EXHIBIT 14

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Technique of goniocurettage: a potential treatment for advanced chronic open angle glaucoma

Philipp C Jacobi, Thomas S Dietlein, Günter K Krieglstein

Abstract

***Aim*—To introduce a new concept of anterior chamber angle microsurgery, designed to scrape pathologically altered trabecular meshwork from the scleral sulcus as a potential treatment in primary open angle glaucoma.**

***Methods*—Gonioscopically controlled ab interno abrasion of the trabecular meshwork was performed on six human eye banking eyes for morphological analysis. Thereafter, four eyes suffering from terminal glaucomatous optic nerve atrophy as a result of medically uncontrolled intraocular pressure were also treated by 'goniocurettage'. The newly designed instrument resembles a modified cyclodialysis spatula with a bowl-shaped tip, 300 µm in diameter, and with its edges sharpened. The treatment zone comprised 4–5 clock hours of the chamber angle circumference.**

***Results*—Microscopic examination of the treatment zone revealed that in addition to a complete disruption of the trabecular meshwork and internal wall of Schlemm's canal goniocurettage also caused damage to intracanalicular septa. A splitting along the posterior wall of Schlemm's canal was also noted in one specimen. The clinical data of goniocurettage also showed some promising results. Mean pretreatment IOP averaged 40.7 (SD 8.8) mm Hg (range 32–51 mm Hg) and was significantly ($p<0.04$) reduced to 18.0 (4.2) mm Hg (12–22 mm Hg) after 6 months, representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. Clinically significant hyphaema occurred in one eye, caused by iatrogenic trauma to a prominent chamber angle vessel. In three eyes a minor reflux of blood occurred at the treatment site. However, no hypotony, choroidal effusion, flattened anterior chamber, or cyclodialysis were observed in these patients.**

***Conclusion*—Morphological analysis of treated postmortem eyes confirmed that goniocurettage completely removed the trabecular meshwork and opened Schlemm's canal, ensuring direct access into the anterior chamber. In a small number of patients over a limited period of time this new surgical procedure resulted in a clinically significant pressure reduction. However, longer term follow up and a greater number of patients are warranted before this experimental procedure is applicable to eyes that would do well with conventional surgery.**

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Conventional glaucoma filtering surgery is the mainstay of surgical treatment to control intraocular pressure (IOP) in primary open angle glaucoma.[1–3] There is a growing trend to perform surgery earlier in the course of glaucoma management.[4] However, despite increasing success rates, especially with the use of adjunct antimetabolites, several problems remain, such as hyphaema, flat anterior chamber, and variable wound healing response to conjunctival manipulation. In order to avoid the latter, various techniques have been investigated that minimise conjunctival dissection to improve the success rate of filtration surgery. Laser sclerotomy has recently become a viable alternative to conventional glaucoma filtration surgery.[5] However, varying success rates have been reported using different laser systems and techniques.[6–10] Based on the concept of abnormal resistance to outflow of aqueous humour as a result of maldevelopment of the trabecular meshwork,[11] goniotomy,[12] ab externo trabeculotomy,[13] and trabeculopuncture[14] have each been recommended as surgical procedures of choice in juvenile open angle glaucoma. In recent years, trabeculotomy has again received increasing interest among some glaucoma surgeons as a first choice surgical treatment of chronic open angle glaucoma,[15] including combined glaucoma and cataract surgery.[16]

Based on transmission and scanning electron microscopy of trabeculectomy specimens various authors have suggested that in most cases of chronic open angle glaucoma the primary increase of outflow resistance lies in the cribriform layer of the trabecular meshwork adjacent to the inner wall endothelium of Schlemm's canal.[17–21] Presuming that the outer layers of the trabecular meshwork play the key role in the pathology of primary open angle glaucoma, incisional surgery (goniotomy) or mechanical disruption (trabeculotomy) of the trabecular meshwork could then be a valid surgical approach to medically uncontrolled open angle glaucoma. Unfortunately, simple disruption of the trabecular meshwork with the trabeculotomy approach or punching small holes with the Q switched Nd:YAG laser

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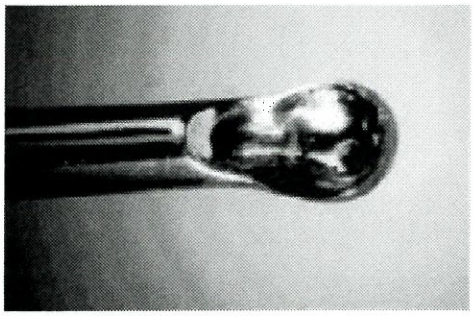
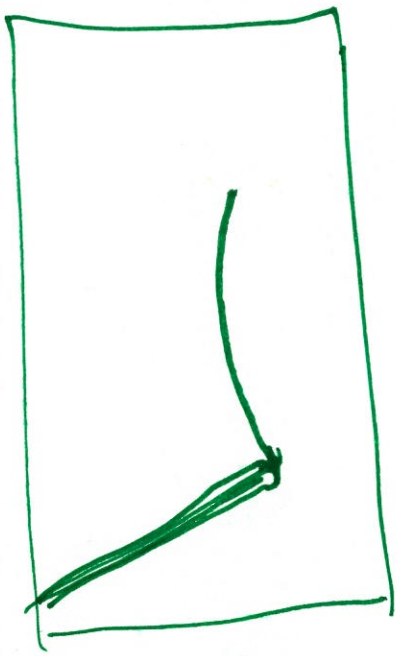


Figure 1 The tip of the 'gonioscraper'. The bowl is 300 μm in diameter with its edges sharpened.



(trabeculopuncture) removes little tissue and allows filling in and scarring to occur with subsequent closure of the trabecular opening.[22 23]

The present study was carried out to introduce a new approach in glaucoma surgery aiming to scrape pathologically altered trabecular meshwork off the scleral sulcus in six patients suffering from uncontrolled IOP due to glaucoma absolutum. The aim of the surgical procedure was to abrade rather than incise uveal meshwork; this novel method, therefore, is termed goniocurettage. A description of instrumentation, surgical technique, and preliminary clinical results are given.

Materials and methods

INSTRUMENTATION AND SURGICAL TECHNIQUE

In order to shell the trabecular meshwork out of its scleral sulcus a new surgical instrument was designed. The 'gonioscraper' consists of a small handle and a slightly convex-shaped arm for intraocular use and very much resembles a cyclodialysis spatula. However, the tip of the instrument is shaped as a tiny bowl with 300 μm diameter and with its edges sharpened (Fig 1). In order to abrade clockwise and anticlockwise the scoop is angulated vertically at 90 degrees to the left and right, respectively.

The experimental part of the surgical procedure was carried out on six human eye bank globes, classified unsuitable for keratoplasty. Death had occurred no more than 12 hours before surgery. Gonioabrasion was performed under direct visualisation of the anterior chamber angle with an operating microscope and a surgical gonioscopy lens. Following injection of viscoelastic, the 'gonioscraper' was inserted into the anterior chamber through a clear corneal incision at the temporal limbus and directed against the trabecular meshwork at the opposite side. In order to peel off trabecular meshwork the 'scraper' was lightly passed over 2–3 clock hours to either side at the nasal circumference of the anterior chamber angle in sweeping movements (Fig 2). Great care was taken to selectively pare uveal meshwork and not to traumatise adjacent intraocular structures, such as the corneal endothelium or the base of the iris. Gonioscopically, strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, leaving a 'denuded' grey-white scleral sulcus. At the end of surgery the viscoelastic along with abraded trabecular debris were removed by means of an irrigation-aspiration probe.

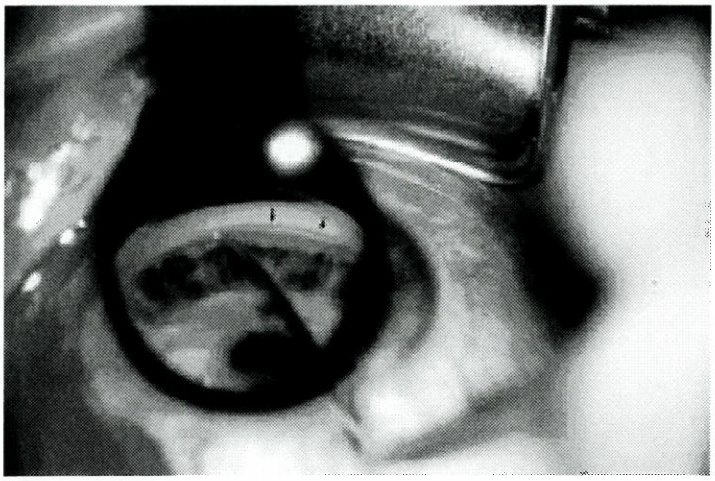


Figure 2 With the aid of an operating microscope and under gonioscopic control ab interno goniocurettage is performed. Following abrasion an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white sulcus scleralis can be seen (black arrows).

HISTOLOGICAL PREPARATION

Following surgery three eye banking eyes were processed for scanning electron microscopy as follows: within 5 minutes after treatment, the eyes were immersed in a fixative of 2% glutaraldehyde and 2% paraformaldehyde in 0.1 M phosphate buffer at a pH of 7.4. After 2 hours, the eyes were rinsed in phosphate buffer, and the treated area was dissected out. Specimens for scanning electron microscopy were postfixed with 1% osmium tetroxide in 0.1 M phosphate buffer at a pH of 7.4. After 2 hours in osmium tetroxide, the scanning specimens were dehydrated in graded alcohols, critical point dried in carbon dioxide, and sputter coated with gold. The specimens were then examined with the scanning electron microscope. Those samples designated for light microscopy were fixed in a 10% formalin solution. After 2 hours dissected samples were dehydrated, embedded in paraffin, sectioned by a microkeratome, and stained with haematoxylin and eosin for light microscopy.

PATIENTS

Six patients were included in this study all suffering from medically uncontrolled IOP, terminal optic nerve atrophy, and no light perception consequent on chronic open angle glaucoma. Exclusion criteria were: reduced (≥20/40) or threatened vision in the unoperated eye, a history of uveitis, anterior segment media opacity, ocular trauma, and neovascular or angle closure glaucoma. Preoperative evaluation included measurement of visual acuity, quantitative visual field testing if possible, measurement of IOP, gonioscopy, anterior and posterior segment slit-lamp biomicroscopy, indirect ophthalmoscopy of the retina, and ultrasonography when required. Informed consent was obtained from all the patients, following the tenets of the Declaration of Helsinki, after they had been fully informed about the experimental nature of the procedure. Surgery was performed in the above manner using retrobulbar anaesthesia. Treatment in the immediate preoperative period

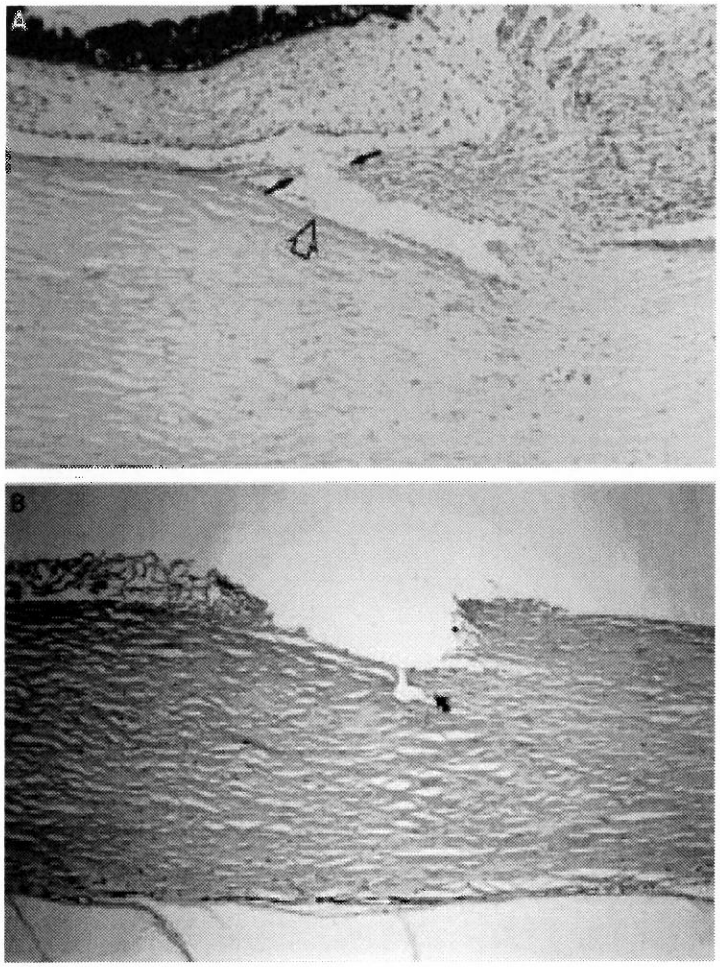


Figure 3 (A) Histological specimen of human anterior chamber angle structures following goniocurettage. The wide iatrogenic defect (black arrow) within the trabecular meshwork opening the canal of Schlemm (open arrow) is discernible. Light micrograph, haematoxylin and eosin. Magnification × 40. (B) Histological specimen at a greater magnification. Note the complete removal of trabecular tissue in conjunction with damage to the posterior wall of Schlemm's canal. A collector vessel (arrow) is opened. Light micrograph, haematoxylin and eosin. Magnification × 100.

included oral acetazolamide (500 mg), mannitol infusion (Osmofundin, 125 ml, intravenously), oculopression for 10–15 minutes, and prophylactic antibiotic drops and ointment.

All IOP readings were obtained with the Goldmann applanation tonometer. Two to four days preoperatively IOP was measured five times a day over a period of 15 hours and the mean was taken as baseline pressure. Postoperatively, regular pressure readings were taken during the period extending to the 12th month. The same time intervals were used in all patients. The number of postoperative pressure determinations at a specific visit varied from three to as many as five individual determinations for some patients. Analogous mean IOP was taken as a baseline value. Before considering glaucoma surgery and admittance to the present study great care was taken to seek the most effective and tolerable medical treatment for IOP reduction 1–3 months preoperatively (that is, medications being used before surgery were discontinued to find out if they were superfluous). Postoperatively, pressure reducing medication was discontinued in all patients for at least 5 days. Thereafter, recommencement of medical treatment was titrated according to the postoperative pressure measurements. However, there was no switch in type of medication.

Results

EXPERIMENTAL RESULTS

Goniocurettage performed internally with a newly designed 'gonioscraper' in one third of the chamber angle circumference was gonioscopically controlled under high magnification of an operating microscope. The scraper was observed to pass along near the scleral spur (Fig 2), tending to push trabecular tissue ahead of it, but usually leaving the anterior portion of the trabecular meshwork and Schwalbe's line in place. Gonioscopically, ragged strings of trabecular tissue could be observed intraoperatively to be removed by goniocurettage, leaving an irregular pattern of a glistening white band corresponding to the 'denuded' grey-white scleral sulcus as exposed by histology. From light microscopy of histological sections (Fig 3A and B) it was evident that in addition to peeling and disruption of the trabecular meshwork the gonioscraper caused damage to septa and endothelium of the external wall of Schlemm's canal, and disruption along the posterior wall of the canal. Flaps of uveal tissue, capable of returning to its predissection position, were not observed in the specimens. Scanning electron microscopy (Fig 4) showed that the trabecular meshwork was pulled from its attachments, leaving ragged structures of Schlemm's canal within the scleral sulcus exposing bare sclera.

CLINICAL RESULTS

Following its experimental application on human eye bank globes goniocurettage was performed on six patients (two male and four females) with glaucoma absolutum whose ages ranged from 63 to 79 years. Follow up averaged 8.2 (SD 3.5) months (range 4–12 months). Pressure elevation was due to primary open angle glaucoma in five eyes and pseudoexfoliation glaucoma in one eye. The pseudoexfoliative patient was phakic the other five patients were pseudophakic. Goniocurettage was performed over 90–120° of the chamber angle circumference in all patients. Retreatment was not performed. Preoperative IOP ranged from 32 mm Hg to 51 mm Hg (mean 40.7 mm Hg). Final postoperative IOP ranged from 12 mm Hg to 22 mm Hg (mean 18 mm Hg), representing an absolute decrease in IOP of 22.7 mm Hg and a mean decrease in IOP of 56%. All patients demonstrated a decrease in IOP (Fig 5), the smallest change being 25 mm Hg and the largest being 42 mm Hg. Postoperatively, the phakic and two of the pseudophakic patients had an IOP less than 19 mm Hg with only the pseudoexfoliative patient requiring continued medication with a topical β blocker. In one pseudophakic patient, however, the final pressure readings at 10 months postoperatively ranged between 19 and 24 mm Hg despite adjunct local antiglaucoma medication. The authors, in accordance with

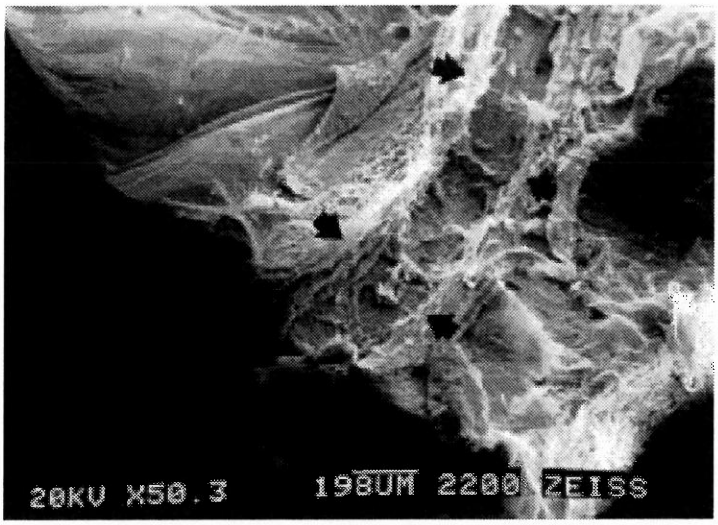


Figure 4 Scanning electron microscopy depicts the deep furrow within the anterior chamber angle, leaving ragged structures of Schlemm's canal within the scleral sulcus. Furrow following treatment in between black arrows.

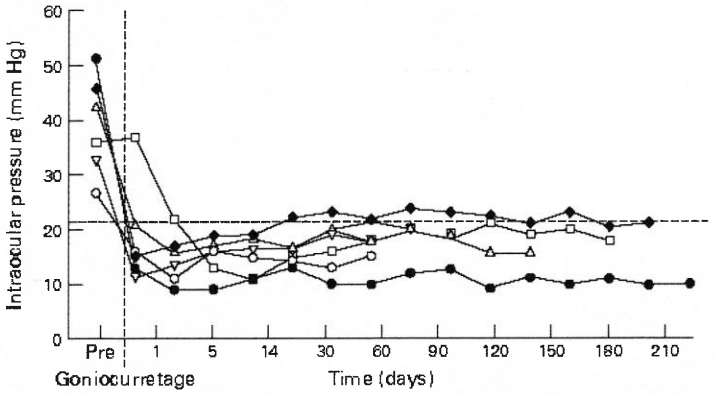


Figure 5 Intraocular pressure of six patients suffering from intractable open angle glaucoma.

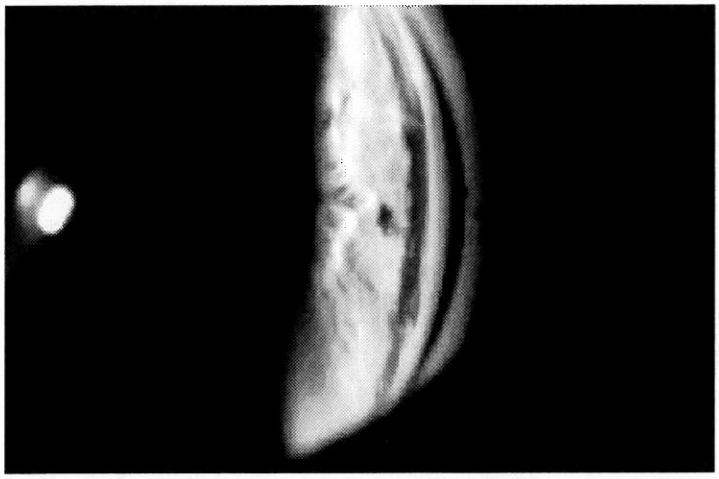


Figure 6 Gonioscopic view of the treatment area following goniocurettage. A small reflux of blood was notified on a regular basis, however, with no further sequelae.

the patient, opted against a retreatment because of a ferre absolutum and reduced general health. All patients were able to discontinue systemic carbonic anhydrase inhibitor postoperatively.

A reflux of blood within the treatment area occurred in four eyes, however, with no further sequelae (Fig 6). In one patient there was significant bleeding into the anterior chamber. This was caused by an iatrogenic trauma to a prominent chamber angle vessel. During the postoperative period the anterior chamber cleared without any further surgical intervention being necessary. In the phakic eye inadvertent descemetolysis of the treatment site occurred. No corneal haze was associated with it. Hypotony (IOP in the 0–5 mm Hg range) or choroidal effusion or flattened anterior chamber were not observed. Intraocular inflammation was not prominent after surgery and no patient had a flat anterior chamber.

Discussion

Microsurgical procedures of Schlemm's canal and the human aqueous outflow system for controlling intraocular pressure in refractory forms of chronic open angle glaucoma have been evolving over the past decades. The basis for most of the present approaches to microsurgery of Schlemm's canal is the finding by Grant,[24] that the largest portion of resistance to outflow is located within the trabecular meshwork, namely the cribriform layer,[18 19] and can be eliminated by incising the trabecular meshwork and entering Schlemm's canal.[25 26] Attempts to develop surgical approaches are to be found both in conventional and laser surgery. Microsurgical dissection of the trabecular meshwork (trabeculotomy, goniotomy) has again received increasing interest from ophthalmic surgeons, both as treatment for congenital glaucoma as well as for primary chronic open angle glaucoma including combined glaucoma and cataract surgery.[15 16 27–30] The procedures themselves have changed little since their original description.[31 32] Nevertheless, there has been a trend towards newer approaches. With advances in laser technology, many incisional intraocular procedures can now be performed using different kinds of lasers.[7 10 14 22] Gonioscopic, non-contact ab interno laser surgery such as neodymium-YAG laser trabeculopuncture,[33] short pulsed neodymium-YAG laser trabeculotomy,[34] neodymium-YLF laser sclerotomy,[35] and pulsed dye laser sclerostomy[36] are some good examples of alternative treatment methods using available laser technology. However, incisional surgery as in goniotomy and simple disruption of the trabecular meshwork with the traditional trabeculotomy approach or punching small holes with the Q switched Nd:YAG laser, remove little tissue and allow filling in and scarring to occur with subsequent closure of the trabecular opening. Ito and associates[37] reported that in monkey eyes 1 year after trabeculotomy, the chamber angle was almost completely restored by newly formed trabecular tissue identical to normal trabecular tissue. At that time no direct communication between Schlemm's canal and the anterior chamber was discernible. In the early postoperative phase,

however, they observed rather large wound surfaces, possibly facilitating subsequent fibroproliferation and scarring. Thus they came to the conclusion that the observed increase in resistance to aqueous outflow following trabeculotomy is caused by a secondary repair processes of the endothelio-trabecular meshwork closing the sites of earlier trabeculotomy.

In this study we describe a new technique in glaucoma microsurgery aimed at dealing directly with the pathoanatomical site of maximum resistance to aqueous outflow. In an attempt to avoid early reclosure by secondary fibroproliferation of the remaining uveal meshwork goniocurettage removes tissue rather than incising or disrupting the uveal meshwork. In order to do so we designed the 'gonioscraper', a novel microsurgical instrument for transcameral use. Despite the obvious difference in surgical instrumentation the procedure itself, to a certain extent, is comparable with the classic technique of goniotomy. Clear visualisation of the chamber angle structures by gonioscopy and a deep and stable anterior chamber are prerequisites for successful surgical treatment. The intended mechanism of action of goniocurettage is to remove pathologically altered trabecular meshwork and to open a route for aqueous humour to egress either into Schlemm's canal or, in the case of damage of the canal's external wall, to ooze out through microsplittings within the posterior scleral wall.

Microscopic examination of sections of the angles of treated eye bank eyes confirmed that this new technique produced a deep furrow within the trabecular meshwork, completely removing the inner wall of Schlemm's canal. It commonly disrupted intracanalicular septa and damage to the external wall of the Schlemm's canal was also recognisable. Thus, the increase in outflow may not be attributable entirely to the elimination of resistance to flow through the trabecular meshwork and inner wall of Schlemm's canal, but also involve a splitting of sclera posteriorly to Schlemm's canal. This ab interno approach may be an advantageous procedure because the conjunctiva remains undisturbed and, if required, a fistulating procedure can be easily performed at a later point.

A clinical trial evaluating the efficacy of goniocurettage as an antiglaucoma microsurgical procedure in primary open angle glaucoma is currently being carried out. So far, preliminary data from a small group of treated eyes are already available. All six patients experienced an absolute decrease in IOP (mean 22.7 mm Hg; 56% from baseline), but IOP in one patient remained significantly greater than 20 mm Hg. Intraoperatively, the surgical procedure of this phakic patient proved to be more difficult, since extra care had to be taken not to damage the crystalline lens. Surgery was complicated postoperatively by a hyphaema from sustained bleeding of the circulus arteriosus iridis major. Five days postoperatively, the hyphaema almost cleared without further surgical intervention. Undue inflammation was not observed postoperatively in the remaining two eyes. Complications relating to postoperative bulbar hypotony or reduced anterior chamber depth did not evolve. Inadvertent cyclodialysis as a mechanism of pressure reduction was ruled out by means of high frequency ultrasound biomicroscopy in all four cases.

However, the limited number of treated eyes and maximum follow up of only 12 months restrict clinical interpretation. At this point goniocurettage has to be regarded as an experimental procedure aiming to relieve trabecular outflow resistance. Longer term follow up and a greater number of patients are warranted before this procedure is applicable to eyes that would do well with conventional surgery.

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EXHIBIT 15

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DATE MAILED: 05/19/2015

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TITLE OF INVENTION: METHOD FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	08/19/2015

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THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

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If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450
or Fax (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

33197 7590 05/19/2015
STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission
I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOMI-019A3-US-G2	9581

TITLE OF INVENTION: METHOD FOR FORMING AN OPENING IN THE TRABECULAR MESHWORK OF THE EYE OF A PATIENT

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0	$0	$480	08/19/2015

EXAMINER	ART UNIT	CLASS-SUBCLASS
WEISBERG, AMY REGINA	3734	606-167000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).
☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.
1 _____
2
3

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:
☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies

4b. Payment of Fee(s): (**Please first reapply any previously paid issue fee shown above**)
☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The director is hereby authorized to charge the required fee(s), any deficiency, or credits any overpayment, to Deposit Account Number (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)
☐ Applicant certifying micro entity status. See 37 CFR 1.29
NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
☐ Applicant asserting small entity status. See 37 CFR 1.27
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
☐ Applicant changing to regular undiscounted fee status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name Registration No.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/481,754	09/09/2014	John T. Sorensen	NEOMI-019A3-US-G2	9581

33197 7590 05/19/2015

STOUT, UXA & BUYAN LLP
4 VENTURE, SUITE 300
IRVINE, CA 92618

EXAMINER	
WEISBERG, AMY REGINA	

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 05/19/2015

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Examiner-Initiated Interview Summary	**Application No.**	**Applicant(s)**	
	14/481,754	SORENSEN ET AL.	
	Examiner	**Art Unit**	
	AMY R. WEISBERG	3734	

All participants (applicant, applicant's representative, PTO personnel):

(1) *AMY R. WEISBERG*. (3)_____.

(2) *Robert Buyen*. (4)_____.

Date of Interview: *14 May 2015*.

Type: ☒ Telephonic ☐ Video Conference
☐ Personal [copy given to: ☐ applicant ☐ applicant's representative]

Exhibit shown or demonstration conducted: ☐ Yes ☒ No.
If Yes, brief description: _____.

Issues Discussed ☐101 ☐112 ☐102 ☐103 ☒Others
(For each of the checked box(es) above, please describe below the issue and detailed description of the discussion)

Claim(s) discussed: *all*.

Identification of prior art discussed: *n/a*.

Substance of Interview
(For each issue discussed, provide a detailed description and indicate if agreement was reached. Some topics may include: identification or clarification of a reference or a portion thereof, claim interpretation, proposed amendments, arguments of any applied references etc...)

Examiner suggested claim amendments to expedite prosecution.

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

☒ Attachment

/AMY R WEISBERG/ Examiner, Art Unit 3734	

Notice of Allowability	Application No. 14/481,754	Applicant(s) SORENSEN ET AL.	
	Examiner AMY R. WEISBERG	Art Unit 3734	AIA (First Inventor to File) Status No

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 5/8/15*.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on_____.
2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.
3. ☒ The allowed claim(s) is/are *1-10*. As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to PPHfeedback@uspto.gov .
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some *c) ☐ None of the:
   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has **THREE MONTHS FROM THE "MAILING DATE"** of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
4. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____.
5. ☒ Examiner's Amendment/Comment
6. ☒ Examiner's Statement of Reasons for Allowance
7. ☒ Other *interview supplemental amendment*.

/AMY R WEISBERG/
Examiner, Art Unit 3734

DETAILED ACTION

The present application is being examined under the pre-AIA first to invent provisions.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Robert Buyen on 5/14/15.

The application has been amended as follows:

In the specification (replace [0001] with the following:

[0001] This application is a division of copending United States Patent Application No. 131159,356 filed June 13, 2011 currently abandoned which is a division of United States Patent Application Serial No. 10/560,267 filed May 11,2006 and issued as United States Patent NO. 7,959,641 on June 14, 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed June 10, 2004, which claims priority to United States Provisional Patent Application No. 60/477,258 timed on June 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

In the claims (replace with the following):

1. (Currently Amended) An *ab interno* method for forming an opening in ~~the~~ trabecular meshwork of a patient's eye, said method comprising the steps of:

obtaining a dual blade device which comprises a) an elongate proximal portion sized to be grasped by a hand of a human operator and b) an elongate probe extending from the proximal portion, wherein the elongate probe comprises i) a shaft, ii) a distal protruding tip that extends ~~at an angle~~ from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and iii) first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D;

forming an opening into an anterior chamber of the eye;

inserting the elongate probe through the opening and into the anterior chamber;

advancing the elongate probe through the anterior chamber, while the anterior chamber is filled with fluid, to an operative position where the distal protruding tip is positioned within Schlemm's Canal and the first and second cutting edges are contacting the trabecular meshwork; and, thereafter

causing the distal protruding tip to advance through a sector of Schlemm's Canal with the first and second cutting edges concurrently cutting, from the trabecular meshwork, a strip of tissue having approximate width W, said approximate width W being approximately equal to the distance D between the first and second cutting edges.

2. (Original) A method according to claim 1 further comprising the step of infusing fluid into the anterior chamber under controlled pressure to keep the anterior chamber filled with fluid during performance of the method.

3. (Previously Presented) A method according to claim 1 wherein the strip of tissue cut from the trabecular meshwork has a length of about 2 to 10 millimeters.

4. (Previously Presented) A method according to claim 1 further comprising the step of:

removing the strip of tissue from the ~~subject's~~ patient's eye.

5. (Previously Presented) A method according to claim 4 wherein, after the first and second cutting edges have cut the strip of tissue from the trabecular meshwork, the strip of tissue remains connected to the trabecular meshwork and wherein the method further comprises the step of:

disconnecting the strip of tissue such that it may be removed from the eye.

6. (Previously Presented) A method according to claim 5 wherein the disconnecting step comprises using a tissue severing apparatus to transect or sever the strip of tissue so as to disconnect it from the patient's body.

7. (Previously Presented) A method according to claim 1 wherein the step of forming an opening into the anterior chamber of the eye comprises forming an incision through a cornea of the eye.

8. (Previously Presented) A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

9. (Currently Amended) A method according to claim 1 wherein the angle is less than ~~distal protruding tip extends from the shaft at an angle is of be between approximately 30 and~~ approximately 90 degrees.

10. (Currently Amended) A method according to claim 9 wherein the ~~distal protruding tip extends from the shaft at an~~ angle is ~~of~~ approximately 90 degrees.

2. The following is an examiner's statement of reasons for allowance:

The present invention pertains to an *ab interno* method for forming an opening in the trabecular meshwork of a patient's eye, said method comprising the steps of obtaining a dual blade device comprising a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees, said distal protruding tip being sized to be inserted in Schlemm's Canal and first and second cutting edges located at a junction of the shaft and the distal protruding tip, said first and second cutting edges being formed at spaced-apart locations on the distal end of the shaft, said first and second cutting edges being separated by a distance D; forming an opening into an anterior chamber of the eye; inserting the device through the opening and into the anterior chamber; and advancing the device into the Schlemm's Canal with the first and second cutting edges concurrently cutting a strip of tissue having an approximate width equal to the distance between the first and second cutting blades.

The closest prior art includes Lee USP 4,900,300 which teaches a method of excising a piece of tissue from the anterior chamber angle (trabecular meshwork and the inner wall of Schlemm's Canal) utilizing a device with a U-shaped cutting edge (14) which has dual blades corresponding to the U-shape. However Lee fails to teach a device comprising a shaft and a distal protruding tip that extends from a distal end of the

shaft to form a bend or curve having an angle of at least 30 degrees. It would not have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Lee to include using a device with a shaft and a distal protruding tip that extends from a distal end of the shaft to form a bend or curve having an angle of at least 30 degrees.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Amy Weisberg whose telephone number is (571)270-5500. The examiner can normally be reached on 7:00-5:30pm M-Th.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, SPE Darwin Erezo, at* (571)272-4695**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy Weisberg
Patent Examiner
/Amy Weisberg/
AU 3734
5/14/15

EXHIBIT 16

US009820885B2

(12) **United States Patent**
Sorensen et al.

(10) **Patent No.: US 9,820,885 B2**
(45) **Date of Patent: Nov. 21, 2017**

(54) **DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE**

(71) Applicant: **Neomedix Corporation**, Tustin, CA (US)

(72) Inventors: **John T. Sorensen**, Lake Elsinore, CA (US); **Michael Mittelstein**, Laguna Niguel, CA (US); **Soheila Mirhashemi**, Laguna Niguel, CA (US)

(73) Assignee: **NeoMedix Corporation**, Tustin, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/076,624**

(22) Filed: **Mar. 21, 2016**

(65) **Prior Publication Data**

US 2016/0220418 A1 Aug. 4, 2016

Related U.S. Application Data

(60) Continuation of application No. 14/789,632, filed on Jul. 1, 2015, now Pat. No. 9,358,155, which is a (Continued)

(51) **Int. Cl.**
A61B 17/32 (2006.01)
A61F 9/007 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ... ***A61F 9/00781*** (2013.01); ***A61B 17/320016*** (2013.01); ***A61B 18/1482*** (2013.01); ***A61F 9/007*** (2013.01); ***A61F 9/0079*** (2013.01); ***A61F 9/00736*** (2013.01); *A61B 2017/320064* (2013.01); *A61B 2018/00083* (2013.01); *A61B 2018/1497* (2013.01)

(58) **Field of Classification Search**
CPC A61F 9/00781; A61F 9/0079; A61F 9/007; A61F 2009/00868; A61F 9/00736 9/00763; A61F 9/013 9/0133; A61B 17/320016; A61B 18/1482; A61B 2018/00083; A61B 2018/1497
USPC 606/167, 107, 166, 170, 184, 185; 600/566 567; 30/304 305, 287
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

421,855 A 2/1890 Burk
637,463 A 11/1899 Hegerty
(Continued)

FOREIGN PATENT DOCUMENTS

EP 0073803 A1 3/1983
EP 1455698 A1 9/2004
(Continued)

OTHER PUBLICATIONS

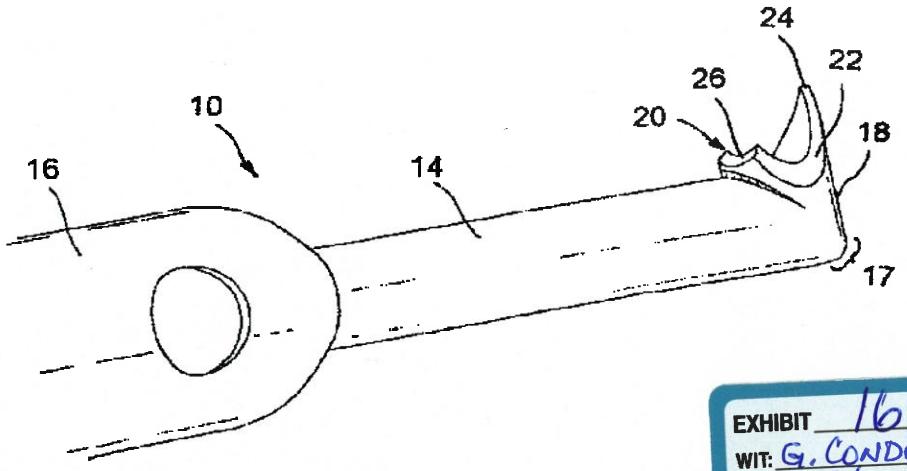
U.S. Patent Office Action dated Sep. 29, 2009 in related U.S. Appl. No. 10/560,267, filed May 11, 2006.
(Continued)

Primary Examiner Amy R Weisberg
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A dual blade device and method useable for performing an ab interno procedure within a human eye to remove a strip of trabecular meshwork tissue.

11 Claims, 3 Drawing Sheets



Related U.S. Application Data

continuation of application No. 14/481,754, filed on Sep. 9, 2014, now Pat. No. 9,107,729, which is a division of application No. 13/159,356, filed on Jun. 13, 2011, now abandoned, which is a division of application No. 10/560,267, filed as application No. PCT/US2004/018488 on Jun. 10, 2004, now Pat. No. 7,959,641.

(60) Provisional application No. 60/477,258, filed on Jun. 10, 2003.

