(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
17 February 2005 (17.02.2005)

PCT

(10) International Publication Number
WO 2005/014097 A1

(51) International Patent Classification[7]: A61M 25/06, 25/00

(21) International Application Number: PCT/IL2003/000657

(22) International Filing Date: 7 August 2003 (07.08.2003)

(25) Filing Language: English

(26) Publication Language: English

(71) Applicants and
(72) Inventors: **HIRSZOWICZ, Eran** [IL/IL]; 171 Aluf David Street, 52236 Ramat-chen (IL). **OSTFELD, Ishay** [IL/IL]; 171B Aluf David Street, IL-52236 Ramat Gan (IL).

(74) Agent: **PYERNIK RUTMAN PATENT ATTORNEYS**; P.O. Box 10012, 84106 Beer Sheva (IL).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

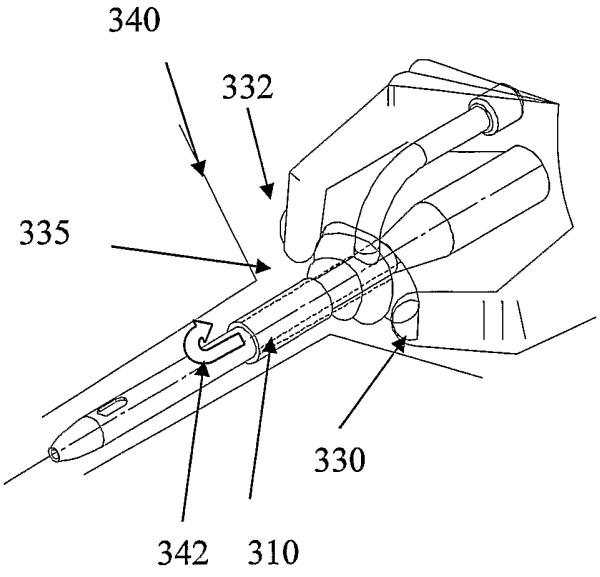
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

WO 2005/014097 A1

(54) Title: INDWELLING DEVICE



(57) Abstract: A medical device for insertion into a body having a surface covered by a detachable cover. The cover may be detached from the surface and removed from the body while the device remains in place in the body. The device may be, for example, a catheter, cannula, drain, stent, pacemaker, or electrode.

INDWELLING DEVICE

FIELD OF THE INVENTION

The present invention is in the field of medical devices, and more specifically relates to indwelling medical devices.

BACKGROUND OF THE INVENTION

There are many medical devices that are inserted into the body and left indwelling for a prolonged period of time. These include, for example, various types of catheters, cannulae, drains, implants, stents, pacemakers, electrodes and other devices. Some of these devices, such as a urinary catheter, when in use, extend from the exterior of the body into the body interior, passing through an orifice on the body surface. The orifice may be a natural orifice (e.g. mouth, meatus, nostrils, etc.) or an artificial orifice (e.g. a hole formed in the skin by a surgical incision). Other indwelling devices, such as a pacemaker or stent, are completely enclosed inside the body during use. Accessing these devices typically requires surgical incising or other invasive approaches.

Although using indwelling devices is a common medical procedure, it is often limited due to formation of biofilm such as calcifications and other debris, and colonization of microorganisms, such as bacteria and fungi, on the surface on the device. This may cause inflammation and further infection around the device. The formation of biofilm and contamination is common with exposed indwelling devices, limiting the amount of time that they may be left in the body before having to be removed and possibly replaced with a new device.

Contamination of the device and tissues surrounding it may occur as the device is inserted into the body. For example, the end of a urethra closest to the

meatus is naturally contaminated with various infectious agents, while the remainder of the urethra, nearer to the urinary bladder is normally sterile. During insertion of a catheter through the urethra to the urinary bladder, the catheter contacts infectious agents in the beginning of the urethra and spreads them up the urethra into the normally sterile portion and into the bladder. In order to reduce the spread of microorganisms up the urethra during insertion of a urinary catheter, it is known to first insert a hollow sheath into the beginning of the urethra that extends in the urethra to just beyond the contaminated region. A urinary catheter is then inserted through the sheath into the normally sterile part of the urethra, and into the bladder. The sheath thus intervenes between the catheter and the microorganisms in the infected part of the urethra, and thus decreases the chance of microorganisms spreading into the normally sterile portion of the urethra and into the bladder. After insertion of the catheter, the sheath is withdrawn from the body. Such sheaths are disclosed, for example, in U.S. Patent No. 5,417,666.

Microorganisms may also migrate along an exposed indwelling device after its insertion along the outside surface of the device at its interface with the surrounding tissue. In order to inhibit the migration of microorganisms along the device, it is known to impregnate the device with antiseptic substances that are released from the catheter over time. A catheter designed to release antiseptic substances is disclosed, for example, in U.S. Patent No. 3,598,127. Antiseptic impregnation, however, is not effective in the prevention of biofilm formation and is of very limited value in preventing infection due to the development of resistance among the microorganisms to the antibiotic.

SUMMARY OF THE INVENTION

The present invention provides indwelling medical devices having an outer surface at least a portion of which is protected by a manually detachable cover. During insertion, the cover is attached to the surface so as to prevent relative movement of the surface and the cover. This allows the integrity of the device and cover to be maintained during insertion. At any time after insertion, the cover may

be detached from the shaft and removed from the body, leaving the device in place. Removing the cover from the device removes the biofilm and contamination that has accumulated on the cover.

The device may comprise means for facilitating detachment of the cover from the device, and removal of the cover from the body. Suitable means for this include, but are not limited to, cords, inflatable balloons and cutters.

The cover is preferably made from non-allergic biocompatible materials such as silicone rubber, latex, woven metal mesh, parylene, polyvinylchloride, and the like. The cover may be impermeable to body fluids or microorganisms. The cover may have a rough or smooth surface.

In a preferred embodiment, the device has a surface that is protected by a stack of two or more sequentially detachable covers. A first, innermost, cover is in direct contact with the surface. A second detachable cover is in contact with the first cover, so that the first cover is between the second cover and the surface. Additional covers may also be present, as required. At any time after insertion of the device into the body, the outermost cover may be detached from the surface and removed from the body, leaving the device in place with one less cover over the surface. The newly exposed outermost cover may, later on, be detached from the surface and removed from the body. This process may be repeated until all of the covers have been removed. When using multiple covers, the covers may be made from the same material as the surface of the device or from a different material. the covers may be identical or different. They may be made from different materials or the same material. The thickness of each layer may be the same or different.

A detachable cover for a device may be made using a pre-formed cover that is applied to the surface. A cover may be formed having a lumen that is dimensioned to receive the entire device, or a portion of it in the lumen. Alternatively, a liquid coating substance may be applied to the device or to a portion of its surface and allowed to solidify by curing, polymerizing, or drying. For example, a 2:1 solution of silicone rubber:toluene may be applied to the surface and allowed to dry and cure. The coating substance may be applied to the device or

an outermost detachable cover previously applied to the surface, for example, by brushing, immersion, spraying, or any other method of deposition.

Two adjacent members (a detachable outermost cover and the surface of the device, or two adjacent detachable covers on a multiple coated device), may be reversibly attached to each other by any known method. For example, an adhesive may be introduced between the members and allowed to cure. The bond formed by the adhesive is subsequently broken when desired, for example, by applying an axial or radially outward force to the outermost member so as to break the bond. Alternatively, the bond may be broken by introducing a fluid between the members that breaks the bond either chemically or mechanically. As yet another alternative, the bond may be broken over time, either spontaneously or during prolonged contact of the adhesive with body fluids such as blood plasma or urine.

The reversible attachment of the two adjacent members may extend along the entire contact area between the members, or only at specific regions between the members. For example, one or more clips may be disposed on the device that presses the outermost cover to the underlying member at various locations. The clips may be formed, for example, by a rubber ring that may be rolled onto the outermost layer. The outermost layer is detached by cutting the ring or by rolling it off the outermost layer. The clip may be a toroidal balloon that constricts the members when inflated and releases the attachment when deflated.

A detachable cover may be made from an elastic material. An elastic cylinder may be stretched over the shaft of a catheter or over detachable covers already present on the shaft and allowed to contract with the shaft and any previously existing detachable covers in its lumen. In this case, a reversible attachment is formed between the new cover and an adjacent member by the elastic forces of the new outermost cover. The attachment may be broken by making a longitudinal cut along the outermost cover. The cover may have one or more lines of preformed perforations that are easily torn by splaying apart an end of the coating.

The space between the device and a cover or between two adjacent covers may contain material to reinforce the attachment or to enhance relative sliding. The

material may repel deposits or have anti-microbial properties. The interface material can be the same or different, for each pair of adjacent members. For example, mineral oil may be present to enhance sliding and prevent penetration of contamination between the members.

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, preferred embodiments will now be described, by way of non-limiting examples only, with reference to the accompanying drawings, in which:

Fig. 1 shows an indwelling device having a tearable cover in accordance with one embodiment of the invention;

Fig. 2 shows an indwelling device having a cutable cover in accordance with another embodiment of the invention;

Fig. 3 shows an indwelling device having a rollable cover in accordance with another embodiment of the invention;

Fig. 4 shows an indwelling device having a helical cover in accordance with another embodiment of the invention;

Fig. 5 shows an indwelling device having a cover attached with internal balloons in accordance with another embodiment of the invention;

Fig. 6 shows use of a clamp securing the distal end of a cover to a surface.

Fig. 7 shows an indwelling device having a cover attached on an inner surface;

Fig. 8 shows an indwelling device having a tearable cover in accordance with another embodiment of the invention.

Fig. 9 shows a system for preparing a cover on a mandrill in accordance with one embodiment of the invention;

Fig. 10 shows a system for transferring a cover from a mandrill onto a device; and

Fig. 11 shows an indwelling device having a cover with an inflatable lumen.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

The invention will now be described by non-limiting embodiments. For the sake of clarity, the invention is exemplified by devices having a slender shaft such as catheters, cannulae, and drains. This is by way of example only, however, and the invention is not limited to such devices. Other devices having detachable covers are included within the scope of the invention, such as implants, stents, and pacemakers.

First Embodiment

Fig. 1a shows an indwelling device **100** in accordance with a first embodiment of the invention. The device **100** has a proximal end **102,** a distal end **104,** and a cylindrical shaft **105** that may be solid or hollow. The shaft **105** is contained in an outer cover **110** having the general shape of a thin cylindrical shell. The outer cover **110** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **105,** and allowed to contract on the shaft **105.** The outer cover **110** is reversibly attached to the shaft **105** by circumferential elastic forces in the outer cover **110** that are exerted on the shaft **105.** This prevents slipping of the outer cover **110** over the shaft **105** during insertion of the device **100** into the body, and maintains the outer cover **110** on the shaft **105** after insertion.

The outer cover **110** is formed from two materials. The first material is used to form the cover except in a narrow strip **125** that is formed from a second material. The two materials are joined at two parallel seams **120a** and **120b** extending along the length of the outer cover **110.** The strip of **125** formed from the second material preferably extends circumferentially for less than one quarter of the circumference of the outer cover **110.** The first material has a relatively high tear stress, for example, a silicone rubber having a tear stress of 25 to 50 kN/M. the second material has a relatively low tear stress, such as a silicone rubber having a tear stress of less than 5 kN/M. The preparation of silicone rubbers and other materials having a particular tear stress are known in the art.

Between the shaft **105** and the outer cover **110** is a cord **130.** The cord is attached at one of its ends to the distal end of the strip **125.** At its other end, the cord extends beyond the proximal end of the coating. A ring **150** holds the end of cord **130** on the shaft **105.** As shown in Fig. 6, the device **100** may optionally comprise a distally located annular clamp **610** that secures the distal end of the outer cover **110** to the shaft **105** and prevents debris from accumulating under the distal end of the outer cover **110** during insertion.

Fig. 1b shows the catheter of Fig. 1a after insertion into the body. The catheter **100** was inserted into the body through a hole **135** on the body surface **140.** The hole **135** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the cord **130** extends through the hole **135** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **130.** Relative movement of the shaft **105** and the outer cover **110** is prevented during insertion due to the circumferential elastic forces of the outer cover **110** on the shaft **105.**

At any time after insertion, the outer cover **110** may be detached from the device **100** by removing the ring **150** and pulling the distal end of the cord **130.** Pulling the cord **130** away from the body draws the distal end of the strip **125** into the space between the coating **110** and the shaft **105,** tearing the distal ends of the seams **120a** and **120b**. (Fig. 1c). As the cord **130** continues to be pulled, tearing of the seams **120a** and **120b** progresses from the distal end towards the proximal end, until the entire strip **125** has been detached from the rest of the layer **110** and removed from the body (Fig. 1d). This detaches the outer cover **110** to the shaft **105.** The proximal end of the torn outer cover **110** may now be grasped and manually removed from the body leaving the device **100** in place. If after removal of the outer cover **110,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fig. 9 shows a system, generally indicated by **900** for preparing the cover **110**. A reservoir **905** contains a first liquid suspension **910** for preparing the first material in the cover **110**. A cylindrical mandrill **915** is used upon which the cover **110** is to be formed. The mandrill **915** has a diameter corresponding to the inner diameter of the cover **110**. A length of the mandrill **915** is submerged in the suspension **910**. As the mandrill **915** is withdrawn from the suspension **910**, a layer **920** of the first material coating the mandrill is formed.

A wiper blade **925** is used to remove a portion of the coating **920** as the mandrill **915** is withdrawn from the suspension **910**. Above the wiper **925**, a narrow strip **930** of the surface of the mandrill **915** thus becomes exposed.

A second reservoir **935** contains a second suspension **940** that is used to form the second material of the coating **110**. The second suspension **940** is delivered to the surface of the mandrill **915** through a tube **945**. A nozzle **950** applies the second suspension to the exposed strip **930** of the mandrill **915** surface, as the mandrill **915** is withdrawn from the first suspension **910**. The second suspension **940** thus forms a coating **955** on the mandrill **915** in the exposed strip **930** created by the wiper **925**.

Fig. 9c shows the mandrill **915** after having been removed from the reservoir **905**. A cylindrical coating **960** has been formed on the mandrill **915**. The coating consists of the first portion **920** formed by the first suspension **910** and the second portion **955** formed by the second suspension **940**. The mandrill **915** is then placed in an oven in order to allow the coating to cure so as to form the cover **110**. The first suspension **910** thus formed the first material of the cover, and the second suspension **940** formed the second material.

Fig. 10 shows a system, generally indicated by **1000**, for transferring the cover **110** from the mandrill **915** to the shaft **105** of the device **100**. The system **1000** is shown in plan view in Fig. 10a and in cross-section in Fig. 10b. The system **1000** has a housing **1005**. A cylindrical tube **1010** passes through the housing **1005** and has a diameter configured to alternately receive the coated mandrill **915** and the shaft **105** of the device **100**, as described below.

