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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
29 March 2018 (29.03.2018)

WIPO | PCT

(10) International Publication Number
WO 2018/055431 A1

(51) International Patent Classification:
A61F 9/007 (2006.01) *A61F 9/008* (2006.01)
A61B 18/20 (2006.01) *A61B 17/3209* (2006.01)

(21) International Application Number:
PCT/IB2016/001797

(22) International Filing Date:
21 December 2016 (21.12.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/396,888 20 September 2016 (20.09.2016) US
15/385,882 21 December 2016 (21.12.2016) US

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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, DJ, 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, KH, KN, KP, KR, KW, 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,

(54) Title: SURGERY DEVICE

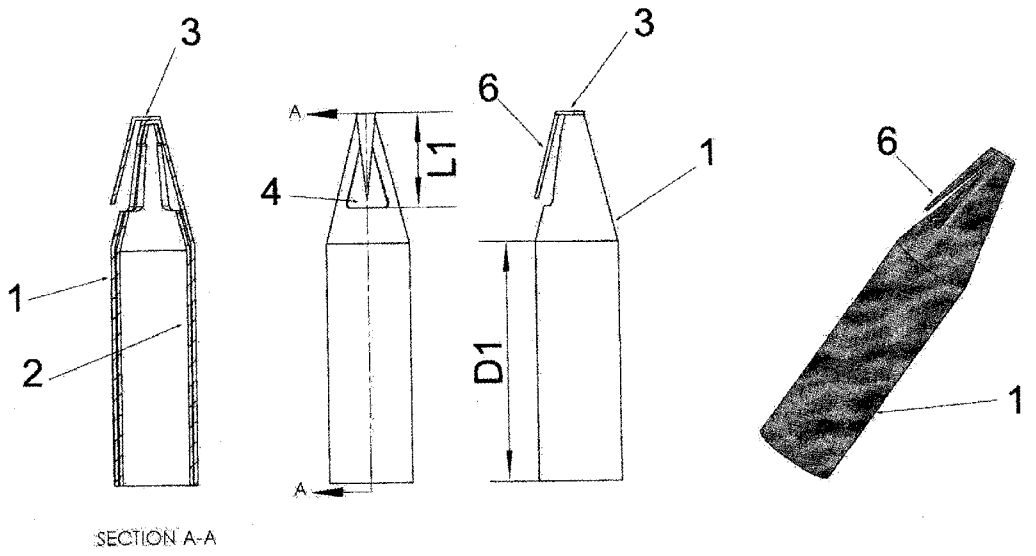

FIG. 1

(57) Abstract: The invention relates to a device for surgery used in microsurgery (eye surgery, glaucoma surgery, vitreo-retinal surgery, neurosurgery, plastic surgery, ENT, and / or other surgical fields), in laparoscopic surgery, endoscopic surgery, general surgery, gynecology, orthopedic and / or other human and/or animal surgical fields, more exactly to a device for cutting, suction, endo- illumination, endo-coagulation. This device can coagulate and/or remove by cutting and/or suction parts and/or tissues of the eye globe, but which can also be used for removing other parts and/or tissues of the body, with the possibility of visualizing through a fiber optic visioning system that can project images on a screen. The surgery device consists of two metal tubes of cylindrical shape, one outer tube (1) and one inner tube (2). that are arranged concentrically with respect to one another. The outer tube (I) being fixed while the inner tube (2) can be rotated around its longitudinal axis by means of mechanical, electromechanical and/or piezoelectric actuators, and/or by means

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[Continued on next page]

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).

Declarations under Rule 4.17:

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

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

of pneumatic (air or another) actuators. The actuators can be placed at the proximal part and/or at the base of the device and/or in a compartment separated from it at a short distance from the tip. The outer tube can be enveloped with fiber optic filaments that can be used for illumination, imaging and laser coagulation. The irrigation/inflation system consists of a cylindrically shaped hollow piece that slides onto the outer tube and on top of the finer optic envelope. The piece has an opening that is placed on the opposite side with respect to the cutting opening. Through this opening fluid (liquid or gas) is pumped in order to keep the pressure inside the virtual cavity (eye, peritoneum, and/or others) at a desired value. The flow of fluid is controlled by a system, not illustrated here, that is placed at some distance away from the end piece. This system maintains the desired pressure inside the virtual cavity where the device works in, by controlling both the amount of suction from the inner tube and the irrigation from this outer sleeve. The tubes (1) and (2) are forming at the distal part an area in the shape of a truncated cone which ends with an end-piece (3), and near the tip of the device, the outer tube (1) has an opening (4), which may overlap with one or more openings (5) of the inner tube (2), symmetrically placed on the surface of the inner truncated cone, and which, by rotation of the inner tube, they are sliding under the opening (4) of the outer tube (1), thus cutting the tissue/material, which is sucked and discharged to the base of the device due to a negative pressure created inside the inner tube (2) The fiber optic envelope contains fibers responsible for illumination, fibers that will serve to have a light source inside the eye and/or other organ and/or body, fibers that will be responsible to capture the image and carried to a visioning system that will recreate a bi-dimensional and/or tridimensional imagines that can be projected on a screen and the third type of fibers will be responsible for the transmission of the laser radiation used for photocoagulation. This fiber optic envelope can be placed on different others intra-ocular instruments (scissors, forceps, picks, hooks, and/or others) and/or other instruments used in other human surgical fields, and in combination with images capture by a second instrument and/or device having the same envelope, with the help of a visioning system with a integrating video software, not illustrated here, to measure and recreate a tridimensional image that can be projected on a screen.

Surgery device

Specification

The invention relates to a device for coagulation, cutting and aspiration, with the possibility of visualizing through a fiber optic visioning system, which can be used in microsurgery (eye surgery, neurosurgery, plastic surgery. ENT. and / or other surgical fields), in laparoscopic surgery, endoscopic surgery, general surgery-, gynecology, orthopedic and / or other human and/or animal surgical fields requiring more or less selective excision and / or cutting of normal and/or abnormal tissues (e.g. tumors, cysts, and / or other forms of physiological and / or pathological lesions). The dimensions of this device can be adapted both for use at microscopic level under conventional microscope, and/or endoscopically projecting an imagine on a screen, and/or to its use at macroscopic level, depending on the amount of space available for maneuvering and depending on the type of surgery' it needs to be used in.

There is a known device with disposable endo-coagulator laser used in ophthalmic surgery according to US patent 4537193. device that includes an elongated hand tool provided with a stainless steel probe, positioned at the leading end of the tool, which has an optical fiber inserted into a hole of the tool, so that the fiber ends at the distal end of the probe, the optical fiber is attached to a connector comprising a plastic body with a metal plug introduced therein, metal plug made of stainless steel, worked with great precision so that the optical fiber can be accurately positioned and aligned with respect to the conventional argon-ion laser beam.

It is also known in KR20140103435 a surgical stapling instrument used in laparoscopic surgery, which is characterized by a rod-shaped bar which moves inside the abdominal cavity by trocar system, consisting of a hook part placed on the bar, to form an inlet for the suturing thread entering the inlet and allowing the suture and an opening and closing lid for the thread entering the inlet, which tool reduces the time to suture during laparoscopic surgery and the surgery can be performed easily.

The document US 2012041358 discloses a device to operate with one hand to irrigate and aspirate the eye. which has a tube with a tip at a front end. the tip being at outlet of the irrigation fluid, and a suction opening for taking the material to be extracted by the suction; an irrigation fluid pump is disposed in the tube and it is connected to the output of the irrigation fluid, a suction pump being fitted in an irrigation pipe inside the tube, connected to the suction inlet through a suction pipe, and a controller regulates the flow through the irrigation pipe so as to be equal to the flow through the suction pipe, preferably the device be provided with a cutting / milling tool which has the possibility of rotating in the suction inlet.

Devices that use laser for destructing the tissue do not offer the possibility' of aspirating the

cauterized material. This makes the interventions for glaucoma to be an ineffective solution because the cauterized tissue remaining in the eye will inevitably lead to clogging of collector channels and ultimately to increased intra-ocular pressure. (US4537193). There is a device tor intra-ocular surgery that uses laser cauterization and offers the possibility of vacuuming the burnt material, but the outer diameter of the device is too large to be used in the restricted space between the iris and the cornea. (US)

The devices used in laparoscopic surgery perform cutting by clamping and severing, thus requiring more than one operation, while the proposed solution allows the high-precision cutting of the tissue. Since the device only cuts the tissue entering through the opening in the outer tube, it allows a very fine and precise control of the amount of material cut and the affected area. Suture devices do not provide the opportunity to cut the material and remove it by suction (K.R20140103435)

The devices using a high intensity electric field (US2011144638A1) for destroying the tissue only achieves a temporary separation of the proteins in the tissue, which is not sufficient to detach the trabecular meshwork: on the contrary, it may result in a repositioning of the tissue which will further prevent the removal of the intra-ocular fluids. Such a process cannot cut tissues with harder consistency such as the trabecular meshwork.