(51) **Int. Cl.**

A61B 18/14	(2006.01)
A61B 18/00	(2006.01)

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,130,949	A		9/1938	Collens
2,220,169	A		11/1940	Murdock
2,364,333	A		12/1944	Wisher
3,294,085	A		12/1966	Wallace
3,365,798	A		1/1968	Cunningham
3,776,238	A		12/1973	Peyman et al.
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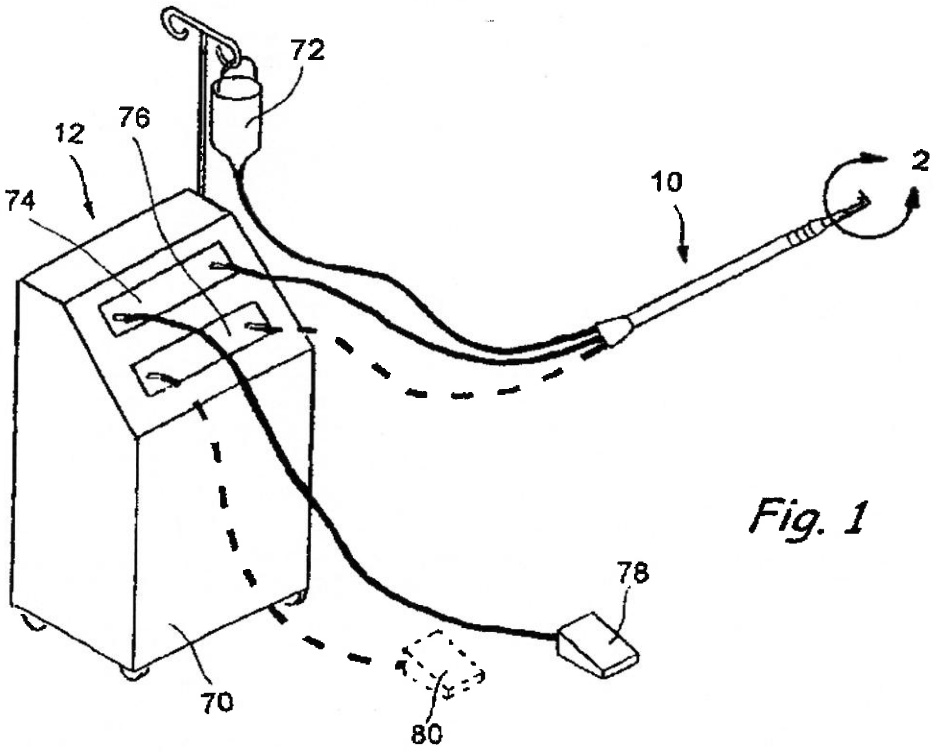

Fig. 1

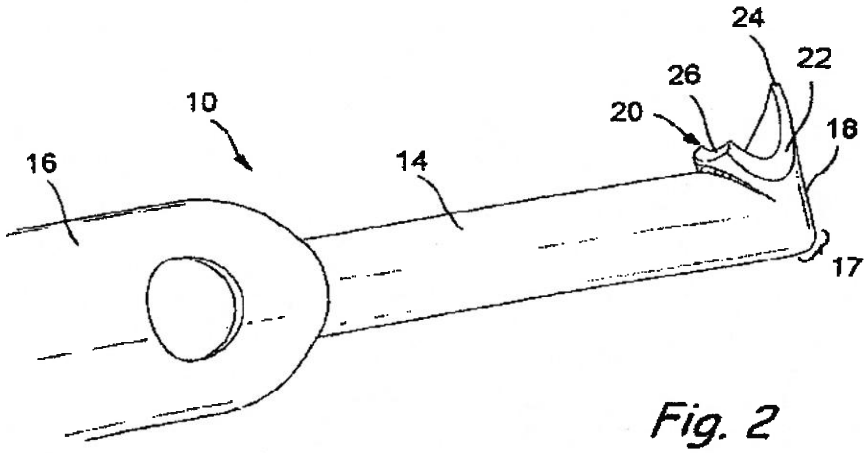

Fig. 2

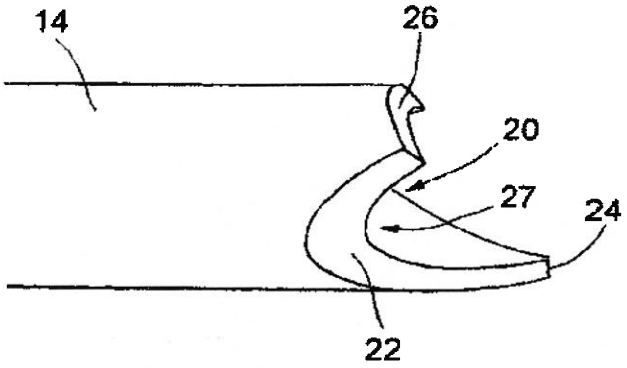

Fig. 3A

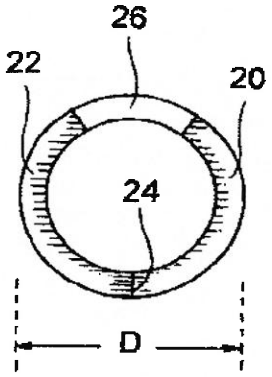

Fig. 3B

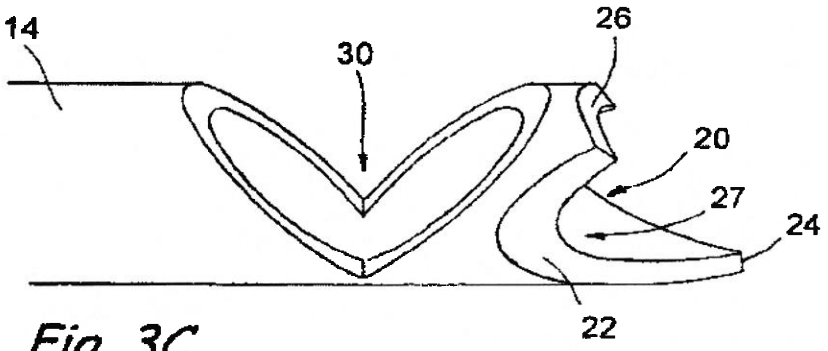

Fig. 3C

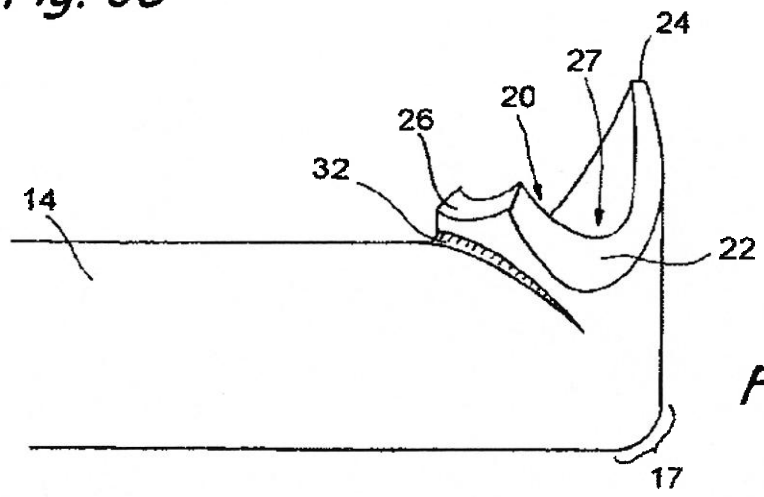

Fig. 3D

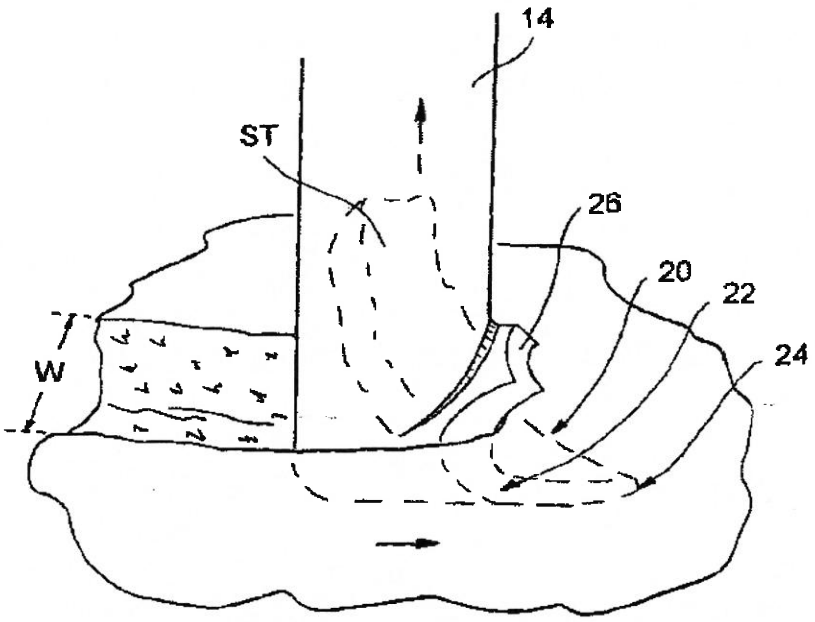

Fig. 4

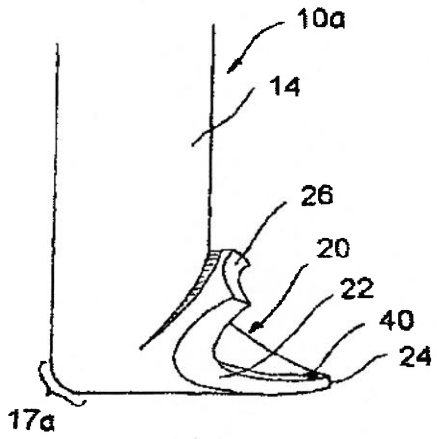

Fig. 5

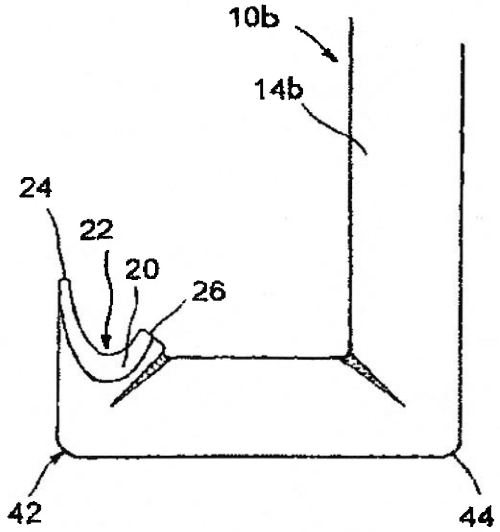

Fig. 6

DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/789,632 filed Jul. 1, 2015 and issued as U.S. Pat. No. 9,358,155 issued on Jun. 7, 2016, which is a continuation of U.S. patent application Ser. No. 14/481,754 filed Sep. 9, 2014 and issued as U.S. Pat. No. 9,107,729 on Aug. 18, 2015, which is a division of U.S. patent application Ser. No. 13/159,356 filed Jun. 13, 2011 and now abandoned, which is a division of U.S. patent application Ser. No. 10/560,267 filed May 11, 2006 and issued as U.S. Pat. No. 7,959.641 on Jun. 14. 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed Jun. 10, 2004, which claims priority to U.S. Provisional Patent Application No. 60/477,258 filed on Jun. 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider than an incision made by a typical scalpel or cutting blade) in the skin. mucous membrane. tumor. organ or other tissue or a human or animal. Also, it may sometimes desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes. etc. Also, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.

One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes referred to as a goniectomy. In a goniectomy procedure. a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 μm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosly organized, porous network of tissue that overlies a collecting canal known as Schlemm's canal. A fluid, known as aqueous humor. is continually produced in the anterior chamber of the eye. In normal individuals. aqueous humor flows through the trabecular meshwork, into Shlemm's Canal and out of the eye through a series of ducts. In patients who suller from glaucoma. the drainage of aqueous humor from the eye may be impaired by elevated flow resistance through the trabecular meshwork, thereby resulting in an increase in intraocular pressure. The goniectomy procedure can restore normal drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork. thus allowing the aqueous humor to drain through the open area from which the strip of trabecular meshwork has been removed. The goniectomy procedure and certain prior art instruments useable to perform such procedure are described in U.S. patent application Ser. No. 10/052,473 published as No. 2002/011608A1 (Baerveldt). the entirety of which is expressly incorporated herein by reference.

At present there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.

SUMMARY OF THE INVENTION

The present invention provides a device for cutting a strip of tissue of approximate width W from a mass of tissue. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The cutting tube is advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W, wherein the approximate width W is approximately equal to the distance D between the first and second cutting edges. In some embodiments, the strip of tissue may be aspirated or otherwise removed through the lumen of the cutter tube. In some embodiments, the device may include apparatus useable to sever (e.g.. transversely cut or transect) the strip of tissue when the strip of tissue has reached a desired length.

Further in accordance with the invention there is provided a method for cutting a strip of tissue of width W from a tissue mass. This method generally comprises the steps of a) providing a device that comprises i) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and ii) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and b) advancing the distal end of the cutting tube through the mass of tissue such that the first and second cutting edges cut a strip of tissue of approximate width W. Further aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a system incorporating a needle cutting device of the present invention.

FIG. **2** is an enlarged perspective view of section 2 of FIG. 1.

FIGS. **3A-3D** show various steps in a method for manufacturing a needle cutter of the present invention.

FIG. **4** is a side view of a distal portion of a needle cutter device of the present invention being used to cut a strip of tissue of approximate width W.

FIG. **5** is a perspective view of the distal portion of a needle cuter device of the present invention incorporating apparatus for severing a strip of tissue cut by the needle cutter device after the strip of tissue has reached a desired length.

FIG. **6** is a side view of the distal portion of another embodiment of a needle cutter device of the present invention having a plurality of curves or bends formed in the cutting tube.

DETAILED DESCRIPTION

The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples

of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the invention. Thus, the following detailed description and the accompanying drawings shall not be construed to limit, in any way, the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device **10** of the present invention is shown in FIGS. **1-4**. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20**, **22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20**, **22** are separated by a distance D, as shown in the distal end view of FIG. **3B**. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The blunt, protruding tip **24** can, in some applications, be configured and used to facilitate insertion of the device **10** to its intended location and/or the blunt protruding tip **24** may be placed in an anatomical or man made grove or channel (e.g., Schlemm's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device **10**.

One or more bends or curves may optionally be formed in the cutting tube **14** to facilitate its use for its intended purpose. For example, in the embodiment of the device **10** shown in FIG. **2**, a single bend **17** of approximately 90 is formed near the distal end of the cutting tube **14**. In the embodiment of the device **10***b* shown in FIG. **6**, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube **14**, thereby giving the cutting tube **14** a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any direction and of any severity may be formed in the cutting tube **14** to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube **14** each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

As shown in FIG. **4**, when the cutting tube **14** is advanced through tissue, distal end first, the first and second cutting edges **20**, **22** will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges **20**, **22**. The severed strip ST of tissue will enter the lumen **27** of the cutting tube **14** as the device advances. Negative pressure may be applied to lumen **27** to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen **27**.

The device **10** may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device **10** or for other purposes. In the embodiment shown in FIGS. **1** and **2**, the device **10** comprises an outer tube **16** in addition to the cutting tube **14**. The cutting tube **14** is of smaller diameter than the outer tube **16** and the cutting tube **14** may extend through the lumen **19** of the outer tube **16** such that a distal portion of the cutting tube **14** extends out of and beyond the distal end of the outer tube **16**, as may be seen in FIG. **2**. The distal end of the outer tube **16** is tapered and in close approximation with the outer surface of the cutting tube **14**. Fluid may be infused through the lumen **19** of the outer tube **16**, through the space between the outer surface of the cutting tube **14** and the inner surface of the outer tube **16**. Fluid that is infused through the lumen **19** of the outer tube **16** may flow out of one or more apertures **11** formed near the distal end of the outer tube.

In some embodiments, the device **10** may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guilloline, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. FIG. **5** shows an example of an embodiment of the device **10***a* wherein monopolar or bipolar electrode(s) **40** are located on the distal end of the cutting tube **14**. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device **10**, the cutting edges **20**, **22** may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges **20**, **22** may be accomplished by placement of electrode(s) near the cutting edges **20**, **22** such that, when the electrode(s) is/are energized, the cutting edges **20**, **22** will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device **10** of the present invention may optionally be used as part of a system **12**, as shown in FIG. **1**. The basic components of the system **12** comprise an aspiration pump module **74** and a source of irrigation fluid **72**, mounted on a surgical roller cart **70**. Control of the console functions during procedures may be accomplished by an aspiration foot pedal **78** which controls an aspiration pump **74** and variation in the height of the source of infusion fluid **72** to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device **10**. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges **20**, **22** and/or for severing the strip ST of tissue (FIG. **5**), the system **11** may additionally comprise an electrical current source, such as an electrosurgical generator **76** and electrosurgical foot pedal **80** which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device **10**. As an option, all of the basic control functions of system **12** may be integrated into a single footpedal to facilitate use.

The device **10** may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Fla. After the device **10** has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module **76**, aspiration pump module **74** and the source of irrigation fluid **72**, as shown. Thus, the device **10** may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g.,

stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **30**. Thereafter, the tube **14** is bent to bring the edges of each angular cut out **30** into apposition and weld, adhesive or other joining techniques are used to weld or join the apposed edges of the cut outs together, thereby forming the desired bend(s) or curve(s) in the cutting tube **14**. Likewise, if it is desired to have one or more bends or curves in the cutting tube **14**, the tube **14** may be directly bent to form said curves or bends without the use of angular cut outs(s) **30**. It may be appreciated that the use of angular cut-out(s) **30** allow a tube **10** of a given diameter to incorporate a curve or angle in a more compact form than is possible by bending tubing **10** of a given diameter to said curve or angle without kinking or damaging tube **10**.

The device **10** and system **12** are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove, from a mass of tissue, a strip ST of tissue of a desired width.

One particular procedure that may be performed to treat glaucoma, using the device **10** and system **12** of the present invention, is a goniectomy. As explained herein a goniectomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber of the eye through Schlemm's Canal and the associated collector channels, thereby relieving elevated intraocular pressure.

To perform a goniectomy procedure using the device **10**, first a small incision is made in the cornea at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision.

The device **10** is attached to the source of irrigation fluid **72** (e.g., basic balanced salt solution) such that irrigation fluid will flow through lumen **19** of the outer tube **16** and out of outflow aperture **11**. The device **10** is then inserted through the incision and into the anterior chamber of the eye (with irrigation flowing). In some cases, during the insertion of the device **10**, the source of irrigation fluid **72** may initially connected to the device such that the irrigation fluid will flow through the lumen **27** of the cutter tube **14**. In this manner, irrigation fluid will begin to infuse into the anterior chamber of the eye as soon as the distal end of the cutter tube **14** has entered the anterior chamber, rather than being delayed until the larger outer tube **16** and aperture **11** have been advanced through the incision and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the distal end of the cutter tube **14** as the device **10** is being inserted, thereby spreading or opening the incision by hydraulic force while in addition increasing the fluid pressure in the anterior chamber. Such spreading or opening of the incision may facilitate advancement of the larger diameter outer tube **16** through the incision. Pressurizing the fluid in the anterior chamber causes the anterior chamber to deepen and may facilitate maneuvering of device **10** within the anterior chamber. In cases where this alternative approach is used, the source of infusion fluid **72** may be disconnected from lumen **27** of the cutter tube **14** after the device **10** has been inserted into the anterior chamber and, thereafter, the infusion fluid source **72** may be reconnected to lumen **19** of outer tube **16** such that infusion fluid will flow out of aperture **11**. Negative pressure (e.g., via aspiration pump module **74**) may then be applied to lumen **27** of the cutter tube **14** so as to aspirate fluid and debris through lumen **27** as shown in FIG. **4**. The vertical height of the infusion fluid source **72** may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber through lumen **27**, thereby maintaining the desired pressure of fluid within the anterior chamber during the procedure.

A lens device (e.g., Ocular Swan-Jacob Autoclavable Gonioprism, Model OSJAG, Ocular Instruments Inc., Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle of the eye where the segment of trabecular meshwork is to be removed. Under direct visualization, the device **10** is advanced until the distal tip of the cutter tube **14** is positioned adjacent to the trabecular meshwork at the location where the strip ST is to be removed. Thereafter, the protruding tip **24** is advanced through the trabecular meshwork and into Schlemm's Canal.

The device **10** is then advanced along Schlemm's Canal, thereby causing the cutting edges **20**, **22** to cut a strip of the trabecular meshwork, thereby creating an opening through which aqueous humor may drain from the anterior chamber of the eye.

After a strip of tissue of the desired length (e.g., about 2-10 mm) has been cut by the lateral cutting edges **20**, **22**, any optional tissue severing apparatus (e.g., electrode(S) **40** may be used (if present) to transect or sever the strip ST of tissue thereby disconnecting it from the patient's body and allowing it to be aspirated or drawn into or through lumen **27**.

Thereafter, the aspiration is stopped, the device **10** is removed from the eye, and the infusion is stopped.

Following completion of the surgery, aqueous humor will drain from the anterior chamber through the opening that was created by removal of the strip of tissue from the trabecular meshwork TM.

Although the invention has been described above with respect to certain embodiments and examples, it is to be appreciated that such embodiments and examples are non-limiting and are not purported to define all embodiments and examples of the invention. Indeed, those of skill in the art will recognize that various modifications may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention and it is intended that all such modifications be included within the scope of the following claims.

What is claimed is:

1. A method for cutting a strip of trabecular meshwork tissue within an eye of a subject, said eye having an anterior chamber, trabecular meshwork tissue and a Schlemm's canal, said method comprising:

a) providing or obtaining a device which comprises:

an elongate probe that extends along a longitudinal axis;

a tip which extends laterally from an end of the probe, said tip comprising a platform which has a top surface, a bottom surface, a right side edge, a left side edge and a terminal end, the terminal end being configured to penetrate through trabecular meshwork tissue;

the tip having a transverse width from the right side edge to the left side edge, said transverse width being narrowest at the terminal end; and

first and second spaced-apart cutting edges positioned on the device so as to cut tissue that passes along the top surface of the tip and into contact with the cutting edges;

b) inserting the probe into the anterior chamber of the eye;

c) advancing the tip through trabecular meshwork tissue and into the Schlemm's Canal of the eye such that trabecular meshwork tissue is in contact with the top surface;

d) moving the probe to cause the tip to advance through the Schlemm's Canal such that trabecular meshwork tissue moves along the top surface of the tip and into contact with the first and second spaced-apart cutting edges, thereby cutting a strip of the trabecular meshwork tissue.

2. A method according to claim 1 further comprising the step of keeping the anterior chamber filled.

3. A method according to claim 2 wherein the device further comprises an infusion lumen and wherein fluid is infused through the infusion lumen to keep the anterior chamber filled.

4. A method according to claim 3 wherein step a comprises:

forming an incision in the eye:

causing fluid to flow out of the infusion lumen and into the incision, thereby spreading or opening the incision; and

thereafter inserting the probe through the incision and into the anterior chamber of the eye.

5. A method according to claim 3 wherein the device further comprises an aspiration lumen and the method further comprises aspirating fluid through the aspiration lumen.

6. A method according to claim 1 wherein the strip of trabecular meshwork tissue cut in step d has a length of about 2 to 10 millimeters.

7. A method according to claim 1 wherein, after cutting of the strip of trabecular meshwork tissue in step d, the strip of trabecular meshwork tissue remains connected to the eye and wherein the method further comprises the step of disconnecting the strip of strip of trabecular meshwork tissue from the eye.

8. A method according to claim 7 wherein the step of disconnecting the strip of trabecular meshwork tissue from the eye comprises using a tissue disconnecting apparatus to disconnect the strip of trabecular meshwork tissue from the eye.

9. A method according to claim 1 wherein the method is performed under direct visualization through a lens device positioned on an anterior aspect of the eye.

10. A method according to claim 1 wherein the tip extends laterally from said end of the probe at an angle of between approximately 30 and approximately 90 degrees relative to the longitudinal axis of the probe and wherein step d comprises moving the distal end of the probe laterally such that the tip advances through Schlemm's Canal.

11. A method according to claim 1 wherein a curve is formed in the elongate probe proximal to the end of the probe from which the tip laterally extends.

* * * * *

EXHIBIT 17

US010123905B2

(12) **United States Patent**
Mittelstein et al.

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(45) **Date of Patent: Nov. 13, 2018**

(54) **DEVICES USEABLE FOR TREATMENT OF GLAUCOMA AND OTHER SURGICAL PROCEDURES**

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A61F 9/007 (2006.01)
A61B 18/14 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61F 9/00781*** (2013.01); ***A61B 18/1402*** (2013.01); ***A61B 18/1482*** (2013.01);
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(58) **Field of Classification Search**
CPC A61F 9/007; A61F 9/00781; A61F 9/0079; A61B 18/1402; A61B 18/1482;
(Continued)

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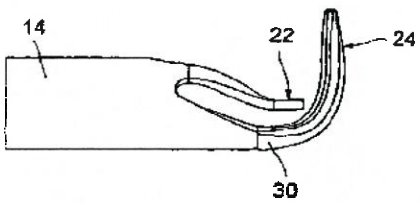
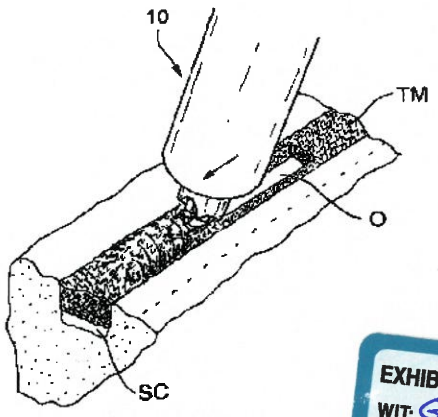
(74) *Attorney, Agent, or Firm* — Robert D. Buyan; Stout, Uxa & Buyan, LLP

(57) **ABSTRACT**

A device and method for cutting or ablating tissue in a human or veterinary patient includes an elongate probe having a distal end, a tissue cutting or ablating apparatus located adjacent within the distal end, and a tissue protector extending from the distal end. The protector generally has a first side and a second side and the tissue cutting or ablating apparatus is located adjacent to the first side thereof. The distal end is structured to be advanceable into tissue or otherwise placed and positioned within the patient's body such that tissue adjacent to the first side of the protector is cut away or ablated by the tissue cutting or ablation apparatus while tissue that is adjacent to the second side of the protector is not substantially damaged by the tissue cutting or ablating apparatus.

7 Claims, 5 Drawing Sheets





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(51) **Int. Cl.**
A61B 18/00 (2006.01)
A61B 17/00 (2006.01)

(52) **U.S. Cl.**
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See application file for complete search history.

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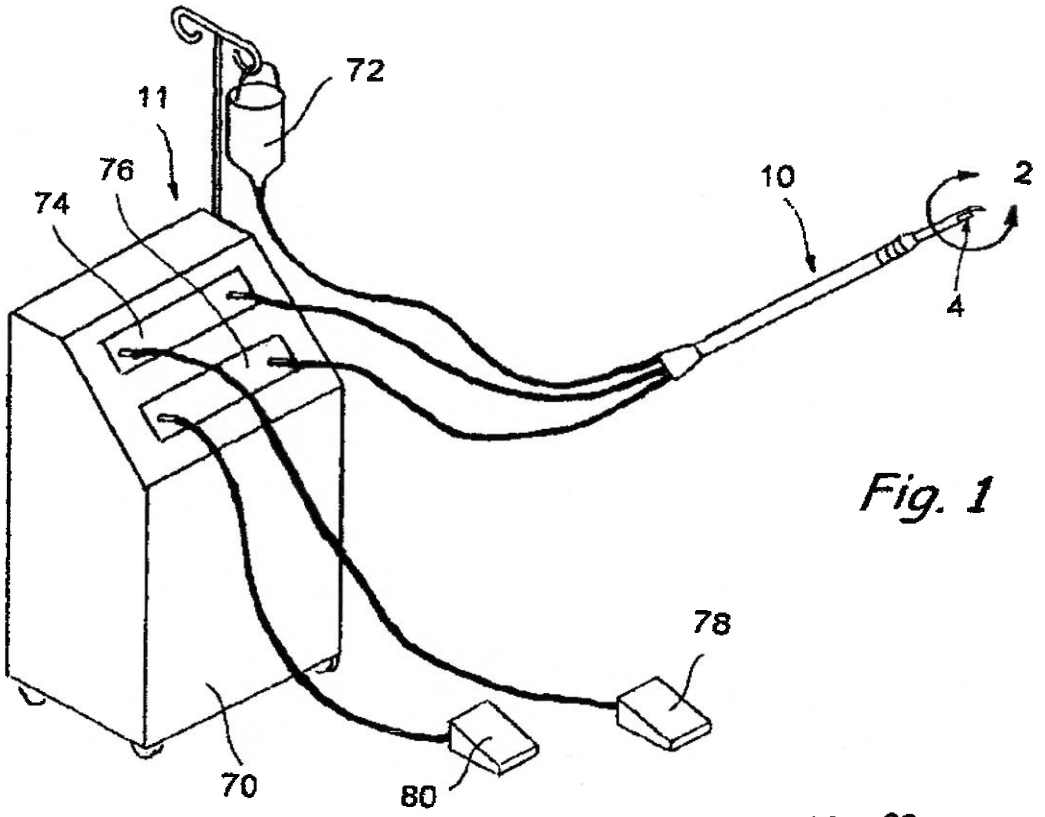


Fig. 1

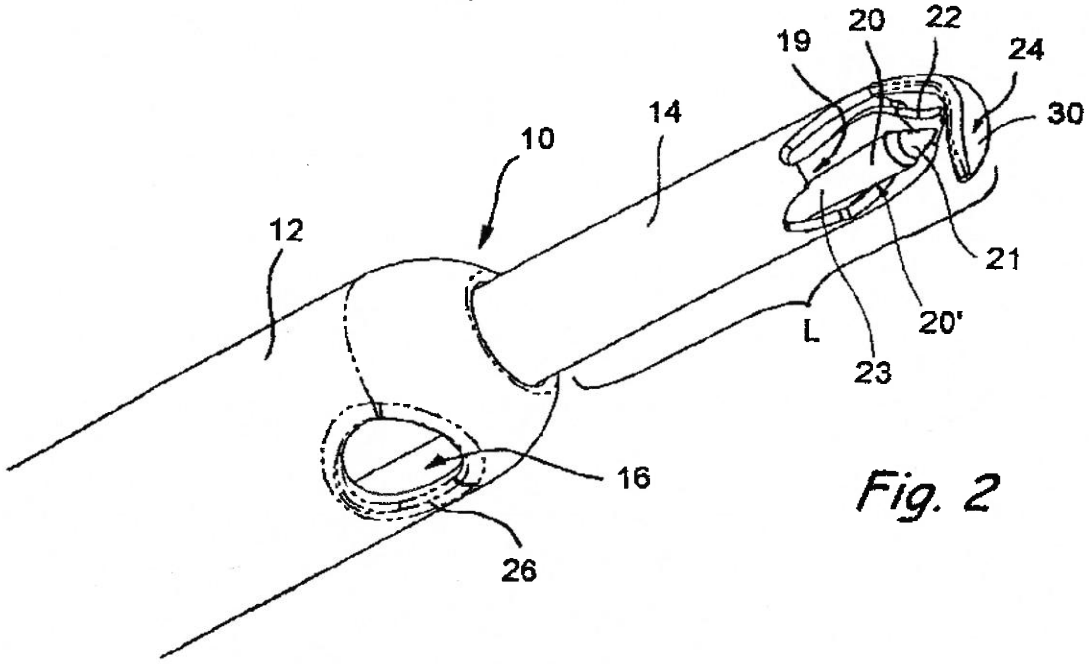


Fig. 2

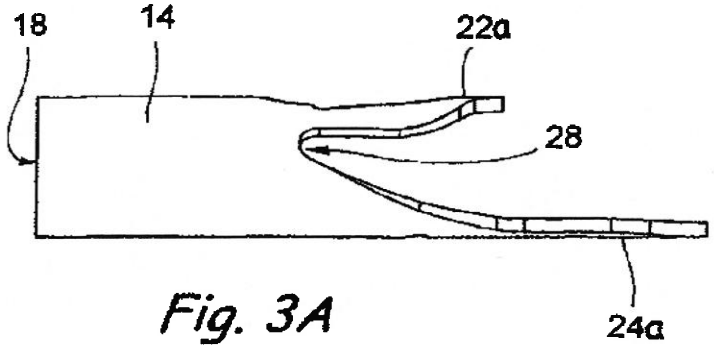
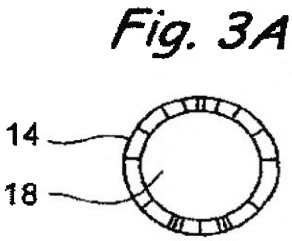


Fig. 3A



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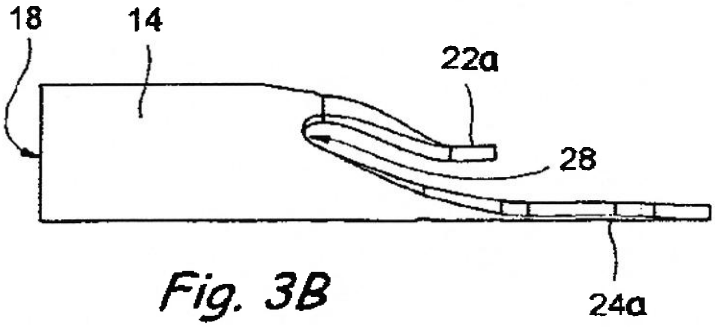
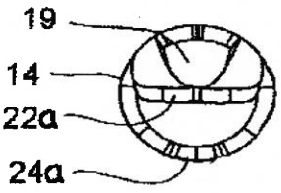


Fig. 3B



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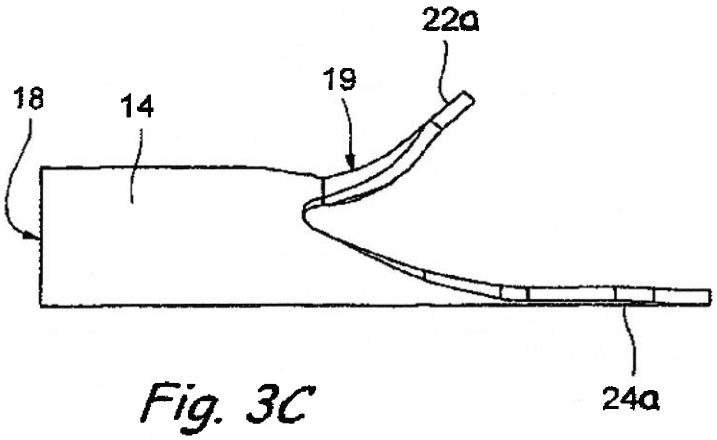
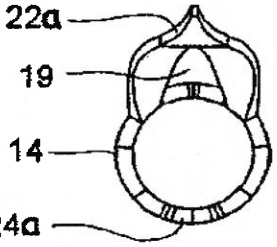


Fig. 3C



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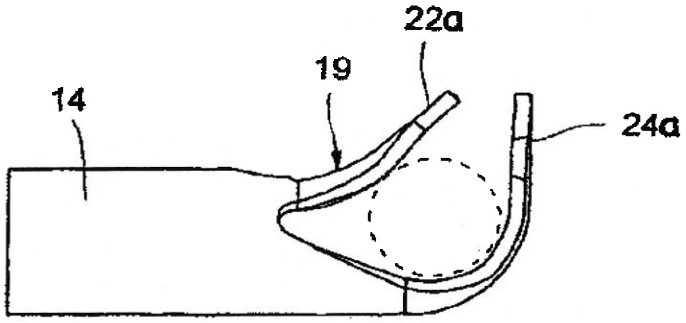
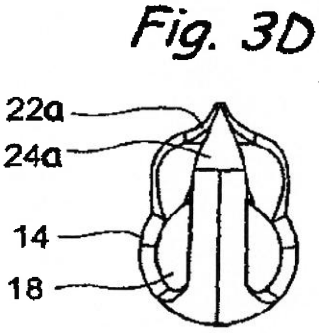


Fig. 3D



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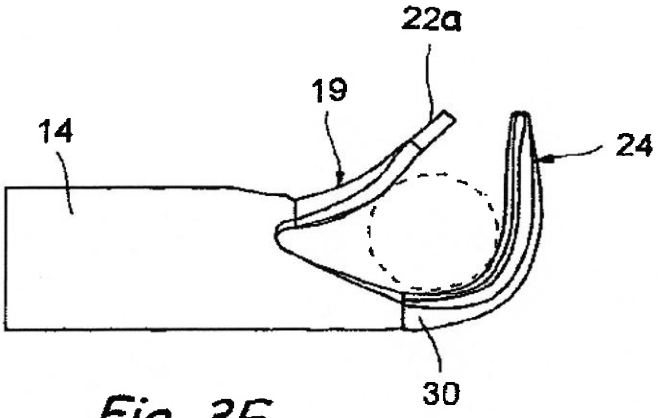


Fig. 3E

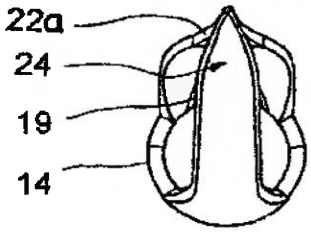


Fig. 3E'

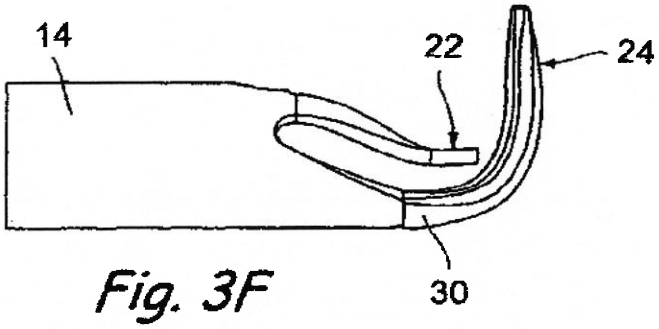


Fig. 3F

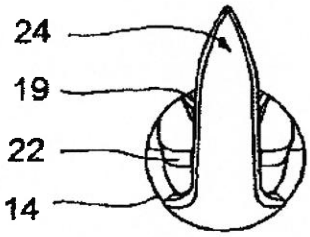


Fig. 3F'

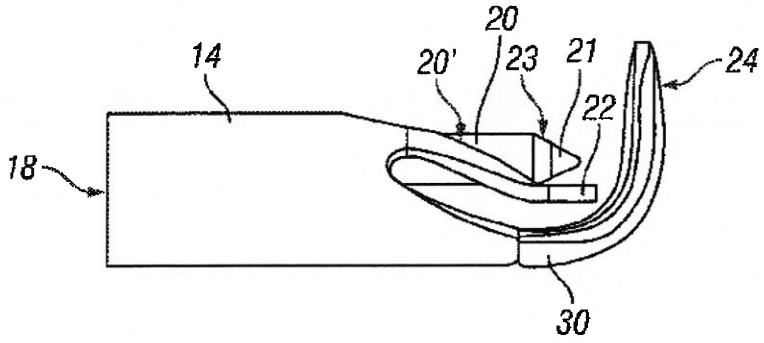


FIG. 3G

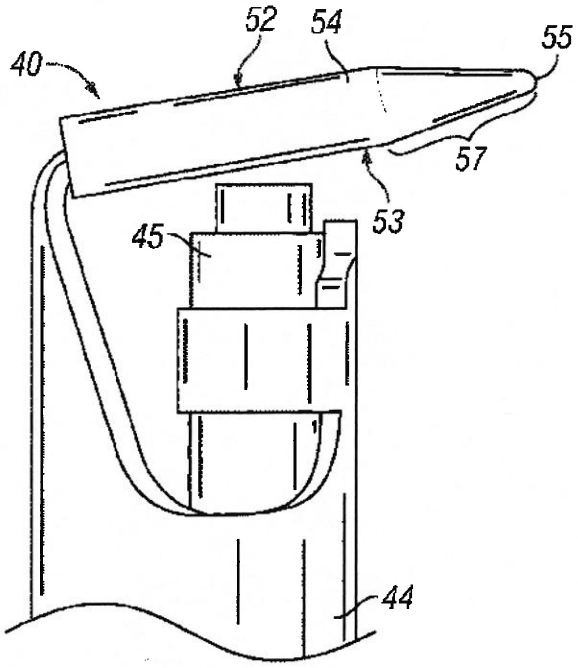


FIG. 5B

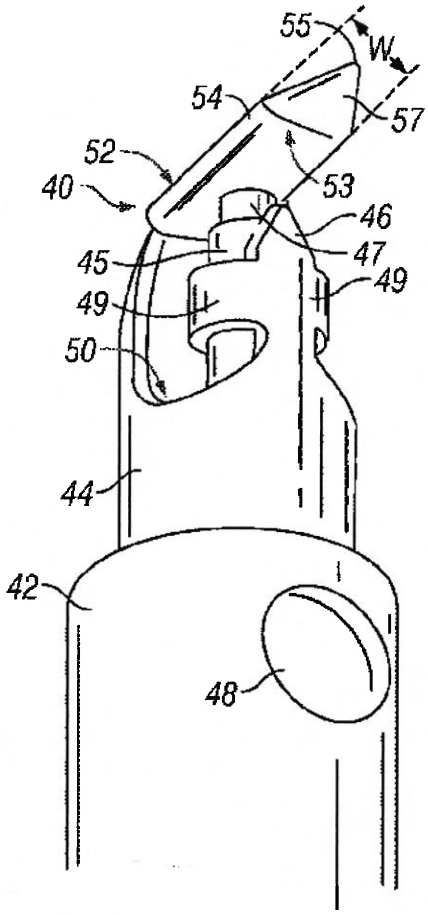


FIG. 5A

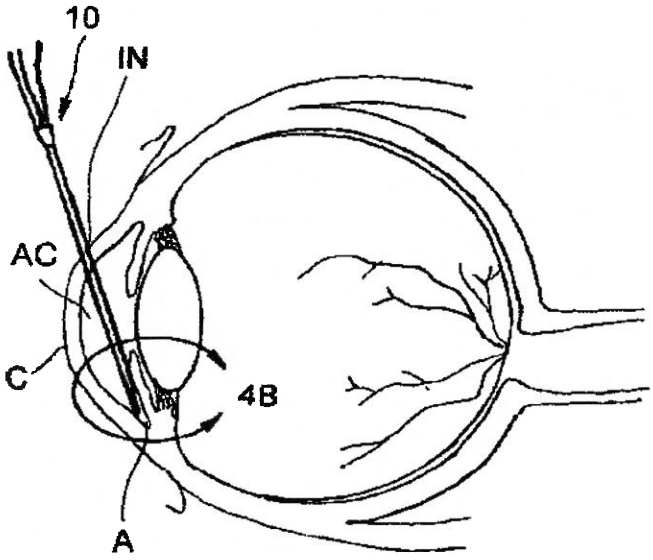
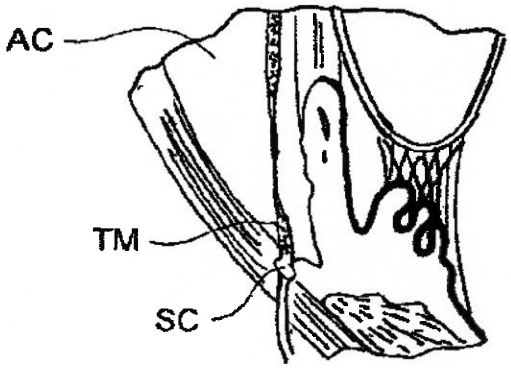


Fig. 4A

Fig. 4B



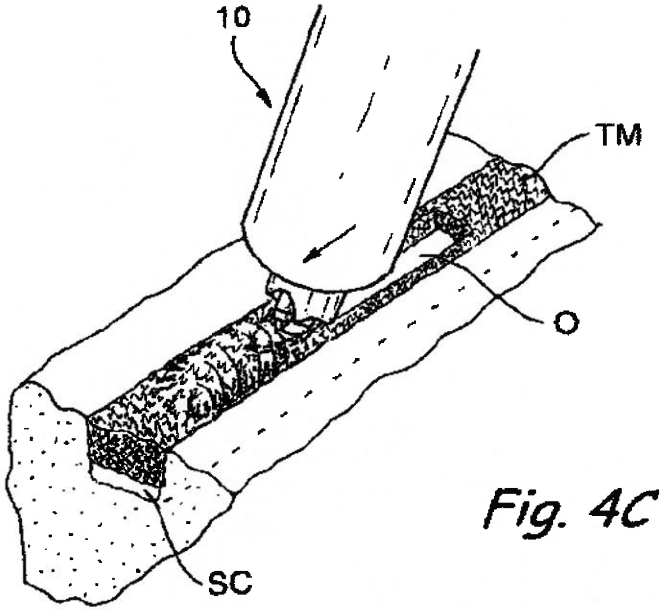


Fig. 4C

DEVICES USEABLE FOR TREATMENT OF GLAUCOMA AND OTHER SURGICAL PROCEDURES

RELATED APPLICATIONS

This application is a division of copending U.S. patent application Ser. No. 10/560,266 filed May 11, 2006, which is a 35 U.S.C. § 371 national stage of PCT International Patent Application No. PCT/US2004/018483 filed Jun. 10, 2004, which claims priority to U.S. Provisional Patent Application No. 60/477,258 filed Jun. 10, 2003, the entire disclosure of each such application being expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

A. Symptoms and Etiology of Glaucoma

The term "glaucoma" refers generally to a group of diseases which cause progressive damage to the optic nerve and resultant optical field defects, vision loss and, in some cases, blindness. Glaucoma is frequently, but not always, accompanied by abnormally high intraocular pressure. Aqueous humor is continually produced by cells of the ciliary body and such aqueous humor fills the anterior chamber of the eye. Excess aqueous humor normally drains from the anterior chamber of the eye, through a structure known as the trabecular meshwork and then out of the eye through a series of drainage tubules. However, in many glaucoma patients, drainage of the aqueous humor through the trabecular meshwork is impaired, thereby causing the pressure of aqueous humor within the anterior chamber to increase.

