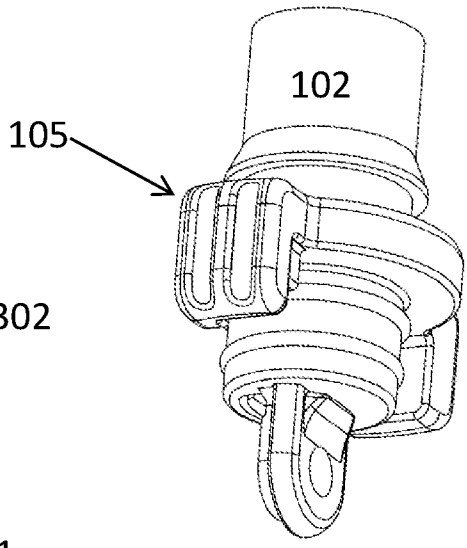


Fig. 16B

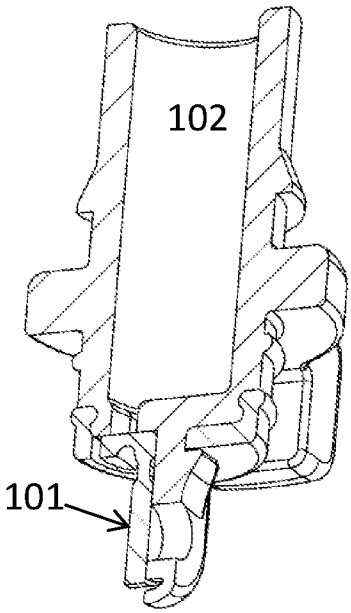


Fig. 16C

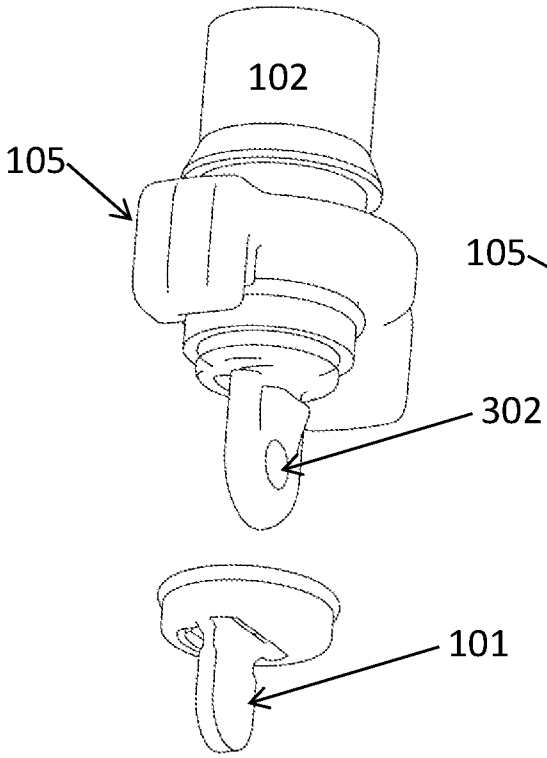


Fig. 16D

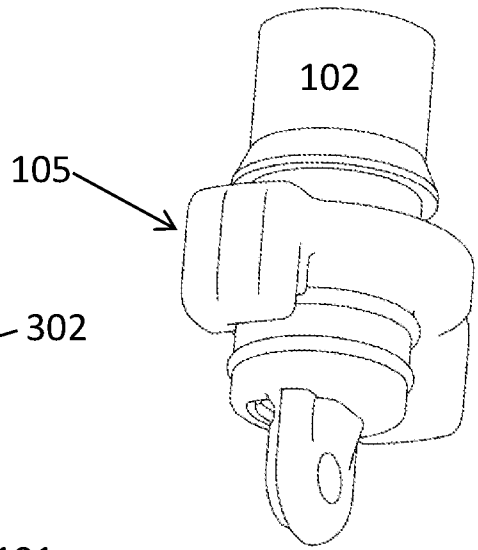


Fig. 16E

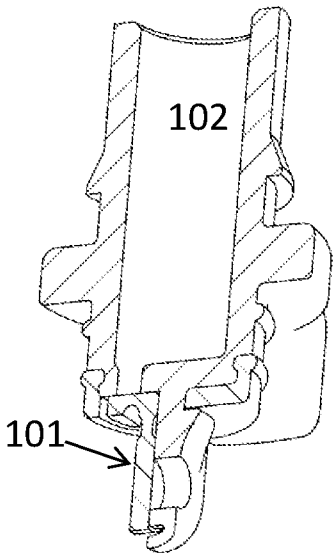
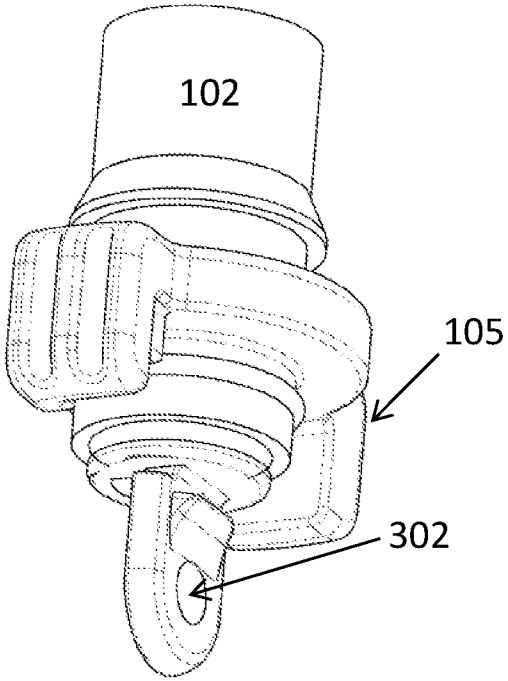