The devices that enable suction and, eventually, irrigation are not strong enough to detach the tissue, or could lead to uncontrolled tearing of a too large part of material, which is undesirable. These devices can be used for the soft tissues which can be easily cut even by the edges of the tube, during the suction process. (US 2012041358, US4386927).

There are also devices that enable cutting by rotating the inner tube or by translational motion, but all these devices have a right angle ending of the tube which does not allow their use in the limited space between the iris and cornea, or if the diameter is small enough, the hole for making the cut is too small to allow the suction of a harder tissue. (IJS5019035, US4696298, US474532, US5176628). On the other hand, the cylindrical shape leads the tip of the device to force the iris which can lead to its damage and furthermore, it does not allow the annexation to the eye wall in order to effectively suck and then cut the tissue.

The problem to be solved by the present invention consists in the possibility of coagulation, removal and suction of different types of tissues of the eye and / or from various parts of the human body, with the possibility of visualizing through a fiber optic visioning system that can project images on a screen.

This proposed solution to the illustrated issue is achieved by a device for eye surgery consisting of two metal tubes of cylindrical shape, arranged concentrically with respect to one another, the outer tube is fixed, and the inner tube is rotated by means of mechanical, electromechanical or piezoelectric and/or pneumatic actuator, or by means of compressed air. The actuators are placed at the proximal end of the device and/or at the base of the device and / or in a compartment

separated from it at a short distance from the tip. The diameter of the outer tube gradually decreases, forming a region in the shape of a truncated cone, which ends with a flat or rounded end-piece. Near the top of the device, the outer tube has an opening, which overlaps with one or more openings in the inner tube, symmetrically placed on the surface of this inner truncated cone, and which, by rotation of the inner tube, the inner opening(s) slides under the opening of the outer tube, thus cutting the tissue/material, which is sucked and discharged to the base of the device due to a negative pressure created inside the inner tube.

The benefits of the device as per the present invention are:

- it can be used for small areas (example: between the cornea and iris) and / or other tissues;
- This invention can be used in laparoscopic surgery by inserting the device through the trocar system in physiological and / or pathological cavities inside the human and / or animal body, and it can further access more or less narrow and difficult to access areas, where it can operate the functions of aspiration and / or irrigation and / or cutting of the tissue and / or physiological and / or pathological collections;
- it may participate in the separation and / or removal of various membranes, collections of physiological and / or pathological fluids, blood and other normal and / or pathological tissues in the ocular structure and / or in other parts of the human and /or animal body, with the possibility of visualizing through a fiber optic visioning system that can project images on a screen.

The following is an example for producing the invention in connection with Figures I - 3, representing:

Fig. 1 view and section view through the device;

Fig. 2 View and section view through the outer tube

Fig. 3 View and section view through the inner tube

Fig. 4 View and section view through the device with fiber optic and irrigation

The device for eye surgery according to the invention consists of two metal tubes 1 and 2 that are arranged concentrically with respect to one another. The outer tube 1 is fixed, while the inner tube 2 is set in motion by means of mechanical electromechanical and/or piezoelectric, and/or pneumatic (air or another) actuators, or by means of compressed air. The actuators are placed at the proximal part, or are placed at the base of the device and/or in a compartment separated from it.

The two tubes 1, 2 are made of steel, titanium, carbon fiber, polycarbonate, plastics, ceramic material, and / or any other materials that are compatible with the scope of the invention.

The tubes 1, 2 have a cylindrical shape, and the tip can be cut and/or formed into various shapes. At a short distance from the tip, the diameter D1 of the outer tube 1 decreases gradually, forming a region in the shape of a truncated cone, which ends with an end piece 3 of the same material. The end piece 3 may also be made of another material which is able to maintain sealed the outer tube 1.

The outer lube 1 has an opening 4 which may have a length L1 up to half the diameter of the tube 1 and whose size is different depending on the diameter of the outer tube 1. The opening 4 is positioned near the tip of the device, on the part of the area shaped like a truncated cone. The distance from the beginning of the opening 4 to the tip may vary depending on the diameter of the tube 1.