Fig. 10b shows the interior **1015** of the system **1000**. A cylindrical space **1020** surrounds the cylinder **1010**. The wall **1022** that is common to the space **1020** and the cylinder **1010** contains a plurality of pores **1025** allowing he flow of air between the interior**1015** of the cylinder **1010** and the space **1020**. When the ends of the cylinder **1010** are sealed, as described below, the chambers **1015** and **1020** may be evacuated by removing air in the chambers through a tube **1027** that is connected to a source of negative pressure (not shown).

Fig. 10c shows the system **1000** after the mandrill **915** has been inserted into the cylindrical tube **1010**. As described above, the mandrill **915** is contained in the cover **110** that is to be transferred from the mandrill **915** to the shaft **105** of the device **100**.

As shown in Fig. 10d, the ends **128** of the cover **110** are then rolled off the mandrill **915** and onto the ends of the tube **1010**, thus sealing the ends of the cylinder **1010**. The chamber **1020** is then evacuated causing the cover **110** to dissociate from the mandrill **915** and associated with the to the inner surface of the cylinder **1010**, as shown in Fig. 10e. Dissociation of the cover **110** from the mandrill **915** may be enhanced if the mandrill is formed with a hollow core **1030** that is confluent with the exterior by pores **1035** in the wall of the mandrill **915**, as shown in Fig. 10f. A source of positive pressure (not shown) is applied to the core **1030** by means of a tube **1040**. The mandrill is then removed from the cylinder **1010** leaving the cover **110** mounted on the inner surface of the cylinder **1010**, as shown in Fig. 10f.

Now the shaft **105** of the device **100** is inserted into the cylinder **1010** as shown in Fig. 10 g. . The source of negative pressure is then disconnected from the tube **1027**, causing the cover **110** to dissociate from the wall of the cylinder **1010** and associate with the shaft **105** of the device **100**, as shown in Fig. 10h. The ends of the cover **110** are then unrolled from the cylinder **1010** onto the shaft **105**, and the shaft **105** is removed from the interior of the cylinder **1010** with the cover **110** in place.

Second Embodiment

Fig. 2a shows an indwelling device **200** in accordance with another embodiment of the invention. The device **200** has a proximal end **202,** a distal end **204,** and a cylindrical shaft **205** that may be solid or hollow. The shaft **205** is contained in an outer cover **210** having the general shape of a thin cylindrical shell. The outer cover **210** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **205,** and allowed to contract on the shaft **205.** The outer cover **210** is reversibly attached to the shaft **205** by circumferential elastic forces in the outer cover **210** that are exerted on the shaft **205.** This prevents slipping of the outer cover **210** over the shaft **205** during insertion of the device **200** into the body, and maintains the outer cover **210** on the shaft **205** after insertion.

As shown in the insert Fig. 2a-I of Fig. 2a, the shaft has a longitudinal groove **215** that forms a track for a blade **220.** The blade **220** is slidable along the groove **215.** During insertion into the body, the blade **220** is positioned at the distal end of the groove **215.** Between the shaft **205** and the outer cover **210** is a cord **230.** The cord is attached at one of its ends to the blade **220.** At its other end, the cord **215** extends beyond the proximal end of the coating.

Fig. 2b shows the device **200** after insertion into the body. The device **200** was inserted into the body through a hole **235** on the body surface **240.** The hole **235** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the cord **230** extends through the hole **235** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **230.** Relative movement of the shaft **205** and the outer cover **210** is prevented during insertion due to the circumferential elastic forces of the outer cover **210** on the shaft **205.**

At any time after insertion, the outer cover **210** may be detached from the device **200** by pulling the proximal end of the cord **230.** Pulling the cord **230** away from the body draws the blade **220** towards the proximal end of the shaft **205** thus making a longitudinal cut **233** in the cover **210.** (Fig. 2c). A guard **222** (Fig. 2a-I)

on the blade prevents the blade from cutting any underlying covers. As the cord **230** continues to be pulled, cutting of the cover **210** progresses from the distal end towards the proximal end, until the cut extends along the entire length of the cover **210.** This detaches the outer cover **210** from the shaft **205.** The proximal end of the cut outer cover **210** may now be grasped and manually removed from the body leaving the device **200** in place. If after removal of the outer cover **210,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Third Embodiment

Fig. 3a shows a device **300** in accordance with an other embodiment of the invention. The device **300** has a proximal end **302,** a distal end **304,** and a cylindrical shaft **305.** The shaft **305** is contained in an outer cover **310** having the general shape of a thin cylindrical shell. The outer cover **310** is formed from a biocompatible, elastic material, such as latex. The outer cover **310** was formed from an inner cylindrical shell **322** and an outer cylindrical shell **324.** The inner and outer shells **322** and **324** are welded together at a first circular seam **326** at its distal end and a second circular seam **327** at its proximal end. The outer cover **310** was stretched over the shaft **305,** and allowed to constrict on the shaft **305.** The outer cover **310** is reversibly attached to the shaft **305** by circumferential elastic forces in the outer cover **310** that are exerted on the shaft **305.** This prevents movement of the outer cover **310** relative to the shaft **305** during insertion of the device **300** and maintains the outer cover **310** on the shaft **305** after insertion.

Fig. 3b shows the device of Fig. 3a after insertion into the body. The catheter **300** was inserted into the body through a hole **335** on the body surface **340.** The hole **335** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). The proximal end of the outer cover **310** extends through the hole **335** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is

made in order to access the proximal end of the outer cover **310.** Relative movement of the shaft **305** and the outer cover **310** is prevented during insertion due to the circumferential elastic forces of the outer cover **310** on the shaft **305.**

At any time after insertion, the outer cover **310** may be detached from the device **300** by causing the outer cylindrical shell **324** to slide proximally over the inner cylindrical shell **322.** As shown in Fig. 3c, this may be accomplished by placing a thumb **330** and an index finger **332** on the outer cylindrical shell **324** and urging the outer cylindrical shell **324** to slide proximally over the inner cylindrical shell **322,** as indicated by the arrow **342** This draws the distal end of the inner cylindrical shell **322** into the outer shell **324,** while the remainder of the inner shell remains stationary, relative to the shaft **305.** As the outer shell **324** continues to slide proximally, the shaft **305** becomes progressively more exposed at its distal end, as shown in Fig. 3d. This process continues until the shaft **305** has been completely exposed and the outer cover **310** has been removed from the body. If after removal of the outer cover **310,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fourth Embodiment

Fig. 4a shows an indwelling device **400** in accordance with another embodiment of the invention. The device **400** has a proximal end **402,** a distal end **404,** and a cylindrical shaft **405** that may be solid or hollow. The shaft **405** is contained in an outer cover **410** having the general shape of a thin cylindrical shell. The outer cover **410** is formed from a strip of biocompatible material, such as latex or silicone rubber. The outer cover **410** is formed by winding the strip of biocompatible material in a helical pattern around the length of the shaft **405.** Consecutive turns of the helix overlap so as to completely cover the shaft **405.** The distal end **411** of the strip is tucked under the first few turns of the helix, so as to immobilize the distal end of the strip as shown in the insert to Fig. 4a. The proximal end of the strip is held in place by a ring **425.** The ring **425** has a lumen

dimensioned to fit snugly on the shaft **405** and the proximal end of the outer cover **410.** This prevents slipping of the outer cover **410** over the shaft **405** during insertion of the device **400** into the body, and maintains the outer cover **410** on the shaft **405** after insertion.

Fig. 4b shows the device of Fig. **4a** after insertion into the body. The device **400** was inserted into the body through a hole **435** on the body surface **440.** The hole **435** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device **400,** including the ring **425,** extends through the hole **435** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device **400** and the ring **425.** Relative movement of the shaft **405** and the outer cover **410** is prevented during insertion due to the radial force of the ring **425** on the proximal end of the outer cover **410,** and the radial force of the last few turns of the helix on the distal end of the outer cover **410.**

At any time after insertion, the outer cover **410** may be detached from the device **400.** Referring to Fig. 4c, the ring **425** is removed from the shaft **405** and the outer cover **410** is unwound from its proximal end **408.** (Fig. 4c). The outer cover **410** continues to be unwound, until the distal end of the outer cover **410** is freed. The proximal end of the outer cover **410** may now be grasped and manually removed from the body leaving the device **400** in place. If after removal of the outer cover **410,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Fifth embodiment

Fig. 5a shows an indwelling device **500** in accordance with another embodiment of the invention. The device **500** has a proximal end **502,** a distal end **504,** and a cylindrical shaft **505** that may be solid or hollow. The shaft **505** is contained in an outer cover **510** having the general shape of a thin cylindrical shell.

The outer cover **510** is formed from a biocompatible, rigid material, such as plastic or metal. One or more balloons **515** are located in a space **520** formed between the outer cover **510** and the shaft **505.** In Fig. 5a, the balloons are shown in their deflated state. As shown in Fig. 5b, before inserting the device **500** into the body, the balloons **515** are inflated with a fluid such as air or water. A syringe **525** containing the fluid **530** is inserted into a valve **570.**

The balloons are inflated by opening the valve **570** and depressing the plunger **550** of the syringe. The fluid **530** is conducted from the syringe **525** through a first tube **560** and then through a second tube **565** running along the shaft **505** and then into each of the balloons **515.** When inflated, the balloons apply a pressure to both the shaft **515** and the outer cover **510.** The valve **570** is then closed to prevent fluid from leaving the balloons. The outer cover **510** thus becomes reversibly attached to the shaft **505** by the balloons **515** that are lodged between the outer cover **510** and the shaft **505.**

Fig. 5c shows the device of Fig. 5a and b after insertion into the body. The device **500** was inserted into the body through a hole **535** on the body surface **540.** The hole **535** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole **535** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cover **510.**

At any time after insertion, the outer cover **510** may be detached from the device **100** by deflating the balloons **515.** This may be done, for example, by inserting the syringe **530** into the valve **570** and drawing the fluid from the balloons so as to puncture the balloon by pulling on the plunger **550**. Once the balloons have been deflated, the proximal end of the cover **510** may be grasped and manually removed from the body leaving the device **500** in place. If after removal of the outer cover **510,** a new detachable outer cover (not shown) becomes exposed

on the shaft, the newly exposed detachable layer may later on be removed from the device.

Sixth Embodiment

Fig. 7 shows an indwelling device **700** in accordance with another embodiment of the invention. The device **700** has a proximal end **702,** a distal end **704,** and a hollow cylindrical shaft **705.** The shaft **705** has a lumen **708.** In this embodiment, the cover 710 lines the inner surface of the hollow shaft **705.** The lumen **708** contains a cover **710** having the general shape of a thin cylindrical shell covering the wall of the lumen **708.** The cover **710** is formed from a biocompatible, rigid material, such as plastic. The proximal end of the cover **710** is glued to the lumen of a restraining ring **711.** A circumferential clamp **750** around the ring **711** secures the ring **711** to the proximal end **702** of the device **700.**

Fig. 7b shows the catheter of Fig. 7a after insertion into the body. The catheter **700** was inserted into the body through a hole **735** on the body surface **740.** The hole **735** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole **735** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the device **700.**

Fig.7b further shows removal of the outer cover. The ring **711** is detached from the proximal end **702** of the device **700,** and the ring **711** is removed from the device **700** together with the cover **710** attached to it. As the ring 711 continues to be pulled away from the proximal end **702** of the device **700,** the cover **710** becomes attenuated and detaches from the inner surface of the shaft lumen **708.** If after removal of the outer cover **710,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Seventh embodiment

Fig. 8a shows an indwelling device **800** in accordance with a first embodiment of the invention. The device **800** has a proximal end **802,** a distal end **804,** and a cylindrical shaft **805** that may be solid or hollow. The shaft **805** is contained in an outer cover **810** having the general shape of a thin cylindrical shell. The outer cover **810** is formed from a biocompatible, elastic material, such as latex, that was stretched over the shaft **805,** and allowed to contract on the shaft **805.** The outer cover **810** is reversibly attached to the shaft **805** by circumferential elastic forces in the outer cover **810** that are exerted on the shaft **805.** This prevents slipping of the outer cover **810** over the shaft **805** during insertion of the device **800** into the body, and maintains the outer cover **810** on the shaft **805** after insertion.

The outer cover **810** has a line of perforation **820** extending along the length of the outer cover **810.** A ring **811** located on the shaft **805** contains a cord **830** that fixes the proximal end of the cover **810** onto the shaft **805.** As shown in Fig. 6, the device **800** may optionally comprise a distally located annular clamp **615** that secures the distal end of the outer cover **810** to the shaft **805** and prevents debris from accumulating under the distal end of the outer cover **810** during insertion.

Fig. 8b shows the device **800** after insertion into the body. The device **800** was inserted into the body through a hole **835** on the body surface **840.** The hole **835** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device **800** extends through the hole **835** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cord **830.** Relative movement of the shaft **805** and the outer cover **810** is prevented during insertion due to the circumferential elastic forces of the outer cover **810** on the shaft **805.**

At any time after insertion, the outer cover **810** may be detached from the device **800.** The cord **830** is released as shown in Fig. 8c. The proximal end of the perforation **820** is then torn. The cover **810** is then made to slide proximally over

the shaft **805** as shown in Fig. 8d. This causes a new region of the perforation **820** to be exposed outside the body. This section of the perforation is then torn, and the cover **810** is then made to slide proximally over the shaft **805** (Fig. 8d). This process continues until all of the perforation **820** is completely torn, and the cover is removed from the body. If after removal of the outer cover **810,** a new detachable outer cover (not shown) becomes exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

Eighth embodiment

Fig. 11a shows an indwelling device **1100** in accordance with another embodiment of the invention. The device **1100** has a proximal end **1102,** a distal end **1104,** and a cylindrical shaft **1105** that may be solid or hollow. The shaft **1105** is contained in an outer cover **1110**. The outer cover **1110** is formed from a biocompatible, elastic material , such as latex or silicone rubber.

Fig. 11b shows the cross section AA' of the device **1100** shown in Fig. 11a. The cover **1105** has a primary lumen **1115** that contains the shaft **1105**. The cover **1105** has a secondary lumen **1120**. The secondary lumen is a blind lumen not having an opening at the distal end to the device **1100**. Fig. 11b shows the device **1100** with the secondary lumen in an uninflated state.

As shown in Fig. 11c, before inserting the device **1100** into the body, the secondary lumen is inflated with a fluid such as air or water. A syringe **1125** containing the fluid **1130** is inserted into a valve **1170.** The secondary lumen **1120** is inflated by opening the valve 1170 and depressing the plunger **1150** of the syringe. The fluid **1130** is conducted from the syringe **1125** through a tube **1160** to the secondary lumen **1120**.

