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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
18 February 2016 (18.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/023942 A1

(51) International Patent Classification:
A61F 9/007 (2006.01)

(21) International Application Number:
PCT/EP2015/068532

(22) International Filing Date:
12 August 2015 (12.08.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
P 2014 0103054 14 August 2014 (14.08.2014) AR

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

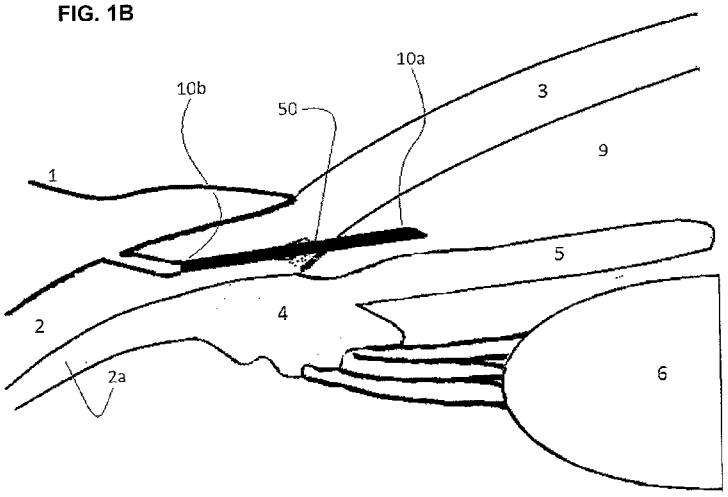
(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: KIT FOR THE TREATMENT OF GLAUCOMA, DRAINAGE DEVICE AND INSERTION ARRANGEMENT AND IMPLANTATION METHOD

FIG. 1B



(57) Abstract: A kit used for the treatment of Glaucoma which comprises an aqueous humor drainage device 50 and an insertion arrangement, which has a hollow needle 16 that contains said drainage device 50 inside, for its subsequent implantation into the eye, wherein said devices form a structural and functional unit that enables a novel transconjunctival implantation method without the need of a previous conjunctival opening or closure. Said drainage device 50 consists of a tube with lumen, that is implanted in the scleral hole of the eye created by said insertion arrangement needle 16, thus allowing the aqueous humor drainage from the anterior chamber 9 of the eye into the subconjunctival space for its subsequent reabsorption. The invention also includes an implantation method carried out by means of the kit.

WO 2016/023942 A1

KIT FOR THE TREATMENT OF GLAUCOMA, DRAINAGE DEVICE AND INSERTION ARRANGEMENT AND IMPLANTATION METHOD

TECHNICAL FIELD OF THE INVENTION

The invention belongs to the field of medical devices, more specifically, a kit that comprises an aqueous humor drainage device, an insertion arrangement thereof and a method for the treatment of Glaucoma.

STATE OF THE ART BACKGROUND

The aqueous humor is an intraocular fluid produced by the ciliary body which migrates through the pupil into the anterior chamber, then through the trabecular meshwork into the Schlemm's canal and finally it is carried by veins which form aqueous fluid collection channels under the conjunctiva. When there is not enough aqueous humor outflow to offset the production rate at the ciliary body level, the intraocular pressure rises, thus resulting in the risk of glaucoma. Research has shown that sustained ocular hypertension may cause damage to the optic nerve, which transmits visual information to the brain.

The consequence of sustained ocular hypertension can be a progressive damage of the optic nerve, with the progressive impairment of the visual field, leading to blindness in advanced stages, Glaucoma being the second cause of blindness worldwide (Quigley HA et. al, 2006). There are medical treatments by means of eye drop instillation, Laser treatments (Trabeculoplasty with Argon laser) and surgical treatments. The first choice of treatments usually applied to patients with Glaucoma is the medical treatment with eye drops. In some cases, they are associated with complications due to the adverse effects of these drugs, allergic reactions or lack of effectiveness because of non-compliance on the part of the patient. In those patients for whom medical treatment fails to properly regulate

intraocular pressure, glaucoma filtering surgery (GFS) is recommended in order to prevent progression of the optic nerve damage and visual impairment.

One of the classifications for the glaucoma filtering surgery may be:

1) Ab-interno procedures that consist of surgical techniques which may include tissue cuttings such as incisions in the trabeculate or drainage device implants from the inside of the eye (anterior chamber of the eye **9**) towards outside, for which the anterior chamber of the eye must be previously entered with said drainage device; and

2) ab-externo procedures that consist of surgical techniques which comprise tissue cuttings (such as trabeculectomy) or drainage device implants from the outside to the inside of the eye (Anterior chamber of the eye).

Trabeculectomy (ab-externo surgical procedure), consists of making an ocular tissue (trabeculate) resection to produce a fistula which connects the anterior chamber to the subconjunctival space, having been for many years, and today being, the traditional and most widely used surgery for the treatment of Glaucoma. However, flow control is still inaccurate, despite the introduction of several wound suture techniques. In addition, despite the good long-term results, it is associated with a high rate of early postoperative complications (Choroidal Detachment, Hypotalamia, anterior chamber bleeding and postoperative inflammation). Glaucoma filtering surgery has shown to be more effective in preventing the progression of the disease than other primary treatments. If it were possible to avoid the complications associated with poor flow control, these surgeries would be more widely used (Lim K.S.; 1998). In recent years, Glaucoma drainage devices (GDDs) have regained importance, through the development of implants with biocompatible materials and improved designs with the aim of reducing early postoperative complications in the traditional trabeculectomy. GDDs

have the potential to regulate flow continuously, thus eliminating postoperative hypotonia. GDDs current situation is somehow similar to that of intraocular lens in the 1970s, with frequent complications attributable to the design and biocompatibility of the materials. Like the improved intraocular lenses which have revolutionized cataract surgery in the recent past, the new materials and designs can transform Glaucoma filtering surgery in a near future (Lim K.S. et al; 1998).

Some of the documents related to the state of the art of the aqueous humor drainage devices, the method for their implantation and, in some cases, their inserter are described below, taking into account the abovementioned classification.

Within group 1, drainage devices which are implanted ab-interno, the following background can be included:

US 4,968,296 (1990) A, US 6,007,511 A (1999), US 6,638,239 B1 (2003), US 6,780,164 B2 (2004), US 7,291,125 B2 (2007), US 7,815,592 B2 (2010), US 20120323159 A1 (2012), US 8,337,509 B2 (2012), US 8,128,588 B2 (2012), US 8,372,026 B2 (2013), US 8,721,656 B2 (2014), refer to an aqueous humor drainage device which is implanted ab-interno by using any kind of inserter.

Document US 4,968,296 A describes an aqueous humor drainage device, an inserter thereof and a method for ab-interno implantation. The implant has a 0.25 mm lumen and connects the anterior chamber of the eye with the subconjunctival space. It has a kind of fastening disc on each side of the sclera, where one of them is implanted under the conjunctiva. The disadvantages of said drainage device lie in the fact that the disc outer diameter of the end which is implanted into the anterior chamber of the eye is 1.25 mm and it could come into contact with the iris or endothelium in the anterior chamber of the eye in case of mild to moderate hypotalamia, thus causing tissue inflammation. Another

disadvantage lies in the fact that its 0.25 mm lumen may produce an excessive aqueous humor flow, especially since the outer end is directly implanted into the subconjunctival space, without scleral protection, and where said subconjunctival ring without scleral protection could additionally erode the conjunctiva. In addition, the needle or cannula of the insertion device used for the implant must be large enough to allow the introduction of a drainage tube which is compacted up to a minimum of 0.75 mm. Likewise, the required implantation method has all the disadvantages of the ab-interno procedures stated below.

The abovementioned documents, US 7,291,125 B2, US 7,815,592 B2 and US 8,128,588 B2, refer to a drainage device composed of a tube and a disc which is implanted ab-interno into the suprachoroidal space by using an insertion device. The entire device is wound up to a diameter of 1.5 mm, and the implant technique requires a corneal-scleral incision, injection of a viscoelastic substance in the anterior chamber, introduction of an instrument to the anterior chamber in order to perform a cyclodialysis (separation at the junction of the sclera and the choroid) assisted by the use of a gonioscopy lens; then, the drainage device is implanted into the created space, locating the disc in the intrascleral space and the tube in the anterior chamber. One of the disadvantages of this drainage device is its size, which can be up to 1.5 mm when wound. Additionally, its implant technique has the disadvantages of the ab-interno procedures stated below, and it requires cyclodialysis before the implantation.

One of the disadvantages of the drainage device ab-interno implantation procedures is that a corneal incision is required to introduce the handling instruments to the anterior chamber of the eye, the corneal incisions (avascular area of the eye) being of higher risk as regards possible intraocular infections in relation to the scleral incisions, which are covered and protected by a conjunctiva with blood vessels and lymphatic system that provide protection. Turning the

situation worse, said corneal incisions of the ab-interno procedures are generally made in the lower area of the cornea, leaving it in contact with the lacrimal lake, which contains usual germs of the ocular flora that may enter the eye since the implants are usually located in the upper part of the eye (180º from the corneal incision). Additionally, the ab-interno procedures often require the use of intraoperative gonioscopy lens to locate the incision site where said device is to be implanted, and this requires certain complexity and experience. Another important issue to consider is that any manipulation performed inside the anterior chamber of the eye may compromise its internal structures, such as the corneal endothelium and the crystalline lens, being potencially cataractogenic; therefore, it is advisable that these devices, designed to be inserted by ab-interno procedures, are implanted into patients who have already been operated on cataracts, or as specifically stated by the Company Glaukos in its webpage for its GDD called iStent® Trabecular Micro-Bypass, associated to a cataract surgery (joint procedure for which it was approved by the F.D.A.).

Within group 2 of the abovementioned classification (Ab-externo procedures), the following state of the art background can be included:

The following documents refer to drainage devices which consist of an aqueous humor drainage tube that connects the anterior chamber of the eye to one or two plates which serve as reservoir, and which are fixed to the sclera subconjunctivally: US 4,457,757 A (1984); US 4,750,901 A (1998); US 5,397,300 (1995); US 5,454,796 A (1995); US 5,882,327 A (1999) and US 6,050,970 (2000). The surgical technique is similar for most of said implants: wide conjunctival flap, scleral tunneling and closure in layers with sutures. The main complication of these devices is over-filtering, which is addressed by adding suture binding around the tube or inner valves which try to create flow resistance. Postoperative inflammation in these patients is often intense (Thomas R, 1998). Additionally,

they may cause diplopia in some cases, especially when the plates are placed in the subTenon-conjunctival space of the nasal area (Prata et al 1993).

Other documents which refer to drainage devices which are implanted ab-externo are detailed below: US 4,634,418 A (1987), US 5,704,907 A (1998), US 6,450,984 B1 (2002), US 6,468,283 B1 (2002), US 6,589,203 B1 (2003), US 6,699,210 B2 (2004), WO 2004073564 A2 (2004), US 7,160,264 B2 (2007), US 20070293872 A1 (2007), US 20130184631 A1 (2013), US 2013/0184631 A1 (2013), US 8,628,492 B2 (2014).

A problem associated with traditional implants which include a tube and a plate or artificial reservoir, and are inserted ab-externo, is the size of the incision required for them to be implanted, where the resulting conjunctival wound must be large enough to expose the sclera and subsequently make a scleral tunnel to introduce the drainage tube in the anterior chamber and the plate or reservoir under the conjunctiva. Additionally, the scleral coat created must be sutured and, in some cases, implants must be fixed to the sclera with sutures, and the conjunctiva must also be closed with sutures. The larger the wound, the higher the risk of infection, inflammation and fibrosis, and therefore, a greater chance of surgery failure as well as a longer time to recovery. Additionally, procedures with large conjunctival incisions or large scleral tunnels may compromise another future ab-externo glaucoma surgery (Parul Ichhpujani; 2011).

Document US 6,468,283 B1 (2002) reveals an aqueous humor drainage device which is supported by its insertion device on the outside of its distal end and an application method thereof, where the drainage tube is inserted in a hole in the sclera, placing its distal end in the anterior chamber of the eye and its proximal end, which is disc- or plate- shaped, under the conjunctiva. The disadvantage of said implant lies in the fact that the plate or disc is designed to be implanted under the conjunctiva, in direct contact therewith, where lack of scleral

protection may cause erosions in the conjunctiva with serious consequences, and additionally, if said device lumen, which directly drains into the subconjunctival space without scleral protection, is about 0.3 mm or even smaller, as stated in this document, it may cause a marked decompression of the eye due to hyperfiltering, with the consequences of postoperative hypotonia. In a study where the drainage devices related to this document were implanted by using the method which is also described herein, the authors concluded that the percentage of complications obtained seemed to be quite high (Wamsley et. al. 2004; Karmel 2004). Additionally, the implantation method requires a conjunctival opening to gain access to the sclera, which must be subsequently sutured to prevent aqueous humor leakage (Seidel's Phenomenon).

Document US 20130338564 A1 (2013) refers to a drainage device with an inner valve to prevent excessive aqueous humor drainage.

Document US 8,628,492 B2 (2014) also refers to a drainage device with at least one inner valve to prevent excessive aqueous humor drainage. This device has the disadvantage of requiring one or more inner valves to produce a suitable flow, and another disadvantage is that it requires fixing means which are not an integral part of, but are attached to, the drainage tube. This document mentions that it is implanted subconjunctivally by means of a needle 19G, but it does not specify how said implantation is performed, for example, it does not mention the place of the previous conjunctival opening or how the Tenon's membrane dissection is performed, or the specific method to access the sclera, or the specific place to incise it and enter the anterior chamber of the eye.

Document US 2013/0184631 A1 (2013) refers to a drainage device and an insertion device which has a needle to create a hole in the sclera. The drainage tube measures 8.5 mm and connects the anterior chamber with the subconjunctival space, placing its outer end under the conjunctiva. Said device

has the disadvantage of requiring a previous conjunctival opening with the dissection of the Tenon's membrane exposing the sclera to incise it with the inserter needle, and then the conjunctiva must be sutured, thus causing an inflammatory reaction of the eye. Another disadvantage is that the small hole created by the insertion needle must be expanded with a stylet included in the needle proximal end or with another stylet in order to introduce the fixing means of the drainage device to the sclera.

Document WO 2004073564 A2 (2004) refers to a method and system to reduce flow resistance in an aqueous humor drainage device implanted into the eye. This system and the method thereof have the disadvantages of the ab-externo procedures which require a wide conjunctival incision and the scleral tunneling to insert the tube, the disadvantages of the ab-interno procedures which require the manipulation inside the anterior chamber of the eye, and the disadvantages of requiring an inner valve complex system to limit the aqueous humor drainage, plus an element passing through the valve to reduce flow resistance generated by said valve.

Some of the aqueous humor drainage devices have the advantage that they can be implanted by insertion systems, such as for example, the device in document US 2002/0133168 (2002), which describes an insertion system for implanting a drainage device for the Glaucoma disease ab-interno, from the anterior chamber of the eye by means of a corneal incision.

A more complex insertion system is proposed in document US 2004/0236343 A1 (2004).

Document WO 2011106781 A1 (2011) refers to a device which contains a cable, wire or cutting element which is introduced in the Schlemm's canal to create a fistula with the suprachoroidal space after an opening of the

conjunctiva, Tenon and sclera, and with the subsequent traditional closure in layers with sutures.

The abovementioned document US 6,589,203 B1 (2003) refers to a tube and a plate or reservoir which folds and is implanted by means of an insertion device in order to reduce the size of the conjunctival wound and for the closure thereof to be smaller than with the traditional implants, even though it still requires opening said conjunctiva and Tenon and creating a space under the conjunctiva by using any instrument to place said plate or reservoir under said membranes, which also causes a surgical trauma due to tissue manipulation with an inflammatory response.

Document US 2007/0293872 A1 consists of a drainage device composed of a tube, which works as a fistula, enclosed in a collapsible conduit which must be connected to a reservoir in one of its ends. The disadvantage of this device is that it requires a previous conjunctival opening, which must be then closed by sutures and the need of making a connection of the device during the surgical procedure, thus extending the surgical procedure and making it more complex.

There is a GDD called xen gel stent® from AqueSys, Inc. that is implanted into a scleral tunnel created by the inserter needle, placing its distal end on the sclera; such a device drains the aqueous humor from the anterior chamber of the eye into the subconjunctival space (Vera V., 2014), but its disadvantage is that it is implanted ab-interno (Preferred approach) with the abovementioned disadvantages for said approach. As this procedure is a potentially cataractogenic, it should be performed in association with a cataract surgery or in a patient who has previously had a cataract surgery. Additionally, requires a gonioscopy lens and the use of viscoelastic substance for its implantation. It is also described the

possibility for an ab-externo approach for this GDD, but it requires previous dissection and pullback of the conjunctival and tenon tissue to allow access to the sclera for implant placement. After that, the conjunctiva must be sutured on a tight fashion.

Furthermore, some GDDs have drainage tubes with a large inner lumen and they require inner valves which are attached to their inside in order to prevent excessive drainage and trying to avoid the complications caused as a result. However, the disadvantage of the drainage devices which have inner valves is that they make the manufacturing of said device more complex, thus increasing the costs, and additionally, they add another piece that may fail or stop working over time, and where elements such as inflammatory cells, blood cells or fibrin may be attached to, thus obstructing the drainage tube lumen.

If the device is not relatively affordable, if it does not have a simple manufacturing and implantation technique and does not provide reduced tissue damage for its implant, its medical application makes no sense in terms of the cost/benefit ratio in relation to traditional trabeculectomy, as published in a research work for one of the currently used GDDs (Tucker M E, 2014).

Advantages of the invention over the known art:

There is no document that specifically or literally refers to a GDD which can be implanted "transconjunctivally" due to its structural characteristics or its inserter. The drainage tube of as well as the inserter of the invention, are specifically designed to enable a transconjunctival implantation method without the need of a previous opening or subsequent closure of the conjunctival and tenon tissue.

Some documents of the known art refer to a GDD that can be implanted subconjunctivally by means of an inserter, but they do not clarify whether they are

implanted transconjunctivally or if they require a previous opening of the conjunctiva with scissors, and they do not clarify how the elastic and translucent membrane (Tenon's membrane) underlying the conjunctiva is treated in order to have access to the sclera and visualize the place to be incised in said sclera to enter the anterior chamber of the eye.

In the hypothetical case that it can be transconjunctivally implanted, no document mentions how to solve the difficulties to visualize the inserter needle under the conjunctiva and the Tenon.

The invention comprises an insertion device with a needle having luminescent properties to improve needle visualization under the conjunctiva and the Tenon.