The inner tube 2 has a shape similar to that of the outer tube 1, but has a smaller diameter than the diameter of the outer tube 1 so that it can slide into it. In the vicinity of the tip, this inner tube 2 also has an area in the shape of a truncated cone, with an opening 5. as shown in Figure 2, two openings 5 as shown in Figure 3, or more openings, placed symmetrically on the surface of the tube.

By means of a kinematic chain and/or gears, not shown, which are connected to the inner tube 2, it rotates around its longitudinal axis inside the outer tube 1. In this way. the openings 4 and 5 slide with one another and carry out the cutting of the material.

Inside the inner tube 2 low negative pressure is created, aspiring the sliced tissue/material.by inserting it into the inner tube 2 and then evacuating it to the base of the device.

The variation of this device involves the integration of an irrigation system in addition to the cutting, suction and fiber optic layer, all in one instrument as seen in Figure 4. The irrigation/inflation system consists of a cylindrically shaped hollow piece 7 that slides onto the outer tube, and on top of the finer optic envelope 9. The piece has an opening 6 that is placed on the opposite side with respect to the cutting opening 4. Through this opening fluid (liquid or gas) is pumped in order to keep the pressure inside the virtual cavity (eye, peritoneum, etc) at a desired value. The flow of fluid is controlled by a system, not illustrated here, that is placed at some distance away from the end piece. This system maintains the desired pressure inside the virtual cavity that the device works in, by controlling both the amount of suction from the inner tube and the irrigation from this outer sleeve.

The two tubes may have very similar diameters only in the area shaped like a truncated cone, and in the tubular area the diameter of the inner tube 2 must be smaller so that there's a gap between the two tubes. Through the space between the two tubes there may circulate a fluid (liquid or gas) carried out through an opening in the outer tube 1. other than 5. In this way. the irrigation of the eye/organ/cavity can be achieved to maintain a nominal pressure in the desired range.

At the tip of the outer tube 1 there can be attached a sharp blade 6, which extends from the end point and, at a certain distance, it forms a curve off the tube, passes over the opening 4 and ends at the edge of the opening, covering the entire length of the opening or just a section thereof.

From the point of bending the blade 6 gradually narrows until it reaches the shape of a sharp tip.

The outer tube 1 has markings on its outer surface, as continuous lines around, spaced equally, and intermediate lines covering only half the diameter of the part.

The outer tube can be enveloped with fiber optic filaments 9 that can be used for illumination, imaging and laser coagulation. Different types of fiber optics can be used depending on their utilization. Optic fibers can extend onto the truncated cone section, but not beyond the cutting opening 4.

In one variation, all three types of fibers are used such that the fibers form a cylindrically shaped piece that envelopes the outer tube. The fibers from the immediate vicinity of the cutting opening can be used to send images to a visioning system, not illustrated here, that can project images on a screen. The imaging fibers are isolated by means of light blocking material from the other fibers found on each side. Using the images captured from inside the cavity the visioning system can measure and recreate a bi-dimensional and/or tridimensional image that can be used to point the laser fibers with great precision towards the material to be irradiated, coagulated and/or cauterized. If any residual material is resulting from the laser exposure, it can be removed using the cutting opening of the instrument. The fiber optic envelope contains fibers responsible for illumination, fibers that will serve to have a light source inside the eye and/or other organ and/or body, fibers that will be responsible to capture the imagine and carried to a visioning system that will recreate a bi-dimensional and/or tridimensional imagine that can be projected on a screen and the third type of fibers will be responsible to carry the laser signal for photocoagulation.

CLAIMS

1. Device for eye surgery, microsurgery (eye surgery, glaucoma surgery, vitreo-retinal surgery, neurosurgery, plastic surgery, ENT, and / or other surgical fields), in laparoscopic surgery, general surgery', gynecology, orthopedic and / or other human and/or animal surgical fields characterized by that it consists of two metal tubes of cylindrical shape, having a tip in the shape of a truncated cone, an outer tube (l) and an inner tube (2), arranged concentrically with respect to one another, the outer tube (1) being fixed and the inner tube (2) being rotated by means of mechanical, electromechanical or piezoelectric actuator, or by means of compressed air, the actuators being placed at the base of the device and / or in a compartment separated from it; the diameter of the outer tube gradually decreases near the tip, forming a region in the shape of a truncated cone, which ends or not with an end-piece (3), and near the top of the device, the outer tube has an opening (4), which may overlap with some openings (5) in the inner tube (2). symmetrically placed on the surface of the truncated cone, and which, by rotation of the inner tube, slides under the opening (4) of the outer tube (1), thus cutting the material, which is sucked and discharged to the base of the device due to a negative pressure created inside the inner tube (2), all this with the possibility of visualizing this procedure through a fiber optic (9) visioning system that can project images on a screen.