In general, there are four types of glaucoma-primary, secondary, congenital and pigmentary. Primary glaucoma, which is the most common form, can be classified as either open angle or closed angle. Secondary glaucoma (e.g., neovascular glaucoma) occurs as a complication of a variety of other conditions, such as injury, inflammation, vascular disease and diabetes. Congenital glaucoma is elevated eye pressure present at birth due to a developmental defect in the eye's drainage mechanism. Pigmentary glaucoma is a rare form of the disease wherein pigment from the iris clogs the trabecular meshwork, preventing the drainage of aqueous humor from the anterior chamber.

Glaucoma is a leading cause of blindness in the United States. The loss of vision in glaucoma patients is typically progressive and may be due, at least in part, to compression of the vasculature of the retina and optic nerve as a result of increased intraocular pressure. It is generally accepted that reducing intraocular pressure, through the use of drugs and/or surgery, can significantly reduce glaucomatous progression in patients who suffer from normal-tension glaucoma and can virtually halt glaucomatous progression in patients who suffer from primary open-angle glaucoma with elevated intraocular pressures. Furthermore, it is generally acknowledged that lowering intraocular pressure in glaucoma patients can prevent or lessen the irreversible glaucoma-associated destruction of optic nerve fibers and the resultant irreversible vision loss.

B. Surgical Treatment of Glaucoma

The surgical treatment of glaucoma is generally aimed at either a) decreasing the amount of aqueous humor produced by the ciliary body or b) improving drainage of aqueous humor from the anterior chamber of the eye.

The procedures aimed at decreasing the production of aqueous humor include cyclocryotherapy, wherein a cryosurgical probe is used to freeze a portion of the ciliary body, thereby destroying cells that produce aqueous humor, and laser cyclophotocoagulation, wherein a laser is used to destroy part of the ciliary body resulting in decreased production of aqueous humor.

The procedures intended to improve drainage of aqueous humor from the anterior chamber include trabeculoplasty, trabeculectomy, goniectomy and shunt implantation.

In trabeculoplasty, the surgeon uses a laser to create small holes through the trabecular meshwork to increase aqueous humor drainage through the normal drainage channels.

In trabeculectomy, the surgeon removes a tiny piece of the wall of the eye, which may include a portion of the trabecular meshwork, thereby creating a new drainage channel which bypasses the trabecular meshwork and the normal drainage channels. Aqueous humor then drains with relative ease through the new drainage channel into a reservoir known as a "bleb" that has been created underneath the conjunctiva. Aqueous humor that drains into the bleb is then absorbed by the body. Trabeculectomy is often used in patients who have been unsuccessfully treated with trabeculoplasty or who suffer from advanced glaucoma where optic nerve damage is progressing and intraocular pressure is significantly elevated.

In goniectomy, a tissue cutting or ablating device is inserted into the anterior chamber of the eye and used to remove a full thickness strip of the tissue from the trabecular meshwork overlying Schlemm's canal. In many cases, a strip of about 2 mm to about 10 mm in length and about 50 μm to about 200 μm in width is removed. This creates a permanent opening in the trabecular meshwork through which aqueous humor may drain. The goniectomy procedure and certain prior art instruments useable to perform such procedure are described in U.S. patent application Ser. No. 10/052,473 published as No. 2002/0111608A1 (Baerveldt), the entirety of which is expressly incorporated herein by reference.

In shunt implantation procedures, a small drainage tube or shunt is implanted in the eye such that aqueous humor may drain from the anterior chamber, through the shunt and into a surgically created sub-conjunctival pocket or "bleb." Aqueous humor that drains into the bleb is then absorbed by the patient's body.

Trabeculoplasty, trabeculectomy and shunt implantation procedures are sometimes unsuccessful due to scarring of closure of the surgically created channels or holes and/or clogging of the drainage tube. Because it involves removal of a full thickness strip from the trabecular meshwork, the goniectomy procedure is less likely to fail due to scarring or natural closure of the surgically created channel. Although the previously described devices can be used to successfully perform goniectomy procedures, there remains a need in the art for the development of new tissue cutting and ablation instruments that may be used to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from the body of a human or veterinary patient.

SUMMARY OF THE INVENTION

The present invention provides a device for cutting or ablating tissue in a human or veterinary patient. This device generally comprises, consists essentially of, or consists of: a) an elongate probe having a distal end, b) a tissue cutting or ablating apparatus and c) a protector that extends from the probe. The protector generally has a first side and a second side and the tissue cutting or ablating apparatus is located

adjacent to the first side of the protector. The distal end of the probe having protector extending therefrom, is structured to be advanceable into tissue or otherwise placed and positioned within the patient's body such that tissue adjacent to the first side of the protector is cut away or ablated by the tissue cutting or ablation apparatus while tissue that is adjacent to the second side of the protector is not substantially damaged by the tissue cutting or ablating apparatus.

Additionally, the protector may be formed entirely or partially of an insulating material. For example, the protector may be formed of a core made of an electrically and/or thermally conductive material, for example a conductive metallic material, and may include a non-conductive coating or covering, for example a polymer coating that is electrically and thermally insulating. In some embodiments of the invention, the electrically and thermally insulating material, hereinafter sometimes simply referred to as "coating" may comprise a flexible, pliable material in comparison with the more rigid core.

In some embodiments of the invention, the protector is configured not only to provide protection to tissue located adjacent to the second side of the protector, but also may be configured to facilitate positioning and/or advancement of the device within the surgical site. In this particular regard, above-incorporated United States Patent Application No. 2002/0111608A1 (Baerveldt) describes goniectomy devices that have a foot plate sized and configured to be inserted through the trabecular meshwork and into Schlemm's Canal and to, thereafter, advance through Schlemm's Canal as the device is used to remove a portion of the trabecular meshwork. In embodiments of the present invention that are used to remove portions of the trabecular meshwork (i.e., to perform a goniectomy procedure) the protector may be configured, for example shaped and sized, for insertion and advancement through Schlemm's Canal in substantially the same manner as that described in the above-incorporated United States Patent Application No. 2002/0111608A1 (Baerveldt).

It is to be appreciated that in embodiments of the device of the present invention that are designed and/or intended for use in tissue cutting or ablating applications other than goniectomy procedures, the protector may be of any other suitable configuration required to perform the desired protection and/or positioning/guidance functions.

The tissue cutting or ablating apparatus may comprise any suitable type of apparatus that is operative to cut or ablate tissue, for example a strip of tissue. For example, the cutting and ablating apparatus may comprise a electrosurgical or radiofrequency tissue cutting or ablation apparatus (e.g., monopolar or bipolar configured electrodes), apparatus (e.g., a light guide and/or lens) that emits light energy to cause thermal cutting or ablation of tissue (e.g., pulsed or non-pulsed optical incoherent high intensity light, pulsed or non-pulsed laser light, light that is infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s), etc.), ultrasonic cutting or ablation apparatus (e.g., an ultrasound transmission member that extends through the device to a location adjacent the first side of the protector and undergoes axial or radial ultrasonic vibration), or any other suitable mechanism.

Optionally, the device may further include one or more lumen(s) for providing fluid infusion and/or aspiration to and/or from the surgical site, for example from a remote infusion and/or aspiration source.

In some embodiments of the invention, the device is in the form of an elongate probe that is attachable to a surgical handpiece for facilitating manual manipulation of the probe. In some embodiments of the invention, the entire device is structured and intended for one time use, and in other embodiments of the invention, one or more components of the device are autoclavable and reusable. For example, in some embodiments of the invention, the device comprises a disposable catheter probe having a molded distal end including the protector and/or the cutting or ablating apparatus integrally molded or formed in the distal end of the catheter. In other embodiments of the invention, the device includes a elongate probe, made of one or more segments of stainless steel hypotubing, and including a proximal portion that is configured to be received within a conventional surgical handpiece, which may include various functionable switches, conduit ports, electrical connections and the like for enabling manual operation of the various functions of the device to be described elsewhere herein.

For example, the present device may be configured and structured to be couplable to 1) a console, for example, a control console, or other separate apparatus having for example, but not limited to an electrosurgical signal generator for transmitting energy needed to operate the tissue cutting or ablation apparatus, for example an electrosurgical signal generator suitable for providing electrical energy to the cutting or ablating apparatus utilizing incoherent or laser light energy, such as infrared, visible, and/or ultraviolet wave energy, rotating shaft or other mechanical drive, etc., and/or 2) an aspiration source, for example comprising a pump mechanism for aspirating fluid from the surgical site through the optional aspiration lumen (if present) of the device and/or 3) a source of fluid, for example an irrigation source, for infusing or irrigating the surgical site through the optional fluid infusion lumen (if present) of the device. Examples of commercially available surgical consoles that may be suitable for use with the present invention, for example, surgical consoles of which the present devices may be attached or connected to, include but are not limited to the Infinity/Accurus/Legacy Systems, available from Alcon, Inc., Fort Worth, Tex., the Millinium System, available from the Bausch & Lomb Corporation, Rochester, N.Y., or the Sovereign System, available from Advanced Medical Optics, Santa Ana, Calif.

Further in accordance with the invention, some embodiments of the device may be constructed to cut and remove a strip or pieces of tissue from the patient's body and to permit retrieval of that strip or pieces of tissue to prevent them from causing untoward postsurgical effects within the body or for preservation, biopsy, chemical/biological analysis or other purposes. In embodiments of the device that are equipped with the optional aspiration lumen, the aspiration lumen may be positioned such that a strip or pieces of tissue cut or severed by the tissue cutting or ablation apparatus may be withdrawn from the body through the aspiration lumen.

Still further in accordance with the invention, the width or size of the tissue that is cut or ablated from the patient's body, as well as the degree to which adjacent tissues that remain in the body are damaged by thermal energy or other affects of the cutting or ablation process, may be controlled in some embodiments of the device by controlling the amount of power or energy that is delivered to the tissue cutting or ablation apparatus. In this regard, in embodiments where the tissue cutting or ablation apparatus is a monopolar or bipolar electrosurgical apparatus, there will be a high power density zone closest to the electrode(s) wherein thermal cutting or ablation of tissue will occur. This high power density zone may be surrounded by a medium power density zone wherein the thermal energy is great enough to

also cut or ablate tissue under some circumstances. The voltage and/or current supplied to the electrode(s) may be adjusted to control the size and extent of the high power density zone and/or the surrounding medium power density zone, thereby providing for cutting or ablation of a strip of tissue of a desired size while avoiding significant or irreparable damage to tissue that is to be protected (e.g., tissue located on the second side of the protector) or other tissue at the margins of or in close proximity to the strip of tissue that has been cut or ablated.

Still further in accordance with the invention there are provided methods for performing medical or surgical procedures, including percutaneous surgical procedures, using the devices of the present invention. For example, the present invention provides method for performing a goniectomy procedure, wherein the protector of the device, for example the device of the present invention described elsewhere herein, is inserted through the trabecular meshwork into Schlemm's Canal, and the tissue cutting or ablating apparatus is energized and the device is advanced in a manner that results in cutting or ablation of a portion of the trabecular meshwork. In a general tissue cutting procedure, the protector of the device is inserted to a desired position, the tissue cutting or ablation device is energized and the device is advanced, thereby causing a strip to be cut or ablated from tissue that becomes positioned on the first side of the protector while no substantial damage occurs to tissue located on the second side of the protector.

Further in accordance with the invention, some embodiments of the device may be fabricated in part from tubing, such as stainless steel hypotubing (referred to as "tube-fabricated" embodiments. In such tube-fabricated embodiments, the device generally comprises an outer tube and an inner tube, wherein the inner tube extends through the lumen of the outer tube and a distal portion of the inner tube extends out of and beyond the distal end of the outer tube. The protector is formed on the distal end of the inner tube and the tissue cutting or ablation apparatus may be formed on and/or inserted through the inner tube such that it is positioned at a location adjacent to the first side of the protector. Also, the lumens of the inner and/or outer tubes may be used for infusion and/or aspiration of fluid.

Still further in accordance with the invention, there is provided a method for manufacturing the tube-fabricated embodiments of the device. Such method generally comprises A) providing an inner tube and an outer tube and inserting the inner tube through the lumen of the outer tube such that a distal portion of the inner tube extends out of and beyond the distal end of the outer tube, B) forming cuts in the distal portion of the inner tube to form at least one leg thereon, C) bending a leg formed in Step B to create a protector having a first side and a second side and D) positioning the tissue cutting or ablation apparatus adjacent to the first side of the protector. Optionally, in some embodiments, the method may further comprise the step of E) applying an insulating material (e.g., a polymer such as polyimide) to the protector. Such insulating material may be applied to the protector by any suitable method, such as by single layer dip coating, multiple layer dip coating, spray coating, painting, electrostatic powder deposition, vapor deposition, advancement of a fabricated insulating cover over the protector, etc.

Still further in accordance with the invention, in manufacturing some tube-fabricated embodiments wherein the tissue cutting or ablation apparatus comprises an electrosurgical apparatus, an electrode may be formed by additionally cutting and bending a part of the distal portion of the inner tube to form such electrode. In this regard, Step B of the above-summarized manufacturing method may comprise cutting the distal portion of the inner tube to create first and second legs thereon and, thereafter, Step C of the above-summarized manufacturing method may comprise i) bending the first leg to create a protector having a first side and a second side and ii) bending the second leg to create an electrode adjacent to the first side of the protector. Electrical energy may then be transmitted through the inner tube to the electrode formed on its distal portion. In embodiments where the electrosurgical apparatus is monopolar, only one electrode need be formed adjacent to the first side of the protector and an exposed or capacitively coupled grounding electrode may be attached to the patient's body near the site of the surgery or elsewhere on the body. In embodiments where the electrosurgical apparatus is bipolar, it will be necessary to locate a second electrode adjacent to the first side of the protector. Such second electrode may be so positioned by advancing an electrical conduction member that has an electrode surface on its distal end (e.g., an insulated wire having the insulation removed from its distal tip) through the lumen of the inner tube to a position where the electrode surface of the electrical conduction member is located adjacent to the first side of the protector and a desired distance from the other electrode. The electrical conduction member/second electrode may be secured in place by adhesive, mechanical constraint or any other suitable affixation means. In this regard, aperture(s) may be formed in one or both of the leg(s) formed in Step B and the electrically conductive member may extend through such aperture(s) such that the aperture(s) will localize, guide the positioning of, hold, stabilize or affix the location of the electrical conducting member/second electrode.

Further aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth hereinbelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a system incorporating an electrosurgical goniectomy device of the present invention.

FIG. **2** is an enlarged perspective view of section **2** of FIG. **1**.

FIGS. **3A-3G** are step-by-step showings of an example of a method for manufacturing an electrosurgical goniectomy device of the present invention.

FIG. **4A** is a cross section of a human eye having electrosurgical goniectomy device inserted thereinto.

FIG. **4B** is an enlarged view of a portion of the human eye showing the angle, Schlemm's Canal and the trabecular meshwork.

FIG. **4C** is an enlarged view of a distal portion of the device being used to remove trabecular meshwork tissue from an eye during a goniectomy procedure.

FIG. **5A** is a perspective view of a distal portion of another electrosurgical goniectomy device of the present invention.

FIG. **5B** is a side view of the distal end of the electrosurgical goniectomy device of FIG. **5A**.

DETAILED DESCRIPTION

Turning now to FIG. **1**, a device in accordance with the present invention for cutting and/or ablating tissue, for example, tissue of an eye during a goniectomy procedure, is shown generally at **10**. The device **10** generally comprises an elongate handpiece or probe having a distal end having a

tissue cutting or ablating apparatus **4** disposed generally within the distal end or distal portion of the probe **3**. The tissue cutting or ablating apparatus **4** may be a suitable mechanism designed to cut, ablate, cauterize, sever and/or remove tissue from a target region, for example, from a surgical site. The device **10** may be part of a larger surgical system **11**. for example, the device **10** may be structured and adapted to be operatively connectable to a separate apparatus, for example a surgical control console **70** for controlling and powering operation of various functions of the device during a surgical procedure. Examples of surgical consoles that may be suitable include but are not limited to the Infinity/Accurus/Legacy Systems. available from Alcon, Inc., Fort Worth, Tex., the Millinium System, available from the Bausch & Lomb Corporation. Rochester. N.Y.. or the Sovereign System, available from Advanced Medical Optics, Santa Ana, Calif.

A distal end of a tube-fabricated embodiment of the device **10** is shown in FIG. **2**. This particular device **10** is designed to be especially effective for cutting/ablating and sometimes removing tissue, for example portions of the trabecular meshwork during a goniectomy procedure. It should be appreciated that although the following description will generally refer to this specific embodiment, the scope of the present invention is not intended to be limited thereby. For example, the device **10** may be modified as necessary and/or desirable to be effective for use in surgical procedures other than goniectomy procedures and such modified devices are considered to be within the scope of the present invention.

The tube-fabricated device **10** generally comprises a probe **3** comprising an outer tube **12** and an inner tube **14** disposed therein and having a distal portion extending or projecting therefrom.

As shown in FIG. **2**. the inner tube **14** has a smaller outer diameter than an inner diameter of the outer tube **12** such that when inner tube **14** is positioned within the outer tube **12**. for example. substantially coaxial therewith. the outer tube **12** inner surface is spaced apart from the inner tube **14** outer surface as shown.

More specifically. the outer tube **12** defines a lumen **16** which may serve as an infusion lumen, hereinafter sometime referred to as an irrigation lumen. For example. the outer tube **12** may include an irrigation or infusion port **26** disposed on the distal portion of the outer tube **12** as shown. During a surgical procedure. irrigation fluid, such as a balanced salt solution (BSS) may be passed through lumen **16** and out of port **26** and into the anterior chamber of an eye as needed to maintain a desired intraocular pressure in the eye.

The inner tube **14** generally contains or defines the cutting or ablating portion of the device **10**. as will be described in greater detail elsewhere herein. The inner tube **14** also defines a lumen **19**. preferably having a port adjacent the cutting or ablating apparatus, wherein the lumen **19** may serve as an aspiration lumen during the surgical procedure. Accordingly, an aspiration source may be connected to inner tube lumen **19** to allow cut tissue, excess fluid or other material to be suctioned or removed from the surgical site during the procedure.

In embodiments of the device that are designed for cutting or ablating tissue during a goniectomy procedure, the device **10** is preferably sized and configured such that the distal end thereof can be placed within an eye, for example within the anterior chamber of the eye, as far as and including the

irrigation port **26**. It is noted that irrigation port **26** may alternatively be utilized as an aspiration port in some circumstances, if desirable.

It is further contemplated that in some instances it may be helpful to utilize the aspiration lumen **19** as a temporary or even permanent irrigation lumen such that irrigation fluid is passed from the distal opening of the inner tube **14**. For example. as the device **10** is initially being inserted into the anterior chamber prior to the cutting or ablation of tissue, it may be helpful to pass irrigation fluid into the anterior chamber of the eye through the inner tube **14** in order to maintain ocular pressure and facilitate further insertion of the distal end of the relatively wider outer tube **12** of the device **10**. Once the distal end of the outer tube **12** is in place in the anterior chamber a sufficiently distance such that port **26** is located within the anterior chamber, irrigation of the eye may be moved to the outer tube irrigation port **26**. Initial irrigation by means of the inner lumen **19** may also be helpful in causing gentle widening of the insertion site so as to more easily allow insertion of the relatively wider outer tube through the insertion site.

Preferably, all components of the device **10** are comprised of surgical grade materials. In addition, with the exception of the cutting or ablating surfaces of the device **10**, exposed surfaces of the distal end of the device are preferably formed and/or treated such that they include substantially no sharp portions. burrs or contaminants. For example. in the embodiment shown in FIG. **2**, the distal most portion of the outer tube **12** is rounded or frustro-conical in shape, so as to prevent or reduce the occurrence of any substantial damage to tissue upon insertion. operation and removal of the device **10** from the eye.

For devices of the invention designed for goniectomy surgical procedures. the outer tube **12** may comprise about 19 gauge to about 20 gauge stainless steel hypotubing, and the inner tube **14** may comprise about 25 gauge stainless steel hypotubing. In addition. preferably for such devices of the invention. the projecting distal portion of the inner tube **14** has a length L of between about 1 mm and about 4 mm, and more preferably about 2.5 mm.

The cutting or ablating portion of the device **10** may comprise any suitable mechanism for cutting or ablating tissue. For example, in the specific embodiment shown in FIG. **2**. the cutting or ablating apparatus comprises an electrosurgical tissue cutting/ablating apparatus. More specifically, the device **10** includes a bipolar electrode mechanism comprising a first pole or first electrode **22** and a second pole or second electrode **21**. In use, one of the first and second electrodes is provided with electrical energy and to operate as an active electrode and the other of the first and second electrodes operates as a return electrode. When such an electrode is powered it generates a zone of high energy in immediate proximity of the electrode, and a zone of relatively lower energy outside of the zone of high energy. This zone of relatively lower energy is a zone of thermal energy that is effective in cutting or ablating ocular tissue, for instance. particularly tissue of the trabecular meshwork. The return electrode may be electrically couplable to the patient's body.

It is contemplated that alternative embodiments of the invention may include any other suitable mechanism or apparatus that is operative to cut or ablate tissue. for example a strip of tissue, such as a monopolar electrode mechanism, a radiofrequency tissue cutting or ablation apparatus, apparatus (e.g., a light guide and/or lens) that emits light energy to cause thermal cutting or ablation of tissue (e.g., pulsed or non-pulsed optical incoherent high

intensity light, pulsed or non-pulsed laser light. light that is infrared, visible and/or ultraviolet, etc.), mechanical tissue cutting or ablation apparatus (e.g., knife blade(s), scissor(s), rotating cutter(s). etc.), ultrasonic cutting or ablation apparatus (e.g., an ultrasound transmission member that extends through the device to a location adjacent the first side of the protector and undergoes axial or radial ultrasonic vibration) or others.

The device **10** further comprises a protector **24** having a first side located adjacent to the cutting or ablating apparatus, and a second side located on a distal-most portion of the device **10**. The protector **24** is structured and designed to preventing damage to tissue located near the tissue to be cut. For example, the protector **24** is designed to protect or prevent any substantial damage to surfaces of Schlemm's canal while the device **10** is being utilized to cut portions of the trabecular meshwork during a goniectomy procedure.

More particularly, the device **10** may be structured such that the tissue cutting or ablating apparatus (e.g. the electrode mechanism **20.22**) is structured to cause thermal cutting or ablating of tissue and the protector **24** is structured to isolate or protect adjacent tissue located adjacent the second side of the protector **24**. For example. the protector **24** may be formed partially or entirely of an insulating material. Alternatively or additionally. the protector **24** may be formed of metal and include a coating **30** made of an insulating material. such as a polymer. for example. a polyimide material.

Turning back now to FIG. **1**. the cutting or ablating device **10** may be used as part of a surgical system **11**. The system **11** may comprise or consist of a surgical control console **70** including a high frequency electrosurgical generator module **76** and an aspiration pump module **74**. A source of irrigation fluid **72** may also be provided which preferably operates as a gravity feed irrigation line. Control of the console **70** during surgical procedures may be accomplished by use of an aspiration footpedal **78** which controls an aspiration pump **74**, and use of an electrosurgical footpedal **80** which controls the electrosurgical generator **76**. One or both of the footpedals **78** and **80** may be pressure sensitive such that operating power is controllable by the depth or distance at which the footpedal is pressed or moved by the operator. Furthermore, footpedals **78** and **80** may be combined into a single functional unit. The cutting or ablation device **10** may be provided as a pre-sterilized. single-use disposable probe that is attachable to a standard surgical handpiece. After the cutting and ablation device has been attached to the handpiece, further connections to the electrosurgical generator module **76**, the aspiration pump module **74** and the source of irrigation fluid **72**. may be implemented as shown. Thus. the cutting or ablation device **10** has irrigation. aspiration, and electrosurgical capabilities, as described herein.

A surgical procedure using the device **10** of the present invention may be performed as follows.

Method for Performing Goniectomy

The device **10** and system **11** are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove, from a mass of tissue, a strip of tissue of a desired width.

FIGS. **4A-4C**. show an example of a goniectomy procedure that may be performed to treat glaucoma. using the device **10** and system **11** of the present invention. This goniectomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork TM is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber AC of the eye through Shlemm's Canal and the associated collector channels CC, thereby relieving elevated intraocular pressure.

First. a small incision IN is made in the cornea C at about 3 o'clock in the left eye, or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision IN.

The device **10** is attached to the source of irrigation fluid **72** (e.g., balanced salt solution) such that irrigation fluid will flow through lumen **16** of the outer tube **12** and out of outflow aperture **26**. The device **10** is then inserted through the incision IN and into the anterior chamber AC (with irrigation flowing). In some cases. during the insertion of the device **10**, the source of irrigation fluid **72** may initially connected to the device such that the irrigation fluid will flow through the lumen **19** of the distal portion of inner tube **14**. In this manner, irrigation fluid will begin to infuse into the anterior chamber AC as soon as the distal tip of the protruding distal portion of inner tube **14** has entered the anterior chamber AC. rather than being delayed until the larger outer tube **12** and aperture **26** have been advanced through the incision IN and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the incision IN as the device **10** is being inserted, thereby spreading or opening the incision. Such spreading or opening of the incision IN may facilitate advancement of the larger diameter outer tube **12** through the incision IN. In cases where this alternative approach is used, the source of infusion fluid **72** will be disconnected from lumen **19** after the device has been inserted into the anterior chamber AC and, thereafter. the infusion fluid source **72** will be reconnected to lumen **16** of outer tube **12** such that infusion fluid will flow out of aperture **26**. Negative pressure (e.g., via aspiration pump module **74**) may then be applied to lumen **19** of the inner tube **14** so as to aspirate fluid and debris through lumen **19**. The vertical height of the infusion fluid source **72** may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber AC through lumen **19**. thereby maintaining the desired pressure of fluid within the anterior chamber AC during the procedure.

A lens device (e.g. Ocular Single Mirror Gonio, Model OSMG, Ocular Instruments, Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle A where the segment of trabecular meshwork TM is to be removed. Under such visualization, the device **10** is advanced until the distal tip of the cutter tube or inner tube **14** is positioned adjacent to the trabecular meshwork TM at the location where the strip is to be removed. Thereafter, the protector is advanced through the trabecular meshwork TM and into Schlemm's Canal SC.

The tissue cutting or ablation apparatus, such as bipolar electrodes **21**. **22** or **46**, **47**. is/are then energized and the device **10** is advanced along Schlemm's Canal. thereby causing the cutting or ablation apparatus. such as bipolar electrodes **21** and **22**. to cut or ablate a strip of the trabecular meshwork TM to create opening O, as shown in FIG. **4C**.

In the bipolar embodiments of the device **10** shown in FIG. **2** or **5A-5B**. discharge of electrosurgical energy via the bipolar electrodes **21**. **22** or **46**, **47** will remove a full thickness strip of tissue from the trabecular meshwork TM without traumatizing the underlying walls of Schlemm's canal and/or the collector channels. as those structures remain protected from the electrosurgical energy by the advancing protector **24** or **52**. The insulated protector **24** or **52** serves two primary purposes: 1) the size and shape of the protector **24** or **52** allows its placement in Schlemm's Canal

SC to facilitate guiding the device along Schlemm's Canal SC during the cutting of the strip from the trabecular meshwork TM and 2) the protector **24** or **52** protects and shields the underlying walls of Schlemm's Canal SC and the collector channels from trauma during electrosurgical discharge.

After a strip of tissue of the desired length (e.g., about 2 mm to about 10 mm) has been removed, the tissue cutting or ablation apparatus, such as bipolar electrodes **21**, **22** or **46**, **47**, is/are then de-energized, the aspiration and possibly infusion are stopped and the device **10** is removed from the eye.

Following completion of the surgery, aqueous humor will drain from the anterior chamber AC through the opening O that was created by removal of the strip of tissue from the trabecular meshwork TM.

The present invention further provides a method for manufacturing a device such as tube-fabricated device **10** shown in FIG. **2**.

A method in accordance with the present invention for manufacturing the tube-fabricated device **10** generally comprises the steps of providing outer tube **12** and inner tube **14** made of suitable material, for example hypotubing or other material suitable for use in ophthalmic surgery as described elsewhere herein, and inserting the inner tube within the lumen **16** of the outer tube **12** such that a distal portion of inner tube **14** extends or projects a sufficient distance beyond a distal end of the outer tube **12**, as shown.

The method further comprises the steps of forming at least one leg on a distal portion of the inner tube **14**, for example by beveling the distal end of the inner tube **14** and forming cuts therein and bending the at least one leg to form the protector **24**.

FIGS. **3A-3G** show the steps involved in manufacturing the device **10** shown in FIG. **2**, in accordance with one embodiment of the present invention.

Turning now to FIGS. **3A** and **3A'**, the step of forming at least one leg comprises cutting the distal portion of the inner tube **14**, for example, having a beveled distal end of about 45 degrees, to form a first leg **24A** and a second leg **22A**. The legs **22A** and **24A** may be formed by cutting substantially U-shaped or V-shaped grooves or notches **28** into the beveled distal portion of the inner tube **14** in order to form relatively longer first leg **24A** and a relatively shorter second leg **22A**. In this embodiment, the second leg **22A** includes a narrow distal tip region and a relatively wider flared region proximal thereto.

The method may further comprise providing the cutting or ablating apparatus of the device **10** adjacent the first side of the protector **24**. More particularly, this step may comprise forming the electrode mechanism from a portion of the inner tube **14**, for example, from the second leg **22A**. For example, turning now to FIG. **3B**, the final position of the second leg **22A** is pressed or bent radially inwardly as shown in FIG. **3B** such that the distal most tip of the second leg **22A** is appropriately positioned to form one pole of the bipolar electrode mechanism. In order to accommodate a second pole of the bipolar electrode mechanism, the method may comprise forming an aperture **19** in the second leg **22A**, shown more clearly in FIG. **3B'** and passing a wire or other electrically conductive member **20** (hereinafter "electrode member **20**") therethrough. The aperture **19** is cut to a size and configuration such that it will accommodate the electrode member **20** such as shown in FIG. **2**.

The step of bending the second leg **22A** may be accomplished by using tweezers or other suitable tool for gripping and bending the second leg **22A**. The distal tip of the second leg **22A** (which will form a pole of the electrode) is positioned such that it is substantially aligned with a central axis of the inner tube **14** in the final manufacturing process.

Next, the protector **24** (shown in FIG. **2**) may be formed as follows. Second leg **22A** is bent slightly radially outwardly, as shown in FIGS. **3C** and **3C'**. A forming member, for example a pin, wire or other preferably rigid cylindrical member (shown in dashed lines in FIGS. **3C** and **3D**) is then placed between the first leg **24A** and second leg **22A**.

Referring now to FIGS. **3D** and **3D'**, the first leg **24A** is pressed, bent or otherwise shaped, for example by using substantially constant radial pressure, around the forming member, to form the curved configuration of first leg **24A** shown in FIG. **3D**.

Protector **24**, shown in FIGS. **3E** and **3E'** may be formed by insulating the bent first leg **24A** with insulating coating **30**. This step may be accomplished using any suitable means, for example, by dip coating, spray coating, or advancement of a fabricated cover over the first leg **24A**. The step of insulating or providing insulation may comprise dipping the first leg **22A** in a polymer precursor, for example a liquid polyimide, and allowing the liquid polyimide to cure. In some embodiments of the invention, liquid polyimide is applied to both the inside, or first surface, and the outside, or second surface by using a suitable applicator, for example, a tip of a small diameter wire, for example 0.006" diameter wire dipped in a liquid polyimide. In any event, care is taken not to coat the distal tip of second leg **22A**.

Turning now to FIGS. **3F** and **3F'**, the present invention may comprise the step of forming first electrode **22**, (hereinafter sometimes referred to as first pole of bipolar electrode) from distal portion of the inner tube **14**. This step may be accomplished by bending second leg **22A** radially inwardly, or in some circumstances, allowing second leg **22A** to rebound or spring back to its preformed, inwardly bent shape upon removal of the cylindrical forming member (shown in dashed lines in FIGS. **3C** and **3D**).

As shown, in this particular embodiment, upon being bent inwardly, the distal tip of the second leg **22A** is positioned such that it is spaced apart from and adjacent the first side (inside surface) of the protector **24** and is substantially aligned with the central axis of the inner tube **14**. The distal most tip of the second leg **22A** forms the first pole of the bipolar electrode cutting mechanism.

Next, electrode member **20** is inserted or passed through aperture **19** as shown in FIG. **3G** such that a distal tip of the electrode member **20** will form the second pole of the bipolar electrode. For example, the first pole and the second pole of the bipolar electrode are preferably spaced apart from each other a distance of about ½n mm. The electrodes **21** and **22** are operated to create high temperature region spanning/bridging the electrodes **21** and **22**, for example by formation of a high energy plasma. More specifically, the method of the invention may further include the step of providing the electrode member **20** by stripping or removing a distal most portion of an insulated electrically conductive wire in order to expose the conductive portion thereof which will form the second pole or second electrode **21** of the bipolar electrode mechanism. In other words, the electrically conductive member **20** may comprise an insulated wire **20'** having insulation **23** stripped or removed from a distal tip thereof as shown in FIG. **2** and FIG. **3G**, to expose the electrically conductive tip. Alternatively, the method may comprise providing a non-insulated electrically conductive wire and applying insulation to a proximal portion of the wire while leaving a distal most portion exposed. Such

insulation may be applied in a liquid form. for example, the insulation may be applied as liquid polyimide, which is then cured.

Once the second electrode **21** is appropriately placed, electrically conductive member **20** is secured in place, for example by securing the electrically conductive member **20** to the inner tube **14** for example. by adhesive or other suitable means.

The bipolar electrode and the first side of the protector **24** are spaced apart from each other a distance suitable to receive the tissue to be cut by the device **10**. It is noted that preferably, in this embodiment of the invention, the distal-most tip of the electrically conductive member **20** is somewhat proximally located with respect to the distal-most tip of the second leg **22**A in order to facilitate operation of the device, for example to substantially prevent or reduce the occurrence of tissue becoming unintentionally trapped or wedged within the device. This feature of the invention is shown most clearly in FIG. 3G.

Turning now to FIG. **5**A, an alternative distal end **40** of the tube-fabricated embodiment of the invention is shown, including outer tube **42** and inner tube **44** that are similar or substantially identical to outer tube **12** and inner tube **14** described hereinabove with respect to the device **10** shown in FIG. **2**.

This alternative distal end may operate in substantially the same fashion as the distal end of device **10** shown in FIG. **2** However, the alternative distal end is formed somewhat differently than the distal end shown in FIG. **2**. For example, as seen in FIGS. **5**A and **5**B. the protector member **54** has first side **53**, a second side **52** and a tip **55**. The first side **53** of the protector member **54** forms an incline **57** which slopes upwardly from the tip **55**. Also, the width W of the protector member **54** tapers to its narrowest point at the tip **55**.

The differences may be more readily appreciated by comparing the distal end shown in FIG. **5**B with the distal end shown in FIG. **3**G. For example, it can be appreciated that second leg **46** (FIG. **5**B) which may form a first pole or first electrode of the electrode mechanism. is not bent radially inwardly like second leg **22** (FIG. 3G). In addition electrically conductive member **45** may be positioned or disposed generally along a central axis of the inner tube **44** rather than outwardly therefrom such as electrically conductive member **20**. The electrically conductive member **45** includes second pole or second electrode **47** of the electrode mechanism.

As shown. electrically conductive member **45** may be held in place by means of bracket portions **49** formed from portions of second leg **46**, as shown. The bracket portions **49** are preferably utilized for facilitating positioning of the electrically conductive member **45** during assembly. Adhesive and/or other means may be provided for securing the electrically conductive member **45** in place.

As shown, outer tube **42** may define an irrigation lumen in fluid communication with irrigation port **48**. Inner tube **44** may include aspiration/irrigation lumen **50**.

The invention has been described herein with reference to certain examples and embodiments only. No effort has been made to exhaustively describe all possible examples and embodiments of the invention. Indeed, those of skill in the art will appreciate that various additions, deletions. modifications and other changes may be made to the above-described examples and embodiments, without departing from the intended spirit and scope of the invention as recited in the following claims. It is intended that all such additions, deletions, modifications and other changes be included within the scope of the following claims.

What is claimed is:

1. A device that is insertable into the anterior chamber of an eye and useable to form an opening in the trabecular meshwork of that eye, said device comprising:

an elongate probe having a longitudinal axis and a distal portion that is insertable into the anterior chamber of the eye;

a protector member on a distal end of the distal portion of the probe, said protector member being oriented in a lateral direction relative to said longitudinal axis and having a first side, a second side and a tip, wherein the first side of the protector member comprises an incline which slopes upwardly from the tip and wherein the protector member has a width which tapers to its narrowest point at the tip: and

a plurality of knife blades positioned to cut tissue that passes over the first side of the protector member;

wherein the protector member is configured such that, after an insertion of the distal portion of the elongate probe into an anterior chamber of an eye. the protector member is insertable. tip first. through the trabecular meshwork and into Schlemm's Canal, the distal end of the probe being thereafter moveable in the lateral direction thereby causing the protector member to advance through Schlemm's Canal such that trabecular meshwork tissue passes over the incline and a strip of trabecular meshwork tissue becomes cut by said knife blades.

2. A device according to claim **1** wherein the knife blades are operative to cut a strip of tissue having a width from 50 μm to 200 μm, from the trabecular meshwork.

3. A device according to claim **1** further comprising an irrigation lumen.

4. A device according to claim **1** further comprising an aspiration lumen.

5. A device according to claim **1** further comprising an irrigation lumen and an aspiration lumen.

6. A device according to claim **1** wherein the second side of the protector member is configured so as not to damage tissues adjacent thereto as the protector member is advanced through Schlemm's Canal.

7. A device according to claim **1** wherein said knife blades are located a spaced distance apart to cut a strip of tissue the width of which is substantially equal to the distance between the first and second knife blades.

* * * * *

EXHIBIT 18

US009999544B2

(12) **United States Patent**
Baerveldt et al.

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(45) **Date of Patent: *Jun. 19, 2018**

(54) **MINIMALLY INVASIVE GLAUCOMA SURGICAL INSTRUMENT AND METHOD**

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This patent is subject to a terminal disclaimer.

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(58) **Field of Classification Search**
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(Continued)

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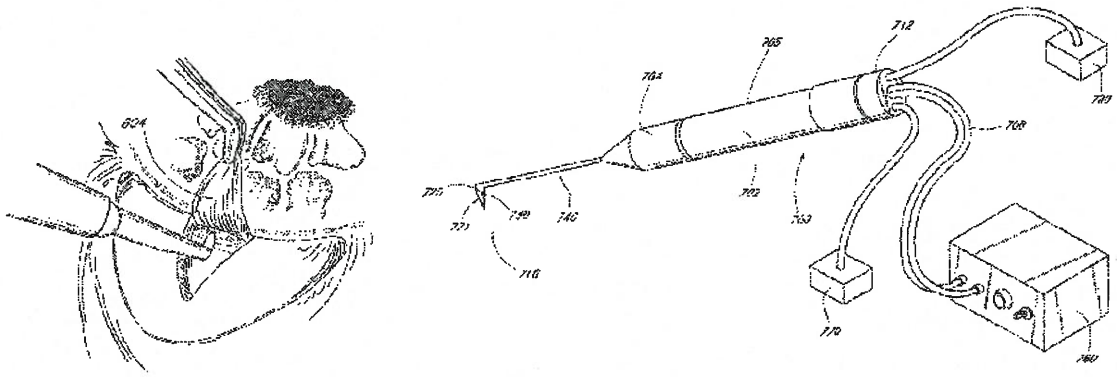
(57) **ABSTRACT**

Apparatuses and methods for the treatment of glaucoma are provided. The instrument uses either cauterization, a laser to ablate, sonic or ultrasonic energy to emulsify, or mechanical cutting of a portion of the trabecular meshwork. The instrument may also be provided with irrigation, aspiration, and a footplate. The footplate is used to enter Schlemm's canal, serves as a guide, and also protects Schlemm's canal.

11 Claims, 37 Drawing Sheets



Related U.S. Application Data

continuation of application No. 12/843,458, filed on Jul. 26, 2010, now Pat. No. 8,512,321, which is a continuation of application No. 11/273,914, filed on Nov. 14, 2005, now Pat. No. 7,785,321, which is a continuation of application No. 10/052,473, filed on Jan. 18, 2002, now Pat. No. 6,979,328.

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USPC 606/4, 6, 10, 166, 167, 170, 185; 128/898

See application file for complete search history.