In some embodiments of the drainage device disclosed herein, the body **11** and the distal end **10b** are implanted transconjunctivally in the scleral thickness, with a small hypodermic needle that could be as small as a 28G needle, where no part of the GDD, once implanted, remains in direct contact with the conjunctiva to avoid erosions thereof. There are no documents that refer to GDD devices which are implanted ab-externo and are completely inserted by transconjunctival route in the intrascleral space without contacting the conjunctiva.

No document mentions that the fixing means to the eye consist of fragments belonging to the opposite walls or the same opposite walls of the drainage tube that open at angle (Figures 2A, 3A, 3C, 3D, 3E, 3F y 3G), thus allowing said fragments or walls to compress in order to enter the inserter needle and self expand, at least partially, when exiting it, remaining within the intrascleral space, without contacting the conjunctiva. This design of the fixing means implies an advantage as regards simple manufacturing and therefore, final costs.

Another benefit of the invention is that not internal valve is required, diminishing costs and complexity.

In some embodiments of the drainage device disclosed herein, its proximal end **10b** is implanted under the conjunctiva and the Tenon without injuring them as said Glaucoma drainage device is made out of a very soft biopolymer. There is no other GDD in the prior art documents or the market as this latest version (very soft biopolymer with the subconjunctival proximal end 10b and a transconjunctival route through a small hypodermic needle that could be as small as a 28G needle) that can be implanted into such a simple manner and so affordable to every ophthalmologist.

BRIEF DESCRIPTION OF THE DRAWINGS

The drawings included herein are only intended as being explanatory of the invention, but are not necessarily an exclusively exact embodiment thereof. Some of the embodiments of the present invention are illustrated below, without altering the true spirit thereof, since other advisable and preferred modifications are also included in the claims section.

Figure 1A shows a schematic drawing of the eye at the iridocorneal angle level, including: the conjunctiva **1**, the sclero-corneal limbus **1a**, the Tenon's capsule **1b**, the sclera **2**, the choroid **2a**, the cornea **3**, the ciliary body **4**, the iris **5**, the crystalline lens **6**, the Schlemm's canal **7**, the trabeculate **8** and the anterior chamber **9**, where the conjunctiva **1** and the Tenon **1b**, are shown separate from the sclera **2** only for explanatory purposes.

Figure 1B shows a schematic drawing of the aqueous humor drainage device implanted into the eye that represents several preferred embodiments of the invention, said figure including: the conjunctiva **1**, the sclera **2**, the choroid **2a**, the cornea **3**, the ciliary body **4**, the iris **5**, the crystalline lens **6**, the anterior

chamber **9**, the front or distal end **10a** and the rear or proximal end **10b** of the drainage device **50**.

Figure 1C shows another preferred embodiment of the aqueous humor drainage device implanted into the eye, in an axial section that shows its inner lumen, said figure including: the conjunctiva **1**, the sclera **2**, the choroid **2a**, the cornea **3**, the ciliary body **4**, the iris **5**, the crystalline lens **6**, the anterior chamber **9**, the front end **10a** and the rear end **10b** of the drainage device **50**.

Figure 2A shows a perspective view of the aqueous humor drainage device according to a preferred embodiment of the present invention, including: the bevel **10** of the front or distal end **10a**, the body **11**, the fragments of the fixing side walls **12**, where the angle **α** between them and the hole **15** connecting the lumen to the outside are both open.

Figure 2B shows a side view of the aqueous humor drainage tube of Fig. 2A, including: the bevel **10** of the front or distal end **10a**, the rear or proximal end **10b** of the drainage tube, the body **11** of the drainage tube, the fragment of the side wall **12**, used as fixing means.

Figure 3A shows a perspective view of another preferred embodiment of the aqueous humor drainage tube of the present invention, including: the front end **10a**, the rear end **10b**, the body **11**, the fragments of the side walls **12a** y **12b**, the opening angles **α** and **β** between them in both ends, the bottom **14** and the hole **15** which connects the lumen with the outside.

Figure 3B shows a side view of the aqueous humor drainage tube of figure 3A, including: the front end **10a**, the rear end **10b**, the body **11** of the drainage tube, the fragment of the front end side wall **12a** and the fragment of the rear end side wall **12b**.

Figure 3C shows a representation of the aqueous humor drainage tube in

another preferred embodiment of the invention, including: the front end **10a** with bevel, the rear end **10b** with the side walls **13** open at angle **α1** serving as a fixing system and the body **11**.

Figure 3D shows a perspective view of the drainage device **50** proximal end **10b**, including: the walls **13c** which are open at an outward angle like flower petals, with wedge-shaped openings that serve as a fixing system, and only present in the proximal or rear end **10b**.

Figure 3E shows a perspective view of another preferred embodiment of the drainage device **50**, including: the distal end **10a** and the proximal end **10b** linked by the body **11**, and the opposite walls **13c** of their ends **10a**,**10b** open at angle like flower petals, serving as a fixing system.

Figure 3F shows a representation of the aqueous humor drainage device in another preferred embodiment of the invention, including: a gap of its opposite walls **13** and **13a** with opening at angle **α1** and **β1** respectively, at both ends **10a** and **10b**, and the body **11.**

Figure 3G shows a representation of the aqueous humor drainage tube in another preferred embodiment of the invention, including: the front end **10a** which is beveled and tilted below its lower wall **10c**, the rear end **10b** with the opposite walls open at angle **α1**, and the body **11**.

Figure 3H shows an embodiment of the aqueous humor drainage device with a tube shape, exiting the insertion device needle, including: the hole **15** of the distal end **10a** which connects the lumen with the exterior, the proximal end **10b**, the insertion device needle **16**, the distal portion **19** of the drainage device **50** pushing means.

Figure 3I shows another embodiment of said drainage device, including: the distal end **10a**, the proximal end **10b**, the side fixing tabs **13b** and the connection

holes **15** of the lumen with the outside.

Figure 3J shows another embodiment of said drainage device, including: the distal end **10a**, the proximal end **10b**, the side fixing flaps **13b** and the connection holes **15** of the lumen with the outside.

Figure 3K shows another representation of the aqueous humor drainage device in another preferred embodiment of the invention, including: a gap of its opposite walls **13** and **13a** with opening at angle **α1** and **β1** respectively, at both ends **10a** and **10b**, and the body **11**, wherein these lateral and opposing walls, bent backwards like hooks on both extremes.

Figure 3L shows a representation of the aqueous humor drainage device in another preferred embodiment of the invention, consisting in a cylinder shaped body **11** with no inner conduit and two opposite ends **10a** and **10b**, made out of a porous biopolymer material.

Figure 3M illustrates another preferred embodiment of the aqueous humor drainage device **50** with a tube-like shape, including: the hole **15** of the distal end **10a** which connects the lumen with the exterior, the proximal end **10b**, and the lumen in discontinuous line.

Figure 4 shows an explanatory drawing of the insertion arrangement of the present invention in a longitudinal section that shows its inside: the needle **16**, the body **17**, the connection **26** of the needle **16** and the body **17**, the connection **20** of the front part **19** of the plunger with the rear part **18** of the plunger and the front end **21** of the needle **16**.

Figure 4A shows a side view of the insertion arrangement in one of the preferred embodiments of the present invention, including: the needle **16**, the body **17**, the connection **20** of the front part **19** of the plunger represented by the broken line with the rear part **18** of the plunger represented by the broken line and larger

than the front part, the connection **26** of the needle **16** and the body **17**, the connection **33** of the actuating arrangement **34** and the plunger **18** and **19**, the groove **35** of the insertion device body **17**.

Figure 5 shows the insertion arrangement of the drainage tube in one of the preferred embodiments of the present invention, including: the needle **16**, the body **17**, the rear part of the plunger **18**, the front end **21** of the needle **16**, the loading hole **22** of the drainage device **50**, the side groove **23** which connects to the loading hole **22**, the pressure actuated head **24a** of the plunger, the male screw **25** built-in into the body **17** of the insertion arrangement and the **26** needle **16** – body **17** connection.

Figure 5A shows in detail the female inner screw of the insertion arrangement foldable head **24b** in relation to Figure 5.

Figure 5B shows in detail the insertion arrangement needle where the drainage device is introduced, including: the loading hole **22** of the drainage device **50** in the needle **16** body and the groove **23** of the needle **16** body.

Figure 5C shows the opposite side of the insertion device needle of Figure 5B including: the groove **23** of the insertion arrangement needle **16** body.

Figure 5D shows in detail another preferred embodiment of the invention in relation to the insertion arrangement needle, including: the needle **16**, the insertion arrangement body **17**, the groove **23** in both side walls of the needle **16**, the foldable needle **16** - body **17** connection **26** of the insertion arrangement and the drainage device **50** shown with broken lines in the inside of the needle **16**, with its side walls **12** portions projected outwards.

Figure 5E shows a rear perspective view of another preferred variant of the invention in relation to the insertion arrangement needle, including: the needle **16** with an elliptical cross-section, and the end **21** thereof.

Figure 5F shows another rear perspective view of another preferred variant of the invention in relation to the insertion arrangement needle, including: the needle **16** with a flat cross-section, and the distal end **21** thereof.

Figure 5G shows another rear perspective view of another preferred variant of the invention in relation to the insertion arrangement needle, including: the needle **16** with a round cross-section and without side grooves, and the distal end **21** thereof.

Figure 6 shows an enlarged image of the insertion arrangement needle tip **16**, in one of the preferred embodiments of the invention, including: the front (also called the distal) end of the needle **21**, an edged **27** tip, an edged **21a** bevel and a step **28** which acts as a scleral stop in the connection of the needle **16** front end **21** and its body.

Figure 7 shows one of the embodiments of the invention in relation to the insertion arrangement, in a longitudinal section thereof, including: the front (that is, the distal) end **21** of the needle **16**, the front part **19** of the plunger and the rear part **18** of the plunger which is larger than the first portion **19** and the plunger head **24a**.

Figure 8 shows in more detail the engagement of the foldable screwable head to the rear end male screw of said insertion device body in one of the preferred embodiments of the invention, including: the insertion device body **17**, the rear part **18** of the plunger, the head **24a** of the pressure actuated plunger, the rear end male screw **25** of the insertion device body **17** and the foldable head **24b** with an inner female screw, represented in an axial section.

Figure 9A shows the introduction of the drainage tube folded on its bevel tip according to the embodiment example N°1 of the invention, within the needle inner conduit of the insertion arrangement according to the embodiment example

Nº2, using the method of the embodiment example Nº3, the figure including: the front (or distal) end **10a** and the beveled rear (or proximal) end **10b** of the drainage tube **50**, the body **11** of the drainage tube **50**, the body **17** of the insertion arrangement, the plunger rear portion **18**, composed of a long needle 21G, the 0.25 mm diameter stainless steel inner wire **19** represented by a broken line, the end **21** of the insertion arrangement needle **16**, the needle **16** - body **17** connection **26** of the insertion arrangement, the folding **32** in the bevel tip of the drainage tube **50**.

Figure 9B shows the introduction of the drainage tube unfolded on its bevel tip according to the embodiment example Nº1 of the invention, within the needle inner conduit of the insertion arrangement according to the embodiment example Nº2, using the method of the embodiment example Nº3 of the present invention, the figure including: the front end **10a** and the beveled rear end **10b** of the drainage tube **50**, the body **11** of the drainage tube **50**, the plunger rear portion **18**, composed of a long needle 21G, the 0.25 mm diameter stainless steel inner wire **19** represented by a broken line, the end **21** of the insertion arrangement needle **16**, the needle **16** - body **17** connection **26** of the insertion device.

Figure 10 shows a schematic drawing of the insertion arrangement, according to the embodiment example Nº 2 of the present invention, including: the needle **16**, the insertion device body **17** (cut syringe), the 0.25 mm diameter stainless steel inner wire **19**, the connection **26** of the needle **16** and the syringe **17**, the connection **20** of the stainless steel cable **19** and the long 21G hypodermic needle **18**, the end **21** of the insertion arrangement needle **16**, the head **24a** of the long 21G disposable hypodermic needle **18**.

DETAILED DESCRIPTION OF THE INVENTION

Due to the above mentioned problems of the known prior art, the invention disclosed herein is intended to provide, within the therapeutic arsenal of Glaucoma surgery, a drainage device that is implanted ab-externo to avoid the disadvantages of the ab-interno drainage devices, and that additionally has a small outer diameter to prevent protrusions or injuries of the sclera where it is inserted, that does not additionally require inner valve sophisticated systems for excessive drainage in which said valves may fail or stop working overtime and may be a place of potential adherence of elements such as fibrin and cells that may obstruct its lumen. The invention further provides a solution related to the wound size, since it can be implanted by means of an insertion device where it is preloaded, and where the insertion device allows a transconjunctival implantation method to be performed, that is to say, without the need of a previous conjunctival opening or closure thereof with sutures, cauterization or adhesives, as required by the prior art drainage devices implanted ab-externo. The invention is also intended to provide a simple system and method that can be used not only by those skilled in Glaucoma surgery but also by general ophthalmologists.

By way of introduction, and for a better understanding the present invention, figure 1A is shown, as a schematic drawing of the iridocorneal angle in an axial section of the eye.

It is important to mention that the conjunctiva **1** is an elastic and transparent mucous membrane, which covers the outer part of the eye, outside the cornea **3** (Figure 1A), the latter **3** being a transparent and resistant membrane. The conjunctiva **1** is composed of an epithelium and a chorion containing histiocytes, mast cells, lymphocytes and blood vessels that serve as protection, nutrition and defense elements of the eye. Said conjunctiva **1** is loosely attached by its undersurface to a translucent and elastic membrane called the Tenon's capsule **1b**

(Figure 1A) which is also adhered to the underlying sclera **2** (white, opaque, resistant membrane with some degree of slight elasticity).

This invention describes a kit for the treatment of Glaucoma disease, that comprises an aqueous humor drainage device **50** and an insertion arrangement which includes a needle **16** containing the first device **50** preloaded inside and wherein both pieces form a structural and functional unit designed to allow the performance of a novel transconjunctival implantation method, without previously opening the conjunctiva **1**, said method allowing to avoid the need to close the wounds with sutures, cauterization or adhesives once the implantation procedure has finished, since the conjunctival and scleral wounds produced are reduced to the size of a small hypodermic needle that could be as small as a 28G needle.

Figure 1B shows one of the preferred embodiments of the invention where said aqueous humor drainage device **50** can be seen implanted into the eye, and where the distal (or front) end **10a** is implanted into the anterior chamber **9** of the eye and the proximal (or rear) end **10b** is implanted into the intrascleral space, thus allowing the aqueous humor drainage from the anterior chamber **9** of the eye into the subconjunctival space for later reabsorption.

Figure 1C shows another preferred embodiment of the invention where said aqueous humor drainage device **50** can be seen implanted into the eye, where the distal end **10a** is implanted into the anterior chamber **9** of the eye and the proximal end **10b** is implanted into the subconjunctival space, thus allowing the aqueous humor drainage from the anterior chamber **9** of the eye into the subconjunctival space for later reabsorption.

In the two cases described above and represented in figures 1B and 1C, said drainage device **50** is inserted into the eye, by means of said insertion device, by using the transconjunctival implantation method in which, by means of said

insertion device needle **16** containing said drainage device **50** preloaded, the conjunctiva **1** is incised away from the sclero-corneal limbus **1a,** and then, the needle is moved forward underneath said conjunctiva **1** or conjunctiva **1** and Tenon **1b** towards the cornea **3**, to incise the sclera **2** at the intended distance from the sclero-corneal limbus **1a** and subsequently enter the anterior chamber **9** of the eye with said needle **16**, where the implantation of said drainage device **50** is then performed by placing at least one portion of said drainage device **50** into the hole in the sclera **2** created by said insertion device needle **16**, and placing the distal end **10a** in the anterior chamber **9** of the eye to drain the aqueous humor from said chamber into the subconjunctival space. Said distance between the incision of the conjunctiva **1** and the incision of the sclera **2**, together with the small hole created in said conjunctiva **1** by the insertion device needle **16** and the scleral incision coating by said conjunctiva **1**, allow a safer surgery process, since they reduce postoperative infection risks.

Said drainage device **50** of the invention comprises:

a) In the majority of the embodiments of the invention (Figures: 2A,2B,3A,3B,3C,3D,3E,3F,3G,3H,3I,3J,3K,3M), a tube-like body **11** with two opposite ends **10a,10b,** and an inner conduit, which defines an outer diameter from 0.127mm to 0.5 mm, and an inner diameter from 0.05mm to 0.35mm, and where each opposite end **10a,10b,** have at least one hole **15** which connects said inner conduit to the outside.

In many preferred embodiments of the invention, said drainage device **50**, has a body **11** outer diameter from 0.127 to 0.31 mm and inner diameter from 0.05 to 0.152 mm, depending on the draining needs according to the case to be treated.

In a preferred embodiment of the invention, at least one of the holes **15** that

connect the inner conduit of the drainage device **50** to the outside has the same diameter as the inner conduit of said drainage device **50**.

In other preferred embodiments of the invention, at least one of the holes **15** that connect the inner conduit of the drainage device **50** to the outside has a different diameter from the inner conduit of said drainage device **50**.

b) In one of the preferred embodiment of the invention (Fig. 3L), an aqueous humor drainage device **50** having a cylinder shaped body with two opposite ends **10a,10b**, composed of a porous biopolymer material with no inner conduit, wherein said drainage device **50** is hydrated and swells in contact with liquid, and allows the passage of liquid from one end to the other.

c) A total length of the drainage device **50** from 2 mm to 8.5 mm.

In some preferred embodiments, the total length of said drainage device **50** is from 2.5 to 3.5 mm.

d) A constituting material thereof, including, but not limited to, at least one of the materials selected from the following group: stainless steel, titanium, nickel-titanium alloys, synthetic biopolymers including PMMA,PHEMA, Fluorocarbon, hydrogels, polyacetals, polyamide elastomers, polyester elastomers, poly(olefine) elastomers, poly(urethanes), Carbothane®, Pellethane®, Tecoflex®, Tecophilic®, Tecoplast®, Tecothane® and silicones, as well as copolymers, biocompatible ceramic materials, or a combination thereof.

