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(54) Title: METHOD AND APPARATUS FOR INSERTING A CATHETER DEVICE

(57) Abstract: The present invention relates to systems and methods for inserting a catheter device into a subject, wherein the catheter insertion system (100) generally comprises a flexible sleeve (120) containing a catheter tube (121) and advancing means for advancing the catheter contained within said system in a distal direction, wherein the flexible sleeve has a sealed proximal end (132) and a distal end which may comprise a slender passage (104) adapted to allow passage of said catheter tube therethrough while preventing backflow of fluid into the flexible sleeve.

METHOD AND APPARATUS FOR INSERTING A CATHETER DEVICE

Field of the Invention

The present invention relates to intravascular catheter devices. More particularly, the invention relates to methods and apparatuses for facilitating and controlling the insertion of a catheter device.

Background of the Invention

It is known in the art to provide peripheral intravenous therapy using a catheter having a cannula or catheter tube to provide access into subcutaneous veins thereby to introduce medication, drugs, chemotherapy, nutrition and various other fluids into a vein of a subject. The present procedure includes inserting a hypodermic needle together with a catheter having an in-dwelling cannula into a suitable vein, withdrawing the needle and leaving the in-dwelling cannula in the vein. Such a catheter is typically provided with a suitable closure and various adapter mechanisms to enable the aseptic introduction of fluid medicaments from a hypodermic syringe or from an intravenous drip.

US 5,478,326 describe an arterial device for the control of bleeding from a puncture in an artery wall. This device consists of a flexible cannula the size of which is gradually decreased from its access end towards its insertion tip, which enables bleed control by matching the partly inserted cannula to the size of the arterial puncture.

US 3,757,771 describe a sterile inserter apparatus wherein an elongated catheter is adapted to move through the inserter via a sealed and flexible sleeve. The sealing sleeve is secured to a member that is connected to the inserter end after insertion of an in-dwelling cannula.

The catheter apparatus described in US 3,825,001 includes catheter tubing sealed in a flexible plastic sheath having a male fitting secured to its distal end for connecting it to an inserter catheter and a female fitting secured to its proximal end. The male fitting is provided with axial openings to allow insertion of the catheter tubing through the inserter catheter.

An intravenous catheter system is described in WO 03/084428. This system comprises a multi-use entry-port element and a flexible catheter tube that is adapted for slidable insertion into a vein through the entry port. The flexible catheter tube is provided in a sterile environment containment element that allows insertion of the catheter tube in a generally non-sterile environment.

A considerable disadvantage of the prior art catheter devices stems from the requirement to insert the full length of the catheter tube into the artery site for performing continuous in vivo procedures. It is difficult to estimate the length of the catheter tube required for carrying out a specific procedure. Due to this requirement practitioners are often required to withdraw a partially inserted catheter tube whenever it is realized that a shorter catheter tube should be used.

None of the aforementioned publications provides means for controlling the insertion of the catheter. Heretofore, the insertion of intravenous catheter devices was carried our by grasping the catheter tube via the sterile containment and pushing the catheter tube inwardly into the entry port of the indwelling cannula. The prior art devices do not include control means for controlling the insertion of the catheter

tube. In addition, the prior art catheter devices do not provide means for preventing accidental withdrawal, or means for preventing the use of excess force that may result in internal injuries. Moreover, the prior art devices do not provide means for carrying out the requisite procedure with a partially inserted catheter.

It is therefore an object of the present invention to provide methods and apparatuses for the controlled, aseptic insertion of an intravascular catheter into a peripheral blood vessel.

It is another object of the present invention to provide intravascular catheter insertion device comprising means for preventing accidental withdrawal of a partially inserted catheter tube.

It is a further object of the present invention to provide an intravascular catheter insertion device which permits the performance of *in vivo* procedures with a partially inserted catheter tube.

It is yet another object of the present invention to provide an intravascular catheter insertion device that can prevent exertion of excess forces during the insertion of the catheter tube.

It is still another object of the present invention to provide an intravascular catheter insertion device suitable for insertion of extremely thin catheter tubes, and that can prevent bleeding from the peripheral blood vessel into the catheter device.

It is also an object of the present invention to provide a method and accessories for trimming a catheter into a required length prior to its insertion in a sterile environment.

An additional object of the present invention is to provide disposable catheter insertion devices.

Other objects and advantages of the invention will become apparent as the description proceeds.

Summary of the Invention

The present invention provides a catheter insertion system that may be used for the controlled, aseptic insertion of catheters and similar indwelling tubular elements into the vasculature by means of the transcutaneous route.

The terms "resilient material", "resilient section" and the like refer to materials, and elements made therefrom, that are capable of restoring their original shape and/or position after being compressed.

The present invention is primarily directed to a catheter insertion system comprising, at a first end, a distal entry port, at a second end a proximal section, a sealed catheter sleeve situated between said entry port and said proximal section, and further comprising advancing means for advancing a catheter contained within said system in a distal direction,

wherein said entry port comprises a hollow body terminating at one end in a hollow cannula suitable for insertion into a peripheral blood vessel and having an internal diameter suitable for permitting passage of an intravascular catheter, and terminating at the other end with a connector element;

wherein said proximal section comprises a hollow body having at least one external opening permitting the withdrawal and/or addition of fluid from or into the proximal opening of a catheter placed within said proximal section;

and wherein said sealed catheter sleeve is sealably connected at one of its ends to either said entry port connector element or to advancing means located between said sleeve and said entry port connector element, said sealed catheter sleeve being sealably connected at its other end to said proximal section;

such that when the aforementioned elements are connected together, a continuous hollow passageway exists from said proximal section through to the terminal portion of said hollow cannula, wherein said passageway contains the catheter that is to be inserted into a peripheral blood vessel.

Optionally, the aforementioned entry port may also comprise an external opening permitting the withdrawal and/or addition of fluid from or into the proximal opening of a catheter placed within said entry port.

It should be noted that the term "proximal" is used here to refer to elements of the catheter device which are located in relative proximity to the operator, and the term, "distal" is used herein to refer to elements of the catheter device the location of which is relatively distant from the operator.

In one preferred embodiment of the aforementioned catheter insertion system, the advancing means comprises the sealed catheter sleeve and a plurality of blades situated in close proximity to the distal end of said sleeve, such that when said sleeve is grasped and advanced in a distal direction, the catheter situated within said sleeve is similarly advanced, and said sleeve is progressively cut by said blades, thereby facilitating its removal from said system.

In another preferred embodiment of the catheter insertion system of the present invention, the advancing means comprises a flexible tube situated between the entry port and the sealed catheter sleeve, wherein said tube is adapted to permit an operator to grasp and compress said tube such that the catheter situated therewithin may be advanced in a distal direction. In a particularly preferred embodiment, the flexible tube contains corrugations along at least part of its length, such that said corrugations provide increased friction between the operator's hand and the catheter tube.

In accordance with a further preferred embodiment of the catheter system of the present invention, the advancing means comprises a rotating wheel mechanism situated between the entry port and the sealed catheter sleeve, such that rotation of an externally-situated thumb wheel causes rotation of one or more internally-situated wheels that cause the catheter to move in a distal or proximal direction. The internally-situated wheels are preferably designed to provide a limited amount of friction between said wheels and said catheter tube, thereby limiting the amount of force applied on the thumb wheel.

In a further preferred embodiment, the advancing means comprises a rotating wheel mechanism as disclosed hereinabove and described in further detail hereinbelow, and the sealed catheter sleeve consists of a pair of mutually adhered sealing strips, wherein said rotating wheel mechanism further comprises a pair of winding wheels for separating and winding each of said sealing strips onto a spool.

In another preferred embodiment of the system of the present invention, an affixing device is utilized for affixing the

proximal section of the system to the distal section for allowing performance of procedures with a partially inserted catheter. The affixing device preferably comprise fastening arms adapted to clasp the distal section and retaining arms adapted to receive and hold the proximal section of the system. The affixing device may further comprise supporting pins for wrapping a portion of the adhered sealing strips therebetween, whenever the length of the none-inserted strip bilayer is greater than the length of the affixing device.

In another preferred embodiment of the system of the present invention, a sealed separator is utilized for separating the adhered sealing strips, exposing the catheter sealed therein, and advancing it into the entry port. The separator comprises a proximal aperture and retaining members for guiding the catheter sealed in the adhered strips, entering the separator via said proximal aperture, towards an opening of a passage tube linked to the entry port. The adhered strips are separated in the vicinity of the passage tube opening, advanced along the sides of splitting means, and leave the separator via apertures provided thereon. The catheter is exposed and advanced into said passage tube and therefrom into the entry port. The tips of the separated strips may be adhered outside the separator to allow convenient insertion of the catheter by pulling the adhered tips distally.

In another aspect, the present invention is also directed to an advancing mechanism for advancing a sterile catheter in a distal direction, wherein said mechanism comprises a sealed spool containing a sterilized catheter wound around a central axis in a spiral manner, and a distal exit, such that said catheter is rolled in or out via said distal exit by rotations of the spool. The distal exit is connected to an entry port via suitable connector means having an inner passage for

advancing the catheter therethrough. The inner lumen of the catheter can be accessed via a catheter port connected to the proximal end of the catheter wound, allowing performance of procedures with a partially inserted catheter. After insertion of the catheter tube the spool is dismantled and a portion of the catheter tube and the catheter port attached thereto are affixed to the arm of the treated patient.

Optionally, the sealed spool containing the sterilized catheter wound is advanced utilizing the advancing means comprising a rotating wheel mechanism situated between the entry port and the sealed spool, such that rotation of the externally-situated thumb wheel causes rotation of one or more internally-situated wheels that cause the catheter to move in a distal or proximal direction. The internally-situated wheels are preferably designed to provide a limited amount of friction between said wheels and said catheter tube, thereby limiting the amount of force applied on the thumb wheel.

According to yet another preferred embodiment the present invention is directed to a catheter insertion system comprising a flexible sleeve containing a catheter tube, wherein the flexible sleeve has a sealed proximal end, and wherein the distal end of the flexible sleeve comprises a slender passage adapted to allow passage of the catheter tube therethrough while preventing backflow of fluid into the sleeve.

The catheter insertion system may further comprise a resilient portion formed near the slender passage. This resilient portion may be implemented as a corrugated portion of the flexible sleeve.

The catheter insertion system may further comprise tear lines longitudinally passing along at least a portion of the length of the flexible sleeve, for facilitating tearing thereof.

The catheter insertion system may further comprise one or more permeable portions provided on the flexible sleeve for allowing gas sterilization of the interior of the flexible sleeve. Alternatively or additionally, the proximal end of the flexible sleeve is sealed by a plug having a bore, wherein one end of the bore opens into the interior of the flexible sleeve, and wherein the other end of the bore is covered by a permeable sheet for allowing gas sterilization of the interior of the flexible sleeve.

Preferably, the proximal end of the flexible sleeve is closed by a guide wire stopper element, wherein the guide wire stopper element comprises an aperture suitable for the passage of a guide wire holder connected to the proximal end of a guide wire, and wherein the passage of the guide wire holder into the flexible sleeve can be prevented by rotation of the guide wire holder about the axis of the guide wire.

Optionally, a fastening cap adapted to fit in or over the proximal side of the guide wire stopper element is used for sealing the flexible sleeve, wherein the fastening cap may comprise gripping means adapted to grip the guide wire holder and prevent passage thereof into the flexible sleeve.

The slender passage element may be a part of a splittable head sealably fitted into the distal end of the flexible sleeve, wherein the splittable head is constructed such that it can be longitudinally split into two or more parts, thereby facilitating tearing of the flexible sleeve. Additionally, the splittable head may comprise pins adapted to be engaged in

respective apertures provided in the flexible sleeve. The splittable head may further comprise splitting tabs provided on each splittable part thereof.

The catheter tube may comprise a lateral port adapted to allow access to the lumen of the catheter tube by a syringe needle passing through the wall of the flexible sleeve. Additionally, the flexible sleeve may also comprise a lateral port adapted to allow sealable access to the interior of the flexible sleeve by a syringe needle.

The proximal end of the catheter insertion device may be sealed by a sealing plug comprising a slender passage through which the catheter tube is sealably passed such that its proximal port is external to the sleeve.

The catheter insertion system may further comprise a depressible element adapted for advancing the catheter tube contained in the flexible sleeve, wherein the depressible element comprises a flexible inverted "V" structure that is capable of advancing the catheter tube distally when pressed.

The present invention is also directed to an adapter for a catheter tube cutter, comprising a hollow connector for connecting a catheter insertion device thereto, a base connected to the hollow connector, and an arm connected to the base opposite to the hollow connector, the arm comprises an aperture inline with an opening of the hollow connector, wherein a gap formed between the connector and the arm is suitable for fitting a catheter tube cutter therein and passing a catheter tube in the hollow interior of the connector via a cutter passage provided in the catheter cutter and the aperture in the arm.

Brief Description of the Drawings

The present invention is illustrated by way of example in the figures of the accompanying drawings, in which like references indicate similar elements and in which:

- Fig. 1A is a perspective view of a catheter insertion device of the invention comprising a firm sealing sleeve and small blades;
- Fig. 1B is a longitudinal section view of the catheter insertion device shown in Fig. 1A;
- Fig. 1C is a longitudinal section view of the distal portions of the catheter insertion device shown in Fig. 1A;
- Fig. 1D is a longitudinal perspective section view of the catheter insertion device shown in Fig. 1A in its "inserted" state;
- Fig. 2A is a perspective view of a catheter insertion device of the invention comprising a flexible corrugated tube;
- Fig. 2B is a longitudinal section view of the catheter insertion device shown in Fig. 2A;
- Fig. 2C is a longitudinal section view of the distal portions of the catheter insertion device shown in Fig. 2A;
- Fig. 2D is a perspective longitudinal section view of the catheter insertion device shown in Fig. 2A in its "inserted" state;
- Fig. 3A is a perspective view of a catheter insertion device of the invention which comprises a rotating mechanism for advancing the catheter tube;
- Fig. 3B is a longitudinal section view of the distal portions of the catheter insertion device shown in Fig. 3A;

- Fig. 3C is a longitudinal section view of the catheter insertion device shown in Fig. 3A;
- Fig. 3D shows the elements inside the advancing mechanism used in the catheter insertion device shown in Fig. 3A;
- Fig. 3E is a perspective view of the catheter insertion device shown in Fig. 3A in its "inserted" state;
- Fig. 4A is a perspective view of a catheter insertion device of the invention which comprises a stripe for sealing and advancing the catheter tube;
- Fig. 4B is a longitudinal section view of the distal portions of the catheter insertion device shown in Fig. 4A;
- Fig. 4C is a longitudinal section view of the catheter insertion device shown in Fig. 4A;
- Figs. 4D is a bottom close-up on the inner elements of the advancing mechanism shown in Fig. 4A;
- Fig. 4E is a top close-up view on the inner elements of the advancing mechanism shown in Fig. 4A;
- Fig. 4F is a perspective view of a catheter insertion device of the invention affixed in a partially inserted state using an affixing device;
- Fig 5A is a perspective view a catheter insertion device of the invention wherein the catheter tube is advanced by a "pull" action;
- Fig 5B is a top angled view of the catheter insertion device shown in Fig. 5A;
- Fig 5C is a longitudinal section view of the distal portions of the catheter insertion device shown in Fig. 5A;
- Fig. 5D is a perspective view of the catheter insertion device shown in Fig. 5A in its "inserted" state;
- Fig. 6 shows an advancing mechanism wherein the catheter tube is wound on a spool;

- Fig. 7A is a perspective view of another catheter insertion device of the invention consisting of a single flexible sleeve;
- Fig. 7B is a close-up perspective view on the proximal portion of the catheter insertion device shown in Fig. 7A;
- Fig. 7C is a longitudinal section view of the distal portion of a tearable application of the catheter insertion assembly shown in Fig. 7A;
- Fig. 7D is a perspective view of the tearable application shown in Fig. 7C;
- Fig. 7E demonstrates tearing the flexible sleeve of a tearable catheter insertion device;
- Fig. 8A schematically illustrates a conventional catheter cutter;
- Fig. 8B schematically illustrates a cutter adapter according to the invention;
- Fig. 8C schematically illustrates fitting a conventional catheter cutter in the cutter adapter of the invention;
- Fig. 8D is a perspective view of a further catheter insertion device of the invention based on a flexible corrugated tube that is connected to a catheter cutter device;
- Fig. 8E is a close-up on the distal portion of the assembly shown in Fig. 8D;
- Fig. 8F is a close-up on the rear portion of the catheter insertion device shown in Fig. 8A which comprises a guide-wire stopper mechanism;
- Fig. 8G is a longitudinal section of the rear portion shown in Fig. 8F;
- Fig. 8H is a close-up on the guide wire stopper mechanism shown in Fig. 8F;

- Fig. 9A illustrates a guide-wire stopper mechanism comprising a fastening cap;
- Fig. 9B is a perspective view of the guide-wire stopper mechanism with the fastening cap;
- Fig. 9C is a perspective view of the fastening cap;
- Fig. 9D is a rear view of the guide-wire stopper mechanism shown in Fig. 9A;
- Fig. 9E is a perspective front view of the fastening cap;
- Fig. 10A is a perspective view of a catheter insertion device of the invention having splittable head;
- Fig. 10B is a longitudinal view of the splittable head of the catheter insertion device shown in Fig. 10A;
- Fig. 10C is a longitudinal view of a splitted portion of the splittable head shown in Fig. 10B;
- Fig. 10D schematically illustrates splitting of the splittable head and flexible sleeve of the catheter insertion device shown in Fig. 10A;
- Fig. 11A is a longitudinal section view of a catheter insertion device of the invention which comprises a depressible element;
- Fig. 11B is a top view of the catheter insertion device shown in Fig. 11A;
- Fig. 11C is a perspective view of the depressible element of the catheter device shown in Figs. 11A and 11B;
- Fig. 12 schematically illustrates a catheter tube comprising a slidable element comprising an antimicrobial substance;
- Fig. 13A schematically illustrates a guide wire insertion device and a catheter insertion device having a splittable head wherein the catheter port exits the device via the rear end of the device;

- Fig. 13B demonstrates insertion of the guide wire into the catheter when connecting the devices shown in Fig. 13B;
- Fig. 13C schematically illustrates devices similar to those shown in Figs. 13B and 13C wherein the catheter tube is threaded over a guide wire contained in the catheter insertion device;
- Fig. 14A schematically illustrates a catheter insertion device of the invention wherein the catheter tube is provided with a lateral port; and
- Fig. 14B schematically illustrates a catheter insertion device of the invention wherein the catheter tube and the flexible sleeve are provided with a lateral port.

Detailed Description of Preferred Embodiments

Fig. 1A shows a perspective view of a catheter insertion device of the present invention (before insertion of the catheter tube into the blood vessel). In this preferred embodiment the intravascular catheter insertion device **100** comprises three main elements: entry port **110** (bearing an insertion cannula **111** at its distal-most end), proximal hub **132** and sealing sleeve **120**, said sleeve **120** being located between said entry port **110** and said proximal hub **132**. Sealing sleeve **120** is sealably connected at its proximal end to the inner bore of proximal hub **132**, and sealably connected at its distal end to entry port **110**, as will be described in more detail hereinbelow.

Before use, the device is preferably provided in two sections: (i) a distal section comprising the entry port **110** (having a disposable needle inserted within its central bore), and (ii) a proximal section comprising proximal hub **132** connected to sealing sleeve **120**.

Following placement of the insertion cannula **111** (which forms part of entry port **110**) into the desired blood vessel (not shown), the aforementioned proximal section is connected to the distal section, such that the catheter insertion device comprises a sealed, internal passageway extending from proximal hub **132**, through sealing sleeve **120** to the distal extremity of entry port **110**. As best seen in the longitudinal view of Fig. 1B, catheter tube **121** is disposed within said internal passageway. During use of the insertion device, said catheter **121** is advanced through the internal passageway, in a distal direction, such that it protrudes from the distal end of entry port **110** (through the internal bore of insertion cannula **111**), thereby becoming inserted into the desired blood vessel. Each of the three main structural elements defined above will now be described in more detail.

As best seen in Fig. 1C, the most distally placed of the three main structural elements of the device, namely entry port **110** comprises a hollow body (preferably of round cross-sectional geometry) which continues distally as hollow insertion cannula **111**, and ends proximally with a connector **112**. Optionally, the main body of entry port **110** also contains one or more hubs **115** that permit the introduction or removal of fluids into or from the internal bore of the entry port. Entry port **110** further comprises flexible wings **116** which may be taped or otherwise secured to the skin surface of the patient being treated, thereby stabilizing the entire catheter insertion device **100**. The proximal extremity of entry port **110** is adapted to reversibly connect with connector **112**, which is located at the distal end of sealing sleeve **120**, as will be described in due course. Before use, entry port **110** is fitted with an appropriately-sized disposable needle (not shown) within its internal bore, such that the tip of said needle projects distally from the end of insertion cannula **111**. By

means of said needle, said cannula may be inserted into the desired blood vessel (subcutaneous over-the-needle cannula insertion). The needle is then removed from entry port **110**, and the proximal end of said entry port is then connected with sealing sleeve **120** by means of connector **112**, the structure of which will be described in more detail hereinbelow.

The opening of the hollow insertion cannula **111** inside entry port **110** may comprise a rubber septum (not shown), having an annular ("O") or star shape, that applies some pressure (low tack) to the outer surface of catheter tube **121** in order to prevent blood from flowing via entry port **110** into sleeve **120**.

Turning now to the most proximally-located element, as shown in Figs. 1B and 1C the proximal hub **132** comprises a socket **130**, for receiving the proximal end of catheter **121** and a quick connector (e.g., Luer lock connector) **131** for connecting the guide wire assembly **133** (guide wire holder) to proximal hub **132**, as provided in standard Peripherally Inserted Central Catheters (PICC).

Quick Connector **131** can be unscrewed, thereby exposing the Luer opening and providing access to the proximal opening of catheter tube **121**. Quick connector **131** and guide wire holder **133** are usually discarded after the insertion of the catheter tube is completed.

Sealing sleeve **120** is preferably made of a type of transparent plastic silicon having thick walls for providing rigidity to the catheter insertion device **100**, and is sealably attached at its proximal end to proximal hub **132**, as described hereinabove. The distal end of sleeve **120** is fitted with a connector **112**, which is used to sealably connect the sleeve with entry port **110**. Projecting in a proximal direction from

the external surface of connector **112** are two or more small blades **102**, which are disposed such that they are covered by sealing sleeve **120**, with their cutting edges facing in an outward direction. By means of this arrangement, small blades **102** are used to incise sealing sleeve **120**, thus enabling its removal during the catheter insertion process, as will be described in more detail hereinafter.