Fig. 11d shows the cross section AA' of the device **1100** with the secondary lumen **1120** in an inflated state. A partition **1155** separating the primary lumen **1115** and the secondary lumen **1120** is more compliant than the wall of the cover **110** adjacent to the secondary lumen **1120**. Thus, when inflated, the partition **1155** bulges outward from the secondary lumen **1120** towards the primary lumen **1115,** while the shape of the wall of the cover **110** is less effected by the inflation. The

valve **1170** is then closed to prevent fluid from leaving the secondary lumen **1120.** The bulging partition **1155** applies a force on the shaft **1105** of the device which causes the cover **1105** to be reversibly attached to the shaft.

Fig. 11e shows the device of Figs. 11a 11d after insertion into the body. The device **1100** was inserted into the body through a hole **1135** on the body surface **1140.** The hole **1135** may be a natural hole on the body surface (e.g. mouth, meatus, nostrils, etc.) or an artificial hole (e.g. a hole formed in the skin by a surgical incision). After insertion, the proximal end of the device extends through the hole **1135** and is exposed on the body surface. This is by way of example only, and the device may in use be completely enclosed within the body. In this case, a surgical cut is made in order to access the proximal end of the cover **1110.**

At any time after insertion, the outer cover **1110** may be detached from the device **100** by deflating the secondary lumen **1120.** This may be done, for example, by inserting the syringe **1130** into the valve **570** and drawing the fluid from the secondary lumen **1120** by pulling on the plunger **1150**. Once the secondary lumen **1120** has been deflated, the proximal end of the cover **1110** may be grasped and manually removed from the body leaving the device **1100** in place. If after removal of the outer cover **1110,** a new detachable outer cover (not shown) may become exposed on the shaft, the newly exposed detachable layer may later on be removed from the device.

CLAIMS:

1. A medical device for insertion into a body, the device having at least one surface covered by at least one detachable cover, the cover being detachable from the surface and removed from the body while the surface remains in place in the body.

2. The device according to Claim 1, the device being selected from the group comprising;

(a) a catheter;

(b) a cannula;

(c)drain;

(d) a stent;

(e) a pacemaker; and

(f) an electrode.

3. The device according to Claim 1 wherein the surface is an inner surface.

4. The device according to Claim 1 wherein the surface is an outer surface.

5. The device according to Claim 1 having at least two detachable covers, each cover being detachable from the surface and removed from the body while the device is inserted in the body.

6. The device according to Claim 5 wherein the at least two covers are identical.

7. The device according to Claim 5 having two covers with different properties.

8. The device according to Claim 1 wherein the cover is formed from a material selected from the group comprising:

(a) rubber;

(b) silicone rubber;

(a) polyvinlylchloride;

(b) latex;

(c) woven metal mesh; and

(d) parylene.

9. The device according to Claim 1 wherein the cover is formed from a biocompatible material.

10. The device according to Claim 1 wherein the cover is formed from a non-allergenic material.

11. The device according to Claim 1 wherein the cover has a smooth surface.

12. The device according to Claim 1 wherein the cover has a rough surface.

13. The device according to Claim 5 containing an antibiotic between two adjacent covers.

14. The device according to Claim 1, wherein the cover is reversibly attached to a surface by means of elastic forces in the cover.

15. The device according to Claim 1 wherein the cover is detached from the surface by tearing the cover.

16. The device according to Claim 1 wherein the cover is torn along one or more preformed seams or perforations in the cover.

17. The device according to Claim 1 comprising a blade slidable over the surface so as to cut the cover and detach the cover from the surface.

18. The device according to Claim 1 wherein the surface is a surface of a slender shaft associated with the device.

19. The device according to Claim 18 wherein the cover is formed from a strip of material, the cover being attached to the shaft when wrapped around the shaft in a helix, and the cover being detached from the shaft by unwrapping the strip.

20. The device according to Claim 18 wherein further comprising a ring placed at a distal end of the shaft to prevent materials from entering between the cover and the surface.

21. The device according to Claim 18 wherein the cover comprises an inner cylindrical shell and an outer cylindrical shell, the inner and out cylindrical shells having a distal end and a proximal end, the inner and outer cylindrical shells being attached to each other at their proximal ends and at their distal ends.

22. The device according to Claim 1 wherein the cover is formed by depositing on the surface a liquid and allowing the liquid to solidify on the surface.

23. The device according to Claim 22 wherein the liquid is deposited by brushing, spraying, or immersion.

24. The device according to Claim 1 comprising one or more balloons located between the cover and the surface, the cover being attached to the surface when the balloons are inflated, and detached from the surface when the balloons are not inflated.

25. The device according to Claim 18 wherein the cover has a primary lumen containing the shaft and an inflatable secondary lumen, the inflated secondary lumen applying a force on the shaft so as to reversibly attach the cover to the lumen.

26. The device according to Claim 1 in which the cover is impenetrable to microorganisms.

27. The device according to Claim 1 wherein the cover is impenetrable to water.

28. The device according to any one of the previous claims in the cover stores and releases a substance.

29. The device according to Claim 1 wherein the cover releases an anti-microbial or anti-fungal compound.

30. The device according to Claim 1 wherein the cover has two parallel rows of perforations or seams separating a strip of the cover, the strip being attached at a distal end to a first end of a cord and a second end of the cord being accessible at a proximal end of the device.

31. The device according to Claim 1 further comprising a cutter slidable along the surface of the device, the cutter being configured to cut the cover when sliding along the surface.

32. The device according to Claim 1 wherein the cover has a row of perforation such that when a proximal end of the perforation is torn, the cover may be made to slide over the surface in a proximal direction.

33. A system for forming a cylindrical cover on a mandrill, comprising:

(a) a first reservoir containing a first suspension;

(b) a wiper for removing a portion of the first suspension when applied onto the mandrill

(c) a second reservoir containing a second suspension; and

(d) a nozzle for applying the second suspension to the mandrill.

34. A system for transferring a cover from a mandrill to a cylindrical shaft of a device, comprising:

(a) a first chamber configured to receive the mandrill;

(b) a second chamber surrounding a portion of the first chamber, the first and second chambers having a common wall containing a plurality of pores;

(c) an outlet for evacuating the first and second chambers.

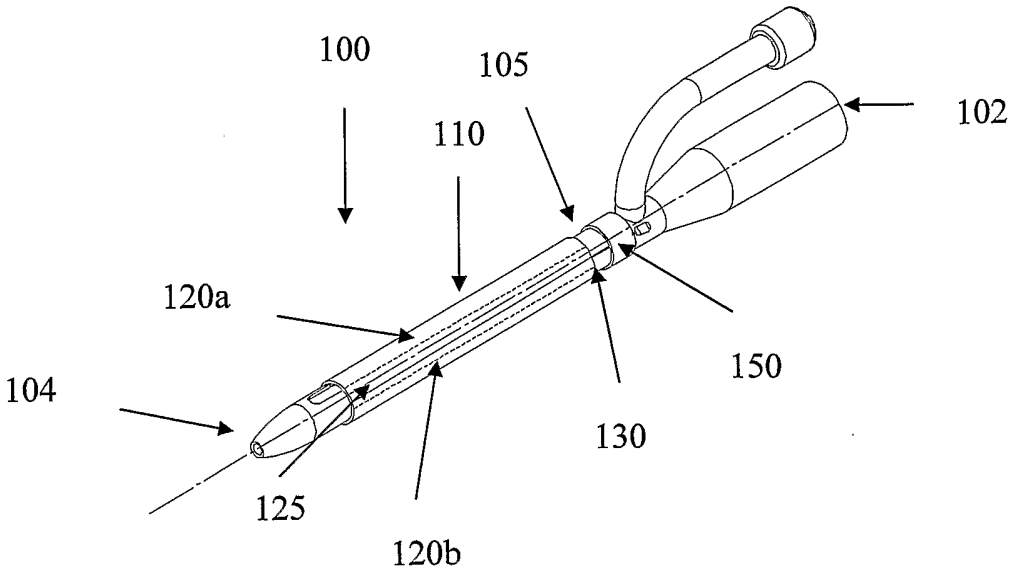

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Fig.1a

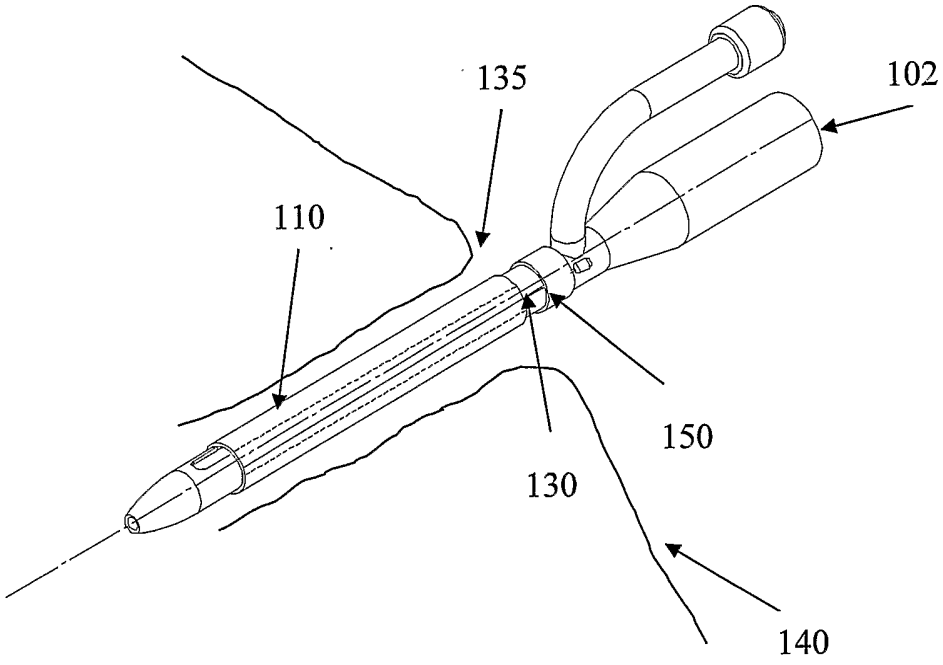
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Fig.1b

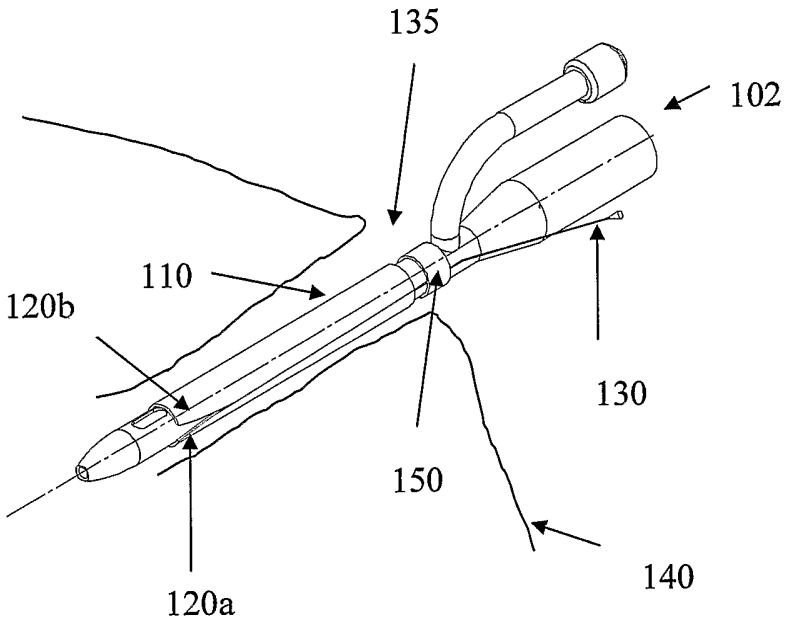

Fig.1c

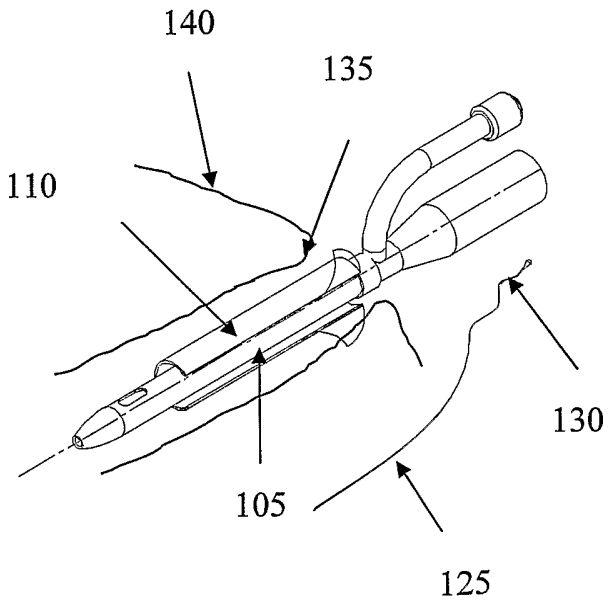

Fig.1d

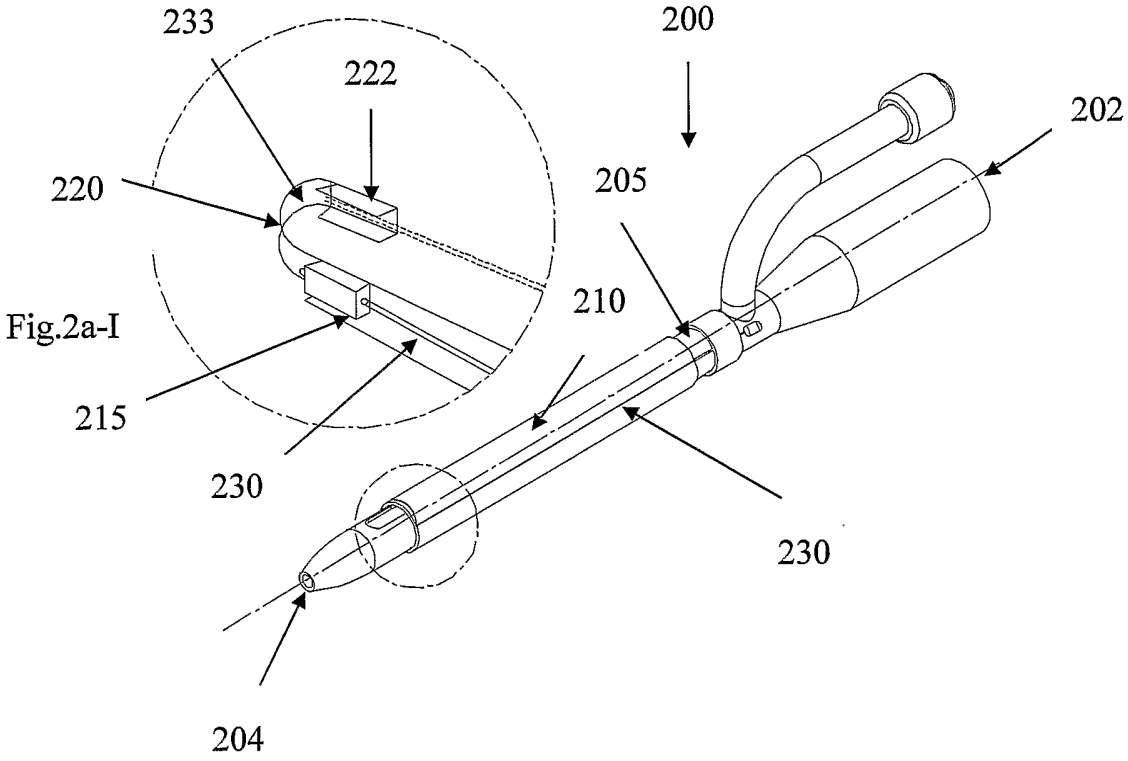
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Fig.2a-I
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Fig.2a