Fig. 16F

Figure 16



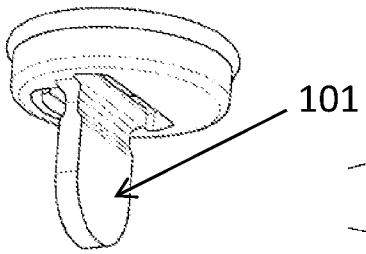


Fig. 17A

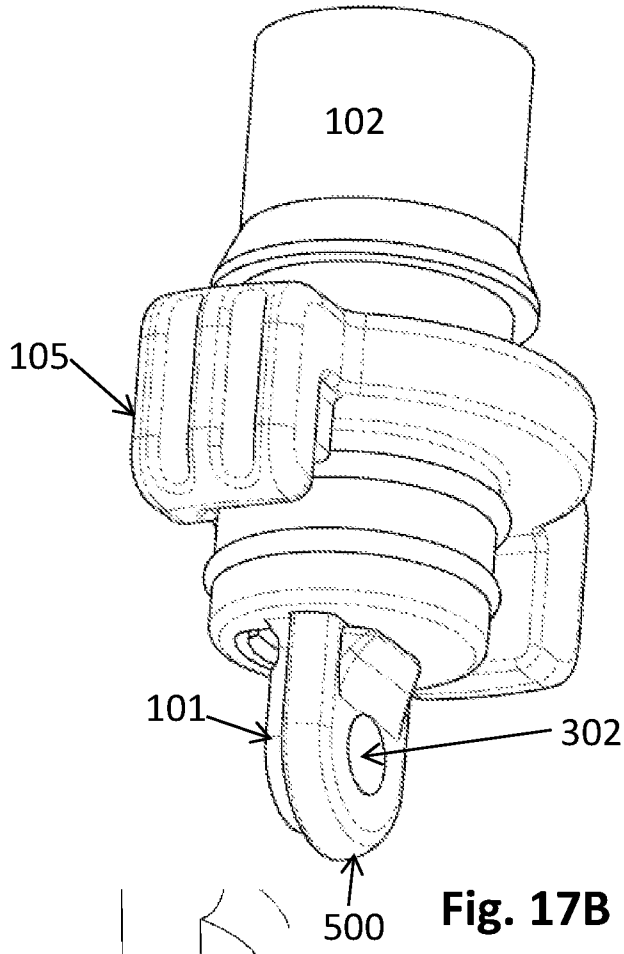


Fig. 17B

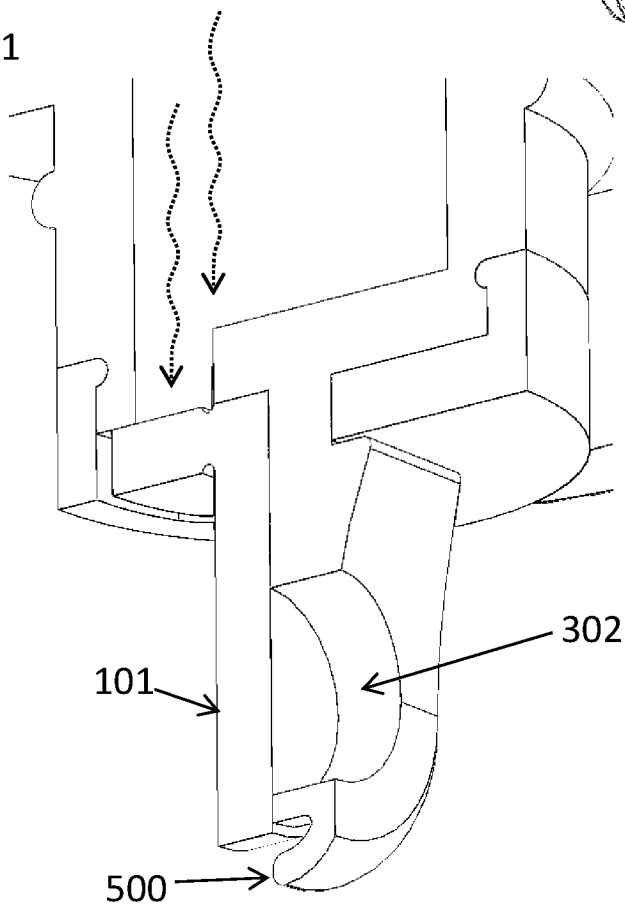


Figure 17

Fig. 17C

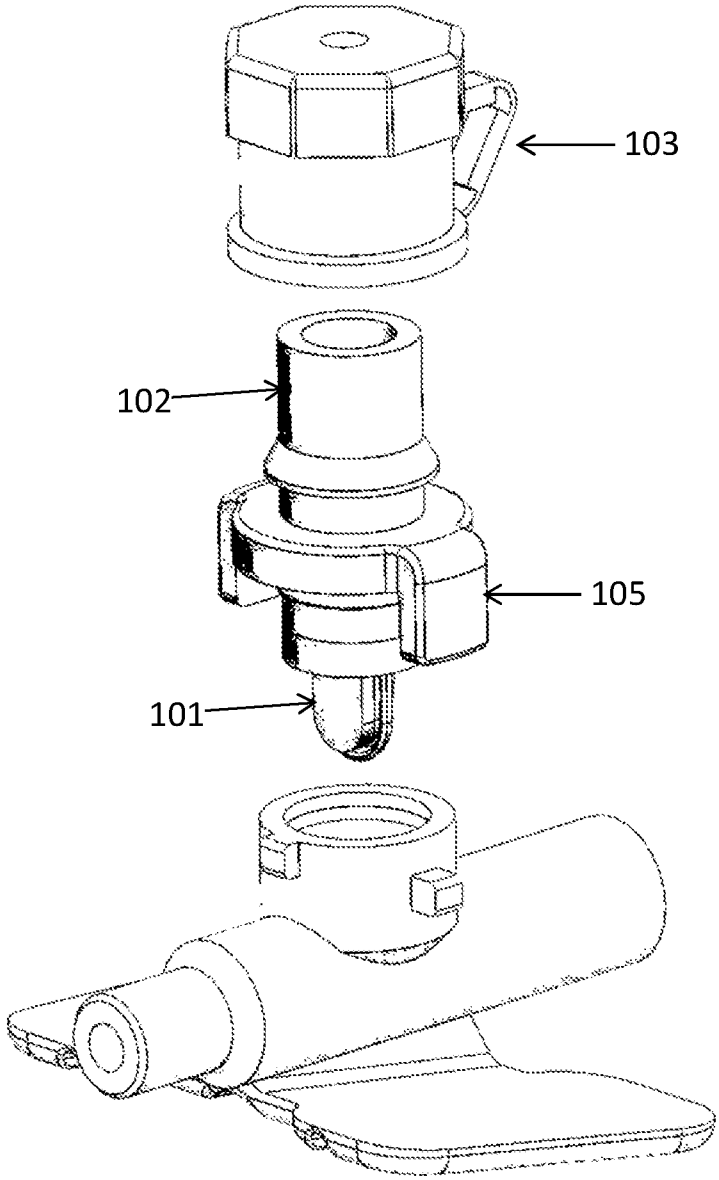


Figure 18

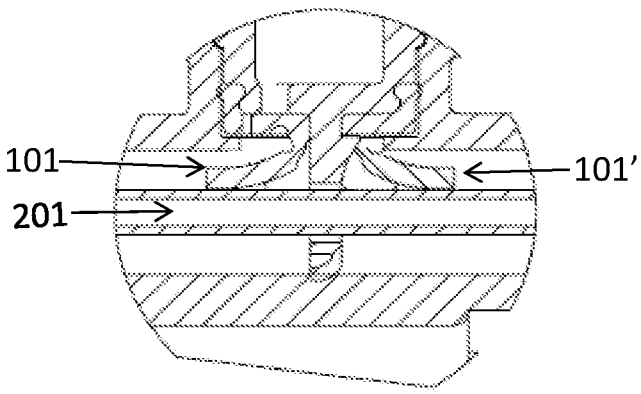


Fig. 19A

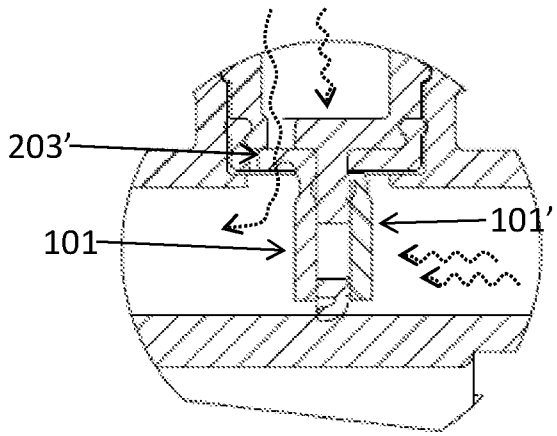


Fig. 19B

Figure 19

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL2016/050464

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 25/00; A61M 25/06; A61M 39/00; A61M 39/02; A61M 39/04; A61M 39/06 (2016.01)
CPC - A61M 25/00; A61M 25/06; A61M 25/0606; A61M 25/0631; A61M 25/0693; A61M 39/00 (2016.08)