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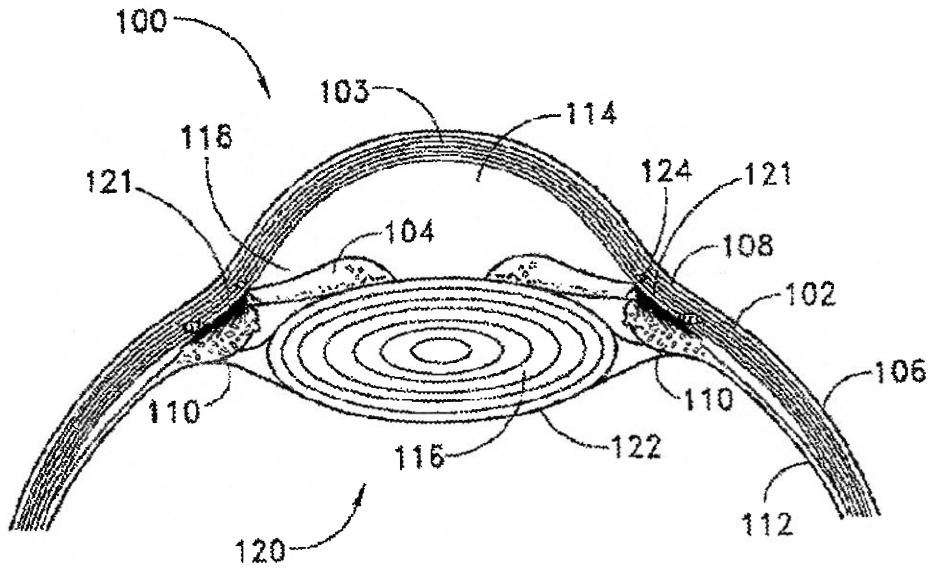
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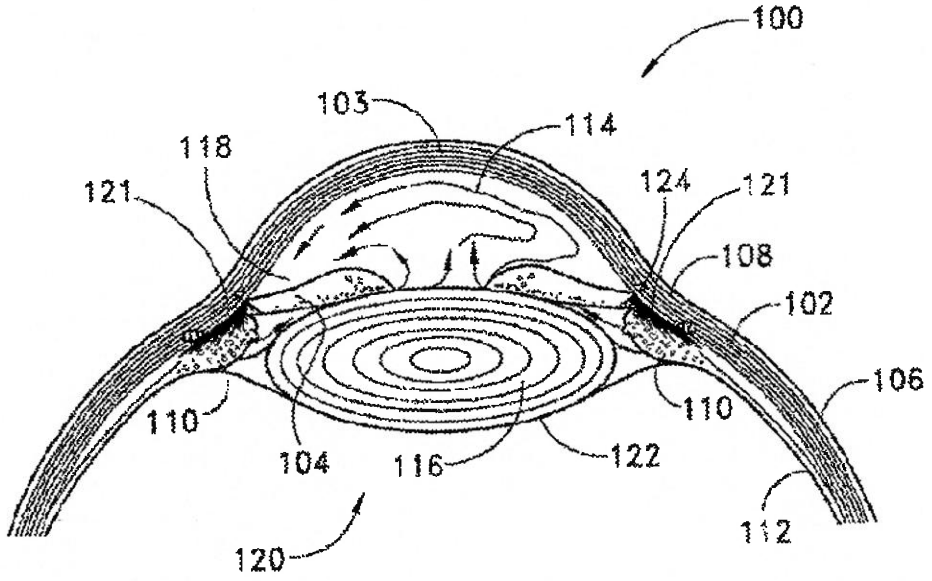
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FIG. 2

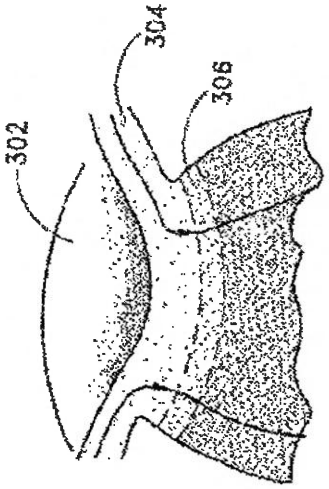


FIG. 3B

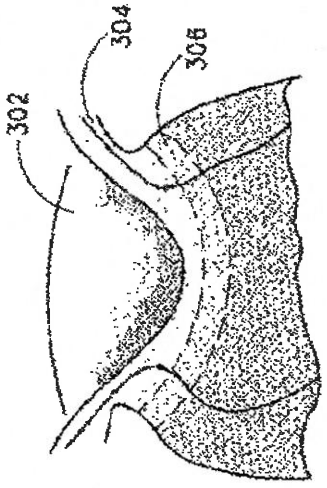


FIG. 3D

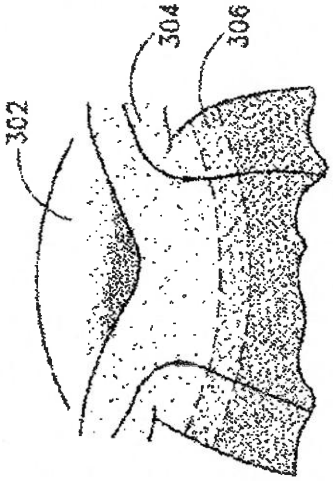


FIG. 3A

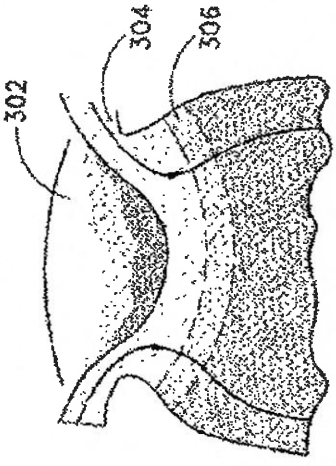


FIG. 3C

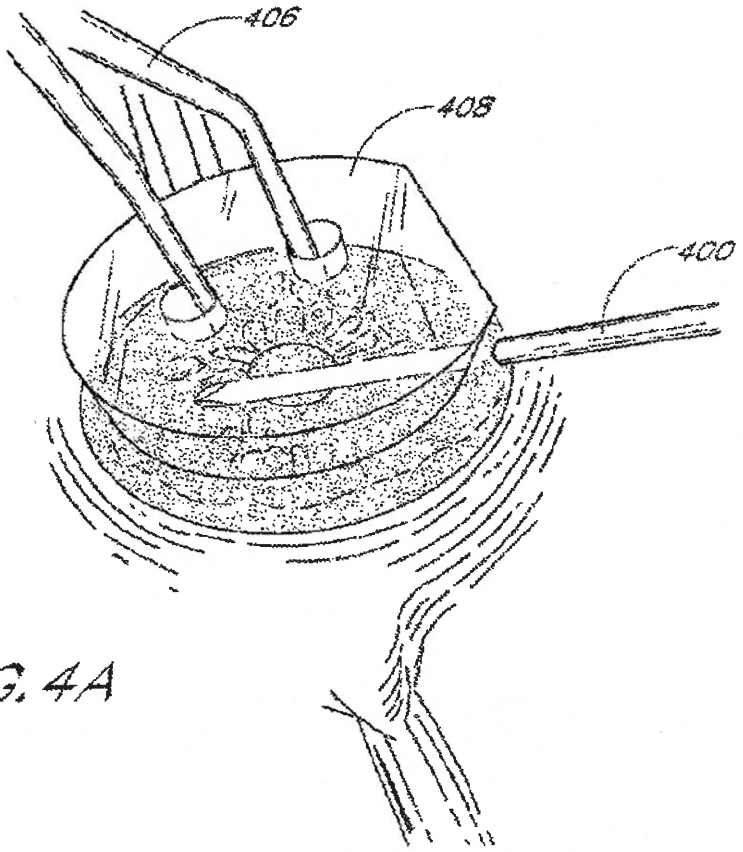


FIG. 4A

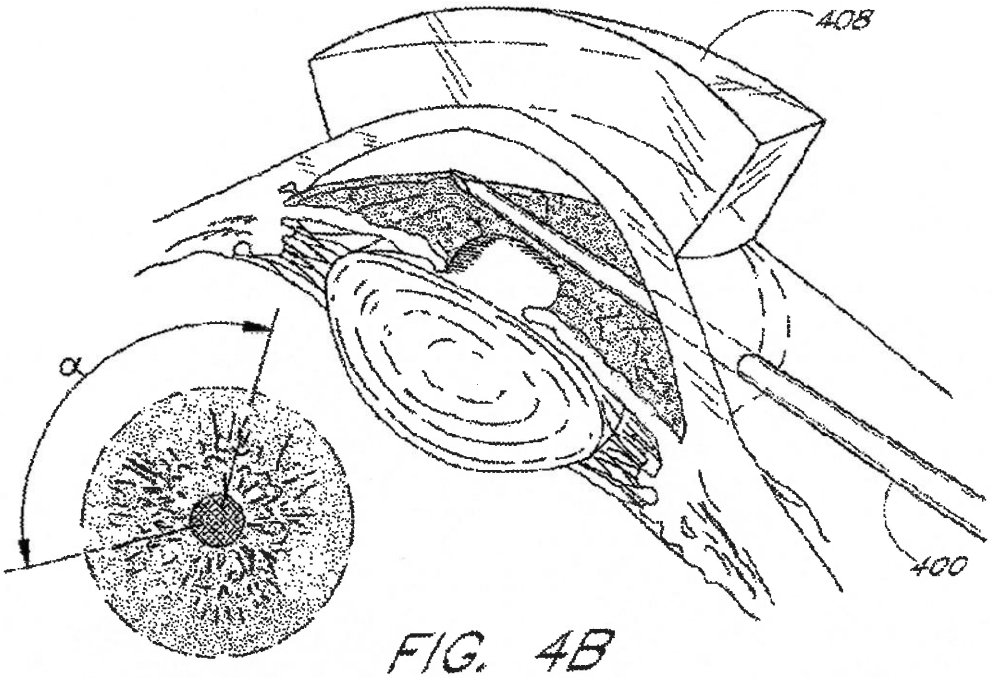


FIG. 4B

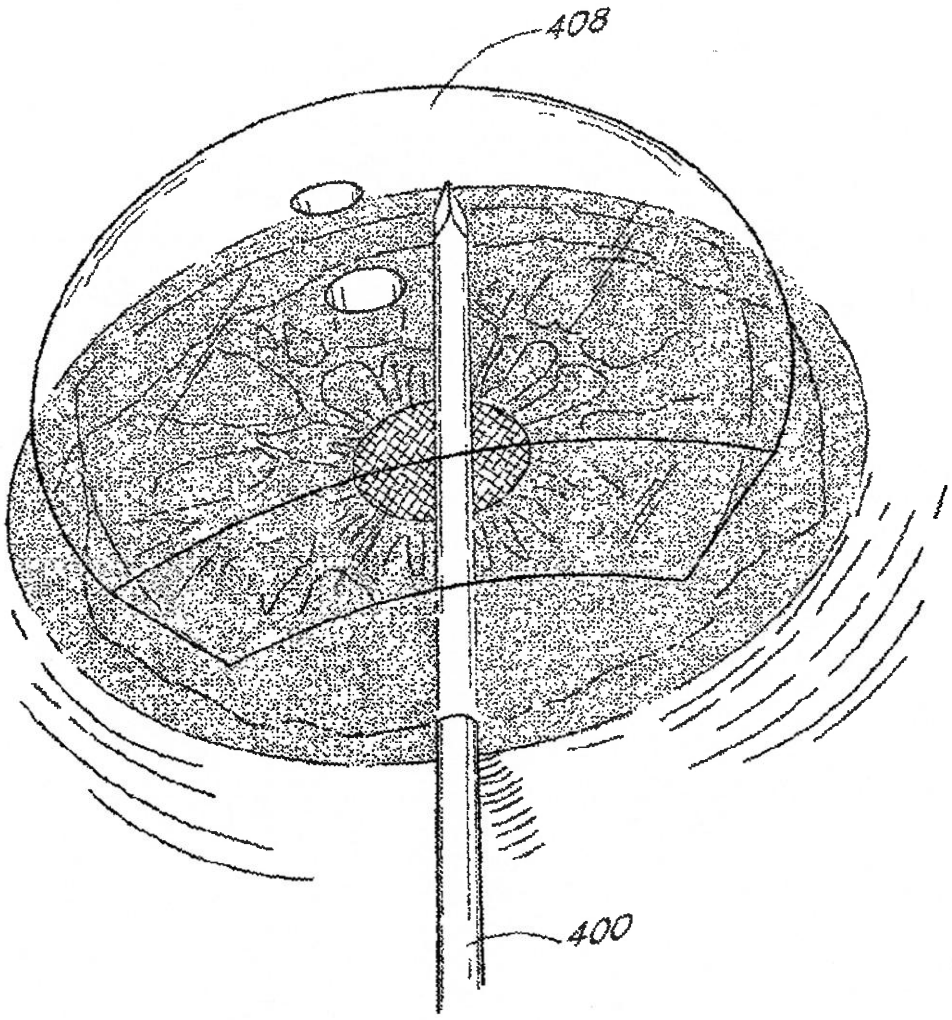
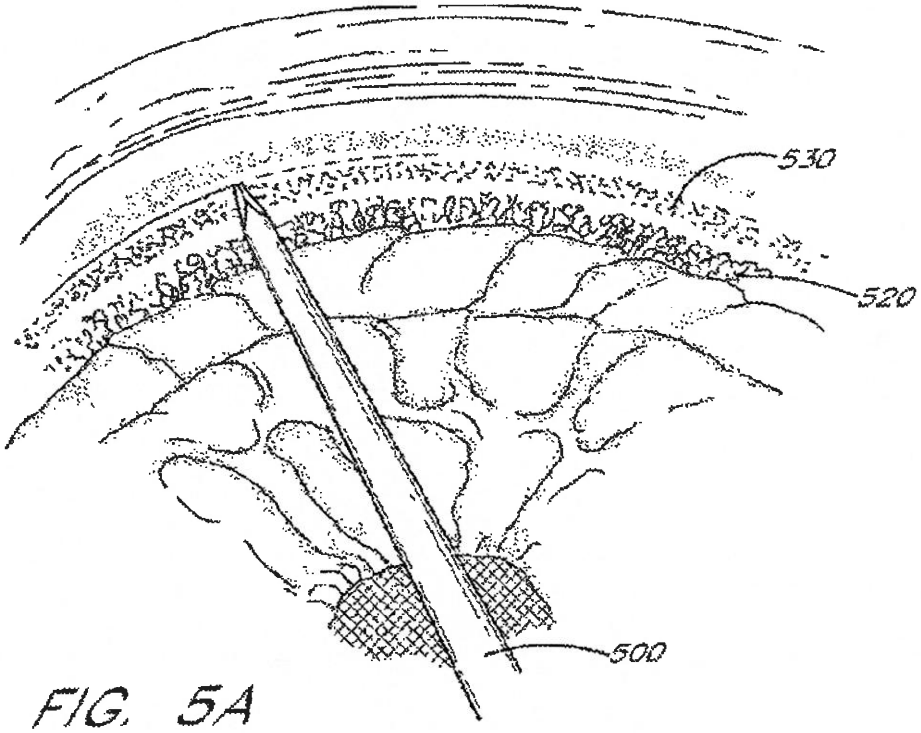


FIG. 4C



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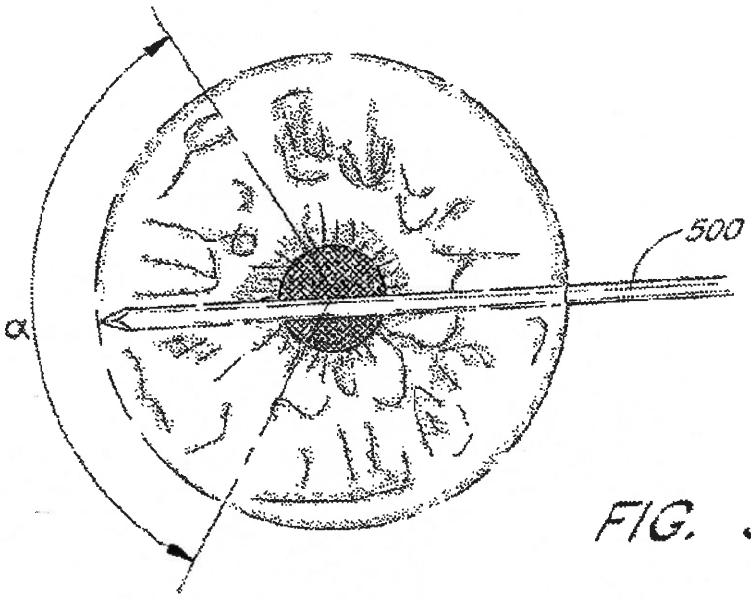

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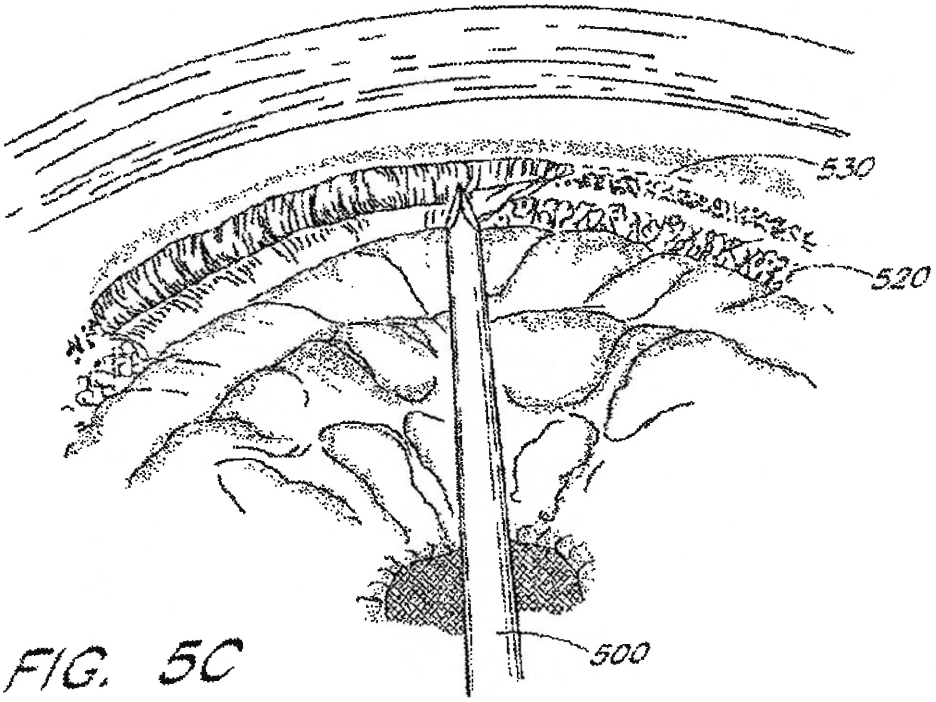

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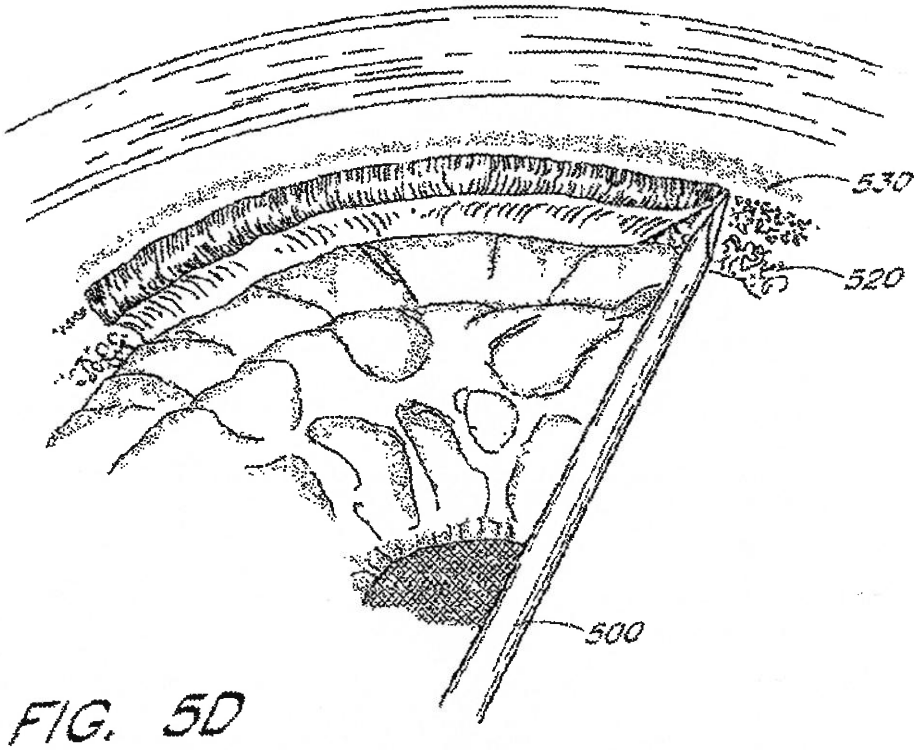
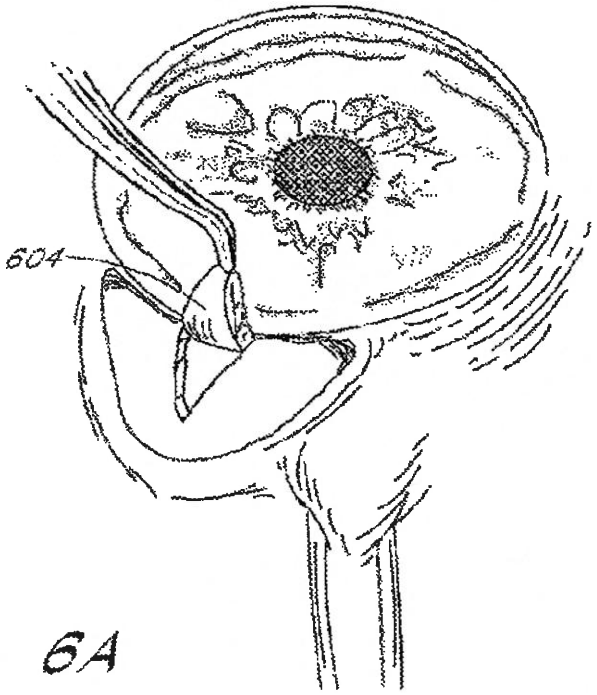


FIG. 5D



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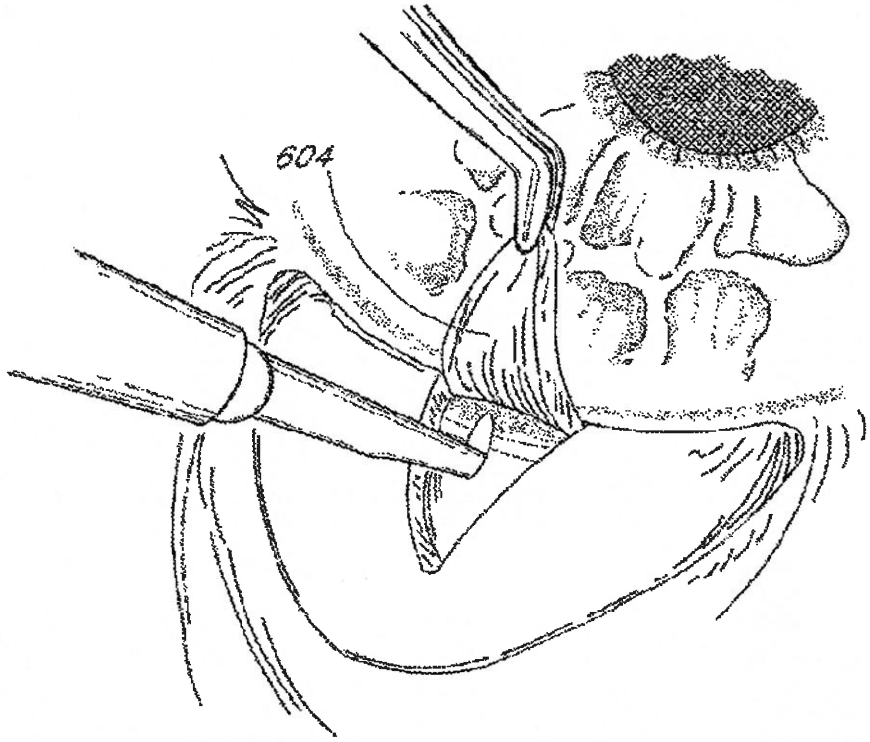

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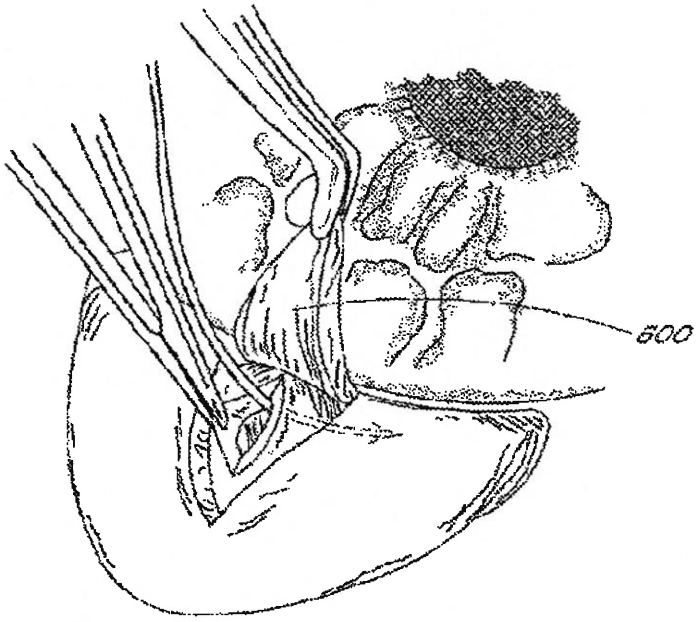

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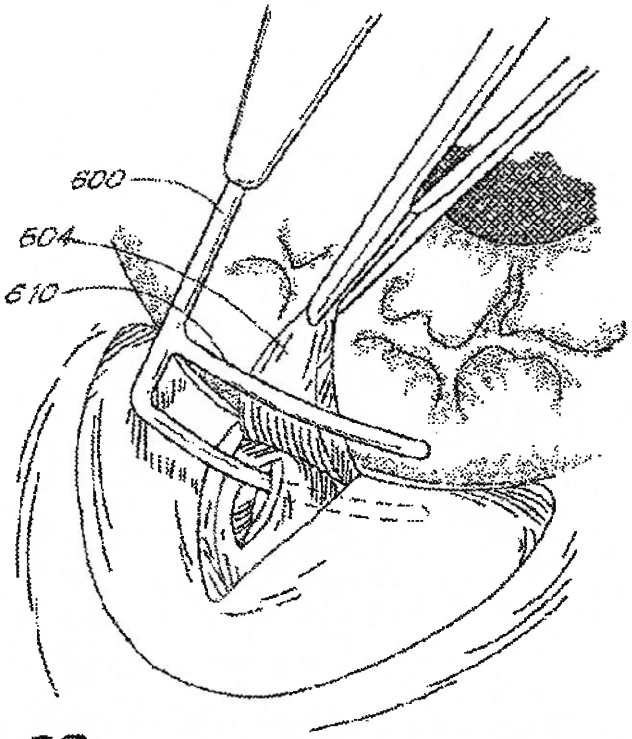
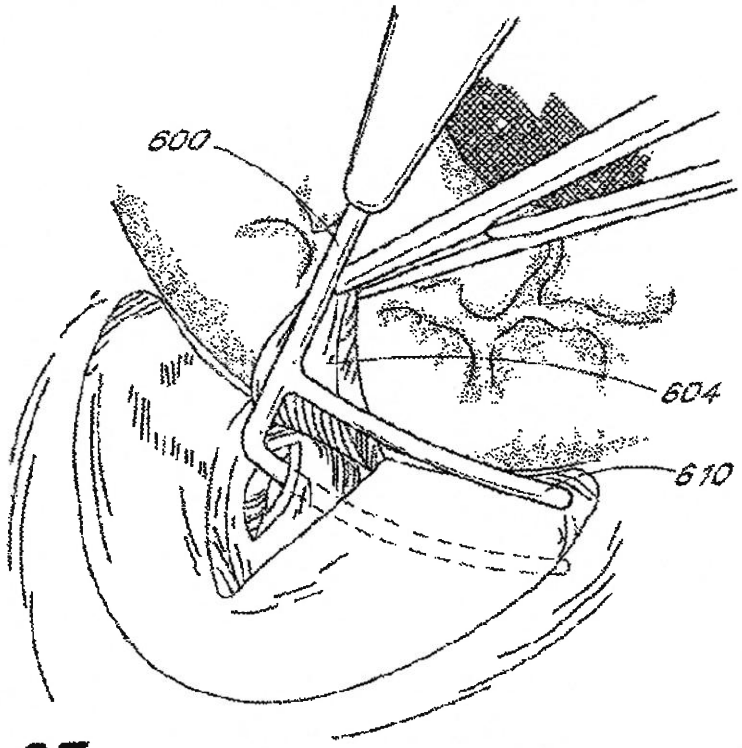


FIG. 6D



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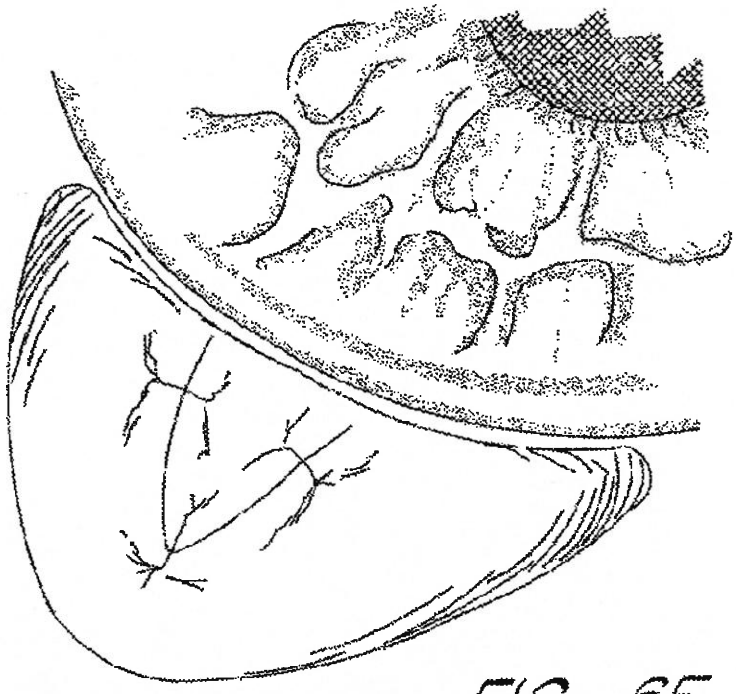


FIG. 6F

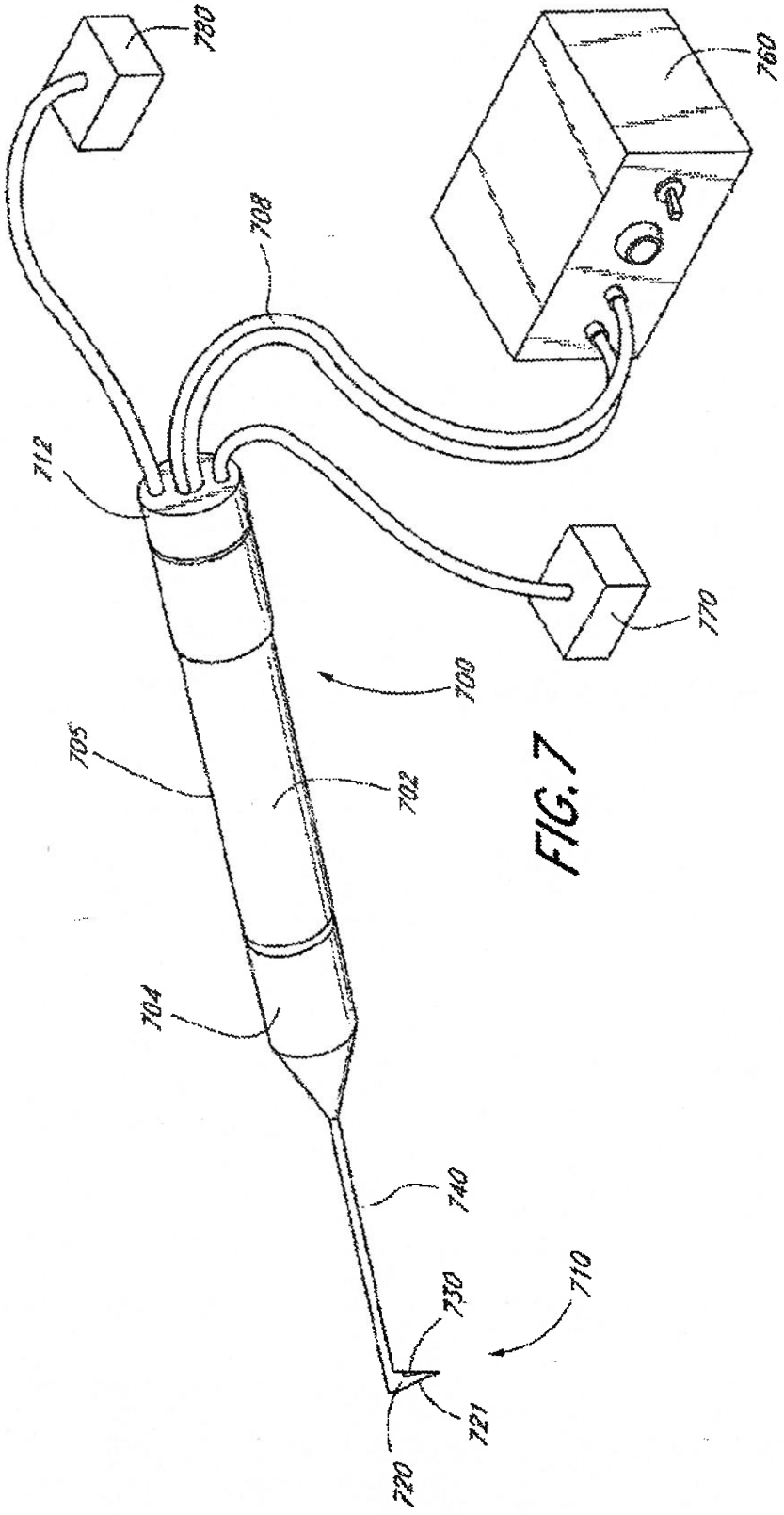
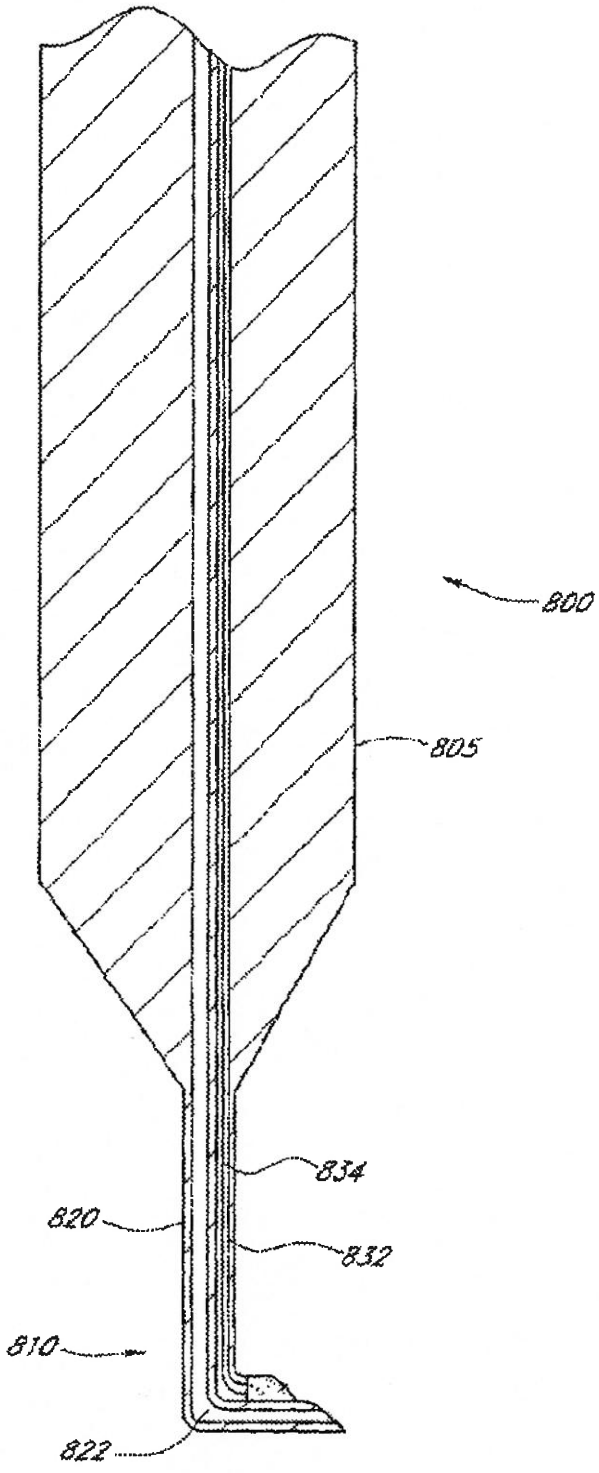


FIG. 7



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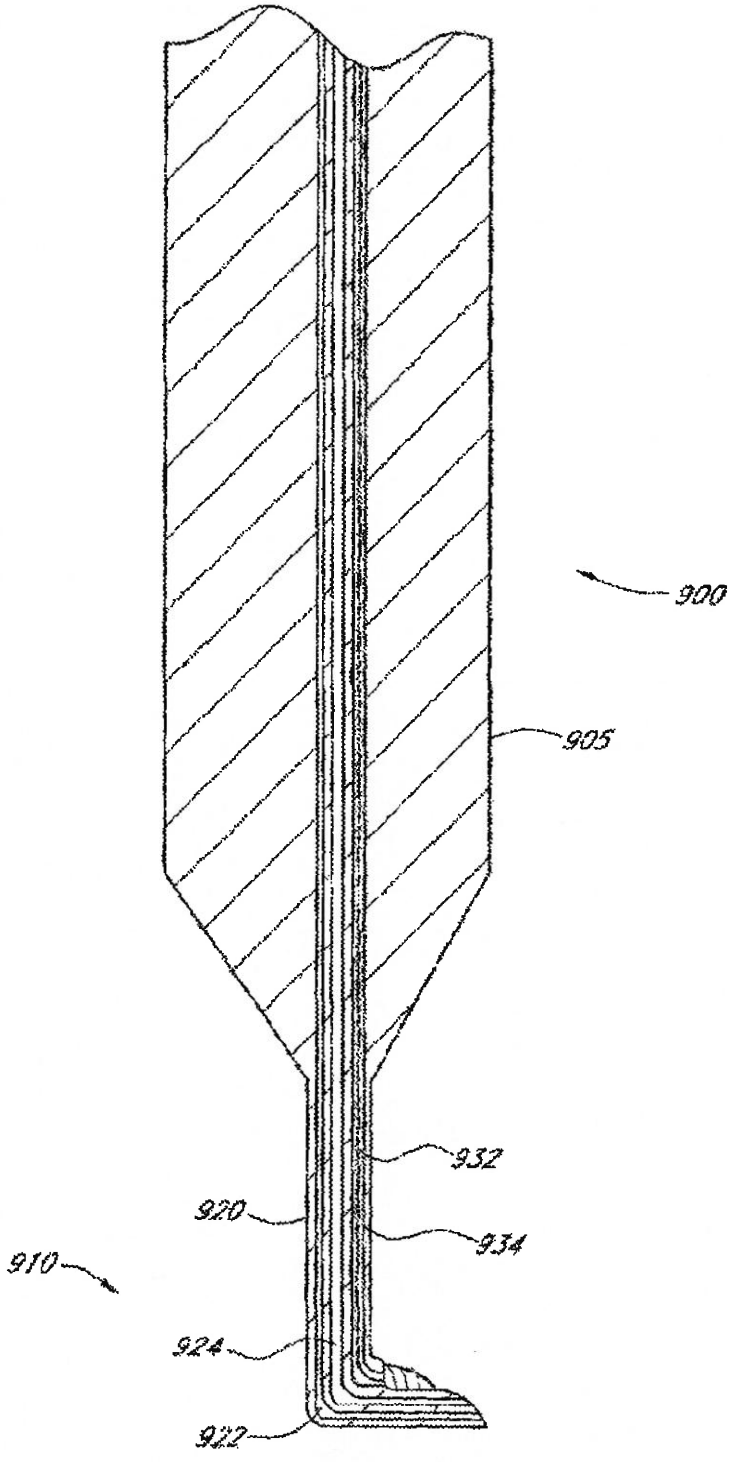
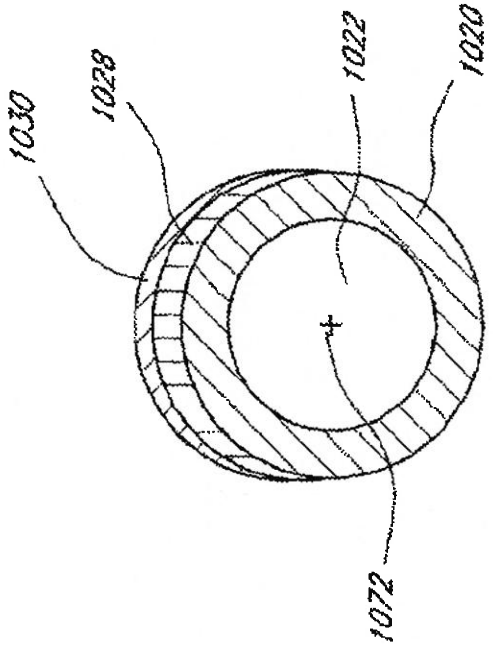