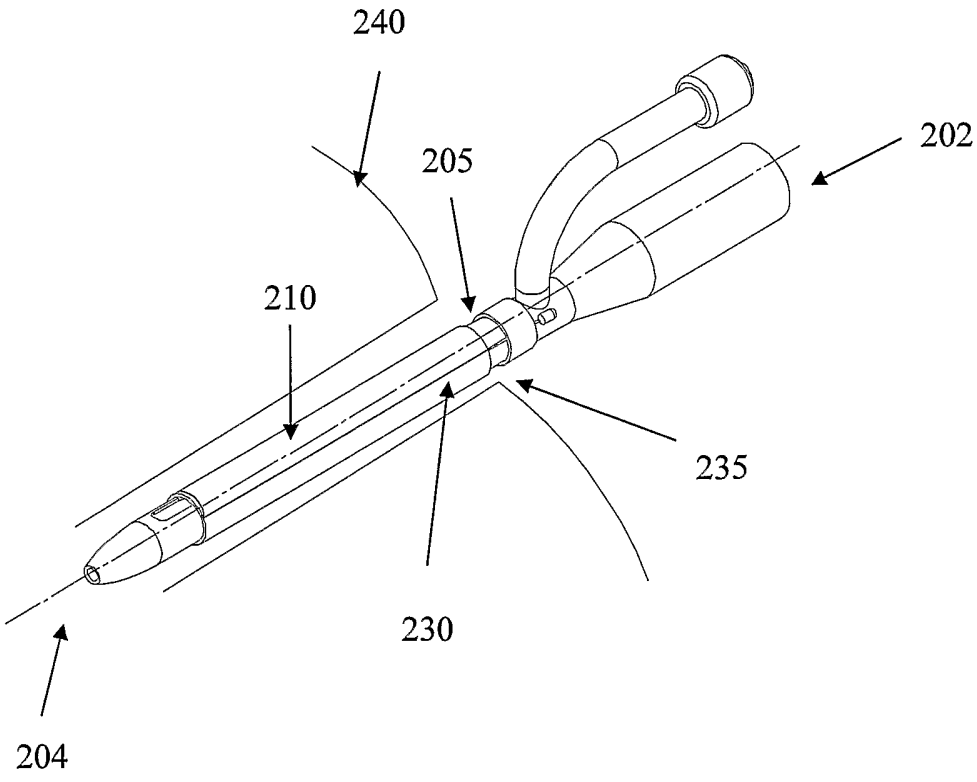
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Fig 2b

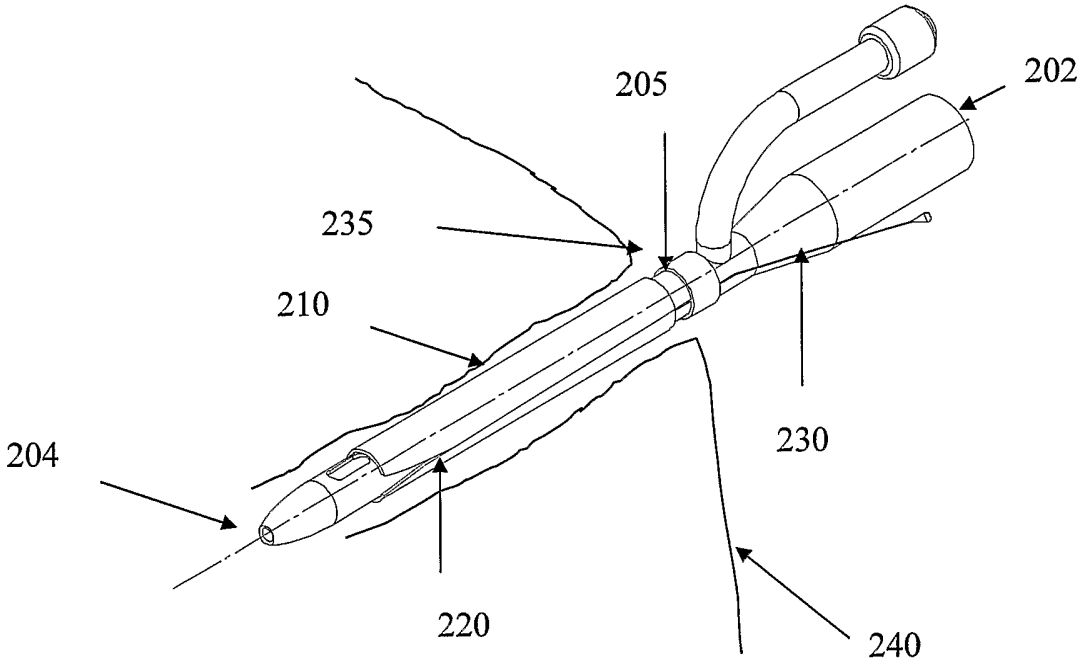


Fig 2c

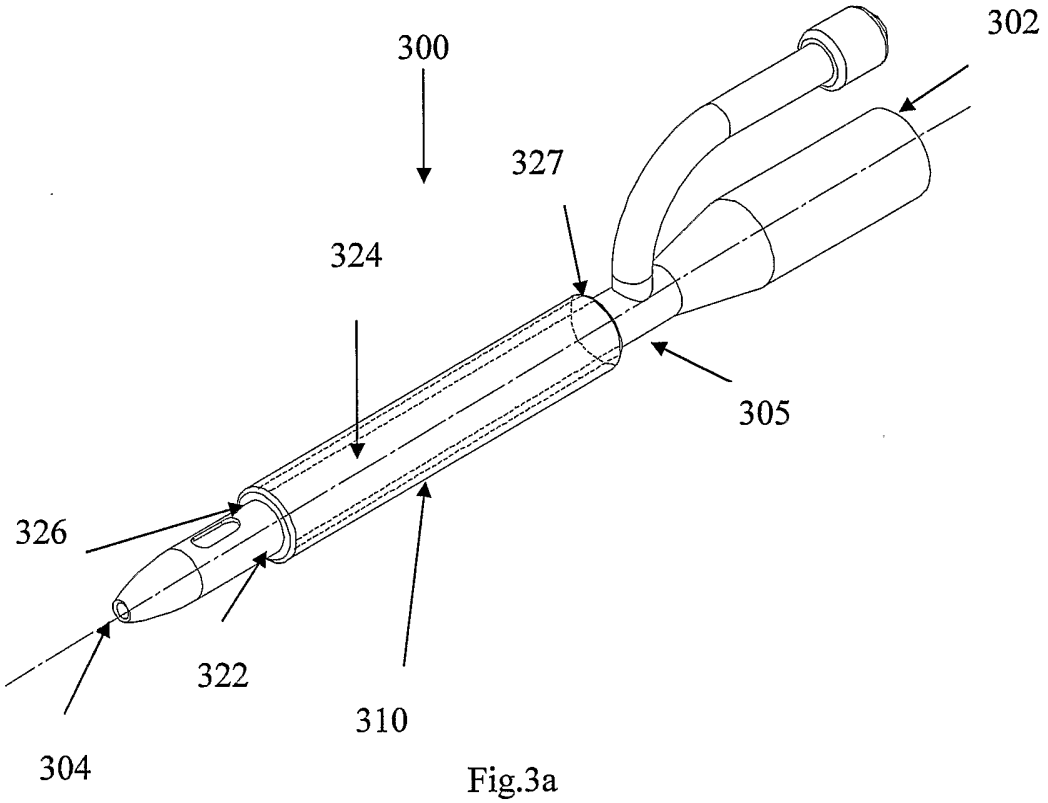


Fig.3a

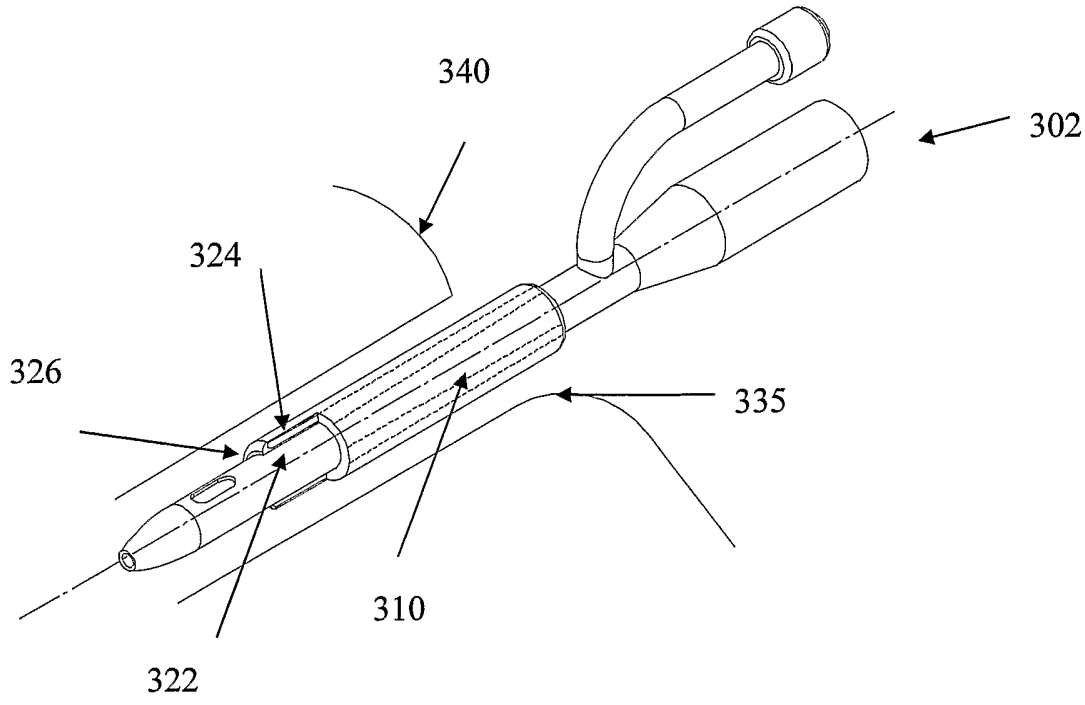


Fig.3b

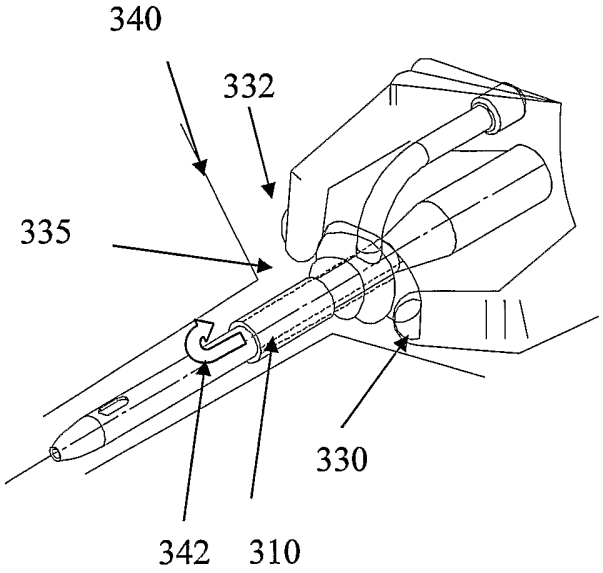


Fig.3c

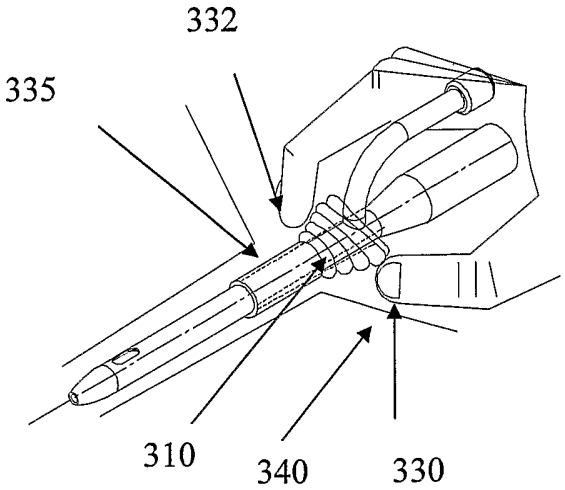
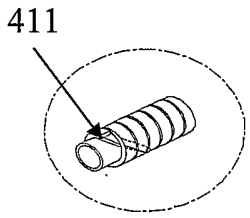