In some preferred embodiments, the constituting material of said drainage device **50**, comprises some of the materials selected from the following group: Carbothane®, Pellethane®, Tecoflex®, Tecophilic®, Tecoplast®, Tecothane®.

e) In many of the embodiments of the invention, a fixing means applied to the eye, comprising, but not limited to, at least one item selected from the following group: a) at least a pair of side opposite flaps **13d** (see Figure 3J), an open-angle

gap of at least a portion of the opposite walls **12**,**12a**,**12b**,**13**,**13a**,**13c**, (see Figures 2A, 3A, 3C, 3D, 3E, 3F, 3G, 3K) belonging to said drainage device, c) burrs, d) folding **10c** of the distal end **10a** (See Figure 3G), e) spines; f) spurs; g) clamps; h) fragments of different shapes and materials; i) outer surface roughness ,j) tabs **13b** (see Figure 3I); k) hooks (see Figure 3K) or l) a combination thereof, and where said fixing means, is or are placed in at least one of the portions of said drainage device **50,** selected from the following group: the rear end (or proximal end) **10b** of said drainage device **50** (Figures 2A, 2B, 3C, 3D), both ends **10a, 10b** of said drainage device **50** (Figures 3A, 3B, 3E, 3F, 3G, 3J,3K), the body **11** of the drainage device **50** (Figure 3I), the body **11** and the rear end **10b** of the drainage device **50** (Not shown in the figures), or on the bottom side of said drainage device **50** (Figure 3J).

Said fixing means may additionally have several shapes and inclination angles, and a length from 0.2 mm to 1.5 mm from said drainage device **50** body **11**.

In some embodiments of the invention, the fixing means includes pieces which are not an integral part of the drainage tube, said pieces being made of several materials and attached to the drainage device **50** by means of glue or by welding.

In several preferred embodiments of the invention, the fixing means is an integral part of said drainage device, thus simplifying manufacturing and reducing production costs; in these cases, said fixing means is composed of at least a fragment of both opposite walls belonging to said drainage device **50,** both walls or wall fragments being open at angle (Figures 2A, 3A, 3C, 3D, 3E, 3F, 3G3K), and said splay angle being greater than 5º, vertically or horizontally oriented, in any of their ends **10a**, **10b**. Said opposite walls or opposite wall fragments are so flexible that enable the insertion and sliding of said drainage device **50** inside the insertion

device needle **16**, by aligning with said drainage device **50** body **11** and at least partially returning to the original angle when exiting said insertion device needle **16**.

In other embodiments, said drainage device **50** also has fixing means **13b**, **13d** (see Figures 3I, 3J), which can be folded to align themselves with the drainage device **50** body **11** in order to enter said insertion device needle **16**, and at least partially returning to their original state when exiting said insertion device needle **16**.

In some preferred embodiments of the invention (Figures 3H, 3L, 3M), the anchoring system to the eye, comprises the compression of the body **11** of the drainage device **50** carried out by the sclera **2**, along the scleral hole (Figures 1b, 1c) created by the insertion needle **16** where it is preloaded.

f) A finish of any of said drainage device **50** ends **10a**, **10b**, comprising, but not limited to, any of the several configurations selected from the group consisting of: right-angled to the tube axis, beveled, flattened, tilted down (See distal end **10a** of Figure 3G), trumpet shaped, pointed, fish mouth-shaped (Figures 3C, 3F, 3G), an extension of said distal end **10a** lower wall (See Figure 3A) capable of preventing possible aqueous flow blocking by the iris **5**, flower-shaped (Figures 3D, 3E), or a combination thereof.

In several preferred embodiments of the invention, said drainage device **50** distal end **10a** has a beveled finish to prevent potential obstructions by the iris of the hole **15** in said end.

In another embodiment of said drainage device **50**, both ends **10a, 10b**, can have the same kind of finish (Figures 3A, 3B, 3E, 3F, 3H, 3K, 3L, 3M).

In another embodiment of said drainage device (Figure 3G), the distal or front end **10a,** has a beveled finish and is tilted down **10c**.

Some variations related to the drainage device **50** of the invention are listed below:

In some preferred embodiments of the invention, the front (or distal) end **10a** of the drainage device **50**, which is implanted into the anterior chamber of the eye, has a hole on the front and another hole behind it, on the upper part of said drainage tube, in order to enable the aqueous humor flow in the event that the iris **5** obstructs the first hole (this variant is not shown in the figures).

In some embodiments of the present invention, the outer surface of said drainage device does not have any kind of additional coating or treatment.

In another embodiment of the invention, said drainage device has an outer surface treatment selected from the group consisting of: a passivation treatment, a polymer coating such as silicone, acrylics or parylene, a copolymer coating, or hydroxoapatite film coating.

In some embodiments of the invention, the cross-section of the drainage device **50** body **11** is round.

In other embodiments of the invention, the cross-section of the drainage device **50** body **11** is elliptical.

In another embodiment of the invention, the cross-section of the drainage device **50** body**11** is flat.

Below, there is a detailed description of some examples of the preferred embodiments of the invention, in relation to the aqueous humor drainage device, without affecting the spirit of the invention, since it may include some of the above mentioned modifications, which are not illustrated in the figures.

In one of the preferred embodiments illustrated in Figures 2A and 2B, the front end **10a** of the drainage tube **50** has a beveled cut **10** and is implanted into

the anterior chamber **9** of the eye, while its body **11**, is implanted into the intrascleral space formed by the insertion device needle **16**, thus allowing the aqueous humor flow from the anterior chamber **9** of the eye into the subconjunctival space for further reabsorption. In addition, said drainage device has a fixing arrangement which is only present in the rear end (or proximal end) **10b** and comprises two fragments of the side opposite walls **12** open at angle, and therefore, with no additional welds, thus simplifying the process and reducing production costs, and where said side wall **12** fragments are at an angle **α** greater than 5º and smaller than 180º between them, before entering said insertion device needle **16**. Said fixing means have certain flexibility in order to compress and slide inside said insertion device needle **16** and they have certain memory to recover, at least partially, their opening angle **α**, after exiting said needle **16.**

In another preferred embodiment of the present invention, in relation to the drainage device represented in figures 2A, 2B, 3C, 3I, the frontal end **10a** has any of the above described fixing systems that prevent it from being expelled from the anterior chamber **9** of the eye (Not shown in the figures).

Figures 3A and 3B show another preferred embodiment of the present invention in relation to the drainage device **50**. In this example, both ends **10a** and **10b**, have two fragments of the side opposite walls **12a**, **12b** open at angle **α** and **β**, preferably greater than 5° and smaller than 180º, before entering the needle **16**, and they have certain flexibility such as that described for Figures 2A and 2B. In addition, the front end **10a** has a bottom **14**, which may have different lengths and shapes, that may act as a fixing means with a downward inclination angle to the axis of the tube body **11**, and it serves to prevent the iris **5** from obstructing the hole **15** through which the aqueous humor enters. The two fragments of the front end **10a** side opposite walls **12a** prevent the removal of the drainage tube **50**, while the two fragments of the rear end **10b** side opposite walls **12b** act as fixing

means outside the anterior chamber.

In another preferred embodiment of the present invention, in relation to the drainage device **50** represented in figures 3A and 3B, the angle **β** formed between the fragments of the front end **10a** side opposite walls **12a** is such that there is no need for a bottom **14** in said end, since the iris **5** will not obstruct the hole **15** through which the aqueous humor enters (Not shown in the figures).

Figure 3C shows another preferred embodiment of the invention in relation to said drainage device **50**, which consists of a tube with an inner lumen that connects to the outside through its ends **10a** y **10b**. Its front (or distal) end **10a** has a beveled finish, while the rear (or proximal) end **10b** has an expansion of the diameter in relation to the body **11**, where two of its opposite walls **13** (by opposite walls meaning: side walls or bottom and top) open outwardly at open angle **α1**, to serve as a fixing means to the eye. Said rear end **10b** walls **13** additionally have such a flexibility that they can compress to enter or pass through the lumen of the insertion device needle **16** and self-expand, at least partially, when exiting it.

In another preferred embodiment of the invention, in relation to the drainage device **50** and represented in Figure 3D, the fixing means to the eye comprises the expansion of the proximal end **10b,** where the walls **13c** in said end are at least partially open like four flower petals, and where said walls have such a flexibility that they can compress to enter said insertion device hollow needle **16** and then expand when exiting said needle **16.**

In another preferred embodiment of the invention, in relation to the drainage device **50** and represented in Figure 3E, the fixing means to the eye comprises the expansion of both ends **10b** and **10b**, where the walls in said ends are at least partially open like four flower petals, and where said walls have such a flexibility that they can compress to enter and slide in the lumen of said insertion device

hollow needle **16** and then expand when exiting said needle **16**.

Another preferred embodiment of the invention in relation to the drainage device **50** is represented in Figure 3F and consists of a tube with an inner lumen which connects to the outside through its ends **10a** y **10b**. Its front end **10a** has an expansion of the diameter in relation to the body **11** in order to serve as a retaining system in the anterior chamber **9** of the eye, while the rear end **10b** also has an expansion of the diameter which serves as a fixing system inside the scleral tunnel (Figure 1B) created by the insertion device needle **16** or into the subconjunctival space (Figure 1C). This expansion consists of an outward opening at an open angle **α1** and **β1** of two of the opposite walls **13**, **13a**, belonging to ends **10b** and **10a**, by opposite walls meaning: side walls or bottom and top. Said ends have a wedged opening with an angle **α1** and **β1** between both opposite walls **13**, **13a**, which have such a flexibility that they can compress to enter or pass through the lumen of the insertion device needle **16** and self-expand, at least partially, when exiting the needle, to perform the implantation of the drainage tube **50** into the eye.

Another preferred embodiment in relation to the drainage tube **50** is represented in Figure 3G and consists of a tube with an inner lumen which connects to the outside through its ends **10a** y **10b**. Its front end **10a** has an upper bevel and is tilted below its lower wall **10c** in relation to the body **11** axis, which serves as a retaining means, while its rear end **10b** has an expansion where two of its opposite walls **13**, by opposite walls meaning: side walls or bottom and top, open outwardly at an open angle to serve as fixing means to the scleral tunnel created by the insertion device needle **16**, having a wedged opening with an angle **α1** between both walls **13**, which have such a flexibility that they can compress to enter or pass through the lumen of the insertion device needle **16** and self-expand, at least partially, when exiting the needle in order to perform the implantation of the drainage tube **50**.

As previously mentioned in figures 3C, 3F and 3G, the expansion of the ends is achieved with an open-angle opening of its opposite walls, by opposite walls meaning the side walls or the bottom and the top; therefore, the wedged openings with angle **α1 and β1** may be vertically or horizontally oriented.

Other preferred embodiment of the invention represented in Figure 3H comprises, a tube shaped body with an inner conduit, and two opposite ends **10a, 10b**. Said drainage device **50,** is constituted by a biopolymer material which is hydrated and swells in contact with liquid, thus allowing the anchoring to the eye when implanted. Its distal end **10a** is implanted into the anterior chamber **9** of the eye and its proximal end **10b** into the scleral thickness **2** (Figure 1B) or into the subconjunctival space (Figure 1C), depending on the length of said drainage device **50**. The aqueous humor enters said drainage device **50** lumen through at least one hole **15** on the distal end **10a**, and exits through at least a hole, located on at least its proximal end **10b,** into the subconjunctival space.

Another variant related to the Figure 3H, include several holes that connect the lumen with the exterior along the tube (Not shown in the figures).

The figure 3K represents another preferred embodiment of the drainage device **50** which consists of a tube with an inner lumen which connects to the outside through its ends **10a** y **10b**. Its front end **10a** has an expansion of the diameter in relation to the body **11**, in order to serve as a retaining system in the anterior chamber **9** of the eye, while the rear end **10b** also has an expansion of the diameter which serves as a fixing system outside the anterior chamber. This expansion consists of an outward opening at an open angle **α1** and **β1** of two of the opposite walls **13, 13a**, belonging to ends **10b** and **10a**, which are backwards bent at the tip, meaning by opposite walls: side walls or bottom and top. Said ends have a wedged opening with an angle **α1** and **β1** between both opposite walls **13, 13a**, which have such a flexibility that they can compress to enter or pass through

the lumen of the insertion device needle **16** and self-expand, at least partially, when exiting the needle, to perform the implantation of the drainage tube **50** into the eye.

Other preferred embodiment of the invention, represented in Figure 3L, comprises a cylinder shaped body, made out of a porous biopolymer material with no inner conduit, and wherein said drainage device **50** is hydrated and swells in contact with liquid, and allows the passage of liquid from one end to the other, and where the anchoring system to the eye comprises the compression of the body **11** of the drainage device **50** carried out by the sclera, along the scleral hole created by the insertion needle **16** where it is preloaded. Thus its distal end **10a** is implanted into the anterior chamber **9** of the eye and its proximal end **10b** into the scleral thickness **2** (Figure 1B) or into the subconjunctival space (Figure 1C), depending on the length of said drainage device **50**. The aqueous humor enters said drainage device **50** through the distal end **10a**, and exits through its proximal end **10b,** into the subconjunctival space.

Other preferred embodiment of the invention, represented in Figure 3M, comprises a tube-like shape, an inner conduit and two ends **10a**, **10b,** with at least one hole on each end that connect the lumen with the exterior, allowing the passage of liquid from one end to the other, and where the anchoring system to the eye comprises the compression of the body **11** of the drainage device **50** carried out by the sclera, along the scleral hole created by the insertion needle **16** where it is preloaded. Thus its distal end **10a** is implanted into the anterior chamber **9** of the eye and its proximal end **10b** into the scleral thickness **2** (Figure 1B) or into the subconjunctival space (Figure 1C), depending on the length of said drainage device **50**. The aqueous humor enters said drainage device **50** through the distal end **10a**, and exits through its proximal end **10b,** into the subconjunctival

space.

Another variant related to the Figure 3M, include several holes that connect the lumen with the exterior along the tube (Not shown in the figures).

In all cases, the drainage devices of the present invention are preloaded in the insertion arrangement needles **16** of the invention and are delivered ready to use, packed and sterilized.

The kit for the treatment of Glaucoma allows for a procedure even without the use of a surgical microscope, since the implantation method is very simple and easy, and this could take place in places which are far from medical centers and have limited resources in terms of equipment.

Said insertion device of the drainage device **50** (Figures 4A, 5, 5A, 7 and 10) included in the treatment kit of the present invention, comprises: a body **17**, a pushing means **18** and **19**, an actuating means **24a**, **24b**, **34** of said pushing means **18** and **19**, and as previously mentioned, a hollow needle **16** which serves to contain said drainage device **50** inside (Figure 5D) as well as to incise and penetrate the conjunctiva **1** without a previous incision thereof, moving forward into the cornea under said conjunctiva **1**, or conjunctiva **1** and Tenon **1b** up to the intended place for the incision in the sclera **2**, in order to make a hole in this last membrane **2**, entering the anterior chamber **9** of the eye, where said drainage device **50** is implanted, placing at least a part of said drainage device **50** in said hole in the sclera **2**, and the front end **10a** in the anterior chamber **9** of the eye.

Said needle **16** inner conduit of said insertion device connects to the outside by its front end **21**, while through its rear (or proximal) end, it connects to and meets the body **17** inner conduit, where the rear part of the needle **16** joins to **26** the front (or distal) part of said insertion device body **17**, said connection **26** being fixed or removable. In said insertion device inner conduit, there is a pushing means **18 and 19**, which when actuated, allows its distal portion **19** to slide inside

the needle **16** inner conduit, pushing the aqueous humor drainage device **50** to be implanted into the eye.

As shown in Figure 4, the pushing means **18** and **19** may be composed of a front cable or wire **19** attached to a rod **18** of a larger diameter in its rear end in a point **20**, or composed of a front cable or wire **19** attached **20** to a tube **18** of a larger diameter in its rear end, or it may be completely composed of only one cable or wire **19** with only one diameter (Not shown in the figures).

The front cable or wire **19** of said pushing means is preferably made of, but not limited to, stainless steel, and has such a diameter that allows it to slide inside the needle **16** lumen, generally from 0.2 mm to 0.5 mm, and such a length that allows it to reach at least the tip of said needle **16** end **21**, when actuating the actuating means to the maximum, while in the cases that have another cable, rod, or tube in said pushing means rear end **18,** they can be composed of several materials, whether plastic or metal. The plunger, or pushing means **18** and **19**, is pushed by an actuating arrangement, which can have different mechanisms such as sliding of a knob **34** (Figure 4A), button, trigger or lever, or it can have a pressure mechanism **24a** (Figures 5, 7 and 8), or screw **24b** mechanism (Figures 5, 5A and 8), which makes it slide forward, pushing the aqueous humor drainage device **50**, which is inside said needle **16** inner conduit of said insertion device, into its front end **21**, for its implantation into the eye.

Said insertion device needle **16** can have different diameters along its length, and its inner conduit is the place where the aqueous humor drainage tube **50** is inserted, remaining there, prepared for its subsequent implantation into the eye, the loading being possible through the front (or distal) end, or through said needle **16** rear (or proximal) end (Figures 5D,5E,5F,5G) or through a hole **22** (Figures 5, 5B) in said needle **16** body, created for such purpose. Said insertion device needle **16** has a length from 1.5 to 4 cm, and it can be straight, curved or

angled, and it has an outer diameter from 0.35 mm to 1.2 mm, an inner diameter from 0.22 mm to 0.8 mm, and its end **21** has a length from 1.5 mm to 6 mm. Likewise, in some embodiments, said insertion device needle **16** is completely made of only one material, while in other embodiments of the invention, said insertion device needle **16** is made of a combination of materials; the materials used in both cases being selected from the following group: metal, ceramic, glass, diamond, sapphire, quartz or polymers derived from plastic, and in the event of using glass, sapphire or diamond, they are located in said needle distal end **21**.

Furthermore, the lumen of said insertion device needle **16** has a cross-section selected from the following group: round (Figures 5D and 5G), elliptical (Figure 5E), or flat (Figure 5F).

According to all the preferred embodiments of the present invention in relation to said insertion device, said needle **16** has in its front end **21** an edged finish, which serves to incise the conjunctiva **1**, the Tenon **1b** and the sclera **2** and penetrate the anterior chamber **9** of the eye, without requiring previous incisions in the conjunctiva, even though it will be understood by those skilled in the art that, if desired, a previous incision of the conjunctiva **1** and Tenon **1b** could be made, thus exposing the sclera **2**, to subsequently incise it and enter the anterior chamber **9** of the eye.

Likewise, the front end **21** of the insertion device needle **16** may comprise an edged bevel all along its length with only one cutting angle as in the hypodermic needles, or as shown in Figure 6, it may have more than one cutting angle **21a, 27**, and include the combination of one edged area **21a, 27** with another blunt area **28** and an area with bevel with an area without bevel, which do not necessarily have the same width and length.