Referring now to the longitudinal section view shown in Fig. 1C the structure of connector **112** and the interaction between said connector and entry port **110** will be described in more detail. In this example, connector **112** comprises a hollow cylindrical member **118**, adapters **113** and **117**, and an axial bore **104** passing therebetween. Adapter **117** extends outwardly from the interior of connector **112**. Adapter **117** is received in the proximal opening **103** of entry port **110** and thereby provides a sealed connection by fitting the inner surface of proximal opening **103** over the tapering tip of adapter **117**. This connection provides a sealed and secure connection between the central bore **140** of entry port **110** and axial bore **104** of connector **112**.

A cylindrical section **105** is provided between adapter **113** and the hollow cylindrical member **118** of connector **112**. Cylindrical section **105** is adapted to be received into one end of the sealing sleeve **120** by fitting the inner surface of the sleeve's end around it. In this way the catheter tube **121** can be inserted via the sterile zone defined by the passage provided through sealing sleeve **120**, axial bore **104**, central bore **140**, and therefrom into the insertion cannula **111**. Annular groove **106** provided on the outer surface of cylindrical section **105** is used to receive socket **130** in a secure and sealed fashion.

The catheter insertion device, as described hereinabove is used in the following manner.

Firstly, insertion cannula **111** together with its indwelling disposable needle (not shown) is inserted into the desired blood vessel, following puncture of the overlying skin and the wall of said vessel by the tip of said needle. The entry port is then secured in place by affixing flexible wings **116** to the skin surface. Next, the needle is removed from entry port **110**, and the proximal portion of the device (i.e. sleeve **120** pre-connected to proximal hub **132** is then connected to the proximal end of entry port **110** by means of connector **112**. The catheter tube **121** is then slidably inserted through the insertion cannula **111** into the desired blood vessel by advancing proximal hub **132** in a distal direction, i.e. towards connector **112**. In this way portions of catheter tube **121** are inserted into the insertion cannula **111** and the sealing sleeve **120** is pressed against blades **102**, which "peel off" portions of said sleeve.

The proximal hub **132** is thus directed distally until the entire sleeve is peeled off and socket **130** receives adapter **113** into its hollow interior, as shown in Fig. 1D. The interior of socket **130** comprise a female fitting **138** adapted to fasten the proximal end of sleeve **120** inside socket **130**, and to receive adapter **113** and provide a sealed connection between the axial bore **104** of connector **112** and the inner bore (not shown) of proximal hub **132**. Aperture **134** (Fig. 1B) at the distal side of socket **130** define an inward annular protrusion **137** that is engaged with the annular groove **106** when the insertion of the catheter tube **121** is completed, thereby providing a sealed connection with connector **112**.

The length of proximal hub **132** is generally in the range of 10 to 35 millimeters, and preferably about 20 millimeters, and the diameter of its inner bore is generally slightly larger than the external diameter of catheter tube **121**. The length of adapter **130** is generally in the range of 10 to 30 millimeters, and preferably about 20 millimeters, its outer diameter is generally in the range of 8 to 20 millimeters, and preferably about 14 millimeters, and the sizes of its aperture and female fitting **138** provided therein should be defined according to the dimensions of adapter **113**. Proximal hub **132** can be fabricated from any suitable material (e.g., metal, plastic), and utilizing fabrication techniques, such as ordinarily use in the fabrication of such devices (e.g. injection molding). The length of catheter tube **121** is generally in the range of 150 to 700 millimeters, and preferably about 250 millimeters, and it diameter is generally in the range of 0.8 to 2 millimeters, and preferably about 1 millimeters. Catheter tube **121** can be fabricated from any material suitable for catheters implementations such as polyurethane, silicone, or Teflon.

The length of the sealing sleeve **120** should be determined according to the length of the catheter tube used, and its diameter is generally in the range of 10 to 70 millimeters, and preferably about 25 millimeters. The sealing sleeve **120** is preferably transparent and may be fabricated from Silicone or polyurethane. The thickness of the walls of the sealing sleeve is generally in the range of 0.1 to 2 millimeters, and preferably about 1 millimeter, in order to obtain some rigidity of said sleeve. The length of connector **112** is generally in the range of 5 to 15 millimeters, and preferably about 10 millimeters, its outer diameter is generally in the range of 5 to 15 millimeters, and preferably about 8 millimeters, and its inner diameter is preferably defined according to the parameters of the entry port to be used.

Connector **112** is preferably fabricated by injection molding techniques from polypropylene, polyethylene, or ABS, materials. The Blades **102** are preferably made from a thin, sharp metal strip the length of which is generally in the range of 1 to 8 millimeters, and preferably about 2 millimeters.

As described hereinabove the catheter insertion device of the invention generally consists of three portions: a proximal portion comprising the catheter port, a guide wire grip, and a socket for sealably connecting said portion to the distal portion; an intermediate portion comprising a sealed containment including portion of the catheter tube sealed therein, and a distal portion connected to the entry port and comprising means for removing said sealed containment and advancing the portions of exposed catheter tube therethrough into the entry port. In general, the elements of the proximal portion, and the entry port, in the different embodiments of the catheter insertion device of the invention are similar in structure and shape, *mutatis mutandis*, and therefore they will not be described in details hereinafter. Moreover, it should be understood that the subcutaneous "over the needle" insertion of the cannula described hereinbefore is similarly performed in all other embodiments of the invention, and therefore will not be described with reference to each embodiment of the invention for the sake of brevity.

Another catheter insertion device **200** of the invention is shown in Figs. 2A-2D. Figs. 2A-2C shows the catheter insertion device **200** prior to its insertion into a blood vessel. This embodiment comprises a sealing sleeve **220** enclosing a proximal hub **232** and a catheter tube **221** disposed therewithin. The distal end of the sealing sleeve **220** is secured to the proximal side of adapter **243** by a clip (e.g., "U" shaped clip)

242, and the distal side of adapter **243** is attached to the proximal end of a flexible and partially corrugated tube **240**. Adapter **243** connects the interiors of sealing sleeve **220** and flexible tube **240** via inner bore **246** (Fig. 2B) formed therewithin.

Proximal hub **232** comprise a socket **230** a quick connector **231** (e.g., Luer lock), and a guide wire holder **233**. The catheter tube **221** passes via the interior of proximal hub **232** and its lumen can be accessed via port **233**. Proximal hub **232** further comprises a sleeve clamp **234**. The sealing sleeve **220** includes a single opening at the distal end thereof, and the proximal end of sleeve **220** is permanently sealed. The entry port **110** comprises an insertion cannula **111**, hub **115**, and wings **116** for securing entry port **110** to the body of a treated subject.

Depressions **241** (Fig. 2A), on lateral sides of flexible tube **240** and adjacent to its proximal end, allows the practitioner to conveniently grasp the lateral sides of catheter tube **221** passing via the interior space **245** (Fig. 2B) of tube **240**. The section adjacent to the distal end of flexible tube **240** comprise annular corrugations **244** for advancing the catheter tube **221** passing therewithin by grasping its lateral sides via depressions **241** and advancing the same in a distal direction with the entire proximal section of the catheter insertion device **200** by applying a forward pressure and thereby reducing the total length of corrugated section **244**. Corrugated section **244** serves as a spring for restoring the original length of flexible tube **240**, thereby allowing insertion of portions of the catheter tube **221** via forward movements without requiring application of backward movements before insertion of further portions of the catheter **221**. Similar operation can be achieved by using other resilient mechanisms, such us springs and/or resilient tubes, or combinations hereof.

Fig. 2C shows a longitudinal section view of the distal portion of catheter insertion device **200** comprising flexible tube **240**, connector **212**, and adapter **243**. Catheter tube **221** is shown passing through passage **246** provided inside adapter **243**, via the interior space **245** of flexible tube **240**, via conical passage **217** inside connector **212**, and therefrom into the central bore **140** of entry port **110**. The tip of conical passage **217** preferably tightly fits over the outer surface of catheter tube **221** in order to prevent blood from flowing via entry port **110** into flexible tube **240**.

Adapter **243** comprises cylindrical sections at its proximal and distal sides, wherein the cylindrical section at the distal side comprise annular groove **248** that receives an inward annular protrusion at the proximal end of flexible tube **240**, and wherein the cylindrical section at the proximal side comprise an annular groove **249** adapted to receive the distal end of sealing sleeve **220**, which is securely sealed thereto by clip **242**, and an inward annular protrusion **137** at the distal side of socket **230**. Optionally, an additional annular groove may be provided proximally adjacent to groove **249** for receiving the annular protrusion of socket **230**. In this way a sealed passage is defined for advancing the catheter tube **221** starting from the interior of sleeve **220** via the interior space **245** of flexible tube **240** and through the central bore **140** of entry port **110**.

Connector **212** consists of a cylindrical hollow member **211** having an opening **213** at a distal side thereof, wherein the diameter of opening **213** is greater than the outer diameter of the proximal end of entry port **110**, thereby allowing insertion of the proximal end of entry port **110** into the interior of connector **212**. The conical passage **217** inside connector **212**

extends outwardly via opening **213**, such that its distal end leaves the interior of cylindrical hollow member **211**. The diameter of the distal end of conical passage **217** is smaller than the diameter of the opening at the proximal end of entry port **110** thereby providing secure sealing therebetween by fitting the proximal end of entry port **110** a round the distal end of conical passage **217**. Connector **212** comprises a cylindrical section at its proximal side, where said cylindrical section includes an annular groove **218** which receives the inward annular protrusion **137** at the distal end of flexible tube **240**.

In this preferred embodiment rigidity of the sealing sleeve **220** is not required, such that it may be produced from a type of transparent plastic silicon or from Polyethylene. The catheter tube **221** is slidably inserted via the insertion cannula **111** into the blood vessel by grasping its lateral sides via depressions **241** and forwardly pushing it toward entry port **110**, thereby reducing the total length of the corrugated section **244** and moving portions of catheter tube **221** towards the insertion cannula **111**. The inner diameter of conical passage **217** at its distal tip approaches the outer diameter of catheter tube **221** for tightly fitting it around the outer surface of catheter **221**, in order to provide a grip of catheter tube **221** for preventing its withdrawal after the applied grasp of depressions **241** is released. When said grasp is released, the corrugated section **244** expands backwardly and restores its previous shape, thereby sliding depressions **241** and adapter **243** backwardly over catheter tube **221**.

By repeatedly pushing portions of the catheter tube **221** the Proximal hub **232** is moved forwardly until the socket **230** receives the cylindrical section at the proximal side of adapter **243** inside its hollow interior, as shown in Fig. 2D.

Male fitting **238** inside socket **230** is adapted to be received in passage **246** and thereby provide a sealed connection between the interior space **245** of tube **240** and the inner bore (not shown) of proximal hub **232**.

At this stage inward annular protrusion **237** at the distal side of socket **230** is engaged with annular groove **249** which provides a sealed and secured connection therebetween. After the secured connection between adapter **243** and socket **230** is obtained the sealing sleeve **220** can be removed by detaching clip **242** from annular groove **249**. After the sealing sleeve **220** is removed the requisite procedure can be carried out.

The length of adapter **243** is generally in the range of 8 to 20 millimeters, and preferably about 12 millimeters. Its diameter is preferably in the range of 5 to 15 millimeters, and preferably about 8 millimeters. Adapter **243** is preferably made of polypropylene, polyethylene, or Teflon. The length of the cylindrical sections at the proximal and distal sides of adapter **243** is generally in the range of 4 to 12 millimeters, and preferably about 8 millimeters, and the diameter of annular groove **249** is determined according to the diameter of the sealing sleeve for providing sealed connection therewith, and the diameter of annular groove **248** is determined to provide sealed closing according to the diameter of flexible tube **240**.

Flexible tube **240** is preferably made of flexible, "memory" type of material (i.e., capable of restoring its original shape) such as Silicone, and manufactured utilizing known techniques, such as injection molding. Its length is generally in the range of 15 to 40 millimeters, and preferably about 25 millimeters, and its diameter is generally in the range of 8 to 20 millimeters, and preferably about 15 millimeters. The

dimensions of connector **212** are generally similar to the dimensions of connector **112**, and accordingly the dimensions of the conical passage **217** should be determined according to the entry port **110** used. Clip **242** is preferably made from a type of flexible hard material such as polypropylene, or stainless steel.

An advancing mechanism **350** can be used for advancing the catheter tube **321**, as shown in Figs. 3A to 3D. The catheter insertion device **300** in this embodiment comprises a proximal hub **232** and catheter tube **231** enclosed within sealing sleeve **220**, advancing mechanism **350**, and a hollow connector **312** connecting the interior of advancing mechanism **350** with the central bore (**140** shown in Fig. 1C) of entry port **110**. The opening at the distal end of the sleeve **220** is sealed by clip **342** placed over its edge and fastening it over an annular groove **355** (Fig. 3B) provided at the proximal end of advancing mechanism **350**. Advancing mechanism **350** comprises cylindrical sections, **352** (comprising annular groove **355**) - at its proximal end and **354** - at its distal end, a sealing cover **351** (Fig. 1), and an applicator wheel **353**. Axial bores, **352a** and **354a**, (Fig. 3B) are provided inside cylindrical sections **352** and **354**, respectively. Cylindrical section **352** is adapted to be received inside socket **230** and comprises an annular groove adapted to receive clip **342** while grasping the edge of sleeve **220** over it. Said annular groove is also adapted to receive an inward annular protrusion **137** at the distal side of socket **230**. Alternatively, an additional annular groove may be provided for receiving said inward annular protrusion **137** at the distal side of socket **330**.

As shown in Fig. 3B connector **312** comprises an inward annular protrusion at its proximal side adapted to fit over the outer surface of cylindrical section **354**. The proximal opening of

entry port **110** is adapted to fit over the distal potion of cylindrical section **354** and thereby to provide a sealed connection between the central bore **140** of entry port **110** and the internal space of advancing mechanism **350**. Connector **312** may be secured to the proximal end of entry port **110**, for example via an inward annular protrusion (not shown) provided at the opening at its distal, where said annular protrusion is adapted to fit over the outer surface of the proximal end of entry port **110**. In this way a sealed passage is provided for advancing catheter tube **321** from the sealing sleeve **220** via advancing mechanism **350** utilizing the axial bores, **352a** and **354a**, of cylindrical sections **352** and **354**, and through central bore of entry port **110**.

Referring now to Fig. 3D, which is a close-up on the inner elements of advancing mechanism **350**. For the sake of clarity, the container enclosing the elements of advancing mechanism **350** is not shown in Fig. 3F. Applicator **353** is attached to wheel **357b** via upper end of shaft **358b**. Shaft **358b** passes vertically via the axial center of wheel **357b** and leaves the interior of advancing mechanism **350** via an aperture in sealing cover **351**. The upper tip of shaft **358b** is received inside a central bore in applicator **353**. Wheel **357a** is situated adjacent to wheel **357b**, and the vertical shaft **358a** passing through its axial center is parallel to shaft **358b**. Canals **359** are formed on the outer circumferential surfaces of wheels **358a** and **358b**. Catheter tube **321** passes between wheels **357a** and **357b** such that portions of canals **359** tangential to catheter tube **321** are engaged with a portion of its outer surface.

Applicator **353** can be manually rotated by the practitioner, thereby applying a tangential force on portions of the outer surface of catheter tube **321** that are in contact with portions

of canals **359**, thus causing forward or backward movement of catheter tube **321**, according to the direction of rotation. The advancing mechanism **350** is preferably designed such that only a certain amount of friction can be obtained between the portions of canals **359** being in contact with portions of the outer surface of catheter tube **321**.

Limiting the friction between the contact surfaces of canals **359** and catheter **321** dictates a limitation on the amount of force that can be applied during the movement of the catheter tube **321**. In this way, applying an excess amount of force will result in a slide of the wheels over the outer surface portion of catheter tube **321** being in contact with canals **359**. As a result, the possibility of causing internal injuries to the treated subject by applying excess forces during insertion is substantially diminished.

Fig. 3E illustrates the catheter insertion device **300** in the inserted state. After completing the insertion of catheter tube **321**, socket **230** receives into its interior the proximal cylindrical section **352** of advancing mechanism **350**, and male fitting **238** (Fig. 3C) inside socket **230** is received in the respective female fitting provided in cylindrical section **352**, thereby provide a sealed connection between the interior space of advancing mechanism **350** and the inner bore (not shown) of proximal hub **232**. A sealed connection is obtained therebetween by engaging an inward inner protrusion **137** defined by the opening at the distal side of socket **230** with the annular groove **355** provided on the cylindrical section **352**. After obtaining this sealed connection the sealing sleeve **320** can be removed by detaching clip **342** and thereby releasing the sleeve edge from the clip grasp, thereafter the requisite procedure can be performed.

The container of advancing mechanism **350** is preferably made from a type of polymer such as polypropylene, ABS, or polycarbonate, and it may be manufactured by injection molding techniques. Its height is generally in the range of 10 to 25 millimeters, and preferably about 15 millimeters, its vertical length is generally in the range of 15 to 35 millimeters, and preferably about 25 millimeters, and its width is generally in the range of 15 to 35 millimeters, and preferably about 20 millimeters. Cover **351** is preferably made from the same type of material and its sizes are determined according to the dimensions of container **350**. Wheels **357a** and **357b** are preferably made from a type of polymer, such as polypropylene, Teflon, or ABS, and their diameters are generally in the range of 8 to 20 millimeters, and preferably about 12 millimeters. The vertical length of shaft **358** is determined according to the height of the container of mechanism **350**. Shaft **358b** is slightly prolonged in order to receive applicator at its upper end. The diameter of applicator **353** is generally in the range of 10 to 30 millimeters, and preferably about 18 millimeters.

In another catheter insertion device of the invention a pair of adhered sealing strips **460** (hereinafter referred to as 'sealing strip bilayer') is used in catheter insertion device **400** for sealing and inserting the catheter tube **421**, as shown in Figs. 4A to 4E. The sealing strip bilayer **460** encloses catheter tube **421** which passes via the interior of proximal hub **432**. The lumen of catheter tube **421** can be accessed via port **233**. The sealing strip bilayer **460** is attached to socket **430** at its interior where an opening of an axial bore (not shown) in proximal hub **432** is provided. The sealing strip bilayer **460** is inserted into advancing mechanism **450** via a slender vertical passage provided along a cylindrical section **452** at the proximal end of advancing mechanism **450**. In the advancing mechanism **450** the catheter tube **421** is separated

from the sealing strip bilayer **460** and further advanced via an axial bore provided in a cylindrical section **454** at the distal end of advancing mechanism **450**. Therefrom the catheter tube **421** is advanced into the central bore (**140**, Fig. 4C) of entry port **110**, via an inner passage provided inside connector **412**.

Figs. 4D and 4E show the elements of the advancing mechanism **450**, and other elements attached thereto. For the sake of clarity the container enclosing mechanism **450** is not shown in this Fig. 4D. The advancing mechanism **450** comprise two adjacently disposed winding wheels, **457a** and **457b**, each of which consists of a hollow cylindrical member for winding the respective strips **460a** and **460b** thereon, a gear wheel at one side of the cylindrical member and a guard wheel at the other side of said cylindrical member. The winding wheels **457a** and **457b** are attached at their guard wheel side by pivot protrusions **459** to the inner bottom side of the container such that their cylindrical members are substantially parallel. Similarly, winding wheel **457a** is attached at the gear wheel side to the cover **451**. Winding wheels **457a** and **457b** can freely rotate over pivot protrusions **459**, and the teeth of their gear wheels are engaged such that rotation of one of said wheels is induced by the gear wheels to the other wheel. Shaft **455** attached to the axial center of winding wheel **457b** passes via an aperture in cover **451** and received in a respective bore at the center of the applicator wheel **453**.

Two adhered sealing strips **460a** and **460b** enclose the catheter tube **421** therewithin. The distal ends of said strips are attached to cylindrical members of the winding wheels **457a** and **457b**, respectively. In order to advance the catheter tube **421** the practitioner rotates (e.g., counterclockwise rotation in Fig. 4E) applicator wheel **453** thereby rotates the winding wheels **457a** and **457b**. In effect, the adhered strips **460a** and

460b are separated and wound around the respective winding wheel, thereby exposing the catheter tube enclosed therein and advancing it toward passage tube **417**.

Strips **460** may be adhered utilizing a high tack glue (i.e., having high degree of stickiness), but of a low strength, thereby enabling the operator to retract the portions of the inserted catheter tube and sealing it back inside strips **460** as it is pulled out. Such action may be required when the catheter is stuck and there is a need to retract a portion thereof in order to further advance it in a forward direction.

With reference to the longitudinal section view in Fig. 4B, where it is shown that passage tube **417** provides a passage for catheter tube **421** via an axial bore in cylindrical section **454**. The proximal opening of passage tube **417** is conveniently of a conical shape for allowing easy insertion of the tip of catheter tube **421** thereto. The cylindrical section **452** comprises an annular groove adapted to receive an inward annular protrusion at the opening at the proximal side of connector **412**. An inward annular protrusion is preferably also provided at the opening at the distal side of connector **412**, which is adapted to fit over the outer surface of the proximal end of entry port **110**. Cylindrical section **454** is followed by a conical member **418** the outer diameter of which is gradually decreased toward its distal end. The outer diameter of conical member **418** at the distal end is smaller than the diameter of the opening at the proximal end of entry port **110**, which allows inserting it thereto in order to provide a sealed connection therebetween.

As shown in Fig. 4E, retaining members **458a** and **458b** are perpendicularly situated on the bottom side of the container of advancing mechanism **450** near the inner opening of the

slender passage provided in cylindrical section **452**. The sealing strip bilayer **460** passes between the retaining members **458a** and **458b**, which directs it towards the passage tube **417**. For the sake of clarity, winding wheel **457a** is not depicted in the advancing mechanism shown in Fig. 4F.

With reference to Fig. 4C, the cylindrical section **454** at the proximal side of the advancing mechanism **450** comprises an annular groove adapted to receive an inward annular protrusion **437** defined by the opening in socket **430**. After completing the insertion of catheter tube **421** cylindrical section **454** is received inside socket **430** and a sealed connection therebetween is achieved by engaging inward annular protrusion **437** with the annular groove provided on cylindrical section **452**, and the requisite procedure can be performed thereafter. Connector **412** preferably includes an inward annular protrusion at the opening at its distal side (not shown), which is adapted to fit over the outer surface of the proximal end of entry port **110**.