Fig.3d



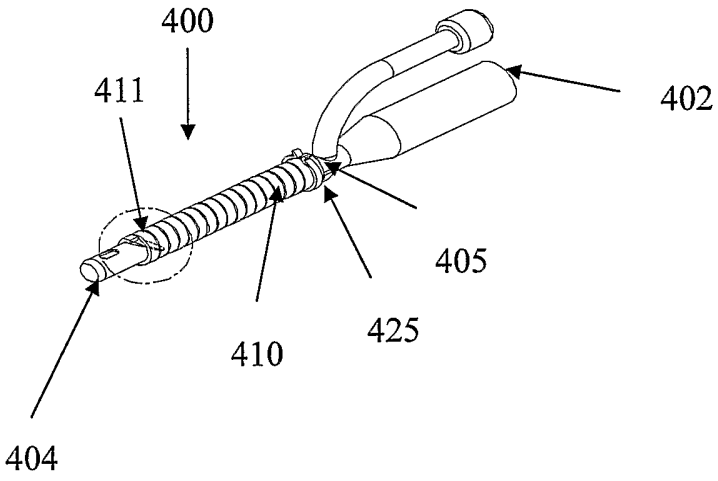


Fig. 4a

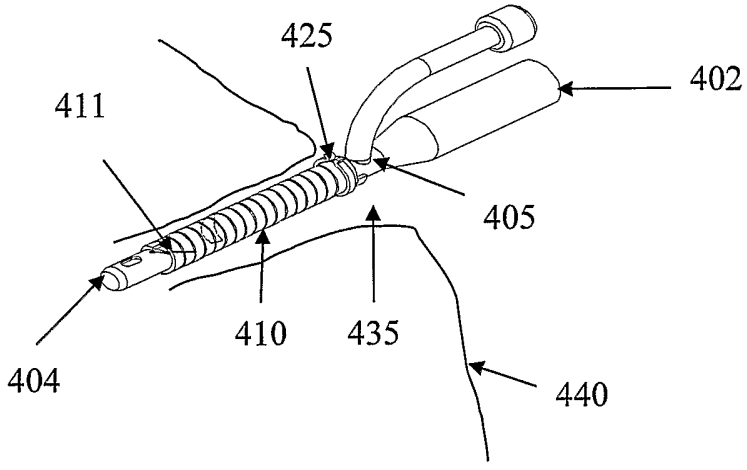


Fig.4b

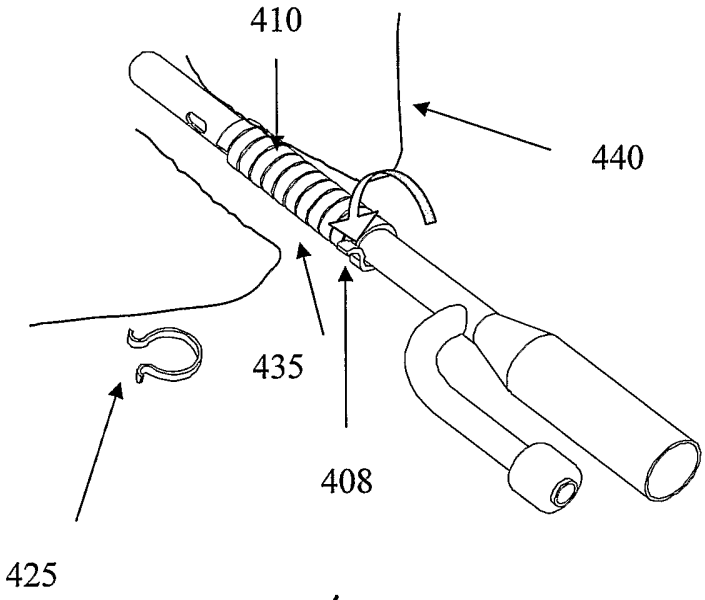


Fig. 4c

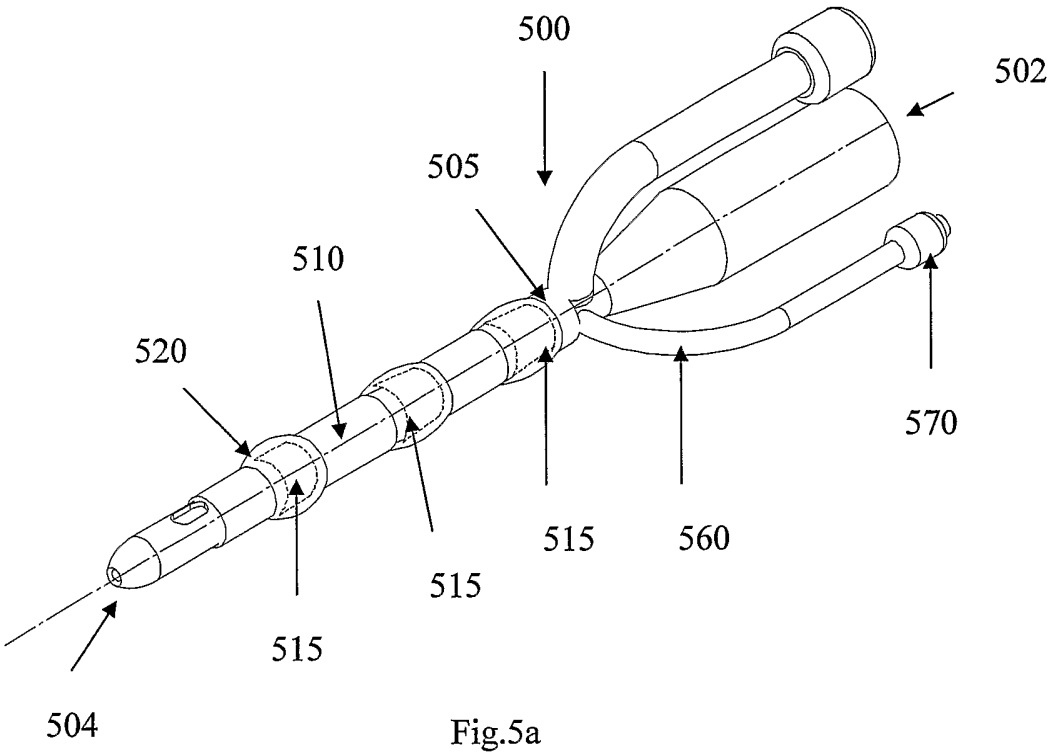

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Fig.5a

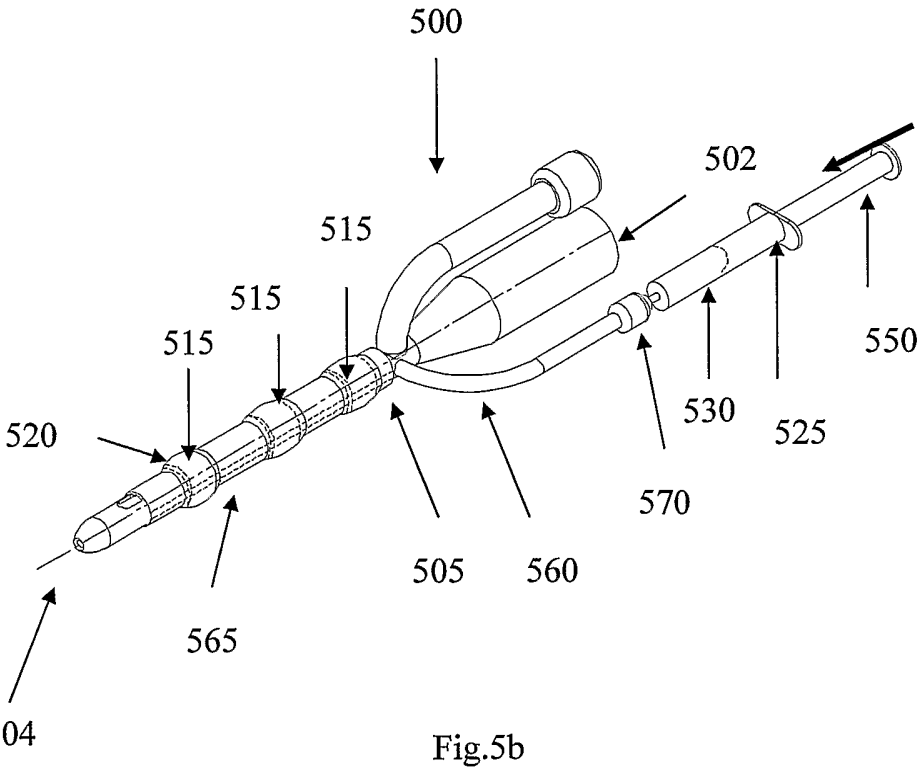
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Fig.5b