In one preferred embodiment of the invention, said insertion device needle

16 has, at least in its distal end **21** which incises the sclera, luminescent properties, among which fluorescence and phosphorescence are included, therefore, when being stimulated by a suitable means such as for example a light with UV (Ultraviolet) filter, such as Wood's light or a cobalt blue filtered light, a fluorescence phenomenon is produced, allowing visualization under the conjunctiva **1** and the Tenon's capsule **1b** to incise the sclera **2** at the intended distance from the sclero-corneal limbus **1a**.

Furthermore, the body **17** of the different insertion devices may be made of metal, or preferably, plastic materials or by-products, and they may have different lengths.

In one of the preferred embodiments of the invention, shown in Figure 4A, the displacement of the plunger or pushing means **18** and **19**, is performed by sliding a knob **34** along a groove **35** located in the insertion device body **17**. Said knob **34** is connected **33** to said insertion device inner plunger **18**.

In another preferred embodiment in relation to the insertion device in Figure 4A, the actuating knob **34** is attached **33** to the distal cable or wire **19**, and does not have the proximal segment **18** of the plunger. (Not shown in the drawings).

Figures 5 and 5A represent another preferred embodiment of the present invention, where the rear end of the plunger **18** axially exceeds the body **17** of the insertion device in its rear part, and connects to a head **24a** (similar to a syringe with plunger) at such a distance from the body **17** that it can push the plunger **18** and **19**, until its distal portion **19** frontally exceeds the tip **21** of the insertion device needle **16** when the head **24a** of the plunger is actuated up to its stop. Furthermore, as also shown in Figure 8 in an enlarged image of the rear area of the insertion device in Figure 5, the rear end of said insertion device body **17** has an outer male screw **25** in which a second foldable head **24b** with inner female

screw is embedded and screwed, the second head being larger than the first pressure head **24a** and enclosing it, so that when the screw is actuated, this second head **24b** compresses the first head **24a** and this one, in turn, actuates the plunger **18** and **19**, pushing the drainage device **50** contained in the needle **16** lumen outwardly. The screwable removably head **24b** provides the option to the operator of choosing the pressure **24a** or screwable **24b** system.

One preferred embodiment in relation to the insertion device needle **16** is shown in Figures 5B y 5C, where the needle **16** body has an opening **22**, which serves to load the aqueous humor drainage tube **50** inside, and additionally has two opposite grooves **23**, which are longitudinal and axial to said needle **16** body, where both have different lengths and are smaller than said needle **16** lumen, with the aim of containing the drainage tube **50** inside and additionally being the place where the fixing means of the drainage tube **50** proximal end **10b** rest and slide (See fixing means **12**, **12b**, of Figures 2A,2B,3A,3B), and project outwards from the needle **16** through said grooves **23**. Said grooves **23** provide stability to the aqueous humor drainage tube **50,** which has said fixing means **12**, **12b** inside said needle **16** inner conduit**,** where it is preloaded, and they prevent possible rotations during the implantation. In the event of using an insertion device with this kind of needle **16**, the distal end **10a** fixing means **12a** of the drainage device in Figure 3A, 3B, slide into said grooves **23** when inserting said drainage tube **50** into said needle **16** but then they are pushed inwardly and remain inside the needle **16** lumen, without the needle projecting outwards until the implantation of said drainage device **50**.

As shown in figure 5D, in another preferred embodiment of the invention, the loading of the drainage device **50** is performed on the rear end of the insertion device needle **16**, making the drainage device **50** fixing means match, such as for example, the fragments of the side walls **12, 12a, 12b** (Figures 2A, 3A), with the

grooves **23** existing in the rear (or proximal) end of the needle **16**. In the case of the drainage device **50** related to figure 3A, the fixing means of the end **10a** must be pushed into the said needle **16** lumen when they reach the distal portion of said needle **16** side grooves **23**. The needle **16** is fixed or removably attached **26** to the insertion device body **17**, and by pushing the plunger **18**, **19**, the drainage device **50** is moved along the needle **16** lumen until said drainage device **50** is placed in the middle-rear part of the needle **16**, and the fixing elements of the rear end **10b**, such as the side wall **12**, **12b** fragments (Figures **2A**, **3A**), protrude from the side grooves **23** and said drainage device **50** remains in said position until its implantation.

In another preferred embodiment represented in figure 5E, the loading of the drainage device **50** is also performed by the rear end of the insertion device needle **16**, but in this case, said needle **16** has a cross-section of its inner diameter with elliptical shape all along its length.

In another preferred embodiment represented in figure 5F, the loading of the drainage device **50** is also performed by the rear end of the insertion device needle **16**, but in this case, said needle **16** has a cross-section of its inner diameter with flat shape all along its length.

In another preferred embodiment represented in figure 5G, the loading of the drainage device **50** is also performed by the rear end of the insertion device needle **16**, but in this case, said needle **16** has a cross-section of its inner diameter with round shape all along its length, without side grooves in its body.

Figure 6 shows one of the preferred embodiments of the present invention in relation to said insertion device needle **16**, where its tip **21** has an edge **27,** which serves to incise the conjunctiva **1**, the Tenon **1b** and the sclera **2** penetrating into the anterior chamber **9** of the eye, thus allowing the

transconjunctival implantation of said drainage device **50** without the need of a previous conjunctival opening or closure by sutures, cauterization or adhesives, or if desired, as it will be understood by those skilled in the art, after making a small previous opening of the conjunctiva **1** and Tenon **1b** exposing the sclera **2**, such as performed by the methods mentioned in the state of the art, but in this latter case, the conjunctival wound must be closed by sutures, cauterization or adhesives. Said tip **27** has an inclination angle different from the beveled area **21a** immediately after it, and in the rear part of the end **21** attached to the needle **16** body there is a step **28** with a straight or almost straight angled cut, which serves as a stop to the needle **16** advancement in the sclera **2**.

Below, there is a description of the examples performed by the inventor in relation to the aqueous humor drainage device **50**, the insertion arrangement thereof, and the method used for its performance, without altering the true spirit of the present invention, since the drainage device **50** and insertion device thereof may have desirable modifications, such as those previously described, for the present invention to be feasible from the medical and industrial point of view.

Embodiment example N° 1: For the creation of the drainage tube **50**, 30 G and 32 G disposable hypodermic needles were used. In some of them, the bevel front (or distal) part was folded **32** to the opposite side of said disposable hypodermic needle inner conduit at an angle lower than 45° (see Fig. 9A), controlling said needles with a 10X zoom microscope, while in others, the bevel was left unfolded (see Figure 9B). Such 30G and 32G disposable hypodermic needles were cut and then examined under a microscope, by using only the 3 front millimeters of the needle containing the bevel and discarding the rest of the needle. The cut segments were measured with caliper and observed under a microscope, discarding those segments which presented significant cut deformations or measured more than 3.5 or less than 2.5 mm.

Embodiment example N° 2: In order to manufacture the insertion arrangement (Shown in Figures 9A, 9B and 10), 25G disposable hypodermic needles **16** were used for containing the 32G drainage devices **50** of Example 1, while 23G disposable hypodermic needles **16** were used for containing the 30G drainage devices **50** of Example 1, $1cm^3$ syringes were cut to a length of 2.5 to 5 cm, using only the part joining them to the needles **16** and discarding the rest. Said syringe sections were used to form the body **17** of the insertion arrangement. Likewise, 12 cm sections of 0.25 mm stainless steel wire for dental use were cut to be used as distal portion **19** of the pushing plunger. These last sections **19** were threaded separately, in the 23G and 25G disposable hypodermic needles**16**, each of them with their inner cable**19** and then, the 1 ml cut syringe sections were threaded **17** with wire **19**, adjusting the disposable hypodermic needles threaded with the stainless steel section **19** to the cut syringe sections **17** in a traditional manner. The wire **19** end protruding from the syringe section **17** was inserted in the inner conduit of another long 21G disposable hypodermic needle whose bevel was removed, and was fixed by compressing said long 21G needle with a clamp, thus said long 21G needle forming the plunger rear (or proximal) section **18,** so that said long 21G needle head **24A** is the area pushed to actuate the plunger **18, 19**. The other cable or steel wire end **19** emerging from the distal end **21** of the 23G and 25G needles **16** was cut until it protruded 1 to 2 mm from the needle bevel **16** when the plunger **18**, **19** head **24A** was pushed to the maximum, thus forming the insertion arrangement.

Embodiment example N° 3: As shown in figures 9A and 9B, the drainage tubes **50** of Example 1 were inserted in the insertion arrangement needles **16** of Example 2, with the bevel facing upwards in all cases. To that purpose, the plunger **18**, **19** was retracted from these insertion devices, and the 30G and 32G drainage tubes **50** were inserted inside said 23G and 25G disposable hypodermic

needles **16**, respectively. Segments with part of their bevel folded **32,** which did not fit in the inner conduit of the injection needle **16** because of having a large burr, were discarded. In all cases, the beveled end, hereinafter the rear end **10b** of the drainage tubes, was first introduced in the inner conduit of the injection needles **16** (Figs. 9A and 9B) with the bevel facing upwards, coinciding with the bevel **21** of the injection needle end **16**, but in opposite direction, leaving the cross-section front (or distal) end **10a**, pointing at the outlet of the injection needle **16** in order to be the first part of the tube to exit the needle **16** when actuating the plunger **18**, **19**, while the beveled end or rear end **10B** of the drainage tube **50** was the last one to exit. Although in this example, the front end **10a** of the drainage tube **50**, which remains implanted in the anterior chamber **9**, was perpendicular to the axis thereof, such end must preferably have modifications in order to avoid possible obstructions of its entrance hole with the iris **5** in the anterior chamber **9** of the eye. After inserting the drainage tubes **50** in the insertion device needle **16**, the system behavior was observed under a microscope when the plunger **18 19** head **24a** was actuated to expel the drainage tube **50**, observing a greater stability inside the needle **16** in those drainage tubes **50** with a part **32** of their bevel folded (Figure 9A), while the drainage tubes **50** which did not have a folded bevel (Figure 9B) came out of the containing needle **16** when the needle was repeatedly shaken.

Embodiment example N° 4: Research was conducted on the performance of the drainage tubes **50** according to Example 1, on pig eyes and rabbit eyes with the aim of assessing the efficacy of said drainage tubes **50**. Materials and Method: 8 pig eyes and 6 rabbit eyes were used, all of which had been killed less than 24 hours earlier. Some of the pig eyes used were enucleated and others were exenterated, including in this latter case, the ocular annexes, while rabbit eyes were left in situ. 30G drainage tubes **50** of Example 1, with part of the bevel folded

32 in opposite direction to the inner conduit, (Fig. 9A) and 30G drainage tubes **50** of Example 1, with unfolded bevel (Fig. 9B), were used, all of them pre-loaded inside the 23G needles **16** of the insertion arrangements of Example 2, according to the method provided in Example 3. A Moller Wedel® Ophthalmic surgery microscope was used. The enucleated eyes were fixed with clamp systems, and since they presented some hypotonia, a 27G needle connected to a Ringer solution bottle through an IV line was introduced in the anterior chamber **9** through the sclero-corneal limbus **1a** in order to create tension in them so as to resemble the actual state. The exenterated pig eyes presented greater tension than the enucleated eyes, due to the presence of their annexes, as in the case of the rabbit eyes, which were not enucleated or exenterated. A traction suture was placed on the exenterated pig eyes and rabbit eyes to better expose the area to be incised. In some of the pig eyes, the conjunctiva **1**was dissected to access the sclera **2**, since the former was very thick and opaque, thus making it difficult to visualize the needle**16** end **21** below the conjunctiva **1** and the Tenon **1b** to incise the sclera **2** in the intended place, while the needle **16** of the insertion device used in this example was inserted transconjunctivally in the rabbit eyes, by incising the conjunctiva **1** and the Tenon **1b** far from the limbus **1a**, moving towards the cornea **3** through the subconjunctival space. By using said needle **16** in both cases (pig and rabbit eyes), a scleral **2** incision was made at a distance from the sclero-corneal limbus **1a** between 3 to 3.5 mm; then, by lowering the insertion device body **17**, and, consequently changing the inclination angle of said needle **16,** the latter was moved through the scleral thickness **2** by 1-2 mm, where again, the inclination angle of the needle **16** was changed to enter the anterior chamber **9** of the eye, in parallel to the iris plane **5**, at the iridocorneal angle. When visualizing the bevel of said insertion device needle **16** in the anterior chamber **9** of the eye, the plunger **18 19** head **24a** was pushed until the drainage tube **50** appeared in

the needle **16** bevel. Then, as said insertion device was being removed, the plunger **18**, **19** head **24a** was pushed further, until the needle **16** was completely removed, leaving the unbeveled end **10a** (distal end) of the drainage tube **50** in the anterior chamber **9** of the eye, and the beveled end (or proximal end) **10b** in the scleral thickness **2**, thus the drainage device **50** being implanted into the eye (Figure 1B). Subsequently, Ringer's solution was pressure injected in the anterior chamber **9** by using a 27G needle in those cases which were not connected to a Ringer's bag, and the cornea **3** and the sclera **2** were pressed around the incision to assess the implant **50** stability. Additionally, Fluoresceine was injected in the anterior chamber **9** to evaluate filtering through the drainage tube **50**. This procedure was repeated with the other drainage tubes **50** pre-loaded in their insertion systems in the other eyes, to assess the system and method reproducibility, and to evaluate implant **50** performance. Liquid was injected under the conjunctiva in an attempt to separate it from the underlying tenon and move forward with the needle **16** between them, but this made visualization of the sclera **2** even more difficult. Additionally, the method of this example 4 was tested, without using the surgery microscope, to evaluate the technical degree of difficulty under these conditions. Results: Implants **50** with part of the bevel unfolded (Figure 9B) showed less stability through the previously mentioned manipulation and even two of them were expelled from their implantation area; however, none of the implants **50** with folded bevel **32** was expelled, despite the scleral incision made with a 23G needle, while the external diameter of the implant **50** fitted with a 30G needle. None of the drainage devices **50** fell in the anterior chamber **9** of the eye during the implantation or during said manipulation. One of the drainage devices **50** implanted into a rabbit eye had its distal end **10a**blocked by the iris **5**, without liquid flow. This was caused because the distal end **10a** was unbeveled, and because all rabbit eyes used in this study showed a narrow to moderately

narrow iridocorneal angle, as opposed to what happened in pig eyes. It is worth remembering that all aqueous humor drainage devices must be implanted into eyes with an open iridocorneal angle. Furthermore, except in the blockage case and in the two cases of implant **50** expelling, in the rest of the cases, fluoresceine filtering was achieved through said drainage tube **50**. In some cases, visualization of the needle **16** end **21** became difficult due to the conjunctival or tenon tissue dragging, in which cases, flattening and stretching of the conjunctiva **1** and the tenon **1b** must be performed to improve their visualization. In some cases, the Tenon's membrane **1b** made it difficult to visualize said needle **16** end **21,** due to its thickness or because of being more opaque. Furthermore, the implantation method without the use of the microscope proved to be equally easy, reproducible and effective. Conclusion: The implant **50** proved to be effective to drain liquid from the anterior chamber **9** of the eye into the outside. The implantation method by means of the insertion device used, proved to be simple, short and reproducible although the viscoelastic substance was not used in the anterior chamber **9**, and despite the hardness of the tissues such as the conjunctiva **1**, the tenon **1b** and the sclera **2**, which was greater in many of the eyes used, specially in pigs, than the usual hardness observed in adult human beings who are subject to a Glaucoma surgery.

In the case of the present embodiment example N° 4, the unbeveled end was implanted in distal situation, into the anterior chamber **9**, while the beveled end of the drainage tube **50** was implanted in proximal situation to evaluate the scleral fixing effect in those cases with part of the bevel folded **32** and to compare it to those cases with unfolded bevel; however, in several preferred embodiments of the invention, the distal end **10a** implanted in the anterior chamber **9** of the eye have modifications to avoid drainage blocking.

Embodiment example N° 5: Since an important aspect of the invention method consists of locating through the conjunctiva **1** and the tenon **1b** (Figure 1A), the place intended to be incised in the sclera **2** with the insertion device needle, taking into account the existing distance to the sclero-corneal limbus **1a**, a study was conducted to evaluate the visualization of the hypodermic needles under the conjunctiva **1** and the underlying Tenon's capsule **1b** under different conditions. Purpose of the study: finding an affordable method which improves visualization of the needle or cutting element belonging to the aqueous humor insertion device, under the conjunctiva **1** and the Tenon's capsule **1b** to enable the implantation of drainage devices into the eye by means of a transconjunctival implantation method.

As previously mentioned, the conjunctiva **1** is an elastic and transparent mucous membrane attached to other underlying elastic and translucent membrane called Tenon's capsule **1b**. Therefore, in some occasions, manipulations under the conjunctiva **1**and the Tenon's capsule **1b**, do not provide good visualization. Additionally, if a subconjunctival anesthetic is injected to perform an ocular surgery, these tissues are soaked in said anesthetic, making visualization even more difficult. Furthermore, when the needle **16** is introduced under both membranes **1** and **1b** and it slides forward, it drags, by friction, and gathers tissue, thus adding another difficulty to said needle visualization. Likewise, when a gap is intended to be created between the conjunctiva **1** and the Tenon **1b** by means of liquid injection, the tissues are also soaked in this liquid, thus making visualization of the underlying sclera **2** even more difficult. Materials and method: Three 23 G needles (Needles **A**, **B** and **C**), fluorescent acrylic paint, fish eyes, and pig and rabbit eyes which had been killed less than 24 hours earlier, a standard white incandescent lamp and a UV (Ultraviolet) filtered light, commonly called black light, and a cobalt blue filtered light were used. Needle **A** was painted with a single coat

of said fluorescent acrylic paint only on the bevel inner wall, needle **B** had the outside of its body and the bevel inner wall painted by using the same technique, and needle **C** was left unpainted. None of the needles **A** and **B** was previously painted with top coat, although this was advisable to achieve a better adherence of the fluorescent paint to the stainless steel of the needle, with the aim of evaluating the adherence of the fluorescent paint under these conditions. The paint was allowed to dry for 24 hs. Subsequently, the three needles were introduced below the conjunctiva and the Tenon's capsule in the fish eyes, pig eyes and rabbit eyes. Then, the visualization of such needles was assessed when lighting with standard white incandescent light, as that in surgery microscopes, and then with UV filtered light and blue cobalt filtered light lamps. Results: Both membranes, the conjunctiva **1** and the sclera, **1b** were in most cases, thicker, more resistant and opaque than the usual for said membranes in adult human beings, and they were more similar in the case of rabbits, although, even so, in some of these last cases, the Tenon's capsule was thick. Flattening and stretching of the conjunctiva **1** and the Tenon **1b** favored visualization of the three needles (**A**, **B** and **C**). Needle **A** showed excellent paint adherence on the bevel inner wall although it had not been previously painted with top coat, while needle **B** body showed regular to poor paint adherence on the body and excellent adherence on the bevel inner wall. Lighting with UV filtered light resulted in a much higher visualization in all of the eyes in relation to the traditional white lightning, in the painted section of needles **A, B** under the conjunctiva **1** and the Tenon **1b**. Visualization of the needle end with luminescent paint was good enough under the UV filtered light so as not to require painting the needle body surface to serve as a guide. Conclusion: The needle having luminescent properties incorporated at least in its distal end enables localizing such end under the conjunctiva **1** and the Tenon's capsule **1b** when being stimulated by a suitable means, as in this case, with a UV filtered light or a

cobalt blue filtered light, in order to incise the sclera **2** at the intended distance from the sclero-corneal limbus **1a** and to make the transconjunctival implantation of the drainage device **50**, without the previous conjunctival opening, which in some cases becomes difficult when illuminating with conventional white light.