FIG. 9



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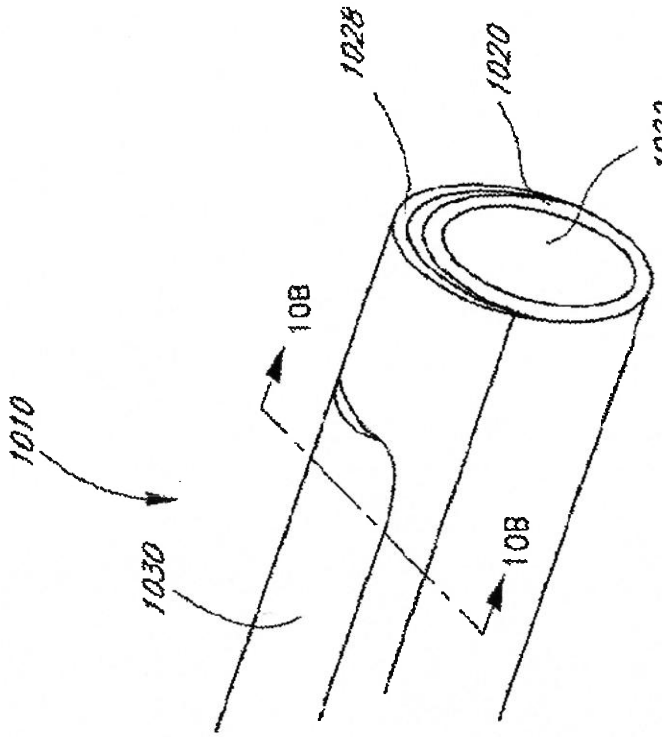

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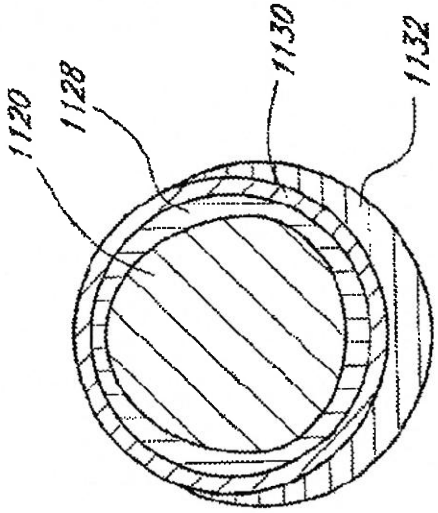

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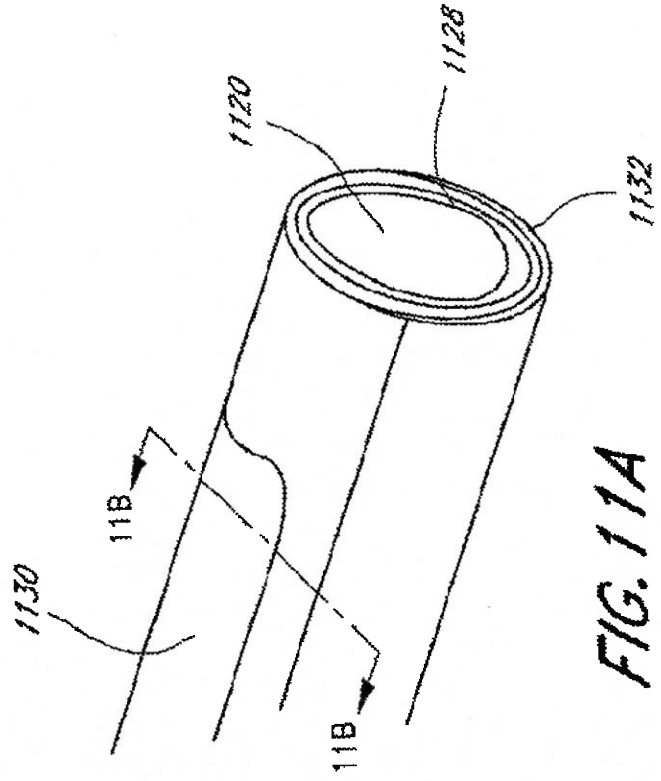

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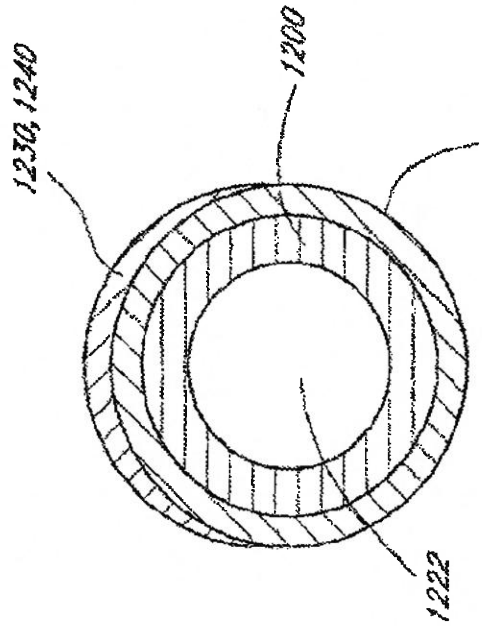

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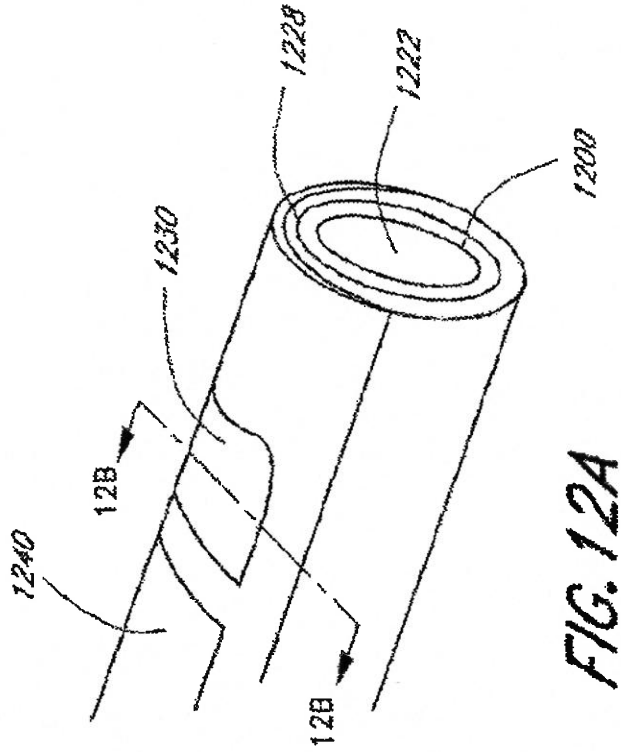

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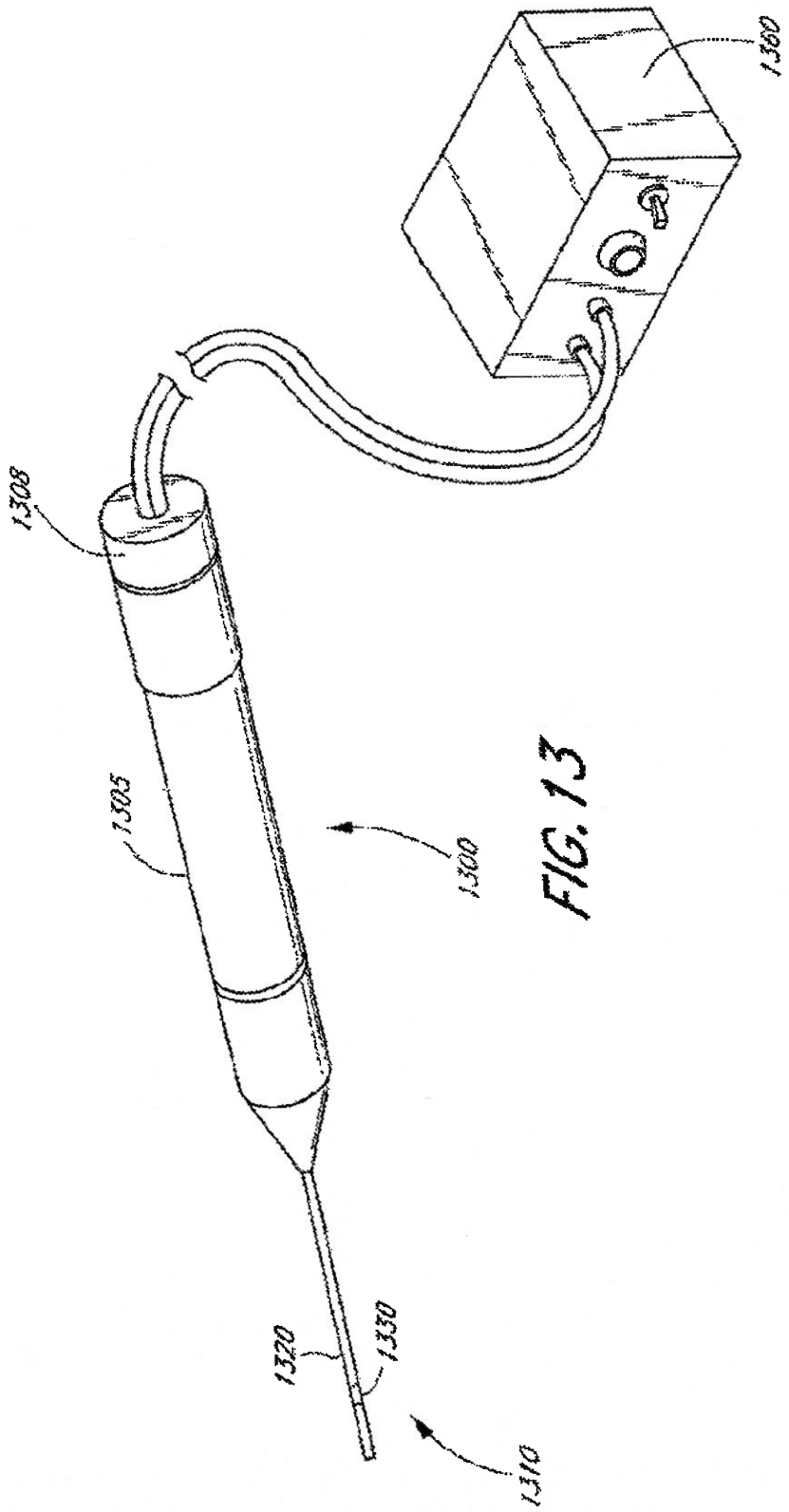

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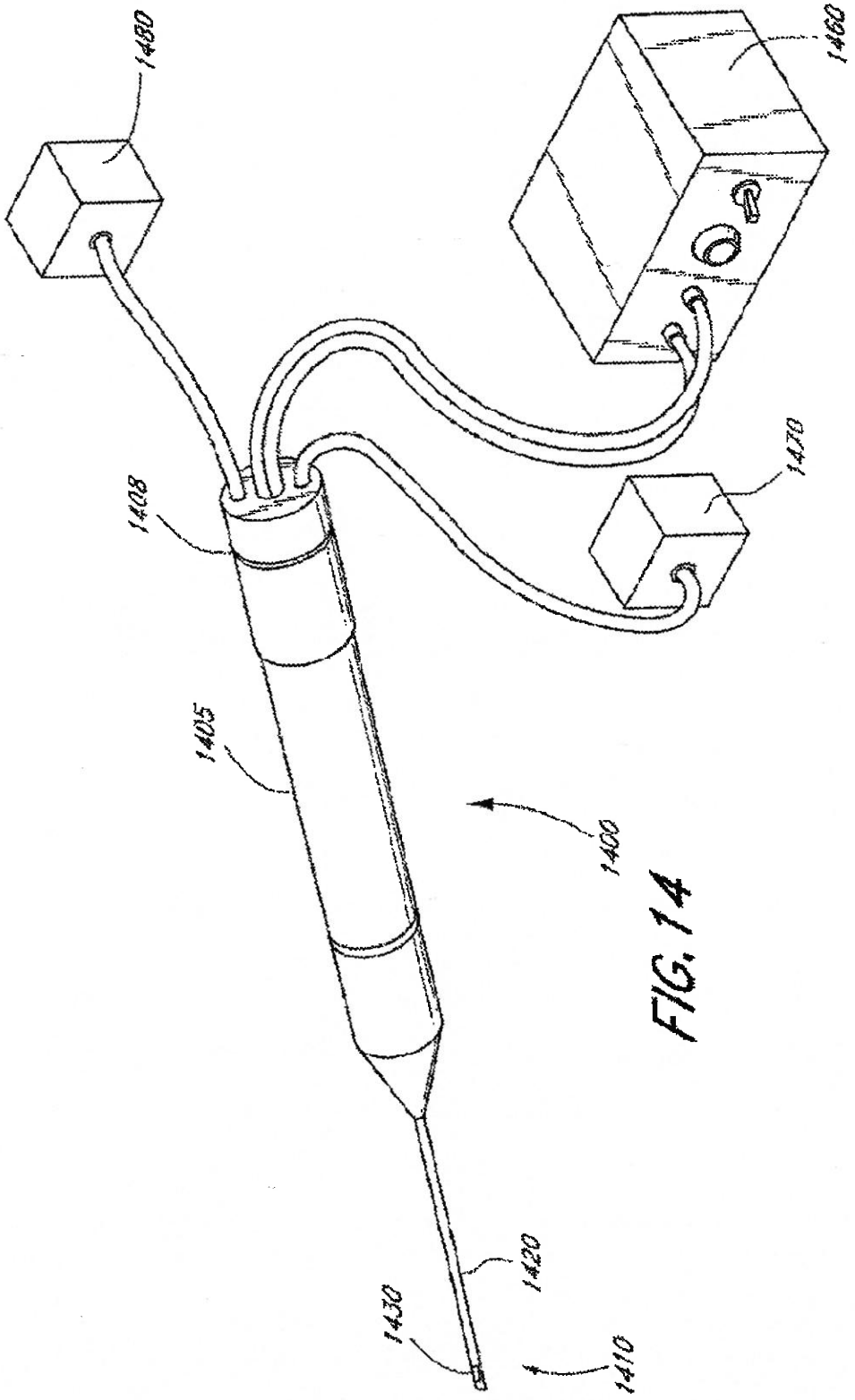

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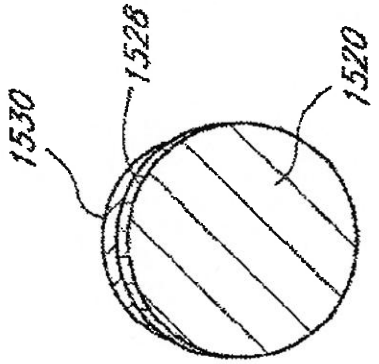

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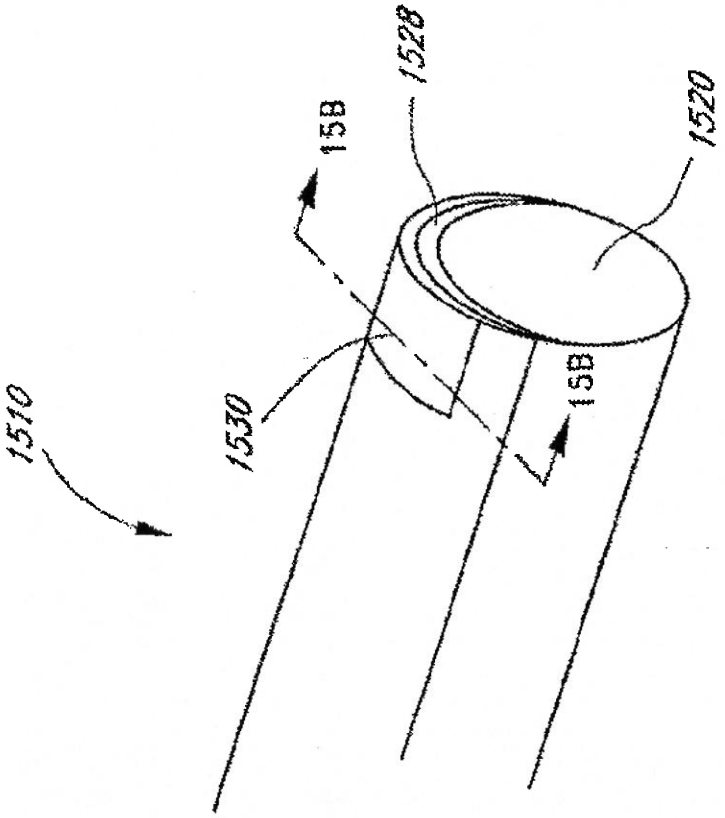

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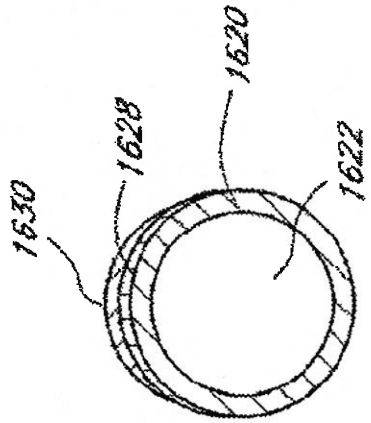

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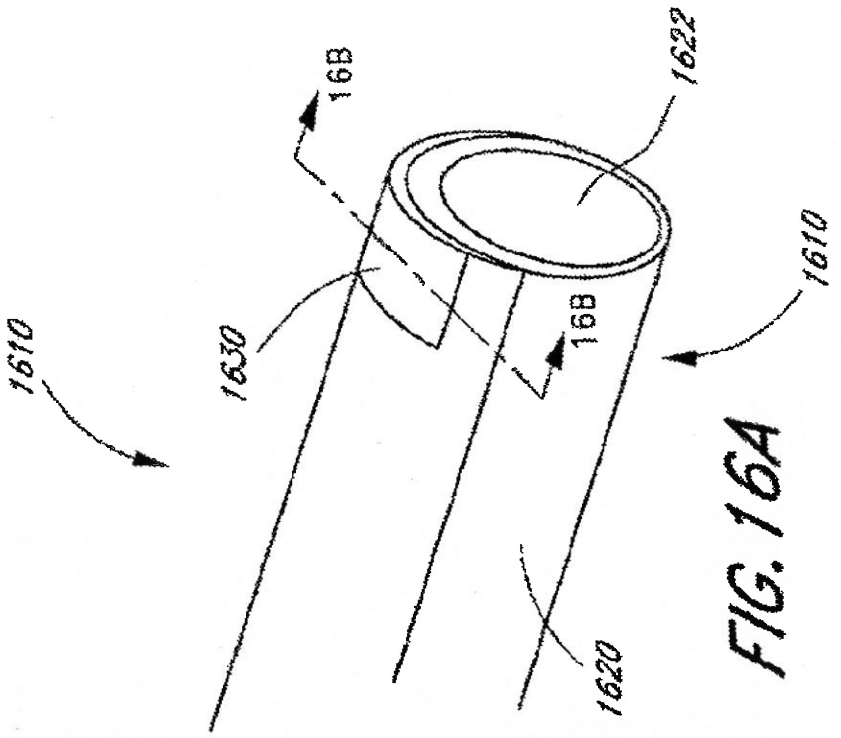

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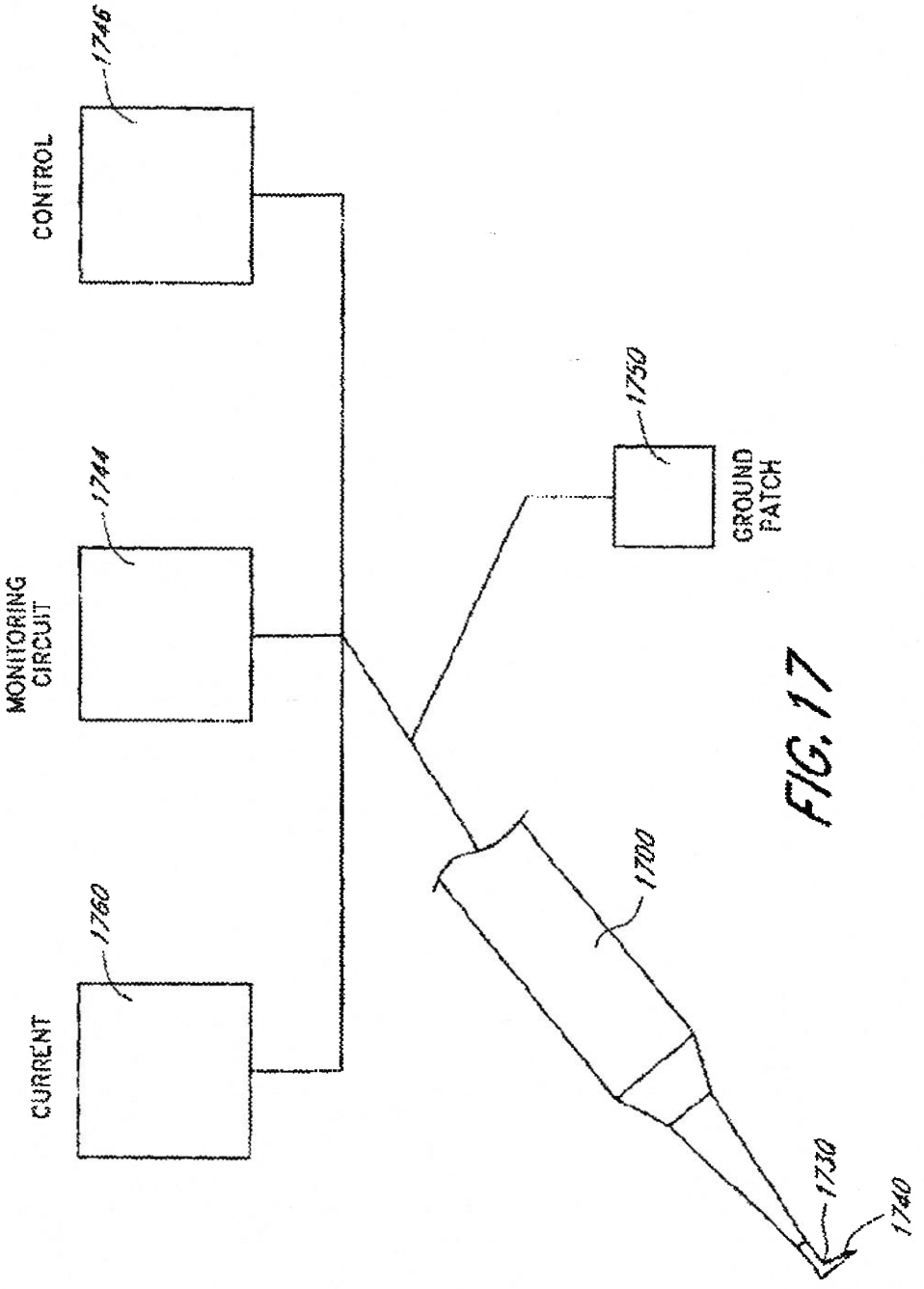
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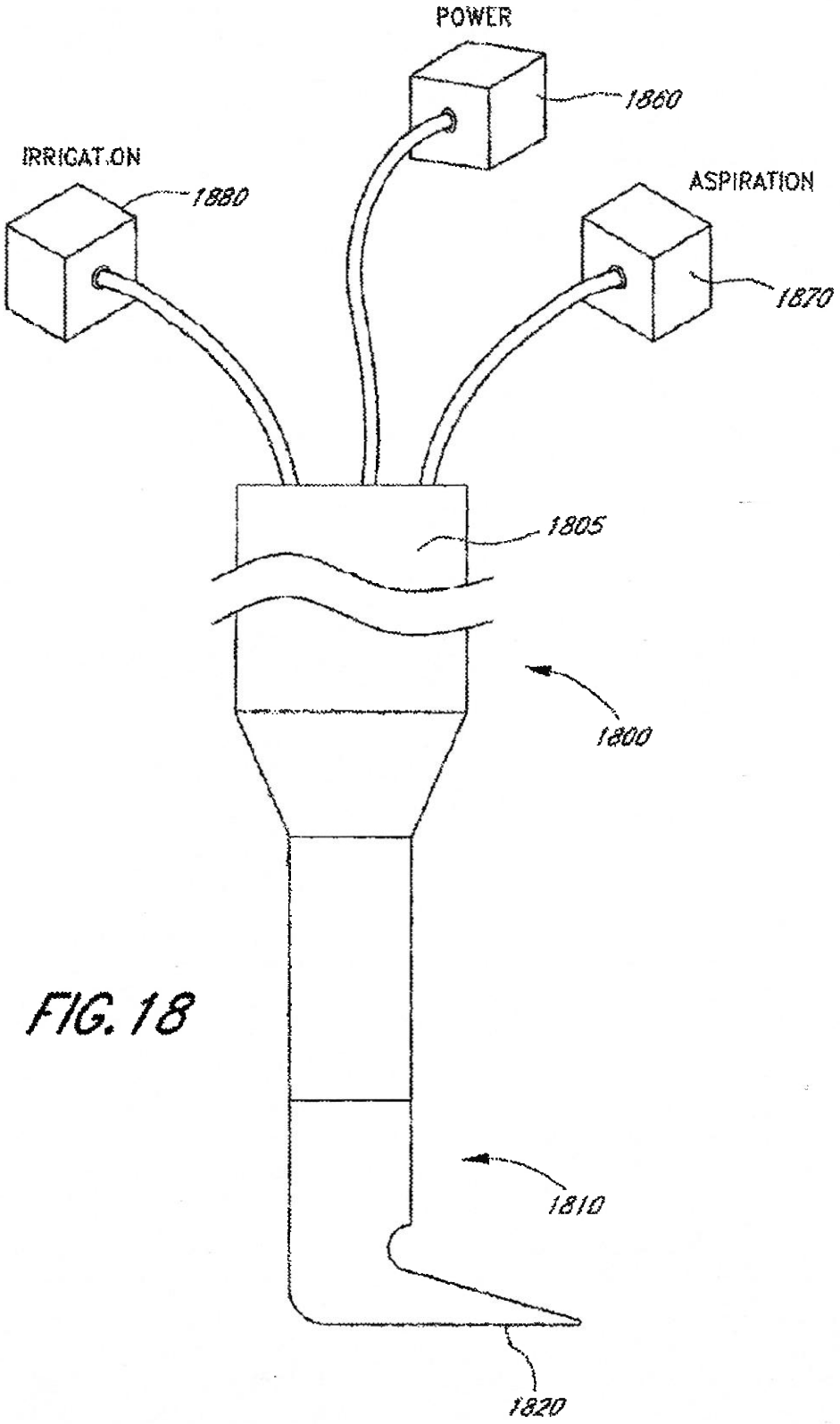
CURRENT
1750
GROUND PATCH
1700
1730
1740

FIG. 17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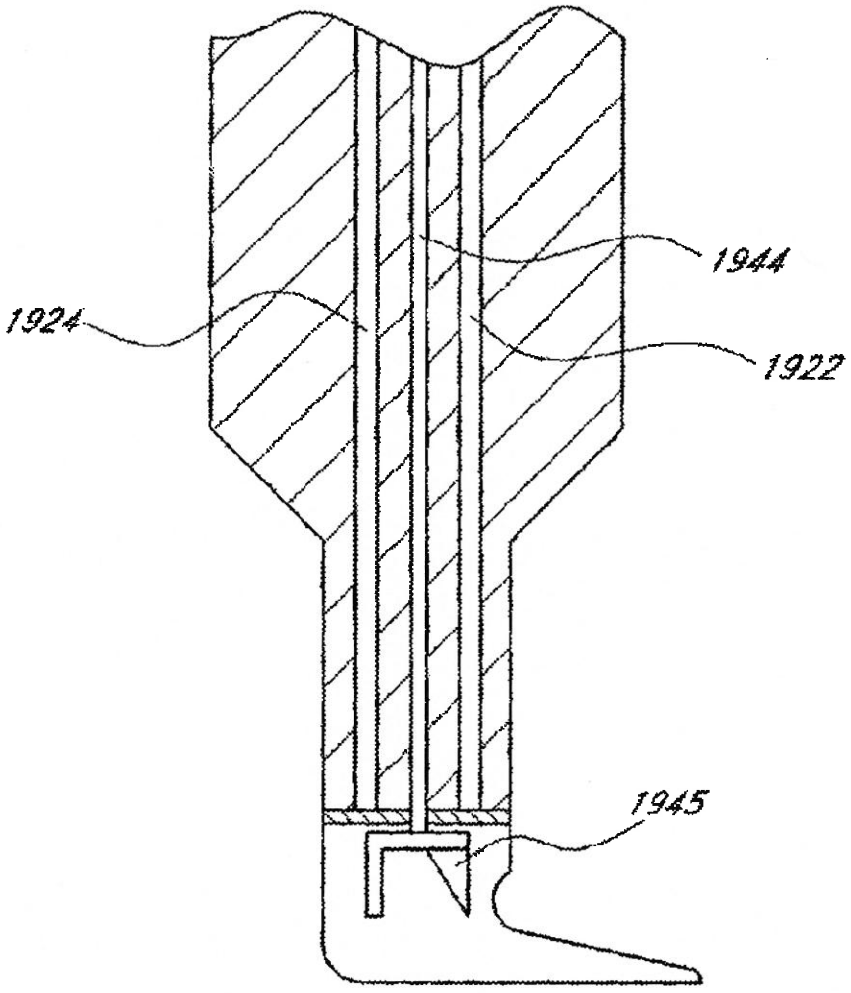
IRRIGATION
1880
ASPIRATION
1870
1805
1800
1810
1820

FIG. 18



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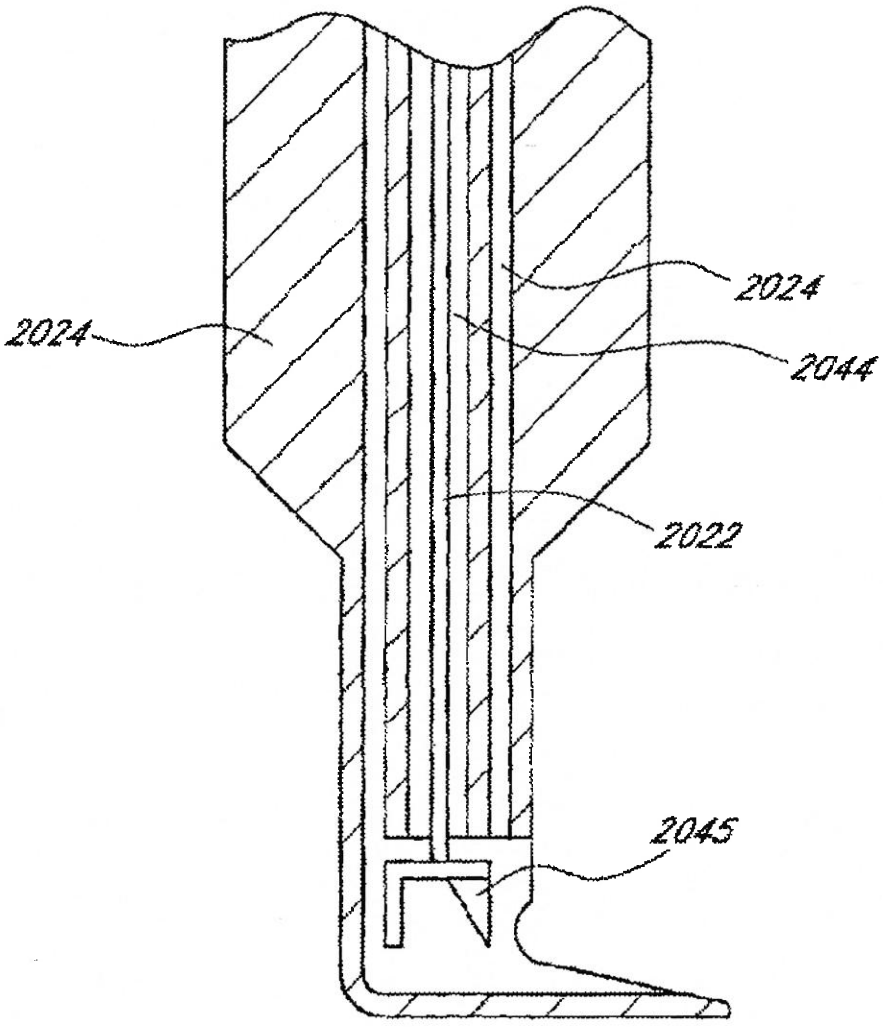

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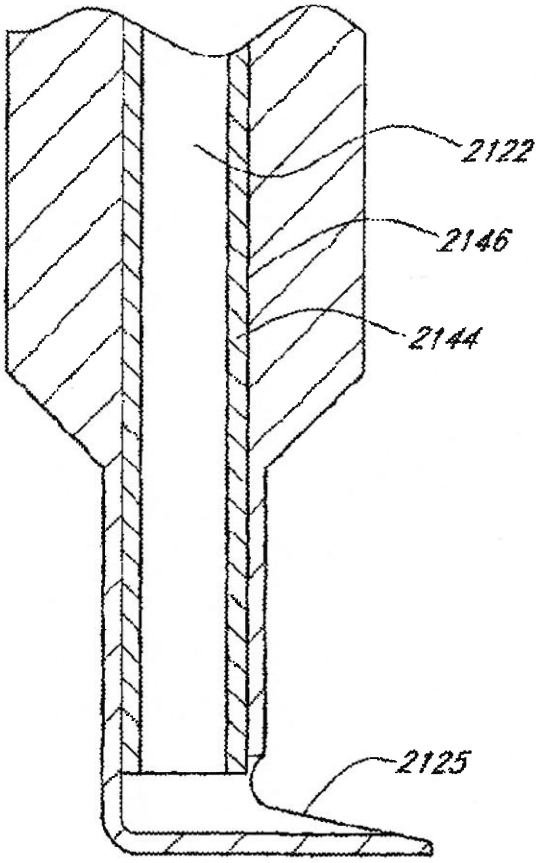

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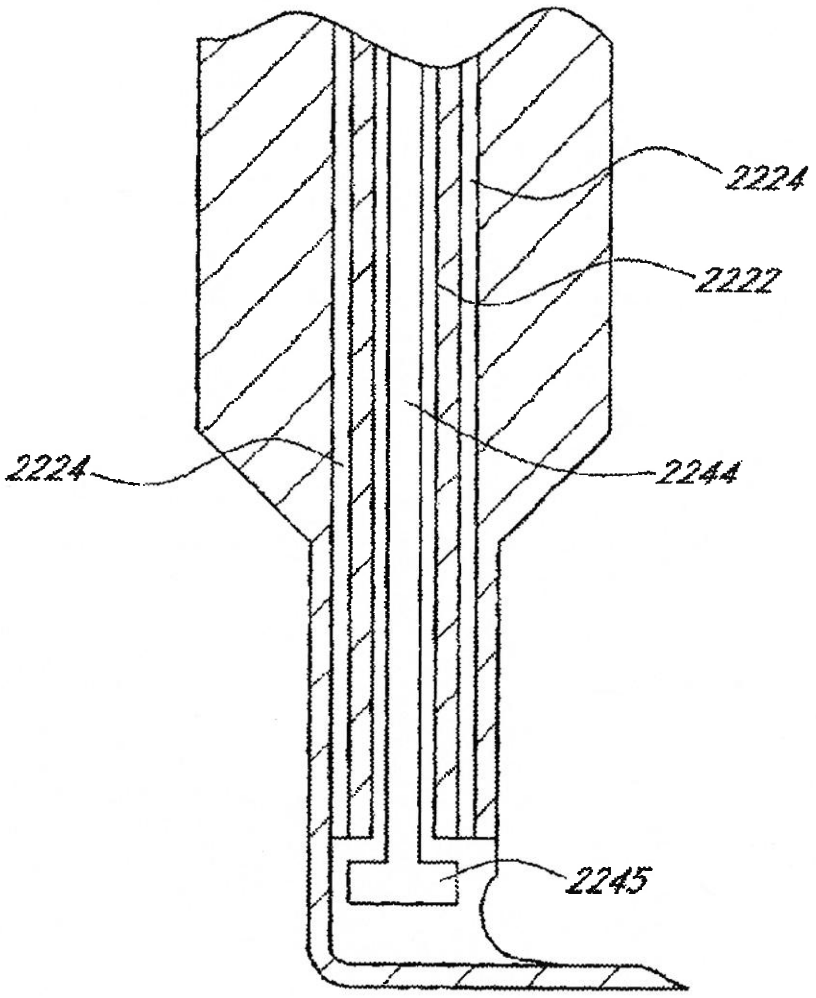
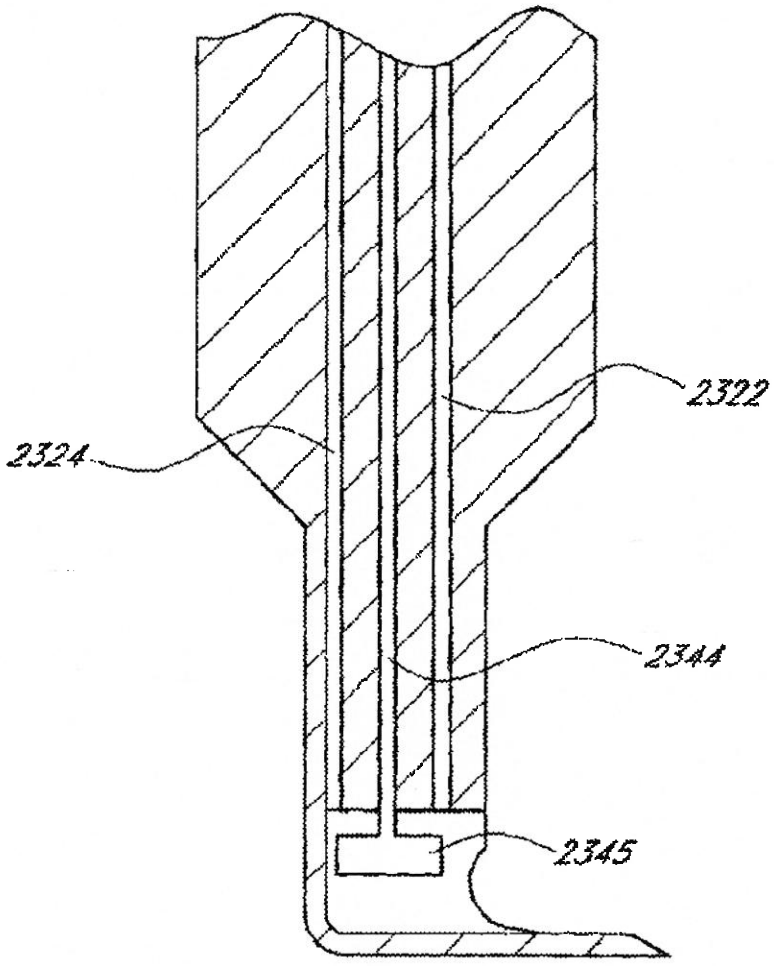


FIG. 22



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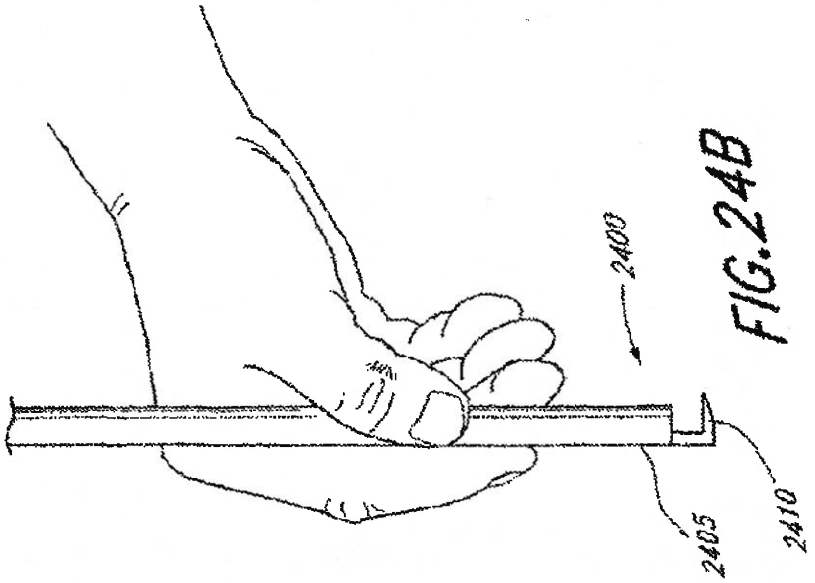