Winding wheels **457** are preferably made from a type of polymer, such as polypropylene, polyethylene, or Teflon, and the diameter of their cylindrical members is generally in the range of 8 to 20 millimeters, and preferably about 12 millimeters. Strips **460a** and **460b** are preferably made from flexible, bacteria resistant with low "memory" type of material, such as paper or a non-woven fabric, and their width is generally in the range of 5 to 15 millimeters, and preferably about 8 millimeters. The strips **460a** and **460b** may be joined to seal catheter tube **421** therewithin by means of pressure stamping or low strength glue, preferably by utilizing an acrylic or silicone based glue.

The catheter insertion device which was described immediately hereinabove with reference to Figs. 4A to 4D, can be modified in order to allow procedures to be performed with this device when partially inserted. Fig. 4E shows such a modification wherein vertical affixing canals **557** are provided on the lateral sides of the advancing mechanism **550**. In this example, each canal **557** is formed by two adjacent parallel ribs formed on the lateral sides of advancing mechanism **550**. Canals **557** are adapted to receive fastening arms **571** of affixing device **570**. In this example fastening arms **571** are slightly elevated relative to the plane of the affixing device **570**.

Affixing device **570** further comprise retaining arms **572** situated at the proximal end of said device. Retaining arms **572** protrude perpendicularly from the plane of affixing device **570** and adapted to receive an annular groove **439** formed between socket **430** and gripping section **231**, thereby fastening proximal hub **432** thereto. The length of the strip between the advancing mechanism **550** and the socket **430** may vary (e.g., 20 to 60 millimeter). Since in the affixed state a predetermined distance is provide between the socket **230** and the advancing mechanism **550** (e.g., about 50 millimeters) supporting pins **575** situated at opposite sides of affixing device **570** and along its longitudinal length are provided for wrapping a portion of sealing strip bilayer **460** therebetween, whenever the length of the none-inserted strip bilayer is greater than said predetermined distance.

The advancing mechanism **550** used in this embodiment is substantially similar to the mechanism used in the embodiment previously described with reference to Figs. 4A to 4D, and therefore it will not be discussed herein for the sake of brevity.

Affixing device **570** is preferably made from a type of polymer, such as polypropylene, ABS, or Polyethylene, its vertical length is generally in the range of 20 to 60 millimeters, and preferably about 50 millimeters, its width is generally in the range of 20 to 50 millimeters, and preferably about 30 millimeters.

As was shown hereinabove, insertion of the catheter tube utilizing a sealing strip bilayer can be carried out without a sealing sleeve, and as was previously described, this preferred embodiment of the invention can be further utilized for carrying out procedures with a partially inserted catheter. An additional advantage of this insertion mechanism will be now discussed with reference to Figs. 5A to 5D, which illustrates a catheter insertion device designed for allowing insertion of the catheter tube by a "pull" operation.

In this embodiment, shown in Figs. 5A to 5D, the catheter insertion device **600** comprises a proximal hub **432**, a sealing strip bilayer **460** containing catheter tube **421**, strip separator apparatus **680**, and entry port **110**. Strip bilayer **460** is attached to the inner distal wall of socket **430** where an opening of a bore (not shown) in proximal hub **432** is provided. The catheter tube **421** sealed in strip bilayer **460** passes *via* said bore towards entry port **110**. The distal portion of strip bilayer **460** is inserted into separator **680** via a slender passage passing via proximal adapter **682** of separator **680**. This slender passage leads to the interior of separator **680**, which further includes cover **685**, retaining members **684**, passage tube **683**, splitters **686**, distal adapter **652**, and slender apertures **669a** and **669b**.

The retaining members, **684a** and **684b**, are perpendicularly disposed on the inner bottom side of the container of

separator **680** adjacent to the inner opening of the slender passage at the proximal inner side of separator **680**. The retaining members **684** define a slender passage therebetween which provides a passage for directing strip bilayer **680** towards the opening of passage tube **683** (fig. 5B). The distance between the retaining members **684** is gradually increased toward the opening of passage tube **683**, such that said tube can be received therebetween. Strip bilayer **460** is directed via the passage defined by retaining members, **684a** and **684b**, towards the opening of passage tube **683**, disposed therein.

Strips **460a** and **460b** are separated near the opening of passage tube **683** and therefrom advanced separately towards respective slender apertures, **669a** and **669b**, along the lateral sides of splitters, **686a** and **686b**, respectively. Concurrently, Catheter tube **421** is exposed near the opening of passage tube **683**, advanced into said tube towards an opening connecting the interior of said tube with an axial bore provided in the distal adapter **652** (Fig. 5C), and therefrom into the central bore **140** of entry port **110**. The distal ends of strips **460a** and **460b** leave separator **680** via slender apertures **669**, and their tips are joined together at **603**, near hub **115**.

In this state, shown in Figs. 5A to 5C, the catheter insertion device **600** is ready for insertion, which is carried out by pulling the adhered strip tips at **603** forwardly towards the distal tip of insertion cannula **111**. The catheter tube can be partially inserted and affixed utilizing an affixing device similar to that shown in Fig. 4E, or it may be fully inserted as shown in Fig. 5D.

When fully inserted, socket **430** is advanced until proximal adapter **682** is received via a distal aperture thereof into the

hollow interior of socket **430**. A sealed connection is obtained as the inward protrusion **437** at said aperture is engaged with an annular groove on the outer surface of adapter **682**.

An inward annular protrusion is preferably provided at the opening at the distal side of connector **612** (not shown), which is adapted to fit over the outer surface of the proximal end of entry port **110**. Distal adapter **652** comprise a conical member **618** adapted to be received in the proximal opening of entry port **110**. In this example, the catheter insertion device **600**, shown in Figs. 5A-5C, includes a sealing sleeve **220** and a clip **642** for securing the sealing sleeve **220** to proximal adapter **682**. However, it should be recognized that these elements are optional and in fact may be redundant due to the sealing of the catheter tube **421** that is provided by strip bilayer **460**. For instance, the sealing sleeve **220** may be used as an extra defense for use when the glue used to join strip bilayer **460** is not suitable for retracting portions of catheter tube.

Separator **680** is preferably made from a type of polymer, such as polypropylene, ABS, or polycarbonate, and its vertical length is generally in the range of 20 to 50 millimeters, and preferably about 30 millimeters, its width is generally in the range of 10 to 30 millimeters, and preferably about 20 millimeters, and its height is generally in the range of 8 to 20 millimeters, and preferably about 15 millimeters.

Fig. 6 demonstrates an advancing mechanism **700** wherein the catheter tube **721** is wound on a spool **701**. Spool **701** comprises an axial cylindrical opening adapted to receive therein cylindrical member **702** which is provided in the center of sealed housing **710**. The advancing mechanism **700** further comprises an exit tube **705** attached thereto from which the

wound catheter tube **721** is rolled out. Connector **704** is attached to the exit tube **705** via a cylindrical member which is inserted into said tube. An axial bore (not shown) is provided inside connector **704**, wherein the catheter tube **721** enter said bore at opening provided at the proximal end of the cylindrical member, and it leaves said bore at opening provided at the distal end of connector **704**. Said distal end is adapted to provide a sealed connection with the proximal opening of an entry port in a way similar to the like connections which were previously discussed hereinabove. Catheter port **703** is attached to the proximal end of catheter tube **721** and provides access to its inner lumen for performing the requisite procedure.

The advancing mechanism **700** can be connected directly to an entry port **110**, which was previously placed into a blood vessel, and the catheter tube **721** can be then advanced into said blood vessel via entry port **110** by rotating the spool **701** via a handle (not shown) connected to the inner side of cylindrical member **702**, thereby allowing the operator to rotate spool **701**. This advancing mechanism also permits performing procedures with a partially inserted catheter tube. The practitioner can carry out the requisite procedure via catheter port **703** at any suitable stage during the catheter insertion. The lid **707** of advancing mechanism **700** may be removed to allow access to the catheter port **703** at any stage during the insertion.

Advancing mechanism **700** is preferably made from a type of rigid polymer, such as polypropylene, polycarbonate, or ABS, its diameter is generally in the range of 30 to 60 millimeters, and preferably about 40 millimeters, its height is generally in the range of 8 to 20 millimeters, and preferably about 12 millimeters. The diameter of cylindrical

member **702** is determined to fit in the cylindrical opening provide if spool **701**.

The advancing mechanism **700** may be dismantled after insertion of the catheter tube **721**, leaving a portion of the catheter tube **721** to be attached to the body of the treated patient. For example, exit tube **705** may include a longitudinal slit **708** through which catheter tube **721** may be removed. In this way after insertion of catheter tube **721** is completed connector **704** may pulled out of exit tube **705** and thereafter the housing **710** of advancing mechanism **700** may be discarded by removing the proximal portion of catheter tube **721** therefrom via an opening provided in housing **710** and via said slit **708**.

Fig. 7A is a perspective view of another catheter insertion device **750** of the invention which is made from a single flexible sleeve **760**. While flexible sleeve may be permanently sealed at its proximal end, in the preferred embodiment illustrated in Fig. 7A cap **758** is sealably fitted into the proximal end opening of sleeve **760**. The distal portion of sleeve **760** preferably comprises a tapering end in which a slender passage element **752** is sealably fitted. Slender passage **752** comprises a concentric bore (shown in Fig. 7D) suitable for passing catheter tube **751** therethrough.

The inner diameter of the concentric bore of slender passage element **752** is configured to provide close-fitting with the outer surface of catheter tube portion passing therethrough and thereby prevent passage of fluids (blood) therethrough into the interior of sleeve **760**. In addition, slender passage element is preferably configured to produce sufficient traction for holding the catheter tube in place while flexible sleeve **760** moves back.

Catheter tube **751** is contained in catheter insertion apparatus **750** in a sterile and sealed environment defined by sleeve **760**. Flexible sleeve **760** may be manufactured from a resilient material (e.g., silicon, polyurethane) to allow insertion of catheter tube **751** contained therein by grasping portions thereof by externally squeezing respective portions of sleeve **760** and pushing the same distally towards the slender passage element **752**. In this way in each of these push actions portions of catheter tube **751** are advanced out of sleeve **760** via the concentric bore of slender passage element **752**, and sleeve **760** restores its original shape when its grasped portions are released. In the preferred embodiment illustrated in Fig. 7A sleeve **760** comprises a resilient section **753** provided near the distal end of the sleeve **760** which conveniently enable the operator to carry out this advancing operation of catheter tube **751**.

Flexible sleeve **760** may further comprise annular supports **755** provided along its length for increased stiffness and to help prevent kink and collapse of sleeve **760**. Annular supports **755** may be implemented as annular portions of sleeve **760** wherein the said sleeve if thicker or by applying an external layer over the sleeve in various locations along its length. Alternatively, the entire sleeve **760** may be made thick to prevent kink and collapse thereof.

The distal portion of slender passage element **752** protrudes distally via a distal opening at the tapering distal end of sleeve **760** and it may comprise quick connection means (e.g., luer lock) for connecting catheter insertion device **750** to supplementary devices, such as entry port **110** (not shown) or a splittable introducer **761** (shown if Fig. 7D). For example, in Figs. 7C and 7D, the distal portion of slender passage element **752** is fitted into an entry port of a splittable introducer

761 (e.g., PeelAway®). After completing the insertion of catheter tube **751** into the patient the splittable introducer **761** may be splitted and discarded by pulling tabs **768**. In this state the entire length of catheter tube **751** is advanced into the patient and the tapering end of catheter port **757** (Fig. 7A) is fitted into cavity **771** (Fig. 7D) provided at the proximal end of slender passage element **752**.

Cap **758** may comprise a concentric bore which at one end thereof opens into the interior of sleeve **760**, and which other end is closed by a permeable material **759** (e.g., Tyvac, paper, polypropylene membrane) thus enabling the application of gas sterilization of the device's interior prior to carrying out any procedure therewith. Alternatively or additionally, permeable material portions may be provided at one or more locations on the lateral sides of sleeve **760**.

With reference to Figs. 7C and 7D, wherein a modified catheter insertion device **770** is illustrated which may be teared away. For this purpose tearing tab **766** is preferably provided at the distal end portion of sleeve **760**, perpendicularly protruding therefrom between parallel tear lines **769** provided along the longitudinal length of sleeve **760**. In this preferred embodiment the flexible sleeve **760** of the catheter insertion device **750** can be ripped and discarded, after completing the insertion of the catheter tube **751**, by pulling upwardly tearing tab **766**, as demonstrated in Fig. 7E.

It should be noted that slender passage element **752** can be made splittable in order to allow removal thereof after completing the catheter insertion. Furthermore, slender passage element **752** can be an integral part of flexible sleeve **760**. Additionally, slender passage element **752** is preferably designed such that it will apply sufficient traction on the

outer surface of the catheter tube portions passing thereinside in order to hold the catheter tube in place while the resilient section **753** restores its original shape. Optionally, slender passage element **752** may be configured as a one way valve which requires application of low forces in moving the catheter distally and relatively greater forces in retracting it proximally. It should be however clear that the catheter insertion device of the invention may be implemented without the slender passage element.

Flexible sleeve **760** may be manufactured by injection molding process from a resilient material such as silicon or polyurethane, its length is generally in the range of 10 to 300 mm, preferably about 50 mm, and its diameter is generally in the range of 6 to 30 mm, preferably about 18 mm. The diameter of slender passage element **752** is generally in the range of 0.5 to 3 mm, preferably about 1 mm, its length is generally in the range of 0.1 to 5 mm, preferably about 1 mm, and may be manufactured by injection molding from silicon, rubber, polyurethane, polyethylene. The diameter of cap **758** is generally in the range of 5 to 25 mm, preferably about 20 mm, its length is generally in the range of 5 to 20 mm, preferably about 15 mm, and it may be manufactured by injection molding from ABS, polypropylene . Tear lines **769** may be implemented by thin or weakened lines introduced during the manufacture process.

The resilient section **753** may be implemented by forming a corrugated section near the distal end of sleeve **760**. Of course resilient section **753** may be also implemented in various other ways, for example by attaching a spring to the respective inner (or outer) surface of flexible sleeve **760**.

Fig. 8A schematically illustrates a conventional catheter cutter **50**. This conventional cutter comprises a rectangular cutting blade **52** enclosed in housing **51**. Portion of catheter tube may be trimmed by catheter cutter **50** by passing it (without its guide-wire) via apertures **53** provided on opposing lateral walls of housing **50**, such that it is passed via the inner space of housing **50** and under the blade of cutting blade **52**. After passing a certain portion of catheter tube for cutting via apertures **53** said portion may be cut off by pushing down the side of the cutting blade which protrudes outwardly via opening **54**, thus pressing the blade of cutting blade **52** against the catheter tube passing in the inner space of housing **51** and cutting said portion off.

In order to allow carrying out such a trimming process with the catheter insertion device of the invention and the conventional catheter tube cutter **50** while maintaining a sterile environment the cutter adapter **55** shown in Fig. 8B may be used. Cutter adapter **55** is preferably made from a rigid material and formed in a "U"-like shape. The arms **56** of cutter adapter **55** are adapted to fit over the corresponding portions of the lateral walls of catheter tube cutter **50** in which apertures **53** resides, such that apertures **53** may be accessed via corresponding apertures **58** provided in arms **56** when the catheter tube cutter **50** is centered between arms **56** of cutter adapter **55**, as shown in Fig. 8C.

Connector **57** provided on the outer side of arms **56** provides a sealed access to apertures **58** via a concentric bore **59** provided therein, thereby allowing connecting cutter adapter **55** to a corresponding connectors means of the catheter insertion device of the invention (e.g., **943** in Fig. 10C) and advancing the catheter tube into the interior of catheter tube cutter **50** therethrough. It should be appreciated that the

sealed connection obtained in this way between the catheter insertion device and the inner space of catheter tube cutter **50** provides the sterile environment required for carrying out catheter trimming.

Cutter adapter **55** can be made from a plastic or metal material, such as poly ethylene, poly propylene, ABS, Nylon, preferably from polypropylene, utilizing an injection molding manufacture process. The width of its arms **56**, and of the side connecting the arms, is generally in the range of 5 to 20 mm, preferably about 12 mm, and their length is generally in the range of 10 to 20 mm, preferably about 15 mm. The distance between the arms should be set according to the width of the catheter tube cutter **50**, for example it may range between 2 to 20 mm, preferably about 8 mm. The diameter of apertures **58** and concentric bore **59** should be set according to the diameter of apertures **53** of catheter tube cutter **50**, for example it may range between 0.5 to 5 mm, preferably about 1 mm.

Cutter adapter **55** preferably comprise two connectors **57** each of which is attached on the outer surface of an arm **56** such that its concentric bores is in connection with the respective apertures **58**, which allows sealing the passage provided between the concentric bores and via apertures **58** and **53** by a cap (not shown).

It should be clear that a sealed connection of the catheter insertion apparatus of the invention may be also obtained by utilizing a dedicated catheter tube cutter (not shown) which has one or two connectors **57** integrally attached to its sides over apertures **53** such that the interior of said dedicated catheter cutter may be accessed *via* concentric bores of the connectors. Of course, when such a dedicated catheter tube cutter is used cutter adapter **55** is not required.

Another catheter insertion device **800** of the invention is illustrated in Fig. 8D, wherein the insertion device **800** is implemented using a flexible sleeve **817** comprising a plurality of stiffening portions **816**. Alternatively, flexible sleeve can be made rigid by increasing its thickness for preventing kink and collapse thereof. Catheter insertion device **800** may be manufactured from a resilient material and/or it may comprise a resilient (e.g., corrugated) portion **803**. The catheter insertion procedure carried out using catheter insertion device **800** is substantially similar to the catheter insertion procedure that was previously described herein with reference to Figs. 7A-7C.

In this example, sleeve **817** further comprises a tearing tab **811** and a slender passage element **812**. The proximal section of catheter tube **801** contained in sleeve **817** comprises anchoring means **802** and catheter port **807**. Guide wire **829** passing inside catheter tube **801** further comprises guide wire holder **821**, which will be described in details hereinbelow.

Catheter insertion device **800** is connected via adapter **55'** to a catheter trimming device **50** which facilitates catheter trimming within a sterile environment, as may be required. Fig. 8E exemplifies the connection of the catheter insertion device of the invention **800** to conventional catheter cutter **50** *via* a suitable cutter adapter **55'**. Such connection is preferably obtained by providing suitable quick connecting means (e.g., Luer lock) at the distal tip of the catheter insertion device and at the cutter adapter **55'** and thereby providing a sealed connection therebetween. Guide wire **829** (shown in Fig. 8G) may pass along the entire length of catheter tube **801** via its inner lumen or via a dedicated wire lumen (not shown). In this example the proximal end of guide

wire **829** is attached to the sealed proximal end of sleeve **817** for preventing it from being advanced into the inner space of catheter tube cutter **50**, thereby preventing the situation wherein its distal portion is cut.

Sleeve **817** may comprise permeable portions (not shown) for allowing applying gas sterilization procedures (e.g., Ethylene Oxide) to the interior of sleeve **817**. Alternatively, one or all sides of the sleeve **817** may be manufactured from a permeable material (e.g., paper). It should be appreciated that this sleeve embodiment, which comprises permeable portions, may be advantageously used for production of catheter insertion kits that does not require the sterilization blister packaging that is commonly nowadays.

As seen in Figs. 8D and 8E during the trimming process a proximal section **801a** of the catheter tube **801** is advanced distally out of the catheter insertion device **800** for trimming. As shown in this example the catheter tube **801** is advanced distally via slender passage element **812**, for example by using the resilient section **803** as was previously described hereinabove. While portions of catheter tube **801** are advanced distally, corresponding portions of guide wire **829** are withdrawn from catheter tube **801**.

While attaching the proximal end of the guide wire to the proximal end of sleeve **817** may be sufficient to obtain the withdrawal of guide wire **829** during the advancing of catheter tube **801**, it is also beneficial to have sleeve **817** made from a relatively rigid material (e.g., polypropylene), and/or of a sufficient thickness (e.g., 1.5mm) to prevent displacements of guide wire **829** relative to sleeve **817**. Alternatively, sleeve **817** may be packaged inside a rigid sleeve (not shown) that will prevent wrinkling and or collapse of sleeve **817** and

thereby prevent displacements of guide wire **829** relative to sleeve **817**.

The catheter portion **801a** is trimmed by pushing the cutting blade down, after which the length of catheter tube **801** required for the specific procedure is obtained in the catheter insertion device **801**. The procedure may then proceed by removing the catheter tube cutter **50** and cutter adapter assembly and connecting the catheter insertion apparatus **800** to a suitable introducer.

Fig. 8F is a close-up on the rear portion of the catheter insertion device shown in Fig. 8A which comprise a guide-wire stopper mechanism **808**. In this example the proximal end of sleeve **817** terminates in a guide wire stopper **808** comprising a rigid partition **825** which close the proximal end of sleeve **817** while allowing it to hold guide wire holder **821** provided at the proximal end of guide wire **829**. Aperture **820** may be provided in partition **825** through which guide wire holder **821** can be passed proximally out of sleeve **817**. Aperture **820** and guide wire holder **821** can be configured in a plurality of shapes (e.g., curved, triangular, "X", waved) for preventing distally longitudinal movements of guide wire **829** by rotating guide wire holder **821** about the longitudinal axis of guide wire **829** after passing it through aperture **820**.

In the example shown in Fig. 8F the guide wire stopper **808** utilizes a rectangular aperture **820** and a corresponding rectangular guide wire holder **821** which provide the requisite proximal fixture of guide wire **829** by rotating (less than 180°) holder **821** about the axis of wire **829**. This proximal fixture of guide wire **829** is conveniently established during catheter tube trimming for preventing cutting of the distal end portion or the wire **829**. After completing the trimming

process this proximal fixture can be released by rotating guide wire holder **821** until it is fitted into aperture **820** such that it may pass therethrough back into sleeve **817**, as demonstrated in Fig. 8H.

Guide wire stopper **808** may be implemented by a hollow cylindrical element comprising a partition **825** thereinside which defines an external compartment **827** in which guide wire holder **821** can be fixtured, as demonstrated in Fig. 8F. Said external compartment **827** (Fig. 8G) may be sealed by a suitable cap **826** which may be fastened thereover by the aid of one or more flexible fasteners **823** provided on the external surface of stopper **808**. Cap **826** may further contain a permeable section permeable to gases for allowing sterilization of the inner space of sleeve **817**. During the trimming process portions of catheter tube are advanced distally out of sleeve **817** while respective portions of guide wire **829** are retracted from the catheter tube via catheter port **807**.