The present invention also comprises a method for the treatment of Glaucoma which comprises the following steps:

anesthetizing the patient's eye by using eye drops, optionally subconjunctival anesthesia, or subTenonian anesthesia, unpacking the insertion arrangement where the drainage device is contained in a pre-loaded manner;

implanting the drainage device **50**, by using the transconjunctival insertion device, beginning with a conjunctival incision by means of the inserter needle **16** far from the incision to be made in the underlying sclera **2** to enter the anterior chamber **9**, and advancing under the conjunctiva **1**, or the conjunctiva **1** and the Tenon **1b**, until incising in the scleral **2** thickness at a distance of 1 to 3.5 mm from the sclero-corneal limbus **1a**, to subsequently enter the anterior chamber **9** of the eye, in parallel to the iris, by using a method which does not require the previous opening of the conjunctiva **1**, thus, providing the possibility of not requiring the closure of the conjunctival wound with sutures, cauterization or adhesives; and

where at least a portion of the drainage device **50** is implanted in the scleral hole **2** of the eye created by the insertion device needle **16**, thus allowing the aqueous humor drainage from the anterior chamber **9** of the eye into the subconjunctival space.

As previously mentioned, although embodiment examples of the present invention have been described and shown, desirable and preferred modifications may be made. Therefore, the purpose of the claims section is to cover all those changes and modifications which are within the true spirit and scope of the present

invention.

REFERENCES:

- GLAUKOS; web: http://www.glaukos.com/istent.

- Karmel M (2004) quoted by Chaudhry et al, 2012. Filtering surgery takes a new direction: Will it revolutionize the field? Eye Net; 8:33-36.

- Lim K S, Allan B D S, Lloyd A W, Muir A, Khaw P T; Glaucoma drainage devices; past, present, and future; Br J Ophthalmol 1998;82:1083-1089 doi:10.1136/bjo.82.9.1083.

-Parul Ichhpujani and Marlene R. Moster (2011). Novel Glaucoma Surgical Devices, Glaucoma - Basic and Clinical Concepts, Dr. Shimon Rumelt (Ed.), ISBN: 978-953-307-591-4, InTech, DOI: 10.5772/23554. Available from: http://www.intechopen.com/books/glaucoma-basic-and-clinical-concepts/novel-glaucoma-surgical-devices.

-Prata JA Jr, Minckler DS, Green RL (1993). Pseudo-Brown's syndrome as a complication of glaucoma drainage implant surgery. Ophthalmic Surg; 24(9):608-11).

-Quigley HA, Broman AT, The number of people with glaucoma worldwide in 2010 and 2020; Br J Ophthalmol. 2006 Mar; 90(3):262-7.

-Singh Parul, Kuldeep Krishna, Tyagi Manoj, Sharma Parmeshwari D, Kumar Yogesh. Glaucoma drainage devices. Journal of Clinical Ophthalmology and Research - May-Aug 2013 - Volume 1 - Issue 2.

-Thomas R, Braganza A, Chandrasekhar G, Honavar S, Mandal A K, Ramakrishnan R, Rao B S, Sihota R, Sood N N, Shantha B, Vijaya L. The role of artificial drainage devices in glaucoma surgery. Indian J Ophthalmol 1998;46: 41-6.

- Tucker Miriam E., 10/03/2014 Ex-PRESS Shunt 3-Year Outcomes Don't Top Trabeculectomy American Glaucoma Society (AGS) 24th Annual Meeting: Abstract 5, presented February 27, 2014; abstract 29, presented March 1, 2014.

- Wamsley S, Moster MR, Rai S, Alvim HS, Fontanarosa J. Results of the use of the Ex-PRESS miniature glaucoma implant in technically challenging, advanced glaucoma cases: a clinical pilot study. Am J Ophthalmol. 2004 Dec;138(6):1049-51.

- Vera V, Horvath C, XEN Gel Stent: The Solution Designed by AqueSys®, Surgical Innovations in Glaucoma, Part V, pp 189-198, DOI: 10.1007/978-1-4614-8348-9_17, print ISBN: 978-1-4614-8347-2, online ISBN: 978-1-4614-8348-9, 2014.

RELATED PATENTS

-US 4.457.757 A; 3/07/1984; Anthony C. B. Molteno; Device for draining aqueous humour.

-US 4.634.418 A; Perry S. Binder; 06/01/1987; Treating uncontrolled glaucoma; a conduit for fluid migration; surgical implant.

-US 4.750.901 A; 14/06/1988; Molteno Anthony C B; Implant for drainage of aqueous humour

-US 4.936.825 A; 26/06/1990; Bruce A. Ungerleider; Method for reducing intraocular pressure caused by glaucoma.

-US 4.968.296 A; 06/11/1990; Robert Ritch, Edward E. Klein; Transscleral drainage implant device for the treatment of glaucoma.

-US 5.372.577 A; α; β/12/1994; Bruce A. Ungerleider; Apparatus for reducing intraocular pressure.

- US 5.397.300 A; 14/03/1995; George Baerveldt, Larry W. Blake, George

M. Wright; Glaucoma Implant.

-US 5.454.796 A; 03/10/1995; Theodore Krupin; Device and method for controlling intraocular fluid pressure.

-US 5.882.327 A; 16/03/1999; Jean T. Jacob; Long-term glaucoma drainage implant.

-US 6.007.511 A; 28/12/1999; Arnold S. Prywes; Shunt valve and therapeutic delivery system for treatment of glaucoma and methods and apparatus for its installation.

-US 6.050.970A; 18/04/2000; George Baerveldt; Method and apparatus for inserting a glaucoma implant in an anterior and posterior segment of the eye.-US 6.450.984 B1, Sept 17/2002. Mary G Lynch, Shunt device and method for treating glaucoma.

-US 6.468.283 B1; 22/10/2002; Richter Jacob, Gregory Pinchasik, Ira Yaron; Method of regulating pressure with an intraocular implant.

-US 6.589.203 B1; 08/07/2003; Peter Mitrev; Glaucoma drainage device implant.

-US 6.595.945 B2; 09/01/2001; J. David Brown; Glaucoma treatment device and method.

-US 6.638.239 B1; 28/10/2003; Olav B. Bergheim, Morteza (Mory) Gharib; Apparatus and method for treating glaucoma.

-US 6.699.210 B2; 02/03/2004; Stuart K. Williams, Robert Snyder; Glaucoma shunt and a method of making and surgically implanting the same.

-US 6.780.164 B2; 24/08/2004; Olav B. Bergheim, Morteza (Mory) Gharib; L-shaped implant with bi-directional flow.

-WO 2004073564; 02/09/2004; J David Brown, Tingrui Pan, Babak Ziaie;

Bypass for glaucoma drainage device.

-US 7.291.125 B2; Minas Theodore Coroneo; 16/11/2007; Ocular pressure regulation.

-US 7.160.264 B2; 09/01/2007; James R. Lisk, Jr., James E. Memmen, Scott M. Hampton, Robert E. Nordquist, Philip Vincent Robledo, Ming-Kok Tai; Article and method for ocular aqueous drainage.

-US 7.431.709 B2; 07/10/2008 ; Leonard Pinchuk, Jean-Marie Parel, Francisco Fantes, Saul Gottlieb, John B. Martin, Jr., Yasushi Pedro Kato, ; Glaucoma implant device.

-US 7.815.592 B2; 19/10/2010; Coroneo Minas T; Ocular pressure regulation.

-WO 2011106781; 01/09/2011; Amy Lee Hammack, Paul S. Gollnick, Stanley R. Conston; Apparatus for enhancement of aqueous humor drainage from the eye.

-US 8.128.588 B2; 06/03/2012; Coroneo Minas T; Ocular pressure regulation.

-US 8.337.509 B2; 25/12/2012; Andrew T. Schieber, John L Wardle, Edward Matthees, Charles L. Euteneuer; Methods and apparatus for delivering ocular implants into the eye.

-US 8.545.431 B2; 01/10/2013; Matthew J. A. Rickard; Conducto interior clearing valve for Glaucoma drainage device.

-US 8,372,026 B2; 12/02/2013; Andrew T. Schieber, Charles L. Euteneuer; Ocular Implant Architectures.

-US 8.628.492 B2; 14/01/2014; Jeffrey Chun-Hui Lin, Po-Jui Chen, Yu-Chong Tai, Damien Craig Rodger; Implantable glaucoma drainage device.

-US 8.721.656 B2; 13/05/2014; Eugene de Juan, Jr., Stephen Boyd, Mark E. Deem, Hanson S. Gifford, III, Dan Rosenman; Glaucoma treatment device.

-US 20020133168 A1, 19/09/2002; Gregory Smedley, Morteza Gharib, Hosheng Tu; Applicator and methods for placing a trabecular shunt for glaucoma treatment.

-US 20040236343 A1; 25/11/2004; Dana Cote, Edwin Lee, Timothy Morrill, Margaret Mulhern, Jon Taylor; Insertion tool for ocular implant and method for using same.

-US 20070293872 A1; 20/12/2007; Gholam A. Peyman; Ocular Drainage Device.

-US 20120323159 A1; 20/12/2012; John Wardle, Andrew T. Schieber, Kenneth M. Galt; Ocular Implants for Delivery Into the Eye.

-US 20130184631 A1; 18/07/2013; Leonard Pinchuk; Method, Surgical Kit and Device for Treating Glaucoma.

- US20130338564 A1; 19/12/2013; Matthew A. Rickard, Leslie A. Field, Sebastian Bohm; Glaucoma drainage devices including vario-stable valves and associated systems and methods.

WHAT WE CLAIM

1. A kit used for the treatment of Glaucoma, comprising:

an aqueous humor drainage device (50);

an insertion arrangement that has a hollow needle (16) within which said drainage device (50) is inserted and is located in a preloaded manner for its subsequent implantation into the eye;

the kit allowing the transconjunctival implantation of said drainage device (50) by using said insertion device, without requiring the previous opening of said conjunctiva (1), and thus providing the possibility of not requiring the closure of the conjunctival wound by sutures, cauterization or adhesives; wherein said kit is able to carry out said implantation method without the use of a surgical microscope; and

wherein at least one portion of said drainage device (50) is implanted into the hole in the sclera (2) of the eye, created by said insertion device needle (16), its distal (or front) end (10a) is implanted into the anterior chamber (9) of the eye and, therefore, its proximal (or rear) end (10b) is implanted in the opposite direction, outwards from the anterior chamber (9), thus allowing the aqueous humor drainage from the anterior chamber (9) of the eye into the subconjunctival space.

2. An aqueous humor drainage device (50) comprised within the kit according to claim 1, comprising:

a tube-like body (11) with an inner lumen (or inner conduit), that defines an outer diameter and an inner diameter;

two opposite ends (10a, 10b), each of them having at least one hole (15) that connects said drainage tube (50) lumen to the outside.

3. The aqueous humor drainage device (50) according to claim 2,

wherein said drainage device (50) has a tube-like shape in its entirety.

4. The aqueous humor drainage device (50) according to claim 2, wherein said drainage device (50) has a fixing means selected from the group that consists of:

at least a pair of side opposite flaps (13d), an open-angle gap of at least a portion of the opposite walls (12,12a,12b,13,13a,13c) belonging to said drainage device, folding (10c) of the distal end (10a), tabs (13b), burrs, roughness of the outer surface, tabs, hooks or a combination thereof, and

wherein said fixing means may additionally have several shapes and inclination angles, and a length from 0.2 mm to 1.5 mm from said drainage device (50) body (11); and

wherein said fixing means, have such a flexibility that allows for the insertion and sliding of said drainage device (50) into said insertion arrangement needle (16), aligning themselves with said drainage device (50) body (11) and returning, at least partially, to said original angle when exiting said needle (16).

5. The aqueous humor drainage device (50) according to any of claims 2 – 4, further comprising a finish of any of its ends, selected from the group consisting of: straight angled to the tube axis, beveled, flattened, tilted down (10c) plus an upper bevel, trumpet shaped, pointed, fish mouth-shaped, with an extension of said distal end (10a) lower wall capable of preventing possible aqueous flow blocking by the iris, flower-shaped, lateral and opposing walls of the tips bent backwards like hooks on one or both extremes or a combination thereof .

6. The aqueous humor drainage device (50) according to any of claims 2 – 5, wherein the constituting material comprises any of the options selected from the group consisting of: stainless steel, titanium, nickel-titanium alloys, synthetic biopolymers, as well as copolymers, biocompatible ceramic materials, or a combination thereof.

7. The aqueous humor drainage device (50) according to any of claims 2 – 5, wherein the constituting material comprises any of the following options: Carbothane®, Pellethane®, Tecoflex®, Tecophilic®, Tecoplast®, Tecothane®.

8. The aqueous humor drainage device (50) according to claim 3, composed of a biopolymer material, which is hydrated and swells in contact with liquid, thus facilitating the anchoring to the eye when implanted, and allowing the passage of liquid from one end to the other.

9. The aqueous humor drainage device (50) according to claim 1, comprising:

a cylinder shaped body, made out of a porous biopolymer material with no inner conduit, and wherein said drainage device (50) is hydrated and swells in contact with liquid, and allows the passage of liquid from one end to the other, and where the anchoring system to the eye comprises the compression of the body (11) of the drainage device (50) carried out by the sclera, along the scleral hole created by the insertion needle (16) where it is preloaded.

10. The aqueous humor drainage device (50) according to any of claims 2 – 9, comprising:

a total length from 2 mm to 8.5 mm; an outer diameter of said drainage (50) device body (11) from 0.127 mm to 0.5 mm; and an inner diameter of said drainage (50) device body (11) from 0.05 mm to 0.35 mm.

11. The aqueous humor drainage device (50) according to any of claims 2 – 9, comprising a total length from 2.5mm to 3.5 mm; an outer diameter of said drainage tube (50) body (11) from 0.127 mm to 0.31 mm; and an inner diameter of said drainage tube (50) body (11) from 0.05 mm to 0.152 mm.

12. An insertion arrangement comprised in the kit according to claim 1,

comprising:

a) said hollow needle (16), capable of containing said drainage device (50) inside and incise the conjunctiva (1) the Tenon (1b) and the sclera (2) in order to insert said aqueous humor drainage device (50) into the eye;

b) a body (17) with an inner conduit, wherein the latter connects by its distal end to and meets the inner conduit of said hollow needle (16), wherein the latter connects to the outside by its distal end (21);

c) a pushing means that has: a distal portion (19) capable of sliding into said hollow needle (16) inner conduit and another proximal portion (18) capable of sliding into said insertion arrangement body (17); and

d) an actuating arrangement (24a, 24b, 34) which actuates said pushing means (18, 19) to implant said drainage device (50) into the eye.

13. The insertion arrangement according to claim 12, wherein said insertion arrangement needle (16) includes luminescent properties at least in said distal end (21), which facilitates visualization under the conjunctiva and Tenon's capsule when stimulated by a source capable of producing said luminescence phenomenon, thus facilitating to locate the place wherein the sclera is to be incised to access the anterior chamber of the eye.

14. A method for treating Glaucoma carried by means of the kit according to claim 1, comprising the following steps:

anesthetizing the patient's eye by using eye drops, optionally subconjunctival anesthesia or subTenonian anesthesia, unpacking the insertion arrangement wherein the drainage device is contained in a pre-loaded manner;

implanting the drainage device (50), by using the transconjunctival insertion device, beginning with a conjunctival incision by means of the inserter needle (16) belonging to the kit of the invention, far from the incision to be made in the underlying sclera (2) to enter the anterior chamber (9), and advancing under the

conjunctiva (1), or the conjunctiva (1) and the Tenon (1b), until incising in the scleral (2) thickness at a distance of 1 to 3.5 mm from the sclero-corneal limbus (1a), to subsequently enter the anterior chamber (9) of the eye, in parallel to the iris (5), by using a method which does not require the previous opening of the conjunctiva (1), thus providing the possibility of not requiring the closure of the conjunctival wound with sutures, cauterization or adhesives; and

wherein at least a portion of the drainage device (50) is implanted into the scleral hole (2) of the eye created by the insertion device needle (16), thus allowing the aqueous humor drainage from the anterior chamber (9) of the eye into the subconjunctival space.