FIG. 24B

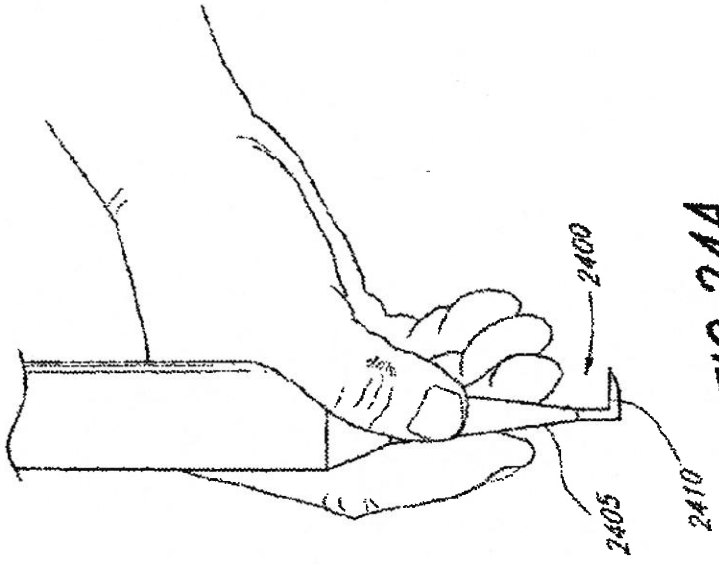

FIG. 24A

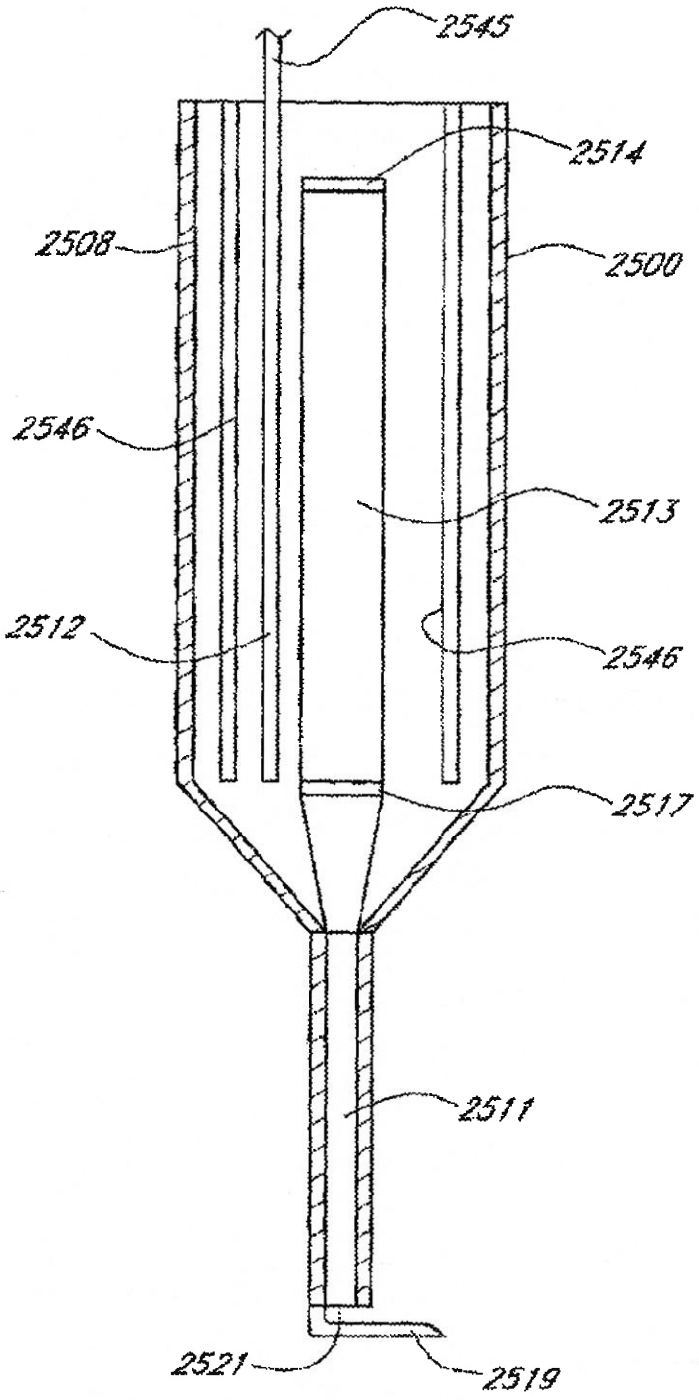

FIG. 25

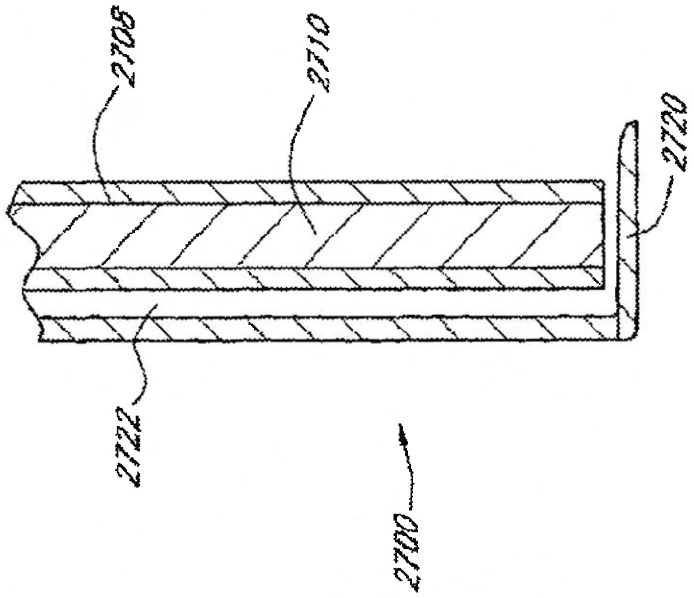

FIG. 27

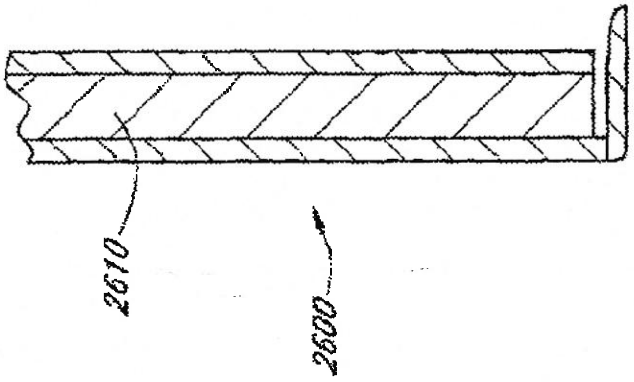

FIG. 26

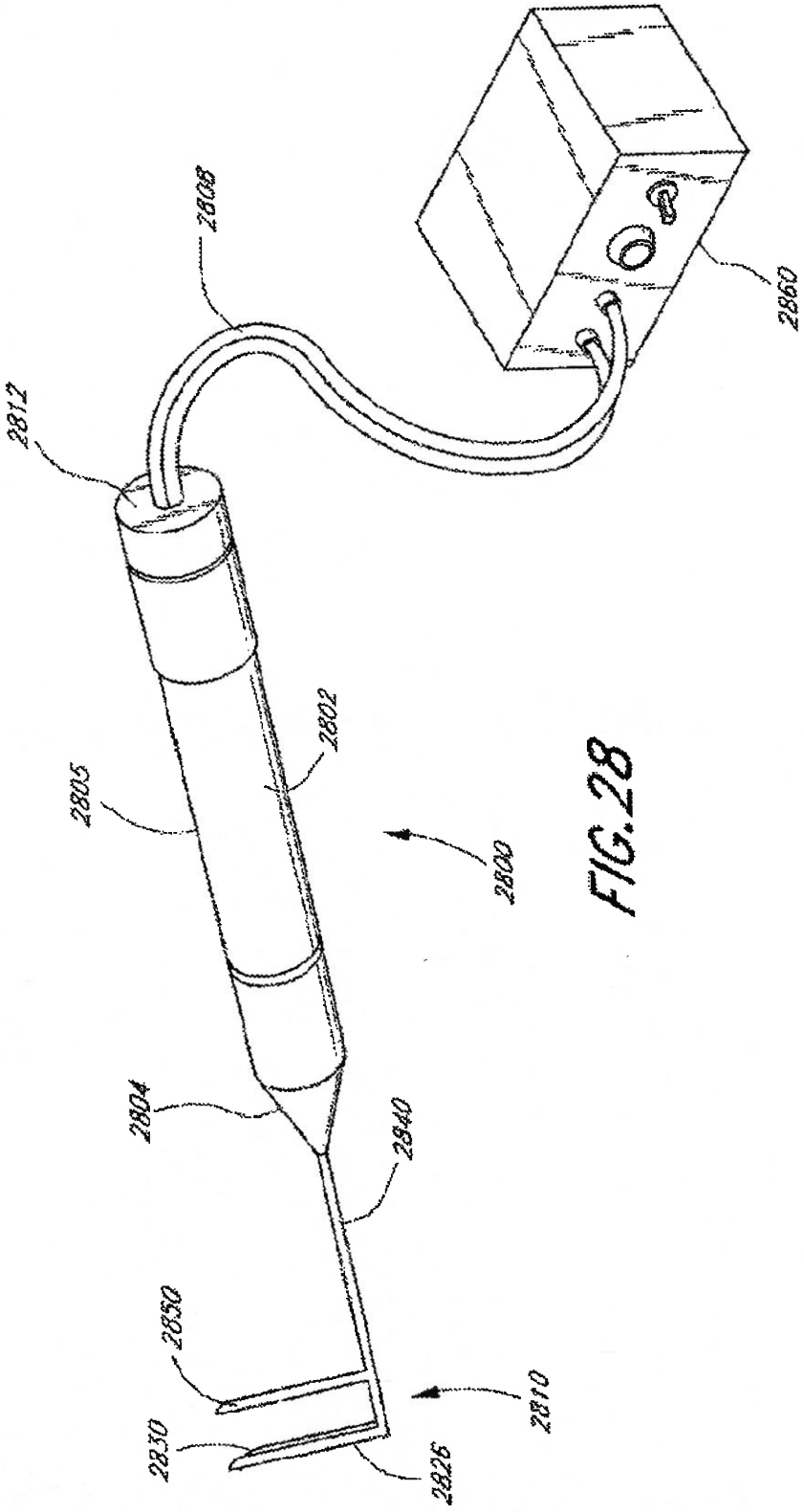

FIG. 28

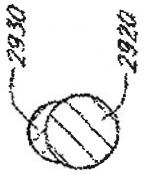

FIG. 29B

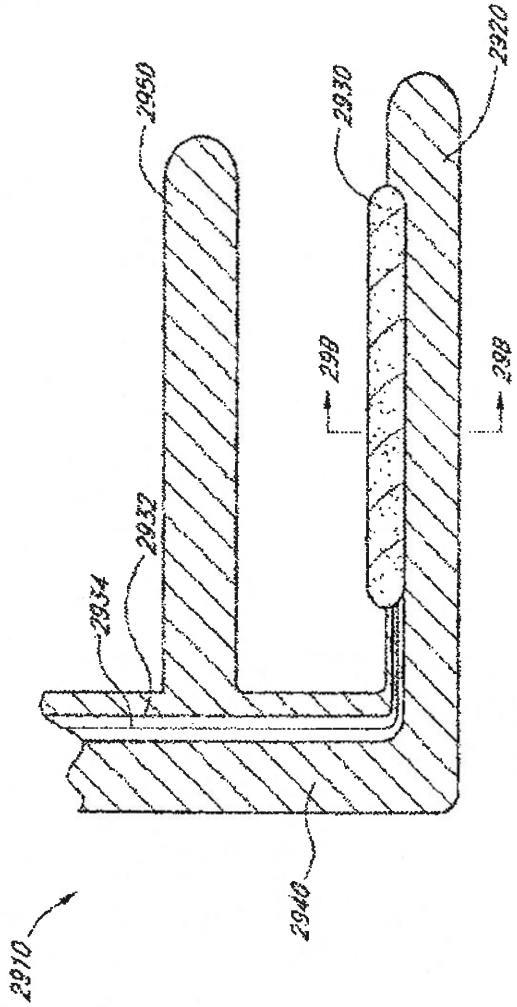

FIG. 29A

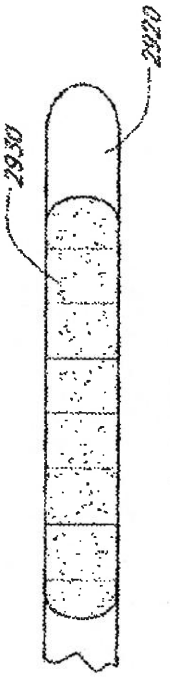

FIG. 29C

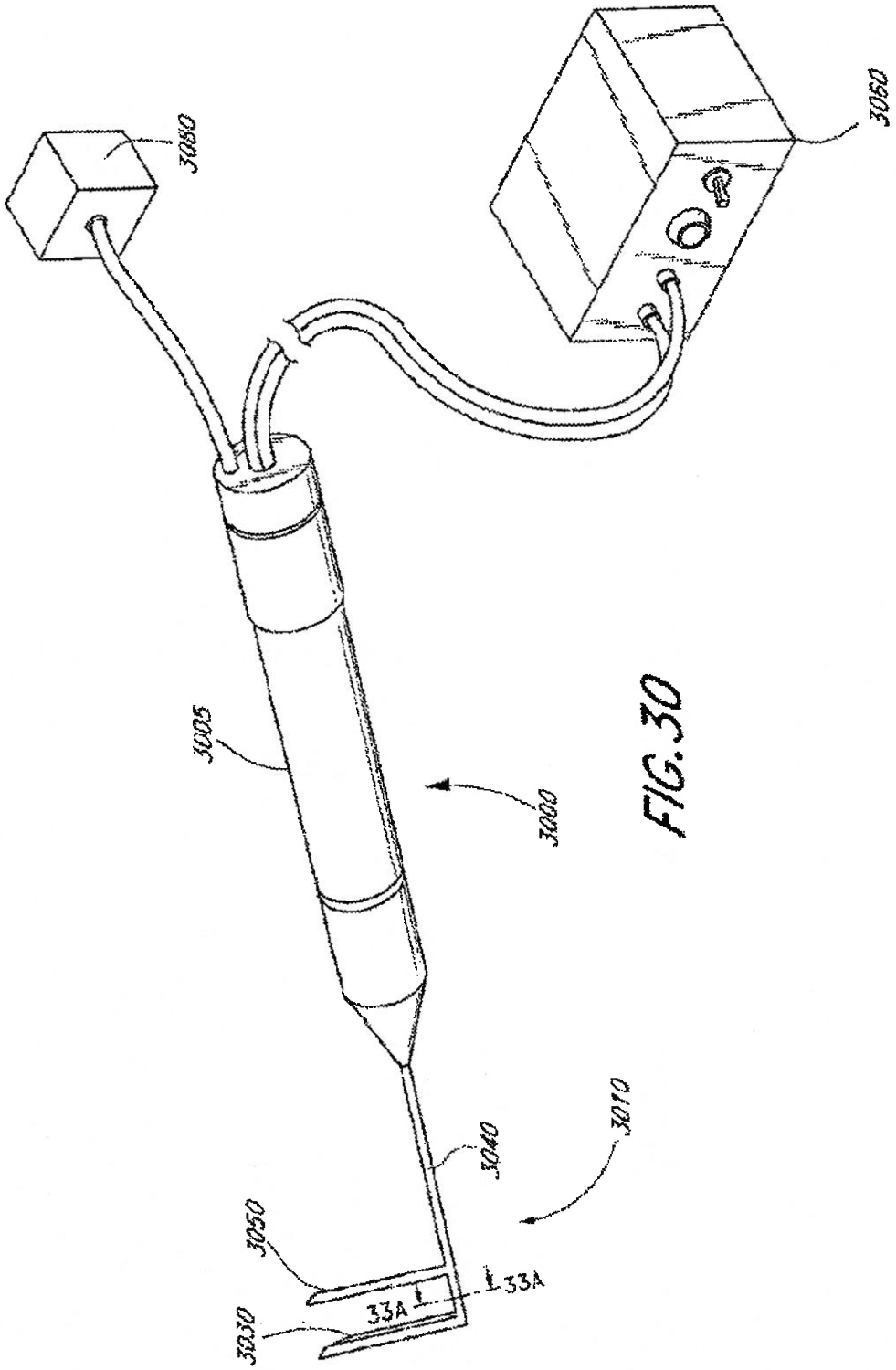

FIG. 30

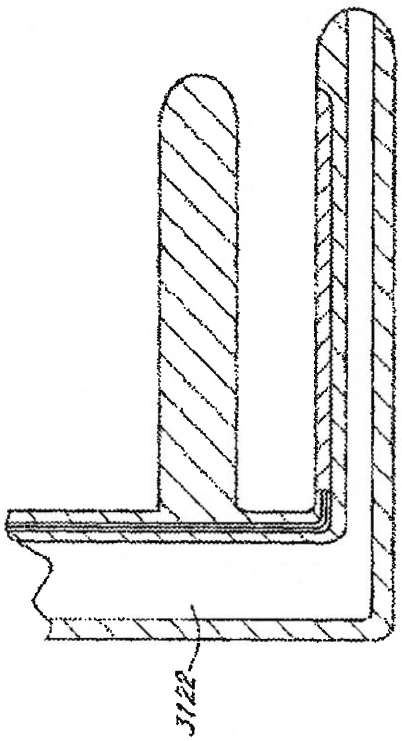

FIG. 31A

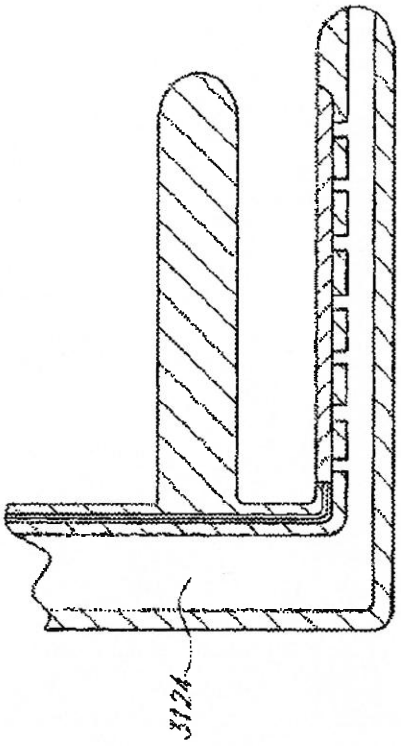

FIG. 31B

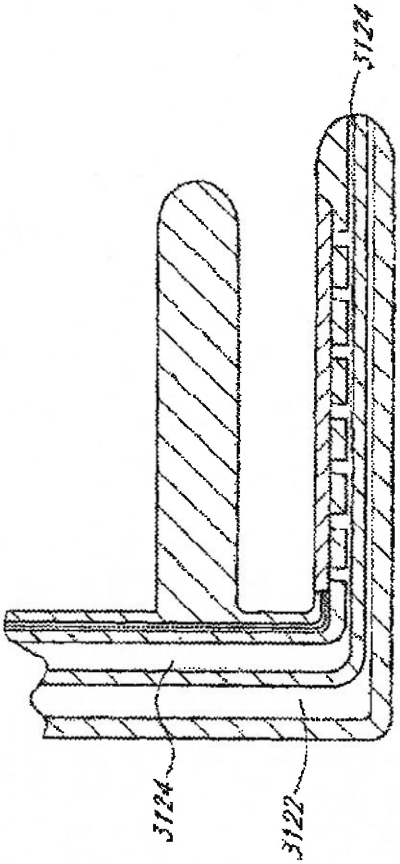

FIG. 31C

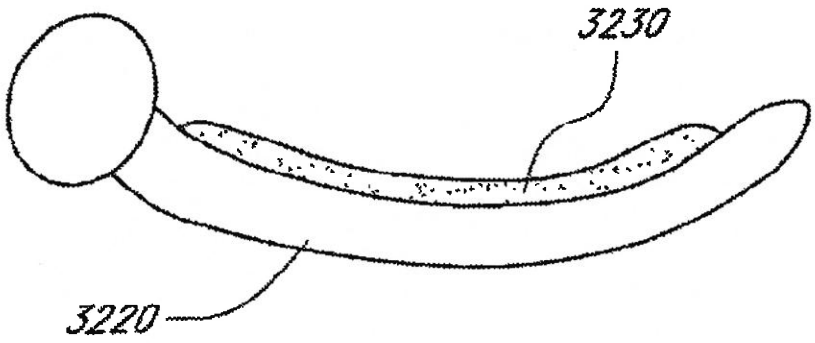

FIG. 32A

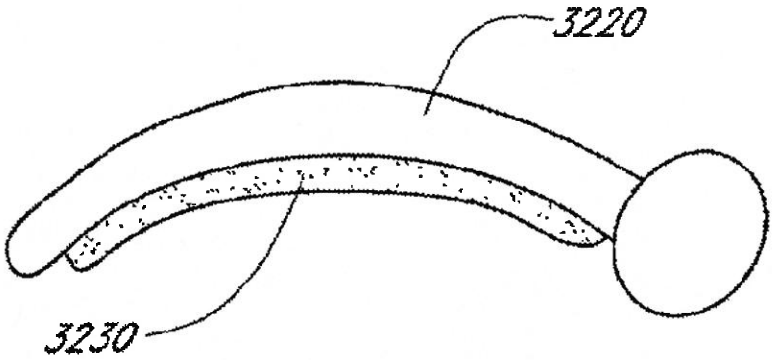

FIG. 32B

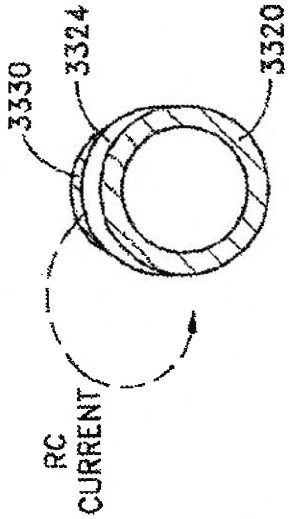

FIG. 33B

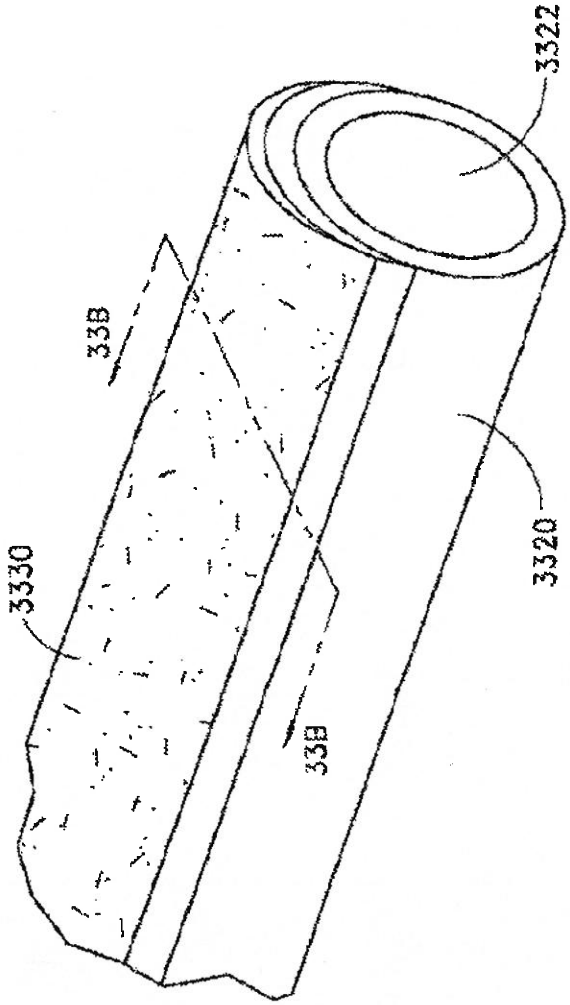

FIG. 33A

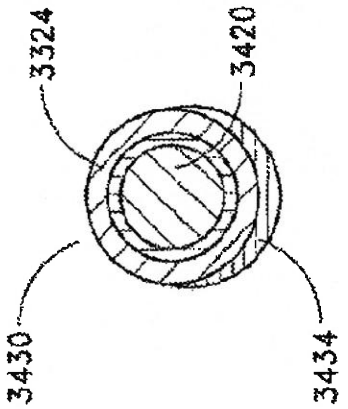

FIG. 34B

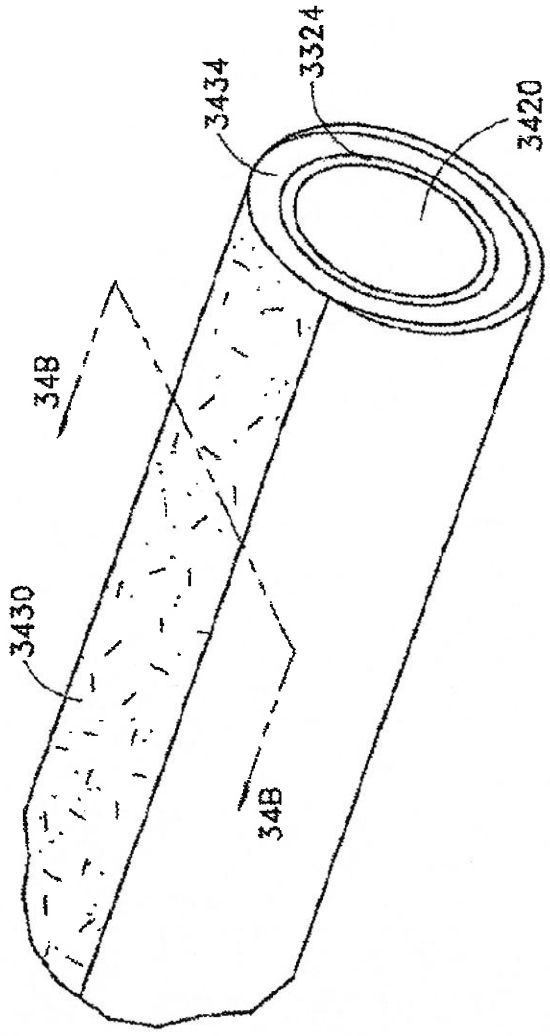

FIG. 34A

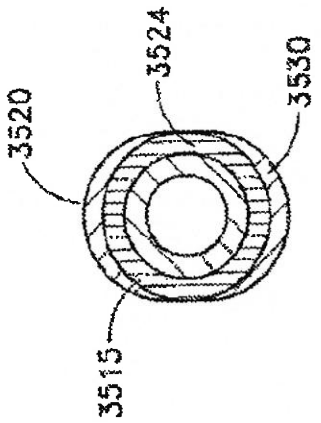

FIG. 35B

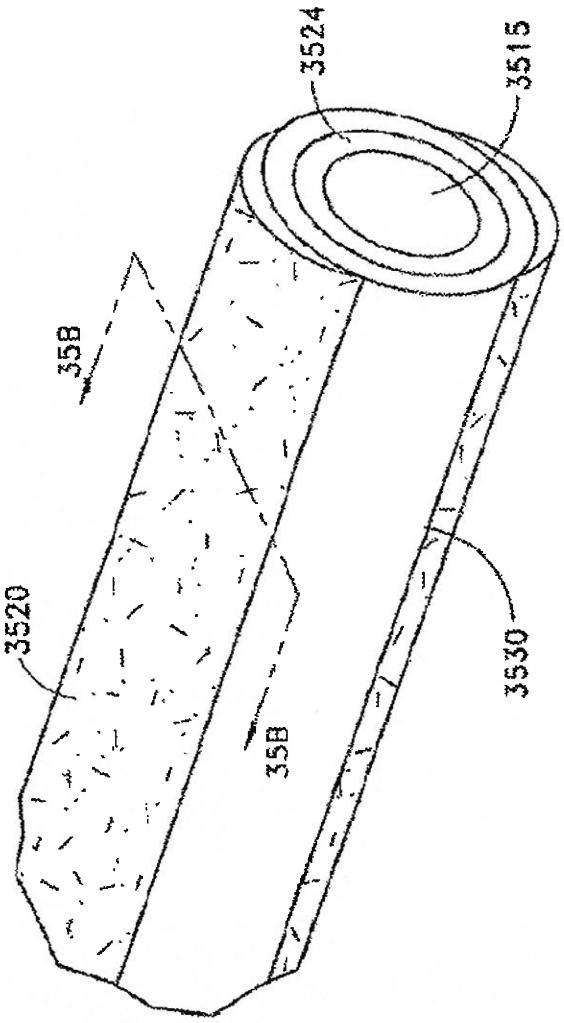

FIG. 35A

MINIMALLY INVASIVE GLAUCOMA SURGICAL INSTRUMENT AND METHOD

CROSS-REFERENCES TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 13/850,231, filed Mar. 25, 2013, which is a continuation of U.S. patent application Ser. No. 12/843,458, filed Jul. 26, 2010, now U.S. Pat. No. 8,512,321, which is a continuation of U.S. patent application Ser. No. 11/273,914, filed Nov. 14, 2005, now U.S. Pat. No. 7,785,321, which is a continuation of U.S. patent application Ser. No. 10/052,473, filed Jan. 18, 2002, now U.S. Pat. No. 6,979,238, which claimed priority to U.S. Provisional Application Ser. No. 60/263,617, filed Jan. 18, 2001, the full disclosures of which are herein incorporated by reference in their entirety.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a new glaucoma surgical instrument and method, and, in particular, removal of the trabecular meshwork by mechanical cautery, vaporization or other tissue destruction means optionally coupled to an instrument with infusion, aspiration, and a footplate.

2. Description of the Related Art

Aqueous is a clear, colorless fluid that fills the anterior and posterior chambers of the eye. The aqueous is formed by the ciliary body in the eye and supplies nutrients to the lens and cornea. In addition, the aqueous provides a continuous stream into which surrounding tissues can discharge the waste products of metabolism.

The aqueous produced in the ciliary process circulates from the posterior chamber to the anterior chamber of the eye through the pupil and is absorbed through the trabecular meshwork, a plurality of crisscrossing collagen cords covered by endothelium. Once through the trabecular meshwork, the aqueous passes through Schlemm's canal into collector channels that pass through the scleral and empty into the episcleral venous circulation. The rate of production in a normal eye is typically 2.1 μL/min. Intraocular pressure in the eye is maintained by the formation and drainage of the aqueous. All the tissues within the corneoscleral coat covering the eyeball are subject to this pressure, which is higher than pressure exerted on tissues at other locations in the body.

Glaucoma is a group of diseases characterized by progressive atrophy of the optic nerve head leading to visual field loss, and ultimately, blindness. Glaucoma is generally associated with elevated intraocular pressure, which is an important risk factor for visual field loss because it causes further damage to optic nerve fibers. Other causes of glaucoma may be that the nerve is particularly vulnerable to the pressure due to poor local circulation, tissue weakness or abnormality of structure. In a "normal" eye, intraocular pressure ranges from 10 to 21 mm mercury. In an eye with glaucoma, this pressure can rise to as much as 75 mm mercury.

There are several types of glaucoma, including open and closed angle glaucoma, which involve the abnormal increase in intraocular pressure, primarily by obstruction of the outflow of aqueous humor from the eye, or, less frequently, by over production of aqueous humor within the eye. The most prevalent type is primary open angle glaucoma in which the aqueous humor has free access to the iridocorneal angle, but aqueous humor drainage is impaired through

obstruction of the trabecular meshwork. In contrast, in closed angle glaucoma, the iridocorneal angle is closed by the peripheral iris. The angle block can usually be corrected by surgery. Less prevalent types of glaucoma include secondary glaucomas related to inflammation, trauma, and hemorrhage.

Aqueous humor is similar in electrolyte composition to plasma, but has a lower protein content. The aqueous humor keeps the eyeball inflated, supplies the nutritional needs of the vascular lens and cornea and washes away metabolites and toxic substances within the eye. The bulk of aqueous humor formation is the product of active cellular secretion by nonpigmented epithelial cells of the ciliary process from the active transport of solute, probably sodium, followed by the osmotic flow of water from the plasma. The nonpigmented epithelial cells of the ciliary process are connected at their apical cell membranes by tight junctions. These cells participate in forming the blood/aqueous barrier through which blood-borne large molecules, including proteins, do not pass.

Intraocular pressure (IOP) is a function of the difference between the rate at which aqueous humor enters and leaves the eye. Aqueous humor enters the posterior chamber by three means: 1) active secretion by nonpigmented epithelial cells of the ciliary process; 2) ultrafiltration of blood plasma; and 3) diffusion. Newly formed aqueous humor flows from the posterior chamber around the lens and through the pupil into the anterior chamber; aqueous humor leaves the eye by 1) passive bulk flow at the iridocorneal angle by means of the uveoscleral outflow, or by 2) active transportation through the trabecular meshwork, specifically the juxta canalicar portion. Any change in 1), 2), or 3) will disturb aqueous humor dynamics and likely alter intraocular pressure.

Primary open angle glaucoma is caused by a blockage in the trabecular meshwork. This leads to an increase in intraocular pressure. The major obstruction is at the juxtacanalicular portion which is situated adjacent to Schlemm's canal. In infants a goniotomy or a trabeculotomy can be performed. In goniotomy or trabeculotomy a small needle or probe is introduced into Schlemm's canal and the trabecular meshwork is mechanically disrupted into the anterior chamber. Approximately 90°-120° of trabecular meshwork can be disrupted. The anatomical difference between congenital glaucoma and adult glaucoma is that in congenital glaucoma the ciliary body muscle fibers insert into the trabecular meshwork and once disrupted the trabecular meshwork is pulled posteriorly allowing fluid to enter Schlemm's canal and to be removed through the normal collector channels that are present in the wall of Schlemm's canal. In adults the trabecular meshwork tears but remains intact and reattaches to the posterior scleral wall of Schlemm's canal blocking the collector channels.

Most treatments for glaucoma focus on reducing intraocular pressure. Treatment has involved administration of beta-blockers such as timolol to decrease aqueous humor production, adrenergic agonists to lower intraocular pressure or diuretics such as acetazolamide to reduce aqueous production, administration of miotic eyedrops such as pilocarpine to facilitate the outflow of aqueous humor, or prostaglandin analogs to increase uveoscleral outflow. Acute forms of glaucoma may require peripheral iridectomy surgery to relieve pressure where drug therapy is ineffective and the patient's vision is at immediate risk. Other forms of treatment have included physical or thermal destruction ("cy-

clodestruction") of the ciliary body of the eye, commonly by surgery or application of a laser beam, cryogenic fluid or high frequency ultrasound.

In guarded filtration surgery (trabeculectomy). a fistula created through the limbal sclera is protected by an overlying partial thickness sutured scleral flap. The scleral flap provides additional resistance to excessive loss of aqueous humor from the eyeball. thereby reducing the risk of early postoperative hypotony.

In accordance with one recently introduced procedure, a full thickness filtering fistula may be created by a holmium laser probe, with minimal surgically induced trauma. After retrobulbar anesthesia. a conjunctival incision (approximately 1 mm) is made about 12-15 mm posterior to the intended sclerostomy site, and a laser probe is advanced through the sub-conjunctival space to the limbus. Then, multiple laser pulses are applied until a full thickness fistula is created. This technique has sometimes resulted in early hypotony on account of a difficulty in controlling the sclerostomy size. In addition. early and late iris prolapse into the sclerostomy has resulted in abrupt closure of the fistula and eventual surgical failure. Further, despite its relative simplicity, the disadvantage of this procedure, as well as other types of glaucoma filtration surgery, is the propensity of the fistula to be sealed by scarring.

Various attempts have been made to overcome the problems of filtration surgery. for example, by using ophthalmic implant instruments such as the Baerveldt Glaucoma Implant. Typical ophthalmic implants utilize drainage tubes so as to maintain the integrity of the openings formed in the eyeball for the relief of the IOP.

Typical ophthalmic implants suffer from several disadvantages. For example. the implants may utilize a valve mechanism for regulating the flow of aqueous humor from the eyeball; defects in and/or failure of such valve mechanisms could lead to excessive loss of aqueous humor from the eyeball and possible hypotony. The implants also tend to clog over time, either from the inside by tissue. such as the iris, being sucked into the inlet. or from the outside by the proliferation of cells, for example by scarring. Additionally, the typical implant insertion operation is complicated. costly and takes a long time and is reserved for complicated glaucoma problems.

There are many problems, however, in effectively treating glaucoma with long term medicinal or surgical therapies. One problem is the difficulty in devising means to generate pharmacologically effective intraocular concentrations and to prevent extraocular side effects elicited by a systemic administration. Many drugs are administered topically or locally. The amount of a drug that gets into the eye is, however, only a small percentage of the topically applied dose because the tissues of the eye are protected from such substances by numerous mechanisms. including tear turnover. blinking. conjunctival absorption into systemic circulation, and a highly selective corneal barrier.

Pharmacological treatment is prohibitively expensive to a large majority of glaucoma patients. In addition, many people afflicted with the disease live in remote or undeveloped areas where the drugs are not readily accessible. The drugs used in the treatment often have undesirable side effects and many of the long-term effects resulting from prolonged use are not yet known. Twenty-five percent of patients do not use their medications correctly.

Glaucoma is a progressively worsening disease. so that a filtration operation for control of intraocular pressure may become necessary. Present surgical techniques to lower intraocular pressure, when medication fails to decrease fluid

flow into the eye or to increase fluid outflow. include procedures that permit fluid to drain from within the eye to extraocular sites by creating a fluid passageway between the anterior chamber of the eye and the potential supra-scleral/sub-Tenon's space, or, alternatively, into or through the Canal of Schlemm (see, e.g., U.S. Pat. No. 4,846.172). The most common operations for glaucoma are glaucoma filtering operations, particularly trabeculectomy. These operations involve creation of a fistula between the subconjunctival space and the anterior chamber. This fistula can be made by creating a hole at the limbus by either cutting out a portion of the limbal tissues with either a scalpel blade or by burning with a cautery through the subconjunctival space into the anterior chamber. Fluid then filters through the fistula and is absorbed by episcleral and conjunctival. In order for the surgery to be effective, the fistula must remain substantially unobstructed. These drainage or filtering procedures, however, often fail by virtue of closure of the passageway resulting from the healing of the very wound created for gaining access to the surgical site. Failures most frequently result from scarring at the site of the incisions in the conjunctiva and the Tenon's capsule. The surgery fails immediately in at least 15% of patients. and long term in a much higher percentage. Presently, this consequence of trabeculectomy, closure of the passageway, is treated with 5-fluorouracil and Mitomycin_C, which apparently prevent closure by inhibiting cellular proliferation. These drugs, however, are highly toxic and have undesirable side effects, including scleral melting, hypotony. leaks, and late infections.

Other surgical procedures have been developed in an effort to treat victims of glaucoma. An iridectomy. removal of a portion of the iris, is often used in angle-closure glaucoma wherein there is an occlusion of the trabecular meshwork by iris contact. Removal of a piece of the iris then gives the aqueous free passage from the posterior to the anterior chambers in the eye. The tissue of the eye can grow back to the pre-operative condition. thereby necessitating the need for further treatment.

In view of the limited effectiveness of treatment options, there is, therefore, a need to develop more effective treatments for glaucoma.

BRIEF SUMMARY OF THE INVENTION

The present invention is a surgical instrument and minimally invasive surgical method to remove at least a portion of the trabecular meshwork of the eye, providing for aqueous drainage in the treatment of glaucoma.

A preferred embodiment of the present invention involves inserting a surgical instrument through a small corneal incision transcamerally under direct visualization to ablate the trabecular meshwork. The instrument may include a foot plate. such that the instrument can penetrate the trabecular meshwork into Schlemm's canal. The footplate may also act as a protective device for the endothelial cells and collector channels lining the scleral wall of Schlemm's canal. The instrument may also comprise an infusion system and aspiration system. Infusion maintains and deepens the anterior chamber so that easy access of the angle of the eye is obtained to the trabecular meshwork and Schlemm's canal. Infusion also allows fluid to flow out to the collector channels whilst the surgery is being performed, thus keeping the surgical site blood free. Aspiration is designed to remove ablated tissue, gas and bubble formation, and all intraocular debris generated. The aspiration may be directly linked to either a cutting mechanism, such as a guillotine cutting

machine, laser probe, a piezo-electric crystal producing sonic or ultrasonic energy, or cautery element. These modalities are capable of substantially complete tissue removal by mechanical means, cautery, vaporization, or other tissue destruction techniques.

The surgical instrument is used to perform a goniectomy procedure, by removing a portion of the trabecular meshwork consisting of the pigmented trabecular meshwork, allowing free access of aqueous from the anterior chamber through to the scleral portion of Schlemm's canal that contains the endothelial cells and most importantly the collector channels that lead back to the episcleral venous system.

In another embodiment, a Schlemmectomy surgical procedure, similar to a trabeculotomy, a schlemmectomy probe is inserted into Schlemm's canal under direct visualization through a scleral incision, such that the surface of the instrument faces the trabecular meshwork and the tissue comprising the pigmented and a portion of the non-pigmented trabecular meshwork facing into Schlemm's canal is removed by a cautery element, radio-frequency electrode, or an ultrasound transducer formed from a piezo-electric crystal.

This instrument is advantageous because it combines existing procedures with new technology, providing a simple solution for glaucoma treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG **1** is a cross sectional schematic diagram of a human eye.

FIG. **2** is a cross sectional schematic diagram which shows aqueous flow into and through the anterior chamber in a human eye.

FIGS. **3***a-d* shows diagrammatically the progression of the deformation of the lamina cribrosa in glaucoma.

FIGS. **4***a-c* show diagrammatically the steps of performing a goniectomy.

FIGS. **5***a-d* show diagrammatically the steps of performing a trabeculodialysis.

FIGS. **6***a-f* show diagrammatically the steps of a trabeculotomy procedure using a probe of a preferred embodiment.

FIG. **7** is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

FIG. **8** is a cross-sectional schematic diagram which shows the goniectomy cautery probe of FIG. **7**.

FIG. **9** is a cross sectional schematic diagram which shows another embodiment of the goniectomy cautery probe of FIG. **7**.

FIG. **10***a* is a detailed view which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **10***b* is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **11***a* is a detailed view which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **11***b* is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **12***a* is a detailed view which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **12***b* is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of FIG. **7**.

FIG. **13** is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

FIG. **14** is a perspective view which shows a goniectomy cautery probe of a preferred embodiment.

FIG. **15***a* is a detailed view which shows the probe tip of the goniectomy cautery probe of FIG. **13**.

FIG. **15***b* is a cross-sectional schematic diagram which shows the probe tip of the goniectomy cautery probe of FIG. **13**.

FIG. **16***a* is a detailed view which shows the probe tip of the cautery probe of FIG. **14**.

FIG. **16***b* is a cross-sectional schematic diagram which shows the probe tip of the cautery probe of FIG. **14**.

FIG. **17** shows a schematic of a circuit diagram of a preferred embodiment of a goniectomy probe.

FIG. **18** is a perspective view which shows a goniectomy probe.

FIG. **19** is a cross-sectional schematic diagram which shows an embodiment of the probe of FIG. **18**.

FIG. **20** is a cross-sectional schematic diagram which shows an embodiment of the probe of FIG. **18**.

FIG. **21** is a cross-sectional schematic diagram which shows an embodiment of the probe of FIG. **18**.

FIG. **22** is a cross-sectional schematic diagram which shows an embodiment of the probe of FIG. **18**.

FIG. **23** is a cross-sectional schematic diagram which shows an embodiment of the probe of FIG. **18**.

FIG. **24***a* is a perspective view which shows a preferred embodiment of a laser goniectomy probe.

FIG. **24***b* is a perspective view which shows a preferred embodiment of a laser goniectomy probe.

FIG. **25** is a cross sectional schematic diagram of the laser goniectomy probe of FIG. **24***a*.

FIG. **26** is a cross sectional schematic diagram of the laser goniectomy probe of FIG. **24***b*.