Guide wire stopper **800** may be fabricated by injection molding techniques from rigid, polypropylene, ABS, polycarbonate type of material, preferably from ABS. The outer diameter of guide wire holder **800** is generally in the range of 6 to 30 mm, preferably about 20 mm, and its length is generally in the range of 5 to 30 mm, preferably about 20 mm.

Another example for a guide wire stopper **900** is demonstrated in Figs. 9A to 9E. In this example guide wire stopper **900** is designed to received a fastening cap **924** into an external compartment **925** provided therein. Fastening cap **924** is further configured to grip the guide holder (Fig. 9E) and thereby prevent accidental rotation and release thereof during the trimming process.

Guide wire stopper **900** may be implemented as a hollow cylindrical element having sealing threads **911** on the outer surface of a distal portion thereof adapted to be inserted into sleeve **901** of a catheter insertion device of the invention. Guide wire holder may further comprise a proximal flange **910** for preventing it from being pressed into sleeve **901**. Sealing may have a hollow cylindrical shape which interior may be accessed via a distal opening. Fastening cap **924** further comprise an actuating tab **921** (Fig. 9C) and griping means provided in its hollow interior, for griping guide wire holder (not shown). An external groove **923** may be provided on the outer surface of fastening cap **924** near its distal rim **922** for locking it into guide wire stopper **900**.

As seen in Fig. 9D, guide wire stopper **900** has a hollow cylindrical shape and its interior may be accessed via the proximal opening **927** or via aperture **920** provided in its distal side wall **925**. Aperture **920** is configure to enable passage of a guide wire holder therethrough and fixture thereof by rotation, as was described herein above with reference to Figs. 8F to 8H. Proximal opening **927** may be sealed by fastening cap **924** by fitting said cap into the internal space of guide wire stopper **900**, and sliding inner protrusions **926** provided in stopper **900** into the external groove **923** of fastening cap **924**.

Fig. 9E shows the interior of the fastening cap **924** as seen via opening **928** provided at its proximal side. Gripping means **929** provided in the hollow interior of fastening cap **924** are designed to enable gripping the guide wire holder when it is being held by guide wire stopper **900**. Gripping means may be implemented by two or more opposing walls attached perpendicularly to the inner side of the base of fastening cap **924**, as demonstrated in Fig. 9E.

Guide wire stopper **900** and fastening cap **924** may be manufactured by an injection molding process from a rigid material, preferably from ABS or polypropylrnr. The inner diameter of guide wire stopper **900** is generally in the range of 6 to 30 mm, preferably about 20 mm, and its length is generally in the range of 5 to 30 mm, preferably about 20 mm. The outer diameter of fastening cap **924** is configured to allow tight fitting it into guide wire stopper 900, its inner diameter is generally in the range of 5 to 25 mm, preferably about 10 mm, and its length is generally in the range of 5 to 25 mm, preferably about 15 mm.

A catheter insertion device **930** of the invention having a splittable head **932** is shown in Fig. 10A. Catheter insertion device **930** comprises a flexible sleeve **936** comprising a distal resilient portion **931** and which distal end is sealed by a splittable head **932**. Flexible sleeve **936** may be manufactured from a single continuous sleeve, or alternatively, from two separate sleeves, **936a** and **936b**. For example, the catheter insertion device **930** may advantageously comprise a tearable sleeve section **936a** and a relatively rigid sleeve section **936b**, where the flexible sleeve **936** is assembled by fitting the proximal end of tearable sleeve **936a** over the distal end of rigid sleeve **936b**, as shown in Fig. 10A.

Catheter tube **801** comprised in sleeve **936** may be distally advanced out of catheter insertion device **930** via passage provided in the splittable head **932** by pushing it distally via resilient portion **931** of sleeve **936**, as was previously described herein above with reference to Figs. 7A to 7B. Resilient section **931** (e.g., corrugated section or containing shape restoring means such as a spring) is preferably provided near the distal end of catheter insertion device **930**, however,

the entire tearable sleeve section **936a** may be advantageously manufactured from a resilient material (e.g., silicon). Tearable sleeve section **936a** further comprise tear lines **935** for facilitating ripping thereof after the catheter insertion procedure in completed.

While tear lines **935** may be implemented in various ways (e.g., thin or weakened lines introduced during the manufacture process), in a preferred embodiment of the invention tear lines **935** are implemented by lines which are made on the tearable sleeve section **936a** with a relatively decreased thickness.

Splittable head **932** comprise a cylindrical main body **933** having lateral pins **942** adapted to fasten splittable head **932** in the distal end of sleeve **936** by corresponding lateral apertures provided therein. Splittable head **932** further comprise splitting tabs **941** and a quick connector **943** (e.g., Luer lock) provided at its distal end portion. Quick connector **943** may be used to connect catheter inserter device **930** to a splittable introducer by means of a suitable adapter (not shown) for carrying our the catheter insertion process as was described hereinabove with reference to Figs. 7A to 7D.

Fig. 10B shows a longitudinal section view of splittable head **932**. In this example splittable head **932** is assembled from two connectable parts, **932a** and **932b**, each of which comprises a respective splitting tab **941**, lateral pin **942**, and cross-sectional portions of cylindrical main body **933** and quick connector **943**. The hollow interiors of cylindrical main body **933** and of quick connector **943** are connecter via slender passage element **937**. Slender passage element **937** is configured to allow the passage of catheter tube **801** therethrough while preventing backflow of fluids such as blood into sleeve **936**.

Slender passage element **937** may be an integrated part of splittable head **932** such that each connectable part thereof, **932a** and **932b**, comprises a portion thereof, or alternatively, it may be a separate element attached to the inner wall of quick connector **943**.

As demonstrated in Figs. 10B to 10C, slender passage element **937** is made splittable in order to allow removal thereof after completing the catheter insertion. Additionally, slender passage element **937** is preferably designed such that it will apply sufficient traction on the outer surface of the catheter tube portions passing thereinside in order to hold the catheter tube in place while the resilient portion **931** restores its original shape. Optionally, slender passage element **937** may be configured as a one way valve which requires application of low forces in moving the catheter distally and relatively greater forces in retracting it proximally. It should be however clear that the catheter insertion device of the invention may be implemented without the slender passage element.

The connectable parts of splittable head **932** may be attached in various ways, for example by utilizing suitable glue or by welding. In a preferred embodiment of the invention splittable head **932** is assembled via coupling pegs **945** and corresponding peg-holes **947** which are provided in connectable parts **932a** and **932b**, as best seen in Figs. 10B and 10C. After the insertion of the catheter tube **761** into the patient's body is completed the catheter insertion device **930** may be discarded by pulling apart splitting tabs **941** in opposite direction, or by pushing their tips proximally, and thereby splitting the coupled parts **932a** and **932b** of splittable head **932**. After splitting splittable head **932** further pulling apart splitting tabs **941**

will result in tearing of sleeve **936** along tear lines **935** provided thereon.

Fig. 10D schematically illustrates splitting splittable head **932** and tearing tearable sleeve section **936a**, which is typically performed after completing insertion of the catheter tube **801**. As demonstrated in Fig. 10D the splittable head **932** is splitted into two parts, **932a** and **932b**, which are pulled laterally in opposite directions. Pins **942** threaded into respective apertures provided in tearable sleeve section **936a** initiate tearing of tearable sleeve section **936a** along tear lines **935**. Rigid sleeve portion **936b** sealed by plug **938** remains intact and the proximal portion of the catheter **801** may be withdrawn and thereafter the catheter insertion device **930** may be disposed.

Rigid sleeve section **936b** can be manufactured by extrusion from a semi-rigid type of material, preferably from polyethylene, its diameter is generally in the range of 10 to 35 mm, preferably about 20 mm, its length is generally in the range of 100 to 80 mm, preferably about 20 mm, and its thickness is preferably about 0.5 mm. Tearable sleeve section **936a** can be manufactured by injection molding from a flexible type of material, preferably from silicon, its diameter is generally in the range of 5 to 30 mm, preferably about 15 mm, its length is generally in the range of 10 to 150 mm, preferably about 50 mm, and its thickness is preferably about 0.3 mm.

Splittable head **932** may manufactured by injection molding from a rigid type of material, preferably from polypropylene, its diameter is generally in the range of 8 to 25 mm, preferably about 15 mm, its length is generally in the range of 10 to 35 mm, preferably about 15 mm. Splitting tabs **941** are preferably

an integral part of splittable head **932**, their lateral length is generally in the range of 5 to 20 mm, preferably about 10 mm, and they may have a tapering shape as demonstrated in Fig. 10A.

Another catheter insertion device **150** of the invention is schematically illustrated in Fig. 11A. In this catheter insertion device **150** a depressible element **152** is utilized for advancing catheter tube **162** passing inside elastic sleeve **160**. Elastic sleeve **160** is sealed at its proximal end **153** and comprise a slender passage element **158** and an adapter **157** fitted in its distal end. The inner surface portion near the distal end of sleeve **160** is tightly fitted around the outer surface of adapter **157** and the tapering distal end of slender passage element **158** is tightly fitted into a concentric bore of adapter **157**, thereby sealing the distal opening of sleeve **160** and providing an opening **156** through which catheter tube **162** may be advanced distally.

Sleeve **160** comprise an elevated section **159** which defines a forwarding tray on which the outer surface of catheter tube **162** may be grasped by the pushing edge of a depressible element **152**, as seen in the side and top views in Figs. 11A and 11B. Catheter tube **152** preferably comprises a guide wire **163** passing along its length *via* its lumen provided therein. Guide wire **163** is preferably attached to the distal end of sleeve **160** such that portions thereof are retracted from catheter tube **162** as portions thereof are distally advanced when trimming the catheter tube before inserting it into the vessel. Thereafter, the end of guide wire **163** must be released to enable insertion of the catheter into the vessel. Sealing cap **165** comprising a suitable connector may be fitted into adapter **157** for sealing the distal opening **156** of catheter insertion apparatus **150**.

Fig. 11C schematically illustrates depressible member **152**. Depressible member **152** consists of an inverted elongated "U" shaped member comprising arms **152d** and a base section **152a** connecting said arms **152d**. An inverted "v" shaped member is attached to one of the lateral edges of base section **152a** *via* a first "leg" **152b** such that its second leg **152c** extends downward away from said inverted elongated "U" shaped member. "U" shaped member is preferably made rigid while the "v" shaped member is made flexible to allow depressing it downward for pushing portions of catheter tube **162** distally *via* the free edge of leg **152c**.

The apex of said "v" shaped member protrudes upwardly *via* an opening at the upper wall of sleeve **160** which is sealed by a flexible cupola shaped member **151** comprising said apex therein. Arms **152d** are placed beside the proximal side of elevated section **159**.

Sleeve **160** is preferably made from a transparent material, such as polyethylene, its length is generally in the range of 80 to 500 mm, preferably about 300 mm and its width is generally in the range of 8 to 30 mm, preferably about 22 mm. Slender passage element **158** is preferably made from a soft material, such as silicon, its length is generally in the range of 5 to 20 mm, preferably about 8 mm, the diameter of its tapering distal end is generally in the range of 2 to 10 mm, preferably about 4 mm, and the diameter of its inner bore is adjusted to allow passage of catheter tube therethrough while at least portions thereof are in contact with the outer surface of catheter tube, thereby sealing the interior of sleeve **160**.

Adapter **157** is preferably made from a rigid material, such as polypropylene, its length is generally in the range of 8 to 30 mm, preferably about 15 mm, its outer diameter is generally in the range of 2 to 30 mm, preferably about 15 mm, and the diameter of its concentric bore is generally in the range of 3 to 10 mm, preferably about 4 mm.

Depressible element **152** may be manufactured from a flexible material, such as polypropylene, the length of its inverted elongated "U" shaped member is generally in the range of 5 to 80 mm, preferably about 10 mm, and the height of arms **152d** is generally in the range of 5 to 50 mm, preferably about 20 mm. The length of the legs **152b** and **152c** of inverted "v" shaped member is generally in the range of 5 to 40 mm, preferably about 15 mm.

Fig. 12 schematically illustrates a catheter tube **162** comprising a slidable element **92** containing an antimicrobial substance. slidable element **92** is preferably situated near the distal tapering end of slender passage element **168**, such that the outer surface of each portion of catheter **162** that is being advanced therethrough is treated and disinfected by said antimicrobial material. A further use of this antimicrobial agent is to disinfect the catheter as it moves in and out (micro-movements) after completing the insertion and when it is secured to the hand, this phenomenon is believed to be one of the causes for catheter infections. Antimicrobial substance, contained in slidable element **92** may be chlorhexidine, povidone Iodine or any other suitable disinfectant. The length of slidable element **92** is generally in the range of 1 to 20 mm, preferably about 5 mm, and it may be of cylindrical shape having a diameter in the range of 1 to 6 mm, preferably about 2 mm, and a concentric bore through which catheter tube 12 may pass. Slidable element **92** may of

course be of any suitable shape allowing adhering it to the patient body while covering as much skin area as necessary. Slidable element **92** is preferably made from a soft material that can release the disinfectant contained therein over time and thereby keep the catheter's insertion area clean.

Fig. 13A schematically illustrates a catheter insertion device **950** of the invention containing catheter tube **801**, wherein catheter port **902** passes via a tight aperture **959** provided in the plug **952** sealing the rear opening of rigid sleeve **936b**. This configuration allows accessing the catheter lumen by by removing sealing cap **957**.

Also shown in Fig. 13A is a guide wire insertion device **960**. Guide wire insertion device **960** comprises a sealed flexible sleeve **965** comprising guide wire **963** and having a distal exit port **964** holding a distal end portion of guide wire **963**. Distal exit port **964** is configured to fit into catheter port **902** and thereby establish a sealed connection between the lumen of catheter tube **801** and the inner space of guide wire insertion device **960**, as illustrated in Fig. 13B. This connection can be established by removing the sealing caps **962** and **975** and fitting the tip of distal exit port **964** into catheter port **902**. In this state guide wire **963** may be advanced into the lumen of catheter tube **801** by grasping portions thereof via sleeve **965** and pushing guide wire **963** distally.

Fig. 13C demonstrates insertion devices **950'** and **960'** similar to those shown in Figs. 13A and 13B, and which are configured to allow threading catheter tube **801** contained in insertion device **960'** over guide wire **963** contained in catheter insertion device **950'**. In this example catheter insertion device **950'** is provided with hollow connector **966** configured

to receive the tip of distal exit port **964** and thereby provide a sealed connection between the interior of catheter insertion device **950'** and of insertion device **960'**.

Flexible sleeve 965 of insertion device 960' may be manufactured by extrusion process from a transparent type of materials, preferably from polyethylene. The inner diameter of sleeve 965 is generally in the range of 2 to 20 mm, preferably about 6 mm, and its length is generally in the range of 100 to 600 mm, preferably about 300 mm. Distal exit port 964 may be manufactured by injection molding process from a rigid material, preferably from polypropylene and it may be sealably connected to the distal opening of flexible sleeve 965 by welding.

Fig. 14A schematically illustrates an embodiment of the catheter insertion device of the invention wherein the catheter tube **801** is provided with a lateral port **951**. Lateral port is designed to provide access to the inner lumen of catheter tube **801** by a needle of syringe **957**, for example, which may be required for washing said inner lumen of catheter tube **801**. While the needle of syringe **957** may access lateral port 951 directly by puncturing sleeve **936b** therewith, in another embodiment of the invention shown in Fig. 14B an access port **958** is provided for providing sealed access to lateral port **951**.

Lateral port 951 may be manufactured by injection molding process from a sealable material, preferably from silicon. The inner diameter of lateral port 951 is generally in the range of 1 to 10 mm, preferably about 5 mm, and it may be applied over catheter tube 801 by welding. Access port 958 may be manufactured by injection molding process from a sealable material, preferably from silicon. The diameter of access port

958 is generally in the range of 2 to 15 mm, preferably about 6 mm, and it may be applied in a portion of the wall of sleeve 936b by tight fittings of materials.

All of the abovementioned parameters are given by way of example only, and may be changed in accordance with the differing requirements of the various embodiments of the present invention. Thus, the abovementioned parameters should not be construed as limiting the scope of the present invention in any way. In addition, it is to be appreciated that the different cylindrical/conical adapters, connectors, and other members, described hereinabove may be constructed in different shapes (e.g. having oval, square etc. form in plan view) and sizes from those exemplified in the preceding description.

The above examples and description have of course been provided only for the purpose of illustration, and are not intended to limit the invention in any way. As will be appreciated by the skilled person, the invention can be carried out in a great variety of ways, employing more than one technique from those described above, all without exceeding the scope of the invention.

CLAIMS

1. A catheter insertion system comprising a flexible sleeve containing a catheter tube, wherein said flexible sleeve has a sealed proximal end, and wherein the distal end of said flexible sleeve comprises a slender passage adapted to allow passage of said catheter tube therethrough while preventing backflow of fluid into said sleeve.

2. The catheter insertion system according to claim 1, further comprising a resilient portion formed near the slender passage.

3. The catheter insertion system according to claim 2, wherein the resilient portion is corrugated.

4. The catheter insertion system according to claim 1, further comprising tear lines longitudinally passing along at least a portion of the length of the flexible sleeve, for facilitating tearing thereof.

5. The catheter insertion system according to claim 1, further comprising one or more permeable portions provided on the flexible sleeve for allowing gas sterilization of the interior of said flexible sleeve.

6. The catheter insertion system according to claim 1 or 5, wherein the proximal end of the flexible sleeve is sealed by a plug having a bore, wherein one end of said bore opens into the interior of the flexible sleeve, and wherein the other end of said bore is covered by a permeable sheet for allowing gas sterilization of the interior of said flexible sleeve.

7. The catheter insertion system according to claim 1, wherein the proximal end of the flexible sleeve is closed by a guide

wire stopper element, wherein said guide wire stopper element comprises an aperture suitable for the passage of a guide wire holder connected to the proximal end of a guide wire, and wherein the passage of said guide wire holder into the flexible sleeve can be prevented by rotation of said guide wire holder about the axis of said guide wire.

8. The catheter insertion system according to claim 7, further comprising a fastening cap adapted to fit in or over the proximal side of the guide wire stopper element, thereby sealing the flexible sleeve, wherein said fastening cap comprises gripping means adapted to grip the guide wire holder and prevent passage thereof into said flexible sleeve.

9. The catheter insertion system according to claim 1, wherein the slender passage element is part of a splittable head sealably fitted into the distal end of the flexible sleeve, wherein said splittable head is constructed such that it can be longitudinally split into two or more parts, thereby facilitating tearing of the flexible sleeve.

10. The catheter insertion system according to claim 9, wherein the splittable head comprises pins adapted to be engaged in respective apertures provided in the flexible sleeve.

11. The catheter insertion system according to claim 9 or 10, further comprising splitting tabs provided on each splittable part of the splittable head.

12. The catheter insertion system according to claim 1, wherein the catheter tube comprises a lateral port adapted to allow access to the lumen of said catheter tube by a syringe needle passing through the wall of the flexible sleeve.

13. The catheter insertion system according to claim 12, wherein the flexible sleeve comprises a lateral port adapted to allow sealable access to the interior of said flexible sleeve by a syringe needle.

14. The catheter insertion system according to claim 1, wherein the proximal end of said catheter insertion device is sealed by a sealing plug comprising a slender passage through which the catheter tube is sealably passed such that its proximal port is external to said sleeve.

15. The catheter insertion system according to claim 1, further comprising a depressible element adapted for advancing the catheter tube contained in the flexible sleeve, wherein said depressible element comprises a flexible inverted "V" structure that is capable of advancing said catheter tube distally when pressed.

16. An adapter for a catheter tube cutter, comprising a hollow connector for connecting a catheter insertion device thereto, a base connected to said hollow connector, and an arm connected to said base opposite to said hollow connector, said arm comprises an aperture inline with an opening of said hollow connector, wherein a gap formed between said connector and said arm is suitable for fitting a catheter tube cutter therein and passing a catheter tube in the hollow interior of said connector via a cutter passage provided in said catheter cutter and said aperture in said arm.

17. A catheter insertion system comprising, at a first end, a distal entry port, at a second end a proximal section, a sealed catheter sleeve situated between said entry port and said proximal section, and further comprising advancing means

for advancing a catheter contained within said system in a distal direction,

wherein said entry port comprises a hollow body terminating at one end in a hollow cannula suitable for insertion into a peripheral blood vessel and having an internal diameter suitable for permitting passage of an intravascular catheter, and terminating at the other end with a connector element;

wherein said proximal section comprises a hollow body having at least one external opening permitting the withdrawal and/or addition of fluid from or into the proximal opening of a catheter placed within said proximal section;

and wherein said sealed catheter sleeve is sealably connected at one of its ends to either said entry port connector element or to advancing means located between said sleeve and said entry port connector element, said sealed catheter sleeve being sealably connected at its other end to said proximal section;

such that when the aforementioned elements are connected together, a continuous hollow passageway exists from said proximal section through to the terminal portion of said hollow cannula, wherein said passageway contains the catheter that is to be inserted into a peripheral blood vessel.

18. The catheter insertion system according to claim 17, wherein the advancing means comprises the sealed catheter sleeve and a plurality of blades situated in close proximity to the distal end of said sleeve, such that when said sleeve is grasped and advanced in a distal direction, the catheter situated within said sleeve is similarly advanced, and said sleeve is progressively cut by said blades, thereby facilitating its removal from said system.

19. The catheter insertion system according to claim 17, wherein the advancing means comprises a flexible tube situated between the entry port and the sealed catheter sleeve, wherein said tube is adapted to permit an operator to grasp and compress said tube such that the catheter situated therewithin may be advanced in a distal direction.

20. The catheter insertion system according to claim 19, wherein the flexible tube contains corrugations along at least part of its length.

21. The catheter insertion system according to claim 17, wherein the advancing means comprises a rotating wheel mechanism situated between the entry port and the sealed catheter sleeve, such that rotation of an externally-situated thumb wheel causes rotation of one or more internally-situated wheels that cause the catheter to move in a distal or proximal direction.

22. The catheter insertion system according to claim 21, wherein the rotating wheels are adapted to provide a limited amount of friction between said wheels and the catheter tube, thereby limiting the amount of force applied on said catheter.

23. The catheter insertion system according to claim 21, wherein the sealed catheter sleeve consists of a pair of mutually adhered sealing strips, and wherein the rotating wheel mechanism further comprises a pair of winding wheels for separating and winding each of said sealing strips onto a spool.

24. The catheter insertion system according to claim 23, wherein the rotating wheel mechanism is adapted to retract portions of the inserted catheter tube and thereby to unwind

portions of the sealing strips and seal the retracted portions therewithin.