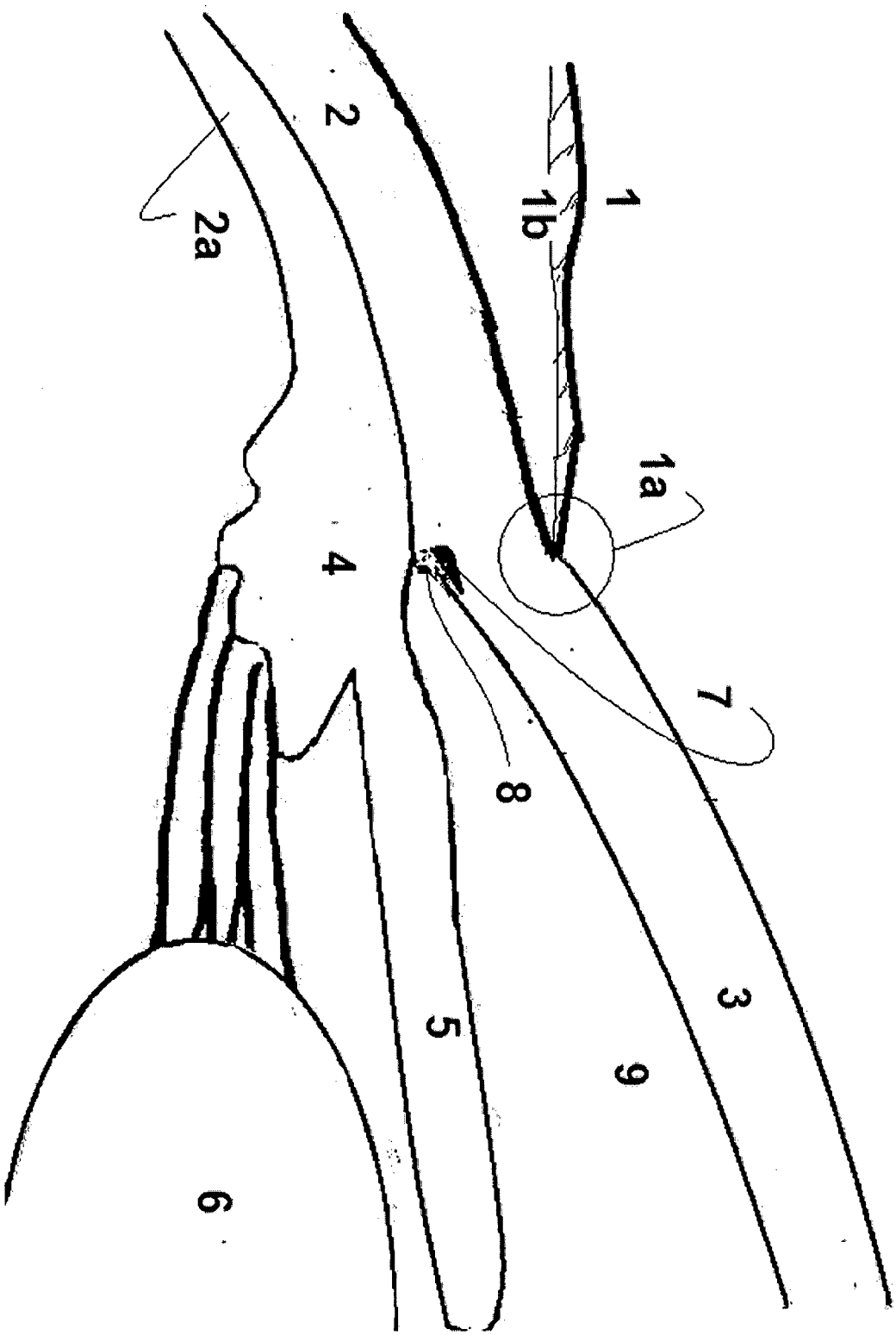


FIG. 1A

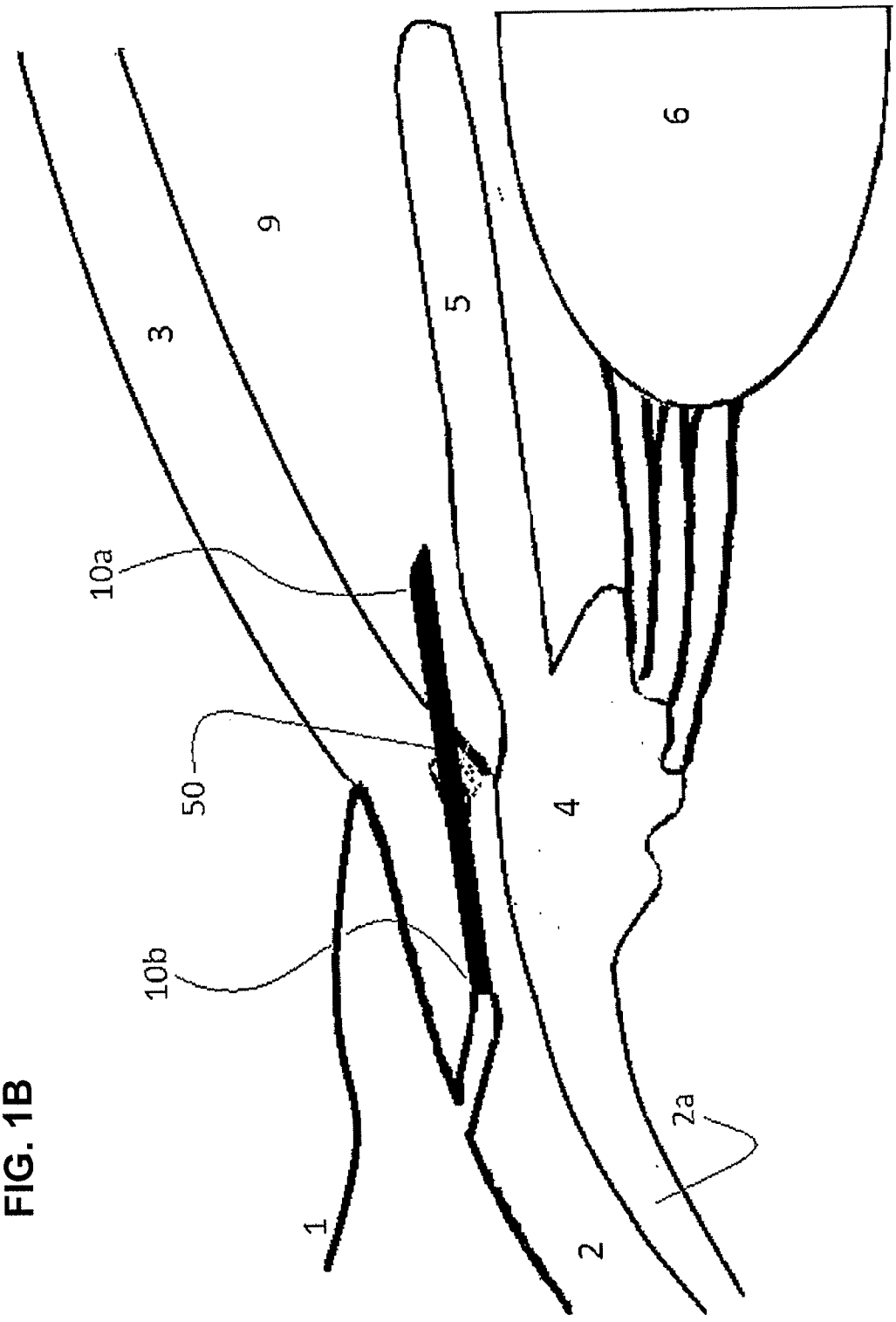


FIG. 1B

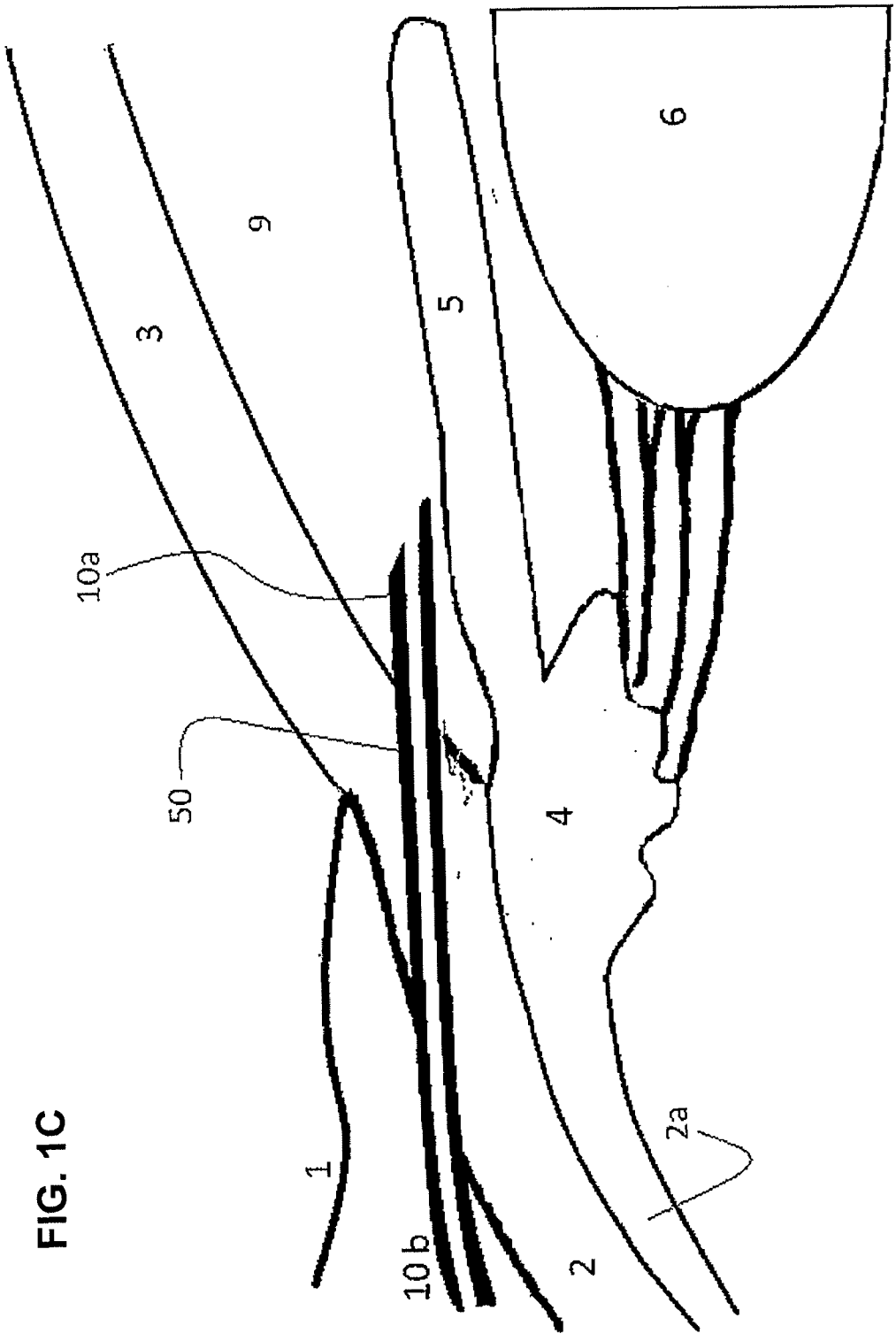


FIG. 1C

FIG. 2B

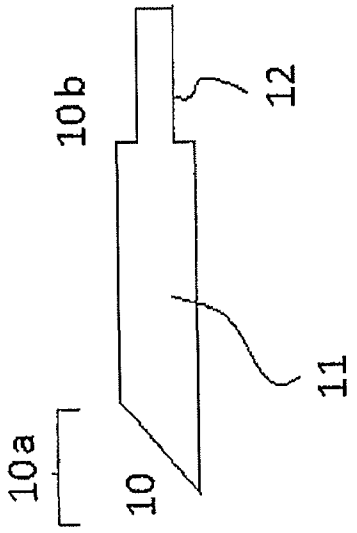


FIG. 2A

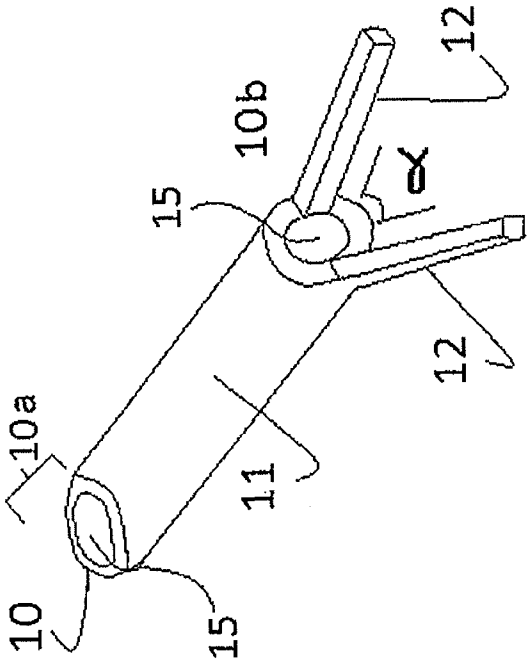


FIG. 3B

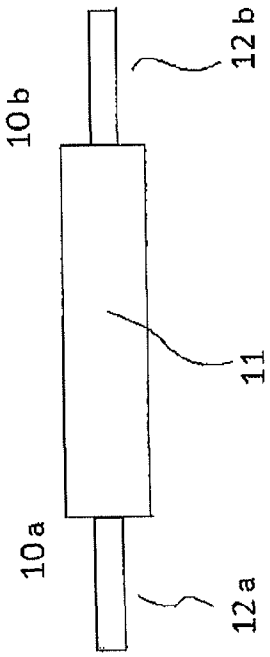
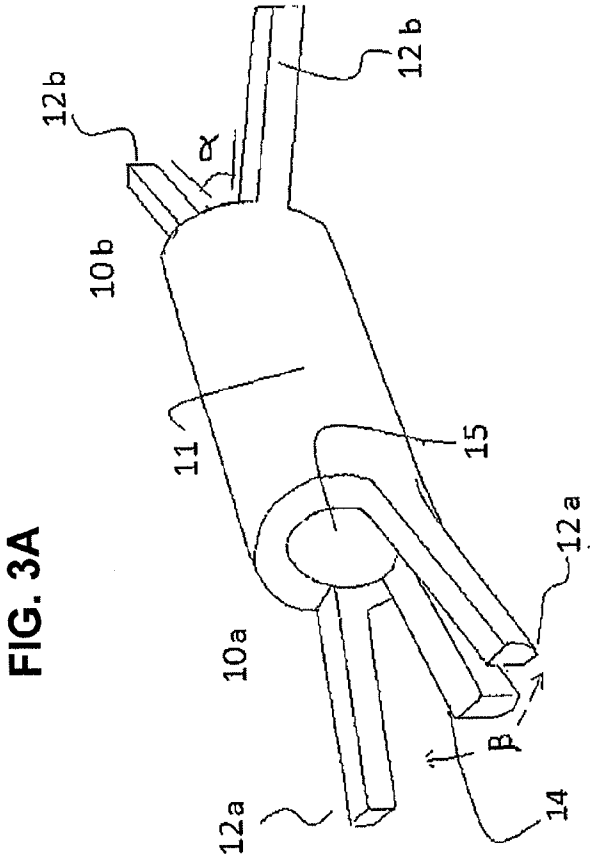