2. Device for surgery according to Claim 1 characterized by the fact that the outer tube (1) is enveloped with fiber optic filaments (9) that can be used for illumination, imaging and laser coagulation The fiber optic envelope contains fibers responsible for illumination, fibers that will serve to have a light source inside the eye and/or other organ and/or body, fibers that will be responsible to capture the image and carried to a visioning system that will recreate a bi-dimensional and/or tridimensional imagines that can be projected on a screen and the third type of fibers will be responsible to carry the laser signal for photocoagulation. This fiber optic envelope can be placed on different others intra-ocular instruments, and/or other instruments used in other human surgical fields, and in combination with images capture by a second instrument and/or device having the same envelope, with the help of a visioning system with an integrating video software, not illustrated here, to measure and recreate a tridimensional image that can be projected on a screen. The irrigation system consists of a cylindrically shaped hollow piece (7) that slides onto the outer tube and on top of the finer optic envelope (9). The piece has an opening (8) that is placed on the opposite side with respect to the cutting opening (4). Through this opening fluid is pumped in order to keep the pressure inside the eye at a desired value. The flow of fluid is controlled by a system, not illustrated here, that is placed at some distance from the end piece and that permits by controlling the suction from the inner tube and the irrigation to maintain the desired pressure in the cavity. This device can be used in glaucoma surgery with the

irrigation system or without that in vitreo-retinal surgery and/or other types of surgery fields.

3. Device for surgery according to Claim 1, characterized by that at the tip of the outer tube (1) there can be attached a sharp blade (6). which extends from the end point and. at a certain distance, it forms a curve off the tube, passes over the opening (4) and ends at the edge of the opening, covering the entire length of the opening or just a section thereof.