25. The catheter insertion system according to claim 23, wherein an affixing device is utilized for affixing the proximal section of the system to the distal section for allowing performance of procedures with a partially inserted catheter.

26. The catheter insertion system according to claim 25, wherein the affixing device comprise supporting pins for wrapping a portion of the adhered sealing strips therebetween.

27. The catheter insertion system according to claim 17, wherein the sealed catheter sleeve consists of a pair of mutually adhered sealing strips and wherein the advancing means comprises a sealed separator situated between the entry port and the sealed catheter sleeve, for separating the adhered sealing strips, exposing the catheter sealed therein, and advancing it into the entry port,

and wherein said separator comprises a proximal aperture, splitting means, and retaining members for guiding said adhered strips, entering said separator via said proximal aperture, towards an opening of a passage tube linked to said entry port,

and wherein the adhered strips are separated in the vicinity of said passage tube opening, advanced along the sides of said splitting means, and leave said separator via apertures provided thereon.

28. The catheter insertion system according to claim 27, wherein the tips of the separated strips are adhered outside the separator to allow convenient insertion of the catheter by pulling said adhered tips distally.

29. A catheter insertion system comprising, a distal entry port and advancing means for advancing a catheter contained within said system in a distal direction,

wherein said entry port comprises a hollow body terminating at one end in a hollow cannula suitable for insertion into a peripheral blood vessel and having an internal diameter suitable for permitting passage of an intravascular catheter, and terminating at the other end with a connector element;

and wherein said advancing means comprises a sealed spool containing a sterilized catheter wound around a central axis in a spiral manner, and a distal exit, such that said catheter is rolled in or out via said distal exit by rotations of the spool

and wherein the lumen of said catheter can be accessed via a catheter port connected to one end of the catheter wound for permitting the withdrawal and/or addition of fluid from or into the catheter.

30. The catheter insertion system according to claim 29, further comprising advancing means comprising a rotating wheel mechanism situated between the entry port and the sealed spool, such that rotation of said wheel causes rotation of one or more internally-situated wheels that cause the catheter to move in a distal or proximal direction, wherein the internally-situated wheels are preferably designed to provide a limited amount of friction between said wheels and said catheter tube, thereby limiting the amount of force applied on the thumb wheel.

Fig. 1A

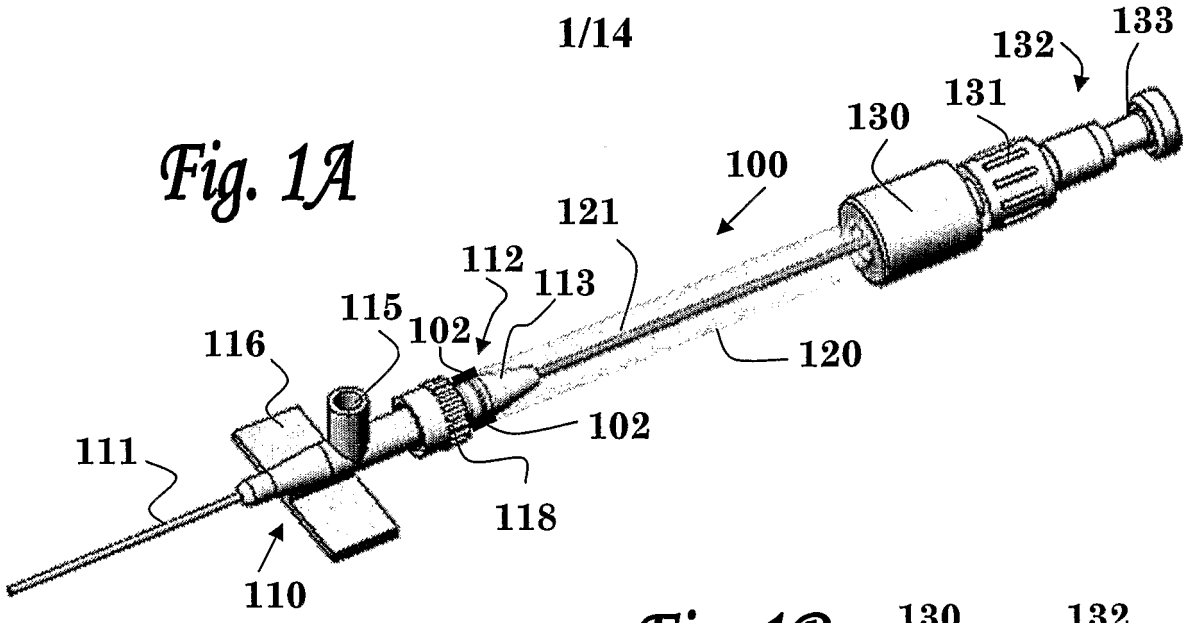


Fig. 1B

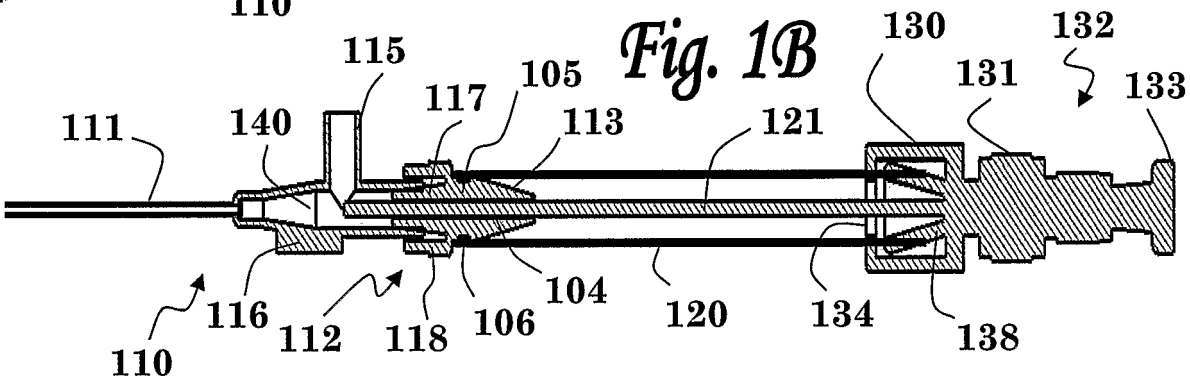


Fig. 1C

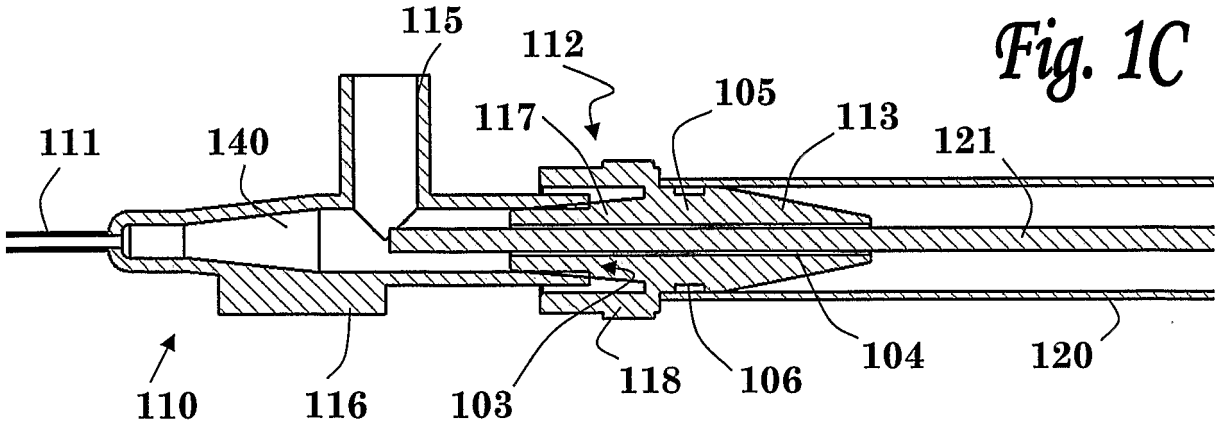


Fig. 1D

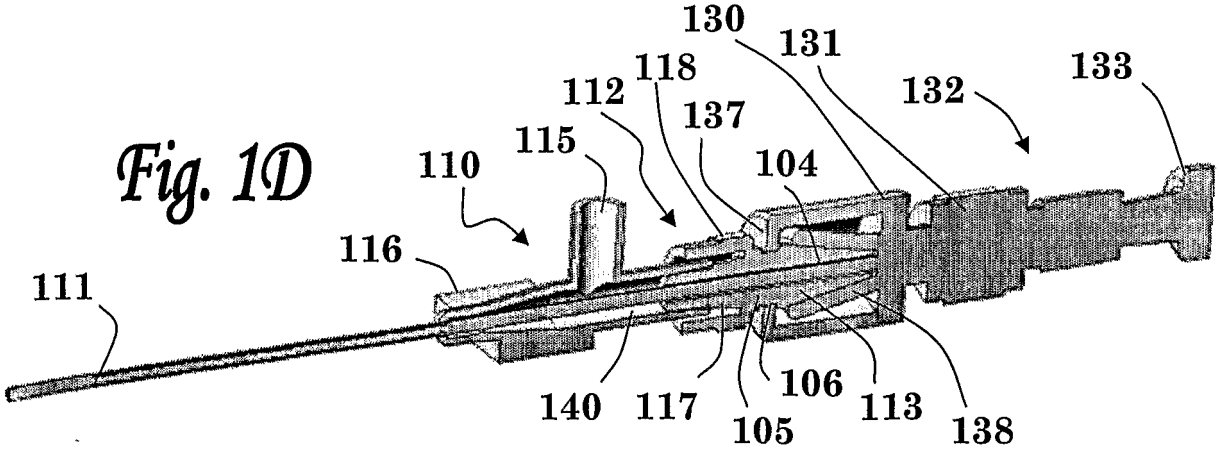


Fig. 2A

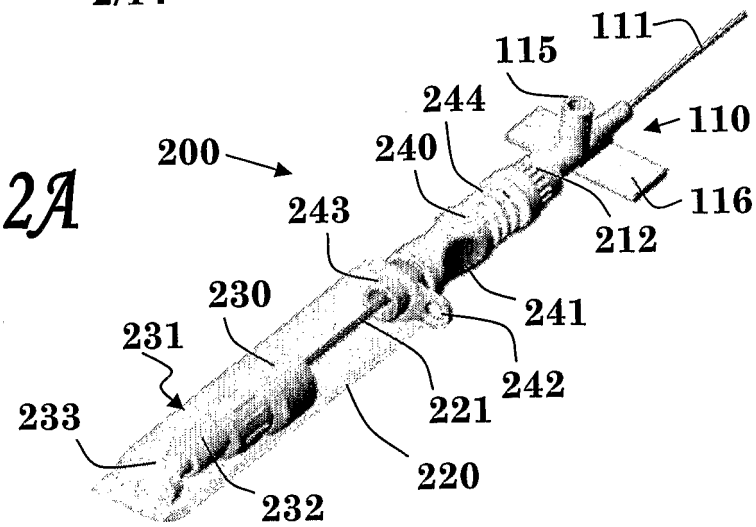
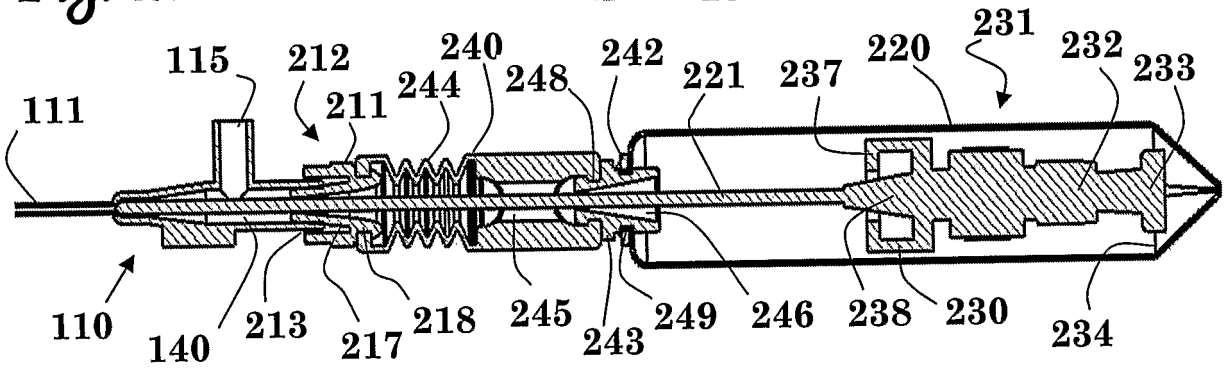


Fig. 2B



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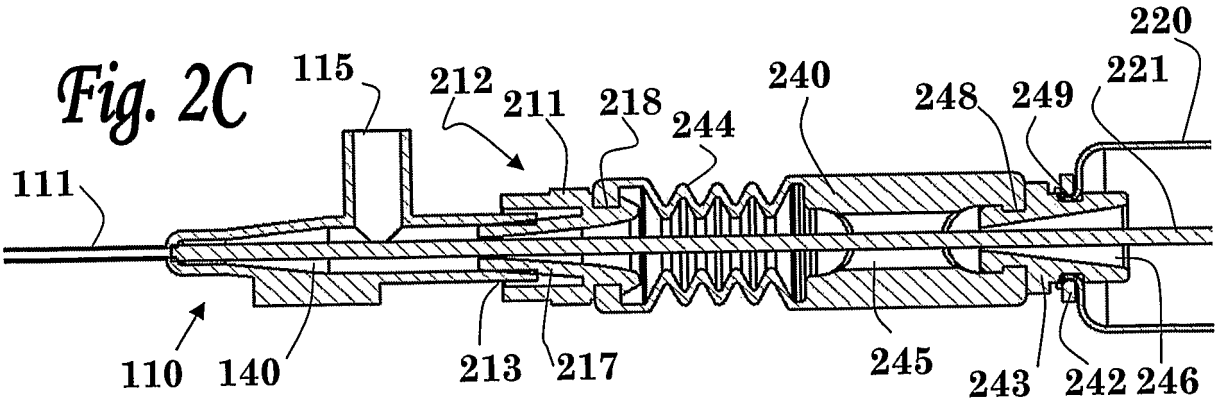