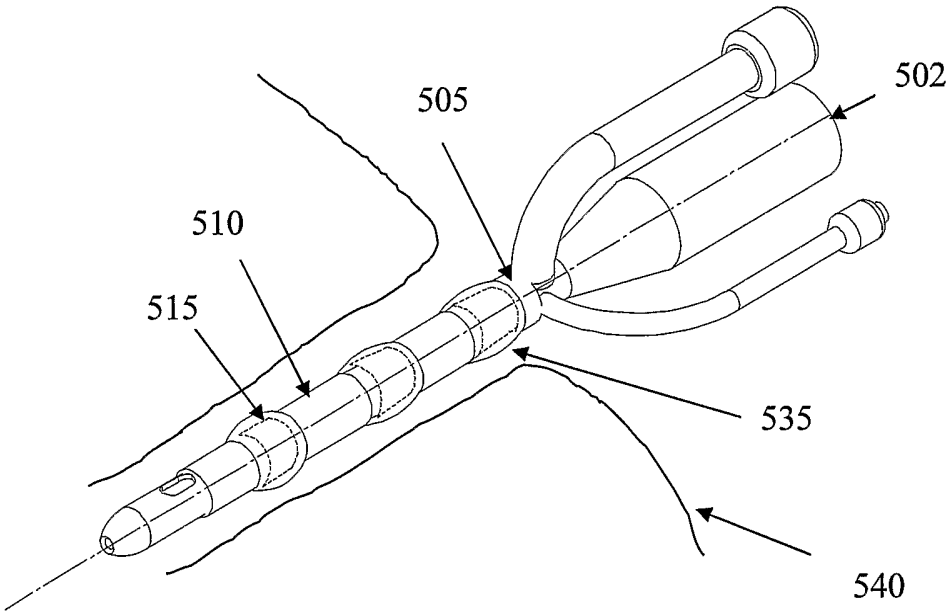

Fig 5c

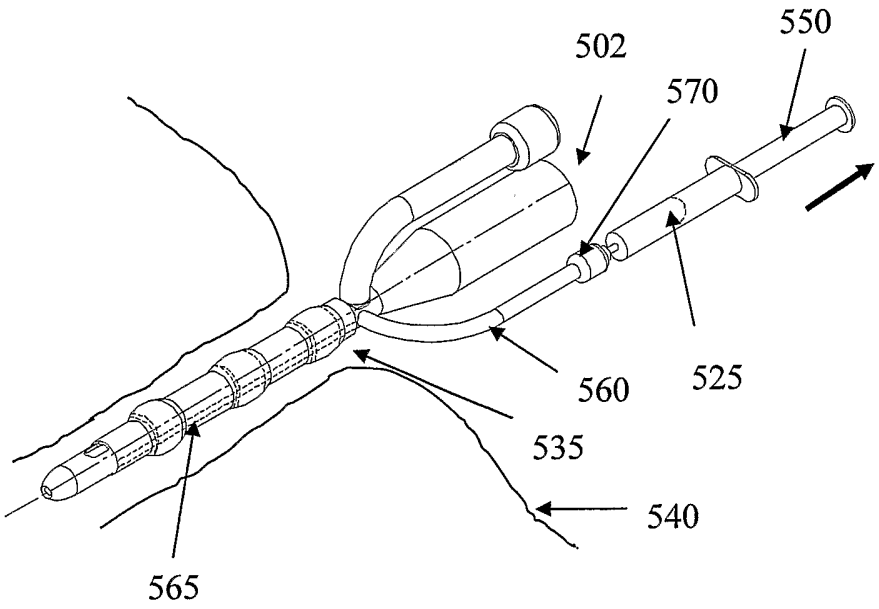

Fig 5d

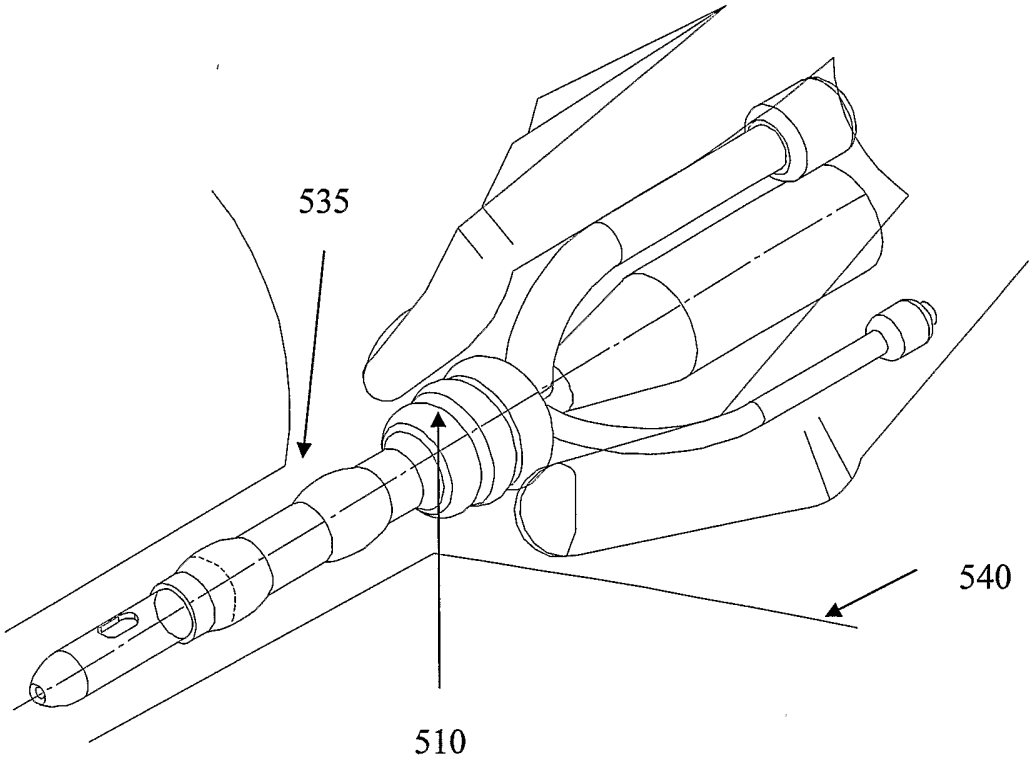

Fig.5e

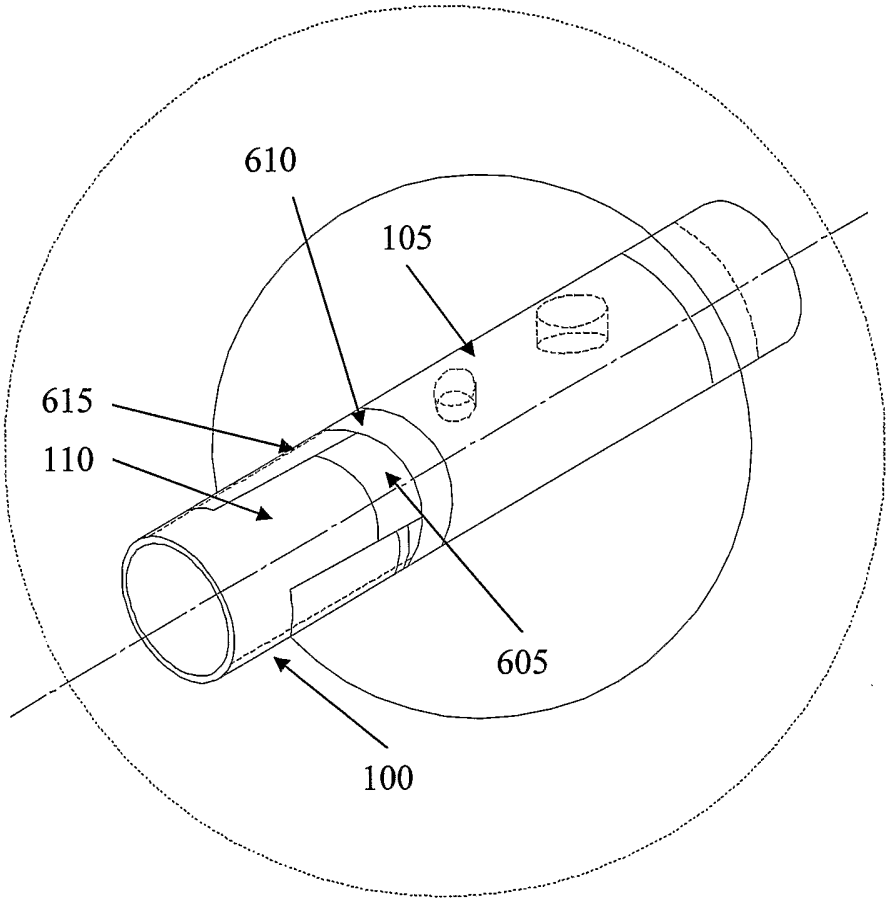

Fig 6

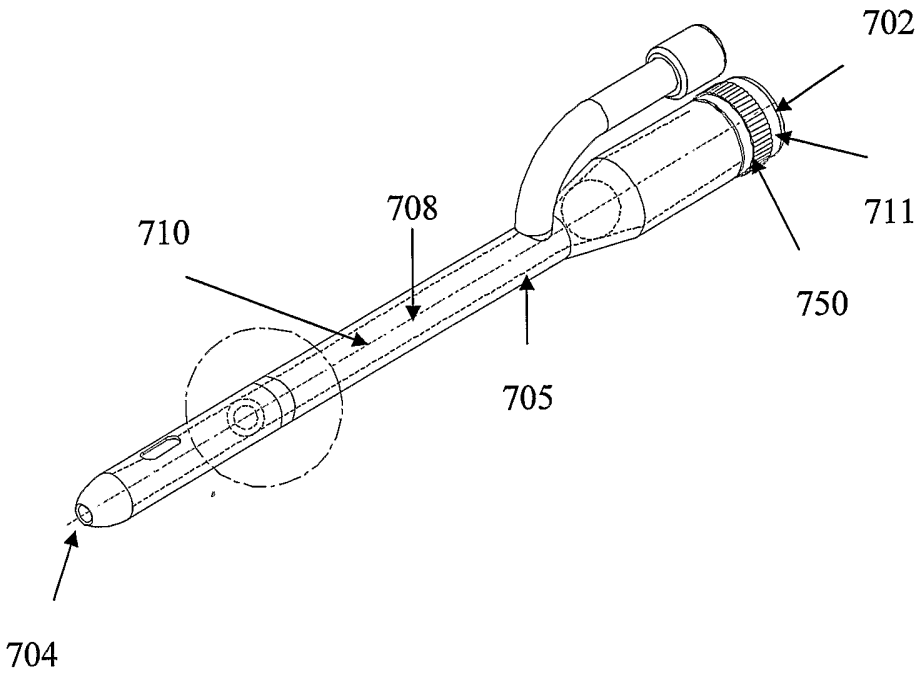

Fig.7a

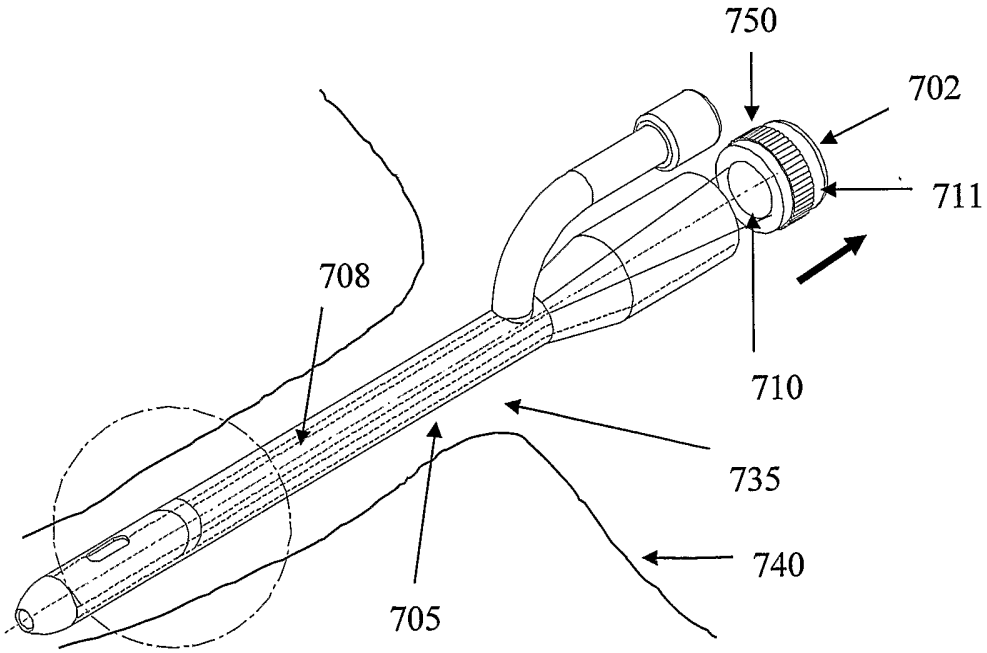

Fig.7b

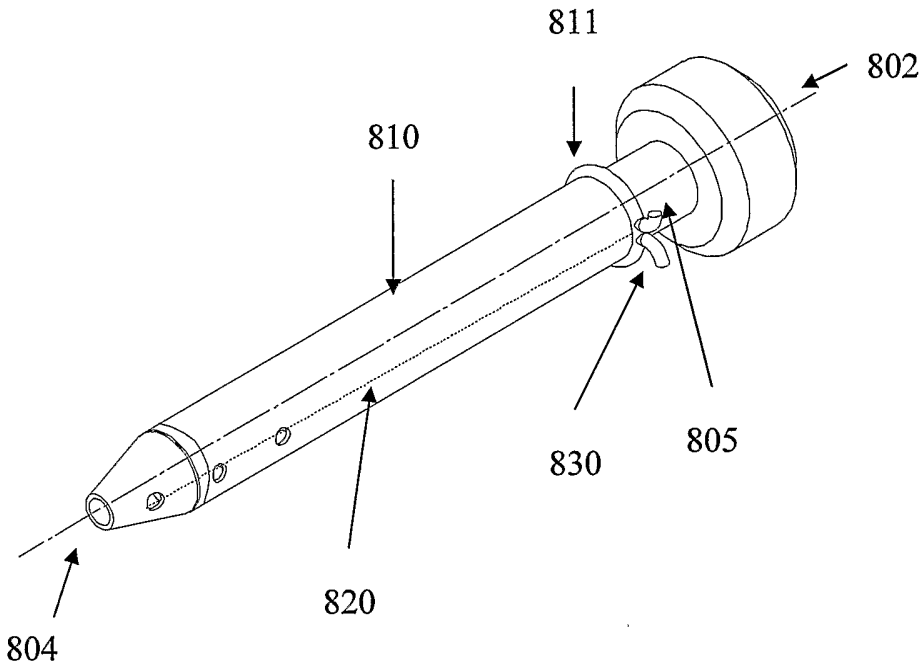

Fig.8a

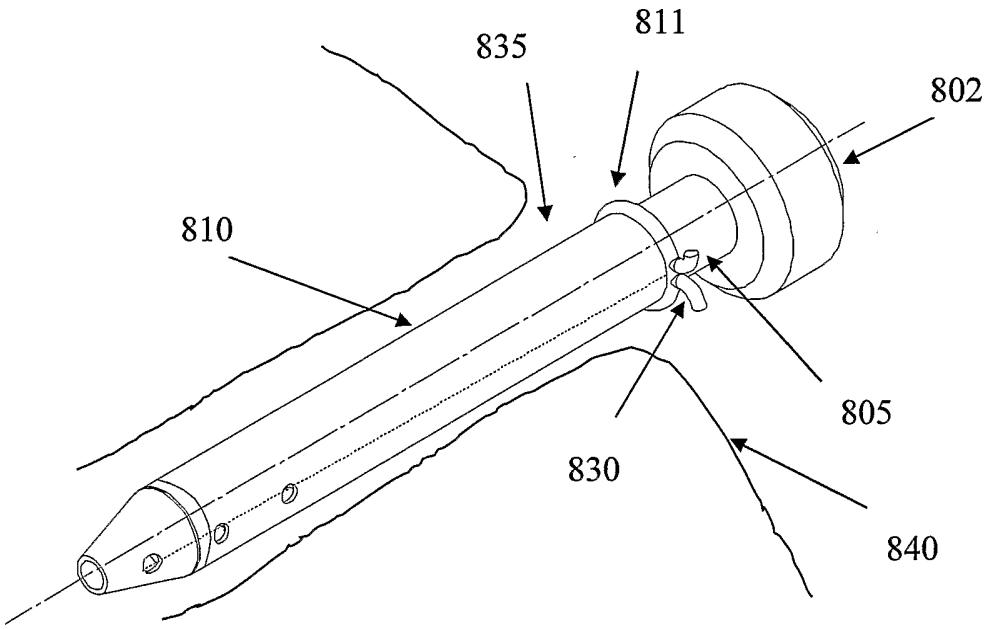

Fig.8b

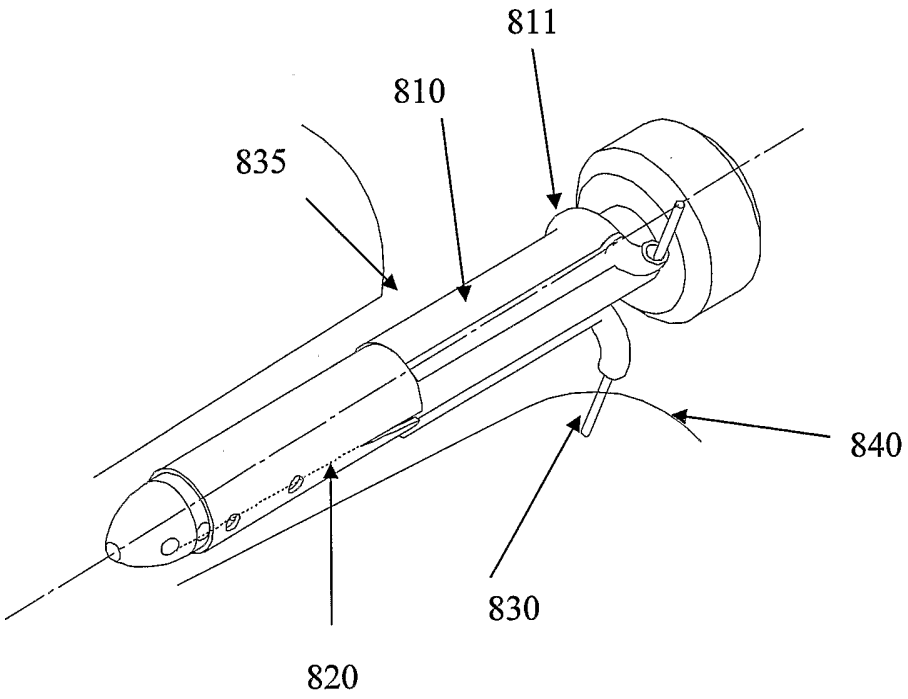

Fig.8c

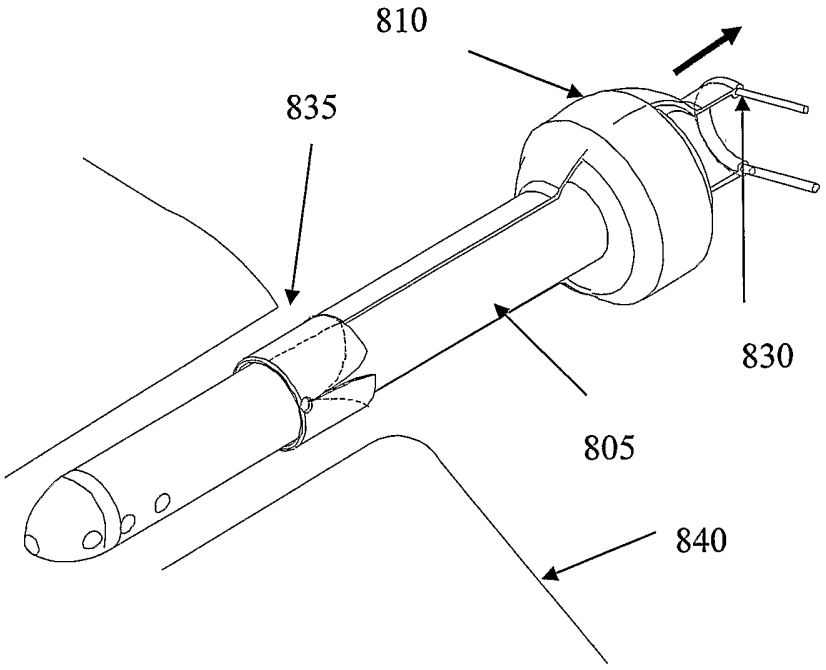

Fig.8d

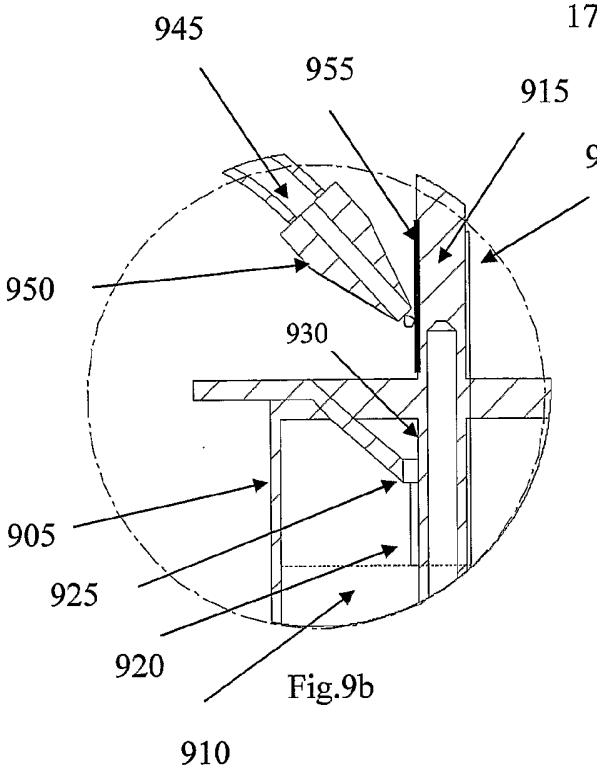

Fig.9b

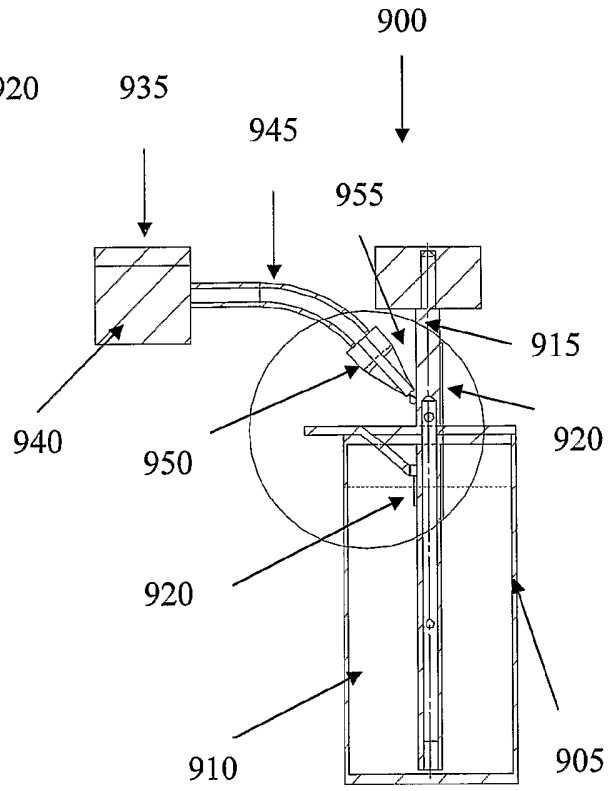

Fig.9a

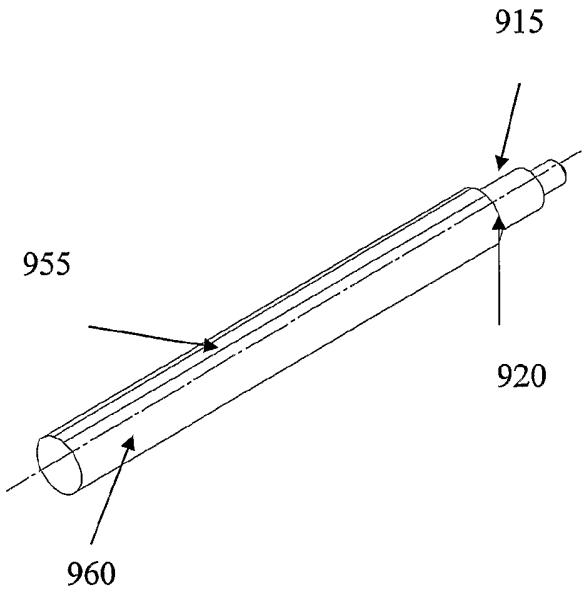

Fig.9c

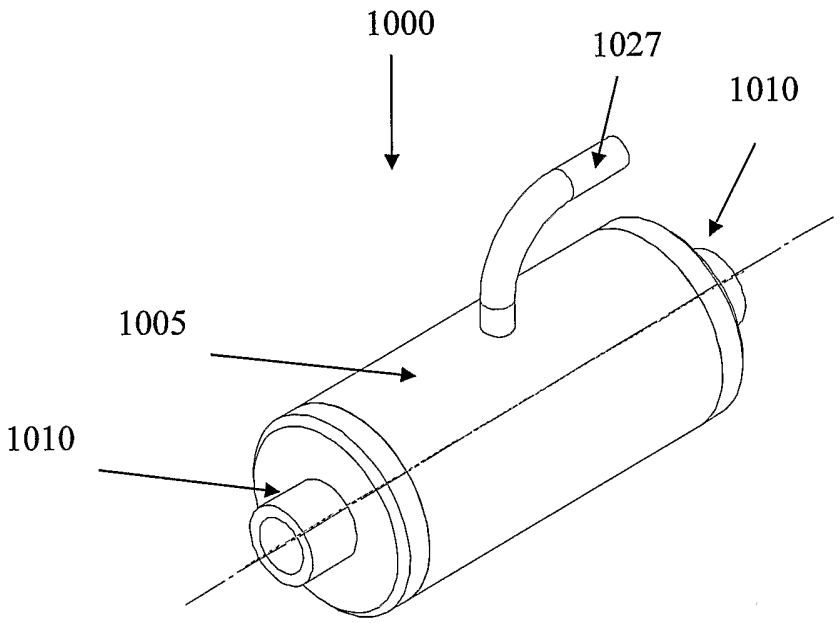

Fig 10a

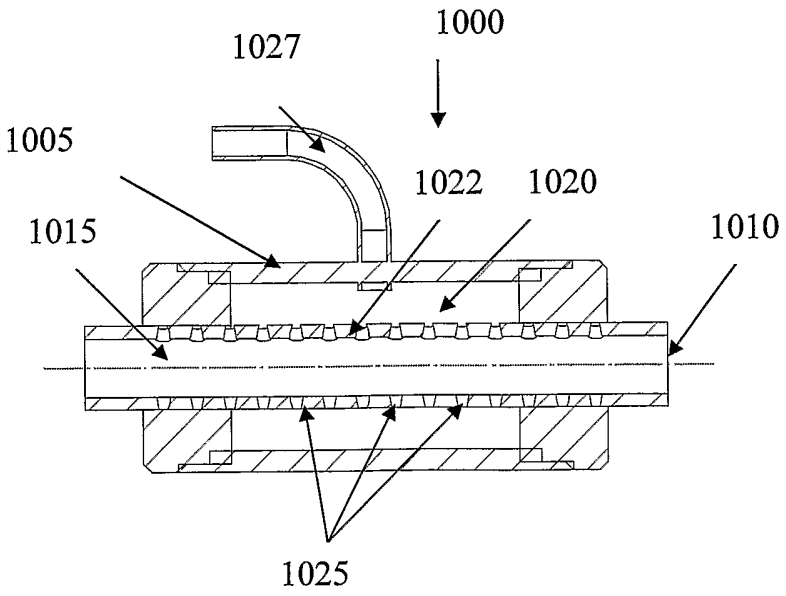

Fig.10b

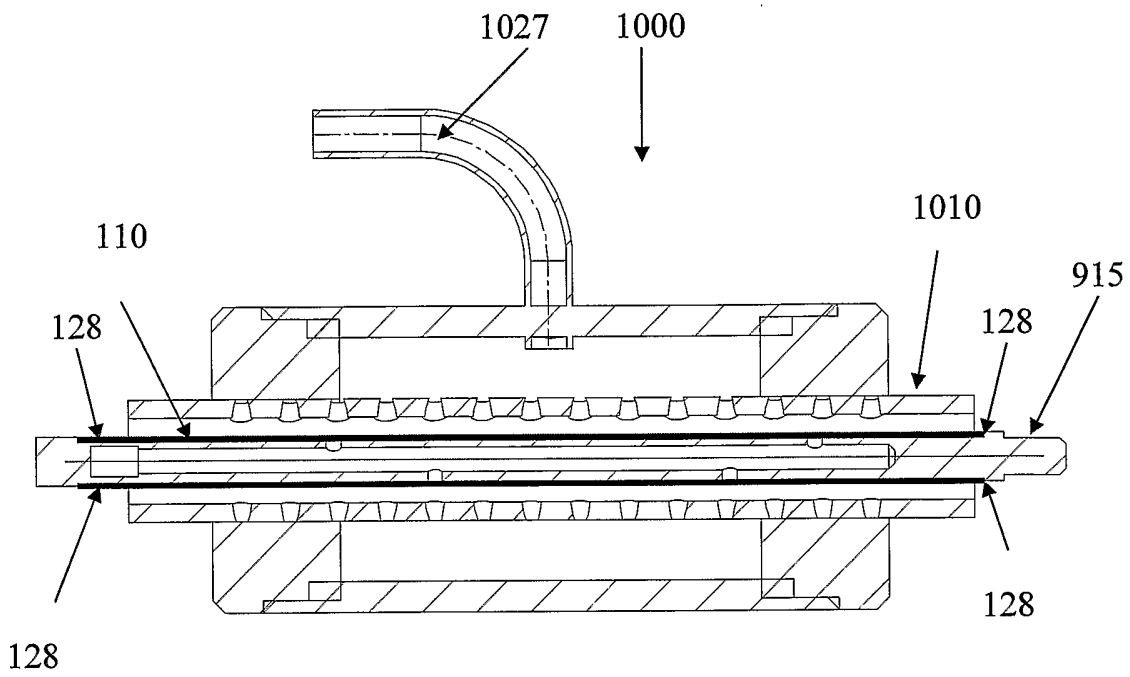

Fig 10c

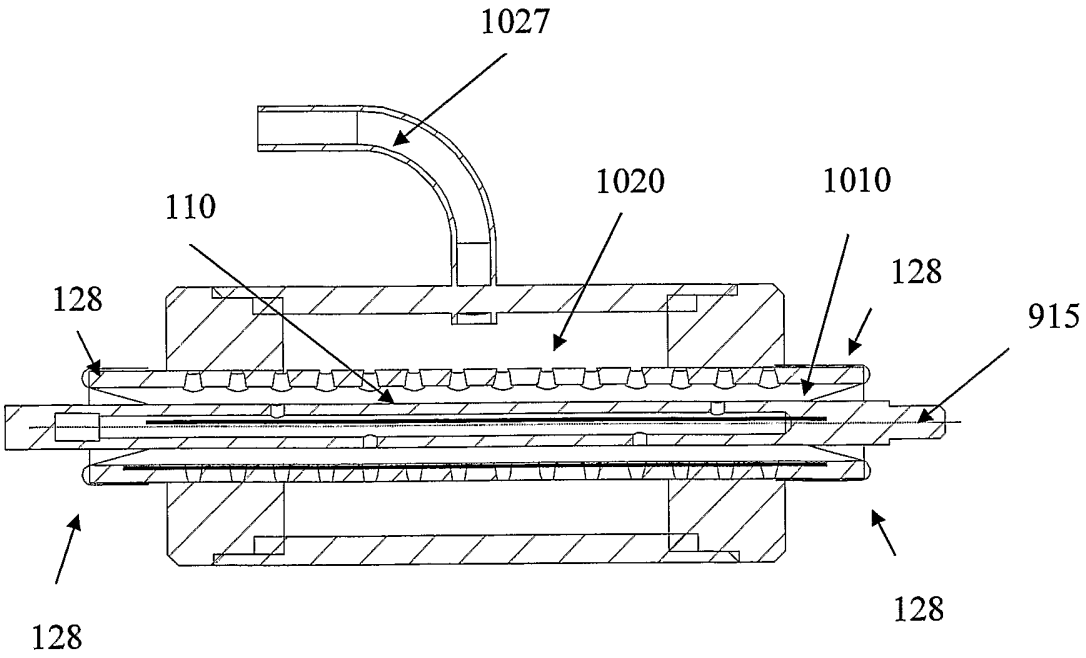

Fig 10d

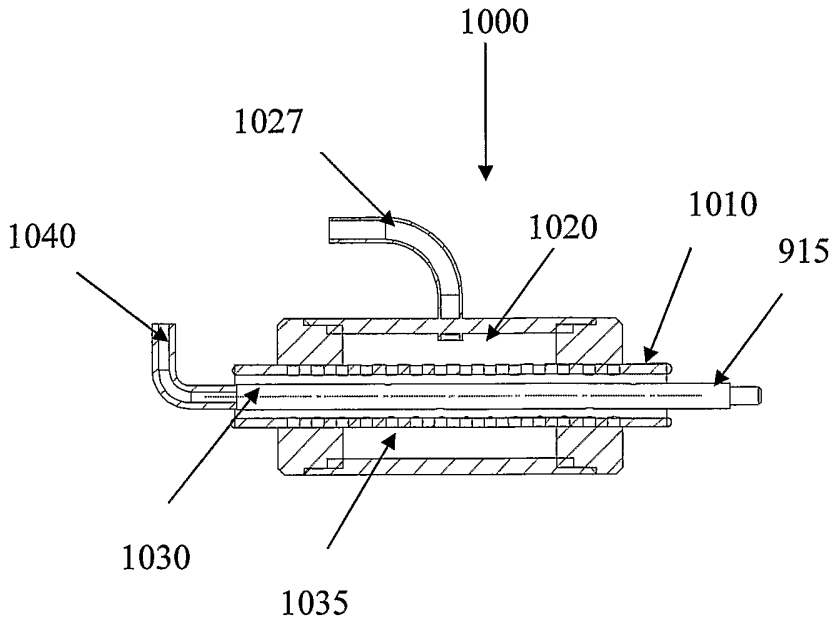

Fig 10e

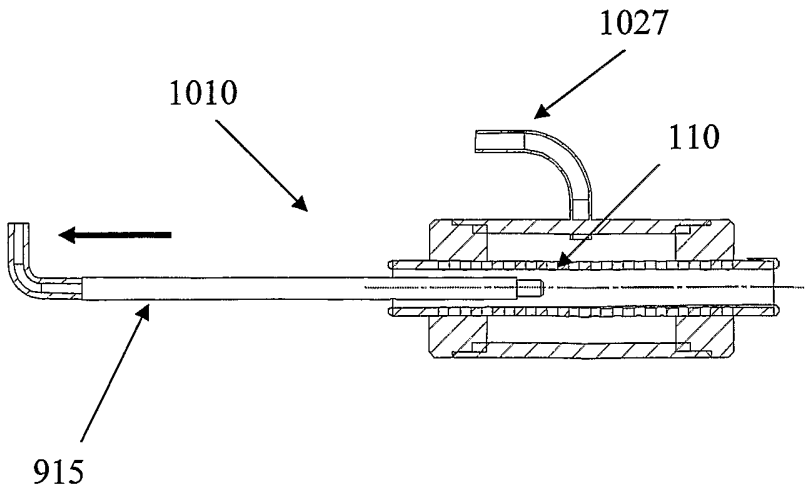

Fig 10f

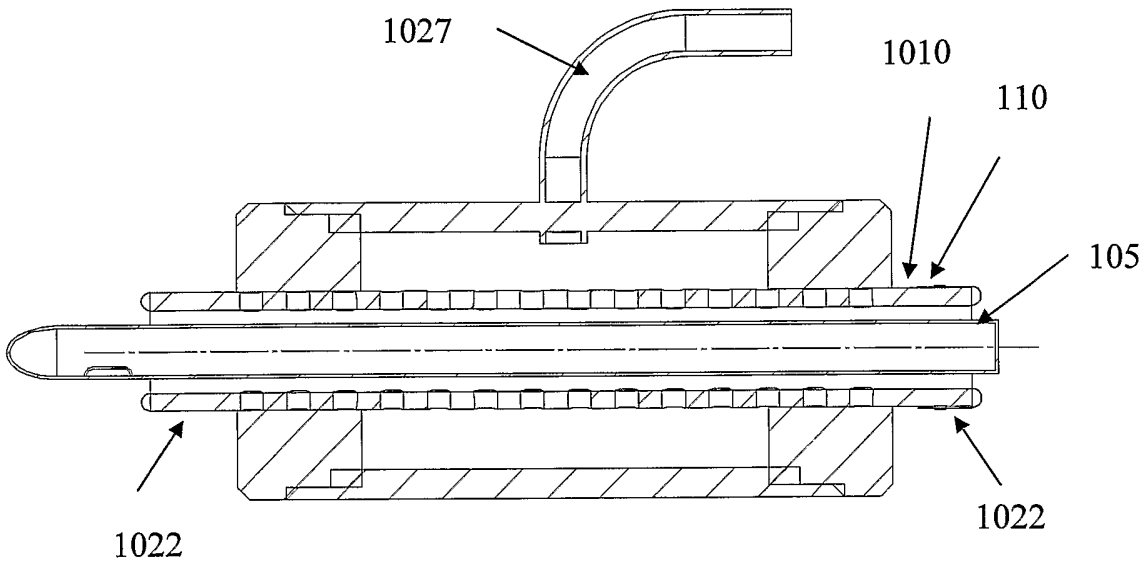

Fig.10g

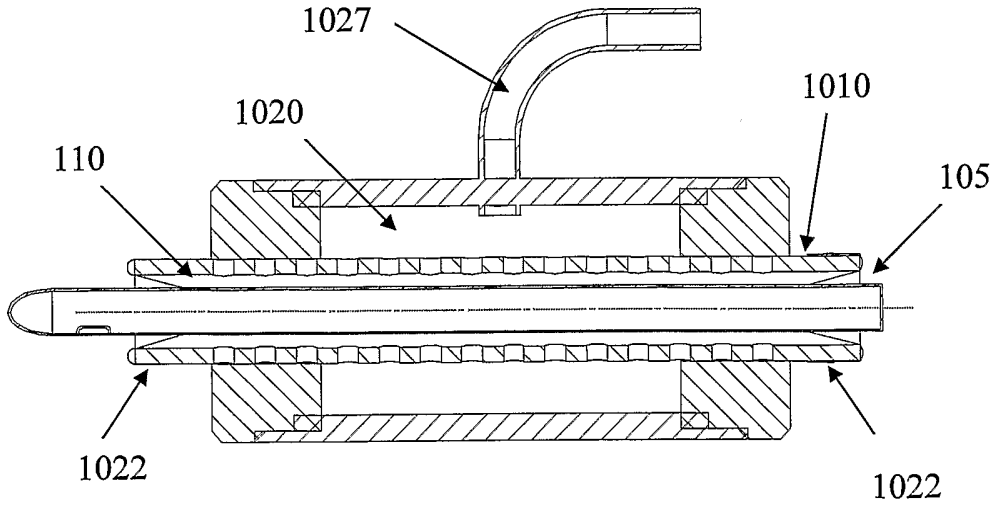

Fig. 10h

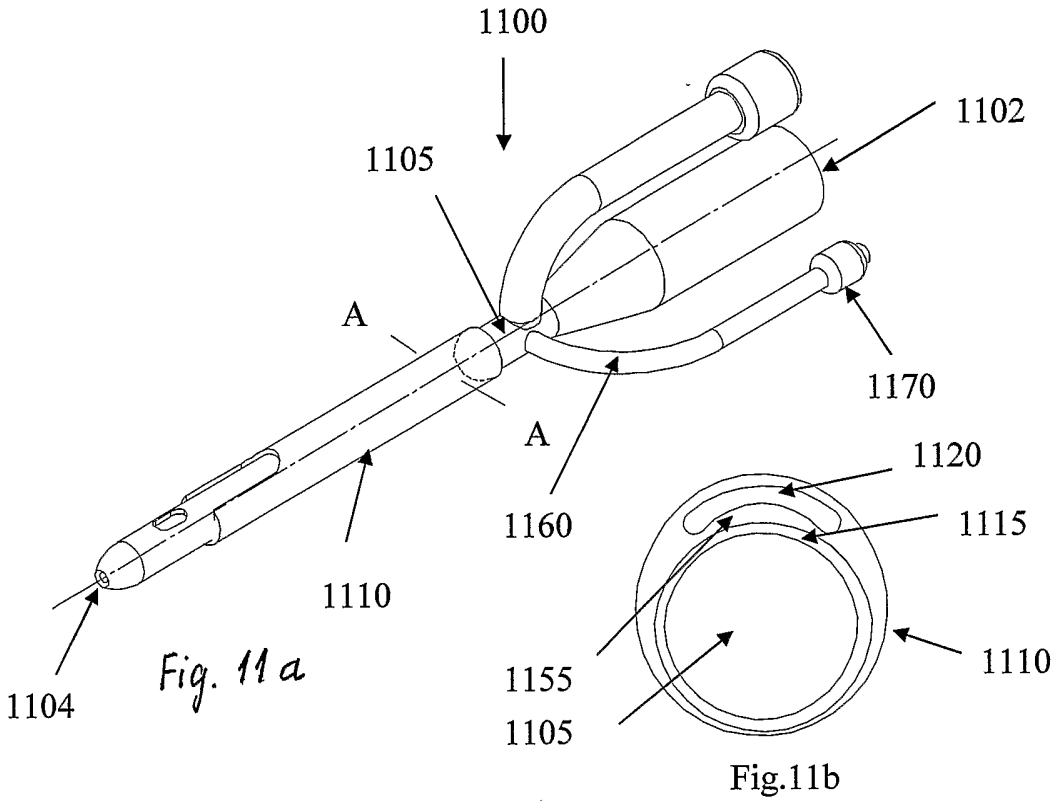

Fig. 11a

Fig.11b

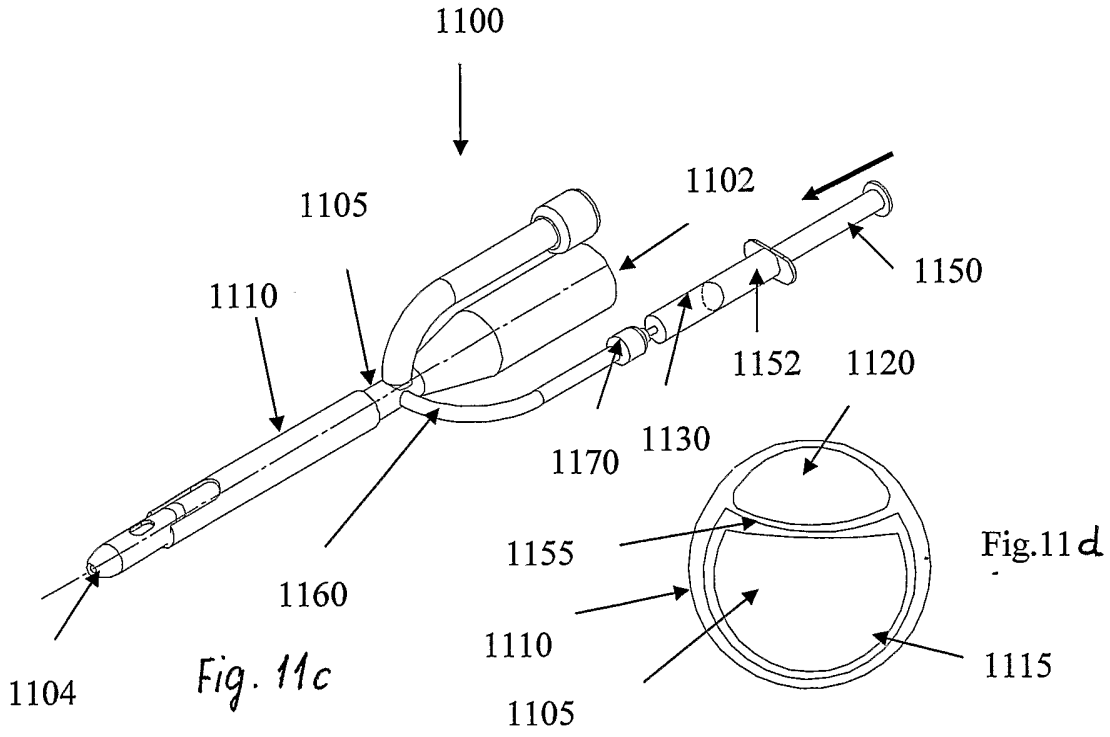

Fig. 11c

Fig.11d

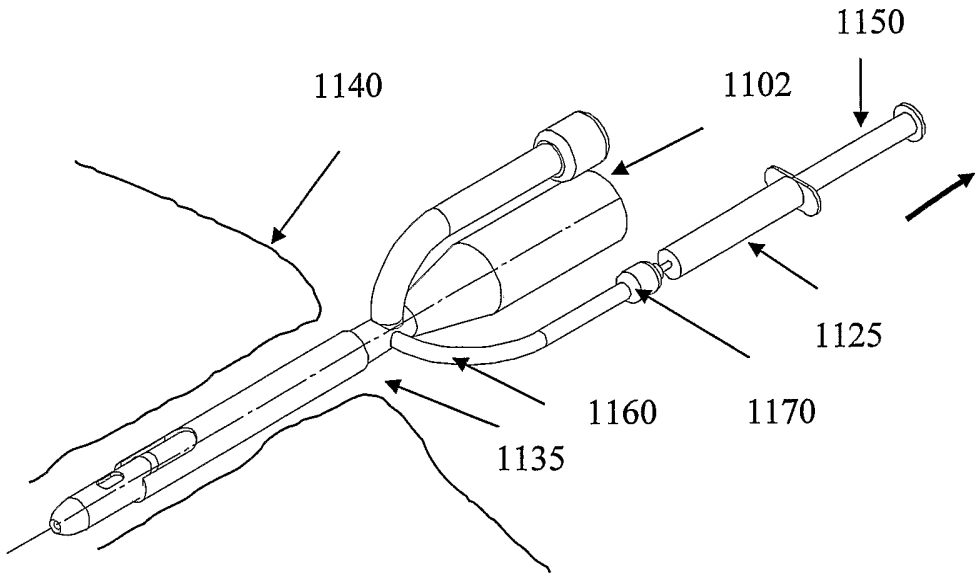

Fig.11e

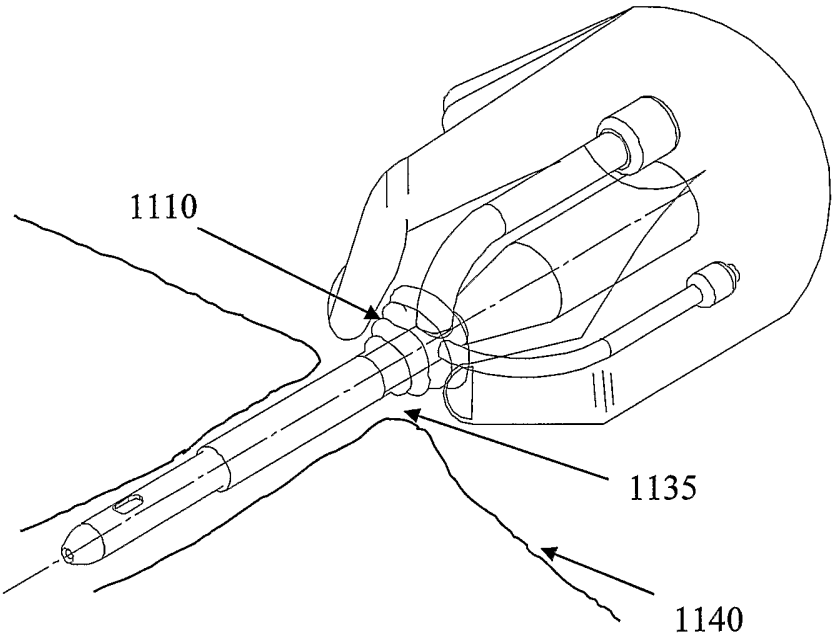

Fig.11f

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 03/00657

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M25/06 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