FIG. **27** is a cross sectional schematic diagram of the laser goniectomy probe of FIG. **24***b*.

FIG. **28** is a perspective view which shows a Schlemmectomy probe of a preferred embodiment.

FIGS. **29***a-c* are detailed views which show the probe tip of the probe of FIG. **28**.

FIG. **30** is a perspective view of an alternative preferred embodiment of the probe of FIG. **28**.

FIGS. **31***a,b,c* are detailed views of the probe tip of FIG. **30**.

FIGS. **32***a,b* are detailed views which show the probe tip of the probe of FIG. **30**.

FIG. **33***a* is a detailed view which shows the probe tip of the probe of FIG. **30**.

FIG. **33***b* is a cross-sectional schematic diagram which shows the probe tip of the probe of FIG. **30**.

FIG. **34***a* is a detailed view which shows the probe tip of the probe of FIG. **30**.

FIG. **34***b* is a cross-sectional schematic diagram which shows the probe tip of the probe of FIG. **30**.

FIG. **35***a* is a detailed view which shows the probe tip of the probe of FIG. **30**.

FIG. **35***b* is a cross-sectional schematic diagram which shows the probe tip of the probe of FIG. **30**.

DETAILED DESCRIPTION OF THE INVENTION

Referring to FIG. **1**, relevant structures of the eye will be briefly described, so as to provide background for the anatomical terms used herein. Certain anatomical details, well known to those skilled in the art, have been omitted for clarity and convenience.

As shown in FIG. **1**, the cornea **103** is a thin, transparent membrane which is part of the outer eye and lies in front of the iris **104**. The cornea **103** merges into the sclera **102** at a juncture referred to as the limbus **108**. A layer of tissue called bulbar conjunctiva **106** covers the exterior of the sclera **102**. The bulbar conjunctiva **106** is thinnest anteriorly at the limbus **108** where it becomes a thin epithelial layer which continues over the cornea **103** to the corneal epithelium. As the bulbar conjunctiva **106** extends posteriorly, it becomes more substantial with greater amounts of fibrous tissue. The bulbar conjunctiva **106** deseends over Tenon's capsule approximately 3 mm from the limbus **108**. Tenon's capsule is thicker and more substantial encapsulatory tissue which covers the remaining portion of the eyeball. The subconjunctival and sub-Tenon's capsule space become one when these two tissues meet, approximately 3 mm from the limbus. The ciliary body or ciliary process **110** is part of the uveal tract. It begins at the limbus **108** and extends along the interior of the sclera **102**. The choroid **112** is the vascular membrane which extends along the retina back towards the optic nerve. The anterior chamber **114** of the eye is the space between the cornea **103** and a crystalline lens **116** of the eye. The crystalline lens of the eye is situated between the iris **104** and the vitreous body **120** and is enclosed in a transparent membrane called a lens capsule **122**. The anterior chamber **114** is filled with aqueous humor **118**. The trabecular meshwork **121** removes excess aqueous humor **118** from the anterior chamber **114** through Schlemm's canal **124** into collector channels which merge with blood-carrying veins to take the aqueous humor **118** away from the eye.

As shown in FIG. **2**, the flow of aqueous **118** is from the posterior chamber, through the pupil, into the anterior chamber **114**.

FIGS. **3***a-d* show longitudinal sections through the optic nerve head, illustrating the progressive deepening of the cup **302** in the nerve head from normal to advanced glaucoma. FIG. **3***a* shows a normal nerve and FIG. **3***d* shows an effected nerve in advanced glaucoma. As the cup **302** deepens and the lamina cribrosa **306** becomes more curved, axons **304** passing through the lamina **306** are subject to kinking and pressure as they make their way through the lamina **306**.

Goniotomy. FIGS. **4***a-c* show the steps for performing a goniotomy procedure. As shown in FIG. **4***a*, locking forceps **406** are typically used to grasp the inferior and superior rectus muscles. A goniotomy lens **408** is positioned on the eye. A goniotomy knife **400** is inserted from the temporal aspect beneath the goniotomy lens and viewed through a microscope. The cornea is irrigated with balanced salt solution. The surgeon positions the goniotomy lens **408** on the cornea, holding the lens **408** with an angled, toothed forceps **406** placed into the two dimples at the top of the lens **408**.

The surgeon places the goniotomy knife **400** into and through the cornea 1.0 mm anterior to the limbus, maintaining the knife **400** parallel to the plane of the iris (FIG. **4***b*). Slight rotation of the knife **400** facilitates smooth penetration into the anterior chamber without a sudden break through the cornea. The surgeon continues to gently apply pressure and rotate the goniotomy knife **400**, directing it across the chamber, parallel to the plane of the iris, until reaching the trabecular meshwork in the opposite angle.

The surgeon visualizes the trabecular meshwork under direct microscopy and engages the superficial layers of the meshwork at the midpoint of the trabecular band. The incision is typically made 100° to 120°, as designated by a in FIG. **4***b*, circumferentially, first incising clockwise 50° to 60°, then counterclockwise for 50° to 60°.

As the tissue is incised, a white line can be seen and the iris usually drops posteriorly. An assistant facilitates incision by rotating the eye in the opposite direction of the action of the blade (FIG. **4***c*).

The surgeon completes the goniotomy incision and promptly withdraws the blade. If aqueous escapes from the wound and the chamber is shallow, the surgeon can slide the goniotomy lens over the incision as the blade is withdrawn. The anterior chamber can be reformed with an injection of balanced salt solution through the external edge of the corneal incision. The leak can be stopped using a suture and burying the knot.

Trabeculodialysis. Trabeculodialysis is similar to goniotomy but is performed primarily in young patients with glaucoma secondary to inflammation. Trabeculodialysis differs from goniotomy only in the position of the incision. FIGS. **5***a-d* show the steps of a trabeculodialysis procedure. The knife **500** passes across the anterior chamber and engages the trabecular meshwork at Schwalbe's line rather than at the midline of the meshwork, as shown in FIG. **5***a*.

The incision is typically made 100° to 120° circumferentially, as designated by a in FIG. **5***b*, first incising clockwise 50° to 60°, then counterclockwise for 50° to 60° (FIG. **5***b*).

With the flat side of the blade, the surgeon pushes the trabecular meshwork inferiorly toward the surface of the iris, as shown in FIG. **5***c*. FIG. **6***d* shows the meshwork, disinserted from the scleral sulcus, exposing the outer wall of Schlemm's canal.

Trabeculotomy. Trabeculotomy displaces trabecular meshwork as a barrier to aqueous outflow. Initially, the surgeon creates a triangular scleral flap **604** that is dissected anteriorly of the limbus, as shown in FIG. **6***a*. A radial incision is made over the anticipated site of Schlemm's canal (FIG. **6***b*). The incision is deepened until the roof of Schlemm's canal is opened (FIG. **6***c*).

The surgeon locates Schlemm's canal through the external surface of the limbus, threads a trabeculotome **600** into the canal and rotates the instrument into the anterior chamber, as shown in FIG. **6***d*. The upper arm **610** of the instrument should be kept parallel to the plane of the iris. The instrument **600** is then rotated within the anterior chamber and maintained parallel to the iris. After rotating the instrument **600** through the meshwork in one direction, the surgeon withdraws the instrument and inserts a second instrument with the opposite curve. The identical procedure is then performed in the opposite direction.

Collapse of the anterior chamber often occurs during the procedure. The chamber can be reformed by injecting irrigation fluid. Aspiration may be used to remove the tissue. The scleral flap **604** may then be sutured closed, as shown in FIG. **6***e*.

Goniectomy Cauterization Probe. A preferred embodiment of a goniectomy probe, used to cauterize and ablate the trabecular meshwork is shown in FIGS. **7** and **8**. The probe **700** comprises a handle **705** and a probe tip **710**. Preferably, the handle is approximately 20 gauge and the probe tip is approximately 27 gauge. The proximal end of the handle is adapted for mating with a connector **712** to the output terminals of an energy source **760**.

The probe also includes electrical leads **834** (FIG. **8**), a power cable **708**, preferably a coaxial cable, and actuation means. These components extend from the handle **705**, through an electrical lead lumen **832** (FIG. **8**) in the probe shaft **705**, to the corresponding components of the probe **700** disposed on the distal end. The proximal ends of the cables and lumens connect to the corresponding connectors that extend from the distal end of the probe handle **705**.

Aspiration and irrigation may be provided by an aspiration pump **770** and irrigation pump **780**. The aspiration pump **770** is connected to a standard vacuum supply line to promote the withdrawal of the aspiration fluid. Aspiration vacuum control may be provided by an aspiration valve. In a preferred embodiment, as shown in FIG. **8**, both irrigation and aspiration may be provided by the same lumen **822**, alternating the pump as needed. However, the irrigation lumen **922** and aspiration lumen **924** are separate in the embodiment of FIG. **9**, providing for simultaneous irrigation and aspiration. Irrigation under pressure flushes blood from the eye and expands the anterior chamber, providing more room for the procedure.

The handle **705** may be made of an electrically insulating polymeric material, configured in a pencil-shape form having a cylindrical body region **702** and a tapered forward region **704**. A contoured handle helps to reduce the holding force required and increase proprioceptive sensitivity. Although a pencil-shape configuration is preferred, it is noted that any configuration of the handle **705** which is easily, comfortably and conveniently grasped by the operator will also be suitable and is considered to be within the scope of the present invention.

The probe tip **710** is connected to the main body of the handle **705**. The probe tip further comprises a footplate **721**, which protects the collector channels, penetrates the trabecular meshwork, and serves as a guide in Schlemm's canal. The cautery element **730**, located at the distal end of the probe tip **710** may have a variety of configurations.

The tip **710** may be any material, such as titanium, brass, nickel, aluminum, stainless steel, other types of steels, or alloys. Alternatively, non-metallic substances may also be used, such as certain plastics. The malleable probe tips can be configured as straight, angled or curved, for example, which provides for optimal access to specific anatomy and pathology. Unique tip designs improve tactile feedback for optimal control and access, and provide for improved tissue visualization with greatly reduced bubbling or charring.

The probe tip **710** comprises an electrode **730**, suitable for cautery, as known to those of skill in the art. Various electrode configurations and shapes may be suitable. The cautery element **730** may be any electrode that may provide ablation or cauterization of tissue, such as an ultrasound transducer, a RF electrode, or any other suitable electrode.

The cautery element may also include other cautery energy sources or sinks, and particularly may include a thermal conductor. Examples of suitable thermal conductor arrangements include a metallic element which may, for example, be constructed as previously described. However, in the thermal conductor embodiment such a metallic element would be generally resistively heated in a closed loop circuit internal to the probe, or conductively heated by a heat source coupled to the thermal conductor.

The probe tip may have a coating such as a non-stick plastic or a coating comprising diamond to prevent undesirable sticking or charring of tissue. The electrode may be provided on the inner surface of the tip. Alternatively, the electrode is embedded in a sheath of a tube. Insulation is provided around the cautery element so that other areas of the eye are not affected by the cauterization. A sleeve shield or a non-conductive layer may be provided on the probe tip to expose only a selected portion of the electrode. The sleeve preferably has sufficient thickness to prevent both current flow and capacitance coupling with the tissue.

The electrode or other device used to deliver energy can be made of a number of different materials including, but not limited to stainless steel, platinum, other noble metals, and the like. The electrode can also be made of a memory metal, such as nickel titanium. The electrode can also be made of composite construction, whereby different sections are constructed from different materials.

In a preferred embodiment, the probe assembly is bipolar. In a bipolar system, two electrodes of reversed polarity are located on the probe tip, thus eliminating the contact plate for completion of the circuit. Additionally, any number of pairs of electrodes may be provided on the probe tip.

In an alternative embodiment, the probe assembly is monopolar. In a monopolar system, the system comprises a single electrode and a contact plate is attached to the surface of the human body. The contact plate is further connected to the minus terminal of the power source via a lead wire. Voltages of reversed polarity are applied to the electrode and the contact plate.

In a preferred embodiment as shown in FIGS. **10***a* and **10***b*, an electrode assembly of a bipolar probe includes one electrode **1020** made from a stainless steel 20 gauge hollow needle and a second electrode **1030** formed as a layer of electrically conductive material (such as silver or nickel) deposited over and adhered on an exterior surface of the needle electrode **1020**. A thin electrical insulator **1028** separates the electrodes **1020**, **1030**, along their lengths to avoid short circuiting.

The electrode **1020** extends along a longitudinal axis **1072** of the footplate **721** (FIG. **7**) from a proximal region at which bipolar electrical power is applied to a distal region of the electrode assembly.

In a preferred embodiment, the second electrode **1030** extends over a limited portion of the circumference of the first electrode **1020**, rather than entirely around the first electrode. Current flows over a relatively small portion of the circumference and length of the first electrode **1020**. This limits the area in the body that receives current, and provides the operator with a high degree of control as to where the current is applied. The second electrode **1030** extends over an arc of approximately one quarter of the circumference of the first electrode **1020**. The second electrode **1030** is disposed symmetrically about an axis **1072**.

In a preferred embodiment, the first electrode, and thus the footplate **721**, has a central passage **1022** that is open at the distal region, providing for irrigation and aspiration. The irrigation and aspiration lumens extend from the distal end of the probe tip **1010**, through the probe handle, to the connector, providing for irrigation and aspiration capability.

In an embodiment as shown in FIGS. **11***a* and **11***b*, the electrode assembly includes a central or axial electrode **1120** formed by a solid cylindrical metal member, and an elongate hollow outer electrode **1130** formed by a cylindrical metal tube member, which is coaxially positioned around the central electrode **1120**. The cylindrical outer surface of electrode **1130** forms the circumferential surface of the probe. The outer electrode **1130** is preferably made of stainless steel or other corrosive resistant, conductive material for strength as well as conductivity. The inner electrode **1120** may be made of copper, but less conductive materials may also be employed. The coaxial relationship and spacing between the electrodes **1120**, **1130**, as well as their electrical isolation from one another, is provided by a tubular sleeve **1128** of an electrically insulating material between the electrode.

A layer of insulation **1132** may also surround the second electrode **1130**. One or more regions of insulating area **1132** may be removed at any suitable location along the axis to expose a region of electrode **1130**. Cauterization would occur at the exposed region. The circumferential extent of

the second electrode **1130** can be further limited, depending on the degree of control desired over the size of the area to which current is applied.

In an alternative embodiment, as shown in FIG. **12**, the active region at a remote end of a bipolar electrode is formed by a hollow metal tube **1200** having a substantially cylindrical layer of insulation **1228** on the outer surface of the metal tube. The metallic tube **1200** is not an electrode and is provided only for the strength of the probe assembly. The tip supports two metal electrodes **1230**, **1240**. Each of the electrodes **1230**, **1240** have electric leads, which extend through the hollow interior of the tube **1200** to a supporting insulative handle where it is coupled by appropriate means with a power source in the manner previously described. Energy flows between the electrodes **1230**, **1240**, heating only the tissue adjacent the gap therebetween. Aspiration and irrigation may be provided through a lumen **1222**.

FIGS. **13** and **14** show alternative embodiments of a goniectomy cauterization probe **1300**, **1400**. The probe comprises a handle **1305**. **1405** and a probe tip **1310**, **1410**. The probe tip includes a cautery element **1330**, **1430**.

The probes **1300**. **1400** are provided with an energy source; however, probe **1400** also includes an irrigation supply **1480** and an aspiration pump **1470**. These components connect to the probe **1300**. **1400** at connector **1308**, **1408**.

FIGS. **15***a,b* show detailed views of probe tip **1310**. The probe tip **1510** is straight and includes an electrode **1530** attached to electrode **1520**, which are separated by a layer of insulation **1528**.

FIGS. **16***a,b* show detailed views of probe tip **1410**. The probe tip **1610** is straight and includes an electrode **1630** attached to a hollow electrode **1620**. which are separated by a layer of insulation **1628**. The hollow electrode **1620** forms a hollow passage **1622** for irrigation and aspiration.

In an alternative embodiment. the needle tip of FIG. **14** may comprise a hollow needle, with or without a cauterizing element. acoustically coupled to an ultrasonic handle and surrounded by a hollow sleeve. The handle includes an ultrasonic transducer, such as that used for phacoemulsification. which may be either piezoelectric or magnetostrictive. When the handle is activated. the needle is vibrated longitudinally at an ultrasonic rate. Simultaneously, a hydrodynamic flow of irrigation fluid may be introduced into the eye. The vibrating needle emulsifies the tissue, and the particles are preferably simultaneously aspirated. along with the fluid, out of the eye through the hollow needle tip. Aspiration is effected by a vacuum pump, which is connected to the handle. The ultrasonically vibrated needle emulsifies the tissue by combining i) the mechanical impact of the needle tip which varies depending on its mass, sharpness. and acceleration. ii) the ultrasonic acoustical waves generated by the metal surfaces of the vibrating needle, iii) the fluid wave created at the needle's leading edge, and iv) implosion of cavitation bubbles created at the tip of the vibrating needle.

In an alternative embodiment, sonic technology may be used to ablate the tissue. Sonic technology offers an innovative means of removing material without the generation of heat or cavitational energy by using sonic rather than ultrasonic technology. The tip expands and contracts, generating heat, due to intermolecular frictional forces at the tip. that can be conducted to the surrounding tissues. The tip does not need a hollow sleeve if sonic energy is used to remove the trabecular meshwork.

The use of acoustic energy, and particularly ultrasonic energy, offers the advantage of simultaneously applying a dose of energy sufficient to ablate the area without exposing the eye to current. The ultrasonic driver can also modulate the driving frequencies and/or vary power in order to smooth or unify the produced collimated ultrasonic beam.

The amount of heat generated is directly proportional to the operating frequency. The sonic tip does not generate cavitational effects and thus true fragmentation, rather than emulsification or vaporization. of the tissue takes place. This adds more precision and predictability in cutting and less likelihood of damage to other areas of the eye. The tip can be utilized for both sonic and ultrasonic modes. The surgeon can alternate between the two modes using a toggle switch on a foot pedal when more or less energy is required.

FIG. **17** shows the control system for a goniectomy cauterization probe. The cautery element **1730** is coupled to a cautery actuator. The cautery actuator generally includes a radio-frequency ("RF") current source **1760** that is coupled to both the RF electrode and also a ground patch **1750** which is in skin contact with the patient to complete an RF circuit, in the case of a monopolar system. The cautery actuator may include a monitoring circuit **1744** and a control circuit **1746** which together use either the electrical parameters of the RF circuit or tissue parameters such as temperature in a feedback control loop to drive current through the electrode element during cauterization. Also. where a plurality of cautery elements or electrodes are used, switching capability may be provided to multiplex the RF current source between the various elements or electrodes.

The probe is connected to a low voltage power source via a power cord that mates with the handle. The source may be a high frequency. bipolar power supply, preferably. a solid state unit having a bipolar output continuously adjustable between minimum and maximum power settings. The source is activated by an on/off switch. which may comprise a foot pedal, or a button on the probe or interface. The source provides a relatively low bipolar output voltage. A low voltage source is preferred to avoid arcing between the electrode tips, which could damage the eye tissue. The generator is coupled to first and second electrodes to apply a biologically safe voltage to the surgical site.

Delivery of energy to the tissue is commenced once the cautery element is positioned at the desired location. The energy source preferably provides RF energy. but is not limited to RF and can include microwave, ultrasonic, coherent and incoherent light thermal transfer and resistance heating or other forms of energy as known to those of skill in the art. Energy is typically delivered to the cautery element via electrical conductor leads. The cautery control system may include a current source for supplying current to the cautery element.

The current source is coupled to the cautery element via a lead set (and to a ground patch in some modes). The monitor circuit **1744** desirably communicates with one or more sensors (e.g., temperature) **1730** which monitor the operation of the cautery element. The control circuit **1746** may be connected to the monitoring circuit **1744** and to the current source **1760** in order to adjust the output level of the current driving the cautery element based upon the sensed condition (e.g. upon the relationship between the monitored temperature and a predetermined temperature set point).

The procedure for performing goniectomy with the goniectomy cauterization probe of an embodiment of the present invention is similar to a traditional goniotomy surgery, as previously described. The surgeon preferably sits on the temporal side of the operating room table utilizing an operating microscope. The patient's head is rotated 45° away from the surgeon after a retrobulbar injection has

anesthetized the eye. A knife, preferably 20 gauge, is used to make a clear corneal temporal incision. The goniectomy instrument is inserted into the anterior chamber up to the infusion sleeve to maintain the intraocular pressure and deepen the anterior chamber. The surgeon positions the gonio lens, preferably a Schwann-Jacobs lens or a modified Barkan goniotomy lens, on the cornea. The goniectomy probe is advanced to the trabecular meshwork. The sharp end point of the footplate incises the middle one third of the trabecular meshwork, which is known as the pigmented portion of the trabecular meshwork. The footplate **721** (FIG. **7**) is further inserted into Schlemm's canal. The cautery element is activated, preferably by a footplate, which may also be used to activate irrigation and aspiration. The current provided to the cautery element heats the tissue. The instrument is slowly advanced through the trabecular meshwork maintaining the footplate **721** in Schlemm's canal, feeding the pigmented trabecular meshwork into the opening of the instrument where the tissue removal occurs. The instrument is advanced until no further tissue can be removed inferiorly. The tissue may also be aspirated through the probe, thus substantially removing a portion of the trabecular meshwork. The instrument may be rotated in the eye and reintroduced into Schlemm's canal where the initial incision began. The superior portion of the trabecular meshwork is then removed using cautery and aspiration. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. The corneal incision is preferably sealed by injecting a balanced salt solution into the corneal stroma or by placing a suture. The anterior chamber is reformed. A viscoelastic substance may be utilized to maintain the anterior chamber with the initial incision and at the end of the surgery.

Trabeculodialysis. Trabeculodialysis is similar to goniectomy; therefore, a goniectomy cauterization probe may also be used to perform trabeculodialysis. The procedure for performing a trabeculodialysis procedure with a cauterization probe is similar to the trabeculodialysis procedure previously described. However, rather than cutting the tissue with a knife, the tissue is ablated with the probe. Similarly, in a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed.

Goniectomy Cutting Probe. Another preferred embodiment of a goniectomy cutting probe, used to cut and remove trabecular meshwork, is shown in FIG. **18**. The probe comprises a handle **1805** and a probe tip **1810**. Preferably, the handle is 20 gauge and the probe tip is approximately 25 gauge. The handle **2405** is sized and configured to fit completely and comfortably within a hand. The handle **2405** may be formed of a variety of materials, including plastics, and may be designed in a variety of shapes. Generally, it will be preferred that a convenient shape for gripping, such as a cylindrical shape, be provided. The probe tip **1810** further comprises a footplate **1820**, protecting endothelial cells and collector channels lining the scleral wall of Schlemm's canal. The footplate **1820** also serves as a guide in Schlemm's canal. The sharpened end of the footplate is used to penetrate the trabecular meshwork.

FIGS. **19-20** show sectional views of different embodiments of the internal components and construction of the probe **1800**. The probe is configured to define therewithin a hollow inner chamber. A drive member, coupled to a rotatable drive cable within a drive cable assembly, extend into the hollow inner chamber, as shown. A rotatable drive shaft **1944, 2044** is rotatably connected or engaged to the drive member, such that the shaft may be rotatably driven at speeds required for the trabecular meshwork removal. The rotatable drive shaft is inserted into a bore formed in the distal face of the drive member.

The elongate rotatable drive shaft **1944, 2044** passes longitudinally through the probe and terminates, at its distal end, in a cutting head **1945, 2045**. A protective tubular sheath may be disposed about the rotatable shaft. The rotatable shaft and/or sheath are axially movable so as to allow the cutting head to be alternately deployed in a) a first non-operative position wherein the cutting head is fully located within the inner bore of the tubular sheath so as to be shielded during insertion and retraction of the instrument or b) a second operative position wherein the cutting head is advanced out of the distal end of the sheath so as to contact and remove the trabecular meshwork. The cutting head **1945, 2045** may be configured such that rotation of the head will create and sustain a forced circulation of fluid within the meshwork. Such forced circulation causes the trabecular meshwork to be pulled or drawn into contact with the rotating, cutting head, without the need for significant axial movement or manipulation of the probe while the cutting head is rotating.

A control pedal may be connected to the motor-drive system to induce actuation/deactuation, and speed control of the rotatable drive cable within the drive cable assembly by the operator. Additional switches or control pedals may be provided for triggering and actuating irrigation and/or aspiration of fluid and/or debris through the probe.

The probe of FIG. **19**, shows the probe **1900** having two separate lumens. **1922, 1924**, for irrigation and aspiration. The hollow passageway **2022** extending longitudinally through the probe of FIG. **20**, containing the rotatable drive shaft, is in fluid communication with an irrigation pump (not shown). By such arrangement, a flow of irrigation fluid may be infused through the tube. A separate lumen **2024** is also provided for aspiration.

The independent processes of irrigation and aspiration may be performed simultaneously with the rotation of the head or while the head is in a non-rotating, stationary mode. It will also be appreciated that the infusion and aspiration pathways may be reversed or interchanged by alternately connecting the aspiration pump to the irrigation tubing and irrigation pump to the aspiration tubing.

In an alternative embodiment, as shown in FIGS. **21-23**, the probe cuts tissue in a guillotine fashion. As shown in FIG. **21**, the probe **2100** may include an inner sleeve **2144** that moves relative to an outer sleeve **2146**. The sleeves are coupled to the handle. The inner sleeve **2144** may be coupled to a vacuum system which pulls tissue into the port **2125** when the inner sleeve **2144** moves away from the port. The inner sleeve **2144** then moves in a reverse direction past the outer port to sever tissue in a guillotine fashion. The vacuum system draws the severed tissue away from the port, so the process may be repeated. The inner sleeve may be connected to a diaphragm and a spring, rigidly attached to the handle. The diaphragm is adjacent to a pneumatic drive chamber that is in fluid communication with a source of pressurized air (not shown). The drive chamber is pressurized, expanding the diaphragm. Expansion of the diaphragm moves the inner sleeve so that the tissue within the port is severed by the sleeve. Alternatively, the inner sleeve **2144** is driven by a motor located within the handle. The inner sleeve **2144** is coupled to the motor by a rotating lever mechanism or wobble plate, inducing an oscillating translational movement of the sleeve in response to a rotation of the output shaft. The motor is preferably an electrical device coupled to an external power source by wires that are attached to a control system at the handle.

FIG. **22** shows an embodiment wherein the irrigation lumen **2222** contains the cutting sleeve **2244**. Cutting sleeve **2244** has a cutting blade **2245** integrally formed at its distal end. FIG. **23** shows an alternative embodiment, wherein the irrigation lumen **2322** does not contain the cutting sleeve. An aspiration lumen **2224**, **2324** is also provided. The aspiration line may be directly coupled to an aspiration pump; the irrigation lumen may be directly coupled to an irrigation pump.

The procedure for goniectomy with the goniectomy cutting probe is similar to the goniectomy procedure discussed for the goniectomy cauterization probe. However, rather than cauterizing the trabecular meshwork, the tissue is cut using a rotatable blade or cut in a guillotine fashion, and subsequently aspirated. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed.

Goniectomy Laser Probe. A laser probe **2400**, as shown in FIGS. **24***a* and **24***b*, is provided to ablate the trabecular meshwork. The probe **2400** comprises a handle **2405** and a probe tip **2410**. The handle **2405** is sized and configured to fit completely and comfortably within a hand. It will be understood that the handle **2405** may be formed from a variety of materials, including plastics, and may be designed in a variety of shapes. Generally, it will be preferred that a convenient shape for gripping, such as a cylindrical shape, be provided. The main body of the handle **2405** comprises a plastic housing within which a laser system is contained. The plastic housing is provided to enable easy manipulation of the handle **2405** by the user. The laser is preferably an excimer laser.

FIG. **24***a* shows an embodiment wherein the laser source is contained within the probe, but rather within the control system. A fiber is provided to direct the light energy from the source to the proximal end of the probe tip. The laser radiation is generated in close proximity to the eye, so that relatively little laser light is lost during transmission.

FIG. **24***b* shows an embodiment wherein the laser source is not contained within the probe. The source may include a longitudinal flashlamp. A fiber is provided to direct the light energy from the source to the proximal end of the probe tip.

The probe tip **2410** is connected to the main body **2405**. The probe tip comprises a footplate to protect the outer wall of Schlemm's canal, such that only the tissue of the trabecular meshwork is cauterized. The footplate also is used to penetrate the trabecular meshwork and serves as a guide in Schlemm's canal. In general, the probe tip **2410** is straight or curved.

FIG. **25** shows a detailed view of FIG. **24***a*. The handle includes a reflective tube **2508** which has a mirrored inside surface. An Er: YAG rod **2513** is located along the axis of the tube **2508**. The pump for the laser light source is preferably a high pressure flashtube **2512** or a similar suitable light source which is located adjacent the rod **2513** within the reflective tube **2508**. The flashtube **2512** produces very brief, intense flashes of light, there being approximately 10 to 100 pulses per second.

Er:YAG rods generate an output wavelength of approximately 2.94 microns. Use of an erbium doped laser, such as an Er: YAG laser, is advantageous because it requires less power to ablate the eye tissue than do the Nd: YAG and Holmium:YAG lasers of the prior art. Preferably the Er: YAG laser has a pulse repetition rate of 5 to 100 Hz, a pulse duration of 250 μs to 300 μs, and a pulse energy of 10 to 14 mJ per pulse. Using an Er: YAG laser at the above parameters limits the thermal damage of surrounding tissue to a depth of 5 to 50 microns. By reducing the thermal damage of surrounding tissue, the amount of scar tissue buildup caused by the laser is minimal. Thus, the likelihood that the passageway will become blocked with scar tissue is reduced, and the likelihood that the procedure will need to be repeated is reduced.

The reflective inner surface **2546** of the tube **2508** serves to reflect light from the flashlamp **2512** to the rod **2513**. Reflection of the light by the cylindrical mirror focuses as much light as possible toward the rod **2513**. This results in efficient coupling between the light source **2512** and the laser rod **2513**. Thus, essentially all light generated in the flashtube **2512** is absorbed by the laser rod **2513**.

The rod **2513** has a totally reflective mirror **2514** and output mirror **2517** at its two ends. The mirror **2514** at the proximal end of the rod **2513** provides 100% reflection of light back to the rod **2513**. At the remote end of the rod **2513**, the output mirror **2517** provides less than 100% reflection. Thus, while most of the light energy directed toward the output mirror **2517** of the rod **2513** is reflected back into the rod **2513**, intensifying the beam, some of the waves of energy pass through the output mirror **2517** and into the transmission system **2511** for conducting it toward the probe tip **2515**. A reflective coating on the end of the laser rod **2513** may be used to supplement or replace the mirrors **2517**, **2514**.

The mirrors **2517**, **2514** on either end of the rod form a resonator. Radiation that is directed straight along the axis of the rod **2513** bounces back and forth between the mirrors **2517**, **2514** and builds a strong oscillation. Radiation is coupled out through the partially transparent mirror **2517**

The transmission system **251** is preferably an optical fiber. Preferably, a sapphire or fused silica fiber will be used with the laser, contained within the handle. A germanium oxide Type IV fiber is also suitable for carrying erbium laser light with reduced attenuation. It is also possible to deliver laser light through hollow waveguides. Such waveguides often include multi-layer dielectric coatings to enhance transmission.

FIG. **26** shows a detailed view of one embodiment of a probe tip **2600**, in which the fiber **2610** is centrally located within the probe tip **2600**.

Alternatively, the probe tip may be hollow, forming an aspiration/irrigation lumen (not shown). The lumen extends the entire length of the probe. Alternatively, as shown in FIG. **27**, the lumen **2722** may extend adjacent the probe tip **2710**. The aspiration lumen **2722** communicates with a vacuum source for withdrawal of emulsified material through an aperture or aspiration port. During use, the vacuum source can be employed to aspirate material which has been fragmented or ablated by the pulsed laser light. The vacuum source can also be used to draw the tissue into close proximity with the delivery end of the probe thereby facilitating its destruction. Fluid introduced through the lumen, chamber, and aperture can provide for flushing of the site and replacement of lost volume due to removal of the emulsified material.

The probe is inserted under direct vision to ablate the trabecular meshwork for use in treating glaucoma, thus obtaining a free flow of aqueous from the anterior chamber into Schlemm's canal and through the collector channels. The end of the probe is inserted through a relatively small incision in the eye, and can be maneuvered very close to the tissue to be emulsified.

The procedure is similar to the goniectomy procedure previously discussed with reference to the goniectomy cauterization probe. The surgeon visualizes the trabecular meshwork under direct microscopy and engages the superficial

layers of the meshwork at the midpoint of the trabecular band, by placing the tissue between the end **2521** of the fiber **2511** and the probe tip (footplate) **2519**. Once inserted, the fiber **2511** is positioned to focus laser energy directly on the trabecular meshwork. The probe tip **2519** absorbs any laser energy which is not absorbed by the trabecular meshwork, thus protecting Schlemm's canal from damage. Light is transmitted to and through the probe, and the tissue is ablated. The area may be irrigated and aspirated, removing the tissue from the eye. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. After treatment, the probe is readily withdrawn from the eye. Leakage may be stopped using a suture and burying the knot.

Laser treatment with an Er:YAG laser is advantageous because as wavelength increases, contiguous thermal effects decrease. In the visible portion of the spectrum, water has minimal absorption. Above 2.1 μm however, this absorption increases to a level comparable to excimer lasers operating around 200 nm. This increase is quite rapid. A marked difference therefore exists between radiation at 2.79 μm and 2.94 μm. This confines the energy delivered to a smaller volume, allowing more ablation to occur at lower total energy levels and limiting contiguous thermal damage. Er:YAG lasers produce ablations with minimal amounts of contiguous thermal damage. Light in the infrared region has an additional advantage over ultraviolet radiation in that it is not known to have mutagenic or carcinogenic potential.

Due to the large absorption band of the water at the wavelength of the erbium laser, no formation of sticky material on the probe tip takes place, which can be a serious problem at other wavelengths.

Schlemmectomy Cauterization Probe. Schlemmectomy is a new surgical procedure, similar to trabeculotomy. However, in a schlemmectomy, procedure, disrupted tissue is removed using a schlemmectomy cauterization probe. FIG. **28** illustrates a probe **2800** in accordance with this invention for removal of the trabecular meshwork, using a cautery element **2830** on a probe similar to a traditional trabeculotome, such as Harm's trabeculotome. The probe uses both cautery and mechanical disruption to ablate the fibers of the trabecular meshwork, leaving a patent open Schlemm's canal.

The probe **2800** comprises a handle **2805** and a probe tip **2810**. The proximal end of the handle is adapted for mating with a connector **2812** to the output terminals of an energy source **2860**.

The probe also includes electrical leads **2934** (FIG. **29**), a power cable **2808**, preferably a coaxial cable, and an actuator. These components extend from the handle **2805**, through an electrical lead lumen **2932** (FIG. **29**) in the probe shaft **2805**, to the corresponding components of the probe **2800** disposed on the distal end. The proximal ends of the cables and lumens connect to the corresponding connectors that extend from the distal end of the probe handle **2805**.

FIGS. **29***a-c* illustrate one probe tip configuration. The probe tip **2910** comprises two parallel arms **2920**, **2950**. The probe tip **2910** comprises an electrode **2930**, which will be described in further detail below, disposed on the lower arm **2920**. The probe tip **2910** comprises an electrical lead lumen **2932** which extends the length of the probe tip **2910** from the electrode **2930** through the cylindrical body **2802** to the connector of the probe handle **2812**. (FIG. **28**)

FIG. **30** shows a preferred embodiment of a probe **3000**. The probe of FIG. **30** is similar to the probe of FIG. **28**, except that probe **3000** further comprises irrigation means. Irrigation may be provided by an irrigation pump **3080** or hydrostatic pressure from a balanced salt solution bottle and tubing.

In a preferred embodiment, as shown in FIG. **31***a*, the irrigation lumen **3122** is situated at the end of the probe. Irrigation under pressure flushes blood from the eye and expands Schlemm's canal and the anterior chamber, providing more room for the procedure. Alternatively, lumen **3122** provides for aspiration by connecting the lumen to an aspiration pump. Aspiration ports may be provided equidistantly along the length of the cauterizing element of the trabeculotome, as shown in FIG. **31***b*. In an embodiment, as shown in FIG. **31***c*, two lumens are provided, an irrigation lumen **3122** and an aspiration lumen **3124**. Two separate lumens provide for simultaneous irrigation and aspiration.

With reference to the schlemmectomy probes of FIGS. **28** and **30**, the handle **2805**, **3005** may be made of an electrically insulating polymeric material, configured in a pencil-shape form having a cylindrical body region **2802**, **3002** and a tapered forward region **2804**, **3004**. Although a pencil-shape configuration is preferred, it is noted that any configuration of the handle **2805**, **3005** which is easily, comfortably and conveniently grasped by the operator will also be suitable and is considered to be within the scope of the present invention.

The probe tip **2810**, **3010** is connected to the main body of the handle **2805**, **3005**. The cautery element **2830**, **3030** at the distal end of the probe tip **2810**, **3010** can have a variety of configurations.

The tip **2810**, **3010** may be any material, such as titanium, brass, nickel, aluminum, stainless steel, other types of steels, or alloys. Alternatively, non-metallic substances may also be used, such as certain plastics. The tip may be conductive or non-conductive, depending on the specific embodiment, as will be discussed.

FIGS. **32***a* and **32***b* show alternative distal probe tip configurations, wherein the second electrode **3230** extends along the entire length of the first electrode **3220**. The probe tip **3210** may be curved to better maneuver within the anatomy of the eye. The malleable probe tips can be configured as straight, angled or curved, for example, which provides for optimal access to specific anatomy and pathology. Unique tip designs improve tactile feedback for optimal control and access, and provide for improved tissue visualization with greatly reduced bubbling or charring.

Referring again to the probes of FIGS. **28** and **30**, the probe tip **2810**, **3010** comprises an electrode or cautery element **2830**, **3030**, suitable for cautery, as known to those of skill in the art. Various electrode configurations and shapes may be suitable. The cautery element **2830**, **3030** is any electrode that may provide ablation or cauterization of tissue, such as a RF electrode, an ultrasound transducer, or any other suitable electrode. Alternatively, or in addition to the RF electrode variations, the cautery element may also include other cautery energy sources or sinks, and particularly may include a thermal conductor. Examples of suitable thermal conductor arrangements include a metallic element which may, for example, be constructed as previously described. In the thermal conductor embodiment such a metallic element would be generally resistively heated in a closed loop circuit internal to the probe, or conductively heated by a heat source coupled to the thermal conductor.

The electrode **2830**, **3030** may be provided on the inner surface of the tip. Alternatively, the electrode **2830**, **3030** may be embedded in a sheath of a tube. Insulation may be provided around the cautery element so that other areas of the eye are not affected by the cauterization. A sleeve shield

or a non-conductive layer may also be provided on the probe tip to expose only a selected portion of the electrode. The sleeve preferably has sufficient thickness to prevent both current flow and capacitance coupling with the tissue.

The cautery element can be made of a number of different materials including, but not limited to stainless steel, platinum, other noble metals, and the like. The electrode can also be made of a memory metal, such as nickel titanium. The electrode can also be made of composite construction, whereby different sections are constructed from different materials.

In a preferred embodiment of an RF electrode, the electrode system is bipolar. In a bipolar system, two electrodes of reversed polarity are located on the probe tip and RF energy bridges the electrodes. Additionally, any number of pairs of electrodes may be provided on the probe tip.

In an alternative RF electrode embodiment, the electrode system is monopolar. In a monopolar system, the system comprises a single electrode and a contact plate. The contact plate is attached to the surface of the human body. The contact plate is further connected to the return terminal of the power source via a lead wire. Voltages of reverse polarity are applied to the electrode and the contact plate.

In a preferred embodiment, as shown in FIGS. **33***a* and **33***b*, an electrode assembly of a bipolar probe includes one electrode **3320** made from a stainless steel 20 gauge hollow needle and a second electrode **3330** formed as a layer of electrically conductive material (such as silver or nickel) deposited over and adhered to an exterior surface of the needle electrode. A thin electrical insulator **3324** separates the electrodes **3320**, **3330**, along their lengths to avoid short circuiting.

The electrodes **3320**, **3330** extend along a longitudinal axis **3372** of the instrument from a proximal region at which bipolar electrical power is applied to a distal region of the electrode assembly.

In a preferred embodiment, the second electrode **3330** extends over a limited portion of the circumference of the first electrode **3320**, rather than entirely around the first electrode **3320**. Current flows from the relatively small portion of the circumference of the second electrode **3330** where heat is generated in the adjacent tissue, and into the layer surface of the first electrode **3320**, where little heat is generated. This limits the area in the body that receives dense current, and provides the operator with a high degree of control as to where the current is applied. The second electrode **3330** extends over an arc of approximately one quarter of the circumference of the first electrode. The second electrode **3330** is disposed symmetrically about an axis **3372**.

In a preferred embodiment, the first electrode **3320** has a central passage **3322** that is open at the distal region, providing for irrigation. The irrigation lumen **3322** extends from the distal end of the probe tip, through the probe handle, to the connector, providing for irrigation capability.

FIG. **34** shows an alternative embodiment, wherein the electrode assembly includes a central or axial electrode **3420** formed by a solid cylindrical metal member, and an elongate hollow outer electrode **3430** formed by a cylindrical metal tube member, which is coaxially positioned around the central electrode. The cylindrical outer surface of electrode **3430** forms the circumferential surface of the probe. The outer electrode **3430** is preferably made of stainless steel or other corrosive resistant, conductive material for strength as well as conductivity. The inner electrode **3420** may be made of copper, but less conductive materials may also be employed. The coaxial relationship and spacing between the electrodes, as well as their electrical isolation from one another, is provided by a tubular sleeve **3424** of an electrically insulating material between the electrode, completing the probe assembly. An additional layer of insulation **3434** may be provided on outer electrode **3430** to expose only a limited portion of the electrode to concentrate RF energy at the limited exposed region.