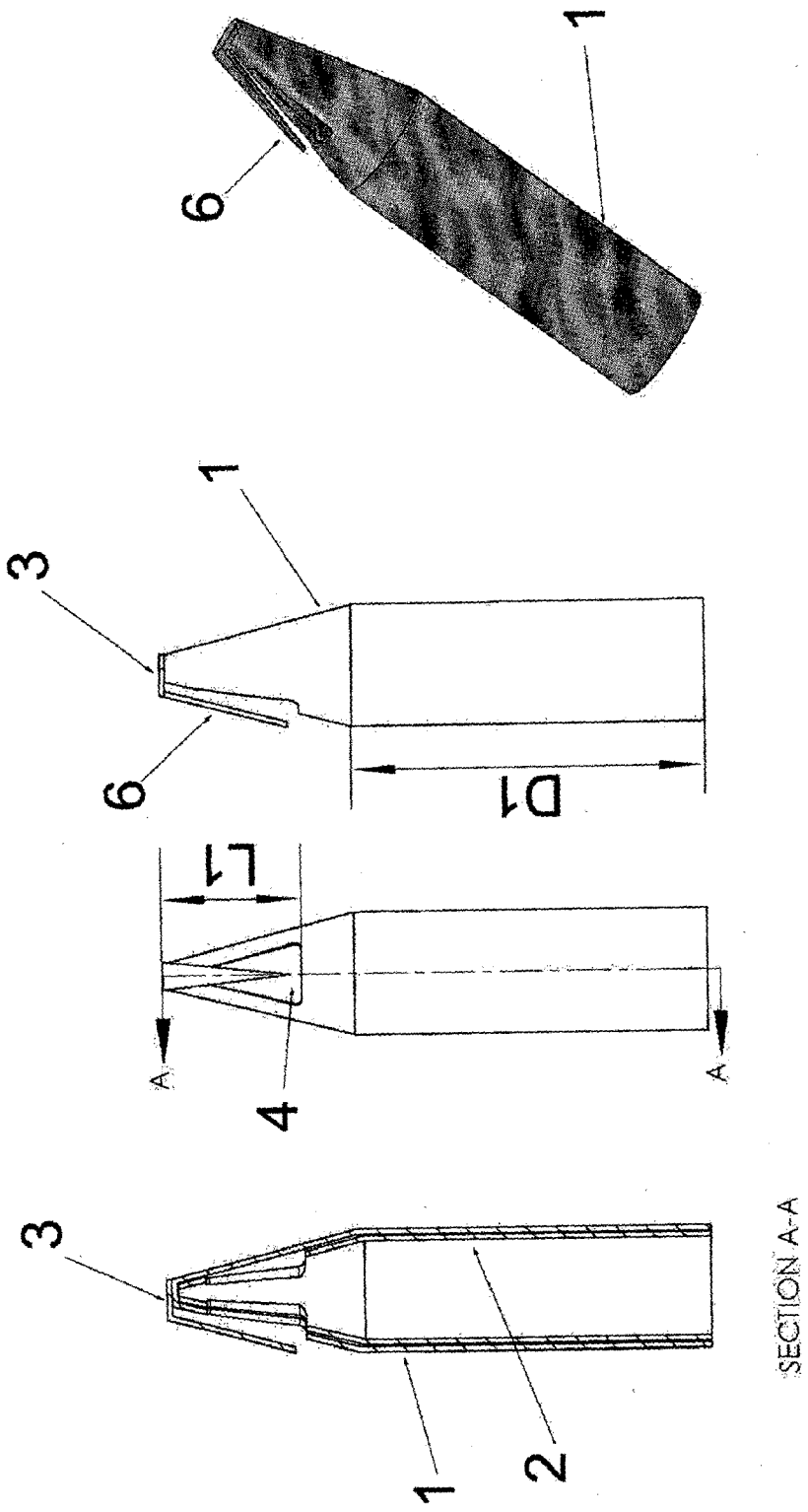


FIG. 1

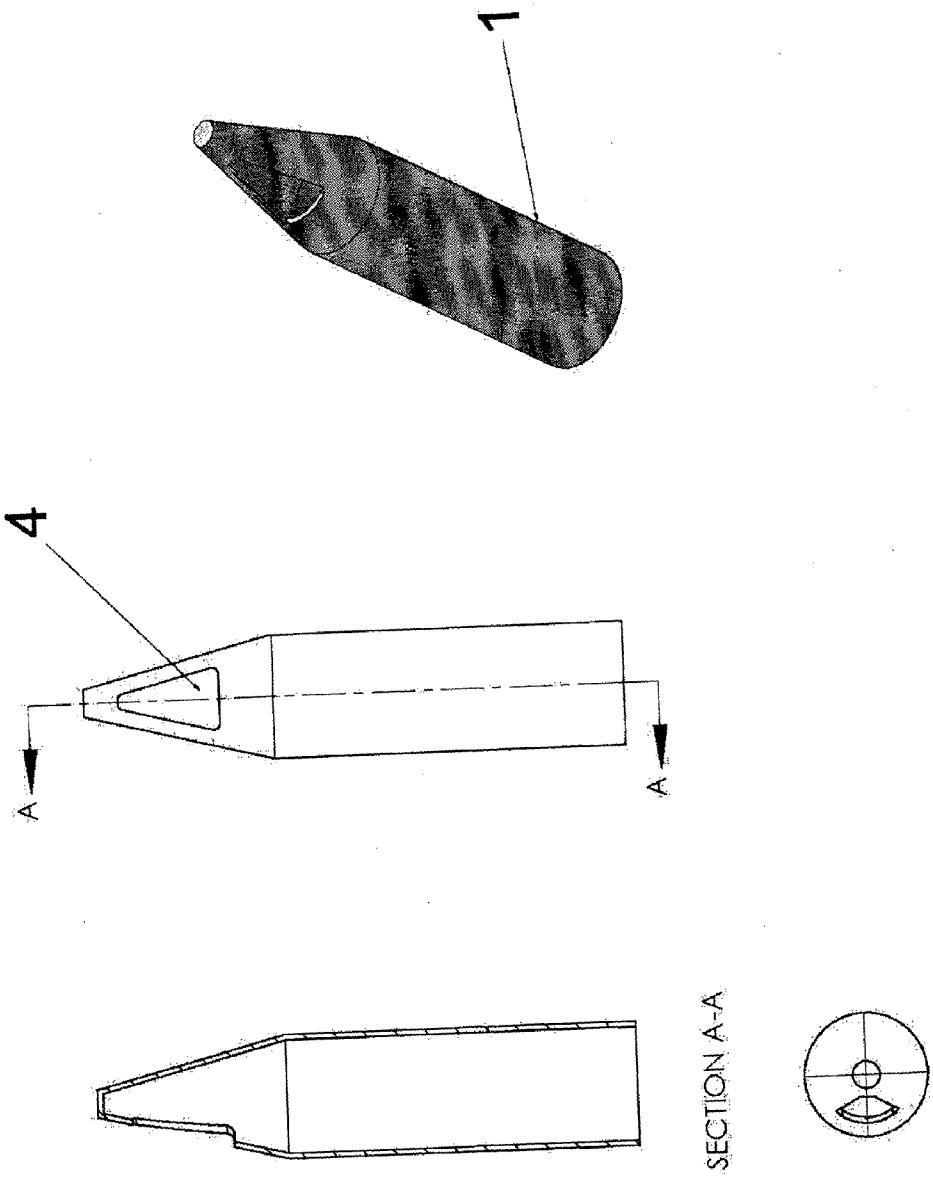


FIG. 2

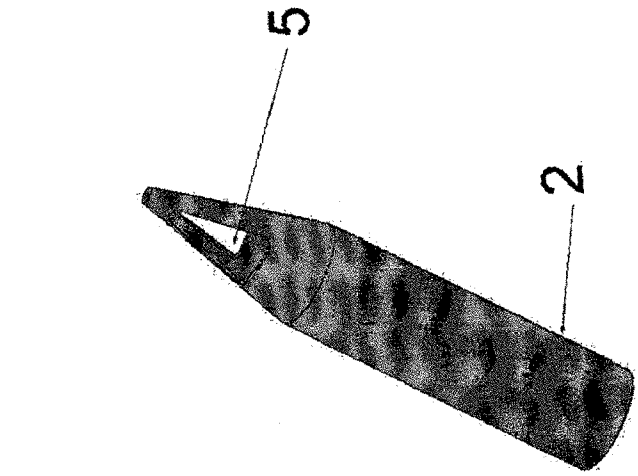
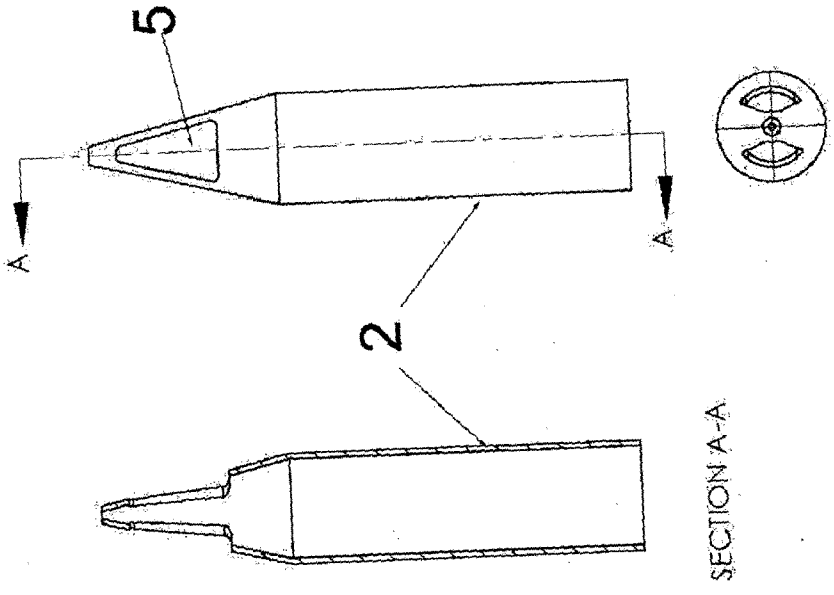
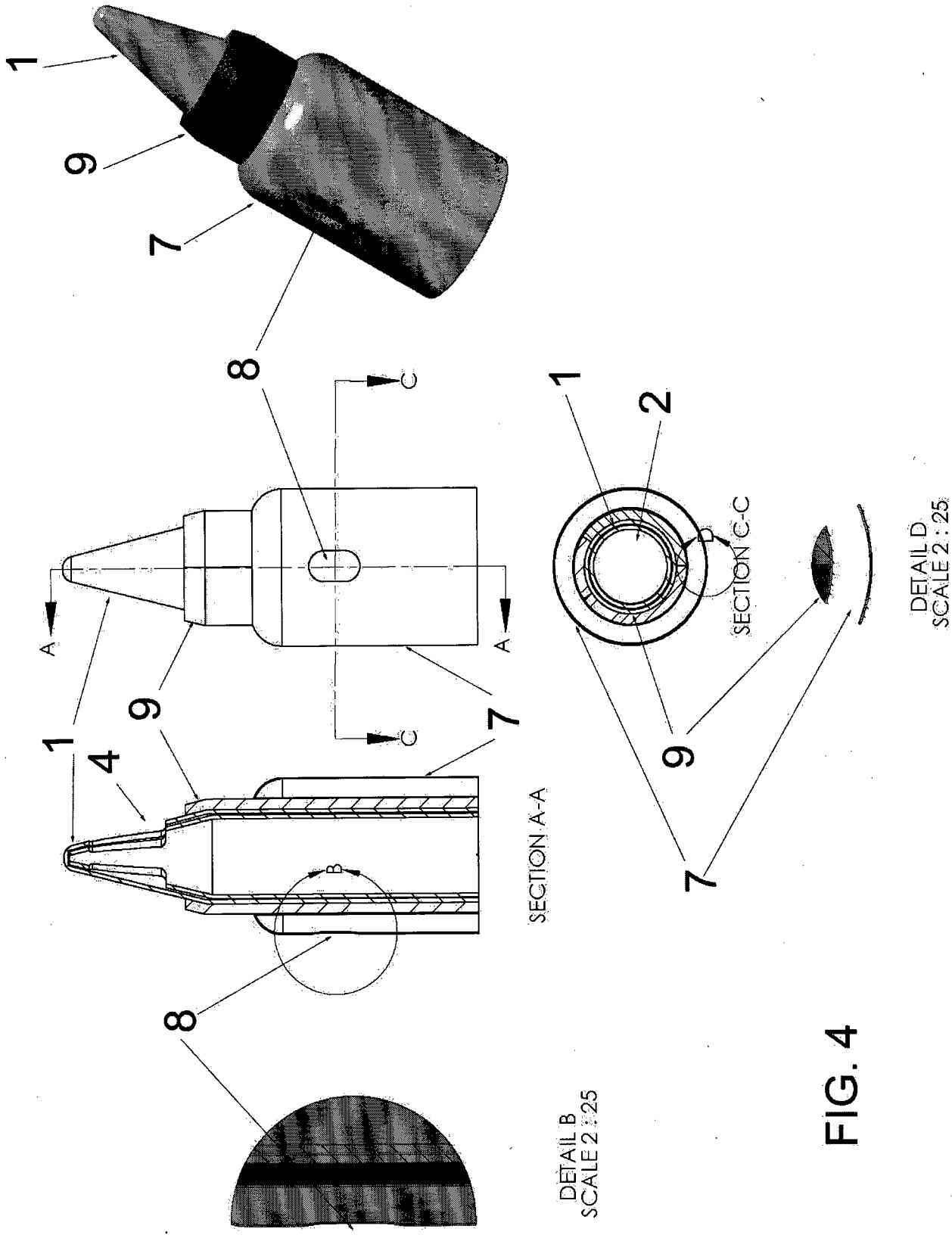


FIG. 3

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9
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A
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8
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SECTION A-A
DETAIL B
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D
SECTION C-C
9
7
DETAIL D
SCALE 2 : 25

FIG. 4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB 2016/001797

A. CLASSIFICATION OF SUBJECT MATTER

A61F 9/007 *(2006.01)*
A61B 18/20 *(2006.01)*
A61F 9/008 *(2006.01)*
A61B 17/3209 *(2006.01)*

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 9/007, 9/008, A61B 18/00, 18/20, 17/3209

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)

Espacenet, USPTO, CIPO, PatSearch (RUPTO Internal)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4099529 B (PEYMAN GHOLAM A.) 11.07.1978	1-3
A	US 5871492 A (OPTEX OPHTHALMOLOGICS INC.) 16.02.1999	1-3
A	WO 2001/26543 A1 (C.R. BARD, INC.) 19.04.2001	1-3

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

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"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
30 June 2017 (30.06.2017)	13 July 2017 (13.07.2017)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer I. Sergomasov Telephone No. (495) 531-64-81

Form PCT/ISA/210 (second sheet) (January 2015)