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 practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97/34654 A (MERIT MEDICAL SYSTEMS INC) 25 September 1997 (1997-09-25)	1,2,4, 8-10,14, 18-21, 26-29
A	page 6, line 1 - page 21, line 24, paragraph 1-20	13

X	WO 01/83017 A (WILSON COOK MEDICAL INC) 8 November 2001 (2001-11-08)	1,2,4, 8-13,18, 21,28,32
	page 20, lines 1-31; figures 11,27 page 18, lines 1-26; figure 10	
A	page 10, line 17 - page 15, line 31; figures 1-4	15,29

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in 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 document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 June 2004	12. 10. 2004
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Jameson, P

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 03/00657

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 948 970 A (H L MEDICAL INVENTIONS INC) 13 October 1999 (1999-10-13)	1,2,4,9, 10,18, 27,30,32
A	page 5, paragraph 38 - page 6, paragraph 49; figures 3-10	15

X	US 6 159 198 A (SOMMER JOHN L ET AL) 12 December 2000 (2000-12-12)	1,2,4, 8-10, 15-18, 26,27,31
A	column 2, line 66 - column 6, line 53; figures 1-13	30

X	WO 01/64279 A (COOK VASCULAR INC) 7 September 2001 (2001-09-07)	1,2,5,7, 9,10,18, 24,25
	the whole document	

X	US 6 221 081 B1 (EUM JAY J ET AL) 24 April 2001 (2001-04-24)	1,2,4,5, 7,10,11, 15
	column 3, line 6 - column 6, line 49; figures 1-6	

X	US 5 415 639 A (ATKINSON ROBERT E ET AL) 16 May 1995 (1995-05-16) abstract column 15, lines 22-33; figures 12-14	1-4,9,15

A	US 4 266 999 A (BAIER ROBERT E) 12 May 1981 (1981-05-12) column 2, line 33 - column 4, line 28, paragraph 1-16	1,2,22, 23

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL 03/00657

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-32

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-32

Medical device for insertion inot a body, the device having at least one surface covered by a least one detachable cover, the cover being detachable from the surface and removed from the body while the surface remains in place in the body

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2. claim: 33

A system for forming a cylindrical cover on a mandrill, comprising (a) a first reservoir containing a first suspension,
(b) a wiper for removing a portion of the first suspension when applied onto the mandrill,
(c) a second reservoir contianing a second suspension, and
(d) a nozzle for applying the second suspension to the mandrill

---

3. claim: 34

A system for transferring a cover from a mandrill to a cylindrical shaft of a device, comprising:
(a) a first chamber configured to receive the mandrill,(b) a second chamber surrounding a portion of the first chamber, the first and second chamber having a common wall containing a plurality of pores, (c) an outlet for evacuating the first and second chamber.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/IL 03/00657

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9734654 A	25-09-1997	US 5647859 A	15-07-1997
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