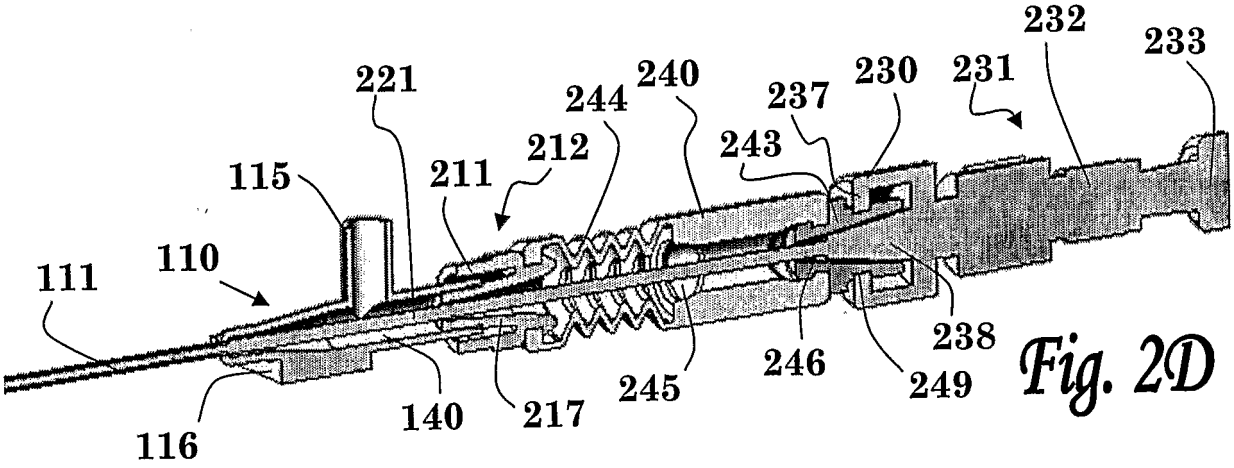


Fig. 2D

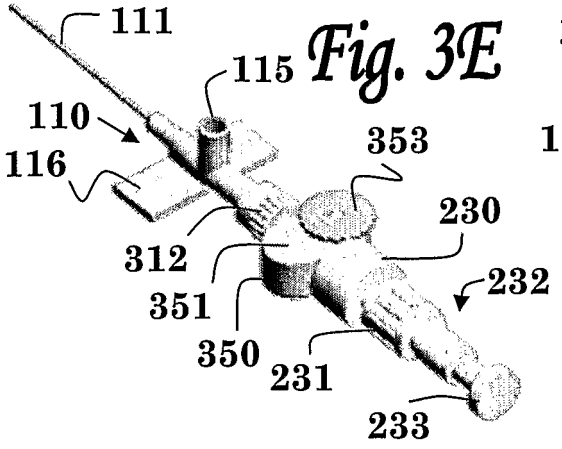


Fig. 3E

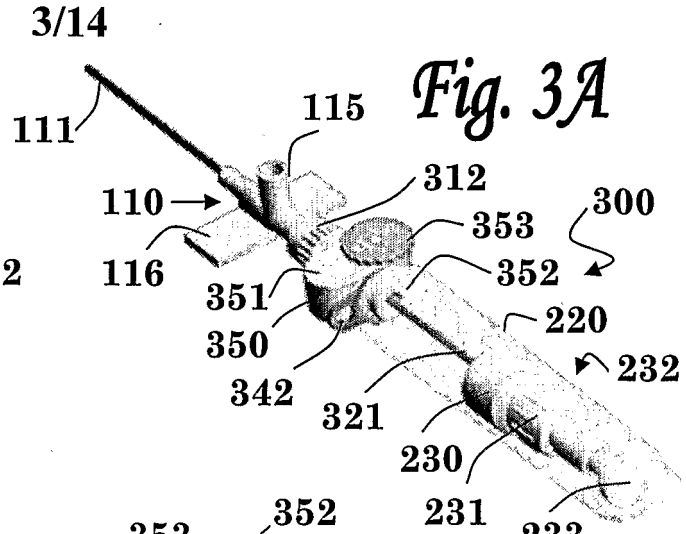


Fig. 3A

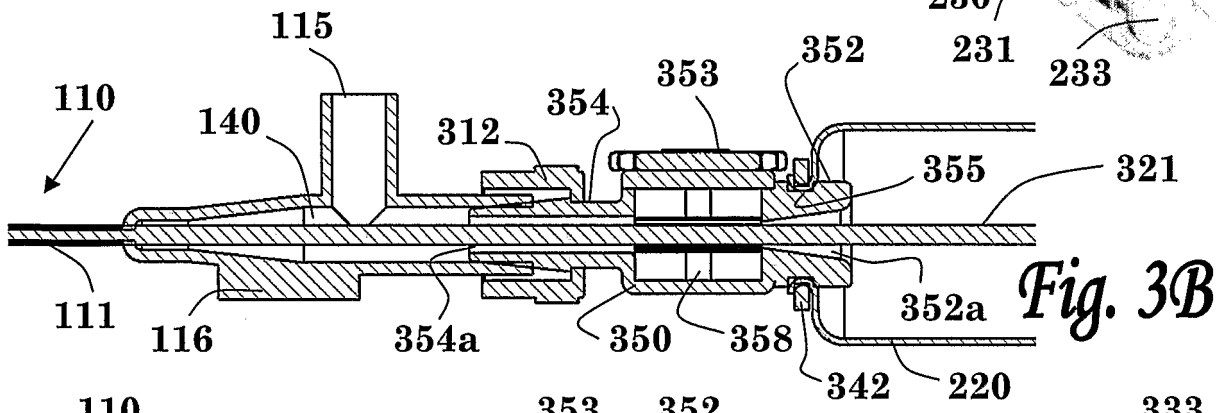


Fig. 3B

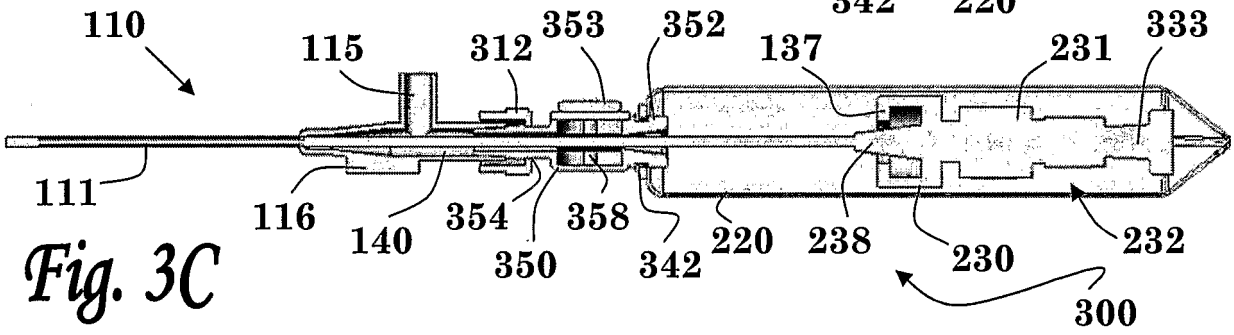


Fig. 3C

Fig. 3D

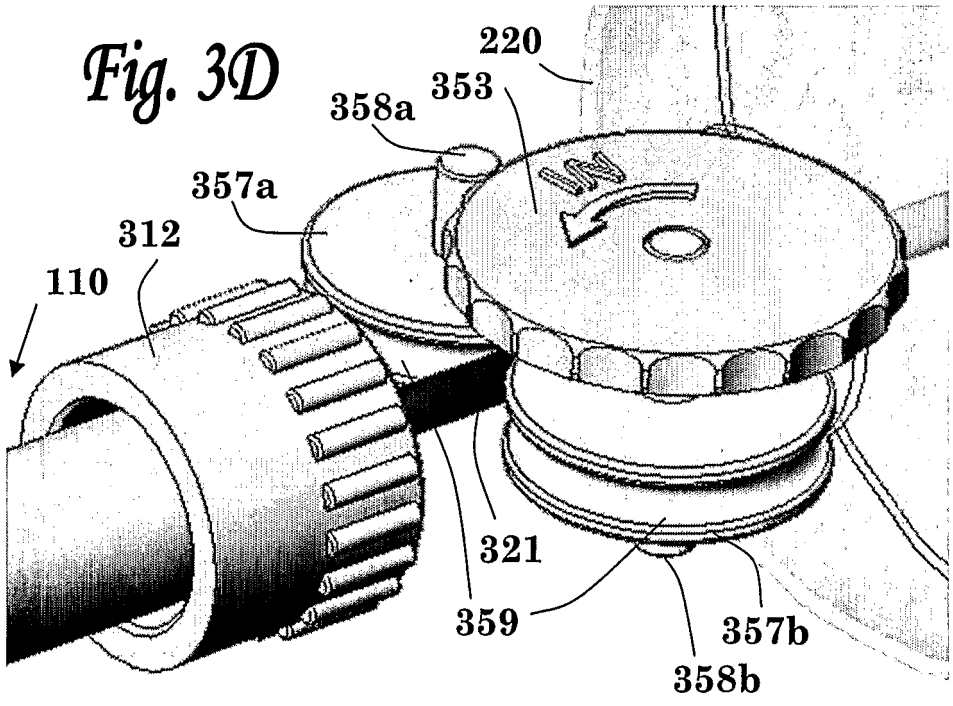


Fig. 4A

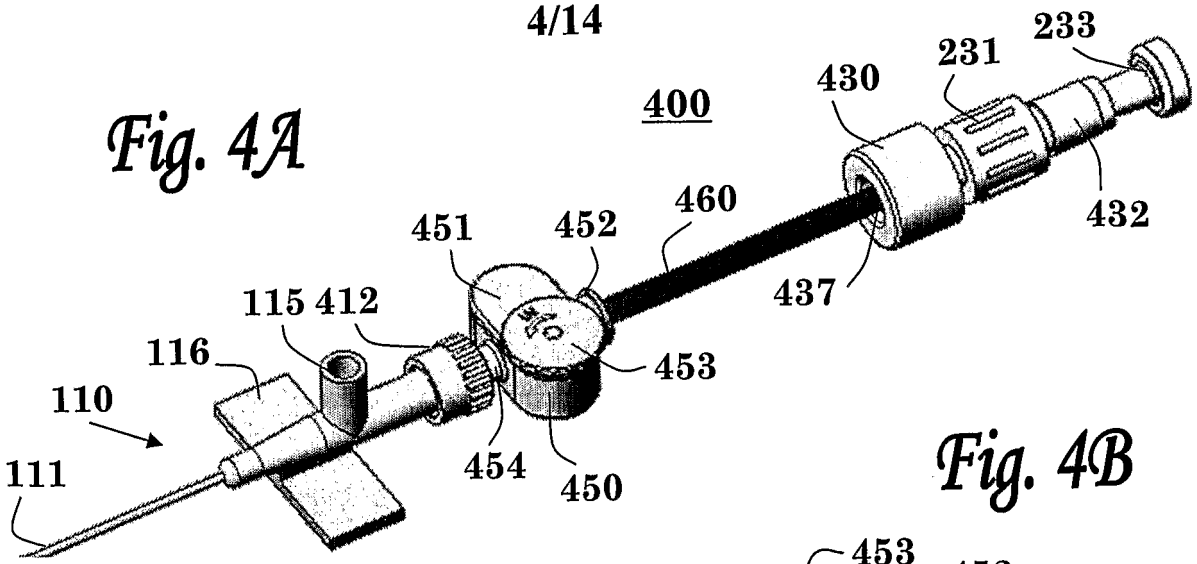


Fig. 4B

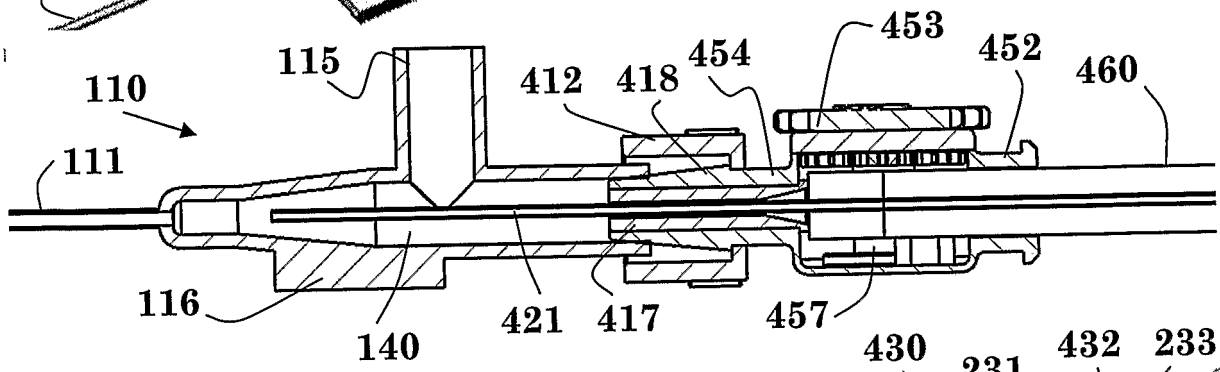


Fig. 4C

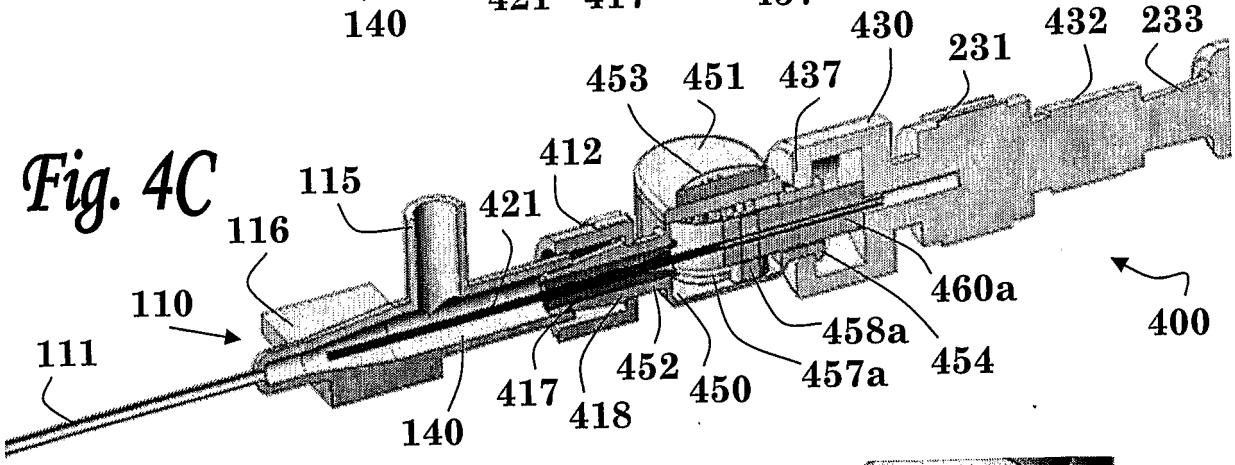
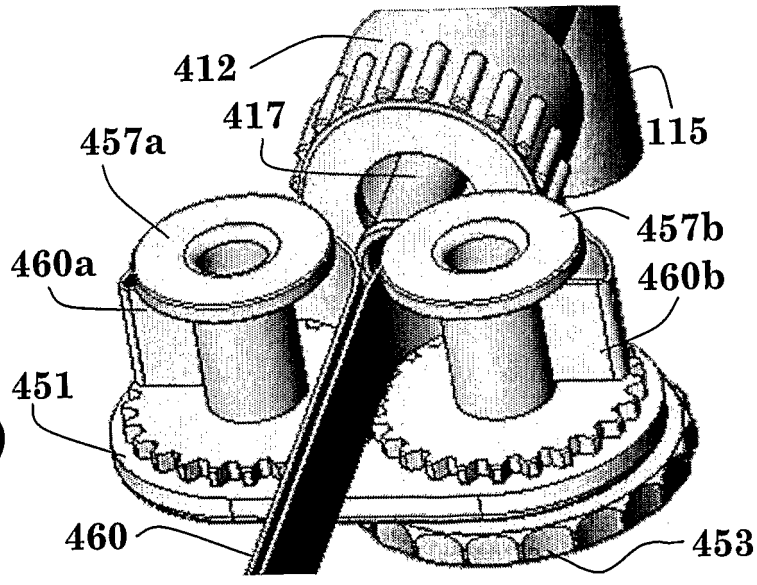


Fig. 4D



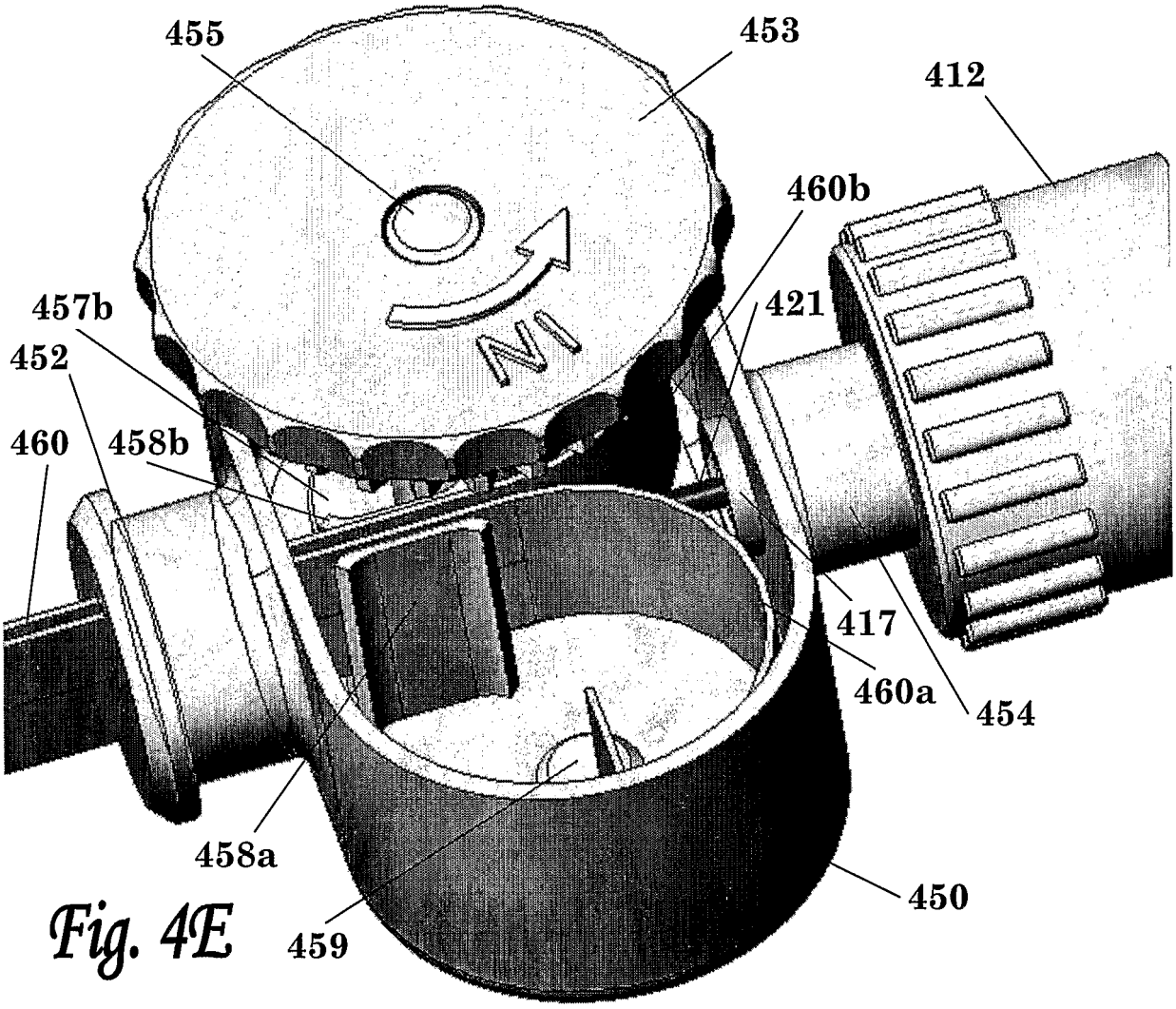

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Fig. 4E

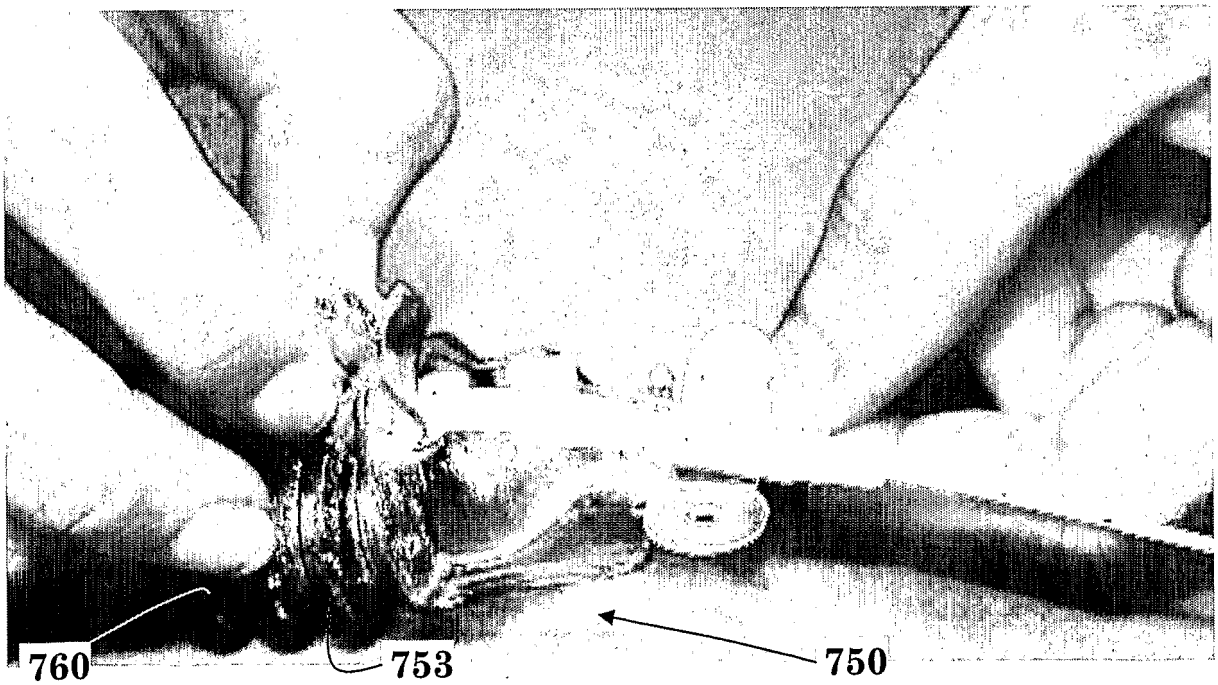
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Fig. 7E