FIG. 3A



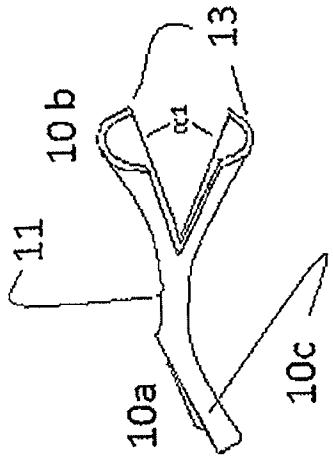


FIG. 3G

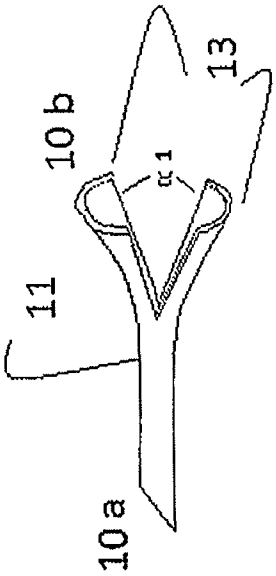


FIG. 3C

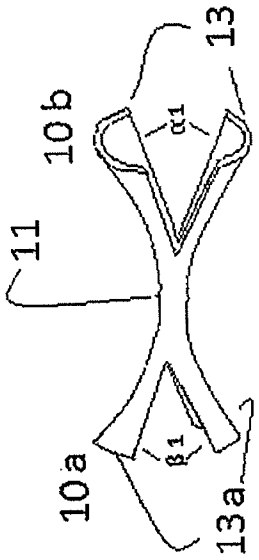


FIG. 3F

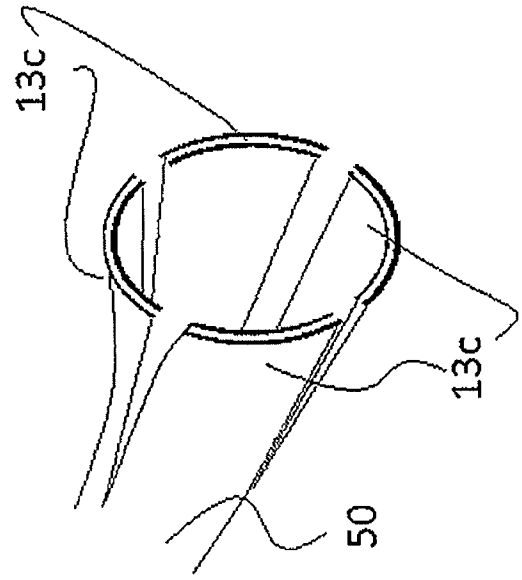


FIG. 3D

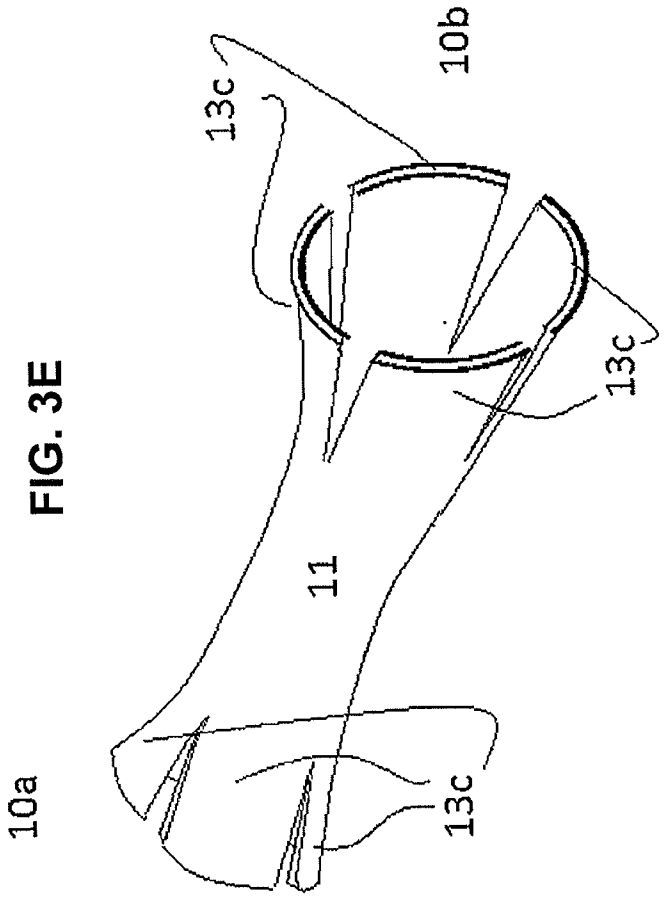


FIG. 3E

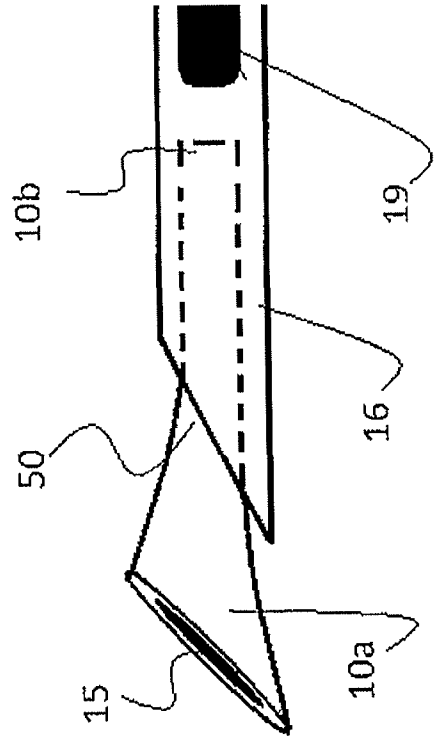


FIG. 3H

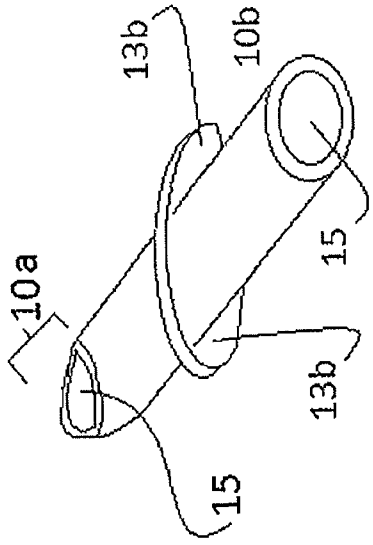


FIG. 3I

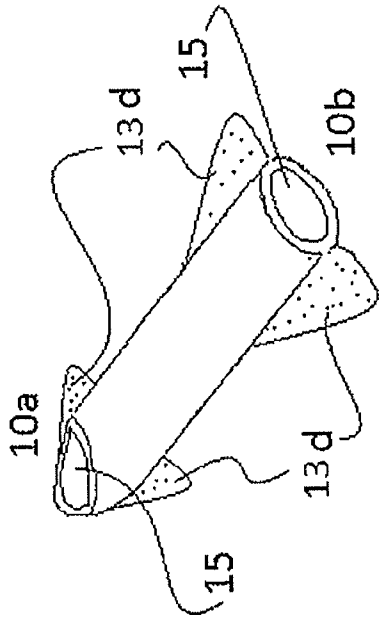


FIG. 3J

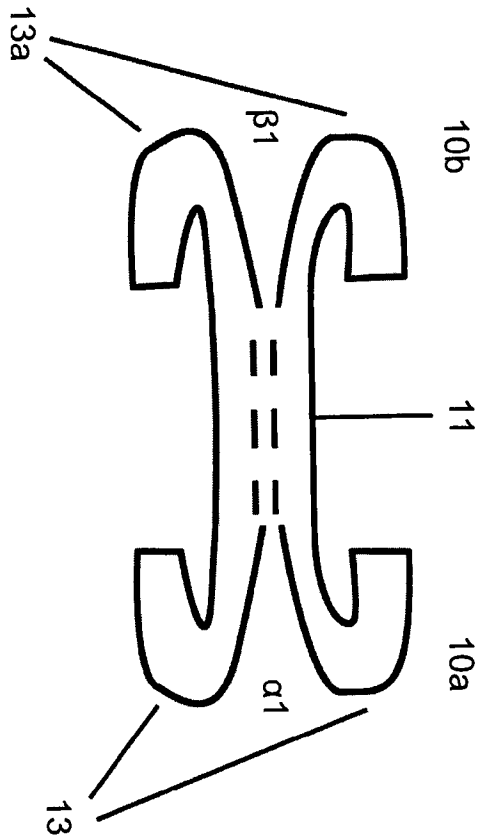
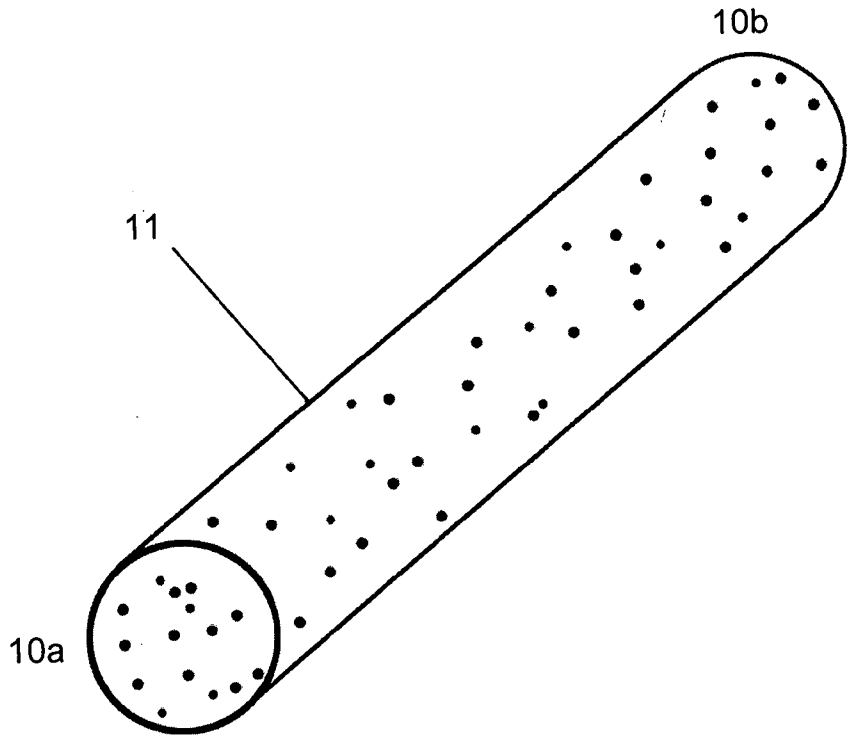


FIG. 3K

FIG. 3L



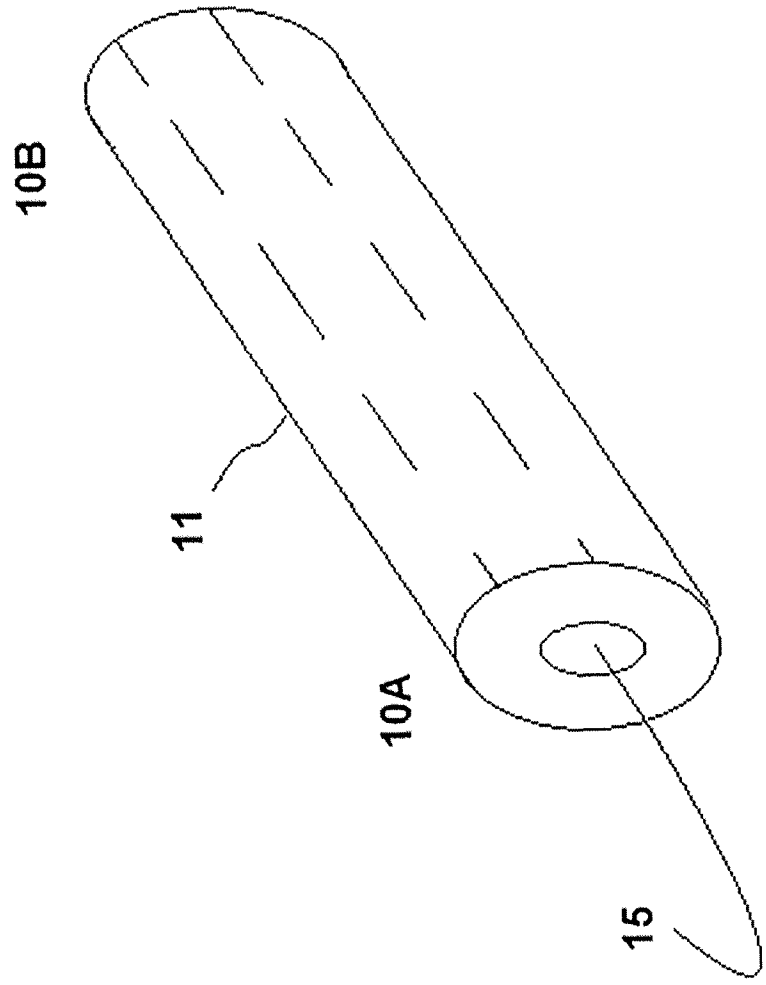
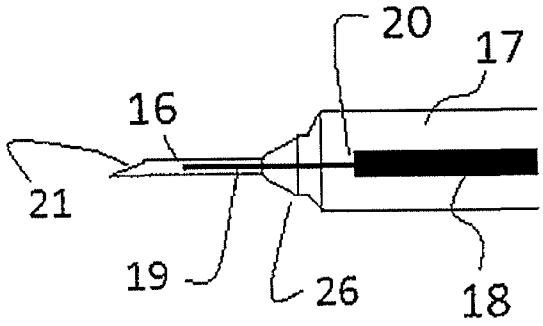