Alternatively, one or more regions of insulating area **3434** may be removed at any suitable location along the axis to expose a region of electrode **3430**. Cauterization would then occur at the exposed region. The circumferential extent of the second electrode **3430** can be further limited, depending on the degree of control desired over the size of the area to which current is applied.

In an alternative embodiment as shown in FIGS. **35***a* and **35***b*, the active region of a bipolar electrode probe assembly is formed by a hollow metal tube **3515** having a substantially semi-cylindrical sleeve **3524** on tube **3515**. The metallic tube **3515** is not an electrode and is provided only for the strength of the probe assembly. The tip supports two cautery elements **3520**, **3530**. Each of the elements **3520**, **3530** is connected to electrical leads, which extend through the hollow interior of the tip **3510** to a supporting insulative handle where it is coupled by appropriate means with a power source in the manner previously described.

The probe is connected to a low voltage RF power source via a power cord that mates with the handle. The source may be a high frequency, bipolar power supply, preferably, a solid state unit having a bipolar output continuously adjustable between minimum and maximum power settings. The source is activated by an on/off switch, which may comprise a foot pedal, or a button on the probe or interface. The source provides a relatively low bipolar output voltage. A low voltage source is preferred to avoid arcing between the electrode tips, which could damage the eye tissue. The RF generator is coupled to first and second electrodes to apply a biologically safe voltage to the surgical site. This probe has the advantage of cauterizing at both of the bipolar elements, each of which has a limited, RF current concentration area.

Delivery of energy to the tissue is commenced once the cautery element is positioned at the desired location. Energy is typically delivered to the cautery element via electrical conductor leads. The energy source preferably provides RF energy, but is not limited to RF and can include microwave, electrical, ultrasonic, coherent and incoherent light thermal transfer and resistance heating or other forms of energy, as known to those of skill in the art.

The cautery actuator may include a monitoring circuit **1744** and a control circuit **1746** (FIG. **17**) which together use either the electrical parameters of the RF circuit or tissue parameters such as temperature in a feedback control loop to drive current through the electrode element during cauterization. Feedback control systems can be used to obtain the desired degree of heating by maintaining the selected sight at a desired temperature for a desired time. A sensor, such as a thermocouple may be used to monitor temperature in a feedback loop. Where a plurality of cautery elements or electrodes are used, switching capability may be provided to multiplex the RF current source between the various elements or electrodes.

FIG. **17** shows the monitor circuit **1744**, which desirably communicates with one or more sensors (e.g., temperature) **1740** which monitor the operation of the cautery element **1730**. The control circuit **1746** may be connected to the monitoring circuit **1744** and to the current source in order to adjust the output level of the current driving the cautery element **1730** based upon the sensed condition (e.g. upon the

relationship between the monitored temperature and a predetermined temperature set point).

Circuitry, software and feedback to a controller, which result in full process control, may be used to change (i) power including RF, incoherent light, microwave, ultrasound, and the like, (ii) the duty cycle, (iii) monopolar or bipolar energy delivery, (iv) fluid (electrolyte solution delivery, flow rate and pressure) and (v) determine when ablation is completed through time, temperature and/or impedance.

In a preferred embodiment, a bipolar electrode is part of a circuit that includes the RF signal generator, connecting cables, probe tip for insertion into the eye, a grounding electrode attached to the probe and a return cable that connects the grounding electrode to the RF generator completing the circuit. Because such a RF electrode is a relatively good conductor, the electrode itself does not heat up. The tissues that the electrode comes in contact with heat up in response to current passing from the electrode through the tissues. The tissue heats up because it is a relatively poor conductor as compared to the rest of the circuit. It is when the tissues heat up as a result of molecular friction, that heat is then conducted back to the electrode itself. At that point, a thermocouple senses the increase in temperature and supplies that information to the RF generator so that the feedback mechanism can attenuate the energy delivered in order to attain temperature control.

It may also be advantageous to regulate RF delivery through both temperature and impedance monitoring. It may also be advantageous to monitor irrigation fluid flow to maintain clarity at the site. There is also an opportunity for synergy between RF and irrigation fluid delivery to the surgical site to provide, for example, a greater level of control of temperatures at the site.

The controller may include an RF generator, temperature profile, temperature regulator, temperature monitor, surgical instrument, impedance monitor, impedance regulator, pump, flow regulator and flow monitor.

The RF generator may be capable of delivering monopolar or bipolar power to the probe. The probe is positioned at the surgical site. The impedance monitor obtains impedance measurements by, for example, measuring current and voltage and performing a RMS calculation. The measurements of the impedance monitor are delivered to the impedance regulator. The impedance regulator performs several functions. Generally the impedance regulator keeps the impedance levels within acceptable limits by controlling the power supplied by the RF generator. In one embodiment of the current invention the impedance regulator can control the flow regulator to deliver more or less irrigation fluid to the surgical site.

To maintain the appropriate temperature for cauterizing tissue, the distal tip of the probe may also be equipped with a thermocouple **1740**. Temperature feedback, in combination with a timing device, permits a precise degree of cautery to be delivered, obtaining the desired effect without causing any intraocular heating. The heating effect on tissue may be mitigated with a viscoelastic agent to deepen the anterior chamber.

Referring to FIG. **17**, the temperature monitor **1744** may include one or more types of temperature sensors, e.g. thermocouples, thermistors, resistive temperature device (RTD), infrared detectors, etc.

Suitable shapes for the thermocouple include, but are not limited to, a loop, an oval loop, a "T" configuration, an "S" configuration, a hook configuration or a spherical ball configuration. These shapes provide more surface area for the thermocouple without lengthening the thermocouple. These thermocouples, with more exposed area than a straight thermocouple, are believed to have better accuracy and response time. The thermocouple is attached by a fastener. The fastener may be a bead of adhesive, such as, but not limited to, epoxies, cyanoacetate adhesives, silicone adhesives, flexible adhesives, etc. It may also be desirable to provide multiple thermocouples at different locations and compare their operating parameters (e.g. response times, etc.), which may provide useful information to allow certain such variables to be filtered and thereby calculate an accurate temperature at the thermocouple location.

The output of the temperature monitor **1744** is delivered to the temperature regulator **1746**. The temperature regulator **1746** may control both the RF generator **1760** and the flow regulator. When, for example, temperatures have increased beyond an acceptable limit, power supplied by the RF generator to the surgical instrument may be reduced. Alternately, the temperature regulator may cause the flow regulator to increase irrigation fluid, thereby decreasing the temperature at the surgical site. Conversely, the temperature regulator can interface with either the RF generator or the flow regulator when measured temperatures do not match the required temperatures. The flow regulator interfaces with the pump to control the volume of irrigation fluid delivered to the surgical site.

The procedure for performing a Schlemmectomy with the probe of the present invention is similar to a traditional trabeculotomy procedure, as previously described. The surgeon preferably sits on the temporal side of the operating room table utilizing the operating microscope. An infrotemporal fornix based conjunctival flap is made and the conjunctive and Tenons capsule are mobilized posteriorly. A triangular flap is made and the superficial flab is mobilized into the cornea. A radial incision is made over the canal of Schlemm, thus creating an entrance into the canal. Vanua scissors are preferably introduced into the Schlemm's canal, opening the canal for approximately 1 mm on either side. A clear corneal parenthesis is performed and the anterior chamber is deepened, preferably with Haelon GV. The probe is introduced into Schlemm's canal inferiorly. The instrument is now aligned such that the cauterization element faces into the deepened anterior chamber. Alternatively, the cauterization surface faces the trabecular meshwork and is activated by the foot switch at the time of the rotation of the probe into the anterior chamber. The foot switch may then be used to activate cauterization. Aspiration and irrigation may also be activated using the foot switch. The trabeculotome is slowly rotated into the anterior chamber and when the blade of the trabeculotome is seen in the anterior chamber, the cautery (and aspiration and/or irrigation) are deactivated. The superior aspect of Schlemm's canal may be entered with a trabeculotome having the opposite curvature. Following the same steps, more of the trabecular meshwork is removed. In a preferred embodiment, a substantial portion, preferably at least half, of the trabecular meshwork is removed. After removing the trabeculotome, the superficial trabeculotomy flap is sutured closed using sutures.

Radiowave surgery uses high frequency radio waves instead of heat to cut and coagulate tissue without the burning effect that is common with traditional electrosurgical devices and cautery equipment. The resistance of tissue to the spread of radio wave energy produces heat within the cell, causing the water within the cell to volatilize and destroy the cell without damaging other cellular layers.

While particular forms of the invention have been described, it will be apparent that various modifications can be made without departing from the spirit and scope of the

invention. Accordingly, it is not intended that the invention be limited, except as by the appended claims.

What is claimed is:

1. A device useable to create an opening in the trabecular meshwork of the eye comprising:

an elongate surgical instrument comprising a probe shaft having a distal end and a longitudinal axis: and

a foot member which comprises a platform on the distal end of the probe shaft. said platform having a tip. an upper side, a lower side and being set at an angle relative to the longitudinal axis of the probe shaft;

wherein the foot member is insertable, tip first, from a position within the anterior chamber. through the trabecular meshwork, and into Schlemm's Canal such that the lower side is next to the scleral wall of Schlemm's Canal and the upper side is next to the trabecular meshwork: and

wherein, after being so inserted in Schlemm's Canal, the foot member is then advanceable. tip first. through Schlemm's Canal to facilitate performance of a surgical procedure using the surgical instrument.

2. A device according to claim 1 wherein the trabecular meshwork slides over the upper side as the foot member is advanced through Schlemm's Canal.

3. A device according to claim 2 wherein a surface of the upper side of the foot member slopes upwardly from the tip toward the shaft.

4. A device according to claim 1 wherein the surgical instrument is useable to perform an ab interno procedure to form an opening in the trabecular meshwork.

5. A device according to claim 4 wherein the surgical instrument comprises a goniectomy probe.

6. A device according to claim 4 wherein the platform is configured to protect collector channels which emanate from Schlemm's canal from damage during performance of the surgical procedure.

7. A device according to claim 1 wherein the bottom side of the foot member is configured such that advancing the foot member through Schlemm's Canal does not cause clinically significant damage to collector channels which emanate from Schlemm's Canal.

8. A method for performing a surgical procedure within the eye of a subject, said method comprising the steps of:

A) obtaining or providing a device according to any of claims 1 through 7;

B) forming an opening into the anterior chamber of the eye;

C) inserting the surgical instrument, distal end first, through the opening and into the anterior chamber of the eye;

D) inserting the foot member, tip first, from a position within the anterior chamber. through the trabecular meshwork, and into Schlemm's Canal such that the lower side is next to the scleral wall of Schlemm's Canal and the upper side is next to the trabecular meshwork; and. thereafter,

E) advancing the foot member through Schlemm's Canal to facilitate performance of the surgical procedure using the surgical instrument.

9. A method according to claim 8 wherein the surgical procedure comprises forming an opening in the trabecular meshwork.

10. A method according to claim 9 wherein the trabecular meshwork slides over the upper side as the foot member as the foot member is advanced through Schlemm's Canal.

11. A device according to claim 10 wherein the trabecular meshwork slides over a surface of the upper side of the foot member which slopes upwardly from the tip toward the probe shaft.

* * * * *

EXHIBIT 19

US009358155B2

(12) **United States Patent**
Sorensen et al.

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(45) **Date of Patent: Jun. 7, 2016**

(54) **DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE**

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See application file for complete search history.

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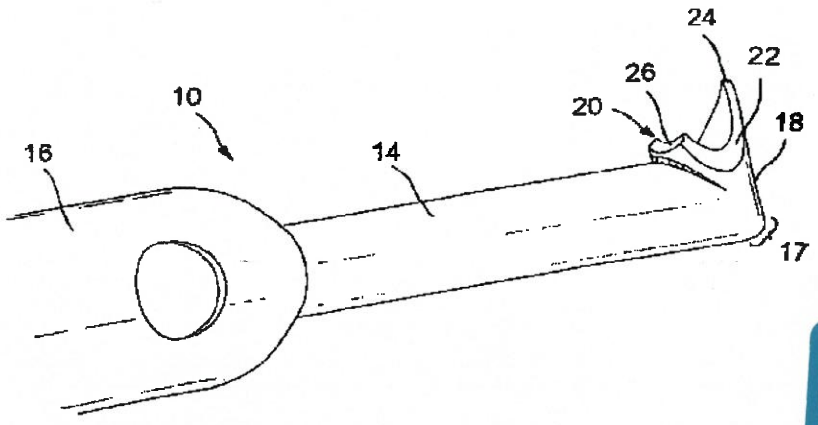
(57) **ABSTRACT**

A dual blade device comprising an elongate probe having first and lateral second cutting edges and a blunt protruding distal tip, useable for performing an ab interno procedure to remove a strip of trabecular meshwork tissue from a human eye.

7 Claims, 3 Drawing Sheets



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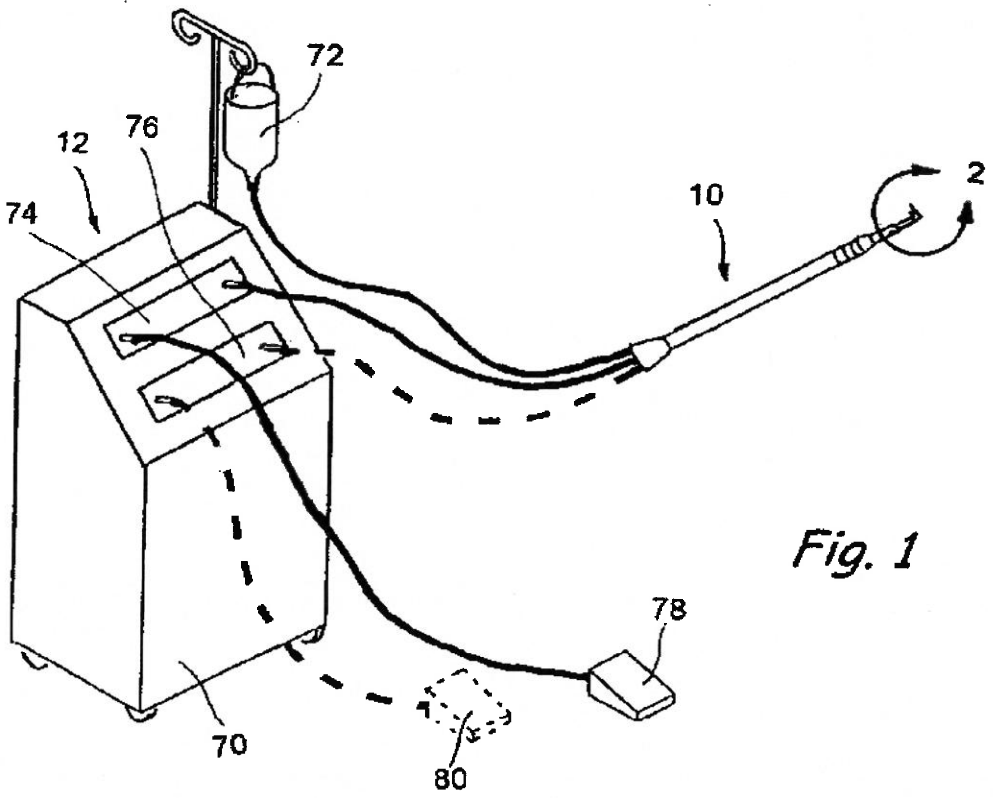

Fig. 1

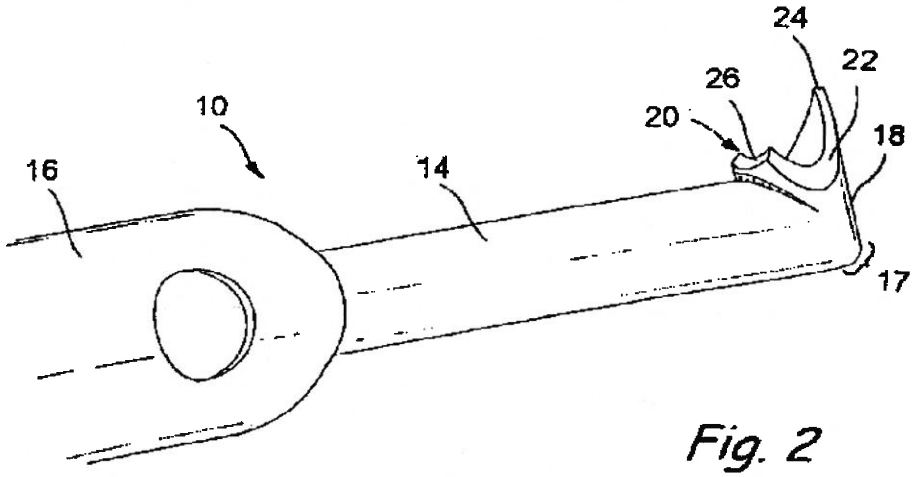

Fig. 2

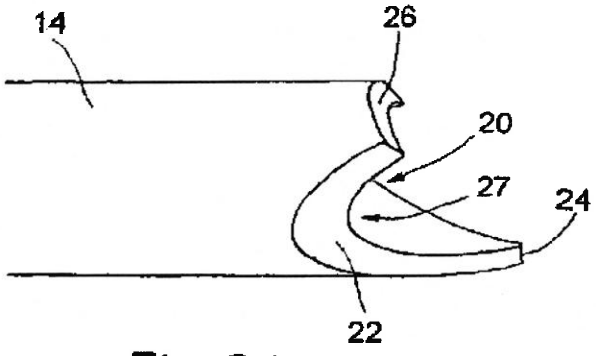

Fig. 3A

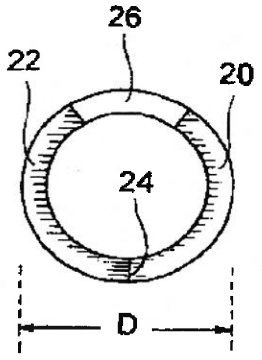

Fig. 3B

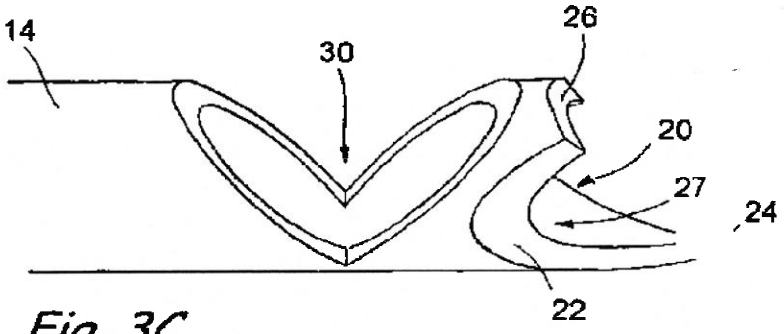

Fig. 3C

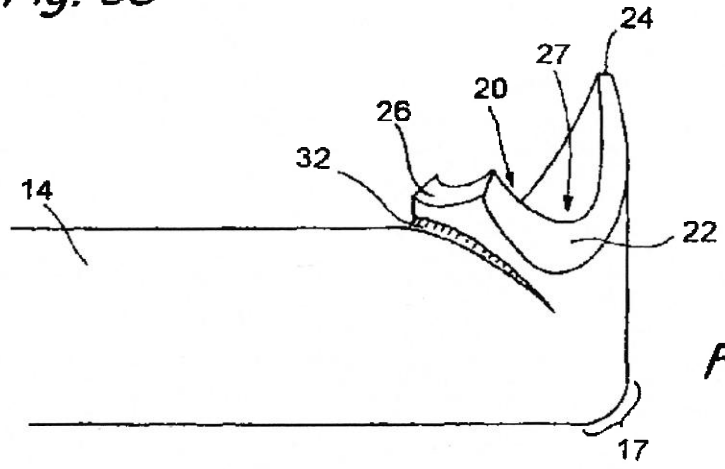

Fig. 3D

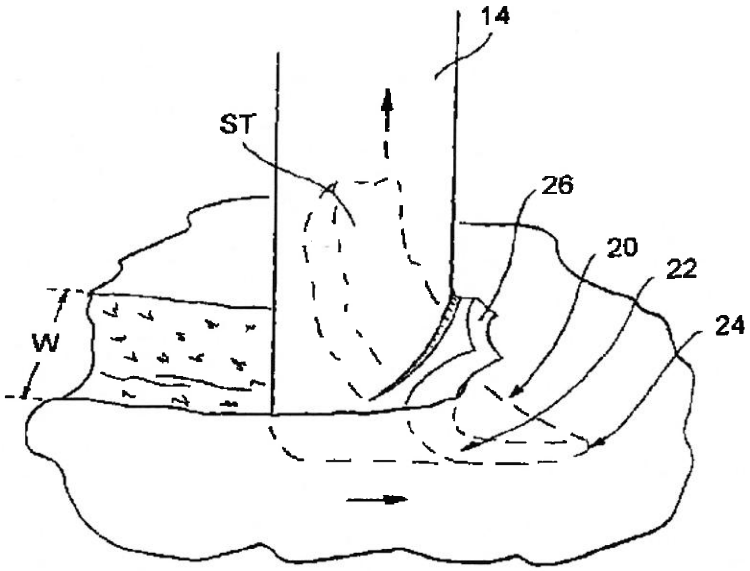

Fig. 4

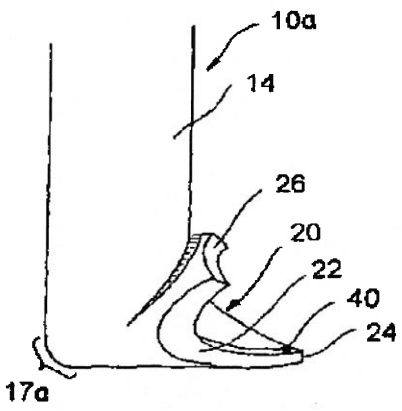

Fig. 5

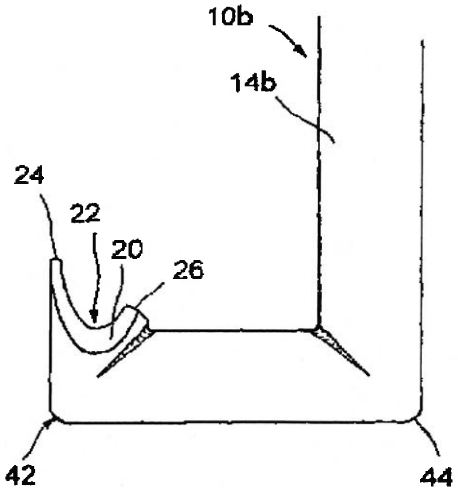

Fig. 6

DUAL BLADE OPHTHALMOLOGIC SURGERY DEVICE

RELATED APPLICATIONS

This application is a continuation of copending U.S. patent application Ser. No. 14/481,754 filed Sep. 9, 2014 and issued as U.S. Pat. No. 9,107,729 on Aug. 18, 2015 which is a division of U.S. patent application Ser. No. 13/159,356 filed Jun. 13, 2011 and currently abandoned, which is a division of U.S. patent application Ser. No. 10/560,267 filed May 11, 2006 and issued as U.S. Pat. No. 7,959,641 on Jun. 14, 2011, which is a 35 U.S.C. §371 national stage of PCT International Patent Application No. PCT/US2004/018488 filed Jun. 10, 2004, which claims priority to U.S. Provisional Patent Application No. 60/477,258 filed on Jun. 10, 2003, the entire disclosure of each such prior patent and application being expressly incorporated herein by reference.

BACKGROUND OF THE INVENTION

There are numerous medical and surgical procedures in which it is desirable to cut and remove a strip of tissue of controlled width from the body of a human or veterinary patient. For example, it may sometimes be desirable to form an incision of a controlled width (e.g., an incision that is wider than an incision made by a typical scalpel or cutting blade) in the skin, mucous membrane, tumor, organ or other tissue or a human or animal. Also, it may sometimes desirable to remove a strip or quantity of tissue from the body of a human or animal for use as a biopsy specimen, for chemical/biological analysis, for retention or archival of DNA identification purposes, etc. Also, some surgical procedures require removal of a strip of tissue of a known width from an anatomical location within the body of a patient.

One surgical procedure wherein a strip of tissue of a known width is removed from an anatomical location within the body of a patient is an ophthalmological procedure used to treat glaucoma. This ophthalmological procedure is sometimes referred to as a goniectomy. In a goniectomy procedure, a device that is operative to cut or ablate a strip of tissue of approximately 2-10 mm in length and about 50-200 μm in width is inserted into the anterior chamber of the eye and used to remove a full thickness strip of tissue from the trabecular meshwork. The trabecular meshwork is a loosely organized, porous network of tissue that overlies a collecting canal known as Schlemm's canal. A fluid, known as aqueous humor, is continually produced in the anterior chamber of the eye. In normal individuals, aqueous humor flows through the trabecular meshwork, into Shlemm's Canal and out of the eye through a series of ducts. In patients who suffer from glaucoma, the drainage of aqueous humor from the eye may be impaired by elevated flow resistance through the trabecular meshwork, thereby resulting in an increase in intraocular pressure. The goniectomy procedure can restore normal drainage of aqueous humor from the eye by removing a full thickness segment of the trabecular meshwork, thus allowing the aqueous humor to drain through the open area from which the strip of trabecular meshwork has been removed. The goniectomy procedure and certain prior art instruments useable to perform such procedure are described in U.S. patent application Ser. No. 10/052,473 published as No. 2002/011608A1 (Baerveldt), the entirety of which is expressly incorporated herein by reference.

At present there remains a need in the art for the development of simple, inexpensive and accurate instruments useable to perform the goniectomy procedure as well as other procedures where it is desired to remove a strip of tissue from a larger mass of tissue.

SUMMARY OF THE INVENTION

The present invention provides a device for cutting a strip of tissue of approximate width W from a mass of tissue. The device generally comprises a) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and b) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D. The cutting tube is advanceable through tissue such that the first and second cutting edges will cut a strip of tissue having approximate width W, wherein the approximate width W is approximately equal to the distance between the first and second cutting edges. In some embodiments, the strip of tissue may be aspirated or otherwise removed through the lumen of the cutter tube. In some embodiments, the device may include apparatus useable to sever (e.g., transversely cut or transect) the strip of tissue when the strip of tissue has reached a desired length.

Further in accordance with the invention there is provided a method for cutting a strip of tissue of width W from a tissue mass. This method generally comprises the steps of a) providing a device that comprises i) an elongate cutting tube that has a distal end and a lumen that opens through an opening in the distal end and ii) first and second cutting edges formed on generally opposite edges of the distal end of the cutting tube and separated by a distance D that is approximately equal to the width W of the strip of tissue to be cut; and b) advancing the distal end of the cutting tube through the mass of tissue such that the first and second cutting edges cut a strip of tissue of approximate width W. Further aspects and elements of the invention will be understood by those of skill in the art upon reading the detailed description of specific examples set forth herebelow.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a system incorporating a needle cutting device of the present invention.

FIG. **2** is an enlarged perspective view of section **2** of FIG. **1**.

FIGS. **3A-3D** show various steps in a method for manufacturing a needle cutter of the present invention.

FIG. **4** is a side view of a distal portion of a needle cutter device of the present invention being used to cut a strip of tissue of approximate width W.

FIG. **5** is a perspective view of the distal portion of a needle cutter device of the present invention incorporating apparatus for severing a strip of tissue cut by the needle cutter device after the strip of tissue has reached a desired length.

FIG. **6** is a side view of the distal portion of another embodiment of a needle cutter device of the present invention having a plurality of curves or bends formed in the cutting tube.

DETAILED DESCRIPTION

The following detailed description, and the drawings to which it refers, are provided for the purpose of describing and illustrating certain preferred embodiments or examples of the invention only, and no attempt has been made to exhaustively describe all possible embodiments or examples of the invention. Thus, the following detailed description and the accompanying drawings shall not be construed to limit, in any way,

the scope of the claims recited in this patent application and any patent(s) issuing therefrom.

One example of a needle cutter device **10** of the present invention is shown in FIGS. **1-4**. This needle cutter device **10** generally comprises an elongate cutting tube **14** that has a distal end and a lumen **27** that opens through an opening in the distal end. First and second cutting edges **20**, **22** are formed on generally opposite edges of the distal end of the cutting tube **14**. These first and second cutting edges **20**, **22** are separated by a distance D, as shown in the distal end view of FIG. **3B**. In the particular example shown in the drawings, the first and second cutting edges **20**, **22** are located on opposite lateral sides of the distal end of the cutting tube **14** and a blunt, protruding tip **24** is located on the bottom of the distal end of the cutting tube. Also, a blunt edge **26** is located at the top of the distal end of the cutting tube **14**. Thus, only the lateral cutting edges **20**, **22** are sharp and intended to cut tissue. The blunt, protruding tip **24** can, in some applications, be configured and used to facilitate insertion of the device **10** to its intended location and/or the blunt protruding tip **24** may be placed in an anatomical or man made grove or channel (e.g., Schlemm's Canal of the eye) such that it will then advance through the channel or groove and guide the advancement and positioning of the remainder of the device **10**.

One or more bends or curves may optionally be formed in the cutting tube **14** to facilitate its use for its intended purpose. For example, in the embodiment of the device **10** shown in FIG. **2**, a single bend **17** of approximately 90 degrees is formed near the distal end of the cutting tube **14**. In the embodiment of the device **10***b* shown in FIG. **6**, two separate bends of approximately 90 degrees each are formed at spaced apart locations on the cutting tube **14**, thereby giving the cutting tube **14** a generally U shaped configuration. It will be appreciated that any number of bends or curves, in any direction and of any severity may be formed in the cutting tube **14** to facilitate its use in specific procedures or to enable it to be inserted through tortuous anatomical channels of the body. In most cases, the degree of curvature in embodiments where a single bend or curve is formed will be between approximately 30 and approximately 90 degrees and in embodiments where more than one bend or curve are formed in the cutting tube **14** each such bend or curve will typically be between approximately 15 to approximately 90 degrees.

As shown in FIG. **4**, when the cutting tube **14** is advanced through tissue, distal end first, the first and second cutting edges **20**, **22** will cut a strip ST of tissue having approximate width W, such approximate width W being approximately equal to the distance D between the first and second cutting edges **20**, **22**. The severed strip ST of tissue will enter the lumen **27** of the cutting tube **14** as the device advances. Negative pressure may be applied to lumen **27** to aspirate the strip ST of tissue and/or fluid and/or other matter through lumen **27**.

The device **10** may optionally include a second lumen. Such second lumen may be used for infusion of fluid through the device **10** or for other purposes. In the embodiment shown in FIGS. **1** and **2**, the device **10** comprises an outer tube **16** in addition to the cutting tube **14**. The cutting tube **14** is of smaller diameter than the outer tube **16** and the cutting tube **14** may extend through the lumen **19** of the outer tube **16** such that a distal portion of the cutting tube **14** extends out of and beyond the distal end of the outer tube **16**, as may be seen in FIG. **2**. The distal end of the outer tube **16** is tapered and in close approximation with the outer surface of the cutting tube **14**. Fluid may be infused through the lumen **19** of the outer tube **16**, through the space between the outer surface of the cutting tube **14** and the inner surface of the outer tube **16**.

Fluid that is infused through the lumen **19** of the outer tube **16** may flow out of one or more apertures **11** formed near the distal end of the outer tube.

In some embodiments, the device **10** may be equipped with severing apparatus for severing (e.g., transversely cutting or transecting) the strip ST of tissue to fully excise or detach the strip ST of tissue from the remaining tissue mass and/or from the body of a human or animal subject. Such severing apparatus may comprise any suitable type of tissue cutter such as a blade, scissor, guillotine, electrode(s), laser, energy emitting tissue cutter, mechanical tissue cutter, etc. FIG. **5** shows an example of an embodiment of the device **10***a* wherein monopolar or bipolar electrode(s) **40** are located on the distal end of the cutting tube **14**. When it is desired to sever the strip ST of tissue, the electrode(s) is/are energized with sufficient energy to sever the strip ST, thereby disconnecting the strip ST from the remaining tissue mass and/or the body of the human or animal subject.

In some embodiments of the device **10**, the cutting edges **20**, **22** may be heated such that they will cauterize as the cut. As those of skill in the art will appreciate, such heating of the cutting edges **20**, **22** may be accomplished by placement of electrode(s) near the cutting edges **20**, **22** such that, when the electrode(s) is/are energized, the cutting edges **20**, **22** will become heated to a temperature suitable for the desired cauterization function.

The needle cutter device **10** of the present invention may optionally be used as part of a system **12**, as shown in FIG. **1**. The basic components of the system **12** comprise an aspiration pump module **74** and a source of irrigation fluid **72**, mounted on a surgical roller cart **70**. Control of the console functions during procedures may be accomplished by an aspiration foot pedal **78** which controls an aspiration pump **74** and variation in the height of the source of infusion fluid **72** to change the gravity fed pressure or flow rate of infusion fluid through the device. A pinch valve, or other means, may also be incorporated in the console to control flow of the irrigation fluid to the needle cutter device **10**. In embodiments that include apparatus (e.g., electrode(s)) for heating the cutting edges **20**, **22** and/or for severing the strip ST of tissue (FIG. **5**), the system **11** may additionally comprise an electrical current source, such as an electrosurgical generator **76** and electrosurgical foot pedal **80** which controls the electrosurgical generator to deliver desired amount(s) of energy to the electrode(s) or other electrical elements (e.g., resistance heater(s), etc.) on the device **10**. As an option, all of the basic control functions of system **12** may be integrated into a single foot pedal to facilitate use.

The device **10** may be provided as a pre-sterilized, single-use disposable probe or tip that is attachable to a standard surgical irrigation/aspiration handpiece such as that commercially available as The Rhein I/A Tip System from Rhein Medical, Inc., Tampa, Fla. After the device **10** has been attached to the handpiece, it may be connected to any or all of the electrosurgical generator module **76**, aspiration pump module **74** and the source of irrigation fluid **72**, as shown. Thus, the device **10** may be fully equipped for irrigation, aspiration, and electrosurgical capabilities, as described herein.

FIGS. **3A-3D** show an example of a method for manufacturing the cutting tube **14** from standard tubing (e.g., stainless steel hypodermic tubing). Initially, the distal end of a tube is cut to form the lateral cutting edges **20**, **22**, the protruding tip **24** and the blunt top edge **26**. Thereafter, if it is desired to have one or more bends or curves in the cutting tube **14**, angular cut out(s) **30** may be formed in the tube **14**, as shown in FIG. **3C**. Thereafter, the tube **14** is bent to bring the edges of each

angular cut out **30** into apposition and weld. adhesive or other joining techniques are used to weld or join the apposed edges of the cut outs together, thereby forming the desired bend(s) or curve(s) in the cutting tube **14**. Likewise. if it is desired to have one or more bends or curves in the cutting tube **14**, the tube **14** may be directly bent to form said curves or bends without the use of angular cut outs(s) **30**. It may be appreciated that the use of angular cut-out(s) **30** allow a tube **10** of a given diameter to incorporate a curve or angle in a more compact form than is possible by bending tubing **10** of a given diameter to said curve or angle without kinking or damaging tube **10**.

The device **10** and system **12** are useable to perform a variety of procedures wherein it is desired to form an incision or opening of a desired width or to remove. from a mass of tissue, a strip ST of tissue of a desired width.

One particular procedure that may be performed to treat glaucoma, using the device **10** and system **12** of the present invention, is a goniectomy. As explained herein a goniectomy procedure is an ab interno surgical procedure wherein a sector of the trabecular meshwork is removed from the eye of the patient to facilitate drainage of aqueous humor from the anterior chamber of the eye through Schlemm's Canal and the associated collector channels, thereby relieving elevated intraocular pressure.

To perform a goniectomy procedure using the device **10**, first a small incision is made in the cornea at about 3 o'clock in the left eye. or at about 9 o'clock in the right eye. A 1.5 mm slit knife may be used to make this incision.

The device **10** is attached to the source of irrigation fluid **72** (e.g., basic balanced salt solution) such that irrigation fluid will flow through lumen **19** of the outer tube **16** and out of outflow aperture **11**. The device **10** is then inserted through the incision and into the anterior chamber of the eye (with irrigation flowing). In some cases, during the insertion of the device **10**, the source of irrigation fluid **72** may initially connected to the device such that the irrigation fluid will flow through the lumen **27** of the cutter tube **14**. In this manner, irrigation fluid will begin to infuse into the anterior chamber of the eye as soon as the distal end of the cutter tube **14** has entered the anterior chamber, rather than being delayed until the larger outer tube **16** and aperture **11** have been advanced through the incision and into the anterior chamber. By this alternative approach, irrigation fluid may be caused to flow out of the distal end of the cutter tube **14** as the device **10** is being inserted, thereby spreading or opening the incision by hydraulic force while in addition increasing the fluid pressure in the anterior chamber. Such spreading or opening of the incision may facilitate advancement of the larger diameter outer tube **16** through the incision. Pressurizing the fluid in the anterior chamber causes the anterior chamber to deepen and may facilitate maneuvering of device **10** within the anterior chamber. In cases where this alternative approach is used, the source of infusion fluid **72** may be disconnected from lumen **27** of the cutter tube **14** after the device **10** has been inserted into the anterior chamber and, thereafter, the infusion fluid source **72** may be reconnected to lumen **19** of outer tube **16** such that infusion fluid will flow out of aperture **11**. Negative pressure (e.g., via aspiration pump module **74**) may then be applied to lumen **27** of the cutter tube **14** so as to aspirate fluid and debris through lumen **27** as shown in FIG. **4**. The vertical height of the infusion fluid source **72** may be adjusted to provide sufficient gravity feed of infusion fluid to make up for the volume of fluid or matter being aspirated from the anterior chamber through lumen **27**. thereby maintaining the desired pressure of fluid within the anterior chamber during the procedure.

A lens device (e.g.. Ocular Swan-Jacob Autoclavable Gonioprism, Model OSJAG, Ocular Instruments Inc., Bellevue, Wash.) may be positioned on the anterior aspect of the eye to enable the physician to clearly visualize the angle of the eye where the segment of trabecular meshwork is to be removed. Under direct visualization, the device **10** is advanced until the distal tip of the cutter tube **14** is positioned adjacent to the trabecular meshwork at the location where the strip ST is to be removed. Thereafter, the protruding tip **24** is advanced through the trabecular meshwork and into Schlemm's Canal.

The device **10** is then advanced along Schlemm's Canal. thereby causing the cutting edges **20**, **22** to cut a strip of the trabecular meshwork. thereby creating an opening through which aqueous humor may drain from the anterior chamber of the eye.

After a strip of tissue of the desired length (e.g., about 2-10 mm) has been cut by the lateral cutting edges **20**, **22**, any optional tissue severing apparatus (e.g., electrode(s) **40** may be used (if present) to transect or sever the strp ST of tissue thereby disconnecting it from the patient's body and allowing it to be aspirated or drawn into or through lumen **27**.

Thereafter, the aspiration is stopped. the device **10** is removed from the eye, and the infusion is stopped.

Following completion of the surgery, aqueous humor will drain from the anterior chamber through the opening that was created by removal of the strip of tissue from the trabecular meshwork TM.

Although the invention has been described above with respect to certain embodiments and examples, it is to be appreciated that such embodiments and examples are non-limiting and are not purported to define all embodiments and examples of the invention. Indeed, those of skill in the art will recognize that various modifications may be made to the above-described embodiments and examples without departing from the intended spirit and scope of the invention and it is intended that all such modifications be included within the scope of the following claims.

What is claimed is:

1. A dual blade device useable for performing an ab intern procedure within a human eye to remove a strip of trabecular meshwork tissue, said device comprising:

a handle configured to be grasped by an operator's hand:

an elongate probe comprising a shaft that extends from the handle along a longitudinal axis;

a blunt protruding tip that extends in a lateral direction from a distal end of the shaft to form a bend or curve of approximately 30 degrees to approximately 90 degrees relative to the adjacent longitudinal axis of the shaft;

first and second lateral cutting edges formed at stationary side-by-side locations on the shaft. said first and second lateral cutting edges facing in the same lateral direction as the blunt protruding tip and being spaced apart such that an area exists between the first and second lateral cutting edges; and

a blunt top edge that extends transversely from a top end of the first lateral cutting edge to a top end of the second lateral cutting edge and traverses above the area between the first and second lateral cutting edges;

the blunt protruding tip having a transverse width, a top surface, a bottom surface and a terminal end, the transverse width being narrowest at the terminal end;

the blunt protruding tip being below the area between the first and second lateral cutting edges and protruding in the lateral direction beyond the first and second lateral cutting edges such that tissue may pass over the top

surface of the blunt protruding tip before coming into contact with the first and second lateral cutting edges;

a distal portion of the shaft and the blunt protruding tip being sized to pass through an incision formed in the eye by a 1.5 mm slit knife; and

the blunt protruding tip being further sized to fit within Schlemm's Canal of the human eye and, when so positioned, to be advanceable through Schlemm's Canal with trabecular meshwork tissue passing over its top surface and into contact with the first and second lateral cutting edges.

2. A device according to claim 1 wherein the first and second lateral cutting edges are spaced apart by a distance D and cut a strip of trabecular meshwork tissue having a width W that is substantially equal to distance D.

3. A device according to claim 1 useable for cutting a sector of trabecular meshwork tissue having a length of 2 to 10 millimeters.

4. A device according to claim 1 wherein the bottom surface of the blunt protruding tip extends at an angle of approximately 90 degrees relative to the adjacent longitudinal axis of the shaft.

5. A system comprising a device according to claim 1 in combination with a 1.5 mm slit knife for forming said incision in the human eye.

6. A device according to claim 1 wherein the device is manually operable to remove a strip of trabecular meshwork tissue.

7. A device according claim 1 wherein the shaft comprises a tube having at least one lumen.

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