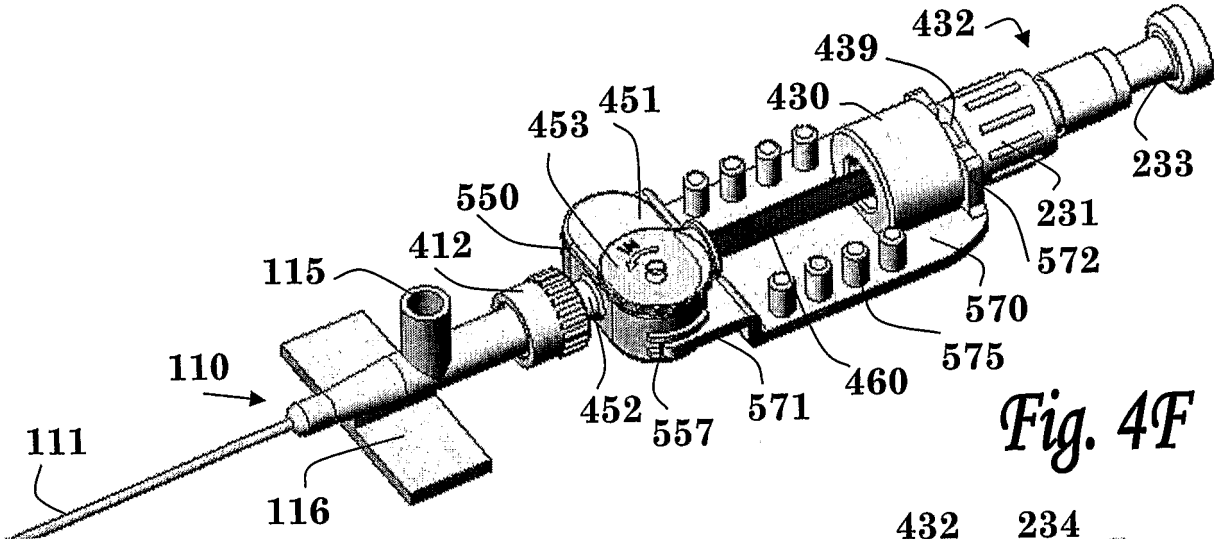


Fig. 4F

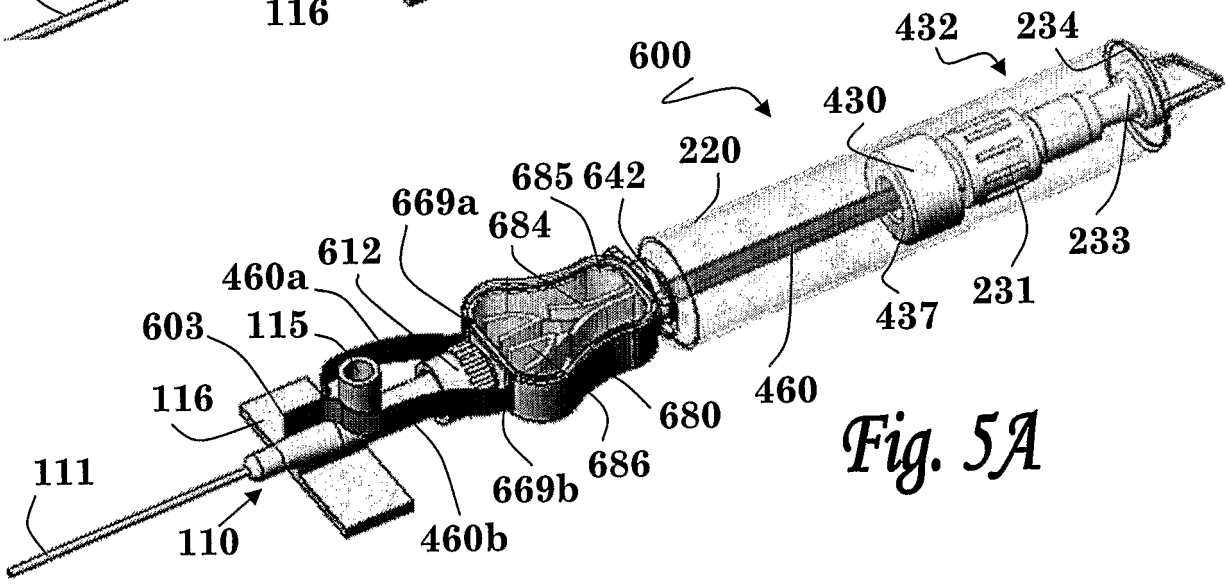


Fig. 5A

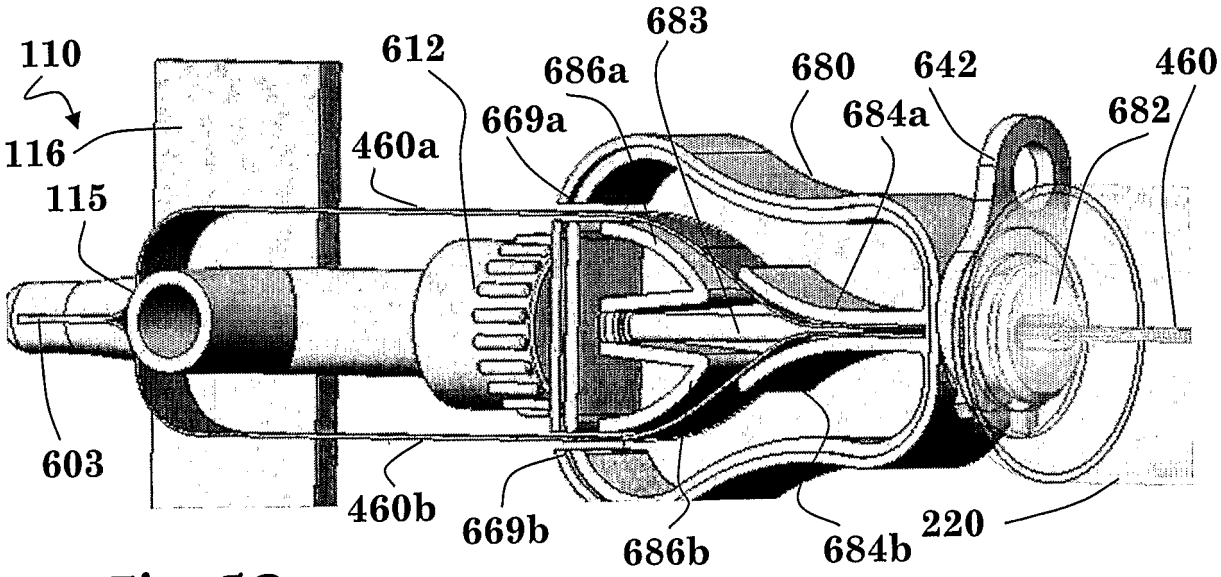


Fig. 5B

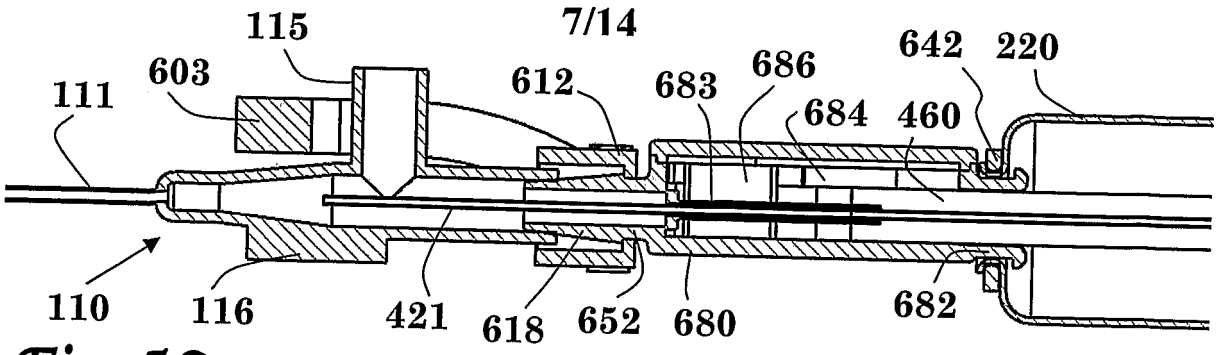


Fig. 5C

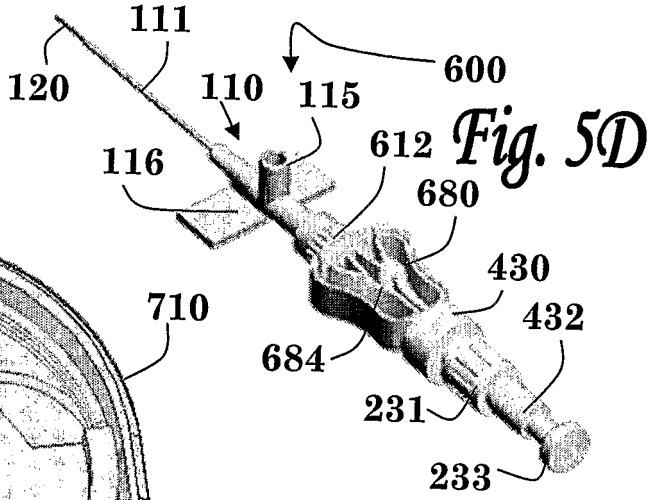


Fig. 5D

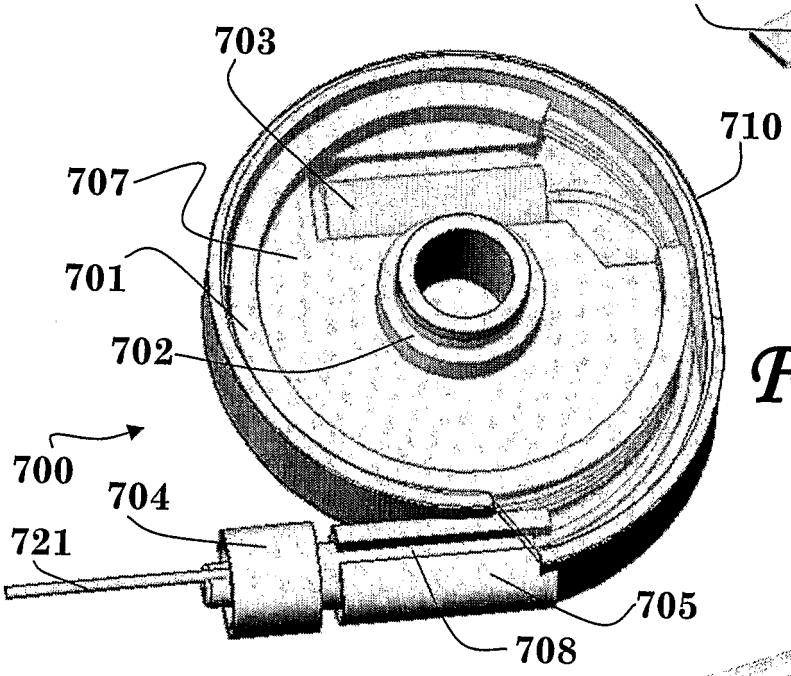


Fig. 6

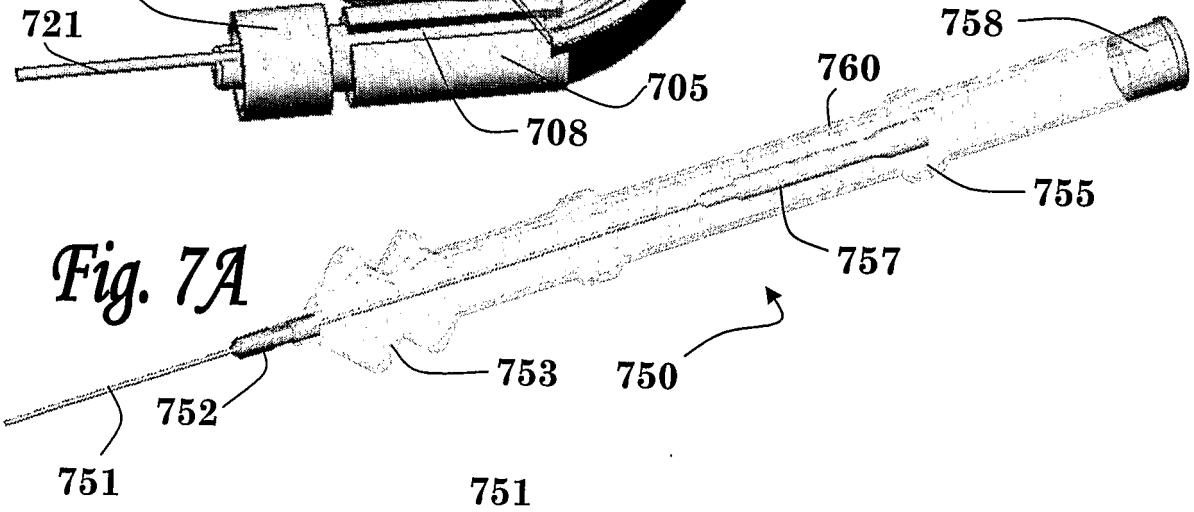


Fig. 7A

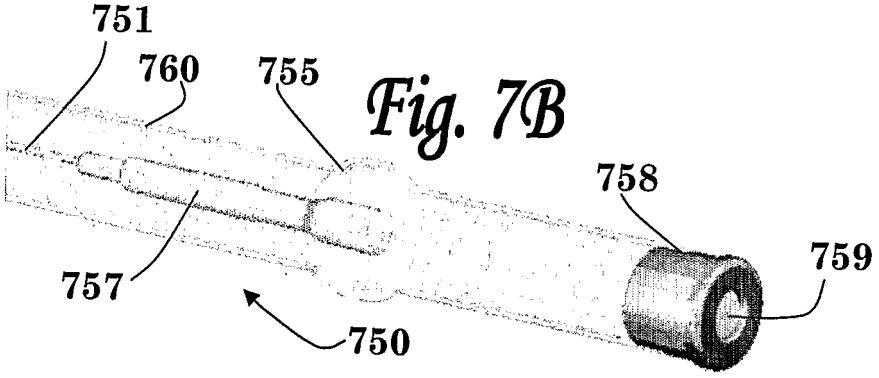


Fig. 7B

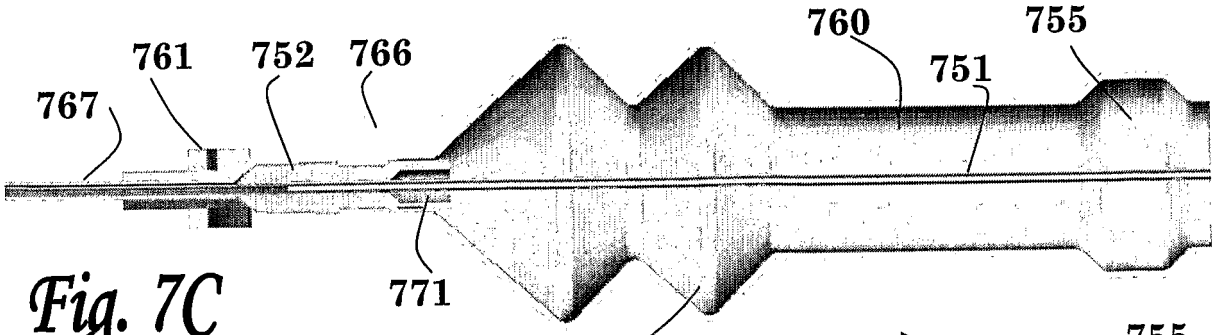


Fig. 7C

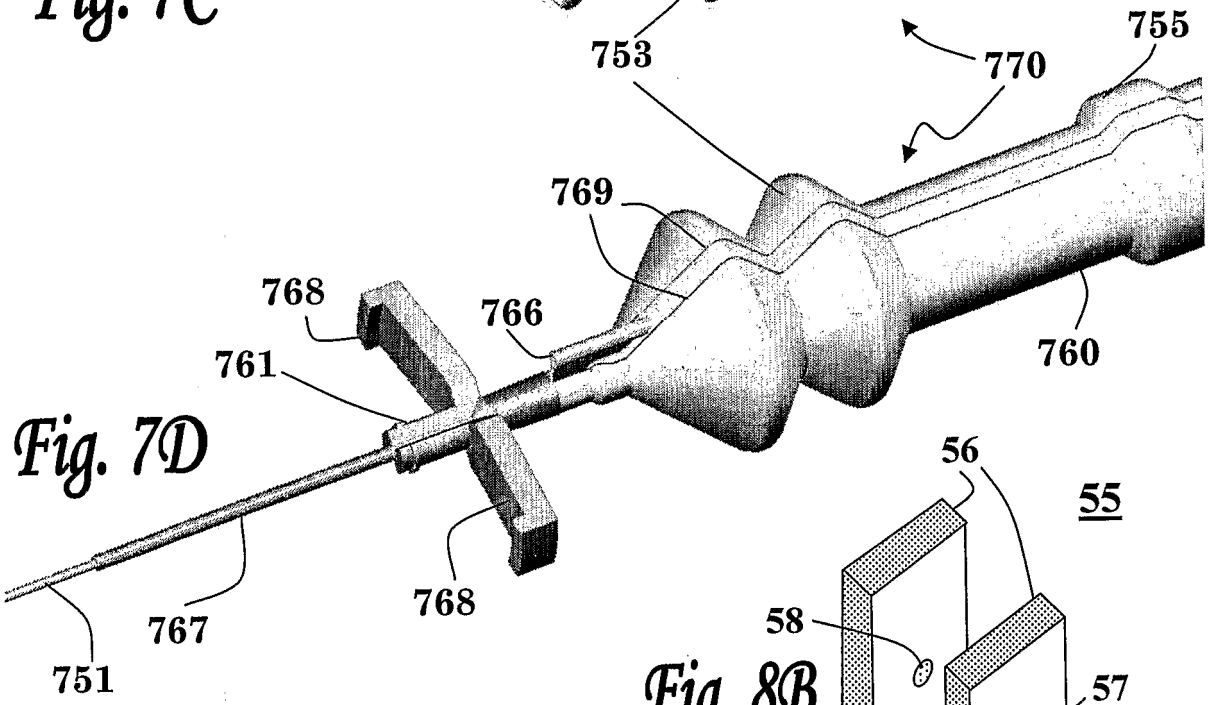
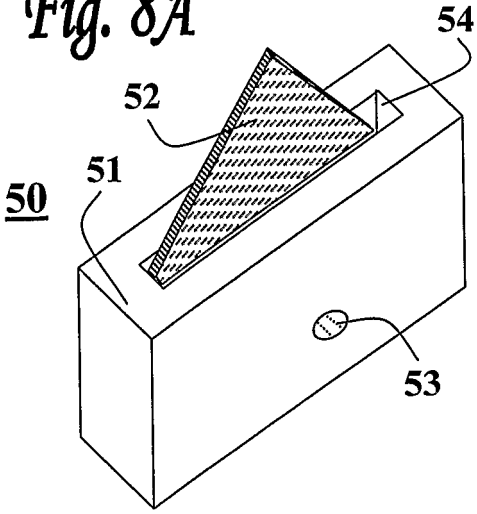


Fig. 7D

Fig. 8B

Fig. 8A



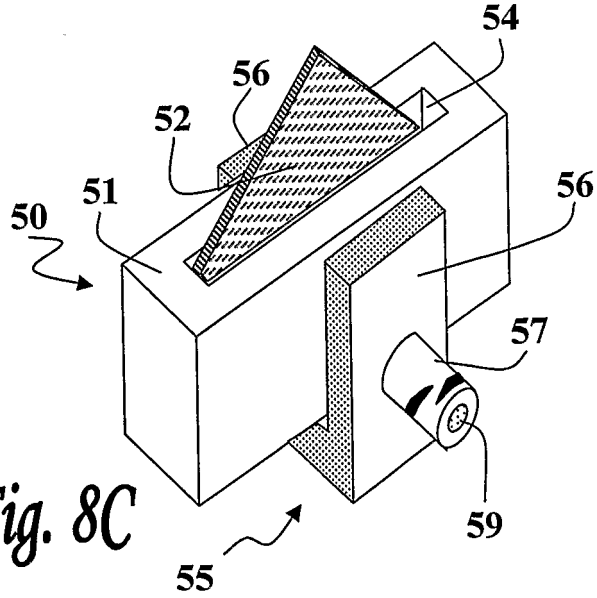


Fig. 8C

Fig. 8D

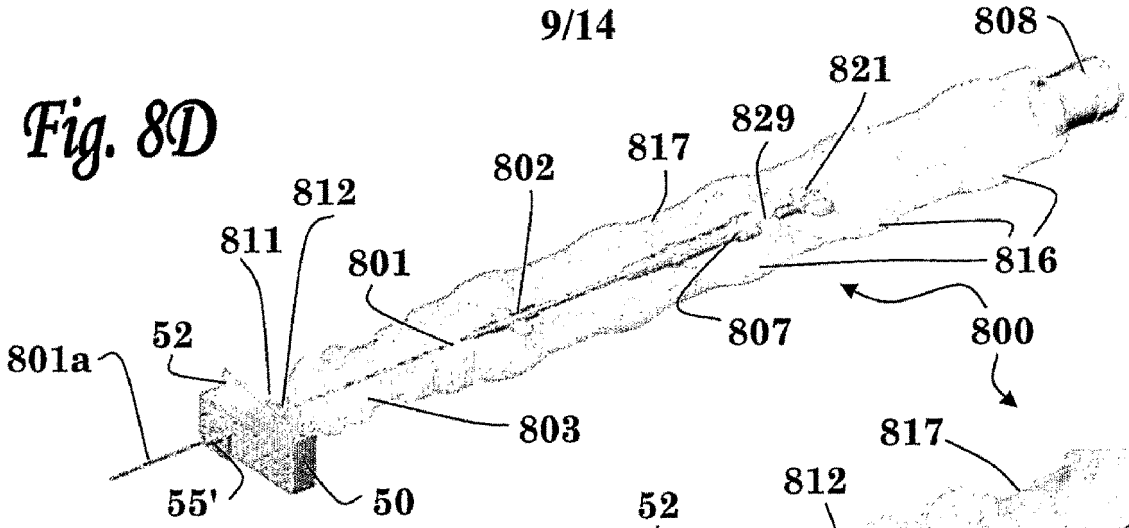


Fig. 8E

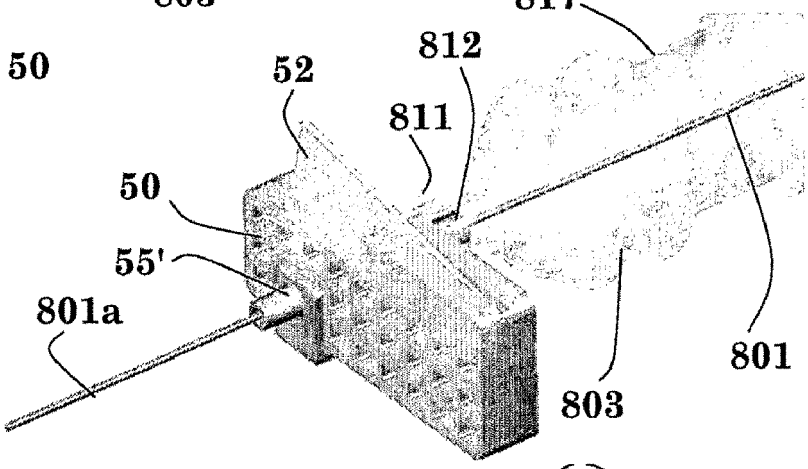


Fig. 8F

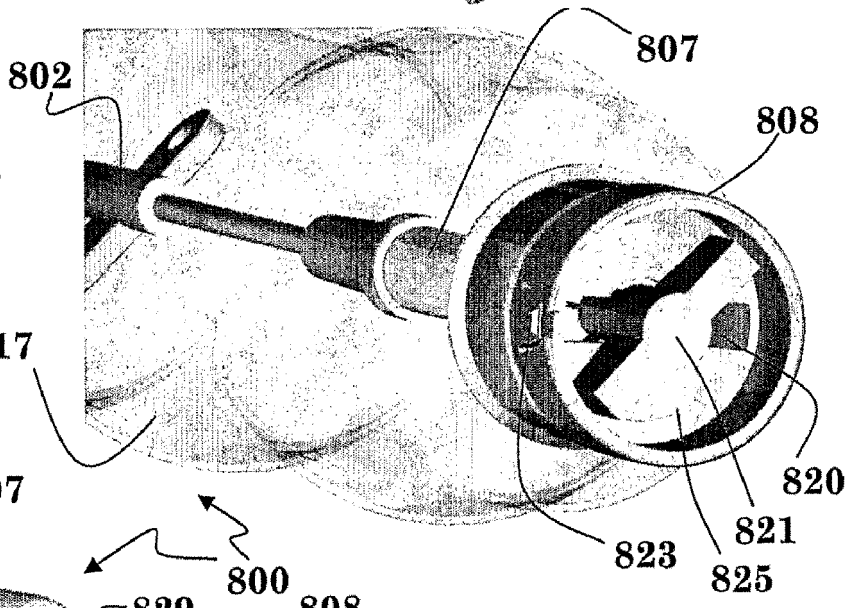
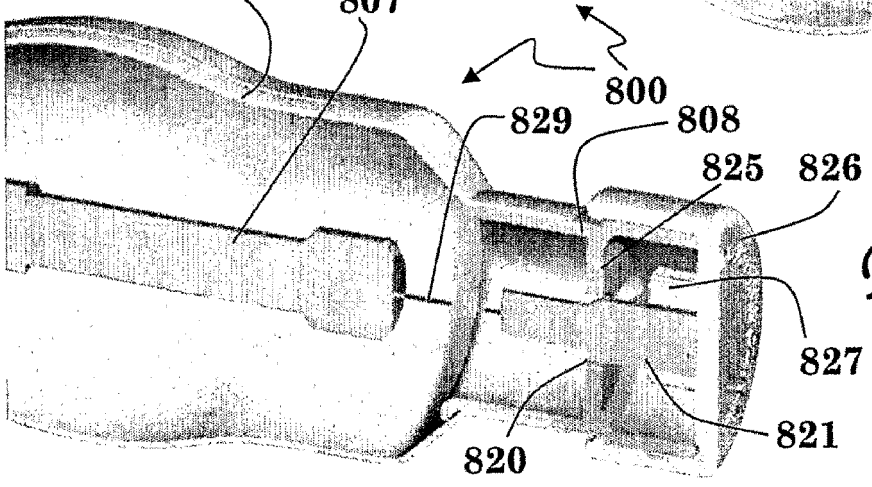


Fig. 8G



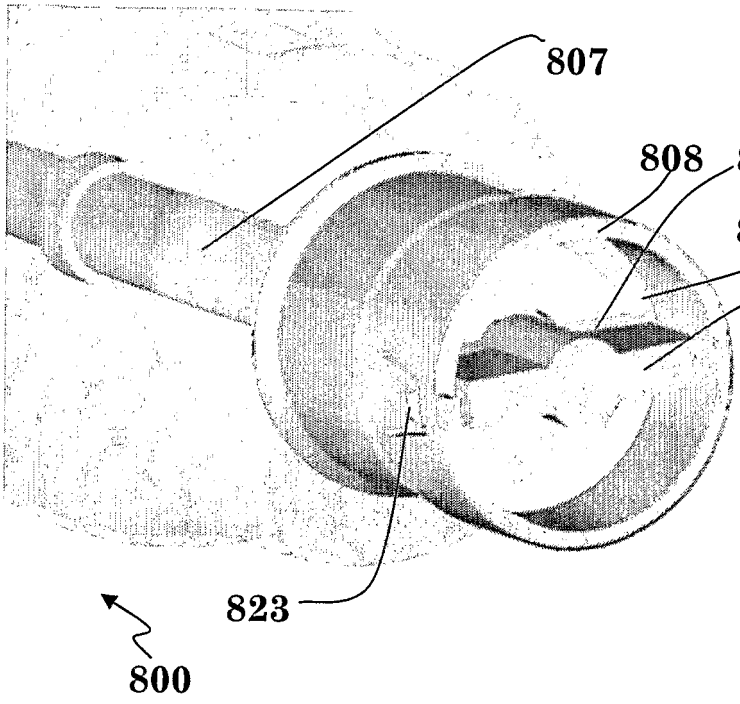


Fig. 8H

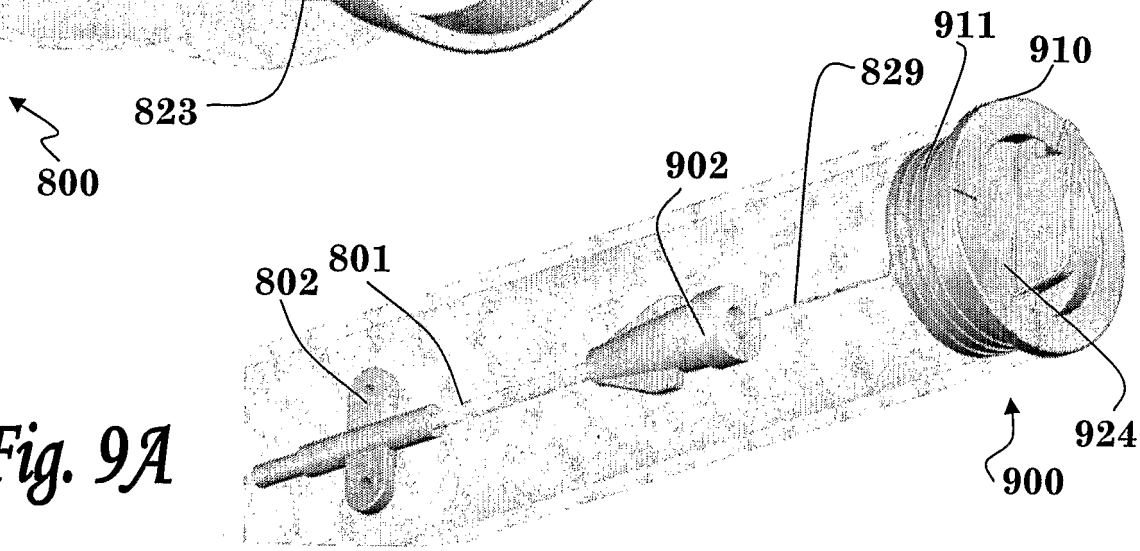


Fig. 9A

Fig. 9B

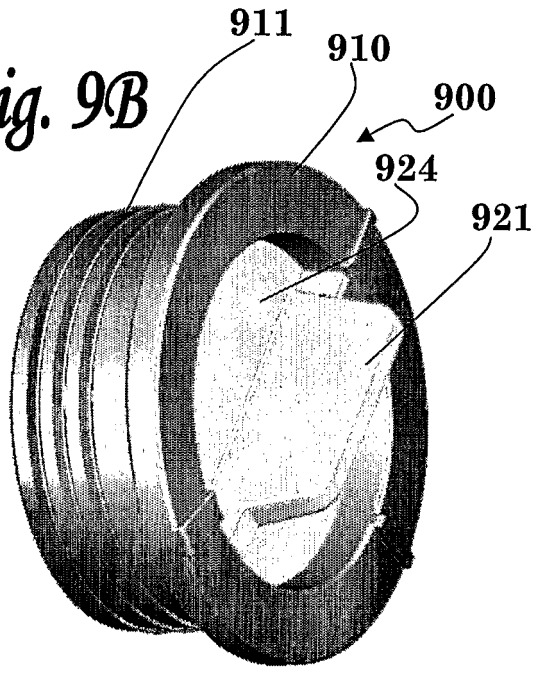
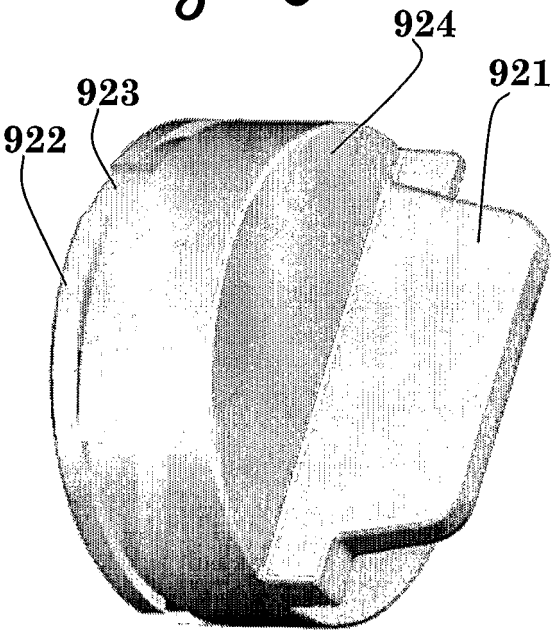