FIG. 3M

FIG. 4



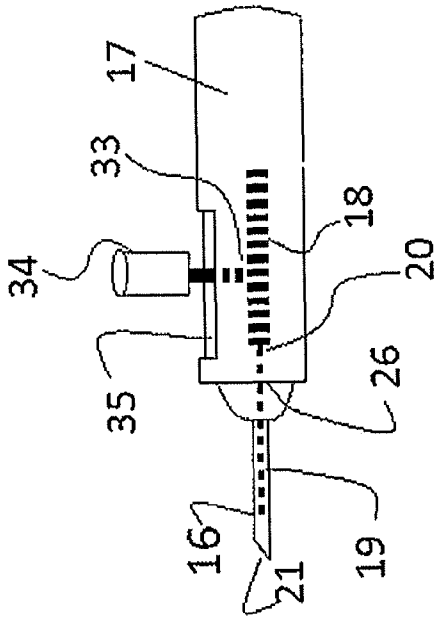


FIG. 4A

FIG. 5

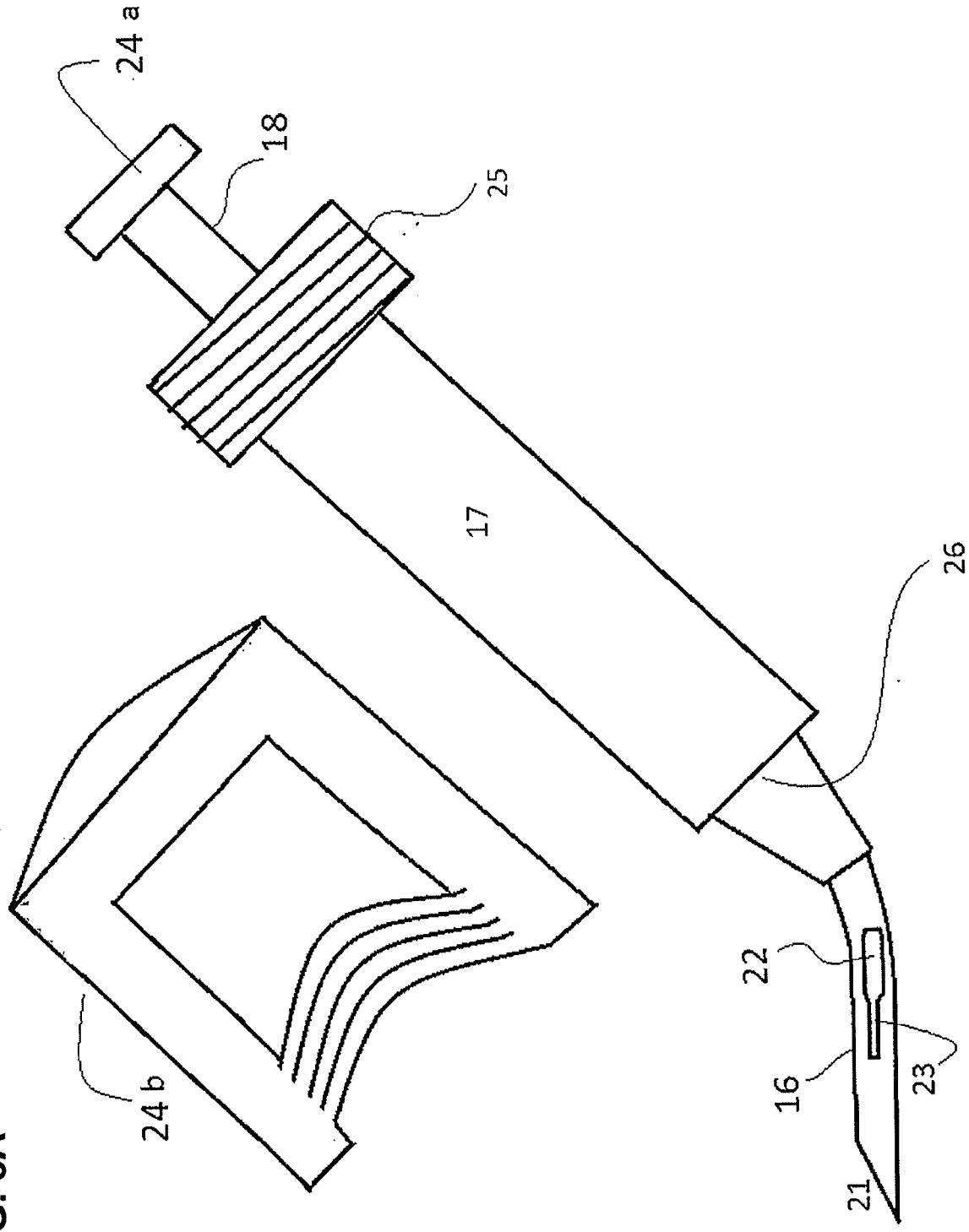


FIG. 5A

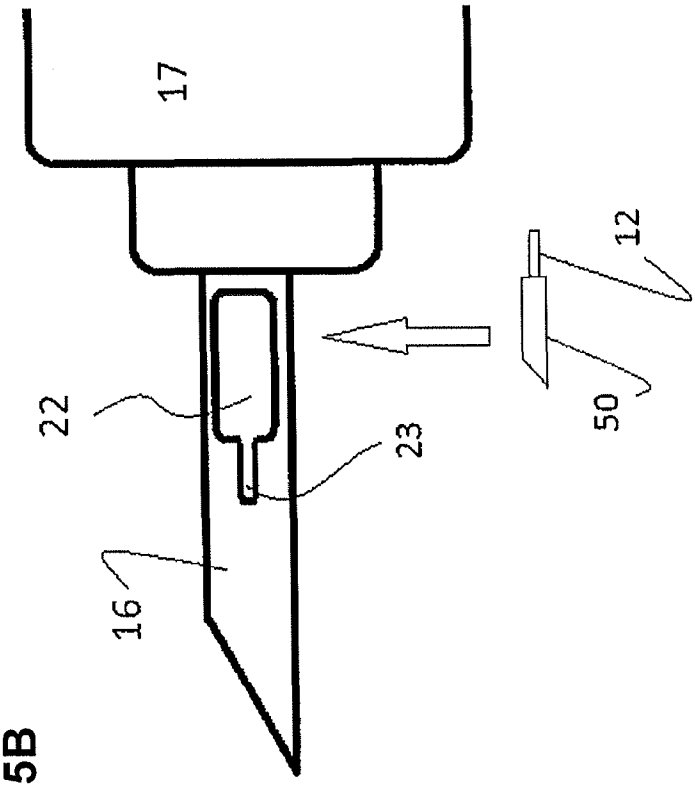


FIG. 5B

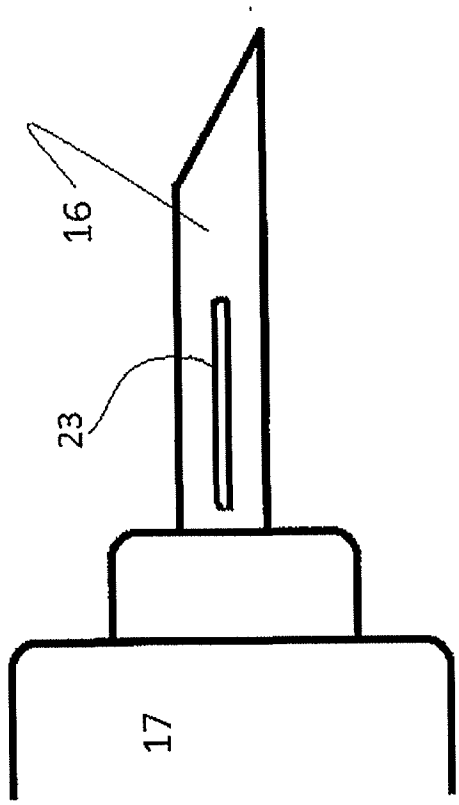


FIG. 5C

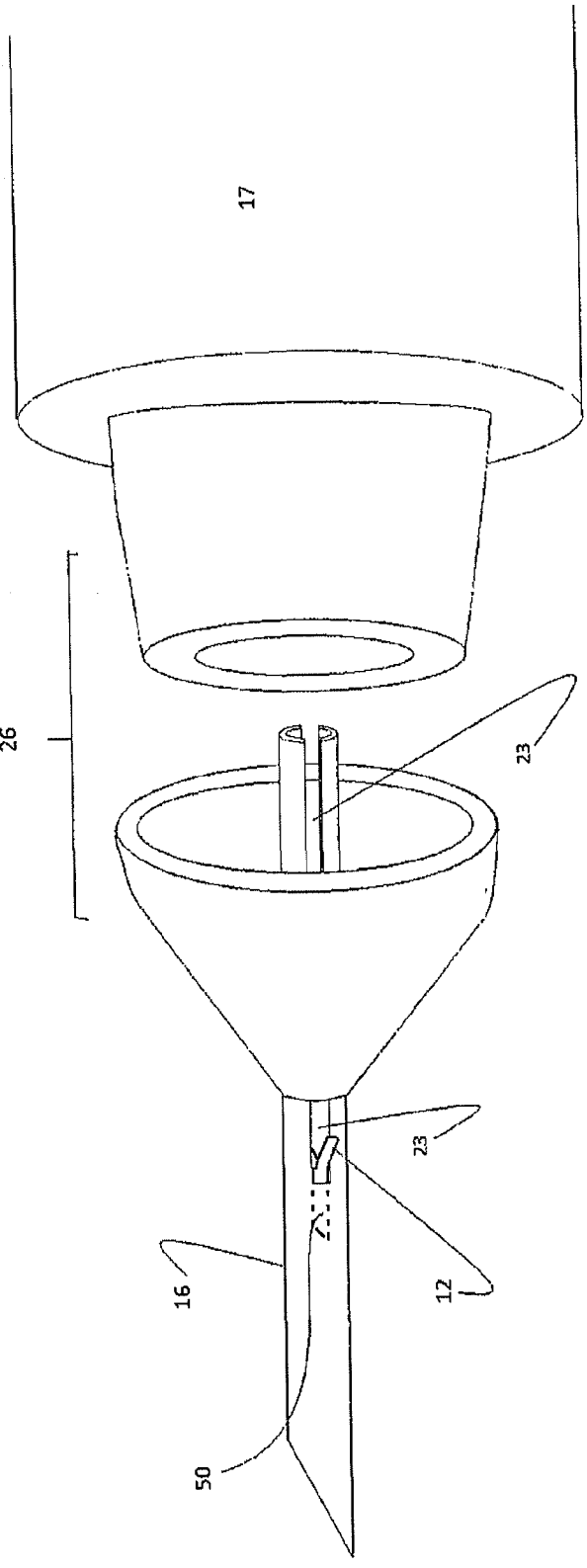


FIG. 5D

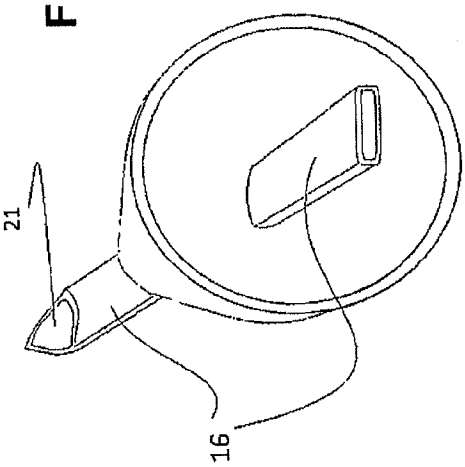


FIG. 5G

FIG. 5F

FIG. 5E

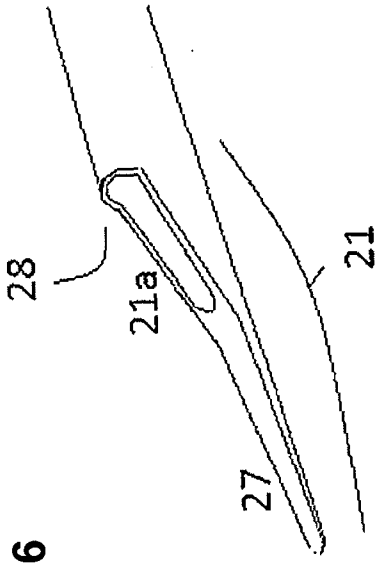


FIG. 6

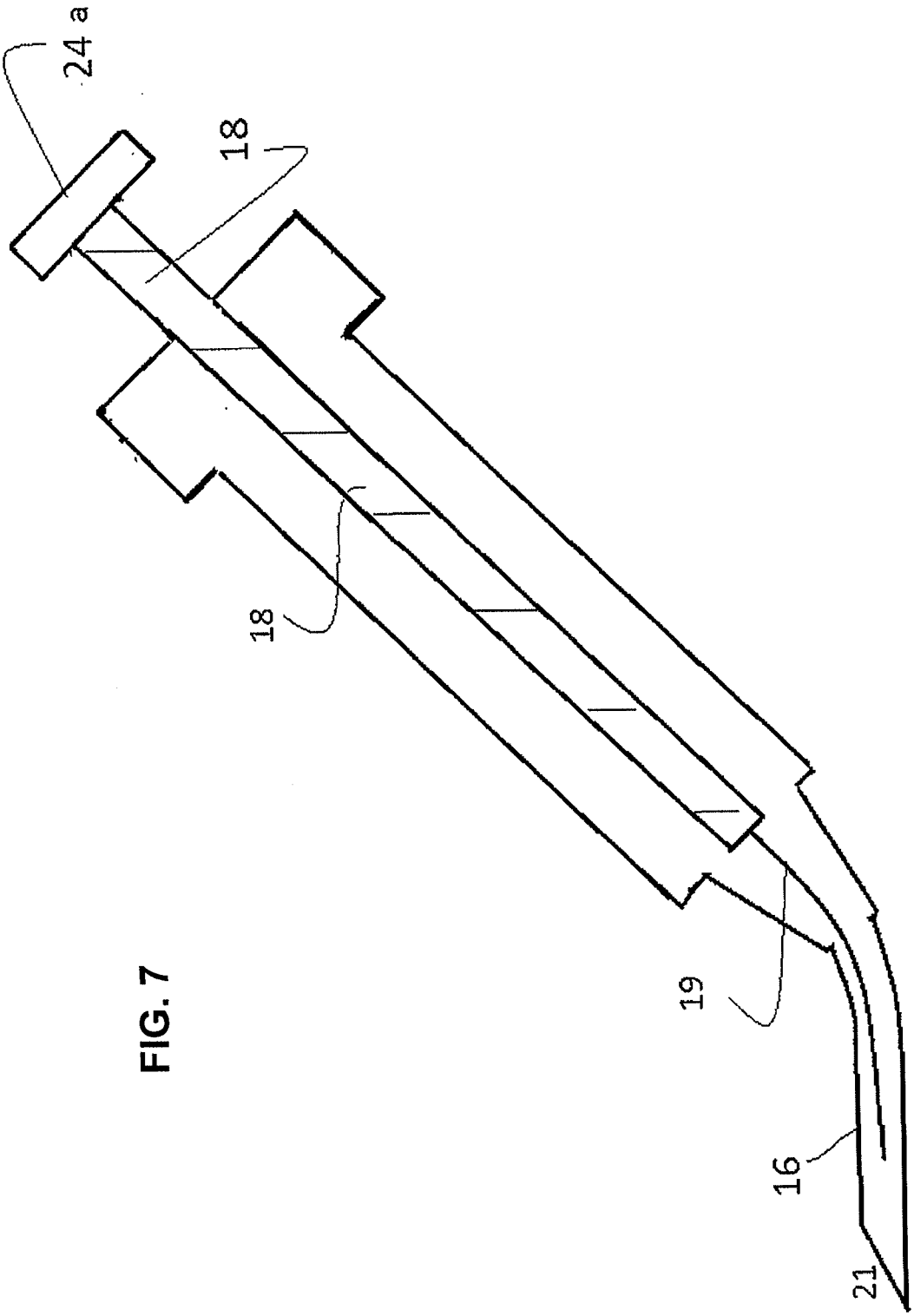


FIG. 7

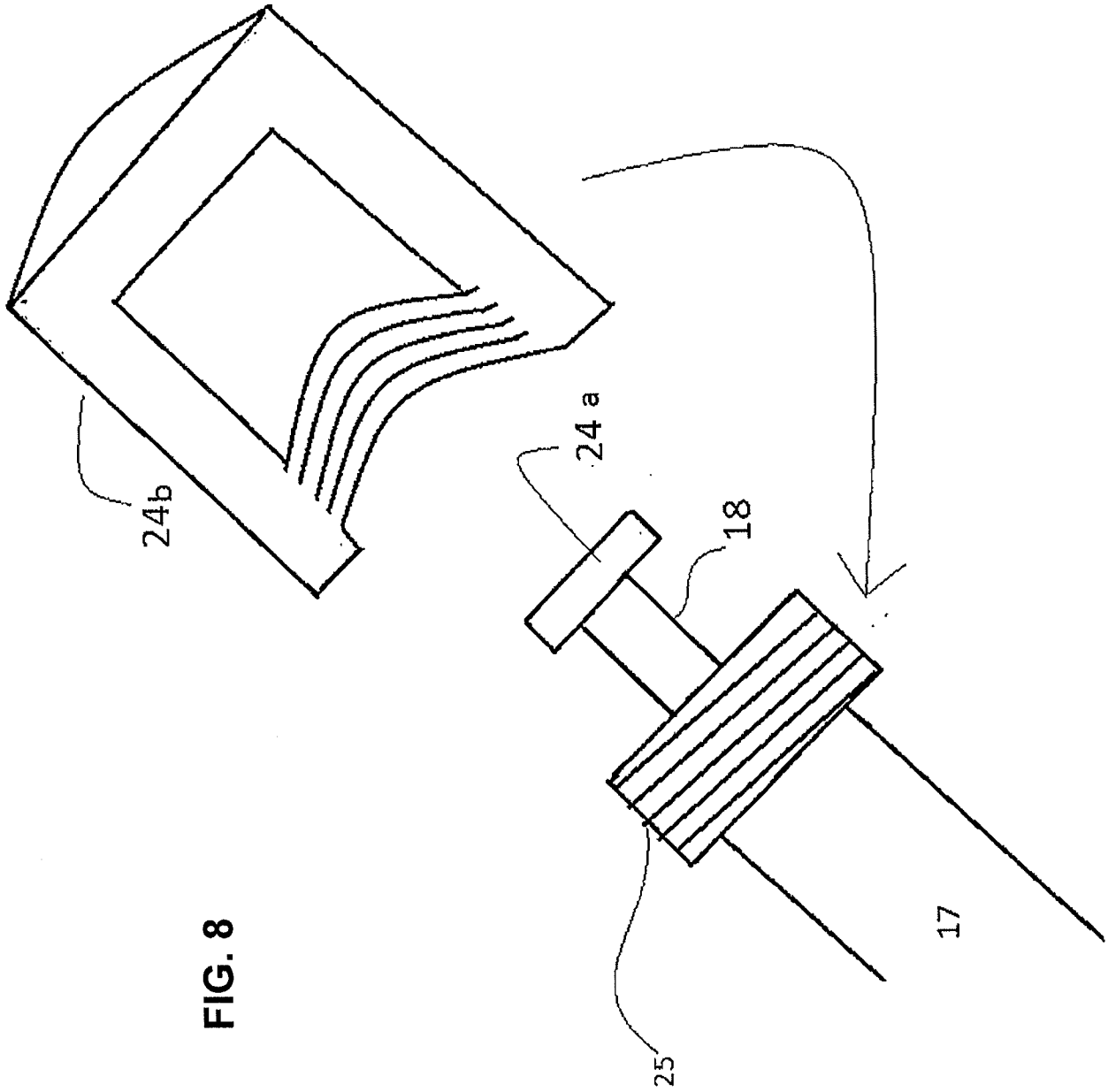


FIG. 8

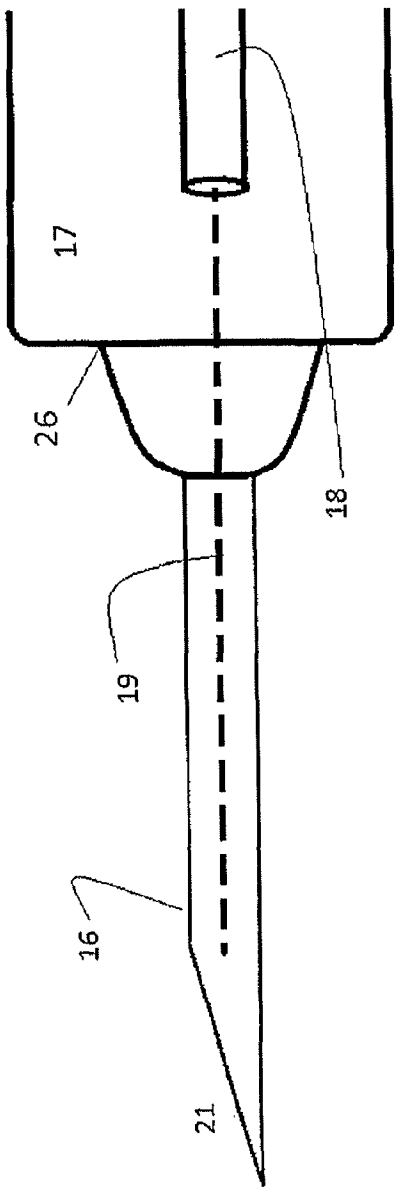
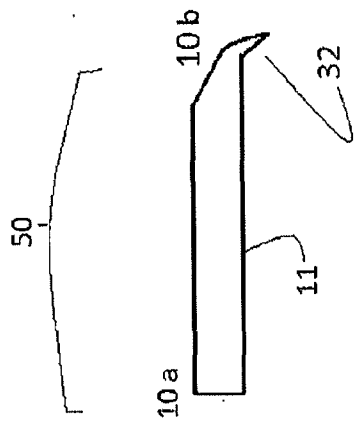


FIG. 9A



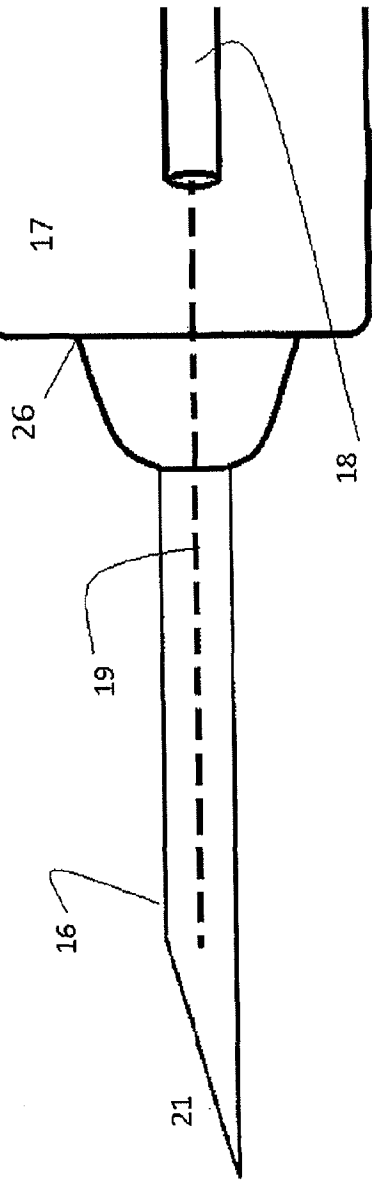
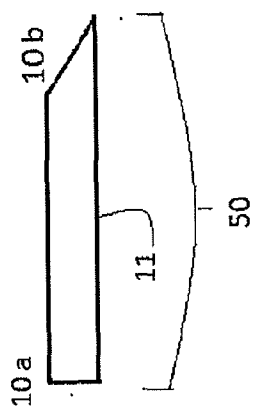


FIG. 9B



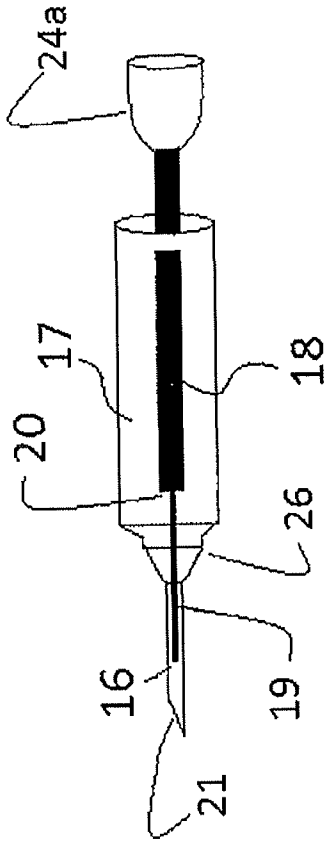


FIG. 10

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/068532

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F9/007
ADD.

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)
A61F

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)
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	US 8 721 656 B2 (DE JUAN EUGENE JR [US] ET AL) 13 May 2014 (2014-05-13) cited in the application	1-6,8, 10-12
Y	column 7, line 41 - column 32, line 35; figures 1-63	7,9,13

X	US 2010/057055 A1 (CAMRAS CARL B [US] ET AL) 4 March 2010 (2010-03-04) paragraph [0036] - paragraph [0055] paragraph [0065] - paragraph [0067]; figures 1-12,17,18	1-6,12

X	US 4 968 296 A (RITCH ROBERT [US] ET AL) 6 November 1990 (1990-11-06) cited in the application column 3, line 19 - column 7, line 10; figures 1-4D	1-6,12

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

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 November 2015	24/11/2015

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Lega, A

2

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2015/068532

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2013/069018 A2 (OPR GROUP LTD; PENHASI ADEL [IL]) 16 May 2013 (2013-05-16) page 34, line 1 - line 11 page 50, line 11 - page 51, line 27 claim 1	7,9
Y	US 2012/197176 A1 (BADAWI DAVID Y [US] ET AL) 2 August 2012 (2012-08-02) paragraph [0010] paragraph [0017]	13
A	US 5 743 868 A (BROWN REAY H [US] ET AL) 28 April 1998 (1998-04-28) the whole document	1

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2015/068532

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 8721656 B2	13-05-2014	AU 2006336598 A1	02-08-2007
		CA 2637656 A1	02-08-2007
		CN 101360523 A	04-02-2009
		CN 103284833 A	11-09-2013
		EP 1979023 A2	15-10-2008
		EP 2526910 A1	28-11-2012
		JP 5581351 B2	27-08-2014
		JP 2009523540 A	25-06-2009
		JP 2012125606 A	05-07-2012
		US 2007191863 A1	16-08-2007
		US 2010010416 A1	14-01-2010
		US 2011028883 A1	03-02-2011
		US 2011098629 A1	28-04-2011
		US 2011306915 A1	15-12-2011
		US 2014378886 A1	25-12-2014
		US 2015238360 A1	27-08-2015
		WO 2007087061 A2	02-08-2007
US 2010057055 A1	04-03-2010	NONE	
US 4968296 A	06-11-1990	BR 9007938 A	24-11-1992
		CA 2071947 A1	21-06-1991
		EP 0506849 A1	07-10-1992
		JP H05502811 A	20-05-1993
		US 4968296 A	06-11-1990
		WO 9108784 A1	27-06-1991
WO 2013069018 A2	16-05-2013	US 2014343476 A1	20-11-2014
		WO 2013069018 A2	16-05-2013
US 2012197176 A1	02-08-2012	EP 2034937 A1	18-03-2009
		EP 2338445 A1	29-06-2011
		ES 2391307 T3	23-11-2012
		JP 5520600 B2	11-06-2014
		JP 2009541005 A	26-11-2009
		JP 2013017836 A	31-01-2013
		JP 2014198268 A	23-10-2014
		US 2007298068 A1	27-12-2007
		US 2010191329 A1	29-07-2010
		US 2011130831 A1	02-06-2011
		US 2012197176 A1	02-08-2012
		WO 2008002377 A1	03-01-2008
US 5743868 A	28-04-1998	NONE	