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC - A61M 25/00; A61M 25/06; A61M 39/00; A61M 39/02; A61M 39/04; A61M 39/06; A61M 39/22; A61M 39/24; A61M 39/26
CPC - A61M 25/00; A61M 25/06; A61M 25/0606; A61M 25/0631; A61M 25/0693; A61M 39/00; A61M 39/02; A61M 39/04; A61M 39/06; A61M 39/0613; A61M 2039/062; A61M 39/0693; A61M 39/22; A61M 39/225; A61M 39/227; A61M 2039/229;

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC - 604/164.08; 604/167.01; 604/167.02; 604/167.03; 604/167.05; 604/167.06; 604/198; 604/256
CPC - A61M 39/24; A61M 39/26; A61M 2039/268 (keyword delimited)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google, Google Scholar, YouTube
Search terms used: catheter, needle, gate, back, splash, removable, valve

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 3,895,632 A (PLOWIECKI) 22 July 1975 (22.07.1975) entire document	1-41
A	US 3,774,604 A (DANIELSSON) 27 November 1973 (27.11.1973) entire document	1-41
A	US 6,217,556 B1 (ELLINGSON et al) 17 April 2001 (17.04.2001) entire document	1-41
A	US 5,370,624 A (EDWARDS et al) 06 December 1994 (06.12.1994) entire document	1-41
A	US 2013/0237925 A1 (TRAINER et al) 12 September 2013 (12.09.2013) entire document	1-41

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 August 2016	30 SEP 2016
Name and mailing address of the ISA/ Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, VA 22313-1450 Facsimile No. 571-273-8300	Authorized officer Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774