Fig. 9C



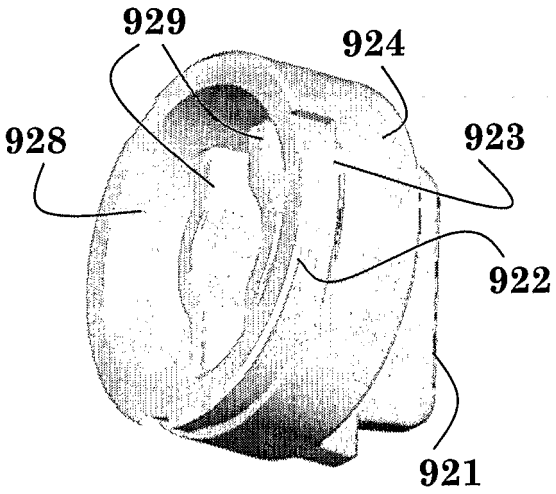


Fig. 9E

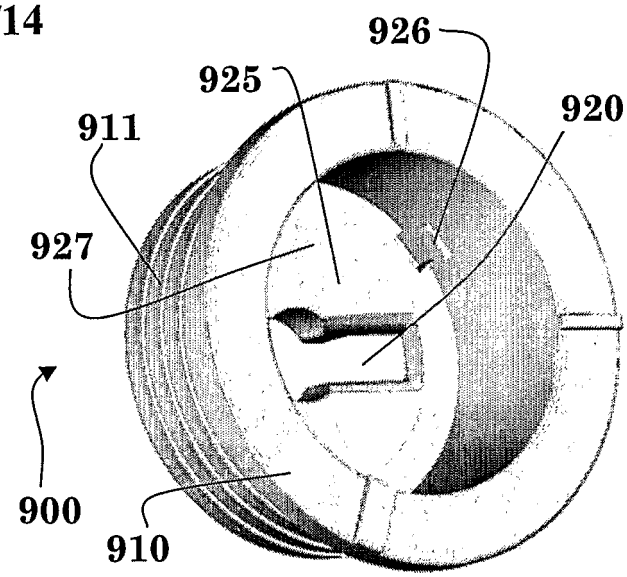


Fig. 9D

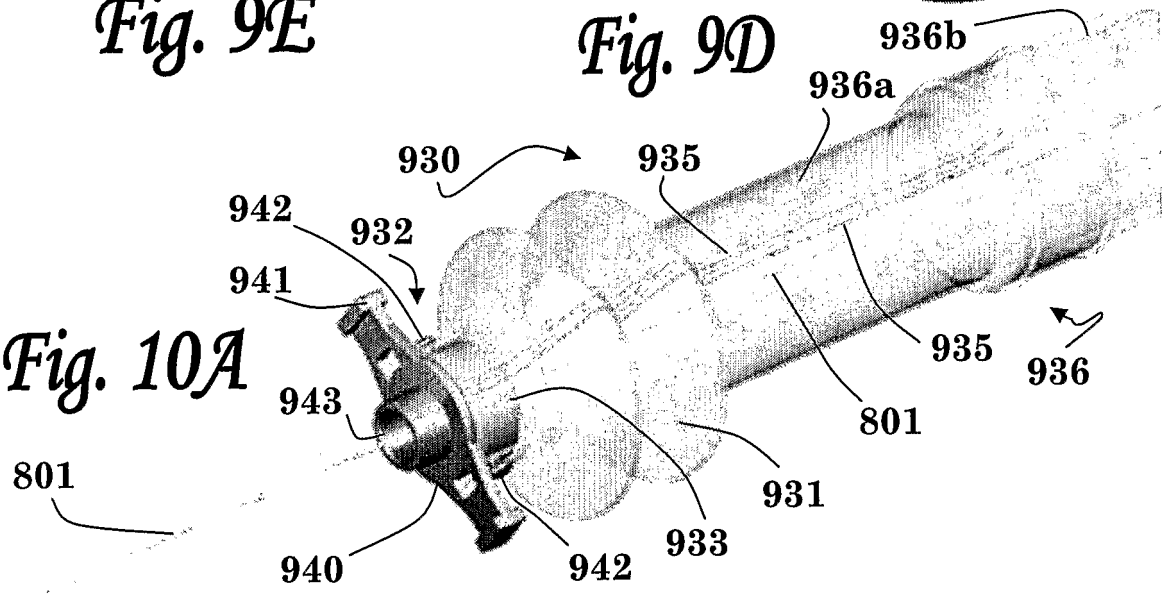


Fig. 10A

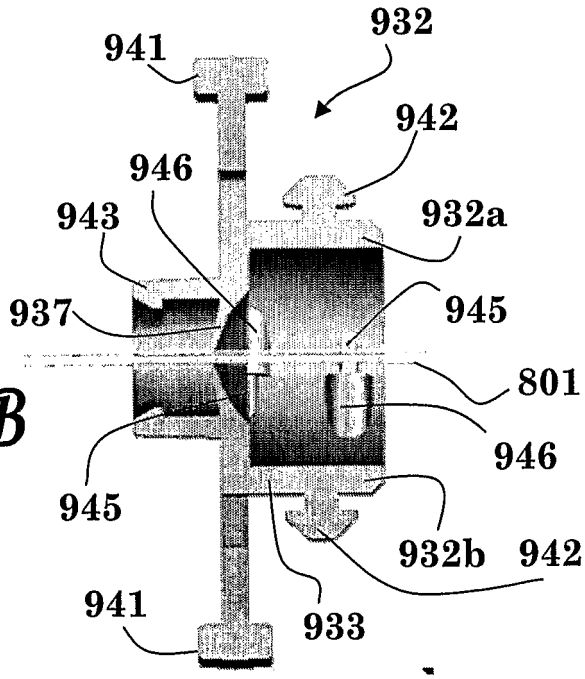


Fig. 10B

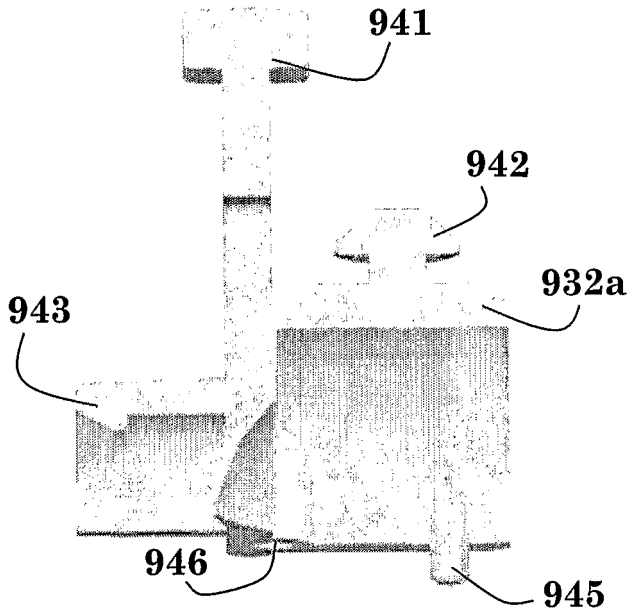


Fig. 10C

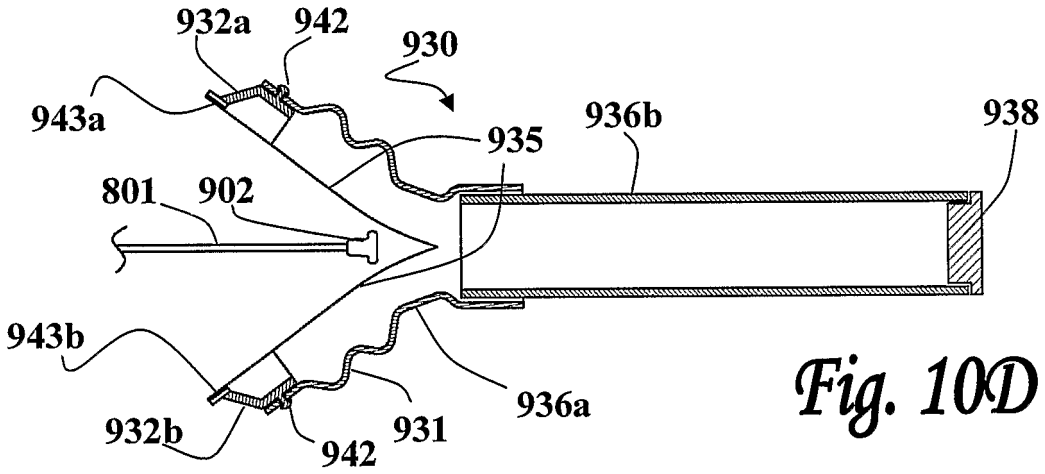


Fig. 10D

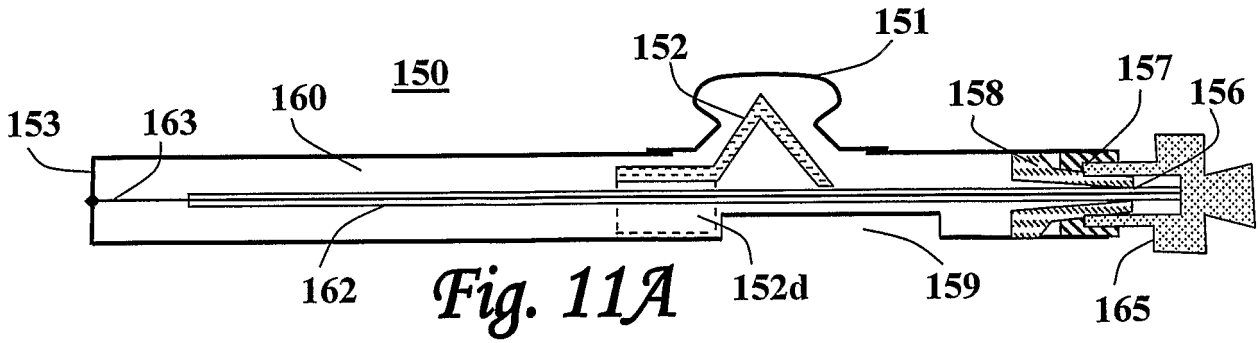


Fig. 11A

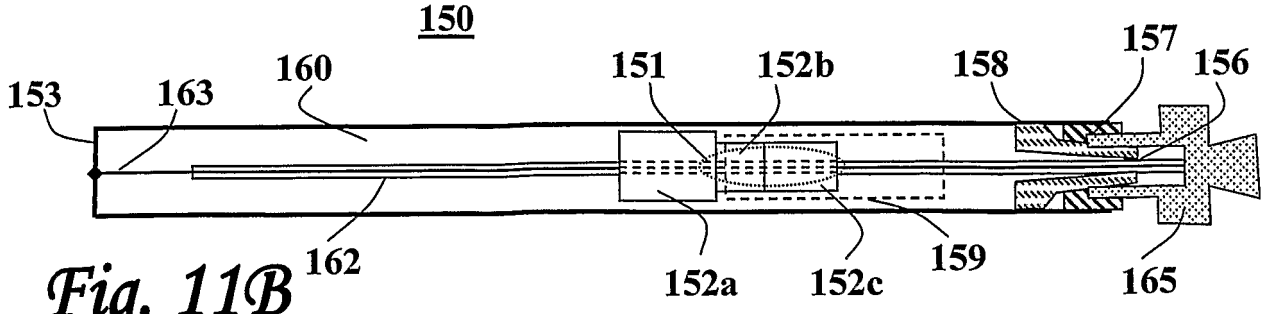


Fig. 11B

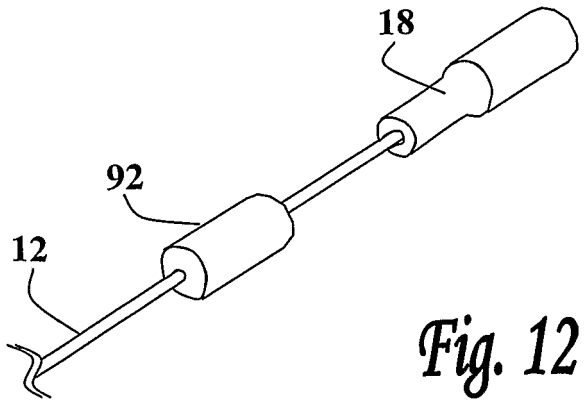


Fig. 12

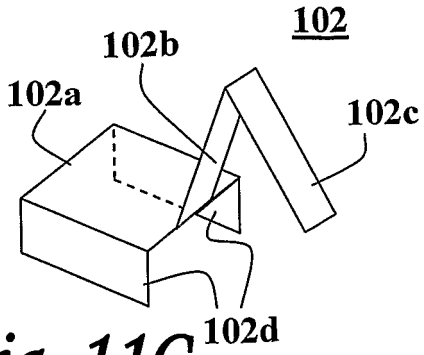


Fig. 11C

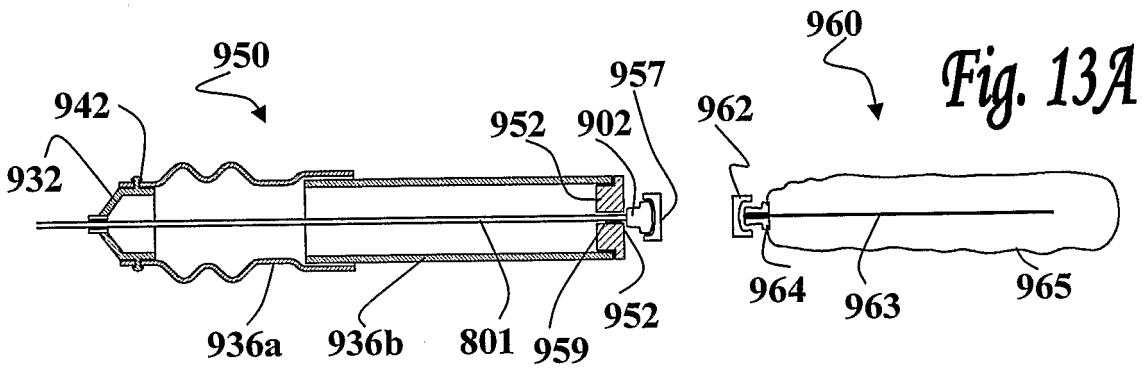


Fig. 13A

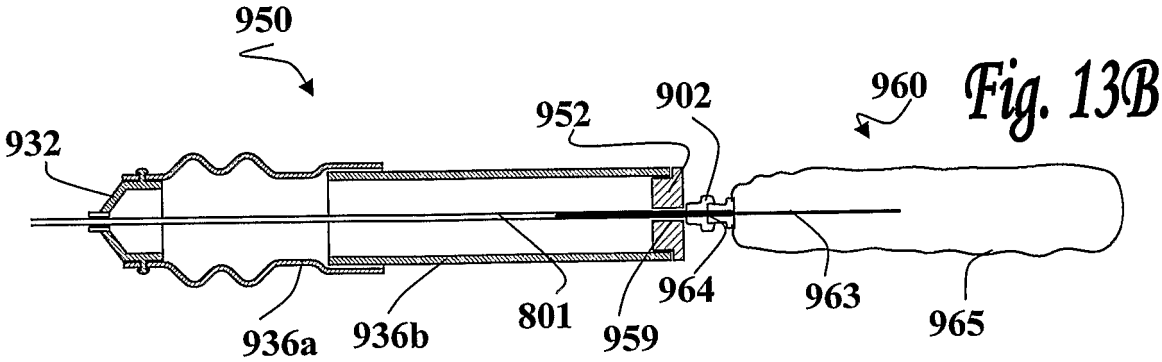


Fig. 13B

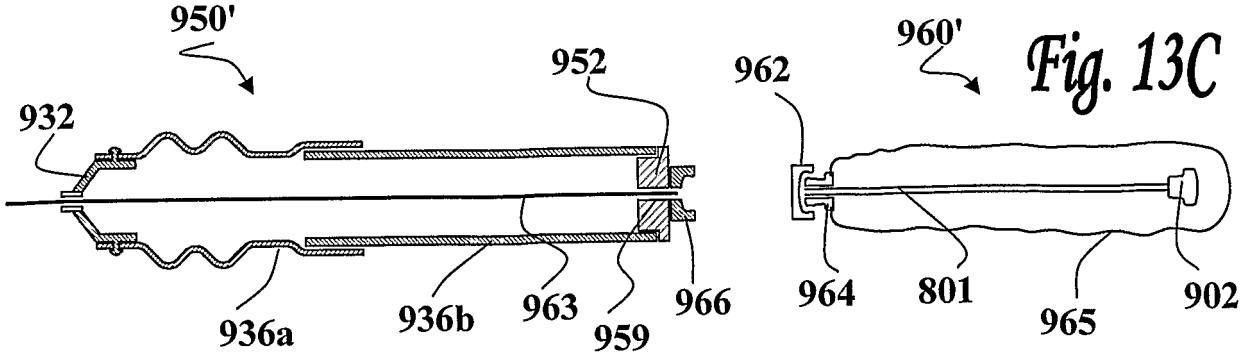


Fig. 13C

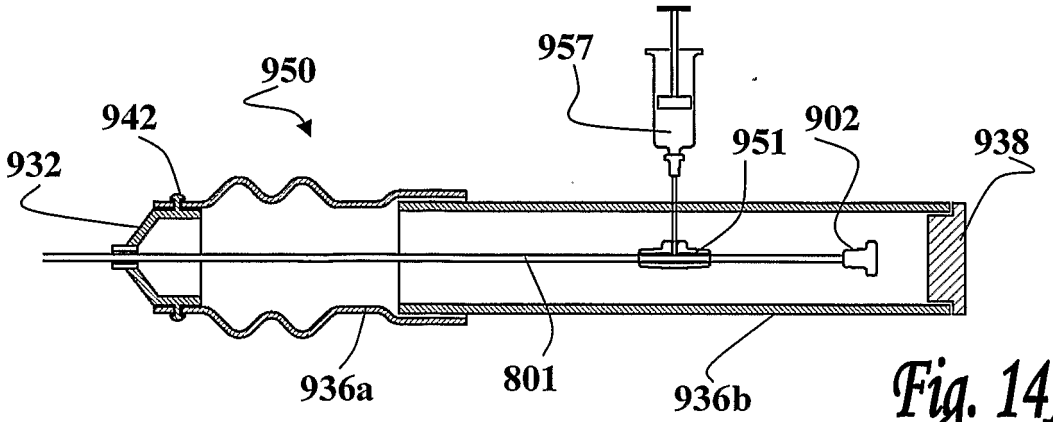


Fig. 14A

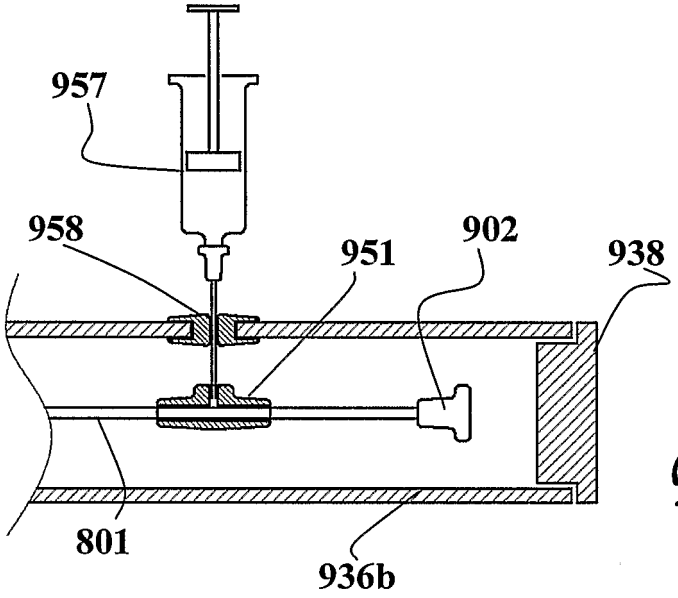


Fig. 14B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL06/00194

A. CLASSIFICATION OF SUBJECT MATTER
IPC: **A61M 5/178**(2006.01)

USPC: 604/158
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)
U.S. : 604/158, 164, 165, 167, 93.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST: catheter, insertion, cannula, plug, advance, guidewire, port, steer, seal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/084428 A2 (CYCLO SCIENCE LTD.) 16 October 2003 (16.10.2003), entire reference	1-3,5-8,12-15,17,19-20
Y		4
A		9-11,16,18,21-30

☐ 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 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
17 September 2006 (17.09.2006)

Date of mailing of the international search report
28 NOV 2006

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